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NY ZIP: 10112

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FORM 10KSB

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

(Mark One)

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

For the fiscal year ended DECEMBER 31, 1996

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

For the transition period from to

Commission file number 1-12584

SHEFFIELD MEDICAL TECHNOLOGIES INC.

(Name of Small Business Issuer in its Charter)

Delaware 13-3808303
----(State or Other Jurisdiction of Incorporation or Organization)

(IRS Employer Identification Number)

30 Rockefeller Plaza, New York, New York 10112
----(Address of Principal Executive Offices) (Zip Code)

Issuer's Telephone Number, Including Area Code: (212) 957-6600

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

Name of Each Exchange
Title of Each Class on Which Registered

Common Stock, \$.01 par value American Stock Exchange

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

None

Check whether the issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes /X/ No //

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. / X /

(CONTINUED NEXT PAGE)

State the issuer's revenues for its most recent fiscal year: The issuer's revenues for the fiscal year ended December 31, 1996 were \$673,664.

The aggregate market value at March 14, 1997 of shares of the issuer's Common Stock, \$.01 par value per share (based upon the closing price of \$3.1875 per share of such stock on the American Stock Exchange on such date), held by non-affiliates of the issuer was approximately \$35,033,000. Solely for the purposes of this calculation, shares held by directors and officers of the issuer have been excluded. Such exclusion should not be deemed a determination or an admission by the issuer that such individuals are, in fact, affiliates of the issuer.

Indicate the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: At March 14, 1997, there were outstanding 11,388,274 shares of the issuer's Common Stock, \$.01 par value.

PART I

Sheffield Medical Technologies, Inc. (the "Company") is a healthcare company involved in the development of therapies, delivery systems and devices. The Company is in the development stage and as such has been principally engaged in licensing and research and development of certain biomedical technologies. Under sponsored research agreements with independent companies, universities and other institutions ("Sponsored Research Agreements"), the Company funds pharmaceutical, biomedical and medical research and clinical testing in exchange for license rights to commercialize resulting products and technologies. By utilizing third party development and distribution resources, the Company believes that it can effectively avoid the substantial fixed costs traditionally associated with in-house research, development, production and distribution.

The Company does not intend to manufacture or market its products. Instead, the Company intends to finance research projects in consideration for license rights. Thereafter, the Company will attempt to enter into manufacturing and marketing agreements with one or more established biomedical or pharmaceutical companies for any products which are developed.

The Company was originally formed in 1986 as Sheffield Strategic Metals, Inc., a Canadian company, to engage in mineral exploration and development. It conducted no significant business activities from 1986 until late 1991. The Company commenced its biotechnology business in the United States in January 1992 under new management and became domesticated as a Wyoming Corporation in May 1992. The Company became a Delaware corporation in June 1995 through its merger with and into a wholly-owned Delaware subsidiary. U-Tech Medical Corporation ("U-Tech") and Ion Pharmaceuticals, Inc. ("Ion") were formed as wholly-owned subsidiaries of the Company on January 13, 1992 and January 10, 1996, respectively. Unless the context requires otherwise, references to the "Company" herein are references to Sheffield Medical Technologies Inc. and its subsidiaries, Ion and U-Tech.

The Company's headquarters are located at 30 Rockefeller Plaza, Suite 4515, New York, New York 10112, and its telephone number is (212) 957-6600.

## **BUSINESS STRATEGY**

## COMMERCIALIZATION OF MEDICAL TECHNOLOGIES

The Company acquires the rights to and develops technologies for commercialization. The Company's strategy is to convert intellectual property rights for compounds and devices into marketable products by licensing and managing effective commercialization, rather than by replicating the development laboratories and sales forces of the mainstream industry. The Company competes in three of the leading areas of potential value generation in the pharmaceutical industry today: (i) supporting high technology, (ii) bringing patient satisfying innovative drugs to market and (iii) developing medical and diagnostic devices to improve patient care. If Company-sponsored research and clinical testing are successful, the Company intends to enter into sublicense, joint venture or other collaborative agreements with one or more pharmaceutical, biomedical or medical companies to pursue later phase clinical testing and product manufacturing and marketing. By utilizing third party development and distribution resources, the Company believes that it can effectively avoid the substantial fixed costs traditionally associated with in-house research, development, production and distribution.

The Company is developing a group of diversified technologies having markedly different time horizons to potential commercialization. The Company believes that this product portfolio approach diminishes some of the risk of investing in single-product biotech, pharmaceutical or device companies. Since the Company neither invests in laboratory facilities nor in salaried research workers, it has reduced vulnerability and increased flexibility to enter into technology development programs and exit such programs through a variety of exit strategies. By investing only in direct development costs, the Company can immediately divest itself of any program with reduced financial consequences upon indications that such program is not meeting planned milestones.

## **IDENTIFICATION OF RESEARCH PROJECTS**

The Company identifies and conducts due diligence regarding new medical technologies and thereafter assists in the management of research, development, marketing, commercialization and patent prosecution of technologies and products. The Company's management has substantial experience in the areas of technology transfer, licensing, product acquisition and intellectual property protection and management. Additionally, the Company's management has established relationships with certain pharmaceutical, biomedical and medical companies and universities and medical schools.

## RESEARCH AND DEVELOPMENT

The Company conducts its research and development under Sponsored Research Agreements with universities and other research institutions. Under these agreements, the Company finances the research and development costs of a project in return for a percentage of the revenues which may result from the commercial sale of resulting products, if any. Through this arrangement the Company believes that it saves significant fixed costs associated with research and development, such as facilities and full-time personnel, which it would incur if it attempted to independently develop products. The Company manages the preparation and submission of IND's (Investigational New Drug Applications) and NDA's (New Drug Applications) and protocols to the U.S. Food and Drug Administration (the "FDA"), monitors the approval process of such notification and applications and conducts the initial assessment of commercial markets for developed products.

## **TECHNOLOGY TRANSFER**

The Company believes that its management strength is in bridging the gap between research and commercial markets for developed products. Therefore, management's principal focus is on technology transfer and licensing. The Company endeavors to identify viable research projects and to negotiate financing at the appropriate stage of such projects. In addition, the Company will analyze and attempt to identify the appropriate stage to sell or sublicense the technology related to such projects in order to maximize the economic return to the Company. The Company does not intend to establish an in-house research staff or to construct or operate manufacturing or distribution facilities. Instead, the Company's strategy is to finance existing research projects in return for a license agreement, sublicense agreement, royalty or other arrangement whereby it acquires proprietary rights to the technologies and products developed in such projects. At an appropriate stage, the Company anticipates that it will sell, sublicense or enter into a joint venture or other

collaborative agreement with a pharmaceutical or other biomedical company for the manufacture and marketing of the Company's products.

## ALLOCATION OF RESOURCES

The Company has utilized and will continue to utilize the proceeds from the sales of its securities and, ultimately, will use its operating revenues, to finance research and development of specific projects. If its research is successful, the Company may continue to finance the project through subsequent stages or, depending on market, financial and other considerations, it may attempt to enter into a collaborative agreement with a third party. In the case of unsuccessful research projects or where commercialization is impossible or impractical, the Company may terminate such projects and reallocate its resources to new projects. Revenues from commercialized projects will be used to finance additional projects, and the Company may attempt to raise additional debt or equity to finance existing or new projects.

## RELATIONSHIP WITH RESEARCH INSTITUTIONS

The Company's success depends, in part, on its ability to develop and maintain relationships with leading research institutions. In addition, the Company relies on principal investigators who are members of the faculties or staff of research institutions. Such individuals generally are subject to policies established by their institutions regarding commercial activities. The Company is not aware of any conflicts between the activities of researchers it sponsors and the present policies of the respective universities with which they are associated.

-2-

## PROJECTS UNDER DEVELOPMENT

## **RBC-CD4 ELECTROINSERTION TECHNOLOGY**

BACKGROUND. The Company is the worldwide licensee of certain technology (the "RBC-CD4 Electroinsertion Technology") relating to the electroinsertion of full-length CD4 protein into red blood cells ("RBC-CD4") for use as a potential therapeutic in the treatment of human immunodeficiency virus ("HIV") that leads to Acquired Immune Deficiency Syndrome ("AIDS"). The electroinsertion process inserts CD4, the protein that serves as the binding site of the HIV virus, into a red blood cell. This altered cell complex acts as a decoy and is designed to cleanse the blood of infection by binding to and removing the HIV virus from circulation before it can infect other cells in the human immune system.

TECHNOLOGY. A number of AIDS research projects have studied CD4, which is a glycoprotein found on the surface of T4 lymphocytes. T4 lymphocytes are helper cells that mediate antigen presentation of the immune system. CD4 attaches to a glycoprotein on the surface of HIV known as gp120. HIV binds the CD4 glycoprotein, which enables it to enter the T4 cells, where it can replicate. By this process, HIV attacks T4 cells and, as a result, debilitates the immune system by rendering the immune system incapable of neutralizing HIV. Eventually, the number of T4 cells decrease and the level of HIV in the blood increases. This typically leads to the development of AIDS which is characterized by the ultimate collapse of the immune system. Once the immune system is destroyed, other germs and viruses that ordinarily would be

successfully neutralized by the immune system lead to opportunistic diseases. These opportunistic diseases are ultimately the cause of death in AIDS patients.

A number of approaches have been used in the search for a treatment for AIDS. Scientific efforts have focused principally on the use of compounds or vaccines with the ability to stop the multiplication or replication of HIV. The four principal compounds that have been approved by the FDA to date are AZT, ddl, ddC and d4T.

The use of CD4 as a potential treatment for AIDS is not new. Previous research by many others focused on the soluble form of CD4. This technique has proved ineffective because: (i) the half-life of soluble CD4 or hybrid molecules such as CD4-lgG is short in blood circulation; (ii) the binding of soluble CD4 to HIV appears to tear some of the viral envelope glycoprotein without reducing infectivity; and (iii) the amounts of soluble CD4 needed to establish therapeutic concentrations are very large.

The Company's RBC-CD4 Electroinsertion Technology differs from the traditional focus on compounds and vaccines that inhibit the replication of HIV. RBC-CD4 Electroinsertion Technology has its basis in studies that indicate that HIV will bind to red blood cells ("RBC") containing CD4 in its membrane and that once so internalized into the RBC, may disintegrate. In simplest terms, the technology focuses on incorporating the full-length CD4 into the RBC membrane. The technology is intended to slow the spread of HIV in the body of an infected patient and diminish or eliminate the possibility of HIV infection being spread to others by contact with the infected person, and to help eliminate cells that produce HIV from circulation. Because the technology may slow or eliminate the advancement of HIV infection to AIDS, it is a potential therapeutic, but may not be a cure.

The Company's RBC-CD4 Electroinsertion Technology was originated in 1987 by Dr. Y. Claude Nicolau and other scientists then associated with The Texas A&M University System ("TAMUS"). Dr. Nicolau is the principal investigator for the RBC-CD4 Electroinsertion Technology research sponsored by the Company. RBC-CD4 Electroinsertion Technology exposes RBC to a pulsed electric field that allows the incorporation of certain proteins into the cell membrane. Many types of proteins can be used as therapeutics. Proteins which contain a sequence called a "hydrophobic membrane spanning sequence" can be attached to RBC by the electroinsertion technique. The hydrophobic membrane spanning sequence is a portion of the protein that is not water soluble. This is critical in order for the protein to immerse itself into the membrane during the electroinsertion procedure. The electroinsertion process causes a temporary disordering of the cell membrane lipid bilayer. When this disordering of the membrane occurs in the presence of a protein with a hydrophobic sequence, the hydrophobic portion of the protein immerses itself into the membrane at the point of disordering, resulting in a cell with the protein inserted in the membrane. One such protein that contains a hydrophobic sequence is "full-length" CD4. Significantly, full-length CD4 consists of the hydrophobic portion and a soluble extracellular domain and a cytoplasmic domain. When the hydrophobic sequence is deleted, CD4 is secreted as a soluble protein which, as described below, is the protein that has been unsuccessful in research for the development of HIV/AIDS therapeutics. The Company's licensed technology is for insertion of the potentially more effective "full-length" CD4 into red blood cells for use as a therapeutic for the treatment of HIV/AIDS. In the research funded by the Company, Dr. Nicolau has successfully electroinserted full-length CD4 into rabbit, mouse, pig and human red blood cell membranes to determine the affinity and binding

strength of the RBC-CD4 with the HIV virus. These tests have shown that RBC-CD4 may overcome the problems associated with soluble CD4, including: (i) RBC-CD4 has shown no immune response in animals or humans; (ii) RBC-CD4 remains in the body for almost the normal half life span of a RBC, which is 60 days; and (iii) RBC-CD4 has shown a significantly improved binding affinity and indicates the capacity to inhibit HIV infection of susceptible cells.

Because infection also occurs in the lymph nodes, the Company is developing a companion technology, Liposome-CD4, to address the elimination of HIV in the lymphatic system. In addition, the Company is developing an AIDS Vaccine for preventing HIV infection.

PROGRESS OF RESEARCH AND DEVELOPMENT. The IND and test protocols were submitted in 1991 and were approved by the FDA in 1992. Phase I Clinical Trials with HIV-infected patients began in February 1992 on four patients. Researchers affiliated with TAMUS, the Center for Blood Research Laboratories, Inc. ("CBRL"), a wholly owned subsidiary of The Center for Blood Research, Inc. (an affiliate of Harvard Medical School), and Baylor College of Medicine, in conjunction with the Veterans Affairs Medical Center, completed these Phase I Clinical Trials in Houston, Texas, in April 1992. The 60-day trial included meeting three criteria: (i) adequate residence time in the blood stream by RBC-CD4 (the red blood cells into which the CD4 protein has been inserted that act as the binding site for HIV) to permit the HIV virus to bind with the cells and potentially be eliminated from the circulation; (ii) no reduction in the normal functioning of the red blood cell; and (iii) no adverse immune response or toxicity.

The completion of Phase I Clinical Trials essentially confirmed that there are no significant adverse human responses to the process at sub-therapeutic doses. Results indicated that (i) the red blood cell's normal functioning is not altered by the electroinsertion procedure; (ii) the life span of the RBC-CD4 is equal to the life span of normal red blood cells; (iii) the majority of the electroinserted CD4 remains on the red blood cell surface for the entire life span and little shedding of CD4 occurs, if any; and (iv) no side effects or immune responses were observed. The companion studies demonstrated that RBC-CD4 reproducibly inhibits the transmission of primary "wild type" HIV strains cultured from HIV-infected patients, or cell-to-cell transmission of the virus, up to nearly 100 percent. IN VITRO studies also have shown that the RBC-CD4 loaded with HIV virus does not infect macrophages during phagocytosis, the process of normally removing foreign particles and red cells at the end of their life span (approximately 120 days). Phase I Clinical Trials did not confirm anti-viral activity in humans, which is the purpose of additional trials.

The IND for Phase I/IIA Clinical Trials was submitted by the Company to the FDA on August 18, 1994 for approval to conduct Phase I/II human clinical studies at Johns Hopkins to test the product's safety and anti-viral activity at various doses, and the Company received approval from the FDA to commence the trial on July 17, 1995. The Phase I/IIA Clinical Trial consists of a safety study with two patients at the lowest dose of RBC-CD4 and a safety and activity study with two parts: (1) five patients being dosed with a middle dose of RBC-CD4, one of which receives placebo; and (2) 12 patients being dosed at the highest dose of RBC-CD4, two of which receive placebo. The first patient under

the Phase I/IIA Clinical Trials was dosed on August 8, 1995, the first patient to be dosed with the middle dose of RBC-CD4 was dosed on November 16, 1995, and the first patient to be dosed at the highest dose of RBC-CD4 was dosed on January 29, 1996.

RECENT DEVELOPMENTS The last patient in the trial completed the last time point for clinical and laboratory assessment in late October 1996. All data analyses and review has been completed and the medical and statistical report is expected to be completed during the second quarter of 1997.

## LIPOSOME-CD4 TECHNOLOGY

BACKGROUND. The Company is the worldwide licensee of certain technology (the "Liposome-CD4 Technology") relating to the incorporation of CD4 antigens into liposome bilayers and their use as a potential therapeutic agent in the treatment of HIV/AIDS. While RBC-CD4 Electroinsertion Technology is being developed by the Company to target HIV and HIV-infected cells in the blood, Liposome-CD4 Technology is being developed by the Company to target infections in the human lymphatic system, a major reservoir for infection not directly reached by blood circulation.

TECHNOLOGY. CD4 is a glycoprotein found on the surface of T4 lymphocytes, which are helper cells that mediate antigen presentation of the immune system. CD4 also acts as the receptor for a glycoprotein on the surface of the HIV virus known as gp120. HIV binds to the CD4 glycoprotein which enables

-4-

the virus to enter the T4 cells where it can replicate. By this process, HIV attacks T4 cells and debilitates the immune system, which typically leads to the development of AIDS. Once the immune system is destroyed, other germs and viruses that would ordinarily be successfully neutralized by the immune system lead to opportunistic diseases, which ultimately cause death to AIDS patients.

Lipids consist of two layers (bilayers) of fatty acids surrounded by water; such bilayers are fluid and very flexible. Liposomes can be formed by agitating phospholipids in water suspensions at high frequencies to form a closed vesicle surrounded by a continuous lipid bilayer. Liposomes have properties that are very similar to those of natural membranes and have been studied for carrying, in their interior, specific drugs for the purpose of increasing their potency and safety. Liposomes are eventually broken down and metabolized by the body, or fuse with their target, at which time the content of the liposome is released. The Company is researching the use of liposomes in treating HIV/AIDS because the virus is not only found in the circulatory system, but the lymphatic system as well, which is an area that liposomes can reach. It is believed that the lymph nodes, which are a reservoir of HIV infection, could be targeted for removal of HIV and HIV-infected cells. Liposomes inserted with CD4 ("Liposome-CD4") would be used in conjunction with the Company's RBC-CD4 Electroinsertion Technology which targets the circulatory system, thereby providing a treatment package for both the blood stream and the lymph nodes.

The strategy of Liposome-CD4 is to incorporate CD4 in the bilayer of the liposomes, providing a specific target (I.E., HIV and HIV-infected cells) for liposome fusion. The Liposome-CD4 may also be loaded with cytotoxic agents, or agents that will kill the target cell. When the free-floating HIV comes in contact with Liposome-CD4, the virus fuses with Liposome-CD4 and is inactivated.

The remains of the killed infected T4 cell and inactivated virus fused with Liposome-CD4 would then be removed by macrophages (white blood cells). The therapeutic aim, as with RBC-CD4, is to reduce HIV infectivity and slow or eliminate the advancement of HIV infection to AIDS.

PROGRESS OF RESEARCH AND DEVELOPMENT. The first milestone of the Liposome-CD4 research, which included IN VITRO studies of Liposome-CD4 interaction with HIV from patient (and simian immunodeficiency virus ("SIV") from M. Rhesus monkeys) isolate studies with Liposome-CD4 encapsulating a cytotoxic agent, was completed in August 1994 with the IN VITRO studies demonstrating promising anti-viral activity. In vitro HIV inactivation results have shown favorable viral inhibition against HIV patient isolates and a new SHIV (hybrid virus of SIV containing the HIV envelope) isolate.

RECENT DEVELOPMENTS. On July 17, 1996, the Company entered into a Sublicense Agreement with SEQUUS Pharmaceuticals, Inc. ("SEQUUS") for the continued development and commercialization of the Liposome-CD4 Technology. Under development by SEQUUS, a clinical formulation prototype has been chosen, a scaleable process to formulate Liposome-CD4 has been developed, CD4 from various constructs are being produced, and additional feasibility studies are currently underway.

RBC-CD4 ELECTROINSERTION AND LIPOSOME CD4 TECHNOLOGIES-COMMERCIALIZATION AND POTENTIAL MARKETS.

The World Health Organization estimated in 1996 that there were approximately 26.6 million persons worldwide infected with HIV. The Pan American Health Organization (the "PAHO") estimates that as of November 1996, the total cases of AIDS reported worldwide is 1,544,067, the total estimated number of AIDS cases (reported and not reported) worldwide is 8.4 million and the estimated number of cases of HIV infection worldwide is 20.6 million.

RBC-CD4 could be administered to HIV and AIDS patients either as a typical pharmaceutical through blood transfusion injections or through autologous transfusions at licensed treatment centers. In the first method, recombinant full-length CD4 would be produced on a large scale and electroinserted in a universal donor blood from public blood supplies. RBC-CD4 could then be sold much like blood for transfusions for treatment in a clinical setting with periodic infusions as required based on the level of viral burden. In the second method, the distributor could decentralize the production and infusion through local treatment centers. The centers would most likely be set up through a large medical outpatient or hospital management firm.

Liposome-CD4 could be administered to HIV and AIDS patients for treatment in a clinical setting with periodic treatments as required based on the level of viral burden. An alternative would be to administer Liposome-CD4 through local treatment centers, perhaps at the same center that RBC-CD4 would be administered. The centers would most likely be set up through a large medical outpatient or hospital management firm.

-5-

#### HIV/AIDS VACCINE

BACKGROUND. The Company holds an exclusive worldwide license to a potential HIV/AIDS vaccine (the "HIV/AIDS Vaccine") and diagnostic under

development at the French Institute of Health and Medicine ("INSERM"). This research project is headed by Professor Jean-Claude Chermann, one of the original Pasteur Institute discoverers of the HIV virus. The vaccine concept developed by Professor Chermann utilizes a portion of (beta)2 microglobulin (the epitope), a cellular antigen, that is presented on the HIV viral coating after the HIV virus has reproduced in a human cell. This cellular antigen does not appear to vary across the various strains of the virus and may provide a stable target to develop antibodies that can prevent infection. The Company believes this approach may also protect against both blood-born and sexual transmission of HIV. The Company's goal is to develop an oral formulation that would make the vaccine potentially less costly and easier to distribute to a broad population.

TECHNOLOGY. When the HIV virus infects a cell, it replicates and then it buds from the infected cell's surface. A protein which is present on the cell's surface then becomes incorporated in HIV's viral envelope as it leaves the infected cell. The classical path of vaccine development to date has been one of raising antibodies against a viral protein in an attempt to neutralize the pathogen. All these attempts have been largely unsuccessful. The HIV/AIDS Vaccine encompasses a new and different approach directed toward immunization against HIV/AIDS. The HIV/AIDS Vaccine is designed to be different than previous attempts for two basic reasons: (i) it would use a cellular versus a viral antigenic approach and is therefore, common to all strains of HIV, and (ii) it would utilize a delivery system that would offer both humoral (blood transmission) and mucosal (sexual transmission) protection, as opposed to other vaccines now being investigated as therapeutics for preventing cell to cell transmission of the virus.

PROGRESS OF RESEARCH AND DEVELOPMENT. Research has been directed toward HIV/AIDS prevention following isolation of the virus in 1983. Research began in 1988 in this area and in the use of a cellular antigenic approach directed toward conquering the disease. Preclinical research has demonstrated neutralization of HIV IN VITRO. The peptide sequence that encodes this portion of a cellular protein has been identified and sequenced and will be incorporated in a vaccine to test for production of antibodies against the epitope. The Company plans to produce a vaccine for humans that will elicit mucosal as well as humoral immunity and that can be delivered orally. Upon the successful completion of pre-clinical animal studies, the Company plans to submit an IND for conducting Human Clinical Trials. The Company entered into an agreement with an unaffiliated third party in December of 1995 to develop a commercial diagnostic assay for detection of the antibody. This assay would be used in animal and human clinical studies for the vaccine and could be sold for research purposes prior to receiving approval from the FDA. Upon approval from the FDA, the assay could be sold to physicians and clinical laboratories. In April 1996, researchers published data on the isolation and characterization of the novel binding site of the cellular protein and reported that antibodies to this binding site inhibited replication of several strains of HIV in VITRO studies.

RECENT DEVELOPMENTS. The Company is in the final stage of development of a commercial diagnostic assay for the detection of the antibody and is expected to commence large-scale testing in the near future.

COMMERCIALIZATION AND POTENTIAL MARKET. The Company anticipates that the vaccine would first be used to vaccinate healthy individuals for preventing HIV infection. The Company also anticipates that, long-term, the vaccine might be used as a therapeutic vaccine for treating the HIV infected and AIDS patients by preventing HIV strains that replicate in the body, or additional HIV strains,

from additionally infecting cells. A commercial market may also exist for a diagnostic assay for detecting the monoclonal antibody in blood for purposes of following progressors and non-progressors who are HIV infected, as well as determining the activity and usefulness of the vaccine.

PRINCIPAL INVESTIGATOR. Professor lean-Claude Chermann is the inventor of the HIV/AIDS Vaccine technology and the principal investigator for the research sponsored by the Company. Professor Chermann is Research Director of INSERM's Research Unit 322 for Retroviruses and Associated Diseases in Marseilles, France. Professor Chermann was previously Chief of Research at the Pasteur Institute in Paris where he spent 25 years in research. Professor Chermann, in conjunction with two other scientists, first isolated the HIV virus in 1983 at the Pasteur Institute in Paris. In 1987 he was awarded the Louis Pasteur Medal. A retrovirologist before embarking on AIDS research, Professor Chermann originally suspected that AIDS was caused by a retrovirus. Since discovering the HIV virus, Professor Chermann has devoted his research to discovering a preventive to the disease, along with a therapeutic to help restore the immune system in HIV-infected patients. Professor Chermann is published widely with over 200 publications in international journals, including publications specific to the research sponsored by the Company. Professor Chermann is a member of the Company's Scientific Advisory Board.

-6-

## **UGIF TECHNOLOGY - PROSTATE CANCER**

BACKGROUND. The Company holds an exclusive worldwide license to a growth regulatory factor, termed Urogenital Sinus Derived Growth Inhibitory Factor ("UGIF/ps20"), which could serve as a potential prostate cancer therapy (the "UGIF Technology").

TECHNOLOGY. Based on studies at Baylor College of Medicine directed at understanding how one particular tissue type influences the growth of an adjacent tissue in the development of the prostate gland, UGIF/ps20 was identified. Specifically, UGIF/ps20 has been isolated and purified from rat fetal urogenital sinus tissue which differentiates into the mature prostate gland as a result of tissue-tissue interactions. Since UGIF/ps20 was demonstrated to be active in human cells, it was believed that UGIF/ps20 isolated from the rat would be essentially identical to human UGIF/ps20. Commercial application and economic feasibility of UGIF/ps20 is not dependent upon the availability of either rat or human fetal urogenital sinus tissue, but rather the successful cloning, expression and testing of recombinant UGIF/ps20.

The discovery of UGIF/ps20 indicates that urogenital sinus tissue, and more specifically UGIF/ps20, may possibly be effective in altering the phenotype (state of cell differentiation) of cells that affect the secretion of newly synthesized proteins. UGIF/ps20 has shown inhibition of the growth of transformed cells and tumors in culture including human prostate cancer cells with non-toxic and reversible effects. In addition to the treatment of cancer, there exists a potential use of UGIF/ps20 or its analogues in the treatment of other diseases or conditions dealing with abnormalities of the genitourinary system.

PROGRESS OF RESEARCH AND DEVELOPMENT. A method for successfully purifying UGIF/ps20 was identified in April 1992 by Dr. David R. Rowley and biological activity of the factor was demonstrated in mice in May 1992. Research

to date has shown that UGIF/ps20 inhibits the growth of transformed cells and tumors in culture including human prostate cancer cells with non-toxic and reversible effects. In addition, in preliminary animal studies, UGIF/ps20 has shown an ability to inhibit DNA synthesis and cell proliferation of human prostatic carcinoma cells. Results confirmed that there is a human form of UGIF/ps20 and that it is a growth factor associated with the prostate gland. The rat and human genes for UGIF/ps20 were sequenced in late 1995. The rat gene for UGIF/ps20 has been incorporated into an expression system and recombinant rat UGIF/ps20 is currently being produced. The human gene for UGIF/ps20 has been incorporated into an expression system and recombinant human UGIF/ps20 is currently being produced.

RECENT DEVELOPMENTS Recombinant UGIF/ps20 is currently being tested for verification of its activity in IN VITRO and IN VIVO studies. Studies to determine the protein's mechanism of action are also currently underway. Additional animal studies will be conducted during 1997 to determine the modes of delivery and biological effects of recombinant UGIF/ps20 on prostate cancer in "nude" mice. In the event that recombinant UGIF/ps20 is verified in these studies, additional preclinical studies with a delivery system, and toxicity tests, will be conducted prior to commencement of human clinical trials.

COMMERCIALIZATION AND POTENTIAL MARKET. The American Cancer Society estimates that approximately 317,000 new cases of prostate cancer occurred in the U.S. in 1996 and that approximately 41,400 deaths occurred in the U.S. in 1996 from prostate cancer. As a result of the population aging, prostate cancer is expected to increase significantly over the next 15 years. Risk factors for prostate cancer increase with age. More than 80% of all prostate cancers are diagnosed in men over the age of 65. In addition to age, other factors regarding the incidence of prostate cancer occurrence include a higher incidence rate among black Americans, familial association and dietary fat intake.

PRINCIPAL INVESTIGATOR. Dr. David R. Rowley is the principal investigator for the UGIF Technology project. Dr. Rowley is Associate Professor in the Department of Cell Biology at Baylor College of Medicine. Dr. Rowley has studied growth inhibitory factors, mechanism of action in tissue differentiation and neoplastic disease, and the mechanisms of steroid hormone action in relation to the prostate gland for over 13 years. Dr. Rowley received a Bachelors and a Doctorate of Philosophy degree in Anatomy from the University of Iowa and served as a National Institutes of Health Postdoctoral Fellow at Baylor College of Medicine. He has lectured and published numerous articles on growth inhibitory factors, cell differentiation and receptors in the prostate gland.

-7-

## MEMBRANE ATTACK COMPLEX (MAC)/COMPLEMENT TECHNOLOGY

BACKGROUND. The Company holds exclusive worldwide license rights to a certain membrane attack complex ("MAC") complement technology (the "MAC/Complement Technology"). Through the Company's funding of Dr. Jose Halperin's laboratory, scientists in Dr. Halperin's lab made certain discoveries with regard to complement cascade, which consists of a number of proteins and regulatory polypeptides, and discovered that the MAC pore opens a pathway for the entry of high molecular weight organic compounds into cells.

TECHNOLOGY. The MAC/Complement Technology consists of five complement proteins, C5-C9, which assemble in a lipid bilayer, such as a cell membrane or a

virus membrane, to form a pore or a channel of sufficient size to allow many molecules and growth factors to pass into the cell. If enough channels are formed in the cell membrane, the cell becomes disabled and is typically lysed or broken down and eliminated. The size of the pore depends in part on the number of one of the complement proteins, C9, that form the pore. The number of C9 protein molecules that form the pore is limited or regulated by a complement regulatory protein called CD59. Dr. Halperin's lab has demonstrated that the formation of MAC pores by the addition of purified complement proteins creates a pathway for the entry of molecules of various sizes into various cell types and that the MAC pore can be used to load target cells with drugs or other molecules without affecting the viability of the cell. In addition, concentrations of the complement proteins needed to efficiently load molecules into the cell via the MAC pore have been demonstrated to be at levels that are not toxic to the cell, i.e. at concentrations that would not cause lysis of the cell. Therefore, by exposing a target cell to MAC channel-forming agents and a therapeutic or diagnostic agent, the desired agents could be selectively delivered into the target cell or cells. Therapeutic agents such as polypeptides, oligonucleotides, toxins, antibiotics, antivirals, antiparasitics, antifungals and anti-cancer agents could be delivered into target cells that otherwise are not taken up by the cells or are inefficiently taken up by cells. This technology, if successful, could provide for the selective delivery of such therapeutics or diagnostic agents to target cells, for example, cancer cells or viruses, without affecting the surrounding cells that are not meant to be targeted.

As mentioned above, if enough MAC pores are formed in a cell membrane, the cell becomes disabled. Experimental evidence indicates that this mechanism may be involved in ridding the body of viruses, bacteria and parasites. Viruses, bacteria or parasites may become resistant to cell lysing by producing CD59 on its surface to inhibit the formation of MAC pores. Since CD59 regulates the number of C9 molecules that form MAC pores, such activity would result in an insufficient amount of MAC pores being formed to create lysis of the cell. Consequently, it may be possible to treat such viruses, bacteria and parasites by inhibiting the formation of CD59.

PROGRESS OF RESEARCH AND DEVELOPMENT. The MAC/Complement Technology was added to the Company's technology portfolio in late 1996, therefore, research on this project is in early stages. To date, the functional size of the MAC pore has been determined using purified complement proteins. Dr. Halperin's lab will be optimizing the MAC pore size and attempting to load in different cell types different functional molecules for therapeutic and/or diagnostic purposes.

The active site of CD59 is currently being identified. The role of CD59 in protecting viruses form complement lysis will then need to be confirmed and the possible protective effect of human CD59 against complement mediated lysis of virus needs to be analyzed. Once these experiments are completed, the Company will evaluate the possibility of designing molecules to block the effect of CD59.

## COMMERCIALIZATION AND POTENTIAL MARKET.

The potential market for the MAC/Complement Technology, if successful, is substantial and includes therapies for bacterial diseases, viral diseases, hormone deficiency diseases, cancer, artherosclerosis, arteriosclerosis, diabetes, organ transplants, arthritis and other immune disorders. For example, the American Diabetics Association estimates that approximately 14 million people in the U.S. have diabetes and more than 650,000 people are diagnosed each

year as having diabetes. According to the American Heart Association, the estimated prevalence of artherosclerosis in 1992 was 2.28 million.

PRINCIPAL INVESTIGATORS. Dr. Jose A. Halperin, Associate Professor of the Department of Medicine at Harvard Medical School, is the principal investigator for the MAC/Complement Technology research sponsored by the Company. Dr. Halperin's major research interests have been in membrane transport, red cell physiology and regulation of ion pumps as they relate to the mitogenic effect of membrane in proliferative disorders. Dr. Halperin was educated in Buenos Aires, Argentina, receiving his medical degree (CUM LAUDE) in 1972 from the University of Buenos Aires. In 1983 Dr. Halperin received the Annual Prize for the best work in Medical Research from

-8-

Venezuela's National Council for Scientific and Technological Research (CONICIT). Dr. Halperin's postdoctoral training includes internships and residencies in Buenos Aires and a clinical fellowship at Brigham and Women's Hospital in Boston. He joined Harvard Medical School's Department of Physiology in 1984. In 1988 he was named Instructor in Medicine and in 1994 Associate Professor of Medicine. In 1985 he became associated with Brigham and Women's Hospital in several capacities and presently serves as Associate Physician for the hospital.

## ION PHARMACEUTICALS, INC. TECHNOLOGIES

BACKGROUND. The Company, through its wholly-owned subsidiary, Ion, holds exclusive worldwide license rights to certain compounds and their uses for the treatment of conditions characterized by unregulated cell proliferation or cell growth and sickle cell anemia and holds an exclusive option to license certain compounds and their uses for the treatment of gastrointestinal disorders, such as secretory diarrhea. Ion's intellectual property portfolio consists of clotrimazole ("CLT"), its metabolites and a number of proprietary new chemical entities co-owned by Ion termed the Trifens(TM). Such compounds have demonstrated promise in therapeutic applications for treating a number of conditions characterized by unregulated cell proliferation, such as cancer (including multiple drug resistance cases) and certain proliferative dermatological conditions, as well as sickle cell anemia and secretory diarrhea. Ion has an ongoing collaborative program with an unaffiliated company to develop the Trifens(TM). Ion acquired the Company's rights in the anti-proliferative technologies at the time of Ion's organization as a wholly-owned subsidiary of the Company in January 1996.

TECHNOLOGY. CLT, its metabolites, and the Trifens(TM) are active through ion transport modulation and may be applicable for treating, either by topical, oral, or intravenous administration, a number of diseases and conditions. CLT is a broad spectrum antimycotic agent used to treat pathogenic dermatophytes, yeast infections and topical fungal infections. Through research conducted by Dr. Jose Halperin at Harvard Medical School, new potential uses for these compounds have been identified based on inhibition of cell proliferation or the regulation of the growth of cancer cells and other cell types, including the use of such compounds in treating cancer, proliferative dermatological conditions, cardiovascular disorders, such as arteriosclerotic conditions, and diseases caused by neovascularization, such as diabetic retinopathy. In addition to the compounds ability to inhibit cell proliferation, the compounds have also been shown to inhibit the Ca++-activated K+ channel in the human red blood cell

membrane. Dr. Carlo Brugnara at Children's Hospital in Boston has studied and is continuing to study the effects of such compounds in blocking this channel to prevent the dehydration of sickled red blood cells. Such an approach could potentially be used in the treatment of sickle cell anemia. In addition, under a sponsored research and license option agreement between Ion and Children's Hospital in Boston, Dr. Wayne Lencer is studying the effects of the compounds in inhibiting intestinal chloride secretion, which is the primary transport event of secretory diarrhea in both humans and animals.

It is anticipated that CLT, its metabolites and/or the Trifens(TM) would be formulated in three new formulations: an oral formulation, an intravenous or injectable formulation and a topical formulation. The new oral and/or intravenous formulation could be used in the study and potential treatment of cancers including multiple drug resistant cancers, sickle cell anemia, diarrhea and atherosclerotic conditions, including restenosis after balloon angioplasty. The new topical formulation will be used by Ion in the study and potential treatment of proliferative dermatological conditions, such as actinic keratosis, certain cancers, such as basal cell carcinoma and Kaposi's sarcoma and, possibly, other dermatological conditions.

PROGRESS OF RESEARCH AND DEVELOPMENT. An initial human efficacy study with a preliminary topical formulation of one of the parent compounds at a low concentration in comparison with a placebo was conducted by the Company in Kaposi's sarcoma patients which led to inconclusive results. Results showed that the topical formulation was not optimized. Ion entered into an agreement with an unaffiliated company to develop an optimal topical formulation at a higher concentration of drug for use in additional clinical trials for actinic keratosis and Kaposi's sarcoma.

Dr. Halperin has demonstrated that IN VITRO proliferation of numerous human cancer cell lines were strongly inhibited by one of the parent compounds in a dose-dependent manner. Dr. Halperin's group has also studied the effects of one of the parent compounds in experimental models for lung metastasis and squamous cell carcinoma, both resulting in favorable results.

For the sickle cell application, IN VITRO studies performed by Dr. Brugnara have demonstrated that one of the parent compounds blocked ion transport in homozygous sickle cells, and studies in a transgenic mouse model for sickle cells have demonstrated that the compound given orally produced inhibition of the red cell Gardos channel,

-9-

increased red cell potassium content and decreased mean corpuscular hemoglobin concentration. A pilot Phase I clinical trial has been completed in which four normal subjects were given the compound orally and the peak inhibition of the Gardos channel was measured. Results from the first stage of a Phase II Clinical Trial supported by the National Institutes of Health and the FDA were reported in March 1996 in which five sickle cell anemia patients were given one of the parent compounds orally. The administration of the compound resulted in a reduction of the dehydration and sickling of red blood cells associated with sickle cell anemia. The next phase of the ongoing Phase II clinical trial will assess the survival of red blood cells and hemoglobin levels over a longer-term period. Ion plans to initiate additional laboratory and clinical studies to assess the use of the Trifens(TM) in the treatment of sickle cell anemia.

A topical formulation of one of the parent compounds has been developed for Ion pursuant to an agreement with an unaffiliated company. Clinical trial material has been manufactured under Good Manufacturing Practices ("GMP") conditions for use in Ion's Phase I/II Clinical Trial for the treatment of actinic keratosis. The Phase I/II Clinical Trial was initiated in July 1996 at two clinical sites in Israel.

RECENT DEVELOPMENTS. The actinic keratosis Phase I/II Clinical Trial is currently ongoing and enrollment was completed in December of 1996. Upon successful results of this study, Ion plans to either file an IND application with the FDA for conducting a clinical trial in the U.S. for the treatment of actinic keratosis or sublicense the technology for further development and commercialization.

Additional IN VITRO and animal tumor model studies are underway, some of which are being conducted under contract with an unaffiliated third party, to test the effects of the Trifens(TM) in the treatment of certain cancers, alone and in combination with currently used anti-cancer drugs.

The Company is currently participating in discussions with certain third parties regarding the possibility of partnering or licensing this technology.

COMMERCIALIZATION AND MARKET POTENTIAL. The American Academy of Dermatology reports that approximately 5 million Americans have actinic keratosis. The American Cancer Society estimates that there were 1,359,150 new cases of cancer in the U.S. in 1996 and 554,740 deaths due to cancer in the U.S. in 1996. Reuters (09-12-96) reported that drug resistant tumors account for 40% of all cancer cases and 90% of drug treated cancer patients who have undergone chemotherapy. The U.S. Department of Health and Human Services estimates that there are over 50,000 sickle cell anemia patients in the U.S. and according to NDTI, the national audit source, 246,000 physician visits for sickle cell anemia were recorded in 1995. In addition to the market for traveller's diarrhea, a substantial market exists for treatment of infectious diarrhea and AIDS-related diarrhea. The National Institute of Diabetes and Digestive and Kidney Diseases reports that in 1980, there were 99 million new cases of infectious diarrhea in the U.S. and, in 1985, there were 8-12 million physician office visits for infectious diarrhea. AIDS-related diarrhea occurs in the majority of AIDS patients and may be caused by drugs, viruses or bacteria.

PRINCIPAL INVESTIGATORS. Dr. Jose A. Halperin, Associate Professor of the Department of Medicine at Harvard Medical School, is the principal investigator for the anti-proliferative/growth regulatory research sponsored by the Company.

Dr. Carlo Brugnara, Associate Professor of Pathology at Harvard Medical School and Director of the Hematology Laboratory at Children's Hospital in Boston, is the principal investigator for research related to the sickle cell anemia application sponsored by the Company. Dr. Brugnara's major research interests have been in the determinants of cell sickling in sickle cell anemia, membrane transport in red blood cells, and clinical and laboratory hematology. Dr. Brugnara was educated in Italy, receiving his medical degree (MAGNA CUM LAUDE IN MEDICINE AND SURGERY) in 1979 from the University of Padue in Verona, Italy. Dr. Brugnara's postdoctoral training includes internships and residencies in Italy and with Brigham and Women's Hospital in Boston. He joined Harvard's Department of Physiology in 1983 and was named Associate Professor in 1993.

Dr. Wayne I. Lencer, Assistant Professor of Pediatrics at Harvard Medical School and Assistant Pediatrician at Massachusetts General Hospital and Children's Hospital in Boston, is the principal investigator for the intestinal diseases research sponsored by the Company. Dr. Lencer's major research interests have been in the mechanism of vesicular traffic in the intestinal epithelia, the mechanism and regulation of salt, water and macromolecular transport in the intestine, and host and pathogen interactions in the intestine. Dr. Lencer received a Bachelors degree from the University of Michigan and a medical degree from Boston University School of Medicine. Dr. Lencer received the Miles and Shirley Fitterman/American Digestive Health Foundation Basic Research Award in 1996.

-10-

#### **MARKETING**

The Company does not intend to manufacture or market any products. Instead, the Company intends to enter into joint venture or other collaborative arrangements with pharmaceutical companies or biomedical companies for the manufacture and distribution of such products. There can be no assurance that the Company will be able to enter into such agreements on terms acceptable to it.

#### **GOVERNMENT REGULATION**

The Company's research and development activities and, ultimately, the production and marketing of its licensed products, are subject to comprehensive regulation by numerous governmental authorities in the United States and other countries. Among the applicable regulations in the United States, pharmaceutical products are subject to the Federal Food, Drug & Cosmetic Act, the Public Health Services Act, other federal statutes and regulations, and certain state and local regulations. These regulations and statutes govern the development, testing, formulation, manufacture, labeling, storage, record keeping, quality control, advertising, promotion, sale, distribution and approval of such pharmaceutical products. Failure to comply with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production, refusal by the government to approve marketing of the product and criminal prosecution.

A new drug may not be legally marketed for commercial use in the United States without FDA approval. In addition, upon approval, a drug may only be marketed for the indications, in the formulations and at the dosage levels approved by the FDA. The FDA also has the authority to withdraw approval of drugs in accordance with applicable laws and regulations. Analogous foreign regulators impose similar approval requirements relating to commercial marketing of a drug in their respective countries and may impose similar restrictions and limitations after approval.

In order to obtain FDA approval of a new product, the Company and its strategic partners must submit proof of safety, efficacy, purity and stability, and the Company must demonstrate validation of its manufacturing process. The testing and application process is expensive and time consuming, often taking several years to complete. There is no assurance that the FDA will act favorably or quickly in reviewing such applications. With respect to patented products, processes or technologies, delays imposed or caused by the governmental approval

process may materially reduce the period during which the Company will have the exclusive right to exploit them. Such delays could also affect the commercial advantages derived from proprietary processes. There is no assurance that the regulatory agencies will find these submissions to be adequate.

As part of the approval process, the FDA reviews the Drug Master File (the "DMF") for a description of product chemistry and characteristics, detailed operational procedures for product production, quality control, process and methods validation, and quality assurance. As process development continues to mature, updates and modifications of the DMF are submitted.

The FDA approval process for a pharmaceutical product includes review of (i) chemistry and formulations, (ii) preclinical laboratory and animal studies to enable FDA approval of an IND application, (iii) initial IND clinical studies to define safety and dose parameters, (iv) well-controlled IND clinical trials to demonstrate product efficacy and safety, followed by submission and FDA approval of an NDA. Preclinical studies involve laboratory evaluation of product characteristics and animal studies to assess the safety of the product. Products must be formulated in accordance with GMP requirements and preclinical tests must be conducted by laboratories that comply with FDA regulations governing the testing of drugs in animals. The results of the preclinical tests are submitted to the FDA as part of the IND application and are reviewed by the FDA prior to granting the sponsor permission to conduct clinical studies in human subjects. Unless the FDA objects to an IND application, the application will become effective 30 days following its receipt by the FDA. There can be no certainty that submission of an IND will result in FDA authorization to commence clinical studies.

Human clinical trials are typically conducted in three sequential phases with some amount of overlap allowed. In the most basic terms, the three phases are intended to answer the following three questions with respect to the product being tested: Phase I - is it safe?; Phase II - is it effective?; and Phase III - how effective is it? Phase I trials normally consist of testing the product in a small number of patient volunteers for establishing safety and pharmacokinetic parameters using single and multiple dosing regiments. In Phase II, the continued safety and initial efficacy of the product are evaluated in a somewhat larger patient population, and appropriate dosage amounts and

-11-

treatment intervals are determined. Phase III trials typically involve more definitive testing of the appropriate dose for safety ad clinical efficacy in an expanded patient population at multiple clinical testing centers. A clinical plan, or "protocol," accompanied by the approval of the institution participating in the trials, must be submitted to the FDA prior to commencement of each clinical trial phase. Each clinical study must be conducted under the auspices of an Institutional Review Board ("IRB") at the institution performing the clinical study. An IRB may require changes in a protocol, and there can be no assurance that an IRB will permit any given study to be initiated or completed. In addition, the FDA may order the temporary or permanent discontinuation of clinical trials at any time. In light of this process, the Company must necessarily rely on other persons and institutions to conduct studies.

All the results of the preclinical and clinical studies on a pharmaceutical product are submitted to the FDA in the form of an NDA for

approval to commence commercial distribution. The information contained in the DMF is also incorporated into the NDA. Submission of an NDA does not assure FDA approval for marketing. The application review process takes more than two years on average to complete. However, the process may take substantially longer if the FDA has questions or concerns about a product or studies regarding the product. In general, the FDA requires at least two adequate and controlled clinical studies demonstrating efficacy with sufficient levels of statistical assurance. However, additional support may be required. The FDA also may request additional information relating to safety or efficacy, such as long-term toxicity studies. In responding to an NDA, the FDA may grant marketing approval, require additional testing and/or information, or deny the application. Accordingly, there can be no assurance about any specific time frame for approval, if any, of products by the FDA or foreign regulatory agencies. Continued compliance with all FDA requirements and conditions relative to an approved application, including product specification, manufacturing process, labeling and promotional material, and record keeping and reporting requirements, is necessary throughout the life of the product. In addition, failure to comply with FDA requirements, the occurrence of unanticipated adverse effects during commercial marketing or the result of future studies could lead to the need for product recall or other FDA-initiated actions that could delay further marketing until the products or processes are brought into compliance.

The facilities of each pharmaceutical manufacturer must be registered with and approved by the FDA as compliant with United States GMP. Continued registration requires compliance with standards for United States GMP. In complying with United States GMP, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to ensure technical compliance. In addition, manufacturers must comply with the United States Department of Health and Human Services and similar state and local regulatory authorities if they handle controlled substances, and they must be registered with the United States Environmental Protection Agency and similar state and local regulatory authorities if they generate toxic or dangerous waste streams. Other regulatory agencies such as the Occupational Safety and Health Administration also monitor a manufacturing facility for compliance. Each of these organizations conducts periodic establishment inspections to confirm continued compliance with its regulations. Failure to comply with any of these regulations could mean fines, interruption of production and even criminal prosecution.

For foreign markets, a pharmaceutical company is subject to regulatory requirements, review procedures and product approvals which, generally, may be as extensive, if not more extensive, as those in the United States. Although the technical descriptions of the clinical trials are different, the trials themselves are often substantially the same as those in the United States. Approval of a product by regulatory authorities of foreign countries must be obtained prior to commencing commercial product marketing in those countries, regardless of whether FDA approval has been obtained. The time and cost required to obtain market approvals in foreign countries may be longer or shorter than required for FDA approval and may be subject to delay. There can be no assurance that regulatory authorities of foreign countries will grant approval. The Company has no experience in manufacturing or marketing in foreign countries nor in matters such as currency regulations, import-export controls or other trade laws.

#### RBC-CD4 ELECTROINSERTION TECHNOLOGY PATENTS

Under its license agreement for the RBC-CD4 Electroinsertion Technology, the Company is responsible for financing and prosecuting patent applications for the benefit of the owners and licensors of this technology. To date, one U.S. patent has issued, one U.S. patent application is pending, eight foreign patents have issued and three foreign patent applications are pending.

-12-

## LIPOSOME-CD4 TECHNOLOGY PATENTS

Under its license agreement for the Liposome-CD4 Technology, the Company is responsible for financing and prosecuting patent applications for the benefit of the owners and licensors of this technology. Currently, one U.S. patent application is pending, two foreign patent applications are pending and four foreign patent applications have issued.

#### HIV/AIDS VACCINE PATENTS

Under its license agreement for the AIDS Vaccine, the Company is responsible for financing and jointly prosecuting patent applications for the benefit of the licensor of this technology. Currently, one U.S. patent application is pending, one international patent application is pending and one European patent application has issued.

## **UGIF TECHNOLOGY PATENTS**

Under its license agreement for the UGIF Technology, the Company is responsible for financing and prosecuting patent applications for the benefit of the licensor of this technology. Currently, two U.S. patents have issued, one U.S. patent application is pending, one international patent application is pending and one Canadian patent has issued.

## MEMBRANE ATTACK COMPLEX (MAC)/COMPLEMENT TECHNOLOGY PATENTS

Under its license agreement for the MAC/Complement Technology, the Company is responsible for financing and jointly prosecuting patent applications for the benefit of the licensor of this technology. To date, one U.S. patent application is pending.

## ION PHARMACEUTICALS, INC. PATENTS

Under its license agreement for the anti-proliferative/growth regulatory technology, the Company is responsible for financing and jointly prosecuting patent applications for the benefit of the owners of this technology. To date, four U.S. patents have issued, seven U.S. patent applications are pending and 12 foreign patent applications are pending.

Under its license agreement for the sickle cell technology, the Company is responsible for financing and jointly prosecuting patent applications for the benefit of the owners of this technology. To date, two U.S. patents have issued, three U.S. patent applications are pending and two international application are pending.

Under its research and license option agreement for the intestinal

disorders technology, the Company is responsible in certain cases for financing the prosecution of patent applications and is responsible for jointly prosecuting all patent applications for the benefit of the owners of this technology. To date, one U.S. patent application and one international patent application is pending.

#### COMPETITION

The biopharmaceutical industry is characterized by rapidly evolving technology and intense competition. Research on AIDS and cancer, the areas in which the Company has particular interests, is being conducted by numerous highly skilled scientists at prestigious universities, research institutions and governmental agencies throughout the world. Accordingly, the competition to develop and commercialize medical products and processes must be regarded as intense. Further, competition in the medical field is likely to intensify. Many of the Company's competitors have substantially greater financial and other resources, large in-house research, development, manufacturing and marketing staffs and significantly greater experience with regulatory approval procedures. The Company does not have such resources and does not intend to compete with major pharmaceutical companies in drug manufacturing or marketing.

Colleges, universities, governmental agencies and other public and private research organizations continue to conduct research and are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed, some of which may be directly competitive with that of the Company. The Company expects technological development to occur at a rapid rate and expects competition to intensify as advances occur in the development of pharmaceutical products of biologic origin. However, the

-13-

Company intends to obtain, in consideration for research funding, sublicenses or other rights to technologies from such entities and to pay royalties upon any successful commercial development of products derived therefrom. To such extent, such entities may be considered to be assisting the Company rather than competing with it.

Although the principal investigators under the Company's existing and proposed Sponsored Research Agreements are not aware of other researchers conducting substantially similar research to that encompassed by their projects, no assurance can be given in this regard. The scientific community and the medical field of research regarding AIDS and prostate cancer is relatively small, and the number of approaches and scientific theories may be narrowing. Accordingly, there can be no assurance that others are not contemporaneously conducting the same or similar research to that of the Company and, accordingly, that others might not complete and commercialize their research prior to the time that the Company does so. The Company would likely be adversely impacted if competitors complete and commercialize their research prior to the Company if such resulting therapeutic or diagnostic pharmaceutical is effective, notwithstanding that the product may not infringe upon any of the Company's proprietary rights.

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#### **EMPLOYEES**

As of March 14, 1997, the Company employed 11 persons, four of whom are executive officers.

## ITEM 2. DESCRIPTION OF PROPERTY

The Company's principal executive offices are located at 30 Rockefeller Plaza, Suite 4515, New York, New York 10112. These premises consist of approximately 3,900 square feet subleased until December 31, 1998. The annual rent for these premises is \$166,428. The Company also maintains small offices at 5100 Westheimer, Suite 200, Houston, Texas (for a monthly rent of \$900), 37 S. Main Street, Pittsford, New York (for a monthly rent of \$800) and 124 Mount Auburn Street, Cambridge, Massachusetts (for a monthly rent of \$3,024). Each of the leases on the Houston, Pittsford and Cambridge offices expires in less than a year. The Company maintains no laboratory, research or other facilities, but conducts research and development in outside laboratories under contracts with universities. The Company believes that its existing office arrangements will be adequate to meet its reasonably foreseeable needs.

## ITEM 3. LEGAL PROCEEDINGS

The Company is not a party to any material threatened or pending litigation.

-14-

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

None.

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

The following table sets forth the high and low closing sale prices of the Company's Common Stock on the American Stock Exchange (the "AMEX") for the periods indicated.

1997:	HIGH LOW	
First Quarter (through	March 14, 1997) \$3.75	\$2.75
1996:		
Fourth Quarter	\$4.125 \$4.125	
Third Quarter	\$4.625 \$3.0625	
Second Quarter	\$6.50 \$3.062	5
First Quarter	\$6.8125 \$3.5625	
1995:		
Fourth Quarter	\$4.3125 \$3.00	
Third Quarter	\$5.6875 \$3.875	
Second Quarter	\$5.125 \$3.50	
First Quarter	\$5.750 \$3.125	

The closing sale price for the Company's Common Stock on the AMEX on March 14, 1997 was \$3.1875 per share. At March 14, 1997, there were approximately 350 holders of record of the Company's Common Stock. The Company has never paid dividends on its Common Stock and does not intend to pay cash dividends on its Common Stock in the foreseeable future.

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

## **OVERVIEW**

The Company was originally formed in 1986 as Sheffield Strategic Metals, Inc., a Canadian company, to engage in mineral exploration and development. It conducted no significant business activities from 1986 until late 1991. Between December 1991 and February 1992 the Company changed its strategic direction to focus on the acquisition, development and commercialization of promising biomedical technologies and raised capital in private placements of its common stock. In April 1992, the Company changed its name to Sheffield Medical Technologies Inc. to reflect the nature of its new business and listed its common stock on the NASDAQ Small Cap Market. In November 1993, the Company commenced trading of its Common Stock on the AMEX.

Since its inception in 1986, the Company has been a development stage enterprise. The Company has incurred a net loss in each of the fiscal years since its inception and has had to rely on outside sources of funds to maintain its liquidity. Substantial operating losses are expected to be incurred for the next several years as the Company expends its resources for product acquisition, sponsored research and development and preclinical and clinical testing. The Company has financed its technology development activities and operations primarily through public and private offerings of securities. The Company's operating results have fluctuated significantly during each quarter since its change of strategic direction in 1992, and the Company anticipates that such fluctuations, largely attributable to varying sponsored research and development commitments and expenditures, will continue into the foreseeable future.

## FISCAL YEARS ENDED DECEMBER 31, 1996 AND 1995

In 1996, the Company signed its first sub-license agreement for its Liposome-CD4 technology and earned a sub-license fee, which is included in sub-license fee revenue. Interest income was \$163,664 in 1996 and \$80,610 in 1995, and a total of \$396,913 since the Company's inception in 1986. The increase in 1996 interest income of \$83,054, compared to 1995, was due primarily to the increase in the amount of funds available for investment as the result of the completion of the Company's warrant discount program completed in 1996, which raised total gross proceeds of \$5.6 million.

Research and product development expenses for 1996 decreased by \$582,336 to \$3,841,818 compared with 1995 expenses of \$4,424,154. The lower research and development costs were attributable to negotiating extensions of two major Sponsored Research Agreements signed in October 1996 and the winding down of the RBC-CD4 Electroinsertion Technology project, partially offset by the increased development of the Ion Anti-Proliferative technology projects. In 1996, the Company entered into five (5) major research and development agreements. See Note 6 to the consolidated financial statements. The funds expended for these new projects totaled \$892,694 in 1996.

General and administrative expenses for 1996 were \$3,831,204, an increase of \$851,767 compared with expenses of \$2,979,437 for 1995, primarily resulting from the one-time cashless exercise of options and warrants by a former employee of the Company, totaling \$562,912, and private placement professional fees relating to Ion.

Interest expense for 1996 was \$9,531, a decrease of \$55,205 compared with interest expense for 1995 of \$64,736. The decrease was due to satisfaction in full of the Company's \$550,000 loan from SMT Investment Partnership in 1995. See Notes 4 and 7 to the consolidated financial statements.

As a result of the above, net loss for 1996 decreased by \$378,828 to \$7,008,889 compared with a net loss of \$7,387,717 for 1995.

## LIQUIDITY AND CAPITAL RESOURCES

Since its inception, the Company has financed its operations primarily through the sale of securities, from which it has raised an aggregate of approximately \$24.7 million through December 31, 1996. On February 28, 1997, the Company closed a private offering of 35,000 shares of its 7% Series A Cumulative Convertible Redeemable Preferred Stock, which raised total gross proceeds of \$3.5 million. See Note 9 to the consolidated financial statements. The proceeds of this offering will be used to fund research and development, patent prosecution and for working capital and general corporate purposes, including the possible acquisition of rights in new technologies in the Company's ordinary course of business.

From inception through December 31, 1996, the Company earned \$396,913 in interest on cash, cash equivalents and short-term investments. The Company invests excess cash in cash equivalents and short-term investments in a cash management account that invests in U.S. government securities and high grade

corporate investments. In addition, in 1996, the Company signed its first sub-license agreement for its Liposome-CD4 technology and earned a sub-license fee that is included in sub-license fee revenue.

Net cash used in development stage activities was \$6,043,876, \$7,541,937 and \$23,521,045 during 1996, 1995, and from inception in 1986 through 1996, respectively. Cash of \$6,420,834, \$9,346,901 and \$25,220,193 was provided by the issuance of securities in 1996, 1995 and from inception in 1986 through 1996, respectively.

The Company's total assets at December 31, 1996, were \$2,773,884, an increase of \$552,834 from the previous year's total assets of \$2,221,050, principally due to an increase in cash and cash equivalents and marketable securities, reflecting the cash received from the warrant discount program and sub-license revenue. The Company's liabilities at December 31, 1996, consisting of accounts payable, sponsored research and capital lease obligations, totaled \$1,078,047 compared to \$428,687 at December 31, 1995.

The Company spent approximately \$15.5 million through December 31, 1996 to fund certain ongoing technology research projects and expects to incur additional costs in the future, including costs relating to its ongoing sponsored research and development activities, preclinical and clinical testing of its product candidates and the hiring of additional personnel. The Company may also bear considerable costs in connection with filing, prosecuting, defending and/or enforcing its patent and other intellectual property claims. Therefore, the Company will need substantial additional capital before it will recognize significant cash flow from operations, which is contingent on

-16-

the successful commercialization of the Company's technologies by third parties through licenses, joint ventures or other arrangements. There can be no assurance that any of the technologies to which the Company currently has or may acquire rights to can or will be commercialized or that any revenues generated from such commercialization will be sufficient to fund existing and future research and development activities.

While the Company does not believe that inflation has had a material impact on its results of operations, there can be no assurance that inflation in the future will not impact financial markets which, in turn, may adversely affect the Company's valuation of its securities and, consequently, its ability to raise additional capital, either through equity or debt instruments, or any off-balance sheet refinancing arrangements, such as collaboration and licensing agreements with other companies.

The Company expects that its existing capital resources, including the current private placement offering noted above, will enable it to fund its operations for at least the next 12 months. Because the Company does not expect to generate significant cash flows from operations for at least several years, the Company believes it will require additional funds to meet future costs.

The Company will attempt to meet the balance of its capital requirements with existing cash balances and through additional public or private offerings of its securities, debt financing, and collaboration and licensing arrangements with other companies. There can be no assurance that the Company will be able to obtain such additional funds or enter into such

collaborative and licensing arrangements on terms favorable to the Company, if at all. The Company's sponsored research and technology development program may be curtailed if future financings are not completed.

#### ITEM 7. FINANCIAL STATEMENTS

See page F-1.

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

On January 10, 1995, KPMG Peat Marwick LLP ("KPMG") resigned as independent accountants to the Company. KPMG's accountant's report on the financial statements of the Company for the past two years did not contain an adverse opinion or a disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope, or accounting principles, except that KPMG's report dated February 11, 1994 on the consolidated balance sheet as of December 31, 1993, and the consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 1993 and 1992 and the period from October 17, 1986 (inception) to December 31, 1993 contained a separate paragraph stating that the Company's "recurring losses and net deficit position raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are described in Note 8. The financial statements do not include any adjustments that might result from the outcome of this uncertainty." There were no disagreements on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of KPMG, would have caused it to make reference to the subject matter of the disagreements in connection with its reports. On March 2, 1995, Ernst & Young LLP was engaged as the new independent accountants to the Company.

-17-

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

#### **DIRECTORS AND EXECUTIVE OFFICERS**

The directors and executive officers of the Company and their positions with the Company are set forth below.

Name Age Position

Douglas R. Eger 35 Chairman, Chief Executive Officer and Director

Thomas M. Fitzgerald 47 President and Chief Operating Officer and Director

Michael Zeldin 59 Chief Scientific Officer and Director

Anthony B. Alphin, Jr. 51 Director

Dr. Stephen Sohn 52 Director

Bernard Laurent 45 Director

George Lombardi 53 Vice President, Chief Financial Officer, Treasurer and Secretary

DOUGLAS R. EGER. Mr. Eger has been a Director of the Company since November 1991, served as President of the Company from March 1992 through June 1994 and has served as Chairman of the Company since June 1994. On February 13, 1995, Mr. Eger was elected Co-Chief Executive Officer of the Company and was elected Chief Executive Officer in February 1996. From 1987 to 1990, Mr. Eger was the owner of Eger Innovation Group, a privately held company engaged in a variety of technology development and venture capital activities. Mr. Eger was a founder of Eger Innovation Group, Inc. and a successor company, TechSource Development Corporation, a company founded in 1990 to assist universities in the development and commercialization of promising scientific discoveries.

THOMAS M. FITZGERALD. Mr. Fitzgerald has been a Director of the Company since September, 1996, has served as Chief Operating Officer of the Company since June 1996 and has served as President of the Company since February 1997. From 1989 to 1996 Mr. Fitzgerald was the Vice President and General Counsel of Fisons Corporation, an operating unit of Fisons Group plc, a U.K.-based ethical pharmaceutical company ("Fisons"). Mr. Fitzgerald was Assistant General Counsel of SmithKline Beecham prior to joining Fisons.

MICHAEL ZELDIN, PH.D. Mr. Zeldin has been a Director of the Company since May 1996, served as the Chief Operating Officer and Executive Vice President - Corporate Development of the Company from March 1996 to June 1996 and has served as Chief Scientific Officer of the Company since June 1996. From 1989 to March 1996, Mr. Zeldin was President of Cambridge Biomedical Management, a management assistance firm specializing in the biomedical and pharmaceutical industries. From 1985 to 1989, Mr. Zeldin was President and Director of Research of Procept, Inc., a developer of immunotherapeutic technologies and products.

ANTHONY B. ALPHIN, JR. Mr. Alphin has been a Director of the Company since November 1993. Mr. Alphin has been Chairman and Chief Executive Officer of Moneywatch Investments, Inc., a real estate investment and development company, since 1981. Mr. Alphin has been a director of Norcross & Co., Inc., the managing underwriter of the Company's February 1993 public offering, since 1991.

-18-

DR. STEPHEN SOHN. Dr. Sohn has been a Director of the Company since January 1995. Dr. Sohn has been on the plastic and reconstructive surgery staff of the Brigham & Women's Hospital since 1974. From 1974 to 1990 Dr. Sohn was a Clinical Instructor in surgery at the Harvard University Medical School.

BERNARD LAURENT. Mr. Laurent has been a Director of the Company since May 1995. Mr. Laurent has been the owner of B. Laurent & Co., an investment firm based in London, England, since 1990. Prior to 1990, Mr. Laurent served in various positions at Charterhouse Bank Limited (London), Dillon Read Limited and Bear Stearns & Co. Mr. Laurent is a director of International CHS Resources Corporation (Canada), International Telepresence (Canada) Inc. and Global Equities S.A. (Paris).

GEORGE LOMBARDI. Mr. Lombardi has been the Vice President and Chief Financial Officer of the Company since September 1995. From October 1994 until September 1995, Mr. Lombardi was Vice President and Chief Financial Officer and Director of Fidelity Medical Inc. From 1993 to 1994, Mr. Lombardi was the Senior Financial Executive for the New Jersey and New England operations of National Health Laboratories Inc. From 1986 until 1992, Mr. Lombardi was Vice President, Finance and Administration for Henley Chemicals, Inc., a subsidiary of Boehringer Engleheim Pharmaceutical Company. From 1976 until 1986, Mr. Lombardi held various financial positions with the Revlon Healthcare Group in New York.

## **MEETINGS AND COMMITTEES**

The Board of Directors of the Company held five meetings during the fiscal year ended December 31, 1996. From time to time during such fiscal year, the members of the Board acted by unanimous written consent. The Company has standing Stock Option, Compensation, Audit and Scientific Review Committees. The Stock Option Committee reviews, analyzes and approves grants of stock options and stock to eligible persons under the Company's 1993 Stock Option Plan and the Company's 1993 Restricted Stock Plan. The current members of the Stock Option Committee (appointed in June 1996) are Anthony B. Alphin, Jr. and Stephen Sohn. The Stock Option Committee did not hold any formal meetings in 1996, but approved certain actions by written consent. The Compensation Committee reviews, analyses and makes recommendations to the Board of Directors regarding compensation of Company directors, employees, consultants and others, including grants of stock options (other than stock option grants under the Company's 1993) Stock Option Plan). The current members of the Compensation Committee (appointed in June 1996) are Anthony B. Alphin, Jr., Stephen Sohn and Bernard Laurent. The Compensation Committee did not hold any formal meeting in 1996, but approved certain actions by written consent. The Audit Committee reviews, analyzes and makes recommendations to the Board of Directors with respect to the Company's compensation and accounting policies, controls and statements and coordinates with the Company's independent public accountants. The current members of the Audit Committee (appointed in June 1996) are Anthony B. Alphin, Jr. and Bernard Laurent. The Audit Committee held one formal meeting in 1996. The Scientific Review Committee was established to discuss the science and potential commercialization, clinical development and business development of existing and future technologies of the Company. The current members of the Scientific Review Committee (appointed in June 1996) are Douglas R. Eger, Dr. Stephen Sohn and Dr. Michael Zeldin. The Scientific Review Committee held no formal meetings in 1996. The Company does not have a standing nominating committee or a committee which serves nominating functions.

-19-

## ITEM 10. EXECUTIVE COMPENSATION

The following table sets forth, for the fiscal years indicated, all compensation awarded to, earned by or paid to the chief executive officer of the Company ("CEO") and the executive officers of the Company (other than the CEO) who were executive officers of the Company during the fiscal year ended December 31, 1995 and whose salary and bonus exceeded \$100,000 with respect to the fiscal years ended December 31, 1996.

SUMMARY COMPENSATION TABLE

Long-Term Compensation Annual Compensation Awards

Name and Principal Position	Year Sal	ary(\$) 	(\$) 	Other annu Compens (\$)(1) 	···		
Douglas R. Eger, Chairman  and Chief Executive Officer		<del>\$172,</del> !	<del>500 C</del>	<del>5,000 0</del>	<del>0 0</del> <del>80,000</del> <del>0</del>		
Michael Zeldin, Chief Scientific							
		1 <del>31,250</del>	0	0	<del>250,000</del>		
General Lombardi, Chief Financial							
Officer, Treasurer and Secretary		\$122,6! \$32,500		0	<del>0</del> 100,000		

(1) Perquisites and other personal benefits, securities or property delivered to each executive officer did not exceed the lesser of \$50,000 or 10% of such executive's salary and bonus.

The following table sets forth certain information regarding stock option grants made to Messrs. Fitzgerald and Zeldin during the fiscal year ended December 31, 1996.

OPTION GRANTS IN LAST FISCAL YEAR

## **Individual Grants**

-----

# % of Total Options

	Options			
		Granted to	Exercise	or
Opt	ions Em <sub>l</sub>	ployees in	Base Price	Expiration
Name	Granted(#)	Fiscal Year	(\$/sh)	Date
Thomas M. Fitzgerald,	50,000	11%	\$5.25	5/31/01
-President and Chief	50,000	11%	\$6.75	5/31/01
-Executive Officer	50,000	11%	\$8.25	5/31/01
Michael Zeldin, Chief	75,000	16%	\$5.25	2/28/01
-Scientific Officer	100,000	<del>21%</del>	<del>\$6.75</del>	<del>2/28/01</del>
	75,000	16%	\$8.25	<del>2/28/01</del>

-20-

The following table sets forth certain information regarding stock options held by Messrs. Eger, Fitzgerald, Zeldin and Lombardi as of December 31, 1996.

AGGREGATED OPTION EXERCISES
DURING THE MOST RECENTLY COMPLETED
FISCAL YEAR AND FISCAL YEAR-END OPTION VALUES

# No. of

		Securities			
		Shares Value (1) of			
		Un	derlying Unex	ercised In-	
		Ur	nexercised Th	ie-Money	
		Opt	ions at fY- Opti	ons at FY-	
	Shares		End (#)	End (\$)	
	Acquired on	Value	Exercisable/	Exercisable/	
Name	Exercise(#)	Realized	Unexercisable	Unexercisable	
Douglas R. Eger	50,000 Chairman, Ch	•	——————————————————————————————————————	<del>365,850/46,250</del>	
Thomas M. Fitzgerald, President 0/150,000 and Chief Operating Officer					
<del>Michael Zeldir</del>	•		<del>75,000/175,00</del> <del>er</del>	0	
<del>George Lomba</del>	rdi,	<del></del>	50,000/50,00	<del></del>	

Vice President, Chief Financial
Officer, Treasurer and Secretary

(1) Represents the total gain that would be realized if all-in-the-money options held at December 31, 1996 were exercised, determined by multiplying the number of shares underlying the options by the difference between the per share option exercise price and the closing sale price of Common Stock of \$3.75 per share reported by AMEX for December 31, 1996. An option is in-the-money if the fair market value of the underlying shares exceeds the exercise price of the option.

## **BOARD OF DIRECTORS COMPENSATION**

The Company does not currently compensate directors who are also executive officers of the Company for their service on the Board of Directors. Under current Company policy, each non-employee Director of the Company receives a fee of \$750 for each Board meeting attended and \$400 for each Board committee meeting attended. Directors are reimbursed for their expenses incurred in attending meetings of the Board of Directors.

## LONG-TERM INCENTIVE AND PENSION PLANS

The Company does not have any long-term incentive or defined benefit pension plans.

## **OTHER**

No director or executive officer is involved in any material legal proceeding in which he is a party adverse to the Company or has a material interest adverse to the Company.

# **EMPLOYMENT AGREEMENTS**

In October 1995, the Company entered into a two-year agreement with Douglas R. Eger, pursuant to which Mr. Eger serves as the Company's Chairman and Chief Executive Officer. The term of the agreement is automatically extended for an additional one year term from year to year unless either party notifies the other of its

-21-

intention to terminate at least 60 days prior to the end of the then current term. Mr. Eger is required to devote such time, attention and energy to the Company as required for performance of his duties under the agreement. The agreement includes confidentiality and non-compete provisions. Mr. Eger's annual base salary under the agreement is currently \$230,000.

In September 1995, the Company entered into a two-year employment agreement with George Lombardi pursuant to which Mr. Lombardi agreed to serve as Vice President and Chief Financial Officer of the Company. Such agreement automatically renews for successive one-year terms unless either party provides written notice to the other of his or its intent to terminate at least 90 days prior to the initial day of new term. If Mr. Lombardi's employment is terminated other than for cause, he is entitled to receive a severance payment of \$65,000 payable in six \$10,833 installments. The agreement contains non-compete and confidentiality provisions. Mr. Lombardi's annual base salary under the agreement is currently \$130,000.

In March 1996, the Company entered into a two-year employment agreement with Michael Zeldin pursuant to which Mr. Zeldin agreed to serve as Chief Scientific Officer of the Company. The Agreement automatically renews for successive one year terms unless wither party provides written notice to the other of his or its intent to terminate at least 90 days prior to the end of the current term. The agreement contains non-compete and confidentiality provisions. Mr. Zeldin's annual base salary under the agreement is currently \$175,000.

In June 1996, the Company entered into a three-year employment agreement with Thomas M. Fitzgerald pursuant to which Mr. Fitzgerald agreed to serve as Chief Operating Officer of the Company. Such agreement automatically renews for successive one-year terms unless either party provides written notice to the other of his or its intent to terminate at least six months prior to the end of the then current term. If Mr. Fitzgerald's employment is terminated other than for cause, he is entitled to receive a severance payment of \$87,500, payable in six equal monthly installments. The agreement contains non-compete and confidentiality provisions. Mr. Fitzgerald's annual base salary under the agreement is currently \$175,000.

# COMPLIANCE WITH SECTION 16(A) OF THE SECURITIES EXCHANGE ACT OF 1934

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's officers and directors, and persons who own more than ten percent of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange

Commission (the "Commission"). Officers, directors and greater than ten percent shareholders are required by the Commission's regulations to furnish the Company with copies of all Section 16(a) forms they file. To the Company's knowledge, all Section 16(a) forms that were required to be filed during the fiscal year ended December 31, 1996 were filed in compliance with the applicable requirements of Section 16(a).

## ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The voting securities of the Company outstanding on March 14, 1997 consisted of 11,388,274 shares of Common Stock. The following table sets forth information concerning ownership of the Company's Common Stock, as at March 14, 1997, by (i) each director, (ii) each executive officer, (iii) all directors and executive officers as a group, and (iv) each person who, to the knowledge of management, owned beneficially more than 5% of the Common Stock.

Share	s Percent of	of			
Beneficially Outstanding					
Beneficial Owner(1)	Owned (2)	Common Stock(2)			
Douglas R. Eger	827,456(3)	7.0%			
Thomas M. Fitzgerald	9,972	*			
Michael Zeldin	80,118(5)	*			
Anthony B. Alphin, Jr	75,000(6)	*			
Dr. Stephen Sohn	286,000(7)	2.5%			

Shares Percent of Beneficially Outstanding

-22-

Beneficial Owner(1) Owned (2) Common Stock(2)

All Directors and Executive Officers as a Group (7 persons)...... 1,545,990 12.3%

- (1) The persons named in the table, to the Company's knowledge, have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable and the information contained in the footnotes hereunder.
- (2) Calculations assume that all options and warrants held by each

<sup>\*</sup> Less than 1%.

director, director nominee and executive officer and exercisable within 60 days after March 14, 1997 have been exercised.

- (3) Includes 475,000 shares of Common Stock issuable upon exercise of options and warrants exercisable within 60 days of March 14, 1997. Mr. Eger's address is c/o Sheffield Medical Technologies Inc., 30 Rockefeller Plaza, Suite 4515, New York, New York 10112.
- (4) Mr. Fitzgerald's address is c/o Sheffield Medical Technologies, Inc., 30 Rockefeller Plaza, Suite 4515, New York, New York 10112.
- (5) Includes 75,000 shares of Common Stock issuable upon exercise of options exercisable within 60 days after March 14, 1997. Mr. Zeldin's address is c/o Sheffield Medical Technologies Inc., 30 Rockefeller Plaza, Suite 4515, New York, New York 10112.
- (6) Includes 65,000 shares of Common Stock issuable upon exercise of options exercisable within 60 days after March 14, 1997. Mr. Alphin's address is 2692 Richmond Road, Lexington, Kentucky 40509.
- (7) Represents (i) 65,000 shares of Common Stock issuable upon exercise of options exercisable within 60 days after March 14, 1997, (ii) 191,000 shares of Common Stock issuable upon exercise of a warrant issued to SMT Investment Partnership, a Massachusetts limited partnership ("SMT") and (iii) 30,000 shares of Common Stock subject to a warrant issued to The Fort Hill Group, Inc. ("Fort Hill"). Dr. Sohn is a general partner of SMT and a former officer of Fort Hill. Dr. Sohn disclaims beneficial ownership of (a) any shares of Common Stock that SMT has the right to acquire and (b) any shares of Common Stock that Fort Hill has the right to acquire (other than 10,000 shares issuable upon exercise of the above-mentioned warrant issued to Fort Hill that Dr. Sohn has the right to receive upon issuance). Dr. Sohn's address is 170 Commonwealth Avenue, Boston, Massachusetts 02116.
- (8) Includes (i) 110,000 shares of Common Stock issuable upon exercise of options exercisable within 60 days after March 14, 1997, (ii) 25,000 shares of Common Stock owned by Global Equities and (iii) 12,500 shares of Common Stock issuable upon exercise of warrants exercisable within 60 days after March 14, 1997 held by Global Equities. Mr. Laurent is a director of Global Equities. Mr. Laurent disclaims beneficial ownership of any shares of Common Stock that Global Equities has the right to acquire. Mr. Laurent's address is 168 Sloan Street, London, England SW1X9QF.
- (9) Includes 100,000 shares of Common Stock issuable upon exercise of options exercisable within 60 days after March 14, 1997. Mr. Lombardi's address is c/o Sheffield Medical Technologies Inc., 30 Rockefeller Plaza, Suite 4515, New York, New York 10112.

-23-

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

**SMT LOAN** 

the principal amount of \$550,000 pursuant to a demand loan agreement (the "SMT Loan Agreement"). Under the terms of the SMT Loan Agreement, SMT could demand the payment in full of the SMT Loan at any time. To secure the Company's obligations under the SMT Loan Agreement, the Company granted SMT a security interest in substantially all of the Company's assets, which security interest has since been released. The note evidencing the SMT Loan (the "Original SMT Note") was exchanged pursuant to the terms of the SMT Loan Agreement for a new note (the "SMT Convertible Note") that permitted the holder to exchange the SMT Convertible Note (in whole, but not in part) into 200,000 shares of Common Stock. In addition, the SMT Loan Agreement required the Company upon issuance of the SMT Convertible Note to issue to SMT warrants (the "SMT Warrants") to acquire 200,000 shares of Common Stock at any time within five years after the date of issue for a price of \$4.00 per share. The SMT Warrants are redeemable by the Company for \$4.00 per share at any time after the price of the Common Stock exceeds an average of \$6.00 per share for 20 business days. SMT was granted certain registration rights with respect to the Common Stock issuable to SMT upon conversion of the SMT Convertible Note and the SMT Warrants. By letter dated June 1, 1995, SMT exercised its right to convert the SMT Convertible Note into 200,000 shares of Common Stock and subsequently assigned the right to such shares to an unaffiliated third party.

As a condition to making the SMT Loan, the Board of Directors was expanded by the election of John R. Lakian, George R. Begley, Andrew Monness and Dr. Stephen Sohn, all nominees of SMT. Messrs. Lakian and Monness resigned as directors of the Company as of May 24, 1995 and Mr. Begley resigned as a director as of July 6, 1995.

All the time of the making of the SMT Loan, Messrs. Begley and Lakian and Dr. Stephen Sohn were general partners of SMT. In addition, Messrs. Begley and Lakian and Dr. Stephen Sohn were executive officers of The Fort Hill Group, Inc. ("Fort Hill"), a former financial adviser to the Company, at such time.

Fort Hill served as financial advisor to the Company in connection with the Company's private placement of units (each consisting of two shares of Common Stock and one warrant to purchase an additional share of Common Stock) that was consummated in April 1995 (the "First 1995 Unit Private Placement"). For its financial advisory services, Fort Hill was paid \$177,470 in fees and commissions. In addition, the Company issued Fort Hill a five year warrant to purchase 30,000 shares of Common Stock with an exercise price of \$3.25 per share.

Global Equities, an investment firm headquartered in Paris, France, was paid commissions totalling \$45,440 for services provided in connection with the First 1995 Unit Private Placement. In addition, the Company issued Global Equities units consisting of 25,000 shares of Common Stock and warrants to purchase 12,500 additional shares of Common Stock at an exercise price of \$5.00 per share. Bernard Laurent, a Director of the Company, and Patrick Piard, a former Director of the Company, are also principals of Global Equities.

## **CONSULTING ARRANGEMENTS**

Dr. Stephen Sohn and Bernard Laurent received fees of \$16,667 and \$72,000, respectively, in 1996 from the Company in consideration of scientific and financial consulting services rendered to the Company by them.

In connection with Arthur M. Jenke's resignation as Director and Chief Financial Officer of the Company in September 1994, the Company entered into a consulting agreement with Mr. Jenke. Pursuant to the consulting agreement, Mr. Jenke agreed to provide advice to the Company in connection with various Company matters, including periodic filings and registration statements with the Commission. Mr. Jenke received approximately \$5,300 per month for his services under the consulting agreement, and was reimbursed for his related expenses. In addition, the consulting agreement provides that the Company shall permit Mr. Jenke to effect a "cashless" exercise of all of his outstanding options and warrants. Mr. Jenke's services to the Company as a consultant concluded in January 1995. The Company issued Mr. Jenke 162,877 shares of Common Stock in September, 1996 in satisfaction of its obligation to effect a cashless exercise of Mr. Jenke's outstanding options and warrants.

Reference

-24-

## ITEM 13. EXHIBITS, LIST AND REPORTS ON FORM 8-K

(a) Exhibits:

No.

3.1	Certificate of Incorporation of the Company, as amended (1)		
3.2	By-Laws of the Company (2)		
4.1	Form of Common Stock Certificate (2)		
4.2	Certificate of Designation defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series A Cumulative Convertible Redeemable Preferred Stock	1	
10.1	1 Employment Agreement dated as of October 1, 1995 between the Company and Douglas R. Eger	(2)	
10.2	2 Employment Agreement dated as of September 7, 1995 between the Company and George Lombardi	5 (2	)
10.3	3 Amendment dated as of September 22, 1996 to Employ Agreement dated as of September 7, 1995 between the Company and George Lombardi	/ment	(1)
10.4	4 Employment Agreement dated as of March 28, 1996 be the Company and Michael Zeldin	tween	(2)
10.5	5 Amendment dated June 6, 1996 to Employment Agreen dated as of March 28, 1996 between the Company and M Zeldin		(1)
10.6	6 Employment Agreement dated as of June 6, 1996 betwee Company and Thomas M. Fitzgerald	een the	(3)

10.7 Agreement of Sublease dated as of November 17, 1995 (2) between the Company and Brumbaugh Graves Donohue & Raymond relating to 30 Rockefeller Plaza, Suite 4515, New York, New York				
10.8	1993 Stock Option Plan, as amended	(1)		
10.9	1993 Restricted Stock Plan, as amende	ed (2)		
10.10	1996 Directors Stock Option Plan	(1)		
	Demand Loan Agreement dated Janu Company and SMT Investment Partner general partnership	•	(4)	
10.12 Demand Note dated January 23, 1995 payable to SMT (4) Investment Partnership, a Massachusetts general partnership				
16.1	Letter of KPMG Peat Marwick LLP dat	ed February 1, 1995 (2)		
21	Subsidiaries of Registrant	(2)		
23.1	Consent of Ernst & Young LLP	(1)		
23.2	Consent of KMPG Peat Marwick LLP	(1)		
27	Financial Data Schedule	(1)		
	-25-			

(1) Filed herewith.

- (3) Incorporated by reference to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 1996 filed with the Securities and Exchange Commission.
- (4) Incorporated by reference to the Company's Annual Report on Form 10-KSB for its fiscal year ended December 31, 1994 filed with the Securities and Exchange Commission.
- (b) Reports on Form 8-K:

None.

-26-

### **SIGNATURES**

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

<sup>(2)</sup> Incorporated by reference to the Company's Annual Report on Form 10-KSB for its fiscal year ended December 31, 1995 filed with the Securities and Exchange Commission.

### SHEFFIELD MEDICAL TECHNOLOGIES INC.

Dated: March 28, 1997	/s/ Douglas R. Eger	
_	as R. Eger nan and Chief Executive Officer	
	Exchange Act of 1934, this reporing persons on behalf of the Regindicated.	
Signatu 	re Title 	Date 
	Director, Chairman and Chief Exe Officer Douglas R. Eger	
<del>/s/ Thomas M. Fitzgerald</del>	— Director, President and Chief Op Officer — Thomas M. Fitzgerald	_
<del>/s/ Michael Zeldin, Ph.D.</del>	— Director and Chief Scientific Off   Michael Zeldin	icer <u>March 28, 1997</u>
<del>/s/ Anthony B. Alph</del> i	n, Jr. Director  — Anthony B. Alphin, Jr.	<del>March 28, 1997</del>
<del>-/s/ Stephen Sohn, M</del>	.D. Director	<del>March 28, 1997</del>

-/s/ George Lombardi Vice President, Treasurer and March 28, 1997
----- Chief Financial Officer (Principal
George Lombardi Financial and Accounting Officer)

Bernard Laurent

**Director** 

March 28, 1997

-/s/ Bernard Laurent

Consolidated Financial Statements

Reports of Independent Auditors F-2

Consolidated Balance Sheet as of December 31, 1996...... F-4

Consolidated Statements of Operations for the years ended December 31, 1996 and 1995 and for the period from October 17, 1986 (inception) to December 31, 1996 and 1995 and for the period from October 17, 1986 (inception) to December 31, 1996 and 1995 and for the period from October 17, 1986 (inception) to December 31, 1996 (in

Report of Independent Auditors

To Board of Directors and Stockholders Sheffield Medical Technologies Inc.

We have audited the accompanying consolidated balance sheet of Sheffield Medical Technologies Inc. and subsidiaries (a development stage enterprise) as of December 31, 1996, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years ended December 31, 1996 and 1995, and for the period October 17, 1986 (inception) through December 31, 1996. 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. The consolidated financial statements as of December 31, 1993, and for the period October 17, 1986 (inception) through December 31, 1993, were audited by other auditors whose report dated February 11, 1994 expressed an unqualified opinion on those statements and included an explanatory paragraph that stated that the Company's "recurring losses and net deficit position raise substantial doubt about its ability to continue as a going concern. The 1993 financial statements do not include any adjustments that might result from the outcome of this uncertainty." The consolidated financial statements for the period October 17, 1986 (inception) through December 31, 1993 include cumulative

net losses of \$5,872,416. Our opinion on the consolidated statements of operations, stockholders' equity and cash flows for the period October 17, 1986 (inception) through December 31, 1996, insofar as it relates to amounts for prior periods through December 31, 1993, is based solely on the report of other auditors.

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

In our opinion, based on our audits, and for the period October 17, 1986 (inception) through December 31, 1993, the report of other auditors, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Sheffield Medical Technologies Inc. and subsidiaries at December 31, 1996, and the consolidated results of their operations and their cash flows for the years ended December 31, 1996 and 1995 and the period from October 17, 1986 (inception) through December 31, 1996, in conformity with generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that Sheffield Medical Technologies Inc. and subsidiaries will continue as a going concern. As more fully described in Note 1, the Company has generated only minimal operating revenue, has incurred recurring operating losses and requires additional capital. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ ERNST & YOUNG LLP

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ERNST & YOUNG LLP Princeton, New Jersey February 12, 1997, except for Note 9 as to which the date is March 14, 1997

F-2

INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders Sheffield Medical Technologies Inc.:

We have audited the accompanying consolidated statements of operations, stockholders' equity (net capital deficiency) and cash flows of Sheffield Medical Technologies Inc. and subsidiary (a development stage enterprise) for the period from October 17, 1986 (inception) to December 31, 1993 (not included

separately herein). The 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 generally accepted auditing standards. 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 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 presents fairly, in all material respects, the results of Sheffield Medical Technologies Inc. and subsidiary's operations and cash flows for the period from October 17, 1986 (inception) to December 31, 1993 in conformity with generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As reflected in the accompanying consolidated financial statements, the Company's recurring losses raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters were described in note 8 to the December 31, 1993 financial statements (not included separately herein). The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG Peat Marwick LLP
----KPMG Peat Marwick LLP

Houston, Texas February 11, 1994

F-3

SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED BALANCE SHEET

DECEMBER 31, 1996

### **ASSETS**

	12/31/96
Current Assets:	
Cash and cash equivalents Investments	\$ 1,979,871
Prepaid expenses and other current assets	43,975

Total current assets	<del>2,484,614</del> ======
Property and Equipment:	
Laboratory equipment	<del>185,852</del>
- Leashold Improvements	61,390
Office equipment	<del>89,019</del>
	<del>336,261</del>
Less accumulated depreciation ————————————————————————————————————	<del></del>
Net property and equipment	<del></del> <del>174,254</del>
Segregated cash	<del></del>
Other Assets	<del>40,016</del> 
Total assets	<del></del>
LIABILITIES AND STOCKHOLDERS'  Current liabilities:  Accounts payable and accrued liabilities  Sponsored research payable  Capital lease obligation-current portion	\$ 446,965 580,157
Total current liabilities	<del></del>
Capital lease obligation - non-current portion	<del>27,206</del>
<del>Stockholders' equity</del>	
— Preferred stock, \$.01 par value. Authorized, 3,000,000	<del>) shares; none issued</del>
— Common stock, \$.01 par value. Authorized, 30,000,00	<del>00 shares; issued and</del>
	113,883
Notes receivable in connection with sale of stock	(110,000)
Additional paid-in capital	28,319,838
	<del>(39,232)</del>
Deficit accumulated during development stage	
	<del>1,695,837</del> 
Total liabilities and stockholders' equity	<del>\$ 2,773,884</del>

F-4

SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 1996 AND 1995 AND FOR
THE PERIOD FROM OCTOBER 17, 1986 (INCEPTION) TO
DECEMBER 31, 1996

	Years ended December 31,		eption) to
	1996	1995 	1996 
	Revenues:		
Sub-license revenue	\$ 510,000	_	510,000
Interest income	63,664	<del>80,610</del>	<del></del>
<del>Total revenue</del>	673,664	80,610	<del>906,913</del>
	Expenses:		
Research and development			15,523,197
General and administrative			<del>11,894,692</del>
	9,531	64,736	<del></del>
Total expenses	<del>7,682,553</del>	<del>7,468,327</del>	<del>27,538,352</del>
oss before extraordinary item	(7,008,889)	<del>\$(7,387,717</del>	
Extraordinary item  Net loss			<del></del>
<del></del>	<del>7,008,889)     \$(7,3</del> ======	<del>887,717)     \$</del>	<del>(26,588,652)</del> =======
<del>Loss per</del>	share of common:	<del>stock:</del>	
Loss before extraordinary item			<del>\$ (6.25)</del>
Extraordinary item ————————————————————————————————————			<del></del>
Net loss	<del>\$ (0.65)</del>	<del>(0.90)</del>	\$ (6.24)
nted average common shares outst	anding 10,800	5 <del>,799 8,1</del>	85,457 4,2!

F-5

SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY) FOR THE PERIOD FROM OCTOBER 17,
1986 (INCEPTION) TO DECEMBER 31, 1996

Notes Deficit Total

receivable Unrealized accumulated stockholders' in connection Additional loss during equity with sale paid-in on marketable development (Net capital Stock of stock capital securities stage deficiency) Balances at October 17, 1986 -Common stock issued \$11,288,329 - \$ 254,864 - - 11,543,193 Common stock options issued - - 75,000 - - 75,000 Net loss <del>- (12,192,046) (12,192,046)</del> Balances at December 31, 1994 11,288,329 - 329,864 - (12,192,046) (573,853) Reincorporation in Delaware at <del>- 9,726,277</del> <del>- 9.753.933</del> <del>27,656</del> Common stock issued <del>- - (7,387,717) (7,387,717)</del> Net loss Balances at December 31, 1995 95,616 - 21,276,510 - (19,579,763) 1,792,363 Common stock issued 18,267 - 7,043,328 - - 7,061,595 Notes receivable in connection <del>- (110,000)</del> - with sale of stock - (110,000) -Unrealized loss on marketable (39,232) -securities <del>- (7,008,889) (7,008,889)</del> Net loss Balances at December 31, 1996 \$ 113,883 \$ (110,000) \$28,319,838 \$ (39,232) \$ (26,588,652) \$ 1,695,837

F-6

### and 1995 and for the period from October 17, 1986 (inception) to December 31, 1996

	Years ended December 31,	October 17, 19 (inceptio Decemb	n) to
		 995 1990	
——————————————————————————————————————	•		\$ (26.631.439)
extraordinary gain. Loss before extraordinary item	\$(7,000,009	y (7,567,717)	<del>\$ (26,631,439)</del>
Extraordinary gain on extinguishment of deb	t		<del>42,787</del>
	<del>(,889) \$ (7,</del> 3		<del>,588,652)</del>
Adjustments to reconcile ne development st		<del>sh used by</del>	
Issuance of common stock, stock options/warrants for	<del>r services 64</del>	0 <del>,762 357,0</del> 3	32 1,541,003
- Non-cash interest expense	<u>-</u>	50,000	<del>- 50,000</del>
<ul> <li>Issuance of common stock for license</li> </ul>		<del>-</del>	<del>5,216</del>
— Securities acquired under sub-license agreement	: (500,0	<del>)00) -                                 </del>	(500,000)
Issuance of common stock for intellectual prope			866,250
- Amortization of organizational and debt issuan	, ,		<del>77,834</del>
		<del>47,992 1</del>	•
- Amortization			0 <del>,463</del>
<ul> <li>Increase in debt issuance and organization co-</li> </ul>			<del>(77,834)</del>
— Decrease (increase) in prepaid expenses and other cu	urrent 109	<del>810 (88,618</del>	` ' '
— ass — Decrease (increase) in other assets		(4 207)	<del>19.025</del>
Increase (decrease) in accounts payable, accrued liak			
— Increase (decrease) in sponsored research payable————————————————————————————————————	332,73	<del>5 (140,454)</del> 	<del></del>
Net cash used by development stage activities	(6,043,876	<del>(7,541,937)</del>	<del>(23,521,045)</del>
Cash flows from inv	esting activitie	<del>S:</del>	
-Acquisition of laboratory and office equipment	(51,136	<del>5) (24,517) </del>	<del>(263,809)</del>
<ul> <li>Increase in segregated cash</li> </ul>	<del>(75,000)</del>	<u>-</u>	<del>(75,000)</del>
-Increase in notes receivable in connection with sale	of stock (24	<del>-0,000) -</del>	(240,000)
-Payments of notes receivable	130,000	-	<del>130,000</del>
Net cash used by investing activities	(236,136)	<del>(24,517)</del>	<del></del> (448,809)
Cash flows from fin	ancing activitie	<del>S:</del>	
Duin aire al reservos arete con alore as reita l la con	(21,528	3) -	<del>(21,528)</del>
- Principal payments under capital lease			<del>749,976</del>
- Conversion of convertible, subordinated notes			
		550,000	550,000
-Conversion of convertible, subordinated notes	-	<del>550,000</del> 7,699,574	<del>550,000</del> <del>13,268,035</del>
<ul> <li>Conversion of convertible, subordinated notes</li> <li>Proceeds from issuance of debt</li> </ul>	- - 471,550		•

Net cash and cash equivalents provided by financing

<del>activities</del>	6,399,306	9,346,9	01	<del>25,948,</del>	<del>641</del>
Net increase in cash and cash equivalents     Cash and cash equivalents at beginning of p		9,294 1,860,577	1,780,4 8	<del></del> <del>47</del> 0,130	<del>1,978,787</del> <del>1,084</del>
Cash and cash equivalents at end of period		<del>'9,871</del>	<del></del> <del>\$ 1,860,</del> ===	<del></del> 5 <del>77 :</del>	\$ 1,979,871 ======
Noncash investing	•	•		257.022	4.544.0
ommon stock, stock options and warrants issued in Common stock issued for license	for services	\$ 640,762	<del>2 \$</del>	<del>357,032</del>	<del>\$ 1,541,0(</del> <del>,216</del>
Common stock issued for intellectual prope	rty rights	_	_	J	<del>,210</del> 866,250
Common stock issued to retire debt	try rigitis		600,000		600,000
Securities acquired under sub-license agreem	nont	<del>-</del> 500,000	000,000		<del>500,000</del>
- Unrealized depreciation of investments	Territ	39,232			<del>39,232</del>
Equipment acquired under capital lease		72,453			<del>72,453</del>
Notes payable converted to common stoc	-k	72, <del>4</del> 33			749,976
					=======
<del>Supplemental disclos</del> i	<del>ure of cash flo</del>	<del>w informa</del>	<del>ition:</del>		
-Interest paid	<del>\$ 9,531</del>	\$ 64,7	736	\$ 120,	<del>463</del>

F-7

# SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### 1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Sheffield Medical Technologies Inc. ("Sheffield") was incorporated on October 17, 1986, under the Canada Business Corporations Act. The Company's wholly-owned subsidiary, U-Tech Medical Corporation ("U-Tech") was incorporated in the state of Texas on January 13, 1992 and is inactive at December 31, 1996. On January 10, 1996, Ion Pharmaceuticals, Inc., a Delaware corporation ("Ion"), was formed as a wholly-owned subsidiary of the Company. At that time, Ion acquired the Company's rights with respect to the anti-proliferative technology. Unless the context requires otherwise, Sheffield, U-Tech and Ion are referred to as "the Company". The Company commenced its biotechnology operations in the United States in January 1992 under new management and Sheffield became domesticated as a Wyoming corporation in May 1992. At the Annual Meeting of shareholders of the Company held on January 26, 1995, the Company's shareholders approved the proposal to reincorporate the Company in Delaware, which was effected on June 13, 1995. All significant intercompany transactions are eliminated in consolidation.

The Company is in the development stage and to date has been principally engaged in research and licensing efforts. The Company has generated minimal operating revenue and requires additional capital which the Company intends to obtain through equity and debt offerings 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 starting 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 1997 are dependent upon obtaining additional financing.

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 net losses of \$7,008,889 and \$7,387,717 during the years ended December 31, 1996, and 1995 respectively, and has an accumulated deficit of \$26,588,652 from inception (October 17, 1986) through December 31,1996.

### 2. SIGNIFICANT ACCOUNTING POLICIES

### **CASH EQUIVALENTS**

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents.

### MARKETABLE SECURITIES

Marketable securities generally consist of investments which can be readily purchased or sold using established markets. The Company's securities, which are classified as available-for-sale, are carried at market with unrealized gains and losses reported as a separate component of stockholders equity.

F-8

# SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### PROPERTY AND EQUIPMENT

Property and equipment is stated at cost. Depreciation is computed over three or five year periods using the straight-line method.

Assets under capital leases, consisting primarily of office equipment and improvements, are amortized over the lesser of the useful life or the applicable lease terms, whichever is shorter, which approximate three years.

#### RESEARCH AND DEVELOPMENT COSTS

Company-sponsored research and development costs ("R & D costs") are expensed as incurred, except for fixed assets, to which the Company has

title, which are capitalized and depreciated over their estimated useful lives. LOSS PER SHARE OF COMMON STOCK

The computation of loss per common share is based on the weighted-average number of outstanding common shares. Common stock equivalents are not included because the effect would be antidilutive. USE OF ESTIMATES

The preparation of the financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

### STOCK BASED COMPENSATION

As permitted by FASB Statement No. 123, "Accounting for Stock-Based Compensation" (FASB 123), the Company has elected to follow Accounting Principal Board Opinion No. 25, "Accounting for Stock Issued Employees" (APB 25) and related interpretations in accounting for its stock option plans. Under APB 25, no expense is recognized at the time of option grant because the exercise price of the Company's employee stock option equals the fair market value of the underlying common stock on the date of grant.

### 3. LEASES

Included in property and equipment are capital leases as follows at December 31, 1996:

Office equipment \$51,978

Leasehold improvements 20,475

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72,453

Less accumulated amortization (20,463)

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\$ 51,990

There were no assets under capital leases at December 31, 1995.

The company has sub-leases for office space in four locations which expire at various times between April, 1997 and December 31, 1998. The Company also leases certain office equipment under a capital lease that expires in

F-9

### SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 1998. The future minimum payments under capital leases and operating leases at December 31, 1996 are as follows:

Capital Operating
Leases Leases

1997 \$ 29,280 \$ 190,524

1998 29,280 166,428

\_\_\_\_\_

Total Minimum Lease Payments \$58,560 \$356,952

=======

Amounts Representing Interest (7,635)

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Present Value of Net Minimum Lease Payments \$50,925

======

Rent expense for the years ended December 31, 1996, 1995 and the period from October 17, 1986 (inception) to December 31, 1996 was \$147,104; \$105,946; and \$332,525, respectively.

### 4. CAPITAL STOCK TRANSACTIONS

The following table represents the issuance of common stock since the Company's incorporation:

### Number of common Shares Issued

-----

Date of incorporation	900,000	
Issued during year ended D	ecember 31, 1986	990,000
Issued during year ended D	ecember 31, 1991	412,500
Issued during year ended D	ecember 31, 1992	850,000
Issued during year ended D	ecember 31, 1993	2,509,171
Issued during year ended D	ecember 31, 1994	1,134,324
Issued during year ended D	ecember 31, 1995	2,765,651
Issued during year ended D	ecember 31, 1996	1,826,628
Balance outstanding at Dec	ember 31, 1996	11,388,274
=	=======	

The shares issued during 1993 included (i) 1,666,668 shares related to the initial public offering; (ii) 272,500 shares related to the exercise of warrants at a price of Can. \$3.50 per share; (iii) 31,250 shares as consideration for fiscal agency fees; (iv) 10,000 shares related to the exercise of warrants at a price of Can. \$1.00 per share; (v) 524,753 shares related to the conversion of 10% Convertible Notes at an average price of Can. \$1.82 per share; (vi) 4,000 shares to members of the Scientific Advisory Board, in consideration of their services, at \$1.78 per share.

Under the UGIF Technology Option Agreement (the "Option Agreement") dated November 11, 1992, and approved by the shareholders of the Company on December 2, 1993, the Company obtained an option from E/J Development Corporation d/b/a TechSource Development Corporation ("TechSource") to acquire an exclusive sublicense to the UGIF Technology in exchange for 300,000 shares of Common Stock of the Company (after taking into account a one-for-two reverse stock split effective on February 11, 1993). Mr. Douglas R. Eger, who is Chairman of the Company, is a former 50% shareholder of TechSource. On January 10, 1994, TechSource assigned its right to receive 215,000 shares of Common Stock pursuant to the Option

Agreement to Mr. Eger and assigned its right to receive 85,000 shares of Common Stock pursuant to the Option Agreement to Mr. Jenke. Effective January 10, 1994, the Company issued such shares to Messrs. Eger and Jenke at approximately \$0.02 per share (market value of

F-10

### SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

\$4.8125 per share) on January 10, 1994, at which time the Company recorded the estimated fair market value of \$866,250 as an expense. Mr. Eger sold his interest in TechSource to Mr. A.M. Jenke, a former director and officer of Sheffield, in September 1994.

In March 1994, a total of \$3,121,164 was received from the exercise of 832,324 of the Company's Redeemable Stock Purchase Warrants issued in connection with the Company's February 1993 initial United States public offering of 833,334 units, each such unit consisting of two shares of Common Stock and one Redeemable Common Stock Purchase Warrant exercisable for one share of Common Stock at a price of \$3.75, net of the buyback of 1,010 warrants at \$0.05 per warrant.

In April 1995, gross proceeds of \$3,280,600 were received through the issuance of 410,075 units by private placement at a price of \$8.00 per unit. Each such unit consisted of two shares of the Company's Common Stock and a warrant to purchase one share of common stock at a price of \$5.00 at any time up until and including February 10, 2000. The warrants are redeemable by the Company under certain circumstances.

On January 23, 1995, SMT made a 10% loan (the "SMT Loan") to the Company in the principal amount of \$550,000 pursuant to a demand loan agreement (the SMT Loan Agreement"). Under the terms of the SMT Loan Agreement, SMT could demand the payment in full of the SMT Loan at any time or December 31, 1996 whichever came first. To secure the Company's obligations under the SMT Loan Agreement, the Company granted SMT a security interest in substantially all of the Company's assets, which security interest has since been released. The note evidencing the SMT Loan (the "Original SMT Note") was exchanged pursuant to the terms of the SMT Loan Agreement for a new note (the "SMT Convertible Note") that permitted the holder to exchange the SMT Convertible Note (in whole or in part) into 200,000 shares of Common Stock. In addition, the SMT Loan Agreement required the Company upon issuance of the SMT Convertible Note to issue to SMT warrants (the "SMT Warrants") to acquire 200,000 shares of Common Stock at any time within five years after the date of issue for a price of \$4.00 per share. The SMT Warrants are redeemable by the Company for \$4.00 per share at any time after the price of the Common Stock exceeds an average of \$6.00 per share for 20 business days. SMT was granted certain registration rights with respect to the Common Stock issuable to SMT upon conversion of the SMT convertible Note and SMT Warrants. By letter dated June 1, 1995, SMT exercised its right to convert the SMT Convertible Note into 200,000 shares of Common Stock and subsequently assigned the right to such shares to an unaffiliated third party.

In July 1995, the Company completed a private placement of 1,375,000 units

to accredited investors at a price of \$4.00 per unit for gross proceeds of \$5,500,000. Each such unit consists of one share of the Company's Common Stock and a warrant to purchase one share of common stock at a price of \$4.50 at any time up until and including February 10, 2000. The warrants are redeemable by the Company under certain circumstances.

On April 30, 1996, the Company completed its warrant discount program through which the Company offered holders of warrants issued in private placements completed in 1995 the opportunity to exercise such warrants at up to a 121/2 % discount from the actual exercise prices of such warrants. A total of \$5.6 million was received from the exercise of such warrants with the related issuance of 1,373,250 shares of common stock.

### 5. STOCK OPTIONS AND WARRANTS

The 1993 Stock Option Plan was adopted by the Board of Directors in August 1992 and approved by the shareholders at the annual meeting in December 1993. An amendment to the Plan received shareholder approval on March 15, 1995. Under the Stock Option Plan, the maximum aggregate number of shares which may be optioned and sold is 1,000,000 shares of common stock. The Stock Option Plan permits the grant to employees and officers of the Company of both incentive stock options and non-statutory stock options. The Stock Option Plan is administered by the Board of Directors or a committee of the Board, which determines the persons to whom options will be granted and the terms thereof, including the exercise price, the number of shares subject to each option, and the exercise by granted under the Stock Option

F-11

### SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Plan must be at least equal to the fair market value on the date of grant in the case of incentive stock options and 85% of the fair market value on the date of grant in the case of incentive stock options and 85% of the fair market value on the date of grant in the case of non-statutory stock options. Options generally expire five years from the date of grant and vest upon continuous employment by the Company for 12 months after the date of grant.

The 1993 Restricted Stock Plan under which shares of the Company are reserved, in such amounts as determined by the Board of Directors, for issuance as part of the total shares reserved under the Stock Option Plan described above, was adopted by the Board of Directors in August 1992 and approved by the shareholders at the annual shareholders meeting in December 1993. The Restricted Stock Plan authorized the grant of a maximum of 150,000 shares of common stock to key employees, consultants, researchers and members of the Company's Scientific Advisory Board. The Restricted Stock Plan is administered by the Board of Directors or a committee of the Board, which determines the person to whom shares will be granted and the terms of such share grants. As of the date hereof, no shares have been granted under the 1993 Restricted Stock Plan.

The 1996 Directors Stock Option Plan was adopted by the Board of Directors and approved by the shareholders on June 20, 1996. Under the Stock Option Plan, the maximum aggregate number of shares which may be optioned and sold is 500,000 shares of common stock. The Directors Stock Option Plan granted each eligible director 15,000 stock options. To the extent that shares remain available, any new directors shall receive the grant of an Option to purchase 25,000 shares. To the extent that Shares remain available under the plan, on January 1 of each year commencing January 1, 1997, each eligible director shall be granted an option to purchase 15,000 shares. The exercise price of all options granted under the Directors Stock Option Plan shall be the fair market value at the date of the grant. Options generally expire five years from the date of grant. As of the December 31, 1996, 45,000 shares have been granted under the 1996 Directors Stock Option Plan.

At the annual meeting of stockholders of the Company held on January 26, 1995, the company's shareholders approved an increase in the number of shares of common stock available for issuance pursuant to the Company's 1993 Stock Option Plan from 250,000 shares to 500,000 shares.

On January 23, 1995, the Company granted stock purchase warrants to purchase 200,000 shares of the Company's common stock issuable upon conversion of an exchangeable demand note to a financial advisor. In June 1995, such warrants were exercised for 200,000 shares of the Company's Common Stock.

On February 13, 1995, the Company granted options to purchase a total of 200,000 shares of the Company's common stock to four new members of the Board of Directors at an exercise price of \$4.00 which approximated fair market value.

At the annual meeting of stockholders of the Company held on June 20, 1996, the Company's shareholders approved an increase in the number of shares available for issuance pursuant to the Company's 1993 Stock Option Plan from 500,000 shares to 1,000,000 shares.

FASB 123 requires pro forma information regarding net income and earnings per share as if the Company has accounted for its stock options and warrants granted subsequent to December 31, 1994, under the fair value method of FASB 123. The fair value of these stock options and warrants is estimated at the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions for 1996 and 1995: risk-free interest of 6.23%, 6.13%, 6.00% and 5.57%; expected volatility of 0.60; expected option life of one to four years from vesting and an expected dividend yield of 0.0%.

F-12

SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For purposes of pro forma disclosures, the estimated fair value of the stock options and warrants is amortized to expense over the options' vesting period. The Company's pro forma information is as follows:

1996 1995

----

Pro forma net loss......\$ 8,500,149 \$ 8,993,554 Pro form net loss per share of common stock... \$ 0.79 \$ 1.10

Because FASB 123 is applicable only to equity awards granted subsequent to December 31, 1994, its pro forma effect will not be fully reflected until 1998.

Transactions involving stock options and warrants are summarized as follows:

	1996	1995	
Common S	Average Con Stock Exercise	Weighted  Meighted  Meighted  Neighted  Neight	rcise
Outstanding, January 1           Granted	4,922 5.52 70,000 3.77 42,501 3.76	3,091,408 4.0 0 0 345,500 3.5	<del>63</del> <del>51</del>
Outstanding3,6	)33,755 4.49 	<del></del>	<del>1.02</del>
— Exercisable at end of year	2,094,833 	——————————————————————————————————————	<del>)</del>
<del>- Weighted a</del>	verage fair value	<del>-of</del>	
options granted during the ye	ar \$2	<del>2.30                                    </del>	<del>2.30</del>

Stock Options outstanding at December 31, 1996 are summarized as follows:

		verage V	ighted Veighted
Range of	Outstanding	Remainir	ig Average
Exercise	Options at	Contractual	Life Exercise
Prices	Dec. 31, 1996	(Yrs.)	Price
 		1.06 2 2.35	\$ 1.95
, ,	• •		,
<del>\$5.06 - \$8.2</del>	<del>5 854,503</del>	<del>3.48</del>	<del>\$ 6.07</del>
<del>\$ .73 - \$8.2</del> 5	<del>5 3,033,755</del>	<del>2.54</del>	<del>\$ 4.49</del>

### SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

During the period January 1, 1995 through December 31, 1996, the exercise prices of options and warrants issued by the Company were as follows:

	Number of	Exercise
Year	Options/War	rants Price
1995	3,091,408	\$3.25 - 5.00
1996	1,014,922	\$3.381-98.25

At December 31, 1996, a total of 829,000 shares were available for future grants under the 1993 Stock Option Plan, the 1993 Restricted Stock Plan, and the 1996 Directors Stock Option Plan.

#### 6. RESEARCH AND DEVELOPMENT AGREEMENTS

On May 31, 1996, the Company obtained an exclusive, worldwide right and license with Baylor College of Medicine. The License Agreement gives the Company an exclusive license to inventions and discoveries relating to ps20/Urogenital Sinus Derived Growth Inhibitory Factor. The agreement requires the Company to pay Baylor College 30% of gross compensation received for licensed products covered by a valid claim and 10% of gross compensation not covered by a valid claim for a period of ten years.

On June 1, 1996, the Company entered into a Research Agreement with Children's Hospital of Boston, MA. Under the agreement, Children's Hospital has agreed to perform certain scientific research, under the direction of principal investigator Dr. Wayne I. Lencer, related to the discovery, manufacturing and novel uses of certain imidazoles, their metabolites and analogues thereof, and other related compounds. The agreement requires the Company to pay \$200,050 for related research and related equipment on an agreed upon payment schedule through March 1997, subject to extensions upon the occurrence of certain events.

This agreement also grants the Company an exclusive option to obtain a world-wide license under the Background Technology, Research Technology, Patent Rights and Research Patent rights. Under this agreement the Company has funded \$143,663 through December 31, 1996.

In July of 1996 the Company entered into a sub-license agreement with SEQUUS Pharmaceuticals, Inc. ("SEQUUS") whereby the Company granted an exclusive sub-license to SEQUUS for the continued development and commercialization of the Liposome-CD4 technology. In connection with the signing of the sub-license agreement, the Company received a license issue fee payment from SEQUUS in the form of SEQUUS common stock which is classified as marketable securities in the Company's December 31, 1996 balance sheet. The Company is also entitled to receive milestone payments and royalty payments based on clinical trial results and future product sales, if any which utilize the sub-licensed technology.

On August 22, 1996, the Company entered into Amendment #2 to the Research Agreement, dated August 22, 1994, with The President and Fellows of Harvard College. Under the agreement, Harvard has agreed to conduct research under the direction of principal investigator Dr. Jose A. Halperin to conduct laboratory and animal studies for the potential use of Clotrimazole and to screen new proprietary analogues and/or drugs that potentially have the same effect as Clotrimazole. The agreement requires the Company to pay \$992,232 for related research and equipment on an agreed upon payment schedule through July 1996, subject to extensions upon the occurrence of certain events. Under this amendment and its previous agreement the Company has funded \$985,404 for the year ended December 31, 1996.

In October of 1996, the Company entered into an amendment of a Research and Option License Agreement dated June 17, 1995. The Amendment was effective as of June 17, 1995 for a two year period through June 17, 1997. The Agreement allows the Company to obtain an exclusive worldwide license from the French National Institute of Health and Medical Research ("INSERM") to an HIV-AIDS vaccine being developed by Inserm. Under this

F-14

### SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Agreement the Company has agreed to pay \$100,000 for related research through April 1997. In connection with this research, the Company has entered into an agreement with Association Claude Bernard, also in October of 1996. The agreement requires the Company to pay \$300,000 for the related research and supplies on an agreed upon payment schedule through April 1997. Under both agreements, the Company has funded \$300,000 through December 31, 1996.

On November 1, 1996, the Company entered into Amendment #6 to the Research Agreement, dated June 1, 1995 with Children's Hospital of Boston, MA. Under the agreement, Children's Hospital has agreed to perform certain research under the direction of principal investigator Dr. Carl Brugnara on the study of analogues of Clotrimazole and/or Clotrimazole metabolites. The agreement requires the Company to pay \$224,468 for related research and equipment on an agreed upon payment schedule through July 1997, subject to extensions upon the occurrence of certain events. Also on November 1, 1996, the Company elected to exercise its option to a license agreement related to the Research Agreement. This agreement grants the Company the exclusive worldwide license on the Background Technology and the Research Technology derived from the agreement. Under this amendment and its previous agreement, the Company has funded \$180,153 for the year ended December 31, 1996.

In 1996, the Company entered into quarterly Research and Consulting Agreements with Pharm-Eco Laboratories, Inc. for the development and synthesis of novel compounds related to the Ion Pharmaceuticals Technologies. The agreements require the Company to pay \$175,000 plus expenses each quarter for related research and consulting. Under these agreements the Company has funded \$773,522 for the year ended December 31,

### 7. RELATED PARTY TRANSACTIONS

On January 23, 1995, SMT made a \$550,000 loan to the Company pursuant to a demand loan agreement. In June 1995, SMT exercised its right to convert the SMT convertible note to 200,000 shares of common stock and subsequently assigned the right to such shares to an unaffiliated third party in exchange for repayment of the loan and interest. In addition, the Company, as required under the Note, issued warrants to acquire 200,000 shares of common stock at any time within five years after the date of issuance at a price equal to \$4.00 per share (See Note 4). Dr. Stephen Sohn, a member of the Board of Directors of the Company, is also general partner of SMT.

### 8. INCOME TAXES

The Company utilizes the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax asset at December 31, 1996 which is considered noncurrent, are as follows:

### Deferred tax assets:

Net operating loss carryforwards \$ 8,800,000 Capitalized start-up costs for tax purposes 578,000 Deferred tax asset valuation allowance (9,378,000)

Net deferred tax asset \$ -

The valuation allowance for deferred tax assets as of December 31, 1995, was \$6,678,000. The net change in the total valuation allowance for the year ended December 31, 1996, was an increase of \$2,700,000. At December 31, 1996, the Company has net operating loss carryforwards of approximately \$24,400,000 for tax purposes which are available to offset federal taxable income, if any, through 2011. An ownership change pursuant to Section 382 of the

F-15

SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Internal Revenue Code occurred in April 1995 as a result of a private placement of the Company's common stock and warrants. Accordingly, utilization of the Company's pre-change net operating loss carryforward (approximately \$13,600,000) is restricted to approximately \$2,220,000 per year, and the related deferred tax assets have been fully reserved.

### 9. SUBSEQUENT EVENTS

On February 28, 1997, the Company closed a private offering of 35,000 shares of 7% Series A Cumulative Convertible Redeemable Preferred Stock at a purchase price of \$100.00 per Share, which raised total gross proceeds of \$3.5 million. Each investor is also entitled to receive five-year Warrants to purchase Common Stock of the Company equal to 1/3 the number of shares of Common Stock issuable upon conversion of the Preferred Stock. The Warrants will be issued at 110% of the closing bid price per share of the common stock on the closing date. Proceeds will be used for funding research and development, patent prosecution, and for working capital and general corporate purposes, including the possible acquisition of rights in new technologies in the Company's ordinary course of business.

On March 14, 1997, the Company signed a letter of intent to acquire, for stock, Camelot Pharmacal, L.L.C., a privately held emerging pharmaceutical company. As part of the contemplated transaction, Camelot's management team would join the Company. Camelot's product portfolio consists of late-stage development opportunities. The acquisition is expected to be completed by the end of May, 1997. As part of the business combination, Camelot's principals will have the opportunity to invest in the Company by purchasing up to \$5.0 million of common stock at current market prices.

F-16

EX-3.1 2 CERTIFICATE OF INCORPORATION

**EXHIBIT 3.1 TO FORM 10-KSB** 

Certificate of Incorporation of the Company, as Amended

CERTIFICATE OF INCORPORATION

OF

SHEFFIELD MERGER CO.

The undersigned, a natural person, for the purpose of organizing a corporation for conducting the business and promoting the purposes hereinafter stated, under the provisions of subject to the requirements of the laws of the State of Delaware (particularly Chapter 1, Title 8 of the Delaware Code and the acts amendatory thereof and supplemental thereto, and known, identified and referred to as the "General Corporation Law of the State of Delaware"), hereby certifies that:

FIRST: The name of the corporation (hereinafter sometimes called the "Corporation") is Sheffield Merger Co.

SECOND: The address, including street, number, city and county of the registered office of the Corporation in the State of Delaware is 32 Loockerman

Square, Suite L-100, City of Dover 19901, County of Kent; and the name of the registered agent of the Corporation in the State of Delaware at such address is The Prentice-Hall Corporation System, Inc.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

FOURTH: The total number of shares of stock which the Corporation shall have the authority to issue is (i) 15,000,000 shares of Common Stock, \$.01 par value ("Common Stock") and (ii) 1,000,000 shares of Preferred Stock, \$.01 par value ("Preferred Stock").

### A. COMMON STOCK.

- 1. GENERAL. The voting, dividend and liquidation rights of the holders of Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.
- 2. VOTING. The holders of Common Stock are entitled to one vote for each share held at all meetings of stockholders (and written actions in lieu of meetings). There shall be no cumulative voting.
- 3. DIVIDENDS. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any

preferential dividend rights of any then outstanding Preferred Stock.

4. LIQUIDATION. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders after payment of creditors and subject to any preferential and/or participating rights of any then outstanding Preferred Stock.

#### B. PREFERRED STOCK.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by resolution or resolutions providing for the issue of the shares thereof, to determine and fix such voting powers, full or limited, or no voting powers, and such designations, preferences and relative, participating, optional or other special rights and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent not or hereafter permitted by the General Corporation Law of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or junior to the Preferred Stock of any other series to the extent permitted by law. Except as expressly provided elsewhere in this Article FOURTH, no vote of the holders of the Preferred Stock or Common Stock shall be required in connection with the designation or the issuance of any shares of any series of any Preferred Stock

authorized by and complying with the conditions herein, the right to have such being vote being expressly waived by all present and future holders of the capital stock of the Corporation.

FIFTH: The name and the mailing address of the incorporator is as follows:

Gary Weston Olshan Grundman Frome & Rosenzweig 505 Park Avenue New York, New York 10022

SIXTH: The Corporation is to have perpetual existence.

SEVENTH: Whenever a compromise or arrangement is proposed between the Corporation and its creditors or any class of them and/or between the Corporation and its stockholders or any class of them, any court of equitable jurisdiction within the State of Delaware may, on the application in a summary way of the

-2-

Corporation or of any creditor or stockholder thereof or on the application of any receiver or receivers appointed for the Corporation under the provisions of ss.291 of Title 8 of the Delaware Code or on the application of trustees in dissolution or of any receiver or receivers appointed for the Corporation under the provisions of ss.279 of Title 8 of the Delaware Code order a meeting of the creditors or class of creditors, and/or the stockholders or class of stockholders of the Corporation, as the case may be, to be summoned in such manner as the said court directs. If a majority in number representing three fourths in value of the creditors or class of creditors, and/or of the stockholders or class of stockholders of the Corporation, as the case may be, agree to any compromise or arrangement and to any reorganization of the Corporation as consequence of such compromise or arrangement, the said compromise or arrangement and the said reorganization shall, if sanctioned by the court to which the said application has been made, be binding on all the creditors or class of creditors, and/or on all the stockholders or class of stockholders, of the Corporation, as the case may be, and also on the Corporation.

EIGHTH: For the management of the business and for the conduct of the affairs of the Corporation, and in further definition, limitation and regulation of the powers of the Corporation and of its directors and its stockholders or any class thereof, as the case may be, it is further provided:

1. The management of the business and the conduct of the affairs of the Corporation shall be vested in its Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed by, or in the manner provided in, the By-Laws. The phrase "whole Board" and the phrase "total number of directors" shall be deemed to have the same meaning, to wit, the total number of directors which the Corporation would have if there were no

vacancies. No election of directors need be by written ballot.

2. After the original or other By-laws of the Corporation have been adopted, amended, or repealed, as the case may be, in accordance with the provisions of ss.109 of the General Corporation Law of the State of Delaware, and, after the Corporation has received any payment for any of its stock, the power to adopt, amend, or repeal the By-laws of the Corporation may be exercised by the Board of Directors of the Corporation; provided, however, that any provision for the classification of directors of the Corporation for staggered terms pursuant to the provisions of subsection (d) of ss.141 of the General Corporation Law of the State of Delaware shall be set forth in an initial By-law or

-3-

in a By-law adopted by the stockholders entitled to vote of the Corporation unless provisions for such classification shall be set forth in this Certificate of Incorporation.

3. Whenever the Corporation shall be authorized to issue only one class of stock, each outstanding share shall entitle the holder thereof to notice of, and the right to vote at, any meeting of stockholders. Whenever the Corporation shall be authorized to issue more than one class of stock, no outstanding share of any class of stock which is denied voting power under the provisions of the Certificate of Incorporation shall entitle the holder thereof to the right to vote at any meeting of stockholders except as the provisions of paragraph (2) of subsection (b) of ss.242 of the General Corporation Law of the State of Delaware shall otherwise require; provided, that no share of any such class which is otherwise denied voting power shall entitle the holder thereof to vote upon the increase or decrease in the number of authorized shares of said class.

NINTH: The personal liability of the directors of the Corporation is hereby eliminated to the fullest extent permitted by paragraph (7) of subsection (b) of ss.102 of the General Corporation Law of the State of Delaware, as same may be amended and supplemented.

TENTH: The Corporation shall, to the fullest extent permitted by ss.145 of the General Corporation Law of the State of Delaware, as the same may be amended and supplemented, indemnify any and all persons whom it shall have power to indemnify under said section from and against any and all of the expenses, liabilities or other matters referred to in or covered by said section, and the indemnification provided for herein shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any By-Law, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in his official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director,

officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

ELEVENTH: From time to time any of the provisions of this Certificate of Incorporation may be amended, altered or repealed, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted in the

-4-

manner and at the time prescribed by said laws, and all rights at any time conferred upon the stockholders of the Corporation by this Certificate of Incorporation are granted subject to the provisions of this Article ELEVENTH.

Signed on September 20, 1993

/s/ Gary Weston

Gary Weston, Incorporator

-5-

Certificate of Amendment

of

Certificate of Incorporation

of

SHEFFIELD MERGER CO.

Under Section 242 of the General Corporation Law

It is hereby certified that:

- 1. The name of the corporation is Sheffield Merger Co. (the "Corporation").
- 2. The certificate of incorporation of the Corporation is hereby amended by striking out Article FOURTH thereof and by substituting in lieu of said Article the following new Article FOURTH:

"FOURTH: The total number of shares of stock which the Corporation shall have the authority to issue is (i) twenty million (20,000,000) shares of Common Stock, \$.01 par value ("Common Stock") and (ii) 3,000,000 shares of Preferred Stock, \$.01 par value ("Preferred Stock").

COMMON STOCK.

GENERAL. The voting, dividend and liquidation rights of the holders of Common Stock are subject to and qualified by the rights of the

holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

VOTING. The holders of Common Stock are entitled to one vote for each share held at all meetings of stockholders (and written actions in lieu of meetings). There shall be no cumulative voting.

DIVIDENDS. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend rights of any then outstanding Preferred Stock.

LIQUIDATION. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation

available for distribution to its stockholders after payment of creditors and subject to any preferential and/or participating rights of any outstanding Preferred Stock.

### PREFERRED STOCK.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by resolution or resolutions providing for the issue of the shares thereof, to determine and fix such voting powers, full or limited, or no voting powers, and such designations, preferences and relative, participating, option or other special rights and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent now or hereafter permitted by the General Corporation Law of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or junior to the Preferred Stock of any other series to the extent permitted by law. Except as expressly provided elsewhere in this Article FOURTH no vote of the holders of the Preferred Stock or Common Stock shall be required in connection with the designation or the issuance of any shares of any series of any Preferred Stock authorized by and complying with the conditions herein, the right to have such vote being expressly waived by all present and future holders of the capital stock of the Corporation."

3. The amendment of the certificate of incorporation herein certified has been duly adopted in accordance with the provisions of Sections 228 and 242 of the General Corporation Law of the State of Delaware.

By: /s/ Douglas R. Eger
----Douglas R. Eger, Chairman

/s/ Harvey L. Lellman

\_\_\_\_\_

Harvey L. Kellman, Secretary

-2-

CERTIFICATE OF MERGER

OF

SHEFFIELD MEDICAL TECHNOLOGIES INC.

INTO

SHEFFIELD MERGER CO.

(Under Section 252 of the General Corporation Law of the State of Delaware)

\_\_\_\_\_

Sheffield Merger Co., a Delaware corporation, hereby certifies as follows:

FIRST: The name and state of incorporation of each of the constituent corporations of the merger is as follows:

Name State of Incorporation

----

Sheffield Medical Technologies Inc. Wyoming

Sheffield Merger Co. Delaware

SECOND: An Agreement of Merger has been approved, adopted, certified, executed and acknowledged by each of the constituent corporations in accordance with Section 252(c) of the General Corporation Law of the State of Delaware.

THIRD: The name of the surviving corporation (the "Surviving Corporation") is Sheffield Merger Co.

FOURTH: The Certificate of Incorporation of the Surviving Corporation is hereby amended by striking out Article FIRST thereof and by substituting in lieu of said Article the following new Article FIRST as follows:

FIRST: The name of the corporation (hereinafter sometimes called the "Corporation") is Sheffield Medical Technologies Inc.

FIFTH: An executed copy of the Agreement of Merger is on file at the

principal place of business of the Surviving Corporation, 666 Fifth Avenue, New York, New York 10103, and a copy of the Agreement of Merger will be furnished by the Surviving Corporation, on request and without cost, to any stockholder of either of the constituent corporations.

SIXTH: The authorized capital stock of Sheffield Medical Technologies Inc., a Wyoming corporation, consists of

50,000,000 shares of common stock, no par value, and 10,000,000 shares of preferred stock, no par value.

SEVENTH: This Certificate of Merger shall be effective upon filing with the Secretary of State of the State of Delaware.

IN WITNESS WHEREOF, Sheffield Merger Co. has caused this Certificate of Merger to be executed in its corporate name by its Chairman of the Board and attested by its Secretary this 12th day of June, 1995.

SHEFFIELD MERGER CO.

By: /s/ Douglas R. Eger

Douglas R. Eger

Chairman of the Board

[SEAL]

Attest:

By: /s/ Kathleen Rawlinson

Kathleen Rawlinson Secretary

-2-

**CERTIFICATE OF AMENDMENT** 

of

**CERTIFICATE OF INCORPORATION** 

of

SHEFFIELD MEDICAL TECHNOLOGIES INC.

Under Section 242 of the General Corporation Law

It is hereby certified that:

- 1. The name of the corporation is Sheffield Medical Technologies Inc. (the "Corporation").
- 2. The certificate of incorporation of the Corporation is hereby amended to increase the authorized shares of common stock of the Corporation by striking out Article FOURTH thereof and by substituting in lieu of said Article FOURTH the following new Article FOURTH:

"FOURTH: The total number of shares of stock that the Corporation shall have the authority to issue is (i) thirty million (30,000,000) shares of Common Stock, \$.01 par value ("Common Stock"), and (ii) three million (3,000,000) shares of Preferred Stock, \$.01 par value ("Preferred Stock").

### COMMON STOCK.

GENERAL. The voting, dividend and liquidation rights of the holders of Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

VOTING. The holders of Common Stock are entitled to one vote for each share held at all meetings of stockholders (and written actions in lieu of meetings). There shall be no cumulative voting.

DIVIDENDS. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend rights of any then outstanding Preferred Stock.

LIQUIDATION. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation

available for distribution to its stockholders after payment of creditors and subject to any preferential and/or participating rights of any outstanding Preferred Stock.

### PREFERRED STOCK.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by resolution or resolutions providing for the issue of the shares thereof, to determine and fix such voting powers, full or limited, or no voting powers, and such designations, preferences and relative, participating, option or other special rights and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent now or hereafter permitted by the General Corporation Law of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or junior to the Preferred Stock of any other series to the extent permitted by law. Except as expressly provided elsewhere in this Article FOURTH no vote of the holders of the Preferred Stock

or Common Stock shall be required in connection with the designation or the issuance of any shares of any series of any Preferred Stock authorized by and complying with the conditions herein, the right to have such vote being expressly waived by all present and future holders of the capital stock of the Corporation."

3. The amendment of the certificate of incorporation herein certified has been duly adopted in accordance with the provisions of Sections 228 and 242 of the General Corporation Law of the State of Delaware.

Signed on February 5, 1997

SHEFFIELD MEDICAL TECHNOLOGIES INC.

By: /s/ George Lombardi

-----

George Lombardi Vice President and Chief Financial Officer

Attest:

/s/ Jacqueline Bova - -----

Jacqueline Bova Assistant Secretary

-2-

CERTIFICATE OF DESIGNATION

OF

SERIES A CUMULATIVE CONVERTIBLE REDEEMABLE

PREFERRED STOCK

OF

SHEFFIELD MEDICAL TECHNOLOGIES INC.

(Pursuant to Section 151 of the General Corporation Law of the State of Delaware)

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Sheffield Medical Technologies Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), hereby certifies that the following resolution was adopted by the Board of Directors of the Corporation:

RESOLVED, that pursuant to the authority expressly granted to and vested in the Board of Directors of the Corporation (the "Board of Directors") by the provisions of the Certificate of Incorporation of the Corporation (the "Certificate of Incorporation"), there hereby is created, out of the 3,000,000 shares of preferred stock of the Corporation authorized in Article FOURTH of the Certificate of Incorporation (the "Preferred Stock"), a series of Preferred Stock consisting of 40,800 shares, which series shall have the following powers, designations, preferences and relative, participating, optional or other rights, and the following qualifications, limitations and restrictions (in addition to

the powers, designations, preferences and relative, participating, optional or other rights, and the qualifications, limitations and restrictions, set forth in the Certificate of Incorporation which are applicable to the Preferred Stock).

Section 1. DESIGNATION AND AMOUNT. The shares of such series shall be designated as "Series A Cumulative Convertible Redeemable Preferred Stock" (the "Series A Preferred Stock") and the authorized number of shares constituting such series shall be 40,800. The par value of the Series A Preferred Stock shall be \$.01 per share.

### Section 2. DIVIDENDS.

Subject to Section 4(d), the holders of shares of the Series A Preferred Stock will be entitled to receive, when, as and if declared by the Board of Directors, cumulative stock dividends on the shares of the Series A Preferred Stock, payable in shares of the Corporation's common stock, \$.01 par value per share ("Common Stock"), at the rate per share of 7.0% per annum

of the original \$100.00 purchase price per share of the Series A Preferred Stock, and no more. Such stock dividends shall be cumulative from the date of the initial issuance of shares of Series A Preferred Stock (the "Closing Date") or the most recent date on which the full amount of accrued stock dividends have been paid, as the case may be, on the Series A Preferred Stock by the Corporation. Subject to, and as provided in, Section 4, the Corporation shall pay all cumulative stock dividends on the shares of Series A Preferred Stock held by a holder on the Conversion Date (as defined below) in respect of such holder's election to convert Series A Preferred Stock. The number of shares of Common Stock to be issued as cumulative stock dividends on any such Conversion Date shall equal the cash value of such cumulative dividends divided by the current market price per share of Common Stock (determined as provided in Section 5) as of such Conversion Date. The cash value of stock dividends payable on shares of Series A Preferred Stock for any full annual dividend period shall be computed by multiplying the original \$100.00 purchase price per share by 7.0%. The cash value of dividends payable on shares of the Series A Preferred Stock for any period less than a full annual dividend period shall be computed on the basis of a 360-day year of twelve 30-day months and the actual number of days elapsed in the period for which payable.

If stock dividends are not paid in full, or declared in full, upon the shares of the Series A Preferred Stock and shares of any other preferred stock ranking on a parity as to payment of stock dividends with the Series A Preferred Stock, all dividends declared upon shares of the Series A Preferred Stock and any other preferred stock ranking on a parity as to payment of dividends with the Series A Preferred Stock shall be paid or declared PRO RATA so that in all cases the amount of dividends paid or declared per share on the Series A Preferred Stock and such other shares of preferred stock ranking on a parity as to payment of dividends with the Series A Preferred Stock shall bear to each other the same ratio that accumulated stock dividends per share, including dividends accrued or in arrears, if any, on the shares of the Series A Preferred Stock and such other shares of preferred stock bear to each other. Except as provided in the preceding sentence, unless full cumulative stock dividends on the shares of the Series A Preferred Stock have been paid or declared in full, no dividends (other than dividends in shares of Common Stock, or in shares of any other capital stock of the Corporation ranking junior to the Series A Preferred Stock as to payment of dividends and distribution of assets upon

liquidation) shall be paid or declared and set aside for payment or other distribution upon the Common Stock or, except as provided above, on any other capital stock of the Corporation ranking junior to or on a parity with the Series A Preferred Stock as to dividends, nor shall any shares of Common Stock or shares of any other capital stock of the Corporation ranking junior to or on a parity with the Series A Preferred Stock as to dividends be redeemed, purchased or otherwise acquired for any consideration (or any payment made to or available for a sinking fund for the redemption of any such

-2-

shares) by the Corporation or any subsidiary of the Corporation (except by conversion into or exchange for shares of capital stock of the Corporation ranking junior to the Series A Preferred Stock as to dividends and distribution of assets upon liquidation). Holders of shares of the Series A Preferred Stock shall not be entitled to any dividends, whether payable in capital stock, cash or property, in excess of full accrued and cumulative stock dividends as herein provided. No interest or sum of money in lieu of interest shall be payable in respect of any stock dividend payment or payments on the shares of the Series A Preferred Stock that may be in arrears; provided, however, that if, on an applicable Conversion Date (as defined herein), stock dividends that would have been payable on such date are not paid solely due to the failure of the Corporation's Board of Directors to declare such dividends, then the rate of conversion of the Series A Preferred Stock to be converted on such Conversion Date shall be adjusted so that the holders would receive the same amount of shares of Common Stock on such Conversation Date as such holder would have received if the Corporation's Board of Directors had timely declared such stock dividends.

The terms "accrued dividends," "dividends accrued" and "dividends in arrears," whenever used herein with reference to shares of preferred stock shall be deemed to mean an amount which shall be equal to dividends thereon at the applicable annual dividend rates per share for the respective series thereof from the date or dates on which such dividends commence to accrue to the applicable payment date less the amount of all dividends paid, or declared in full and sums set aside for the payment thereof, upon such shares of preferred stock.

### Section 3. LIQUIDATION RIGHTS.

(a) In the event of any liquidation, dissolution or winding up of the affairs of the Corporation, whether voluntary or otherwise, after payment or provision for payment of the debts and other liabilities of the Corporation, the holders of shares of the Series A Preferred Stock shall be entitled to receive, in cash, out of the remaining net assets of the Corporation (whether from capital or from earnings available for distribution to shareholders), the amount of One Hundred Dollars (\$100.00) for each share of the Series A Preferred Stock, plus the cash value determined in accordance with Section 2 above of all stock dividends accrued and unpaid at the applicable rate on each such share up to the date fixed for distribution, before any distribution shall be made to the holders of shares of Common Stock or any other capital stock of the Corporation ranking (as to any such distribution) junior to the Series A Preferred Stock. If upon any liquidation, dissolution or winding up of the Corporation, the assets distributable among the holders of shares of the Series A Preferred Stock and all other classes and series of preferred stock ranking (as to any such

distribution) on a parity with the Series A Preferred Stock are insufficient to permit the payment in full to the holders of all such shares of

-3-

all preferential amounts payable to all such holders, then the entire assets of the Corporation thus distributable shall be distributed ratably among the holders of the shares of the Series A Preferred Stock and such other classes and series of preferred stock ranking (as to any such distribution) on a parity with the Series A Preferred Stock in proportion to the respective amounts that would be payable per share if such assets were sufficient to permit payment in full.

- (b) For purposes of this Section 3, a distribution of assets in any dissolution, winding up or liquidation shall not include (i) any consolidation or merger of the Corporation with or into any other corporation or other entity, (ii) any dissolution, liquidation, winding up or reorganization of the Corporation immediately followed by reincorporation of another corporation or other entity or (iii) a sale or other disposition of all or substantially all of the Corporation's assets to another corporation or other entity; PROVIDED, HOWEVER, that, in each case, effective provision is made in the certificate of incorporation of the resulting and surviving corporation or otherwise for the protection of the relative rights of the holders of shares of the Series A Preferred Stock.
- (c) After the payment of the full preferential amounts provided for herein to the holders of shares of the Series A Preferred Stock or funds necessary for such payment have been set aside in trust for the holders thereof, such holders shall be entitled to no other or further participation in the distribution of the assets of the Corporation.

### Section 4. CONVERSION AND REDEMPTION OF SERIES A PREFERRED STOCK.

(a) Each holder of Series A Preferred Stock shall have the right, exercisable at any time and from time to time during the period commencing on the date that is ninety (90) days after the Closing Date and ending on the date that is two years after the Closing Date (the "Mandatory Conversion Date"), to convert any or all of the Series A Preferred Stock owned by such holder for shares of Common Stock, at a conversion rate determined by multiplying the number of shares of Series A Preferred Stock to be converted by a fraction, the numerator of which shall equal one hundred (100) and the denominator of which (a "Denominator") shall equal (i) the current market price per share of the Common Stock (determined as provided in Section 5) as of the Closing Date (such current market price being referred to herein as the "Closing Price"), if the applicable Conversion Date (as defined below) occurs on or before the 119th day following the Closing Date, (ii) the lessor of (A) 100% of the Closing Price or (B) the current market price per share of Common Stock (determined as provided in Section 5) as of the applicable Conversion Date, if the applicable Conversion Date occurs on or after the 120th day after the Closing Date and on or before the 179th day after the Closing Date or (iii) the lesser of (A) 100% of the Closing Price

-4-

and (ii) 85% of the current market price per share of Common Stock (determined as provided in Section 5) as of the applicable Conversion Date for any

Conversion Date occurring on or after the 180th day after the Closing Date, subject to adjustment and the conditions described herein.

(b) (i) Any holder of shares of the Series A Preferred Stock electing to convert shares thereof pursuant to Section 4(a) shall (A) transmit by facsimile, for receipt on the proposed date of conversion, a copy of a fully completed and executed notice of conversion ("Notice of Conversion") to the Corporation at the office of the Corporation or its designated transfer agent (the "Transfer Agent"), in the form attached as Exhibit A hereto, and (B) surrender to a common carrier for delivery to the office of the Corporation or the Transfer Agent, the original certificates representing the Series A Preferred Stock being converted (the "Preferred Stock Certificates"), duly endorsed for cancellation. The Corporation shall, upon the timely written request of a holder of shares of the Series A Preferred Stock, promptly provide in writing to such holder, via facsimile transmission, the appropriate numbers for the Corporation and the Transfer Agent to be used to effect an election in accordance with this subparagraph (i).

(ii) Upon receipt by the Corporation of transmission of a facsimile copy of such Notice of Conversion, the Corporation shall as soon as practicable (but in no event later than 12:00 noon on the next business day after receipt thereof) send, via facsimile, a confirmation of receipt of such Notice of Conversion to such holder, which shall specify that the Notice of Conversion has been received and the name and telephone number of a contact person at the Corporation whom the holder should contact regarding information related to such conversion. Upon receipt by the Corporation or the Transfer Agent of the certificate(s) representing the shares of Series A Preferred Stock to be converted pursuant to such Notice of Conversion (or an indemnification undertaking in form and substance reasonably satisfactory to the Corporation with respect to such shares in the case of their loss, theft or destruction) together with the originally executed and completed Notice of Conversion (such date of the Corporation's receipt of all such documents being referred to herein as the "Final Receipt Date"), the Corporation or Transfer Agent (as applicable) shall, as soon as possible on or after the applicable Final Receipt Date, but in any event within two (2) business days after the applicable Final Receipt Date, issue and surrender to a common carrier for either overnight delivery (if delivery is to be made inside the United States) or two (2) day delivery (if delivery is to be made outside the United States) to such holder at the address specified in the Notice of Conversion, a certificate for the number of shares of Common Stock to which such holder shall be entitled as in respect of the related conversion. In the

-5-

event of a partial conversion of shares of Series A Preferred Stock represented by certificate(s) delivered to the Corporation in respect of any conversion, the Corporation will return to the applicable holder a certificate representing such holder's remaining shares of Series A

Preferred Stock that were not so converted. In the case of any dispute between the Corporation and such holder as to the calculation of the applicable Conversion Price evidenced by a notice to such effect (a "Dispute Notice") delivered to the Corporation by such holder prior to the Final Receipt Date, the Corporation shall promptly issue to such holder the number of shares of Common Stock that is not disputed and shall submit the disputed calculations to its outside accountant within two (2) business days after the Final Receipt Date. The Corporation shall cause such accountant to perform the calculations and notify the Corporation and the holder of the results no later than two (2) business days after the date that such outside accountant is delivered a copy of such holder's Dispute Notice by the Corporation pursuant to the preceding sentence. Such accountant's calculation shall be deemed conclusive and binding on the Corporation and such holder absent manifest error.

(iii) The effective date of a particular conversion (the "Conversion Date") other than pursuant to Section 4(c) shall be deemed to be the date on which the advance copy of the related Notice of Conversion in respect of such conversion is received by either the Corporation or the Transfer Agent by facsimile transmission as provided in paragraph (ii) above, provided that (A) such advance copy of the Notice of Conversion is transmitted by facsimile to and received by the Corporation before 11:59 p.m., New York City time, on such date and (B) the original certificates representing the Series A Preferred Stock to be converted (or an indemnification undertaking in form and substance reasonably satisfactory to the Corporation with respect to such shares in the case of their loss, theft or destruction), together with the originally executed and completed Notice of Conversion, are surrendered by depositing such certificates and Notice of Conversion with a common carrier, as provided above, and received by the Corporation or the Transfer Agent on or before the second (2nd) business day following the date that the related advance copy of the related Notice of Conversion is received by the Corporation or the Transfer Agent. In the event that all such documents are not received within two (2) business days after such date, such Notice of Conversion shall be deemed null and void and no conversion of Series A Preferred Stock shall be effected thereby.

(iv) As of any Conversion Date, the person or persons entitled to receive the shares of the Common Stock issuable upon the related conversion of shares of Series A Preferred Stock pursuant to this Section 4 shall be treated

-6-

for all purposes as the record holder or holders of the shares of Common Stock issuable in respect of such conversion on said date. From and after the Conversion Date in respect of such shares of Series A Preferred Stock, all such shares of Series A Preferred Stock shall be deemed to have been converted into shares of Common Stock at the applicable conversion rate, all stock dividends on such shares of the Series A Preferred Stock shall cease to accrue, and all rights of the holders thereof as holders of Series A Preferred Stock, except the right to receive all accrued and unpaid stock dividends to such Conversion Date at the applicable rate for such shares of Series A Preferred Stock and the right to receive certificates representing

shares of Common Stock issuable upon conversion of such shares (including, without limitation, with respect to such stock dividends), shall cease and terminate, such shares of Series A Preferred Stock shall not thereafter be transferred (except with the consent of the Corporation) on the books of the Corporation and such shares shall not be deemed to be outstanding for any purpose whatsoever. The rights of a holder to elect to convert shares of Series A Preferred Stock under this Section 4(a) and 4(b) shall cease and terminate immediately after the Mandatory Conversion Date.

(c) Subject to Section 4(d), to the extent that any shares of Series A Preferred Stock held by a holder thereof have not been converted pursuant to Sections 4(a) and 4(b) as of the Mandatory Conversion Date, such holder shall be deemed to have elected to convert such remaining shares of Series A Preferred Stock as of the Mandatory Conversion Date (without any action required by such holder) and the Corporation shall issue shares of Common Stock to such holder and satisfy its other obligations under Section 4(a) and (b) as if such holder had elected to convert such remaining shares of Series A Preferred Stock pursuant to Sections 4(a) and 4(b) as of the Mandatory Conversion Date.

(d) Notwithstanding anything herein to the contrary, in the event that (i) a holder of Series A Preferred Stock elects (or is deemed to have elected) to convert shares of Series A Preferred Stock pursuant to Sections 4(a) and 4(b) or pursuant to Section 4(c) for which a Denominator that is less than the Closing Price is utilized in the calculation (pursuant to Section 4(a)) of the number of shares of Common Stock to be issued in such conversion and (ii) such conversion would result in such holder receiving, as a result of such conversion, a number of shares of Common Stock that, together with other shares of Common Stock issued to such holder (or any affiliate of such holder) in any prior conversion(s) of Series A Preferred Stock that utilized a Denominator that was less than the Closing Price in the calculation (pursuant to Section 4(a)) of the number of shares of Common Stock to be issued in such conversion, would equal or exceed twenty percent (20%) of the shares of Common Stock of the Corporation outstanding on the Closing Date (the "Threshold Amount"), the Corporation shall (i) issue to such holder the

-7-

number of shares of Common Stock otherwise required to be issued to such holder as a result of such conversion (including any shares of Common Stock representing cumulative stock dividends accrued to the applicable Conversion Date pursuant to Section 2) LESS the number of shares of Common Stock otherwise issuable to such holder pursuant to such conversion in excess of the Threshold Amount (the "Excess Shares") and (ii) shall remit to such holder, in lieu of the Excess Shares, an amount of cash equal to the number of Excess Shares multiplied by the current market price per share of Common Stock (determined as provided in Section 5) determined as of such Conversion Date. Upon such issuance of Common Stock and payment of such cash to the holder in lieu of the Excess Shares, the Corporation's obligations to such holder arising as a result of such conversion (including the Corporation's obligation to pay cumulative stock dividends through the applicable Conversion Date) shall be deemed fully satisfied.

(e) No fractional shares of Common Stock or scrip representing fractional shares shall be issued upon conversion of shares of the Series A Preferred Stock pursuant to this Section 4. If more than one share of the Series

A Preferred Stock shall be surrendered for conversion by the same holder, the number of full shares of Common Stock which shall be issuable upon conversion thereof shall be computed on the basis of the aggregate number of shares of the Series A Preferred Stock so surrendered. Instead of any fractional shares of Common Stock which would otherwise be issuable upon conversion of any shares of the Series A Preferred Stock, the Corporation shall pay a cash adjustment in respect of such fraction in an amount equal to the same fraction of the closing bid price for Common Stock determined as of the last business day preceding the Conversion Date in respect of such shares. The closing bid price for such day shall be the last reported bid price on the American Stock Exchange, or if Common Stock is not listed or admitted to trading on such exchange, on the principal national securities exchange on which Common Stock is listed or admitted to trading or, if not listed or admitted to trading on any national securities exchange, the closing bid price of Common Stock on NASDAQ or any comparable system. If Common Stock is not quoted on NASDAQ or any comparable system, the Board of Directors of the Corporation shall in good faith determine the current market price on such basis as it considers appropriate.

- (f) When shares of Series A Preferred Stock are converted (or deemed converted) by a holder pursuant to this Section 4, the Corporation shall pay any documentary, stamp or similar issue or transfer tax due on the issue of Common Stock upon such conversion.
- (g) The Corporation shall reserve at all times out of the Corporation's authorized but unissued shares of Common Stock a sufficient number of shares of Common Stock to permit the conversion of the then outstanding shares of the Series A Preferred Stock pursuant to this Section 4 and such reserved

-8-

shares shall not be used for any other purpose. All shares of Common Stock which may be issued upon conversion of shares of the Series A Preferred Stock pursuant to this Section 4 shall be validly issued, fully paid and nonassessable. In order that shares of Common Stock may be issued upon conversion of shares of the Series A Preferred Stock, the Corporation shall comply with all applicable Federal and State securities laws and use its best efforts to list such shares of Common Stock to be issued upon conversion on each securities exchange on which Common Stock is listed.

- (h) The conversion rate (and the components thereof) in effect at any time for conversion of Series A Preferred Stock into Common Stock pursuant to this Section 4 shall be subject to adjustment from time to time as follows:
  - (i) In the event that the Corporation shall (1) pay a dividend in shares of Common Stock to holders of Common Stock, (2) make a distribution in shares of Common Stock to holders of Common Stock, (3) subdivide the outstanding shares of Common Stock into a greater number of shares of Common Stock, (4) combine the outstanding shares of Common Stock into a smaller number of shares of Common Stock or (5) otherwise increase or decrease the number of outstanding shares of Common Stock through reclassification or any other event similar to the events described in clauses (1) through (4) above, the conversion rate (and the components thereof) in effect pursuant to this Section 4 immediately prior to such action shall be adjusted to the extent required to give effect to the impact of any such event so that the holder of any shares of the Series A Preferred Stock thereafter

surrendered for conversion pursuant to this Section 4 shall be entitled to receive the number of shares of Common Stock which he would have owned immediately following such action had such shares of the Series A Preferred Stock been converted immediately prior thereto. Such adjustment shall be made whenever any event listed above shall occur and shall become effective (A) immediately after the record date in the case of a dividend or a distribution or other applicable event for which a record date is used and (B) immediately after the effective date in the case of a subdivision or combination or other applicable event for which a record date is not used.

(ii) In case the Corporation shall distribute to all holders of the Common Stock shares of any class of capital stock other than Common Stock, evidences of indebtedness or other assets (other than non-extraordinary cash dividends out of current or retained earnings), or shall distribute to substantially all holders of Common Stock rights or warrants to subscribe for securities, then in each such case the number of shares of the Common Stock into which each share of the Series A Preferred Stock shall be converted shall be adjusted (and appropriate adjustments shall be made to the component parts of the applicable

-9-

conversion rate) so that such number shall equal the number determined by multiplying the number of shares of Common Stock into which such share of the Series A Preferred Stock was convertible immediately prior to the date of such distribution by a fraction of which the numerator shall be the current market price of Common Stock (determined as provided in Section 5) on the record date mentioned below, and of which the denominator shall be such current market price of Common Stock, less the then fair market value (as determined in good faith by the Board of Directors of the Corporation, whose determination shall be conclusive evidence of such fair market value) of the portion of the assets so distributed or of such subscription rights or warrants applicable to one share of Common Stock. Such adjustment shall become effective immediately after the record date for the determination of the holders of Common Stock entitled to receive such distribution.

(iii) The Corporation shall provide at least 10 business days advance notice to holders of Series A Preferred Stock of any record date or other applicable date for determining shareholders entitled to participate in any of the events described in this Section 4(h) or other similar events not described in this Section 4(h) which would have a dilutive effect on the Series A Preferred Stock or the Common Stock into which the Series A Preferred Stock is convertible.

(i) No adjustment in the conversion rate (or its component parts) under this Section 4 shall be required until cumulative adjustments result in a concomitant change of 1% or more of the conversion rate as in effect prior to the last adjustment of the conversion rate; PROVIDED, HOWEVER, that any adjustments which by reason of this Section 4(i) are not required to be made shall be carried forward and taken into account in any subsequent adjustment. All calculations under this Section 4 shall be made to the nearest cent or to the nearest one-hundredth of a share, as the case may be. No adjustment to the

conversion rate shall be made for non-extraordinary cash dividends.

- (j) In the event that, as a result of an adjustment made pursuant to Section 4(h), the holder of any share of the Series A Preferred Stock thereafter surrendered for conversion shall become entitled to receive any shares of capital stock of the Corporation other than shares of Common Stock, thereafter the number of such other shares so receivable upon conversion of any shares of the Series A Preferred Stock shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the Common Stock contained in this Section 4.
- (k) The Corporation may make such increases in the conversion rate, in addition to those required by Sections 4(h)(i) and (ii), as it considers to be advisable in order that any event treated for Federal income tax purposes as a dividend

-10-

of stock or stock rights shall not be taxable to the recipients thereof.

(I) Whenever the conversion rate (or any components thereof) is adjusted pursuant to this Section 4, the Corporation shall promptly mail to all holders of record of shares of the Series A Preferred Stock a notice of the adjustment and shall cause to be prepared a certificate signed by the chief financial officer of the Corporation or, if requested in writing by holders of a majority of the shares of Series A Preferred Stock then outstanding, the Corporation's outside accountants or a reputable investment banking firm selected by the Corporation setting forth the adjusted conversion rate (and the component parts thereof) and a brief statement of the facts requiring such adjustment and the computation thereof. Such certificate shall forthwith be filed with each transfer agent for the shares of the Series A Preferred Stock.

(m) If any of the following shall occur: (i) any reclassification or change of outstanding shares of Common Stock issuable upon conversion of shares of the Series A Preferred Stock (other than a change in par value, or from par value to no par value, or from no par value to par value, or as a result of a subdivision or combination), (ii) any consolidation or merger to which the Corporation is a party other than a merger in which the Corporation is the continuing corporation and which does not result in any reclassification of, or change (other than a change in name, or par value, or from par value to no par value, or from no par value to par value, or as a result of a subdivision or combination) in, outstanding shares of Common Stock or (iii) any sale or conveyance of all or substantially all of the property or business of the Corporation as an entirety, then the Corporation, or such successor or purchasing corporation, as the case may be, shall, as a condition precedent to such reclassification, change, consolidation, merger, sale or conveyance, provide in its certificate of incorporation or other charter document that each share of the Series A Preferred Stock shall be convertible under this Section 4 into the kind and amount of shares of capital stock and other securities and property (including cash) receivable upon such reclassification, change, consolidation, merger, sale or conveyance by a holder of the number of shares of Common Stock deliverable upon conversion of such share of the Series A Preferred Stock immediately prior to such reclassification, change, consolidation, merger, sale or conveyance. Such certificate of incorporation or other charter document shall provide for adjustments and protection which shall be as nearly equivalent

as may be practicable to the adjustments provided for in this Section 4. If, in the case of any such consolidation, merger, sale or conveyance, the stock or other securities and property (including cash) receivable thereupon by a holder of Common Stock includes shares of capital stock or other securities and property of a corporation other than the successor purchasing corporation, as the case may be, in such consolidation, merger, sale or conveyance, then the certificate of incorporation or other charter document of such other

-11-

corporation shall contain such additional provisions to protect the interests of the holders of shares of the Series A Preferred Stock as the Board of Directors of the Corporation shall reasonably consider necessary by reason of the foregoing. The provision of this Section 4(m) shall similarly apply to successive consolidations, mergers, sales or conveyances.

(n) No sooner than fifteen (15) business days nor later than five (5) business days prior to the consummation of a transaction referred to in clauses (ii) or (iii) of Section 4(m) (a "Major Transaction"), but not prior to the public announcement of such Major Transaction, the Corporation shall deliver written notice (a "Notice of Major Transaction") to each holder of Series A Preferred Stock, which Notice of Major Transaction shall be deemed to have been delivered to the holder one (1) business day after the Corporation's sending of such notice (for overnight delivery) by a common carrier, if such delivery is to be made in the United States, or two (2) business days after the Corporation's sending of such notice (for two (2) day delivery) by common carrier, if such notice is to be delivered outside the United States. Such Notice of Major Transaction shall indicate the amount and type(s) of consideration (the "Major Transaction Consideration") the holders of Series A Preferred Stock would receive for their shares of Series A Preferred Stock in the related Major Transaction. Such holder may elect to redeem all or a portion of such holder's shares of Series A Preferred Stock for an amount in cash equal to \$125 per share of Series A Preferred Stock held by such holder to be so redeemed in lieu of the Major Transaction Consideration or other securities and/or property that would otherwise be payable to such holder pursuant to Section 4(m). A holder may exercise such election by delivering written notice of such election to the Corporation, together with certificates for the shares of Series A Preferred Stock to be redeemed in connection with such election, within five (5) business days of the holder's receipt of the related Notice of Major Transaction, which notice shall be deemed given one (1) business day after the holder sends such notice (together with such certificates) from the United States by common carrier for overnight delivery or two (2) business days after the holder sends such notice (together with such certificates) from outside the United States by common carrier for two (2) day delivery. In the event that such Major Transaction is not completed within fifteen (15) business days after the Corporation is given a holder's related notice of election pursuant to the prior sentence, such election shall be null and void and the Corporation shall promptly return the certificate(s) representing the Series A Preferred Stock delivered by such holder to such holder; provided, that the Corporation will comply with the notice provisions of this Section 4(n) with respect to any later consummation of such Major Transaction. This Section 4(n) shall not apply in respect of any Major Transaction that occurs after the second anniversary of the Closing Date.

Transaction, each holder of Series A Preferred Stock shall have the right, at such holder's option, to require the Corporation to redeem all or a portion of such holder's Series A Preferred Stock for an amount per share in cash equal to the greater of (A) \$125 and (B) the product of the aggregate number of shares of Common Stock into which a share of Series A Preferred Stock is convertible (assuming such conversion were to occur on the last day preceding the effective date for the Change of Control) multiplied by the current market price per share of Common Stock (determined as provided in Section 5) as of the last date preceding the effective date of such Change of Control. As used in this Section 4(o), a "Change in Control" shall be deemed to have occurred at such time as either Douglas R. Eger or Thomas M. Fitzgerald cease to be either a director or officer of the Corporation. The rights of holders of Series A Preferred Stock under this Section 4(o) shall not apply in respect of any Change of Control that occurs after the first anniversary of the Closing Date.

- (ii) The Corporation shall provide each holder of Series A Preferred Stock with written notice of the occurrence of any Change of Control (a "Change of Control Notice") within two (2) business days after the occurrence of such Change of Control. Each holder may require the Corporation to redeem all or a portion of such holder's shares of Series A Preferred Stock pursuant to this Section 4(o) by delivering written notice (a "Notice of Redemption at Option of Holder") to the Corporation to such effect within ten (10) business days after receipt of the applicable Change of Control Notice, which Notice of Redemption at Option of Holder shall be deemed to have been delivered one (1) business day after such holder's sending, if such notice is sent within the United States for overnight delivery by a common carrier, or two (2) business days after such holder's sending, if such notice is sent from outside the United States by two (2) day delivery by a common carrier. Each such Notice of Redemption at Option of Holder shall indicate the number of shares of Series A Preferred Stock that have been selected by such holder for redemption.
- (iii) Each holder submitting certificate(s) representing shares of Series A Preferred Stock for redemption under this Paragraph 4(o) shall send such holder's Preferred Stock Certificates to be redeemed to the Corporation or its Transfer Agent and the Corporation shall pay the applicable redemption price to that holder within thirty (30) business days after the Corporation's receipt of such holder's Notice of Redemption at Option of Holder; provided that such holder's certificate(s) representing shares of Series A Preferred Stock to be redeemed (or an indemnification undertaking with respect to such shares in the case of their loss, theft or destruction) shall have been so delivered to the Corporation or its Transfer Agent.

banks are not required or authorized to close in New York City, New York.

(q) It is understood that the restrictions on any holder's ability to convert such holder's shares of Series A Preferred Stock contained herein may be supplemented by separate written agreement between such holder and the Corporation.

Section 5. CALCULATIONS OF CURRENT MARKET PRICE OF COMMON STOCK. For purposes of calculations relating to the Series A Preferred Stock that refer to the current market price per share of Common Stock, the current market price per share of Common Stock on or as of any day shall be deemed to be the average of the closing bid prices for the ten (10) consecutive trading days ending the last trading day before the day in question. The closing bid price for each day shall be the last reported bid price on the American Stock Exchange, or if Common Stock is not listed or admitted to trading on such exchange, on the principal national securities exchange on which Common Stock is listed or admitted to trading or, if not listed or admitted to trading on any national securities exchange, the closing bid price of Common Stock on NASDAQ or any comparable system, or if Common Stock is not quoted on NASDAQ or any comparable system, the closing bid price as furnished by any two members of the National Association of Securities Dealers, Inc. selected from time to time by the Corporation for that purpose. If Common Stock is not so quoted on NASDAQ or any comparable system, the Board of Directors of the Corporation shall reasonably and in good faith determine the current market price on such basis as it considers appropriate. For example, in the event that the current market price per share of Common Stock is to be determined as of a Conversion Date, the current market price per share of Common Stock shall equal the average of the last reported bid price as reported by the American Stock Exchange for the ten (10) consecutive trading days ending the last trading day before such Conversion Date (assuming that the Common Stock is listed and admitted for trading on the American Stock Exchange and a reported bid price for Common Stock is placed on the American Stock Exchange on each such trading day).

Section 6. LIMITATIONS. (a) In addition to any other rights provided by applicable law, so long as any shares of the Series A Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote, or the written consent as provided by law, of the holders of at least two-thirds (2/3) of the outstanding shares of the Series A Preferred Stock, voting as a separate class,

(i) create, authorize or issue any class or series of capital stock, or rights to subscribe to or acquire, or any security convertible into, any class or series of capital stock ranking as to payment of dividends, distribution of assets upon liquidation or

-14-

voting rights, prior to the Series A Preferred Stock; or

(ii) amend, alter or appeal, whether by merger, consolidation or otherwise, any of the provisions of the Certificate of Incorporation (including this Certificate of Designation) that would change the preferences, rights or powers with respect to the Series A Preferred

Stock so as to affect the Series A Preferred Stock adversely.

(b) In addition to any other rights provided by applicable law, so long as any shares of the Series A Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote, or the written consent as provided by law, of the holders of at least two-thirds (2/3) of the outstanding shares of the Series A Preferred Stock, voting as a separate class, issue or agree to issue any Common Stock or any security convertible or otherwise exchangeable, directly or indirectly, for Common Stock if such shares of Common Stock are to be issued, or such convertible securities are to be converted to or exchanged for shares of Common Stock, at a price per share less than the current market price for the Common Stock (determined as provided in Section 5) as of the day immediately preceding the date of the issuance of such Common Stock or such convertible or exchangeable security (as the case may be); provided, however, that the restrictions contained in this paragraph (b) shall not apply (i) to the issuance of any such convertible or exchangeable securities that are convertible or exchangeable at a fixed price (and not a floating price) per share equal to or greater than the current market price for the Common Stock (determined as provided in Section 5) as of the date of issuance of such convertible or exchangeable security, (ii) to the issuance of Common Stock and other securities of the Corporation issuable upon the exercise or conversion of options, warrants on other rights to purchase securities of the Corporation outstanding as of the date hereof, (iii) to the issuance of any securities to officers, directors or employees of the Corporation or any of its subsidiaries, (iv) to the issuance of any securities of the Corporation in an underwritten public offering or (v) to any other issuance of securities after the date that is 90 days after the Closing Date if the holders of Series A Preferred Stock are first delivered a written notice (a "Right of First Refusal Notice") from the Corporation offering such holders on a PRO RATA basis the right to purchase all or a portion of the related securities at the same price (and on the same terms and conditions, offered to other proposed investors (which notice shall set forth such price, terms and conditions). In the event that the Corporation delivers a Right of First Refusal Notice to any holder of Series A Preferred Stock, the failure by such holder to commit in writing to purchase such holder's pro rata portion of the securities identified in such Right of First Refusal Notice within five (5) business days of delivery thereof may be deemed by the Corporation to constitute such holder's determination not to so purchase such securities and the Corporation shall then be

-15-

permitted to sell such securities to other investors at the price and on the terms and conditions set forth in such notice. The rights of holders of Series A Preferred Stock under this paragraph (b) shall terminate on the first anniversary of the Closing Date.

(c) Notwithstanding the foregoing, except as otherwise required by applicable law, nothing herein contained shall require a vote or consent of the holders of Series A Preferred Stock in connection with any increase in the total number of authorized shares of Common Stock. The holders of Series A Preferred Stock shall not be entitled to vote on any matter except (i) as provided in this Section 6 and (ii) as required by law.

Section 7. LOST OR STOLEN CERTIFICATES. Upon (i) receipt by the Corporation from a holder of evidence satisfactory to the Corporation of the

loss, theft, destruction of any certificate(s) representing shares of Series A Preferred Stock and of an indemnification undertaking by the holder to the Corporation that is reasonably satisfactory to the Corporation or (ii) upon surrender and cancellation of certificate(s) representing shares of Series A Preferred Stock that have been mutilated, the Corporation shall execute and deliver to such holder new certificate(s) representing shares of Series A Preferred Stock of like tenor and date. However, the Corporation shall not be obligated to re-issue such lost, stolen, destroyed or mutilated certificate(s) representing shares of Series A Preferred Stock if such holder contemporaneously requests the Corporation to convert such shares of Series A Preferred Stock into shares of Common Stock or otherwise redeem such shares pursuant to the terms hereof.

-16-

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Designation to be signed by Douglas R. Eger, its Chairman and Chief Executive Officer, and attested by George Lombardi, its Secretary, this day of February, 1997.

SHEFFIELD MEDICAL TECHNOLOGIES INC.

By: /s/ Douglas R. Eger

Douglas R. Eger

Chairman and Chief Executive

Officer

Attested:

By: /s/ George Lombardi

George Lombardi

Secretary

-17-

EXHIBIT A
TO CERTIFICATE
OF DESIGNATION

NOTICE OF CONVERSION

(To be completed, executed and delivered upon conversion of shares of Series A Preferred Stock)

TO: Sheffield Medical Technologies Inc.

Attention: Chief Financial Officer

The undersigned holder of shares of Series A Cumulative Convertible Redeemable Preferred Stock ("Series A Preferred Stock") of Sheffield Medical Technologies Inc. (the "Company") hereby converts \_\_\_\_\_\_ shares of Series A Preferred Stock into Common Stock of the Company at the applicable conversion rate on the terms and conditions specified in the Certificate of Designation for the Series A Preferred Stock. The undersigned surrenders herewith certificate(s) representing such number of shares of Series A Preferred Stock to be converted and all right, title and interest therein to the Company and directs that the Common Stock deliverable upon the conversion of such shares of Series A Preferred Stock be registered or placed in the name and at the address specified below and delivered thereto.


[Insert Common Stock Registration Information]

In the event that the certificate(s) surrendered represent a number of shares of Series A Preferred Stock in excess of the shares of Series A Preferred Stock converted pursuant to this notice, you are advised to issue and deliver to the undersigned holder a certificate representing the remaining balance of shares of Series A Preferred Stock represented by the surrendered certificate(s) not so converted.

Date:	
Your Sig	nature:
	(Sign exactly as your name appears on the
	certificate representing the Shares of Series A
	Preferred Stock being converted)

-18-

EX-4.2 3 CERTIFICATE OF DESIGNATION

Exhibit 4.2 to Form 10-KSB

CERTIFICATE OF DESIGNATION
OF
SERIES A CUMULATIVE CONVERTIBLE REDEEMABLE
PREFERRED STOCK
OF
SHEFFIELD MEDICAL TECHNOLOGIES INC.

(Pursuant to Section 151 of the General Corporation Law of the State of Delaware)

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Sheffield Medical Technologies Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), hereby certifies that the following resolution was adopted by the Board of Directors of the Corporation:

RESOLVED, that pursuant to the authority expressly granted to and vested in the Board of Directors of the Corporation (the "Board of Directors") by the provisions of the Certificate of Incorporation of the Corporation (the "Certificate of Incorporation"), there hereby is created, out of the 3,000,000 shares of preferred stock of the Corporation authorized in Article FOURTH of the Certificate of Incorporation (the "Preferred Stock"), a series of Preferred Stock consisting of 40,800 shares, which series shall have the following powers, designations, preferences and relative, participating, optional or other rights, and the following qualifications, limitations and restrictions (in addition to the powers, designations, preferences and relative, participating, optional or other rights, and the qualifications, limitations and restrictions, set forth in the Certificate of Incorporation which are applicable to the Preferred Stock).

Section 1. DESIGNATION AND AMOUNT. The shares of such series shall be designated as "Series A Cumulative Convertible Redeemable Preferred Stock" (the "Series A Preferred Stock") and the authorized number of shares constituting such series shall be 40,800. The par value of the Series A Preferred Stock shall be \$.01 per share.

# Section 2. DIVIDENDS.

Subject to Section 4(d), the holders of shares of the Series A Preferred Stock will be entitled to receive, when, as and if declared by the Board of Directors, cumulative stock dividends on the shares of the Series A Preferred Stock, payable in shares of the Corporation's common stock, \$.01 par value per share ("Common Stock"), at the rate per share of 7.0% per annum of the original \$100.00 purchase price per share of the Series A Preferred Stock, and no more. Such stock dividends shall be cumulative from the date of the initial issuance of shares of Series A Preferred Stock (the "Closing Date") or the most recent date on which the full amount of accrued stock dividends have been paid, as the case may be, on the Series A Preferred Stock by the Corporation. Subject to, and as provided in, Section 4, the Corporation shall pay all cumulative stock dividends on the shares of Series A Preferred Stock held by a holder on the Conversion Date (as defined below) in respect of such holder's election to convert Series A Preferred Stock. The number of shares of Common Stock to be issued as cumulative stock dividends on any such Conversion Date shall equal the cash value of such cumulative dividends divided by the current market price per share of Common Stock (determined as provided in Section 5) as of such Conversion Date. The cash value of stock dividends payable on shares of Series A Preferred Stock for any full annual dividend period shall be computed by multiplying the original \$100.00 purchase price per share by 7.0%. The cash value of dividends payable on shares of the Series A Preferred Stock for any period less than a full annual dividend period shall be computed on the basis of a 360-day year of twelve 30-day months and the actual number of days elapsed in the period for which payable.

If stock dividends are not paid in full, or declared in full, upon the shares of the Series A Preferred Stock and shares of any other preferred stock ranking on a parity as to payment of stock dividends with the Series A Preferred Stock, all dividends declared upon shares of the Series A Preferred Stock and any other preferred stock ranking on a parity as to payment of dividends with the Series A Preferred Stock shall be paid or declared PRO RATA so that in all cases the amount of dividends paid or declared per share on the Series A Preferred Stock and such other shares of preferred stock ranking on a parity as to payment of dividends with the Series A Preferred Stock shall bear to each other the same ratio that accumulated stock dividends per share, including dividends accrued or in arrears, if any, on the shares of the Series A Preferred Stock and such other shares of preferred stock bear to each other. Except as provided in the preceding sentence, unless full cumulative stock dividends on the shares of the Series A Preferred Stock have been paid or declared in full, no dividends (other than dividends in shares of Common Stock, or in shares of any other capital stock of the Corporation

-2-

ranking junior to the Series A Preferred Stock as to payment of dividends and distribution of assets upon liquidation) shall be paid or declared and set aside for payment or other distribution upon the Common Stock or, except as provided above, on any other capital stock of the Corporation ranking junior to or on a parity with the Series A Preferred Stock as to dividends, nor shall any shares of Common Stock or shares of any other capital stock of the Corporation ranking junior to or on a parity with the Series A Preferred Stock as to dividends be redeemed, purchased or otherwise acquired for any consideration (or any payment made to or available for a sinking fund for the redemption of any such shares) by the Corporation or any subsidiary of the Corporation (except by conversion into or exchange for shares of capital stock of the Corporation ranking junior to the Series A Preferred Stock as to dividends and distribution of assets upon liquidation). Holders of shares of the Series A Preferred Stock shall not be entitled to any dividends, whether payable in capital stock, cash or property, in excess of full accrued and cumulative stock dividends as herein provided. No interest or sum of money in lieu of interest shall be payable in respect of any stock dividend payment or payments on the shares of the Series A Preferred Stock that may be in arrears; provided, however, that if, on an applicable Conversion Date (as defined herein), stock dividends that would have been payable on such date are not paid solely due to the failure of the Corporation's Board of Directors to declare such dividends, then the rate of conversion of the Series A Preferred Stock to be converted on such Conversion Date shall be adjusted so that the holders would receive the same amount of shares of Common Stock on such Conversation Date as such holder would have received if the Corporation's Board of Directors had timely declared such stock dividends.

The terms "accrued dividends," "dividends accrued" and "dividends in arrears," whenever used herein with reference to shares of preferred stock shall be deemed to mean an amount which shall be equal to dividends thereon at the applicable annual dividend rates per share for the respective series thereof from the date or dates on which such dividends commence to accrue to the applicable payment date less the amount of all dividends paid, or declared in full and sums set aside for the payment thereof, upon such shares of preferred stock.

(a) In the event of any liquidation, dissolution or winding up of the affairs of the Corporation, whether voluntary or otherwise, after payment or provision for payment of the debts and other liabilities of the Corporation, the holders of shares of the Series A Preferred Stock shall be entitled to receive, in cash, out of the remaining net assets of the Corporation (whether from capital or from earnings available for distribution to

-3-

shareholders), the amount of One Hundred Dollars (\$100.00) for each share of the Series A Preferred Stock, plus the cash value determined in accordance with Section 2 above of all stock dividends accrued and unpaid at the applicable rate on each such share up to the date fixed for distribution, before any distribution shall be made to the holders of shares of Common Stock or any other capital stock of the Corporation ranking (as to any such distribution) junior to the Series A Preferred Stock. If upon any liquidation, dissolution or winding up of the Corporation, the assets distributable among the holders of shares of the Series A Preferred Stock and all other classes and series of preferred stock ranking (as to any such distribution) on a parity with the Series A Preferred Stock are insufficient to permit the payment in full to the holders of all such shares of all preferential amounts payable to all such holders, then the entire assets of the Corporation thus distributable shall be distributed ratably among the holders of the shares of the Series A Preferred Stock and such other classes and series of preferred stock ranking (as to any such distribution) on a parity with the Series A Preferred Stock in proportion to the respective amounts that would be payable per share if such assets were sufficient to permit payment in full.

- (b) For purposes of this Section 3, a distribution of assets in any dissolution, winding up or liquidation shall not include (i) any consolidation or merger of the Corporation with or into any other corporation or other entity, (ii) any dissolution, liquidation, winding up or reorganization of the Corporation immediately followed by reincorporation of another corporation or other entity or (iii) a sale or other disposition of all or substantially all of the Corporation's assets to another corporation or other entity; PROVIDED, HOWEVER, that, in each case, effective provision is made in the certificate of incorporation of the resulting and surviving corporation or otherwise for the protection of the relative rights of the holders of shares of the Series A Preferred Stock.
- (c) After the payment of the full preferential amounts provided for herein to the holders of shares of the Series A Preferred Stock or funds necessary for such payment have been set aside in trust for the holders thereof, such holders shall be entitled to no other or further participation in the distribution of the assets of the Corporation.

### Section 4. CONVERSION AND REDEMPTION OF SERIES A PREFERRED STOCK.

(a) Each holder of Series A Preferred Stock shall have the right, exercisable at any time and from time to time during the period commencing on the date that is ninety (90) days after the Closing Date and ending on the date that is two years after

-4-

the Closing Date (the "Mandatory Conversion Date"), to convert any or all of the Series A Preferred Stock owned by such holder for shares of Common Stock, at a conversion rate determined by multiplying the number of shares of Series A Preferred Stock to be converted by a fraction, the numerator of which shall equal one hundred (100) and the denominator of which (a "Denominator") shall equal (i) the current market price per share of the Common Stock (determined as provided in Section 5) as of the Closing Date (such current market price being referred to herein as the "Closing Price"), if the applicable Conversion Date (as defined below) occurs on or before the 119th day following the Closing Date, (ii) the lessor of (A) 100% of the Closing Price or (B) the current market price per share of Common Stock (determined as provided in Section 5) as of the applicable Conversion Date, if the applicable Conversion Date occurs on or after the 120th day after the Closing Date and on or before the 179th day after the Closing Date or (iii) the lesser of (A) 100% of the Closing Price and (ii) 85% of the current market price per share of Common Stock (determined as provided in Section 5) as of the applicable Conversion Date for any Conversion Date occurring on or after the 180th day after the Closing Date, subject to adjustment and the conditions described herein.

(b) (i) Any holder of shares of the Series A Preferred Stock electing to convert shares thereof pursuant to Section 4(a) shall (A) transmit by facsimile, for receipt on the proposed date of conversion, a copy of a fully completed and executed notice of conversion ("Notice of Conversion") to the Corporation at the office of the Corporation or its designated transfer agent (the "Transfer Agent"), in the form attached as Exhibit A hereto, and (B) surrender to a common carrier for delivery to the office of the Corporation or the Transfer Agent, the original certificates representing the Series A Preferred Stock being converted (the "Preferred Stock Certificates"), duly endorsed for cancellation. The Corporation shall, upon the timely written request of a holder of shares of the Series A Preferred Stock, promptly provide in writing to such holder, via facsimile transmission, the appropriate numbers for the Corporation and the Transfer Agent to be used to effect an election in accordance with this subparagraph (i).

(ii) Upon receipt by the Corporation of transmission of a facsimile copy of such Notice of Conversion, the Corporation shall as soon as practicable (but in no event later than 12:00 noon on the next business day after receipt thereof) send, via facsimile, a confirmation of receipt of such Notice of Conversion to such holder, which shall specify that the Notice of Conversion has been received and the name and telephone number of a contact person at the Corporation whom the holder should contact regarding information related to such conversion.

-5-

Upon receipt by the Corporation or the Transfer Agent of the certificate(s) representing the shares of Series A Preferred Stock to be converted pursuant to such Notice of Conversion (or an indemnification undertaking in form and substance reasonably satisfactory to the Corporation with respect to such shares in the case of their loss, theft or destruction) together with the originally executed and completed Notice of Conversion (such date of the

Corporation's receipt of all such documents being referred to herein as the "Final Receipt Date"), the Corporation or Transfer Agent (as applicable) shall, as soon as possible on or after the applicable Final Receipt Date, but in any event within two (2) business days after the applicable Final Receipt Date, issue and surrender to a common carrier for either overnight delivery (if delivery is to be made inside the United States) or two (2) day delivery (if delivery is to be made outside the United States) to such holder at the address specified in the Notice of Conversion, a certificate for the number of shares of Common Stock to which such holder shall be entitled as in respect of the related conversion. In the event of a partial conversion of shares of Series A Preferred Stock represented by certificate(s) delivered to the Corporation in respect of any conversion, the Corporation will return to the applicable holder a certificate representing such holder's remaining shares of Series A Preferred Stock that were not so converted. In the case of any dispute between the Corporation and such holder as to the calculation of the applicable Conversion Price evidenced by a notice to such effect (a "Dispute Notice") delivered to the Corporation by such holder prior to the Final Receipt Date, the Corporation shall promptly issue to such holder the number of shares of Common Stock that is not disputed and shall submit the disputed calculations to its outside accountant within two (2) business days after the Final Receipt Date. The Corporation shall cause such accountant to perform the calculations and notify the Corporation and the holder of the results no later than two (2) business days after the date that such outside accountant is delivered a copy of such holder's Dispute Notice by the Corporation pursuant to the preceding sentence. Such accountant's calculation shall be deemed conclusive and binding on the Corporation and such holder absent manifest error.

(iii) The effective date of a particular conversion (the "Conversion Date") other than pursuant to Section 4(c) shall be deemed to be the date on which the advance copy of the related Notice of Conversion in respect of such conversion is received by either the Corporation or the Transfer Agent by facsimile transmission as provided in paragraph (ii) above, provided that (A) such advance copy of the Notice of Conversion is transmitted by facsimile to and

-6-

received by the Corporation before 11:59 p.m., New York City time, on such date and (B) the original certificates representing the Series A Preferred Stock to be converted (or an indemnification undertaking in form and substance reasonably satisfactory to the Corporation with respect to such shares in the case of their loss, theft or destruction), together with the originally executed and completed Notice of Conversion, are surrendered by depositing such certificates and Notice of Conversion with a common carrier, as provided above, and received by the Corporation or the Transfer Agent on or before the second (2nd) business day following the date that the related advance copy of the related Notice of Conversion is received by the Corporation or the Transfer Agent. In the event that all such documents are not received within two (2) business days after such date, such Notice of Conversion shall be deemed null and void and no conversion of Series A Preferred Stock shall be effected thereby.

(iv) As of any Conversion Date, the person or persons entitled to receive the shares of the Common Stock issuable upon the related conversion of shares of Series A Preferred Stock pursuant to this Section 4 shall be treated for all purposes as the record holder or holders of the shares of Common Stock issuable in respect of such conversion on said date. From and after the Conversion Date in respect of such shares of Series A Preferred Stock, all such shares of Series A Preferred Stock shall be deemed to have been converted into shares of Common Stock at the applicable conversion rate, all stock dividends on such shares of the Series A Preferred Stock shall cease to accrue, and all rights of the holders thereof as holders of Series A Preferred Stock, except the right to receive all accrued and unpaid stock dividends to such Conversion Date at the applicable rate for such shares of Series A Preferred Stock and the right to receive certificates representing shares of Common Stock issuable upon conversion of such shares (including, without limitation, with respect to such stock dividends), shall cease and terminate, such shares of Series A Preferred Stock shall not thereafter be transferred (except with the consent of the Corporation) on the books of the Corporation and such shares shall not be deemed to be outstanding for any purpose whatsoever. The rights of a holder to elect to convert shares of Series A Preferred Stock under this Section 4(a) and 4(b) shall cease and terminate immediately after the Mandatory Conversion Date.

(c) Subject to Section 4(d), to the extent that any shares of Series A Preferred Stock held by a holder thereof have not been converted pursuant to Sections 4(a) and 4(b) as of the Mandatory Conversion Date, such holder shall be deemed to have elected to convert such remaining shares of Series A Preferred

-7-

Stock as of the Mandatory Conversion Date (without any action required by such holder) and the Corporation shall issue shares of Common Stock to such holder and satisfy its other obligations under Section 4(a) and (b) as if such holder had elected to convert such remaining shares of Series A Preferred Stock pursuant to Sections 4(a) and 4(b) as of the Mandatory Conversion Date.

(d) Notwithstanding anything herein to the contrary, in the event that (i) a holder of Series A Preferred Stock elects (or is deemed to have elected) to convert shares of Series A Preferred Stock pursuant to Sections 4(a) and 4(b) or pursuant to Section 4(c) for which a Denominator that is less than the Closing Price is utilized in the calculation (pursuant to Section 4(a)) of the number of shares of Common Stock to be issued in such conversion and (ii) such conversion would result in such holder receiving, as a result of such conversion, a number of shares of Common Stock that, together with other shares of Common Stock issued to such holder (or any affiliate of such holder) in any prior conversion(s) of Series A Preferred Stock that utilized a Denominator that was less than the Closing Price in the calculation (pursuant to Section 4(a)) of the number of shares of Common Stock to be issued in such conversion, would equal or exceed twenty percent (20%) of the shares of Common Stock of the Corporation outstanding on the Closing Date (the "Threshold Amount"), the Corporation shall (i) issue to such holder the number of shares of Common Stock otherwise required to be issued to such holder as a result of such conversion (including any shares of Common Stock representing cumulative stock dividends

accrued to the applicable Conversion Date pursuant to Section 2) LESS the number of shares of Common Stock otherwise issuable to such holder pursuant to such conversion in excess of the Threshold Amount (the "Excess Shares") and (ii) shall remit to such holder, in lieu of the Excess Shares, an amount of cash equal to the number of Excess Shares multiplied by the current market price per share of Common Stock (determined as provided in Section 5) determined as of such Conversion Date. Upon such issuance of Common Stock and payment of such cash to the holder in lieu of the Excess Shares, the Corporation's obligations to such holder arising as a result of such conversion (including the Corporation's obligation to pay cumulative stock dividends through the applicable Conversion Date) shall be deemed fully satisfied.

(e) No fractional shares of Common Stock or scrip representing fractional shares shall be issued upon conversion of shares of the Series A Preferred Stock pursuant to this Section 4. If more than one share of the Series A Preferred Stock shall be surrendered for conversion by the same holder, the number of full shares of Common Stock which shall be issuable upon conversion thereof shall be computed on the basis of the aggregate number of shares of the Series A Preferred Stock so

-8-

surrendered. Instead of any fractional shares of Common Stock which would otherwise be issuable upon conversion of any shares of the Series A Preferred Stock, the Corporation shall pay a cash adjustment in respect of such fraction in an amount equal to the same fraction of the closing bid price for Common Stock determined as of the last business day preceding the Conversion Date in respect of such shares. The closing bid price for such day shall be the last reported bid price on the American Stock Exchange, or if Common Stock is not listed or admitted to trading on such exchange, on the principal national securities exchange on which Common Stock is listed or admitted to trading or, if not listed or admitted to trading on any national securities exchange, the closing bid price of Common Stock on NASDAQ or any comparable system. If Common Stock is not quoted on NASDAQ or any comparable system, the Board of Directors of the Corporation shall in good faith determine the current market price on such basis as it considers appropriate.

- (f) When shares of Series A Preferred Stock are converted (or deemed converted) by a holder pursuant to this Section 4, the Corporation shall pay any documentary, stamp or similar issue or transfer tax due on the issue of Common Stock upon such conversion.
- (g) The Corporation shall reserve at all times out of the Corporation's authorized but unissued shares of Common Stock a sufficient number of shares of Common Stock to permit the conversion of the then outstanding shares of the Series A Preferred Stock pursuant to this Section 4 and such reserved shares shall not be used for any other purpose. All shares of Common Stock which may be issued upon conversion of shares of the Series A Preferred Stock pursuant to this Section 4 shall be validly issued, fully paid and nonassessable. In order that shares of Common Stock may be issued upon conversion of shares of the Series A Preferred Stock, the Corporation shall comply with all applicable Federal and State securities laws and use its best efforts to list such shares of Common Stock to be issued upon conversion on each securities exchange on which Common Stock is listed.

- (h) The conversion rate (and the components thereof) in effect at any time for conversion of Series A Preferred Stock into Common Stock pursuant to this Section 4 shall be subject to adjustment from time to time as follows:
  - (i) In the event that the Corporation shall (1) pay a dividend in shares of Common Stock to holders of Common Stock, (2) make a distribution in shares of Common Stock to holders of Common Stock, (3) subdivide the outstanding shares of Common Stock into a greater number of shares of Common Stock, (4) combine the outstanding shares of Common Stock into a smaller number of shares of Common Stock or (5)

-9-

otherwise increase or decrease the number of outstanding shares of Common Stock through reclassification or any other event similar to the events described in clauses (1) through (4) above, the conversion rate (and the components thereof) in effect pursuant to this Section 4 immediately prior to such action shall be adjusted to the extent required to give effect to the impact of any such event so that the holder of any shares of the Series A Preferred Stock thereafter surrendered for conversion pursuant to this Section 4 shall be entitled to receive the number of shares of Common Stock which he would have owned immediately following such action had such shares of the Series A Preferred Stock been converted immediately prior thereto. Such adjustment shall be made whenever any event listed above shall occur and shall become effective (A) immediately after the record date in the case of a dividend or a distribution or other applicable event for which a record date is used and (B) immediately after the effective date in the case of a subdivision or combination or other applicable event for which a record date is not used.

(ii) In case the Corporation shall distribute to all holders of the Common Stock shares of any class of capital stock other than Common Stock, evidences of indebtedness or other assets (other than non-extraordinary cash dividends out of current or retained earnings), or shall distribute to substantially all holders of Common Stock rights or warrants to subscribe for securities, then in each such case the number of shares of the Common Stock into which each share of the Series A Preferred Stock shall be converted shall be adjusted (and appropriate adjustments shall be made to the component parts of the applicable conversion rate) so that such number shall equal the number determined by multiplying the number of shares of Common Stock into which such share of the Series A Preferred Stock was convertible immediately prior to the date of such distribution by a fraction of which the numerator shall be the current market price of Common Stock (determined as provided in Section 5) on the record date mentioned below, and of which the denominator shall be such current market price of Common Stock, less the then fair market value (as determined in good faith by the Board of Directors of the Corporation, whose determination shall be conclusive evidence of such fair market value) of the portion of the assets so distributed or of such subscription rights or warrants applicable to one share of Common Stock. Such adjustment shall become effective immediately after the record date for the determination of the holders of Common Stock entitled to receive such distribution.

Preferred Stock of any record date or other applicable date for determining shareholders entitled to participate in any of the events described in this Section 4(h) or other similar events not described in this Section 4(h) which would have a dilutive effect on the Series A Preferred Stock or the Common Stock into which the Series A Preferred Stock is convertible.

- (i) No adjustment in the conversion rate (or its component parts) under this Section 4 shall be required until cumulative adjustments result in a concomitant change of 1% or more of the conversion rate as in effect prior to the last adjustment of the conversion rate; PROVIDED, HOWEVER, that any adjustments which by reason of this Section 4(i) are not required to be made shall be carried forward and taken into account in any subsequent adjustment. All calculations under this Section 4 shall be made to the nearest cent or to the nearest one-hundredth of a share, as the case may be. No adjustment to the conversion rate shall be made for non-extraordinary cash dividends.
- (j) In the event that, as a result of an adjustment made pursuant to Section 4(h), the holder of any share of the Series A Preferred Stock thereafter surrendered for conversion shall become entitled to receive any shares of capital stock of the Corporation other than shares of Common Stock, thereafter the number of such other shares so receivable upon conversion of any shares of the Series A Preferred Stock shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the Common Stock contained in this Section 4.
- (k) The Corporation may make such increases in the conversion rate, in addition to those required by Sections 4(h)(i) and (ii), as it considers to be advisable in order that any event treated for Federal income tax purposes as a dividend of stock or stock rights shall not be taxable to the recipients thereof.
- (I) Whenever the conversion rate (or any components thereof) is adjusted pursuant to this Section 4, the Corporation shall promptly mail to all holders of record of shares of the Series A Preferred Stock a notice of the adjustment and shall cause to be prepared a certificate signed by the chief financial officer of the Corporation or, if requested in writing by holders of a majority of the shares of Series A Preferred Stock then outstanding, the Corporation's outside accountants or a reputable investment banking firm selected by the Corporation setting forth the adjusted conversion rate (and the component parts thereof) and a brief statement of the facts requiring such adjustment and the computation thereof. Such certificate shall forthwith be filed with each transfer agent for the shares of the Series A Preferred Stock.

-11-

(m) If any of the following shall occur: (i) any reclassification or change of outstanding shares of Common Stock issuable upon conversion of shares of the Series A Preferred Stock (other than a change in par value, or from par value to no par value, or from no par value to par value, or as a result of a subdivision or combination), (ii) any consolidation or merger to which the

Corporation is a party other than a merger in which the Corporation is the continuing corporation and which does not result in any reclassification of, or change (other than a change in name, or par value, or from par value to no par value, or from no par value to par value, or as a result of a subdivision or combination) in, outstanding shares of Common Stock or (iii) any sale or conveyance of all or substantially all of the property or business of the Corporation as an entirety, then the Corporation, or such successor or purchasing corporation, as the case may be, shall, as a condition precedent to such reclassification, change, consolidation, merger, sale or conveyance, provide in its certificate of incorporation or other charter document that each share of the Series A Preferred Stock shall be convertible under this Section 4 into the kind and amount of shares of capital stock and other securities and property (including cash) receivable upon such reclassification, change, consolidation, merger, sale or conveyance by a holder of the number of shares of Common Stock deliverable upon conversion of such share of the Series A Preferred Stock immediately prior to such reclassification, change, consolidation, merger, sale or conveyance. Such certificate of incorporation or other charter document shall provide for adjustments and protection which shall be as nearly equivalent as may be practicable to the adjustments provided for in this Section 4. If, in the case of any such consolidation, merger, sale or conveyance, the stock or other securities and property (including cash) receivable thereupon by a holder of Common Stock includes shares of capital stock or other securities and property of a corporation other than the successor purchasing corporation, as the case may be, in such consolidation, merger, sale or conveyance, then the certificate of incorporation or other charter document of such other corporation shall contain such additional provisions to protect the interests of the holders of shares of the Series A Preferred Stock as the Board of Directors of the Corporation shall reasonably consider necessary by reason of the foregoing. The provision of this Section 4(m) shall similarly apply to successive consolidations, mergers, sales or conveyances.

(n) No sooner than fifteen (15) business days nor later than five (5) business days prior to the consummation of a transaction referred to in clauses (ii) or (iii) of Section 4(m) (a "Major Transaction"), but not prior to the public announcement of such Major Transaction, the Corporation shall deliver written notice (a "Notice of Major Transaction") to each holder of Series A Preferred Stock, which Notice of Major Transaction shall be deemed to have been delivered to the holder one (1) business day

-12-

after the Corporation's sending of such notice (for overnight delivery) by a common carrier, if such delivery is to be made in the United States, or two (2) business days after the Corporation's sending of such notice (for two (2) day delivery) by common carrier, if such notice is to be delivered outside the United States. Such Notice of Major Transaction shall indicate the amount and type(s) of consideration (the "Major Transaction Consideration") the holders of Series A Preferred Stock would receive for their shares of Series A Preferred Stock in the related Major Transaction. Such holder may elect to redeem all or a portion of such holder's shares of Series A Preferred Stock for an amount in cash equal to \$125 per share of Series A Preferred Stock held by such holder to be so redeemed in lieu of the Major Transaction Consideration or other securities and/or property that would otherwise be payable to such holder pursuant to Section 4(m). A holder may exercise such election by delivering

written notice of such election to the Corporation, together with certificates for the shares of Series A Preferred Stock to be redeemed in connection with such election, within five (5) business days of the holder's receipt of the related Notice of Major Transaction, which notice shall be deemed given one (1) business day after the holder sends such notice (together with such certificates) from the United States by common carrier for overnight delivery or two (2) business days after the holder sends such notice (together with such certificates) from outside the United States by common carrier for two (2) day delivery. In the event that such Major Transaction is not completed within fifteen (15) business days after the Corporation is given a holder's related notice of election pursuant to the prior sentence, such election shall be null and void and the Corporation shall promptly return the certificate(s) representing the Series A Preferred Stock delivered by such holder to such holder; provided, that the Corporation will comply with the notice provisions of this Section 4(n) with respect to any later consummation of such Major Transaction. This Section 4(n) shall not apply in respect of any Major Transaction that occurs after the second anniversary of the Closing Date.

(o) (i) After the occurrence of a Change in Control (as defined below), other than in connection with a Major Transaction, each holder of Series A Preferred Stock shall have the right, at such holder's option, to require the Corporation to redeem all or a portion of such holder's Series A Preferred Stock for an amount per share in cash equal to the greater of (A) \$125 and (B) the product of the aggregate number of shares of Common Stock into which a share of Series A Preferred Stock is convertible (assuming such conversion were to occur on the last day preceding the effective date for the Change of Control) multiplied by the current market price per share of Common Stock (determined as provided in Section 5) as of the last date preceding the effective date of such Change of Control. As used in this

-13-

Section 4(o), a "Change in Control" shall be deemed to have occurred at such time as either Douglas R. Eger or Thomas M. Fitzgerald cease to be either a director or officer of the Corporation. The rights of holders of Series A Preferred Stock under this Section 4(o) shall not apply in respect of any Change of Control that occurs after the first anniversary of the Closing Date.

(ii) The Corporation shall provide each holder of Series A Preferred Stock with written notice of the occurrence of any Change of Control (a "Change of Control Notice") within two (2) business days after the occurrence of such Change of Control. Each holder may require the Corporation to redeem all or a portion of such holder's shares of Series A Preferred Stock pursuant to this Section 4(o) by delivering written notice (a "Notice of Redemption at Option of Holder") to the Corporation to such effect within ten (10) business days after receipt of the applicable Change of Control Notice, which Notice of Redemption at Option of Holder shall be deemed to have been delivered one (1) business day after such holder's sending, if such notice is sent within the United States for overnight delivery by a common carrier, or two (2) business days after such holder's sending, if such notice is sent from outside the United States by two (2) day delivery by a common carrier. Each such Notice of Redemption at Option of Holder shall indicate the number of shares of Series A Preferred Stock that have

been selected by such holder for redemption.

- (iii) Each holder submitting certificate(s) representing shares of Series A Preferred Stock for redemption under this Paragraph 4(o) shall send such holder's Preferred Stock Certificates to be redeemed to the Corporation or its Transfer Agent and the Corporation shall pay the applicable redemption price to that holder within thirty (30) business days after the Corporation's receipt of such holder's Notice of Redemption at Option of Holder; provided that such holder's certificate(s) representing shares of Series A Preferred Stock to be redeemed (or an indemnification undertaking with respect to such shares in the case of their loss, theft or destruction) shall have been so delivered to the Corporation or its Transfer Agent.
- (p) As used herein, "business day" means a day of the year on which banks are not required or authorized to close in New York City, New York.
- (q) It is understood that the restrictions on any holder's ability to convert such holder's shares of Series A Preferred Stock contained herein may be supplemented by separate written agreement between such holder and the Corporation.

-14-

Section 5. CALCULATIONS OF CURRENT MARKET PRICE OF COMMON STOCK. For purposes of calculations relating to the Series A Preferred Stock that refer to the current market price per share of Common Stock, the current market price per share of Common Stock on or as of any day shall be deemed to be the average of the closing bid prices for the ten (10) consecutive trading days ending the last trading day before the day in question. The closing bid price for each day shall be the last reported bid price on the American Stock Exchange, or if Common Stock is not listed or admitted to trading on such exchange, on the principal national securities exchange on which Common Stock is listed or admitted to trading or, if not listed or admitted to trading on any national securities exchange, the closing bid price of Common Stock on NASDAQ or any comparable system, or if Common Stock is not quoted on NASDAQ or any comparable system, the closing bid price as furnished by any two members of the National Association of Securities Dealers, Inc. selected from time to time by the Corporation for that purpose. If Common Stock is not so quoted on NASDAQ or any comparable system, the Board of Directors of the Corporation shall reasonably and in good faith determine the current market price on such basis as it considers appropriate. For example, in the event that the current market price per share of Common Stock is to be determined as of a Conversion Date, the current market price per share of Common Stock shall equal the average of the last reported bid price as reported by the American Stock Exchange for the ten (10) consecutive trading days ending the last trading day before such Conversion Date (assuming that the Common Stock is listed and admitted for trading on the American Stock Exchange and a reported bid price for Common Stock is placed on the American Stock Exchange on each such trading day).

Section 6. LIMITATIONS. (a) In addition to any other rights provided by applicable law, so long as any shares of the Series A Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote, or the written consent as provided by law, of the holders of at least two-thirds (2/3) of the outstanding shares of the Series A Preferred Stock, voting as a separate

- (i) create, authorize or issue any class or series of capital stock, or rights to subscribe to or acquire, or any security convertible into, any class or series of capital stock ranking as to payment of dividends, distribution of assets upon liquidation or voting rights, prior to the Series A Preferred Stock; or
- (ii) amend, alter or appeal, whether by merger, consolidation or otherwise, any of the provisions of the Certificate of Incorporation (including this Certificate of Designation) that would change the

-15-

preferences, rights or powers with respect to the Series A Preferred Stock so as to affect the Series A Preferred Stock adversely.

(b) In addition to any other rights provided by applicable law, so long as any shares of the Series A Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote, or the written consent as provided by law, of the holders of at least two-thirds (2/3) of the outstanding shares of the Series A Preferred Stock, voting as a separate class, issue or agree to issue any Common Stock or any security convertible or otherwise exchangeable, directly or indirectly, for Common Stock if such shares of Common Stock are to be issued, or such convertible securities are to be converted to or exchanged for shares of Common Stock, at a price per share less than the current market price for the Common Stock (determined as provided in Section 5) as of the day immediately preceding the date of the issuance of such Common Stock or such convertible or exchangeable security (as the case may be); provided, however, that the restrictions contained in this paragraph (b) shall not apply (i) to the issuance of any such convertible or exchangeable securities that are convertible or exchangeable at a fixed price (and not a floating price) per share equal to or greater than the current market price for the Common Stock (determined as provided in Section 5) as of the date of issuance of such convertible or exchangeable security, (ii) to the issuance of Common Stock and other securities of the Corporation issuable upon the exercise or conversion of options, warrants on other rights to purchase securities of the Corporation outstanding as of the date hereof, (iii) to the issuance of any securities to officers, directors or employees of the Corporation or any of its subsidiaries, (iv) to the issuance of any securities of the Corporation in an underwritten public offering or (v) to any other issuance of securities after the date that is 90 days after the Closing Date if the holders of Series A Preferred Stock are first delivered a written notice (a "Right of First Refusal Notice") from the Corporation offering such holders on a PRO RATA basis the right to purchase all or a portion of the related securities at the same price (and on the same terms and conditions, offered to other proposed investors (which notice shall set forth such price, terms and conditions). In the event that the Corporation delivers a Right of First Refusal Notice to any holder of Series A Preferred Stock, the failure by such holder to commit in writing to purchase such holder's pro rata portion of the securities identified in such Right of First Refusal Notice within five (5) business days of delivery thereof may be deemed by the Corporation to constitute such holder's determination not to so purchase such securities and the Corporation shall then be permitted to sell such securities to other investors at the price and on the terms and conditions set forth in such notice. The rights of holders of Series A Preferred Stock under this paragraph (b) shall terminate on the first anniversary of the Closing Date.

(c) Notwithstanding the foregoing, except as otherwise required by applicable law, nothing herein contained shall require a vote or consent of the holders of Series A Preferred Stock in connection with any increase in the total number of authorized shares of Common Stock. The holders of Series A Preferred Stock shall not be entitled to vote on any matter except (i) as provided in this Section 6 and (ii) as required by law.

Section 7. LOST OR STOLEN CERTIFICATES. Upon (i) receipt by the Corporation from a holder of evidence satisfactory to the Corporation of the loss, theft, destruction of any certificate(s) representing shares of Series A Preferred Stock and of an indemnification undertaking by the holder to the Corporation that is reasonably satisfactory to the Corporation or (ii) upon surrender and cancellation of certificate(s) representing shares of Series A Preferred Stock that have been mutilated, the Corporation shall execute and deliver to such holder new certificate(s) representing shares of Series A Preferred Stock of like tenor and date. However, the Corporation shall not be obligated to re-issue such lost, stolen, destroyed or mutilated certificate(s) representing shares of Series A Preferred Stock if such holder contemporaneously requests the Corporation to convert such shares of Series A Preferred Stock into shares of Common Stock or otherwise redeem such shares pursuant to the terms hereof.

-16-

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Designation to be signed by Douglas R. Eger, its Chairman and Chief Executive Officer, and attested by George Lombardi, its Secretary, this day of February, 1997.

SHEFFIELD MEDICAL TECHNOLOGIES INC.

By: /s/ Douglas R. Eger

Douglas R. Eger

Chairman and Chief Executive
Officer

Attested:

By: /s/ George Lombardi

George Lombardi Secretary

-17-

### OF DESIGNATION

### **NOTICE OF CONVERSION**

(To be completed, executed and delivered upon conversion of shares of Series A Preferred Stock)

TO: Sheffield Medical Technologies Inc.
Attention: Chief Financial Officer

The undersigned holder of shares of Series A Cumulative Convertible Redeemable Preferred Stock ("Series A Preferred Stock") of Sheffield Medical Technologies Inc. (the "Company") hereby converts \_\_\_\_\_\_ shares of Series A Preferred Stock into Common Stock of the Company at the applicable conversion rate on the terms and conditions specified in the Certificate of Designation for the Series A Preferred Stock. The undersigned surrenders herewith certificate(s) representing such number of shares of Series A Preferred Stock to be converted and all right, title and interest therein to the Company and directs that the Common Stock deliverable upon the conversion of such shares of Series A Preferred Stock be registered or placed in the name and at the address specified below and delivered thereto.

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[Insert Common Stock Registration Information]

In the event that the certificate(s) surrendered represent a number of shares of Series A Preferred Stock in excess of the shares of Series A Preferred Stock converted pursuant to this notice, you are advised to issue and deliver to the undersigned holder a certificate representing the remaining balance of shares of Series A Preferred Stock represented by the surrendered certificate(s) not so converted.

Date: _	<del>-</del>
Your Si	gnature:
	(Sign exactly as your name appears on the
	certificate representing the Shares of Series A

-19-

Preferred Stock being converted)

EX-10.3

AMENDED EMPLOYMENT AGREEMENT

#### AMENDED EMPLOYMENT AGREEMENT

AGREEMENT made as of the 22nd day of September, 1996 and effective September 25, 1996, by and between Sheffield Medical Technologies Inc., a Delaware corporation with its principal offices at 30 Rockefeller Plaza, Suite 4515, New York, New York 10112 (the "Corporation"), and George Lombardi residing at 106 Byrd Avenue, Bloomfield, New Jersey 07003 (the "Executive").

### WITNESSETH:

WHEREAS, the Corporation entered into an employment agreement dated as of September 7, 1995 (the "Employment Agreement") with the Executive relating to the employment of the Executive as Vice President and Chief Financial Officer of the Corporation; and

NOW, THEREFORE, in consideration of the premises and the mutual covenants hereinafter set forth, the parties hereto agree that the Employment Agreement is hereby amended as follows:

- 1. COMPENSATION. The Corporation and the Executive hereby agree to amend and restate clause (i) of Paragraph 4(a) of the Employment Agreement by substituting therefore the following: "(i) a salary at the rate of \$13,000 per annum, payable in equal installments in accordance with the normal payroll practices of the Corporation but in no event less frequently than semi-monthly" and
- 2. TERMINATION OF AGREEMENT; DEATH; SEVERANCE; SURVIVAL. The Corporation and the Executive hereby agree to amend and restate the first sentence of paragraph 11(b) of the Employment Agreement by substituting therefor the following: "In the event of the termination of the Executive's employment by the Corporation other than for Cause, the Executive shall be paid a severance payment of \$65,000 payable in six equal installments of \$10,833.33 with the first installment being payable on the date falling two weeks after the date of such termination and each additional installment being paid every two weeks after such date until such severance is paid in full."

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

SHEFFIELD MEDICAL TECHNOLOGIES, INC.

By: /s/ Douglas R. Eger
----Douglas R. Eger, Chairman

/s/ George Lombardi

George Lombardi, Vice President

Exhibit 10.5 to Form 10-KSB

SHEFFIELD MEDICAL TECHNOLOGIES INC. 30 Rockefeller Plaza, Suite 4515 New York, New York 10112

LETTER AMENDMENT

June 6, 1996

To: Michael Zeldin
2 Clinton Street
Cambridge, Massachusetts 01219

Dear Michael:

Reference is made to the Employment Agreement dated as of March 28, 1996 (the "Agreement") by and between you and Sheffield Medical Technologies Inc. (the "Company"). Unless otherwise referred herein, the terms defined in the Agreement shall be used herein as therein defined.

It has been determine by you and the Company that it is in the best interests of you and the Company that you assume the office of Chief Scientific Officer of the Company in lieu of continuing to serve as Chief Operating Officer and Executive Vice President - Corporate Development of the Company.

Therefore, it is hereby agreed between you and the Company that, effective as of the date first above written, the Agreement is hereby amended as follows:

(a) All references in the Agreement to "Chief Operating Officer and Executive Vice President - Corporate Development" are hereby replaced with references to "Chief Scientific Officer."

You hereby aknowledge that you have resigned as Chief Operating Officer and Executive Vice President - Corporate Development of the Company effective as of the date of this Letter Amendment.

On and after the effective date of this Letter Amendment, each reference in the Agreement to "this Agreement", "hereunder", "hereof" or words of like import referring to the Agreement shall mean and be a reference to the Agreement as amended by this Letter Amendment. The Agreement, as amended by

this Letter Amendment, is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed.

If you agree to the terms and provisions hereof, please evidence your agreement by executing at least two copies of this Letter Amendment. This Lease Letter Amendment shall become effective as of the date first above written when and if copies of this Lease Letter Agreement shall have been executed by Lessee and each of you.

Very truly yours,

SHEFFIELD MEDICAL TECHNOLOGIES INC.

By: /S/ Douglas R. Eger

-----

Douglas R. Eger Chairman & CEO

Agreed as of the date first above written:

/s/ Michael Zeldin

- -----Michael Zeldin

-2-

EX-10.8 6 1993 STOCK OPTION PLAN

Exhibit 10.8 to Form 10-KSB

SHEFFIELD MEDICAL TECHNOLOGIES INC.

1993 STOCK OPTION PLAN (as amended through June 20, 1996)

1. PURPOSES OF THE PLAN. The purposes of this 1993 Stock Option Plan are to attract and retain the best available personnel for positions of responsibility within the Company, to provide additional incentive to Employees of the Company, and to promote the success of the Company's business through the grant of options to purchase shares of the Company's Common Stock.

Options granted hereunder may be either Incentive Stock or Non-Statutory Stock Options, at the discretion of the Board. The type of options granted shall be reflected in the terms of written Stock Option agreements.

- 2. DEFINITIONS. As used herein, the following definitions shall apply:
  - (a) "BOARD" shall mean the Board of Directors of the Company

or, when appropriate, the Committee administering the Plan, if one has been appointed.

- (b) "CODE" shall mean the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder.
- (c) "COMMON STOCK" shall mean the common stock of the Company described in the Company's Certificate of Incorporation, as amended.
- (d) "COMPANY" shall mean SHEFFIELD MEDICAL TECHNOLOGIES INC., a Delaware corporation, and shall include any parent or subsidiary corporation of the Company as defined in Sections 425(e) and (f), respectively, of the Code.
- (e) "COMMITTEE" shall mean the Committee appointed by the Board in accordance with paragraph (a) of Section 4 of the Plan, if one is appointed.
- (f) "EMPLOYEE" shall mean any person, including salaried officers and directors, employed by the Company. The payment of a director's fee by the Company shall not be sufficient to constitute "employment" by the Company.
- (g) "EXCHANGE ACT" shall mean the Securities and Exchange Act of 1934, as amended.
- (h) "FAIR MARKET VALUE" shall mean, with respect to the date a given Option is granted or exercised, the value of the Common Stock determined by the Board in such manner as it may deem equitable for Plan purposes but, in the case of an Incentive Stock Option, no less than is required by applicable laws or regulations; provided, however, that where there is a public market for the Common Stock, the Fair Market Value per Share shall be the mean of the bid and asked prices of the Common Stock on the date of grant, as reported in the WALL STREET JOURNAL (or, if not so reported, as otherwise reported in the National Association of Securities Dealers Automated Quotation System) or, in the event the Common Stock is listed on the New York Stock Exchange or the NASDAQ Stock Market, the American Stock Exchange, the NASDAQ/National Market System, the Fair Market Value per Share shall be the closing price on such exchange on the date of grant of the Option, as reported in the WALL STREET JOURNAL.
- (i) "INCENTIVE STOCK OPTION" shall mean an Option which is intended to qualify as an incentive stock option within the meaning of Section 422 of the Code.
  - (j) "OPTION" shall mean a stock option granted under the Plan.
- (k) "OPTIONED STOCK" shall mean the Common Stock subject to an Option.
- (I) "OPTIONEE" shall mean an Employee of the Company who has been granted one or more Options.

- (m) "NONSTATUTORY STOCK OPTION" shall mean an Option which is not an Incentive Stock Option.
- (n) "PARENT" shall mean a "parent corporation," whether now or hereafter existing, as defined in Section 425(e) of the Code.
  - (o) "PLAN" shall mean this 1993 Stock Option Plan.
- (p) "SHARE" shall mean a share of the Common Stock, as adjusted in accordance with Section 11 of the Plan.
- (q) "STOCK OPTION AGREEMENT" shall mean the written agreement between the Company and the Optionee relating to the grant of an Option.

-2-

- (r) "SUBSIDIARY" shall mean a "subsidiary corporation," whether now or hereafter existing, as defined in Section 425(f) of the Code.
- (s) "TAX DATE" shall mean the date an Optionee is required to pay the Company an amount with respect to tax withholding obligations in connection with the exercise of an option.
- 3. COMMON STOCK SUBJECT TO THE PLAN. Subject to the provisions of Section 11 of the Plan, the maximum aggregate number of shares which may be optioned and sold under the Plan is One Million (1,000,000) Shares of Common Stock. The Shares may be authorized, but unissued, or previously issued Shares acquired by the Company and held in treasury.

If an Option should expire or become unexercisable for any reason without having been exercised in full, the unpurchased Shares covered by such Option shall, unless the Plan shall have been terminated, be available for future grants of Options.

### 4. ADMINISTRATION OF THE PLAN.

### (a) PROCEDURE.

- (i) The Plan shall be administered by the Board in accordance with Rule 16b-3 under the Exchange Act ("Rule 16b-3"); provided, however, that the Board may appoint a Committee to administer the Plan at any time or from time to time, and, provided further, that if the Board is not "disinterested" within the meaning of Rule 16b-3, the Plan shall be administered by a Committee in accordance with Rule 16b-3.
- (ii) Once appointed, the Committee shall continue to serve until otherwise directed by the Board. From time to time the Board may increase the size of the Committee and appoint additional members thereof, remove members (with or without cause), appoint new members in substitution therefor, and fill vacancies however caused: provided, however, that at no time may any person serve on the

Committee if that person's membership would cause the Committee not to satisfy the "disinterested administration" requirements of Rule 16b-3.

(b) POWERS OF THE BOARD. Subject to the provisions of the Plan, the Board shall have the authority, in its discretion: (i) to grant Incentive Stock Options and Nonstatutory Stock Options; (ii) to determine, upon review of relevant information and in accordance with Section 2 of the Plan, the Fair Market Value of the

-3-

Common Stock; (iii) to determine the exercise price per Share of Options to be granted, which exercise price shall be determined in accordance with Section 8(a) of the Plan; (iv) to determine the Employees to whom, and the time or times at which, Options shall be granted and the number of Shares to be represented by each Option; (v) to interpret the Plan; (vi) to prescribe, amend and rescind rules and regulations relating to the Plan; (vii) to determine the terms and provisions of each Option granted (which need not be identical) and, with the consent of the Optionee thereof, modify or amend each Option; (viii) to accelerate or defer (with the consent of the Optionee) the exercise date of any Option; (ix) to authorize any person to execute on behalf of the Company any instrument required to effectuate the grant of an Option previously granted by the Board; (x) to accept or reject the election made by an Optionee pursuant to Section 17 of the Plan; and (xi) to make all other determinations deemed necessary or advisable for the administration of the Plan.

(c) EFFECT OF BOARD'S DECISION. All decisions, determinations and interpretations of the Board shall be final and binding on all Optionees and any other holders of any Options granted under the Plan.

### 5. ELIGIBILITY.

- (a) Consistent with the Plan's purposes, Options may be granted only to Employees of the Company as determined by the Board. An Employee who has been granted an Option may, if he is otherwise eligible, be granted an additional Option or Options. Incentive Stock Options may be granted only to those Employees who meet the requirements applicable under Section 422 of the Code.
- (b) All Options granted to Employees of the Company under the Plan will be subject to forfeiture until such time as the Optionee has been continuously employed by the Company for one year after the date of the grant of the Options, and may not be exercised prior to such time. At such time as the Optionee has been continuously employed by the Company for one year, the foregoing restriction shall lapse and the Optionee may exercise the Options at any time otherwise consistent with the Plan.
- (c) With respect to Incentive Stock Options, the aggregate Fair Market Value (determined at the time the Incentive Stock Option is granted) of the Common Stock with respect to which Incentive Stock Options are exercisable for the first time by the employee during any calendar year (under all employee

benefit plans of the Company) shall not exceed One Hundred Thousand Dollars (\$100,000).

-4-

6. STOCKHOLDER APPROVAL AND EFFECTIVE DATES. The Plan became effective upon approval by the Board. No Option may be granted under the Plan after August 30, 2003 (ten years from the effective date of the Plan); provided, however that the Plan and all outstanding Options shall remain in effect until such Options have expired or until such Options are canceled.

7. TERM OF OPTION. Unless otherwise provided in the Stock Option Agreement, the term of each Option shall be five (5) years from the date of grant thereof. In no case shall the term of any Option exceed ten (10) years from the date of grant thereof. Notwithstanding the above, in the case of an Incentive Stock Option granted to an Employee who, at the time the Incentive Stock Option is granted, owns ten percent (10%) or more of the Common Stock as such amount is calculated under Section 422(b)(6) of the Code ("Ten Percent Stockholder"), the term of the Incentive Stock Option shall be five (5) years from the date of grant thereof or such shorter time as may be provided in the Stock Option Agreement.

# 8. EXERCISE PRICE AND PAYMENT.

- (a) EXERCISE PRICE. The per Share exercise price for the Shares to be issued pursuant to exercise of an Option shall be determined by the Board, but in the case of an Incentive Stock Option shall be no less than one hundred percent (100%) of the Fair Market Value per share on the date of grant, and in the case of a Nonstatutory Stock Option shall be no less than eighty-five percent (85%) of the Fair Market Value per share on the date of grant. Notwithstanding the foregoing, in the case of an Incentive Stock Option granted to an Employee who, at the time of the grant of such Incentive Stock Option, is a Ten Percent Stockholder, the per Share exercise price shall be no less than one hundred ten percent (110%) of the Fair Market Value per Share on the date of grant.
- (b) PAYMENT. The price of an exercised Option and the Employee's portion of any taxes attributable to the delivery of Common Stock under the Plan, or portion thereof, shall be paid:
  - (i) In United States dollars in cash or by check, bank draft or money order payable to the order of the Company; or
  - (ii) At the discretion of the Board, through the delivery of shares of Common Stock with an aggregate Fair Market Value equal to the option price and withholding taxes, if any; or

-5-

(iii) At the election of the Optionee pursuant to Section 17 and with the consent of the Board pursuant to Section 4(b)(x), by the Company's retention of such number of shares of Common Stock subject to the exercised Option which have an aggregate Fair Market Value on the exercise date equal to the Employee's portion of the Company's aggregate federal, state, local and foreign tax withholding and FICA and FUTA obligations with respect to income generated by the exercise of the Option by Optionee;

- (iv) By a combination of (i), (ii) and (iii) above; or
- (v) In the manner provided in subsection (c) below.

The Board shall determine acceptable methods for tendering Common Stock as payment upon exercise of an Option and may impose such limitations and prohibitions on the use of Common Stock to exercise an Option as it deems appropriate.

- (c) FINANCIAL ASSISTANCE TO OPTIONEES. The Board may assist Optionees in paying the exercise price of Options granted under this Plan in the following manner:
  - (i) The extension of a loan to the Optionee by the Company; or
  - (ii) Payment by the Optionee of the exercise price in installments; or
  - (iii) A guaranty by the Company of a loan obtained by the Optionee from a third party.

The terms of any loans, installment payments or guarantees, including the interest rate and terms of repayment, and collateral requirements, if any, shall be determined by the Board, in its sole discretion. Subject to applicable margin requirements, any loans, installment payments or guarantees authorized by the Board pursuant to the Plan may be granted without security, but the maximum credit available shall not exceed the exercise price for the Shares for which the Option is to be exercised, plus any federal and state income tax liability incurred in connection with the exercise of the Option.

### 9. EXERCISE OF OPTION.

(a) PROCEDURE FOR EXERCISE; RIGHTS AS A STOCKHOLDER. Any Option granted hereunder shall be exercisable at such times and under such conditions as determined by the Board, including performance criteria with respect to the Company and/or the

-6-

Optionee, and as shall be permissible under the terms of the Plan. Unless otherwise determined by the Board at the time of grant, an Option may be exercised in whole or in part. An Option may not be exercised for a fraction of a Share.

An Option shall be deemed to be exercised when written notice of such exercise has been given to the Company in accordance with the terms of the Option by the person entitled to exercise the Option and full payment for the Shares with respect to which the Option is exercised has been received by the company. Full payment may, as authorized by the Board, consist of any

consideration and method of payment allowable under Section 8(b) of the Plan. Until the issuance (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company) of the stock certificate evidencing such Shares, no right to vote or receive dividends or any other rights as a stockholder shall exist with respect to the Optioned Stock, notwithstanding the exercise of the Option. No adjustment will be made for a dividend or other right for which the record date is prior to the date the stock certificate is issued, except as provided in Section 11 of the Plan.

Exercise of an Option in any manner shall result in a decrease in the number of Shares which thereafter may be available, both for purposes of the Plan and for sale under the Option, by the number of Shares to which the Option is exercised.

- (b) TERMINATION OF STATUS AS AN EMPLOYEE. If an Employee's employment by the Company is terminated for cause, then any Option held by the Employee shall be immediately canceled upon termination of employment and the Employee shall have no further rights with respect to such Option. Unless otherwise provided in the Stock Option Agreement (which may reduce but not increase the time period described below), if an Employee's employment by the Company is terminated for reasons other than cause, and does not occur due to death or disability, then the Employee may, with the consent of the Board, but only within ninety (90) days after the date he ceases to be an Employee of the Company, exercise his Option to the extent that he was entitled to exercise it at the date of such termination. To the extent that he was not entitled to exercise the Option at the date of such termination, or if he does not exercise such Option (which he was entitled to exercise) within the time specified herein, the Option shall terminate.
- (c) DISABILITY. Unless otherwise provided in the Stock Option Agreement (which may reduce but not increase the time period described below), notwithstanding the provisions of Section 9(b) above, in the event an Employee is unable to continue his employment with the Company as a result of his permanent and total disability (as defined in Section 22(e)(3) of

-7-

the Code), he may, but only within twelve (12) months from the date of termination, exercise his Option to the extent he was entitled to exercise it at the date of such termination. To the extent that he was not entitled to exercise the Option at the date of termination, or if he does not exercise such Option (which he was entitled to exercise) within the time specified herein, the Option shall terminate.

(d) DEATH. Unless otherwise provided in the Stock Option Agreement (which may reduce but not increase the time period described below), if an Employee dies during the term of the Option and is at the time of his death an Employee of the Company who shall have been in continuous status as an Employee since the date of grant of the Option, the Option may be exercised at any time within twelve (12) months following the date of death (or such other period of time as is determined by the Board) by the Employee's estate or by a person who acquired the right to exercise the Option by bequest or inheritance, but only to the extent that an Employee was entitled to exercise the Option on the date of death. To the extent the Employee was not entitled to exercise the Option on the date of death, or if the Employee's estate, or person who acquired the right to

exercise the Option by bequest or inheritance, does not exercise such Option (which he was entitled to exercise) within the time specified herein, the Option shall terminate.

10. NON-TRANSFERABILITY OF OPTIONS. An Option may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by the laws of descent or distribution, or pursuant to a "qualified domestic relations order" under the Code and ERISA, and may be exercised, during the lifetime of the Optionee, only by the Optionee.

11. ADJUSTMENTS UPON CHANGES IN CAPITALIZATION OR MERGER. Subject to any required action by the stockholders of the Company, the number of shares of Common Stock covered by each outstanding Option, and the number of shares of Common Stock which have been authorized for issuance under the Plan but as to which no Options have yet been granted or which have been returned to the Plan upon cancellation or expiration of an Option, as well as the price per share of Common Stock covered by each such outstanding Option, shall be proportionately adjusted for any increase or decrease in the number of issued shares of Common Stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the Common Stock, or any other increase or decrease in the number of issued shares of Common Stock effected without receipt of consideration by the Company; provided, however, that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Such adjustment shall be made by the Board, whose determination in that respect shall be final, binding and conclusive. Except as expressly

-8-

provided herein, no issuance by the company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect and no adjustment by reason thereof, shall be made with respect to the number or price of shares of Common Stock subject to an Option.

In the event of the proposed dissolution or liquidation of the Company, the Option will terminate immediately prior to the consummation of such proposed action, unless otherwise provided by the Board. The Board may, in the exercise of its sole discretion in such instances, declare that any Option shall terminate as of a date fixed by the Board and give each Optionee the right to exercise his Option as to all or any part of the Optioned Stock, including Shares as to which the Option would not otherwise be exercisable. In the event of a proposed sale of all or substantially all of the assets of the Company, or the merger of the Company with or into another corporation, the Option shall be assumed or an equivalent option shall be substituted by such successor corporation or a parent or subsidiary of such successor corporation, unless the Board determines, in the exercise of its sole discretion and in lieu of such assumption or substitution, that the Optionee shall have the right to exercise the option as to all of the Optioned Stock, including Shares as to which the Option would not otherwise be exercisable. If the Board makes an Option fully exercisable in lieu of assumption or substitution in the event of a merger of sale of assets, the Board shall notify the Optionee that the Option shall be fully exercisable for a period of sixty (60) days from the date of such notice (but not later than the expiration of the term of the Option under the Option Agreement), and the Option will terminate upon the expiration of such period.

12. TIME OF GRANTING OPTIONS. The date of grant of an Option shall, for all purposes, be the date on which the Board makes the determination granting such Option. Notice of the determination shall be given to each Employee to whom an Option is so granted within a reasonable time after the date of such grant.

### 13. AMENDMENT AND TERMINATION OF THE PLAN.

- (a) AMENDMENT AND TERMINATION. The Board may amend or terminate the Plan from time to time in such respects as the Board may deem advisable; provided, however, that the following revisions or amendments shall require approval of the Stockholders of the Company, to the extent required by law, rule or regulation:
  - (i) Any material increase in the number of Shares subject to the Plan, other than in connection with an adjustment under Section 11 of the Plan;

-9-

- (ii) Any material change in the designation of the Employees eligible to be granted Options; or
- (iii) Any material increase in the benefits accruing to participants under the Plan.
- (b) EFFECT OF AMENDMENT OR TERMINATION. Any such amendment or termination of the Plan shall not affect Options already granted and such Options shall remain in full force and effect as if this Plan had not been amended or terminated, unless mutually agreed otherwise between the Optionee and the Board, which agreement must be in writing and signed by the Optionee and the Company.
- 14. CONDITIONS UPON ISSUANCE OF SHARES. Shares shall not be issued pursuant to the exercise of an Option unless the exercise of such Option and the issuance and delivery of such Shares pursuant thereto shall comply with all relevant provisions of law, including, without limitation, the Securities Act of 1933, as amended, the Exchange Act, the rules and regulations promulgated thereunder, and the requirements of any stock exchange upon which the Shares may then be listed, and shall be further subject to the approval of counsel for the Company with respect to such compliance.

As a condition to the exercise of an Option, the Company may require the person exercising such Option to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the company, such a representation is required by any of the aforementioned relevant provisions of law.

Inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.

In the case of an Incentive Stock Option, any Optionee who disposes of Shares of Common Stock acquired upon the exercise of an Option by sale or exchange (a) either within two (2) years after the date of the grant of the Option under which the Common Stock was acquired or (b) within one (1) year after the acquisition of such Shares of Common Stock shall notify the Company of such disposition and of the amount realized upon such disposition.

-10-

- 15. RESERVATION OF SHARES. The Company will at all times reserve and keep available such number of Shares as shall be sufficient to satisfy the requirements of the Plan.
- 16. OPTION AGREEMENT. Options shall be evidenced by Stock Option Agreements in such form as the Board shall approve.
- 17. WITHHOLDING TAXES. Subject to Section 4(b)(x) of the Plan and prior to the Tax Date, the Optionee may make an irrevocable election to have the Company withhold from those Shares that would otherwise be received upon the exercise of any Option, a number of Shares having a Fair Market Value equal to the minimum amount necessary to satisfy the Company's federal, state, local and foreign tax withholding obligations and FICA and FUTA obligations with respect to the exercise of such Option by the Optionee.

An Optionee who is also an officer of the Company must make the above described election:

- (a) at least six months after the date of grant of the Option (except in the event of death or disability); and
- (b) either:
  - (i) six months prior to the Tax Date, or
  - (ii) prior to the Tax Date and during the period beginning on the third business day following the date the Company releases its quarterly or annual statement of sales and earnings and ending on the twelfth business day following such date.

## 18. MISCELLANEOUS PROVISIONS.

- (a) PLAN EXPENSE. Any expense of administering this Plan shall be borne by the Company.
- (b) USE OF EXERCISE PROCEEDS. The payment received from Optionees from the exercise of Options shall be used for the general corporate purposes of the Company.
- (c) CONSTRUCTION OF PLAN. The place of administration of the Plan shall be in the State of Wyoming, and the validity, construction, interpretation, administration and effect of the Plan and of its rules and regulations, and rights relating to the Plan, shall be determined in accordance with the laws of the State of Wyoming without regard to conflict of law principles and, where applicable, in accordance with

- (d) TAXES. The Company shall be entitled if necessary or desirable to pay or withhold the amount of any tax attributable to the delivery of Common Stock under the Plan from other amounts payable to the Employee after giving the person entitled to receive such Common Stock notice as far in advance as practical, and the Company may defer making delivery of such Common Stock if any such tax may be pending unless and until indemnified to its satisfaction.
- (e) INDEMNIFICATION. In addition to such other rights of indemnification as they may have as members of the Board, the members of the Board shall be indemnified by the Company against all costs and expenses reasonably incurred by them in connection with any action, suit or proceeding to which they or any of them may be party by reason of any action taken or failure to act under or in connection with the Plan or any Option, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by the Company) or paid by them in satisfaction of a judgment in any such action, suite or proceeding, except a judgment based upon a finding of bad faith; provided that upon the institution of any such action, suit or proceeding a Board member shall, in writing, give the Company notice thereof and an opportunity, at its own expense, to handle and defend the same before such Board member undertakes to handle and defend it on her or his own behalf.
- (f) GENDER. For purposes of this Plan, words used in the masculine gender shall include the feminine and neuter, and the singular shall include the plural and vice versa, as appropriate.
- (g) NO EMPLOYMENT AGREEMENT. The Plan shall not confer upon any Optionee any right with respect to continuation of employment with the Company, nor shall it interfere in any way with his right or the Company's right to terminate his employment at any time.

-12-

EX-10.10 7 1996 DIRECTORS STOCK OPTION PLAN

Exhibit 10.10 to Form 10-KSB

SHEFFIELD MEDICAL TECHNOLOGIES INC.

1996 DIRECTORS STOCK OPTION PLAN

ARTICLE I

### **PURPOSE**

The purpose of the Sheffield Medical Technologies Inc. 1996 Directors Stock Option Plan (the "Plan") is to secure for Sheffield Medical Technologies Inc. and its stockholders the benefits arising from stock ownership by its Directors. The Plan will provide a means whereby such Directors may purchase shares of the common stock, \$.01 par value, of Sheffield Medical Technologies Inc. pursuant to options granted in accordance with the Plan.

#### **ARTICLE II**

### **DEFINITIONS**

The following capitalized terms used in the Plan shall have the respective meanings set forth in this Article:

- 2.1 "AMEX" shall mean the American Stock Exchange.
- 2.2 "Board" shall mean the Board of Directors of Sheffield Medical Technologies Inc.
  - 2.3 "Code" shall mean the Internal Revenue Code of 1986, as amended.
- 2.4 "Company" shall mean Sheffield Medical Technologies Inc. and any of its Subsidiaries.
- 2.5 "Director" shall mean any person who is a member of the Board of Directors of the Company.
- 2.6 "Eligible Director" shall be any Director who is not a full or part-time Employee of the Company.
- 2.7 "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.
- 2.8 "Exercise Price" shall mean the price per Share at which an Option may be exercised.
- 2.9 "Fair Market Value" shall mean the closing price of publicly traded Shares on the national securities exchange on which Shares are listed (if the Shares are so listed) or on the Nasdaq Stock Market System (if the Shares are regularly quoted on the Nasdaq Stock Market System), or, if not so listed or regularly quoted, the average of the closing bid and asked prices of publicly traded Shares in the over-the-counter market, or, if such bid and asked prices shall not be available, as reported by any nationally recognized quotation service selected by the Board.
- 2.10 "Grant Date" shall mean the Initial Grant Date and any Subsequent Grant Date.
- 2.11 "Initial Grant Date" shall mean June 30, 1996 with respect to each Eligible Director that is a member of the Board on such date.
  - 2.12 "New Director Grant Date" shall mean, with respect to an Eligible

Director first elected a member of the Board after June 30, 1996, the date such Eligible Director is first elected a member of the Board.

- 2.13 "Option" shall mean an Option to purchase Shares granted pursuant to the Plan.
- 2.14 "Option Agreement" shall mean the written agreement described in Article VI herein.
- 2.15 "Permanent Disability" shall mean the condition of an Eligible Director who is unable to participate as a member of the Board by reason of any medically determined physical or mental impairment that can be expected to result in death or which can be expected to last for a continuous period of not less than 12 months.
- 2.16 "Purchase Price" shall be the Exercise Price multiplied by the number of whole Shares with respect to which an Option may be exercised.
- 2.17 "Securities Act" shall mean the Securities Act of 1933, as amended.
- 2.18 "Shares" shall mean shares of common stock, \$.01 par value, of the Company.
- 2.19 "Subsequent Grant Date" shall mean any Grant Date other than the Initial Grant Date.

-2-

2.20 "Subsidiaries" shall have the meaning provided in Section 425(f) of the Code.

#### ARTICLE III

## **ADMINISTRATION**

- 3.1 GENERAL. The Plan shall be administered by the Board in accordance with the express provisions of the Plan.
- 3.2 POWERS OF THE BOARD. The Board shall have full and complete authority to adopt such rules and regulations and to make all such other determinations not inconsistent with the Plan as may be necessary for the administration of the Plan.

### **ARTICLE IV**

## SHARES SUBJECT TO PLAN

Subject to adjustment in accordance with Article IX, an aggregate of 500,000 Shares is reserved for issuance under the Plan. Shares sold under the Plan may be either authorized but unissued Shares or reacquired Shares. If an Option, or any portion thereof, shall expire or terminate for any reason without having been exercised in full, the unpurchased Shares covered by such Option shall be available for future grants of Options.

## ARTICLE V

### **GRANTS**

5.1 INITIAL GRANTS. On June 30, 1996, each Eligible Director on such date shall receive the grant of an Option to purchase 15,000 Shares. If an Eligible Director is granted an option under the Plan prior to the date of approval of the Plan by the Company's stockholders, such option shall not become effective until the Company's stockholders approve the Plan.

5.2 NEW DIRECTOR GRANTS. To the extent that Shares remain available for the grant of Options under the Plan, on the New Director Grant Date with respect to an Eligible Director, such Eligible Director shall receive the grant of an Option to purchase 25,000 Shares.

5.3 SUBSEQUENT GRANTS. To the extent that Shares remain available for the grant of Options under the Plan, on January 1 of each year commencing January 1, 1997, each Eligible Director shall be granted an Option to purchase 15,000 Shares.

-3-

5.4 ADJUSTMENT OF GRANTS. The number of Shares set forth in Section 5.1, 5.2 and 5.3 as to which Options shall be granted shall be subject to adjustment as provided in Section 9.1 hereof.

5.5 COMPLIANCE WITH RULE 16B-3. The terms for the grant of Options to an Eligible Director may only be changed if permitted under Rule 16b-3 under the Exchange Act and, accordingly, the formula for the grant of Options may not be changed or otherwise modified more than once in any six month period, other than to comport with changes in the Code, the Employee Retirement Income Security Act, or the rules and regulations thereunder.

#### **ARTICLE VI**

# **TERMS OF OPTION**

Each Option shall be evidenced by a written Option Agreement executed by the Company and the Eligible Director which shall specify the Grant Date, the number of Shares subject to the Option, the Exercise Price and shall also include or incorporate by reference the substance of all of the following provisions and such other provisions consistent with the Plan as the Board may determine.

6.1 TERM. The term of each Option shall be 5 years from the Grant Date thereof, subject to earlier termination in accordance with Articles VI and X.

6.2 RESTRICTION ON EXERCISE. Options shall be exercisable at such time or times and subject to such terms and conditions as shall be determined by the Board at grant; PROVIDED, HOWEVER, that in the case of the Eligible Director's death or Permanent Disability, the Options held by him will become immediately exercisable, unless a longer vesting period is otherwise determined by the Board at grant. The Board may waive any installment exercise provision at any time in

whole or in part based on performance and/or such other factors as the Board may determine in its sole discretion; PROVIDED, HOWEVER, that no Option shall be exercisable until at least than six months have elapsed from the Grant Date and, PROVIDED, FURTHER, that no Option will be exercisable until the requisite approval of the Plan by the Company's stockholders shall have been obtained.

6.3 EXERCISE PRICE. The Exercise Price for each Share subject to an Option shall be the Fair Market Value of the Share as determined in Section 2.9 herein.

6.4 MANNER OF EXERCISE. An Option shall be exercised in accordance with its terms, by delivery of a written notice of exercise to the Company and payment of the full purchase price of the Shares being purchased. An Eligible Director may exercise an Option with respect to all or less than all of the Shares for which the Option may then be exercised, but an Eligible Director must exercise the Option in full Shares.

-4-

6.5 PAYMENT. The Purchase Price of Shares purchased pursuant to an Option or portion thereof, may be paid:

- (a) in United States Dollars, in cash or by check, bank draft or money order payable to the Company; or
- (b) at the discretion of the Board by delivery of Shares already owned by an Eligible Director with an aggregate Fair Market Value on the date of exercise equal to the Purchase Price, subject to the provisions of Section 16(b) of the Exchange Act.

6.6 TRANSFERABILITY. No Option shall be transferable otherwise than by will or the laws of descent and distribution or pursuant to a qualified domestic relations order as defined by the Code or Title I of the Employee Retirement Income Security Act, or the rules thereunder. An Option shall be exercisable during the Eligible Director's lifetime only by the Eligible Director, his guardian or legal representative.

6.7 TERMINATION OF MEMBERSHIP ON THE BOARD. If an Eligible Director's membership on the Board terminates for any reason, an Option held on the date of termination may be exercised in whole or in part at any time within one (1) year after the date of such termination (but in no event after the term of the Option expires) and shall thereafter terminate.

### **ARTICLE VII**

### **GOVERNMENT AND OTHER REGULATIONS**

7.1 DELIVERY OF SHARES. The obligation of the Company to issue or transfer and deliver Shares for exercised Options under the Plan shall be subject to all applicable laws, regulations, rules, orders and approvals which shall then be in effect.

7.2 HOLDING OF STOCK AFTER EXERCISE OF OPTION. The Option Agreement shall provide that the Eligible Director, by accepting such Option, represents

and agrees, for the Eligible Director and his permitted transferees hereunder that none of the Shares purchased upon exercise of the Option shall be acquired with a view to any sale, transfer or distribution of the Shares in violation of the Securities Act and the person exercising an Option shall furnish evidence satisfactory to that Company to that effect, including an indemnification of the Company in the event of any violation of the Act by such person. Notwithstanding the foregoing, the Company in its sole discretion may register under the Act the Shares issuable upon exercise of the Options under the Plan.

-5-

### ARTICLE VIII

### WITHHOLDING TAX

The Company may, in its discretion, require an Eligible Director to pay to the Company, at the time of exercise of an Option an amount that the Company deems necessary to satisfy its obligations to withhold federal, state or local income or other taxes (which for purposes of this Article includes an Eligible Director's FICA obligation) incurred by reason of such exercise. When the exercise of an Option does not give rise to the obligation to withhold federal income taxes on the date of exercise, the Company may, in its discretion, require an Eligible Director to place Shares purchased under the Option in escrow for the benefit of the Company until such time as federal income tax withholding is required on amounts included in the Eligible Director's gross income as a result of the exercise of an Option. At such time, the Company, in its discretion, may require an Eligible Director to pay to the Company an amount that the Company deems necessary to satisfy its obligation to withhold federal, state or local taxes incurred by reason of the exercise of the Option, in which case the Shares will be released from escrow upon such payment by an Eligible Director.

## ARTICLE IX

# ADJUSTMENTS

9.1 PROPORTIONATE ADJUSTMENTS. If the outstanding Shares are increased, decreased, changed into or exchanged into a different number or kind of Shares or securities of the Company through reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar transaction, an appropriate and proportionate adjustment shall be made to the maximum number and kind of Shares as to which Options may be granted under the Plan. A corresponding adjustment changing the number or kind of Shares allocated to unexercised Options or portions thereof, which shall have been granted prior to any such change, shall likewise be made. Any such adjustment in the outstanding Options shall be made without change in the Purchase Price applicable to the unexercised portion of the Option with a corresponding adjustment in the Exercise Price of the Shares covered by the Option. Notwithstanding the foregoing, there shall be no adjustment for the issuance of Shares on conversion of notes, preferred stock or exercise of warrants or Shares issued by the Board for such consideration as the Board deems appropriate.

the Company, or upon a reorganization, merger or consolidation of the Company with one or more corporations as a result of which the Company is not the surviving corporation, or upon a sale of substantially all of the property or more than 80% of the then outstanding Shares of the Company to another corporation, the Company shall give to each Eligible Director at the time of adoption of the plan for liquidation, dissolution, merger or sale either (1) a reasonable time thereafter within which to exercise the Option prior to the effective date of such liquidation or

-6-

dissolution, merger or sale, or (2) the right to exercise the Option as to an equivalent number of Shares of stock of the corporation succeeding the Company or acquiring its business by reason of such liquidation, dissolution, merger, consolidation or reorganization.

-7-

#### **ARTICLE X**

### AMENDMENT OR TERMINATION OF PLAN

- 10.1 AMENDMENTS. The Board may at any time amend or revise the terms of the Plan, provided no such amendment or revision shall, unless appropriate approval of such amendment or revision by the Company's stockholders is obtained:
- (a) increase the maximum number of Shares which may be sold pursuant to Options granted under the Plan, except as permitted under the provisions of Article IX;
  - (b) change the minimum Exercise Price set forth in Article VI;
- (c) increase the maximum term of Options provided for in Article  $\,$  VI; or
- (d) permit the granting of Options to anyone other than as provided in Article V.
- 10.2 TERMINATION. The Board at any time may suspend or terminate the Plan. The Plan, unless sooner terminated, shall terminate on the tenth (10th) anniversary of its adoption by the Board. Termination of the Plan shall not affect Options previously granted thereunder. No Option may be granted under the Plan while the Plan is suspended or after it is terminated.
- 10.3 CONSENT OF HOLDER. No amendment, suspension or termination of the Plan shall, without the consent of the holder of Options, alter or impair any rights or obligations under any Option theretofore granted under the Plan.

### MISCELLANEOUS PROVISIONS

- 11.1 PRIVILEGE OF STOCK OWNERSHIP. No Eligible Director entitled to exercise any Option granted under the Plan shall have any of the rights or privileges of a stockholder of the Company with respect to any Shares issuable upon exercise of an Option until certificates representing the Shares shall have been issued and delivered.
- 11.2 PLAN EXPENSES. Any expenses incurred in the administration of the Plan shall be borne by the Company.
- 11.3 USE OF PROCEEDS. Payments received from an Eligible Director upon the exercise of Options shall be used for general corporate purposes of the Company.

-8-

11.4 GOVERNING LAW. The Plan has been adopted under the laws of the State of New York. The Plan and all Options which may be granted hereunder and all matters related thereto, shall be governed by and construed and enforceable in accordance with the laws of the State of New York as it then exists.

### ARTICLE XII

### STOCKHOLDER APPROVAL

The Plan is subject to approval of the Company's stockholders, at a duly held meeting of the Company's stockholders, within 12 months after the date the Board approves the Plan, by the affirmative vote of holders of a majority of the voting Shares of the Company represented in person or by proxy and entitled to vote at the meeting. Options may be granted, but not exercised, before such stockholder approval is obtained. If the stockholders fail to approve the Plan within the required time period, any Options granted under the Plan shall be void, and no additional Options may thereafter be granted.

-9-

EX-23.1

CONSENT OF INDEPENDENT AUDITORS

EXHIBIT 23.1

### CONSENT OF INDEPENDENT AUDITORS

We consent to the incorporation by reference in Amendment No. 1 to the Registration Statement (Form S-3 No. 33-95732) of Sheffield Medical Technologies Inc. and in the related Prospectus, in Amendment No. 1 to the Registration

Statement (Form S-8 No. 33-95262) pertaining to the 1993 Stock Option Plan of Sheffield Medical Technologies Inc., the 1993 Restricted Stock Plan of Sheffield Medical Technologies Inc. and Options granted to directors, officers, employees, consultants and advisors of the Company pursuant to other employee benefit plans of Sheffield Medical Technologies Inc. and in the Registration Statement (Form S-8 No. 333-14867) pertaining to the 1993 Stock Option Plan of Sheffield Medical Technologies Inc., the 1996 Directors Stock Option Plan of Sheffield Medical Technologies Inc. and Options granted to directors, officers, employees, consultants and advisors of the Company pursuant to other employee benefit plans of Sheffield Medical Technologies Inc. of our report dated February 12, 1997, except for Note 9 as to which the date is March 14, 1997, with respect to the consolidated financial statements of Sheffield Medical Technologies Inc. and subsidiaries included in this Annual Report (Form 10-KSB) for the year ended December 31, 1996.

/s/ Ernst & Young LLP

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ERNST & YOUNG LLP Princeton, New Jersey March 24, 1997

EX-23.2 9 CONSENT OF INDEPENDENT AUDITORS

Exhibit 23.2

The Board of Directors
Sheffield Medical Technologies Inc.:

We consent to incorporation by reference in the Registration Statement (Form S-3 No. 33-95732, Form S-8 No. 33-95262 and Form S-8 No.333-14867) of Sheffield Medical Technologies Inc. of our report dated February 11, 1994, relating to the consolidated financial statement of Sheffield Medical Technologies Inc. and subsidiary included in the Annual Report (Form 10-KSB) for the year ended December 31, 1996.

Our report dated February 11, 1994, contains an explanatory paragraph that states that the Company's recurring losses and net deficit position raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG Peat Marwick LLP

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KPMG Peat Marwick LLP

EX-27 10 FINANCIAL DATA SCHEDULE

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THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE CONDENSED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 1996 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH STATEMENTS.

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DEC-31-1996
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