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10-Q
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FORM 10-Q

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the Quarter Ended September 30, 1999

Commission file number 1-12584

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

DELAWARE	13-3808303
(State of Incorporation)	(IRS Employee Identification Number)

425 SOUTH WOODSMILL 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 27,296,346 shares of Common Stock as of November 12, 1999.

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

Form 10-Q
For the Quarter Ended September 30, 1999

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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

	September 30, December 31, 1998	
	1999	1998
Current assets:	(unaudited)	
Cash and cash equivalents	\$ 828,620	\$ 2,456,290
Marketable equity security	163,992	127,774
Prepaid expenses and other current assets	305,842	39,035
Total current assets	1,298,454	2,623,099
Property and equipment:		
Laboratory equipment	351,291	317,032
Office equipment	168,871	175,062
Leasehold improvements	16,323	1,323
Total at cost	536,485	493,417
Less accumulated depreciation and amortization	(293,278)	(253,995)
Property and equipment, net	243,207	239,422
Other assets	15,642	
Total assets	\$ 1,557,303	\$ 2,862,521
Liabilities and Stockholders' Equity (Net Capital Deficiency)		

Current liabilities:

~~Current liabilities:~~

Accounts payable and accrued liabilities	\$ 573,213	\$ 615,138
Sponsored research payable	449,805	449,805
Notes payable - related party	600,000	101,323
Total current liabilities	1,623,018	1,166,266
Unearned revenue	1,000,000	--
Convertible promissory note	2,000,000	1,000,000
Other long-term liabilities	135,067	41,050
Commitments and contingencies	--	--
Total liabilities	4,758,085	2,207,316
 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; 12,556 and 11,914 shares issued and outstanding at September 30,		
1999 and December 31, 1998, respectively		
125		
119		
Common stock, \$.01 par value, authorized 60,000,000 shares at September 30,		
1999 and 50,000,000 at December 31, 1998; issued and outstanding		
27,296,346 and 27,058,419 shares at September 30, 1999 and December 31,		
1998, respectively		
272,963		
270,584		
Notes receivable in connection with sale of stock	--	(10,000)
Additional paid-in capital	56,617,173	55,773,491
Other comprehensive income (loss)	(186,008)	(222,226)
Deficit accumulated during development stage	(59,905,035)	(55,156,763)
Total stockholders' equity (net capital deficiency)	(3,200,782)	655,205
 Total liabilities and stockholders' equity (net capital deficiency)	 \$ 1,557,303	 \$ 2,862,521

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, 1999 and 1998 and

for the Period October 17, 1986 (inception) to September 30, 1999

(Unaudited)

	Three Months Ended		Nine Months Ended		October 17, 1986
	September 30		September 30		(inception) to
	1999	1998	1999	1998	September 30, 1999

Revenues:

Sublicense revenue	\$ --	\$ --	\$ --	\$ 350,000	\$ 1,360,000
Interest income	6,696	32,450	46,049	35,965	560,149
Total revenues	6,696	32,450	46,049	385,965	1,920,149

Expenses:

Acquisition of research and development in-
process technology

	--	741,745	--	13,241,745	14,975,000
Research and development	919,718	218,063	2,410,672	2,014,167	24,014,363
General and administrative	498,734	1,039,390	1,631,090	2,534,289	21,196,419
Interest	43,186	175,662	108,895	304,343	520,013
Total expenses	1,461,638	2,174,860	4,150,657	18,094,544	60,705,795
Loss before extraordinary item	(1,454,942)	(2,142,410)	(4,104,608)	(17,708,579)	(58,785,646)
Extraordinary item	--	--	--	--	42,787
Net loss	\$(1,454,942)	\$(2,142,410)	\$(4,104,608)	\$(17,708,579)	\$(58,742,859)
Accretion of mandatorily redeemable preferred stock ...	--	--	--	(23,900)	(103,400)
Net loss - attributable to common shares	\$(1,454,942)	\$(2,142,410)	\$(4,104,608)	\$(17,732,479)	\$(58,846,259)

Weighted average common shares outstanding-

basic and diluted	27,296,346	26,858,366	27,216,481	20,203,133	7,541,197
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Net loss per share of common stock - basic and diluted:

Loss before extraordinary item	\$ (0.05)	\$ (0.08)	\$ (0.15)	\$ (0.88)	\$ (7.80)
Extraordinary item	--	--	--	--	.01
Net loss per share	\$ (0.05)	\$ (0.08)	\$ (0.15)	\$ (0.88)	\$ (7.79)

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, 1999 and 1998 and for the Period

October 17, 1986 (inception) to September 30, 1999

(Unaudited)

	Nine Months Ended September 30,		October 17, 1986 (inception) to
	1999	1998	Sept. 30, 1999
	---	---	-----
<hr/>			
Cash outflows from development stage activities and			
—extraordinary gain: Loss before extraordinary item	\$(4,104,608)	\$(17,708,579)	\$(58,785,646)
—Extraordinary gain on extinguishment of debt			42,787
	<hr/>		
—Net loss	(4,104,608)	(17,708,579)	(58,742,859)
	<hr/>		
Adjustments to reconcile net loss to net cash used by development stage			
—activities:			
—Issuance of common stock, stock options/warrants for			
—services	129,692	359,914	2,411,665
—Non-cash acquisition of research and development in-process technology			1,650,000
—Depreciation and amortization	67,867	42,438	461,086
—Other items	102,072	(304,496)	513,666
—(Increase) decrease in other assets	(15,642)	20,057	55,941
—Increase in unearned revenue	1,000,000		1,000,000
—(Increase) decrease in prepaid expenses & other current assets	(266,807)	8,284	(377,424)
—Decrease in accounts payable and accrued liabilities	(44,735)	(361,128)	(17,432)
—(Decrease) increase in sponsored research payable		(20,963)	1,026,875
	<hr/>		
Net cash used by development stage activities	(3,132,161)	(17,964,473)	(52,018,482)
	<hr/>		
Cash flows from investing activities:			
—Proceeds on sale of marketable securities			175,085
—Acquisition of laboratory and office equipment, and			
—leasehold improvements	(71,652)	(89,506)	(520,776)
—Disposition of office equipment		33,560	
—Increase in notes receivable in connection with sale of stock			(240,000)
—Decrease in loan receivable - former officer		12,124	
—Payments of notes receivable	10,000	49,700	229,600
—Purchase of Camelot Pharmacal, L.L.C., net cash acquired			(46,687)
	<hr/>		
Net cash provided (used) by investing activities	(61,652)	5,878	(402,778)
	<hr/>		
Cash flows from financing activities:			
—Principal payments under capital lease	(4,087)		(80,560)
—Proceeds from notes payable - related party	600,000		754,145
—Repayments of notes payable - related party	(104,145)		(154,145)
—Proceeds from issuance of convertible securities	1,000,000	500,000	4,300,000
—Conversion of convertible, subordinated notes			749,976
—Proceeds from issuance of common and preferred stock		20,000,000	27,452,847

Proceeds from issuance of common and preferred stock	--	20,900,000	57,452,847
— Redemption of preferred stock	--	(1,250,000)	(1,250,000)
— Proceeds from exercise of warrants/stock options	--	74,375	11,476,533
Net cash provided by financing activities	1,566,143	20,150,000	53,248,796
Net (decrease) increase in cash and cash equivalents	(1,627,670)	2,191,405	827,536
Cash and cash equivalents at beginning of period	2,456,290	393,608	1,084
Cash and cash equivalents at end of period	\$ 828,620	\$ 2,585,013	\$ 828,620

Noncash investing and financing activities:

Common stock, stock options and warrants issued for services	\$ 129,692	\$ 359,914	\$ 2,411,665
— Common stock redeemed in payment of notes receivable	--	10,400	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	--	4,019,263	5,353,368
— Securities acquired under sublicense agreement	--	350,000	850,000
— Equipment acquired under capital lease	--	--	121,684
— Notes payable converted to common stock	--	--	749,976
— Stock dividends	643,664	182,194	1,422,206

Supplemental disclosure of cash flow information:

— Interest paid	\$ 5,078	\$ 183,081	\$ 272,479
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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 September 30, 1999

(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	--	11,334,252	--	17,024,469
Reincorporation in Delaware at \$.01 par value	--	(11,220,369)	--	11,220,369
Common stock options issued	--	--	--	75,000
Common stock subscribed	--	--	(110,000)	--
Comprehensive income (loss):				
— Unrealized loss on marketable security	--	--	--	--
— Net loss	--	--	--	--

Comprehensive income (loss)			
Balance at December 31, 1996	113,883	(110,000)	28,319,838
Issuance of common stock in connection with			
Acquisition of Camelot Pharmacal, L.L.C	6,000		1,644,000
Common stock issued	6,612	37,400	1,041,750
Common stock options and warrants issued			165,868
Common stock options extended			215,188
Accretion of issuance costs for Series A preferred stock			
Comprehensive income (loss):			
Unrealized gain on marketable security			
Net loss			
Comprehensive income (loss)			
Balance at December 31, 1997	126,495	(72,600)	31,386,644
Common stock issued	144,089	62,600	12,472,966
Series C preferred stock issued	115		11,499,885
Series C preferred stock dividends	4		413,996
Accretion of issuance costs for Series A preferred stock			
Comprehensive income (loss):			
Unrealized loss on marketable security			
Net loss			
Comprehensive income (loss)			
Balance at December 31, 1998	119	270,584	(10,000) 55,773,491
Common stock issued	2,379	10,000	71,996
Series C preferred stock dividends	6		641,994
Common stock warrants issued			129,692
Comprehensive income (loss):			
Unrealized gain on marketable security			
Net loss			
Comprehensive income (loss)			
Balance at September 30, 1999	\$ 125	\$ 272,963	\$ -- \$56,617,173

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	Deficit	Total
Other	accumulated	stockholders'
comprehen-	during	equity (net
sive income	development	capital
(loss)	stage	deficiency)
-----	-----	-----

Balance at October 17, 1986	\$ --	\$ --	\$ --
Common stock issued			28,358,721
Reincorporation in Delaware at \$.01 par value			

reincorporation in Delaware at \$.01 par value	--	--	--
Common stock options issued	--	--	75,000
Common stock subscribed	--	--	(110,000)
Comprehensive income (loss):			
— Unrealized loss on marketable security	(39,232)	--	(39,232)
— Net loss	--	(26,588,652)	(26,588,652)
Comprehensive income (loss)	--	--	(26,627,884)
Balance at December 31, 1996	(39,232)	(26,588,652)	1,695,837
Issuance of common stock in connection with			
— Acquisition of Camelot Pharmacal, L.L.C	--	--	1,650,000
Common stock issued	--	--	1,085,762
Common stock options and warrants issued	--	--	165,868
Common stock options extended	--	--	215,188
Accretion of issuance costs for Series A preferred stock	--	(79,500)	(79,500)
Comprehensive income (loss):			
— Unrealized gain on marketable security	39,232	--	39,232
— Net loss	--	(9,489,138)	(9,489,138)
Comprehensive income (loss)	--	--	(9,449,906)
Balance at December 31, 1997	(36,157,290)	(4,716,751)	
Common stock issued	--	--	12,679,655
Series C preferred stock issued	--	--	11,500,000
Series C preferred stock dividends	--	(415,112)	(1,112)
Accretion of issuance costs for Series A preferred stock	--	(23,900)	(23,900)
Comprehensive income (loss):			
— Unrealized loss on marketable security	(222,226)	--	(222,226)
— Net loss	--	(18,560,461)	(18,560,461)
Comprehensive income (loss)			(18,782,687)
Balance at December 31, 1998	(222,226)	(55,156,763)	655,205
Common stock issued	--	--	84,375
Series C preferred stock dividends	--	(643,664)	(1,664)
Common stock warrants issued	--	--	129,692
Comprehensive income (loss):			
— Unrealized gain on marketable security	36,218	--	36,218
— Net loss	--	(4,104,608)	(4,104,608)
Comprehensive income (loss)			(4,068,390)
Balance at September 30, 1999	\$(186,008)	\$(59,905,035)	\$(3,200,782)

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

September 30, 1999

(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, 1998. 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, 1999 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, 1999 and 1998 are not necessarily indicative of the operating results for the full years. These consolidated financial statements include the accounts of Sheffield Pharmaceuticals, Inc. and its wholly-owned subsidiaries, including Systemic Pulmonary Delivery, Ltd., and Ion Pharmaceuticals, Inc. and are herein referred to as "the Company." All significant intercompany transactions are eliminated in consolidation.

The accompanying unaudited consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company is 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. The Company's ability to meet its obligations as they become due and to continue as a going concern must be considered in light of the expenses, difficulties and delays frequently encountered in developing a new business, particularly since the Company will focus on product development that may require a lengthy period of time and substantial expenditures to complete. Even if the Company is able to successfully develop new products, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products to be profitable. Management believes that the Company's ability to meet its obligations as they become due and to continue as a going concern through December 2000 is dependent upon obtaining additional funding. However, the accompanying consolidated interim financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. BASIC LOSS PER COMMON SHARE

Basic net loss per share is calculated in accordance with Statement of Financial Accounting Standards No. 128, Earnings Per Share. Basic net loss per share is based upon the weighted average common stock outstanding during each period. Potentially dilutive securities such as stock options, warrants, convertible debt and preferred stock, have not been included in any periods presented as their effect is antidilutive.

3. SUBSEQUENT EVENT

On October 18, 1999, pursuant to a definitive agreement with an affiliate of Elan Corporation, plc, Elan International Services, Ltd. ("Elan International"), the Company and Elan International formed a new joint venture to develop certain respiratory steroid products. Under the terms of the agreement, the Company issued to Elan International 12,015 shares of Series D Cumulative Convertible Exchangeable Preferred Stock, convertible into shares of Common Stock of the Company at \$4.86 per Common Share or exchangeable for an additional 30.1% ownership interest in the new joint venture, for \$12.015 million. In turn, the Company made an equity investment of \$12.015 million representing an initial 80.1% ownership in the joint venture. The joint venture paid \$15.0 million to license certain pulmonary NanoCrystal(TM) dispersion technology from Elan Pharmaceutical Technologies, a division of Elan Corporation, plc. Elan International has also committed to purchase, on a drawdown basis, up to an additional \$4.0 million of the Company's Series E Cumulative Convertible Preferred Stock, convertible into shares of Common Stock of the Company at \$3.89 per Common Share. The Series E Preferred Stock will be utilized by the Company to fund its portion of the joint venture's operating and development costs. In addition to the above, the Company issued to Elan International 5,000 shares of Series F Cumulative Convertible Preferred Stock, convertible into shares of Common Stock of the Company at \$3.40 per Common Share, for \$5.0 million. The proceeds of the Series F Preferred Stock will be utilized by Sheffield for its own operating purposes. As part of this transaction, Elan International also received a warrant to purchase 150,000 shares of Common Stock of the Company at an exercise price of \$6.00 per share. To satisfy applicable American Stock Exchange requirements, Sheffield will seek shareholder approval for the issuance of the Series D and E Preferred Stock within the next year.

Item 2.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This report 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. Important factors that could cause actual results to differ materially from the forward-looking statements include the Company's need to obtain substantial additional capital (through financings or otherwise) to fund its operations and the progress of development and licensing/commercialization of the Company's technologies. 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.

OVERVIEW

The Company is a specialty pharmaceutical company focused on the development and commercialization of later stage, lower risk pharmaceutical products that utilize the Company's delivery technologies. In 1997, the Company acquired the Metered Solution Inhaler ("MSI") pulmonary delivery system through a worldwide exclusive license and supply arrangement with Siemens AG. During the second half of 1998, the Company acquired the rights to an additional pulmonary delivery technology, the Aerosol Drug Delivery System ("ADDS") from a subsidiary of Aeroquip-Vickers, Inc. ("Aeroquip-Vickers"). The ADDS technology is a new generation propellant-based pulmonary delivery system.

Using these pulmonary delivery systems as platforms, the Company has established strategic alliances with Elan Corporation, plc ("Elan"), Siemens AG ("Siemens") and Zambon Group SpA ("Zambon") for developing initial products. In a collaboration with Zambon, the Company is developing a range of pharmaceutical products delivered by the MSI to treat respiratory diseases. As part of the strategic alliance with Elan, a world leader in pharmaceutical delivery technology, the Company is developing therapies for systemic diseases to be delivered to the lungs. The initial systemic programs are for therapies in the breakthrough pain and migraine headache markets. Elan licensed two of its own delivery technologies to the Company that complement the MSI and ADDS technologies. Outside of its strategic alliances, the Company owns the worldwide rights to respiratory disease applications of all of its technologies, subject only to the MSI respiratory rights licensed to Zambon. The Company will seek to acquire additional novel platform drug delivery systems and technologies.

RESULTS OF OPERATIONS

REVENUE

From inception through the period ended June 30, 1999, the Company has earned sublicense revenue of \$1,360,000 related to the sublicensing of various early stage technologies. As part of the Company's focus on later stage opportunities, the Company continues seeking to outlicense its remaining portfolio of early stage technologies. There can be no assurance that the Company will receive license fees or other payments related to these technologies. The Company believes these early stage technologies will have no material impact on the financial position of the Company.

Interest income earned from available cash balances for investment was \$6,696 and \$32,450 for the quarters ended September 30, 1999 and 1998, respectively, and \$46,049 and \$35,965, for the nine months ended September 30, 1999 and 1998, respectively. From inception through the period June 30, 1999, the Company has earned interest income of \$560,149.

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.

ACQUISITION OF RESEARCH & DEVELOPMENT IN-PROCESS TECHNOLOGY

Acquisition of research and development in-process technology were \$0 and \$741,745 for the third quarter of 1999 and 1998, respectively, and \$0 and \$13,241,745 for the first nine months of 1999 and 1998, respectively. In the

second quarter of 1998 the Company licensed certain delivery technologies from Elan for \$12,500,000 and in the third quarter of 1998 the Company purchased the ADDS from Aeroquip-Vickers, Inc. The acquisition of research and development in-process technology from inception to June 30, 1999 of \$14,975,000 reflects the acquisitions of Camelot Pharmacal, LLC in 1997 for \$1,650,000, and the previously mentioned licensing of Elan delivery technologies and purchase of the ADDS.

RESEARCH AND DEVELOPMENT

Research and development expenses were \$919,718 and \$218,063 for the third quarter of 1999 and 1998, respectively, and \$2,410,672 and \$2,014,167, for the first nine months of 1999 and 1998, respectively. The increase in both the three and nine month periods of 1999 of \$701,655 and \$396,505, respectively, primarily resulted from certain device development expenses relating to the MSI and ADDS, costs associated with the completion of the Company's study for the delivery of morphine utilizing the MSI, and the initiation of a study for migraine therapy using the ADDS. These increases were partially offset by the shifting of responsibility for development expenses of the respiratory applications of the MSI to the Company's partner, Zambon.

GENERAL AND ADMINISTRATIVE

General and administrative expenses were \$498,734 and \$1,039,390 for the three months ended September 30, 1999 and 1998, respectively, and \$1,631,090 and \$2,534,289 for the nine months ended September 30, 1999 and 1998, respectively. The decrease in the third quarter of 1999 of \$540,656 was primarily attributable to the 1998 costs associated with the retention of the Company's former investor relations firm, as well as the legal fees associated with completing the 1998 agreement with Elan. In addition to the above-mentioned investor relations expense and higher legal fees, the decrease for the first nine months of 1999 of \$903,199 reflects additional legal and consulting costs associated with completing the Zambon agreement and the expense associated with the settlement of an old dispute with the innovator of one of the Company's early stage research projects, both of which occurred in 1998.

INTEREST EXPENSE

Interest expense was \$43,186 and \$175,662 for the third quarters of 1999 and 1998, respectively, and \$108,895 and \$304,343 for the first nine months of 1999 and 1998, respectively. The decrease in 1999 as compared to 1998 primarily resulted from interest associated with the Company's Series A Cumulative Convertible Preferred Stock and 6% Convertible Subordinated Debentures which were both converted into Common Stock during 1998.

LIQUIDITY AND CAPITAL RESOURCES

The Company's cash available as of September 30, 1999 for funding its operations was \$828,620. As of such date, the Company had trade payables of \$573,213 and current research obligations of \$449,805. Subsequent to September 30, 1999, the Company has committed to fund an additional \$543,713 for development of pulmonary delivery systems, as well as \$4.0 million for the development of certain inhaled steroid products through its new joint venture with Elan International.

On September 30, 1999, the Company signed a letter of agreement to enter into a licensing and funding arrangement with Elan Corporation, plc. As part of this agreement, Elan advanced the Company \$600,000 in the form of a short-term note payable. On October 18, 1999, pursuant to the definitive agreement with an affiliate of Elan Corporation, plc, Elan International Services, Ltd. ("Elan International"), the Company and Elan International formed a new joint venture to develop certain respiratory steroid products. Under the terms of the agreement, the Company issued to Elan International 12,015 shares of Series D Cumulative Convertible Exchangeable Preferred Stock, convertible into shares of Common Stock of the Company at \$4.86 per Common Share or exchangeable for an additional 30.1% ownership interest in the new joint venture, for \$12.015 million. In turn, the Company made an equity investment of \$12.015 million representing an initial 80.1% ownership in the joint venture. The joint venture paid \$15.0 million to license certain pulmonary NanoCrystal(TM) dispersion technology from Elan Pharmaceutical Technologies, a division of Elan Corporation, plc. Elan International has also committed to purchase, on a drawdown basis, up to an additional \$4.0 million of the Company's Series E Cumulative Convertible Preferred Stock, convertible into shares of Common Stock of the Company at \$3.89 per Common Share. The Series E Preferred Stock will be utilized by the Company to fund its portion of the joint venture's operating and development costs. In addition to the above, the Company issued to Elan International 5,000 shares of Series F Cumulative Convertible Preferred Stock, convertible into shares of Common Stock of the Company at \$3.40 per Common Share, for \$5.0 million. A portion of the proceeds of the Series F Preferred Stock was used to repay the short-term note payable, with the remainder to be utilized by Sheffield for its own operating purposes. As part of this transaction, Elan International also received a warrant to purchase 150,000 shares of Common Stock of the Company at an exercise price of \$6.00 per share. To satisfy applicable American Stock Exchange requirements, Sheffield will seek shareholder approval for the issuance of the Series D and E Preferred Stock within the next year.

As part of a 1998 joint venture agreement with Elan relating to the formation of the Company's subsidiary, Systemic Pulmonary Delivery, Ltd. ("SPD"), Elan agreed to make available to the Company a convertible promissory note that provides the Company the right to borrow up to \$2,000,000, subject to satisfying certain conditions. No more than \$500,000 may be drawn under the note in any calendar quarter and at least one-half of the proceeds must be used to fund SPD's development activities. As of September 30, 1999, \$2,000,000 was outstanding under this note.

In May 1999, in conjunction with the completion of its Phase I/II Metered Solution Inhaler-albuterol trial, Zambon Group, SpA provided the Company with a \$1 million interest-free advance against future milestone payments. Upon the attainment of certain future milestones, the Company will recognize this advance 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 this advance are not restricted as to their use by the Company. Upon the achievement of certain other early milestones, Zambon will provide an additional \$1,000,000 advance under the terms of the agreement.

The Company expects to incur additional costs in the future 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. There can be no assurance that any of the technologies to which the Company currently has or may acquire rights to 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. The Company will attempt to meet its capital requirements with existing cash balances and through additional public or 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.

YEAR 2000 COMPLIANCE

The inability of computers, software and other equipment utilizing microprocessors to recognize and properly process data fields containing a two digit year is commonly referred to as the Year 2000 compliance issue. Such systems that are not Year 2000 compliant may not be able to properly interpret dates beyond the Year 1999, which could lead to business disruptions in the U.S. and internationally. The potential costs and uncertainties associated with the Year 2000 issue will depend on a number of factors, including software, hardware and the nature of the industry in which a company operates. Additionally, companies must coordinate with other entities with which they electronically interact, such as customers, creditors and borrowers.

During 1998, the Company conducted an assessment of its computer systems to identify systems that could be affected by the Year 2000 issue. All identified systems that could potentially be affected by the turnover to the Year 2000 were tested. During the second quarter of 1999, all noncompliant internal software and hardware were replaced or upgraded to reach compliance.

The Company continues to seek to obtain Year 2000 compliance certification from its significant third party suppliers. To date, all third party suppliers that have responded to the Company's inquiries have advised that they are Year 2000 compliant or plan to be Year 2000 compliant or substantially compliant by year end. However, there can be no assurance that the computer systems of third party suppliers (and their respective vendors) will be Year 2000 compliant on a timely basis.

The Company relies on several universities and independent laboratories (collectively, "CROs") for conducting a significant portion of the research and development of its technologies and products. In addition, the Company relies on its strategic alliance partners to perform certain manufacturing, research and development activities related to its products in development. If these CROs and/or strategic alliance partners (or their significant vendors) were to experience Year 2000 computer failures, these failures could have a material adverse affect on the Company's business, including the possibility of material delays in the progress of clinical trials, product development and future receipt of product sales and related royalties.

Given the lack of legacy systems at the Company, the limited number of issues that have arisen to date, and the level of development activity anticipated during the end of the year, the Company does not plan to develop a formal contingency plan for its worst case scenario described above. While the Company does not anticipate that its worst case scenario will occur, in the event that any of its major CROs or strategic alliance partners suffer material Year 2000 disruptions that negatively impact the Company, the Company will evaluate the materiality of the disruptions at that time. Following the completion of any necessary evaluation, the Company will determine whether to delay the related clinical trials or other research and development while corrective efforts are being implemented. Depending on the anticipated period of time it will take to complete such efforts, the Company may consider replacing the applicable CRO with another Year 2000 compliant provider.

As of September 30, 1999 the Company has spent approximately \$15,000 to replace software and hardware which were identified as lacking compliance. The Company estimates that it will incur less than an additional \$5,000 to complete its Year 2000 efforts. These costs and the date on which the Company plans to complete the Year 2000 modification and testing processes are based on management's best estimates, which were derived utilizing numerous assumptions of future events including the continued availability of certain resources, third party modification plans and other factors. However, there can be no assurance that these estimates will be achieved and actual results could differ from those plans.

PART II: OTHER INFORMATION

Item 2. CHANGES IN SECURITIES.

The following unregistered securities were issued by the Company during the quarter ended September 30, 1999:

			Number of Shares Sold/Issued		
	Date of	Description	/Subject to	Options or	Offering/Exercise
Sale/Issuance	Issued	Warrants	Price per Share(\$)	Purchaser or Class	
-----	-----	-----	-----	-----	-----

July 1999	Common stock	50,000	\$2.625	Advisors in lieu of
	warrants			cash consideration.

July 1999	Common stock	10,000	\$2.3125	Advisor in lieu of
	warrants			cash consideration.

The issuance of these securities is claimed to be exempt from registration pursuant to Section 4 (2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving a public offering. There were no underwriting discounts or commissions paid in connection with the issuance of any of these securities.

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

No reports on Form 8-K were filed during the quarter ended September 30, 1999.

Exhibits

No.	Description
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27	Financial Data Schedule.

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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: November 12, 1999 /s/ Loren G. Peterson

Loren G. Peterson
President & Chief Executive Officer

Dated: November 12, 1999 /s/ Scott A. Hoffmann

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

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FINANCIAL DATA SCHEDULE

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This schedule contains summary financial information extracted from the condensed financial statements for the quarter ended September 30, 1999 and is qualified in its entirety by reference to such statements.

9-Mos	
Dec-31-1999	
SEP-30-1999	
	828,620
	163,992
	0
	0
	0
	1,298,454
	536,485
	293,278
	1,557,303
	1,623,018
	0
	0
	125
	272,963
	(3,473,870)
	1,557,303
	0
	46,049
	0
	0
	4,150,657
	0
	108,895
	(4,104,608)
	0
	(4,104,608)
	0
	0
	0
	(4,104,608)
	(.15)
	(.15)

-----END PRIVACY-ENHANCED MESSAGE-----