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QUARTERLY REPORT DATED 3/31/01

1

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, 2001

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)

14528 SOUTH OUTER FORTY 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 28,935,321

shares as of May 11, 2001.

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

FORM 10-Q
For the Quarter Ended March 31, 2001

Table of Contents

Page

PART I: FINANCIAL INFORMATION
Item 1. Financial Statements

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

ASSETS

	March 31, 2001 (unaudited)	December 31, 2000
Current assets:		
Cash and cash equivalents	$2,381,084	$3,041,948
Marketable equity securities	300,887	327,422
Milestone advance receivable	--	1,000,000
Prepaid expenses and other current assets	400,575	540,272
Total current assets	3,082,546	4,909,642
Property and equipment:		
Laboratory equipment	275,219	271,748
Office equipment	220,654	211,609
Leasehold improvements	18,320	18,320
Total at cost	514,193	501,677
Less accumulated depreciation and amortization	(261,891)	(235,389)
Property and equipment, net	252,302	266,288
Patent costs, net of accumulated amortization of $11,609 and $9,287, respectively	256,575	258,897
Other assets	15,830	15,830
Total assets	$3,607,253	$5,450,657

LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

Current liabilities:		
Accounts payable and accrued liabilities	$840,468	$1,234,765

Sponsored research payable	235,757	235,757
Total current liabilities	1,076,225	1,470,522
Convertible promissory note	2,000,000	2,000,000
Unearned revenue	2,000,000	2,000,000
Other long-term liabilities	448,850	393,855
Commitments and contingencies	--	--
Total liabilities	5,525,075	5,864,377
Minority interest in subsidiary	--	--
Stockholders' equity (net capital deficiency):		
Preferred stock, $.01 par value, authorized 3,000,0000 shares:		
Series C cumulative convertible preferred stock, authorized 23,000 shares; issued and outstanding 13,951 and 13,712 shares at March 31, 2001 and December 31, 2000, respectively	139	137
Series D cumulative convertible exchangeable preferred stock, authorized 21,000 shares; 12,870 issued and outstanding at March 31, 2000 and December 31, 2000	129	129
Series E cumulative convertible non-exchangeable preferred stock, authorized 9,000 shares; 1,004 shares issued and outstanding at March 31, 2001 and December 31, 2000, respectively	10	10
Series F convertible non-exchangeable preferred stock, 5,000 shares authorized; 5,000 shares issued and outstanding at March 31, 2001 and December 31, 2000	50	50
Common stock, $.01 par value, authorized 60,000,000 shares; issued and outstanding 28,905,321 and 28,791,643 shares at March 31, 2001 and December 31, 2000, respectively	289,053	287,916
Additional paid-in capital	80,449,759	80,108,095
Other comprehensive income	130,932	157,467
Deficit accumulated during development stage	(82,787,894)	(80,967,524)
Total stockholders' equity (net capital deficiency)	(1,917,822)	(413,720)
Total liabilities and stockholders' equity (net capital deficiency)	$3,607,253	$5,450,657

See notes to consolidated financial statements.

4

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

CONSOLIDATED STATEMENTS OF OPERATIONS
For the Three Months Ended March 31, 2001 and 2000 and for the Period

from October 17, 1986 (inception) to March 31, 2001
(Unaudited)

	Three Months Ended March 31,		October 17, 1986 (inception) to March 31,
	2001	2000	2001
Revenues:			
Contract research revenue	$ 180,747	$ 121,170	$ 1,081,697
Sublicense revenue	--	--	1,365,000
Total revenues	180,747	121,170	2,446,697
Expenses:			
Acquisition of research and development in-process technology	--	--	29,975,000
Research and development	1,045,773	902,023	29,818,634
General and administrative	758,269	694,724	25,093,354
Total expenses	1,804,042	1,596,747	84,886,988
Loss from operations	(1,623,295)	(1,475,577)	(82,440,291)
Interest income	28,383	52,501	759,332
Interest expense	(57,849)	(50,033)	(855,564)
Realized loss on sale of marketable securities.	--	--	(85,286)
Minority interest in loss of subsidiary	72,351	16,019	3,212,423
Loss before extraordinary item	(1,580,410)	(1,457,090)	(79,409,386)
Extraordinary item	--	--	42,787
Net loss	$(1,580,410)	$(1,457,090)	$(79,366,599)
Accretion of mandatorily redeemable preferred stock	--	--	(103,400)
Net loss - attributable to common shares	$(1,580,410)	$(1,457,090)	$(79,469,999)
Weighted average common shares outstanding- basic and diluted	28,828,015	27,588,397	9,665,089

Net loss per share of common stock - basic and diluted:			
Loss before extraordinary item.....	$(0.05)	$(0.05)	$(8.22)
Extraordinary item.....	--	--	--
Net loss per share.....	$(0.05)	$(0.05)	$(8.22)

See notes to consolidated financial statements.

5

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, 2001
(Unaudited)

	Preferred stock	Common Stock	Notes receivable in connection with sale of stock	Additional paid-in capital	Other comprehensive income (loss)
Balance at October 17, 1986.....	--	$ --	$ --	$ --	$ --
Common stock issued.....	--	11,484,953	100,000	30,539,185	--
Reincorporation in Delaware at $.01 par value.....	--	(11,220,369)	--	11,220,369	--
Common stock subscribed.....	--	--	(110,000)	--	--
Common stock options and warrants issued.....	--	--	--	240,868	--
Issuance of common stock in connection with acquisition of Camelot Pharmacal, L.L.C.....	--	6,000	--	1,644,000	--
Common stock options extended.....	--	--	--	215,188	--
Accretion of issuance costs for Series A preferred stock.....	--	--	--	--	--
Series C preferred stock issued.....	115	--	--	11,499,885	--
Series C preferred stock dividends.....	4	--	--	413,996	--
Comprehensive income (loss):					
Unrealized loss on marketable securities...	--	--	--	--	(222,226)
Net loss.....	--	--	--	--	--
Comprehensive income (loss).....	--	--	--	--	--
Balance at December 31, 1998.....	119	270,584	(10,000)	55,773,491	(222,226)

Common stock issued	--	2,504	10,000	89,059	--
Series C preferred stock dividends	9	--	--	865,991	--
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	--	--	--	--	391,613
Net loss	--	--	--	--	--
Comprehensive income (loss)	--	--	--	--	--
Balance at December 31, 1999	298	273,088	--	73,638,128	169,387
Common stock issued	--	15,738	--	3,796,072	--
Repurchase and retirement of common stock	--	(910)	--	(312,279)	--
Series C preferred stock dividends	9	--	--	931,991	--
Series D preferred stock dividends	9	--	--	854,991	--
Series E preferred stock issued	10	--	--	999,990	--
Series E preferred dividends		--	--	4,000	--
Common stock warrants issued	--	--	--	195,202	--
Comprehensive income (loss):					
Unrealized loss on marketable securities	--	--	--	--	(11,920)
Net loss	--	--	--	--	--
Comprehensive income (loss)	--	--	--	--	--
Balance at December 31, 2000	326	287,916	--	80,108,095	157,467
Common stock issued	--	1,137	--	60,546	--
Series C preferred stock dividends	2	--	--	238,998	--
Common stock warrants issued	--	--	--	42,120	--
Comprehensive income (loss):					
Unrealized loss on marketable securities	--	--	--	--	(26,535)
Net loss	--	--	--	--	--
Comprehensive income (loss)	--	--	--	--	--
Balance at March 31, 2001	$ 328	$ 289,053	$ --	$80,449,759	$ 130,932

See notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Three Months Ended March 31, 2001 and 2000 and for the Period from October 17, 1986 (inception) to March 31, 2001
(Unaudited)

	Three Months Ended March 31,		October 17, 1986 (inception) to March 31,
	2001	2000	2001
Cash outflows from operating activities:			
Net loss	$(1,580,410)	$(1,457,090)	$(79,366,599)
Adjustments to reconcile net loss to net cash used by development stage activities:			
Issuance of common stock, stock options/warrants for services	42,120	44,502	2,734,747
Depreciation and amortization	28,824	31,012	627,159
Non-cash acquisition of research and development in-process technology	--	--	1,650,000
Loss realized on sale of marketable securities	--	--	85,286
Decrease (increase) in prepaid expenses & other current assets	139,697	(204,475)	(459,616)
Decrease in milestone advance receivable	1,000,000	--	--
Increase in other assets	--	(5,239)	(224,973)
(Decrease) increase in accounts payable and accrued liabilities	(322,217)	(238,409)	479,285
(Decrease) increase in sponsored research payable	--	(21,969)	812,827
Increase in unearned revenue	--	--	2,000,000
Other	(16,287)	32,978	281,761
Net cash used by operating activities	(708,273)	(1,818,690)	(71,380,123)
Cash flows from investing activities:			
Proceeds from sale of marketable securities	--	--	594,759
Acquisition of laboratory and office equipment, and leasehold improvements	(12,516)	(34,907)	(684,335)
Other	--	--	(57,087)
Net cash used by investing activities	(12,516)	(34,907)	(146,663)
Cash flows from financing activities:			
Payments on debt and capital leases	(1,758)	(1,523)	(844,367)
Net proceeds from issuance of:			

Debt	--	--	5,050,000
Common stock	--	--	23,433,660
Preferred stock	--	--	33,741,117
Proceeds from exercise of warrants/stock options	61,683	1,468,575	13,339,589
Repurchase and retirement of common stock	--	--	(313,189)
Other	--	--	(500,024)
Net cash provided by financing activities	59,925	1,467,052	73,906,786
Net (decrease) increase in cash and cash equivalents	(660,864)	(386,545)	2,380,000
Cash and cash equivalents at beginning of period	3,041,948	3,874,437	1,084
Cash and cash equivalents at end of period	$ 2,381,084	$ 3,487,892	$ 2,381,084
Noncash investing and financing activities:			
Common stock, stock options/warrants issued for services	$ 42,120	$ 44,502	$ 2,734,747
Common stock redeemed in payment of notes receivable	--	--	10,400
Acquisition of research and development in-process technology	--	--	1,655,216
Common stock issued for intellectual property rights	--	--	866,250
Common stock issued to retire debt	--	--	600,000
Common stock issued to redeem convertible securities	--	--	5,353,368
Securities acquired under sublicense agreement	--	--	850,000
Equipment acquired under capital lease	--	--	121,684
Notes payable converted to common stock	--	--	749,976
Stock dividends	239,960	226,000	3,681,329
Supplemental disclosure of cash flow information: Interest paid	$ 585	$ 821	$ 279,845

See notes to consolidated financial statements.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2001
(Unaudited)

1. 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, 2000. 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, 2001 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, 2001 and 2000 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 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.

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. The Company's actual results may differ materially from the results anticipated in the forward-looking statements. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Important Factors that May Affect Future Results" included herein for a discussion of factors that could contribute to such material differences. 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. The Company disclaims any obligation to update or revise the information provided in this report to reflect future events.

OVERVIEW

The Company is a specialty pharmaceutical company focused on development and commercialization of later stage 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 ten 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 inhaled 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%). 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.

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 to Zambon by the Company. Zambon and the Company are having discussions regarding the possible modification of their agreement, including the future marketing arrangements for the MSI respiratory products. Concurrently, the Company is having discussions with third parties regarding an arrangement for the development and commercialization of MSI respiratory products in North America.

As part of a strategic alliance with Elan, 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.

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 revenues earned from a collaborative research agreement with Zambon relating to the development of respiratory applications of the MSI. Contract research revenues for the quarters ended March 31, 2001 and 2000 were $180,747 and $121,170, respectively. The increase of $59,577 from 2000 is due to higher costs associated with MSI device development work and testing prior to the start of Phase III MSI-albuterol clinical trials. Costs of contract research revenues approximate such revenues 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 $1,045,773 for the first quarter of 2001 as compared to $902,023 for the first quarter of 2000. The increase of $143,750 from 2000 primarily reflects higher development expenses related to RSD's unit-dose and MSI steroid products and feasibility studies associated with new product development, as well as higher costs associated with the above-mentioned increase in contract research revenues. The increase in research and development expenses also reflects higher ADDS device development costs, partially offset by nonrecurring costs incurred in the first quarter of 2000 associated with modifications made to the MSI to enhance its commercial appeal.

General and Administrative

General and administrative expenses were $758,269 for the quarter ended March 31, 2001, compared with $694,724 for the same quarter of 2000. The increase from the first quarter of 2000 of $63,545 was primarily due to higher consulting costs and legal fees associated with expanded business development and financing activities.

Interest

Interest income was $28,383 for the quarter ended March 31, 2001 as compared to $52,501 for the same quarter of 2000. The $24,118 decrease in interest income was primarily due to less cash available for investment and slightly lower yields on those investments.

Interest expense was $57,849 for the first quarter of 2001, compared with $50,033 for the first quarter of 2000. The increase of $7,816 in 2001 as compared to 2000 resulted from a slightly higher average interest rate on the Company's convertible promissory note with Elan.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2001, the Company had $2,381,084 in cash and cash equivalents compared to $3,041,948 at December 31, 2000. The decrease of $660,864 primarily reflects $1,708,273 of cash disbursements used to fund operating activities, partially offset by the receipt of a $1 million milestone advance from Zambon, and $61,683 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 $17.0 million 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 this preferred stock issuance were utilized for general operating purposes. As part

of the agreement, Elan has also committed to purchase, on a drawdown basis, up to an additional $4.0 million of the Company's Series E Preferred Stock, of which $3.0 million of such commitment remains outstanding. 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.

In May 1999, in conjunction with the completion of its Phase I/II MSI-albuterol trial, Zambon provided the Company with a $1.0 million interest-free advance against future milestone payments. In January 2001, the Company received an additional $1.0 million interest-free milestone advance resulting from the demonstration of the technical feasibility of delivering an inhaled steroid formulation in the MSI. Upon the attainment of certain future milestones, the Company will recognize these advances 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 these advances are not restricted as to their use by the Company.

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 $75.6 million through March 31, 2001, of which approximately $30.0 million has been spent to acquire certain in-process research and development technologies, and $29.8 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.

IMPORTANT FACTORS THAT MAY AFFECT FUTURE RESULTS

The following are some of the factors that could affect the Company's future results. They should be considered in connection with evaluating forward-looking statements contained in this report and otherwise made by the Company or on the Company's behalf, because these factors could cause actual results and conditions to differ materially from those projected in forward-looking statements.

The Company's future results are subject to risks and uncertainties including, but not limited to, the risks that (1) the Company may not be able to obtain additional financing on acceptable terms, or at all, to continue to fund its operations, and may be required to delay, reduce the scope of, or eliminate one or more of its research and development programs, or obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop; (2) the Company's product opportunities may not be successfully developed, proven to be safe and efficacious in clinical trials, may not meet applicable regulatory standards, may not receive the required regulatory approvals, or may not be produced in commercial quantities at reasonable costs or be successfully commercialized and marketed; (3) the Company may default in payments required under certain licensing agreements, thereby potentially forfeiting its rights under those agreements; (4) due to rapid technological change and innovation, the Company may not have a competitive advantage in its fields of technology or in any of the fields in which the Company may concentrate its efforts; (5) government regulation may prevent or delay regulatory approval of the Company's products; (6) the Company may not develop or receive sublicenses or other rights related to proprietary technology that are patentable, one or more of the Company's pending patents may not issue, any issued patents may not provide the Company with any competitive advantages, or issued patents may be challenged by third parties; (7) the Company may not have the resources available to build or otherwise acquire its own marketing capabilities, or agreements with other pharmaceutical companies to market the Company's products may not be reached on terms acceptable to the Company; (8) manufacturing and supply agreements entered into by the Company will not be adequate or the Company will not be able to enter into future manufacturing and supply agreements on acceptable terms; (9) private health insurance and government health program reimbursement price levels may not be sufficient to provide a return to the Company on its investment in new products and technologies; (10) the Company may not be able to maintain or obtain product liability insurance for any future clinical trials; (11) the failure to meet the American Stock Exchange's ("AMEX") listing guidelines may result in the Common Stock of the Company no longer being eligible for listing on the AMEX, which would make it more difficult for investors to dispose of, or to obtain accurate quotations as to the market value of the Company's Common Stock and would make it more difficult for the Company to raise additional funds; (12) announcements of developments in the

medical field generally, or in the Company's research areas or by the Company's competitors specifically, may have a materially adverse effect on the market

price of, the Company's Common Stock; (13) the exercise of options and outstanding warrants, the conversion of the Company's currently outstanding convertible securities or convertible promissory notes, or conversion of convertible securities issuable in the future may significantly dilute the market price of shares of the Company's Common Stock, and could impair the Company's ability to raise capital through the future sale of its equity securities.

Readers are also directed to other risks and uncertainties discussed, as well as to further discussion of the risks described above, in other documents filed by the Company with the Securities and Exchange Commission. The Company specifically disclaims any obligation to update or revise any forward-looking information, whether as a result of new information, future developments, or otherwise.

PART II: OTHER INFORMATION

Item 2. Changes in Securities

The following unregistered securities were issued by the Company during the quarter ended March 31, 2001:

Sale/Issuance	Date of Issued	Description of Securities Warrants	Number of Shares Subject to Options or Warrants	Exercise Price per Share ($)	Purchaser or Class
~~January 2001~~	~~Warrants to purchase Common stock.~~	~~27,440~~		~~$4.6875~~	~~Consultant 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 6. Exhibits and Reports on Form 8-K.

No reports on Form 8-K were filed during the quarter ended March 31, 2001.

Exhibits
None.

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, 2001 /s/ Loren G. Peterson

Loren G. Peterson
President & Chief Executive Officer

Dated: May 11, 2001 /s/ Scott A. Hoffmann

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