-----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, B+arF3+wxwR6iwyDE/ZsY3aoJgJcO3XeofeEFMKWjKNojffTd++/pfsgUnZSnGk2 NlzJiBIPtqLgIxYK2WRLHA== 0000921895-96-000317.txt : 19960809 0000921895-96-000317.hdr.sgml : 19960809 ACCESSION NUMBER: 0000921895-96-000317 CONFORMED SUBMISSION TYPE: 10QSB PUBLIC DOCUMENT COUNT: 3 CONFORMED PERIOD OF REPORT: 19960620 FILED AS OF DATE: 19960808 SROS: AMEX FILER: COMPANY DATA: COMPANY CONFORMED NAME: SHEFFIELD MEDICAL TECHNOLOGIES INC CENTRAL INDEX KEY: 0000894158 STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834] IRS NUMBER: 760372381 STATE OF INCORPORATION: DE FISCAL YEAR END: 1231 FILING VALUES: FORM TYPE: 10QSB SEC ACT: 1934 Act SEC FILE NUMBER: 001-12584 FILM NUMBER: 96606227 BUSINESS ADDRESS: STREET 1: 666 FIFTH AVENUE STREET 2: 13TH FLOOR CITY: NEW YORK STATE: NY ZIP: 10103 BUSINESS PHONE: 2129576600 MAIL ADDRESS: STREET 1: 30 ROCKEFELLER PLAZA STREET 2: SUITE 4515 CITY: NEW YORK STATE: NY ZIP: 10112
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QUARTERLY REPORT

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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FORM 10-QSB

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

For quarter Ended June 30, 1996
Commission File Number 1-12584

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SHEFFIELD MEDICAL TECHNOLOGIES INC.

| DELAWARE | 13-3808303 |
| --- | --- |
| (State or Other Jurisdiction of Incorporation or organization) | (I.R.S. Employer Identification Number) |

| 30 Rockefeller Plaza, Suite 4515 New York, New York (Address of Principal Executive Offices) | 10112 (Zip Code) |
| --- | --- |

Registrant's telephone number, including area code: (212) 957-6600

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

Yes /X/ No / /

The number of shares outstanding of the Issuer's Common Stock is 11,175,397 shares of Common Stock as of June 30, 1996.

Transitional Small Business Disclosure Format:

Yes / / No /X/

SHEFFIELD MEDICAL TECHNOLOGIES INC.
(A DEVELOPMENT STAGE ENTERPRISE)

INDEX



SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED BALANCE SHEET
JUNE 30, 1996
(UNAUDITED)

ASSETS

| | |
|---|---|
| Current Assets: | |
| Cash and cash equivalents | $ 5,158,751 |
| Prepaid expenses and other current assets | 84,367 |
| Total current assets | 5,243,118 |
| Property and Equipment: | |
| Laboratory equipment | 185,852 |
| Office equipment | 85,700 |
| Leasehold improvements | 61,390 |
| | 332,942 |
| Less accumulated depreciation | 126,727 |
| Net property and equipment | 206,215 |
| Other Assets | 234,786 |
| Total assets | $ 5,684,119 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | |
| Current liabilities: | |
| Accounts payable and accrued liabilities | $ 247,669 |
| Sponsored research payable | 415,000 |
| Deferred license fee | 100,000 |
| Capital lease obligation-current portion | 24,422 |
| Total current liabilities | 787,091 |
| Capital lease obligation - non-current portion | 34,991 |
| Stockholders' equity | |
| Preferred stock, $.01 par value. Authorized, 3,000,000 shares; none issued | -- |
| Common stock, $.01 par value. Authorized, 30,000,000 shares; issued and outstanding, 11,175,397 shares | 111,754 |
| Additional paid-in capital | 27,643,656 |
| Deficit accumulated during development stage | (22,893,373) |
| | 4,862,037 |
| Total liabilities and stockholders' equity | $ 5,684,119 |



See accompanying notes to unaudited consolidated financial statements

SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 1996 AND 1995 AND FOR THE PERIOD
FROM OCTOBER 17, 1986 (INCEPTION) TO JUNE 30, 1996
(UNAUDITED)

| | Three months ended June 30, | | Six months ended June 30, | | October 17, 1986 inception) to June 30, |
|---|---|---|---|---|---|
| | 1996 | 1995 | 1996 | 1995 | 1996 |
| Interest Income | $ 52,724 | $ 12,702 | $ 69,239 | $ 13,301 | $ 302,488 |
| Expenses: | | | | | |
| Research and development | 924,439 | 1,045,469 | 2,164,230 | 1,926,968 | 13,845,609 |
| General and administrative | 783,675 | 789,239 | 1,214,223 | 1,335,493 | 9,277,711 |
| Interest | 2,567 | 60,057 | 4,396 | 62,871 | 115,328 |
| Loss before extraordinary item | 1,657,957 | 1,882,063 | 3,313,610 | 3,312,031 | 22,936,160 |
| Extraordinary item | -- | -- | -- | -- | 42,787 |
| Net Loss | $ 1,657,957 | $ 1,882,063 | $ 3,313,610 | $ 3,312,031 | $22,893,373 |
| Loss per share of common stock: | | | | | |
| Loss before extraordinary item | $ 0.15 | $ 0.25 | $ 0.32 | $ 0.46 | $ 5.90 |
| Extraordinary item | -- | -- | -- | -- | 0.01 |
| Net Loss | $ 0.15 | $ 0.25 | $ 0.32 | $ 0.46 | $ 5.89 |
| Weighted average common shares outstanding | 10,873,102 | 7,646,747 | 10,264,818 | 7,223,721 | 3,890,116 |



SHEFFIELD MEDICAL TECHNOLOGIES INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 1996 AND 1995 AND FOR THE PERIOD
FROM OCTOBER 17, 1986 (INCEPTION) TO JUNE 30, 1996
(UNAUDITED)

| | Three months ended June 30 | | Six months ended June 30 | | October 17, 1986 (inception) to June 30 |
|---|---|---|---|---|---|
| | 1996 | 1995 | 1996 | 1995 | 1996 |

| | | | | | |
|---|---|---|---|---|---|
| Cash outflows from development stage activities and extraordinary gain: | | | | | |
| Loss before extraordinary item | $ (1,657,957) | $ (1,882,063) | $ (3,313,610) | $ (3,312,031) | $(22,936,160) |
| Extraordinary gain on extinguishment of debt | -- | -- | -- | -- | 42,787 |
| Net loss | (1,657,957) | (1,882,063) | (3,313,610) | (3,312,031) | (22,893,373) |
| Adjustments to reconcile net loss to net cash used by development stage activities: | | | | | |
| Issuance of common stock, stock options/warrants for services | -- | 266,407 | -- | 266,407 | 900,241 |
| Non-cash interest expense | -- | 50,000 | -- | 50,000 | 50,000 |
| Issuance of common stock for license | -- | -- | -- | -- | 5,216 |
| Issuance of common stock for intellectual property rights | -- | -- | -- | -- | 866,250 |
| Amortization of organizational and debt issuance costs | -- | -- | -- | -- | 77,834 |
| Depreciation | 17,835 | 12,023 | 36,372 | 24,045 | 126,727 |
| Increase in debt issuance and organizational costs | -- | -- | -- | -- | (77,834) |
| Decr.(incr.) in prepaid expenses and other current assets | (22,266) | (36,958) | 69,418 | (71,125) | (143,408) |
| (Incr.) decr. in other assets | (33,696) | -- | (150,416) | 49,941 | (175,745) |
| (Incr.) decr. in accounts payable and accrued liabilities | 72,960 | -- | 46,384 | -- | (329,401) |
| Incr. (decr.) in sponsored research payable | 170,061 | (542,368) | 187,598 | (367,111) | 992,070 |
| Increase in deferred license fee | 100,000 | -- | 100,000 | -- | 100,000 |
| Net cash used by development stage activities | (1,353,063) | (2,132,959) | (3,024,254) | (3,359,874) | (20,501,423) |
| Cash flows from investing activities: | | | | | |
| Acquisition of laboratory and office equipment | (3,502) | -- | (47,816) | (8,543) | (260,489) |
| Net cash used by investing activities | (3,502) | -- | (47,816) | (8,543) | (260,489) |
| Cash flows from financing activities: | | | | | |
| Principal payments under capital lease | (7,549) | -- | (13,040) | -- | (13,040) |
| Conversion of convertible, subordinated notes | -- | -- | -- | -- | 749,976 |
| Proceeds from issuance of debt | -- | -- | -- | 550,000 | 550,000 |
| Proceeds from issuance of common stock | -- | (377,284) | -- | 2,915,395 | 13,268,035 |
| Proceeds from exercise of stock options | -- | -- | 137,175 | -- | 1,003,302 |
| Proceeds from exercise of warrants | 4,480,106 | -- | 6,246,109 | -- | 10,361,306 |
| Net cash provided (used) by financing activities | 4,472,557 | (377,284) | 6,370,244 | 3,465,395 | 25,919,579 |
| Net increase (decrease) in cash and cash equivalents | 3,115,992 | (2,510,243) | 3,298,174 | 96,978 | 5,157,667 |
| Cash and cash equivalents at beginning of period | 2,042,759 | 2,687,351 | 1,860,577 | 80,130 | 1,084 |
| Cash and cash equivalents at end of period | $ 5,158,751 | $ 177,108 | $ 5,158,751 | $ 177,108 | $ 5,158,751 |
| Noncash investing and financing activities: | | | | | |
| Common stock, stock options and warrants issued for services | $ -- | $ 266,407 | $ -- | $ 266,407 | $ 900,241 |
| Common stock issued for license | -- | -- | -- | -- | 5,216 |
| Common stock issued for intellectual property rights | | | | | 866,250 |

| | | | | | |
|---|---|---|---|---|---|
| Common stock issued for intellectual property rights | -- | -- | -- | -- | 866,250 |
| Common stock issued to retire debt | -- | 600,000 | -- | 600,000 | 600,000 |
| Equipment acquired under capital lease | -- | -- | 72,453 | -- | 72,453 |
| Notes payable converted to common stock | -- | -- | -- | -- | 749,976 |

Supplemental disclosure of cash flow information:

| | | | | | |
|---|---|---|---|---|---|
| Interest paid | $ 2,567 | $ 60,057 | $ 4,396 | $ 62,871 | $ 115,328 |



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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 1996
(UNAUDITED)

1. CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated balance sheet as of June 30, 1996 and the accompanying consolidated statements of operations and cash flows for the three and six months ended June 30, 1996 and 1995 and for the period from October 17, 1986 (inception) to June 30, 1996 have been prepared by Sheffield Medical Technologies Inc. (the "Company"), without audit. In the opinion of management, all adjustments (consisting only of normal recurring accruals) necessary to present fairly the financial position, results of operations, and changes in cash flows at June 30, 1996, and for all periods presented have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. It is suggested that these consolidated financial statements be read in conjunction with the financial statements and notes thereto included in the Company's annual report on Form 10-KSB for the year ended December 31, 1995. The results of operations for the three and six months ended June 30, 1996 and 1995 are not necessarily indicative of the operating results for the full years.

Sheffield Medical Technologies Inc. ("Sheffield") was incorporated on October 17, 1986, under the Canada Business Corporations Act. The Company's wholly-owned subsidiary, U-Tech Medical Corporation ("U-Tech") was incorporated in the state of Texas on January 13, 1992. The Company commenced its biotechnology operations in the United States in January 1992 under new management and Sheffield became domesticated as a Wyoming corporation in May 1992. At the Annual Meeting of shareholders of the Company held on January 26, 1995, the Company's shareholders approved the proposal to reincorporate the Company in Delaware, which was effected on June

13, 1995. On January 10, 1996, Ion Pharmaceuticals, Inc., a Delaware corporation ("Ion"), was formed as a wholly-owned subsidiary of the Company. At that time, Ion acquired the Company's rights with respect to the anti-proliferative technology. Unless the context requires otherwise, Sheffield, U-Tech and Ion are referred to collectively as "the Company". All significant intercompany transactions are eliminated in consolidation.

The Company is in the development stage and as such has been principally engaged in licensing and research efforts. The Company has not generated any operating revenue and requires additional capital, which it intends to obtain through equity and debt offerings to continue to operate its business. The likelihood of the success of the Company must be considered in light of the expenses, difficulties and delays frequently encountered in emerging technology-related businesses, particularly since the Company will focus on research, development and unproven technologies which may require a lengthy period of time and substantial expenditures to complete. Even if the Company is able to successfully develop new products or technologies, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products and technologies to be profitable.





2. 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 six months ended June 30, 1996 | 1,613,751 |
| Balance outstanding at June 30, 1996 | 11,175,397 |

On March 15, 1996, the Company offered holders of warrants issued in private placements completed in 1995 the opportunity to exercise such warrants at up to a 12 1/2 % discount from the actual exercise prices of such warrants. This warrant discount offer expired on April 30, 1996. A total of $5,567,781 was received from the exercise of 1,373,250 of the Company's stock purchase warrants

under the warrant discount program. In addition to proceeds received from the warrant discount program, $755,428 was received from the exercise of 240,501 of the Company's stock purchase warrants and options during the six months ended June 30, 1996.

At the Annual Meeting of shareholders of the Company held on June 20, 1996, the Company's shareholders approved the proposal to increase the number of authorized shares of Common Stock from 20,000,000 shares to 30,000,000 shares.

3. STATUS OF RESEARCH AND DEVELOPMENT ACTIVITIES

RBC-CD4 ELECTROINSERTION TECHNOLOGY

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

TECHNOLOGY. A number of AIDS research projects have studied CD4, which is a glycoprotein found on the surface of T4 lymphocytes. T4 lymphocytes are helper cells that mediate antigen presentation of the immune system. CD4 attaches to a glycoprotein on the surface of HIV known as gp120. HIV binds the CD4 glycoprotein, which enables it to enter the T4 cells, where it can replicate. By this process, HIV





attacks T4 cells and, as a result, debilitates the immune system by rendering the immune system incapable of neutralizing HIV. Eventually, the number of T4 cells decrease and the level of HIV in the blood increases. This typically leads to the development of AIDS which is characterized by the ultimate collapse of the immune system. Once the immune system is destroyed, other germs and viruses that ordinarily would be successfully neutralized by the immune system lead to opportunistic diseases. These opportunistic diseases are ultimately the cause of death in AIDS patients.

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

The use of CD4 as a potential treatment for AIDS is not new. Previous research by many others focused on the soluble form of CD4. This technique

has proved ineffective because: (i) the half-life of soluble CD4 or hybrid molecules such as CD4-IgG is short in blood circulation; (ii) the binding of soluble CD4 to HIV appears to tear some of the viral envelope glycoprotein without reducing infectivity; and (iii) the amounts of soluble CD4 needed to establish therapeutic concentrations are very large.

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

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





soluble CD4, including: (i) RBC-CD4 has shown no immune response in

animals or humans; (ii) RBC-CD4 remains in the body for almost the normal half life span of a RBC, which is 60 days; and (iii) RBC-CD4 has shown a significantly improved binding affinity and indicates the capacity to inhibit HIV infection of susceptible cells.

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

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

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

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

RECENT DEVELOPMENTS. The first patient under the Phase I/IIA Clinical

Trials was dosed on August 8, 1995, the first patient to be dosed with the middle dose of RBC-CD4 was dosed on November 16, 1995, and the first patient to be dosed at the highest dose of RBC-CD4 was dosed on January 29, 1996. No significant adverse events have been reported to date, and the last portion of the trial with patients receiving the highest dose of RBC-CD4 is ongoing. The Company is currently participating in discussions with certain third parties regarding the possibility of partnering or licensing this technology.



LIPOSOME-CD4 TECHNOLOGY

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

TECHNOLOGY. CD4 is a glycoprotein found on the surface of T4 lymphocytes, which are helper cells that mediate antigen presentation of the immune system. CD4 also acts as the receptor for a glycoprotein on the surface of the human immunodeficiency virus (HIV) known as gp120. HIV binds to the CD4 glycoprotein which enables the virus to enter the T4 cells where it can replicate. By this process, HIV attacks T4 cells and debilitates the immune system, which typically leads to the development of AIDS. Once the immune system is destroyed, other germs and viruses that would ordinarily be successfully neutralized by the immune system lead to opportunistic diseases, which ultimately cause death to AIDS patients.

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

The strategy of Liposome-CD4 is to incorporate CD4 in the bilayer of the liposomes, providing a specific target (I.E., HIV and HIV-infected cells)

for liposome fusion. The Liposome-CD4 may also be loaded with cytotoxic agents, or agents that will kill the target cell. When the free-floating HIV comes in contact with Liposome-CD4, the virus fuses with Liposome-CD4 and is inactivated. The remains of the killed infected T4 cell and inactivated virus fused with Liposome-CD4 would then be removed by macrophages (white blood cells). The therapeutic aim, as with RBC-CD4, is to reduce HIV infectivity and slow or eliminate the advancement of HIV infection to AIDS.

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

RECENT DEVELOPMENTS. On July 18, 1996, the Company entered into a Sublicense Agreement with SEQUUS Pharmaceuticals, Inc. for the continued development and commercialization of the Liposome-CD4 Technology.





HIV/AIDS VACCINE

BACKGROUND. The Company holds an option to acquire an exclusive worldwide license to a potential HIV/AIDS vaccine (the "HIV/AIDS Vaccine") under development at the French National 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 utilizes a portion of b2 microglobulin (the epitope), a cellular antigen, that is presented on the HIV viral coating after the HIV virus has reproduced in a human cell. This cellular antigen does not appear to vary across the various strains of the virus and may provide a stable target to develop antibodies that can prevent infection. The Company believes this approach may also protect against both blood-born and sexual transmission of HIV. The Company's goal is to develop an oral formulation that would make the vaccine potentially less costly and easier to distribute to a broad population.

TECHNOLOGY. When the HIV virus infects a cell, it replicates and then it buds from the infected cell's surface. A protein which is present on the cell's surface then becomes incorporated in HIV's viral envelope as it leaves the infected cell. The classical path of vaccine development to date has been one of raising antibodies against a viral protein in an attempt to neutralize the pathogen. All these attempts have been largely unsuccessful. The HIV/AIDS Vaccine encompasses a new and different approach directed toward immunization against HIV/AIDS. The HIV/Vaccine is designed to be different than previous attempts for two basic reasons: (i) it would use a cellular versus a viral antigenic approach and is

therefore, common to all strains of HIV, and (ii) it would utilize a delivery system that would offer both humoral (blood transmission) and mucosal (sexual transmission) protection, as opposed to other vaccines now being investigated as therapeutics for preventing cell to cell transmission of the virus.

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

RECENT DEVELOPMENTS. The Company is in the final stage of development of the assay and expects to commence large-scale testing in the near future. In April, 1996, researchers published data on the isolation and characterization of the novel binding site of the cellular protein and reported that antibodies to this binding site inhibited replication of several strains of HIV in IN VITRO studies.





UGIF TECHNOLOGY - PROSTATE CANCER

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

TECHNOLOGY. Based on studies at Baylor College of Medicine directed at understanding how one particular tissue type influences the growth of an adjacent tissue in the development of the prostate gland, UGIF/ps20 was identified. Specifically, UGIF/ps20 has been isolated and purified from rat fetal urogenital sinus tissue which differentiates into the mature prostate gland as a result of tissue-tissue interactions. Since UGIF/ps20

was demonstrated to be active in human cells, it was believed that UGIF/ps20 isolated from the rat would be essentially identical to human UGIF/ps20. Commercial application and economic feasibility of UGIF/ps20 is not dependent upon the availability of either rat or human fetal urogenital sinus tissue, but rather the successful cloning, expression and testing of recombinant UGIF/ps20.

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

Dr. David R. Rowley is the principal investigator for the UGIF Technology project. Dr. Rowley is an Associate Professor in the Department of Cell Biology at the Baylor College of Medicine.

PROGRESS OF RESEARCH AND DEVELOPMENT. A method for successfully purifying UGIF/ps20 was identified in April 1992 by Dr. David R. Rowley and biological activity of the factor was demonstrated in mice in May 1992. Research to date has shown that UGIF/ps20 inhibits the growth of transformed cells and tumors in culture including human prostate cancer cells with non-toxic and reversible effects. In addition, in preliminary animal studies, UGIF/ps20 has shown an ability to inhibit DNA synthesis and cell proliferation of human prostatic carcinoma cells. Results confirmed that there is a human form of UGIF/ps20 and that it is a growth factor associated with the prostate gland. The rat and human genes for UGIF/ps20 were sequenced in late 1995.

RECENT DEVELOPMENTS. The Company recently exercised its option to acquire an exclusive worldwide license to the UGIF/ps20 technology. The rat gene for UGIF/ps20 has been incorporated into an expression system and recombinant rat UGIF/ps20 is currently being produced. The human gene for UGIF/ps20 has been incorporated into an expression system and recombinant human UGIF/ps20 is currently being produced. Once sufficient quantifies of recombinant UGIF/ps20 are produced and purified, the activity of the UGIF/ps20 protein will be tested for verification in IN VITRO and IN VIVO studies. It is anticipated that additional animal studies will be conducted to determine the modes of delivery and biological effects of recombinant UGIF/ps20 on prostate cancer in "nude" mice. In the event that recombinant UGIF/ps20 is verified in these studies, additional preclinical studies with a delivery system, and toxicity tests, will be conducted prior to commencement of human clinical trials.

ION PHARMACEUTICALS, INC. TECHNOLOGIES

BACKGROUND. The Company, through its wholly-owned subsidiary, Ion Pharmaceuticals, Inc. ("Ion"), holds exclusive worldwide license rights to certain compounds and their uses for the treatment of conditions characterized by abnormal cell proliferation and holds exclusive options to license certain compounds and their uses for the treatment of sickle cell anemia and gastrointestinal disorders, such as secretory diarrhea. Ion's intellectual property portfolio consists of parent compounds, their analogues and metabolites, and a number of proprietary new chemical entities termed the TrifensTM. Such compounds have demonstrated promise in therapeutic applications for treating a number of conditions characterized by abnormal cell proliferation, such as cancer and certain proliferative dermatological conditions, as well as sickle cell anemia and secretory diarrhea. Ion has an ongoing collaborative program with an unaffiliated company to develop the Trifens.TM

TECHNOLOGY. The parent compounds and the TrifensTM are active through ion transport modulation and may be applicable for treating, either by topical, oral, or intravenous administration, a number of diseases and conditions. Through research conducted by Dr. Jose Halperin at Harvard Medical School, new potential uses for the parent compounds and the TrifensTM have been identified based on inhibition of cell proliferation, including the use of such compounds in treating cancer, proliferative dermatological conditions, cardiovascular disorders, such as arteriosclerotic conditions, and diseases caused by neovascularization, such as diabetic retinopathy. In addition to the compounds' ability to inhibit cell proliferation, the parent compounds and the TrifensTM have also been shown to inhibit the Ca++-activated K+ channel in the human red blood cell membrane. Dr. Carlo Brugnara at Children's Hospital in Boston has studied and is continuing to study the effects of such compounds in blocking this channel, one of the erythrocyte's principal dehydration pathways, to prevent the sickling tendency of erythrocytes. Such an approach could potentially be used in the treatment of sickle cell anemia. In addition, Dr. Wayne Lencer at Children's Hospital in Boston is studying the effects of the TrifensTM in inhibiting intestinal chloride secretion, which is the primary transport event of secretory diarrhea in both humans and animals.

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

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

clinical trials for actinic keratosis and Kaposi's sarcoma.

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





For the sickle cell application, IN VITRO studies performed by Dr. Brugnara have demonstrated that one of the parent compounds blocked ion transport in homozygous sickle cells, and studies in a transgenic mouse model for sickle cells have demonstrated that the compound given orally produced inhibition of the red cell Gardos channel, increased red cell potassium content, and decreased mean corpuscular hemoglobin concentration. A pilot Phase I clinical trial has been completed in which four normal subjects were given the compound orally and the peak inhibition of the Gardos channel was measured.

RECENT DEVELOPMENTS. Ion entered into a sponsored research and license option agreement with Children's Hospital in Boston which grants Ion an option to license the use of the parent compounds, their metabolites and analogues, and the TrifensTM in treating gastrointestinal disorders.

A topical formulation of one of the parent compounds has been developed for Ion pursuant to an agreement with an unaffiliated company. Clinical trial material has been manufactured under GMP conditions for use in Ion's Phase I/II Clinical Trial for the treatment of actinic keratosis. The Phase I/II Clinical Trial is currently underway at two clinical sites in Israel. Upon successful results of this study, Ion plans to file an IND application with the FDA for conducting a clinical trial in the U.S. for the treatment of actinic keratosis.

Additional IN VITRO and animal tumor model studies are underway, some of which will be conducted under contract with an unaffiliated third party, to test the effects of the TrifensTM in the treatment of certain cancers.

Results from the first stage of a Phase II Clinical Trial supported by the National Institutes of Health and the FDA were reported in March in which five sickle cell anemia patients were given one of the parent compounds orally. The administration of the compound resulted in a reduction of the dehydration and sickling of red blood cells associated with sickle cell anemia. The next phase of the ongoing Phase II Clinical Trial will assess the survival of red blood cells and hemoglobin levels over a longer-term period. Ion plans to initiate additional laboratory and clinical studies to further assess the use of the TrifensTM in the treatment of sickle cell anemia.

4. SUBSEQUENT EVENT

On July 17, 1996, SEQUUS Pharmaceuticals, Inc. exercised its option to license the Company's liposome-CD4 technology as a potential HIV/AIDS

therapeutic. Terms include a signing fee, payable to the Company in SEQUUS common stock, milestone payments and royalties on product sales. In addition, SEQUUS will continue funding of certain liposome CD4-related laboratory work under the direction of Dr. Y. Claude Nicolau, Director of CBRL.





Item 2:

MANAGEMENT'S DISCUSSION AND ANALYSIS
OR PLAN OF OPERATION

PLAN OF OPERATIONS

The Company, being a development enterprise, has incurred a net loss in each of the fiscal years since its inception and has had to rely on outside sources of funds to maintain its liquidity. Substantial operating losses are expected to be incurred for the next several years as the Company expends its resources for product acquisition, sponsored research and development and preclinical and clinical testing.

As a development stage company without revenues, the Company has financed its technology development activities and operations primarily through public and private offerings of securities. In connection with this, the Company completed two private offerings in 1995, raising total gross proceeds of $8.8 million. On March 15, 1996, the Company offered holders of warrants issued in private placements completed in 1995 the opportunity to exercise such warrants at up to a 12 1/2% discount from the actual exercise prices of such warrants. As of the close of business on April 30, 1996, the expiration date of the warrant discount program, a total of $5.6 million was received. Management estimates that based on its current cash position, its plans to seek additional funds through planned offerings, and the continued focus on selling, licensing and commercialization of its technologies, the Company will have sufficient resources to fund its activities for at least the next twelve months. There can be no assurance that planned offerings will be completed or, if not completed as planned, that other sources of capital can be obtained in amounts and upon terms acceptable to the Company during the twelve month plan period. In the event that such funds are not available when needed, the Company would be required to reduce or delay its funding of current research projects and delay making commitments for future research projects. The Company's operating results have fluctuated significantly during each quarter since its reorganization, and the Company anticipates that such fluctuations, largely attributable to varying sponsored research and development commitments and expenditures, will continue into the foreseeable future.

The Company continues to conduct scientific research, clinical trials, development, and intellectual property protection. During the three months ended June 30, 1996, the Company paid $0.9 million for research and development on its projects. During the succeeding 12-month period, approximately $4.0 million in additional funding is projected to be spent on clinical and laboratory research and development.

Of the $4.0 million estimated to be spent on clinical and laboratory research and development during the next 12 months, approximately $100,000 is expected to

be applied to RBC-CD4 Technology, $800,000 to the HIV/AIDS project, $200,000 to the UGIF Technology, and $2,900,000 to the Ion Technologies.

In addition to clinical and laboratory research development, the Company expects to incur ongoing costs in connection with its intellectual property protection and patent prosecution, which costs are expected to approximate $100,000 over the next 12 months.





REVENUES AND EXPENSES

Interest Income:

From inception through the period ended June 30, 1996, the Company has earned interest income of $302,488 and an extraordinary item from gain on early extinguishment of debt of $42,787. The Company's ability to generate material revenues is contingent on the successful commercialization of the RBC-CD4 Electroinsertion Technology, the Liposome-CD4 Technology, the HIV/AIDS Vaccine, UGIF Technology, Ion Technologies and other technologies which it may acquire, followed by the successful marketing and commercialization of such technologies through licenses, joint ventures or other arrangements.

Income for the three months ended June 30, 1996 was $52,724 compared to $12,702 for the same period ended June 30, 1995. The increase in interest earned is attributable to a higher amount of cash invested. In each period interest income represented all of the Company's income.

Operating Expenses:

From inception through the period ended June 30, 1996, the Company incurred $23,238,648 of operating expenses. Sixty percent (60%) or $13,845,609 of the total operating expenses for that period were costs of research and development for the Company's technologies. The remainder of expenses for the same period were incurred principally as consulting costs, costs of management, legal and other professional support for the Company's technologies, and for its completed and proposed financing plans. Research and development costs will remain high as the Company implements later-stage research projects of its technologies and such costs will continue to be expensed for financial reporting purposes.

Operating expenses for the three months ended June 30, 1996, were $1,710,681 compared to $1,894,765 for the same period ended June 30,1995. The decrease was due to lower research and development expenditures ($121,030), a reduction in interest expense ($57,490) and lower general and administrative expenses ($5,564). The lower research and development costs were attributable to last years high costs of CD4 production for the Company's RBC-CD4 and Liposome-CD4 projects.

LIQUIDITY AND CAPITAL RESOURCES

In February 1993, the Company conducted its initial United States public offering of 833,334 Units, each 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, subject to adjustment in certain

circumstances, at any time until February 10, 1998 (the "public offering"). The net proceeds of the public offering to the Company, after payment of Underwriter's discounts and commissions, non-accountable expenses and reimbursable expenses, and other expenses of the offering, were approximately $4,190,000. Also, during fiscal year 1993, the Company received $762,833 in total proceeds from the exercise of warrants. 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. Each warrant was exercisable for one share of Sheffield's Common Stock at an exercise price of $3.75.

In April 1995, the Company completed a private placement of 410,075 units to accredited investors at a price of $8.00 per unit for gross proceeds of $3,280,600. Each unit consists 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 to and including February 10, 2000. The warrants are redeemable by the Company under certain circumstances. Proceeds are being used for funding research and development for projects and licensing arrangements, patent prosecution and working capital and general corporate purposes.





In July 1995, the Company completed a second private placement of 1,375,000 units at $4.00 per unit, which grossed $5,500,000. Each unit consists of one share of the Company's common stock and one warrant to purchase one share of common stock at a price of $4.50 at any time from March 1, 1996 to and including February 10, 2000. The warrants are subject to redemption under certain conditions.

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 12 1/2% discount from the actual exercise prices of such warrants. At the expiration of the discount program, on April 30, 1996, a total of $5.6 million was received from the exercise of such warrants and the related issuance of 1,373,250 shares of common stock.

In addition to the potential commercialization of its technologies, the Company plans to seek additional funds through exercise of outstanding warrants and options, financings and/or public grants, joint ventures or other commercial arrangements to obtain necessary working capital. It is not uncommon, for instance, for a third-party commercial partner to enter into a license agreement with a development company, on the merits of successful research relating to a given technology, which would yield up-front royalty advances to such company before market-ready products are developed. It is also not uncommon for a third-party commercial partner to enter into an agreement with a development company whereby a third party will contribute funds in support of the research and operating needs of such development companies in consideration for rights related to the technologies.

At June 30, 1996, the Company's assets were $5.7 million of which $5.2 million was cash and cash equivalents.

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

PART II: OTHER INFORMATION

Item 4. Submission of Matters to a Vote of Security-Holders

An annual Meeting of Stockholders was held on June 20, 1996. All of management's nominees for Director, as listed in the Proxy Statement for the Annual Meeting, were elected. Listed below are the matters voted on by stockholders and the number of votes cast at the Annual Meeting:

(a) Election of five members of the Board of Directors.

| Name | Voted For | Voted Against | Votes Withheld and Abstentions | Broker Non-Votes |
|---|---|---|---|---|
| Douglas R. Eger | 8,161,784 | 0 | 198,075 | 0 |
| Michael Zeldin | 8,161,684 | 0 | 198,175 | 0 |
| Anthony B. Alphin, Jr. | 8,161,684 | 0 | 198,175 | 0 |
| Dr. Stephen Sohn | 8,161,784 | 0 | 198,075 | 0 |
| Bernard Laurent | 8,161,684 | 0 | 198,175 | 0 |

(b) Ratification of the appointment of Ernst & Young LLP as independent auditors of the Company for the Fiscal Year ending December 31, 1996.

| | |
|---|---|
| Voted For: | 8,179,141 |
| Voted Against: | 128,043 |
| Voted Abstained: | 52,675 |
| Broker Non-Votes | 0 |

(c) Approval of the 1996 Directors Stock Option Plan.

| | |
|---|---|
| Voted For: | 2,353,304 |
| Voted Against: | 298,503 |
| Voted Abstained: | 112,225 |
| Broker Non-Votes | 5,595,827 |

(d) Approval of the Amendment of the Company's 1993 Stock Option Plan.

| | |
|---|---|
| Voted For: | 2,256,341 |
| Voted Against: | 469,816 |
| Voted Abstained: | 148,525 |
| Broker Non-Votes | 5,485,177 |

(e) Approval of the Amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of the Company's Common Stock from 20,000,000 shares to 30,000,000 shares.

| | |
|---|---|
| Voted For: | 7,905,311 |
| Voted Against: | 403,448 |
| Voted Abstained: | 51,100 |
| Broker Non-Votes | 0 |





Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits:

Employment Agreement dated as of June 6, 1996 between the Company and Thomas M. Fitzgerald.

(b) Reports on Form 8-K:

No reports on Form 8-K were filed by the Company during the quarter ended June 30, 1996.





In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SHEFFIELD MEDICAL TECHNOLOGIES INC.

Dated: August 7, 1996 /s/ Douglas R. Eger
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Douglas R. Eger
Chairman & Chief Executive Officer

/s/ George Lombardi
Dated: August 7, 1996 ---
George Lombardi
Vice President & Chief Financial Officer
(Principal Financial and Accounting Officer)

EX-99
2
EMPLOYMENT AGREEMENT

Exhibit to FORM 10-QSB

EMPLOYMENT AGREEMENT

AGREEMENT made as of the 6th day of June, 1996, by and between Sheffield Medical Technologies Inc., a Delaware corporation with its principal offices at 30 Rockefeller Plaza, Suite 4515, New York, New York 10112 (the "Corporation"), and Thomas M. Fitzgerald residing at 4 St. Andrews Hill, Pittsford, New York 14534
("Executive").

W I T N E S S E T H :

WHEREAS, the Corporation desires to employ and retain the Executive as its Chief Operating Officer, 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. Effective as of June 17, 1996 the Corporation hereby employs Executive as its Chief Operating Officer, 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 his employment hereunder, except as hereinafter provided, he will devote his full business and professional time in utilizing his business and professional expertise, with proper attention, knowledge and skills faithfully, diligently and to the best of his ability in furtherance of the business of the Corporation and its subsidiaries and will perform the duties assigned to him pursuant to Paragraph 1 hereof. As Chief Operating Officer, 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 his 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 do not materially interfere with his duties hereunder during vacations,

holidays and other periods outside of business hours or (ii) working on projects and receiving compensation which arise from Permitted Projects (as hereinafter defined), but only to the extent that such work does not interfere with Executive's duties hereunder. As used herein, "Permitted Projects" shall mean (a) the completion of existing projects by Executive on behalf of RhonePoulenc-Rorer Corp. ("RPR") and Fisons Corporation ("Fisons") relating to (i) the sale of RPR's pharmaceutical business (formerly owned by Fisons) location in Rochester, New York (ii) the termination of Fisons' ophthalmic products joint venture with Allergan and (iii) the sale of Fison's aerosol manufacturing business located in Massachusetts and (b) such other projects as may be agreed to in advance in writing between Executive and the Corporation.

(c) It is anticipated that the Corporation's principal executive office shall remain in New York City, but that Executive shall be required to spend substantial amounts of time at locations in and outside of New York City relating to the business of the Corporation and its subsidiaries. It is understood that Executive shall continue to reside in the vicinity of Rochester, New York until Executive is relocated to the Corporation's executive offices in New York City, New York as described below. The Corporation agrees to reimburse Executive for his reasonable expenses, including hotel and travel costs, associated with his business travel outside Rochester, New York until completion of such relocation. It is understood that the Executive may, to the extent practicable, perform his duties and fulfill his obligations hereunder from his office in Rochester, New York until completion of his relocation to New York City as described below. It is understood that the Corporation will lease an office to be utilized by Executive at a monthly rent of up to $1,000 per month in Rochester, New York until the earlier to occur of Executive's relocation to New York City as described below or the termination of Executive's employment hereunder. The location of such office (the "Rochester Office") shall be mutually acceptable to Executive and the Corporation. In addition, until completion of such relocation, it is understood that Executive shall visit the Corporation's executive office in New York City on a regular basis for meetings and to conduct Corporation business that is more appropriately conducted from such executive office. Upon 60 days notice to Executive, Executive shall relocate his principal residence to the New York City metropolitan area. Upon completion of such relocation, Executive shall be headquartered in the Company's executive offices located in the New York City metropolitan area and shall continue to fulfill his obligations under this Agreement from such offices rather than from the Rochester Office. In no event shall the Company deliver such notice of relocation prior to April 1, 1997. The Company shall reimburse Executive for all appropriately documented and reasonable out-of-pocket expenses associated with moving his possessions in connection with such relocation.

(d) The Corporation shall reimburse Executive for all appropriately documented operating expenses (i.e., telephone, fax, personal computer, copier, etc.) incurred by Executive on behalf of



the Corporation after the date of this Agreement as may be necessary for the efficient operation of the Rochester, New York office referred to in subparagraph (c) of this Paragraph 2; PROVIDED, HOWEVER, that Executive will not incur any such individual expense in excess of $1,000 without the prior written

approval of the Chairman, Chief Executive Officer or Chief Financial Officer of the Corporation.

(e) It is understood the Corporation will pay an annual salary of up to $40,000 for an administrative assistant to Executive during the term of Executive's employment under this Agreement. Such administrative assistant shall be an employee of the Corporation selected by Executive and approved by the Corporation.

3. TERM. Except as otherwise provided herein, the term of Executive's employment hereunder shall commence on June 17, 1996 and shall continue to and including June 16, 1999. 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 six months before the end of the then current term (including the initial term) of its or his desire to terminate this Agreement. The last day of the term of this Agreement pursuant to this Paragraph 3 is referred to herein as the "Termination Date."

4. COMPENSATION. (a) As compensation for his services hereunder, the Corporation shall pay to Executive (i) a base annual salary at the rate of $175,000, 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). The Corporation agrees to consider the appropriateness of granting Executive a bonus at such time as any other executive officer of the Corporation is being considered for a bonus. All compensation paid to Executive shall be subject to withholding and other employment taxes imposed by applicable law.

(b) As additional compensation for his 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 150,000 shares of the Corporation's common stock, with the terms of such option to be evidenced by an option letter agreement to be delivered on or before June 21, 1996 by the Corporation to Executive in the form annexed as Exhibit "A" hereto. In the event that there are not sufficient shares of the Corporation's common stock available for such grant under the Plan at such date, the Corporation shall issue Executive an option letter in its customary form on such date providing Executive with a comparable stock option grant that is issued independent of the Plan.



(c) 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 he is elected or appointed.

(d) In the event that Executive is elected to the Corporation's Board of Directors, Executive will receive compensation and benefits as a director of the Corporation consistent with the compensation and benefits received by the Corporation's other directors who are also employees of the

Corporation.

5. ADDITIONAL BENEFITS; VACATION. (a) In addition to such base salary, Executive shall receive and be entitled to participate, to the extent he 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 entitled to four (4) weeks' paid vacation in respect of each 12-month period during the term of his employment hereunder, such vacation to be taken at times mutually agreeable to Executive and the Board of Directors of the Corporation. Vacation time shall not be cumulative from one 12- month period to the next, but Executive shall receive vacation pay at the then current salary rate for any vacation time not taken by him.

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

6. REIMBURSEMENT OF EXPENSES. The Corporation shall reimburse Executive in accordance with applicable policies of the Corporation for all expenses reasonably incurred by him in connection with the performance of his duties hereunder and the business of the Corporation, upon the submission to the Corporation of appropriate receipts or vouchers.

7. RESTRICTIVE COVENANT. (a) In consideration of the Corporation's entering into this Agreement, Executive agrees that during the period of his 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 12 hereof), (ii) by the Corporation for Cause (as that term is defined in Paragraph 13 hereof) or (iii) by Executive otherwise than for Employer Breach (as that term is defined in Paragraph 14 hereof), for a further period of six months thereafter, he 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 himself 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 his 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 involved in the research, development, manufacturing or commercialization in any way of any technology, product, compound, device or method that acts or functions by, through or on the same active, binding or receptor site, mechanism of action, signaling pathway or channel as any technology, 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 his 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 7 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 7, 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.

8. 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 he shall not, at any time during his 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 8(a) hereof shall not apply to any information which:



(i) becomes rightfully known to Executive subsequent or prior to his 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 his 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 his 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.

9. 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 his 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 his 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. The provisions of this Paragraph 9 shall not apply to any idea, invention, design, written material, manual, system, procedure, improvement, development or discovery conceived, developed, created or made by Executive exclusively from his work on Permitted Projects.

10. 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 his obligations under Paragraphs 7, 8 or 9 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 7, 8 or 9 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.

11. 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 12 hereof); (ii) Executive's death; (iii) termination of Executive's employment by the Corporation for Cause or pursuant to subparagraph (b) of this Paragraph 11; (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 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 of $87,500 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, the Corporation shall have no further obligation to the Executive under this Agreement other than the Corporation's obligation to make such severance payment to the Executive and to maintain Executive's hospitalization and medical service insurance coverage provided by the Corporation until the payment in full of such severance payments.

(c) Paragraphs 6, 7, 8 and 9 of this Agreement shall survive the termination of Executive's employment hereunder, except in the case of termination pursuant to Paragraph 14.

12. DISABILITY. In the event that during the term of his employment by the Corporation Executive shall become Disabled (as that term is hereinafter defined) he shall continue to receive the full amount of the base salary to which he was theretofore entitled for a period of six months after he 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 his 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 his base salary until he shall cease to be Disabled and shall have resumed his 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 12. 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 his duties hereunder for a period of 90 consecutive days or for 120 days in any consecutive 180-day period or (y) when Executive's physician or a physician designated by the Corporation shall have determined that Executive shall not be able, by reason of physical or mental incapacity, to perform a substantial portion of his duties hereunder. In the event that Executive shall dispute any determination of his 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.

13. 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 other material provision of this Agreement, 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 his base



salary to and including the date of termination. Should Executive in good faith dispute his termination for Cause, he shall give prompt written notice thereof to the Corporation, in which event such dispute shall be submitted to and determined by arbitration in New York City. Such arbitration shall be conducted before a single arbitrator agreed upon between the Corporation and Executive; provided, however, that if the parties are unable to agree on a single arbitrator, the dispute shall be conducted before a panel of three arbitrators consisting of one arbitrator selected by the Corporation, one the second arbitrator selected by Executive and the third arbitrator selected by the other two arbitrators. Such arbitration shall be conducted in accordance with such rules as shall be promulgated by the arbitrator (or panel), which may include any or all of the rules then obtaining 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 Corporation. Executive shall not be entitled to receive compensation for any period subsequent to his dismissal pursuant to this Paragraph 13.

14. TERMINATION FOR EMPLOYER BREACH. Executive may upon written notice to the Corporation terminate this Agreement (including paragraphs 7, 8 and 9) 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. Executive's right to terminate this Agreement under this Paragraph 14 shall be in addition to any other remedies Executive may have under law or equity. Paragraphs 2(d), 6 and 11(b) of this Agreement shall survive the termination of this Agreement by Executive pursuant to this Paragraph 14.

15. 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 himself to such physical examinations and execute and deliver such documents as the Corporation may reasonably deem necessary or desirable.

16. 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 himself shall be valid or binding unless made in writing and signed by the party against whom enforcement thereof is sought.

17. 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 Financial Officer and, if to Executive, at his 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 17. Notices shall be deemed effective upon receipt.

18. 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, his heirs, executors and administrators and upon the Corporation, its successors and assigns.

19. 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.

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

21. 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.

22. 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.

23. 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.

24. 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.



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

SHEFFIELD MEDICAL TECHNOLOGIES INC.

/s/ Douglas R. Eger
---
Douglas R. Eger
Chairman & CEO

/s/ Thomas M. Fitzgerald
---
Thomas M. Fitzgerald





EXHIBIT A TO
EMPLOYMENT AGREEMENT

SHEFFIELD MEDICAL TECHNOLOGIES INC.
30 ROCKEFELLER PLAZA, SUITE 4515
NEW YORK, NEW YORK 10112

, 1996

To: Thomas M. Fitzgerald
4 St. Andrews Hill
Pittsford, New York 14534

By unanimous written consent of the Stock Option Committee of the Board of Directors of Sheffield Medical Technologies Inc. (the "Company") dated , 1996, the Company authorized the grant to you of an option (the "Option") to purchase One Hundred Fifty Thousand (150,000) shares (the "Shares") of Common Stock, par value $.01 per share, of the Company. The Option is being granted in connection with the Employment Agreement dated as of June 6, 1996

between the Company and you.

No part of the option is currently exercisable. The option may first be exercised on the respective dates, in the respective amounts and for the respective exercise prices listed below:

| First Date of Exercise | No. of Shares Exercisable | Exercise Price Per Share |
|---|---|---|
| June 1, 1997 | 50,000 | $ 5.25 |
| June 1, 1998 | 50,000 | $ 6.75 |
| June 1, 1999 | 50,000 | $ 8.25 |

This Option must be exercised as to any and all Shares on or prior to June 1, 2001 (on which date the Option will, to the extent not previously exercised, expire).

Unless at the time of the exercise of the Option a registration statement under the Securities Act of 1933, as amended (the "Act"), is in effect as to such Shares, any Shares purchased by you upon the exercise of the Option shall be

acquired for investment and not for sale or distribution, and if the Company so requests, upon any exercise of the Option, in whole or in part, you will execute and deliver to the Company a certificate to such effect. The Company shall not be obligated to issue any Shares pursuant to the Option if, in the opinion of counsel to the Company, the Shares to be so issued are required to be registered or otherwise qualified under the Act or under any other applicable statute, regulation or ordinance affecting the sale of securities, unless and until such Shares have been so registered or otherwise qualified. The Company confirms that the Shares have been registered under a currently effective registration statement.

You understand and acknowledge that, under existing law, unless at the time of the exercise of the Option a registration statement under the Act is in effect as to such Shares (i) any Shares purchased by you upon exercise of this option may be required to be held indefinitely unless such Shares are subsequently registered under the Act or an exemption from such registration is available; (ii) any sales of such Shares made in reliance upon Rule 144 promulgated under the Act may be made only in accordance with the terms and conditions of that Rule (which, under certain circumstances, restrict the number of shares which may be sold and the manner in which shares may be sold); (iii) in the case of securities to which Rule 144 is not applicable, compliance with Regulation A promulgated under the Act or some other disclosure exemption will be required; (iv) certificates for Shares to be issued to you hereunder shall bear a legend to the effect that the Shares have not been registered under the Act and that the Shares may not be sold, hypothecated or otherwise transferred in the absence of an effective registration statement under the Act relating thereto or an opinion of counsel satisfactory to the Company that such registration is not required; and (v) the Company will place an appropriate

"stop transfer" order with its transfer agent with respect to such Shares. In addition, you understand and acknowledge that the Company has no obligation to you to furnish information necessary to enable you to make sales under Rule 144. The Company confirms that the Shares have been registered under a currently effective registration statement.

In the event that the Company shall at any time prior to the expiration of the Option and prior to the exercise thereof: (i) declare or pay to the holders of the Common Stock a dividend payable in any kind of shares of stock of the Company; or (ii) change or divide or otherwise reclassify its Common Stock into the same or a different number of shares with or without par value, or into shares of any class or classes; or (iii) consolidate or merge with, or transfer its property as an entirety or substantially all of its assets to any other corporation; or (iv) make any distribution of its assets to holders of its Common Stock as a liquidation, or partial



liquidation dividend or by way of return of capital; then, upon the subsequent exercise of the Option, the purchase price of the Shares issuable upon the exercise hereof shall be appropriately adjusted by the Board of Directors of the Company so that you shall receive for the exercise price, in addition to or in substitution for the Shares to which you would be entitled upon such exercise, such additional shares of stock of the Company, or such reclassified shares of stock of the Company, or such securities or property of the Company resulting from such consolidation or merger or transfer, of such assets of the Company, which you would have been entitled to receive had you exercised the Option prior to the happening of any of the foregoing events.

The Option (or installment thereof) is to be exercised by delivering to the Company a written notice of exercise in the form attached hereto as Annex A, specifying the number of Shares to be purchased, together with payment of the purchase price of the Shares to be purchased. The purchase price is to be paid in cash.

The Option does not confer upon you any right whatsoever as a stockholder of the Company.

The Option is granted to you under the Company's 1993 Stock Option Plan, as amended, (the "Plan") and is intended to be an incentive stock option. The terms of the Plan are incorporated by reference into the Option, except as modified by the terms set forth herein. A copy of the Plan has been delivered to you with this letter.

The Option shall be binding upon any successors or assigns of the Company.



If the foregoing correctly sets forth our understanding, please indicate your acceptance by signing this letter in the space provided below.

Very truly yours,

SHEFFIELD MEDICAL TECHNOLOGIES INC.

---
Douglas R. Eger
Chairman & CEO

AGREED TO AND ACCEPTED:

- ---
Thomas M. Fitzgerald



Annex A
---

STOCK SUBSCRIPTION FORM

To: Sheffield Medical Technologies Inc.

Gentlemen:

I hereby exercise my option to purchase from Sheffield Medical Technologies Inc. (the "Company"), pursuant to the Stock Option Letter Agreement between us dated as of , 1996, -------- shares of the Company's Common Stock, $.01 par value, and herewith tender payment therefor at the rate of $--- per share. The option was originally granted pursuant to the terms of the Company's 1993 Stock Option Plan.

I represent and warrant that I am acquiring the said shares for my own account for investment purposes only; that I have no present intention of selling or otherwise disposing of such shares or any part thereof; that I will not transfer said shares in violation of the securities laws of the United States; that I am familiar with the business operations, management and financial condition and affairs of the Company; that I have not relied upon any representation of the Company with respect thereto; and that I have the personal financial means to comply with all of said representations. I further confirm that I have been advised that said shares will not be registered under the Securities Act of 1933, as amended, and that I have consulted with and been advised by counsel as to the restrictions on resale to which said shares will thereby be subject.

The form in which I wish my name and address to appear on the Company's stock records is as follows:

Name:
---
Address:
---
---
---

Very truly yours,

---
Thomas M. Fitzgerald



EX-27
3
ARTICLE 5 FDS QUARTER 10-QSB

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~~5~~

~~THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE CONDENSED FINANCIAL STATEMENTS FOR THE SECOND QUARTER ENDED JUNE 30, 1996 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH STATEMENTS.~~

~~3-MOS~~
~~DEC-31-1996~~
~~JUN-30-1996~~
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~~5,243,118~~
~~332,942~~
~~126,727~~
~~5,684,119~~
~~787,091~~
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~~0~~
~~111,754~~
~~4,750,283~~
~~5,684,119~~
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~~52,724~~
~~0~~
~~0~~
~~1,708,114~~
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~~2,567~~
~~(1,657,957)~~
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~~-----END PRIVACY-ENHANCED MESSAGE-----~~