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FORM 10-Q FOR QUARTER ENDING JUNE 30, 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 JUNE 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.
[X]Yes [ ] No

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

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

FORM 10-Q
For the Quarter Ended June 30, 2002

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PART I: FINANCIAL INFORMATION
Item 1. Financial Statements

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

Assets	June 30, 2002	December 31, 2001
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 855,920	$ 859,298
Clinical supplies	499,422	427,550
Prepaid expenses and other current assets	208,173	86,080
Total current assets	1,563,515	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	(426,714)	(355,014)
Property and equipment, net	306,563	347,234
Patent costs, net of accumulated amortization of $26,977 and $20,216, respectively	392,116	308,203
Other assets	27,913	27,913
Total assets	$ 2,290,107	$ 2,056,278
Liabilities and Stockholders' Equity (Net Capital Deficiency)		
Current liabilities:		
Accounts payable	$ 2,263,452	$ 856,216
Accrued liabilities	376,044	441,778
Sponsored research payable	235,757	235,757
Note payable	--	4,000,000
Total current liabilities	2,875,253	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	1,024,341	608,803
Commitments and contingencies	--	--
Total liabilities	15,399,594	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 15,229 and 14,708 shares at June 30, 2002 and December 31, 2001, respectively	152	147
Series D cumulative convertible exchangeable preferred stock, authorized 21,000 shares; issued and outstanding 14,287 and 13,779 shares at June 30, 2002 and December 31, 2001, respectively	143	138
Series E cumulative convertible non-exchangeable preferred stock, authorized 9,000 shares; issued and outstanding 3,231 and 2,124 shares at		

June 30, 2002 and December 31, 2001, respectively	32	21
Series F convertible non-exchangeable preferred stock, 5,000 shares authorized; 5,000 shares issued and outstanding at June 30, 2002 and December 31, 2001	50	50
Common stock, $.01 par value, authorized 100,000,000 shares; issued and outstanding 29,563,712 and 29,001,602 shares at June 30, 2002 and December 31, 2001, respectively	295,637	290,016
Additional paid-in capital	86,519,602	83,120,316
Other comprehensive income	--	--
Deficit accumulated during development stage	(99,925,103)	(92,496,964)
Total stockholders' equity (net capital deficiency)	(13,109,487)	(9,086,276)
Total liabilities and stockholders' equity (net capital deficiency)	$ 2,290,107	$ 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 and Six Months Ended June
30, 2002 and 2001 and for the Period
from October 17, 1986 (inception) to June 30, 2002
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		October 17, 1986 (inception) to June 30,
	2002	2001	2002	2001	2002
Revenues:					
Contract research revenue	$ 5,000	$ 688,348	$ 5,000	$ 869,095	$ 1,775,045
Sublicense revenue	5,000	5,000	5,000	5,000	1,375,000
Total revenues	10,000	693,348	10,000	874,095	3,150,045
Expenses:					
Acquisition of research and development in-process technology	--	--	--	--	29,975,000
Research and development	1,622,136	1,934,362	2,775,926	2,980,135	37,548,481
General and administrative	1,442,734	1,119,531	3,381,400	1,877,800	32,268,146
Total expenses	3,064,870	3,053,893	6,157,326	4,857,935	99,791,627
Loss from operations	(3,054,870)	(2,360,545)	(6,147,326)	(3,983,840)	(96,641,582)
Interest income	4,356	22,382	7,018	50,765	796,405
Interest expense	(180,926)	(51,398)	(330,757)	(109,247)	(1,404,327)
Realized loss on sale of marketable securities	--	--	--	--	(5,580)
Minority interest in loss of subsidiary	54,544	110,151	160,586	182,502	3,679,279
Net loss	$ (3,176,896)	$ (2,279,410)	$ (6,310,479)	$ (3,859,820)	$ (93,575,805)
Preferred stock dividends	(588,914)	(504,953)	(1,141,576)	(992,728)	(6,871,097)
Accretion of mandatorily redeemable preferred stock	--	--	--	--	(103,400)
Net loss - attributable to common shares	$ (3,765,810)	$(2,784,363)	$ (7,452,055)	$ (4,852,548)	$ (100,550,302)
Weighted average common shares outstanding-basic and diluted	29,541,954	28,965,925	29,284,410	28,897,350	11,209,969
Net loss per share of common stock - basic and diluted	$ (0.13)	$ (0.10)	$ (0.25)	$ (0.17)	$ (8.97)

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 June 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	5	--	--	520,995
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	--	--	--	281,928
Net loss	--	--	--	--
Balance June 30, 2002	$ 377	$ 295,637	$ --	$86,519,602

	Other comprehen-sive 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.....	--	--	1,007,000
Series C preferred stock dividends.....	--	(522,187)	(1,187)
Series D preferred stock dividends.....	--	(488,331)	(331)
Series E preferred stock issued.....	--	--	1,000,000
Series E preferred stock dividends.....	--	(107,142)	(142)
Common stock warrants issued.....	--	--	281,928
Net loss.....	--	(6,310,479)	(6,310,479)
Balance June 30, 2002.....	$ --	$(99,925,103)	$ (13,109,487)

See notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Six Months Ended June 30, 2002 and 2001 and for the Period
from October 17, 1986 (inception) to June 30, 2002
(Unaudited)

	Six Months Ended June 30,		October 17, 1986 (inception) to June 30,
	2002	2001	2002
Cash outflows from operating activities:			
Net loss.....	$ (6,310,479)	$ (3,859,820)	$ (93,575,805)
Adjustments to reconcile net loss to net cash used by development stage activities:			

Issuance of common stock, stock options/warrants for services	281,928	126,741	3,101,296
Depreciation and amortization	78,461	62,506	807,351
Non-cash acquisition of research and development in-process technology	--	--	1,650,000
Loss on sale of marketable securities	--	--	5,580
Increase in clinical supplies, prepaid expenses & other current assets	(193,965)	(545,393)	(766,636)
Decrease in milestone advance receivable	--	1,000,000	--
Increase in other assets	(90,674)	(57,494)	(387,966)
Increase in accounts payable and accrued liabilities	1,593,511	542,130	2,747,659
Increase in sponsored research payable	--	--	812,827
Other	166,003	(78,773)	391,706
Net cash used by operating activities	(4,475,215)	(2,810,103)	(85,213,988)
Cash flows from investing activities:			
Proceeds from sale of marketable securities	--	--	844,420
Acquisition of laboratory and office equipment, and leasehold improvements	(31,029)	(107,979)	(903,419)
Other	--	--	(57,087)
Net cash used by investing activities	(31,029)	(107,979)	(116,086)
Cash flows from financing activities:			
Payments on debt and capital leases	(4,134)	(3,581)	(854,170)
Net proceeds from issuance of:			
Debt	2,500,000	--	14,550,000
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	343,683	14,770,358
Repurchase and retirement of common stock	--	--	(956,031)
Other	--	--	(500,024)
Net cash provided by financing activities	4,502,866	1,340,102	86,184,910
Net increase (decrease) in cash and cash equivalents	(3,378)	(1,577,980)	854,836
Cash and cash equivalents at beginning of period	859,298	3,041,948	1,084
Cash and cash equivalents at end of period	$ 855,920	$ 1,463,968	$ 855,920
Noncash investing and financing activities:			
Common stock, stock options/warrants issued for services	$ 281,928	$ 126,741	$ 3,101,296
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.....	1,117,660	985,000	6,609,334
Supplemental disclosure of cash flow information:			
Interest paid.....	$ 1,162	$ 1,106	$ 287,482

See notes to consolidated financial statements.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 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 June 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 six months ended June 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., 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. Management believes that the Company's ability to meet its obligations as they become due and to continue as a going concern is dependent upon obtaining additional funding immediately. In an effort to meet this capital requirement, the Company is evaluating various financing alternatives including private offerings of its securities, debt financings, and collaboration and licensing arrangements with other companies. However, the accompanying financial statements do not include any adjustments that might result from the failure to obtain additional financing.

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. 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 June 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 June 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 June 30, 2002, and December 31, 2001, was $2.5 million and $1.0 million, respectively.

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

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.

As part of a strategic alliance with Elan, we are 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"), 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.

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.

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. Contract research revenues for the second quarter of 2002 and 2001 were $5,000 and $688,348, respectively. For the first six months of 2002 and 2001, contract research revenues were $5,000 and $869,095, respectively. The decrease for both the second quarter and first half of 2002 was due to 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, on part, in 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 $1.6 million and $1.9 million for the second quarter of 2002 and 2001, respectively. The decrease of $.3 million for the second quarter of 2002 was primarily due to lower design and development costs associated with finalizing the to-be-marketed Premaire device in December 2001 ($.4 million), higher development expenses in the second quarter of 2001 related to the anticipation of a Phase I trial of RSD's unit dose product ($.3 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 ($.3 million), and lower new product development in the area of polypeptides ($.1 million). These decreases were partially offset by higher expenses related to formulation work on the Tempo dyhydroergotamine ("DHE") product ($.8 million). For the six months ended June 30, 2002 and 2001, R&D costs were $2.8 million and $3.0 million, respectively. The decrease of $.2 million was primarily due to lower design and development costs associated with finalizing the to-be-marketed Premaire device in December 2001 ($.4 million), lower expenses related to formulation work on certain Tempo respiratory products ($.3 million), lower Tempo development costs resulting from industrialization of the device in the first half of 2002 for Phase I and II trials ($.1 million), higher development expenses in the second quarter of 2001 related to the anticipation of a Phase I trial of RSD's unit dose product ($.1 million), and lower product development work in the area of polypeptides ($.1 million). These decreases were partially offset by higher expenses related to formulation work on the Tempo DHE product ($.8 million) and Premaire steroid product ($.1 million).

The following details the status of each of our development programs as of June 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 June 30, 2002, we had spent $3.6 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 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 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, 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 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. 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 June 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 is 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 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 June 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 June 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, we estimate incurring approximately $2.0 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"), 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 June 30, 2002, we incurred-to-date approximately $2.8 million on this project. We intend to fund the continued development work for this program up through the period of outlicensing, currently estimated at approximately $.7 million, after which time it is anticipated that the licensee would assume funding responsibility for further development work. Our additional funding of this program will be through the sale of our remaining $1.0 million of Series E Preferred Stock committed to be purchased by Elan.

General and Administrative

General and administrative expenses were $1.4 million for the second quarter of 2002 as compared to $1.1 million for the second quarter of 2001. The increase of $.3 million from 2001 was primarily due to higher severance-related costs and ongoing benefit coverage associated with the resignation of the Chief Executive Officer effective April 30, 2002. For the six months ended June 30, 2002 and 2001, general and administrative expenses were $3.4 million and $1.9 million, respectively. The increase of $1.5 million from 2001 was primarily due to higher consulting costs, legal fees and severance-related costs. The higher consulting costs and legal fees were associated with expanded business development, and merger and acquisition activities in the area of licensing and partnering of our delivery systems, as well as potential acquisitions of complementary pulmonary delivery technologies and companies ($.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).

Interest

Interest income was $4,356 and $22,382 for the second quarter of 2002 and 2001, respectively, and $7,018 and $50,765 for the first six months of 2002 and 2001, respectively. The decrease in interest income for both the second quarter and first six months of 2002 was primarily due to less cash available for investment and lower yields on those investments.

Interest expense was $180,926 and $51,398 for the second quarter of 2002 and 2001, respectively, and $330,757 and $109,247 for the first half of 2002 and 2001, respectively. The increase for both the second quarter and first six months of 2002 resulted primarily from interest associated with the borrowings on the August 2001 Note Purchase Agreement with Elan Pharma. The borrowings totaled $4 million as of January 1, 2002 and $5 million as of April 5, 2002; no borrowings were outstanding for the first half of 2001.

LIQUIDITY AND CAPITAL RESOURCES

At both June 30, 2002 and December 31, 2001, we had $.9 million in cash and cash equivalents. The comparable cash balances between periods reflect 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, and $1.0 million in proceeds from the exercise of a portion of a common stock warrant by Elan International Services, Ltd., offset by cash disbursements of $4.5 million used primarily to fund operating activities.

Cash available for funding our operations as of June 30, 2002 was $.9 million. As of such date, we had trade payables and accrued liabilities of $2.6 million, and current research obligations of $.2 million. In addition, committed and/or anticipated funding of research and development after June 30, 2002 is estimated at approximately $.3 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 the Company to fund its portion of RSD's operating and development costs. As of August 12, 2002, we had cash and equivalents of approximately $.5 million, of which $.2 million is committed to fund our portion of RSD's expenditures. In addition, through the sale of our Series E Preferred Stock, we have available $1.0 million to fund our portion of future RSD expenditures. As of such date, we had trade payable and accrued liabilities of approximately 2.8 million. In an effort to trim our short-term costs, we recently decreased our total headcount by 27% by reducing our administrative headcount. In addition, we have reduced all R&D expenditures not specifically related to the Tempo DHE, unit dose nebulizer, Premaire and certain Tempo respiratory programs. We may consider future cost reductions by curtailing these development programs, as well as other administrative and R&D headcount reductions.

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 may be curtailed if future financings are not completed.

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 June 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 its 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, of which $1.0 million of such commitment remains outstanding. The proceeds from the Series E Preferred Stock will be utilized by us to fund our 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 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 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 $96.6 million of operating losses since our inception, including $6.1 million during the six months ended June 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.

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

We need to raise substantial additional capital to fund our operations. 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, 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.

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 $13.1 million at June 30, 2002. We have been requested by the AMEX to submit a plan advising the AMEX of the action we will take that will bring us into compliance with continued listing standards. If this plan is accepted by the AMEX, we will be able to continue our listing pursuant to an extension, and subject to periodic reviews to determine whether we are progressing consistent with the plan. There can be no assurance that the plan will be accepted by the AMEX, or that we will be able to meet the objectives outlined in the plan, both of 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. In addition, we also have a commitment from Elan International to purchase shares of Series E cumulative convertible non-exchangeable preferred stock at our option (subject to satisfaction of certain conditions). Except for the previously-mentioned purchase commitment for Series E preferred stock, and 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 have granted anti-dilutions rights to The Tail Wind Fund Ltd. which may require us to issue additional shares to Tail Wind, make cash payments to Tail

Wind and may hinder our ability to raise additional funds.

Pursuant to our December 2000 private placement with The Tail Wind Fund Ltd., until at least August 29, 2002, if we sell shares of our common stock or securities convertible into or exercisable for common stock for less than $3.5888 per share, we are obligated to issue to Tail Wind additional shares so that the number of shares purchased by Tail Wind in the December 2000 private placement plus the additional shares issued to Tail Wind equals the number of shares that Tail Wind could have purchased for $2,250,000 at the price per share at which the new shares are sold. The presence of these anti-dilution rights may negatively affect our ability to obtain additional financing. In addition, in the event that we are required to issue additional shares to Tail Wind, we may not issue an aggregate of over 5,630,122 shares of our common stock in total to Tail Wind in connection with the December 2000 private placement. If we would otherwise be required to issue more than 5,630,122 shares to Tail Wind, we must instead pay Tail Wind 105% of the cash value of such shares we do not issue.

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

As of June 30, 2002, we had reserved approximately 5,433,206 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 June 30, 2002, we had $2,000,000 principal amount of a convertible promissory note, 15,229 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 10,800,709 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 1,534,052 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.

PART II: OTHER INFORMATION

Item 2. Changes in Securities

The following unregistered securities were issued by the Company during the quarter ended June 30, 2002:

Date of Sale/Issuance	Description of Securities Issued	Number of Shares	Aggregate Offering Price
March 2002	Series E Preferred Stock	1,000	$1,000,000

Each share of these securities is generally convertible prior to September 30, 2006 and into the number of shares of common stock determined by multiplying the number of shares by $1,000, and dividing by $3.89. The issuance of these securities is claimed to be exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving a public offering. There were no underwriting discounts or commissions paid in connection with the issuance of any of these securities.

Item 4. Submission of Matters to a Vote of Security Holders

An annual Meeting of Stockholders was held on June 12, 2002. All management's nominees for director, as listed in the Proxy Statement for the Annual Meeting, were elected. Listed below are the matters voted on by Stockholders and the number of votes cast at the Annual Meeting.

(a) Election of members of the Board of Directors.

Name	Voted for	Voted Against	Votes Withheld	Broker Non-Votes and Abstentions
John M. Bailey	27,513,177	--	1,161,922	--
Thomas M. Fitzgerald	27,292,966	--	1,382,103	--
Digby W. Barrios	27,512,677	--	1,162,422	--
Todd C. Davis	27,513,677	--	1,161,422	--
Andrew J. Ferrara	27,510,677	--	1,164,422	--
Allan M. Fox	27,511,677	--	1,163,422	--

In accordance with Section 121 of the Amex Company Guide (the "Guide"), the Amex requires that the Audit Committee (the "Committee") be comprised solely of independent directors. Todd C. Davis, an affiliate of the Company as defined by the Guide, serves as a member of the Committee under an exception as provided by the Guide. The Board of Directors has determined that it is in the best interest of the Company and its shareholders for Mr. Davis to serve on the Committee for the following reasons: (1) the remaining four Committee members are independent as defined by the Amex, (2) Mr. Davis's financial experience and expertise are important to matters brought forth to the Audit Committee, (3) Mr. Davis does not control a majority of the votes on the Audit Committee and (4) the Board has required, and Mr. Davis has agreed, to abstain from voting on any issues that may be considered in conflict with his current or past affiliations.

(b) Amendment to the Company's 1993 Stock Option Plan to increase the aggregate number of shares of Common Stock reserved for issuance pursuant to the exercise of options granted thereunder from 4,000,000 shares to 5,000,000 shares.

Voted For:	23,691,837
Voted Against:	4,919,402
Votes Abstained:	63,860
Broker Non-Votes:	--

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

(a) Exhibits

10.40 Separation Agreement dated as of April 26, 2002 between the Company and Loren G. Peterson.

(b) Reports on Form 8-K

A current Report on Form 8-K filed with the Securities and Exchange Commission on May 13, 2002 to announce the filing of a press release under Item 5.

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: August 14, 2002 /s/ Thomas M. Fitzgerald

Thomas M. Fitzgerald
President & Chief Executive Officer

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

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