### SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 10-SB/A

GENERAL FORM FOR REGISTRATION OF SECURITIES OF SMALL BUSINESS ISSUERS UNDER SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

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

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

9948 HIBERT ST., SUITE 100 SAN DIEGO, CALIFORNIA 92131 (Address of principal executive offices) (Zip Code)

Registrant's telephone number: (858) 271-9671

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)

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#### COMPANY BACKGROUND

Biokeys Pharmaceuticals, 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 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 anti cancer 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.

Until our merger with Biokeys, Inc., a privately-held biomedical research and development company based in San Diego, California, our parent company was known as BioQuest, Inc. When our merger was 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.

Prior to the merger, BioQuest, Inc. had devoted its limited resources solely to its research and development activities conducted at M.D. Anderson in connection with HIV/ AIDS therapy. By early 2000, BioQuest, Inc. had determined that its future growth would require the broadening of its product base and the addition of one or more strategic partners. With the assistance of an investment banking firm, Biokeys, Inc. was introduced to BioQuest, Inc. Early discussions indicated that there were a compatibility of management goals and significant potential benefits for BioQuest, Inc. to be gained from the addition of an established research and development connection between Biokeys, Inc. and USC. Arms-length negotiations were conducted between the two companies and their managements in early 2000, which resulted in the execution of a Agreement and Plan of Merger (referred to as the "Merger Agreement") on May 19, 2000. The stockholders of BioQuest, Inc. approved the transaction at a stockholder's meeting held on June 23, 2000 and the stockholders of Biokeys, Inc. also aproved the combination.

Under the Merger Agreement, the former stockholders of Biokeys, Inc. were entitled to receive 6,999,990 shares of Common Stock of BioQuest, Inc., which was approximately equal to the 7,000,000 shares of BioQuest, Inc. outstanding immediately prior to the merger. In addition, the Merger Agreement required the two companies to adjust their respective options and warrants outstanding at the time, so that the options and warrants which had been issued by Biokeys, Inc. prior to the effective date of the merger were approximately equal to those which had been previously granted by BioQuest, Inc.

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Among the reasons for, and the significant potential benefits resulting from, the merger are the following:

- o BioQuest, Inc. and Biokeys, Inc. have combined their personnel resources, resulting in a more diversified management than either company had prior to the merger.
- o The combination of BioQuest, Inc. and Biokeys, Inc. significantly expanded the potential biomedical product lines and technologies available to BioQuest, Inc.
- Biokeys, Inc. brought with it a promising anti-cancer pharmaceutical, Co-Factor, which had undergone initial human trials in Sweden and was therefore significantly closer to potential commercialization than any technology sponsored and developed by BioQuest, Inc.
- Biokeys, Inc. added a new and significant source of biomedical research and technology through its license arrangements with USC.
- Biokeys, Inc. made available the services of additional research consultants, particularly Dr. Colin Paul Spears and Dr. Bengt Gustavsson.
- The creation of a larger entity through the merger made possible better access to research institutions, other potential strategic partners and future sources of financing.

Since the merger, we have maintained two offices. Our principal executive office is located at 9948 Hibert Street, Suite 100, San Diego, California 92131, (telephone number 858/271-9671). We also have an office at 333 N. Sam Houston Parkway, Suite 1035, Houston, TX 77060 (telephone number 281/272-0000) where a number of administrative and financial functions are carried out. We maintain a website located at WWW.BIOKEYS.COM, but the information on our website is not part of this registration statement.

Our Common Stock has been traded in the over-the-counter market and quoted in the "pink sheets" under the ticker symbol "BKYS." (See Part II, Item 1 below.)

## COMPANY TECHNOLOGIES UNDER DEVELOPMENT

We have six potential drug products in development:

PRODUCT LINE FOCUS APPLICATION CoFactor(TM) Anticancer 5-FU biomodulator Selone(TM) Anticancer alkylating agent for drugresistant 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

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### COFACTOR

CoFactor (5,10-methylenetetrahydrofolate) is a patented new drug which greatly improves 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 under which he has been paid \$70,000 per year in equal monthly installments. 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/leucvorin standard traditional therapy for cancer patients.

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:

- curative results with 5-FU therapy in combination with CoFactor for liver cancer in animal studies compared to 5-FU alone or to 5-FU/leucovorin therapy;
- significant response to 5-FU/CoFactor in animal colon cancer studies;

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- 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-disection 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, for approval of Phase II / III trials for second-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 or 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 leading compound in a new class of compounds which are potential new cancer drugs for drug resistant cancer, discovered through USC research focused on the use of the element selenium, an anti-oxidant. We are the exclusive licensee of a patent from USC, which encompasses the use of Selone and other oxygen-carbon-selenium compounds as anticancer agents, as well as the method for their synthesis.

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

Based upon current IN VITRO screening methods, Selone shows promise of being broadly effective, at even very low concentrations, against human ovarian, breast, lung and head/neck

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

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 showed rapidly induced immunodeficiency (profound reduction in CD-4 positive cell counts within three to four weeks after infection), progressing to an AIDS state nearly identical to that seen in humans infected with HIV.

Preliminary trials were conducted at the University of Texas animal research facility in Bastrop, Texas under the supervision of Dr. Jagan Sastry. Rhesus monkeys were used along with SHIV developed by a group of research labs, including M.D. Anderson. M.D. Anderson's SHIV

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development work was supported in part by the Company. In the trial, test animals were vaccinated with the Company's cell-mediated immunity agent known as EradicAide, and subsequently challenged with live SHIV. Compared to 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.

These data demonstrate scientific proof of principle for the cell-mediated immunity strategy. Subsequent confirmatory trials and safety testing are now being performed by the Company. We expect that the Company may be able to qualify for the FDA's Fast Track Program for human trials, which provides for an accelerated FDA review process of HIV therapeutic drugs.

#### 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 U.S. National Institutes of Health, indicate that at least two cell surface receptors are involved in the mechanism for HIV binding and immune cell penetration. One is the CD4 receptor, largely found on T helper cells which are part of the human

immune system. The second receptor, which has only recently been described, is represented by members of a family of chemokine receptors, a type of target cell molecule. 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 these CD4 receptors and chemokine receptors, thus initiating the infection process.

M.D. Anderson researchers believe that the BlockAide/CR compound, which is structurally similar to a portion of the V3 Loop, mimics the V3 Loop and, by occupying CD4 receptor sites on immune system cells, prevents the virus from binding to immune cell receptors and subsequently penetrating the cell. Dr. Jagan K. Sastry of M.D. Anderson is credited with discovering the inhibitory effects of BlockAide/CR. He likens the V3 Loop to a key: when HIV, using the V3 Loop as a key tries to enter a human cell via a CD4 receptor site (the keyhole), the virus is unsuccessful because the entrance key hole is already blocked by BlockAide/CR.

In addition, based on their work to date, Dr. Sastry and his research colleagues believe that BlockAide/CR can effectively block syncytium formation and prevent or limit the T-cell loss that invariably occurs with a progressive HIV infection. Syncytium formation is a very important step in the spread of HIV infection and the destruction of T-cells. In this process, an HIV infected cell combines with a number of healthy T-cells to form a large multinuclear mass or syncytium. The syncytia die quickly, killing the incorporated T-cells and releasing massive numbers of

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### newly formed HIV particles.

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.

The Company intends to conduct large animal toxicology testing for BlockAide/CR which, if successful, is expected to enable the Company to proceed with preparations for human testing under the FDA's Fast Track Program.

## 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 though a preliminary primate trial, with encouraging results. Further preclinical and animal toxicity testing must be conducted before progressing to human trials, in the same manner as described above for BlockAide/CR. If proven safe and effective in preclinical testing, and if approved by the FDA through its Fast Track Program, BlockAide/VP could be used for HIV infected individuals as an adjunct to Triple Combination Therapy, a multiple drug regimen widely used to suppress HIV in HIV infected humans to prevent the onset of AIDS, or as a primary therapy for newly infected individuals. 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 thiophosphonoformates (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 be many proprietary derivatives. 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 happens to be 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. Assuming continued positive research results, 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

## ANTI-CANCER 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,

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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) (campecctabine).

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

#### HIV/AIDS THERAPY

Significant advancements have been made in the treatment of asymptomatic HIV positive patients. It is now understood that early combination therapy with a three or four drug "cocktail" can push HIV viral load to below "detectable levels." This therapy is often referred to as

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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 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 HIVinfected 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 soar to 40 million in 2001. HIV infections are not being treated in the third world, to even the smallest extent, since cost is prohibitive and the ability to administer complex therapy is nearly impossible. Thus, simple, inexpensive new therapies are required.

#### THIOVIR AND HPV

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

Transmission of HPV usually occurs through direct skin contact during vaginal, anal or oral sex with an infected individual, and warts (called genital warts or condylomas) may or may not begin to appear on the skin surrounding the entrance to infection, depending on the length of the latency period. Because

one of the consequences of HPV infection is the introduction of abnormal cells, the infection may lead to cancerous growths, particularly on the cervix. Although HPV and genital warts are treatable, there is currently no known cure for the infection.

 $\ensuremath{\mathsf{HPV}}$  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.

### MARKETING AND SALES

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 2 below.

#### MANUFACTURING

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.

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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 2 below.)

## LICENSING AND RESEARCH AGREEMENTS

## M.D. ANDERSON AGREEMENTS

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

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 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.

No royalties have been paid under the M.D. Anderson Agreement and Amendment.

## USC AGREEMENTS

Under an Option and License Agreement with USC dated January 23, 1998, amended August 16, 2000, we hold exclusive license rights to a total of three patents, two relating to Biokeys' 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

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licensed patent rights and all future patent-related expenses paid by USC, as long as the USC License Agreements remain in effect and until the patent rights have expired. USC's retained interest consists of a running royalty on net sales of licensed products and a share of consideration received by Biokeys from all sublicenses and assignments. No royalties have been paid under these agreements.

#### 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 administered after HIV infection as a therapeutic. This 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.

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

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

PATENT # PATENT DESCRIPTION APPLICATION APPLICATION ISSUE DATE EXPIRATION /FOCUS DATE

DATE 5,072,032 Preparation and use of thiophos-Antiviral 6/21/1989 12/10/1991 6/21/2009 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 acquired immunodeficiency syndrome 5,183,812 Preparation and use of thiophos-Antiviral 09/30/1991 2/2/1993 9/30/2011 phonates and thio-analogues /Anticancer of phosphonoformic acid 5,376,658 5,10-methylenetetrahydrofolate Anticancer 12/23/1993 12/27/1994 12/23/2013 as a modulator of a chemotherapeutic agent 5,534,519 5,10methylenetetrahydrofolate Anticancer 10/20/1994 7/9/1996 10/20/2014 as a modulator of a chemothera-

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	peutic agent				
5,603,933	CD4 peptides for binding to viral envelope proteins	Antiviral	8/31/1993	2/18/1997	2/18/2014
5,614,562	Method of treating drug resistant tumor cells using organoselenones	Anticancer	12/16/1992	3/25/1997	3/25/2014
EP 0 671 947	Compositions for eliciting cytotoxic T-lymphocyte responses against viruses	Antiviral	2/12/1992	8/3/2000	2/12/2012
6,147,244	Preparations of thiophosphites and Thiophosphonates	Antiviral /Anticancer	5/3/1999	11/14/2000	5/3/2019
6,147,245	Preparation and use of Alpha-Keto Bisphosphonates	Antiviral	7/13/1999	11/14/2000	7/13/2019
6,210,873	Methods and compositions for the priming of specific cytotoxic T-lymphocyte response	Antiviral	12/2/1991	4/3/2001	4/3/2018

6,265,539	Prophylaxis and therapy of acquired immunodeficiency syndrome	Antiviral	2/13/1992	7/24/2001	7/24/2018
6,284,909	Preparations of thiophosphites and thiophosphonates	Antiviral	11/1/2000	9/4/2001	11/1/2020

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

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

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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.

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

The FDA has developed several regulatory procedures to accelerate the clinical testing and approval of drugs intended to treat serious or life-threatening illnesses under certain circumstances. For example, in 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 III 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

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effects. Product approvals may be withdrawn, or sanctions imposed, if compliance with regulatory requirements is not maintained.

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

## HEALTH CARE REFORM MEASURES AND THIRD PARTY REIMBURSEMENT

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

### RESEARCH AND DEVELOPMENT OUTLAYS

During 1999 and 2000, the Company expended \$351,446 and \$983,198, respectively, on research and development activities. In addition, the Company has expended \$591,394 for research and development during the nine months ending September 30, 2001.

#### **EMPLOYEES**

The Company presently has three full-time employees and one part-time employee. No significant increase in the number of employees is anticipated in the next 12 months.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### GENERAL

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 \$15,527,553 as of September 30, 2001. Our expenses from inception have related to costs incurred in research activities for the development of our drug

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candidates, to administrative expenses required to support these efforts and, more recently, to substantial charges for amortization of goodwill resulting from the October 2000 merger with Biokeys, Inc. We expect losses to continue for the near future, and such losses will likely increase as human clinical trials in the U.S. are undertaken 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."

#### **RESULTS OF OPERATIONS**

NINE MONTHS ENDED SEPTEMBER 30, 2001 COMPARED WITH NINE MONTHS ENDED SEPTEMBER 30,2000

The Company had no revenues from operations for the nine months ended September 30, 2001, as research and development activities continued. Interest income for the nine month period totaled \$30,693, compared with \$8,014 for the prior period, reflected interest earned on the balance of the proceeds from the Company's overseas private placement offering completed in the fall of 2000.

Funding from the overseas private placement enabled the Company to increase research and development expenditures by 80% for the nine months ended September 30, 2001, to \$591,384 from \$328,706 for the prior period.

General and administrative costs rose from \$567,625 for the prior period to \$1,555,539 for the current nine months, an increase of \$987,914 or 174%. The increase was due primarily to the issuance of shares of common stock and warrants in payment for medical and other consulting services, the addition of salaried personnel as a result of the merger, and higher professional fees and other costs reflecting greater corporate activity after the merger. Depreciation and amortization amounted to \$5,707,101 compared to \$4,974 for the prior nine months, due entirely to the merger between BioQuest, Inc. and Biokeys, Inc., which resulted in a total of \$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 is being amortized over a two-year period beginning in the last quarter of 2000, resulting in goodwill amortization charges of \$1,902,367 per fiscal quarter.

There was no interest expense in the nine months ended September 30, 2001, compared with \$19,696 for the prior nine-month period, because the earlier indebtedness had been paid or converted into shares of Common Stock.

As a result of the factors described, the Company's net loss increased from (917, 542) for the prior nine months to (7, 823, 331) for the current period, and from a loss of (0.07) per share for the prior period to a loss of (0.55) per share for the current period.

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## 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 180% from \$351,446 in 1999 to \$983,198 in 2000.

General and Administrative expenses increased by approximately 17% from \$708,562 in 1999 to \$827,970 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 entirely 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 is 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, due to the accrual of interest on the Company's subordinated convertible notes issued in a private offering in the spring of 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.

## LIQUIDITY AND CAPITAL RESOURCES

The Company has incurred negative cash flows since its inception, and has funded its activities primarily through short-term loans and sales of equity securities. As of December 31, 2000, the Company had cash and equivalents and a certificate of deposit totaling \$1,484,208, compared with only \$58,463 at the end of the prior year. As of September 30, 2001, cash and cash equivalents totaled \$165,535, compared with \$467,878 plus a \$1,016,320 certificate of deposit at September 30, 2000.

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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, if the FDA approves our pending application. If granted approval, 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 \$2.5 and \$3.5 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, depending on whether animal testing or initial human trials are scheduled.

We have raised approximately \$450,000 through private interim financing and the issuance of short-term notes and warrants in November and December of 2001. We believe our current resources are sufficient to fund our general and administrative overhead until the end of April 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 funding is available, we may add up to two additional management-level 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 raising additional capital will continue at least until the Company is able to begin marketing its new technologies. The Company's future capital requirements and the adequacy of its financing 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, the cost and timing of production arrangements, the development of effective sales and marketing activities, government grants, 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.

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#### QUANTITATIVE AND QUALITATIVE INFORMATION ABOUT MARKET RISK

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

#### NEW ACCOUNTING PRONOUNCEMENTS

The Financial Accounting Standards Board (FASB) has issued Statement of Financial Accounting Standards No. 141, BUSINESS COMBINATIONS (SFAS 141). SFAS 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. The Company does not expect the adoption of SFAS 141 to have a material impact on its business because it currently has no planned or pending acquisitions.

The FASB has also issued Statement of Financial Accounting Standards No. 142 GOODWILL AND OTHER INTANGIBLE ASSETS (SFAS 142) which will be effective for the Company as of January 1, 2002. SFAS 142 requires that goodwill and other intangible assets with indefinite lives no longer be amortized. SFAS 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 142 will result in the elimination of annual amortization expense related to goodwill; however, because of the extensive effort needed to comply with this statement, the impact of related impairment, if any, on our financial position or results of operations has not been determined. We believe this registration statement contains "forward-looking statements." These statements are subject to risks and uncertainties and are based on the beliefs and assumptions of our management based on information currently available on it. When we use words such as "believes", "expects", "anticipates", "intends", "plans", "estimates", "should", "likely", or similar expressions, we are making forward-looking statements. Forward-looking statements are not guarantees of performance. They involve risks, uncertainties, and assumptions. Our future results and stockholder values may differ materially from those expressed in the forward-looking statements. Many of the factors that will determine these results and values are beyond our ability of control or predict.

Assumptions relating to budgeting, marketing, and other management decisions are subjective in many respects and thus susceptible to interpretations and periodic revisions based

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on actual experience and business developments, the impact of which may cause us to alter our marketing, capital expenditure, or other budgets, which may in turn affect our business, financial position, results of operations, and cash flows.

#### RISK FACTORS

THERE IS A SUBSTANTIAL ACCUMULATED DEFICIT AND LIMITED WORKING CAPITAL.

The Company had an accumulated deficit of \$(15,527,553) as of September 30, 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. In addition, the Company has funded its operations primarily through the sale of Company securities, and has had limited working capital for its product development and other activities.

WE HAVE NO CURRENT 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. We cannot assure you that we will be able to consummate any such financing 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.

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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.

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 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, Immunex Corporation, which is a biotech company 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 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.

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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.

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.

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 newlyapproved medical products. The Company cannot guarantee that adequate third-party insurance

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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.

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

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

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

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

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

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

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

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

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

The license agreements pursuant to which the Company has licensed its core technologies for its potential drug products permit the licensors, respectively M.D. Anderson 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'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, respectively. 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 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.

# THERE ARE NO MANUFACTURING CAPABILITIES.

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.

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

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assurance that such third parties will perform all of their obligations under arrangements with the Company or will perform those obligations satisfactorily.

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 THE SHARES OF PREFERRED STOCK IN THE FUTURE MAY AFFECT 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 (i) restrict 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

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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 September 30, 2001, there were outstanding options and warrants for the purchase of an aggregate of 3,072,078 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 holder. Assuming that all options and warrants were exercised and that all of the Series A Preferred Stock was converted, a total of 3,872,078 additional shares of Common Stock would be issued, for which the Company would receive aggregate cash proceeds of approximately \$3,309,318. After various holding period requirements under Rule 144 of the Securities and Exchange Commission were 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.

ITEM 3. DESCRIPTION OF PROPERTY

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 a rental of \$33,600 per year.

The Company also has an office handling administration and finance, at 333 N. Sam Houston Parkway, Suite 1035, Houston, Texas, which consists of approximately 800 square feet.

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The lease on this office expired as of October 31, 2001, and the Company has entered into a month-to-month lease arrangement at \$19.00 per square foot. We believe the Company could easily find comparable space should the Company need to 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 4. 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 September 30, 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 July 2000.

Name and Address of Beneficial Owners Number of Shares Percent of Class - ------ - - - - - - - - - - - - - - -------------- Louis R. Reif 201,010(1) 1.38% c/o Biokevs Pharmaceuticals, Inc. 333 N. Sam Houston Pkwy, Suite 1035 Houston, Texas

77060 Warren C. Lau 885,797(2) 6.07% c/o Biokeys Pharmaceuticals, Inc. 333 N. Sam Houston Pkwy, Suite 1035 Houston, Texas 77060 Nicholas Jon Virca 476,693(3) 3.27% c/o Biokeys Pharmaceuticals, Inc. 9948 Hibert Street, Suite 100 San Diego, CA 92131 Robert D. Whitworth 50,205 0.52% c/o Biokeys Pharmaceuticals, Inc. 333 N. Sam Houston Pkwy, Suite 1035 Houston, Texas 77060 Francis E. O'Donnell, Jr., M.D. 1,323,646(4) 9.07% 709 The Hamptons Lane

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(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.

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Name and Address of Beneficial Owners Number of Shares Percent of Class - --- - - - - - - - - -- - - - - - - - - - -- - - - - - - - - - ----- ----- - - - - - - - - --- ------ - - - - - - - - -Town & Country, Missouri 63017 Thomas DePetrillo 957,922(5) 6.57% 988 Centerville Road Warwick, Rhode Island 02886 Matthew Balk 976,275(6) 6.69% 245

Park Avenue. 44th Floor New York, NY 10167 M. Ross Johnson, Ph.D. 502, 538(7)3.45% 53524 Bickett Street Chapel Hill, North Carolina 27514 Jonnie R. Williams 1,072,085 7.35% 1 Starwood Lane Manakin Sabot, VA 23103 All directors and executive officers of the 3,465,064 23.75% Company (including the directors and executive officers of Biokeys, Inc.) as a group (6 persons)

#### ITEM 5. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

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 directors and executive officers of each of Biokeys Pharmaceuticals, Inc. and Biokeys, Inc., and their respective positions and ages as of June 30, 2001, are as follows:

(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.

(7) Represents currently exercisable warrants.

. ---- Louis R. Reif 78 Chairman, Chief Executive Officer and Director of Biokeys Pharmaceuticals, Inc.; Director and Secretary of Biokeys, Inc. Nicholas Jon Virca 54 President, Chief Executive Officer and Director of Biokeys, Inc. Warren C. Lau 48 President, Chief Financial Officer and Director of Biokeys Pharmaceuticals, Inc.; Chief Financial Officer of Biokeys, Inc. M. Ross Johnson, Ph.D. 56 Chairman and Director of Biokeys, Inc. Francis E. O'Donnell, Jr. M.D. 52 Director of Biokeys, Inc. Robert D. Whitworth 48 Director and Secretary of Biokeys Pharmaceuticals, Inc.

LOUIS R. REIF is a co-founder of Biokeys Pharmaceuticals, Inc. and has served as its Chief Executive Officer and Chairman and as a member of its Board of Directors since 1996. From 1952 to 1993, Mr. Reif was associated with National Fuel Gas Company, a U.S. natural gas company listed on the New York Stock Exchange. He served as Vice President from 1958 to 1974, President and Chief Executive Officer from 1974 to 1988, a Director from 1966 to 1993, and Chairman of the Board from 1980 to 1993. In 1989, Mr. Reif served as Chief Operating 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) since1996. 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 Opthamology 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

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Society for Testing and Materials and the International Standards Association. Mr. Whitworth holds a B.S. degree in Chemistry from Southern Methodist University.

## ITEM 6. 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, 2000:

Annual Compensation Awards Payouts (i) (a) (b) (c) (d) (e) (f) (g) (h) Name Year 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 2000 30,000(1)President & CEO 1999 Biokeys, Inc. 1998 Warren C. Lau 2000 114,000 President 1999 114,000 5,000 Biokeys 1998 94,000 5,000 Pharmaceuticals, Inc. Louis R. Reif (2)

- 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.

## EXECUTIVE EMPLOYMENT AGREEMENTS

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. 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 \$120,000 per year.

The Company provides health and life insurance coverage for Messrs. Virca and Lau.

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## ITEM 7. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Warren C. Lau, a founder, stockholder, officer and director of Biokeys Pharmaceuticals Inc., is party to an executive employment agreement providing for a salary of \$114,000 per year. Nicholas Jon Virca, an officer and director of Biokeys, Inc. and a stockholder of the Company, is paid a salary of \$120,000. (See Item 6 above).

Louis R. Reif, a founder, stockholder, officer and director of Biokeys Pharmaceuticals, Inc., is not compensated for his service for the Company, but receives reimbursement of actual expenses incurred in performing services for the Company, including attending meetings and undertaking business trips for the Company. Directors who are not executive officers of the Company are similarly reimbursed, but are not paid a salary.

M. Ross Johnson, a Director and Chairman of Biokeys, Inc., has provided consulting services to the Company from time to time. In consideration of such services, the Company issued warrants to Dr. Johnson in 1999 for the purchase of up to 502,528 shares of Common Stock. From time to time, the Company has also paid Dr. Johnson cash consulting fees which amounted to \$15,000 in the aggregate as of December 31, 2000.

Matthew Balk, a principal stockholder of the Company, is affiliated with H.C. Wainwright & Co., Inc., a brokerage and investment banking firm. H.C. Wainwright & Co., Inc. represented the Company in its merger arrangements with Biokeys, Inc., for which the Company agreed to issue 150,000 shares of Common Stock in payment of such services. In connection with the Merger Agreement, the directors of BioQuest, Inc. and Biokeys, Inc. authorized the issuance of warrants (referred to as the "Incentive Warrants") for the purchase of an aggregate of 229,482 shares of 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 Agreement. The Incentive Warrants were not initially assigned to specific individuals, but were issued to the Company's directors and its counsel, to be held 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 September 30, 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 September 30, 2001, but will be recorded in the future when an award is made to a specific recipient.

#### ITEM 8. DESCRIPTION OF SECURITIES

The authorized capital stock of Biokeys Pharmaceuticals, Inc. consists of 1,000,000 shares of Preferred Stock, \$0.01 par value, and 50,000,000 shares of Common Stock, \$0.001 par value.

#### PREFERRED STOCK

Our Board of Directors is authorized, without action by the stockholders, to issue preferred stock in one or more series. In the year 2000, we issued 3,200 shares of Series A 8% Convertible Preferred Stock, which are currently outstanding, to three investors in an overseas

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private placement offering under Regulation S promulgated by the Securities and Exchange Commission.

SERIES A 8% CONVERTIBLE PREFERRED STOCK (referred to as the "Preferred Stock")

DIVIDEND RIGHTS. Holders of shares of Preferred Stock are entitled to receive, when, as and if declared by the Company's Board of Directors out of earnings at the time legally available therefor, dividends at the annual rate of 8% per share, payable semi- annually on June 30 and December 31, pro-rated to the date of original issuance of the shares. Dividends are cumulative and will be payable to holders of record as they appear on our stock books on such record dates as are fixed by the Board of Directors. At the election of the holder, such dividends will be payable in shares and fractional shares of Preferred Stock, valued for this purpose at the rate of \$1,000 per share.

LIQUIDATION PREFERENCE. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the Preferred Stock will have preference and priority over the Common Stock of the Company for payment, out of the assets of the Company or proceeds thereof available for distribution to shareholders, of the sum of \$1,000 per share plus all cumulative dividends payable and unpaid thereon to the date of such distribution.

 $\ensuremath{\mathsf{CONVERSION}}\xspace$  The shares of Preferred Stock have the following conversion rights:

(i) The Preferred Stock is convertible into Common Stock at the election of the holder. Each share of Preferred Stock is convertible into 250 shares of the Company's Common Stock, which is equal to a conversion price of \$4.00 per share.

(ii) The conversion price and ratio will be subject to adjustment for subsequent events such as stock splits, recapitalization, and certain financing. In addition, if within two years after issuance the Company sells Common Stock in a private placement or in a underwritten public offering at a price per share which is less than the conversion price, the Company will issue a sufficient number of additional shares of Common Stock to each holder of Preferred Stock so as to reduce the effective conversion price to the level established in such private placement or public offering; PROVIDED, HOWEVER, that (i) such provisions shall not apply to a specified transaction previously pending between the Company and an institutional investor, (ii) such reduced conversion price shall not be less than \$2.50 per share, and (iii) such price adjustment provisions shall not apply to an interim financing of \$1,000,000 or less.

REDEMPTION: The Company may call the Preferred Stock for redemption at any time the closing price of Common Stock remains at a level of at least \$8.00 per share for a period of at least 20 consecutive trading days. The redemption price will be equal to the liquidation preference plus accrued and unpaid dividends. Also, at any time beginning after July 1, 2003, the Company may call all or 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 of such shares, plus all accrued and unpaid dividends. On the effective date fixed for redemption in the redemption notice, the Preferred Stock will cease to be outstanding but conversion rights will be exercisable up until the effective redemption date.

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VOTING RIGHTS. The Preferred Stock will have no voting rights, except that the written consent or affirmative vote of the holders of a majority of the outstanding Preferred Stock is required to approve (i) any proposed amendment to the Company's Certificate of Incorporation that would materially alter or change the powers, preferences, or special rights of the Preferred Stock so as to affect the holders adversely, and (ii) any plan of merger or consolidation that contains provisions which, if contained in a proposed amendment to the Company's Certificate of Incorporation, would have entitled the holders of the Preferred Stock to vote, as a class, on the issue.

## OTHER SERIES OF PREFERRED SHARES

Of the remaining authorized but unissued shares of preferred stock, our Board of Directors is authorized, without action by the stockholders, to issue shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges may include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of any series, all or any of which may be greater than the rights of the Common Stock. We have no present plans to issue any new shares of preferred stock.

#### COMMON STOCK

The Company's Common Stock consists of 50,000,000 authorized shares of \$0.001 par value. As of September 30, 2001 there were 14,906,387 shares of Common Stock outstanding. In addition, the Company had reserved and set aside a total of 3,072,078 shares for issuance upon future exercise of outstanding warrants, and 800,000 shares for issuance upon future conversion of the Company's Series A Convertible Preferred Stock.

The holders of our Common Stock are entitled to one vote per share held of record on all matters submitted to a vote of the stockholders. Our certificate of incorporation does not provide for cumulative voting in the election of directors. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of Common Stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our Board of Directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, holders of our Common Stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. Holders of our Common Stock have no preemptive or other subscription or conversion rights. There are no redemption or sinking fund provisions applicable to our Common Stock.

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#### PART II

ITEM 1. MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

## MARKET INFORMATION

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 non-existent. All prices shown have been adjusted to reflect 1 for 1.989949857 reverse stock split in July 2000. When this registration statement becomes effective, the Company intends to reapply for quotation privileges on the OTC Bulletin Board.

The following represents high and low prices on the OTC Bulletin Board until December 7, 1999 and thereafter in the Pink Sheets, during the last 24 months:

Quarter Ending High Low - - - - - ----------December 31, 1999 \$0.736 \$0.239 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

## HOLDERS

The number of record and beneficial holders of our Common Stock as of September 30, 2001 is approximately 600.

TRANSFER AGENT

Biokeys Pharmaceutical's transfer agent is Interwest Transfer Co., Inc., 1981 East 4800 South, Salt Lake City, UT 84117.

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### ITEM 2. LEGAL PROCEEDINGS

The Company is a defendant in an action entitled Karo Bio USA, Inc. vs. Biokeys Pharmaceuticals, Inc., recently commenced in the United States District Court for the District of Delaware. The action alleges infringement of Karo Bio's federal trademark registration for the name "Biokey," based upon their claimed prior use in connection with a particular Karo Bio product, and the use of "Biokeys" in our Company's name. The plaintiff seeks to prevent us from continuing to use "Biokeys" as part of our name, as well as an unspecified amount of damages.

The case is at an early stage and no discovery proceedings have yet taken place. Although the Company intends to defend the action vigorously, we have been conducting settlement discussions with the plaintiff and believe that the proceeding may be settled in the near future without monetary liability by either party. We believe that the lawsuit by Karo Bio will not have a material adverse effect on the Company.

ITEM 3. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS

None

0

#### ITEM 4. RECENT SALES OF UNREGISTERED SECURITIES

From January 1999 to September 30, 2001, the Company issued the following securities which were not registered under the Securities Act of 1933, as amended (the "Securities Act").

four accredited investors a total of 678,412 shares of 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 additional shares of Common Stock at an exercise price of \$0.40 per share. In March 2000, these warrants were exercised under a cashless exercise provision, resulting in the issuance of 599,066 shares of Common Stock to the warrant holders. This transaction was undertaken pursuant to exemption under Section 4(2) of the Securities Act.

- o From April to June 2000, the Company issued an aggregate of \$472,000 principal amount of 8.5% subordinated convertible promissory notes in a private placement offering to approximately 10 accredited investors under Regulation D, made through Company officers and without the assistance of any placement agent. In accordance with the terms of the notes, the principal amounts of the notes and all accrued interest were converted into shares of Common Stock at a conversion price of \$1.19 per share, effective as of the consummation of the Company's merger with Biokeys, Inc. which resulted in the issuance of 412,487 restricted shares to the note holders.
- o As of October 2000, the Company issued, pursuant to the exemption contained in Section 4(2) of the Securities Act, a total of approximately 6,999,990 shares of its Common Stock to 38 former stockholders of Biokeys, Inc., in accordance with the terms of the Merger Agreement between BioQuest, Inc. and Biokeys, Inc.

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- o In October and November 2000, the Company, agreed to issue, pursuant to the exemption contained in Section 4(2) of the Securities Act, 8,727 shares of Common Stock to a creditor in settlement of certain outstanding obligations of Biokeys, Inc. which preceded the date of consummation of the merger.
- o In August and September 2000, the Company sold a total of 3,200 shares of Series A 8% Convertible Preferred Stock to three overseas investors for a total of \$3,200,000, and issued to such investors warrants to purchase 400,000 shares of Common Stock at \$5.00 per share. Such sale and issuance were conducted in accordance with Regulation S of the Securities and Exchange Commission.
- o In February 2001, the Company granted 100,000 shares of Common Stock to a consulting firm for financial advisory services to be provided in 2001. Such shares were issued pursuant to the exemption available under Section 4(2) of the Securities Act.
- o In August 2001, two warrant holders exercised warrants through a cashless exercise provision in the warrants. Warrants to purchase a total of 271,758 shares of Common Stock were accordingly exchanged for the issuance of a total of 218,493 shares of Common Stock. This transaction was undertaken pursuant to the exemption available under Section 4(2) of the Securities Act.

All of the foregoing transactions were undertaken pursuant to written agreements between the Company and the recipients of shares or warrants, which agreements referred specifically or generally to restrictions on transfer under the Securities Act, Regulation S or Regulation D. All certificates for shares and/or warrants contained restrictive legends prohibiting the transfer of same, in the standard form used by the Company for such transactions. The Company's transfer agent was directed in each instance to provide for a "stop transfer" notation in its shareholder records.

#### ITEM 5. INDEMNIFICATION OF DIRECTORS AND OFFICERS

As permitted by Section 102(b) (7) of the Delaware General Corporation Law (the "DGCL"), Biokeys Pharmaceutical's Certificate of Incorporation and By Laws eliminate in certain circumstances the liability of directors of Biokeys Pharmaceuticals for monetary damages for breach of their fiduciary duty as directors. This provision does not eliminate the liability of a director: (i) for breach of the director's duty of loyalty to Biokeys Pharmaceuticals or its stockholders; (ii) for acts or omissions by the director not in good faith or which involve intentional misconduct or a knowing violation of the law; (iii) under Section174 of the DGCL; or (iv) for transactions from which the director derived an improper personal benefit. Such limitation of liability does not affect the availability of equitable remedies such as injunctive relief or rescission. Subsection (a) of Section 145 of the DGCL empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative (other than an action by or in the right of the corporation) by reason of the fact that he is or was a director, officer, employee, or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee, or agent of another corporation, partnership, joint

venture, trust, or other enterprise, against expenses (including attorneys' fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit, or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

Subsection (b) of Section 145 of the DGCL empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending, or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such a person acted in any of the capacities set forth above, against expenses (including attorney's fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification may be made in respect of any claim, issue, or matter as to which such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine that despite the adjudication of liability, but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the court shall deem proper.

Section 145 of the DGCL further provides that to the extent a director, officer, employee, or agent of a corporation has been successful in the defense of any action, suit, or proceeding referred to in subsections (a) and (b) or in the defense of any claim, issue, or matter therein, he shall be indemnified against expenses (including attorney's fees) actually and reasonably incurred by him in connection therewith; that indemnification provided for by Section 145 of the DGCL shall not be deemed exclusive of any other rights to which the indemnified party may be entitled; and empowers the corporation to purchase and maintain insurance on behalf of any person acting in any of the capacities set forth in the second preceding paragraph against any liability asserted against him or incurred by him in any such capacity or arising out of his status as such whether or not the corporation would have the power to indemnify him against such liabilities under Section 145 of the DGCL.

The Company's Bylaws require it, under certain circumstances, to indemnify any person who is or was a director or officer against expense (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with any threatened, pending or completed action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in, or not opposed to, the best interests of Biokeys Pharmaceuticals and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The Bylaws of the Company also provide that expenses incurred by a director or officer in defending or investigating a threatened or pending action, suit or proceeding shall be paid by the Company in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that he is not entitle to be indemnified by Biokeys Pharmaceuticals as authorized in the Bylaws.

In addition, the Company has applied for directors' and officers' liability insurance which, if issued, insures against liabilities that directors and officers of Biokeys Pharmaceuticals may incur in such capacities. The risks covered by such policies do not exclude liabilities under the Securities Act.

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## PART F/S

The following financial statements are included herein:

#### TITLE OF DOCUMENTS

A. FINANCIAL STATEMENTS OF BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY DECEMBER 31, 2000 AND DECEMBER 31, 1999

<ul> <li>Consolidated Balance Sheets</li> <li>Consolidated Statements of Operations</li> <li>Consolidated Statements of Shareholders' Equity (Deficit</li> <li>Consolidated Statements of Cash Flows</li> <li>Notes to Consolidated Financial Statements</li> </ul>	1	Independent Auditors' Report
<ul> <li>Consolidated Statements of Shareholders' Equity (Deficit</li> <li>Consolidated Statements of Cash Flows</li> </ul>	2	Consolidated Balance Sheets
5 Consolidated Statements of Cash Flows	3	Consolidated Statements of Operations
	4	Consolidated Statements of Shareholders' Equity (Deficit)
6 Notes to Consolidated Financial Statements	5	Consolidated Statements of Cash Flows
	6	Notes to Consolidated Financial Statements

FINANCIAL STATEMENTS OF BIOKEYS, INC. SEPTEMBER 30, 2000 AND DECEMBER 31, 1999

# PAGE

Β.

1	Independent Auditors' Report
2	Balance Sheets
3	Statements of Operations
4	Statements of Shareholders' Equity (Deficit)
5	Statements of Cash Flows
6	Notes to Financial Statements

- С.
  - FINANCIAL STATEMENTS OF BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY NINE MONTHS ENDED SEPTEMBER 30, 2001 (UNAUDITED)

# PAGE

1	Consolidated Balance Sheets
2	Consolidated Statements of Operations
3	Consolidated Statements of Cash Flows
4	Notes to Financial Statements

Notes to Financial Statements

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# PART III

ITEM 1.	INDEX TO EXHIBITS
Exhibit Number	DESCRIPTION
2.1	Agreement and Plan of Merger dated May 19, 2000 among BioQuest, Inc.; BioQuest Acquisition Corp.; and Biokeys, Inc.
3.1	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc October 12, 2000
3.2	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc October 12, 2000
3.3	Certificate of Merger of BioQuest Acquisition Corp. into Biokeys, Inc October 12, 2000
3.4	Certificate of Incorporation of BioQuest Acquisition Corp May 19, 2000
3.6	Amended and Restated Bylaws of Biokeys Pharmaceuticals, Inc.
4.1	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	Amendment to Option and License Agreement with USC dated August 16, 2000 (Co Factor and Selone) (Request for confidential treatment of certain data)
10.5*	Option and License Agreement with USC dated August 17, 2000 (Thiovir) (Request for confidential treatment of certain data)
10.6	Employment Agreement with Warren C. Lau
11.1	Statement Regarding Computation of Per Share Earnings
21.1	Subsidiaries of the Registrant

\* Refiled with this amendment on Form 10-SB/A

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#### SIGNATURES

Pursuant to the requirements of Section 12 of the Securities and Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on the 11th day of January, 2002.

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

### POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints LOUIS R. REIF and WARREN C. LAU, or either of them, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign the Registration Statement of Biokeys Pharmaceuticals, Inc. on Form 10SB, and any and all amendments (including post-effective amendments) to such Registration Statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agents or any of them or their or his substitute or substitutes, may unlawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities and Exchange Act of 1934, this Registration Statement or thereto has been signed below by the following persons in the capacities and on the date indicated.

Signatures Title Date
/s/
LOUIS REIF
Director
January
11, 2002 -
Louis R.
Reif /s/
ROBERT D.
WHITWORTH
Director
January
11, 2002 -
Robert D.
Whitworth
/s/ WARREN
C. LAU
Director
January
11, 2002 -

Warren C. Lau

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BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

Consolidated Financial Statements

December 31, 2000 and 1999

(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 (formerly BioQuest, Inc.) (a development stage enterprise) (the Company) as of December 31, 2000 and 1999, 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, 2000. 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 (formerly BioQuest, Inc.) (a development stage enterprise) as of December 31, 2000 and 1999, 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, 2000, 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 11 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 11. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Houston, Texas June 22, 2001

> BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

> > (A Development Stage Enterprise)

Consolidated Balance Sheets

DECEMBER 31, Assets 2000 1999 -----Current assets: Cash and cash equivalents

\$ 467,878 58,463 Certificate of deposit 1,016,330 --Advances to employees 10,500 6,554 Prepaid expenses 71,624 -- -------------Total current assets 1,566,332 65,017 Property and equipment, net (note 4) 6,356 9,243 Goodwill, net of accumulated amortization of \$1,900,709 in 2000 13,304,966 -. • Other assets 1,180 1,180 --------------Total assets \$ 14,878,834 75,440 ============ ============ LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT) Current liabilities: Accounts payable and accrued liabilities \$ 67,537 165,082 Accrued salary and related taxes 116,034 60,605 Accrued dividends payable 85,000 --Notes payable (note 5) --97,718 Sponsored research payable (note 7) --845,944 **Obligation** under license agreement (note 6) --139,834 -------- ---- - - - - - - - - -Total current liabilities 268,571 1,309,183 -------

Shareholders' equity (deficit) (notes 1, 6 and 8): Cumulative convertible preferred stock, \$.01 par value, (aggregate involuntary liquidation preference \$3,285,000), 1,000,000 shares authorized; issued and outstanding, 3,200 shares in 2000 32 -- Common stock, \$.001 par value, 50,000,000 shares authorized; issued and outstanding, 14,586,984 shares in 2000 and 5,859,976 shares in 1999 14,587 5,860 Additional paid-in capital 22,299,866 2,763,535 Deficit accumulated during the development stage (7,704,222) (4,003,138)----------Total shareholders' equity (deficit) 14,610,263 (1, 233, 743)Commitments and contingencies (notes 6, 7, 11, 12 and 13) -------------- Total liabilities and shareholders' equity (deficit) \$ 14,878,834 75,440 \_\_\_\_\_ ============

See accompanying notes to consolidated financial statements.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

INCEPTION (JUNE 12, 1996) YEAR ENDED DECEMBER 31, THROUGH --------------DECEMBER 31, 2000 1999 2000 ----------- ------ Net sales \$ -- -- 174,830 Cost of goods sold -- --51,094 ------------ Gross margin -- --123,736 Grant revenue -- --80,338 Interest income 40,922 14,234 57,005 ---------- -------40,922 14,234 261,079 ---------------- - - -**Operating** expenses: Research and development 983,198 351,446 2,717,544 General and administrative 827,970 708,562 3,437,098 Depreciation and amortization 1,907,341 5,385 1,989,516 Interest expense 23,497 4,326 111,989 Equity in loss of subsidiary ---- 178,936 ------ ------------- Total operating expenses 3,742,006 1,069,719 8,435,083 ------------------ Loss before cumulative effect of change in accounting principle (3,701,084) (1,055,485)(8, 174, 004)Cumulative effect of

change in accounting principle ---- (25,821) ----- ------- Net loss \$(3,701,084) (1,055,485)(8, 199, 825)========== ========= =========== Loss per common share - basic and diluted (note 10) \$ (0.44) (0.20) =========== ===========

See accompanying notes to consolidated financial statements.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

Consolidated Statements of Shareholders' Equity (Deficit)

Inception (June 12, 1996) through December 31, 2000

DEFICIT CUMULATIVE CONVERTIBLE ACCUMULATED TOTAL PREFERRED STOCK COMMON STOCK ADDITIONAL DURING THE SHAREHOLDERS' ------------------- PAID-IN DEVELOPMENT EQUITY SHARES AMOUNT SHARES AMOUNT CAPITAL STAGE (DEFICIT) -------------- -------------- ------Balances at June 12, 1996 (date of incorporation) - \$ - - \$ - -- - Sale of common stock without par value - 503 5 5 - 10 Change in par value of common stock - - - (4) 4 -- Issuance of common stock and net liabilities assumed in acquisition -- 1,716,132 1,716 3,224 (18,094)

(13, 154)Issuance of common stock - - 2,010,111 2,010 456 (2,466) - Net loss - - - --(259,476)(259,476) ------ --------- ----------------------Balances at December 31, 1996 - -3,726,746 3,727 3,689 (280,036) (272, 620)Sale of common stock, net of offering costs of \$9,976 - -1,004,554 1,004 1,789,975 -1,790,979 Issuance of common stock in acquisition -- 375,891 376 887,874 -888,250 Minority interest deficiency at acquisition charged to the Company -- - - -(45,003)(45,003) Net loss - - - --(1,979,400)(1,979,400) ---------------- ----- ------ ----- Balances at December 31, 1997 - -5,107,190 5,107 2,681,538 (2, 304, 439)382,206 Rescission of acquisition -- (375,891) (376) (887,874) 561,166 (327,084) Issuance of common stock at conversion of notes payable - -450,264 451 363,549 -364,000 Expense related to stock warrants issued - - -- 260,000 -

260,000 Net loss - - - --(1,204,380)(1,204,380) ------------ ----- ------ ------ Balances at December 31, 1998 - -5,181,564 5,182 2,417,213 (2,947,653) (525, 258)Sale of common stock (note 8) - -678,412 678 134,322 -135,000 Expense related to stock warrants issued (note 8) - - - -212,000 -212,000 Net loss - - - -- (1,055,485) (1,055,485) ----- -------------- ---------- --------------- Balances at December 31, 1999 - -5,859,976 5,860 2,763,535 (4,003,138) (1,233,743) Sale of preferred stock, net of offering costs of \$76,500 (note 8) 3,200 32 -3,123,468 -3,123,500 Issuance of common stock at conversion of notes and interest payable (note 8) -412,487 412 492,085 -492,497 Issuance of common stock at conversion of notes payable (note 8) - - 70,354 70 83,930 -84,000 Issuance of common stock to settle obligations (notes 1 and 6) - -495,<sup>111</sup> 496 1,201,664 -1,202,160 Issuance of

common stock for acquisition (note 1) - -6,999,990 7,000 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) - -150,000 150 487,350 -487,500 Expense related to stock warrants issued (note 140,000 -140,000 Dividends payable (note 8) - - - -(85,000) -(85,000)Cashless exercise of warrants (note 8) - -599,066 599 (599) - - Net loss - - - -- (3,701,084) (3,701,084) -. . . . . . . ----------- ------ ------ ------ Balances at December 31, 2000 3,200 \$ 32 14,586,984 \$ 14,587 22,299,866 (7, 704, 222). 14,610,263 ========= ======== =========== ========== ========== ============= =============

See accompanying notes to consolidated financial statements.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

Consolidated Statements of Cash Flows

INCEPTION (JUNE 12, 1996) YEAR ENDED DECEMBER 31, THROUGH -----DECEMBER 31, 2000 1999 2000 -----

---------- Cash flows from operating activities: Net loss \$ (3,701,084) (1,055,485)(8,199,825) Adjustments to reconcile net loss to net cash used in operating activities: Depreciation and amortization 1,907,341 5,385 1,989,516 Expense related to stock warrants issued 140,000 212,000 612,000 Expenses paid by issuance of common stock 211,209 - 211,209 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 (81,382) 11,518 (142,153) Increase in inventory - -(13,490) Increase (decrease) in accounts payable and accrued liabilities (624,376) 67,430 (475,139) Increase in sponsored research payable and license obligation -360,419 924,318 --------------- Net cash used in operating activities (2, 148, 292)(398, 733)(4,735,941) --------------- Cash flows from investing activities: Purchase of certificate of deposit (1,016,330) -(1,016,330)Purchases of property and equipment (3,745) - (87,630) Payment on obligation under license agreement

```
-(106,250)
Cash acquired in
 acquisition of
 subsidiary - -
 64,233 Payments
    on note
  receivable -
 170,000 370,000
   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
  (1,020,075)
170,000 (655,927)
----- ----
 -----
Cash flows from
   financing
  activities:
 Proceeds from
sale of preferred
stock 3,200,000 -
   3,200,000
 Proceeds from
 sale of common
stock - 135,000
1,935,965 Payment
of financing and
 offering costs
   (76, 500) -
(98,976) Payment
of notes payable
 and long-term
debt (17,718) -
(67,718) Proceeds
from issuance of
 notes payable
 472,000 80,000
894,718 Principal
  payments on
 capital lease
obligations - -
(4,243) -----
-----
 ---- Net cash
  provided by
   financing
   activities
3,577,782 215,000
5,859,746 -----
· · ·
-----
  ---- Net
increase in cash
   and cash
  equivalents
409,415 (13,733)
467,878 Cash and
cash equivalents
at beginning of
 period 58,463
72,196 - -----
-----
-----
----- Cash and
cash equivalents
at end of period
$ 467,878 58,463
    467,878
 _____
```

See accompanying notes to consolidated financial statements.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2000 and 1999

#### (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 50% of the total common stock of BioQuest outstanding upon consummation of the merger. 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. 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.

(Continued)

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

# (A Development Stage Enterprise)

## Notes to Consolidated Financial Statements

December 31, 2000 and 1999

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.

#### 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 non-employee stock-based compensation in accordance with Emerging Issues Task Force Issue No. 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, and accounts payable are a reasonable estimate of their fair values at the balance sheet dates due to the short-term nature of these instruments.

The Company maintains cash, 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) is being amortized using the straight-line method over two years.

## 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.

(Continued)

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

# Notes to Consolidated Financial Statements

December 31, 2000 and 1999

#### DEFERRED FINANCING COSTS

Costs associated with arranging debt financing are deferred and amortized using the straight-line method over the term of the notes payable.

## 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.

## SUPPLEMENTARY CASH FLOW INFORMATION

Interest of \$3,000 and \$4,300 was paid during 2000 and 1999, respectively. No income taxes were paid during 2000 and 1999.

(Continued)

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

# December 31, 2000 and 1999

Noncash investing and financing transactions excluded from the statements of cash flows for the years ended December 31, 2000 and 1999 are as follows:

# 2000 1999 ------ - - - - - - - - -- - - - - -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 -Warrants issued for consulting services (note 8) 140,000 212,000 Cashless exercise of warrants (note 8) 599 -Dividends payable (note 8) 85,000 -Issuance of common stock at conversion of notes and interest payable (note 8) 492,497 Acquisition of Biokeys, Inc.: 0ther assets 5,812 -Current liabilities 582,260 -

#### NEW ACCOUNTING PRONOUNCEMENTS

The Financial Accounting Standards Board (FASB) has issued Statement of Financial Accounting Standards No. 141, BUSINESS COMBINATIONS (SFAS 141). SFAS 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. The Company does not expect the adoption of SFAS 141 to have a material impact on its business because it currently has no planned or pending acquisitions.

(Continued)

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

## Notes to Consolidated Financial Statements

December 31, 2000 and 1999

The FASB has also issued Statement of Financial Accounting Standards No. 142, GOODWILL AND OTHER INTANGIBLE ASSETS (SFAS 142), which will be effective for the Company as of January 1, 2002. SFAS 142 requires that goodwill and other intangible assets with indefinite lives no longer be amortized. SFAS 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 142 will result in the elimination of annual amortization expense related to goodwill; however, because of the extensive effort needed to comply with this statement, the impact of related impairment, if any, on our financial position or results of operations has not been determined.

# (3) ACQUISITION OF BIOKEYS, INC.

On October 10, 2000, the Company merged with Biokeys, Inc. (see note 1).

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 0F0

\$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 is 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 Current liabilities \$ 5,812 (500,534)

\$ (494,722)

(Continued)

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2000 and 1999

The following unaudited pro forma results of operations for the years ended December 31, 2000 and 1999 have been prepared as though the merger occurred January 1, 1999. 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.

2000 1999 -------. . . . . . . . . . . Interest income \$ 40,922 14,234 **Operating** expenses (11,706,535)(9, 150, 656)-----\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ Net loss \$(11,665,613) (9,136,422) - - - - - - - - - - - - -Loss per common share \$ (0.83) (0.75)============ =============

Weighted

average number of common shares outstanding 14,027,144 12,183,437 ==========

# (4) PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2000 and 1999 were as follows:

# USEFUL LIVES 2000 1999 -----

Office furniture
and equipment 5
years \$ 13,420
13,420 Computer
software and
equipment 3
years 11,845
8,100
25,265
21,520 Less
accumulated
depreciation and
amortization
(18,909)
(12,277)
\$
Ψ
6,356 9,243
=======================

## (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.

(Continued)

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2000 and 1999

## (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 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.

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, 2000 and 1999. 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

(Continued)

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

# (A Development Stage Enterprise)

## Notes to Consolidated Financial Statements

#### December 31, 2000 and 1999

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. 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.

(Continued)

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

# Notes to Consolidated Financial Statements

December 31, 2000 and 1999

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. At December 31, 2000, dividends payable totaled \$85,000 or \$27 per share. 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 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, 2000.

In June 1999, the Company issued warrants to a key consultant to purchase 502,528 shares of common stock. The fair value of these warrants on the date of issue, \$212,000, has been recorded as a noncash general and administrative expense. The warrants are exercisable at \$0.49 per share and expire in June 2006. No such warrants have been exercised as of December 31, 2000.

In September 1998, the Company issued warrants to several consultants for the purchase of an aggregate of 670,875 shares of common stock. The warrants are exercisable at \$0.49 per share and expire in September 2005. No such warrants have been exercised as of December 31, 2000.

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

## (A Development Stage Enterprise)

# Notes to Consolidated Financial Statements

December 31, 2000 and 1999

In conjunction with the acquisition of Biokeys as discussed in note 1, all outstanding Biokeys warrants were replaced with warrants to purchase a total of 1,468,018 shares of the Company's common stock at \$0.49 per share that expire December 15, 2003.

Non-employee stock-based compensation that is not valued at the fair value of consideration received is valued, as of the grant date, using the Black-Scholes pricing model with the following assumptions for grants in 2000 and 1999: no dividend yield for either year; expected volatility of 125% to 170%; risk-free interest rates 6.1% to 6.8%; and expected lives of three and seven years, respectively.

At December 31, 2000, there were outstanding warrants to purchase a total of 3,222,331 shares of common stock as follows:

ended December

EXERCIS EXPIRATI WARRANT PRICE DA	ON S
	-
80,404 0.49	\$
August	
2002	
100,506	5
0.49 Ma	
2003	
400,000	)
4.00	
August	
2003	
1,468,01	18
0.49	
Decembe	r
2003	
670,875	
0.49	
Septembe	er
2005	
502,528	
0.49 Jur	ne
2006	
(9) I	NCOME TAXES
	ignificant components of income tax expense for the years 1, 2000 and 1999 are as follows:

2000 1999 --------- - - - - - - -Deferred tax benefit \$ 487,617 284,064 Increase in valuation allowance for deferred tax assets (487, 617)(284,064) - - - - - -

2000 1999 -

(Continued)

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

## Notes to Consolidated Financial Statements

December 31, 2000 and 1999

The tax effects of temporary differences that give rise to deferred tax assets at December 31, 2000 and 1999 are as follows:

2000 2000
Net
operating
loss
carryforward
\$ 2,642,171
967,556
Organization
costs and
license
agreement,
due to
differences
in
amortization
39,055
44,538
Total
deferred
tax assets
2,681,226
1,012,094
Less
valuation
allowance
(2,681,226)
(1,012,094)
Net
deferred
tax assets
\$
=========

===========

At December 31, 2000, the Company had an unused net operating loss carryforward of approximately \$7,771,000 for tax reporting purposes, which expires in 2111 through 2112 and 2118 through 2120. Included in the 2000 carryforward is a net operating loss carryforward acquired from Biokeys, Inc. of approximately \$3,475,000.

(10) NET LOSS PER COMMON SHARE

The computation of basic and diluted net loss per share for the years ended December 31, 2000 and 1999 is as follows:

2000 1999 -

Numerator: Net loss \$(3,701,084) (1,055,485) Less

preferred stock dividends (85,000) --. . . . . . . . . . . -----Numerator for basic and diluted loss per share \$(3,786,084) (1,055,485)=========== =========== Denominator for basic and diluted loss per share weighted average shares 8,582,707 5,183,447 =========== ============ Loss per common share basic and diluted \$ (0.44)(0.20) \_\_\_\_ ============

> 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, 2000 and 1999, 4,022,331 and 1,253,807 potentially dilutive shares, respectively, and 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 2000 and 1999.

> > (Continued)

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY (Formerly BioQuest, Inc.)

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2000 and 1999

## (11) 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 \$3,701,084 and \$1,055,485 for the years ended December 31, 2000 and 1999, 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 2001. 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 2001 are dependent upon obtaining additional financing.

#### (12) 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. Rent expense was \$23,522 and \$19,099 during the years ended December 31, 2000 and 1999, respectively. A lease for office space expired in November 2000 and was renewed for an additional one-year term.

(13) SUBSEQUENT EVENTS

In January 2001, the Company entered into a one-year consulting agreement with an individual who will serve as a medical director and provide assistance for anticipated applications to the U.S Food and Drug Administration. The consulting agreement provides for fees of \$42,000.

BIOKEYS, INC.

Financial Statements

September 30, 2000 and December 31, 1999

(With Independent Auditors' Report Thereon)

## INDEPENDENT AUDITORS' REPORT

The Board of Directors BioKeys, Inc.:

We have audited the accompanying balance sheets of BioKeys, Inc. (the Company) as of September 30, 2000 and December 31, 1999, and the related statements of operations, shareholders' equity (deficit), and cash flows for the nine months ended September 30, 2000 and the year ended December 31, 1999. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our 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.

As discussed in note 1 to the financial statements, the Company's outstanding common stock and warrants were acquired in October 2000 in a business combination accounted for as a purchase.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BioKeys, Inc. as of September 30, 2000 and December 31, 1999, and the results of its operations and its cash flows for the nine months ended September 30, 2000 and the year ended December

31, 1999, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 11 to the financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in note 11. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Houston, Texas March 16, 2001

BIOKEYS, INC.

Balance Sheets

SEPTEMBER 30, DECEMBER 31, 2000 1999 ASSETS Current assets - cash and cash equivalents \$ 11,135 Property and equipment, net (note 3) 520 Other assets 5,812	
Total assets \$ 5,812 11,655 ============ LIABILITIES AND	
SHAREHOLDERS' EQUITY (DEFICIT) Current liabilities: Accounts payable and	
accrued liabilities \$ 102,982 325,791 Due to BioQuest, Inc. 494,722 Accrued	
salaries 97,962 107,902 Total current	
liabilities 695,666 433,693 Notes payable (note 4) 617,673	
Total liabilities 695,666 1,051,366	

Commitments and contingencies (notes 5, 10 and 11) Shareholders' equity (deficit) (notes 4 and 7): Preferred stock, \$0.01 par value, 1,000,000 shares authorized; issued and outstanding zero shares in 2000 and 250,000 shares in 1999 --2,500 Common stock, \$0.001 par value, 25,000,000 shares authorized; issued and outstanding 6,330,320 shares in 2000 and 4,858,440 shares in 1999 6,330 4,858 Additional paid-in capital 5,461,787 3,348,500 Accumulated deficit (6, 157, 971)(3,895,569) Preferred shareholder note receivable --(500,000)----------Total shareholders' equity (deficit) (689,854) (1,039,711)----------Total liabilities and shareholders' equity (deficit) \$ 5,812 11,655 =========== ==========

See accompanying notes to financial statements.

BIOKEYS, INC.

Statements of Operations

NINE MONTHS ENDED YEAR ENDED

SEPTEMBER 30, DECEMBER 31, 2000 1999 -------------**Operating** expenses: Research and development \$ 220,470 154,183 General and administrative (note 7) 2,087,356 323,918 -------------- Total operating expenses 2,307,826 478,101 Extraordinary income - gain on forgiveness of debt (note 9) 45, 424 -------------Net loss \$(2,262,402) (478, 101)=========== =========== Loss per common share - basic and diluted (note 2) \$ (0.45) (0.10)=========== =========== Weighted average number of common shares outstanding 5,021,982 4,858,440 ============ ===========

See accompanying notes to financial statements.

BIOKEYS, INC.

Statements of Shareholders' Equity (Deficit)

Nine months ended September 30, 2000 and year ended December 31, 1999

PREFERRED TOTAL PREFERRED STOCK COMMON STOCK ADDITIONAL SHAREHOLDER SHAREHOLDERS' ----------- - - - - - - - - - -PAID-IN ACCUMULATED NOTE EQUITY SHARES AMOUNT SHARES AMOUNT

CAPITAL DEFICIT RECEIVABLE (DEFICIT) --\_\_\_\_\_ -------------- ----------- -------- Balances at December 31, 1998 250,000 \$ 2,500 4,858,440 \$ 4,858 3,348,500 (3, 417, 468)(500,000) (561, 610)Net loss --(478,101) --(478,101) --------------------------------- -------- Balances at December 31, 1999 250,000 2,500 4,858,440 4,858 3,348,500 (3, 895, 569)(500,000)(1,039,711) Conversion of preferred stock to common stock (note 4) (250,000)(2,500) 1,000,000 1,000 1,500 -- 500,000 500,000 Issuance of common stock at conversion of notes payable (note 4) ---- 471,880 472 235,468 -- --235,940 Expense related to stock warrants issued (note 7) -- -- ---- 1,876,319 -- --1,876,319 Net loss ---- -- -- --(2,262,402) - -(2,262,402) -------------- ------------------

Balances
at December
31, 2000
\$
6,330,320 \$
6,330
5,461,787
(6,157,971)
(689,854)
=======
=======
========

See accompanying notes to financial statements.

BIOKEYS, INC.

Statements of Cash Flows

NINE MONTHS ENDED YEAR ENDED SEPTEMBER 30, DECEMBER , 31, 2000 1999 ------------- Cash flows from operating activities: Net loss \$(2,262,402) (478, 101)Adjustments to reconcile net loss to net cash used in operating activities: Extraordinary gain on forgiveness of debt (45,424) --Depreciation 520 3,386 Expense related to stock warrants issued 1,876,319 --Changes in assets and liabilities: Increase in other assets (5,812) --Decrease in deposits --3,910 Increase (decrease) in accounts payable and accrued liabilities (177,385) 1,000 Increase in due to BioQuest, Inc. 494,722

-- Increase (decrease) in accrued salaries (9,940) 100,323 ------------ Net cash used in operating activities (129, 402)(369, 482) - ------------Cash flows from financing activities proceeds from issuance of notes payable 118,267 317,716 -------- --------- Net decrease in cash and cash equivalents (11, 135)(51,766) Cash and cash equivalents, beginning of period 11,135 62,901 -------------- Cash and cash equivalents, end of period \$ --11,135 =========== ===========

See accompanying notes to financial statements.

BIOKEYS, INC.

## Notes to Financial Statements

September 30, 2000 and December 31, 1999

#### (1) DESCRIPTION OF THE COMPANY

BioKeys, Inc. (BioKeys or the Company) was organized as a corporation in the State of Delaware in November 1997, and was formed to develop biotechnology. BioKeys' business strategy is to develop leading-edge medical research, currently being conducted at leading universities and research institutes throughout the world, into commercial medical products. Business opportunities BioKeys has identified include the development of a vaccine for use in cancer chemotherapy and the development of an effective oral anti-AIDS drug.

In October 2000, the Company was acquired by BioQuest, Inc. (BioQuest) of Houston, Texas. Company shareholders received 6,999,990 shares of BioQuest common stock, an aggregate amount equal to 50% of the total common stock of BioQuest outstanding immediately after the transaction. All outstanding BioKeys warrants were replaced with warrants to purchase BioQuest common stock at \$0.49 per share that expire December 15, 2003 (see note 4). The terms further specified that BioQuest change its name to Biokeys Pharmaceuticals, Inc. and that BioKeys, Inc. become a wholly-owned subsidiary. For financial reporting purposes, the acquisition transaction was accounted for as a purchase.

# (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## USE OF ESTIMATES

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

#### CASH EQUIVALENTS

Highly liquid investments purchased with original maturities of three months or less are considered to be cash equivalents. There were no cash equivalents at September 30, 2000 and December 31, 1999.

#### PROPERTY AND EQUIPMENT

Property and equipment are stated at cost. Depreciation is 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.

#### RESEARCH AND DEVELOPMENT COSTS

All research and development costs are expensed as incurred, including Company-sponsored research and development (see note 6).

(Continued)

#### BIOKEYS, INC.

## Notes to Financial Statements

#### September 30, 2000 and December 31, 1999

## 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 related to specifically acquired 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 a write-down to fair value is required. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of these 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.

## NET LOSS PER COMMON SHARE

Net loss per common share - basic is calculated according to Statement of Financial Accounting (SFAS) No. 128, EARNINGS PER SHARE, using the weighted average number of shares of common stock outstanding during the period. At September 30, 2000 and December 31, 1999, 1,227,825 and 710,000 potentially dilutive shares, respectively, relating to outstanding warrants 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 for the nine months ended September 30, 2000 and the year ended December 31, 1999.

# 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 non-employee stock-based compensation in accordance with Emerging Issues Task Force Issue No. 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.

(Continued)

#### BIOKEYS, INC.

## Notes to Financial Statements

September 30, 2000 and December 31, 1999

#### SUPPLEMENTARY CASH FLOW INFORMATION

No interest expense or income taxes were paid during the nine months ended September 30, 2000 or the year ended December 31, 1999.

Noncash investing and financing transactions excluded from the statement of cash flows for the nine months ended September 30, 2000 are as follows:

Conversion of notes payable into common stock (note 4) \$ 235,940 Payment of shareholder note receivable with offset of notes payable (note 4) 500,000

## (3) PROPERTY AND EQUIPMENT

Property and equipment at September 30, 2000 and December 31, 1999 were as follows:

USEEUI LIVES 2000 1999 -----. ........ - - - - - - -Computer equipment 3 years \$ 10,157 10,157 Less accumulated depreciation (10, 157)(9,637) ------- -------- \$ --520 ========= =======

#### (4) NOTES PAYABLE

At December 31, 1999, notes payable consisted of advances from investors and related parties for operating purposes. This debt was non-interest bearing. During the nine months ended September 30, 2000, additional advances totaling \$118,267 were received by the Company.

During September 2000, advances totaling \$235,940 were converted into 471,880 shares of common stock at a conversion price of \$0.50 per share. An additional \$500,000 of outstanding advances were used toward the payment of the preferred shareholder note receivable. The preferred stock was simultaneously converted to 10,000 shares of common stock at a conversion rate of four shares of common stock for every share of preferred stock.

## (5) LICENSE AGREEMENT

Under an Option and License Agreement with the University of Southern California (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

(Continued)

#### BIOKEYS, INC.

#### Notes to Financial Statements

## September 30, 2000 and December 31, 1999

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 a running royalty 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.

#### (6) RESEARCH AGREEMENT

On November 17, 1997, BioKeys entered into a Research Agreement (RA) with USC.

The RA will involve further studies in the therapeutic potential of particular anti-AIDS agents. The RA will involve the following objectives: (1) acquire initial in vitro data relating to the potential use of an oral anti-AIDS drug with other HIV and/or CMV inhibitor drugs as part of a combination therapy; (2) conduct additional research into other potential applications of the oral anti-AIDS drug; (3) conduct additional research into other proprietary compounds related to the oral anti-AIDS drug; (4) transfer to the Company technology related to the oral anti-AIDS drug family of compounds; and (5) continue to patent findings.

# (7) WARRANTS

In exchange for consulting services, in September 2000, the Company issued warrants with a fair value of \$1,876,319 to purchase 517,825 shares of common stock. These transactions have been reported as a noncash general and administrative expense in the accompanying 2000 statement of operations. These warrants were valued using the Black-Scholes pricing model with the following assumptions: no dividend yield, expected volatility of 160%, risk-free interest rate of 5.91%, and expected life of 3.2 years. Because there was not a reliable fair value of the Company's common stock in September 2000, the pricing model used the BioQuest closing price on October 10, 2000, the effective date of the merger.

In conjunction with 1997 and 1998 private placements of common stock, the Company issued warrants to purchase 710,000 shares of common stock.

In conjunction with the acquisition of BioKeys in October 2000 (see note 1), all outstanding Company warrants were exchanged for warrants to purchase common stock in Biokeys Pharmaceuticals, Inc. (New Warrants). The New Warrants expire December 15, 2003 and have an exercise price of \$0.49 per share of common stock.

(Continued)

#### BIOKEYS, INC.

#### Notes to Financial Statements

September 30, 2000 and December 31, 1999

## (8) INCOME TAXES

Significant components of income tax expense for the nine months ended September 30, 2000 and the year ended December 31, 1999 are as follows:

2000 1999 ----- Deferred tax benefit \$ 129,568 159,154 Increase in valuation allowance for deferred tax assets (129,568) (159,154) --- Income tax expense \$ --

\_\_\_\_\_

The tax effects of temporary differences that give rise to deferred tax assets at September 30, 2000 and December 31, 1999 are as follows:

2000 1999 ------ Net operating loss carryforward \$ 1,181,515 1,051,947 Less valuation allowance (1,181,515) (1,051,947) ------ Net deferred tax assets \$ -

- --

At September 30, 2000, BioKeys had an unused net operating loss carryforward of approximately \$3,475,000 for tax reporting purposes which expires in 2112 and 2118 through 2120.

#### (9) EXTRAORDINARY INCOME

During 2000, the Company negotiated reductions in certain payables. Payables of \$228,175 were settled with a cash payment of \$182,751, and \$45,424 was recognized as forgiveness of debt. The forgiveness of debt is reflected as an extraordinary item in the accompanying 2000 statement of operations.

## (10) CONTINGENCIES

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.

# (11) OPERATIONAL STATUS

The accompanying financial statements have been prepared on a going-concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred losses since inception and had net losses of \$2,262,402 and \$478,101 for the nine months ended September 30, 2000 and the year ended December 31, 1999, respectively.

(Continued)

#### BIOKEYS, INC.

# Notes to Financial Statements

September 30, 2000 and December 31, 1999

Through September 30, 2000, the Company has been principally engaged in licensing and research and development efforts. The Company has no current revenues and is not marketing any products. Before the acquisition of the Company by BioQuest, Inc. in October 2000 (see note 1), the Company projected a loss from operations for the remainder of 2000 and for 2001. Following the acquisition, the combined 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 combined 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 combined 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 combined Company is able to successfully develop new products or technologies, there can be no assurance that the combined Company will generate sufficient revenues from the sale or licensing of such products and technologies to be profitable. Management believes that the combined Company's ability to meet its obligations as they become due and to continue as a going concern through December 2001 are dependent upon obtaining additional financing.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Consolidated Financial Statements

Nine months ended September 30, 2001 (Unaudited)

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Consolidated Balance Sheets

SEPTEMBER 30, DECEMBER 31, 2001 2000 ---------(UNAUDITED) Assets Current assets: Cash and cash equivalents \$ 165,535 467,878 Certificate of deposit -- 1,016,330 Note receivable 35,000 --Advances to employees 10,500 10,500 Prepaid expenses 243 71,624 -------------Total current assets 211,278 1,566,332 Property and equipment, net 14,771 6,356 Goodwill, net of accumulated amortization of \$7,602,836 and \$1,900,709 7,602,839 13,304,966 Other assets 4,053 1,180 ----------Total assets \$ 7,832,941 14,878,834 ============ LIABILITIES AND

SHAREHOLDERS' EQUITY Current liabilities: Accounts payable and accrued liabilities \$ 241,847 67,537 Accrued salary and related taxes 215,702 116,034 Accrued dividends payable 277,000 85,000 ------ - - - - - - - -Total current liabilities 734,549 268,571 -------- -------Shareholders' equity: Cumulative convertible preferred stock, \$.01 par value, (aggregate involuntary liquidation preference \$3,477,000), 1,000,000 shares authorized; issued and outstanding, 3,200 shares 32 32 Common stock, \$.001 par value, 50,000,000 shares authorized; issued and outstanding, 14,906,387 and 14,586,984 shares 14,906 14,587 Additional paid-in capital 22,611,007 22,299,866 Deficit accumulated during the development stage (15, 527, 553) (7,704,222)----------Total shareholders' equity 7,098,392 14,610,263 Commitments and contingencies ----------

Total liabilities and shareholders' equity \$ 7,832,941 14,878,834 =============

See accompanying notes to consolidated financial statements.

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

INCEPTION NINE MONTHS ENDED (JUNE 12, 1996) SEPTEMBER 30,
THROUGH  SEPTEMBER 30, 2001 2000
2001  - Net sales \$
174,830 Cost of goods sold 51,094
Gross margin
123,736 Grant revenue 80,338 Interest income 30,693
8,014 87,698  30,693 8,014
291,772
Operating expenses: Research and development 591,384
328,706 3,308,928 General and administrative
1,555,539 567,625 4,992,637 Depreciation
and amortization 5,707,101 4,974 7,696,617
Interest expense 24,251 111,989
Equity in loss of subsidiary 178,936

Total operating expenses 7,854,024 925,556 16,289,107
Loss before cumulative effect of change in accounting principle (7,823,331) (917,542) (15,997,335) Cumulative effect of change in accounting principle (25,821) -
Net loss \$(7,823,331) (917,542) (16,023,156) =========== Loss per common share - basic and diluted \$ (0.55) (0.07) ==============

See accompanying notes to consolidated financial statements.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Consolidated Statements of Cash Flows

(unaudited)

INCEPTION NINE MONTHS ENDED (JUNE 12, 1996) SEPTEMBER 30, THROUGH
SEPTEMBER
30, 2001
2000 2001
Cash flows
from
operating
activities:
Net loss
\$(7,823,331)
(917,542)
(16,023,156)
Adjustments
to reconcile
net loss to
net cash
used in
operating

activities: Depreciation and amortization 5,707,101 4,974 7,696,617 Expense related to stock warrants issued 135,998 140,000 747,998 Expenses paid by issuance of common stock -- 186,712 211,209 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 33,508 (348,216) (108, 645)Increase in inventory ----(13,490)Increase (decrease) in accounts payable and accrued liabilities 273,978 119,759 (201, 161)Increase in sponsored research payable and license obligation - -- 924,318 ----------Net cash used in operating activities (1, 672, 746)(814,313) (6, 408, 687)------ - - - - - - - - - - -Cash flows from investing activities: (Purchase) maturity of certificate

of deposit, net 1,016,330 (2,500,000) -- Purchases of property and equipment (13,389) --(101,019) Payment on obligation under license agreement ---- (106,250) Cash acquired in acquisition of subsidiary -- -- 64,233 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 1,002,941 (2, 500, 000)347,014 ------------------- Cash flows from financing activities: Proceeds from sale of preferred stock --3,000,000 3,200,000 Proceeds from sale of common stock 375,000 --2,310,965 Payment for repurchase of warrants (55,279) --(55, 279)Proceeds from sale of warrants 47,741 --47,741 Payment of financing and offering

costs --(76, 500)(98, 976)Payment of notes payable and long-term debt --(17,718)(67, 718)Proceeds from issuance of notes payable --472,000 894,718 Principal payments on capital lease obligations -- --(4,243) ----------------- Net cash provided by financing activities 367,462 3,377,782 6,227,208 ------ ------ -------Net increase (decrease) in cash and cash equivalents (302,343) 63,469 165,535 Cash and cash equivalents at beginning of period 467,878 58,463 -- --------------------Cash and cash equivalents at end of period \$ 165,535 121,932 165,535 =========== =========== ===========

See accompanying notes to consolidated financial statements.

# BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

#### (A Development Stage Enterprise)

Nine months ended September 30, 2001 (unaudited) and December 31, 2000

# (1) BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES 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  ${\tt BioQuest},\ {\tt Inc.}\ {\tt merged}$ with Biokeys, Inc. (Biokeys) of San Diego, California (see note 2). 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 50% of the total common stock of BioQuest outstanding upon consummation of the merger. 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. Biokeys operating activity is included in the Company's consolidated financial statements from the date of the merger.

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.

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, the statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements.

In the opinion of management, the accompanying unaudited financial statements contain all necessary adjustments (consisting only of normal recurring adjustments) to present fairly the Company's financial position, results of operations and cash flows for the interim periods presented.

Operating results for the nine months ended September 30, 2001 are not necessarily indicative of the results expected for the entire year.

(continued)

#### BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

## (A Development Stage Enterprise)

Nine months ended September 30, 2001 (unaudited) and December 31, 2000

# 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.

# 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.

# NEW ACCOUNTING PRONOUNCEMENTS

The Financial Accounting Standards Board (FASB) has issued Statement of Financial Accounting Standards No. 141, BUSINESS COMBINATIONS (SFAS 141). SFAS 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. The Company does not expect the adoption of SFAS 141 to have a material impact on its business because it currently has no planned or pending acquisitions.

The FASB has also issued Statement of Financial Accounting Standards No. 142, GOODWILL AND OTHER INTANGIBLE ASSETS (SFAS 142), which will be effective for the Company as of January 1, 2002. SFAS 142 requires that goodwill and other intangible assets with indefinite lives no longer be amortized. SFAS 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 142 will result in the elimination of annual amortization expense related to goodwill; however, because of the extensive effort needed to comply with this statement, the impact of related impairment, if any, on financial position or results of operations has not been determined.

The FASB has issued Statement of Financial Accounting Standards No. 143, ACCOUNTING FOR ASSET RETIREMENT OBLIGATIONS (SFAS 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 asset. SFAS 143 is effective for fiscal years beginning after June 15, 2001. The Company does not expect the adoption of SFAS 143 to have a significant impact on its financial condition or results of operations.

(continued)

#### BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

#### (A Development Stage Enterprise)

Nine months ended September 30, 2001 (unaudited) and December 31, 2000

The FASB has also issued Statement of Financial Accounting Standards No. 144, ACCOUNTING FOR THE IMPAIRMENT OR DISPOSAL OF LONG-LIVED ASSETS (SFAS 144), which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. While SFAS 144 supercedes SFAS Statement 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 144 also supercedes 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 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. The Company does not expect adoption of SFAS 144 to have a significant impact on its financial condition or results of operations.

# (2) 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 is 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 as	ssets
Current	liabilities

\$ 5,812 (500,534)

# \$ (494,722)

(continued)

#### BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Nine months ended September 30, 2001 (unaudited) and December 31, 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, 1999. 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	L,706,535)
Net loss	\$(11	L,665,613)
Loss per common share	\$ ====	(0.83)
Weighted average number of common shares outstanding	14 ====	4,027,144 ======

# (3) 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 in March 2000. The \$17,718 note and accrued interest were repaid with cash in May 2000.

#### (4) EQUITY TRANSACTIONS

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.

(continued)

# BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

#### (A Development Stage Enterprise)

Nine months ended September 30, 2001 (unaudited) and December 31, 2000

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. At September 30, 2001, dividends payable totaled \$277,000. 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 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.

In conjunction with the acquisition of Biokeys as discussed in note 1, all outstanding Biokeys warrants were replaced with warrants to purchase a total of 1,468,018 shares of the Company's common stock at \$0.49 per share that expire December 15, 2003.

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 in the first and second quarters of 2001.

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

# (5) 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.

(continued)

# BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

# (A Development Stage Enterprise)

Nine months ended September 30, 2001 (unaudited) and December 31, 2000

The Company has not incurred any income tax expense since its inception due to operating losses and the related increase in the valuation allowance. Significant components of income tax expense for the nine months ended September 30, 2001 and 2000 are as follows:

NINE MONTHS ENDED SEPTEMBER 30, ----- - - - - - - ------ - - -2001 2000 --------\_ \_ \_ \_ \_ \_ \_ \_ Deferred tax benefit \$ 542,441 306,864 Increase in valuation allowance (542, 441)

(306,864)
Income
tax
expense
\$
=======
=======

The tax effects of temporary differences that give rise to deferred tax assets at September 30, 2001 and December 31, 2000 are as follows: SEPTEMBER 30, DECEMBER 31, 2001 2000 --------------- Net operating loss carryforward \$ 3,188,618 2,642,171 Intangible assets, due to differences in amortization 35,049 39,055 --------------Total deferred tax assets 3,223,667 2,681,226 Less valuation allowance (3, 223, 667)(2, 681, 226)---------Net deferred tax assets \$ -- --

The Company has established a valuation allowance for the full amount of these deferred tax assets.

(continued)

# BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Nine months ended September 30, 2001 (unaudited) and December 31, 2000

(6) NET LOSS PER COMMON SHARE

The computation of basic and diluted net loss per share for the nine months ended September 30, 2001 and 2000 is as follows:

NINE MONTHS ENDED SEPTEMBER 30, ------- 2001 2000 ------

Numerator:

Net loss \$ (7, 823, 331)(917, 542)Less preferred stock dividends (192,000)(21,000) --. . . . . . . . . . - Numerator for basic and diluted loss per share \$ (8,015,331)(938, 542)=========== ============ Denominator for basic and diluted loss per share weighted average shares 14,679,929 13,376,368 ============ ================= Loss per common share basic and diluted \$ (0.55)(0.07)============= =============

Net loss per common share is calculated according to Statement of Financial Accounting No. 128, EARNINGS PER SHARE, using the weighted average number of shares of common stock outstanding during the period. At September 30, 2001 and 2000, 3,783,905 and 4,022,330 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.

# (7) 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.

# (8) 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 a net loss of \$7,823,331 for the nine months ended September 30, 2001.

(continued)

# BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

#### (A Development Stage Enterprise)

September 30, 2001 (unaudited) and December 31, 2000

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 2001. 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 are dependent upon obtaining additional financing.

#### PATENT AND TECHNOLOGY LICENSE AGREEMENT

THIS thirteen (13) page AGREEMENT ("AGREEMENT") is made on this 14th day of June, 1996 by and between the BOARD OF REGENTS ("BOARD") of THE UNIVERSITY OF TEXAS SYSTEM ("SYSTEM"), an agency of the State of Texas, whose address is 201 West 7th Street, Austin, Texas 78701, THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER ("MDA"), a component Institution of the SYSTEM and BioQuest, Inc., a Houston, Texas corporation having a principal place of business located at 333 N. Sam Houston Pkwy, Suite 1150, Houston, Texas 77060 ("LICENSEE").

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#### RECITALS

A. BOARD owns certain PATENT RIGHTS and TECHNOLOGY RIGHTS related to LICENSED SUBJECT MATTER, which were developed at MDA, a component institution of SYSTEM.

B. BOARD desires to have the LICENSED SUBJECT MATTER developed in the LICENSED FIELD and used for the benefit of LICENSEE, the inventor, BOARD, and the public as outlined in the Intellectual Property Policy promulgated by the BOARD.

C. LICENSEE wishes to obtain a license from BOARD to practice LICENSED SUBJECT MATTER.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the parties hereto agree as follows:

#### I. EFFECTIVE DATE

1.1 Subject to approval by BOARD, this AGREEMENT shall be effective as of the date written herein above ("EFFECTIVE DATE").

## **II. DEFINITIONS**

As used in this AGREEMENT, the following terms shall have the meanings indicated:

2.1 AFFILIATE shall mean any business entity more than 50% owned by LICENSEE, any business entity which owns more than 50% of LICENSEE, or any business entity that is more than 50% owned by a business entity that owns more than 50% of LICENSEE.

2.2 LICENSED FIELD shall mean all fields of use within the LICENSED SUBJECT

MATTER.

2.3 LICENSED PRODUCTS shall mean any product or service SOLD by LICENSEE comprising LICENSED SUBJECT MATTER pursuant to this AGREEMENT.

2.4 LICENSED SUBJECT MATTER shall mean inventions and discoveries defined herein as PATENT RIGHTS or as TECHNOLOGY RIGHTS.

2.5 LICENSED TERRITORY shall mean all national and international political jurisdiction in which LICENSED PRODUCTS are sold.

2.6 NET SALES shall mean the gross revenues received by LICENSEE from the SALE of LICENSED PRODUCTS less sales and/or use taxes actually paid, import and/or export duties actually paid, outbound transportation prepaid or allowed, and amounts allowed or credited due to returns (not to exceed the original billing or invoice amount).

2.7 PATENT RIGHTS shall only mean any and all of BOARD'S rights in information or

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discoveries claimed in invention disclosures, patents, and/or patent applications, whether domestic or foreign, and all divisionals, continuations, continuations-in-part, reissues, reexaminations or extensions thereof, and any letters patent that issue thereon as defined in Exhibit I hereto subject to the limitations, if any, set forth therein.

 $2.8~{\rm SALE}$  or SOLD shall mean the transfer or disposition of a LICENSED PRODUCT for value to a party other than LICENSEE or an AFFILIATE.

2.9 Subject to the limitations, if any, set forth in Exhibit I hereto, TECHNOLOGY RIGHTS shall mean BOARD'S rights in any technical information, know-how, process, procedure, composition, device, method, formula, protocol, technique, software, design, drawing or data created by the inventors listed in Exhibit I hereto and relating to LICENSED SUBJECT MATTER which is not claimed in PATENT RIGHTS but which is necessary for practicing PATENT RIGHTS regardless of whether any patent is actually issued during the term of this AGREEMENT.

# III. LICENSE

3.1 BOARD hereby grants to LICENSEE a royalty-bearing, exclusive license under LICENSED SUBJECT MATTER to manufacture, have manufactured, use and/or sell LICENSED PRODUCTS within LICENSED TERRITORY for use within LICENSED FIELD and, subject to Paragraph 4.5 herein, shall extend to BOARD's undivided interest in any LICENSED SUBJECT MATTER developed during the term of this AGREEMENT and jointly owned by BOARD and LICENSEE. This grant shall be subject to Paragraph 14.2 and 14.3, hereinbelow, the payment by LICENSEE to BOARD of all consideration as provided in Paragraph 4.1 of this AGREEMENT, (as well as the timely payment of all amounts due under any Sponsored Research Agreement between MDA and LICENSEE in effect during the term of this AGREEMENT) and shall be further subject to rights retained by BOARD and MDA to:

(a) Publish the general scientific findings from research related to LICENSED SUBJECT MATTER; AND

(b) Subject to the provisions of ARTICLE XI herein below, use any information contained in LICENSED SUBJECT MATTER for research, teaching, patient care, and other educationally-related purposes.

3.2 LICENSEE shall have the right to extend the license granted herein to any AFFILIATE provided that such AFFILIATE consents to be bound by all of the terms and conditions of this AGREEMENT.

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3.3 Subject to the Paragraph 3.4 herein below, LICENSEE shall have the right to grant sublicenses under LICENSED SUBJECT MATTER consistent with the terms of this AGREEMENT provided that LICENSEE shall be responsible for its sublicensees relevant to this AGREEMENT, and for diligently collecting all amounts due LICENSEE from subicensees. In the event a sublicensee pursuant hereto becomes bankrupt, insolvent or is placed in the hands of a receiver or trustee, LICENSEE, to the extent allowed under applicable law and in a timely manner, agrees to use its best reasonable efforts to collect any and all consideration owed to LICENSEE and to have the sublicense agreement confirmed or rejected by a court of proper jurisdiction.

3.4 LICENSEE agrees to deliver to BOARD a true and correct copy of each sublicense granted by LICENSEE, and any modification or termination thereof, within thirty (30) days after execution, modification, or termination.

3.5 Upon termination of this AGREEMENT, BOARD agrees to accept as successors to

LICENSEE, existing sublicensees in good standing at the date of termination provided that such sublicensees consent to be bound by all of the terms and conditions of this AGREEMENT.

# IV. CONSIDERATION, PAYMENTS AND REPORTS

4.1 In consideration of rights granted by BOARD to LICENSEE under this AGREEMENT, LICENSEE agrees to pay MDA the following:

(a) Reimbursement for all out-of-pocket expenses paid by MDA through May 31, 1996 in filing, prosecuting, enforcing and maintaining PATENT RIGHTS licensed hereunder as follows: (i) \$53,125.00 due September 1, 1996, (ii) \$53,125.00 due April 1, 1997, and (iii) \$53,125.00 due January 1, 1998; and all future expenses paid by MDA, for so long as, and in such countries as, this AGREEMENT remains in effect. MDA will invoice LICENSEE in accordance with the schedule herein, and upon a quarterly basis thereafter beginning March 1, 1998 for expenses paid by MDA after May 31, 1996 and the amounts invoiced will be due and payable by LICENSEE within thirty (30) days thereafter; AND

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(b) A running royalty equal to six percent (6%) of LICENSEE's NET SALES of LICENSED PRODUCTS in national political jurisdictions in the LICENSED TERRITORY where LICENSED SUBJECT MATTER is covered by one (1) or more issued patents or pending patent applications and three percent (3%) of LICENSEE'S NET SALES of LICENSED PRODUCTS in national political jurisdictions in the LICENSED TERRITORY where LICENSED SUBJECT MATTER is NOT covered by one (1) or more issued patents or pending patent applications, and fifty percent (50%) (or forty percent (40%) when LICENSEE has expended or committed to expend and is current in its obligations to expend Two Million Dollars (\$2,000,000.00) on research and development of the LICENSED SUBJECT MATTER) of all consideration other than Research and Development ("R&D") money received by LICENSEE from (i) any sublicensee pursuant to Paragraphs 3.3 and 3.4 herein above, and (ii) any assignee pursuant to Paragraph 12.1 hereinbelow including but not limited to royalties, up-front payments, marketing, distribution, franchise, option, license, or documentation fees, bonus and milestone payments and equity securities, all payable within thirty (30) days after March 31, June 30, September 30, and December 31 of each year during the term of this AGREEMENT, at which time LICENSEE shall also deliver to BOARD and MDA a true and accurate report, giving such particulars of the business conducted by LICENSEE and its sublicensees, if any exist, during the preceding three (3) calendar months under this AGREEMENT as necessary for BOARD are to account for LICENSEE's payments hereunder. Such report shall include all pertinent data, including, but not limited to: (a) the total quantities of LICENSED PRODUCTS produced; (b) the total SALES, (c) the calculation of royalties thereon; (d) the total royalties (or minimum royalties) so computed and due MDA; and (e) all other amounts covered and due herein. Simultaneously with the delivery of each such report, LICENSEE shall pay to MDA the amount, if any, due for the period of such report. If no payments are due, it shall be so reported. Should LICENSEE be obligated to pay running royalties to third parties to avoid infringing such third parties patent rights which dominate BOARD'S PATENT RIGHTS, LICENSEE may reduce the running royalty due MDA by such running royalties to such third parties, provided, however, the running royalty due MDA shall in no case be less than one-half the rates stated herein.

4.2 During the Term of this AGREEMENT and for one (1) year thereafter, LICENSEE shall keep complete and accurate records of its and its sublicensees' SALES and NET SALES of LICENSED PRODUCTS to enable the royalties payable hereunder to be determined. LICENSEE shall permit MDA or its representatives, at MDA's expense, to periodically examine its books, ledgers, and records during regular business hours for the purpose of and to the extent necessary to verify any report required under this AGREEMENT. In the event that the amounts due to MDA are determined to have been underpaid in an amount equal to or greater than five percent (5%) of the total amount due during the period of time so examined, LICENSEE shall pay the cost of such examination, and accrued interest at the highest allowable rate.

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4.3 Upon the request of BOARD or MDA but not more often than once per calendar year, LICENSEE shall deliver to BOARD and MDA a written report as to LICENSEE'S (and sublicensees') efforts and accomplishments during the preceding year in diligently commercializing LICENSED SUBJECT MATTER in the LICENSED TERRITORY and LICENSEE'S (and sublicensees') commercialization plans for the upcoming year.

4.4 All amounts payable hereunder by LICENSEE shall be payable in United States funds without deductions for taxes, assessments, fees, or charges of any kind. Checks shall be made payable to The University of Texas M. D. Anderson Cancer Center and mailed by U.S. Mail to Box 297402, Houston, Texas 77297 Attention: Manager, Sponsored Programs.

4.5 No payments due or royalty rates under this AGREEMENT shall be reduced as

the result of co-ownership of LICENSED SUBJECT MATTER by BOARD and another party, including LICENSEE.

# V. SPONSORED RESEARCH

5.1 If LICENSEE desires to fund sponsored research within the LICENSED SUBJECT MATTER, and particularly where LICENSEE receives money for sponsored research payments pursuant to a sublicense under this AGREEMENT, LICENSEE shall notify MDA in writing of all opportunities to conduct such sponsored research (including clinical trials, if applicable), shall solicit research and/or clinical proposals from MDA for such purpose, and shall give good faith consideration to funding such proposals at MDA.

## VI. PATENTS AND INVENTIONS

6.1 If after consultation with LICENSEE it is agreed by BOARD and LICENSEE that a new patent application should be filed for LICENSED SUBJECT MATTER, BOARD will prepare and file appropriate patent applications, and LICENSEE will pay the cost of searching, preparing, filing, prosecuting and maintaining same. If LICENSEE notifies BOARD that it does not intend to pay the cost of an application, or if LICENSEE does not respond or make an effort to agree with BOARD on the disposition of rights of the subject invention, then BOARD may file such application at its own expense and LICENSEE shall have no rights to such invention. BOARD shall provide LICENSEE will as copy of the application for which LICENSEE has paid the cost of filing, as well as copies of any documents received or filed during prosecution thereof.

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# VII. INFRINGEMENT BY THIRD PARTIES

7.1 LICENSEE shall have the obligation of enforcing at its expense any patent exclusively licensed hereunder against infringement by third parties and shall be entitled to retain recovery from such enforcement. LICENSEE shall pay MDA a royalty on any monetary recovery to the extent that such monetary recovery by LICENSEE is held to be damages or a reasonable royalty in lieu thereof. In the event that LICENSEE does not file suit against a substantial infringer of such patents within six (6) months of knowledge thereof, then BOARD shall have the right to enforce any patent licensed hereunder on behalf of itself and LICENSEE (MDA retaining all recoveries from such enforcement) and/or reduce the license granted hereunder to non-exclusive.

7.2 In any suit or dispute involving an infringer, the parties shall cooperate fully, and upon the request and at the expense of the party bringing suit, the other party shall make available to the party bringing suit at reasonable times and under appropriate conditions all relevant personnel, records, papers, information, samples, specimens, and the like which are in its possession.

# VIII. PATENT MARKING

8.1 LICENSEE agrees that all packaging containing individual LICENSED PRODUCT(S), and documentation therefor, sold by LICENSEE, SUBSIDIARIES, and sublicensees of LICENSEE will be marked permanently and legibly with the number of the applicable patent(s) licensed hereunder in accordance with each country's patent laws, including Title 35, United States Code.

## IX. INDEMNIFICATION

9.1 LICENSEE shall hold harmless and indemnify BOARD, SYSTEM, MDA, its Regents, officers, employees, students, and agents from and against any claims, demand, or causes of action whatsoever, costs of suit and reasonable attorney's fees including without limitation those costs arising on account of any injury or death of persons or damage to property caused by, or arising out of, or resulting from, the exercise or practice of the license granted hereunder by LICENSEE or its officers, employees, agents or representatives.

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# X. USE OF BOARD AND COMPONENT'S NAME

10.1 LICENSEE shall not use the name of (or the name of any employee of) MDA, SYSTEM or BOARD without the advance, express written consent of BOARD secured through:

The University of Texas M. D. Anderson Cancer Center Office of Public Affairs 1515 Holcombe Boulevard Box 229 Houston, Texas 77030 ATTENTION: Stephen C. Stuyck

#### XI. CONFIDENTIAL INFORMATION

11.1 BOARD and LICENSEE each agree that all information contained in documents marked "confidential" which are forwarded to one by the other shall be received in strict confidence, used only for the purposes of this AGREEMENT, and not disclosed by the recipient party (except as required by law or court order), its agents or employees without the prior written consent of the other party, unless such information (a) was in the public domain at the time of disclosure, (b) later became part of the public domain through no act or omission of the recipient party, its employees, agents, successors or assigns, (c) was lawfully disclosed to the recipient party by a third party having the right to disclose it, (d) was already known by the recipient party at the time of disclosure, (e) was independently developed or (f) is required to be submitted to a government agency pursuant to any preexisting obligation.

11.2 Each party's obligation of confidence hereunder shall be fulfilled by using at least the same degree of care with the other party's confidential information as it uses to protect its own confidential information. This obligation shall exist while this AGREEMENT is in force and for a period of three (3) years thereafter.

# XII. ASSIGNMENT

12.1 Except in connection with the sale of substantially all of the assets of LICENSEE to a third party, this AGREEMENT may not be assigned by LICENSEE without the prior written consent of BOARD.

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## XII. TERMS AND TERMINATION

13.1 Subject to Articles 13.2, 13.3, 13.4, and 13.5 hereinbelow, the term of this AGREEMENT shall extend from the Effective Date set forth hereinabove to the full end of the term or terms for which PATENT RIGHTS have not expired, and if only TECHNOLOGY RIGHTS are licensed and no PATENT RIGHTS are applicable, for a term of fifteen (15) years.

13.2 BOARD shall have the right at any time after one (1) year from the EFFECTIVE DATE of this AGREEMENT to terminate the license granted herein in any national political jurisdiction within the LICENSED TERRITORY if LICENSEE, within ninety days after written notice from BOARD of such intended termination, fails to provide written evidence satisfactory to BOARD that LICENSEE has commercialized or is actively and effectively attempting to commercialize an invention licensed hereunder within such jurisdiction(s). Accurate, written evidence provided by LICENSEE to BOARD within said ninety (90) day period that LICENSEE has an effective, ongoing and active research, development, manufacturing, marketing, or sales program, as appropriate, directed toward obtaining regulatory approval and/or production and/or sale of LICENSED PRODUCTS incorporating PATENT RIGHTS or incorporating TECHNOLOGY RIGHTS within such jurisdiction shall be deemed satisfactory evidence.

13.3 Subject to any rights herein which survive termination, this AGREEMENT will earlier terminate in its entirety:

(a) automatically if LICENSEE shall become bankrupt or insolvent and/or if the business of LICENSEE shall be placed in the hands of a receiver or trustee, whether by voluntary act of LICENSEE or otherwise; or

(b) (i) upon thirty (30) days written notice by BOARD if LICENSEE shall breach or default on the payment obligations of ARTICLE IV, or use of name obligations of ARTICLE X; or (ii) upon ninety (90) days written notice by BOARD if LICENSEE shall breach or default on any other obligation under this AGREEMENT; provided, however, LICENSEE may avoid such termination if before the end of such thirty (30) or ninety (90) day period if LICENSEE provides notice and accurate, written evidence satisfactory to BOARD that such breach has been cured and the manner of such cure; or.

(c) at any time by mutual written agreement between LICENSEE and BOARD, or without cause upon one hundred eighty (180) days written notice by LICENSEE to BOARD, subject to any terms herein which survive termination.

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13.4 Upon termination of this AGREEMENT for any cause:

(a) nothing herein shall be construed to release either party of any obligation matured prior to the effective date of such termination.

(b) LICENSEE covenants and agrees to be bound by the provisions of ARTICLES IX, X AND XI of this AGREEMENT.

(c) LICENSEE may, after the effective date of such termination, sell all

LICENSED PRODUCTS and parts therefore that it may have on hand at the date of termination, provided that LICENSEE pays the earned royalty thereon and any other amounts due pursuant to ARTICLE IV of this AGREEMENT.

(d) LICENSEE grants to BOARD a non-exclusive royalty bearing license with the right to sublicense others with respect to improvements made by LICENSEE (including improvements licensed by LICENSEE from third parties) in the LICENSED SUBJECT MATTER. LICENSEE and BOARD agree to negotiate in good faith the royalty rate for said non-exclusive license. BOARD's right to sublicense others hereunder shall be solely for purposes of permitting others to develop and commercialize the entire technology package.

13.5 This AGREEMENT shall automatically terminate if LICENSEE fails to deliver to MDA by September 1, 1996 (i) payment of \$53,125.00 pursuant to 4.1(a) hereinabove and (ii) notice that LICENSEE has legally binding funding commitments from its investors totaling Two Million Dollars (\$2,000,000.00) or more.

# XIV. WARRANTY: SUPERIOR-RIGHTS

14.1 Except for the rights, if any, of the Government of the United States as set forth hereinbelow, BOARD represents and warrants its belief that it is the owner of the entire right, title, and interest in and to LICENSED SUBJECT MATTER, and that it has the sole right to grant licenses thereunder, and that it has not knowingly granted licenses thereunder to any other entity that would restrict rights granted hereunder except as stated herein.

14.2 LICENSEE understands that the LICENSED SUBJECT MATTER may have been developed under a funding agreement with the Government of the United States of America and, if so, that the Government may have certain rights relative thereto. This AGREEMENT is explicitly made subject to the Government's rights under any such agreement and any applicable law or regulation, including P.L. 96-517 as amended by P.L. 98-620. To the extent that there is a conflict between any such agreement, applicable law or regulation and this AGREEMENT, the terms of such Government agreement, applicable law or regulation shall prevail.

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14.3 LICENSEE understands and agrees that BOARD, by this AGREEMENT, makes no representation as to the operability or fitness for any use, safety, efficacy, approvability by regulatory authorities, time and cost of development, patentability, and/or breadth of the LICENSED SUBJECT MATTER. BOARD, by this AGREEMENT, makes no representation as to whether there are any patents now held, or which will be held, by others or by BOARD in the LICENSED FIELD, nor does BOARD make any representation that the inventions contained in PATENT RIGHTS do not infringe any other patents now held or that will be held by others or by BOARD.

14.4 LICENSEE, by execution hereof, acknowledges, covenants and agrees that LICENSEE has not been induced in anyway by BOARD, SYSTEM, MDA or employees thereof to enter into this Agreement, and further agrees that LICENSEE has conducted sufficient due diligence with respect to all items and issues pertaining to Article XIV herein and all other matters pertaining to this Agreement and agrees to accept all risks inherent herein.

#### XV. GENERAL

15.1 This AGREEMENT constitutes the entire and only AGREEMENT between the parties for LICENSED SUBJECT MATTER and all other prior negotiations, representations, agreements and understandings are superseded hereby. No agreements altering or supplementing the terms hereof may be made except by means of a written document signed by the duly authorized representatives of the parties.

15.2 Any notice required by this AGREEMENT shall be given by prepaid, first class, certified mail, return receipt requested, and addressed in the case of BOARD to:

BOARD OF REGENTS The University of Texas System 201 West Seventh Street Austin, Texas 78701 ATTENTION: System Intellectual Property Office The University of Texas with copy to: M.D. Anderson Cancer Center Office of Technology Development 1020 Holcombe Boulevard, Suite 1405 Houston, Texas 77030 ATTENTION: William J. Doty or in the case of LICENSEE to: BioQuest, Inc. 333 N. Sam Houston Pkwy, Suite 1150

Houston, Texas 77060 ATTENTION: Warren C. Lau

or such other address as may be given from time to time under the terms of this  $% \left( {{{\left[ {{{\rm{s}}} \right]}}_{{\rm{s}}}}_{{\rm{s}}}} \right)$ 

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#### notice provision.

15.3 LICENSEE covenants and agrees to comply with all applicable federal, state and local laws and regulations in connection with its activities pursuant to this AGREEMENT.

15.4 This AGREEMENT shall be construed and enforced in accordance with the laws of the United States of America and of the State of Texas.

15.5 Failure of BOARD to enforce a right under this AGREEMENT shall not act as a waiver of that right or the ability to later assert that right relative to the particular situation involved.

15.6 Headings included herein are for convenience only and shall not be used to construe this AGREEMENT.

15.7 If any provision of this AGREEMENT shall be found by a court to be void, invalid or unenforceable, the same shall be reformed to comply with applicable law or stricken if not so conformable, so as not to affect the validity or enforceability of this AGREEMENT.

IN WITNESS WHEREOF, parties hereto have caused their duly authorized representatives to execute this AGREEMENT.

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

By /s/ DAVID J. BACHRACH David J. Bachrach Executive Vice President

for Administration and Finance

By /s/ RAY FARABEE Ray Farabee Vice Chancellor and General Counsel

APPROVED AS TO CONTENT:

APPROVED AS TO FORM:

BOARD OF REGENTS OF THE

UNIVERSITY OF TEXAS SYSTEM

By /s/ WILLIAM J. DOTY William J. Doty Director, Technology Development By /s/ DUDLEY R. DOBIE. JR Dudley R. Dobie, Jr. Manager, Intellectual Property

BIOTEX, INC.

By /s/ WARREN C. LAU Warren C. Lau President

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# EXHIBIT I

Ralph Arlinghaus, Ph.D., et al, Principal Investigator

- o (MDA REF: UTSC:060-1) (CIP of UTSC:060) entitled "Prophylaxis and Therapy of Acquired Immunodeficiency Syndrome"
- U.S. Patent No. 5,128,319 entitled "Prophylaxis and Therapy of Acquired Immunodeficiency Syndrome", (MDA REF: UTSC:234)
- o MDA REF: UTSC:242 entitled "Methods and Compositions for the Priming of Specific Cytotoxic T-Lymphocyte Response"
- o MDA REF: UTSC:267 (Divisional of UTSC:234) "Prophylaxis and Therapy of Acquired Immunodeficiency Syndrome"
- o MDA REF: UTSC:305 entitled "Compositions and Methods for Eliciting Immune or Anti-Infective Responses"

- o MDA REF: UTSC:331 entitled "CD4 Peptides for Binding to Viral Envelope Proteins"
- o MDA REF: UTSC:381 entitled "Peptides for Inhibitiing the Infection of Target Cells by Lentiviruses"

\* PLEASE NOTE THAT CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED ON A REQUEST FOR CONFIDENTIAL TREATMENT FILED WITH THE COMMISSION ALONG WITH THE INFORMATION REQUESTED TO BE OMITTED.

## AMENDMENT NO. 1 TO

# PATENT AND TECHNOLOGY LICENSE AGREEMENT

This AMENDMENT NO. 1 dated and effective as of the 15th day of June, 2000, to the Patent and Technology License Agreement dated June 14, 1996 (hereinafter referred to as the "AGREEMENT") is between THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER (hereinafter referred to as "MDA"), located at 1515 Holcombe Boulevard, Houston, Texas, and which is a component institution of THE UNIVERSITY OF TEXAS SYSTEM (hereinafter referred to as "SYSTEM") which is governed by a BOARD OF REGENTS (hereinafter referred to as "BOARD") and BioQuest, Inc., which subsequently merged to become BIOKEYS PHARMACEUTICALS, INC., a Delaware corporation, located at 333 N. Sam Houston Parkway, Suite 1035, Houston, Texas 77060 (hereinafter referred to as "LICENSEE").

#### RECITALS

- A. On or about \_\_\_\_\_\_, BIOQUEST, INC. merged to become BIOKEYS PHARMACEUTICALS, INC., wherein LICENSEE agreed to accept all terms and conditions of the 1996 Agreement.
- B. MDA, BOARD and LICENSEE wish to amend the terms of the AGREEMENT as set forth below to modify the consideration for the license granted under the AGREEMENT to provide for the payment by LICENSEE of a portion of such modified consideration by issuing and delivering shares of Common Stock of LICENSEE to MDA as prepaid royalties, and to incorporate additional LICENSED SUBJECT MATTER.

NOW, THEREFORE, it is hereby agreed as follows:

The AGREEMENT is hereby amended as follows:

1. EXHIBIT 1 of the AGREEMENT is hereby replaced in its entirety with the following:

EXHIBIT I Ralph Arlinghaus, Ph.D., et al, Principal Investigator

- MDA Ref: UTSC:060-1 (CIP of UTSC:060) entitled "Prophylaxis and Therapy of Acquired Immunodeficiency Syndrome"
- 2) U.S. Patent No. 5,128,319 entitled "Prophylaxis and Therapy of Acquired Immunodeficiency Syndrome", (MDA Ref: UTSC:234)
- 3) MDA Ref: UTSC:242 entitled "Methods and Compositions for the

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Priming of Specific Cytotoxic T-Lymphocyte Response"

- 4) MDA Ref: UTSC:267 (Divisional of UTSC:234)
   "Prophylaxis and Therapy of Acquired Immunodeficiency
   Syndrome"
- 5) MDA Ref: UTSC:305 entitled "Compositions and Methods for Eliciting Immune or Anti-Infective Responses"
- 6) MDA Ref: UTSC:331 entitled "CD4 Peptides for Binding to Viral Envelope Proteins"
- 7) MDA Ref: UTSC:381 entitled "Peptides for Inhibiting the Infection of Target Cells by Lentiviruses"
- 8) MDA Ref: UTSC:538 entitled "Compositions and Methods for Eliciting Immune or Anti-Infective Responses"
- 9) MDA Ref: UTSC:561PZ1 entitled "HIV-Specific T-Cell Induction"
- 10) MDA Ref: UTSC:561PZ2 entitled "HIV-Specific T-Cell Induction"

- The parties agree that all amounts and balances due to MDA or the BOARD under existing sponsored research agreements (i) SR96-006 Studies on Therapeutic Potential of HIV Synthetic Peptides, (ii) SR96-006/A1 Studies on Therapeutic Potential of HIV Synthetic Peptides: Clinical and Preclinical Studies and (iii) SR96-006/A2 Studies on Therapeutic Potential of HIV Synthetic Peptides: Development of Peptidometic Form of R15K ((i), (ii) and (iii) collectively referred to as the "Existing Sponsored Research Agreements"), shall be considered paid in full and upon the execution by all parties of this AMENDMENT NO. 1 LICENSEE shall owe nothing to MDA or BOARD under the Existing Sponsored Research Agreements. The parties agree that all amounts paid under AMENDMENT NO. 1, paragraph 3 relating to Section 4.1(e) for new sponsored research agreements, further relating to AMENDMENT No. 4 to Research Agreement(SR96-006/A4), are not part of the amounts and balances due under the Existing Sponsored Research Agreements. The parties also agree to terminate the Existing Sponsored Research Agreements and enter into new sponsored research agreements in compliance with this AMENDMENT NO. 1.
- 3. Article 4.1 is hereby replaced in its entirety with the following:

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In consideration of rights granted by BOARD to LICENSEE under this AGREEMENT, LICENSEE agrees to pay MDA the following:

(a) Payment of \$172,490.24 for reimbursement of all out-of-pocket expenses paid by MDA through June 15, 2000 in filing, prosecuting, enforcing and maintaining PATENT RIGHTS

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licensed hereunder (the "Balance Payment"), to be paid by LICENSEE within six (6) weeks of the date the Office of the General Counsel of MDA approves this AMENDMENT NO. 1. LICENSEE agrees to pay all future expenses paid by MDA, for so long as, and in such countries as this Agreement remains in effect. The Balance Payment may be made to MDA either in the form of a cash payment or in lieu of such cash payment, LICENSEE will give BOARD a total of 71,555 duly authorized, validly issued and fully paid shares of Common Stock of LICENSEE, the amount of such shares of Common Stock being calculated by dividing the Balance Payment by the average stock-split adjusted closing price of the LICENSEE's Common Stock during the 10-day period, beginning May 28, 2000 and ending June 7, 2000. Such shares of Common Stock shall be issued by LICENSEE in the name of BOARD within six (6) weeks of the date The University of Texas System Office of the General Counsel approves this AMENDMENT NO. 1. In connection with its receipt of such shares, BOARD is making the representations, and shall have the registration and other rights (subject to the conditions), set forth in Exhibit 2 hereto: and

(b) A running royalty equal to (SPACE) of LICENSEE'S NET SALES of LICENSED PRODUCTS in national political jurisdictions in the LICENSED TERRITORY where LICENSED SUBJECT MATTER is covered by one (1) or more issued patents or pending patent applications; (SPACE) of LICENSEE'S NET SALES of LICENSED PRODUCTS in national political jurisdictions in the LICENSED TERRITORY where LICENSED SUBJECT MATTER is not covered by one (1) or more issued patents or pending patent applications; and (SPACE) of all consideration other than payments covering direct, out-of-pocket Research and Development (R&D) expenses received by LICENSEE from (i) any sublicensee pursuant to Paragraphs 3.3 and 3.4 of the PATENT AND TECHNOLOGY LICENSE AGREEMENT, and (ii) any

assignee pursuant to Paragraph 12.1 of the PATENT AND TECHNOLOGY LICENSE AGREEMENT, including but not limited to royal-ties, up-front payments, marketing, distribution, franchise, option, license, or documentation fees, bonus and milestone payments and equity securities, all payable within thirty (30) days after March 31, June 30, September 30, and December 31 of each year during the term of this AGREEMENT, at which time LICENSEE shall also deliver to MDA a true and accurate report, giving such particulars of the business conducted by LICENSEE and its sublicensees, if any, during the preceding three (3) calendar months under this AGREEMENT as necessary for MDA to account for LICENSEE's payments hereunder. Such

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report shall include all pertinent data, including, but not limited to: (a) the total quantities of LICENSED PRODUCTS produced; (b) the total SALES, (c) the calculation of royalties thereon; (d) the total royalties (or minimum royalties) so computed and due MDA; and (e) all other amounts covered and due herein and (f) copies of all executed agreements between LICENSEE and third parties pursuant to Paragraphs 3.3, 3.4 and 12.1 of the PATENT AND TECHNOLOGY LICENSE AGREEMENT. Simultaneously with the delivery of each such report, LICENSEE shall pay to MDA the amount, if any, due for the period of such report. If no payments are due, it shall be so reported. Should LICENSEE be obligated to pay running royalties to third parties to avoid infringing such third parties' patent rights which dominate BOARD'S PATENT RIGHTS, LICENSEE may reduce the running royalty due MDA by such running royalties to such third parties, provided, however, the running royalty due MDA shall in no case be less than one-half the rates stated herein. For the avoidance of any doubt, the parties hereto acknowledge and agree that any running royalties due MDA under this Paragraph 4.1(b) shall in no event be reduced by any of the consideration due MDA under Paragraph 4.1(a), (c), (d) and (e).

- (c) As a prepaid royalty, Four Hundred and Fourteen Thousand Eight Hundred and Thirty (414,830) duly authorized, validly issued and fully paid shares of Common Stock in LICENSEE, which, the parties agree, had a value of One Million Dollars (\$1,000,000), calculated by dividing \$1,000,000 by the average stock-split adjusted closing price of the LICENSEE's Common Stock for the ten (10) day period of May 28, 2000 through June 7, 2000. Such shares of Common Stock shall be issued in the name of BOARD within five days following execution of this AMENDMENT NO. 1, and, in connection with its receipt of such shares, MDA is making the representations, and shall have the limitations as well as registration and other rights (subject to the conditions), set forth in Exhibit 2 hereto.
- (d) As a prepaid royalty, the number of duly authorized, validly issued and fully paid shares of Common Stock in LICENSEE equal to a value of One Million Dollars (\$1,000,000), calculated by dividing \$1,000,000 by the average closing price of the LICENSEE's Common Stock during the ten (10)day period immediately prior to the LICENSEE enrolling the first patient in the first Phase I Trial of any product which utilizes LICENSED SUBJECT MATTER; provided, however, that, the

minimum price of the shares so calculated shall be no lower than \$0.99 per share and that no more than One Million Five Thousand and Fifty (1,005,000) shares will

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be issued under this paragraph, as adjusted for stock splits. Such shares of Common Stock shall be issued in the name of BOARD within fifteen days following such enrollment of the first patient, and, in connection with its receipt of such shares, MDA is making the representations, and shall have the registration and other rights (subject to the conditions), set forth in Exhibit 2 hereto.

- (e) LICENSEE shall enter into one or more sponsored research agreement(s) with MDA (which agreement shall be satisfactory in form and substance to the parties), in which LICENSEE agrees to provide MDA researchers with at least one million dollars (\$1,000,000) in sponsored research funding by December 31, 2001. The monies owed MDA under Amendment No. 4 to Research Agreement (SR96-006/A4) signed September 7, 2000 shall count towards this one million dollars (\$1,000,000) owed MDA under this section.
- 4. New Section 6.2 below is added to the existing Article 6:
- 6.2 Any new invention, development, or discovery made in the laboratories of a MDA researchers receiving sponsored research monies from LICENSEE and resulting from the LICENSED SUBJECT MATTER (the "New Technology") shall be promptly disclosed in writing to the LICENSEE under a confidentiality agreement (which agreement shall be satisfactory in form and substance to the parties), provided that the LICENSEE has a sponsored research agreement(s) in effect with MDA at that time under which MDA is due to receive payments from LICENSEE aggregating at least Two Hundred Thousand (\$200,000) Dollars per year. LICENSEE is hereby granted, without an option fee other than consideration of research sponsored by LICENSEE and the reimbursement of the BOARD for all patent expenses incurred to the date of disclosure related to the New Technology, an option to acquire an exclusive, worldwide, royalty bearing license of BOARD' rights to such New Technology, which option shall continue for a period of one hundred and twenty (120) days after LICENSEE' receipt of a reasonable written disclosure concerning the New Technology; If LICENSEE notifies BOARD in writing of its intent to exercise its option within the option period, then the parties will proceed in good faith to negotiate a license agreement on commercially reasonable terms within one hundred and twenty (120) days of BOARD's notification to LICENSEE of New Technology. If LICENSEE does not exercise this option, or notifies BOARD that it will not exercise this option, or the parties fail to sign a license agreement within said one hundred and twenty (120) day period, then LICENSEE shall no longer have an option or any other rights in the New Technology.
- 5. Article 13.3 is hereby replaced in its entirety with the following:
- 13.3 Subject to any rights herein, which survive termination, this AGREEMENT will earlier terminate in its entirety:

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- (a) automatically if LICENSEE shall become bankrupt or insolvent and/or if the business of LICENSEE shall be placed in the hands of a receiver or trustee, whether by voluntary act of LICENSEE or otherwise; or
- (b) (i) upon thirty (30) days written notice by MDA if LICENSEE shall breach or default on the payment obligations of ARTICLE IV, or use of name obligations of ARTICLE X, ; (ii) or upon ninety (90) days written notice by MDA if LICENSEE shall breach or default on any other obligation under this AGREEMENT; provided,

however, LICENSEE may avoid such termination if before the end of such thirty (30) or ninety (90) day period, LICENSEE provides notice and accurate, written evidence satisfactory to MDA that such breach has been cured and the manner of such cure; or

- (c) at any time by mutual written agreement between LICENSEE and MDA, or without cause upon one hundred eighty (180) days written notice by LICENSEE to MDA, subject to any terms herein which survive termination.
- 6. New Section 13.6 below is added to the existing Article 13:
- 13.6 Termination of the AGREEMENT will not obligate MDA, the SYSTEM or the BOARD to return the shares of Common Stock issued pursuant to Article 4, nor will it affect the status of such shares as duly authorized, validly issued, fully paid and non-assessable shares of Common Stock.

OTHERWISE, the terms and provisions of the AGREEMENT shall remain in full force and effect, provided, however, that in the event of a conflict in the terms and conditions between this AMENDMENT NO. 1 and the AGREEMENT, AMENDMENT NO. 1 shall prevail. THIS AMENDMENT NO. 1 and AGREEMENT constitute the entire agreement between the parties in connection with the subject matter hereof and thereof and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions, whether oral or written, of the parties.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this AMENDMENT NO. 1.

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER	BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM
By: /s/ LEON LEACH	By: /s/ JOHN MENDELSOHN, M.D.
Leon Leach Executive Vice President	John Mendelsohn, M.D. President, MDA
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Date:	Date:
APPROVED AS TO CONTENT	APPROVED AS TO FORM
By: /s/ WILLIAM J. DOTY	By: /s/ BETHLYNN MAXWELL, ESQ.
William J. Doty Director, Technology Development	BethLynn Maxwell, Esq. Office of General Counsel
Date:	Date:
BIOKEYS PHARMACEUTICALS, INC.	
By: /s/ WARREN LAU	
Warren Lau President	
Date:	
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EXHIBIT	2

The following additional provisions shall apply to the securities being issued to MDA under this Agreement:

(a) MDA, SYSTEM AND BOARD (collectively or singly, LICENSOR) acknowledge that the securities (together with any securities issued in respect thereof upon any stock split, stock dividend, recapitalization, merger, consolidation or similar event, the "Registrable Securities") being issued under this

AGREEMENT, are being acquired from LICENSEE in a transaction not involving a public offering, that they are not being registered for public sale prior to such issuance and that, under such laws and applicable regulations, such securities may not be transferred or resold without registration under the Securities Act of 1933, as amended (the "Securities Act"), or pursuant to an exemption therefrom. For purposes of this Agreement, "HOLDER" shall mean any LICENSOR who holds any of the Registrable Securities and any holder of Registrable Securities to whom the registration rights conferred by this Agreement have been transferred pursuant hereto. In this connection, LICENSOR represents that it is familiar with Rule 144  $\,$ under the Securities act as presently in effect, and understands the resale limitations imposed by the Securities Act and Rule 144.

- (b) LICENSOR is acquiring such securities solely for investment purposes and not with a view to a distribution of all or any part thereof. LICENSOR has the financial ability to bear the economic risk of its investment for an indefinite period, and has adequate means of providing for its current needs and anticipated contingencies without reference to the liquidity of the securities, which may be issued to it. LICENSOR is a not-for-profit organization with more than \$5,000,000 in total assets. LICENSOR has such knowledge and experience in financial and business matters that it is fully capable of evaluating the merits and risks of an investment in LICENSEE.
- (c) If the LICENSEE proposes to make an underwritten public offering of securities solely for cash (except in the case of a first public offering of securities by LICENSEE) the LICENSEE shall, no later than 10 days prior to the filing of a registration statement, send notice of such proposed filing, accompanied by a draft copy of the preliminary prospectus included in such registration statement, to each

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Holder. Upon the written request of a Holder to be included in such registration statement as a selling stockholder, given within 20 days after receipt of such notice, the LICENSEE shall include in such registration statement all or any portion of the securities of such Holder, as such Holder shall so request. However, if the managing underwriter of such public offering shall express objection to the inclusion of all or part of such securities of Holder in such public offering because of prevailing market conditions or other factors, the amount of such securities of such Holder to be so registered in such offering shall be reduced to the level which such managing underwriter deems appropriate in relation to the size of the underwritten offering and the ability of the market to accommodate the sale of such securities of such Holder, provided, however, that if any securities are being included in such offering on behalf of any selling stockholders other than such Holder, any reduction of offered securities imposed on such Holder shall be proportional to any reduction imposed on such other selling stockholders. Notwithstanding any provision hereof to the contrary, LICENSEE shall not be required to include any securities of Holder in a registration statement covering a first public offering of securities by LICENSEE.

(d) Each Holder hereby agrees that such Holder will not, without the prior written consent of the LICENSEE, during the period commencing on the date hereof and ending March 15, 2002 (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Common Stock or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise. The foregoing provisions of this paragraph (d) shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement.

(e) If Holder does not sell all of the Common Stock owned by it under paragraph (c) above, such Holder shall have additional rights to include such securities in any underwritten public offering of securities to be undertaken by the LICENSEE, and the terms and conditions of

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paragraph (c) above and this paragraph (e) shall be applicable to any registration request of such Holder in connection with any such subsequent public offering. The rights of Holder under this paragraph (e) shall cease when it no longer owns at least 1% of the outstanding Common Stock.

- (f) Whenever required under this Exhibit 2 to effect the registration of any securities, the LICENSEE shall, as expeditiously as reasonably possible:
  - (i) Prepare and file with the SEC a registration statement with respect to such securities and use its best efforts to cause such registration statement to become effective, and, upon the request of the Holder, keep such registration statement effective for at least nine (9) months.
  - (ii) Prepare and file with the SEC such amendments and supplements to such registration statement and the prospectus used in connection with such registration statement as may be necessary to comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such registration statement.
  - (iii) Furnish to the Holder such numbers of copies of a prospectus, including a preliminary prospectus, in conformity with the requirements of the Act, and such other documents as they may reasonably request in order to facilitate the disposition of securities owned by them.
  - (iv) Use its best efforts to register and qualify the securities covered by such registration statement under the securities laws of such jurisdictions as shall be reasonably requested by the Holder for the distribution of the securities covered by the registration statement, provided that the LICENSEE shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such jurisdiction.
  - (v) In the event of an underwritten public offering, enter into and perform its obligations under an underwriting agreement with terms generally

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satisfactory to the LICENSEE and the managing underwriter of such offering.

(vi) Notify the Holders promptly after the LICENSEE shall have received notice thereof, of the time when the registration statement becomes effective or any supplement to any prospectus forming a part of the registration statement has been filed.

- (vii) Notify the Holders of any stop order suspending the effectiveness of the registration statement and use its reasonable best efforts to remove such stop order.
- (viii) Notify the Holders if the registration statement is no longer effective or the registration statement or the prospectus or any prospectus supplement is required to be amended in order to comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such registration statement.
- (g) It shall be a condition precedent to the obligations of the LICENSEE to take any action pursuant to this Exhibit 2 that the Holder shall furnish to the LICENSEE such information in writing regarding itself, the securities held by it, and the intended method of disposition of such securities, as the LICENSEE shall reasonably request and as shall be required to effect the registration of such securities. In that connection, the Holder shall be required to represent to the LICENSEE that all such information, which is given, is both complete and accurate in all material respects. Holder shall also deliver to the LICENSEE a statement in writing that it has a bona fide intention to sell, transfer or otherwise dispose of such securities.
- (h) "Registration Expenses" shall mean all expenses incurred by the LICENSEE in complying with this Exhibit 2, including, without limitation, all registration and filing fees, printing expenses, fees and disbursements of counsel for the LICENSEE, blue sky fees and expenses, and the expense of any special audits incident to or required by any such registration. Registration Expenses shall also include fees and disbursements of one special counsel for Holders and other selling stockholders, in an amount not to exceed \$10,000. "Selling Expenses" shall mean all underwriting

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discounts, selling commissions and underwriters' expense allowances applicable to the sale of the securities of Holders. All Registration Expenses incurred in connection with any registration, qualification or compliance pursuant to this Exhibit 2 shall be borne by the LICENSEE, and all Selling Expenses shall be borne by the Holders.

- (i) If the Holders propose to distribute their securities through an underwriter, the LICENSEE shall enter into an underwriting agreement in customary form with the underwriter or underwriters, provided that the terms thereof shall not be materially less favorable to the LICENSEE than those customarily arranged in comparable underwritten offerings.
- (j) Holders shall have no right to obtain or seek an injunction restraining or otherwise delaying any such registration as the result of any controversy that might arise with respect to the interpretation or implementation of this Exhibit 2.
- (k) Nothing contained herein shall be deemed to limit the rights of the Holders to offer or make a public sale of all or any portion of such securities under Rule 144 of the SEC or any other applicable provisions of federal and state securities laws. Furthermore, if, in the opinion of counsel for a Holder, the offering or transfer by such Holder in the manner proposed (including, without limitation, the number of shares proposed to be offered or transferred and the method of offering or transfer) is exempt from the registration requirements of the Securities Act under Rule 144 or otherwise, LICENSEE shall not be required to effect any registration of such securities under the Securities Act.
- (1) At such time as LICENSEE is eligible to register its

Common Stock for public sale under the Securities Act using Form S-3 (or similar successor form), Holders shall have a one-time right to demand that the LICENSEE file a registration statement on Form S-3 covering the offering and sale by Holders of all or a portion of the shares owned by them, such sales to be either at the market from time to time or in an underwritten public offering, or both. LICENSEE will as promptly as practicable after the receipt of such demand file such registration statement and take such other actions with respect to such registration statement as are required by the provisions of paragraphs (f) through (i) of this Exhibit 2. The rights of the Holders under this paragraph (k) shall cease when they no longer

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own collectively at least 1% of the outstanding Common Stock of LICENSEE.

(m) The rights to cause LICENSOR to register a Holder's securities granted by LICENSOR under this Exhibit 2 may be transferred or assigned by a Holder to a transferee or assignee of any Registrable Securities.

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\* PLEASE NOTE THAT CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED ON A REQUEST FOR CONFIDENTIAL TREATMENT FILED WITH THE COMMISSION ALONG WITH THE INFORMATION REQUESTED TO BE OMITTED.

## OPTION AND LICENSE AGREEMENT

# 1. INTRODUCTION

THIS AGREEMENT is between the UNVERSITY OF SOUTHERN CALIFORNIA, (hereinafter USC) a California nonprofit corporation with its principal place of business at University Par, Los Angeles, California 90089, and Biokeys, Inc., a Delaware corporation, with its principal place of business at 16 South Market Street, Petersburg, Virginia 23803 (hereinafter Licensee).

WHEREAS USC warrants that it is the owner and that it has the right to exclusively license those inventions which are the subject matter of the patents and patent applications listed in Appendix A and of which the inventors are Colin Spears and Sang-Ihn Kang (File 2199A) and Colin Spears and Bengt Gustavsson (Files 2266B & 2266C) (Hereinafter Inventors);

WHEREAS Licensee desires to obtain an exclusive license in the defined FIELD OF USE to manufacture and market products utilizing the inventions as hereinafter defined:

WHEREAS, USC is willing to grant a worldwide, exclusive license in the defined FIELD OF USE to Licensee subject to the terms, conditions, limitations, and restrictions set forth below:

NOW, THEREFORE, in consideration of the covenants herein contained, the parties agree as follows:

### 2. DEFINITIONS

For the purposes of this Agreement the following terms have meanings specified below:

- a. The term "PATENT" or "PATENTS" shall mean any and all patents listed in Appendix A, and all patent applications listed in Appendix A including any and all patents issued thereon or any continuation, division, extensions or reissue thereof.
- b. "PRODUCT" or "PRODUCTS" shall mean any article, composition, apparatus, substance, chemical, material, method or service which is made, used, distributed or sold by Licensee which:

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- is covered in whole or in part by one or more pending or unexpired claims contained in a PATENT in the country in which the PRODUCT(S) is made, used, distributed or sold;
- ii. is manufactured using a method or process which is covered in whole or in part by one or more pending or un-expired claims contained in a PATENT in the country in which (a) the PRODUCT(S) is made, used, distributed or sold, or (b) the method or process is used or sold; or
- iii. the use of which is covered in whole or in part by one or more pending or un-expired claims contained in a PATENT in the country in which (a) the PRODUCT(S) is made, used, distributed or sold, or (b) the method or process is used or sold.

A PRODUCT is covered by a pending or un-expired claim of a PATENT if in the course of manufacture, use distribution or sale, it would in the absence of this Agreement, infringe one or more claims of the PATENT which has not been held invalid by a court from which no appeal can be taken.

- c. "FIELD OF USE" shall mean all fields.
- d. "NET SALES PRICE" shall mean:
  - i. the gross billing price of any PRODUCT received by Licensee or SUBLICENSEE for the sale or distribution of any PRODUCT, less the following amounts actually paid by Licensee or SUBLICENSEE:
    - discounts allowed;
    - (2) returns;

- (3) transportation charges or allowances;
- (4) packing and transportation packing material costs (not including product containers or product packing containers as manufactured by the Company);
- (5) customs and duties charges: and
- (6) sales, transfer and other excise taxes or other governmental charges levied on or measured by the sales but no franchise or income tax of any kind whatsoever.
- ii. Every commercial use or disposition of any PRODUCT, in addition to a bona fide sale to a customer, shall be considered a sale of such PRODUCT. The NET SALES PRICE, in the case or a use or disposition other than a bona fide sale, shall be

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equivalent the then payable NET SALES PRICE of such PRODUCT in an arm's length transaction. Excluded from the calculation of NET SALES PRICE shall be any PRODUCT that is: (1) used by Licensee or provided to SUBLICENSEE free of charge for testing and/or conducting clinical trials; (2) that is donated by Licensee or a SUBLICENSEE to a charitable organization; (3) sales between Licensee and any subsidiary, or between Licensee or any subsidiary and a SUBLICENSEE, provided they are for development, testing or re-sale purposes (the latter of which licensee will pay USC a royalty for such re-sale) and not for intended end use;

- e. "SUBLICENSEE" shall mean any third party licensed by Licensee to make, or sell any PRODUCT in accordance with the terms of this Agreement.
- f. "EFFECTIVE DATE" of this Agreement shall be the date when the last party has signed this agreement.
- 3. OPTION PHASE
  - a. USC hereby grants Licensee the exclusive rights to conduct various technical, pre-clinical, marketing, patent, and other studies on PRODUCTS in the FIELD OF USE during a six (6) month period commencing on the EFFECTIVE DATE of this Agreement. The option period may be extended by mutual written agreement of the parties.
- 4. LICENSE PHASE
  - a. In consideration of the license fees and royalties, and subject to the terms and conditions, as set forth in this Agreement and effective upon written notification to USC during the option phase that Licensee desires to license the PATENT(S), USC hereby grants to Licensee:
    - i. the exclusive worldwide license in the FIELD OF USE to use the PATENT to manufacture and sell the PRODUCT(S); and
    - ii. the right to grant sublicenses to any PATENT licensed exclusively hereunder, provided that any SUBLICENSEE agrees to be bound by the terms and conditions of this Agreement applicable to SUBLICENSEES.
  - b. If USC is not notified of Licensee's desire to enter the license phase by the end of the option phase or any extensions thereto, this Agreement and the license granted herein shall immediately terminate.
  - c. All licenses pursuant to 4.a. and 4.b. to inventions conceived or first actually reduced to practice during the course of research funded by a U.S. Federal Agency are subject to the rights, conditions and limitations imposed by U.S. Law. USC agrees to use reasonable efforts to comply with the requirements of such laws and applicable regulations.

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The words "exclusive license" as used herein shall mean exclusive except for the royalty free non-exclusive license granted to the U.S. government by USC pursuant to 35 USC Section 202(c)(4) for any PATENT claiming an invention subject to 35 USC Section 201 and

except for the rights of USC and Inventors as set forth in Paragraphs 6.

- d. In addition to the royalty referred to in Paragraph 5 the Licensee shall pay USC a license fee of One Hundred Thousand Dollars (\$100,000) payable within thirty (30) days of the first private placement of equity in Biokeys (exclusive of the original capital invested by the founders Licensee) and an additional license fee of One Hundred Thousand Dollars (\$100,000) due and payable within thirty (30) days of the first public offering of equity in Biokeys.
- 5. ROYALTY
  - a. On all sales of Products anywhere in the world by Licensee or SUBLICENSEE, Licensee shall pay USC a royalty of (SPACE) of the NET SALES PRICE.
  - b. Licensee shall pay to USC a prepaid royalty of One Hundred Thousand (\$100,000) due and payable within thirty (30) days of market approval of a NEW DRUG APPLICATION (NDA) by the FDA for any product covered by the claims of any PATENT. The prepaid royalty shall be deductible from running royalties based on sales made after the date that the prepaid royalty is due.
  - c. The obligation to pay a royalty under this Agreement on the NET SALES PRICE of a PRODUCT shall be imposed only once with respect to the same unit of the PRODUCT regardless of the number of valid issued or, assuming they were to issue, pending claims included within the PATENTS.
  - d. In the event Licensee is required to pay third party royalty(ies) on patents not owned by USC in order to manufacture, use or sell a PRODUCT, then the royalty rate on the NET SALES PRICE of such PRODUCT shall be reduced by the following formula:

New Royalty Rate = (SPACE) minus either (i) (SPACE) or (ii) (SPACE) of the royalty rate owed to the third party, whichever is less.

- e. Licensee shall pay such royalties to USC on a calendar quarter basis. With each quarterly payment, Licensee shall deliver to USC a full and accurate accounting to include at least the following information:
  - Quantity of each PRODUCT sold (by country) by Licensee and its SUBLICENSEES;
  - ii. Total receipts for each PRODUCT (by country);

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- iii. Quantities of each PRODUCT used by Licensee and its SUBLICENSEES;
- iv. Names and addresses of SUBLICENSEES of Licensee;
- v. Total number of PRODUCTS manufactured (by country); and
- vi. Total royalties payable to USC.
- f. In each year the amount of royalty due shall be calculated quarterly as of March 31, June 30, September 30 and December 31 and shall be paid quarterly within the thirty next (30) days following such date. Every such payment shall be supported by the accounting prescribed in Paragraph 5.e. and shall be made in United States currency. Whenever for the purpose of calculating royalties conversion from foreign currency shall be required, such conversion shall be at the rate of exchange thereafter published in the Wall Street Journal for the business day closest to the applicable end of calendar quarter.
- g. The royalty payments due under this Agreement shall, if overdue, bear interest until payment at a per annum rate equal to one and a half percent (1.5%) in effect at 5:00pm (Eastern Time) on the due date, not to exceed the maximum permitted by law. The payments of such interest shall not preclude USC from exercising any other rights it may have as a consequence of the lateness of the payment.

# 6. RIGHTS RETAINED BY UNIVERSITY

Notwithstanding the exclusive license granted in Paragraph 4a, USC and Inventors will have the absolute, nontransferable right to use the technology covered by the PATENTS and all improvements thereof, for conducting research and educational purposes.

#### 7. PATENT PROSECUTION

- a. USC shall prosecute and maintain the PATENTS during the course of this Agreement.
- b. Licensee shall reimburse all reasonable legal expenses incurred and paid by USC in filing, prosecuting and maintaining the U.S. and foreign PATENTS, including the expenses associated with parent patent applications listed in Appendix A whether such expenses were incurred before or after the date of this Agreement. These legal expenses shall include the attorneys' and agents' fees, filing fees and out-of-pocket costs associated with responding to office actions and any other fees and costs directly related to obtaining and/or maintaining patent protection. Licensee shall advance payments of maintenance fees and annuities as part of such legal expenses to be reimbursed by Licensee within thirty (30) days of request by USC, unless Licensee is advised otherwise by timely notice from USC.

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- c. The first reimbursement payment made by Licensee shall be for the reimbursement of USC's patent expenses to date and shall be made upon the earlier of (i) thirty (30) days following the first public offering of equity in Biokeys or (ii) one year from the date that the option granted herein is exercised by Licensee. Thereafter, reimbursement payments shall be made by Licensee within thirty (30) days of receipt of an invoice from USC citing any additional expenses.
- d. If the Licensee elects (i) not to pursue a PATENT or (ii) to terminate the prosecution or maintenance of a PATENT, the Licensee surrenders its right to make, use or sell PRODUCTS covered by the non-elected PATENT and shall grant to USC the exclusive rights previously granted to Licensee, without limitation. Licensee agrees to execute all necessary documents to carry out this grant of rights to USC. Payments referred to in Paragraphs 7.b. and 7.c. shall not be refunded upon such non-election or termination.

# 8. PATENT INFRINGEMENT

# a. Defensive Controversy.

Licensee shall promptly notify USC of all claims, allegations and notifications of infringement of third party patents. Except for the placing in escrow of a portion of royalties as referred to hereinafter, USC shall have no obligation or liability in the event that legal action is brought against Licensee for patent infringement. Such obligation and liability shall be borne by Licensee. Licensee may choose legal counsel and defend the patent infringement lawsuit. During such lawsuit, Licensee may place all of the royalties derived from the sale of the PRODUCT in the country where such lawsuit, Licensee may place all of the royalties derived from sales of the PRODUCT in the country where such lawsuit is pending in an interest-bearing escrow account. The escrow account shall be established in a bank mutually acceptable to both parties under escrow instructions insulating the funds from claims of any creditor. Upon termination of the action, one half (1/2) of any judgement amount, reasonable attorneys' fees and costs, or \$100,000, whichever amount is greater, may be paid from this escrow account to be applied against such judgement, fees and costs. If the application of the escrow funds is not sufficient to pay for one half (1/2) of such judgement, fees, and costs, then up to (1/2) of all royalties payable to USC may be applied against any such deficit. In addition, should the settlement of any such patent infringement lawsuit involve payment of royalties by Licensee to a third party for the continued right to manufacture, use and sell the PRODUCT, then funds in the escrow account and royalties payable to USC may be applied against up to one half (1/2) of such royalties to a third party. Any funds thereafter remaining in the escrow shall be paid to USC. The above shall constitute USC's sole liability and responsibility in the event of such action. During the patent infringement litigation both parties shall keep each other informed in writing of significant developments in the lawsuit.

# a. Offensive Controversy.

Licensee shall promptly notify USC of any potential infringement of a PATENT. In the event that a third party infringes on a PATENT, Licensee shall have the right but not an obligation to bring legal action to enforce any such patent. If Licensee exercises such right,

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Licensee shall select legal counsel and pay all legal fees and costs of prosecution of such action. In the event that Licensee shall choose not to take such action, USC shall have the right, at its option and at its own expense, to

prosecute any action to enjoin such infringement or to prosecute any claim for damages. The party prosecuting any such action shall be entitled to retain any funds received as a result of settlement or judgement of such action. The parties may also agree to jointly pursue infringers. After deduction and payment to the parties of their respective costs and fees (including without limitation reasonable attorneys' fees) incurred in prosecuting any such actions, the net funds obtained as a result of settlement or of judgement of any such jointly prosecuted action shall be divided in the following manner: 25% of all net funds shall be divided equally by the parties and 75% of all the net funds shall be divided between the parties in the proportion to the amount of legal fees and costs incurred by the parties in the prosecution of such actions. If funds are insufficient to pay all costs and fees then all of the funds shall be paid to the parties in said proportion.

c. During any litigation hereunder both parties shall keep each other timely informed of any significant development in the litigation and provide all reasonably requested technical assistance. During any said controversy, full royalty payment shall continue, except as otherwise provided herein.

#### 9. RECORDS

Licensee shall keep and shall require its SUBLICENSEES to keep complete, true and accurate books of account and records for the purpose of showing the derivation of all amounts payable to USC under this Option and License Agreement. Said books and records shall be kept at Licensee's principal place of business for at least four (4) years following the end of the calendar year to which they pertain, and shall be open at all reasonable times for inspection by a representative of USC for the purpose of verifying Licensee's royalties statement or Licensee's compliance in other respects with this Option and License Agreement. All information obtained as a result of such audit shall be maintained in confidence, except that the representative may disclose to USC the aggregate amount of royalties due to USC during each year, as determined in such audit. Should an audit by USC show an underpayment of royalties by more than 10%, Licensee shall immediately pay such underpayment and all interest, as well as for USC's reasonable audit expenses.

#### 10. SERVICES OF INVENTORS

USC shall make reasonable efforts to make Inventors available during regular business hours to answer questions concerning certain technical aspects of the technology. Should Licensee desire to use the services of Inventors for further testing and/or market studies of the technology, a separate research and development and/or consulting agreement should be negotiated with Inventors and the USC Office of Contracts and Grants.

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## 11. SUBLICENSE PERMISSION

Licensee may sublicense the PATENT(S) only with prior written permission from USC, which permission will not be unreasonably withheld. Notwithstanding the foregoing, no permission will be granted for a sublicense unless the SUBLICENSEE agrees in writing to be bound by the terms of this Agreement.

## 12. PATENT MARKETING

Licensee shall use reasonable efforts to place all appropriate patent and other intellectual property notices, markings and indicia on product and marketing literature for the PRODUCTS as needed to protect the patent and other intellectual property rights of USC and right for damages for infringement thereof.

# 13. PUBLICATIONS

Nothing in this Agreement shall limit or prevent USC or Inventors from publishing any information about the PATENT. Thirty (30) days prior to submission for publication, USC and Inventors will use their reasonable efforts to submit the proposed publication, for review only, to Licensee.

## 14. PUBLICITY

Neither party shall use the name, trade name, trademark or other designation of the other party in connection with any products, promotion or advertising without the prior written permission of the other party.

# 15. ASSIGNMENTS/TRANSFERS

Licensee may not assign or transfer this Agreement in whole or part to any third party without the prior written permission of USC, which permission shall be granted in the sole discretion of USC. However, the Licensee may assign the entire Agreement to successors of the entire business of the PRODUCTS if the successor agrees to be bound by this Agreement and prior written notice is provided to USC.

## 16. TERMINATION

a. Upon the breach or default under this Option and License Agreement by either party, the non-breaching party may terminate this Option and License Agreement by forty-five (45) days written notice to the breaching party. Notwithstanding, USC may terminate this Option and License Agreement upon twenty (20) days written notice to Licensee if the Licensee

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fails to obtain and maintain the insurance coverages required by Paragraph 24 hereof. Said notice shall be effective at the end of such period unless during said period breaching party shall remedy such defect or default. Licensee may also terminate this Agreement at any time, for any reason, by providing USC a thirty (30) days written notice. No option fees, license fees, or royalties shall be returnable. This Agreement may also be terminated immediately by USC upon notice to Licensee upon the occurrence of any of the following: (i) Licensee attempts to use, sublicense, transfer or assign its rights or obligations under this Agreement in any manner contrary to the terms of this Agreement or in derogation of USC's proprietary rights; or ii) Licensee is determined to be insolvent or makes an assignment for the benefit of creditors, or has a bankruptcy petition filed by or against it, or a receiver or trustee in bankruptcy or similar officer is appointed to take charge of all or part of Licensees property. Upon termination of the Agreement all rights granted to or provided by each party to the other shall automatically and irrevocably revert to the granting party.

- b. Surviving any termination are:
  - i. Licensee's obligation to pay royalties accrue or accruable.
  - ii. Licensee's obligation of Paragraph 9 to keep and allow a final audit.
  - iii. Any cause of action or claim of Licensee or USC, accrue or to accrue, because of any breach or default by the other party.
  - iv. The provisions of paragraphs 22, 23 and 24.
- с. Upon termination of this Agreement, Licensee agrees to immediately discontinue the manufacture and sale of the PRODUCTS and the use of the PATENTS. Within twenty (20) days after such termination, Licensee shall provide USC with a written inventory of all PRODUCTS currently in its stock as of the date of termination (the "INVENTORY"). USC shall have the option to grant to Licensee the privilege of disposing of such INVENTORY at its normal prices within three (3) months after said termination. Licensee shall dispose of this INVENTORY only to customers who had previously purchased PRODUCTS from Licensee during the term of this Agreement, and in no event shall Licensee sell such INVENTORY to wholesalers, diverters, jobbers or any other entity which does not sell at retail exclusively or to any one else who intends to sell such INVENTORY at close-out. The disposition of all such INVENTORY, however, shall be subject to all of the terms and conditions of this Agreement. After the three (3) month sell-off period, Licensee shall destroy or return to USC all remaining unsold PRODUCTS, all packaging and marketing materials, and shall certify their destruction or return to USC specifying the number of each destroyed or returned. All royalty obligations, shall be accelerated and shall become immediately due and payable. In addition, Licensee shall immediately deliver to USC (i.) all materials relating to the PATENTS, together with all copies thereof, and (ii) all market studies or other tests or studies conducted by Licensee with respect to the PRODUCTS, all at no cost whatsoever to USC. This Paragraph 16.c. shall not apply if the termination of this Agreement arises from the expiration of the term of this Agreement under Paragraph 21.

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d. Licensee acknowledges and agrees that any violation of Agreement by Licensee would result in irreparable harm to USC. Accordingly, Licensee consents and agrees that, if Licensee violates any of the provisions of this Agreement, USC shall be entitled, in addition to other remedies available to it, to an injunction to be issued by any court of competent jurisdiction restraining Licensee from committing or continuing any violation of this Agreement, without the need for posting any bond or any other undertaking.

#### 17. NOTICES, REPORTS AND PAYMENTS

Any notice, report or payment permitted or required under this Agreement shall be in writing, and shall be sent or delivered to the receiving party at the address set forth below or at such address as either party may from time to time designate in writing.

USC: Office of Patent and Copyright Administration University of Southern California 3716 South Hope Street, Suite 313 Los Angeles, CA 90007-4344 (U.S.A.)

## Attn: Director

LICENSEE:	Biokeys Incorporated
	709 Hamptons Lane
	Chesterfield, MO 63017

Attn: Francis E. O'Donnell Jr., Chief Executive Officer

#### 18. PARAGRAPH HEADINGS

Paragraph headings are for the convenience of this Agreement only and shall not add to or detract from any of the terms or provisions.

#### 19. SEVERABILITY

If any provision of this Agreement is held invalid under any law applicable to the parties, SUBLICENSEES and/or assignees, that provision shall be considered severable and its invalidity shall not affect the remainder of this Agreement, which shall continue in full force and effect.

#### 20. CONTROLLING LAW, JURISDICTION AND VENUE

This Agreement shall be deemed to be executed and to be performed in the State of California, and shall be construed in accordance with the laws of the State of California as to all

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matters, including but not limited to matters of validity, construction, effect and performance. In the event of any controversy, claim or dispute between the parties hereto arising out of or relating to this agreement, such controversy, claim or dispute may be tried exclusively in the courts of the State of California or in the United States Federal District Court for the Central District of California, as either party may elect. Each of the parties hereby waives any defense of lack of in personam jurisdiction, improper venue and forum non conveniens, and agrees that service of process of such court may be made upon each of them by personal delivery or by mailing certified or registered mail, return receipt requested, to the other party at the address provided for in Paragraph 16 hereof. Both parties hereby submit to the jurisdiction of the court so selected, to the exclusion of any other courts which may have had jurisdiction apart from this Paragraph 20.

#### 21. TERMS OF AGREEMENT

Except as otherwise terminated pursuant to the other provisions of this OPTION AND LICENSE AGREEMENT, this Agreement shall terminate upon expiration of the last to expire of the PATENTS.

#### 22. NEGATION OF WARRANTIES

- a. Nothing in this Agreement shall be construed as:
  - i. a warranty or representation by USC as to the validity or scope of the PATENT and/or PATENT Application; or
  - ii. a warranty or representation that any PRODUCTS made, used, sold or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of patents of third parties; or
  - iii. an obligation to bring or prosecute actions or suits against third parties for infringement; or
  - iv. conferring the rights to use in advertising, publicity or otherwise any trademark, trade name, or names or any contraction, abbreviation, simulation or adoption thereof, of USC or Licensee; or
  - v. any obligation to furnish any know-how not provided.

FITNESS FOR A PARTICULAR PURPOSE, nor does USC represent that the rights granted hereunder will result in PRODUCTS that are commercially successful.

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c. Licensee further agrees that it will not rely upon technical information provided by USC and Inventors in developing and manufacturing any PRODUCTS hereunder, but will independently test, analyze and evaluate all PRODUCTS prior to manufacture and distribution of such PRODUCTS.

#### 23. INDEMNITY

- a. Licensee shall defend, indemnify and hold harmless USC and its trustees, officers, medical and professional staff, employees and agents and their respective successors, heirs and assigns (the "Indemnitees"), against all liabilities, demands, losses, costs, and expenses (including without limitation attorneys' fees) incurred by or imposed upon the Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgements arising out of any theory of liability (including but not limited to, actions in the form of tort, warrantee, or strict liability) for death, personal injury, illness, or property damage arising from Licensee's use, sale, or other disposition of the PRODUCTS.
- b. Licensee agrees, at its own expense, to provide attorneys reasonably acceptable to USC to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

# 24. INSURANCE

- Prior to Licensee exercising the option granted herein, Licensee a. shall at its sole cost and expense, procure and maintain in effect a comprehensive general liability policy of insurance in single limit coverage of not less than One Million Dollars (\$1,000,000) per incident and One Million Dollars (\$1,000,000) annual aggregate for death, bodily injury or illness and Two Hundred Thousand Dollars (\$200,000) annual aggregate in property damage. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retention which are in excess of \$50,000 annual aggregate) such self-insurance program must be acceptable to USC. Each such policy of insurance shall name USC as an additional insured and shall provide for not less than thirty (30) days prior written notice before any cancellation or material change in coverage shall be effective. A Certificate evidencing the comprehensive general liability policy herein defined shall be delivered to USC within ten (10) days of the EFFECTIVE DATE of this Agreement. Licensee shall maintain such comprehensive general liability insurance until such time as the policy in Paragraph 25.b. is procured, or until fifteen (15) years after the term of this Agreement.
- b. During such time and in each country where PRODUCT, or any modification thereof, is administered to humans, manufactured or distributed for any purpose (including for the purpose of obtaining regulatory approvals) Licensee or any SUBLICENSEE, Licensee shall at its sole cost and expense, procure and maintain in effect a comprehensive general liability policy of

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insurance in single limit coverage of not less than Ten Million Dollars (\$10,000,000) per incident and Ten Million Dollars (\$10,000,000) annual aggregate for death, bodily injury, illness or property damage. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retention which are in excess of \$250,000 annual aggregate) such self-insurance program must be acceptable to USC. Each such policy of insurance shall name USC as an additional insured and shall provide for not less than thirty (30) days prior written notice before any cancellation or material change in coverage shall be effective. A Certificate evidencing the comprehensive general liability policy herein defined shall be delivered to USC prior to any manufacture, sale, distribution or administration to humans. Licensee shall maintain such comprehensive general liability insurance during the period that the PRODUCT or any modification thereof is being manufactured, sold, distributed or administered to humans by the Licensee or its SUBLICENSEES and a reasonable period thereafter which in no event shall be less than fifteen (15) years.

- Alternatively, Licensee and USC may obtain an independent opinion с. from legal counsel mutually agreeable to the parties in each country in which Licensee intends to manufacture and/or distribute PRODUCTS, such opinion to assist in determining the amount of general and products liability insurance required to be carried by Licensee in such country. Where independent legal counsel determines that little or no liability risk to USC exists under the present and reasonably anticipated future legal trends in that country, Licensee will be required to maintain liability insurance on USC's behalf which is determined by USC to be reasonably adequate to pay litigation defense costs. Where independent legal counsel determines that the risk of liability on the part of USC is more than minimal in that country, USC and Licensee will evaluate such risk and negotiate in good faith to determine the amounts of liability insurance necessary to reasonably insure USC's interests. If USC and Licensee cannot agree on the amounts and types of insurance reasonably necessary to protect USC's interest in a particular country, Licensee will not manufacture or market PRODUCTS in that country.
- d. In the event that Licensee does not maintain such insurance, but is self-insured, or carries a substantial self-retention, USC may grant permission for such self-insurance only if, in the sole discretion of USC, the net worth, assets and earnings of the Licensee are deemed sufficient to protect USC's economic interests in the event of claims, liability, demands, damages, expenses and losses from death, personal injury, illness, or property damage.
- e. The minimum amounts of insurance coverage required under this Paragraph (subparts 24.a., 24.b., and 24.c.) shall not be construed to create a limit of Licensee's liability with respect to its indemnification in Paragraph 23 or any other provision of this Agreement.

## f. By SUBLICENSEES

As a condition precedent to a grant of permission by USC for Licensee to sublicense the PATENT rights herein, the prospective SUBLICENSEE shall agree to indemnify Licensee and USC to the same extent and degree as Licensee has agreed to indemnify USC herein. Such SUBLICENSEE shall also provide insurance identical in coverage and amount to that required

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of Licensee in subparagraph b, above, naming both Licensee and USC as additional insured. A Certificate evidencing the product liability coverage shall be delivered prior to first manufacture of any PRODUCTS by the SUBLICENSEE. In the event a prospective SUBLICENSEE does not maintain such insurance, but rather is self-insured, or carries a substantial self-retention, USC may grant permission for such sublicense only if, in the sole discretion of USC, the net worth, assets and earnings of such prospective SUBLICENSEE are deemed sufficient to protect USC's economic interests in the event of claims, liability, demands, damages, expenses and losses from death, personal injury, illness, or property damage.

## 26. PRODUCT DEVELOPMENT

If Licensee exercises its option, Licensee shall use its reasonable efforts to test, develop the PRODUCT for commercial purposes through the world. On or before January 1 of each year during the term of this Agreement, commencing January 1, 1998, Licensee shall submit to USC a report detailing its research, regulatory approval, marketing and product development objectives the coming year as well as the research, regulatory approval, marketing and development activities which Licensee undertook during the preceding year. The reports shall identify specific future milestones (regulatory approval and product development) and information demonstrating that the Licensee is providing sufficient financial and manpower resources to evidence its use of reasonable efforts. Within six (6) months after the signing of this Agreement and each two (2) years thereafter, a representative of the Office of Patent and Copyright Administration of USC, at Licensee's expense (including transportation, and, if appropriate, lodging and meals), shall visit the manufacturing and marketing facilities of Licensee and be presented with an in-depth updating of the manufacturing capability and marketing network of Licensee.

# 27. EXPORT CONTROLS

It is understood that USC is subject to United State laws and regulations controlling the export of technical data, computer software, laboratory

prototypes and other commodities (such laws include the Arms Export Control Act, as amended and the Export Administration Act), and that its obligations hereunder are contingent on compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities by the Licensee may require a license from the cognizant agency of the United States Government and/or written assurances by Licensee that Licensee shall not export data or commodities to certain foreign countries without prior approval of such agency. USC neither represents that a license shall not be required nor that, if required, it shall be issued. Licensee shall not engage in any activity in connection with this Agreement that is in violation of any applicable U.S. law.

# 28. INDEPENDENT CONTRACTOR

In rendering performances under this Agreement, Licensee will function solely as an independent contractor and not as an agent, partner, employee or joint venturer with USC.

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Nothing in this Agreement shall be deemed or construed to create the relationship of principal and agent, or of partnership or joint venture, and neither party shall hold itself out as an agent, legal representative, partner, subsidiary, joint venturer, servant or employee of the other. Neither party nor any officer, employee, agent or representative thereof shall, in any event, have any right collectively or individually, to bind the other party, to make any representations or warranties, to accept service of process, to receive notice or to perform any act or thing on behalf of the other party, except as expressly authorized under this Agreement or in writing by such other party in its sole discretion.

#### 29. WAIVER

No waiver by either party of any default or breach shall be deemed as a waiver of prior or subsequent default or breach of the same or other provisions of this Agreement.

#### 30. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the parties concerning the subject matter hereof. No amendment, modification, extension or cancellation of this Agreement shall be binding on the parties unless mutually agreed to and executed in writing by each of the parties.

UNIVERSITY OF SOUTHERN CALIFORNIA	BIOKEYS, INC.
/s/ DENNIS F. DOUGHERTY	/s/ FRANCIS E. O'DONNELL, JR.
Signature	Signature
Dennis F. Dougherty Sr. V.P. Admin 1/20/98	Francis E. O'Donnell, Jr. Chairman 1/23/98

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\* PLEASE NOTE THAT CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED ON A REQUEST FOR CONFIDENTIAL TREATMENT FILED WITH THE COMMISSION ALONG WITH THE INFORMATION REQUESTED TO BE OMITTED.

## **OPTION & LICENSE AGREEMENT**

# 1. INTRODUCTION

THIS AGREEMENT is between the UNIVERSITY OF SOUTHERN CALIFORNIA, (hereinafter USC) a California nonprofit corporation with its principal place of business at University Park, Los Angeles, California 90089, and BioKeys, Inc., a Delaware corporation, with its principal place of business at 11466 Winding Ridge Drive, San Diego, California 92141 (hereinafter Licensee).

WHEREAS USC warrants that it is the owner and that it has the right to exclusively license those rights it has in the inventions which are the subject matter of the patent applications listed in Appendix A and of which the inventor is Charles McKenna of USC (hereinafter Inventor);

WHEREAS Licensee desires to obtain an exclusive license in the defined FIELD OF USE to manufacture and market products utilizing the inventions as hereinafter defined;

WHEREAS, USC is willing to grant a worldwide, exclusive license in the defined FIELD OF USE to Licensee subject to the terms, conditions, limitations, and restrictions set forth below;

NOW, THEREFORE, in consideration of the covenants herein contained, the parties agree as follows:

#### 2. DEFINITIONS

For all purposes of this Agreement the following terms shall have the meanings specified below:

- a. The term "PATENT" or "PATENTS" shall mean any and all patent applications listed in Appendix A (Appendix A may be added to from time to time by USC and USC shall notify Licensee of any such additions), any and all patents issued thereon or any continuation, division, extensions or reissue thereof, and any and all foreign patents issuing from any application filed which corresponds to claims contained in any of the foregoing patents or applications.
- b. "PRODUCT" or "PRODUCTS" shall mean any article, composition, apparatus, substance, chemical, material, method or service which is made, used, distributed or sold by Licensee which:
  - i. is covered in whole or in part by one or more pending or unexpired claims contained in a PATENT in the country in which the PRODUCT(S) is made, used, distributed or sold;
  - ii. is manufactured using a method or process which is covered in whole or in part by one or

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more pending or unexpired claims contained in a PATENT in the country in which (a) the PRODUCT(S) is made, used, distributed or sold, or (b) the method or process is used or sold; or

- iii. the use of which is covered in whole or in part by one or more pending or unexpired claims contained in a PATENT in the country in which (a) the PRODUCT(S) is made, used, distributed or sold, or (b) the method or process is used or sold;
- iv. incorporates technology transferred to Licensee pursuant to the confidential disclosure agreement dated May 22, 2000 between USC and Licensee.

A PRODUCT is covered by a pending or unexpired claim of a PATENT if in the course of manufacture, use, distribution or sale, it would, in the absence of this Agreement, infringe one or more claims of the PATENT which has not been held invalid by a court from which no appeal can be taken.

- c. "FIELD OF USE" shall mean use of thiophosphonoformic acid (TPFA) and derivatives thereof for treatment of infection by Human Immunodeficiency Virus (HIV), Human Papillomavirus (HPV) and other viral infections.
- d. "NET SALES PRICE" shall mean the gross billing price of any PRODUCT received by Licensee or its SUBLICENSEE for the sale or distribution of

any PRODUCT, less the following amounts actually paid by Licensee or SUBLICENSEE:

- i. discounts allowed;
- ii. returns;
- iii. transportation charges or allowances;
- iv. packing and transportation packing material costs (not including product containers or product packing containers as manufactured by the Company);
- v. customs and duties charges; and
- vi. sales, transfer and other excise taxes or other governmental charges levied on or measured by the sales but no franchise or income tax of any kind whatsoever.

Every commercial use or disposition of any PRODUCT, in addition to a bona fide sale to a customer, shall be considered a sale of such PRODUCT. The NET SALES PRICE, in the case of a use or disposition other than a bona fide sale, shall be equivalent to the then payable NET SALES PRICE of such PRODUCT in an arm's length transaction.

e. "SUBLICENSEE" shall mean any third party licensed by Licensee to make, or sell any PRODUCT in accordance with the terms of this Agreement.

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- f. "EFFECTIVE DATE" of this Agreement shall be the date when the last party has signed this Agreement.
- 3. OPTION PHASE
  - a. USC hereby grants Licensee the exclusive right to conduct various technical, pre-clinical, marketing, patent, and other studies on PRODUCTS in the FIELD OF USE during a three (3) month period commencing on the EFFECTIVE DATE of this Agreement. The option period may be extended by mutual written agreement of the parties.
  - b. The consideration for the grant of this option phase shall be One Hundred Fifty Thousand Dollars (\$150,000). Such payment shall be due on the earlier to occur of: (i) within three (3) months of the EFFECTIVE DATE of this Agreement or (ii) thirty (30) days from the date Licensee raises its next round of private funding.
- 4. LICENSE PHASE
  - a. In consideration of the license fee and royalties, and subject to the terms and conditions, as set forth in this Agreement and effective upon written notification to USC during the option phase that Licensee desires to license the PATENT(S), USC hereby grants to Licensee:
    - i. the exclusive worldwide license to use the PATENT to manufacture and sell the PRODUCT(S) for application in the FIELD OF USE; and
    - ii. the right to grant sublicenses to any PATENT licensed exclusively hereunder, provided that any SUBLICENSEE agrees to be bound by the terms and conditions of this Agreement applicable to SUBLICENSEES.
  - b. In addition to the consideration referred to in Paragraph 3.b., Licensee and USC shall during the option phase negotiate in good faith the terms of a mutually agreeable research agreement for the purpose of testing and developing the PRODUCT(S) for commercial purposes throughout the world.
  - c. If USC is not notified of Licensee's desire to enter the license phase by the end of the option phase or any extensions thereto and Licensee and USC are not able to agree to the terms of a research agreement pursuant to Paragraph 4.b., this Agreement and the license granted herein shall immediately terminate. Payments referred to in Section 3 shall not be refunded upon such termination.
  - d. All licenses pursuant to Paragraphs 4.a. and 4.c. to inventions conceived or first actually reduced to practice during the course of research funded by a U.S. federal agency are subject to the rights, conditions and limitations imposed by U.S. law, including but not limited to the following:
    - i. The words "exclusive license" as used herein shall mean exclusive except for the

royalty free non-exclusive license granted to the U.S. government by USC pursuant to 35 USC Section 202(c)(4) for any PATENT claiming an invention subject to 35 USC Section 201 and except for the rights of USC and Inventor as set forth in Paragraph 6.

- ii. Licensee agrees that PRODUCTS used or sold in the United States shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the relevant U.S. federal agency.
- 5. ROYALTY
  - a. On all sales of PRODUCTS anywhere in the world by Licensee, Licensee shall pay USC a royalty of (SPACE) the NET SALES PRICE.
  - b. If any PRODUCT is manufactured and sold under sublicense from the Licensee, the Licensee shall pay USC a royalty equal to (SPACE) of all of the Licensee's revenue received from the sublicense, including but not limited to earned royalty, prepaid royalty and license fees.
  - c. The Licensee will pay an annual minimum royalty. The minimum royalty on each PRODUCT will be Twenty-Five Thousand Dollars (\$25,000.00) commencing on the first anniversary date of this Agreement, Seventy-Five Thousand Dollars (\$75,000) on the second anniversary date and on the third anniversary date and thereafter One Hundred Twenty-Five Thousand Dollars (\$125,000.00) for each succeeding year up to the date of expiration of the last PATENT. Minimum royalties are to be paid biannually to USC, one half due and payable on January 1 of each year and the second half due and payable on July 1 of each year. Should Licensee fail to make earned royalty payments sufficient to meet said minimum royalty requirements, it may pay the difference between the earned royalty and the minimum royalty requirement to keep this Agreement in force.
  - d. Licensee shall pay such royalties to USC on a calendar quarter basis. With each quarterly payment, Licensee shall deliver to USC a full and accurate accounting to include at least the following information:
    - Quantity of each PRODUCT sold (by country) by Licensee and its SUBLICENSEES;
    - ii. Total receipts for each PRODUCT (by country);
    - iii. Quantities of each PRODUCT used by Licensee and its SUBLICENSEES;
    - iv. Names and addresses of SUBLICENSEES of Licensee;
    - v. Total number of PRODUCTS manufactured (by country); and
    - vi. Total royalties payable to USC.
  - e. In each year the amount of royalty due shall be calculated quarterly as of March 31, June 30,

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September 30 and December 31 and shall be paid quarterly within the next thirty (30) days following such date. Every such payment shall be supported by the accounting prescribed in Paragraph 5.d. and shall be made in United States currency. Whenever for the purpose of calculating royalties conversion from foreign currency shall be required, such conversion shall be at the rate of exchange thereafter published in the Wall Street Journal for the business day closest to the applicable end of calendar quarter.

f. The royalty payments due under this Agreement shall, if overdue, bear interest until payment at a per annum rate equal to (SPACE) above the prime rate in effect at Bank of America on the due date, not to exceed the maximum permitted by law. The payments of such interest shall not preclude USC from exercising any other rights it may have as a consequence of the lateness of any royalty payment.

# 6. RIGHTS RETAINED BY UNIVERSITY

Notwithstanding the exclusive license granted in Paragraph 4.a., USC and Inventor will have the absolute, nontransferable right to use the technology covered by the PATENTS and all improvements thereof, for conducting research and educational purposes.

- a. USC shall file, prosecute and maintain, during the course of this Agreement, the patent applications and patents listed in Appendix A. Should Licensee require the filing of foreign patents, USC shall take responsibility for filing, prosecuting and maintaining said foreign patents.
- b. Licensee shall reimburse all reasonable legal expenses incurred and paid by USC in filing, prosecuting and maintaining the U.S. and foreign applications listed (or to be listed pursuant to Paragraph 2.a.) in Appendix A, whether such expenses were incurred before or after the date of this Agreement. These legal expenses shall include the attorneys' and agents' fees, foreign filing fees and out-of-pocket costs associated with responding to office actions and any other fees and costs directly related to obtaining and/or maintaining patent protection in the countries listed in Appendix A. Licensee shall advance payments of maintenance fees and annuities as part of such legal expenses to be reimbursed by Licensee within thirty (30) days of request by USC, unless Licensee is advised otherwise by timely notice from USC.
- c. Licensee agrees to pay to USC an initial deposit of Twenty-Five Thousand Dollars (\$25,000.00) within fifteen (15) days of the EFFECTIVE DATE of this Agreement. Such deposit will be held in a trust account. Licensee authorizes USC to use that account to pay all legal expenses incurred pursuant to Paragraph 7.b. When the trust account drops below Twenty-Five Thousand Dollars (\$25,000.00), Licensee agrees to pay within thirty (30) days of USC's written demand, the amount to maintain the balance of the trust account at a minimum of Twenty-Five Thousand Dollars (\$25,000.00). Upon termination of this Agreement, any unused deposit shall be refunded.
- d. If the Licensee elects (i) not to pursue a PATENT or (ii) to terminate the prosecution or

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maintenance of a PATENT in any country, the Licensee surrenders its right to make, use or sell PRODUCTS covered by the non-elected PATENT in that particular country and shall grant to USC the exclusive rights previously granted to Licensee, without limitation, for that country. Licensee agrees to execute all necessary documents to carry out this grant of rights to USC. Payments referred to in Paragraphs 7.a. and 7.b. shall not be refunded upon such non-election or termination.

- e. If the Licensee decides to terminate this agreement pursuant to Paragraph 16, Licensee shall reimburse all reasonable legal expenses incurred up to six (6) months from the date written notification of termination is sent to Licensee; provided, however, such legal expenses shall not exceed (SPACE).
- 8. PATENT INFRINGEMENT
  - a. Defensive Controversy.

Licensee shall promptly notify USC of all claims, allegations and notifications of infringement of third party patents. Except for the placing in escrow of a portion of royalties as referred to hereinafter, USC shall have no obligation or liability in the event that legal action is brought against Licensee for patent infringement. Such obligation and liability shall be borne by Licensee. Licensee may choose legal counsel and defend the patent infringement lawsuit. During such lawsuit, Licensee may place all of the royalties derived from sales of the PRODUCT in the country where such lawsuit is pending in an interest-bearing escrow account. The escrow account shall be established in a bank mutually acceptable to both parties under escrow instructions insulating the funds from claims of any creditor. Upon termination of the action, one-half (1/2) of any judgment amount, reasonable attorneys' fees and costs, may be paid from this escrow account. Should the settlement of any such patent infringement lawsuit involve payment of royalties by Licensee to a third party for the continued right to manufacture, use, and sell the PRODUCT, then funds in the escrow account and royalties payable to USC may be applied against up to one-half (1/2) of such royalties to a third party. Any funds thereafter remaining in the escrow shall be paid to USC. The above shall constitute USC's sole liability and responsibility in the event of such action. Royalties paid to third parties as provided for above shall be included when determining whether the minimum royalty provided for in this Agreement has been paid in a given year. During the patent infringement litigation both parties shall keep each other informed in writing of significant developments in the lawsuit.

# b. Offensive Controversy.

Licensee shall promptly notify USC of any potential infringement of a PATENT. In the event that a third party infringes on a PATENT, Licensee shall have the right but not an obligation to bring legal action to enforce any such patent. If Licensee exercises such right, Licensee shall select legal counsel and pay all legal fees and costs of prosecution of such action. In the event that Licensee shall choose not to take such action, USC shall have the right, at its option and at its own expense, to prosecute any action to enjoin such infringement or to prosecute any claim for damages. The party prosecuting any such action shall be entitled to retain any funds received as a result of settlement

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or judgment of such action. The parties may also agree to jointly pursue infringers. After deduction and payment to the parties of their respective costs and fees (including without limitation reasonable attorneys' fees) incurred in prosecuting any such actions, the net funds obtained as a result of settlement or of judgment of any such jointly prosecuted action shall be divided in the following manner: 25% of all net funds shall be divided equally by the parties and 75% of all the net funds shall be divided between the parties in the proportion to the amount of legal fees and costs incurred by the parties in the prosecution of such actions. If funds are insufficient to pay all costs and fees then all of the funds shall be paid to the parties in said proportion.

c. During any litigation hereunder both parties shall keep each other timely informed of any signifi cant development in the litigation and provide all reasonably requested technical assistance. During any said controversy, full royalty payment shall continue, except as otherwise provided herein.

# 9. RECORDS

Licensee and SUBLICENSEES shall keep complete, true and accurate books of account and records for the purpose of showing the derivation of all amounts payable to USC under this Option and License Agreement. Said books and records shall be kept at Licensee's principal place of business for at least four (4) years following the end of the calendar year to which they pertain and shall be open at all reasonable times for inspection by a representative of USC for the purpose of verifying Licensee's royalties statement or Licensee's compliance in other respects with this Option and License Agreement. All information obtained as a result of such audit shall be maintained in confidence, except that the representative may disclose to USC the aggregate amount of royalties due to USC during each year, as determined in such audit. Should an audit by USC show an underpayment of royalties by more than 10%, Licensee shall immediately pay such underpayment and all interest, as well as for USC's reasonable audit expenses.

# 10. SERVICES OF INVENTOR

USC shall make reasonable efforts to make Inventor available during regular business hours to answer questions concerning technical aspects of the technology necessary to understand the PATENT(S). Should Licensee desire to use the services of Inventor for further technical information and/or market studies of the technology, a separate research and development and/or consulting agreement should be negotiated with Inventor and the USC Office of Contracts and Grants.

#### 11. SUBLICENSE PERMISSION

Licensee may sublicense the PATENT(S) only with prior written permission from USC, which permission will not be unreasonably withheld. Notwithstanding the foregoing, no permission will be granted for a sublicense unless the SUBLICENSEE agrees in writing to be bound by the terms of this Agreement.

## 12. PATENT MARKING

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Licensee shall use reasonable efforts to place all appropriate patent and other intellectual property notices, markings and indicia on product and marketing literature for the PRODUCTS as needed to protect the patent and other intellectual property rights of USC and right for damages for infringement thereof.

# 13. PUBLICATIONS

Nothing in this Agreement shall limit or prevent USC or Inventor from publishing any information about the PATENT. Thirty (30) days prior to submission for publication, USC and Inventor will use their reasonable efforts to submit the proposed publication, for review only, to Licensee.

# 14. PUBLICITY

Neither party shall use the name, trade name, trademark or other designation of the other party in connection with any products, promotion or advertising without the prior written permission of the other party.

#### 15. ASSIGNMENTS/TRANSFERS

Licensee may not assign or transfer this Agreement in whole or part to any third party without the prior written permission of USC, which permission shall be granted in the sole discretion of USC. The Licensee may only assign the entire Agreement to successors of the entire business of the PRODUCTS if the successor agrees to be bound by this Agreement and prior written notice is provided to USC.

## 16. TERMINATION

a. Upon the breach of or default under this Option and License Agreement by either party, the non-breaching party may terminate this Option and License Agreement by forty-five (45) days written notice to the breaching party. Said notice shall be effective at the end of such period unless during said period breaching party shall remedy such defect or default. Licensee may also terminate this Agreement at any time, for any reason, by providing USC a thirty (30) day written notice and paying to USC the legal expenses incurred up to six (6) months from the date written termination is sent to Licensee. No option fees, license fees, or royalties shall be returnable. This Agreement may also be terminated immediately by USC upon notice to Licensee upon the occurrence of any of the following: (i) Licensee attempts to use, sublicense, transfer or assign its rights or obligations under this Agreement in any manner contrary to the terms of this Agreement or in derogation of USC's proprietary rights; (ii) Licensee fails to obtain and maintain the insurance coverages required by Paragraph 24 hereof; or (iii) Licensee is determined to be insolvent or makes an assignment for the benefit of creditors, or has a bankruptcy petition filed by or against it, or a receiver or trustee in bankruptcy or similar officer is appointed to take charge of all or part of Licensee's property. Upon termination of the Agreement all rights granted to or provided by each party to the other shall automatically and irrevocably revert to the granting party.

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- b. Surviving any termination are:
  - i. Licensee's obligation to pay the amount for consideration for the grant of the option phase and royalties accrued or accruable.
  - ii. Licensee's obligation of Paragraph 9 to keep and allow a final audit.
  - iii. Any cause of action or claim of Licensee or USC, accrue or to accrue, because of any breach or default by the other party.
  - iv. The provisions of Paragraphs 22, 23 and 24.
- Upon termination of this Agreement, Licensee agrees to immediately c. discontinue the manufacture and sale of the PRODUCTS and the use of the PATENTS. Within twenty (20) days after such termination, Licensee shall provide USC with a written inventory of all PRODUCTS currently in its stock as of the date of termination (the "INVENTORY"). USC shall have the option to grant to Licensee the privilege of disposing of such INVENTORY at its normal prices within three (3) months after said termination. Licensee shall dispose of this INVENTORY only to customers who had previously purchased PRODUCTS from Licensee during the term of this Agreement, and in no event shall Licensee sell such INVENTORY to wholesalers, diverters, jobbers or any other entity which does not sell at retail exclusively or to anyone else who intends to sell such INVENTORY at close-out. The disposition of all such INVENTORY, however, shall be subject to all of the terms and conditions of this Agreement. After the three (3) month sell-off period, Licensee shall destroy or return to USC all remaining unsold PRODUCTS, all equipment used in the manufacture of the PRODUCTS and all packaging and marketing materials, and shall certify their destruction or return to USC specifying the number of each destroyed or returned. All royalty obligations, including any unpaid portions of the minimum royalty, shall be accelerated and shall become immediately due and payable. In addition, Licensee shall immediately deliver to USC (i) all materials relating to the PATENTS, together with all copies thereof, and (ii) all market studies or other tests or studies conducted by Licensee with respect to the PRODUCTS, all at no cost whatsoever to USC.
- d. LICENSEE acknowledges and agrees that any violation of this Agreement by Licensee would result in irreparable harm to USC. Accordingly, Licensee consents and agrees that, if Licensee violates any of the provisions of this Agreement, USC shall be entitled, in addition to other remedies available to it, to an injunction to be issued by any court of competent jurisdiction restraining Licensee from committing or continuing any violation of this Agreement, without the need for posting any bond or any other undertaking.

#### 17. NOTICES, REPORTS AND PAYMENTS

Any notice, report or payment permitted or required under this Agreement shall be in writing, and shall be sent or delivered to the receiving party at the address set forth below or at such address as either party may from time to time designate in writing.

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- USC: Office of Technology Licensing University of Southern California 3716 South Hope Street, Suite 313 Los Angeles, California 90007-4344 (U.S.A.)
- Attn: Director
- LICENSEE: BioKeys, Inc. 11466 Winding Ridge Drive San Diego, California 92141
- Attn: Nicholas Jon Virca President & Chief Executive Officer
- **18. PARAGRAPH HEADINGS**

Paragraph headings are for the convenience of this Agreement only and shall not add to or detract from any of the terms or provisions.

#### 19. SEVERABILITY

If any provision of this Agreement is held invalid under any law applicable to the parties, SUBLICENSEES and/or assignees, that provision shall be considered severable and its invalidity shall not affect the remainder of this Agreement, which shall continue in full force and effect.

#### 20. CONTROLLING LAW, JURISDICTION AND VENUE

This Agreement shall be deemed to be executed and to be performed in the State of California, and shall be construed in accordance with the laws of the State of California as to all matters, including but not limited to matters of validity, construction, effect and performance. In the event of any controversy, claim or dispute between the parties hereto arising out of or relating to this agreement, such controversy, claim or dispute may be tried exclusively in the courts of the State of California or in the United States Federal District Court for the Central District of California, as either party may elect. Each of the parties hereby waives any defense of lack of in personam jurisdiction, improper venue and forum non conveniens, and agrees that service of process of such court may be made upon each of them by personal delivery or by mailing certified or registered mail, return receipt requested, to the other party at the address provided for in Paragraph 17 hereof. Both parties hereby submit to the jurisdiction of the court so selected, to the exclusion of any other courts which may have had jurisdiction apart from this Paragraph 20.

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# 21. TERM OF THE AGREEMENT

Except as otherwise terminated pursuant to the other provisions of this OPTION AND LICENSE AGREEMENT, this Agreement shall terminate upon expiration of the last to expire of the patents or fifteen (15) years from the Effective Date of this Agreement, whichever is longer.

# 22. NEGATION OF WARRANTIES

- a. Nothing in this Agreement shall be construed as:
  - i. a warranty or representation by USC as to the validity or scope of the PATENT and/or PATENT Application; or
  - ii. a warranty or representation that any PRODUCTS made, used, sold or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of patents of third parties; or
  - iii. an obligation to bring or prosecute actions or suits against third parties for infringement; or
  - iv. conferring the rights to use in advertising, publicity or otherwise any trademark, trade name, or names or any contraction, abbreviation, simulation or adoption thereof, of USC or Licensee; or
  - v. any obligation to furnish any know-how not provided.

- b. USC MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, nor does USC represent that the rights granted hereunder will result in PRODUCTS that are commercially successful.
- c. Licensee further agrees that it will not rely upon technical information provided by USC and Inventor in developing and manufacturing any PRODUCTS hereunder, but will independently test, analyze and evaluate all PRODUCTS prior to manufacture and distribution of such PRODUCTS.
- d. UNDER NO CIRCUMSTANCES SHALL USC BE LIABLE TO LICENSEE OR ANY OF ITS SUBLICENSEES FOR ANY INDIRECT, CONSEQUENTIAL, INCIDENTAL, SPECIAL OR PUNITIVE DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT. NOTWITHSTANDING THE FOREGOING, UNDER NO CIRCUMSTANCE SHALL USC HAVE ANY CUMULATIVE LIABILITY FOR ANY CLAIM ARISING FROM THIS AGREEMENT IN EXCESS OF THE TOTAL AMOUNTS PAID BY LICENSEE TO USE UNDER THIS AGREEMENT.

# 23. INDEMNITY

a. Licensee shall defend, indemnify and hold harmless USC and its trustees, officers, medical and

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professional staff, employees and agents and their respective successors, heirs and assigns (the "Indemnitees"), against all liabilities, demands, losses, costs, and expenses (including without limitation attorneys' fees) incurred by or imposed upon the Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments arising out of any theory of liability (including but not limited to, actions in the form of tort, warrantee, or strict liability) for death, personal injury, illness, or property damage arising from Licensee's use, sale, or other disposition of the PRODUCT(S).

- b. Licensee agrees, at its own expense, to provide attorneys reasonably acceptable to USC to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought. To the extent that any proposed settlement directly affects USC, the Licensee shall obtain the approval of USC before finally agreeing to such settlement proposal, which consent shall not be unreasonably withheld.
- 24. INSURANCE
  - Not less than thirty (30) days prior to the exercise of the license a. phase of this Agreement, Licensee shall at its sole cost and expense, procure and maintain in effect a comprehensive general liability policy of insurance in single limit coverage of not less than One Million Dollars (\$1,000,000) per incident and One Million Dollars (\$1,000,000) annual aggregate for death, bodily injury or illness and Two Hundred Thousand Dollars (\$200,000) annual aggregate in property damage. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retention which are in excess of annual aggregate) such self-insurance program must be acceptable to USC. Each such policy of insurance shall name USC as an additional insured and shall provide for not less than thirty (30) days prior written notice before any cancellation or material change in coverage shall be effective. A Certificate evidencing the comprehensive general liability policy herein defined shall be delivered to USC within ten (10) days of the EFFECTIVE DATE of this agreement. Licensee shall maintain such comprehensive general liability insurance until such time as the policy in Paragraph 24.b. or Paragraph 24.c is procured, or until fifteen (15) years after the term of this Agreement.
  - b. During such time and in each country where PRODUCT, or any modification thereof, is utilized in human clinical trials by Licensee or any SUBLICENSEE, Licensee shall at its sole cost and expense, procure and maintain in effect a comprehensive general liability policy of insurance in single limit coverage of not less than Five Million Dollars (\$5,000,000) per incident and Five Million Dollars (\$5,000,000) annual aggregate for death, bodily injury, illness or property damage. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retention which are in excess of \$125,000 annual aggregate) such self-insurance program must be acceptable to USC. Each such policy of insurance shall name USC as an additional insured and shall provide for not less than thirty (30) days prior written notice before any cancellation or material change in coverage shall be effective. A Certificate evidencing

the comprehensive general liability policy herein defined shall be delivered to USC prior to any manufacture, sale, distribution or administration to humans. Licensee shall maintain such comprehensive

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general liability insurance until such time as the policy in Paragraph 24.c is procured, or until fifteen (15) years after the term of this Agreement.

- c. During such time and in each country where PRODUCT, or any modification thereof, is administered to humans, manufactured or distributed for any purpose other than for human clinical trials as specified in Paragraph 23.b (including for the purpose of obtaining regulatory approvals) by Licensee or any SUBLICENSEE, Licensee shall at its sole cost and expense, procure and maintain in effect a comprehensive general liability policy of insurance in single limit coverage of not less than Ten Million Dollars (\$10,000,000) per incident and Ten Million Dollars (\$10,000,000) annual aggregate for death, bodily injury, illness or property damage. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retention which are in excess of \$250,000 annual aggregate) such self-insurance program must be acceptable to USC. Each such policy of insurance shall name USC as an additional insured and shall provide for not less than thirty (30) days prior written notice before any cancellation or material change in coverage shall be effective. A Certificate evidencing the comprehensive general liability policy herein defined shall be delivered to USC prior to any manufacture, sale, distribution or administration to humans. Licensee shall maintain such comprehensive general liability insurance during the period that the PRODUCT or any modification thereof is being manufactured, sold, distributed or administered to humans by the Licensee or its SUBLICENSEES and a reasonable period thereafter which in no event shall be less than fifteen (15) years.
- d. In the event that Licensee does not maintain such insurance, but is self-insured, or carries a substantial self-retention, USC may grant permission for such self-insurance only if, in the sole discretion of USC, the net worth, assets and earnings of the Licensee are deemed sufficient to protect USC's economic interests in the event of claims, liability, demands, damages, expenses and losses from death, personal injury, illness, or property damage.
- e. The minimum amounts of insurance coverage required under this Paragraph (subparts 24.a., 24.b., and 24.c.) shall not be construed to create a limit of Licensee's liability with respect to its indemnification in Paragraph 23 or any other provision of this Agreement.
- f. By SUBLICENSEES

As a condition precedent to a grant of permission by USC for Licensee to sublicense the PATENT rights herein, the prospective SUBLICENSEE shall agree to indemnify Licensee and USC to the same extent and degree as Licensee has agreed to indemnify USC herein. Such SUBLICENSEE shall also provide insurance identical in coverage and amount to that required of Licensee in subparagraph b, above, naming both Licensee and USC as additional insured. A Certificate evidencing the comprehensive general liability policy shall be delivered to USC prior to USC's giving permission for such sublicensing agreement and a Certificate evidencing the product liability coverage shall be delivered prior to first manufacture of any PRODUCTS by the SUBLICENSEE. In the event a prospective SUBLICENSEE does not maintain such insurance, but is self-insured, or carries a substantial self-retention, USC may grant permission for such sublicense only if, in the sole discretion of USC, the net worth, assets and earnings of such prospective SUBLICENSEE are deemed sufficient to

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protect USC's economic interests in the event of claims, liability, demands, damages, expenses and losses from death, personal injury, illness, or property damage.

# 25. ATTORNEYS' FEES

In any action on or concerning this Agreement, the prevailing party shall be awarded its reasonable attorneys' fees, costs and necessary disbursements, to be paid by the nonprevailing party.

## 26. PRODUCT DEVELOPMENT

If Licensee exercises its option, Licensee shall use diligent efforts to

test and develop the PRODUCT for commercial purposes throughout the world. On or before January 1 of each year during the term of this Agreement, commencing on the EFFECTIVE DATE of this Agreement, Licensee shall submit to USC a report detailing its research, regulatory approval, marketing and product development objectives the coming year as well as the research, regulatory approval, marketing and development activities which Licensee undertook during the preceding year. The reports shall identify specific future milestones (regulatory approval and product development) and information demonstrating that the Licensee is providing sufficient financial and manpower resources to evidence its use of reasonable efforts. If USC desires to know the status of the development of PRODUCTS before January 1, USC shall make a request in writing for the status and Licensee shall provide, within fifteen (15) days, a written summary of the status of such development of PRODUCT(S). Within six (6) months after the signing of this Agreement and each two (2) years thereafter, a representative from the USC Technology Licensing Office, at Licensee's expense (including transportation, and, if appropriate, lodging and meals), shall visit the manufacturing and marketing facilities of Licensee and be presented with an in-depth updating of the manufacturing capability and marketing network of Licensee.

# 27. EXPORT CONTROLS

It is understood that USC is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (such laws include the Arms Export Control Act, as amended and the Export Administration Act), and that its obligations hereunder are contingent on compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities by the Licensee may require a license from the cognizant agency of the United States Government and/or written assurances by Licensee that Licensee shall not export data or commodities to certain foreign countries without prior approval of such agency. USC neither represents that a license shall not be required nor that, if required, it shall be issued. Licensee shall not engage in any activity in connection with this Agreement that is in violation of any applicable U.S. law.

# 28. INDEPENDENT CONTRACTOR

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In rendering performances under this Agreement, Licensee will function solely as an independent contractor and not as agent, partner, employee or joint venturer with USC. Nothing in this Agreement shall be deemed or construed to create the relationship of principal and agent, or of partnership or joint venture, and neither party shall hold itself out as an agent, legal representative, partner, subsidiary, joint venturer, servant or employee of the other. Neither party nor any officer, employee, agent or representative thereof shall, in any event, have any right, collectively or individually, to bind the other party, to make any representations or warranties, to accept service of process, to receive notice or to perform any act or thing on behalf of the other party, except as expressly authorized under this Agreement or in writing by such other party in its sole discretion.

#### 29. WAIVER

No waiver by either party of any default or breach shall be deemed as a waiver of prior or subsequent default or breach of the same or other provisions of this Agreement.

# 30. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the parties concerning the subject matter hereof. No amendment, modification, extension or cancellation of this Agreement shall be binding on the parties unless mutually agreed to and executed in writing by each of the parties.

# UNIVERSITY OF SOUTHERN CALIFORNIA BIOKEYS, INC.

/s/ DENNIS F. DOUGHERTY	/s/ NICHOLAS JON VIRCA
Dennis F. Dougherty Senior Vice President, Administration	Nicholas Jon Virca President & Chief Executive Officer
8/17/00	8/17/00
(Date)	(Date)

USC# TITLE SERIAL # DATE PATENT #
COUNTRY
2227 Preparation and
Use of
Thiophosphonates
369,468 6/21/89 5,072,032 United
States and Thio-
Analogues Of
Phosphonoformic Acid
2227A Preparation
and Use of 768,155 9/30/91 5,183,812
9/30/91 5,183,812
United States
Thiophosphonates and Thio-Analogues Of
Phosphonoformic Acid
2633 Improved
Preparations of
Thiophosphites
09/304,252 5/3/99
United States and Thiophosphonates
2633 Improved
Preparations of
Thiophosphites
5/3/00 PCT and
Thiophosphonates
2788A Preparation
and Use of Alpha- Keto 09/352,236
7/13/99 United
States
Bisphosphonates 2789
Preparation and Use
of Sulfur-Containing
60/092,560 7/13/98
United States Phosphonoformate
Analogues 2871
Synthesis and Use Of
Lipophilic
60/125,805 3/23/99
United States
Phosphonocarboxylate Derivatives
Delitvalives

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