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FORM 10-Q FOR QUARTER ENDED SEPTEMBER 30, 2001

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 SEPTEMBER 30, 2001

Commission file number 1-12584

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

DELAWARE	13-3808303
(State of Incorporation)	(IRS 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 28,953,302 shares as of November 9, 2001.

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

FORM 10-Q
For the Quarter Ended September 30, 2001

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PART I: FINANCIAL INFORMATION
Item 1. Financial Statements

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

	September 30, 2001	December 31, 2000
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,118,149	$ 3,041,948
Marketable equity securities	-	327,422
Milestone advance receivable	-	1,000,000
Prepaid expenses and other current assets	522,048	540,272
Total current assets	2,640,197	4,909,642
Property and equipment:		
Laboratory equipment	341,815	271,748
Office equipment	245,019	211,609
Leasehold improvements	25,309	18,320
Total at cost	612,143	501,677
Less accumulated depreciation and amortization	(324,065)	(235,389)
Property and equipment, net	288,078	266,288
Patent costs, net of accumulated amortization of $17,144 and $9,287, respectively	286,858	258,897
Other assets	29,344	15,830
Total assets	$ 3,244,477	$ 5,450,657
LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 955,368	$ 1,234,765
Sponsored research payable	235,757	235,757
Note payable	2,000,000	-
Total current liabilities	3,191,125	1,470,522
Convertible promissory note	2,000,000	2,000,000
Long-term debt	3,000,000	2,000,000
Other long-term liabilities	560,677	393,855
Commitments and contingencies	-	-
Total liabilities	8,751,802	5,864,377
Minority interest in subsidiary	-	-
Stockholders' equity (net capital deficiency):		
Preferred stock, $.01 par value, authorized 3,000,0000 shares:		
Series C cumulative convertible preferred stock, authorized 23,000 shares; issued and outstanding 14,450 and 13,712 shares at September 30, 2001 and December 31, 2000, respectively	145	137
Series D cumulative convertible exchangeable preferred stock,		

authorized 21,000 shares; 13,325 and 12,870 issued and outstanding at September 30, 2001 and December 31, 2000, respectively	133	129
Series E cumulative convertible non-exchangeable preferred stock, authorized 9,000 shares; 2,049 and 1,004 shares issued and outstanding at September 30, 2001 and December 31, 2000, respectively	21	10
Series F convertible non-exchangeable preferred stock, 5,000 shares authorized; 5,000 shares issued and outstanding at September 30, 2001 and December 31, 2000	50	50
Common stock, $.01 par value, authorized 100,000,000 shares; issued and outstanding 29,153,932 and 28,791,643 shares at September 30, 2001 and December 31, 2000, respectively	291,539	287,916
Additional paid-in capital	82,862,873	80,108,095
Other comprehensive income	-	157,467
Deficit accumulated during development stage	(88,662,086)	(80,967,524)
Total stockholders' equity (net capital deficiency)	(5,507,325)	(413,720)
Total liabilities and stockholders' equity (net capital deficiency)	$ 3,244,477	$ 5,450,657

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, 2001 and 2000 and
for the Period from October 17, 1986 (inception) to September 30, 2001
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		October 17, 1986 (inception) to
	2001	2000	2001	2000	September 30, 2001
Revenues:					
Contract research revenue	$ -	$ 46,109	$ 869,095	$ 291,784	$ 1,770,045
Sublicense revenue	-	-	5,000	-	1,370,000
Total revenues	-	46,109	874,095	291,784	3,140,045
Expenses:					
Acquisition of research and development in-process technology	-	-	-	-	29,975,000
Research and development	1,686,046	892,411	4,666,181	2,677,189	33,439,042
General and administrative	1,031,562	521,060	2,909,362	1,907,205	27,244,447
Total expenses	2,717,608	1,413,471	7,575,543	4,584,394	90,658,489
Loss from operations	(2,717,608)	(1,367,362)	(6,701,448)	(4,292,610)	(87,518,444)
Interest income	4,362	21,193	55,127	115,685	786,076
Interest expense	(95,039)	(57,267)	(204,286)	(164,424)	(1,002,001)
Realized gain (loss) on sale of marketable securities	79,706	67,031	79,706	119,645	(5,580)
Minority interest in loss of subsidiary	135,758	18,264	318,260	62,663	3,458,332
Loss before extraordinary item	(2,592,821)	(1,318,141)	(6,452,641)	(4,159,041)	(84,281,617)
Extraordinary item	-	-	-	-	42,787
Net loss	$(2,592,821)	$(1,318,141)	$ (6,452,641)	$(4,159,041)	$(84,238,830)
Accretion of mandatorily redeemable preferred stock	-	-	-	-	(103,400)
Net loss - attributable to common shares	$(2,592,821)	$(1,318,141)	$ (6,452,641)	$(4,159,041)	$(84,342,230)
Weighted average common shares outstanding-basic and diluted	29,052,998	28,100,673	28,949,802	27,888,877	10,313,147
Net loss per share of common stock - basic and diluted:					
Loss before extraordinary item	$ (0.09)	$ (0.05)	$ (0.22)	$ (0.15)	$ (8.18)
Extraordinary item	-	-	-	-	-
Net loss per share	$ (0.09)	$ (0.05)	$ (0.22)	$ (0.15)	$ (8.18)

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, 2001
(Unaudited)

	Preferred stock	Common stock	Notes receivable in connection with sale of stock	Additional paid-in capital	Other comprehen-sive income (loss)	Deficit accumulated during development stage	Total stockholders' equity (net capital deficiency)
Balance at October 17, 1986.....	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Common stock issued.....	-	11,484,953	100,000	30,539,185	-	-	42,124,138
Reincorporation in Delaware at $.01 par value.....	-	(11,220,369)	-	11,220,369	-	-	-
Common stock subscribed.....	-	-	(110,000)	-	-	-	(110,000)
Common stock options and warrants issued.....	-	-	-	240,868	-	-	240,868
Issuance of common stock in connection with acquisition of Camelot Pharmacal, L.L.C.....	-	6,000	-	1,644,000	-	-	1,650,000
Common stock options extended.....	-	-	-	215,188	-	-	215,188
Accretion of issuance costs for Series A preferred stock.....	-	-	-	-	-	(103,400)	(103,400)
Series C preferred stock issued.....	115	-	-	11,499,885	-	-	11,500,000
Series C preferred stock dividends..	4	-	-	413,996	-	(415,112)	(1,112)
Comprehensive income (loss):							
Unrealized loss on marketable securities.....	-	-	-	-	(222,226)	-	-
Net loss.....	-	-	-	-	-	(54,638,251)	-
Comprehensive income (loss).....	-	-	-	-	-	-	(54,860,477)
Balance at December 31, 1998.....	119	270,584	(10,000)	55,773,491	(222,226)	(55,156,763)	655,205
Common stock issued.....	-	2,504	10,000	89,059	-	-	101,563
Series C preferred stock dividends..	9	-	-	865,991	-	(868,277)	(2,277)
Series D preferred stock issued.....	120	-	-	12,014,880	-	-	12,015,000
Series F preferred stock issued.....	50	-	-	4,691,255	-	-	4,691,305
Common stock warrants issued.....	-	-	-	203,452	-	-	203,452
Comprehensive income (loss):							
Unrealized gain on marketable securities.....	-	-	-	-	391,613	-	-
Net loss.....	-	-	-	-	-	(17,384,788)	-
Comprehensive income (loss).....	-	-	-	-	-	-	(16,993,175)
Balance at December 31, 1999.....	298	273,088	-	73,638,128	169,387	(73,409,828)	671,073
Common stock issued.....	-	15,738	-	3,796,072	-	-	3,811,810
Repurchase and retirement of common stock.....	-	(910)	-	(312,279)	-	-	(313,189)
Series C preferred stock dividends..	9	-	-	931,991	-	(934,045)	(2,045)
Series D preferred stock dividends..	9	-	-	854,991	-	(855,750)	(750)
Series E preferred stock issued.....	10	-	-	999,990	-	-	1,000,000

Series E preferred stock dividends..	-	-	4,000	-	(4,750)		(750)
Common stock warrants issued.....	-	-	-	195,202	-	-	195,202
Comprehensive income (loss):							
Unrealized loss on marketable securities.....	-	-	-	-	(11,920)	-	-
Net loss.....	-	-	-	-	-	(5,763,151)	-
Comprehensive income (loss).....	-	-	-	-	-	-	(5,775,071)
Balance at December 31, 2000.....	326	287,916	-	80,108,095	157,467	(80,967,524)	(413,720)
Common stock issued.....	-	3,623	-	390,060	-	-	393,683
Series C preferred stock dividends..	8	-	-	737,992	-	(740,784)	(2,784)
Series D preferred stock dividends..	4	-	-	454,996	-	(455,455)	(455)
Series E preferred stock issued.....	10	-	-	999,990	-	-	1,000,000
Series E preferred stock dividends..	1	-	-	44,999	-	(45,682)	(682)
Common stock warrants issued.....	-	-	-	126,741	-	-	126,741
Comprehensive income (loss):							
Unrealized loss on marketable securities.....	-	-	-	-	(157,467)	-	-
Net loss.....	-	-	-	-	-	(6,452,641)	-
Comprehensive income (loss).....	-	-	-	-	-	-	(6,610,108)
Balance at September 30, 2001.....	$ 349	$ 291,539	$ -	$82,862,873	$ -	$(88,662,086)	$ (5,507,325)

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, 2001 and 2000 and for
the Period from October 17, 1986 (inception) to September 30, 2001
(Unaudited)

	Nine Months Ended September 30,		October 17, 1986 (inception) to September 30,
	2001	2000	2001
Cash outflows from operating activities:			
Net loss.....	$(6,452,641)	$(4,159,041)	$(84,238,830)
Adjustments to reconcile net loss to net cash used by development stage activities:			
Issuance of common stock, stock options/warrants for services.....	126,741	77,002	2,819,368
Depreciation and amortization.....	96,533	96,622	694,868
Non-cash acquisition of research and development in-process technology.....	-	-	1,650,000
(Gain) loss realized on sale of marketable securities.....	(79,706)	(119,645)	5,580
Decrease (increase) in prepaid expenses & other			

Decrease (increase) in prepaid expenses & other current assets	18,224	(224,037)	(581,089)
Decrease in milestone advance receivable	1,000,000	-	-
(Increase) decrease in other assets	(49,332)	(62,054)	(274,305)
Increase (decrease) in accounts payable and accrued liabilities	38,018	(235,167)	839,520
(Decrease) increase in sponsored research payable	-	(73,052)	812,827
Other	(149,043)	95,918	149,005
Net cash used by operating activities	(5,451,206)	(4,603,454)	(78,123,056)
Cash flows from investing activities:			
Proceeds from sale of marketable securities	249,661	164,656	844,420
Acquisition of laboratory and office equipment, and leasehold improvements	(110,466)	(57,602)	(782,285)
Other	-	-	(57,087)
Net cash provided (used) by investing activities	139,195	107,054	5,048
Cash flows from financing activities:			
Payments on debt and capital leases	(5,471)	(4,739)	(848,080)
Net proceeds from issuance of:			
Debt	3,000,000	-	10,050,000
Common stock	-	-	23,433,660
Preferred stock	1,000,000	1,000,000	34,741,117
Proceeds from exercise of warrants/stock options	393,683	1,584,325	13,671,589
Repurchase and retirement of common stock	-	(313,189)	(313,189)
Other	-	-	(500,024)
Net cash provided by financing activities	4,388,212	2,266,397	80,235,073
Net (decrease) increase in cash and cash equivalents	(923,799)	(2,230,003)	2,117,065
Cash and cash equivalents at beginning of period	3,041,948	3,874,437	1,084
Cash and cash equivalents at end of period	$ 2,118,149	$ 1,644,434	$ 2,118,149
Noncash investing and financing activities:			
Common stock, stock options/warrants issued for services	$ 126,741	$ 77,002	$ 2,819,368
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	1,239,000	1,112,000	4,680,369
Supplemental disclosure of cash flow information:			
Interest paid	$ 1,560	$ 1,777	$ 280,820

See notes to consolidated financial statements.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2001
(Unaudited)

1. BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared in accordance with the instructions to Form 10-Q of the Securities and Exchange Commission and should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2000. In the opinion of management, all adjustments (consisting only of normal recurring accruals) necessary to present fairly the financial position, results of operations, stockholders' equity and cash flows at September 30, 2001 and for all periods presented have been made. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. The results of operations for the three and nine months ended September 30, 2001 and 2000 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 Company has generated minimal operating revenue, sustained significant net operating losses, and requires additional capital that the Company intends to obtain through out-licensing as well as through equity and debt offerings to continue to operate its business. Even if the Company is able to successfully develop new products, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products to be profitable.

2. BASIC LOSS PER COMMON SHARE

Basic net loss per share is calculated in accordance with Statement of Financial Accounting Standards No. 128, Earnings Per Share. Basic net loss per share is based upon the weighted average common stock outstanding during each period. Potentially dilutive securities such as stock options,

warrants, convertible debt and preferred stock, have not been included in any periods presented as their effect is antidilutive.

On October 17, 2001, as part of the September 28, 2001 amendment of the Company's 1998 agreement with Zambon Group, SpA ("Zambon"), the Company repurchased from Zambon, 214,997 shares of common stock for $3.0233 per share ("Repurchase Price"). In addition, the Company received an option, expiring December 31, 2002, to repurchase the remaining shares of the Company's common stock held by Zambon at the Repurchase Price. In the event the Company completes a sublicense for the North American rights or a sublicense for the non- North American rights to the Premaire respiratory products prior to December 31, 2002, the Company will repurchase from Zambon 882,051 shares of the Company's common stock on each of the events.

3. LONG-TERM DEBT

In September 2001, in connection with the amendment of its 1998 agreement with Zambon, the Company entered into a Loan and Security Agreement (the "Loan") 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, with additional borrowings of $1.0 million and $.5 million to be made on January 1, 2002 and April 1, 2002, respectively. The Loan 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 at September 30, 2001, and December 31, 2000, was $1.0 million and $0, respectively.

As part of the amendment of its 1998 agreement with Zambon, the terms of all milestone advances received from Zambon were modified in that the Company shall repay $1.0 million of the advance milestone payments upon the earlier of December 31, 2003, or upon the first regulatory approval for either albuterol or an inhaled steroid delivered in the Premaire. The remaining $1.0 million advance shall be repaid by the Company on the earlier of December 31, 2005, or the regulatory approval of the second product (albuterol or an inhaled steroid) delivered in the Premaire. Due to the modification in the repayment terms, the advances, totaling $2.0 million at both September 30, 2001 and December 31, 2000, have been reclassified in the Company's balance sheet as long-term debt.

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

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

In 1997, the Company acquired the Premaire Delivery System, a portable nebulizer-based pulmonary delivery system, through a worldwide exclusive license and supply arrangement with Siemens AG ("Siemens"). During the second half of 1998, the Company acquired the rights to an additional pulmonary delivery technology, the Tempo Inhaler, from a subsidiary of Aeroquip-Vickers, Inc. ("Aeroquip-Vickers"). The Tempo technology is a new generation propellant-based pulmonary delivery system. Additionally, during 1998, Sheffield licensed from Elan Corporation, plc ("Elan") the Ultrasonic Pulmonary Drug Absorption System ("UPDAS"), a novel disposable unit dose nebulizer system, and Elan's Absorption Enhancing Technology ("Enhancing Technology"), a therapeutic agent to increase the systemic absorption of drugs. In October 1999, the Company licensed Elan's Nanocrystal(TM) technology to be used in developing certain inhaled steroid products.

Using the above pulmonary delivery systems and technologies as platforms, the Company has established strategic alliances for developing some of its initial products with Elan and Siemens.

In June 1998, the Company sublicensed to Zambon Group SpA ("Zambon") worldwide marketing and development rights to respiratory products to be delivered by the Premaire in return for an equity investment in the Company (approximately 10%). From June 1998 to September 2001, Zambon funded the development costs for the respiratory compounds delivered by Premaire. In September 2001, the Company amended its 1998 agreement with Zambon whereby Sheffield regained the rights to the Premaire previously granted to Zambon. As part of the amended agreement, Zambon provided a low-interest, $2.5 million loan to Sheffield to progress the development of the Premaire respiratory program. Upon commercialization, Zambon will be entitled to certain royalties on payments received by Sheffield for albuterol, ipratropium and cromolyn sales for specified periods.

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

In addition to the above alliance with Elan, in 1999, the Company and Elan formed a joint venture, Respiratory Steroid Delivery, Ltd. ("RSD"), to develop certain inhaled steroid products to treat respiratory diseases using Elan's NanoCrystal technology. The inhaled steroid products to be developed include a propellant-based steroid formulation for delivery through the Tempo(TM) Inhaler, 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(TM) Delivery System.

RESULTS OF OPERATIONS

Revenue

Contract research revenues primarily represented revenues earned from a collaborative research agreement with Zambon relating to the development of respiratory applications of Premaire. Contract research revenue for the third quarter of 2001 and 2000 were $0 and $46,109, respectively. The decrease for the third quarter 2001 was due to Sheffield no longer performing development work for Zambon as a result of Sheffield regaining the Premaire respiratory rights in the third quarter of 2001. For the first nine months of 2001 and 2000, contract research revenues were $869,095 and $291,784, respectively. The increase for the first nine months of 2001 is due to higher costs associated with Premaire device development work and testing prior to the start of Phase III Premaire-albuterol clinical trials, partially offset by the Company no longer performing development work for Zambon in the third quarter of 2001. Costs of contract research revenue approximated such revenues and were included in research and development expenses. Future contract research revenues and expenses are anticipated to fluctuate depending, in part, in obtaining additional collaborative agreements and upon the success of current clinical studies.

The Company's ability to generate material revenues is contingent on the successful commercialization of its technologies and other technologies and products that it may acquire, followed by the successful marketing and commercialization of such technologies through licenses, joint ventures and other arrangements.

Research and Development

Research and development ("R&D") expenses were $1,686,046 and $892,411 for the third quarter of 2001 and 2000, respectively. For the nine months ended September 30, 2001 and 2000, R&D costs were $4,666,181 and $2,677,189, respectively. The increase for both the third quarter and the first nine months primarily reflects higher development expenses related to RSD's unit-dose and

Premaire steroid products, higher costs related to development, design and testing of the Tempo Inhaler, and higher costs associated with Premaire device development work and testing prior to the start of Phase III Premaire-albuterol clinical trials. The increase in research and development expenses also reflects slightly higher expenses related to formulation and feasibility work associated with new product development in the area of polypeptides, partially offset by nonrecurring costs incurred in the first nine months of 2000 associated with modifications made to the Premaire Delivery System to enhance its commercial appeal.

General and Administrative

General and administrative expenses were $1,031,562 and $521,060 for the quarters ended September 30, 2001, and 2000, respectively, and $2,909,362 and $1,907,205 for the first nine months of 2001 and 2000, respectively. The increase for both the third quarter and the first nine months of 2001 was primarily due to higher consulting costs and legal fees associated with expanded business development activities.

Interest

Interest income was $4,362 and $21,193 for the third quarter of 2001 and 2000, respectively, and $55,127 and $115,685 for the first nine months of 2001 and 2000, respectively. The decrease in interest income for both the third quarter and first nine months of 2001 was primarily due to less cash available for investment and lower yields on those investments.

Interest expense was $95,039 and $57,267 for the third quarter of 2001 and 2000, respectively, and $204,286 and $164,424 for the first nine months of 2001 and 2000, respectively. The increase for both the third quarter and first nine months of 2001 resulted from interest associated with the August 2001 $2 million convertible promissory note with Elan Pharma International Ltd. ("Elan Pharma").

Realized Gain on Sale of Marketable Securities

Realized gain on sale of marketable securities was $79,706 and $67,061 for the third quarter 2001 and 2000, respectively, and $79,706 and $119,645 for the first nine months of 2001 and 2000, respectively. These gains resulted from the sale of 283,188 and 45,000 shares for the third quarter of 2001 and 2000, respectively, and 283,188 and 75,000 shares for the first nine months of 2001 and 2000, respectively, of the Company's investment in Lorus Therapeutics, Inc. ("Lorus"). As of September 20, 2001, the Company had no remaining investment in Lorus.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2001, the Company had $2,118,149 in cash and cash equivalents compared to $3,041,948 at December 31, 2000. The decrease of $923,799 primarily reflects $6,451,206 of cash disbursements used primarily to fund operating activities, partially offset by the receipt of a $1.0 million milestone advance from Zambon, $1.0 million from the issuance of 1,000 shares of the Company's Series E Cumulative Convertible Preferred Stock, $2.0 million from the proceeds of an unsecured promissory note from Elan Pharma, $1.0 million from the proceeds of a secured loan from Zambon, and $393,683 in net proceeds from the exercise of common stock options and warrants.

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

Zambon, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Zambon, pursuant to which Zambon agreed to lend the Company $2.5 million. The Company received $1.0 million upon signing of the Loan Agreement, with additional borrowings of $1.0 million and $.5 million to be made on January 1, 2002 and April 1, 2002, respectively. The Loan Agreement provides for interest on principal and annually compounded interest at a fixed rate of 2% per annum and is secured by certain security interests in respiratory products developed in the Premaire. One third of the principal balance, together with interest, is payable by the Company upon the Company's execution of an agreement with one or more third parties to develop, co-promote and/or sell certain products in North America, with all remaining unpaid principal and interest due on December 31, 2005.

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

In August 2001, the Company entered into a Note Purchase Agreement with Elan Pharma, pursuant to which Elan Pharma agreed to lend the Company $2 million. All borrowings under the Note Purchase Agreement are evidenced by an unsecured promissory note of the Company of up to $4 million that provides for interest on principal and semi-annually compounded interest at a fixed rate of 10% per annum and a maturity date 360 days after the last funding under the Note Purchase Agreement, or upon the earlier occurrence of one or more specified events.

In October 1999, as part of a licensing agreement with Elan, the Company received gross proceeds of $17,015,000 related to the issuance to Elan of 12,015 shares of Series D Cumulative Convertible Exchangeable Preferred Stock and 5,000 shares of Series F Convertible Non-Exchangeable Preferred Stock. In turn, the Company made an equity investment of $12,015,000 in a joint venture, RSD, representing an initial 80.1% ownership. The remaining proceeds from this preferred stock issuance will be utilized for general operating purposes. As part of the agreement, Elan also committed to purchase, on a drawdown basis, up to an additional $4.0 million of the Company's Series E Preferred Stock, of which $2.0 million of such commitment remains outstanding. The proceeds from the Series E Preferred Stock will be utilized by the Company to fund its portion of RSD's operating and development costs.

In May 1999, in conjunction with the completion of its Phase I/II Premaire-albuterol trial, Zambon provided the Company with a $1.0 million interest-free advance against future milestone payments. In January 2001, the Company received an additional $1.0 million interest-free milestone advance resulting from the demonstration of the technical feasibility of delivering an inhaled steroid formulation in Premaire. The proceeds from these advances are not restricted as to their use by the Company. As part of the amendment of its 1998 agreement with Zambon, the terms of the milestone advances were modified in that the Company shall repay $1.0 million of the advance milestone payments upon the earlier of December 31, 2003, or upon the first regulatory approval for either albuterol or an inhaled steroid delivered in the Premaire. The remaining $1.0 million advance shall be repaid by the Company on the earlier of December 31, 2005, or the regulatory approval of the second product (albuterol or an inhaled steroid) delivered in the Premaire. Due to the modification in the repayment terms, the advances have been reclassified in the Company's balance sheet as long-term debt.

Since its inception, the Company has financed its operations primarily through the sale of securities and convertible debentures, from which it has raised an aggregate of approximately $81.9 million through September 30, 2001, of which approximately $30.0 million has been spent to acquire certain in-process research and development technologies, and $33.4 million has been incurred to fund certain ongoing technology research projects. The Company expects to incur additional costs in the future, including costs relating to its ongoing research and development activities, and preclinical and clinical testing of its product candidates. The Company may also bear considerable costs in connection with filing, prosecuting, defending and/or enforcing its patent and other intellectual property claims. Therefore, the Company will need substantial additional capital before it will recognize significant cash flow from operations, which is contingent on the successful commercialization of the Company's

technologies. There can be no assurance that any of the technologies to which the Company currently has or may acquire rights can or will be commercialized or that any revenues generated from such commercialization will be sufficient to fund existing and future research and development activities.

Because the Company does not expect to generate significant cash flows from operations for at least the next few years, the Company believes it will require additional funds to meet future costs. In an effort to meet its capital requirements, the Company is currently evaluating various financing alternatives including private offerings of its securities, debt financing, and collaboration and licensing arrangements with other companies. There can be no assurance that the Company will be able to obtain such additional funds or enter into such collaborative and licensing arrangements on terms favorable to the Company, if at all. The Company's development programs may be curtailed if future financings are not completed.

IMPORTANT FACTORS THAT MAY AFFECT FUTURE RESULTS

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

The Company's future results are subject to risks and uncertainties including, but not limited to, the risks that (1) the Company may not be able to obtain additional financing on acceptable terms, or at all, to continue to fund its operations, and may be required to delay, reduce the scope of, or eliminate one or more of its research and development programs, or obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop; (2) the Company's product opportunities may not be successfully developed, proven to be safe and efficacious in clinical trials, may not meet applicable regulatory standards, may not receive the required regulatory approvals, or may not be produced in commercial quantities at reasonable costs or be successfully commercialized and marketed; (3) the Company may default in payments required under certain licensing agreements, thereby potentially forfeiting its rights under those agreements; (4) due to rapid technological change and innovation, the Company may not have a competitive advantage in its fields of technology or in any of

the fields in which the Company may concentrate its efforts; (5) government regulation may prevent or delay regulatory approval of the Company's products; (6) the Company may not develop or receive sublicenses or other rights related to proprietary technology that are patentable, one or more of the Company's pending patents may not issue, any issued patents may not provide the Company with any competitive advantages, or issued patents may be challenged by third parties; (7) the Company may not have the resources available to build or otherwise acquire its own marketing capabilities, or agreements with other pharmaceutical companies to market the Company's products may not be reached on terms acceptable to the Company; (8) manufacturing and supply agreements entered into by the Company may not be adequate or the Company may not be able to enter into future manufacturing and supply agreements on acceptable terms; (9) private health insurance and government health program reimbursement price levels may not be sufficient to provide a return to the Company on its investment in new products and technologies; (10) the Company may not be able to maintain or obtain product liability insurance for any future clinical trials; (11) the failure to meet the American Stock Exchange's ("AMEX") listing guidelines may result in the Common Stock of the Company no longer being eligible for listing on the AMEX, which would make it more difficult for investors to dispose of, or to obtain accurate quotations as to the market value of the Company's Common Stock and would make it more difficult for the Company to raise additional funds; (12) announcements of developments in the medical field generally, or in the Company's research areas or by the Company's competitors specifically, may have a materially adverse effect on the market price of, the Company's Common Stock; (13) the exercise of options and outstanding warrants, the conversion of the Company's currently outstanding convertible securities or convertible promissory notes, or conversion of convertible securities issuable in the future may significantly dilute the market price of shares of the Company's Common Stock, and could impair the Company's ability to raise capital through the future sale of its equity securities.

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

PART II: OTHER INFORMATION

Item 2. Changes in Securities.

The following unregistered securities were issued by the Company during the quarter ended September 30, 2001.

Date of Sale/ Issuance	Description of Securities Issued	Number of Shares Sold/Issued	Offering Price per Share ($)	Purchase or Class
September 2001	Common Stock	98,611	$1.375	Advisors in lieu of cash consideration

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

No reports on Form 8-K were filed during the quarter ended September 30, 2001.

Exhibits

10.32 Amendment to Sublicense and Development Agreement dated September 29, 2001, between Sheffield Pharmaceuticals, Inc. and Inpharzam International S.A.

10.33 Loan and Security Agreement dated September 29, 2001, between Sheffield Pharmaceuticals, Inc. and Inpharzam International, S.A.

10.34 Promissory Note dated September 29, 2001 issued to Inpharzam International, S.A.

10.35 Note Purchase Agreement dated August 14, 2001 between Sheffield Pharmaceuticals, Inc. and Elan Pharma International Ltd. (portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).

10.36 Promissory Note dated August 14, 2001 issued to Elan Pharma International Ltd. (portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SHEFFIELD PHARMACEUTICALS, INC.

Dated: November 13, 2001 /s/ Loren G. Peterson

Loren G. Peterson

President & Chief Executive Officer

Dated: November 13, 20001 /s/ Scott A. Hoffmann

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