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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

10-Q

FORM 10Q

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

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FORM 10-Q

QUARTERLY REPORT UNDER SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

For Quarter Ended March 31, 1998 Commission File Number 1-12584

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

DELAWARE 13-3808303

(State of Incorporation) (IRS Employer Identification No.)

425 SOUTH WOODSMILL ROAD, SUITE 270
ST. LOUIS, MISSOURI 63017-3441
(Address of Principal Executive Offices) (Zip Code)

Indicate by check whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No

The number of shares outstanding of the issuer's Common Stock is 15,742,762 shares of Common Stock as of March 31, 1998.

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## SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

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## SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) CONSOLIDATED BALANCE SHEETS

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	March 31, 1998 December 31, (unaudited) 1997 
ASSETS	
Current assets:  Cash and cash equivalents  Loan receivable - former officer  Prepaid expenses and other current assets	
Total current assets	120,705 520,986
Property and equipment:	
— Laboratory equipment — Office equipment ————————————————————————————————————	185,853 185,852 109,002 142,562
Less accumulated depreciation and amortization	<del>294,855 328,414</del> <del>198,683 185,201</del>
Net property and equipment	<del>96,172 143,213</del>
Other assets	11,869 25,738 
Total assets	\$ 228,746 \$ 689,937 
LIABILITIES AND STOCKHOLDERS' EQUITY (NET	<del>F CAPITAL DEFICIENCY)</del>
Current liabilities:  Accounts payable and accrued liabilities	<del>\$ 2,609,156  \$ 887,782</del>
Sponsored research payable Total current liabilities	<del>470,180 470,768</del> <del>3,079,336 1,358,550</del>

<del>i% convertible subordinated debenture</del>	<del>882,000 1,551,000</del>
Interest payable on debenture	<del> 28,875</del>
Cumulative convertible redeemable preferred stock	k, \$.01 par value. Authorized,
3,000,000 shares; issued and outstanding,	. 10,000 and 25,000 shares at
March 31, 1998 and December 31, 1997, respectively	1,000,479 2,468,263
Commitments and continge	<del>encies</del>
Stockholders' equity (net capital	<del>deficiency):</del>
Common stock, \$.01 par value. Autho	<del>orized, 50,000,000 shares;</del>
issued and outstanding, 15,74	<del>2,762 and 12,649,539</del>
shares at March 31, 1998 and December 31, 1997, re	espectively 157,428 126,49
Notes receivable in connection with sale of stock	<del>(49,300) (72,600)</del>
Additional paid-in capital	<del>33,603,041 31,386,644</del>
Deficit accumulated during development stage	(38,444,238) (36,157,290)
	<del>(4,733,069) (4,716,751)</del>
Total liabilities and stockholders' equity (net capital o	<del>deficiency)                                    </del>
-	<del></del>

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See accompanying notes to unaudited consolidated financial statements

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES

(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE MONTHS ENDED MARCH 31, 1998 AND 1997 AND FOR THE PERIOD

FROM OCTOBER 17, 1986 (INCEPTION) TO MARCH 31, 1998

(UNAUDITED)

		Octobe	er 17, 1986
	Three months 6 March 3		(inception) to
	1998	 1997 	
	Revenues:		_
Sub-license revenue Interest income			<del>1,010,000</del> <del>454,780</del> 
<del>Total revenue</del>	953	18,225	<del>1,464,780</del>
	Expenses:		
	ition of R & D in-		
<del>technology technology technology</del>	<del></del>	<del></del>	<del>-1,650,000</del>
— General and administrative			
	<del>42,470</del>	2,679	<del>202,225</del>
Total expenses	2,264,001	2,686,31	<del></del>
Loss before extraordinary item  Extraordinary item	<del>(2,263,04</del> 	8) (2,668 	<del>3,088) (38,383,625)</del> —— <del>42,787</del>
Net loss	\$ (2,263,048)	<del>(2,668,088)</del>	<del></del> <del>(38,340,838)</del> 
Accretion of preferred stock	mandatorily red (23,900)		<del>(103,400)</del>
Net loss - attributable to common shar	es \$ (2,286,	<del></del> <del>948) \$ (2,</del>	<del></del> <del>668,088) \$(38,444,238)</del> <del></del>
Loss per shar Loss before extraordinary item Extraordinary item			0.23) \$ (7.49) 0.01
Basic net loss per share	\$ (0.17	<del>') \$ (0.</del> 2	<del></del>
₩eighted a  outstanding - basic:	average commor 13,655,722		<del>274 5,133,612</del>

# SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE THREE MONTHS ENDED MARCH 31, 1998 AND 1997 AND FOR THE PERIOD FROM OCTOBER 17, 1986 (INCEPTION) TO MARCH 31, 1998 (UNAUDITED)

		0	ctober	17, 198	6
Th	nree mon	nonths ended (incept larch 31, March 3			on) to
	Marc				1,
	1998	19	97	1998	-
				_	
Cash outflows from development stage ac					
Loss before extraordinary item	<del>⊅(∠,∠0.</del>	<del>5,046)</del>	<del>1(2,00</del>	0,000)	
Extraordinary gain on extinguishment of debt					<del>\$ 42,787</del>
— Net loss (2	<del>,263,048)</del>	(2,66	8,088)	(38,3	<del>40,838)</del>
Adjustments to reconcile net loss				( / -	-,,
- development stage			,		
Issuance of common stock, stock options/warrants for fee			16,3	389	<del> 1,938,448</del>
- Non-cash interest expense					<del>120,256</del>
Write-off of in-process technology					<del>,650,000</del>
Securities aquired under sub-license agreement					<del>(500,000)</del>
— Issuance of common stock for intellectual property r	<del>ights</del>				866,250
— Amortization of organizational and debt issuance co	-			<del></del>	<del>77,834</del>
— Depreciation and amortization		13,482	17	<del>7,775</del>	<del>260,073</del>
<ul> <li>Increase in debt issuance and organizational costs</li> </ul>				<del></del>	<del>(77,834)</del>
Loss realized on sale of marketable securities					<del>324,915</del>
Decrease (increase) in prepaid expenses and other curren	<del>t assets</del>		7,049	1.	<del>5,006 (99,370)</del>
					<del>47,172</del>
Increase (decrease) in accounts payable, accrued liabilitie	S	1,721	,374	(114,	<del>400) 2,037,302</del>
— Increase (decrease) in sponsored research payable		<del>(</del> 5	88)	592,15	<del>3 1,047,250</del>
Net cash used by development stage activities		<del>(450,09</del>	<del>2) (2</del>	, <del>156,95</del>	<del>4) (30,648,542)</del>
Cash flows from investir	ng activiti	es:			
Proceeds on sale of marketable securities			-		<del>- 175,085</del>
<ul> <li>Acquisition of laboratory and office equipment</li> </ul>					<del>(317,352)</del>
— Disposition of office equipment		33,56	)——		<del>33,560</del>
<ul> <li>Increase in notes receivable in connection with sale of</li> </ul>	<del>f stock</del>			<del></del>	<del>(240,000)</del>
— Decrease (increase) in loan receivable - former office			<del>7,500</del>		<del>(72,500)</del>
— Payments on notes receivable		<del>23,300</del>	)——		<del>-190,700</del>
— Purchase of Camelot Pharmacal L.L.C., net of cash acc	<del>luired</del>				<del>(46,687)</del>
Net cash provided (used) by investing activities		64,	360		<del>(277,194)</del>
Cash flows from financin	ng activiti	es:			
— Principal payments under capital lease			<del>(7</del>	,550)	<del>(72,453)</del>
Conversion of convertible, subordinated notes					<del>749,976</del>
<ul> <li>Proceeds from issuance of convertible debenture</li> </ul>					<del>2,300,000</del>
Proceeds from issuance of common stock			-	<b></b>	<del>13,268,035</del>
— Proceeds from issuance of preferred stock			3,2	12,136	<del>3,284,812</del>
— Proceeds from exercise of stock options		<del></del>			<del>1,337,677</del>

Proceeds from exercise of warrants	<del> 10</del>	<del>,064,481</del>
Net cash and cash equivalents provided by financing activitie	s 3,204,58	3 <del>6 30,932,528</del>
Net increase (decrease) in cash and cash equivalents  Cash and cash equivalents at beginning of period	(385,732) 1,047,6 393,608 1,979,87	•
-Cash and cash equivalents at end of period	\$ 7,876 \$ 3,027,503	<del>=====</del> <del>\$ 401,484</del>
Noncash investing and financing	activities:	
Common stock, stock options and warrants issued for services	\$ 16,389	<del> 1,937,648</del>
Common stock issued for acquisitions	<del></del> 1	<del>,655,216</del>
— Common stock issued for intellectual property rights	<del></del>	<del>866,250</del>
Common stock issued to retire debt	<del></del>	600,000
Common stock issued to redeem convertible securities	<del>2,136,784</del>	3,470,889
Securities acquired under sub-license agreement		<del>500,000</del>
Unrealized (realized) depreciation of investments	<del> 241,18</del>	3
Equipment acquired under capital lease		<del>72,453</del>
Notes payable converted to common stock	<del></del>	<del>749,976</del>
	<del>104,281 286</del>	<del>,,633</del>
Supplemental disclosure of cash flow	<del></del>	
• •	<del>,089 \$ 2,679 \$ 13</del>	<del>1,969</del>

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See accompanying notes to unaudited consolidated financial statements

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 1998 (UNAUDITED)

#### 1. CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated balance sheet as of March 31, 1998 and the accompanying consolidated statements of operations and cash flows for the three months ended March 31, 1998 and 1997 and for the period from October 17, 1986 (inception) to March 31, 1998, have been prepared by Sheffield Pharmaceuticals, 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 cash flows at March 31, 1998 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, as amended, for the year ended December 31, 1997. The results of operations for the three months ended March 31, 1998 and 1997 are not necessarily indicative of the operating

results for the full years.

Sheffield Medical Technologies Inc. ("Sheffield") was incorporated on October 17, 1986. The Company's wholly-owned subsidiary, U-Tech Medical Corporation ("U-Tech") was incorporated on January 13, 1992 and was liquidated on June 30, 1997. On January 10, 1996, Ion Pharmaceuticals, Inc. ("Ion"), was formed as a wholly-owned subsidiary of the Company. At that time, Ion acquired the Company's rights to certain early-stage biomedical technologies. On April 17, 1997, CP Pharmaceuticals, Inc. ("CP") was formed for the purpose of acquiring Camelot Pharmacal, L.L.C., a privately held pharmaceutical development company, which acquisition was consummated on April 25, 1997. On January 26, 1995, the Company's shareholders approved the proposal to reincorporate Sheffield in Delaware, which was effected on June 13, 1995. On June 26, 1997, the Company's shareholders approved the proposal to change Sheffield's name from Sheffield Medical Technologies Inc. to Sheffield Pharmaceuticals, Inc. Unless the context requires otherwise, Sheffield, U-Tech, Ion and CP are referred to as "the Company." All significant intercompany transactions are eliminated in consolidation.

The Company is in the development stage and to date has been principally engaged in research, development and licensing efforts. The Company has generated minimal operating revenue and requires additional capital which the Company intends to obtain through out-licensing as well as through equity and debt offerings to continue to operate its business. The Company's ability to meet its obligations as they become due and to continue as a going concern must be considered in light of the expenses, difficulties and delays frequently encountered in developing a new business, particularly since the Company will focus on product development that may require a lengthy period of time and substantial expenditures to complete. Even if the Company is able to successfully develop new products, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products to be profitable. Management believes that the Company's ability to meet its obligations as they become due and to continue as a going concern through December 1998 is dependent upon obtaining additional financing. Until such financing is obtained, the Company must rely on short-term loans from its officers in order to meet certain of its obligations.

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SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 1997

(UNAUDITED)

#### 2. BASIC LOSS PER COMMON SHARE

In 1997, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 128, Earnings Per Share. SFAS No. 128 replaced the previously reported primary and fully diluted earnings per share with basic and diluted earnings per

share. Unlike primary earnings per share, basic earnings per share excludes any dilutive effects of options, warrants and convertible securities. Diluted earnings per share is very similar to the previously reported fully diluted earnings per share. Basic net loss per share is based upon the weighted average Common Stock outstanding during each year. Common Stock equivalents are not included as their effect is antidilutive. The effect of adoption of SFAS No. 128 had no financial impact, and accordingly, no restatement of loss per share for prior periods was necessary.

#### 3. IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

On January 1, 1998 the Company adopted SFAS No. 130, "Reporting Comprehensive Income" ("SFAS No. 130"). SFAS No. 130 establishes standards for the reporting and display of comprehensive income and its components and is applied to all enterprises. The adoption of SFAS No. 130 had no impact on the Company's consolidated results of operations, financial position or cash flows.

#### 4. SUBSEQUENT EVENTS

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

On April 15, 1998, the Company issued 1,250 shares of its Series B Cummulative Convertible Redeemable Preferred Stock (the "Series B Preferred Stock") in a private placement for an aggregate purchase price of \$1,250,000. Under the terms of this offering, the Company must redeem the preferred stock at the time it concludes a definitive sub-license agreement on the MSI or other financing. As of May 15, 1998 all of the Series B Preferred Stock remains to be redeemed or available for conversion.

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

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

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## SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

ITFM 2:

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

The Company, being a development stage 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. Additional operating losses are expected to be incurred for the next several years as the Company expends its resources for product acquisition, research and development and preclinical and clinical testing.

As a development stage company without significant revenues, the Company has financed its development activities and operations primarily through public and private offerings of securities, from which it has raised an aggregate of approximately \$30.9 million through March 31, 1998. On April 15, 1998, the Company completed a private offering of 1,250 shares of its Series B Cumulative Convertible Redeemable Preferred Stock, which raised total gross proceeds of \$1.25 million. Also on April 15, 1998, the Company received a \$650,000 option fee from Zambon in the form of an equity investment. The proceeds of these placements were to be used to make a DM 2.0 million payment to Siemens A.G. and for working capital and general corporate purposes. The Company's operating results have fluctuated significantly during each quarter since its inception, and the Company anticipates that such fluctuations, largely attributable to varying development commitments and expenditures, as well as the acquisition of drug delivery technologies and products, 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 March 31, 1998, the Company funded \$1,609,041 for research and development on its projects. During the succeeding 12-month period, approximately \$2.3 million in additional funding is projected to be incurred on clinical and laboratory research and development, as well as the final remaining payment of DM 2.0 million to Siemens relative to the MSI. All this estimated funding of \$2.3 million, is expected to be applied to the MSI. The Company continues to seek appropriate sub-licensing partners for its remaining early-stage 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.

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## SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

#### **REVENUES AND EXPENSES**

#### Revenues:

From inception through the period ended March 31, 1998, the Company has earned sub-license revenue of \$1,010,000 relative to various early-stage technologies.

From inception through the period ended March 31, 1998, the Company has earned interest income of \$454,780 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 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 or other arrangements.

Interest income for the three months ended March 31, 1998 was \$953 compared to \$18,225 for the same period ended March 31, 1997. The decrease in interest earned is attributable to a decrease of cash invested in short-term investments. Except for the sub-license revenue mentioned above, interest income represented all of the Company's income in each of the prior periods.

#### **Operating Expenses:**

From inception through the period ended March 31, 1998, the Company incurred \$39,848,405 of operating expenses. Of the total operating expenses for that period, \$20,861,431 were costs of research and development for the Company's technologies and \$1,650,000 for the acquisition of R & D in-process technology. The remainder of expenses for the same period were incurred principally as consulting costs, costs of management, legal and other professional fees and expenses relating to the Company's technologies, and for its completed and proposed financing plans. Research and development costs are expected to 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.

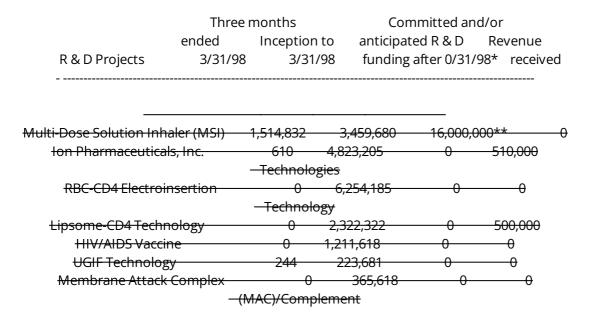
Operating expenses for the three months ended March 31, 1998, were \$2,264,001 compared to \$2,686,313 for the same period ended March 31, 1997. During the quarter ended March 31, 1998, the Company recognized an approximately \$1.1 million expense related to its obligation due in January, 1998 under the MSI license agreement with Siemens A.G. There was no corresponding expense during the quarter ended March 31, 1997 as the prior year obligation under the agreement was not due until the quarter ended June 30, 1997. The remaining decrease in operating expenses of approximately \$1.5 million was primarily due to significantly reduced spending on both research and development (approximately \$1.4 million) and general and administrative expenses (approximately \$130,000).

The table on the following page indicates (i) the Company's direct research and development expenses by project for the three months ended March 31, 1998 and from the Company's inception to March 31, 1998, (ii) the Company's current estimate by project of committed and/or anticipated funding requirements after March 31, 1998 and (iii) revenues received to date by project.

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## SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

Direct Research and Development Expenses (in dollars)



- \* 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.
- \*\* It is contemplated that this amount will be reduced to zero dollars in the event Zambon exercises its option agreement to acquire a sublicense for MSI respiratory applications and assumes related development funding obligations.

In June 1997, the FASB issued SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS No. 131"). SFAS No. 131 establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports issued to stockholders. It also establishes standards for related disclosures about products and services, geographic areas, and major customers. SFAS No. 131 is effective for financial statements for fiscal years beginning after December 15, 1997. The Company will adopt the new requirements

in conjunction with its 1998 Form 10-K. The adoption of SFAS No. 131 will have no significant impact on the Company's financial reporting.

#### LIQUIDITY AND CAPITAL RESOURCES

The Company's cash available for funding its operations as of March 31, 1998 was \$7,876. As of such date, the Company had trade payables of \$2,609,156 and current research obligations of \$470,180. In addition, committed and/or anticipated funding of research and development after March 31, 1998 is currently estimated at approximately \$16,000,000. The Company will be required to obtain additional funds for its business through operations or equity or debt financings, collaborative arrangements with corporate partners or from other resources. No assurance can be given that these funds will be available for the Company to finance its development on acceptable terms, if at all. If adequate funds are not available from operations or additional sources of funding, the Company's business will suffer a material adverse effect.

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

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## SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

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

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

January, 1998 a payment of DM 2.0 million (approximately \$1.1 million) was due to Siemens AG under the terms of the agreement under which the Company holds the world-wide marketing rights to the MSI. Although included as an expense for the period ended March 31, 1998, this payment was not made until April 15, 1998.

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

On April 15, 1998, the Company issued 1,250 shares of its Series B Cummulative Convertible Redeemable Preferred Stock (the "Series B Preferred Stock") in a private placement for an aggregate purchase price of \$1,250,000. Under the terms of this offering, the Company must redeem the preferred stock at the time it concludes a definitive sub-license agreement on the MSI or other financing. As of May 15, 1998, all of the Series B Preferred Stock remains to be redeemed or available for conversion.

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

As stated in the Company's press release on April 16, 1998 and included in a Current Report on Form 8-K filed with the Securities and Exchange Commission on April 17, 1998, the Company continues not to meet certain of the American Stock Exchange's ("AMEX") continued listing guidelines, and, as a result, there can be no assurance that the Company's common stock will continue to be listed on the AMEX.

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.

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## SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

PART II: OTHER INFORMATION

Item 2. CHANGES IN SECURITIES.

The following unregistered securities were issued by the Company during the quarter ended March 31, 1998:

Number of Shares Sold/Issued Description /Subject to

Date of Of Securities Options or Offering/exercise Sale/issuance Issued Warrants Price Per Share (\$) Purchaser Or Class

January - Common Stock 3,093,223 \$0.5719 - \$1.3313 Holders of Series A

March 1998 Preferred Stock and

6% Convertible

Convertible Debentures

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.

(a) EXHIBITS

NO. DESCRIPTION

27 Financial Data Schedule.

(b) REPORTS ON FORM 8-K

The Company filed a Current Report on Form 8-K with the Securities and Exchange Commission on April 17, 1998 relating to (i) the Company's entering into an option agreement to form a strategic arrangement with Zambon Group SpA of Milan, Italy, for the worldwide development and commercialization of drugs to treat respiratory disease in the Company's proprietary MSI system, (ii) the announcement of the Company's financial results for the fourth quarter and year

ended December 31, 1997, (iii) the completion of the offering and sale of the Company's Series B Cumulative Convertible Redeemable Preferred Stock for gross proceeds of \$1.25 million, and (iv) certain other matters.

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## SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

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.

authorized.	
	SHEFFIELD PHARMACEUTICALS, INC.
Dated: May 15, 1	998 /S/ Loren G. Peterson
	Loren G. Peterson President & Chief Executive Officer
Dated: May 15, 1	998 /S/ Judy Roeske Bullock
	Judy Roeske Bullock Vice President & Chief Financial Officer (Principal Financial and Accounting Officer)
EX-27 2 ARTICLE 5 FDS	
- 5	
CONDENSED FIL	E-CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE NANCIAL STATEMENTS FOR THE THREE MONTHS ENDED MARCH 31, 1998 AND IS SENTIRETY BY REFERENCE TO SUCH STATEMENTS.

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120,705
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<del></del>
<del></del>
(2,263,048)
<del>(2,233,618)</del>
<del>(0.17)</del>
(0.17)

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