

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTER ENDED SEPTEMBER 30, 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.

☒ Yes ☐ No

The number of shares outstanding of the Registrant's Common Stock is 29,563,712 shares as of November 14, 2002.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES

(a development stage enterprise)

FORM 10-Q

For the Quarter Ended September 30, 2002

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Item 1. Financial Statements

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

September 30, December 31,
2002 2001

(unaudited)

ASSETS

Current assets:

— Cash and cash equivalents	\$ 348,137	\$ 859,298
— Clinical supplies	499,422	427,550
— Prepaid expenses and other current assets	215,867	86,080
— Total current assets	1,063,426	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	(460,717)	(355,014)
— Property and equipment, net	272,560	347,234

Patent costs, net of accumulated amortization of \$31,862 and \$20,216, respectively ...	426,317	308,203
Other assets	27,913	27,913

— Total assets	\$ 1,790,216	\$ 2,056,278
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LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

Current liabilities:

— Accounts payable	\$ 2,354,989	\$ 856,216
— Accrued liabilities	416,554	441,778
— Sponsored research payable	235,757	235,757
— Note payable	475,000	4,000,000
— Total current liabilities	3,482,300	5,533,751

Convertible promissory note	2,000,000	2,000,000
Long-term debt	9,500,000	3,000,000
Other long-term liabilities	1,200,484	608,803
Commitments and contingencies		

Total liabilities	16,182,784	11,142,554
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Minority interest in subsidiary		
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Stockholders' equity (net capital deficiency):

Preferred stock, \$.01 par value, authorized 3,000,000 shares:		
--	--	--

Series C cumulative convertible preferred stock, authorized 23,000 shares; issued and outstanding 15,501 and 14,708 shares at September 30, 2002 and December 31, 2001, respectively	155	147
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Series D cumulative convertible exchangeable preferred stock, authorized 21,000 shares; issued and outstanding 14,287 and 13,799 shares at September 30, 2002 and December 31, 2001, respectively	143	138
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Series E cumulative convertible non-exchangeable preferred stock, authorized 9,000 shares; issued and outstanding 3,231 and 2,124 shares at September 30, 2002 and December 31, 2001, respectively	32	21
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Series F convertible non-exchangeable preferred stock, 5,000 shares authorized; 5,000 shares issued and outstanding at September 30, 2002 and December 31, 2001	50	50
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Common stock, \$.01 par value, authorized 100,000,000 shares; issued and outstanding 29,563,712 and 29,001,602 shares at September 30, 2002 and December 31, 2001, respectively	295,637	290,016
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Additional paid-in capital	86,811,679	83,120,316
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Other comprehensive income		
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Deficit accumulated during development stage	(101,500,264)	(92,496,964)
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Total stockholders' equity (net capital deficiency)	(14,392,568)	(9,086,276)
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Total liabilities and stockholders' equity (net capital deficiency)	\$ 1,790,216	\$ 2,056,278
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See notes to consolidated financial statements.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS

For the Three and Nine Months Ended September 30, 2002

and 2001 and for the Period from October 17, 1986

(inception) to September 30, 2002

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		October 17, 1986 (inception) to September 30,
	2002	2001	2002	2001	2002
Revenues:					
Contract research revenue	\$	\$	\$ 5,000	\$ 869,095	\$ 1,775,045
Sublicense revenue			5,000	5,000	1,375,000
Total revenues			10,000	874,095	3,150,045
Expenses:					
Acquisition of research and develop- ment in-process technology					29,975,000
Research and development	531,104	1,686,046	3,307,030	4,666,181	38,079,585
General and administrative	607,769	1,031,562	3,989,169	2,909,362	32,875,915
Total expenses	1,138,873	2,717,608	7,296,199	7,575,543	100,930,500
Loss from operations	(1,138,873)	(2,717,608)	(7,286,199)	(6,701,448)	(97,780,455)
Interest income	883	4,362	7,901	55,127	797,288
Interest expense	(195,949)	(95,039)	(526,706)	(204,286)	(1,600,276)
Realized gain (loss) on sale of marketable securities		79,706		79,706	(5,580)
Minority interest in loss of subsidiary	31,207	135,758	191,793	318,260	3,710,486
Net loss	\$ (1,302,732)	\$ (2,592,821)	\$ (7,613,211)	\$ (6,452,641)	\$ (94,878,537)
Preferred stock dividends	(602,321)	(539,465)	(1,743,898)	(1,532,193)	(7,473,418)
Accretion of mandatorily redeemable preferred stock					(103,400)
Net loss attributable to common shares ...	\$ (1,905,053)	\$ (3,132,286)	\$ (9,357,109)	\$ (7,984,834)	\$ (102,455,355)
Weighted average common shares					
outstanding-basic and diluted	29,563,712	29,052,998	29,378,534	28,949,802	11,499,681
Net loss per share of common stock-					
basic and diluted	\$ (0.06)	\$ (0.11)	\$ (0.32)	\$ (0.28)	\$ (8.91)

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 September 30, 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	--	5,621	--	1,001,379
—Series C preferred stock dividends	8	--	--	792,992
—Series D preferred stock dividends	5	--	--	487,995
—Series E preferred stock issued	10	--	--	999,990
—Series E preferred stock dividends	1	--	--	106,999
—Common stock warrants issued	--	--	--	302,008
—Net loss	--	--	--	--

Balance September 30, 2002	\$	380	\$	295,637	\$	--	\$	86,811,679
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See notes to consolidated financial statements.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Nine Months Ended September 30, 2002 and 2001 and for the Period

from October 17, 1986 (inception) to September 30, 2002

(Unaudited)

		October 17, 1986 (inception) to September 30, 2002
	Nine Months Ended September 30,	
	2002	2001

Cash outflows from operating activities:			
— Net loss	\$ (7,613,211)	\$ (6,452,641)	\$ (94,878,537)
Adjustments to reconcile net loss to net cash used by			
— development stage activities:			
— Issuance of common stock, stock options/warrants for			
— services	302,008	126,741	3,121,376
— Depreciation and amortization	117,349	96,533	846,239
— Non-cash acquisition of research and development			
— in-process technology	--	--	1,650,000
— (Gain) loss on sale of marketable securities	--	(79,706)	5,580
— (Increase) decrease in clinical supplies, prepaid			
— expenses & other current assets	(201,659)	18,224	(774,330)
— Decrease in milestone advance receivable	--	1,000,000	--
— Increase in other assets	(129,760)	(49,332)	(427,052)
— Increase in accounts payable and accrued liabilities	1,742,169	38,018	2,896,317
— Increase in sponsored research payable	--	--	812,827
— Other	327,288	(149,043)	552,991
Net cash used by operating activities	(5,455,816)	(5,451,206)	(86,194,589)

Cash flows from investing activities:			
— Proceeds from sale of marketable securities	--	249,661	844,420
— Acquisition of laboratory and office equipment, and			
— leasehold improvements	(31,029)	(110,466)	(903,419)
— Other	--	--	(57,087)
Net cash provided (used) by investing activities	(31,029)	139,195	(116,086)

Cash flows from financing activities:			
— Payments on debt and capital leases	(6,316)	(5,471)	(856,352)
— Net proceeds from issuance of:			
— Debt	2,975,000	3,000,000	15,025,000
— Common stock	--	--	23,433,660
— Preferred stock	1,000,000	1,000,000	35,741,117
— Proceeds from exercise of warrants/stock options	1,007,000	393,683	14,770,358
— Repurchase and retirement of common stock	--	--	(956,031)
— Other	--	--	(500,024)
Net cash provided by financing activities	4,975,684	4,388,212	86,657,728
Net (decrease) increase in cash and cash equivalents	(511,161)	(923,799)	347,053
Cash and cash equivalents at beginning of period	859,298	3,041,948	1,084
Cash and cash equivalents at end of period	\$ 348,137	\$ 2,118,149	\$ 348,137

Noncash investing and financing activities:			
— Common stock, stock options/warrants issued for services ...	\$ 302,008	\$ 126,741	\$ 3,121,376
— 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 retire debt	500,000		
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	1,390,090	1,239,000	6,881,764

Supplemental disclosure of cash flow information:

Interest paid	\$ 1,514	\$ 1,560	\$ 287,834
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See notes to consolidated financial statements.

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SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 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 September 30, 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 and nine months ended September 30, 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., ("RSD") 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 accompanying consolidated financial statements have been prepared
— on a going concern basis that contemplates the realization of assets
— and satisfaction of liabilities and commitments in the normal course of
— business. 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. Unless the Company is able to
— raise significant capital (\$1 million to \$2.5 million) within the next
— 30-60 days, management believes that it is unlikely that the Company
— will be able to meet its obligations as they become due and to
— continue as a going concern. To meet this capital requirement, the
— Company is evaluating various financing alternatives including private
— offerings of its securities, debt financings, collaboration and
— licensing arrangements with other companies, and the sale of non-
— strategic assets and/or technologies to third parties. Should the
— Company be unable to meet its capital requirement through one or more
— of the above-mentioned financing alternatives, the Company may file
— for bankruptcy or similar protection under the 1978 Bankruptcy Code
— and the basis of presentation of the Company's financial statements
— will be adjusted to reflect a liquidation basis of accounting.

— Additionally, 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.

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. — NOTES PAYABLE

— On September 6, 2002, the Company entered into a \$.5 million unsecured
— debt financing with certain shareholders of the Company. The promissory
— notes provide for interest at the rate of 7% per annum and mature on
— January 1, 2003.

— Upon maturity, the Company will repay principal and accrued interest on
— each note, and at the Company's discretion, either a premium of
— approximately 14% of the principal amount, or a warrant to purchase the
— number of shares of Sheffield common stock equal to the principal
— amount each note. Any warrants to be issued under the notes would have
— an exercise price equal to \$.60 per share, the closing price of the
— Company's common stock on the closing date of the notes. The
— outstanding principal balance of the promissory notes at September 30,
— 2002 was \$.5 million.

4. — LONG-TERM DEBT

— On August 14, 2001, the Company entered into a Note Purchase Agreement
— ("Agreement") with Elan Pharma International Ltd. ("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. The
— outstanding principal balance of the Agreement at September 30, 2002,
— and December 31, 2001, was \$5 million and \$4 million, respectively. Due
— to the modification of the maturity date, the borrowings under the
— Agreement, totaling \$5 million at September 30, 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 Group SpA ("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, \$1.0 million
— on January 2, 2002 and \$.5 million on April 5, 2002. 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. The outstanding principal balance of the Loan
— Agreement at September 30, 2002, and December 31, 2001, was \$2.5
— million and \$1.0 million, respectively.

5. — SUBSEQUENT EVENT

— On November 8, 2002 the Company entered into an agreement with Elan
— Pharma. Under the terms of the agreement, the Company received proceeds
— of \$.5 million evidenced by an unsecured demand promissory note of the
— Company that provides for interest on principal and semi-annually
— compounded interest at a fixed rate of 10% per annum. Also as part of
— the agreement, the parties terminated the 1999 license agreement for
— the Elan NanoCrystal technology made between Elan Pharma and RSD. As

— provided in the 1999 license agreement, upon termination of this
— license, all intellectual property of RSD was transferred to and
— jointly owned by Elan and Sheffield.

6. 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

We provide innovative, cost-effective pharmaceutical therapies by combining state-of-the-art pulmonary drug delivery technologies with existing and emerging therapeutic agents. We are developing a range of products to treat respiratory and systemic diseases in our proprietary Premaire(R) Delivery System ("Premaire") and Tempo(TM) Inhaler ("Tempo"). We are in the development stage and, as such, have been principally engaged in the development of our pulmonary delivery systems:

In 1997, we 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, we 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, we 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, we licensed Elan's Nanocrystal(TM) technology to be used in developing certain inhaled steroid products.

Our 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. We believe 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.

Our Tempo is a patented, new generation pMDI that we believe 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, we 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, we amended our 1998 agreement with Zambon whereby we 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 us to progress the development

of the Premaire respiratory program. Upon commercialization, Zambon will be entitled to certain royalties on payments received by us for albuterol, ipratropium and cromolyn sales for specified periods.

In 1998, the systemic applications of Premaire and Tempo were licensed to Systemic Pulmonary Delivery, Ltd. ("SPD"), one of our wholly owned subsidiaries. In addition, two Elan technologies, UPDAS(TM) and the Enhancing Technology, were also licensed to SPD. We retained exclusive rights outside of the strategic alliance to respiratory disease applications utilizing the Tempo technology and the two Elan technologies. On August 21, 2002 we ended this strategic alliance with Elan and regained all intellectual property rights to the systemic applications of Premaire and Tempo that were licensed to SPD. In addition, as part of the termination of this alliance, we will enter into a separate agreement with Elan to license exclusively the UPDAS(TM) and the Enhancing Technology. We have also granted to Elan an ongoing right to receive royalties on commercialization of two products, morphine delivered by Premaire and ergotamine tartrate delivered by Tempo.

In addition to the above alliance with Elan, in 1999, we 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. On November 8, 2002, as part of an agreement between Elan and RSD, the parties terminated the license for the Elan NanoCrystal technology to RSD. As provided in the 1999 license agreement, upon termination of this license, all intellectual property of RSD was transferred to and jointly owned by Elan and Sheffield.

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 Premaire. There were no contract research revenues for the third quarter of 2002 and 2001. For the first nine months of 2002 and 2001, contract research revenues were \$5,000 and \$869,095, respectively. The decrease for the first nine months of 2002 was due to the Company no longer performing development work for Zambon as a result of our 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, in part, on obtaining additional collaborative agreements and upon the success of current clinical studies.

Our ability to generate material revenues is contingent on the successful commercialization of our technologies and other technologies and products that we 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 \$.5 million and \$1.7 million for the third quarter of 2002 and 2001, respectively. The decrease of \$1.2 million for the third quarter of 2002 was primarily due to lower Premaire development costs associated with finalizing the to-be-marketed device in December 2001 as well as reduced formulation work on the Premaire budesonide product (\$.4 million), higher development expenses in the third quarter of 2001 related to the anticipation of a Phase I trial of RSD's unit dose product (\$.4 million),

lower Tempo development costs resulting from finalizing the industrialization of the device in the first half of 2002 for Phase I and II trials and reduced formulation work on certain respiratory products (\$.2 million); lower new product development in the area of polypeptides (\$.1 million) and reduced R&D administrative costs (\$.1 million). For the nine months ended September 30, 2002 and 2001, R&D costs were \$3.3 million and \$4.7 million, respectively. The decrease of \$1.4 million was primarily due to lower design and development costs associated with finalizing the to-be-marketed Premaire device in December 2001 (\$.8 million); lower Tempo development costs resulting from finalizing the industrialization of the device in the first half of 2002 for Phase I and II trials and reduced formulation work on certain respiratory products (\$.6 million); higher development expenses in the third quarter of 2001 related to the anticipation of a Phase I trial of RSD's unit dose product (\$.5 million); and lower new product development work in the area of polypeptides (\$.3 million). These decreases were partially offset by higher expenses related to formulation work on the Tempo dihydroergotamine ("DHE") product (\$.8 million).

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The following details the status of each of our development programs as of September 30, 2002:

Premaire Respiratory Program:

As a result of our 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 to us from Zambon with the Food and Drug Administration ("FDA") being notified accordingly. In the fourth quarter of 2001, we reviewed all of the development work completed to date, identifying a number of deficiencies in the Zambon development program. To address these issues, we 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 September 30, 2002, we had spent \$3.8 million on developing the respiratory products discussed below:

Our strategy is to out license the U.S. rights to the Premaire respiratory products to a third party which we anticipate concluding in 2003. As a result, we estimate a U.S. commercial launch of our first products in Premaire to occur in the last half of 2005 or first half of 2006. Subject to obtaining additional financing from debt and/or equity placements, we intend to 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 it is anticipated that the licensee would 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. We are currently reviewing the FDA's comments and recommendations, integrating the information into the plans for the Phase III trial and NDA submission. Subject to obtaining additional funding by the end of 2002, we anticipate to begin pivotal clinical trials for the albuterol sulfate program at the beginning of 2003.

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 nanocrystalline 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 chronic obstructive pulmonary disease ("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 us. We do not intend to further develop this product on our 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 our development alliance with Elan and SPD formed in 1998, we 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, we 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 had the first right of refusal on the development of any product developed by the joint venture. Elan chose not to license this product from the joint venture. In August 2002, we regained all intellectual property rights to the systemic applications of Premaire from SPD and ended the joint venture relationship with Elan. As such, we now continue to seek to attract a partner for the continued

development and commercialization of this product. Upon

commercialization, Elan will be entitled to certain royalties on payments received. We have spent \$.4 million to date to develop this product and do not anticipate incurring any future costs for further development until such time as a licensing partner is secured.

Tempo Respiratory Program:

In September 2000, we 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 September 30, 2002, we had incurred approximately \$.9 million to-date on this study. We are 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 was being conducted as part of our alliance with Elan. The initial product developed was targeted to address migraine headaches. We utilized ergotamine tartrate as a proof-of-principle product. In December 1999, we 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 had the first right of refusal on the development of any product developed by the joint venture. Elan chose not to license this product from the joint venture. In August 2002, we regained all intellectual property rights to the systemic applications of Tempo from SPD and ended the joint venture relationship with Elan. As such, we now continue to seek to attract a partner for the continued development and commercialization of this product. Upon commercialization, Elan will be entitled to certain royalties on payments received. As of September 30, 2002, we had spent \$1.0 million to date to develop this product and do 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, we announced the initiation of a pulmonary migraine therapy program with Inhale Therapeutic Systems ("Inhale"), a

world-renowned expert in particle design. We will combine Inhale's supercritical fluid technology with our proprietary drug delivery technologies to develop a systemically acting DHE administered through the pulmonary route. We plan 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. We are 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 estimated at approximately \$2.4 billion. As of September 30, 2002, we had incurred to-date approximately \$1.0 million related to this project. Future costs related to this project are dependent upon, among other factors, the timing of securing a development partner. Subject to obtaining additional financing from debt and/or equity placements in 2002, we do not estimate incurring any costs related to the development of the DHE project until the beginning of 2003.

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"), our proprietary nanobudesonide in two different single dose strengths and placebo. The study resulted in no significant adverse events with either of our 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, we plan on initiating discussions with potential partners regarding the outlicensing of this opportunity. As of September 30, 2002, we incurred to-date approximately \$2.9 million on this project. On November 8, 2002, as part of an agreement between Elan and RSD, we and Elan terminated the license for the Elan NanoCrystal technology to RSD. As provided in the 1999 license agreement,

upon termination of this license, all intellectual property of RSD was transferred to and jointly owned by Elan and Sheffield. Subject to disposition of the property rights, we do not intend to incur any additional development costs related to this product.

General and administrative expenses were \$.6 million for the third quarter of 2002 as compared to \$1.0 million for the third quarter of 2001. The decrease of \$.4 million from 2001 was primarily due to cost reduction efforts to conserve cash while various financing alternatives are evaluated, including lower legal and consulting fees (\$.2 million), reduced administrative headcount (\$.1 million), and lower public relations expenditures (\$.1 million). For the nine months ended September 30, 2002 and 2001, general and administrative expenses were \$4.0 million and \$2.9 million, respectively. The increase of \$1.1 million from 2001 was primarily due to higher consulting costs, legal fees and severance-related costs in the first six months of 2002. 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 our delivery systems, as well as potential acquisitions of complementary pulmonary delivery technologies and companies (\$.7 million). The severance costs were associated with the resignation of three executive officers in 2002 and include costs incurred pursuant to their respective separation agreements for severance payments and ongoing benefit coverage (\$.6 million) and modification of the terms of certain stock options (\$.2 million). These increases were partially offset by the above-noted cost reduction efforts during third quarter of 2002 (\$.4 million).

Interest

Interest income was \$883 and \$4,362 for the third quarter of 2002 and 2001, respectively, and \$7,901 and \$55,127 for the first nine months of 2002 and 2001, respectively. The decrease in interest income for both the third quarter and first nine months of 2002 was primarily due to less cash available for investment and lower yields on those investments.

Interest expense was \$195,949 and \$95,039 for the third quarter of 2002 and 2001, respectively, and \$526,706 and \$204,286 for the first nine months of 2002 and 2001, respectively. The increase for both the third quarter and first nine months of 2002 resulted primarily from interest associated with the borrowings on the August 2001 Note Purchase Agreement with Elan Pharma. The borrowings totaled \$5 million as of September 30, 2002, compared to total borrowings of \$2 million as of September 30, 2001.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2002, we had \$.3 million in cash and cash equivalents compared to \$.9 million at December 31, 2001. The decrease of \$.6 million reflects cash disbursements of \$5.6 million used primarily to fund operating activities, partially offset by the receipt of \$1.0 million from the issuance of 1,000 shares of our Series E Cumulative Convertible Preferred Stock, \$1.5 million from the proceeds of a secured loan from Zambon, \$1.0 million from the proceeds of an unsecured promissory note from Elan Pharma, \$.5 million from the proceeds of unsecured promissory notes from certain shareholders and \$1.0 million in proceeds from the exercise of a portion of a common stock warrant by Elan International Services, Ltd.

Cash available for funding our operations as of September 30, 2002 was \$.3 million. As of such date, we had trade payables and accrued liabilities of \$2.8 million, and current research obligations of \$.2 million. In addition, committed and/or anticipated funding of research and development after September 30, 2002 is estimated at approximately \$.2 million, of which \$.1 million has been

committed to be funded by Elan through the issuance of our Series E cumulative convertible preferred stock, which funds are required to be used by us to fund our portion of RSD's operating and development costs. As of November 14, 2002, we had cash and equivalents of approximately \$0.7 million, of which \$0.1 million is committed to fund our portion of RSD's expenditures. As of such date, we had trade payables and accrued liabilities of approximately \$2.9 million. Unless the Company is able to raise significant capital (\$1 million to \$2.5 million) within the next 30-60 days, management believes that it is unlikely that the Company will be able to meet its obligations as they become due and to continue as a going concern. To meet this capital requirement, we are evaluating various financing alternatives including private offerings of our securities, debt financings, collaboration and licensing arrangements with other companies, and the sale of non-strategic assets and/or technologies to third parties. Should the Company be unable to meet its capital requirement through one or more of the above-mentioned financing alternatives, we may file for bankruptcy or similar protection under the 1978 Bankruptcy Code.

Because we do not expect to generate significant cash flows from operations for at least the next few years, we will require additional funds to meet our current obligations and future costs. In an effort to meet both our short- and long-term capital requirements, we are currently evaluating various financing alternatives including private offerings of our securities, debt financings, and collaboration and licensing arrangements with other companies. There can be no assurance that we will be able to obtain such additional funds or enter into such collaborative and licensing arrangements on terms favorable to us, if at all. Our development programs will be stopped if future financings are not completed.

On November 8, 2002 the Company entered into an agreement with Elan Pharma, whereby among other items, the Company received proceeds of \$0.5 million evidenced by an unsecured demand promissory note. The promissory note provides for interest on principal and semi-annually compounded interest at a fixed rate of 10% per annum.

On September 6, 2002, we entered into a \$0.5 million unsecured debt financing with certain of our shareholders. The promissory notes provide for interest at the rate of 7% per annum and mature on January 1, 2003. Upon maturity, we will repay principal and accrued interest on each note, and at our discretion, either a premium of approximately 14% of the principal amount, or a warrant to purchase the number of shares of Sheffield common stock equal to the principal amount each note. Any warrants to be issued under the notes would have an exercise price equal to \$0.60 per share, the closing price of our common stock on the closing date of the notes. The outstanding principal balance of the promissory notes at September 30, 2002 was \$0.5 million.

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 us and purchased 495,000 shares of our common stock at \$2.00 per share. We received approximately \$1.0 million in proceeds as a result of the exercise of a portion of this warrant.

On August 14, 2001, we entered into a Note Purchase Agreement ("Agreement") with Elan Pharma, pursuant to which Elan Pharma agreed to lend us up to \$4 million. On April 4, 2002, we 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, we received proceeds on the loan of \$1 million, increasing the total borrowings to \$5 million. All borrowings under the Agreement are evidenced by our \$5 million unsecured promissory note 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 \$5 million at September 30, 2002, have been classified in our balance sheet as long-term debt.

In September 2001, in connection with the amendment of our 1998 agreement with Zambon, we entered into a Loan and Security Agreement ("Loan Agreement") with Zambon, pursuant to which Zambon agreed to lend us \$2.5 million. We received \$1.0 million upon signing of the Loan Agreement, \$1.0 million on January 2, 2002 and \$.5 million on April 5, 2002. 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 us upon our 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 our 1998 agreement with Zambon, we repurchased from Zambon, 214,997 shares of common stock for \$3.0233 per share ("Repurchase Price"). In addition, we received an option, expiring December 31, 2002, to repurchase the remaining shares of our common stock held by Zambon at the Repurchase Price. In the event we complete 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, we will repurchase from Zambon 882,051 shares of our common stock on each of the events.

In October 1999, as part of a licensing agreement with Elan, we 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, we 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 our Series E Preferred Stock. Although only \$3 million has been drawndown under the Series E Preferred Stock, as part of the November 8, 2002 Note Agreement with Elan, Elan is no longer obligated to provide us with the remaining \$1 million in funding.

In May 1999, in conjunction with the completion of its Phase I/II Premaire-albuterol trial, Zambon provided us with a \$1.0 million interest-free advance against future milestone payments. In January 2001, we 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 us. As part of the amendment of its 1998 agreement with Zambon, the terms of the milestone advances were modified in that we 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 us 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 our balance sheet as long-term debt.

CERTAIN RISK FACTOR THAT MAY AFFECT FUTURE RESULTS, FINANCIAL CONDITION AND MARKET PRICE OF SECURITIES

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 us or on our behalf, because these factors could cause actual results and conditions to differ materially from those projected in forward-looking statements:

We will need additional financing, which if not available, could prevent us from funding or expanding our operations:

Unless the Company is able to raise significant capital (\$1 million to \$2.5 million) within the next 30-60 days, management believes that it is unlikely that the Company will be able to meet its obligations as they become due and to continue as a going concern. To meet this immediate capital requirement, we are evaluating various financing alternatives including private offerings of our securities, debt financings, collaboration and licensing arrangements with other companies, and the sale of non-strategic assets and/or technologies to third parties. Should the Company be unable to meet its capital requirement through one or more of the above-mentioned financing alternatives, we may file for bankruptcy or similar protection under the 1978 Bankruptcy Code.

Provided immediate funding is secured, we will still need to raise substantial additional capital in the very near-term to fund our operations in an effort to continue to meet our obligations as they become due and to continue as a going concern. The development of our technologies and proposed products will require a commitment of substantial funds to conduct costly and time-consuming research, preclinical and clinical testing, and to bring any such products to market. Our future capital requirements will depend on many factors, including continued progress in developing and out-licensing our pulmonary delivery technologies; our ability to establish and maintain collaborative arrangements with others and to comply with the terms thereof; receipt of payments due from partners under research and development agreements; progress with preclinical and clinical trials; the time and costs involved in obtaining regulatory approvals; the cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims; the need to acquire licenses to new technology and the status of competitive products. We are currently seeking such additional funding through collaborative or partnering arrangements, the extension of existing arrangements, or through public or private equity or debt financings. Additional

financing may not be available on acceptable terms or at all. If we raise additional funds by issuing equity securities, stockholders may be further diluted and such equity securities might have rights, preferences and privileges senior to those of our current stockholders. If adequate funds are not available over the longer term, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize. If adequate funds are not available from operations or additional sources of funding, our business will suffer a material adverse effect.

We have experienced significant operating losses throughout our history and expect these losses to continue for the foreseeable future.

Our operations to date have consumed substantial amounts of cash and we have generated to date only limited revenues from contract research and licensing activities. We have incurred approximately \$97.8 million of operating losses since our inception, including \$7.3 million during the nine months ended September 30, 2002. Our operating losses and negative cash flow from operations are expected to continue in the foreseeable future. The Company expects that it will continue to have a high level of operating expenses, negative cash flow from operations and will be required to make significant up-front expenditures in connection with its product development activities. As a result, we anticipate additional operating losses for the remainder of 2002 and that such losses will continue thereafter until such time, if ever, as we are able to generate sufficient revenues to sustain our operations. The independent auditors' report dated February 12, 2002, on our consolidated financial statements for the year ended December 31, 2001 stated that we have incurred recurring operating losses and have a working capital deficiency and that these conditions raise substantial doubt about our ability to continue as a going concern.

If our common stock is delisted from the American Stock Exchange, the price of our common stock and its liquidity could decline.

Our common stock is listed for trading on the American Stock Exchange, or AMEX, under the symbol "SHM". We do not satisfy AMEX standards for continued listing, including a standard that a listed company that has sustained losses from continuing operations and/or net losses in its five most recent fiscal years, have stockholders' equity of at least \$6,000,000. We

had a net capital deficiency of \$14.4 million at September 30, 2002. We submitted a plan advising the AMEX of the action we will take that will bring us into compliance with continued listing standards. On September 11, 2002, the AMEX notified us that it had accepted our plan of compliance and granted us an extension through the 2002 year-end reporting period to regain compliance with the continued listing standards. We will be subject to periodic review by the AMEX staff during the extension period. Failure to make progress consistent with

the plan or to regain compliance with the continued listing standards by the end of the extension period could result in our being delisted from the AMEX. There can be no assurance that we will be able to meet the objectives outlined in the plan, which may result in the AMEX initiating delisting procedures. If our common stock were delisted from AMEX, trading of our common stock, if any, would thereafter likely be conducted in the over-the-counter market, unless we were able to list our common stock on The Nasdaq Stock Market or another national securities exchange, which cannot be assured. If our common stock were to trade in the over-the-counter market it may be more difficult for investors to dispose of, or to obtain accurate quotations as to the market value of our common stock. In addition, it may become more difficult for us to raise funds through the sale of our securities.

In the event of the delisting of our common stock from the AMEX and our inability to list our common stock on The Nasdaq Stock Market or another national securities exchange, the regulations of the SEC under the Securities Exchange Act of 1934, as amended, require additional disclosure relating to the market for penny stocks. SEC regulations generally define a penny stock to be an equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. A disclosure schedule explaining the penny stock market and the risks associated therewith is required to be delivered to a purchaser and various sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors (generally institutions). In addition, the broker-dealer must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. If our securities become subject to the regulations applicable to penny stocks, the market liquidity for our securities could be severely affected. In such an event, the regulations on penny stocks could limit the ability of broker-dealers to sell our securities.

Our products are still in development and we may be unable to bring our products to market.

We have not yet begun to generate revenues from the sale of products. Our products will require significant additional development, clinical testing and investment prior to their commercialization. We do not expect regulatory approval for commercial sales of any of our products in the immediate future. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. Such reasons include the possibility that products will not be proven to be safe and efficacious in clinical trials, that they will not be able to meet applicable regulatory standards or obtain required regulatory approvals, that they cannot be produced in commercial quantities at reasonable costs or that they fail to be successfully commercialized or fail to achieve market acceptance.

If our products are not accepted by the medical community, our business will suffer.

Commercial sales of our products will substantially depend upon the products' efficacy and on their acceptance by the medical community. Widespread acceptance of our products will require educating the medical community as to the benefits and reliability of the products. Our products may not be accepted and, even if accepted, we are unable to estimate the length of time it would take to gain such acceptance.

We will be required to make royalty payments on products we may develop, reducing the amount of revenues with which we could fund ongoing operations.

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

Our dependence on third parties for rights to technology and the development of our products could harm our business.

Under the terms of existing license agreements, we are obligated to make certain payments to our licensors. In the event that we default on the payment of an installment under the terms of an existing licensing agreement, our rights there under could be forfeited. As a consequence, we could lose all rights under a license agreement to the related licensed technology, notwithstanding the total investment made through the date of the default. Unforeseen obligations or contingencies may deplete our financial resources and, accordingly, sufficient resources may not be available to fulfill our commitments. If we were to lose our rights to technology, we may be unable to replace the licensed technology or be unable to do so on commercially

reasonable terms, which would materially adversely affect our ability to bring products based on that technology to market. In addition, we depend on our licensors for assistance in developing products from licensed technology. If these licensors fail to perform or their performance is not satisfactory, our ability to successfully bring products to market may be delayed or impeded.

We face intense competition and rapid technological changes and our failure to successfully compete or adapt to changing technology could make it difficult to successfully bring products to market.

The medical field is subject to rapid technological change and innovation. Pharmaceutical and biomedical research and product development are rapidly evolving fields in which developments are expected to continue at a rapid pace. Reports of progress and potential breakthroughs are occurring with increasing frequency. Our success will depend upon our ability to develop and maintain a competitive position in the research, development and commercialization of products and technologies in our areas of focus. Competition from pharmaceutical, chemical, biomedical and medical companies, universities, research and other institutions is intense and is expected to increase. All, or substantially all, of these competitors have substantially greater research and development capabilities, experience, and manufacturing, marketing, financial and managerial resources. Further, acquisitions of competing companies by large

pharmaceutical or other companies could enhance such competitors' financial, marketing and other capabilities. Developments by others may render our products or technologies obsolete or not commercially viable and we may not be able to keep pace with technological developments.

We are subject to significant government regulation and failure to achieve regulatory approval for our products would severely harm our business.

Our ongoing research and development projects are subject to rigorous FDA approval procedures. The preclinical and clinical testing requirements to demonstrate safety and efficacy in each clinical indication (the specific condition intended to be treated) and regulatory approval processes of the FDA can take a number of years and will require us to expend substantial resources. We may be unable to obtain FDA approval for our products, and even if we do obtain approval, delays in such approval would adversely affect the marketing of products to which we have rights and our ability to receive product revenues or royalties. Moreover, even if FDA approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA, and a later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer. Failure to comply with the applicable regulatory requirements can, among other things, result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. Additional government regulation may be established which could prevent or delay regulatory approval of our products. Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Even if FDA approval has been obtained, approval of a product by comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The time required to obtain such approval may be longer or shorter than that required for FDA approval. We have no experience in manufacturing or marketing in foreign countries nor in matters such as currency regulations, import-export controls or other trade laws. To date, we have not received final regulatory approval from the FDA or any other comparable foreign regulatory authority for any of our products or technologies.

Our failure to meet product release schedules would make it difficult to predict our quarterly results and may cause our operating results to vary significantly.

Delays in the planned release of our products may adversely affect forecasted revenues and create operational inefficiencies resulting from staffing levels designed to support the forecasted revenues. Our failure to introduce new products on a timely basis could delay or hinder market acceptance and allow competitors to gain greater market share.

If our intellectual property and proprietary rights are infringed, or infringe upon the rights of others, our business will suffer.

Our success will depend in part on our ability to obtain patent protection for our technologies, products and processes and to maintain trade secret protection and operate without infringing the proprietary rights of others. The degree of patent protection to be afforded to pharmaceutical, biomedical or medical inventions is an uncertain area of the law. In addition, the laws of foreign countries do not protect our proprietary rights to the same extent as do the laws of the United States. We may not develop or receive sublicenses or other rights related to proprietary technology that are patentable, patents that are pending may be not issued, and any issued patents may not provide us with any

competitive advantages and may be challenged by third parties. Furthermore, others may independently duplicate or develop similar products or technologies to those developed by or licensed to us. If we are required to defend against charges of patent infringement or to protect our own proprietary rights against third parties, substantial costs will be incurred and we could lose rights to certain products and technologies or be required to enter into costly royalty or licensing agreements.

We do not have any marketing or manufacturing capabilities and will likely rely on third parties for these capabilities in order to bring products to market.

We do not currently have our own sales force or an agreement with another pharmaceutical company to market all of our products that are in development. When appropriate, we may build or otherwise acquire the necessary marketing capabilities to promote our products. However, we may not have the resources available to build or otherwise acquire our own marketing capabilities, and we may be unable to reach agreements with other pharmaceutical companies to market our products on terms acceptable to us, if at all.

In addition, we do not intend to manufacture our own products. While we have already entered into two manufacturing and supply agreements related to the Premaire system and one related to the Tempo, these manufacturing and supply agreements may not be adequate and we may not be able to enter into future manufacturing and supply agreements on acceptable terms, if at all. Our reliance on independent manufacturers involves a number of risks, including the absence of adequate capacity, the unavailability of, or interruptions in, access to necessary manufacturing processes and reduced control over product quality and delivery schedules. If our manufacturers are unable or unwilling to continue manufacturing our products in required volumes, we will have to identify acceptable alternative manufacturers. The use of a new manufacturer may cause significant interruptions in supply if the new manufacturer has difficulty manufacturing products to our specifications. Further, the introduction of a new manufacturer may increase the variation in the quality of our products.

Healthcare reimbursement policies are uncertain and may adversely impact the sale of our products.

Our ability to commercialize human therapeutic and diagnostic products may depend in part on the extent to which costs for such products and technologies are reimbursed by private health insurance or government health programs. The uncertainty regarding reimbursement may be especially significant in the case of newly approved products. Reimbursement price levels may be insufficient to provide a return to us on our investment in new products and technologies. In the United States, government and other third-party payers have sought to contain healthcare costs by limiting both coverage and the level of reimbursement for new pharmaceutical products approved for marketing by the FDA, including some cases of refusal to cover such approved products. Healthcare reform may increase these cost containment efforts. We believe that managed care organizations may seek to restrict the use of new products, delay authorization to use new products or limit coverage and the level of reimbursement for new

products. Internationally, where national healthcare systems are prevalent, little if any funding may be available for new products, and cost containment and cost reduction efforts can be more pronounced than in the United States.

We may become subject to product liability claims and our product liability insurance may be inadequate:

The use of our proposed products and processes during testing, and after approval, may entail inherent risks of adverse effects that could expose us to product liability claims and associated adverse publicity. Although we currently maintain general liability insurance, the coverage limits of our insurance policies may not be adequate. We currently maintain clinical trial product liability insurance of \$2.0 million per event for certain clinical trials and intend to obtain insurance for future clinical trials of products under development. However, we may be unable to obtain or maintain insurance for any future clinical trials. Such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. A successful claim brought against us in excess of our insurance coverage would have a material adverse effect upon us and our financial condition. We intend to require our licensees to obtain adequate product liability insurance. However, licensees may be unable to maintain or obtain adequate product liability insurance on acceptable terms and such insurance may not provide adequate coverage against all potential claims.

The price of biotechnology/pharmaceutical company stocks has been volatile which could result in substantial losses to our stockholders:

The market price of securities of companies in the biotechnology/pharmaceutical industries has tended to be volatile. Announcements of technological innovations by us or our competitors, developments concerning proprietary rights and concerns about safety and other factors may have a material effect on our business or financial condition. The market price of our common stock may be significantly affected by announcements of developments in the medical field generally or our research areas specifically. The stock market has experienced volatility in market prices of companies similar to us that has been unrelated to the operating results of such companies. This volatility may have a material adverse effect on the market price of our common stock.

Our ability to issue "blank check" preferred stock may make it more difficult for a change in our control:

Our certificate of incorporation authorizes the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined from time to time by the Board of Directors, without shareholder approval. In the event of issuance, such preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in our control and preventing shareholders from receiving a premium for their shares in connection with a change of control. We issued Series A and Series B cumulative convertible redeemable preferred stock in connection with private placements in February 1997 and April 1998, respectively. All of the Series A preferred stock was converted into common stock during 1998. On July

31, 1998, all of the Series B Preferred stock was redeemed for cash. We also issued shares of our Series C cumulative convertible preferred stock in connection with the consummation of an agreement with Elan International Services, Ltd. ("Elan International") in June 1998. In October 1999, in conjunction with a licensing agreement with Elan International, we issued shares of our Series D cumulative convertible exchangeable preferred stock and Series F cumulative convertible preferred stock. Except for the additional shares of Series C, D and E preferred stock that may be payable as dividends to Elan International, as holder of the outstanding Series C, D and E preferred stock, we have no present intention to issue any additional shares of our preferred stock. As we are currently investigating raising additional equity financing, we may issue additional shares of our preferred stock in the near future.

We are obligated to issue additional securities in the future diluting our stockholders.

As of September 30, 2002, we had reserved approximately 4,236,667 shares of our common stock for issuance upon exercise of outstanding options and warrants convertible into shares of our common stock, including by our officers and directors. In addition, as of September 30, 2002, we had \$2,000,000 principal amount of a convertible promissory note, 15,501 shares of our Series C preferred stock, 14,287 shares of our Series D preferred stock, 3,231 shares of our Series E preferred stock and 5,000 shares of our Series F preferred stock outstanding. Our Series C, D, E and F preferred stock are convertible into 10,993,617 shares, 2,939,712 shares, 830,591 shares and 1,470,588 shares, respectively, of common stock. The convertible promissory note, including accrued interest is convertible into 1,555,975 shares of common stock. The exercise of options and outstanding warrants, the conversion of such other securities and sales of common stock issuable thereunder could have a significant dilutive effect on the market price of our common stock and could materially impair our ability to raise capital through the future sale of our equity securities.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

The Company has no material market risk exposure.

Item 4. Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation within 90 days of the filing date of this report, that our disclosure controls and procedures are effective for gathering, analyzing and disclosing the information we are required to disclose in our reports filed under the Securities Exchange Act of 1934. There have been no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the previously mentioned evaluation.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

The Company has been named as a defendant in Jeffrey Leston v.

Sheffield Pharmaceuticals, Inc., filed on October 16, 2002 in the United States District Court, Southern District of New York. The plaintiff in this action seeks damages of \$100,000 for the breach of a contract under which Leston was retained to introduce and facilitate a business alliance between Sheffield and Zambon Corporation. Plaintiff claims that under this contract, Sheffield was obligated, among other things, to pay Leston a fee equal to 4% of any equity by Zambon in Sheffield or other financing by Zambon, including loans. In January 1999, an agreement was entered into amending the original contract in a manner that the Company believes relieved the Company for any of the obligations claimed in the Complaint. In September 2001, Zambon loaned \$2.5 million to Sheffield as part of a restructuring of their alliance. This action seeks consideration of \$100,000, or 4% of the

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\$2.5 million loaned to Sheffield under this restructuring with Zambon. The Company expects to deny the plaintiff's allegations and plans to counter-claim for the return of monies previously paid to the plaintiff and vigorously defend the action and prosecute its counter-claims. The Company's response to the Complaint is due by December 18, 2002.

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

(a) Exhibits

10.41 Form of promissory notes dated September 6, 2002 with certain Shareholders.

(b) Reports on Form 8-K

A current Report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2002 under Item 9, relating to the certification signed by the Company's Chief Executive Officer and Chief Financial Officer as required pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with the Quarterly Report on Form 10-Q for the period ending June 30, 2002.

A current Report on Form 8-K filed with the Securities and Exchange Commission on September 6, 2002 to announce the filing of a press release under Item 5.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SHEFFIELD PHARMACEUTICALS, INC.

Dated: November 14, 2002 /s/ Thomas M. Fitzgerald

Thomas M. Fitzgerald

President & Chief Executive Officer

Dated: November 14, 2002 /s/ Scott A. Hoffmann

Scott A. Hoffmann

Vice President & Chief Financial Officer

(Principal Financial and Accounting Officer)

CERTIFICATIONS

I, Thomas M. Fitzgerald, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sheffield Pharmaceuticals, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

_____/s/ Thomas M. Fitzgerald

_____ Thomas M. Fitzgerald

_____ President & Chief Executive Officer

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I, Scott A. Hoffmann, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sheffield Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements

were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

_____/s/ Scott A. Hoffmann

Scott A. Hoffmann

Vice President & Chief Financial Officer

(Principal Financial and Accounting Officer)

