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QUARTERLY REPORT ENDED 9/30/00

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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, 2000

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)

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 28,125,293

shares as of November 1, 2000.

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

FORM 10-Q
For the Quarter Ended September 30, 2000

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Item 1. Financial Statements

PART I: FINANCIAL INFORMATION
Item 1. Financial Statements

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

ASSETS	September 30, 2000	December 31, 1999
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 1,644,434	$ 3,874,437
Marketable equity securities	921,091	519,387
Prepaid expenses and other current assets	369,274	145,237
Total current assets	2,934,799	4,539,061
Property and equipment:		
Laboratory equipment	432,356	407,624
Office equipment	208,347	178,797
Leasehold improvements	18,320	15,000
Total at cost	659,023	601,421
Less accumulated depreciation and amortization	(392,673)	(311,752)
Property and equipment, net	266,350	289,669
Patent costs, net of accumulated amortization of $15,700 and $0, respectively	215,947	204,283
Other assets	50,330	15,642
Total assets	$ 3,467,426	$ 5,048,655
LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 476,243	$ 773,206
Sponsored research payable	348,629	421,681
Total current liabilities	824,872	1,194,887
Convertible promissory note	2,000,000	2,000,000
Unearned revenue	1,000,000	1,000,000
Other long-term liabilities	337,240	182,695
Commitments and contingencies	--	--
Total liabilities	4,162,112	4,377,582
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; 13,472 and 12,780 shares issued and outstanding at September 30, 2000 and December 31, 1999, respectively	135	128
Series D cumulative convertible exchangeable preferred stock, authorized 21,000 shares; 12,435 and 12,015 shares issued and outstanding at September 30, 2000 and December 31, 1999, respectively	124	120
Series E cumulative convertible non-exchangeable preferred stock,		

authorized 9,000 shares; 1,000 and 0 shares issued and outstanding at September 30, 2000 and December 31, 1999, respectively	10	--
Series F convertible non-exchangeable preferred stock, 5,000 shares authorized; 5,000 shares issued and outstanding at September 30, 2000 and December 31, 1999	50	50
Common stock, $.01 par value, authorized 60,000,000 shares; issued and outstanding 28,105,293 and 27,308,846 shares at September 30, 2000 and December 31, 1999, respectively	281,053	273,088
Additional paid-in capital	77,090,280	73,638,128
Other comprehensive income	616,102	169,387
Deficit accumulated during development stage	(78,682,440)	(73,409,828)
Total stockholders' equity (net capital deficiency)	(694,686)	671,073
Total liabilities and stockholders' equity (net capital deficiency)	$ 3,467,426	$ 5,048,655

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 Nine Months Ended September 30, 2000 and 1999 and for the Period from October 17, 1986 (inception) to September 30, 2000
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		October 17, 1986 (inception) to September 30,
	2000	1999	2000	1999	2000
Revenues:					
Contract research revenue	$ 46,109	$ 135,740	$ 291,784	$ 229,449	$ 691,162
Sublicense revenue	--	--	--	--	1,360,000
Total revenues	46,109	135,740	291,784	229,449	2,051,162
Expenses:					

Acquisition of research and development in-process technology	--	--	--	--	29,975,000
Research and development	892,411	1,055,458	2,677,189	2,640,121	27,702,613
General and administrative	521,060	498,734	1,907,205	1,631,090	23,424,755
Total expenses	1,413,471	1,554,192	4,584,394	4,271,211	81,102,368
Loss from operations	(1,367,362)	(1,418,452)	(4,292,610)	(4,041,762)	(79,051,206)
Interest income	21,193	6,696	115,685	46,049	721,726
Interest expense	(57,267)	(43,186)	(164,424)	(108,895)	(737,779)
Realized gain (loss) on sale of marketable securities	67,031	--	119,645	--	(205,270)
Minority interest in loss of subsidiary	18,264	--	62,663	--	3,047,663
Loss before extraordinary item	(1,318,141)	(1,454,942)	(4,159,041)	(4,104,608)	(76,224,866)
Extraordinary item	--	--	--	--	42,787
Net loss	$ (1,318,141)	$ (1,454,942)	$ (4,159,041)	$ (4,104,608)	$(76,182,079)
Accretion of mandatorily redeemable preferred stock	--	--	--	--	(103,400)
Net loss - attributable to common shares	$ (1,318,141)	$ (1,454,942)	$ (4,159,041)	$ (4,104,608)	$(76,285,479)
Weighted average common shares outstanding-basic and diluted	28,100,673	27,296,346	27,888,877	27,216,481	8,991,323
Net loss per share of common stock - basic and diluted:					
Loss before extraordinary item	$ (0.05)	$ (0.05)	$ (0.15)	$ (0.15)	$ (8.48)
Extraordinary item	--	--	--	--	--
Net loss per share	$ (0.05)	$ (0.05)	$ (0.15)	$ (0.15)	$ (8.48)

See notes to consolidated financial statements.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)
For the Period from October 17, 1986 (Inception) to September 30, 2000
(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	--	11,340,864	37,400	18,066,219
Reincorporation in Delaware at $.01 par value	--	(11,220,369)	--	11,220,369
Issuance of common stock in connection with acquisition of Camelot Pharmacal, L.L.C	--	6,000	--	1,644,000
Common stock options issued	--	--	--	240,868
Common stock options extended	--	--	--	215,188
Accretion of issuance costs for Series A preferred stock	--	--	--	--
Common stock subscribed	--	--	(110,000)	--
Comprehensive income (loss):				
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 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	--	8,875	--	1,587,450
Repurchase and retirement of common stock	--	(910)	--	(312,279)
Series C preferred stock dividends	7	--	--	691,993
Series D preferred stock dividends	4	--	--	419,996
Series E preferred stock issued	10	--	--	999,990
Common stock warrants issued	--	--	--	65,002
Comprehensive income (loss):				
Unrealized gain on marketable securities	--	--	--	--
Net loss	--	--	--	--
Comprehensive income (loss)	--	--	--	--
Balance at September 30, 2000	$ 319	$ 281,053	$ --	$ 77,090,280

See notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Nine Months Ended September 30, 2000 and 1999 and for the Period from October 17, 1986 (inception) to September 30, 2000
(Unaudited)

	Nine Months Ended September 30,		October 17, 1986 (inception) to September 30,
	2000	1999	2000
Cash outflows from operating activities:			
Net loss	$ (4,159,041)	$ (4,104,608)	$(76,182,079)
Adjustments to reconcile net loss to net cash used by development stage activities:			
Issuance of common stock, stock options/warrants for services	77,002	129,692	2,562,427
Non-cash acquisition of research and development in-process technology	--	--	1,650,000
Depreciation and amortization	96,622	67,867	576,181

(Gain) loss realized on sale of marketable securities	(119,645)	--	205,270
Increase in prepaid expenses & other current assets	(224,037)	(266,807)	(428,315)
Decrease (increase) in other assets	(62,054)	(15,642)	(222,938)
Decrease in accounts payable and accrued liabilities	(235,167)	(44,735)	(49,301)
(Decrease) increase in sponsored research payable	(73,052)	--	925,699
Increase in unearned revenue	--	1,000,000	1,000,000
Other	95,918	102,072	333,994
Net cash used by development stage activities	(4,603,454)	(3,132,161)	(69,629,062)
Cash flows from investing activities:			
Proceeds on sale of marketable securities	164,656	--	339,741
Acquisition of laboratory and office equipment, and leasehold improvements	(57,602)	(71,652)	(643,314)
Other	--	10,000	(57,087)
Net cash provided (used) by investing activities	107,054	(61,652)	(360,660)
Cash flows from financing activities:			
Payments on debt and capital leases	(4,739)	(4,087)	(840,913)
Net proceeds from issuance of:			
Debt	--	1,600,000	5,050,000
Common stock	--	--	21,418,035
Preferred stock	1,000,000	--	33,741,117
Proceeds from exercise of warrants/stock options	1,584,325	74,375	13,078,046
Repurchase and retirement of common stock	(313,189)	--	(313,189)
Other	--	(104,145)	(500,024)
Net cash provided by financing activities	2,266,397	1,566,143	71,633,072
Net (decrease) increase in cash and cash equivalents	(2,230,003)	(1,627,670)	1,643,350
Cash and cash equivalents at beginning of period	3,874,437	2,456,290	1,084
Cash and cash equivalents at end of period	$ 1,644,434	$ 828,620	$ 1,644,434
Noncash investing and financing activities:			
Common stock, stock options/warrants issued for services	$ 77,002	$ 129,692	$ 2,562,427
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	1,112,000	643,664	2,522,824
Supplemental disclosure of cash flow information: Interest paid	$ 1,777	$ 5,078	$ 278,097

See notes to consolidated financial statements.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2000
(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, 1999. 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, 2000 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, 2000 and 1999 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, lower risk 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. 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.

OVERVIEW

The Company is a specialty pharmaceutical company focused on development and commercialization of later stage, lower risk pharmaceutical products that utilize the Company's unique proprietary pulmonary delivery technologies. 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 nine products in various stages of

development.

In 1997, the Company acquired the Metered Solution Inhaler ("MSI"), 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 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. 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 the MSI to treat respiratory diseases. Under its agreement with Zambon, MSI 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 the MSI, as well as make certain milestone payments and pay royalties on net sales to the Company resulting from these MSI products. Initial products for respiratory disease therapy delivered through the MSI 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 MSI respiratory products in the U.S. requires no additional payment to Zambon by the Company. Zambon and the Company are having discussions regarding the possible modification of their agreement, including the future marketing arrangements for the MSI respiratory products in the United States.

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 the ADDS and MSI. In 1998, the systemic applications of the MSI and ADDS 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 ADDS 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 the MSI. Ergotamine, a therapy for the treatment of migraine headaches, is currently being developed for use in the ADDS.

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 ADDS, 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 MSI 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 MSI respiratory rights sublicensed to Zambon.

RESULTS OF OPERATIONS

Revenue

Contract research revenues primarily represent revenue earned from a collaborative research agreement with Zambon relating to the development of respiratory applications of the MSI. Contract research revenue for the third quarter of 2000 and 1999 were $46,109 and $135,740, respectively. For the first nine months of 2000 and 1999, contract research revenues were $291,784 and $229,449, respectively. The decrease of $89,631 for the third quarter of 2000 primarily reflects certain nonrecurring MSI device development work and testing completed by the Company during the third quarter of 1999, partially offset by three additional respiratory programs in development in 2000 as compared to 1999. The increase for the first nine months of 2000 is primarily due to the research performed by the Company on the three additional respiratory programs, partially offset by the nonrecurring development work completed in the third quarter of 1999 as previously discussed. Costs of contract research revenue approximate such revenue 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 $892,411 and $1,055,458 for the third quarter of 2000 and 1999, respectively. For the nine months ended September 30, 2000 and 1999, R&D costs were $2,677,189 and $2,640,121, respectively. The decrease of $163,047 in the third quarter of 2000 was primarily due to lower development costs on the Company's two systemic programs, and costs associated with decreased contract research revenue as discussed above, partially offset by higher expenses related to the development by RSD of three steroid products initiated during the fourth quarter of 1999, and formulation work begun during 2000 on an undisclosed respiratory product to be delivered via the ADDS. The slight increase for the first nine months of 2000 of $37,068 primarily reflects costs associated with modifications being made to the MSI to enhance its commercial appeal prior to the start of Phase III MSI-albuterol clinical trials. In addition, the increase for the nine month period reflects higher costs associated with the above-mentioned steroid

programs and higher contract research costs, partially offset by lower development costs on the Company's two systemic programs and lower engineering costs related to the ADDS device.

General and Administrative

General and administrative expenses were $521,060 and $498,734 for the quarters ended September 30, 2000, and 1999, respectively, and $1,907,205 and $1,631,090 for the first nine months of 2000 and 1999, respectively. The increase for both the third quarter and the first nine months of 2000 was primarily due to higher consulting costs and legal fees associated with expanded business development activity.

Interest

Interest income was $21,193 and $6,696 for the quarter ended September 30, 2000 and 1999, respectively, and $115,685 and $46,049 for the first nine months of 2000 and 1999, respectively. The increase in interest income for both the third quarter and first nine months of 2000 was primarily due to larger balances of cash available for investment and higher average yields on those investments.

Interest expense was $57,267 and $43,186 for the third quarter of 2000, and 1999, respectively, and $164,424 and $108,895 for the first nine months of 2000 and 1999, respectively. The increase in both the third quarter and first nine months of 2000 resulted from higher outstanding balances on the Company's convertible promissory note with Elan, as well as a higher average interest rate on the note.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2000, the Company had $1,644,434 in cash and cash equivalents compared to $3,874,437 at December 31, 1999. The decrease of $2,230,003 primarily reflects $4,603,454 of cash disbursements used primarily to fund operating activities and $313,189 to repurchase and retire 91,043 shares of the Company's common stock, partially offset by $1,584,325 in net proceeds from the exercise of common stock options and warrants and $1,000,000 from the issuance of 1,000 shares of the Company's Series E Cumulative Convertible Preferred Stock ("Series E Preferred Stock").

During the first nine months of 2000, the Company sold 75,000 shares of its investment in Lorus Therapeutics, Inc. ("Lorus") for proceeds of $164,656, resulting in a gain of $119,645. At September 30, 2000, the value of the Company's remaining Lorus investment of 508,188 shares was $921,091.

In October 1999, as part of a licensing agreement with Elan, the Company received gross proceeds of $17,000,000 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 the above-mentioned preferred stock issuance are being utilized for general

operating purposes. As part of the agreement, Elan also committed to purchase, on a drawdown basis, up to an additional $4,000,000 of the Company's Series E Preferred Stock. 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. As of September 30, 2000, $1,000,000 of Series E Preferred Stock has been purchased by Elan.

In May 1999, in conjunction with the completion of its Phase I/II MSI-albuterol trial, Zambon provided the Company with a $1,000,000 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 Company's use of the proceeds from this advance are not restricted. Upon the achievement of certain other technical milestones, Zambon will provide an additional $1,000,000 advance under the terms of the agreement.

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 $73.3 million through September 30, 2000, of which approximately $30.0 million has been spent to acquire certain in-process research and development technologies, and $27.7 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. 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.

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, or that any issued patents may not provide the Company with any competitive advantages, or that the 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 that 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 that 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; (12) announcements of developments in the medical field generally, or in the Company's research areas or by the Company's competitors specifically, may result in having 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 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

On September 29, 2000, the Company sold 1,000 shares of Series E Cumulative Convertible Preferred Stock ("Series E Preferred Stock") to Elan International Services, Ltd. for an aggregate offering price of $1 million. The Company incurred no underwriting discounts or commissions with the sale of these securities. These securities are convertible into shares of Common Stock of the Company at $3.89 per Common Share. The Series E Preferred Stock earns cumulative dividends payable in shares of Series E Preferred Stock at an annual rate of 9% on the stated value of each outstanding share of Series E Preferred Stock on the dividend date. These securities were issued under section 4(2) of the Securities Act of 1933, as amended, as a transaction not involving a public offering, and accordingly, were exempt from registration.

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

No reports on Form 8-K were filed during the quarter ended September 30, 2000.

Exhibits

No.	Description
27	Financial Data Schedule.

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 3, 2000 /s/ Loren G. Peterson

Loren G. Peterson
President & Chief Executive Officer

Dated: November 3, 2000 /s/ Scott A. Hoffmann

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