-----BEGIN PRIVACY-ENHANCED MESSAGE----- Proc-Type: 2001,MIC-CLEAR Originator-Name: webmaster@www.sec.gov Originator-Key-Asymmetric: MFgwCgYEVQgBAQICAf8DSgAwRwJAW2sNKK9AVtBzYZmr6aGjlWyK3XmZv3dTlNen TWSM7vrzLADbmYQaionwg5sDW3P6oaM5D3tdezXMm7z1T+B+twlDAQAB MIC-Info: RSA-MD5,RSA, ITirQDU0kyXnYzOcY7wGftxTwVF2syf2DPtfCqVbKYEEIwBK7RFAMiHffLQF8lCI MCtgdDLg34zuUsmA41cuKA== 0000921895-97-000523.txt : 19970801 0000921895-97-000523.hdr.sgml: 19970801 ACCESSION NUMBER: 0000921895-97-000523 CONFORMED SUBMISSION TYPE: 10KSB/A PUBLIC DOCUMENT COUNT: 1 CONFORMED PERIOD OF REPORT: 19961231 FILED AS OF DATE: 19970731 SROS: AMEX FILER: COMPANY DATA: COMPANY CONFORMED NAME: SHEFFIELD PHARMACEUTICALS INC CENTRAL INDEX KEY: 0000894158 STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834] IRS NUMBER: 133808303 STATE OF INCORPORATION: DE FISCAL YEAR END: 1231 FILING VALUES: FORM TYPE: 10KSB/A SEC ACT: 1934 Act SEC FILE NUMBER: 001-12584 FILM NUMBER: 97648537 BUSINESS ADDRESS: STREET 1: 30 ROCKEFELLER PLAZA STREET 2: SUITE 4515 CITY: NEW YORK STATE: NY ZIP: 10112 BUSINESS PHONE: 2129576600 MAIL ADDRESS: STREET 1: 30 ROCKEFELLER PLAZA STREET 2: SUITE 4515 CITY: NEW YORK STATE: NY ZIP: 10112 FORMER COMPANY: FORMER CONFORMED NAME: SHEFFIELD MEDICAL TECHNOLOGIES INC DATE OF NAME CHANGE: 19940606 10KSB/A FORM 10KSB/A SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-KSB/A (Amendment No. 2) (Mark One) /X/ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE **ACT OF 1934** For the fiscal year ended December 31, 1996 // TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES **EXCHANGE ACT OF 1934** For the transition period from _____ to __ Commission file number 1-12584 SHEFFIELD PHARMACEUTICALS, INC. (Name of Small Business Issuer in its charter)

DELAWARE 13-3808303

(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employ Number)	er Identification
30 Rockefeller Plaza Suite 451	5, New York, New Yo	ork 10112
(Address of Principal Executiv	/e Offices) (2	Zip Code)

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

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

Name of Each Exchange Title of Each Class on Which Registered

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

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

None

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

Yes/X/ No//

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

/X/

(CONTINUED NEXT PAGE)

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

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

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

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

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

1996:	HIGH LOW
Fourth Quarter	\$4.125 \$3.125
Third Quarter	\$4.625 \$3.0625
Second Quarter	\$6.50 \$4.00
First Quarter	\$6.75 \$3.5625
1995:	
Fourth Quarter	\$4.3125 \$3.00
Third Quarter	\$5.6875 \$3.875
Second Quarter	\$5.125 \$3.50
First Quarter	\$5.750 \$3.125

The closing sale price for the Company's Common Stock on the AMEX on March 14, 1997 was \$3.1875 per share. At March 14, 1997, there were approximately 4,000 holders of record of the Company's Common Stock. The Company has never paid dividends on its Common Stock and does not intend to pay cash dividends on its Common Stock in the foreseeable future.

The following unregistered securities were issued by the Company during the fiscal year ended December 31, 1996:

	Description of Securities Issued	•	Offering/ tions Exerc	ise Price Purchaser or Class
January 1, 1996- December 31, 1996	Common Stock Options	472,000	_	4 Issuances to ees pursuant to
_	- G. I	45.000	Plan	
January 1, 1996- C December 31, 19 9		45,000		nt to Directors
			Stock Option	- Plan
January 1, 1996 -		30,000 , 1996 Options		5 Advisor
October 1996	Common Stock	100,000 Options	3-15/16	Advisor
October 1996	Common Stock	250,000 Options	5.25	- Advisor

September 199	Common Stock	25,000	4-1/8 Dir€	ector
		Options		
July 1996	Common Stock	2,922	3-3/8 Adviso	f
		Options		
July 1996	Common Stock	40,000	5.50 Adviso)f
April 1996	Common Stock	100,000	n/a Financial a	dvisor
March 1996	Common Stock	50,000	4-7/16 Direc	tor
		Options		

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

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

OVERVIEW

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

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

FISCAL YEARS ENDED DECEMBER 31, 1996 AND 1995

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

the completion of the Company's warrant discount program completed in 1996, which raised total gross proceeds of \$5.6 million.

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

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General and administrative expenses for 1996 were \$3,831,204, an increase of \$851,767 compared with expenses of \$2,979,437 for 1995, primarily resulting from the one-time cashless exercise of options and warrants by a former employee of the Company, totaling \$562,912, and private placement professional fees relating to Ion. The major items included in general and administrative expenses for 1996 were (i) salaries of \$1,011,527 which increased by \$490,418 as compared to 1995, primarily due to the increase in management and staff, (ii) consulting fees of \$643,508 or \$48,701 less than 1995, (iii) professional fees of \$653,968 or \$31,225 less than last year, (iv) the one-time cashless exercise of options and warrants by a former employee of the Company of \$562,912, (v) private placement professional fees relating to Ion of \$244,515 and (vi) other expenses of \$711,622.

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

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

LIQUIDITY AND CAPITAL RESOURCES

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

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

sub-license agreement for its Liposome-CD4 technology and earned a sub-license fee that is included in sub-license fee revenue.

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

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

The Company spent approximately \$15.5 million through December 31, 1996 to fund certain ongoing technology research projects and expects to incur additional costs in the future, including costs relating to its ongoing sponsored research and development activities, preclinical and clinical testing of its product candidates and the hiring of additional personnel. The Company may also bear considerable costs in connection with filing, prosecuting, defending and/or enforcing its patent and other intellectual property claims. Therefore, the Company will need substantial additional capital before it will recognize significant cash flow from operations, which is contingent on the successful commercialization of the Company's technologies by third parties through licenses, joint ventures or other arrangements. There can be no assurance that any of the technologies to which the Company currently has or may acquire rights to can or will be commercialized or that any revenues generated from such commercialization will be sufficient to fund existing and future research and development activities.

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

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

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

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

The table below indicates (i) the Company's direct research and development expenses by project for the fiscal year ended December 31, 1996 and from the Company's inception to December 31, 1996, (ii) the Company's current estimate by project of committed and/or anticipated funding requirements after December 31, 1996 and (iii) revenues received to date by project.

DIRECT RESEARCH AND DEVELOPMENT EXPENSES (IN DOLLARS)

	_		•		TED AND/OR	
	F	ISCAL YEAR		ANT	TCIPATED R&D)
I	ENDED	INCEPTI	ON TO	FUNDI	NG AFTER	REVENUE
R&D PROJECT	12	/31/96	12/31/96	12	2/31/96*	RECEIVED
Ion Pharmaceuticals,		2,097,020	3,808,5	64	1,462,309	10,000
		-Inc. Tech	nologies			
RBC-CD4 Electroinsertic	on	515,036	6,23	8,426	16,577	0
Technology						
Liposome-CD4 Technolo	egy	60,449	2,32	22,322	0	500,000
HIV/AIDS Vaccine		414,849	1,074,	118	150,000	0
UGIF Technology		16,398	103,4	01	100,000	0
Membrane Attack Comp	olex	121,87	74 12	21,874	262,808	3 0
		(MAC)/Con	nplement			
		- Techn	ology			

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

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

DIRECTORS AND EXECUTIVE OFFICERS

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

NAME	AGE	POSITION

Douglas R. Eger 35 Chairman, Chief Executive

Officer and Director

Thomas M. Fitzgerald 47 President and Chief

Operating Officer and

Director

Michael Zeldin 59 Chief Scientific Officer

and Director

Anthony B. Alphin, Jr. 51 Director

Dr. Stephen Sohn 52 Director

Bernard Laurent 45 Director

George Lombardi 53 Vice President, Chief

Financial Officer,

Treasurer and Secretary

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

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

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

ANTHONY B. ALPHIN, JR. Mr. Alphin has been a Director of the Company since November 1993. Mr. Alphin has been Chairman and Chief Executive Officer of Moneywatch Investments, Inc., a real estate investment and development company,

since 1981. Mr. Alphin has been a director of Norcross & Co., Inc., the managing underwriter of the Company's February 1993 public offering, since 1991.

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

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

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

MEETINGS AND COMMITTEES

The Board of Directors of the Company held five meetings during the fiscal year ended December 31, 1996. From time to time during such fiscal year, the members of the Board acted by unanimous written consent. The Company has standing Stock Option, Compensation, Audit and Scientific Review Committees. The Stock Option Committee reviews, analyzes and approves grants of stock options and stock to eligible persons under the Company's 1993 Stock Option Plan and the Company's 1993 Restricted Stock Plan. The current members of the Stock Option Committee (appointed in June 1996) are Anthony B. Alphin, Jr. and Stephen Sohn. The Stock Option Committee did not hold any formal meetings in 1996, but approved certain actions by written consent. The Compensation Committee reviews, analyses and makes recommendations to the Board of Directors regarding compensation of Company directors, employees, consultants and others, including grants of stock options (other than stock option grants under the Company's 1993 Stock Option Plan). The current members of the Compensation Committee (appointed in June 1996) are Anthony B. Alphin, Jr., Stephen Sohn and Bernard Laurent. The Compensation Committee did not hold any formal meeting in 1996, but approved certain actions by written consent. The Audit Committee reviews, analyzes and makes recommendations to the Board of Directors with respect to the Company's compensation and accounting policies, controls and statements and coordinates with the Company's independent public accountants. The current members of the Audit Committee (appointed in June 1996) are Anthony B. Alphin, Jr. and Bernard Laurent. The Audit Committee held one formal meeting in 1996. The Scientific Review Committee was established to discuss the science and potential commercialization, clinical development and business development of existing and future technologies of the Company. The current members of the Scientific Review Committee (appointed in June 1996) are Douglas R. Eger, Dr. Stephen Sohn and Dr.

Michael Zeldin. The Scientific Review Committee held no formal meetings in 1996. The Company does not have a standing nominating committee or a committee which serves nominating functions.

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SIGNATURES

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

SHEFFIELD PHARMACEUTICALS, INC.

Dated: July 30, 1997 /S/ GEORGE LOMBARDI

Vice President and Chief Financial Officer

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