-----BEGIN PRIVACY-ENHANCED MESSAGE----- Proc-Type: 2001,MIC-CLEAR Originator-Name: webmaster@www.sec.gov Originator-Key-Asymmetric: MFgwCgYEVQgBAQICAf8DSgAwRwJAW2sNKK9AVtBzYZmr6aGjlWyK3XmZv3dTINen TWSM7vrzLADbmYQaionwg5sDW3P6oaM5D3tdezXMm7z1T+B+twIDAQAB MIC-Info: RSA-MD5,RSA, G/8TVtAlEEZ4ARnytyyFkBmL5RMy1shxGvQ0Nn0dfEMAnVla0a7VsV6jlxUJp1wC 6pqFlABkl7pcs/ElGB/rYw== 0000921895-98-000327.txt : 19980416 0000921895-98-000327.hdr.sgml : 19980416 ACCESSION NUMBER: 0000921895-98-000327 CONFORMED SUBMISSION TYPE: 10-K PUBLIC DOCUMENT COUNT: 9 CONFORMED PERIOD OF REPORT: 19971231 FILED AS OF DATE: 19980415 SROS: NASD FILER: COMPANY DATA: COMPANY CONFORMED NAME: SHEFFIELD PHARMACEUTICALS INC CENTRAL INDEX KEY: 0000894158 STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834] IRS NUMBER: 133808303 STATE OF INCORPORATION: DE FISCAL YEAR END: 1231 FILING VALUES: FORM TYPE: 10-K SEC ACT: SEC FILE NUMBER: 001-12584 FILM NUMBER: 98594851 BUSINESS ADDRESS: STREET 1: 30 ROCKEFELLER PLAZA STREET 2: SUITE 4515 CITY: NEW YORK STATE: NY ZIP: 10112 BUSINESS PHONE: 2129576600 MAIL ADDRESS: STREET 1: 30 ROCKEFELLER PLAZA STREET 2: SUITE 4515 CITY: NEW YORK STATE: NY ZIP: 10112 FORMER COMPANY: FORMER CONFORMED NAME: SHEFFIELD MEDICAL TECHNOLOGIES INC DATE OF NAME CHANGE: 19940606
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FORM 10-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTIONS 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

- ----------

(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, 1997

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

For the transition period from to

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Commission file number 1-12584

SHEFFIELD PHARMACEUTICALS, INC.

- ----------

(Name of Registrant as Specified in its Charter)

DELAWARE	13-3808303
(State or Other Jurisdiction of Incorporation or Organi-zation)	(IRS Employer Identification Number)

425 Woodsmill Road, St. Louis, Missouri 63017

- ----------

(Address of Principal Executive Offices) (Zip Code)

Issuer's Telephone Number, Including Area Code: (314) 579-9899

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

TITLE OF EACH CLASS	Name of Each Exchange ON WHICH REGISTERED
Common Stock, $.01 par value	American Stock Exchange

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

None

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the preceding 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 / /

(CONTINUED ON NEXT PAGE)

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/ / Indicate by check mark if disclosure of delinquent filers to

Item 405 of Regulation S-K is not contained herein, and will not 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-K or any amendment to this Form 10-K.

The aggregate market value at March 31, 1998 of the voting stock of the Registrant held by non-affiliates (based upon the closing price of $0.6875 per share of such stock on the American Stock Exchange on such date) was approximately $10,197,487. 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 registrant's classes of common equity, as of the latest practicable date: At March 31, 1998, there were outstanding 15,742,762 shares of the issuer's Common Stock, $.01 par value.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the Registrant's definitive proxy statement to be filed not later than April 30, 1998 pursuant to Regulation 14A are incorporated by reference in Items 10 through 13 of Part III of this Annual Report on Form 10-K.

PART I

ITEM 1. BUSINESS

GENERAL

Sheffield Pharmaceuticals, Inc. (the "Company"), formerly known as Sheffield Medical Technologies Inc., is an emerging pharmaceutical company developing and commercializing prescription pharmaceutical products to be promoted by a specialty pharmaceutical sales force. The Company is in the development stage and as such has been principally engaged in the development of its proprietary drug delivery system, the Premaire(TM) Metered Solution Inhaler (the "Premaire(TM) MSI System"). The Company's lead products are four respiratory drugs for the treatment of asthma and chronic obstructive pulmonary disease ("COPD"). These drugs will be delivered to the lungs by the Premaire(TM) MSI System, the world-wide marketing rights to which were in-licensed by the Company from Siemens AG in March 1997. In addition, the Company is actively seeking partners for the development of other respiratory and non-respiratory drugs for delivery via the Premaire(TM) MSI System. Finally, the Company is seeking to out- license its rights in several early-stage biomedical technologies.

The Company does not currently have any sales or marketing

capabilities. It intends to build or otherwise acquire a specialty pharmaceutical sales force in the United States, as well as the attendant marketing infrastructure, as its lead products near marketing approval.

The Company was originally formed in 1986 and is incorporated in Delaware. In 1996, the Company formed a wholly owned Delaware subsidiary, Ion Pharmaceuticals, Inc. ("Ion"), that owns the rights to certain early- stage biomedical technologies. In 1997, the Company acquired all of Camelot Pharmacal, L.L.C., a Missouri limited liability corporation that was subsequently liquidated. Unless the context requires otherwise, references to the "Company" herein are references to Sheffield Pharmaceuticals, Inc. and its subsidiaries.

The Company's headquarters are located at Suite 270, 425 South Woodsmill Road, St. Louis, Missouri 63017-3441 and its telephone number is (314) 579-9899.

BUSINESS STRATEGY

The principal elements of the Company's business strategy consist of the following: (i) marketing its products directly through the Company's future specialty sales force; (ii) selectively acquiring, in-licensing, co- promoting or obtaining currently marketed pharmaceutical products in selected markets; (iii) focusing on certain chronic diseases, such as asthma, requiring long-term therapy in the large, rapidly growing concentrated respiratory market with a range of drugs delivered by the Premaire(TM) MSI System, (as further described below); and (iv) contracting for the manufacture and development of its products with cost effective, high quality U.S. Food and Drug Administration ("FDA") compliant companies.

The Company's management consists of individuals who possess substantial experience in the acquisition, development and commercialization of pharmaceutical products. Through their experience at such companies as Bock Pharmacal Company and Fisons plc, members of the Company's management team have demonstrated the ability to build and manage the operations of successful pharmaceutical companies. This team provides the Company with extensive industry contacts together with broad and complementary business and scientific skills, which are critical to achieving success in the pharmaceutical industry.

PROJECTS UNDER DEVELOPMENT

PREMAIRE(TM) MSI SYSTEM

BACKGROUND

The Company owns the exclusive worldwide rights to the Premaire(TM) MSI System, a patented, state-of-the- art, multi-dose nebulizer delivery system (the " Premaire(TM) MSI System") from Siemens AG, the multi-national engineering and electronics conglomerate. The system is comprised of a hand-held, pocket-sized, ultrasonic nebulizer, and dosator cartridges containing various medications. The pharmaceutical formulations currently in development by the Company for use with the Premaire(TM) MSI System are for the treatment of asthma and COPD. Through the Premaire(TM) MSI System and the products under development for use in the Premaire(TM) MSI System, the Company plans to be a significant competitor in the respiratory category by the year 2001. Siemens AG will

manufacture and supply the hand-held nebulizer component of the Premaire(TM) MSI System. The Company is in the development phase for commonly used respiratory drugs for use with the Premaire(TM) MSI System.

PULMONARY DRUG DELIVERY MARKET ENVIRONMENT

The Premaire(TM) MSI System pulmonary drug delivery system for which the Company holds exclusive worldwide rights has been developed to meet specific needs within the respiratory market, particularly for those patients suffering from asthma and COPD. In 1995, audited industry sources indicated there were approximately 10 million asthma patients and 3 million COPD patients under physician care in the U.S. Other sources indicate that there are at least 14 million asthma patients being treated by physicians and that the number of newly diagnosed patients is growing at a rate of 10% annually. With the aging of the population, it is believed that COPD is growing at a similar rate. Because the Company will initially focus its future specialty sales force in the U.S., the following information will focus on the U.S. market potential for the Premaire(TM) MSI System. There remains an opportunity to play a significant role in other markets outside of the U.S., particularly in Europe.

Today, three principal types of devices are widely used in aerosol administration: metered dose inhalers (MDIs), dry powder inhalers (DPIs), and nebulizers.

METERED DOSE INHALERS. Currently, MDIs are the most commonly used aerosol delivery system. It is estimated that in the United States, 80% of aerosol drug delivery is via MDIs, with the majority of this use coming from adults with asthma and COPD.

The primary advantages of an MDI include its small size/portability, drug delivery time in seconds, and availability with most respiratory drugs. Disadvantages include patient coordination issues and efficient dose delivery. Additionally, because the use of chlorofluorocarbon (CFC) propellants, traditionally used in MDIs, is being phased out according to international agreement (Montreal Protocol), alternative propellants and formulations are being developed. Over time, all current MDI users will be required to move to a non-CFC MDI or other alternative delivery systems.

DRY POWDER INHALERS. DPIs were introduced in the 1960s as single-dose inhalers. In these devices, the drug is loaded as a unit dose that is mechanically released as a powder for inhalation prior to each use. To date, these systems have been the primary form of DPI available in the United States, and account for approximately 1% of the total aerosol delivery market.

The inconvenience of the single dose DPI has been overcome outside of the U.S. with the development and introduction of multidose DPIs that can deliver up to 200 doses of medication. However, like the single dose systems, they are likely to be inspiratory flow rate dependent,

that is, the amount of drug delivered to the lung is dependent upon the patient's ability to inhale.

Two of the most significant advantages of DPIs include 1) no hand-breath coordination is required as with MDIs; and 2) they contain no CFCs. However, most require a high inspiratory flow rate that can be problematic in younger patients or in patients with compromised lung function. In addition, they often present difficulties for those with manual disabilities (e.g., arthritis) or limited vision and, depending upon the powder load delivered, may induce acute bronchospasm in sensitive individuals.

NEBULIZERS. The third widely-used aerosol delivery system is the nebulizer. Jet nebulizers, which are by far the most commonly used, work on a stream of compressed air or oxygen that is forced through a narrow tube which lies just above the surface of the liquid to be nebulized. It takes approximately 10 to 15 minutes to nebulize this amount of liquid. During nebulization only about 10% of the drug is delivered to the lungs; about 80% gets trapped in the reservoir, tubing and mask; the rest is exhaled.

Nebulizers can be used for a wide range of patients, but are especially useful for those old and young patients who cannot manage other inhaler devices, and for whom inhalation via tidal breathing is preferred. Nebulizers also play a key role in emergency room and intensive care treatment for patients with acute bronchospasm. However, most nebulizers are bulky units that are time consuming, have a high initial cost and can be extremely noisy during operation.

PROJECTED MARKET ENVIRONMENT

The Company believes that the U.S. respiratory market will exceed $4 billion by the year 2001. Many developments are taking place in the technology associated with pulmonary drug delivery. Spurred on by the Montreal Protocol and the ban on CFC propellants, much of the work in research and development has focused on alternative propellants and dry powder systems. It is anticipated that there will be a minimum of 11 and a maximum of 35 approved CFC-free inhaled products on the market in the United States by 2001. Many of these are expected to be MDIs with new propellants or DPIs. However, few of these second generation delivery systems are expected to overcome the disadvantages associated with their earlier counterparts.

There are a number of new devices in development that have been designed specifically to address unmet patient needs. Among these is the Company's patented metered solution inhaler, the Premaire(TM) MSI System, which is designed to combine the therapeutic benefits of nebulization with the convenience of pressurized metered dose inhalers.

DESCRIPTION OF THE TECHNOLOGY

The Premaire(TM) MSI System is a metered solution inhaler comprised of two main components: (i) a reusable, pocket-size inhaler unit developed and manufactured for the Company by Siemens AG, a global leader in electronics and technology, and (ii) interchangeable drug cartridges called dosators. The basic technology of the system involves the rapid nebulization of therapeutic agents for the respiratory tract using ultrasonic energy. This produces a concentrated cloud of medication delivered through the mouthpiece over a two to three second period for inhalation. Key components of the technology include rechargeable batteries, a battery-operated motor, ultrasonic horn, drug cartridge chamber and mouthpiece.

The pocket-size Premaire(TM) MSI System accommodates a variety of drug dosators to allow for administration of a range of drugs in a single, simple-to-use, environmentally-friendly delivery system. Each dosator contains 120 actuations containing approximately a one to two month supply of drug.

The Premaire(TM) MSI System is designed to be patient friendly. A patient simply selects the appropriate color-coded drug cartridge and places it into the chamber of the inhaler unit. Pressing the "on" button activates the small electrical motor that transports a precise dose of drug from the cartridge chamber to the ultrasonic horn which transforms the solution into an aerosolized cloud. The patient's inspiration carries a cloud of medication directly to the lungs where it is needed. The Company expects the delivered dose to be accurate and consistent for the following reasons: (i) the Premaire(TM) MSI System is designed to be inspiratory flow rate independent, that is, delivery of the drug does not depend upon the patient's ability to inhale forcefully, and (ii) the Premaire(TM) MSI System does not require a high level of coordination between inspiration and actuation of the device. The patient's breath carries the medication directly to the lungs, minimizing the amount of drug deposited in the mouth and throat.

POTENTIAL ADVANTAGES OF THE PREMAIRE(TM) MSI SYSTEM.

The Company believes that the Premaire(TM) MSI System may provide significant advantages over other drug delivery systems. It is particularly suited for younger and older asthma patients, and for older COPD patients who have difficulty using MDIs and currently have to depend on larger, more time-consuming table-top nebulizers for delivery of their medications. These potential advantages include:

ACCURACY. The superior engineering and patient-friendly design of the Premaire(TM) MSI System is intended to provide minimal dose to dose variability. Patients can therefore expect to consistently receive the correct therapeutic dose.

ENHANCED PATIENT COMPLIANCE. The pocket-size, portable Premaire(TM) MSI System unit is designed to combine the therapeutic benefits of nebulization with the convenience of pressurized metered dose inhalers. Drug delivery time is measured in seconds, as compared to 10 - 15 minutes or more for the typical nebulizer. Plus, the device is easy to operate and requires minimal coordination between actuation and inhalation for proper drug delivery. All of these features contribute to improved patient compliance resulting from proper

administration of their respiratory medication.

INSPIRATORY FLOW RATE INDEPENDENCE. The Premaire(TM) MSI System is designed to achieve a consistent and significant level of drug deposition over a broad range of inspiratory flow rates. This is especially important in younger patients or in patients with compromised lung function (e.g., during an asthma attack).

VERSATILITY. Many asthma and COPD patients are taking multiple inhalation medications. The Premaire(TM) MSI System accommodates interchangeable drug cartridges, or dosators, to allow for the administration of a broad range of frequently used respiratory drugs in a single, simple to use delivery system. The system utilizes early warning mechanism to signal when the batteries need recharging. These user-friendly features result in a simplified dosing procedure for both patients and their caregivers.

ENVIRONMENTALLY-FRIENDLY. CFCs are associated with the reduction of the Earth's ozone layer, and are subject to worldwide regulations aimed at eliminating their production and use within the decade. The Premaire(TM) MSI System does not use CFCs or any other type of ozone depleting propellant.

ECONOMICAL. The Premaire(TM) MSI System offers significant value to the patient because it allows a single device to be used with a complete family of respiratory medications available in cost-effective interchangeable cartridges. The inhaler unit itself has a life of three years for a patient who uses it several times a day.

THE PREMAIRE(TM) DEVELOPMENT STRATEGY

The Company is implementing a two-tier development strategy for the Premaire(TM) MSI System as described below:

DEVELOP AND COMMERCIALIZE FOUR NON-PATENTED INHALED RESPIRATORY MEDICATIONS. The Company, in collaboration with Chesapeake Biological Laboratories, is currently developing four widely used respiratory drugs for use in the Premaire(TM) MSI System. These include: albuterol sulfate, ipratropium bromide, cromolyn sodium and an inhaled bronchial steroid.

IDENTIFY CORPORATE PARTNERS. The Company plans to identify potential foreign marketing partner or partners for the four initial compounds in the Premaire(TM) MSI System. The Company plans to market albuterol, ipratropium, cromolyn and an inhaled steroid in the U.S.

through the use of a planned specialty sales force. The Company is currently in the process of identifying potential marketing partners outside of the U.S. to cover major foreign markets.

The Company plans to sublicense the Premaire(TM) MSI System technology to pharmaceutical companies for use with new respiratory drugs/non-respiratory drugs. The Company is actively exploring out-licensing opportunities for developing new respiratory medications for the Premaire(TM) MSI System, as well as exploring expansion of the Premaire(TM) MSI for the pulmonary delivery of drugs to the bloodstream (e.g., insulin, morphine). Out-licensing, manufacturing and supply agreements with such companies would provide the Company with additional revenue sources.

EARLY STAGE RESEARCH PROJECTS

As part of the Company's focus on later stage opportunities, the Company is seeking to out-license its portfolio of early stage medical research projects to companies that are committed to early stage biotechnology opportunities. This portfolio consists of opportunities within the Company's wholly-owned subsidiary, Ion, which are focused on development of new compounds for the treatment of cancer and other diseases. In addition, the Company has rights to potential products in the areas of human immunodeficiency virus ("HIV"), Acquired Immune Deficiency Syndrome ("AIDS") and prostrate cancer. These early stage technologies do not fit the emerging pharmaceutical company strategy. Consequently, the Company plans to outlicense these technologies while maintaining an interest in the technologies' promise without incurring the development costs associated with early stage research and development.

RBC-CD4 ELECTROINSERTION TECHNOLOGY

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 for use as a potential therapeutic in the treatment of HIV that leads to 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.

The Company has signed an option agreement with a private investment group that had a prior interest in the RBC-CD4 Electroinsertion Technology, to sell the Company's rights to this HIV/AIDS technologies. As consideration for the option, the third party will fund an additional study related to the RBC-CD4 Electroinsertion Technology. In addition, the Company will retain a one-third interest in all future commercial and sublicensing results.

LIPOSOME-CD4 TECHNOLOGY

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. Liposome-CD4 Technology has been targeted by the Company at infections in the human lymphatic system, a major reservoir for infection not directly reached by blood circulation.

The Company entered into a sublicense agreement in July 1996 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.

HIV/AIDS VACCINE

The Company holds an exclusive worldwide license to a potential HIV/AIDS vaccine (the "HIV/AIDS Vaccine") and diagnostic test under development at the French Institute of Health and Medical Research ("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 targets an antibody binding site or "epitope" which is on a region of the beta-2-microglobulin that is normally associated with the Class I major histocompatability molecule found on the surface of most human cells. It is believed that inducing an antibody to this epitope could either prevent the progression of existing HIV infection or entirely prevent infection of uninfected individuals. The Company believes this approach may also protect against both blood-born and sexual transmission of HIV. The Company's goal has been to develop an oral formulation that would make the vaccine potentially less costly and easier to distribute to a broad population.

The Company is seeking a partner for this technology .

UGIF TECHNOLOGY - PROSTATE CANCER

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"). Identification of UGIF as a growth inhibitory factor for certain prostate cells was based upon laboratory studies conducted at Baylor Medical College. This work identifies the potential of UGIF for the treatment of prostate cancer and potentially other diseases of the prostate by elucidating mechanisms involved in the control of growth in the prostate. The Company is seeking a partner for this technology.

ION PHARMACEUTICALS, INC. TECHNOLOGIES

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. 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 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.

The Company entered into a license arrangement with Imutec Pharma Inc. in November 1997. The arrangement licenses rights to a series of compounds for the treatment of cancer, Kaposi's sarcoma and actinic keratosis to a newly formed company, NuChem Pharmaceuticals, Inc. ("NuChem") for which Imutec Pharma will provide funding and management of the development program. The Company holds a 20% equity interest in NuChem. The Company is currently participating in discussions with certain third parties regarding the possibility of partnering or licensing the use of clotrimazole and the Trifens(TM) in the fields of sickle cell anemia and gastrointestinal disorders.

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 Food and Drug Administration (the "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.

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, (iii) initial Investigational New Drug Application (the "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 a New Drug Application (the "NDA"). Preclinical studies involve laboratory evaluation of the product and animal studies to assess activity and safety of the product. Products must be formulated in accordance with United States Good Manufacturing Procedures ("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. Phase I trials normally consist of testing the product in a small number of patient volunteers for establishing safety and pharmacokinetics 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 treatment intervals are determined. Phase III trials typically involve more definitive testing of the appropriate dose for safety and 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 (the "IRB") at the institution performing the clinical study. The IRB is charged with protecting the safety of patients in trials and 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. The Company must rely on other persons and institutions to conduct these clinical 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 often required 12 months 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 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 specifications, 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 GMP. Continued registration requires compliance with standards for GMP. In complying with 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.

PATENTS AND PROPRIETARY RIGHTS

PREMAIRE(TM) MSI SYSTEM PATENTS

Under its agreement with Siemens AG for the technology underlying the Premaire(TM) MSI System, the Company is responsible for jointly financing and prosecuting the U.S. patent applications for the benefit of the owners and licensors of this technology. To date, one U.S. patent has issued, two U.S. patent applications are pending, and two international patent applications are pending.

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 licensor of this technology. To date, two U.S. patent have issued, nine foreign patents have issued and two foreign patent applications are pending.

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, one foreign patent application is pending and five foreign patent applications have issued.

HIV/AIDS VACCINE PATENTS

Under its license agreements for the HIV/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, and one international patent application 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.

ION TECHNOLOGY 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, six U.S. patents have issued, five U.S. patent applications are pending and eight 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, four U.S. patent applications are pending and one international application is pending.

COMPETITION

The Company will compete with approximately 25 other companies involved in developing and selling respiratory products for the U.S. market. Most of these companies possess financial and marketing resources and developmental capabilities substantially greater than the Company. Some of the products in development by other companies may be demonstrated to be superior to the Company's current or future products. Furthermore, the pharmaceutical industry is characterized by rapid technological change and competitors may complete development and reach the market place prior to the Company. The Company believes that competition in the respiratory category will be based upon several factors, including product efficacy, safety, reliability, availability, and price, among others.

RECENT BUSINESS DEVELOPMENTS

ZAMBON OPTION AGREEMENT

In April, 1998, the Company entered into an option agreement to form a strategic arrangement with Zambon Group SpA of Milan, Italy for the worldwide development and commercialization of drugs to treat respiratory disease with the Company's proprietary Metered Solution Inhaler ("MSI") system. Terms of the contemplated agreement will include an equity investment by Zambon in the Company, funding to develop four respiratory compounds for delivery in the MSI system, royalties, milestone payments, and retention by the Company of co-promotion rights for the respiratory drugs in the United States. The Company will continue to retain all rights to non-respiratory disease applications of the MSI system.

The option agreement serves the basis upon which the parties will negotiate a definitive agreement. Zambon is making a $650,000 equity investment in the Company in connection with the signing of the option agreement.

CONVERTIBLE PREFERRED STOCK OFFERING

The Company completed a $1,250,000 6% redeemable convertible preferred stock offering with an investor group in April, 1998. Under the terms of this offering, the preferred stock must be redeemed at the time the Company concludes a definitive sub-license agreement on the MSI system or other financing.

With proceeds from this transaction, the Company is making the DM 2,000,000 (approximately $1,100,000) payment to Siemens A.G. that was originally

due in January 1998 under the terms of the MSI license agreement.

EMPLOYEES

As of March 31, 1998, the Company employed 9 persons, five of whom are executive officers.

CERTAIN RISK FACTORS THAT MAY AFFECT FUTURE RESULTS, FINANCIAL CONDITION AND MARKET PRICE OF SECURITIES

DEVELOPMENT STAGE COMPANY; HISTORY OF OPERATING LOSSES AND ACCUMULATED DEFICIT; GOING CONCERN OPINION

The Company is in the development stage. The Company has been principally engaged to date in research, development and licensing efforts, and has experienced significant operating losses. The Company experienced operating losses of $9,489,139 and $7,008,889 for the fiscal years ended December 31, 1997 and 1996 and, as of December 31, 1997, the Company had an accumulated deficit of $36,077,790. The independent auditors' report dated February 13, 1998, except for Note 11 as to which the date is April 15, 1998, on the Company's consolidated financial statements stated that the Company has generated only minimal operating revenue, has incurred recurring operating losses and requires additional capital and that these conditions raise substantial doubt about its ability to continue as a going concern. The Company expects that it will continue to have a high level of operating expenses and will be required to make significant up-front expenditures in connection with its product development activities. As a result, the Company anticipates significant additional operating losses for 1998 and that such losses will continue thereafter until such time, if ever, as the Company is able to generate sufficient revenues to sustain its operations.

The Company's ability to achieve profitable operations is dependent in large part on regulatory approvals of its products. There can be no assurance that the Company will ever achieve such approvals or profitable operations.

SIGNIFICANT LIQUIDITY RESTRAINTS

The Company's cash available for funding its operations as of December 31, 1997 was $393,608. As of such date, the Company had trade payables of $887,782 and current research obligations of $470,768. In addition, committed and/or anticipated funding of research and development after December 31, 1997 is estimated at approximately $17,500,000. The Company will be required to obtain additional funds for its business through operations or equity or debt financings, collaborative arrangements with corporate partners or from other resources. No assurance can be given that these funds will be available for the Company to finance its development on acceptable terms, if at all. If adequate funds are not available from operations or additional sources of funding, the Company's business will suffer a material adverse effect.

NEED FOR ADDITIONAL FINANCING; UNCERTAINTY OF OBTAINING ADDITIONAL FUNDING

The Company's operations to date have consumed substantial and increasing amounts of cash. The negative cash flow from operations is expected to continue and to accelerate in the foreseeable future. The development of the Company's technology and proposed products will require a commitment of substantial funds to conduct costly and time-consuming research, preclinical and clinical testing, and to bring any such products to market. The Company's future capital requirements will depend on many factors, including continued progress in out-licensing the early stage technology and developing the Premaire(TM) MSI System, the ability of the Company to establish and maintain collaborative arrangements with others and to comply with the terms thereof, receipt of payments due from partners under research and development agreements, progress with preclinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technology and the status of competitive products.

The Company needs to raise substantial additional capital to fund its operations. The Company intends to seek such additional funding through collaborative or partnering arrangements, the extension of existing arrangements, or through public or private equity or debt financings. There can be no assurance that additional financing will be available on acceptable terms or at all. If additional funds are raised by issuing equity securities, further dilution to shareholders may result. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its research or development programs or obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop or commercialize. If adequate funds are not available from operations or additional sources of funding, the Company's business will suffer a material adverse effect.

NO COMMERCIALIZATION OF PRODUCTS TO DATE

The Company has not yet begun to generate revenues from the sale of products. The Company's products will require significant additional development, clinical testing and investment prior to commercialization. The Company does not expect regulatory approval for commercial sales of any of its products in the immediate future. There can be no assurance that such products will be successfully developed, proven to be safe and efficacious in clinical trials, able to meet applicable regulatory standards, able to obtain required regulatory approvals, or produced in commercial quantities at reasonable costs or be successfully commercialized and marketed.

ROYALTY PAYMENT OBLIGATIONS

The owners and licensors of the technology rights acquired by the

Company are entitled to receive a certain percentage of all royalties and payments in lieu of royalties received by the Company from commercialization, if any, of products in respect of which the Company holds licenses. Accordingly, in addition to its substantial investment in product development, the Company will be required to make substantial payments to others in connection with revenues derived from commercialization of products, if any, developed under licenses the Company holds. Consequently, the Company will not receive the full amount of any revenues that may be derived from commercialization of products to fund ongoing operations.

POTENTIAL LOSS OF RIGHTS UPON DEFAULT

Under the terms of existing agreements, the Company is obligated to make certain payments to its licensors. In the event that the Company defaults on the payment of an installment under the terms of an existing licensing agreement, its rights thereunder could be forfeited. As a consequence, the Company could lose all rights under a license agreement to the related licensed technology, notwithstanding the total investment made through the date of the default. There can be no assurance that unforeseen obligations or contingencies will not deplete the Company's financial resources and, accordingly, sufficient resources may not be available to fulfill the Company's commitments.

In this regard, in January, 1998 a payment of DM 2.0 million was due to Siemens AG under the terms of the agreement under which the Company hold the world-wide marketing rights to the Premaire(TM) MSI System. This payment was not made until April 15, 1998.

RAPID TECHNOLOGICAL CHANGE; COMPETITION

The medical field is subject to rapid technological change and innovation. Pharmaceutical and biomedical research and product development are rapidly evolving fields in which developments are expected to continue at a rapid pace. Reports of progress and potential breakthroughs are occurring with increasing frequency. There can be no assurance that the Company will have a competitive advantage in its fields of technology or in any of the other fields in which the Company may concentrate its efforts.

The Company's success will depend upon its ability to develop and maintain a competitive position in the research, development and commercialization of products and technologies in its areas of focus. Competition from pharmaceutical, chemical, biomedical and medical companies, universities, research and other institutions is intense and is expected to increase. All, or substantially all, of these competitors have substantially greater research and development capabilities, experience, and manufacturing, marketing, financial and managerial resources. Further, acquisitions of competing companies by large pharmaceutical or other companies could enhance such competitors' financial, marketing and other capabilities. There can be no assurance that developments by others will not render the Company's products or technologies obsolete or not commercially viable or that the Company will be able to keep pace with technological developments.

GOVERNMENT REGULATION

The Company's ongoing research and development projects are subject to rigorous FDA approval procedures. The preclinical and clinical testing requirements to demonstrate safety and efficacy in each clinical indication (the specific condition intended to be treated) and regulatory approval processes of the FDA can take a number of years and will require the expenditure of substantial resources by the Company. Delays in obtaining FDA approval would adversely affect the marketing of products to which the Company has rights and the Company's ability to receive product revenues or royalties. Moreover, even if FDA approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA, and a later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer. Failure to comply with the applicable regulatory requirements can, among other things, result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. Additional government regulation may be established which could prevent or delay regulatory approval of the Company's products. Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Even if FDA approval has been obtained, approval of a product by comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The time required to obtain such approval may be longer or shorter than that required for FDA 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. To date, the Company has not received final regulatory approval from the FDA or any other comparable foreign regulatory authority in respect of any product or technology.

RISKS INCIDENT TO PATENT APPLICATIONS AND RIGHTS

The Company's success will depend in part on its ability to obtain patent protection for products and processes and to maintain trade secret protection and operate without infringing the proprietary rights of others. The degree of patent protection to be afforded to pharmaceutical, biomedical or medical inventions is an uncertain area of the law. There can be no assurance that the Company will develop or receive sublicenses or other rights related to proprietary technology which are patentable, that any patents pending will issue, or that any issued patents will provide the Company with any competitive advantages or will not be challenged by third parties. Furthermore, there can be no assurance that others will not independently duplicate or develop similar products or technologies to those developed by or licensed to the Company. If the Company is required to defend against charges of patent infringement or to protect its own proprietary rights against third parties, substantial costs will be incurred and the Company could lose rights to certain products and technologies.

RELIANCE ON THIRD PARTIES; NO MARKETING OR MANUFACTURING CAPABILITIES

The Company does not currently have its own sales force or an agreement with another pharmaceutical company to market the Company's products that are in

development. When appropriate, the Company will attempt to build or otherwise acquire the necessary marketing capabilities to promote its products. There can be no assurance that the Company will have the resources available to build or otherwise acquire its own marketing capabilities, or that agreements with other pharmaceutical companies can be reached to market the Company's products on terms acceptable to the Company.

In addition, the Company does not intend to manufacture its own products. While the Company has already entered into two manufacturing and supply agreements related to the Premaire(TM) MSI System Technology, there can be no assurance that these manufacturing and supply agreements will be adequate or that the Company will be able to enter into future manufacturing and supply agreements on terms acceptable to the Company.

DEPENDENCE UPON OBTAINING HEALTHCARE REIMBURSEMENT

The Company's ability to commercialize human therapeutic and diagnostic products may indirectly depend in part on the extent to which costs for such products and technologies are reimbursed by private health insurance or government health programs. The uncertainty regarding reimbursement may be especially significant in the case of newly approved products. There can be no assurance that reimbursement price levels will be sufficient to provide a return to the Company on its investment in new products and technologies.

ADEQUACY OF PRODUCT LIABILITY INSURANCE

The use of the Company's proposed products and processes during testing, and after approval, may entail inherent risks of adverse effects which could expose the Company to product liability claims and associated adverse publicity. Although the Company currently maintains general liability insurance, there can be no assurance that the coverage limits of the Company's insurance policies will be adequate. The Company currently maintains clinical trial product liability insurance of $2.0 million per event for certain clinical trials and intends to obtain insurance for future clinical trials of products under development. There can be no assurance, however, that the Company will be able to obtain or maintain insurance for any future clinical trials. Such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. A successful claim brought against the Company in excess of the Company's insurance coverage would have a material adverse effect upon the Company and its financial condition. The Company intends to require its licensees to obtain adequate product liability insurance. However, there can be no assurance that licensees will be able to maintain or obtain adequate product liability insurance on acceptable terms or that such insurance will provide adequate coverage against all potential claims.

POTENTIALLY LIMITED TRADING MARKET; POSSIBLE VOLATILITY OF STOCK PRICE.

The Common Stock is listed for trading on American Stock Exchange (the

"AMEX") under the symbol ("SHM"). The Company does not presently satisfy the listing criteria of the AMEX, including the AMEX requirement that a listed company that has sustained losses from operations and/or net losses in three of its four most recent fiscal years have stockholders' equity of at least $4,000,000. The Company has sustained net losses for its four most recent fiscal years and, at December 31, 1997, had stockholders' deficit of $(4,637,251). The failure to meet the AMEX listing criteria may result in the Common Stock no longer being eligible for listing on the AMEX and trading, if any, of the Common Stock would thereafter be conducted in the over-the-counter market. If the Company's Common Stock were to be delisted from the AMEX, it may be more difficult for investors to dispose of, or to obtain accurate quotations as to the market value of, the Common Stock.

In the event of the delisting of the Company's Common Stock from the AMEX, the regulations of the Securities and Exchange Commission ("Commission") promulgated under the Securities Exchange Act of 1934, as amended ("Exchange Act"), require additional disclosure relating to the market for penny stocks. Commission regulations generally define a penny stock to be an equity security that has a market price of less than $5.00 per share, subject to certain exceptions. A disclosure schedule explaining the penny stock market and the risks associated therewith is required to be delivered to a purchaser and various sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors (generally institutions). In addition, the broker-dealer must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. If the Company's securities become subject to the regulations applicable to penny stocks (i.e., by AMEX delisting), the market liquidity for the Company's securities could be severely affected. In such an event, the regulations on penny stocks could limit the ability of broker-dealers to sell the Company's securities and thus the ability of purchasers of the Company's securities to sell their securities in the secondary market. In the absence of an active trading market, holders of the Common Stock may experience substantial difficulty in selling their securities.

VOLATILITY OF MARKET PRICE OF SECURITIES

The market price of securities of firms in the biotechnology/pharmaceuticals industries have tended to be volatile. Announcements of technological innovations by the Company or its competitors, developments concerning proprietary rights and concerns about safety and other factors may have a material adverse effect on the Company's business or financial condition. The market price of the Common Stock may be significantly affected by announcements of developments in the medical field generally or the Company's research areas specifically. The stock market has experienced volatility in market prices of companies similar to the Company that has often been unrelated to the operating results of such companies. This volatility may have a material adverse effect on the market price of the Common Stock.

OUTSTANDING OPTIONS, WARRANTS AND CONVERTIBLE SECURITIES; DILUTION

As of December 31, 1997, the Company had reserved approximately 4,781,290 shares of its Common Stock for issuance upon exercise of outstanding, options, warrants and other securities convertible into shares of its Common Stock, including shares of Common Stock issuable upon the exercise of options and warrants held by officers and directors of the Company. In addition as of December 31, 1997, the Company had $1,551,000 principal amount of Convertible Debentures and 25,000 shares of Series A Convertible Series A Preferred Stock outstanding. Each of the convertible securities provide for conversion into shares of Common Stock of the Company at a discount to the market. The Company has filed registration statements with the Commission covering the resale of substantially all of the shares of Common Stock underlying such options, warrants and other securities. The exercise of options and outstanding warrants, the conversion of such other securities and sales of Common Stock issuable thereunder could have a significant dilutive effect on the market price of shares of the Company's Common Stock and could materially impair the Company's ability to raise capital through the future sale of its equity securities.

AUTHORIZATION OF SERIES A PREFERRED STOCK

The Company's Certificate of Incorporation authorizes the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined from time to time by the Board of Directors, without shareholder approval. In the event of issuance, such preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of the Company and preventing shareholders from receiving a premium for their shares in connection with a change of control. Except for the issuance of shares of the Company's Series A Cumulative Convertible Redeemable Preferred Stock that occurred in connection with the consummation of a private placement in February 1997, the Company has no present intention to issue any shares of its preferred stock; however, there can be no assurance that the Company will not issue additional shares of its preferred stock in the future.

ITEM 2. PROPERTIES

The Company's principal executive offices are located at 425 South Woodsmill Road, St. Louis, Missouri 63017. These premises consist of approximately 4,521 square feet subject to a lease that expires September 14, 2002. The monthly rent for these premises is $9,042. The Company also maintains a small office at 37 S. Main Street, Pittsford, New York (for a monthly rent of $800). The lease on the Pittsford office 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 a defendant in DR. BONNIE S. DUNBAR V. E/J DEVELOPMENT CORPORATION, U-TECH MEDICAL CORPORATION, SHEFFIELD MEDICAL TECHNOLOGIES, INC. AND DOUGLAS R. EGER, No. 97-28899, in the District Court of Harris County, Texas (133rd Judicial District). The plaintiff in this action asserts breach of

contract, fraud and a claim for quantum meruit relating principally to certain stock options exercisable for a total of 40,000 shares of Common Stock issued in 1992 and 1993 to the plaintiff in consideration of consulting and research services provided to the Company. The plaintiff served as the principal investigator at Baylor College of Medicine in Houston, Texas on an ovarian cancer research project that was funded for several years by the Company. The plaintiff seeks actual damages against Sheffield and the other defendants, including Douglas R. Eger, a former Chairman of the Company, together with punitive damages, attorneys' fees, costs and expenses of the lawsuit, and pre- and post-judgment interest. The Company has denied the plaintiff's allegations and is vigorously contesting this action. This action is currently in the discovery phase. The Company and the plaintiff have engaged in settlement discussions, but no agreement has been reached to date. The Company is currently unable predict the likely outcome of this action. However, an unfavorable decision could have a material adverse effect on the business and financial condition of the Company.

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

None.

PART II

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

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

1997	HIGH	LOW
Fourth Quarter	$2.50	$1.125
Third Quarter	$3.00	$2.00
Second Quarter	$3.375	$2.25
First Quarter	$3.75	$2.625
1996:		
Fourth Quarter	$4.125	$3.125
Third Quarter	$4.625	$3.0625
Second Quarter	$6.50	$4.00
First Quarter	$6.75	$3.5625

The closing sale price for the Company's Common Stock on the AMEX on March 31, 1998 was $0.6875 per share. At March 31, 1998, there were approximately 390 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. The terms of the Company's Series A Cumulative Convertible Redeemable Preferred Stock generally prohibit the payment of cash dividends and other distributions on the Company's Common Stock unless full cumulative stock dividends on shares of such Series A Common Stock have been paid or declared in full.

The following unregistered securities were issued by the Company during the quarter ended December 31, 1997:

Date of Sale/Issuance	Description of Securities Issued	Number of Shares Sold/Issued/ Subject to Options or Warrants	Offering/ Exercise Price per share ($)	Purchaser or Class
October 1997	Common Stock	92,895	1 7/8	Holders of Series A Preferred Stock
November - December 1997	Stock Options	146,000	1 1/2 - 4 1/2	Issuances to employees pursuant to 1993 Stock Option Plan
December 1997	Common Stock	44,769	1 3/16	Holders of Series A Preferred Stock

The issuance of these securities are claimed to be exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving a public offering. There were no underwriting discounts or commissions paid in connection with the issuance of any of these securities.

ITEM 6. SELECTED FINANCIAL DATA

SELECTED FINANCIAL INFORMATION
(IN DOLLARS, EXCEPT PER SHARE INFORMATION

	YEARS ENDED DECEMBER 31,				
	1997	1996	1995	1994	1993

STATEMENT OF OPERATIONS DATA:

Sublicense and interest income	$ 556,914	$ 673,664	$ 80,610	$ 63,290	$ 81,671
Operating costs and expenses					
Research and development	5,379,193	3,841,818	4,424,154	3,989,838	2,134,330
General and administrative	4,666,859	3,840,735	3,044,173	2,393,082	1,823,631
Total operating costs and expenses	10,046,052	7,682,553	7,468,327	6,382,920	3,957,961
Loss from operations	$ (9,489,138)	$ (7,008,889)	$ (7,387,717)	$ (6,319,630)	$(3,876,290)
Loss per share of common stock - basic	$ (0.80)	$ (0.65)	$ (0.90)	$ (0.96)	$ (0.75)
Weighted average common shares outstanding	11,976,090	10,806,799	8,185,457	6,596,227	5,169,830

BALANCE SHEET DATA:

Working capital (net)	$ (837,564)	$ 1,433,773	$ 1,585,675	$ (799,629)	$ 1,570,183
Total assets	689,937	2,773,884	2,221,050	371,073	1,834,560
Long-term obligations and redeemable preferred stock	4,019,263	27,206	--	--	--
Accumulated deficit	(36,157,290)	(26,588,652)	(19,579,763)	(12,192,046)	(5,872,416)
Shareholders' equity (net capital deficiency)	(4,637,251)	1,695,837	1,792,363	(573,853)	1,673,113

No cash dividends have been paid for any of the periods presented.

Net loss per share is based upon the weighted average number of common and certain common equivalent shares outstanding.

See consolidated financial statements and accompanying footnotes.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION.

THIS REPORT CONTAINS CERTAIN FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933, AS AMENDED, AND SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, WHICH ARE INTENDED TO BE COVERED BY THE SAFE HARBORS CREATED HEREBY. ALL FORWARD-LOOKING STATEMENTS INVOLVE RISKS AND UNCERTAINTY, INCLUDING WITHOUT LIMITATION, RISKS SET FORTH ABOVE UNDER BUSINESS - CERTAIN RISK FACTORS THAT MAY AFFECT FUTURE RESULTS, FINANCIAL CONDITION AND MARKET PRICE OF SECURITIES".

THE DISCUSSION AND ANALYSIS BELOW SHOULD BE READ IN CONJUNCTION WITH THE FINANCIAL STATEMENTS OF THE COMPANY AND THE RELATED NOTES TO FINANCIAL STATEMENTS INCLUDED ELSEWHERE HEREIN.

OVERVIEW

Sheffield Medical Technologies Inc. ("Sheffield") was incorporated on October 17, 1986. The Company's wholly-owned subsidiary, U-Tech Medical Corporation ("U-Tech") was incorporated on January 13, 1992 and was liquidated on June 30, 1997. On January 10, 1996, Ion Pharmaceuticals, Inc. ("Ion"), was formed as a wholly-owned subsidiary of the Company. At that time, Ion acquired the Company's rights to certain early-stage biomedical technologies. On April 17, 1997, CP Pharmaceuticals, Inc. ("CP") was formed for the purpose of acquiring Camelot Pharmacal, L.L.C., a privately held pharmaceutical development company, which acquisition was consummated on April 25, 1997.

The Company is in the development stage and to date has been principally engaged in research, development and licensing efforts. The Company has generated minimal operating revenue and requires additional capital which the Company intends to obtain through out-licensing as well as 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 developing a new business, particularly since the Company will focus on research, development and unproven technology that may require a lengthy period of time and substantial expenditures to complete. Even if the Company is able to successfully develop new products, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products 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 1998 is dependent upon obtaining additional financing. Until such financing is obtained, the Company must rely on short-term loans from its

officers in order to meet certain of its obligations.

FISCAL YEARS ENDED DECEMBER 31, 1997, 1996 AND 1995

In 1997, the Company signed a sub-license agreement for certain early-stage technologies and earned sub-license fees that are included in revenue. Interest income was $56,914 for the year ended December 31, 1997 compared to $163,664 and $80,610 for the years ended December 31, 1996 and 1995, respectively. The decrease in 1997 interest income of $106,750 compared to 1996 was due primarily to use of funds available for investment as a result of the acquisition of the Premaire(TM) MSI System from Siemens AG. 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 were $3,729,193 for the year ending December 31, 1997 compared to $3,841,818 and $4,424,154 for the years ended December 31, 1996 and 1995, respectively. The 1997 decrease of $112,625 was attributable to the winding down of the early-stage technology projects. In 1997, the Company entered into two (2) major research and development agreements. The Company sub-licensed certain technology to a subsidiary of Imutec Pharma Inc. in exchange for cash, milestone payments, transfer of research expenses to Imutec and a twenty percent (20%) ownership interest upon commercialization. The Siemens AG agreement, and related development expenses incurred relative to the Premaire(TM) MSI System, resulted in funds expended of a total of $1,800,440 in 1997. The 1996 decrease of $582,336 in 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.

General and administrative expenses were $4,627,567 for the year ending December 31, 1997 compared to $3,831,204 and $2,979,437 for the years ended December 31, 1996 and 1995, respectively. The 1997 increase of $796,363 was primarily due to an increased number management salaries resulting from the Camelot acquisition, compensation expense associated with extension of certain option and warrant agreements, and expenses related to the two financings completed during the year. The 1996 increase of $851,767 primarily resulted 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.

Acquisition of in-process technology charges of $1,650,000 relate to the April 25, 1997 acquisition of Camelot Pharmacal, L.L.C.

Interest expense was $39,292 for the year ending December 31, 1997

compared with $9,531 and $64,736 for the years ended December 31, 1996 and 1995, respectively. The 1997 increase of $29,761 was attributable to the 6% convertible debentures issued during the year. The 1996 decrease of $55,205 was due to satisfaction in full of the Company's $550,000 loan from SMT Investment Partnership in 1995.

As a result of the above, net loss for 1997 was $9,489,138 compared to $7,008,889 and $7,387,717 for the years ending December 31, 1996 and 1995, respectively.

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 $28 million through December 31, 1997. 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. The proceeds of this offering were used to fund research and development, patent prosecution and for working capital and general corporate purposes.

In addition, in April 1998 the Company completed two agreements that provided additional capital. The first provided the Company with $650,000 in gross proceeds from the sale of the Company's Common Stock. The second provided the Company with $1,250,000 in gross proceeds from the sale of the Company's Series B Convertible Redeemable Preferred Stock.

From inception through December 31, 1997, the Company earned $453,827 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.

Net cash used in development stage activities was $6,677,405 for the year ended December 31, 1997 compared with $6,043,876, $7,541,937 and $30,198,450 for the years ended December 31, 1996 and 1995, and from inception in 1986 through 1997, respectively. Cash of $3,284,812, $6,420,834, $9,346,901 and $27,955,005 was provided by the issuance of securities in 1997, 1996, 1995 and from inception in 1986 through 1997, respectively.

The Company's total assets were $689,937 at December 31, 1997 compared with $2,773,884 at December 31, 1996. The 1997 decrease of $2,083,947 was primarily attributable to expenditures related to the acquisition and development of the Premaire(TM) MSI System technology. The Company's liabilities at December 31, 1997, consisting of accounts payable, sponsored research, capital lease obligations and the 6% convertible debenture, were $2,938,425 compared with $1,078,047 at December 31, 1996.

The Company spent approximately $19.3 million through December 31, 1997 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, and preclinical and clinical testing of its product candidates. 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 the successful commercialization of the Company's technologies. 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.

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 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 development programs may be curtailed if future financings are not completed.

The table below indicates (i) the Company's direct research and development expenses by project for the fiscal year ended December 31, 1997 and from the Company's inception to December 31, 1997, (ii) the Company's current estimate by project of committed and/or anticipated funding requirements after December 31, 1997 and (iii) revenues received to date by project.

DIRECT RESEARCH AND DEVELOPMENT EXPENSES
(IN DOLLARS)

R&D PROJECT	Fiscal year ended 12/31/97	Inception to 12/31/97	Committed and/or Anticipated R&D Funding After 12/31/97*	Revenue Received
Multi-Dose Solution Inhaler (MSI System)	1,800,440	1,944,848	17,500,000**	0
Ion Pharmaceuticals, Inc. Technologies	1,014,031	4,822,595	0	510,000
RBC-CD4 Electroinsertion Technology	15,760	6,254,185	0	0
Liposome-CD4 Technology	0	2,322,322	0	500,000
HIV/AIDS Vaccine	137,500	1,211,618	0	0
UGIF Technology	120,036	223,437	0	0
Membrane Attack Complex (MAC)/Complement Technology	243,744	365,618	0	0

- ----------

* These figures include management's estimates of anticipated direct R&D funding as of the date of this report. The amounts and rate of application of the Company's funds to any particular project are expected to fluctuate and will depend in part on the Company's successful completion of various stages of research, the availability of additional financing and the Company's identification and acquisition of rights in new technologies in the future.

** Will be zero dollars in the event Zambon exercises its option agreement on the MSI respiratory applications.

The Company has conducted a review of its computer systems to identify the systems that could be affected by the "Year 2000" issue. The Year 2000 problem is the result of computer programs being written using two digits (rather than four) to define the applicable year. Any of the Company's programs that have time-sensitive software may recognize a date using "00" as the year 1900 rather than the year 2000. This could result in a major system failure or miscalculations. The Company presently believes that the Year 2000 problem will not pose significant operational problems for the Company's computer systems. Additionally, the cost of the Year 2000 problem will have no material impact on the operations of the Company.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See page F-1.

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

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT

The information required by this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 1998 pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934 ("Regulation 14A").

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 1998 pursuant to Regulation 14A.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 1998 pursuant to Regulation 14A.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 1998 pursuant to Regulation 14A.

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a)(1) Financial Statements

The following Financial Statements are included:
Report of Independent Auditors
Consolidated Balance Sheets as of December 31, 1997 and 1996
Consolidated Statements of Operations for the years ended December 31, 1997, 1996 and 1995 and for the period October 17, 1986 (inception) to December 31 1997
Consolidated Statements of Stockholders' Equity (net capital deficiency) for the period from October 17, 1986 (inception) to December 31 1997
Consolidated Statements of Cash Flows for the years ended December 31, 1997, 1996 and 1995 and for the period from October 17, 1986 (inception) to December 31 1997
Notes to Financial Statements

(a)(2) Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto.

(a)(3) Exhibits:

NO.		REFERENCE
~~3.1~~	~~Certificate of Incorporation of the Company, as amended~~	~~(4)~~
~~3.2~~	~~By-Laws of the Company~~	~~(4)~~
~~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~~	~~(7)~~
~~10.1~~	~~Employment Agreement dated as of October 1, 1995 between the Company and Douglas R. Eger~~	~~(2)~~
~~10.2~~	~~Employment Agreement dated as of September 7, 1995 between the Company and George Lombardi~~	~~(2)~~
~~10.3~~	~~Amendment dated as of September 22, 1996 to Employment Agreement dated as of September 7, 1995 between the Company and George Lombardi~~	~~(7)~~

10.4	Employment Agreement dated as of March 28, 1996 between the Company and Michael Zeldin	(2)
10.5	Amendment dated June 6, 1996 to Employment Agreement dated as of March 28, 1996 between the Company and Michael Zeldin	(7)
10.6	Employment Agreement dated as of June 6, 1996 between the Company and Thomas M. Fitzgerald	(3)
10.65	Employment Agreement dated as of November 17, 1997 between the Company and Judy Roeske Bullock	(1)
10.7	Agreement of Sublease dated as of November 17, 1995 between the Company and Brumbaugh Graves Donohue & Raymond relating to 30 Rockefeller Plaza, Suite 4515, New York, New York	(2)
10.8	1993 Stock Option Plan, as amended	(1)
10.9	1993 Restricted Stock Plan, as amended	(2)
10.10	1996 Directors Stock Option Plan	(7)
10.11	Agreement and Plan of Merger among the Company, Camelot Pharmacal, L.L.C., David A. Byron, Loren G. Peterson and Carl Siekmann dated April 25, 1997	(6)
10.12	Employment Agreement dated as of April 25, 1997 between the Company and David A. Byron	(6)
10.13	Employment Agreement dated as of April 25, 1997 between the Company and Loren G. Peterson	(6)
10.14	Employment Agreement dated as of April 25, 1997 between the Company and Carl Siekmann	(6)
10.15	Form of the Company's 6% Convertible Subordinated Debentures due September 22, 2000.	(8)

NO.		REFERENCE
10.16	Lease dated August 18, 1997 between Corporate Center, L.L.C. and the Company relating to the lease of office space in St. Louis, Missouri.	(5)
10.17	Assignment and License Agreement dated as of December 3, 1997 between 1266417 Ontario Limited and Ion Pharmaceuticals, Inc. (portions of this exhibit are omitted and were filed separately with the Securities Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(9)
10.18	Sub-License Agreement dated as of December 3, 1997 between 1266417 Ontario Limited and Ion Pharmaceuticals, Inc. (portions of this exhibit are omitted and were filed separately with the Securities Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(9)
10.19	Severance Agreement dated December 24, 1997 between the Company and Douglas R. Eger.	(1)
10.20	Severance Agreement dated October 15, 1997 between the Company and George Lombardi.	(1)
21	Subsidiaries of Registrant	(1)
23.1	Consent of Ernst & Young LLP	(1)
23.2	Consent of KPMG Peat Marwick LLP	(1)
27	Financial Data Schedule	(1)

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(1) Filed herewith.

(2) 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.

(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 Quarterly Report on Form 10-Q for the quarter ended June 30, 1997 filed with the Securities and Exchange Commission.

(5) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997 filed with the Securities and Exchange Commission.

(6) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1997 filed with the Securities and Exchange Commission.
(7) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 1996 filed with the Securities and Exchange Commission.
(8) Incorporated by reference to the Company's Registration Statement on Form S-3 (File No. 333-38327) filed with the Securities and Exchange Commission on October 21, 1997.
(9) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 17, 1997.

(b) Reports on Form 8-K:

The Company filed a Current Report on Form 8-K with the Securities and Exchange Commission on December 17, 1997 relating to the Company's sale of certain patent and other proprietary interests.

SIGNATURES

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

SHEFFIELD PHARMACEUTICALS, INC.

Dated: April 15, 1998 /s/ Loren G. Peterson

Loren G. Peterson
President and Chief Executive Officer

POWER OF ATTORNEY

Sheffield Pharmaceuticals, Inc. and each of the undersigned do hereby appoint Loren G. Peterson and Thomas Fitzgerald and each of them severally, its or his or her true and lawful attorney to execute on behalf of Sheffield Pharmaceuticals, Inc. and the undersigned any and all amendments to this Annual Report and to file the same with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission; each of such attorneys shall have the power to act hereunder with or without the other.

In accordance with the Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Thomas M. Fitzgerald Thomas M. Fitzgerald	Chairman and Director	April 15, 1998
/s/ Loren G. Peterson Loren G. Peterson	Director, President and Chief Executive Officer	April 15, 1998
/s/ John M. Bailey John M. Bailey	Director	April 15, 1998
/s/ Digby W. Barrios Digby W. Barrios	Director	April 15, 1998
/s/ Douglas R. Eger Douglas R. Eger	Director	April 15, 1998
/s/ Judy Roeske Bullock Judy Roeske Bullock	Vice President, Chief Financial Officer, Treasurer and Secretary (Chief Financial and Chief Accounting Officer)	April 15, 1998

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(a development stage enterprise)

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Report of Independent Auditors

The Board of Directors and Stockholders
Sheffield Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Sheffield Pharmaceuticals, Inc. (formerly known as Sheffield Medical Technologies Inc.) and subsidiaries (a development stage enterprise) as of December 31, 1997 and 1996, and the related consolidated statements of operations, stockholders' equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 1997 and for the period October 17, 1986 (inception) through December 31, 1997. 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 (net capital deficiency) and cash flows for the period October 17, 1986 (inception) through December 31, 1997, 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 Pharmaceuticals, Inc. and subsidiaries at December 31, 1997 and 1996, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 1997 and the period from October 17, 1986 (inception) through December 31, 1997, in conformity with generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that Sheffield Pharmaceuticals, 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.

Princeton, New Jersey
February 13, 1998 except for Note 11
as to which the date is April 15, 1998

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). These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with 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.

Houston, Texas
February 11, 1994

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(a development stage enterprise)
Consolidated Balance Sheets

	December 31, 1997	1996
Assets		
Current assets:		
Cash and cash equivalents	$ 393,608	$ 1,979,871
Marketable securities	--	460,768
Loan receivable - former officer	80,000	--
Prepaid expenses and other current assets	47,378	43,975
Total current assets	520,986	2,484,614
Property and equipment:		
Laboratory equipment	185,852	185,852
Office equipment	142,562	89,019

Leasehold improvements	--	61,390
	328,414	336,261
Less accumulated depreciation and amortization	185,201	162,007
Net property and equipment	143,213	174,254
Segregated cash	--	75,000
Other assets	25,738	40,016
Total assets	$ 689,937	$ 2,773,884

Liabilities and Stockholders' Equity (Net Capital Deficiency)

Current liabilities:		
Accounts payable and accrued liabilities	$ 887,782	$ 446,965
Sponsored research payable	470,768	580,157
Capital lease obligation-current portion	--	23,719
Total current liabilities	1,358,550	1,050,841
Capital lease obligation - non-current portion	--	27,206
6% convertible subordinated debenture	1,551,000	--
Interest Payable on 6% convertible subordinated debenture	28,875	--
Cumulative convertible redeemable preferred stock, $.01 par value. Authorized, 3,000,000 shares; issued and outstanding, 25,000 and 0 shares at December 31, 1997 and 1996, respectively	2,468,263	--
Additional paid-in capital associated with cumulative convertible redeemable preferred stock	2,249,145	--
Stock dividends payable on preferred stock	139,368	--
Commitments and contingencies		
Stockholders' equity (net capital deficiency):		
Common stock, $.01 par value. Authorized, 50,000,000 shares; issued and outstanding, 12,649,539 and 11,388,274 shares at December 31, 1997 and 1996, respectively	126,495	113,883
Notes receivable in connection with sale of stock	(72,600)	(110,000)
Additional paid-in capital	31,386,644	28,319,838
Unrealized loss on marketable securities	--	(39,232)
Deficit accumulated during development stage	(36,157,290)	(26,588,652)
	(4,716,751)	1,695,837
Total liabilities and stockholders' equity (net capital deficiency)	$ 689,937	$ 2,773,884

(a development stage enterprise)
Consolidated Statements of Operations
For the years ended December 31, 1997, 1996 and 1995 and for the period
from October 17, 1986 (inception) to December 31, 1997

	Years ended December 31,			October 17, 1986 (inception) to December 31,
	1997	1996	1995	1997
Revenues:				
Sub-license revenue	$ 500,000	$ 510,000	$ --	$ 1,010,000
Interest income	56,914	163,664	80,610	453,827
Total revenue	556,914	673,664	80,610	1,463,827
Expenses:				
Acquisition of R & D in-process technology	1,650,000	--	--	1,650,000
Research and development	3,729,193	3,841,818	4,424,154	19,252,390
General and administrative	4,627,567	3,831,204	2,979,437	16,522,259
Interest	39,292	9,531	64,736	159,755
Total expenses	10,046,052	7,682,553	7,468,327	37,584,404
Loss before extraordinary item	(9,489,138)	(7,008,889)	(7,387,717)	(36,120,577)
Extraordinary item	--	--	--	42,787
Net loss	$ (9,489,138)	$ (7,008,889)	$ (7,387,717)	$(36,077,790)
Acretion of mandatorily redeemable preferred stock		$ (79,500)		$ (79,500)
Net loss - attributable to common shares		$ (9,568,638)		$(36,157,290)
Loss per share of common stock - basic:				
Loss before extraordinary item	$ (0.80)	$ (0.65)	$ (0.90)	$ (7.30)
Extraordinary item	--	--	--	0.01
Basic net loss per share	$ (0.80)	$ (0.65)	$ (0.90)	$ (7.29)
Weighted average common shares outstanding - basic:	11,976,090	10,806,799	8,185,457	4,946,268

SHEFFIELD PHARMACEUTICALS, 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, 1997

	Common stock	Noted receivable in connection with sale of stock	Additional paid-in capital	Unrealized gain (loss) on marketable securities	Deficit accumulated during development stage	Total stockholders' equity (Net capital deficiency)
Balance 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	--	--	--	--	(12,192,046)	(12,192,046)
Balance at December 31, 1994	11,288,329	--	329,864	--	(12,192,046)	(573,853)
Reincorporation in Delaware at $.01 par value	(11,220,369)	--	11,220,369	--	--	--
Common stock issued	27,656	--	9,726,277	--	--	9,753,933
Net loss	--	--	--	--	(7,387,717)	(7,387,717)
Balance 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
Common stock subscribed	--	(110,000)	--	--	--	(110,000)
Unrealized loss on marketable securities	--	--	--	(39,232)	--	(39,232)
Net loss	--	--	--	--	(7,008,889)	(7,008,889)
Balance at December 31, 1996	113,883	(110,000)	28,319,838	(39,232)	(26,588,652)	1,695,837
Issuance of common stock in connection with acquisition of Camelot Pharmacal, L.L.C	6,000	--	1,644,000	--	--	1,650,000
Common stock issued	6,612	37,400	1,041,750	--	--	1,085,762
Common stock options and warrants issued	--	--	165,868	--	--	165,868
Common stock options extended	--	--	215,188	--	--	215,188
Acretion of Issuance costs for cumulative convertible redeemable preferred stock					(179,500)	(179,500)
Unrealized gain on marketable securities	--	--	--	39,232	--	39,232
Net loss	--	--	--	--	(9,489,138)	(9,489,138)
Balance at December 31, 1997	$ 126,495	$ (72,600)	$ 31,386,644	$ --	$(36,157,290)	$ (4,716,751)

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(a development stage enterprise)
Consolidated Statements of Cash Flows
For the years ended December 31, 1997, 1996 and 1995 and for the period
from October 17, 1986 (inception) to December 31, 1997

	Years ended December 31,			October 17, 1986 (inception) to December 31,
	1997	1996	1995	1997
Cash outflows from development stage activities and extraordinary gain:				
Loss before extraordinary item	$ (9,489,138)	$ (7,008,889)	$ (7,387,717)	(36,120,577)
Extraordinary gain on extinguishment of debt	--	--	--	42,787
Net loss	(9,489,138)	(7,008,889)	(7,387,717)	(36,077,790)
Adjustments to reconcile net loss to net cash used by development stage activities:				
Issuance of common stock, stock options/warrants for services	381,056	640,762	357,032	1,922,059
Non-cash interest expense	28,875	--	50,000	78,875
Write-off of in-process technology	1,650,000	--	--	1,650,000
Securities aquired under sub-license agreement	--	(500,000)	--	(500,000)
Issuance of common stock for intellectual property rights	--	--	--	866,250
Amortization of organizational and debt issuance costs	--	--	--	77,834
Depreciation and amortization	84,584	71,652	47,992	246,591
Increase in debt issuance and organizational costs	--	--	--	(77,834)
Loss realized on sale of marketable securities	324,915	--	--	324,915
Decrease (increase) in prepaid expenses and other current assets	(3,403)	109,810	(88,618)	(106,419)
Decrease (increase) in other assets	14,278	44,354	(4,387)	33,303
Increase (decrease) in accounts payable, accrued liabilities	440,817	245,680	(375,785)	310,712
Increase (decrease) in sponsored research payable	(109,389)	352,755	(140,454)	1,047,838
Net cash used by development stage activities	(6,677,405)	(6,043,876)	(7,541,937)	(30,198,450)
Cash flows from investing activities:				
Proceeds on sale of marketable securities	175,085	--	--	175,085
Acquisition of laboratory and office equipment	(53,543)	(51,136)	(24,517)	(317,352)
Decrease (increase) in segregated cash	75,000	(75,000)	--	--
Increase in notes receivable in connection with sale of stock	--	(240,000)	--	(240,000)
Increase in loan receivable - former officer	(80,000)	--	--	(80,000)
Payments of notes receivable	37,400	130,000	--	167,400
Purchase of Camelot Pharmacal, L.L.C., net of cash acquired	(46,687)	--	--	(46,687)
Net cash provided (used) by investing activities	107,255	(236,136)	(24,517)	(341,554)
Cash flows from financing activities:				
Principal payments under capital lease	(50,925)	(21,528)	--	(72,453)
Conversion of convertible, subordinated notes	--	--	--	749,976
Proceeds from issuance of convertible debenture	1,750,000	--	550,000	2,300,000
Proceeds from issuance of common stock	--	--	7,699,574	13,268,035
Proceeds from issuance of preferred stock	3,284,812	--	--	3,284,812
Proceeds from exercise of stock options	--	471,550	866,127	1,337,677
Proceeds from exercise of warrants	--	5,949,284	231,200	10,064,481
Net cash and cash equivalents provided by financing activities	5,199,075	6,399,306	9,346,901	30,932,528
Net increase in cash and cash equivalents	(1,586,263)	119,294	1,780,447	392,524
Cash and cash equivalents at beginning of period	1,979,871	1,860,577	80,130	1,084

Cash and cash equivalents at end of period	$ 393,608	$ 1,979,871	$ 1,860,577	$ 393,608
Noncash investing and financing activities:				
Common stock, stock options and warrants issued for services	$ 381,056	$ 640,762	$ 357,032	$ 1,921,259
Common stock issued for acquisitions	1,650,000	--	--	1,655,216
Common stock issued for intellectual property rights	--	--	--	866,250
Common stock issued to retire debt	--	--	600,000	600,000
Common stock issued to redeem convertible securities	1,334,105	--	--	1,334,105
Securities acquired under sub-license agreement	--	500,000	--	500,000
Unrealized (realized) depreciation of investments	(39,232)	39,232	--	--
Equipment acquired under capital lease	--	72,453	--	72,453
Notes payable converted to common stock	--	--	--	749,976
Stock dividends	182,352	--	--	182,352
Supplemental disclosure of cash flow information:				
Interest paid	$ 10,417	$ 9,531	$ 64,736	$ 130,880

SHEFFIELD PHARMACEUTICALS, 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. The Company's wholly-owned subsidiary, U-Tech Medical Corporation ("U-Tech") was incorporated on January 13, 1992 and was liquidated on June 30, 1997. On January 10, 1996, Ion Pharmaceuticals, Inc. ("Ion"), was formed as a wholly-owned subsidiary of the Company. At that time, Ion acquired the Company's rights to certain early-stage biomedical technologies. On April 17, 1997, CP Pharmaceuticals, Inc. ("CP") was formed for the purpose of acquiring Camelot Pharmacal, L.L.C., a privately held pharmaceutical development company, which acquisition was consummated on April 25, 1997. On January 26, 1995, the Company's shareholders approved the proposal to reincorporate Sheffield in Delaware, which was effected on June 13, 1995. On June 26, 1997, the Company's shareholders approved the proposal to change Sheffield's name from Sheffield Medical Technologies Inc. to Sheffield Pharmaceuticals, Inc. Unless the context requires otherwise, Sheffield, U-Tech, Ion and CP are referred to as "the Company." All significant inter-company transactions are eliminated in consolidation.

The Company is in the development stage and to date has been principally engaged in research, development and licensing efforts. The Company has generated minimal operating revenue and requires additional capital which the Company intends to obtain through out-licensing as well as 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 developing a new business, particularly since the Company will focus on product development that may require a lengthy period of time and substantial expenditures to complete. Even if the Company is able to successfully develop new products, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products 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 1998 are dependent upon obtaining additional financing. (See Note 11.) Until such financing is obtained, the Company must rely on short-term loans from its officers in order to meet certain of its obligations.

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 $9,489,138 $7,008,889 and $7,387,717 during the years ended December 31, 1997, 1996 and 1995 respectively, and has an accumulated deficit of $36,077,790 from inception (October 17, 1986) through December 31, 1997.

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.

PROPERTY AND EQUIPMENT

Property and equipment are 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

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.

BASIC LOSS PER SHARE OF COMMON STOCK

In 1997, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 128, Earnings Per Share. SFAS No. 128 replaced the previously reported primary and fully diluted earnings per share with basic and diluted earnings per share. Unlike primary earnings per share, basic earnings per share excludes any dilutive effects of options, warrants and convertible securities. Diluted earnings per share is very similar to the previously reported fully diluted earnings per share. Basic net loss per share is based upon the weighted average Common Stock outstanding during each year. Common Stock equivalents are not included as their effect is antidilutive. The effect of adoption of SFAS No. 128 had no financial impact, and accordingly, no restatement of loss per share for prior years was necessary. 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" (SFAS No. 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 or exceeds the fair market value of the underlying common stock on the date of grant.

IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

In June 1997, the FASB issued SFAS No. 130, Reporting Comprehensive Income. SFAS No. 130 establishes standards for the reporting and display of comprehensive income and its components in a full set of general purpose financial statements and applies to all enterprises. SFAS No. 130 is effective for financial statements for fiscal years beginning after December 15, 1997. The adoption of SFAS No. 130 will have no impact on the Company's consolidated results of operations, financial position or cash flows.

In June 1997, the FASB issued SFAS No. 131, Disclosures about

Segments of an Enterprise and Related Information, which is effective for years beginning after December 15, 1997. SFAS No. 131 establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. It also establishes standards for related disclosures about products and services, geographic areas and major customers. The Company will adopt the new requirements retroactively in 1998. Management is currently evaluating SFAS No. 131 and does not anticipate that the adoption of this statement will have significant effect on the Company's financial reporting.

3. ACQUISITION

On April 25, 1997, the Company completed its acquisition of Camelot Pharmacal, L.L.C., a newly formed, privately held Missouri limited liability company focusing on the development of specialty pharmaceuticals. The purchase price consisted of 600,000 shares of the Company's common stock (valued at $2.75 per share) and the assumption of certain liabilities in excess of tangible assets acquired of $8,262. The transaction was treated as a purchase for accounting purposes, and accordingly, the assets and liabilities assumed have been recorded at their estimated fair market values at the date of acquisition. Since technological feasibility of the in-process research and development costs have not yet been established and the technology had no alternative future use at the acquisition date, the in-process research and development costs of $1,650,000 were immediately written-off and included in the results of operations as a non-recurring charge for the year ended December 31, 1997. Camelot had no revenue and minimal operating losses for the period ended April 24, 1997 and therefore proforma disclosure has not been included.

4. LEASES

There were no assets under capital leases at December 31, 1997. Capital lease for property and equipment at December 31, 1996 was $51,990 (net of accumulated amortization).

Future minimum lease commitments under operating leases at December 31, 1997 are as follows:

1998	$108,504
1999	110,011
2000	113,025

2001	114,532
2002	83,262
Total future minimum lease commitments	$529,334

Rent expense for the years ended December 31, 1997, 1996, 1995 and the period from October 17, 1986 (inception) to December 31, 1997 was $190,584, $147,104, $105,946, and $523,109, respectively.

5. 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 December 31, 1986	990,000
Issued during year ended December 31, 1991	412,500
Issued during year ended December 31, 1992	850,000
Issued during year ended December 31, 1993	2,509,171
Issued during year ended December 31, 1994	1,134,324
Issued during year ended December 31, 1995	2,765,651
Issued during year ended December 31, 1996	1,826,628
Issued during year ended December 31, 1997	1,261,265
Balance outstanding at December 31, 1997	12,649,539

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 was formerly 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 $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.

On February 26, 1997, 35,700 shares of Series A Preferred Stock were issued pursuant to a private placement. Holders of Series A Preferred Stock have the right, exercisable commencing May 29, 1997 and ending February 28, 1999, to convert shares of Series A Preferred Stock into shares of Common Stock. As of December 31, 1997, 25,000 shares of Series A Preferred Stock were outstanding. Between August 26, 1997 and December 31, 1997, 10,700 shares of Series A Preferred stock, plus related accrued dividends thereon, were converted into 44,769 shares of Common Stock. The number of shares of Common Stock issuable upon conversion of Series A Preferred Stock is determined by reference to the lesser of (i) $3.31875 and (ii) 85% of the "current market price" per share of Common Stock, where "current market price" means, with certain exceptions, the average of the closing bid prices of Common Stock for the 10 consecutive trading days ending the last trading day before the applicable conversion date. Each share of Series A Preferred Stock earns a cumulative dividend payable in shares of Common Stock at a rate per share equal to 7.0% of the original $100 purchase price per share of the Series A Preferred Stock payable at the time of conversion. Stock dividends payable on the Series A Preferred Stock toatalled $139,368 at December 31, 1997. Under certain circumstances, cash is payable to holders of Series A Preferred Stock in lieu of Common Stock. The Series A Preferred Stock is redeemable upon the occurance of certain events.

On April 25, 1997, Camelot Pharmacal, L.L.C., a Missouri limited liability company ("Camelot"), merged with and into CP Pharmaceuticals, Inc., a newly formed, wholly owned subsidiary of the Company. The principals of Camelot at the time of the merger were Loren G. Peterson, Carl F. Siekmann and David A. Byron. Pursuant to the related agreement and plan of merger, Messrs. Peterson, Siekmann and Byron each received 200,000 shares of Common Stock. Following the consummation of the merger, each of Messrs. Peterson, Siekmann and Byron entered into employment agreements with Sheffield and received stock options providing each individual the right to purchase up to 400,000 shares of Common Stock. (See Note 3.)

On September 22, 1997, the Company consummated a private placement of $1,750,000 principal amount of its 6% Convertible Subordinated Debentures due September 22, 2000, $1,551,000 of which was outstanding as of December 31, 1997. In addition, the Company granted the holder of the Debenture warrants to purchase 140,000 shares of the Company's common stock at $2.80 per share. A value of $115,500 was assigned to these warrants. The Convertible Debentures are convertible at the option of holders from December 22, 1997 until maturity, subject to certain limitations, into a number of shares of Common Stock equal to (i) the principal amount of the Convertible Debenture being so converted divided by (ii) 75% of the market price of the Common Stock as of the date of conversion. For purposes of any conversion of Convertible Debentures, "market price" generally means the average of the closing prices of the Common Stock for the five trading day period preceding the applicable conversion date. The Convertible Debentures also earn interest at a rate of 6.0% per annum that is payable by the Company, at the option of the holders and subject to certain conditions, in shares of its Common Stock at a conversion rate generally equal to the average of the closing prices of the Common Stock for the ten trading days preceding the applicable interest payment date. Subject to certain limitations, the Convertible Debentures are subject to redemption upon the occurrence of certain events.

6. 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 exercisability of each option. The exercise price of all options for common stock granted under the Stock Option 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 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.

See also the discussion contained in Note 5 related to the Series A Preferred Stock, the Camelot acquisition, and the 6% Convertible Subordinated Debentures.

SFAS No. 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 SFAS No. 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 1997, 1996 and 1995: risk-free interest of 5.54%, 6.23%, 6.13%, 6.00% and 5.57%; expected volatility of 0.526 and 0.60; expected option life of one to four years from vesting and an expected dividend yield of 0.0%.

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:

	1997	1996	1995
Pro forma net loss.....	$9,500,810	$8,500,149	$8,993,554
Pro forma basic net loss per share of common stock	$ 0.79	$ 0.79	$ 1.10

Because SFAS No. 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:

	1997		1996		1995	
	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price
Outstanding, January 1,	3,033,755	4.49	4,164,834	4.02	1,792,000	3.33
Granted	3,683,039	3.92	1,014,922	5.52	3,091,408	4.63
Expired	327,500	3.18	70,000	3.77	0	0
Exercised	0	0	1,942,501	3.76	345,500	3.51
Canceled	1,608,004	4.11	133,500	4.53	373,074	4.79
Outstanding December 31,	4,781,290	3.65	3,033,755	4.49	4,164,834	4.02
Exercisable at end of year	2,900,290		2,094,833		1,727,759	
Weighted average fair value of options granted during the year	$4.05		$2.30		$2.30	

Stock options outstanding at December 31, 1997 are summarized as follows:

Range of Exercise Prices	Outstanding Options at Dec. 31, 1997	Weighted Average Remaining Contractual Life (Yrs.)	Weighted Average Exercise Price
$ .73 - $3.18	2,046,000	7.25	$ 2.62
$3.25 - $5.00	2,290,791	2.89	$ 4.06
$5.06 - $8.25	444,499	2.60	$ 6.26
$ .73 - $8.25	4,781,290	4.73	$ 3.65

During the period January 1, 1995 through December 31, 1997, the exercise prices of options and warrants issued by the Company were as follows:

Year	Number of Options/Warrants	Exercise Price
1995.....	3,091,408	$3.25 - 5.00
1996.....	1,014,922	$3.38 - 8.25
1997.....	3,683,039	$1.50 - 6.00

At December 31, 1997, a total of 2,995,000 shares were available for future grants under the 1993 Stock Option Plan, the 1993 Restricted Stock Plan, and the 1996 Directors Stock Option Plan.

7. 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 ("UGIF"). The agreement, which is still in effect, 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. The Company funding of UGIF research was approximately $80,000 and $14,000 in the years ended December 31, 1997 and 1996, respectively.

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, which is still in effect, 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 funding of research was approximately $54,000 and $144,000 for the years ended December 31, 1997 and 1996, respectively.

In July, 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 was sold in 1997. 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, which is still in effect, 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 approximately $776,000 and $985,000 for the years ended December 31, 1997 and 1996, respectively.

In October, 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

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, which is still in effect, 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 approximately $50,000 and $300,000 for the years ended December 31, 1997 and 1996, respectively.

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, which is still in effect, 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 approximately $203,000 and $180,000 for the years ended December 31, 1997 and December 31, 1996, respectively.

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 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 approximately $251,000 and $774,000 for the years ended December 31, 1997 and 1996, respectively.

In March 1997, the Company entered into exclusive supply and license agreements for the world-wide rights to the multi-dose inhaler technology (MSI) of Siemens A.G. The agreements call for Siemens to be the exclusive supplier of the MSI system, a hand-held, portable pulmonary drug delivery system. The Company paid a licensing fee of $1.1 million in April 1997 to Siemens pursuant to these agreements. Under the terms of these agreements another DM 2.0 million payment was due in January, 1998. (See Note 11.) In addition, under certain circumstances, the Company will be required to make another DM 2.0 million payment to Siemens in January, 1999.

On November 20, 1997, the Company entered into agreement with Imutec Pharma Inc. Under this sub-license, Imutec acquired from the Company the rights to a series of clotrimazole-related compounds for the treatment of cancer, Kaposi's sarcoma and actinic keratosis. In exchange, Imutec agreed to manage and fund the remaining development program. The Company received $500,000 in cash upon signing the agreement, which has been recognized as revenue during the year ended December 31, 1997, and will receive $350,000 of Imutec stock in June, 1998. In addition, the Company is entitled to receive additional payments upon the completion of certain milestones in the development of these compounds and retains a 20 percent ownership interest upon commercialization.

8. 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, formerly a member of the Board of Directors of the Company, was also a general partner of SMT.

9. 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, 1997 and 1996 which is considered noncurrent, are as follows:

Deferred tax assets:	1997	1996
Net operating loss carryforwards	$ 12,400,000	$ 8,800,000
Capitalized start-up costs for tax purposes	578,000	578,000
Deferred tax asset valuation allowance	(12,978,000)	(9,378,000)
Net deferred tax asset	$ -	$ -

The valuation allowance for deferred tax assets as of December 31, 1996 and 1995 was $9,378,000 and $6,678,000, respectively. The net change in the total valuation allowance for the year ended December 31, 1997 was an increase of $3,600,000. At December 31, 1997, the Company has net operating loss carryforwards of approximately $34,000,000 for tax purposes which are available to offset federal taxable income, if any, through 2012. An ownership change pursuant to Section 382 of the 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. The Company has not performed a detailed analysis to determine whether an additional ownership change under Section 382 of the Internal Revenue Code of 1986 occurred during 1997, but believes that it is very likely that such a change occurred during 1997. The effect of an ownership change would be the imposition of an additional annual limitation on the use of NOL carryforwards attributable to periods before change. If the change occurred in late 1997, substantially all of the NOL carryforwards would be subject to the limitation. The amount of the annual limitation depends upon the value of the Company immediately before the change, changes to the Company's capital during a specified period prior to the change, and an interest rate which is published monthly. Due to uncertainty as to the date of an ownership change during 1997, the Company has not determined the amount of the potential limitation.

10. CONTINGENCY

The Company is a defendant in Dr. Bonnie S. Dunbar v. E/J

Development Corporation, U-Tech Medical Corporation, Sheffield Medical Technologies, Inc. and Douglas R. Eger, No. 97-28899, in the District Court of Harris County, Texas (133rd Judicial District). The plaintiff in this action asserts breach of contract, fraud and a claim for quantum meruit relating principally to certain stock options exercisable for a total of 40,000 shares of Common Stock issued in 1992 and 1993 to the plaintiff in consideration of consulting and research services provided to the Company. The plaintiff served as the principal investigator at Baylor College of Medicine in Houston, Texas on an ovarian cancer research project that was funded for several years by the Company. The plaintiff seeks actual damages against Sheffield and the other defendants, including Douglas R. Eger, a former Chairman of the Company, together with punitive damages, attorneys' fees, costs and expenses of the lawsuit, and pre- and post-judgement interest. The Company has denied the plaintiff's allegations and is vigorously contesting this action. This action is currently in the discovery phase. The Company and the plaintiff have engaged in settlement discussions, but no agreement has been reached to date. The Company is currently unable predict the likely outcome of this action. However, an unfavorable decision could have a material adverse effect on the business and financial condition of the Company.

11. SUBSEQUENT EVENTS

On April 15, 1998, the Company entered into an option agreement with Zambon Group SpA ("Zambon") of Milan, Italy for a sublicense to the Company's proprietary MSI drug delivery system. Under this contemplated transaction, Zambon will receive an exclusive world-wide marketing and development sub-license for respiratory products to be delivered by the MSI system including four drugs currently under development by Sheffield. Sheffield will maintain certain co-promotion rights in the U.S. for respiratory drugs as well as the world-wide marketing and development rights for all applications of the MSI delivery system outside the respiratory therapeutic area. As part of this transaction, Zambon will agree to fund all remaining development costs relating to these respiratory products, will pay Sheffield an up-front fee in the form of an equity investment as well as milestone payments upon marketing approval for each of the four products and royalties upon commercialization. In addition, Zambon will provide Sheffield with an interest free line of credit upon the achievement of certain early milestones. Sheffield is receiving a $650,000 option fee from Zambon in the form of an equity investment. The consummation of the sublicensing transaction with Zambon will be subject to the negotiation by the parties of a definitive sublicensing agreement.

On April 15, 1998, the Company issued 1,250 shares of its Series B Cummulative Convertible Redeemable Preferred Stock (the "Series B Preferred Stock") in a private placement for an aggregate purchase price of $1,250,000. Under the terms of this offering, the Company

must redeem the preferred stock at the time it concludes a definitive sub-license agreement on the MSI or other financing.

On April 15, 1998, the Company made the DM 2.0 million payment to Siemens, A.G. that was originally due in January 1998 under the terms of the MSI license agreement. This payment was made with the proceeds of the Series B Preferred Stock offering

For the period January 1, 1998 through April 15, 1998, a total of 4,075,797 shares of common stock were issued as a result of conversion of Series A Preferred Stock. As of April 15, 1998, all of the Series A Preferred Stock has been converted. For the period January 1, 1998 through April 15, 1998, a total of 2,291,798 shares of common stock were issued as a result of partial conversion and interest payments made on the 6% subordinated convertible debenture. As of April 15, 1998, $447,500 in principal remains to be repaid or available for conversion.

EX-10.8
2
1993 STOCK OPTION PLAN

Annex A

SHEFFIELD MEDICAL TECHNOLOGIES INC.

1993 STOCK OPTION PLAN
(as amended through June 26, 1997)

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. The Company intends that the Plan meet the requirements of Rule 16b-3 and that transactions of the type specified in subparagraphs (c) to (f) inclusive of Rule 16b-3 by officers and directors of the Company pursuant to the Plan will be exempt from the operation of Section 16(b) of the Exchange Act. Further, the Plan is intended to satisfy the performance-based compensation exception to the limitation on the Company's tax deductions imposed by Section 162(m) of the Code. In all cases, the terms, provisions, conditions and limitations of the Plan shall be construed and interpreted consistent with the Company's intent as stated in this Section 1.

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 Stock Option Committee composed of two or more directors who are Non-Employee Directors and Outside Directors and who shall be elected by and shall serve at the pleasure of the Board and shall be responsible for administering the Plan in accordance with paragraph (a) of Section 4 of the Plan.

(f) "EMPLOYEE" shall mean key employees, including salaried officers and directors and other key individuals 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) "NON-EMPLOYEE DIRECTOR" shall mean a non-employee director as defined in Rule 16b-3.

(k) "NON-STATUTORY STOCK OPTION" shall mean an Option which is

not an Incentive Stock Option.

(l) "OPTION" shall mean a stock option granted under the Plan.

(m) "OPTIONED STOCK" shall mean the Common Stock subject to an Option.

(n) "OPTIONEE" shall mean an Employee of the Company who has been granted one or more Options.

(o) "OUTSIDE DIRECTOR" shall mean an outside director as defined in Section 162(m) of the Code or the rules and regulations promulgated thereunder.

(p) "PARENT" shall mean a "parent corporation," whether now or hereafter existing, as defined in Section 425(e) of the Code.

(q) "PLAN" shall mean this 1993 Stock Option Plan.

(r) "SHARE" shall mean a share of the Common Stock, as adjusted in accordance with Section 11 of the Plan.

(s) "STOCK OPTION AGREEMENT" shall mean the written agreement between the Company and the Optionee relating to the grant of an Option.

(t) "SUBSIDIARY" shall mean a "subsidiary corporation," whether now or hereafter existing, as defined in Section 425(f) of the Code.

(u) "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 Three Million (3,000,000) 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. The maximum number of Shares that may be subject to options granted under the Plan to any individual in any calendar year shall not exceed 500,000 Shares and the method of counting such Shares shall conform to any requirements applicable to performance-based compensation under Section 162(m) of the Code or the rules and regulations promulgated thereunder.

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 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 including, without limitation, the terms of exercise (including the period of exercisability) or forfeiture of Options granted hereunder upon termination of the employment of an Employee; (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.

(d) INABILITY OF COMMITTEE TO ACT. In the event that for any reason the Committee is unable to act or if the Committee at the time of any grant, award or other acquisition under the Plan of options or Shares does not consist of two or more Non-Employee Directors, then any such grant, award or other acquisition may be approved or ratified in any other manner contemplated by subparagraph (d) of Rule 16b-3.

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) Unless otherwise provided in the applicable Stock Option Agreement, 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).

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. If an option granted to the Company's chief executive officer or to any of the Company's other four most highly compensated officers is intended to qualify as "performance-based" compensation under Section 162(m)

of the Code, the exercise price of such option shall not be less than 100% of the Fair Market Value of a Share on the date such option is granted.

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

(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 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. Unless otherwise

provided in the applicable Stock Option Agreement, 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, 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, for 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 or in the applicable Stock Option Agreement, the Option shall terminate.

(c) DISABILITY. Unless otherwise provided in the applicable Stock Option Agreement, 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 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 or in the applicable Stock Option Agreement, the Option shall terminate.

(d) DEATH. Unless otherwise provided in the Stock Option Agreement, 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 or in the applicable Stock Option Agreement, 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 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;

(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.

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 the Code.

(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.

EX-10.19
3
SEVERANCE AGREEMENT

SEVERANCE AGREEMENT

AGREEMENT made as of the 22nd day of December, 1997 by and between Sheffield Pharmaceuticals, Inc., a Delaware corporation with its principal offices at 425 South Woodsmill Road, St Louis, Missouri 63017-3441 (the "Company"), and Douglas Eger residing at 4135 Ventura, Coconut Grove, Florida 33133 (the "Employee").

RECITALS

WHEREAS, the Company entered into an employment agreement dated as of October 1, 1995 with the Employee relating to the employment of the Employee as an executive officer of the Company, which employment (such employment agreement, as it may have been amended, being the Employment Agreement"); and

WHEREAS, the Company and the Employee have agreed upon the terms of the Employee's resignation as an officer and an employee of the Company and desire to evidence such terms in this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual covenants hereinafter set forth, the parties hereto agree as follows:

1. RESIGNATION. The Employee hereby resigns as an officer of the Company and as Chairman of the Board of Directors of the Company effective as of the date hereof. The Employee hereby resigns as an employee of the Company and its subsidiaries effective as of January 1, 1998.

2. SEVERANCE. The Company shall pay the Employee severance payments totaling $135,000 payable in six equal installments of $22,500 commencing with the first installment to be paid on January 31, 1998 and with each subsequent installment to be paid monthly thereafter on the last day of each calendar month. The Company shall deduct (and shall therefor not pay to the Employee) $2,500 from each such installment, which deducted amounts shall be applied to reduce outstanding amounts due to the Company under the promissory note of the Employee dated April 4, 1997 issued to the Company in the original principal amount of $80,000 (the "$80,000 Note"). The $2,500 deductions shall be applied first to the reduction of outstanding principal and then to the reduction of outstanding interest and any other amounts payable under the $80,000 Note. Company and Employee acknowledge that $80,000.00 principal amount and $ 4,593.97 of accrued interest remain outstanding under the $80,000 Note on the date hereof. In the event of the occurrence of a Change of Control, the remaining balance of the $135,000 in severance payments shall become immediately due and payable by the Company. As used in this paragraph, "Change of Control" means (i) the sale, lease, exchange

or other transfer of all or substantially all (50% or more) of the consolidated assets of the Company to any person or entity or group of persons or entities acting in concert as a partnership or other group (a "Group of Persons") or (ii) the merger, consolidation or other business combination of the Company with or into another corporation with the effect that the shareholders of the Company immediately following the merger, consolidation or other business combination hold 50% or less of the combined voting power of the then outstanding securities of the surviving corporation of such merger, consolidation or other business combination having the right to vote in the election of directors. The Employee confirms that except as set forth in this Agreement, the Company has no obligations to make any payments to the Employee of any nature.

3. NOTE SATISFACTION. (a) Employee agrees to tender and assign to the Company a stock certificate representing 10,200 shares of the Company's common stock within 10 days of the date hereof. Such certificate shall be freely tradeable (without transfer restrictions). Such stock certificate shall be delivered by Employee with stock powers executed in blank covering the shares represented by such certificate. The delivery of such stock certificate by Employee shall constitute the Employee's representation and warranty that the shares of common stock represented by such certificate are owned by the Employee free and clear of any liens or encumbrances. Upon the delivery of such stock certificate, the Employee's obligations under the promissory note of the Employee dated July 31, 1996 issued to the Company in the remaining principal amount of $20,000 shall be deemed satisfied in full.

(b) In the event that the Company fails to pay any installment of the severance payment when due under paragraph 2 above, the remaining amounts

of principal and interest payable under the Note will automatically be reduced by 25% for each full ten (10) day period that such failure to timely pay continues after such due date.

4. BOARD MEMBERSHIP. The Employee agrees not to seek election as a director of the Company at the next annual meeting of the stockholders of the Company. The Company acknowledges that the Employee is under no contractual obligation to continue as a director of the Company and has the right to resign as a director of the Company at any time.

5. SATISFACTION OF EMPLOYMENT AGREEMENT. The Employee acknowledges that the Company has no further obligations to Employee under the Employment Agreement.

6. AMENDMENT AND RESTATEMENT OF NOTE. Upon the execution of this Agreement by the Employee and the delivery of the stock certificate representing 10,200 shares of the Company's common stock pursuant to paragraph 3 above, the Company agrees to the

amendment and restatement of the $80,000 Note, effective as of the date hereof, to provide (a) for the payment of the outstanding principal amount thereof (after the deductions from the severance payments pursuant to paragraph 2 above) in six equal installments on the last day of each March, June, September and December commencing September 30, 1998, together with accrued interest, with any remaining outstanding principal and accrued interest on the $80,000 Note becoming due and payable on December 31, 1999 (b) for default interest upon the failure to timely repay any amount payable by the Employee under the amended and restated $80,000 Note at an interest rate of 15% per annum and (c) prepayment of the $80,000 Note without prepayment penalty or premium. Except as provided in the preceding sentence, the $80,000 Note will remain unchanged. The Company agrees to promptly prepare and deliver to the Employee for his execution amended and restated $80,000 Note reflecting the above-mentioned amendments and the Employee agrees to promptly execute and return to the Company such amended and restated $80,000 Note.

7. PLEDGE OF STOCK. Within 15 days of the date hereof, Employee will transfer 30,000 shares of freely tradeable (without transfer restrictions) common stock of the Company to an account with Merrill Lynch. At the time of such transfer, such shares shall be owned by the Employee free and clear of any liens or encumbrances. The Employee will execute a letter in the form attached hereto as Exhibit A, will cause an authorized representative of Merrill Lynch to execute such letter and shall deliver such letter (executed by the Employee and by an authorized officer on behalf of Merrill Lynch) within 15 days of the date hereof.

8. CONFIDENTIALITY. (a) The Employee agrees to hold in a fiduciary capacity for the benefit of the Company and its subsidiaries all information developed or originated by the Company (or by the Employee on behalf of the Company) concerning the Company that is confidential or proprietary, including without limitation, financial, technology development and other business information, contracts, trade secrets and patent and trademark information ("Confidential Information"), and he shall not, at any time during the two year

period following the date of this Agreement, use, disclose or divulge any Confidential Information to any person, firm, corporation or other entity other than to the Company and its subsidiaries or their respective designees.

(b) Notwithstanding anything to the contrary contained herein, the Employee's obligations under paragraph 8(a) hereof shall not apply to any information which:

(i) is or becomes available to the public other than as a result of wrongful disclosure by the Employee;

(ii) becomes available to the Employee subsequent to his employment by the Company on a nonconfidential basis from a source other than the Company or its agents which source has a right to disclose such information; or

(iii) results from research and development and/or commercial operations at any time by or on behalf of any person, company or other entity with which or with whom the Employee shall become associated (in a manner consistent with the terms of this Agreement) subsequent to his employment by the Company or its agents totally independent from any disclosure from the Company or its agents.

(c) Notwithstanding anything to the contrary contained in this paragraph 8, in the event that the Employee becomes legally compelled to disclose any Confidential Information, the Employee will provide the Company with prompt notice so that the Company may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the Employee shall furnish only such Confidential Information which is legally required to be disclosed.

9. INDEMNITY. The Company agrees to indemnify the Employee in the event that he is a party or is threatened to be made a party to any threatened, pending or completed action or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that the Employee was an officer or director of the Company against all out-of-pocket expenses (including reasonable attorney's fees and disbursements), judgments, fines and amounts paid in settlement actually and reasonably incurred by the Employee in connection with the action or proceeding, PROVIDED that his actions did not involve willful misconduct or gross negligence. The Employee shall not settle any action or proceeding subject to indemnification under this paragraph 9 without the prior written consent of the Company, which consent shall not be unreasonably withheld.

10. RELEASES. (a) The Employee hereby releases and discharges the Company and all of its directors, officers, employees, agents, subsidiaries and affiliates and its successors and assigns from any and all claims, actions, suits, debts, accounts, contracts, agreements, damages, judgments and demands whatsoever, in law or equity, that the Employee ever had, now has or hereafter can, shall or may, have for, upon, or by reason of any matter, cause or thing whatsoever from the beginning of the world to the date of this Agreement. Notwithstanding the foregoing, this release shall not apply to any rights that

the Employee has under this Agreement. This release is irrevocable and may not be changed orally.

(b) The Company hereby releases and discharges the Employee and his successors and assigns from any and all claims,

actions, suits, debts, accounts, contracts, agreements, damages, judgments and demands whatsoever, in law or equity, that the Company ever had, now has or hereafter can, shall or may, have for, upon, or by reason of any matter, cause or thing whatsoever from the beginning of the world to the date of this Agreement. Notwithstanding the foregoing, this release shall not apply to (i) any rights that the Company has under (i) this Agreement, (ii) the $80,000 Note and (iii) the Pledge Agreement dated April 4, 1997 made by the Employee to the Company. This release is irrevocable and may not be changed orally.

11. GOVERNING LAW. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware.

12. MISCELLANEOUS. (a) The Company confirms that there are currently outstanding stock options evidenced by written agreements that provide the Employee with the right to acquire 500,000 shares of the Company's common stock, which agreements provide for a term of exercise of such options ending in 2002.

(b) The Employee confirms that he has consulted with his own attorney regarding his rights and obligations under this Agreement prior to executing this Agreement.

(c) If any provision of this Agreement is determined to be invalid, illegal or unenforceable by any court of competent jurisdiction, the remaining provisions of this Agreement shall remain in full force and effect provided that the economic and legal substance of the transactions contemplated is not affected in any manner adverse to any party.

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

SHEFFIELD PHARMACEUTICALS, INC.

By:

Loren G. Peterson, CEO

DOUGLAS R. EGER

Exhibit A to Severance Agreement

SHEFFIELD PHARMACEUTICALS,INC.
425 WOODSMILL ROAD, SUITE 270
ST. LOUIS, MISSOURI 63017-3441
(314) 579-9899

[Date]

[MERRILL LYNCH]
[Address]
Attention: _____

You are hereby advised that Douglas R. Eger ("Eger") has granted Sheffield Pharmaceuticals, Inc. ("Sheffield") a first priority security interest in 30,000 shares of common stock, par value $.01 per share, of Sheffield ("Common Stock") held in his name in account no. _____ (the "Eger Account") at [Merrill Lynch] ("Merrill Lynch") as security for a loan made by Sheffield to Eger.

By signing below, (i) you acknowledge that Merrill Lynch is a licensed broker-dealer and that Merrill Lynch holds at least _____ shares of Common Stock in the Eger Account and that such shares are not, to your knowledge, subject to any lien or security interest (other than the security interest granted to Sheffield), (ii) you agree to evidence Sheffield's security interest in such 30,000 shares of Common Stock by appropriate notation in your books and records (iii) you agree not to sell or otherwise transfer such shares without prior written approval of Sheffield and (iv) you agree to transfer such shares upon receipt of written instructions of Sheffield in connection with Sheffield's enforcement of its security interest, which instructions shall state that Sheffield is exercising its rights in connection with a default by Eger in his obligation to repay certain indebtedness owed to Sheffield.

Very truly yours,

SHEFFIELD PHARMACEUTICALS, INC.

By:

Judy Roeske Bullock
Vice President and CFO

ACKNOWLEDGED AND AGREED:

Douglas R. Eger

ACKNOWLEDGED AND AGREED:

[MERRILL LYNCH]

- ---

Name:
Title:

EX-10.20
4
AMENDED EMPLOYMENT AGREEMENT

AMENDED EMPLOYMENT AGREEMENT

AGREEMENT made as of the 15th day of October, 1997 by and between Sheffield Pharmaceuticals, Inc., a Delaware corporation with its principal offices at 425 South Woodsmill Road, St Louis, Missouri 63017-3441 (the "Company"), and George Lombardi residing at 106 Byrd Avenue, Bloomfield, New Jersey 07003 (the "Employee").

RECITALS

WHEREAS, the Company entered into an employment agreement dated as of September 7, 1995 with the Employee relating to the employment of the Employee as Vice President and Chief Financial Officer of the Company, which employment agreement was amended by amendment dated September 22, 1996 (such employment agreement, as so amended, being the Employment Agreement"); and

WHEREAS, the Company and the Employee have agreed upon the terms of the Employee's resignation as an officer and an employee of the Company and desire to evidence such terms in this Agreement Amendment.

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

1. RESIGNATION. The Employee agrees to resign as an officer of the Company and its subsidiaries upon the request of the Chairman or the Chief Executive Officer of the Company (the "CEO") (which request shall not be made before October 31, 1997). The Company agrees to enter into amended and restated option agreement on October 15, 1997 amending the option letter agreement dated September 7, 1995 between the Company and the Employee (relating to the grant of an option to purchase 100,000 shares of the Company's common stock) providing for an extension of the expiration date of such option to March 31, 2002.

2. SEVERANCE. The Company shall pay the Employee severance payments totaling $65,000 in six equal installments of $10,833.33 commencing with the first installment to be paid on November 15, 1997 and with each subsequent installment to be paid bi-monthly thereafter on the dates when the Company's regular payroll payments are paid. Such severance payments become payable by the Company upon Employee's resignation as an officer of the Company and its subsidiaries on or after October 31, 1997. The severance payable to the Employee under this paragraph shall be in lieu of any severance payment otherwise payable under Section 11(b) of the Employment Agreement).

3. EMPLOYMENT AFTER RESIGNATION. (a) The Employee agrees to continue to serve as an employee of the Company until November 15, 1997 devoting his full working day to Company matters assigned to him by the CEO or the Company's new

Chief Financial Officer (the "New CFO"). It is understood that the Employee's principal duties during this period shall be to (i) prepare the Company's report on Form 10-Q for the quarter ended September 30, 1997 under the supervision of the New CFO and (ii) familiarize the New CFO with the Company's financial reporting and accounting practices and the Company's files. Subject to the following sentence, the Employee shall perform his duties either from an office in New York City provided to the Employee by the Company or from his home in New Jersey, as determined by the CEO. It is understood that the Employee may be required to travel to the Company's offices in St. Louis, Missouri, to perform his duties hereunder.

(b) The Employee agrees to resign as an employee of the Company on November 15, 1997. The Employee agrees to serve as a consultant to the Company from November 15, 1997 to and including December 31, 1997. The Employee agrees to devote up to 2/3 of his working day to Company matters assigned to him by the CEO or the CFO during this period.

4. COMPENSATION. (a) As compensation for his services to be provided to the Company pursuant to Section 3(a) above, the Company shall, on November 15, 1997, forgive $12,800 of the principal amount payable to the Company by the Employee under the Amended and Restated $42,800 Promissory Note of the Employee payable to the Company dated July 31, 1997 (the "Note").

(b) As compensation for his consulting services to be provided to the Company pursuant to Section 2(b) above, on December 31, 1997, the Company shall forgive an additional $10,000 of the principal amount of the Note and shall agree to an amendment and restatement of the Note to provide for (i) the principal reductions referred to in this Section 3, (ii) the repayment of the principal amount of the Note in installments of $2,500 each, plus accrued and unpaid interest, on a quarterly basis commencing December 31, 1997, with the final installment being due September 30, 1999, and (iii) a mandatory prepayment of the Note in the event that the Employee sells any of the Company's common stock held by him on the date hereof.

(c) The compensation payable to the Employee under this paragraph shall constitute the only compensation payable under the Employment Agreement in respect of services to be provided by the Employee after October 15, 1997 and shall be payable in lieu of any other compensation (including any severance payment otherwise payable under Section 11(b) of the Employment Agreement) that would otherwise be payable by the Company pursuant to the Employment Agreement after such date.

5. BENEFITS. The Employee shall continue to receive all benefits under Section 5 of the Employment Agreement (but only to the extent the Employee is receiving such benefits as of the date hereof) through November 15, 1997, at which time all such benefits shall terminate except as provided in this Section. The Company shall continue to maintain Employee's benefits under the Company's existing health and medical plans and pay the related insurance premiums currently paid by the Company for the Employee's coverage through January 31, 1998. Thereafter, the Employee shall have the option to continue such health insurance coverage at his own expense under applicable "COBRA" regulations.

6. RELEASE. The Employee hereby releases and discharges the Company and

all of its directors, officers, employees, agents, subsidiaries and affiliates and its successors and assigns from any and all claims, actions, suits, debts, accounts, contracts, agreements, damages, judgments and demands whatsoever, in law or equity, that the Employee ever had, now has or hereafter can, shall or may, have for, upon, or by reason of any matter, cause or thing whatsoever from the beginning of the world to the date of this Agreement. Notwithstanding the foregoing, this release shall not apply to any rights that the Employee has under this Agreement Amendment. This release is irrevocable and may not be changed orally.

7. MISCELLANEOUS. The Company shall provide the Employee with a fax machine to be used at the Employee's home. The Company shall permit Employee to retain ownership of such fax machine after his resignation in accordance with Section 2(a) above. This Agreement Amendment shall constitute a supplement and amendment to the Employment Agreement. To the extent that the Employment Agreement and this Agreement Amendment shall conflict in any respect, the terms of this Agreement Amendment shall be deemed the governing terms.

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

SHEFFIELD PHARMACEUTICALS, INC.

By:

Loren G. Peterson, CEO

George Lombardi

EX-10.65
5
EMPLOYMENT AGREEMENT

EMPLOYMENT AGREEMENT

AGREEMENT made as of the 17th day of November, 1997, by and between Sheffield Pharmaceuticals, Inc., a Delaware corporation with its principal offices at 425 South Woodsmill Road, Suite 270, St. Louis, Missouri 63017-3441 (the "Corporation"), and Judy Roeske Bullock, who currently resides at 3850 35th Avenue Court, Moline, Illinois 61265 ("Executive").

W I T N E S S E T H :

WHEREAS, the Corporation desires to employ and retain Executive as its Vice President - Finance and Administration, Chief Financial Officer and Secretary, upon the terms and subject to the conditions of this Agreement; and

NOW, THEREFORE, in consideration of the premises and the mutual covenants hereinafter set forth, the parties hereto agree as follows:

1. EMPLOYMENT OF EXECUTIVE. The Corporation hereby employs Executive as its Vice President - Finance and Administration, Chief Financial Officer and Secretary, to perform the duties and responsibilities traditionally incident to such office, subject at all times to the control and direction of the Board of Directors of the Corporation.

2. ACCEPTANCE OF EMPLOYMENT; OFFICES; TIME AND ATTENTION, ETC. (a) Executive hereby accepts such employment and agrees that throughout the period of her employment hereunder, except as hereinafter provided, she will devote her full business and professional time in utilizing her business and professional expertise, with proper attention, knowledge and skills faithfully, diligently and to the best of her ability in furtherance of the business of the Corporation and its subsidiaries and will perform the duties assigned to her pursuant to Paragraph 1 hereof. As Vice President - Finance and Administration, Chief Financial Officer and Secretary, Executive shall also perform such specific duties and shall exercise such specific authority related to the management of the day-to-day operations of the Corporation and its subsidiaries as may be reasonably assigned to Executive from time to time by the Board of Directors of the Corporation.

(b) Executive shall at all times be subject to, observe and carry out such rules, regulations, policies, directions and restrictions as the Board of Directors of the Corporation shall from time to time establish. During the period of her employment hereunder, Executive shall not, directly or indirectly, accept employment or compensation from, or perform services of any nature for, any business enterprise other than the Corporation and its subsidiaries. Notwithstanding the foregoing in this Paragraph 2, Executive shall not be precluded from (i) engaging in recreational, eleemosynary, educational and other activities, which activities do not materially interfere with her duties hereunder and shall occur during vacations, holidays and other periods outside of business

hours or (ii) serving as an independent director on the board of directors of up to three for-profit corporations, PROVIDED, HOWEVER, that Executive's election or appointment as a director to any such board of directors shall be subject to the prior written approval of the Chief Executive Officer of the Corporation and shall not materially interfere with her duties hereunder.

3. TERM. Except as otherwise provided herein, the term of Executive's employment hereunder shall commence on the date hereof and shall continue to and including November 17, 2000. Unless terminated earlier in accordance with the terms hereof, this Agreement shall automatically be extended for one or more additional consecutive one year terms unless either party notifies the other party in writing at least 90 days before the end of the then current term (including the initial term) of its or her desire to terminate this Agreement. The last day of the term of this Agreement pursuant to this Paragraph

3 (including any early termination pursuant to the terms hereof) is referred to herein as the "Termination Date."

4. COMPENSATION. (a) As compensation for her services hereunder, the Corporation shall pay to Executive (i) a base annual salary at the rate of $150,000, payable in equal installments in accordance with the normal payroll practices of the Corporation but in no event less frequently than semi-monthly, and (ii) such incentive compensation and bonuses, if any, as the Board of Directors of the Corporation in its absolute discretion may determine to award Executive (it being understood that this Agreement shall in no event be construed to require the payment to Executive of any incentive compensation or bonuses). All compensation paid to Executive shall be subject to withholding and other employment taxes imposed by applicable law.

(b) During the period of Executive's employment hereunder, Executive shall not be entitled to any additional compensation for rendering employment services to subsidiaries of the Corporation or for serving in any office of the Corporation or any of its subsidiaries to which she is elected or appointed.

5. STOCK OPTIONS. As additional compensation for her services hereunder, the Corporation shall grant to Executive an option under the Corporation's 1993 Stock Option Plan (the "Plan") to acquire a total of 130,000 shares of the Corporation's common stock at an exercise price per share equal to the closing sale price of the Corporation's common stock as reported by the American Stock Exchange on the date hereof, with the terms of such option to be evidenced by an option letter agreement in the form annexed as Exhibit "A" hereto.

6. ADDITIONAL BENEFITS; VACATION. (a) In addition to such base salary, Executive shall receive and be entitled to participate, to the extent she is eligible under the terms and conditions thereof, in any profit sharing, pension, retirement, hospitalization, disability, medical service, insurance or other

employee benefit plan generally available to the executive officers of the Corporation that may be in effect from time to time during the period of Executive's employment hereunder. The Corporation agrees to cover Executive under any directors' and officers' liability policy maintained by the Corporation.

(b) Executive shall be paid a one-time relocation allowance equal to 15% of her base annual salary ($22,500).

(c) Executive shall be entitled to four (4) weeks' paid vacation in respect of each 12-month period during the term of her employment hereunder, such vacation to be taken at times mutually agreeable to Executive and the Board of Directors of the Corporation.

(d) Executive shall be entitled to recognize as holidays all days recognized as such by the Corporation.

7. REIMBURSEMENT OF EXPENSES. The Corporation shall reimburse

Executive in accordance with applicable policies of the Corporation for all expenses reasonably incurred by her in connection with the performance of her duties hereunder and the business of the Corporation, upon the submission to the Corporation of appropriate receipts or vouchers.

8. RESTRICTIVE COVENANT. (a) In consideration of the Corporation's entering into this Agreement, Executive agrees that during the period of her employment hereunder and, in the event of termination of this Agreement (i) by the Corporation upon Executive becoming Disabled (as that term is defined in Paragraph 13 hereof), (ii) by the Corporation for Cause (as that term is defined in Paragraph 14 hereof) or (iii) by Executive otherwise than for Employer Breach (as that term is defined in Paragraph 15 hereof), for a further period of six months thereafter, she will not (x) directly or indirectly own, manage, operate, join, control, participate in, invest in, whether as an officer, director, employee, partner, investor or otherwise, any business entity that is engaged in a directly competitive business (as hereinafter defined) to that of the Corporation or any of its subsidiaries within the United States of America, (y) for herself or on behalf of any other person, partnership, corporation or entity, call on any customer of the Corporation or any of its subsidiaries for the purpose of soliciting away, diverting or taking away any customer from the Corporation or its subsidiaries, or (z) solicit any person then engaged as an employee, representative, agent, independent contractor or otherwise by the Corporation or any of its subsidiaries, to terminate her or her relationship with the Corporation or any of its subsidiaries. For purposes of this Agreement, the term "directly competitive business" shall mean any business that is then involved in the research, development, manufacturing or commercialization in any way of any product, compound, device or method that is or becomes a part of the Corporation's business or the business of any of its subsidiaries during Executive's employment by the Corporation or any of its subsidiaries. Nothing contained in this Agreement shall be deemed

to prohibit Executive from investing her funds in securities of an issuer if the securities of such issuer are listed for trading on a national securities exchange or are traded in the over-the-counter market and Executive's holdings therein represent less than 10% of the total number of shares or principal amount of the securities of such issuer outstanding.

(b) Executive acknowledges that the provisions of this Paragraph 8 are reasonable and necessary for the protection of the Corporation, and that each provision, and the period or periods of time, geographic areas and types and scope of restrictions on the activities specified herein are, and are intended to be, divisible. In the event that any provision of this Paragraph 8, including any sentence, clause or part hereof, shall be deemed contrary to law or invalid or unenforceable in any respect by a court of competent jurisdiction, the remaining provisions shall not be affected, but shall, subject to the discretion of such court, remain in full force and effect.

9. CONFIDENTIAL INFORMATION.

(a) Executive shall hold in a fiduciary capacity for the benefit of the Corporation and its subsidiaries all confidential information, knowledge and data relating to or concerned with its operations, sales, business and affairs, and she shall not, at any time during her employment hereunder and

for two years thereafter, use, disclose or divulge any such information, knowledge or data to any person, firm or corporation other than to the Corporation and its subsidiaries or their respective designees or except as may otherwise be reasonably required or desirable in connection with the business and affairs of the Corporation and its subsidiaries.

(b) Notwithstanding anything to the contrary contained herein, Executive's obligations under Paragraph 9(a) hereof shall not apply to any information which:

(i) becomes rightfully known to Executive subsequent or prior to her employment by the Corporation;

(ii) is or becomes available to the public other than as a result of wrongful disclosure by Executive;

(iii) becomes available to Executive subsequent to her employment by the Corporation on a nonconfidential basis from a source other than the Corporation or its agents which source has a right to disclose such information; or

(iv) results from research and development and/or commercial operations at any time by or on behalf of any person, company or other entity with which or with whom Executive shall become associated (in a manner consistent with the terms of this Agreement) subsequent to her employment by the Corporation or its agents totally independent from any disclosure from the Corporation or its agents.

(c) Notwithstanding anything to the contrary contained herein, in the event that Executive becomes legally compelled to disclose any confidential information, Executive will provide the Corporation with prompt notice so that the Corporation may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, Executive shall furnish only such confidential information which is legally required to be disclosed.

10. INTELLECTUAL PROPERTY. Any idea, invention, design, written material, manual, system, procedure, improvement, development or discovery conceived, developed, created or made by Executive alone or with others, during the period of her employment hereunder and applicable to the business of the Corporation or any of its subsidiaries, whether or not patentable or registrable, shall become the sole and exclusive property of the Corporation or such subsidiary. Executive shall disclose the same promptly and completely to the Corporation and shall, during the period of her employment hereunder and at any time and from time to time hereafter at no cost to Executive (i) execute all documents reasonably requested by the Corporation for vesting in the Corporation or any of its subsidiaries the entire right, title and interest in and to the same, (ii) execute all documents reasonably requested by the Corporation for filing and prosecuting such applications for patents, trademarks, service marks and/or copyrights as the Corporation, in its sole discretion, may desire to prosecute, and (iii) give the Corporation all assistance it reasonably requires, including the giving of testimony in any suit, action or proceeding, in order to obtain, maintain and protect the

Corporation's right therein and thereto.

11. EQUITABLE RELIEF. The parties hereto acknowledge that Executive's services are unique and that, in the event of a breach or a threatened breach by Executive of any of her obligations under Paragraphs 8, 9 or 10 this Agreement, the Corporation shall not have an adequate remedy at law. Accordingly, in the event of any such breach or threatened breach by Executive, the Corporation shall be entitled to such equitable and injunctive relief as may be available to restrain Executive and any business, firm, partnership, individual, corporation or entity participating in such breach or threatened breach from the violation of the provisions of Paragraph 8, 9 or 10 hereof. Nothing herein shall be construed as prohibiting the Corporation from pursuing any other remedies available at law or in equity for such breach or threatened breach, including the recovery of damages and the immediate termination of the employment of Executive hereunder, if and to the extent permitted hereunder.

12. TERMINATION OF AGREEMENT; TERMINATION OF EMPLOYMENT; SEVERANCE; SURVIVAL. (a) This Agreement and Executive's employment hereunder shall terminate upon the first to occur of the following: (i) Executive becoming Disabled (as that term is defined in Paragraph 13 hereof); (ii) Executive's death; (iii) termination of Executive's employment by the Corporation for Cause or pursuant to subparagraph (b) of this Paragraph 12; (iv) termination of

Executive's employment for Employer Breach and (v) the termination of this Agreement at the end of the term of this Agreement on the Termination Date pursuant to Paragraph 3.

(b) Notwithstanding anything to the contrary contained in this Agreement, in the event of the termination of the Executive's employment by the Corporation for any reason (other than for Cause), Executive shall be paid a severance payment equal to 50% of Executive's then current annual base salary payable in six equal monthly installments, 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 month after such date until such severance is paid in full. In the event of such termination of the Executive's employment by the Corporation (other than for Cause), the Corporation shall have no further obligation to the Executive under this Agreement other than the Corporation's obligation (i) to make such severance payment to the Executive (ii) to pay Executive's COBRA premium payments for hospitalization and medical insurance coverage provided by the Corporation and to pay Executive's premiums on any death and/or disability insurance being maintained by the Corporation for Executive at the time of such termination, in each case until the payment in full of such severance payments.

(c) Paragraphs 7, 8, 9, 10, 11, 12 and 26 of this Agreement shall survive the termination of Executive's employment hereunder, except in the case of termination pursuant to Paragraph 15.

13. DISABILITY. In the event that during the term of her employment by the Corporation Executive shall become Disabled (as that term is hereinafter defined) she shall continue to receive the full amount of the base salary to which she was theretofore entitled for a period of six months after she shall be deemed to have become Disabled (the "First Disability Payment

Period"). If the First Disability Payment Period shall end prior to the Termination Date, Executive thereafter shall be entitled to receive salary at an annual rate equal to 80% of her then current base salary for a further period ending on the earlier of (i) six months thereafter or (ii) the Termination Date (the "Second Disability Payment Period"). Upon the expiration of the Second Disability Payment Period, Executive shall not be entitled to receive any further payments on account of her base salary until she shall cease to be Disabled and shall have resumed her duties hereunder and provided that the Corporation shall not have theretofore terminated this Agreement as hereinafter provided. The Corporation may terminate Executive's employment hereunder at any time after Executive is Disabled, upon at least 10 days' prior written notice; PROVIDED, HOWEVER, that such termination shall not relieve the Corporation from its obligation to make the payments to Executive described above in this Paragraph 13. For the purposes of this Agreement, Executive shall be deemed to have become Disabled when (x) by reason of physical or mental incapacity, Executive is not able to perform her duties hereunder for a period of 90 consecutive days or for 120 days in any consecutive 180-day period and (y)

Executive's physician or a physician designated by the Corporation shall have determined that it is unlikely that Executive will be able, by reason of physical or mental incapacity, to perform a substantial portion of her duties hereunder for the following 120 days. In the event that Executive shall dispute any determination of her disability pursuant to clauses (x) or (y) above, the matter shall be resolved by the determination of three physicians qualified to practice medicine in the United States of America, one to be selected by each of the Corporation and Executive and the third to be selected by the designated physicians. If Executive shall receive benefits under any disability policy maintained by the Corporation, the Corporation shall be entitled to deduct the amount equal to the benefits so received from base salary that it otherwise would have been required to pay to Executive as provided above.

14. TERMINATION FOR CAUSE. The Corporation may at any time upon written notice to Executive terminate Executive's employment for Cause. For purposes of this Agreement, the following shall constitute Cause: (i) the willful and repeated failure of Executive to perform any material duties hereunder or gross negligence of Executive in the performance of such duties, and if such failure or gross negligence is susceptible to cure by Executive, the failure to effect such cure within twenty (20) days after written notice of such failure or gross negligence is given to Executive; (ii) except as permitted hereunder, unexplained, willful and regular absences of Executive from the Corporation; (iii) excessive use of alcohol or illegal drugs, interfering with the performance of Executives duties hereunder; (iv) indictment for a crime of theft, embezzlement, fraud, misappropriation of funds, other acts of dishonesty or the violation of any law or ethical rule relating to Executive's employment; (v) indicted for any other felony or other crime involving moral turpitude by Executive; or (vi) the breach by Executive of any of the provisions of paragraphs 8, 9 or 10 and if such breach is susceptible of cure by Executive, the failure to effect such cure within twenty (20) days after written notice of such breach is given to Executive. For purposes of this Agreement, an action shall be considered "willful" if it is done intentionally, purposely or knowingly, distinguished from an act done carelessly, thoughtlessly or inadvertently. In any such event, Executive shall be entitled to receive her base salary to and including the date of termination.

15. TERMINATION FOR EMPLOYER BREACH. Executive may upon written notice to the Corporation terminate this Agreement (including paragraphs 8, 9, 10 and 11) in the event of the breach by the Corporation of any material provision of this Agreement, and if such breach is susceptible of cure, the failure to effect such cure within 20 days after written notice of such breach is given to the Corporation (an "Employer Breach"). Executive's right to terminate this Agreement under this Paragraph 15 shall be in addition to any other remedies Executive may have under law or equity. Paragraphs 7 and 12(b) of this Agreement shall survive the termination of this Agreement by Executive pursuant to this Paragraph 15.

16. INSURANCE POLICIES. The Corporation shall have the right from time to time to purchase, increase, modify or terminate insurance policies on the life of Executive for the benefit of the Corporation, in such amounts as the Corporation shall determine in its sole discretion. In connection therewith, Executive shall, at such time or times and at such place or places as the Corporation may reasonably direct, submit herself to such physical examinations and execute and deliver such documents as the Corporation may reasonably deem necessary or desirable; PROVIDED that such examinations shall be performed by, and that such documents shall be delivered only to, qualified physicians and/or medical representatives of licensed insurance companies. At Executive's written request upon the termination of Executive's employment under this Agreement (other than for Cause or as result of Executive's death), the Corporation shall assign to Executive the Corporation's interest in such life insurance policies (to the extent such policies are so assignable by their terms), whereupon Executive shall assume all obligations of the Corporation in respect thereof.

17. ENTIRE AGREEMENT; AMENDMENT. This Agreement constitutes the entire agreement of the parties hereto, and any prior agreement between the Corporation and Executive is hereby superseded and terminated effective immediately and shall be without further force or effect. No amendment or modification herself shall be valid or binding unless made in writing and signed by the party against whom enforcement thereof is sought.

18. NOTICES. Any notice required, permitted or desired to be given pursuant to any of the provisions of this Agreement shall be delivered in person or sent by responsible overnight delivery service or sent by certified mail, return receipt requested, postage and fees prepaid, if to the Corporation, at its address set forth above to the attention of the Corporation's Chief Executive Officer and, if to Executive, at her address set forth above. Either of the parties hereto may at any time and from time to time change the address to which notice shall be sent hereunder by notice to the other party given under this Paragraph 18. Notices shall be deemed effective upon receipt.

19. NO ASSIGNMENT; BINDING EFFECT. Neither this Agreement, nor the right to receive any payments hereunder, may be assigned by either party without the other party's prior written consent. This Agreement shall be binding upon Executive, her heirs, executors and administrators and upon the Corporation, its successors and assigns.

20. WAIVERS. No course of dealing nor any delay on the part of either party in exercising any rights hereunder shall operate as a waiver of any

such rights. No waiver of any default or breach of this Agreement shall be deemed a continuing waiver or a waiver of any other breach or default.

21. GOVERNING LAW. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, except that body of law relating to choice of laws.

22. INVALIDITY. If any clause, paragraph, section or part of this Agreement shall be held or declared to be void, invalid or illegal, for any reason, by any court of competent jurisdiction, such provision shall be ineffective but shall not in any way invalidate or affect any other clause, paragraph, section or part of this Agreement.

23. FURTHER ASSURANCES. Each of the parties shall execute such documents and take such other actions as may be reasonably requested by the other party to carry out the provisions and purposes of this Agreement in accordance with its terms.

24. HEADINGS. The headings contained in this Agreement have been inserted for convenience only and shall not affect in any way the meaning or interpretation of this Agreement.

25. PUBLICITY. The Corporation and Executive agree that they will not make any press releases or other announcements prior to or at the time of execution of this Agreement with respect to the terms contemplated hereby, except as required by applicable law, without the prior approval of the other party, which approval will not be unreasonably withheld.

26. ARBITRATION. Any disputes arising under this Agreement shall be submitted to and determined by arbitration in St. Louis, Missouri. Such arbitration shall be conducted in accordance with the rules of the American Arbitration Association. Any award or decision of the arbitration shall be conclusive in the absence of fraud and judgment thereon may be entered in any court having jurisdiction thereof. The costs of such arbitration shall be paid by the non-prevailing party to the extent directed by the arbitrator(s).

THIS AGREEMENT CONTAINS BINDING ARBITRATION PROVISIONS WHICH MAY BE ENFORCED BY THE PARTIES.

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

SHEFFIELD PHARMACEUTICALS, INC.

By:

Loren G. Peterson

Chief Executive Officer

Judy Roeske Bullock

EX-21
6
SUBSIDIARIES OF SHEFFIELD

EXHIBIT 21

SUBSIDIARIES OF SHEFFIELD PHARMACEUTICALS, INC.

1. Ion Pharmaceuticals, Inc., a Delaware corporation.

2. CP Pharmaceuticals, Inc., a Delaware corporation.

EX-23.1
7
CONSENT

Exhibit 23.1

Consent of Independent Auditors

We consent to the incorporation by reference in the Registration Statements (Form S-3 No. 33-95732, Form S-3 No. 333-27753 and Form S-3 No. 333-38327) of Sheffield Pharmaceuticals, Inc. and in the related Prospectuses, in the Registration Statement (Form S-8 No. 33-95262) pertaining to the 1993 Stock Option Plan of Sheffield Pharmaceuticals, Inc., the 1993 Restricted Stock Plan of Sheffield Pharmaceuticals, Inc. and options granted to directors, officers, employees, consultants and advisors of the Company pursuant to other employee benefit plans of Sheffield Pharmaceuticals, Inc. and in the Registration Statement (Form S-8 No. 333-14867) pertaining to the 1993 Stock Option Plan of Sheffield Pharmaceuticals, Inc., the 1996 Directors Stock Option Plan of Sheffield Pharmaceuticals, Inc. and Options granted to directors, officers, employees, consultants and advisors of the Company pursuant to other employee benefit plans of Sheffield Pharmaceuticals, Inc. of our report dated February 13, 1998, except for Note 11 as to which the date is April 15, 1998, with respect to the consolidated financial statements of Sheffield Pharmaceuticals, Inc. and subsidiaries included in this Annual Report (Form 10-K) for the year ended December 31, 1997.

/s/ Ernst & Young LLP
ERNST & YOUNG LLP

Princeton, New Jersey
April 15, 1998

EX-23.2
8
CONSENT

Exhibit 23.2

The Board of Directors
Sheffield Pharmaceuticals, Inc.

We consent to incorporation by reference in the Registration Statements (Form S-3 No. 33-95732, Form S-8 No. 33-95262, Form S-8 No. 333-14867 and Form S-3 No. 333-38327) of Sheffield Pharmaceuticals, Inc. of our report dated February 11, 1994, relating to the consolidated financial statements of Sheffield Medical Technologies Inc. and subsidiary included in the Annual Report (Form 10-K) for the year ended December 31, 1997.

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
KPMG Peat Marwick LLP

Houston, Texas
April 15, 1998

EX-27
9
ARTICLE 5 FDS

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~~THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE CONDENSED FINANCIAL STATEMENTS FOR THE QUARTER ENDED DECEMBER 31, 1997 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH STATEMENTS.~~

~~12-MOS~~

DEC-31-1997
DEC-31-1997
393,608
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520,986
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(9,489,138)
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0
0
(9,489,138)
(0.79)
(0.79)

-----END PRIVACY-ENHANCED MESSAGE-----