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AUf076pkEAC0vTc/Tgzd8w== 0000921895-99-000327.txt : 19990511 0000921895-99000327.hdr.sgml : 19990511 ACCESSION NUMBER: 0000921895-99-000327 CONFORMED
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PHONE: 3145799899 MAIL ADDRESS: STREET 1: 425 WOODSMILL RD CITY: ST LOUIS STATE:
MO ZIP: 63017 FORMER COMPANY: FORMER CONFORMED NAME: SHEFFIELD MEDICAL
TECHNOLOGIES INC DATE OF NAME CHANGE: 19940606

SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-Q

FORM 10-Q

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

FOR THE QUARTER ENDED MARCH 31, 1999

Commission file number 1-12584

SHEFFIELD PHARMACEUTICALS, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE 13-3808303

(STATE OF INCORPORATION) (IRS EMPLOYEE IDENTIFICATION NUMBER)

425 SOUTH WOODSMILL ROAD 63017 (314) 579-9899
ST. LOUIS, MISSOURI (ZIP CODE) (REGISTRANT'S TELEPHONE,
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) INCLUDING AREA CODE)

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:

TITLE OF CLASS NAME OF EACH EXCHANGE ON WHICH REGISTERED Common Stock. \$.01 par value American Stock Exchange

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT:

None

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

[X] Yes [] No

The number of shares outstanding of the Registrant's Common Stock is 27,266,346 shares of Common Stock as of May 10, 1999.

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

FORM 10-Q For the Quarter Ended March 31, 1999

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PART I: FINANCIAL INFORMATION
Item 1. FINANCIAL STATEMENTS
SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (a development stage enterprise) CONSOLIDATED BALANCE SHEETS
ASSETS
March 31, December
1999 1998
(unaudited)
Current assets:
— Cash and cash equivalents \$ 1,908,615 \$ 2,456,290
Marketable equity security 138,880 127,774
Prepaid expenses and other current assets 34,594 39,035
Total current assets 2,082,089 2,623,099
Property and equipment:
Laboratory equipment 323,263 317,032
Office equipment 146,478 175,062
Leasehold improvements 1,323 1,323
Total at cost 471,064 493,417
Less accumulated depreciation and amortization (245,267) (253,995)
Property and equipment, net 225,797 239,422
Total assets \$ 2,307,886 \$ 2,862,521
— LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

Current liabilities:

	\$ 570,472	2 \$ 615,138
Sponsored research payable	449,805	449,805
Note payable - related party	104,145	101,323
Total current liabilities	1,124,422 1	- ,166,266
Convertible promissory note	1,500,000	1,000,000
Other long-term liabilities	65,237	41,050
Commitments and contingencies		
Total liabilities 2	2,689,659 2,2	- 07,316
Stockholders' equity (net capital defi	ciency):	
Preferred stock, \$.01 par value, authorized	•	'es:
Series C cumulative convertible preferred sto		
shares; 12,122 and 11,914 shares issued and o		
	12	
Common stock, \$.01 par value, authorized		
issued and outstanding 27,083,419 and 27,058		
•	270,83	
Notes receivable in connection with sale of stock		00) (10,000)
Additional paid-in capital	56,093,806 <u>!</u>	, , , ,
Other comprehensive income (loss)) (222,226)
Deficit accumulated during development stage	` ,	9 14) (55,156,763)
Total stockholders' equity (net capital deficiency)	(381,7	 73) 655,205
Total liabilities and stockholders' equity (net capital deficiency)	\$ 2,30	7,886 \$ 2,862,521 =====

See notes to consolidated financial statements

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES

(a development stage enterprise)
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Three Months Ended March 31, 1999 and 1998 and for the Period from October 17, 1986 (inception) to March 31, 1999
(Unaudited)

October 17. Three Months Ended 1986 March 31 (inception) to 1999 1998 December 31, Revenues: - Sublicense revenue....... \$ -- \$ 1.360.000 Total revenues...... 21,877 953 Expenses: - Acquisition of research and development in-process technology.....--14.975.000 Extraordinary item..... ---- 42,787 Accretion of mandatorily redeemable preferred stock. (23.900) Weighted average common shares outstanding-6,746,866 Net loss per share of common stock-basic and — diluted: Loss beforeextraordinary item...... \$(0.04) \$(0.17) Extraordinary item..... -.01 Net loss per share...... \$(0.04) \$(0.17) \$(8.27)

See notes to consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Three Months Ended March 31, 1999 and 1998 and for the Period from October 17, 1986 (Inception) to March 31, 1999 (Unaudited)

> Three Months Ended October 17, 1986 March 31, (inception) to 1999 1998 March 31, 1999

Cash outflows from development	stage activities	and	
extraordinary gain: Loss before extraordinary item	. \$(1,162,656)	\$(2,263,0) 48) \$(55,843,693)
Extraordinary gain on extinguishment of debt			42,787
Net loss(1,162,	,656) (2,263	3,048) (55,8 6	00,906)
Adjustments to reconcile net loss development stage a		ed by	
Issuance of common stock, stock options/warrants for ser	rvices. 62	,567 1	6,389 2,344,540
Non-cash acquisition of research and	l development	in-process	
technology	<u>-</u>	 1,650,0	00
— Depreciation and amortization			413,075
Other items		1,381 44	0,108
— Decrease (increase) in prepaid expenses & other current	assets. 4	441 7	', 049 (93,635)
Decrease in other assets			
— Increase (decrease) in accounts payable and accrued liabi		•	•
— Increase (decrease) in sponsored research payable			
Net cash used by development stage activities	(1,092,641)	(450,09	2) (49,974,817)
Cash flows from investing	g activities:		
Cash flows from investing	•		- 175 085
 Proceeds on sale of marketable securities 			- 175,085
— Proceeds on sale of marketable securities — Acquisition of laboratory and office e			ŕ
— Proceeds on sale of marketable securities — Acquisition of laboratory and office e — improvements		 (455	ŕ
Proceeds on sale of marketable securitiesAcquisition of laboratory and office e improvements Disposition of office equipment	equipment, and (6,231)	 (455 33,560	5,355)
Proceeds on sale of marketable securities	equipment, and (6,231) f stock	 (45 5 33,560	5 ,355) (240,000)
Proceeds on sale of marketable securities	equipment, and (6,231) f stock	33,560 7,500	5,355) (240,000)
Proceeds on sale of marketable securities	equipment, and (6,231) f stock 2,500	33,560 7,500	5,355)
Proceeds on sale of marketable securities	equipment, and (6,231) f stock 2,500	33,560 7,500	5,355) (240,000)
Proceeds on sale of marketable securities	f stock 2,500	33,560 7,500	5,355)
Proceeds on sale of marketable securities	rquipment, and (6,231) fstock 2,500 sired (3,731)	(455 33,560 7,500 23,300 64,360	5,355)
Proceeds on sale of marketable securities	rquipment, and (6,231) f stock 2,500 uired (3,731) g activities:(1,303)	(455 33,560 7,500 23,300 64,360	5 ,355)
Proceeds on sale of marketable securities	rquipment, and (6,231) f stock 2,500 uired (3,731) g activities:(1,303)	(455 33,560 7,500 23,300 64,360	5,355)
Proceeds on sale of marketable securities	g activities:(1,303)	(455 33,560 7,500 23,300 64,360	5,355)
Proceeds on sale of marketable securities	g activities:	(455 33,560 7,500 23,300 64,360	5,355)
Proceeds on sale of marketable securities	rquipment, and (6,231) f stock 2,500 iired (3,731) g activities: (1,303)	(455 33,560 7,500 23,300 64,360	5,355)

Redemption of preferred stock		- (1,250,000)
Proceeds from exercise of warrants/stock options	50,000	 11,452,158
Net cash provided by financing activities	548,697	 52,227,205
Net increase (decrease) in cash and cash equivalents	(547,675)	(385,732) 1,907,531
Cash and cash equivalents at beginning of period	2,456,290	393,608 1,084
Cash and cash equivalents at end of period\$	1,908,615	 \$7,876 \$1,908,615
Noncash investing and financing a Common stock, stock options and warrants issued for services	\$62,567	\$16,389 \$2,344,540
— Common stock redeemed in payment of notes receivable		 10,400
— Acquisition of research and developm	•	1.655.246
technology		1,655,216
— Common stock issued for intellectual property rights — Common stock issued to retire debt	·····	 866,250
— Common stock issued to redeem convertible securities		 600,000 2,136,784 5,353,368
		2,136,784 5,353,368
— Securities acquired under sublicense agreement		 121,684
Notes payable converted to common stock		121,004 749,976
— Stock dividends 208,49		•
— 3tock dividends 200,49	104,20	1 307,0 4 2
Supplemental disclosure of cash flow information: Interest paid	\$1,377	\$1,089 \$268,778

See notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

For the Period from October 17, 1986 (Inception) to March 31, 1999

(Unaudited)

-- 11,220,369

75,000

(110,000)

Reincorporation in Delaware at \$.01 par value...... -- (11,220,369)

Common stock options issued......

Common stock subscribed......

Unrealized loss on marketable securities				
Net loss				-
— Comprehensive income (loss)				-
-				
Balance at December 31, 1996		•	, ,	28,319,838
Issuance of common stock			•	
- acquisition of Camelot Pharmacal, L.L.C				
Common stock issued		6,612	37,400	1,041,750
Common stock options and warrants issued				165,868
Common stock options extended				215,188
Accretion of issuance costs for Series A preferred				
Comprehensive inc	:ome (k	oss):		
— Unrealized gain on marketable securities				
- Net loss				-
				-
— Comprehensive income (loss)				
Balance at December 31, 1997		126.495	(72.600)	31,386,644
Common stock issued		144,089		
Series C preferred stock issued			 1 1	
Series C preferred stock dividends				413,996
Accretion of issuance costs for Series A preferred				
Comprehensive inc				
— Unrealized loss on marketable securities	•	055).		
	•••••			
- Net loss				-
				-
Comprehensive income (loss)				
·				
Balance at December 31, 1998				
Common stock issued			2,500	49,750
Preferred stock dividends	2		 2	07,998
Common stock warrants issued				-62,567
	:ome (k	oss):		
Comprehensive inc				
•				
— Unrealized gain on marketable securities				=
•				- - -
— Unrealized gain on marketable securities — Net loss				- -
— Unrealized gain on marketable securities				- - -

Deficit Total
Other accumulated stockholders
comprehen- during equity (net
sive income development capital
(loss) stage deficiency

Balance at October 17, 1986	 \$	\$	\$	
Common stock issued			28,3	58,721
Reincorporation in Delaware at \$.01 par valu	ı e		·	
Common stock options issued			-	75,000
Common stock subscribed			(1	10,000)
Comprehensiv	e income (loss	5):	`	, ,
— Unrealized loss on marketable securities	•	•		(39,232)
— Net loss		588,652)	(26,588	, , ,
— Comprehensive income (loss)			(26,6	527,884)
Balance at December 31, 1996 Issuance of common si	tock in connec	• • •	·	1,695,837
— acquisition of Camelot Pharmacal, L.L.C				1,650,000
Common stock issued			1,08	8 5,762
Common stock options and warrants issued				165,868
Common stock options extended		_		215,188
Accretion of issuance costs for Series A preferred :	stock	(79,500)	(79,500)
Comprehensiv	e income (loss	5):		
 Unrealized gain on marketable securities 	39,2	232		39,232
Net loss	 (9,	489,138)	(9,489,	138)
Balance at December 31, 1997		(36,157,29		4,716,751) 79,655
Series C preferred stock issued				500,000
Series C preferred stock issued		 (415,1	•	(1,112)
Accretion of issuance costs for Series A preferred:			•	(1,112)
Comprehensiv			23,300)	(23,300)
Unrealized loss on marketable securities				(222,226)
- Net loss	• ,	560,461)	(18,560	
Comprehensive income (loss)			(18,7	786,782)
Balance at December 31, 1998		(55,156	•	655,205
Common stock issued				2,500
Preferred stock dividends		(208,49)	5)	(495)
Common stock warrants issued		.		-62,567
Comprehensiv				
— Unrealized gain on marketable securities — Net loss		-06 -162,656)	 (1,162,	11,106 6 56)
— Comprehensive income (loss)			(1,1	51,550)
Balance at March 31, 1999	\$(211,120)	\$(56,527, 9	 9 14) 	\$(381,773)

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 1999

(Unaudited)

1. CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated balance sheet as of March 31, 1999 and the accompanying consolidated statements of operations, stockholders' equity and cash flows for the three months ended March 31, 1999 and 1998 and for the period from October 17, 1986 (inception) to March 31, 1999, have been prepared by Sheffield Pharmaceuticals, Inc. 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, stockholders' equity and cash flows at March 31, 1999 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-K for the year ended December 31, 1998. The results of operations for the three months ended March 31, 1999 and 1998 are not necessarily indicative of the operating results for the full years.

Sheffield Medical Technologies Inc. ("Sheffield") was incorporated under Canadian law in October 1986. In May 1992, the Company became domesticated as a Wyoming Corporation pursuant to a "continuance" procedure under Wyoming law. In January 1995, the Company's shareholders approved the proposal to reincorporate Sheffield in Delaware, which was effected on June 13, 1995. On January 10, 1996, Ion Pharmaceuticals, Inc. ("Ion"), was formed as a wholly owned subsidiary of the Company. At that time, Ion acquired the Company's rights to certain early-stage biomedical technologies. On April 17, 1997, CP Pharmaceuticals, Inc. ("CP") was formed for the purpose of acquiring Camelot Pharmacal, L.L.C., a privately held pharmaceutical development company, which acquisition was consummated on April 25, 1997. In June 1997, the Company's shareholders approved the proposal to change Sheffield's name from Sheffield Medical Technologies Inc. to Sheffield Pharmaceuticals, Inc. As part of an agreement with Elan Corporation, plc, on June 30, 1998, Systemic Pulmonary Delivery, Ltd. ("SPD") was formed as a wholly owned subsidiary of the Company. At that time, SPD acquired the Company's rights to the systemic applications of the Metered Solution Inhaler and acquired Elan's rights to certain pulmonary delivery technologies. Unless the context requires otherwise, Sheffield, Ion, CP and SPD are referred herein to as "the Company." All significant intercompany transactions are eliminated in consolidation.

The accompanying consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company is in the development stage and to date has been principally engaged in research, development and licensing efforts. The Company has generated minimal operating revenue, sustained significant net operating losses, and requires additional capital that the Company intends

to obtain through out-licensing as well as through equity and debt offerings to continue to operate its business. The Company's ability to meet its obligations as they become due and to continue as a going concern must be considered in light of the expenses, difficulties and delays frequently encountered in developing a new business, particularly since the Company will focus on product development that may require a lengthy period of time and substantial expenditures to complete. Even if the Company is able to successfully develop new products, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products to be profitable. Management believes that the Company's ability to meet its obligations as they become due and to continue as a going concern through December 1999 is dependent upon obtaining additional funding. However, the accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. BASIC LOSS PER COMMON SHARE

Basic net loss per share is calculated in accordance with Statement of Financial Accounting Standards No. 128, EARNINGS PER SHARE. Basic net loss per share is based upon the weighted average common stock outstanding during each year. Potentially dilutive securities such as stock options, warrants, convertible debt and preferred stock, have not been included in any years presented as their effect is antidilutive.

Item 2.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THIS REPORT CONTAINS CERTAIN FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933, AS AMENDED, AND SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, WHICH ARE INTENDED TO BE COVERED BY THE SAFE HARBORS CREATED HEREBY. ALL FORWARD-LOOKING STATEMENTS INVOLVE RISKS AND UNCERTAINTY, INCLUDING WITHOUT LIMITATION, THE SUCCESSFUL DEVELOPMENT AND LICENSING OF THE COMPANY'S TECHNOLOGIES AND THE SUCCESSFUL COMPLETION OF PLANNED FINANCINGS. ALTHOUGH THE COMPANY BELIEVES THAT THE ASSUMPTIONS UNDERLYING THE FORWARD-LOOKING STATEMENTS CONTAINED HEREIN ARE REASONABLE, ANY OF THE ASSUMPTIONS COULD BE INACCURATE, AND THEREFORE, THERE CAN BE NO ASSURANCE THAT THE FORWARD-LOOKING STATEMENTS INCLUDED IN THIS REPORT WILL PROVE TO BE ACCURATE. IN LIGHT OF THE SIGNIFICANT UNCERTAINTIES INHERENT IN THE FORWARD-LOOKING STATEMENTS INCLUDED HEREIN, THE INCLUSION OF SUCH INFORMATION SHOULD NOT BE REGARDED AS A REPRESENTATION BY THE COMPANY OR ANY OTHER PERSON THAT THE OBJECTIVES AND PLANS OF THE COMPANY WILL BE ACHIEVED.

OVERVIEW

The Company is a specialty pharmaceutical company focused on the development and commercialization of later stage, lower risk pharmaceutical products that utilize the Company's delivery technologies. In 1997, the Company acquired the Metered Solution Inhaler ("MSI") pulmonary delivery system through a worldwide exclusive license and supply arrangement with Siemens AG. During the second half of 1998, the Company acquired the rights to an additional pulmonary delivery

technology, the Aerosol Drug Delivery System ("ADDS") from a subsidiary of Aeroquip-Vickers, Inc. ("Aeroquip-Vickers"). The ADDS technology is a new generation propellant-based pulmonary delivery system.

Using these pulmonary delivery systems as platforms, the Company has established strategic alliances with Elan Corporation, plc ("Elan"), Siemens AG ("Siemens") and Zambon Group SpA ("Zambon") for developing the initial products. In a collaboration with Zambon, the Company is developing a range of pharmaceutical products delivered by the MSI to treat respiratory diseases. As part of the strategic alliance with Elan, a world leader in pharmaceutical delivery technology, the Company is developing therapies for systemic diseases to be delivered to the lungs. The initial systemic programs are for therapies in the breakthrough pain and migraine headache markets. Elan licensed two of its own delivery technologies to the Company that complement the MSI and ADDS technologies. Outside of its alliances, the Company owns the worldwide rights to respiratory disease applications of all of its technologies, subject only to the MSI respiratory rights licensed to Zambon. The Company will seek to acquire additional novel platform drug delivery systems and technologies.

RESULTS OF OPERATIONS

REVENUE

From inception through the period ended March 31, 1999, the Company has earned sublicense revenue of \$1,360,000 related to the sublicensing of various early stage technologies. As part of the Company's focus on later stage opportunities, the Company continues seeking to outlicense its remaining portfolio of early stage technologies. There can be no assurance that the Company will receive license fees or other payments related to these technologies. The Company believes these early stage technologies will have no material impact on the financial position of the Company.

Interest income was \$21,877 for the quarter ended March 31, 1999 compared to \$953 for the same quarter of 1998. The increase between years is attributable to an increase in cash available for investment during the period ended March 31, 1999. From inception through the period March 31, 1999, the Company has earned interest income of \$535,977.

The Company's ability to generate material revenues is contingent on the successful commercialization its technologies and other technologies and products that it may acquire, followed by the successful marketing and commercialization of such technologies through licenses, joint ventures and other arrangements.

ACQUISITION OF RESEARCH & DEVELOPMENT IN-PROCESS TECHNOLOGY

The acquisition of research and development in-process technology from inception to March 31, 1999 was attributable to the acquisition of Camelot Pharmacal, LLC in 1997 for \$1,650,000 and the 1998 acquisitions of certain pulmonary delivery technologies from Elan for \$12,500,000 and ADDS from Aeroquip-Vickers for \$825,000.

RESEARCH AND DEVELOPMENT

Research and development expenses were \$654,979 for the first quarter of 1999 as compared to \$1,609,041 for the first quarter of 1998. The decrease of \$954,062 from 1998 primarily reflects the shifting of responsibility for development expenses of the respiratory applications of the MSI to the Company's partner, Zambon. The Company's direct research and development expenses for its pulmonary delivery systems were \$483,273 and \$1,514,832 for the first quarters of 1999 and 1998, respectively, and \$4,275,773 from inception through March 31, 1999. The Company incurred \$894 of R&D costs in 1999 versus \$244 in 1998 associated with its early stage technologies, which include RBC-CD4 Electroinsertion technology, Liposome-CD4 technology, HIV/AIDS vaccine, UGIF technology-prostate cancer, and anti-proliferative technologies. Since the Company is focused on development of its pulmonary delivery systems, it does not anticipate incurring additional research and development costs for these early stage projects.

GENERAL AND ADMINISTRATIVE

General and administrative expenses were \$499,663 for the quarter ended March 31, 1999, compared with the \$612,490 same quarter of 1998. This decrease from 1998 to 1999 of \$112,827 was primarily due to lower compensation expense reflecting fewer employees during the first quarter of 1999 as compared to the same quarter of 1998.

INTEREST EXPENSE

Interest expense was \$29,891 for the first quarter of 1999, compared with \$42,470 for the first quarter of 1998. The decrease of \$12,579 in 1999 as compared to 1998 resulted from interest associated with the Company's Series A Cumulative Convertible Preferred Stock and 6% Convertible Subordinated Debentures which were both converted into Common Stock during 1998.

LIQUIDITY AND CAPITAL RESOURCES

The Company's cash available as of March 31, 1999 for funding its operations was \$1,908,615. As of such date, the Company had trade payables of \$570,472, current research obligations of \$449,805 and a note payable due in May 1999 of \$104,145. In addition, the Company has committed to fund an additional \$1,729,000 for development of pulmonary delivery systems subsequent to March 31, 1999.

As part of an agreement with Elan, Elan agreed to make available to the Company a convertible promissory note that provides the Company the right to borrow up to \$2,000,000, subject to satisfying certain conditions. No more than \$500,000 may be drawn under the note in any calendar quarter and at least one-half of the proceeds must be used to fund SPD's development activities. As of March 31, 1999, the Company had remaining \$500,000 available for borrowing under this note.

In May 1999, in conjunction with the completion of its Phase I/II MSI-albuterol trial, Zambon provided the Company with a \$1 million interest free advance against future milestone payments. The advance will be repaid in quarterly installments of \$250,000 commencing on January 1, 2002 or upon the receipt of certain future milestones, whichever is earlier. The proceeds from this advance are not restricted as to its use by the Company. Upon the achievement of certain other early milestones, Zambon will provide an additional \$1,000,000 advance under the terms of the agreement.

The Company expects to incur additional costs in the future to fund certain ongoing technology research projects, including costs relating to its ongoing research and development activities, and preclinical and clinical testing of its product candidates. The Company may also bear considerable costs in connection with filing, prosecuting, defending and/or enforcing its patent and other intellectual property claims. 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.

Because the Company does not expect to generate significant cash flows from operations for at least the next few years, the Company believes it will require additional funds to meet future costs. The Company will attempt to meet its capital requirements with existing cash balances and through additional public or private offerings of its securities, debt financing and collaboration and licensing arrangements with other companies. There can be no assurance that the Company will be able to obtain such additional funds or enter into such collaborative and licensing arrangements on terms favorable to the Company, if at all. The Company's development programs may be curtailed if future financings are not completed.

YEAR 2000 COMPLIANCE

The inability of computers, software and other equipment utilizing microprocessors to recognize and properly process data fields containing a two digit year is commonly referred to as the Year 2000 compliance issue. Such systems that are not Year 2000 compliant may not be able to properly interpret dates beyond the Year 1999, which could lead to business disruptions in the U.S. and internationally. The potential costs and uncertainties associated with the Year 2000 issue will depend on a number of factors, including software, hardware and the nature of the industry in which a company operates. Additionally, companies must coordinate with other entities with which they electronically interact, such as customers, creditors and borrowers.

During 1998, the Company conducted an assessment of its computer systems to identify systems that could be affected by the Year 2000 issue. Substantially all software programs used by the Company have been determined to be Year 2000 compliant. In addition, the Company believes that with readily available upgrades to existing hardware, the Year 2000 issue will not pose significant operational problems for its computer system. The completion of hardware modifications to assure Year 2000 compliance is expected by the end of the second quarter of 1999.

The Company relies on various universities and laboratories for conducting a significant portion of the research and development of its products. The Company is currently in the process of communicating with the parties with which it does significant business to determine their Year 2000 compliance readiness and the extent to which the Company is vulnerable to any third party Year 2000 issues. The Company expects to complete its assessment of Year 2000 compliance of these third parties by July 1999. However, there can be no guarantee that the systems of other companies on which the Company relies will be timely converted or that

a failure to convert by another company, or a conversion that is incompatible with the Company's systems, would not have material adverse effect on the Company.

The total cost to the Company of these Year 2000 compliance activities is estimated to be less than \$25,000, and is not anticipated to be material to its financial position or results of operations. These costs and the date on which the Company plans to complete the Year 2000 modification and testing processes are based on management's best estimates, which were derived utilizing numerous assumptions of future events including the continued availability of certain resources, third party modification plans and other factors. However, there can be no assurance that these estimates will be achieved and actual results could differ from those plans.

PART II: OTHER INFORMATION

Item 2. CHANGES IN SECURITIES.

The following unregistered securities were issued by the Company during the quarter ended March 31, 1999:

Number of

Stock Option Plan.

Shares Number of Shares Sold/Issued Sold/Issued /Subject to Description /Subject to of Securities Options or Offering/Exercise Date of Sale/Issuance Issued Warrants Price per Share(\$) Purchase or Class January 1999 Common stock 19,640 \$2.3125 Advisor in lieu of cash warrants. consideration. January 1999 Common stock 45,000 2.3125 Issuance to certain options. Directors pursuant to the 1996 Directors Stock Option Plan. 2.3125 January 1999 Common stock 50,000 Holder of short-term warrants. note.

January 1999 Common stock 150,000 0.8125 Advisor under terms of warrants. engagement agreement.

February 1999 Common stock 16,000 2.750 Issuance to employees options. pursuant to 1993

The issuance of these securities is 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. EXHIBITS AND REPORTS ON FORM 8-K.

No reports on Form 8-K were filed during the quarter ended March 31, 1999.

EXHIBITS

NO. DESCRIPTION

27 Financial Data Schedule.

SIGNATURES

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 PHARMACEUTICALS, INC.

Dated: May 10, 1999 /S/ LOREN G. PETERSON
----Loren G. Peterson
President & Chief Executive Officer

Dated: May 10, 1999 /S/ SCOTT A. HOFFMANN

Scott A. Hoffmann
Vice President & Chief Financial Officer
(Principal Financial and Accounting Officer)

EX-27 2 ARTICLE 5 FDS

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This schedule contains summary financial information extracted from the condensed financial statements for the quarter ended March 31, 1999 and is qualified in its entirety by reference to such statements.

2.1406
3-MOS
DEC-31-1999
MAR-31-1999
1,908,615
138,880
0
0
2,082,089
471,064
245,267
2,307,886
1,124,422

•=•
270,834
(652,728)
2,307,886

21.877

1,184,533
1,104,333

0
29,891
(1,162,656)
0
(1,162,656)
0

(1,162,656
(.04)
(.04)

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