-----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, Qr27N1lxQxLqBPknlaXOsptKSdA8TJI/u/3fHxR0+hQPOLxmR/MV0XbPXqmoAE5L w6XkR+7Pz/KdFAEoDBAI/w== 0000921895-00-000372.txt : 20000516 0000921895-00-000372.hdr.sgml: 20000516 ACCESSION NUMBER: 0000921895-00-000372 CONFORMED SUBMISSION TYPE: 10-Q PUBLIC DOCUMENT COUNT: 2 CONFORMED PERIOD OF REPORT: 20000331 FILED AS OF DATE: 20000515 FILER: COMPANY DATA: COMPANY CONFORMED NAME: SHEFFIELD PHARMACEUTICALS INC CENTRAL INDEX KEY: 0000894158 STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834] IRS NUMBER: 133808303 STATE OF INCORPORATION: DE FISCAL YEAR END: 1231 FILING VALUES: FORM TYPE: 10-Q SEC ACT: SEC FILE NUMBER: 001-12584 FILM NUMBER: 631359 BUSINESS ADDRESS: STREET 1: 425 WOODSMILL RD CITY: ST LOUIS STATE: MO ZIP: 63017 BUSINESS 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 10-Q

10-Q 1

FORM 10-Q

SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

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, 2000

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 27,998,310 shares as of May 11, 2000.

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

Form 10-Q For the Quarter Ended March 31, 2000

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PART I: FINANCIAL INFORMATION Financial Statements		
SHEFFIELD PHARMACEUTICALS, INC. AND SUB (a development stage enterprise) Consolidated Balance Sheets	SIDIARIES	
	Assets March 31, 2000 Decem	ber 31, 1999
Current as:	(unaudited) sets:	
-Cash and cash equivalents		\$ 3,874,437
Marketable equity security		519,387
-Prepaid expenses and other current assets		12 145,237
— Total current assets		 4,539,061
Property and eq	•	407,624
Laboratory equipment Office equipment		
- Leasehold improvements	·	15,000
Total at cost	636,328	
Less accumulated depreciation and amortization	·	,530) (311,752)
	(337)	
Property and equipment, net	298,798	
Patent costs, net of accumulate		
and \$0, respectively		
Other assets	15,830	- 15,642
— Total assets		

Liabilities and Stockholders' Equity

Current liabilities:

	\$ 519,148 	\$ 773,206
—Sponsored research payable	399,712	421,681
Total current liabilities	918,860 1	 -,194,887
Convertible promissory note		2,000,000
Unearned revenue		1,000,000
Other long-term liabilities	<u>229,935</u>	- 182,695
Commitments and contingencies		
Total liabilities		 377,582
Minority interest in subsidiary		
Stockholders'	equity:	
Preferred stock, \$.01 par value, at	uthorized 3,000,0000 shares:	
— Series C cumulative convertible	preferred stock, authorized	
23,000 shares; 13,006 and 1	2,780 shares issued and	
— outstanding at March 31, 200		
respectively	130	-128
		120
— Series D cumulative convertible o		120
	xchangeable preferred stock,	120
— Series D cumulative convertible o	xchangeable preferred stock, 5 issued and outstanding at	——————————————————————————————————————
— Series D cumulative convertible c — authorized 21,000 shares; 12,01	xchangeable preferred stock, 5 issued and outstanding at	
— Series D cumulative convertible o — authorized 21,000 shares; 12,01 — March 31, 2000 and December 31, 1999	xchangeable preferred stock, 5 issued and outstanding at	120
— Series D cumulative convertible c — authorized 21,000 shares; 12,01 — March 31, 2000 and December 31, 1999 — Series F convertible non-exch	xchangeable preferred stock, 5 issued and outstanding at	120
— Series D cumulative convertible of authorized 21,000 shares; 12,01 — March 31, 2000 and December 31, 1999 — Series F convertible non-exch — 5,000 shares authorized; 5,000 shares	xchangeable preferred stock, 5 issued and outstanding at	120
— Series D cumulative convertible of the convertibl	xchangeable preferred stock, 5 issued and outstanding at	120
— Series D cumulative convertible of authorized 21,000 shares; 12,010 — March 31, 2000 and December 31, 1999	xchangeable preferred stock, 5 issued and outstanding at	120
— Series D cumulative convertible c — authorized 21,000 shares; 12,01 — March 31, 2000 and December 31, 1999 — Series F convertible non-exch — 5,000 shares authorized; 5,000 shares authorized; 5,000 and E — March 31, 2000 and E — Common stock, \$.01 par value, a	xchangeable preferred stock, 5 issued and outstanding at	——————————————————————————————————————
Series D cumulative convertible of authorized 21,000 shares; 12,01 March 31, 2000 and December 31, 1999 Series F convertible non-exch 5,000 shares authorized; 5,000 shares authorized; 5,000 and E March 31, 2000 and E Common stock, \$.01 par value, a lissued and outstanding 27,877, March 31, 2000 and December 31, 1999, respective	xchangeable preferred stock, 5 issued and outstanding at	120 - - -
Series D cumulative convertible of authorized 21,000 shares; 12,01 March 31, 2000 and December 31, 1999 Series F convertible non-exch 5,000 shares authorized; 5,000 shares authorized; 5,000 and E March 31, 2000 and E Common stock, \$.01 par value, a lissued and outstanding 27,877, March 31, 2000 and December 31, 1999, respective Additional paid-in capital	xchangeable preferred stock, 5 issued and outstanding at	120 273,086 73,638,128
Series D cumulative convertible of authorized 21,000 shares; 12,01 March 31, 2000 and December 31, 1999 Series F convertible non-exch 5,000 shares authorized; 5,000 shares authorized; 5,000 and E March 31, 2000 and E Common stock, \$.01 par value, a lissued and outstanding 27,877, March 31, 2000 and December 31, 1999, respective	xchangeable preferred stock, 5 issued and outstanding at	120 72 273,088 73,638,128 169,387
Series D cumulative convertible of authorized 21,000 shares; 12,01 March 31, 2000 and December 31, 1999 Series F convertible non-exch 5,000 shares authorized; 5,000 shares authorized; 5,000 and E March 31, 2000 and E Common stock, \$.01 par value, a Issued and outstanding 27,877, March 31, 2000 and December 31, 1999, respective Additional paid-in capital	xchangeable preferred stock, 5 issued and outstanding at	120 5 72 273,088 73,638,128

See notes to consolidated financial statements.

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

For the Three Months Ended March 31, 2000 and 1999 and for the Period from October 17, 1986 (inception) to March 31, 2000 (Unaudited)

	Three Months Er March 31	nded	ober 17, 1986 (inception) to March 31,
	2000	1999	2000
Rev	venues:		
- Contract research revenue - Sublicense revenue	,	\$ 26,	900 \$ 520,548 1,360,000
Total revenues	121,170	26,000	1,880,548
•	oenses:		
— Acquisition of rese ———————————————————————————————————	earch and developm 		29,975,000
Research and development			9 79 25,927,447
General and administrative	694,724 	499,6	63 22,537,189
— Total expenses	. 1,596,747	-1,180,642	78,439,636
Loss from operations	(1, 475,577)	(1,154,6 4	12) (76,559,088)
Interest income	 52,501	21,877	658,542
Interest expense	•	•	•
Minority interest in loss of subsidiary	<u>16,0</u>		 3,001,019
Loss before extraordinary item	(1,457,090)	(1,162	, 656) (73,522,915)
Extraordinary item			
Net loss	\$ (1,457,090) \$ (`	1,162,656) 	\$ (73,480,128)
Accretion of mandatorily redeemable preferred	stock		 (103,400)
Net loss - attributable to common shares		0) \$ (1, 1	-62,656) \$(73,583,528)
Weighted average con	nmon shares outsta	nding-	
- hasic and diluted		_	32 8 282 153

— Loss be	fore extra	ordina	ary item				
	\$	(0.0!	5) \$	(0.0)4) \$	(8.8)	38)
Extraordinary item						•	.01
Net loss per share		 \$	(0.05)	\$	(0.04)	 \$	- (8.87)

See notes to consolidated financial statements.

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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, 2000
(Unaudited)

Notes receivable in connection Additional Preferred Common with sale of paid-in stock Stock stock capital Balance at October 17, 1986..... \$ -- \$ -- \$ Common stock issued...... -- 11,340,864 37,400 18,066,219 Reincorporation in Delaware at \$.01 par value................ -- (11,220,369) -- 11,220,369 Issuance of common stock in connection with -- acquisition of Camelot Pharmacal, L.L.C..... -- 6,000 -- 1,644,000 Common stock options issued..... -- ---- 240,868 Common stock options extended..... -- --Accretion of issuance costs for Series A preferred stock..... --Common stock subscribed..... --Comprehensive income (loss):.... Net loss..... --Balance at December 31, 1997...... -- 126,495 (72,600) 31,386,644 Common stock issued..... ---144,089 62,600 12,472,966 11,499,885 Series C preferred stock dividends...... 4 -- -- 413,996 Accretion of issuance costs for Series A preferred stock..... -- --Comprehensive income (loss):..... Unrealized loss on marketable securities...... --Net loss..... Comprehensive income (loss)..... --Common stock issued...... -- 2,504 10,000 89,059

Series D preferred stock issued 120	
Series D preferred stock issued 120	12,014,880
Series F preferred stock issued 50	4,691,255
Common stock warrants issued	 203,452
Comprehensive income (loss):	
Unrealized gain on marketable securities	
Net loss	
Comprehensive income (loss)	
Balance at December 31, 1999	73,638,128
Common stock issued 5,684	1,474,891
Series C preferred stock dividends 2	- 225,998
Common stock warrants issued	 32,502
Comprehensive income (loss):	
— Unrealized gain on marketable securities	
— Net loss	
Comprehensive income (loss)	
<u></u>	
Balance at March 31, 2000 \$300 \$278,772 \$	 \$75,371,519

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

Balance at October 17, 1986 \$ \$ \$
Common stock issued 29,444,483
Reincorporation in Delaware at \$.01 par value
Issuance of common stock in connection with
acquisition of Camelot Pharmacal, L.L.C 1,650,000
Common stock options issued 240,868
Common stock options extended 215,188
Accretion of issuance costs for Series A preferred stock (79,500) (79,500)
Common stock subscribed (110,000)
Comprehensive income (loss):
Net loss (36,077,790)
— Comprehensive income (loss) (36,077,790)
Balance at December 31, 1997 (36,157,290) (4,716,751)
Common stock issued 12,679,655
Series C preferred stock issued 11,500,000
Series C preferred stock dividends (415,112) (1,112)
Accretion of issuance costs for Series A preferred stock (23,900) (23,900)
Comprehensive income (loss):
— Unrealized loss on marketable securities (222,226)
Net loss (18,560,461)
— Comprehensive income (loss) (18,782,687)

Balance at December 31, 1998	(222,226)	(55,156,763)	655,205
Common stock issued		 10	1,563
Series C preferred stock dividends		(868,277)	(2,277)
Series D preferred stock issued		 12, ()15,000
Series F preferred stock issued		 4, 6	91,305
Common stock warrants issued			203,452
Comprehensive income (loss):			
 Unrealized gain on marketable securities 	39) 1,613	
- Net loss	 (17,3 8	84,788)	
- Comprehensive income (loss)		 (16, 9	993,175)
Balance at December 31, 1999	169,387	(73,409,828)	671,073
Common stock issued		 1,48	:0,575
Series C preferred stock dividends		(226,135)	(135)
Common stock warrants issued			32,502
Comprehensive income (loss):			
 Unrealized gain on marketable securities 	 1,4 8	35,322 -	
- Net loss	 (1,45	57,090)	
- Comprehensive income (loss)			28,232
Balance at March 31, 2000 \$1,	654,709 \$	(75,093,053) 	\$2,212,247
		====	

See notes to consolidated financial statements.

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

Consolidated Statements of Cash Flows
For the Three Months Ended March 31, 2000 and 1999 and for
the Period from October 17, 1986 (inception) to
March 31, 2000
(Unaudited)

			31, (ind	ctober 17, 1986 ception) to March 31,
		2000	1999	2000
	Cash outflows from op	erating activitie	es:	
Net loss	justments to reconcile net) \$(73,480,128)
	- development sta	nge activities:	,	
services	suance of common stock, s	 44,502	62,567	2,529,927
- Non-cash a	equisition of research and c	levelopment in		chnology 550,000

— Depreciation and amortization	31,012 19,856 510,572
(Increase) decrease in prepaid expenses & other current ass	sets (204,475) 4,441 (408,753
— Decrease in other assets	
— Decrease in accounts payable and accrued liabilities	
— (Decrease) increase in sponsored research payable	 (21,969) 976,782
— Increase in unearned revenue	
Other	32,978 28,514 595,968
Net cash used by development stage activities	 (1,818,690) (1,092,641) (66,844,298)
Cash flows from investing	g activities:
- Acquisition of laboratory and office e	•
improvements	• •
Other	
	
Net cash used by investing activities	(34,907) (3,731) (502,621)
Cash flows from financing	g activities:
Payments on debt and capital leases	
— Net proceeds from iss	
— Debt	 500,000 5,050,000
— Common stock	 21,418,035
Preferred stock	 32,741,117
Proceeds from exercise of warrants/stock options	
Net cash provided by financing activities	
Not (degrees) in green in each and each equivalents	(200 545) (547 675) 2 400 000
Net (decrease) increase in cash and cash equivalents	
Cash and cash equivalents at beginning of period	
Cash and cash equivalents at end of period	
	
Noncash investing and finan	-
Common stock, stock options/warrants issued for services .	
— Common stock redeemed in payment of notes receival	
— Acquisition of research and deve	·
— technology	
Common stock issued for intellectual property rights	
Common stock issued to retire debt	•
Common stock issued to redeem convertible securities	-,,-
— Securities acquired under sublicense agreement	
— Equipment acquired under capital lease	
Notes payable converted to common stock	
Stock dividends	226,000 208,495 1,872,824
Supplemental disclosure of cash flow information: Interest pa	aid \$ 821 \$ 1,377 \$ 277,141

See notes to consolidated financial statements.

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

Notes to Consolidated Financial Statements March 31, 2000 (Unaudited)

BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared in accordance with the instructions to Form 10-Q of the Securities and Exchange Commission and should 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, 1999. 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, 2000 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. The results of operations for the three months ended March 31, 2000 and 1999 are not necessarily indicative of the operating results for the full years.

These consolidated financial statements include the accounts of Sheffield Pharmaceuticals, Inc. and its wholly owned subsidiaries, Systemic Pulmonary Delivery, Ltd., Ion Pharmaceuticals, Inc., and CP Pharmaceuticals, Inc., and its 80.1% owned subsidiary, Respiratory Steroid Delivery, Ltd. and are herein referred to as "Sheffield" or the "Company." All significant intercompany transactions are eliminated in consolidation.

The Company is focused on the development and commercialization of later stage, lower risk pharmaceutical products that utilize the Company's unique proprietary pulmonary delivery technologies. 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. 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.

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 period. Potentially dilutive securities such as stock options, warrants, convertible debt and preferred stock, have not been included in any periods presented as their effect is antidilutive.

3. RECLASSIFICATIONS

Certain amounts in the prior year financial statements and notes have been reclassified to conform to the current year presentation.

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Item 2.

Management's Discussion and Analysis of Financial Condition and Results of Operations

The following 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 thereby. All forward-looking statements involve risks and uncertainty. 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. Important factors that could cause actual results to differ materially from the forward-looking statements include the Company's need to obtain substantial additional capital (through financings or otherwise) to fund its operations and the progress of development and licensing/commercialization of the Company's technologies. 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 development and commercialization of later stage, lower risk pharmaceutical products that utilize the Company's unique proprietary pulmonary delivery technologies. The Company is in the development stage and, as such, has been principally engaged in the development of its pulmonary delivery systems. The Company and its development partners currently have nine products in various stages of development.

In 1997, the Company acquired the Metered Solution Inhaler ("MSI"), a portable nebulizer-based pulmonary delivery system, through a worldwide exclusive license and supply arrangement with Siemens AG ("Siemens"). 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. Additionally, during 1998, Sheffield licensed from Elan Corporation, plc ("Elan"), the Ultrasonic Pulmonary Drug Absorption System ("UPDAS(TM)"), a novel disposable unit dose nebulizer system, and Elan's Absorption Enhancing Technology ("Enhancing Technology"), a therapeutic agent to increase the systemic absorption of drugs. In October 1999, the Company licensed Elan's Nanocrystal(TM) technology to be used in developing certain steroid products.

Using the above pulmonary delivery systems and technologies as platforms, the Company has established strategic alliances for developing its initial products with Elan, Siemens and Zambon Group SpA ("Zambon").

In a collaboration with Zambon, the Company is developing a range of pharmaceutical products delivered by the MSI to treat respiratory diseases. Under its agreement with Zambon, MSI commercial rights for respiratory products have been sublicensed to Zambon in return for an equity investment in the Company (approximately 10%). The Company has maintained co-marketing rights for the U.S. The Company's ability to co-market MSI respiratory products in the U.S. requires no additional payment by the Company. Zambon has committed to fund the development costs for respiratory compounds delivered by the MSI, as well as make certain milestone payments and pay royalties on net sales to the Company resulting from these MSI products. Initial products for respiratory disease therapy delivered through the MSI include albuterol, ipratropium, cromolyn and inhaled steroids.

As part of a strategic alliance with Elan, a world leader in pharmaceutical delivery technology, the Company is developing therapies for non-respiratory diseases to be delivered to the lungs using both the ADDS and MSI. In 1998, the systemic applications of the MSI and ADDS were licensed to Systemic Pulmonary Delivery, Ltd. ("SPD"), a wholly owned subsidiary of the Company. In addition, two Elan technologies, UPDAS(TM) and the Enhancing Technology, were also licensed to SPD. The Company retained exclusive rights outside of the strategic alliance to respiratory disease applications utilizing the ADDS technology and the two Elan technologies. Two systemic compounds for pulmonary delivery are currently under development. For the treatment of breakthrough pain, the Company is developing morphine delivered through the MSI. Ergotamine, a therapy for the treatment of migraine headaches, is currently being developed for use in the ADDS.

In addition to the above alliance with Elan, in 1999, the Company and Elan formed a joint venture, Respiratory Steroid Delivery, Ltd. ("RSD"), to develop certain inhaled steroid products to treat respiratory diseases using Elan's NanoCrystal technology. The inhaled steroid products to be developed include a propellant-based steroid formulation for delivery through the ADDS, a solution-based unit-dose-packaged steroid formulation for delivery using a conventional tabletop nebulizer, and a solution-based steroid formulation for delivery using the MSI system, subject to further agreement with Zambon.

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Outside of these alliances, the Company owns the worldwide rights to respiratory disease applications of all of its technologies, subject only to the MSI respiratory rights sublicensed to Zambon.

Results of Operations

Revenue

Contract research revenues primarily represent revenue earned from a collaborative research agreement with Zambon relating to the development of respiratory applications of the MSI. Contract research revenue for the quarters ended March 31, 2000 and 1999 were \$121,170 and \$26,000, respectively. The

increase relates to three additional respiratory programs in development in the first quarter of 2000 as compared to 1999. Costs of contract research revenue approximate such revenue and are included in research and development expenses. Future contract research revenues and expenses are anticipated to fluctuate depending, in part, upon the success of current clinical studies, and obtaining additional collaborative agreements.

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 and other arrangements.

Research and Development

Research and development expenses were \$902,023 for the first quarter of 2000 as compared to \$680,979 for the first quarter of 1999. The increase of \$221,044 from 1999 primarily reflects costs associated with modifications being made to the MSI to enhance its commercial appeal prior to the start of Phase III MSI-albuterol clinical trials, partially offset by lower development and engineering costs related to the ADDS device.

General and Administrative

General and administrative expenses were \$694,724 for the quarter ended March 31, 2000, compared with \$499,663 for the same quarter of 1999. The increase from the first quarter of 1999 of \$195,061 was primarily due to higher consulting costs and legal fees associated with expanded business development activity.

Interest

Interest income was \$52,501 for the quarter ended March 31, 2000 as compared to \$21,877 for the same quarter of 1999. The \$30,624 increase in interest income was primarily due to larger balances of cash available for investment and higher average yields on those investments.

Interest expense was \$50,033 for the first quarter of 2000, compared with \$29,891 for the first quarter of 1999. The increase of \$20,142 in 2000 as compared to 1999 resulted from higher outstanding balances on the Company's convertible promissory note with Elan, as well as a higher average interest rate on the note.

Liquidity and Capital Resources

At March 31, 2000, the Company had \$3,487,892 in cash and cash equivalents compared to \$3,874,437 at December 31, 1999. The decrease of \$386,545 primarily reflects \$1,818,690 of cash disbursements used primarily to fund operating activities, partially offset by \$1,468,575 in net proceeds from the exercise of common stock options and warrants.

In October 1999, as part of a licensing agreement with Elan, the Company received gross proceeds of \$17,000,000 related to the issuance to Elan of 12,015 shares of Series D Cumulative Convertible Exchangeable Preferred Stock and 5,000 shares of Series F Convertible Non-Exchangeable Preferred Stock. In turn, the Company made an equity investment of \$12,015,000 in a joint venture, RSD, representing an initial 80.1% ownership. The remaining proceeds from the

above-mentioned preferred stock issuance will be utilized for general operating purposes. As part of the agreement, Elan also committed to purchase, on a drawdown basis, up to an additional \$4,000,000 of the Company's Series E Cumulative Convertible Preferred Stock ("Series E Preferred Stock"). The proceeds from the Series E Preferred Stock will be utilized by the Company to fund its portion of RSD's operating and development costs. As of March 31, 2000, no purchases of Series E Preferred Stock have been made.

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In May 1999, in conjunction with the completion of its Phase I/II MSI-albuterol trial, Zambon provided the Company with a \$1,000,000 interest-free advance against future milestone payments. Upon the attainment of certain future milestones, the Company will recognize this advance as revenue. If the Company does not achieve these future milestones, the advance must be repaid in quarterly installments of \$250,000 commencing January 1, 2002. The proceeds from this advance are not restricted as to their use by the Company. Upon the achievement of certain other technical milestones, Zambon will provide an additional \$1,000,000 advance under the terms of the agreement.

Since its inception, the Company has financed its operations primarily through the sale of securities and convertible debentures, from which it has raised an aggregate of approximately \$72.2 million through March 31, 2000, of which approximately \$30.0 million has been spent to acquire certain in-process research and development technologies, and \$25.9 million has been incurred to fund certain ongoing technology research projects. The Company expects to incur additional costs in the future, 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. Therefore, the Company will need substantial additional capital before it will recognize significant cash flow from operations, which is contingent on the successful commercialization of the Company's technologies. There can be no assurance that any of the technologies to which the Company currently has or may acquire rights 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.

PART II: OTHER INFORMATION

Item 2. Changes in Securities.

The following unregistered securities were issued by the Company during the quarter ended March 31, 2000:

Number of Number of
Shares
Sold/Issued
Description /Subject to
Date of Securities Options or Offering/Exercise
Sale/Issuance Issued Warrants Price per Share(\$) Purchaser or Class

January 2000 Common stock 21.524 #5.00 Advisory in lieu of such
January 2000 Common stock 21,524 \$5.00 Advisor in lieu of cash warrants. consideration.
January 2000 Common stock 45,000 \$5.00 Issuance to certain
Directors pursuant to
the 1996 Directors
Stock Option Plan.
March 2000 Common stock 4,465 \$2.69 Advisor in lieu of cash
consideration.

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 4. Submission of Matters to a Vote of Security Holders

A special meeting of stockholders was held on January 20, 2000. Listed below are the matters voted on by stockholders and the number of votes cast at the meeting.

(a) Approval of issuance of the Company's Series D Cumulative Convertible Exchangeable Preferred Stock and the Company's Common Stock issuable upon conversion of such Preferred Stock.

Voted For 14,535,522 Voted Against 765,533 Votes Withheld 161,450

(b) Approval of issuance of Series E Cumulative Convertible Non-Exchangeable Preferred Stock and the Company's Common Stock issuable upon conversion of such Preferred Stock. Voted For 14,516,258 Voted Again 784,198 Votes Withheld 162,549

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

No reports on Form 8-K were filed during the quarter ended March 31, 2000.

Exhibits

No. Description

27 Financial Data Schedule.

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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 11, 2000 /s/ Loren G. Peterson

Loren G. Peterson

President & Chief Executive Officer

Dated: May 11, 2000 /s/ Scott A. Hoffmann

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

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EX-27

2

ARTICLE 5 FDS

____5

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE CONDENSED FINANCIAL STATEMENTS FOR THE QUARTER ENDED MARCH 31, 2000 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH STATEMENTS.

3-MOS DEC-31-2000 MAR-31-2000 3,487,892 2,004,709 0 0 5,842,313 636,328 337,530 6,361,042 918,860 0 0
DEC-31-2000 MAR-31-2000 3,487,892 2,004,709 0 0 5,842,313 636,328 337,530 6,361,042 918,860 0
MAR-31-2000 3,487,892 2,004,709 0 0 5,842,313 636,328 337,530 6,361,042 918,860 0
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6,361,042
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(1,457,090)
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----END PRIVACY-ENHANCED MESSAGE-----