-----BEGIN PRIVACY-ENHANCED MESSAGE----- Proc-Type: 2001,MIC-CLEAR Originator-Name: webmaster@www.sec.gov Originator-Key-Asymmetric:

MFgwCgYEVQgBAQICAf8DSgAwRwJAW2sNKK9AVtBzYZmr6aGjlWyK3XmZv3dTINen TWSM7vrzLADbmYQaionwg5sDW3P6oaM5D3tdezXMm7z1T+B+twIDAQAB MIC-Info: RSA-MD5,RSA, AnnV3uLBmAN3yJ978ZihZWqnE/Wj2wjw2Xm9dmXNJan0wLbuOIPbfmcLJNWIY6b4 ntNfrmfi/5OfUuutqsnJWA== 0000921895-99-000570.txt: 19990816 0000921895-99-000570.hdr.sgml: 19990816 ACCESSION NUMBER: 0000921895-99-000570 CONFORMED SUBMISSION TYPE: 10-Q PUBLIC DOCUMENT COUNT: 2 CONFORMED PERIOD OF REPORT: 19990630 FILED AS OF DATE: 19990813 FILER: COMPANY DATA: COMPANY CONFORMED NAME: SHEFFIELD PHARMACEUTICALS INC CENTRAL INDEX KEY: 0000894158 STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834] IRS NUMBER: 133808303 STATE OF INCORPORATION: DE FISCAL YEAR END: 1231 FILING VALUES: FORM TYPE: 10-Q SEC ACT: SEC FILE NUMBER: 001-12584 FILM NUMBER: 99687916 BUSINESS ADDRESS: STREET 1: 425 WOODSMILL RD CITY: ST LOUIS STATE: MO ZIP: 63017 BUSINESS PHONE: 3145799899 MAIL ADDRESS: STREET 1: 425 WOODSMILL RD CITY: ST LOUIS STATE: MO ZIP: 63017 FORMER COMPANY: FORMER CONFORMED NAME: SHEFFIELD MEDICAL TECHNOLOGIES INC DATE OF NAME CHANGE: 19940606

10-Q 1 FORM 10-Q

SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-Q

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

For the Quarter Ended June 30, 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 August 6, 1999.

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

Form 10-Q
For the Quarter Ended June 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	
June 30, December 31, 1999 1998 	
(unaudited)	
Current assets: — Cash and cash equivalents \$ 1,259,022 \$ 2,456,290 — Marketable equity security 191,359 127,774 — Prepaid expenses and other current assets 124,814 39,6))35
Total current assets	
Property and equipment:	
— Laboratory equipment	
Leasehold improvements	
Total at cost	
Less accumulated depreciation and amortization (267,554) (25.	3 ,995)
Property and equipment, net 245,271 239,422	
Other assets 15,642	
Total assets \$ 1,836,108 \$ 2,862,521	
— Liabilities and Stockholders' Equity (Net Capital Deficiency)	

синент наршиез.

— Sponsored research payable	 449,805	449,805
Note payable - related party		101,323
Total current liabilities		 1,166,266
Unearned revenue	1,000,000	
Convertible promissory note	1,500,000	1,000,000
Other long-term liabilities	 95,088	41,050
Commitments and contingencies		
Total liabilities	3,577,954	 2,207,316
Stockholders' equity (net cap	ital deficiency):	
Preferred stock, \$.01 par value, auth	orized 3,000,0000 sh	iares:
Series C cumulative convertible pro	eferred stock, autho	rized
23,000 shares; 12,336 and 11,914 share	es issued and outsta	nding at
June 30, 1999 and December 31, 1998, respecti	vely	123 1
June 30, 1999 and December 31, 1998, respecti ——Common stock, \$.01 par value, authorize	•	
	ed 60,000,000 shares	at June 30,
— Common stock, \$.01 par value, authorize	ed 60,000,000 shares ; issued and outstan	at June 30, ding 27,296,
— Common stock, \$.01 par value, authorize — 1999 and 50,000,000 at December 31, 1998	ed 60,000,000 shares ; issued and outstan 1999 and December 3	at June 30, ding 27,296, 31, 1998,
— Common stock, \$.01 par value, authorize — 1999 and 50,000,000 at December 31, 1998 — 346 and 27,058,419 shares at June 30, 1	ed 60,000,000 shares; ; issued and outstan 1999 and December 3 271,134	at June 30, ding 27,296, 31, 1998, –270,584
Common stock, \$.01 par value, authorize 1999 and 50,000,000 at December 31, 1998 346 and 27,058,419 shares at June 30, 1 respectively	ed 60,000,000 shares; ; issued and outstan 1999 and December 3 271,134 ck	at June 30, ding 27,296, 31, 1998, - 270,584 (10,00
— Common stock, \$.01 par value, authorize — 1999 and 50,000,000 at December 31, 1998, — 346 and 27,058,419 shares at June 30, 1 — respectively	ed 60,000,000 shares; ; issued and outstan 1999 and December 3 271,134 ck	at June 30, ding 27,296, 31, 1998, –270,584 –- (10,00 –55,773,491
Common stock, \$.01 par value, authorize 1999 and 50,000,000 at December 31, 1998 346 and 27,058,419 shares at June 30, 1 respectively Notes receivable in connection with sale of sto Additional paid-in capital	ed 60,000,000 shares; issued and outstan 999 and December 3 271,134 ck	at June 30, ding 27,296, 31, 1998, (10,00 55,773,491
Common stock, \$.01 par value, authorize 1999 and 50,000,000 at December 31, 1998 346 and 27,058,419 shares at June 30, 1 respectively Notes receivable in connection with sale of sto Additional paid-in capital	ed 60,000,000 shares; issued and outstan 1999 and December 3 1999 and December 3 1990 and December 3 1990 and December 3 1990	at June 30, ding 27,296, 31, 1998, -270,584 (10,00 -55,773,491 1) (222,22 416) (55,15
Common stock, \$.01 par value, authorize 1999 and 50,000,000 at December 31, 1998 346 and 27,058,419 shares at June 30, 1 respectively Notes receivable in connection with sale of sto Additional paid-in capital Other comprehensive income (loss) Deficit accumulated during development stage	ed 60,000,000 shares; issued and outstan 1999 and December 3 271,134 ck	at June 30, ding 27,296, 31, 1998, -270,584 (10,00 -55,773,491 1) (222,22 416) (55,15 846) 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 Six Months Ended June 30, 1999 and 1998
and for the Period October 17, 1986 (inception)
to June 30, 1999
(Unaudited)

			June 30	ix Months Ende October 17, (inception	1986
	1999 1 			1998 June 30, 	
	Reven	ues:			
- Sublicense revenue	. \$ 9	350,000	\$	\$ 350,000 \$	1,360,000
- Interest income	17,476 	2,562	39,35: 	3 3,515	-553,453
— Total revenues	 17,476	352,562	39,353	353,515	-1,913,453
— Acquisitio		ch and dev	•		44075000
in-process technology					
Research and developmentGeneral and administrative					
- Interest					
					-
— Total expenses 1,5	5 04,486 1	3,655,683	2,689,01	9 15,919,684 	 59,244,156
Loss before extraordinary item (Extraordinary item					169) (57,330,703) 787
Net loss \$ (1,487,0) 10) \$(13,3 (03,121) \$ (2,649,666) ======	\$(15,566,169) ======	\$(57,287,916)
Accretion of n	nandatorily . 	' redeemab 		ed 3 ,900) (103,40	90)
Net loss - attributable to common shares	\$ (1,487,010 -=====) \$(13,303 ,	,121) \$ (2	. 649,666) \$(15,! 	590,069) \$(57,391,316)
Weighted average was and diluted27,2	_			_	9 7,149,495
Net loss per s Loss before extraordinary item Extraordinary item	dilut	ed:		(0.10) \$ (0.93	8) \$ (8.03) 01
Net loss per share	. \$ (0.05)	\$ (0.67)		0) \$ (0.93) \$	 (8.02)

See notes to consolidated financial statements

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES

(a development stage enterprise)
Consolidated Statements of Cash Flows
For the Three and Six Months Ended June 30, 1999
and 1998 and for the Period October 17, 1986
(inception) to June 30, 1999
(Unaudited)

	Six Months Er		
		- /	
	1999 19	98 June	e 30, 1999
			
Cash outflows from developm	•		
xtraordinary gain: Loss before extraordinary item			
Extraordinary gain on extinguishment of de	ebt		 42,787
Net loss((2,649,666) (15	5, 566,169)	 (57,287,916)
Adjustments to reconcile net l	loss to net cas	 h_used b y	
-development-sta	ige activities:		
— Issuance of common stock, st	tock options/w	arrants fo	f
services	. 105,642	16,389	2,387,615
- Non-cash acquisition of research	and developm	ent in-pro	ocess
technology		 1	1,650,000
- Depreciation and amortization	42, 1	43 26	5,377 435,362
Other items	60,457	(303,826)) 472,051
— (Increase) decrease in other assets	(15,0	542) 2 (0,057 55,941
— Increase in unearned revenue	1,000	,000	 1,000,000
(Increases) decreases in prepaid averages 0 attacks			
(mcrease) decrease in prepaid expenses & otner curre	ent assets	(85,779)	
(Increase) decrease in prepaid expenses & other curre — Decrease in accounts payable and accrued liabilitie) 13,927 (196,3
(Increase) decrease in prepaid expenses & other curre — Decrease in accounts payable and accrued liabilitie — (Decrease) increase in sponsored research payak	es (8 3,991)) 13,927 (196,3 -(171,277) (56,688)
— Decrease in accounts payable and accrued liabilitie	es (ble	83,991)) 13,927 (196,3 -(171,277) (56,688) (588) 1,026,875
— Decrease in accounts payable and accrued liabilitie — (Decrease) increase in sponsored research payable — (Decrease)	es(ble(1,626	83,991)) 13,927 (196,3 -(171,277) (56,688) (588) 1,026,875
Decrease in accounts payable and accrued liabilitie (Decrease) increase in sponsored research payable let cash used by development stage activities	ble(1,626	83,991) 5,836) (15) 13,927 (196,3 -(171,277) (56,688) (588) 1,026,875
Decrease in accounts payable and accrued liabilitie (Decrease) increase in sponsored research payable let cash used by development stage activities Cash flows from invest	ble(1,626	83,991)) 13,927 (196,3 -(171,277) (56,688) (588) 1,026,875 5,965,110) (50,513,15
Decrease in accounts payable and accrued liabilities (Decrease) increase in sponsored research payable let cash used by development stage activities Cash flows from investing the proceeds on sale of marketable securities	sting activities:	83,991)) 13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875 5,965,110) (50,513,15
Decrease in accounts payable and accrued liabilitie — (Decrease) increase in sponsored research payable let cash used by development stage activities Cash flows from investable securities — Proceeds on sale of marketable securities — Acquisition of laboratory an	sting activities: ad office equipn (47,99	83,991) 5,836) (15) 13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875 5,965,110) (50,513,15
Decrease in accounts payable and accrued liabilities (Decrease) increase in sponsored research payable let cash used by development stage activities Cash flows from investing and accrued liabilities	sting activities:	83,991) 5,836) (15 nent, and 2) (2,5	13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875
Decrease in accounts payable and accrued liabilitie (Decrease) increase in sponsored research payable let cash used by development stage activities Cash flows from inverting and the company of	es	83,991) 5,836) (15) 13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875
Decrease in accounts payable and accrued liabilitie — (Decrease) increase in sponsored research payable let cash used by development stage activities — Cash flows from inverse and accrued liabilities — Proceeds on sale of marketable securities — Acquisition of laboratory an — leasehold improvements — Disposition of office equipment	sting activities: ad office equipm (47,99)	83,991) 5,836) (15	13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875
Decrease in accounts payable and accrued liabilitie — (Decrease) increase in sponsored research payable Let cash used by development stage activities — Cash flows from inversional from the securities — Acquisition of laboratory an leasehold improvements — Disposition of office equipment — Increase in notes receivable in connection with securities — Decrease in loan receivable - former officer.	sting activities:	83,991) 5,836) (15 nent, and 2) (2,5	13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875
Decrease in accounts payable and accrued liabilitie (Decrease) increase in sponsored research payable and accrued liabilitie (Decrease) increase in sponsored research payable acceptable acceptable acceptable acceptable in acceptable acceptable acceptable and accrued liabilities	es	83,991) 5,836) (15 ent, and 2) (2,5	13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875
Decrease in accounts payable and accrued liabilitie — (Decrease) increase in sponsored research payable let cash used by development stage activities — Cash flows from inversional from the securities — Proceeds on sale of marketable securities — Acquisition of laboratory an leasehold improvements — Disposition of office equipment	es	83,991) 5,836) (15 ent, and 2) (2,5	13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875
Decrease in accounts payable and accrued liabilitie (Decrease) increase in sponsored research payable let cash used by development stage activities Cash flows from investing activities Proceeds on sale of marketable securities Acquisition of laboratory an leasehold improvements Disposition of office equipment	es	83,991) 5,836) (15	13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875
Decrease in accounts payable and accrued liabilitie (Decrease) increase in sponsored research payable let cash used by development stage activities Cash flows from inversion of laboratory an elasehold improvements Disposition of office equipment Increase in notes receivable in connection with second payments of notes receivable Payments of notes receivable Purchase of Camelot Pharmacal, L.L.C., net cash Net cash provided (used) by investing activities Cash flows from finar	es	83,991) 5,836) (15	13,927 (196,3 -(171,277) (56,688) -(588) 1,026,875
Decrease in accounts payable and accrued liabilities (Decrease) increase in sponsored research payable activities	sting activities:	83,991) 5,836) (15 nent, and 2) (2,5	13,927 (196,3 (171,277) (56,688) (588) 1,026,875
Decrease in accounts payable and accrued liabilitie (Decrease) increase in sponsored research payable let cash used by development stage activities	es	83,991) 5,836) (15 nent, and 2) (2,5	13,927 (196,3 (171,277) (56,688) (588) 1,026,875

— Proceeds from issuance of common and preferred stock
Proceeds from exercise of warrants/stock options
Net cash provided by financing activities
Net (decrease) increase in cash and cash equivalents
Cash and cash equivalents at end of period \$ 1,259,022 \$ 5,421,662 \$ 1,259,022
Noncash investing and financing activities: Common stock, stock options and warrants issued for services \$ 105,642 \$ \$ 2,387,615
— 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 4,019,263 5,353,368
— Securities acquired under sublicense agreement
— Equipment acquired under capital lease 121,684
Notes payable converted to common stock 749,976
Stock dividends
Supplemental disclosure of cash flow information:
— Interest paid \$ 4,152 \$ 182,195 \$ 271,553

See notes to consolidated financial statements.

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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, 1999
(Unaudited)

Notes receivable

in connection Additional

Preferred Common with sale of paid-in

stock stock 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) 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
 - 1,644,00

 Common stock issued
 - 6,612
 37,400
 1,041,750
 1,644,000 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 -- -- --126,495 (72,600) 31,386,644 Balance at December 31, 1997 Common stock issued - 144,089 62,600 12,472,966 Series C preferred stock issued 115 -- --11.499.885 Series C preferred stock dividends4 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 -- 550 10,000 73,825 Series C preferred stock dividends 421,996 Common stock warrants issued 105.642 Comprehensive income (loss): Unrealized gain on marketable security - Net loss Comprehensive income (loss) Balance at June 30, 1999 \$ 123 \$ 271,134 \$ -- \$56,374,954

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	-
Common stock options issued 75,000	
Common stock subscribed (110,000)	
Comprehensive income (loss):	
Unrealized loss on marketable security (39,232) (39,232)	32)
— Net loss (26,588,652) (26,588,652)	
(26,627,884)	
Comprehensive income (loss)	
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 1,650,00	0
Common stock issued 1,085,762	
Common stock options and warrants issued 165,8	868
Common stock options extended 215,188	8
Accretion of issuance costs for Series A preferred stock (79,500) (7	
Comprehensive income (loss):	
Unrealized gain on marketable security 39,232 39,2	
· · · · · · · · · · · · · · · · · · ·	32
Net loss (9,489,138) (9,489,138)	32
— Net loss	32
——————————————————————————————————————	
Comprehensive income (loss) (9,449,906) Balance at December 31, 1997 (36,157,290) (4,716,75	
Comprehensive income (loss)	
Comprehensive income (loss)	51)
Comprehensive income (loss)	51) 2)
Comprehensive income (loss)	51) 2)
Balance at December 31, 1997	51) 2) 3,900)
Comprehensive income (loss)	51) 2) 3,900)
Comprehensive income (loss)	51) 3,900) 226)
Comprehensive income (loss)	51) 3,900) 126)
## Comprehensive income (loss) ## (9,449,906) Balance at December 31, 1997 ## (36,157,290) ## (4,716,755) Common stock issued ## 12,679,655 Series C preferred stock issued ## (415,112) ## (1,112) Accretion of issuance costs for Series A preferred stock ## (23,900) ## (222,226) ## (222,226) ## (222,226) ## (18,560,461) ———————————————————————————————————	51) 3,900) 226)
Comprehensive income (loss) (9,449,906)	51) 3,900) 26) 205
Comprehensive income (loss) (9,449,906)	51) 3,900) 26) 205
## Comprehensive income (loss)	51) 3,900) 226)

—— Co	mprehensive income (loss	s)		(2,586,081) —
Balance at J	une 30, 1999	\$(158,641)	\$(58,229,416)	 \$ (1,741,846)

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, 1999
(Unaudited)

1. BASIS OF PRESENTATION

The accompanying consolidated balance sheet as of June 30, 1999 and the accompanying consolidated statements of operations, stockholders' equity and cash flows for the three and six months ended June 30, 1999 and 1998 and for the period from October 17, 1986 (inception) to June 30, 1999, have been prepared by Sheffield Pharmaceuticals, Inc. without audit. 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, 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. It is suggested that these consolidated financial statements 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. The results of operations for the three and six months ended June 30, 1999 and 1998 are not necessarily indicative of the operating results for the full years.

The consolidated interim 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 consolidated interim 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 1999 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 year. Potentially dilutive securities such as stock options, warrants, convertible debt and preferred stock, have not been included in any years presented as their effect is antidilutive.

3. UNEARNED REVENUE

In May 1999, in conjunction with the completion of the 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 on January 1, 2002. The proceeds from this advance are not restricted as to their use by the Company.

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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 hereby. 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 program 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

Sublicense revenue for the three months ended June 30, 1998 relates to an agreement with Lorus Therapeutics, Inc. (formerly Imutec Pharma Inc.) licensing the rights to a series of compounds for the treatment of cancer, Kaposi's sarcoma and actinic kerotosis. The Company received 583,188 shares of Lorus Therapeutics, Inc. stock with a value of \$350,000. 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 was \$17,476 and \$2,562 for the quarter ended June 30, 1999 and 1998, respectively, and \$39,353 and \$3,515, for the six months ended June 30, 1999 and 1998, respectively. The increase between years is attributable to higher available cash balances for investment reflecting the cash received from the sale of stock associated with the 1998 agreements with Zambon and Elan. From inception through the period June 30, 1999, the Company has earned interest income of \$553,453.

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.

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Acquisition of Research & Development In-Process Technology

Acquisition of research and development in-process technology of \$12,500,000 for the second quarter of 1998 relates to the purchase of certain pulmonary device delivery technologies from Elan. 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, certain delivery technologies from Elan totaling \$12,500,000 and the ADDS from Aeroquip-Vickers for \$825,000 in 1998.

Research and Development

Research and development expenses were \$835,975 and \$187,063 for the second quarter of 1999 and 1998, respectively, and \$1,490,954 and \$1,796,104, for the first half of 1999 and 1998, respectively. The increase for the three month period ended June 30, 1999 of \$648,912 primarily resulted from development expenses associated with the ADDS which was purchased during the third quarter of 1998. The decrease for the six months ended June 30, 1999 of \$305,150 reflects the shifting of responsibility for development expenses of the respiratory applications of the MSI to the Company's partner, Zambon, partially offset by the above-mentioned increase in ADDS development expenses.

General and Administrative

General and administrative expenses were \$632,693 and \$882,409 for the three months ended June 30, 1999 and 1998, respectively, and \$1,132,356 and \$1,494,899 for the six months ended June 30, 1999 and 1998, respectively. The decrease for the second quarter of 1999 of \$249,716 was primarily attributable to the expense associated with the settlement of an old dispute with the innovator of one of the Company's early stage research projects, and legal and consulting fees associated with completing the agreements with Zambon and Elan, both of which occurred in 1998. The decrease for the first half of 1999 of \$362,543 was due to lower compensation expense reflecting fewer employees during the first quarter of 1999 as compared to the same period in 1998, in addition to the above-mentioned settlement and lower legal and consulting costs.

Interest Expense

Interest expense was \$35,818 and \$86,211 for the second quarter of 1999 and 1998, respectively, and \$65,709 and \$128,681 for the first six months of 1999 and 1998, respectively. The decrease in 1999 as compared to 1998 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 June 30, 1999 for funding its operations was \$1,259,022. As of such date, the Company had trade payables of \$352,349 and current research obligations of \$449,805. In addition, subsequent to June 30, 1999, the Company has committed to fund an additional \$1,029,322 for development of pulmonary delivery systems.

As part of an agreement with Elan, 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 June 30, 1999, the Company had borrowed \$1,500,000 under this note. In July 1999, the Company borrowed an additional \$500,000 under the 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 on 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 to fund certain ongoing technology research projects, 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. 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.

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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 relies on various universities and laboratories for conducting a significant portion of the research and development of its products. The Company is currently in the process of communicating with third parties with which it does significant business to determine their Year 2000 compliance readiness and the extent to which the Company is vulnerable to any third party Year 2000 issues. The Company anticipates completing its third party review during the third quarter of 1999. To date, all vendors that have responded to the Company's requests are either fully compliant, or plan to be within the timeframe for the completion of this project. However, there can be no guarantee that the systems of third parties, principally clinical research companies and institutions, on which the Company relies will be timely Year 2000 compliant or that a failure to become Year 2000 compliant by another company, or a Year 2000 conversion process that is incompatible with the Company's systems, would not have material adverse effect on the Company, including delays of continued research and development efforts. At this time, the Company does not anticipate this worst case scenario to occur, nor does the Company anticipate any major interruptions in its development efforts.

Due to the lack of legacy systems at the Company and the limited number of issues that have arisen, to date the Company has not formalized a contingency plan. A formal contingency plan will be addressed after the communication effort with outside vendors/contractors is completed. This contingency plan may include alternate vendor selection if necessary, and address potential manual procedures in areas where systems will not operate properly.

As of June 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 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.

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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, 1999:

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

June 1999 Common stock 50,000 \$2.25 Advisors in lieu warrants of 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 4. Submission of Matters to a Vote of Security Holders

An annual Meeting of Stockholders was held on June 29, 1999. 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.

Voted Votes Broker Non-Votes

Name Voted for Against Withheld and Absentions

Loren G. Peterson 23,119,708 - 63,905 - Thomas M. Fitzgerald 23,118,833 - 64,780 John M. Bailey 23,118,883 - 64,730 - Digby W. Barrios 23,120,883 - 62,730 - Todd C. Davis 23,135,383 - 48,230 - George R. Griffiths 23,134,058 - 49,555 -

(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 50,000,000 to 60,000,000.

Voted For: 22,644,577
Voted Against: 422,316
Voted Abstained: 116,720
Broker Non-Votes: -

(c) Ratification of Ernst & Young LLP as independent public accountant for fiscal year ending December 31, 1999.

Voted For: 22,609,648
Voted Against: 449,900
Voted Abstained: 124,065
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, 1999.

Exhibits 	
	Description
	nancial Data Schedule. -12-
	SIGNATURES
	e with the requirements of the Exchange Act, the registrant caused or be signed on its behalf by the undersigned, thereunto duly
	SHEFFIELD PHARMACEUTICALS, INC.
Dated: Augus	st 11, 1999 /s/ Loren G. Peterson
	Loren G. Peterson President & Chief Executive Officer
Dated: Augus	st 11, 1999 /s/ Scott A. Hoffmann
	Scott A. Hoffmann Vice President & Chief Financial Officer (Principal Financial and Accounting Officer)
	-13-
EX-27 2 FINANCIAL D	ATA SCHEDULE
-	-5
condensed f	e contains summary financial information extracted from the inancial statements for the quarter ended June 30, 1999 and is sentirety by reference to such statements.
	6-Mos Dec-31-1999 Jun-30-1999 1,259,022 191,359 0
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----END PRIVACY-ENHANCED MESSAGE-----