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FORM 10-Q FOR QUARTER ENDING MARCH 31, 2002

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, 2002

Commission file number 1-12584

SHEFFIELD PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its Charter)

DELAWARE	13-3808303
(State of Incorporation)	(IRS Employer 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 29,563,712 shares as of May 10, 2002.

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

FORM 10-Q
For the Quarter Ended March 31, 2002

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Item 1. Financial Statements

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

ASSETS	March 31,	December 31,

	2002	2001
	(unaudited)	
Current assets:		
Cash and cash equivalents	$1,056,918	$ 859,298
Clinical supplies	499,422	427,550
Prepaid expenses and other current assets	90,732	86,080
Total current assets	1,647,072	1,372,928
Property and equipment:		
Laboratory equipment	462,949	431,920
Office equipment	245,019	245,019
Leasehold improvements	25,309	25,309
Total at cost	733,277	702,248
Less accumulated depreciation and amortization	(391,066)	(355,014)
Property and equipment, net	342,211	347,234
Patent costs, net of accumulated amortization of $23,349 and $20,216, respectively	308,224	308,203
Other assets	28,214	27,913
Total assets	$2,325,721	$ 2,056,278
LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)		
Current liabilities:		
Accounts payable	$2,102,848	$ 856,216
Accrued liabilities	123,825	441,778
Sponsored research payable	235,757	235,757
Note payable	--	4,000,000
Total current liabilities	2,462,430	5,533,751
Convertible promissory note	2,000,000	2,000,000
Long-term debt	8,000,000	3,000,000
Other long-term liabilities	845,001	608,803
Commitments and contingencies	--	--
Total liabilities	13,307,431	11,142,554
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 14,965 and 14,708 shares at March 31, 2002 and December 31, 2001, respectively	150	147
Series D cumulative convertible exchangeable preferred stock, authorized 21,000 shares; 13,779 issued and outstanding at March 31, 2002 and		

December 31, 2001	138	138
Series E cumulative convertible non-exchangeable preferred stock, authorized 9,000 shares; issued and outstanding 3,124 and 2,124 shares at March 31, 2002 and December 31, 2001, respectively	31	21
Series F convertible non-exchangeable preferred stock, 5,000 shares authorized; 5,000 shares issued and outstanding at March 31, 2002 and December 31, 2001	50	50
Common stock, $.01 par value, authorized 100,000,000 shares; issued and outstanding 29,068,712 and 29,001,602 shares at March 31, 2002 and December 31, 2001, respectively	290,687	290,016
Additional paid-in capital	84,615,171	83,120,316
Other comprehensive income	--	--
Deficit accumulated during development stage	(95,887,937)	(92,496,964)
Total stockholders' equity (net capital deficiency)	(10,981,710)	(9,086,276)
Total liabilities and stockholders' equity (net capital deficiency)	$2,325,721	$ 2,056,278

See notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF OPERATIONS
For the Three Months Ended March 31,
2002 and 2001 and for the Period
from October 17, 1986 (inception) to March 31, 2002
(Unaudited)

	Three Months Ended March 31,		October 17, 1986 (inception) to March 31,
	2002	2001	2002
Revenues:			
Contract research revenue	$ --	$ 180,747	$ 1,770,045
Sublicense revenue	--	--	1,370,000
Total revenues	--	180,747	3,140,045
Expenses:			
Acquisition of research and development in-process technology	--	--	29,975,000
Research and development	1,153,790	1,045,773	35,926,345
General and administrative	1,938,666	758,269	30,825,412
Total expenses	3,092,456	1,804,042	96,726,757
Loss from operations	(3,092,456)	(1,623,295)	(93,586,712)
Interest income	2,662	28,383	792,049
Interest expense	(149,831)	(57,849)	(1,223,401)
Realized loss on sale of marketable securities	--	--	(5,580)
Minority interest in loss of subsidiary	106,042	72,351	3,624,735
Net loss	$ (3,133,583)	$ (1,580,410)	$(90,398,909)
Preferred stock dividends	(552,663)	(487,775)	(6,282,183)
Accretion of mandatorily redeemable preferred stock	--	--	(103,400)
Net loss -- attributable to common shares	$ (3,686,246)	$ (2,068,185)	$(96,784,492)
Weighted average common shares outstanding- basic and diluted	29,024,008	28,828,015	10,914,442
Net loss per share of common stock -- basic and diluted	$ (0.13)	$ (0.07)	$ (8.87)

See notes to consolidated financial statements.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(a development stage enterprise)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)
For the Period from October 17, 1986 (Inception) to March 31, 2002
(Unaudited)

	Preferred stock	Common Stock	Notes receivable in connection with sale of stock	Additional paid-in capital
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 issued	--	2,504	10,000	89,059
Common stock options and warrants issued	--	--	--	444,320
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	13	--	--	1,279,987
Series D preferred stock issued	120	--	--	12,014,880
Series F preferred stock issued	50	--	--	4,691,255
Comprehensive income (loss):				
Unrealized gain on marketable securities	--	--	--	--
Net loss	--	--	--	--
Comprehensive loss	--	--	--	--
Balance at December 31, 1999	298	273,088	--	73,638,128
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 stock dividends		--	--	4,000
Common stock warrants issued	--	--	--	195,202
Comprehensive income (loss):				
Unrealized loss on marketable securities	--	--	--	--
Net loss	--	--	--	--
Comprehensive loss	--	--	--	--
Balance at December 31, 2000	326	287,916	--	80,108,095
Common stock issued	--	4,251	--	481,201
Repurchase and retirement of common stock	--	(2,151)	--	(640,691)
Series C preferred stock dividends	10	--	--	995,990
Series D preferred stock dividends	9	--	--	928,991
Series E preferred stock issued	10	--	--	999,990

Series E preferred stock dividends.....	1	--	--	119,999
Common stock warrants issued.....	--	--	--	126,741
Comprehensive income (loss):				
Unrealized loss on marketable securities...	--	--	--	--
Net loss.....	--	--	--	--
Comprehensive loss.....	--	--	--	--
Balance December 31, 2001.....	$ 356	$ 290,016	$ --	$ 83,120,316
Common stock issued.....	--	671	--	16,329
Series C preferred stock dividends.....	3	--	--	256,997
Series E preferred stock issued.....	10	--	--	999,990
Common stock warrants issued.....	--	--	--	221,539
Net loss.....	--	--	--	--
Balance March 31, 2002.....	$ 369	$ 290,687	$ --	$ 84,615,171

	Other comprehensive income (loss)	Deficit accumulated during development stage	Total stockholders' equity (net capital deficiency)
Balance at October 17, 1986.....	$ --	$ --	$ --
Common stock issued.....	--	--	42,124,138
Reincorporation in Delaware at $.01 par value..	--	--	--
Common stock subscribed.....	--	--	(110,000)
Common stock issued.....	--	--	101,563
Common stock options and warrants issued.....	--	--	444,320
Issuance of common stock in connection with acquisition of Camelot Pharmacal, L.L.C....	--	--	1,650,000
Common stock options extended.....	--	--	215,188
Accretion of issuance costs for Series A preferred stock.....	--	(103,400)	(103,400)
Series C preferred stock issued.....	--	--	11,500,000
Series C preferred stock dividends.....	--	(1,283,389)	(3,389)
Series D preferred stock issued.....	--	--	12,015,000
Series F preferred stock issued.....	--	--	4,691,305
Comprehensive income (loss):			
Unrealized gain on marketable securities...	169,387	--	--
Net loss.....	--	(72,023,039)	--
Comprehensive loss.....	--	--	(71,853,652)
Balance at December 31, 1999.....	169,387	(73,409,828)	671,073
Common stock issued.....	--	--	3,811,810
Repurchase and retirement of common stock.....	--	--	(313,189)
Series C preferred stock dividends.....	--	(934,045)	(2,045)
Series D preferred stock dividends.....	--	(855,750)	(750)
Series E preferred stock issued.....	--	--	1,000,000
Series E preferred stock dividends.....	--	(4,750)	(750)
Common stock warrants issued.....	--	--	195,202
Comprehensive income (loss):			
Unrealized loss on marketable securities...	(11,920)	--	--

Net loss	--	(5,763,151)	--
Comprehensive loss	--	--	(5,775,071)
Balance at December 31, 2000	157,467	(80,967,524)	(413,720)
Common stock issued	--	--	485,452
Repurchase and retirement of common stock	--	--	(642,842)
Series C preferred stock dividends	--	(999,278)	(3,278)
Series D preferred stock dividends	--	(929,603)	(603)
Series E preferred stock issued	--	--	1,000,000
Series E preferred stock dividends	--	(121,422)	(1,422)
Common stock warrants issued	--	--	126,741
Comprehensive income (loss):			
Unrealized loss on marketable securities	(157,467)	--	--
Net loss	--	(9,479,137)	--
Comprehensive loss	--	--	(9,636,604)
Balance December 31, 2001	$ --	$(92,496,964)	$ (9,086,276)
Common stock issued	--	--	17,000
Series C preferred stock dividends	--	(257,390)	(390)
Series E preferred stock issued	--	--	1,000,000
Common stock warrants issued	--	--	221,539
Net loss	--	(3,133,583)	(3,133,583)
Balance March 31, 2002	$ --	$(95,887,937)	$(10,981,710)

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, 2002 and 2001 and for the Period from October 17, 1986 (inception) to March 31, 2002
(Unaudited)

	Three Months Ended March 31,		October 17, 1986 (inception) to March 31,
	2002	2001	2002
Cash outflows from operating activities:			
Net loss	$ (3,133,583)	$ (1,580,410)	$(90,398,909)
Adjustments to reconcile net loss to net cash used by development stage activities:			
Issuance of common stock, stock options/warrants for services	221,539	42,120	3,040,907

Depreciation and amortization	39,185	28,824	768,075
Non-cash acquisition of research and development in-process technology	--	--	1,650,000
Loss realized on sale of marketable securities	--	--	5,580
(Increase) decrease in clinical supplies, prepaid expenses & other current assets	(76,524)	139,697	(649,195)
Decrease in milestone advance receivable	--	1,000,000	--
Increase in other assets	(3,454)	--	(300,746)
Increase (decrease) in accounts payable and accrued liabilities	1,124,040	(322,217)	2,278,188
Increase in sponsored research payable	--	--	812,827
Other	42,476	(16,287)	268,179
Net cash used by operating activities	(1,786,321)	(708,273)	(82,525,094)
Cash flows from investing activities:			
Proceeds from sale of marketable securities	--	--	844,420
Acquisition of laboratory and office equipment, and leasehold improvements	(31,029)	(12,516)	(903,419)
Other	--	--	(57,087)
Net cash used by investing activities	(31,029)	(12,516)	(116,086)
Cash flows from financing activities:			
Payments on debt and capital leases	(2,030)	(1,758)	(852,066)
Net proceeds from issuance of:			
Debt	1,000,000	--	13,050,000
Common stock	--	--	23,433,660
Preferred stock	1,000,000	--	35,741,117
Proceeds from exercise of warrants/stock options	17,000	61,683	13,780,358
Repurchase and retirement of common stock	--	--	(956,031)
Other	--	--	(500,024)
Net cash provided by financing activities	2,014,970	59,925	83,697,014
Net increase (decrease) in cash and cash equivalents	197,620	(660,864)	1,055,834
Cash and cash equivalents at beginning of period	859,298	3,041,948	1,084
Cash and cash equivalents at end of period	$ 1,056,918	$ 2,381,084	$ 1,056,918
Noncash investing and financing activities:			
Common stock, stock options/warrants issued for services	$ 221,539	$ 42,120	$ 3,040,907
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	257,390	239,960	8,749,064
Supplemental disclosure of cash flow information:			
Interest paid	$ 923	$ 585	$ 287,243

See notes to consolidated financial statements.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2002
(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, 2001. 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, 2002 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, 2002 and 2001 are not necessarily indicative of the operating results for the full years.

The 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 accompanying consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company is 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 of rights to its technology, 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 2002 is dependent upon obtaining additional funding. In an effort to meet its capital requirement, the Company will be evaluating various financing alternatives including private offerings of its securities, debt financing, and collaboration and licensing arrangements with other companies. However, the accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. BASIC LOSS PER COMMON SHARE

Basic net loss per share is calculated in accordance with Statement of Financial Accounting Standards No. 128, Earnings Per Share. Basic net loss per share is based upon the weighted average common stock outstanding during each 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. SUBSEQUENT EVENTS

On April 5, 2002, Elan International Services, Ltd. exercised a portion of a warrant that it had received in June 1998 as part of a strategic alliance with the Company and purchased 495,000 shares of Sheffield's common stock at $2.00 per share. Sheffield received approximately $1.0 million in proceeds as a result of the exercise of a portion of this warrant.

On April 4, 2002, the Company amended the Note Purchase Agreement dated as of August 14, 2001 ("Agreement"), with Elan Pharma International Ltd. ("Elan Pharma"). Under the terms of the amended Agreement, Elan Pharma agreed to increase the principal amount of the loan available from $4 million to $5 million and extend the maturity date from November 14, 2002 to April 4, 2004. On April 5, 2002, the Company received proceeds on the loan of $1

million, increasing the total borrowings to $5 million. All borrowings under the Agreement are evidenced by a $5 million unsecured promissory note of the Company that provides for interest on principal and semi-annually compounded interest at a fixed rate of 10% per annum. Due to the modification of the maturity date, the borrowings under the Agreement, totaling $4 million at March 31, 2002, have been classified in the Company's balance sheet as long-term debt.

In September 2001, in connection with the amendment of its 1998

agreement with Zambon, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Zambon, pursuant to which Zambon agreed to lend the Company $2.5 million. The Company received $1.0 million upon signing of the Loan Agreement and $1.0 million on January 2, 2002. On April 5, 2002, the Company received the final installment on the loan of $.5 million. The Loan Agreement provides for interest on principal and annually compounded interest at a fixed rate of 2% per annum and is secured by certain security interests in respiratory products developed in the Company's Premaire(R) drug delivery technology. One third of the principal balance, together with interest, is payable by the Company upon the Company's execution of an agreement with one or more third parties to develop, co-promote and/or sell certain products in North America, with all remaining unpaid principal and interest due on December 31, 2005.

4. RECLASSIFICATIONS

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

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

Sheffield Pharmaceuticals, Inc. ("Sheffield" or the "Company") provides innovative, cost-effective pharmaceutical therapies by combining state-of-the-art pulmonary drug delivery technologies with existing and emerging therapeutic agents. The Company is developing a range of products to treat respiratory and systemic diseases in its proprietary Premaire(R) Delivery System ("Premaire") and Tempo(TM) Inhaler ("Tempo"). The Company is in the development stage and, as such, has been principally engaged in the development of its pulmonary delivery systems.

In 1997, the Company acquired the Premaire, 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, Tempo, from a subsidiary of Aeroquip-Vickers, Inc. ("Aeroquip-Vickers"). The Tempo 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"), 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.

Sheffield's lead drug delivery technology, the Premaire, is a patented, multi-dose nebulizer delivery system. The pocket-sized inhaled drug delivery system features an ultrasonic nebulizer that emits high-frequency sound waves that turn liquid medication into a fine cloud or soft mist. The Premaire combines the therapeutic benefits of nebulization with the convenience of pressurized metered dose inhalers, or pMDIs, in one patient-friendly device. The Premaire is comprised of a hand-held ultrasonic nebulizer and drug-filled cartridges that are inserted into the inhaler unit. The cartridges provide patients who must take multiple respiratory medications with a single, easy-to-use system. The Company believes the soft mist created by the Premaire provides multiple drug administration advantages over the high-velocity pMDIs and dry powder inhalers. Furthermore, the Premaire system is fast and portable as compared to conventional tabletop nebulizers, which are large, cumbersome and more time consuming to use. The Premaire system targets younger and older asthma patients, as well as older chronic obstructive pulmonary disease patients who have difficulty using pMDIs and currently depend on tabletop nebulizers for delivery of their medications.

Sheffield's Tempo is a patented, new generation pMDI that the Company believes has significant efficiency and performance advantages over standard pMDIs. The Tempo technology utilizes a standard aerosol pMDI canister, encased in a compact device that provides an aerosol flow-control chamber and a synchronized triggering mechanism. The aerosol flow-control chamber allows the patient to inhale through the device at a normal breathing rate, instead of a forced

breath. The inspiratory breath establishes flow fields within the device that mix and uniformly disperse the drug in the breath. At the mouthpiece, nearly all the propellant is evaporated leaving only drug particles to be inspired, allowing a significant increase in the amount of drug delivered to the lungs. The Tempo system, like the Premaire system, is designed to reduce patient coordination problems and enhance compliance with the prescribed treatment.

In June 1998, the Company sublicensed to Zambon Group SpA ("Zambon") worldwide marketing and development rights to respiratory products to be delivered by the Premaire in return for an equity investment in the Company (approximately 10%). From June 1998 to September 2001, Zambon funded the development costs for the respiratory compounds delivered by Premaire. In September 2001, the Company amended its 1998 agreement with Zambon whereby Sheffield regained the rights to the Premaire

previously granted to Zambon. As part of the amended agreement, Zambon provided a low-interest, $2.5 million loan to Sheffield to progress the development of the Premaire respiratory program. Upon commercialization, Zambon will be entitled to certain royalties on payments received by Sheffield for albuterol, ipratropium and cromolyn sales for specified periods.

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 Tempo and Premaire. In 1998, the systemic applications of Premaire and Tempo 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 Tempo technology and the two Elan technologies.

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. Currently, RSD is developing 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 Premaire.

RESULTS OF OPERATIONS

Revenue

Contract research revenues primarily represented revenues earned from a collaborative research agreement with Zambon relating to the development of respiratory applications of Premaire. Contract research revenues for the first quarter of 2002 and 2001 were $0 and $180,747, respectively. The decrease was due to Sheffield no longer performing development work for Zambon as a result of Sheffield regaining the Premaire respiratory rights in the third quarter of 2001. Costs of contract research revenue approximated such revenues in 2001 and were included in research and development expenses. Future contract research revenues and expenses are anticipated to fluctuate depending, on part, in

obtaining additional collaborative agreements and upon the success of current clinical studies.

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 ("R&D") expenses were $1.2 million and $1.1 million for the first quarter of 2002 and 2001, respectively. The increase of $.1 million from 2001 primarily reflects higher development expenses related to RSD's unit-dose ($.2 million) and Premaire steroid ($.1 million) products, partially offset by lower expenses related to formulation work on certain Tempo respiratory products ($.1 million) and formulation and feasibility work associated with new product development in the area of polypeptides ($.1 million).

The following details the status of each of the Company's development programs as of March 31, 2002:

Premaire Respiratory Program:

As a result of the Company regaining from Zambon the rights to the respiratory applications to the Premaire in September 2001, the sponsorship of the Premaire respiratory development programs was transferred from Zambon to the Company with the Food and Drug Administration ("FDA") being notified accordingly. In the fourth quarter of 2001, Sheffield reviewed all of the development work completed-to-date, identifying a number of deficiencies in the Zambon development program. To address these issues, Sheffield has made a number of internal management changes and moved the program to a group of highly experienced pulmonary clinical and regulatory experts. The Premaire device is currently in a to-be-marketed form and fully industrialized. As of March 31, 2002, the Company had spent $3.3 million on developing the respiratory products discussed below.

The Company's strategy is to out license the U.S. rights to the Premaire respiratory products to a third party which the Company anticipates concluding in 2003. As a result, the Company estimates a U.S. commercial launch of its first products in Premaire to occur in the last half of 2005 or first half of 2006. Sheffield will fund the continued development work for the Premaire respiratory products up through the period of outlicensing, currently estimated at approximately $10 million, after which time the licensee will assume funding responsibility for further development work.

Albuterol Sulfate. Zambon initiated a Phase II clinical trial in December 1999 that compared the Premaire-albuterol sulfate to a conventional albuterol-pMDI. Findings from Phase II studies indicated

that Premaire-albuterol and pMDI-albuterol were comparable in improving lung function in the 24 adult patients. An end of Phase II meeting was held in February 2002 with the FDA where the results of the development activities-to-date, specifically the results of the Phase II trial, were reviewed. The Company is currently reviewing the FDA's comments and recommendations, integrating the information into the plans for the Phase III trial and NDA submission. The Company expects to begin pivotal clinical trials for the albuterol sulfate program by the end of 2002.

Budesonide. Preclinical formulation development work is currently underway. A formulation developed by Nanosystems has proven a feasible candidate for delivery in the Premaire. The formulation is dependent on a proprietary nanocrystaline dispersion of budesonide in an aqueous carrier. Two other alternative formulation approaches are also under evaluation. Upon scale-up and production of clinical batches released under CMC protocol, an Investigational New Drug Application ("IND") will be prepared for filing with the FDA, which is currently planned for the first half of 2003.

Ipratropium Bromide. Zambon initiated a Phase I/II clinical trial in Europe in January 2000 assessing the safety and efficacy compared to a commercially available ipratropium bromide product delivered by a pMDI and placebo in patients with COPD. The results of the study indicated that both Premaire-ipratropium bromide and pMDI-ipratropium were tolerated and improved lung function in the COPD patients. An IND was filed by Zambon with the FDA in May 2000. During 2001, the IND was transferred to the Company. The Company does not intend to further develop this product on its own as the program has progressed to the point where a potential licensing partner would be in a position to take the product into clinical studies.

Sodium Cromoglycate. An IND was filed by Zambon with the FDA in July 2000. No further development work is anticipated to be completed on this product as the projected market opportunity for sodium cromoglycate is currently deemed too small to justify further progression.

Premaire Systemic Program:

Through its development alliance with Elan and SPD, the Company evaluated certain drugs for systemic treatment by pulmonary delivery through Premaire. By identifying a market opportunity for a rapid-acting, non-invasive treatment for breakthrough pain, the first drug to be tested for delivery in Premaire was morphine. In July 1999, the Company completed a gamma scintigraphy/pharmacokinetic trial comparing morphine delivered using the Premaire to subcutaneous injection. The Premaire demonstrated good pulmonary deposition and very rapid absorption, more rapid peak blood levels vs. subcutaneous injection and low oral and throat deposition. As part of the development alliance with Elan, Elan has the first right of refusal on the development of any product developed by the joint venture. Elan has chosen not to license this product from the joint venture. As such, the joint venture continues to seek to attract a partner for the continued development and commercialization of this product. The Company has spent $.4 million to date to develop this product and does not

anticipate incurring any future costs for further development until such time as a licensing partner is secured.

Tempo Respiratory Program:

In September 2000, the Company completed a pilot study using the Tempo to deliver an undisclosed, patented respiratory drug used to treat asthma. The study measured the distribution of this respiratory drug delivered by Tempo compared to the distribution of this same drug delivered through a commercially available pMDI in 12 healthy volunteers. Results of this study demonstrated that Tempo significantly increased drug deposition in all regions of the lung. Tempo delivered approximately 200% more drug to the lungs, deposited approximately 75% less drug in the mouth, and increased dosing consistency by approximately 55% compared to the currently marketed form of this same drug. As of March 31, 2002, the Company has incurred approximately $.9 million to-date on this study. The Company is using the results of this study as a basis for conducting discussions for feasibility work and/or clinical studies with potential collaboration partners.

Tempo Systemic Program:

The development of systemic drugs using Tempo is being conducted as part of the Company's alliance with Elan. The initial product developed was targeted to address migraine headaches. The Company utilized ergotamine tartrate as a proof-of-principle product. In December 1999, the Company completed a gamma scintigraphy/pharmacokinetic trial comparing the Tempo to a conventional pMDI. The trial showed successful delivery of the drug to all regions of lung with significantly reduced mouth and throat deposition, and rapid drug absorption. As part of the development alliance

with Elan, Elan has the first right of refusal on the development of any product developed by the joint venture. Elan has chosen not to license this product from the joint venture. As such, the joint venture continues to seek to attract a partner for the continued development and commercialization of this product. As of March 31, 2002, the Company has spent $1.0 million to date to develop this product and does not anticipate incurring any future costs for further development until such time as a licensing partner is secured.

As a result of the work performed on the ergotamine product noted above, in April 2002, the Company announced the initiation of a pulmonary migraine therapy program with Inhale Therapeutic Systems ("Inhale"), a world-renowned expert in particle design. Sheffield will combine Inhale's supercritical fluid technology with Sheffield's proprietary drug delivery technologies to develop a systemically acting dyhydroergotamine ("DHE") administered through the pulmonary route. The Company plans to study DHE in sub-categories of migraine where DHE administered by injection is often used to relieve migraine symptoms. These sub-categories are the more serious forms of migraine and often require either hospitalization or treatment in pain or headache clinics. Under the terms of the agreement, Inhale will supply the

particle engineering technology and receive R&D funding, milestone payments, and royalties upon commercialization. Sheffield is responsible for all other aspects of clinical development and marketing of the product. As part of this agreement, Inhale will produce DHE particles using Good Manufacturing Practices (GMP) for clinical development and commercial sale. The treatment of migraine represents a worldwide prescription market valued at $2.4 billion. As of March 31, 2002, the Company has incurred approximately $.2 million to-date related to this project. Future costs related to this project are dependent upon, among other factors, the timing of securing a development partner. The Company estimates incurring approximately $3.0 million in 2002 related to the development of the DHE project.

Unit Dose Nebulizer Program:

As part of an alliance with Elan, RSD is developing a product for inhalation delivery in a standard commercial tabletop device using the steroid budesonide, formulated using the NanoCrystal technology. A Phase I, double-blind safety and pharmacokinetic study of nebulized nanobudesonide in 16 healthy volunteers was satisfactorily completed at Thomas Jefferson University Hospital in February 2002. This study compared single doses of Pulmicort Respules ("Pulmicort"), the Company's proprietary nanobudesonide in two different single dose strengths and placebo. The study resulted in no significant adverse events with either of the Company's dosage strengths or the Pulmicort reference drug. Data from the study is currently undergoing final data and statistical analysis. After such data has been analyzed, the Company plans on initiating discussions with potential partners regarding the outlicensing of this opportunity. As of March 31, 2002, the Company incurred approximately $2.6 million to-date on this project. Sheffield will fund the continued development work for this program up through the period of outlicensing, currently estimated at approximately $1.9 million, after which time it is anticipated that the licensee will assume funding responsibility for further development work.

General and Administrative

General and administrative expenses were $1.9 million for the first quarter of 2002 as compared to $.8 million for the first quarter of 2001. The increase of $1.1 million from 2001 was primarily due to higher consulting costs, legal fees and severance-related costs. The higher consulting costs and legal fees were associated with expanded business development, and merger and acquisition activities in the area of licensing and partnering of the Company's delivery systems, as well as potential acquisitions of complementary pulmonary delivery technologies and companies ($.6 million). The severance costs were associated with the resignation of two executive officers in the first quarter of 2002 and include the costs incurred pursuant to their respective separation agreements for severance payments and ongoing benefit coverage ($.3 million) and modification of the terms of certain stock options ($.2 million).

Interest

Interest income was $2,662 for the first quarter of 2002 as compared to $28,383 for the first quarter of 2001. The decrease in interest income from 2001 was primarily due to less cash available for investment and lower yields on those

investments.

Interest expense was $149,831 for the first quarter of 2002 as compared to $57,849 for the first quarter of 2001. The increase of $91,982 from 2001 resulted primarily from interest associated with the borrowings of $4 million on the August 2001 Note Purchase Agreement with Elan Pharma.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2002, the Company had $1.1 million in cash and cash equivalents compared to $.9 million at December 31, 2001. The increase of $.2 million primarily reflects the receipt of $1.0 million from the issuance of 1,000 shares of the Company's Series E Cumulative Convertible Preferred Stock and $1.0 million from the proceeds of a secured loan from Zambon, partially offset by cash disbursements of $1.8 million used primarily to fund operating activities.

In addition to the $1.1 million of cash and equivalents at March 31, 2002, the Company received a total of $2.5 million of additional funding in April 2002. On April 5, 2002, Elan exercised a portion of a warrant that it had received in June 1998 as part of a strategic alliance with the Company and purchased 495,000 shares of Sheffield's common stock at $2.00 per share. Sheffield received approximately $1.0 million in proceeds as a result of the exercise of a portion of this warrant. In addition, the Company amended its Note Purchase Agreement dated August 14, 2001 with Elan Pharma, receiving $1 million in proceeds on April 5, 2002 (see below). Also, on April 5, 2002, the Company received the final installment of $.5 million on its Loan and Security Agreement with Zambon (see below).

On August 14, 2001, the Company entered into a Note Purchase Agreement ("Agreement") with Elan Pharma, pursuant to which Elan Pharma agreed to lend the Company up to $4 million. On April 4, 2002, the Company amended the Agreement. Under the terms of the amended Agreement, Elan Pharma agreed to increase the principal amount of the loan available from $4 million to $5 million and extend the maturity date from November 14, 2002 to April 4, 2004. On April 5, 2002, the Company received proceeds on the loan of $1 million, increasing the total borrowings to $5 million. All borrowings under the Agreement are evidenced by a $5 million unsecured promissory note of the Company that provides for interest on principal and semi-annually compounded interest at a fixed rate of 10% per annum. Due to the modification of the maturity date, the borrowings under the Agreement, totaling $4 million at March 31, 2002, have been classified in the Company's balance sheet as long-term debt.

In September 2001, in connection with the amendment of its 1998 agreement with Zambon, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Zambon, pursuant to which Zambon agreed to lend the Company $2.5 million. The Company received $1.0 million upon signing of the Loan Agreement and $1.0 million on January 2, 2002. On April 5, 2002, the Company received the final installment on the loan of $.5 million. The Loan Agreement provides for interest on principal and annually compounded interest at a fixed rate of 2% per annum and is secured by certain security interests in respiratory products developed in the Premaire. One third of the principal balance, together with interest, is payable by the Company upon the Company's execution of an

agreement with one or more third parties to develop, co-promote and/or sell certain products in North America, with all remaining unpaid principal and interest due on December 31, 2005. On October 17, 2001, as part of the amendment of its 1998 agreement with Zambon, the Company repurchased from Zambon, 214,997 shares of common stock for $3.0233 per share ("Repurchase Price"). In addition, the Company received an option, expiring December 31, 2002, to repurchase the remaining shares of the Company's common stock held by Zambon at the Repurchase Price. In the event the Company completes a sublicense for the North American rights or a sublicense for the non-North American rights to certain Premaire respiratory products prior to December 31, 2002, the Company will repurchase from Zambon 882,051 shares of the Company's common stock on each of the events.

In October 1999, as part of a licensing agreement with Elan, the Company received gross proceeds of $17,015,000 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 this 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 $4.0 million of the Company's Series E Preferred Stock, of which $1.0 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 Premaire-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 Premaire. The proceeds from these advances are not restricted as to their use by the Company. As part of the amendment of its 1998 agreement with Zambon, the terms of the milestone advances were modified in that the Company shall repay $1.0 million of the advance milestone payments upon the earlier of December 31, 2003, or upon the first regulatory approval for either albuterol or an inhaled steroid delivered in the Premaire. The remaining $1.0 million advance shall be repaid by the Company on the earlier of December 31, 2005, or the regulatory approval of the second product (albuterol or an inhaled steroid) delivered in the Premaire. Due to the modification in the repayment terms, the advances have been reclassified in the Company's balance sheet as long-term debt.

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 $86.0 million through March 31, 2002, of which approximately $30.0 million has been spent to acquire certain in-process research and development technologies, and $35.9 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. In an effort to meet its capital requirements, the Company is currently evaluating various financing alternatives including 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 may not be adequate or the Company may 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, including without limitation, risks set forth in Part I of the Company's Form 10-K for the year ended December 31, 2001. 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.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

The Company has no material market risk exposure.

PART II: OTHER INFORMATION

Item 2. Changes in Securities

The following unregistered securities were issued by the Company during the quarter ended March 31, 2002:

Sale/Issuance	Date of Issued	Description of Securities Warrants	Number of Shares Subject to Options or Price per Share ($)	Exercise	Purchaser or Class
~~January 2002~~	~~Warrants to purchase Common stock.~~	~~30,537~~	~~$4.69~~		~~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, 2002.

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 13, 2002 /s/ Scott A. Hoffmann

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