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QUARTERLY REPORT FOR PERIOD ENDED JUNE 30, 2001

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTER ENDED JUNE 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 of each exchange on which registered
Common Stock. \$.01 par value American Stock Exchange

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

None

Indicate by check mark whether the registrant: (1) has filed all reports
required to be filed by Section 13 or 15(d) of the Securities Exchange Act
during the preceding 12 months (or for such shorter period that the registrant
was required to file such reports), and (2) has been subject to such filing
requirements for the past 90 days. ☒ Yes ☐ No

The number of shares outstanding of the Registrant's Common Stock is 29,035,321 shares as of August 10, 2001.

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

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

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ASSETS

	June 30, 2001	December 31, 2000
	(unaudited)	
Current assets:		
—Cash and cash equivalents	\$ 1,463,968	\$ 3,041,948
—Marketable equity securities.....	308,675	327,422
—Milestone advance receivable.....	--	1,000,000
—Contract research receivable.....	761,529	233,891
—Prepaid expenses and other current assets	324,136	306,381
—Total current assets	2,858,308	4,909,642
Property and equipment:		
—Laboratory equipment	339,328	271,748
—Office equipment	245,019	211,609
—Leasehold improvements	25,309	18,320
—Total at cost	609,656	501,677
—Less accumulated depreciation and amortization	(292,930)	(235,389)
—Property and equipment, net	316,726	266,288
Patent costs, net of accumulated amortization of \$14,252 and \$9,287, respectively	289,750	258,897
Other assets.....	37,506	15,830
—Total assets	\$ 3,502,290	\$ 5,450,657

LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

Current liabilities:		
—Accounts payable and accrued liabilities	\$ 1,594,945	\$ 1,234,765
—Sponsored research payable	235,757	235,757
—Total current liabilities	1,830,702	1,470,522
Convertible promissory note	2,000,000	2,000,000
Unearned revenue	2,000,000	2,000,000
Other long-term liabilities	496,403	393,855
Commitments and contingencies	--	--
—Total liabilities	6,327,105	5,864,377
Minority interest in subsidiary	--	--

Stockholders' equity (net capital deficiency): Preferred stock, \$.01 par value,
—authorized 3,000,000 shares:
—Series C cumulative convertible preferred stock, authorized 23,000
—shares; issued and outstanding 14,197 and 13,712 shares at June 30,

— 2001 and December 31, 2000, respectively	142	137
— Series D cumulative convertible exchangeable preferred stock, authorized		
— 21,000 shares; 13,325 and 12,870 issued and outstanding at June 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 June 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 June 30, 2001 and		
— December 31, 2000	50	50
— Common stock, \$.01 par value, authorized 100,000,000 shares; issued and		
— outstanding 29,035,321 and 28,791,643 shares at June 30, 2001		
— and December 31, 2000, respectively	290,353	287,916
Additional paid-in capital	82,561,062	80,108,095
Other comprehensive income	138,720	157,467
Deficit accumulated during development stage	(85,815,296)	(80,967,524)
— Total stockholders' equity (net capital deficiency)	(2,824,815)	(413,720)
Total liabilities and stockholders' equity (net capital deficiency)	\$ 3,502,290	\$ 5,450,657

See notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF OPERATIONS
For the Three and Six Months Ended June 30, 2001 and 2000
and for the Period
from October 17, 1986 (inception) to June 30, 2001
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		October 17, 1986 (inception) to June 30,
	2001	2000	2001	2000	2001
Revenues:					
— Contract research revenue	\$ 688,348	\$ 124,505	\$ 869,095	\$ 245,675	\$ 1,770,045
— Sublicense revenue	5,000	—	5,000	—	1,370,000

—Total revenues.....	693,348	124,505	874,095	245,675	3,140,045
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Expenses:

—Acquisition of research and develop- ment in-process technology.....	--	--	--	--	29,975,000
—Research and development.....	1,934,362	882,755	2,980,135	1,784,778	31,752,996
—General and administrative.....	1,119,531	691,421	1,877,800	1,386,145	26,212,885

—Total expenses.....	3,053,893	1,574,176	4,857,935	3,170,923	87,940,881
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Loss from operations.....	(2,360,545)	(1,449,671)	(3,983,840)	(2,925,248)	(84,800,836)
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Interest income.....	22,382	41,991	50,765	94,492	781,714
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Interest expense.....	(51,398)	(57,124)	(109,247)	(107,157)	(906,962)
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Realized gain (loss) on sale of

—marketable securities.....	--	52,614	--	52,614	(85,286)
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Minority interest in loss of subsidiary	110,151	28,380	182,502	44,399	3,322,574
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Loss before extraordinary item.....	(2,279,410)	(1,383,810)	(3,859,820)	(2,840,900)	(81,688,796)
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Extraordinary item.....	--	--	--	--	42,787
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Net loss.....	\$(2,279,410)	\$(1,383,810)	\$(3,859,820)	\$(2,840,900)	\$(81,646,009)
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Accretion of mandatorily redeemable

—preferred stock.....	--	--	--	--	(103,400)
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Net loss - attributable to common shares	\$(2,279,410)	\$(1,383,810)	\$(3,859,820)	\$(2,840,900)	\$(81,749,409)
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Weighted average common shares

—outstanding-basic and diluted.....	28,965,925	27,975,234	28,897,350	27,781,815	9,992,155
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Net loss per share of common stock - basic and diluted:

—Loss before extraordinary item..	\$ (0.08)	\$ (0.05)	\$ (0.13)	\$ (0.10)	\$ (8.18)
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—Extraordinary item.....	--	--	--	--	--
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—Net loss per share.....	\$ (0.08)	\$ (0.05)	\$ (0.13)	\$ (0.10)	\$ (8.18)
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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, 2001
(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 options and warrants issued.....	--	--	--	240,868
Issuance of common stock in connection with				
— acquisition of Camelot Pharmacal, L.L.C.....	--	6,000	--	1,644,000
Common stock options extended.....	--	--	--	215,188
Accretion of issuance costs for Series A preferred				
stock.....	--	--	--	--
Series C preferred stock issued.....	115	--	--	11,499,885
Series C preferred stock dividends.....	4	--	--	413,996
Comprehensive income (loss):				
— Unrealized loss on marketable securities...	--	--	--	--
Net loss.....	--	--	--	--
— Comprehensive income (loss).....	--	--	--	--
Balance at December 31, 1998.....	119	270,584	(10,000)	55,773,491
Common stock issued.....	--	2,504	10,000	89,059
Series C preferred stock dividends.....	9	--	--	865,991
Series D preferred stock issued.....	120	--	--	12,014,880
Series F preferred stock issued.....	50	--	--	4,691,255
Common stock warrants issued.....	--	--	--	203,452
Comprehensive income (loss):				
— Unrealized gain on marketable securities.....	--	--	--	--
Net loss.....	--	--	--	--
— Comprehensive income (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):				

— in-process technology.....		1,650,000	
— (Gain) loss realized on sale of marketable securities	(52,614)		85,286
— Increase in prepaid expenses & other current assets	(545,393)	(330,845)	(1,144,706)
— Decrease in milestone advance receivable.....	1,000,000		
— (Increase) decrease in other assets.....	(57,494)	10,760	(282,467)
— Increase (decrease) in accounts payable and accrued liabilities.....	542,130	(220,723)	1,343,632
— (Decrease) increase in sponsored research payable		(73,052)	812,827
— Increase in unearned revenue.....			2,000,000
— Other.....	(78,773)	59,116	219,275
Net cash used by operating activities.....	(2,810,103)	(3,307,833)	(73,481,953)

Cash flows from investing activities:

— Proceeds from sale of marketable securities.....		70,618	594,759
— Acquisition of laboratory and office equipment, and leasehold improvements.....	(107,979)	(40,950)	(779,798)
— Other.....			(57,087)
Net cash provided (used) by investing activities.....	(107,979)	29,668	(242,126)

Cash flows from financing activities:

— Payments on debt and capital leases.....	(3,581)	(3,102)	(846,190)
— Net proceeds from issuance of:			
— Debt.....		5,050,000	
— Common stock.....		23,433,660	
— Preferred stock.....	1,000,000		34,741,117
— Proceeds from exercise of warrants/stock options	343,683	1,566,075	13,621,589
— Repurchase and retirement of common stock.....		(313,189)	(313,189)
— Other.....			(500,024)
Net cash provided by financing activities.....	1,340,102	1,249,784	75,186,963
Net (decrease) increase in cash and cash equivalents.	(1,577,980)	(2,028,381)	1,462,884
Cash and cash equivalents at beginning of period.....	3,041,948	3,874,437	1,084
Cash and cash equivalents at end of period.....	\$ 1,463,968	\$ 1,846,056	\$ 1,463,968

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.....	985,000	876,000	4,426,369

Supplemental disclosure of cash flow information: \$ 1,106 \$ 1,070 \$ 280,266

Supplemental disclosure of cash flow information:	\$ 1,100	\$ 1,070	\$ 200,500
Interest paid.....			

See notes to consolidated financial statements.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 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 June 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 six months ended June 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.

3. SUBSEQUENT EVENT

On August 14, 2001 the Company entered into a Note Purchase Agreement with Elan Pharma International Ltd. ("Elan Pharma"), pursuant to which Elan Pharma agreed to lend the Company \$2 million. Pursuant to the Note Purchase Agreement, Elan Pharma may lend the Company an additional \$2 million if the Company requests such additional financing and Elan Pharma agrees to fund the additional amount. All borrowings under the Note Purchase Agreement are evidenced by a \$4 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 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.

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 its initial products with Elan, Siemens and Zambon Group SpA ("Zambon").

In a collaboration with Zambon, the Company is developing a range of pharmaceutical products delivered by Premaire to treat respiratory diseases. Under its agreement with Zambon, Premaire commercial rights for respiratory products have been sublicensed to Zambon in return for an equity investment in the Company (approximately 10%). Zambon has committed to fund the development costs for respiratory compounds delivered by Premaire, as well as make certain milestone payments and pay royalties on net sales to the Company resulting from these Premaire products. Initial products for respiratory disease therapy delivered through Premaire include albuterol, ipratropium, cromolyn and inhaled steroids. The Company has maintained co-marketing rights for the U.S. The Company's ability to co-market Premaire respiratory products in the U.S. requires no additional payment to Zambon by the Company. Zambon and the Company continue to have discussions regarding the possible modification of their agreement, including the future marketing arrangements for the Premaire respiratory products. Concurrently, the Company, in consultation with Zambon, is having discussions with third parties regarding an arrangement for the development and commercialization of Premaire respiratory products in North America.

As part of a strategic alliance with Elan, the Company is developing therapies for non-respiratory diseases to be delivered to the lungs using both 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, subject to further agreement with Zambon.

Outside of these alliances, the Company owns the worldwide rights to respiratory disease applications of all of its technologies, subject only to the Premaire respiratory rights sublicensed to Zambon.

RESULTS OF OPERATIONS

Revenues

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 2001 and 2000 were \$688,348 and \$124,505, respectively. For the first six months of 2001 and 2000, contract research revenues were \$869,095 and \$245,675, respectively. The increase for both the second quarter and first half 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. Costs of contract research revenues approximate such revenues and are included in research and development expenses. Future contract research revenues and expenses are anticipated to fluctuate depending, in part, upon the success of current clinical studies, and obtaining additional collaborative agreements.

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

Research and Development

Research and development ("R&D") expenses were \$1,934,362 and \$882,755 for the second quarter of 2001 and 2000, respectively. For the six months ended June 30, 2001 and 2000, R&D costs were \$2,980,135 and \$1,784,778, respectively. The increase for both the second quarter and first half of 2001 primarily reflects higher costs associated with the previously described increase in contract research revenues, higher development expenses related to RSD's unit-dose and Premaire steroid products, and formulation and feasibility work associated with

new product development in the area of polypeptides. The increase in research and development expenses also reflects higher costs related to development, design and testing of the Tempo Inhaler, partially offset by nonrecurring costs incurred in the first half of 2000 associated with modifications made to the Premaire Delivery System to enhance its commercial appeal.

General and Administrative

General and administrative expenses were \$1,119,531 and \$691,421 for the quarters ended June 30, 2001, and 2000, respectively, and \$1,877,800 and \$1,386,145 for the first half of 2001 and 2000, respectively. The increase for both the second quarter and the first six months of 2001 was primarily due to higher consulting costs and legal fees associated with expanded business development activities.

Interest

Interest income was \$22,382 and \$41,991 for the second quarter of 2001 and 2000, respectively, and \$50,765 and \$94,492 for the first six months of 2001 and 2000, respectively. The decrease in interest income for both the second quarter and first six months of 2001 was primarily due to less cash available for investment and lower yields on those investments.

Interest expense was \$51,398 and \$57,124 for the second quarter of 2001 and 2000, respectively, and \$109,247 and \$107,157 for the first half of 2001 and 2000, respectively. The decrease in the second quarter of 2001 resulted from a lower interest rate on the Company's convertible note with Elan. The increase in the first half of 2001 resulted from a slightly higher average interest rate on the Company's convertible promissory note with Elan.

LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2001, the Company had \$1,463,968 in cash and cash equivalents compared to \$3,041,948 at December 31, 2000. The decrease of \$1,577,980 primarily reflects \$3,810,103 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, and \$343,683 in net proceeds from the exercise of common stock options and warrants.

On August 14, 2001 the Company entered into a Note Purchase Agreement with Elan Pharma International Ltd. ("Elan Pharma"), pursuant to which Elan Pharma agreed to lend the Company \$2 million. Pursuant to the Note Purchase Agreement, Elan Pharma may lend the Company an additional \$2 million if the Company requests such additional financing and Elan Pharma agrees to fund the additional amount. All borrowings under the Note Purchase Agreement are evidenced by a \$4 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 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 \$17.0 million related to the issuance to Elan of 12,015 shares of Series D Cumulative Convertible Exchangeable Preferred Stock and 5,000 shares of Series F Convertible Non-Exchangeable Preferred Stock. In turn, the Company made an equity investment of \$12,015,000 in a joint venture, RSD, representing an initial 80.1% ownership. The remaining proceeds from this preferred stock issuance 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. Upon the attainment of certain future milestones, the Company will recognize these advances as revenue. If the Company does not achieve these future milestones, the advance must be repaid in quarterly installments of \$250,000 commencing January 1, 2002. The proceeds from these advances are not restricted as to their use by the Company.

Since its inception, the Company has financed its operations primarily through the sale of securities and convertible debentures, from which it has raised an aggregate of approximately \$76.8 million through June 30, 2001, of which approximately \$30.0 million has been spent to acquire certain in-process research and development technologies, and \$31.8 million has been incurred to fund certain ongoing technology research projects. The Company expects to incur additional costs in the future, including costs relating to its ongoing research and development activities, and preclinical and clinical testing of its product candidates. The Company may also bear considerable costs in connection with filing, prosecuting, defending and/or enforcing its patent and other intellectual property claims. Therefore, the Company will need substantial additional capital before it will recognize significant cash flow from operations, which is contingent on the successful commercialization of the Company's technologies. There can be no assurance that any of the technologies to which the Company currently has or may acquire rights can or will be commercialized or that any revenues generated from such commercialization will be sufficient to fund existing and future research and development activities.

Because the Company does not expect to generate significant cash flows from operations for at least the next few years, the Company believes it will require additional funds to meet future costs. 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 will not be adequate or the Company will not be able to enter into future manufacturing and supply agreements on acceptable terms; (9) private health insurance and government health program reimbursement price levels may not be sufficient to provide a return to the Company on its investment in new products and technologies; (10) the Company may not be able to maintain or obtain product liability insurance for any future clinical trials; (11) the failure to meet the American Stock Exchange's ("AMEX") listing guidelines may result in the Common Stock of the Company no longer being eligible for listing on the AMEX, which would make it more difficult for investors to dispose of, or to obtain accurate quotations as to the market value of the Company's Common Stock and would make it more difficult for the Company to raise additional funds; (12) announcements of developments in the medical field generally, or in the Company's research areas or by the Company's competitors specifically, may have a materially adverse effect on the market price of, the Company's Common Stock; (13) the exercise of options and outstanding warrants, the conversion of the Company's currently outstanding convertible securities or convertible promissory notes, or conversion of convertible securities issuable in the future may significantly dilute the market price of shares of the Company's Common Stock, and could impair the

Company's ability to raise capital through the future sale of its equity securities.

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

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PART II: OTHER INFORMATION

Item 2. Changes in Securities

The following unregistered securities were issued by the Company during the quarter ended June 30, 2001:

Date of Sale/ Issuance	Description of Securities Issued	Number of Shares	Aggregate Offering Price
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<hr/>			
June 2001	Series E Preferred Stock	1,000	\$1,000,000

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

An annual Meeting of Stockholders was held on May 8, 2001. 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	Broker Non-Votes Votes Withheld	and Abstentions
---	-----	-----	-----	-----
<hr/>				
Thomas M. Fitzgerald	26,943,208	--	55,034	--
Loren G. Peterson	26,928,208	--	70,034	--
John M. Bailey	26,928,208	--	70,034	--
Digby W. Barrios	26,627,277	--	370,965	--
Todd C. Davis	26,943,208	--	55,034	--
Roberto Rettani	26,572,057	--	426,185	--

(b)

Amendment to the Company's Certificate of Incorporation to increase the number of shares of Common Stock that the Company is authorized to issue from 60,000,000 to 100,000,000.

Voted For: 26,628,741
Voted Against: 337,666
Votes Abstained: 31,835
Broker Non-Votes: --

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

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

~~Exhibits~~
~~3.1 Certification of Incorporation of the Company, as amended.~~

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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: August 10, 2001 /s/ Loren G. Peterson

Loren G. Peterson
President & Chief Executive Officer

Dated: August 10, 2001 /s/ Scott A. Hoffmann

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

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