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NAME: SHEFFIELD PHARMACEUTICALS INC CENTRAL INDEX KEY: 0000894158 STANDARD  
INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834] IRS NUMBER:  
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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  
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FORM 10Q

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
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FORM 10-Q

QUARTERLY REPORT UNDER SECTION 13 OR 15(D)  
OF THE SECURITIES EXCHANGE ACT OF 1934

For Quarter Ended September 30, 1998  
Commission File Number 1-12584

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SHEFFIELD PHARMACEUTICALS, INC.  
(EXACT NAME OF REGISTRANT IN ITS CHARTER)

DELAWARE  
(State of Incorporation)

13-3808303  
(IRS Employer Identification No.)

425 SOUTH WOODSMILL ROAD, SUITE 270  
ST. LOUIS, MISSOURI  
(Address of Principal Executive Offices)

63017-3441  
(Zip Code)

Registrant's telephone number, including area code: (314) 579-9899

Indicate by check whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No  
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The number of shares outstanding of the issuer's Common Stock is 27,058,419 shares of Common Stock as of September 30, 1998.

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SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE ENTERPRISE)

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SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE ENTERPRISE)  
CONSOLIDATED BALANCE SHEETS

September 30,  
1998      December 31,  
(Unaudited)      1997  
-----

## ASSETS

## Current assets:

Cash and cash equivalents	\$ 2,585,013	\$ 393,608
Marketable securities	200,500	--
Loan receivable - former officer	67,876	80,000
Prepaid expenses and other current assets	39,094	47,378
Total current assets	2,892,483	520,986

## Property and equipment:

Laboratory equipment	264,273	185,852
Office equipment	120,087	142,562
	384,360	328,414
Less accumulated depreciation and amortization	227,639	185,201
Net property and equipment	156,721	143,213

Other assets 5,681 25,738

Total assets \$ 3,054,885 \$ 689,937

## LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

## Current liabilities:

Accounts payable and accrued liabilities \$ 526,654 \$ 887,782

Sponsored research payable	449,805	470,768
Total current liabilities	976,459	1,358,550
Convertible promissory note	500,000	--
6% convertible subordinated debenture	--	1,551,000
Interest payable on debenture	--	28,875

Preferred stock, \$.01 par value, authorized 3,000,000 shares:		
Series A cumulative convertible redeemable preferred stock,		
0 and 10,000 shares issued and outstanding at September 30, 1998		
and December 31, 1997, respectively	--	2,468,263
Series B cumulative convertible redeemable preferred stock,		
0 shares issued and outstanding at September 30, 1998		
and December 31, 1997	--	--

#### Commitments and contingencies

Stockholders' equity (net capital deficiency):		
Series C convertible preferred stock, 11,500 and 0 shares issued and		
outstanding at September 30, 1998 and December 31, 1997,		
respectively	115	--
Common stock, \$.01 par value. Authorized, 50,000,000 shares;		
issued and outstanding, 27,058,419 and 12,649,539		
shares at September 30, 1998 and December 31, 1997, respectively	270,584	126,495
Notes receivable in connection with sale of stock	(12,500)	(72,600)
Valuation allowance for unrealized loss on marketable securities	(149,500)	--
Additional paid-in capital	55,359,496	31,386,644
Deficit accumulated during development stage	(53,889,769)	(36,157,290)
	1,578,426	(4,716,751)
Total liabilities and stockholders' equity (net capital deficiency)	\$ 3,054,885	\$ 689,937

See accompanying notes to unaudited 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, 1998 AND 1997 AND FOR THE PERIOD  
FROM OCTOBER 17, 1986 (INCEPTION) TO SEPTEMBER 30, 1998  
(UNAUDITED)

Three months ended		October 17, 1986		
September 30,		Nine months ended		(inception) to
		September 30,		September 30,
1998	1997	1998	1997	1998

Revenues:								
Sub-license revenue	\$	--	\$	--	\$ 350,000	\$	--	1,360,000
Interest income		32,450		9,391	35,965		49,363	489,792
<hr/>								
Total revenue		32,450		9,391	385,965		49,363	1,849,792
<hr/>								
Expenses:								
Acquisition of R & D in-process								
technology		741,745		--	13,241,745		1,650,000	14,891,745
Research and development		218,063		570,170	2,014,167		3,283,632	21,266,557
General and administrative		1,039,390		1,325,874	2,534,289		3,087,103	19,056,548
Interest		175,662		2,183	304,343		6,951	464,098
<hr/>								
Total expenses		2,174,860		1,898,227	18,094,544		8,027,686	55,678,948
<hr/>								
Loss before extraordinary item		(2,142,410)		(1,888,836)	(17,708,579)		(7,978,323)	(53,829,156)
Extraordinary item								42,787
<hr/>								
Net loss	\$	(2,142,410)	\$	(1,888,836)	\$(17,708,579)	\$	(7,978,323)	(53,786,369)
<hr/>								
Accretion of mandatorily redeemable								
preferred stock					(23,900)			(103,400)
<hr/>								
Net loss - attributable to common shares	\$	(2,142,410)	\$	(1,888,836)	\$(17,732,479)	\$	(7,978,323)	\$(53,889,769)
<hr/>								
Loss per share of common stock - basic								
and diluted:								
Loss before extraordinary item	\$	(0.08)	\$	(0.16)	\$ (0.88)	\$	(0.68)	\$ (9.13)
Extraordinary item								0.01
<hr/>								
Basic and diluted net loss per share	\$	(0.08)	\$	(0.16)	\$ (0.88)	\$	(0.68)	(9.12)
<hr/>								
Weighted average common shares								
outstanding - basic and diluted:		26,858,366		12,077,667	20,203,133		11,765,653	5,900,036

See accompanying notes to unaudited consolidated financial statements

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES

(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 1998 AND 1997 AND FOR THE PERIOD

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 1998 AND 1997 AND FOR THE PERIOD  
FROM OCTOBER 17, 1986 (INCEPTION) TO SEPTEMBER 30, 1998  
(UNAUDITED)

	Three months ended September 30,	
	1998	1997
<hr/>		
Cash outflows from development stage activities and extraordinary gain:		
— Loss before extraordinary item	\$ (2,142,410)	\$ (1,888,836)
— Extraordinary gain on extinguishment of debt		
	<hr/>	
— Net loss	(2,142,410)	(1,888,836)
Adjustments to reconcile net loss to net cash used by development stage activities:		
— Issuance of common stock, stock options/warrants for fees/services	343,525	118,750
— Non-cash interest income	(670)	
— Non-cash interest expense		
— Non-cash acquisition of R&D in-process technology		
— Securities acquired under sub-license agreement		
— Issuance of common stock for intellectual property rights		
— Amortization of organizational and debt issuance costs		
— Depreciation and amortization	16,061	35,915
— Increase in debt issuance and organizational costs		
— Loss realized on sale of marketable securities		300,259
— Decrease (increase) in prepaid expenses and other current assets	(5,643)	(14,324)
— Decrease (increase) in other assets		
— Increase (decrease) in accounts payable, accrued liabilities	(189,851)	292,130
— Increase (decrease) in sponsored research payable	(20,375)	(196,598)
	<hr/>	
— Net cash used by development stage activities	(1,999,363)	(1,352,704)
<hr/>		
Cash flows from investing activities:		
— Proceeds on sale of marketable securities		174,407
— Decrease in segregated cash		25,000
— Acquisition of laboratory and office equipment	(86,910)	(1,801)
— Disposition of office equipment		
— Increase in notes receivable in connection with sale of stock		
— Decrease (increase) in loan receivable - former officer	(2,876)	
— Payments received on notes receivable	2,500	37,400
— Purchase of Camelot Pharmacal L.L.C., net of cash acquired		
	<hr/>	
— Net cash provided (used) by investing activities	(87,286)	235,006
<hr/>		
Cash flows from financing activities:		
— Principal payments under capital lease		(6,097)
— Proceeds from issuance of convertible notes	500,000	
— Conversion of convertible, subordinated notes		
— Proceeds from issuance of convertible debenture		1,589,614
— Proceeds from issuance of common stock		
— Proceeds from issuance of preferred stock		
— Redemption of preferred stock	(1,250,000)	

<del>—</del> Proceeds from exercise of stock options		
<del>—</del> Proceeds from exercise of warrants		
<del>=====</del>		
<del>—</del> Net cash provided (used) by financing activities	<del>(750,000)</del>	<del>1,583,517</del>
<del>=====</del>		
<del>—</del> Net increase (decrease) in cash and cash equivalents	<del>(2,836,649)</del>	<del>465,819</del>
<del>—</del> Cash and cash equivalents at beginning of period	<del>5,421,662</del>	<del>539,287</del>
<del>=====</del>		
<del>—</del> Cash and cash equivalents at end of period	<del>\$ 2,585,013</del>	<del>\$ 1,005,106</del>
<del>=====</del>		
Noncash investing and financing activities:		
<del>—</del> Common stock, stock options and warrants issued for services	<del>\$ 343,525</del>	<del>\$ 118,750</del>
<del>—</del> Common stock redeemed in payment of notes receivable	<del>10,400</del>	
<del>—</del> Acquisition of R&D in-process technology		
<del>—</del> Common stock issued for intellectual property rights		
<del>—</del> Common stock issued to retire debt		
<del>—</del> Common stock issued to redeem convertible securities		
<del>—</del> Securities acquired under sub-license agreement		
<del>—</del> Unrealized (realized) depreciation of investments	<del>149,500</del>	
<del>—</del> Equipment acquired under capital lease		
<del>—</del> Notes payable converted to common stock		
<del>—</del> Stock dividends		
<del>=====</del>		
Supplemental disclosure of cash flow information:		
<del>—</del> Interest paid	<del>\$ 175,662</del>	<del>\$ 2,183</del>
<del>=====</del>		

See accompanying notes to unaudited consolidated financial statements

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE ENTERPRISE)  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 1998 AND 1997 AND FOR THE PERIOD  
FROM OCTOBER 17, 1986 (INCEPTION) TO SEPTEMBER 30, 1998  
(UNAUDITED)

	October 17, 1986	
	Nine months ended	(inception) to
	September 30,	September 30,
	1998	1997
	1998	1998
<del>=====</del>		
Cash outflows from development stage activities		
— and extraordinary gain:		
<del>—</del> Loss before extraordinary item	<del>\$ (17,708,579)</del>	<del>\$ (7,978,323)</del>
<del>—</del> Extraordinary gain on extinguishment of debt		<del>42,787</del>
<del>=====</del>		

— Net loss	(17,708,579)	(7,978,323)	(53,786,369)
Adjustments to reconcile net loss to net cash used by			
— development stage activities:			
— Issuance of common stock, stock options/warrants			
— for fees/services	359,914	143,750	2,281,973
— Non-cash interest income	(670)	-	(670)
— Non-cash interest expense	46,174	-	125,049
— Non-cash acquisition of R&D in process technology	-	1,650,000	1,650,000
— Securities acquired under sub-license agreement	(350,000)	-	(850,000)
— Issuance of common stock for intellectual property rights	-	-	866,250
— Amortization of organizational and debt issuance costs	-	-	77,834
— Depreciation and amortization	42,438	71,930	289,029
— Increase in debt issuance and organizational costs	-	-	(77,834)
— Loss realized on sale of marketable securities	-	300,259	324,915
— Decrease (increase) in prepaid expenses and other current assets	-	8,284	(74,769)
— Decrease (increase) in other assets	20,057	600	53,360
— Increase (decrease) in accounts payable, accrued liabilities	(361,128)	350,036	(45,200)
— Increase (decrease) in sponsored research payable	(20,963)	(445,120)	1,026,875
— Net cash used by development stage activities	(17,964,473)	(5,981,637)	(48,162,923)
Cash flows from investing activities:			
— Proceeds on sale of marketable securities	-	174,407	175,085
— Decrease in segregated cash	-	25,000	-
— Acquisition of laboratory and office equipment	(89,506)	(3,888)	(406,858)
— Disposition of office equipment	33,560	-	33,560
— Increase in notes receivable in connection with sale of stock	-	-	(240,000)
— Decrease (increase) in loan receivable - former officer	12,124	-	(67,876)
— Payments received on notes receivable	49,700	37,400	217,100
— Purchase of Camelot Pharmacal L.L.C., net of cash acquired	-	(8,259)	(46,687)
— Net cash provided (used) by investing activities	5,878	224,660	(335,676)
Cash flows from financing activities:			
— Principal payments under capital lease	-	(19,538)	(72,453)
— Proceeds from issuance of convertible notes	500,000	-	500,000
— Conversion of convertible, subordinated notes	-	-	749,976
— Proceeds from issuance of convertible debenture	-	1,589,614	2,300,000
— Proceeds from issuance of common stock	8,150,000	-	21,418,035
— Proceeds from issuance of preferred stock	12,750,000	3,212,136	16,034,812
— Redemption of preferred stock	(1,250,000)	-	(1,250,000)
— Proceeds from exercise of stock options	-	-	1,337,677
— Proceeds from exercise of warrants	-	-	10,064,481
— Net cash provided (used) by financing activities	20,150,000	4,782,212	51,082,528
— Net increase (decrease) in cash and cash equivalents	2,191,405	(974,765)	2,583,929
— Cash and cash equivalents at beginning of period	393,608	1,979,871	1,084
— Cash and cash equivalents at end of period	\$ 2,585,013	\$ 1,005,106	\$ 2,585,013
Noncash investing and financing activities:			
— Common stock, stock options and warrants issued for services	\$ 359,914	\$ 143,750	\$ 2,281,173
— Common stock redeemed in payment of notes receivable	10,400	-	10,400



— Acquisition of R&D in-process technology	1,650,000	1,650,000
— 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 sub-license agreement	350,000	850,000
— Unrealized (realized) depreciation of investments	149,500	149,500
— Equipment acquired under capital lease	-	72,453
— Notes payable converted to common stock	-	749,976
— Stock dividends	182,195	364,547
<hr/>		
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Supplemental disclosure of cash flow information:		
— Interest paid	\$ 183,081	\$ 6,951
	\$ 307,631	
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See accompanying notes to unaudited 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, 1998  
(UNAUDITED)

	Common stock	Notes receivable in connection with sale of stock	Additional paid-in capital
<hr/>			
Balance at October 17, 1986	-	-	-
Common stock issued	\$ 11,288,329	-	\$ 254,864
Common stock options issued	-	-	75,000
Net loss	-	-	-
<hr/>			
Balance at December 31, 1994	11,288,329	-	329,864
Reincorporation in Delaware at \$.01 par value	(11,220,369)	-	11,220,369
Common stock issued	27,656	-	9,726,277
Net loss	-	-	-
<hr/>			
Balance at December 31, 1995	95,616	-	21,276,510
Common stock issued	18,267	-	7,043,328
Common stock subscribed	-	\$(110,000)	-
Unrealized loss on marketable securities	-	-	-
Net loss	-	-	-
<hr/>			
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	27,400	1,041,750

Common stock issued	0,012	37,400	1,041,750
Common stock options and warrants issued			165,868
Common stock options extended			215,188
Accretion of issuance costs for cumulative			
convertible redeemable preferred stock			
Unrealized gain on marketable securities			
Net loss			
Balance at December 31, 1997	126,495	(72,600)	31,386,644
Common stock issued	30,933	23,300	2,216,397
Accretion of issuance costs for cumulative			
convertible redeemable preferred stock			
Net loss			
Balance at March 31, 1998	157,428	(49,300)	33,603,041
Common stock issued	111,106	23,900	9,926,164
Preferred stock issued		\$ 115	11,499,885
Net loss			
Balance at June 30, 1998	268,534	115	(25,400)
Common stock issued	2,050		12,900
Unrealized loss on marketable securities			
Net loss			

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Balance at September 30, 1998	\$ 270,584	\$ 115	\$ (12,500)	\$ 55,359,496
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See accompanying notes to unaudited 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, 1998  
(UNAUDITED)

	Unrealized gain (loss) on marketable securities	Deficit accumulated during development stage	Total stockholders' equity (Net capital deficiency)
Balance at October 17, 1986			
Common stock issued			\$ 11,543,193
Common stock options issued			75,000
Net loss		\$ (12,192,046)	(12,192,046)
Balance at December 31, 1994		(12,192,046)	(573,853)
Reincorporation in Delaware at \$.01 par value			
Common stock issued			9,753,933

Net loss	(7,387,717)	(7,387,717)
Balance at December 31, 1995	(19,579,763)	1,792,363
Common stock issued	-	7,061,595
Common stock subscribed	-	(110,000)
Unrealized loss on marketable securities	\$ (39,232)	(39,232)
Net loss	(7,008,889)	(7,008,889)
Balance at December 31, 1996	(39,232)	(26,588,652)
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 cumulative convertible redeemable preferred stock	(79,500)	(79,500)
Unrealized gain on marketable securities	39,232	39,232
Net loss	(9,489,138)	(9,489,138)
Balance at December 31, 1997	(36,157,290)	(4,716,751)
Common stock issued	-	2,270,630
Accretion of issuance costs for cumulative convertible redeemable preferred stock	(23,900)	(23,900)
Net loss	(2,263,048)	(2,263,048)
Balance at March 31, 1998	(38,444,238)	(4,733,069)
Common stock issued	-	10,061,170
Preferred stock issued	-	11,500,000
Net loss	(13,303,121)	(13,303,121)
Balance at June 30, 1998	(51,747,359)	3,524,980
Common stock issued	-	345,356
Unrealized loss on marketable securities	(149,500)	(149,500)
Net loss	(2,142,410)	(2,142,410)
Balance at September 30, 1998	\$ (149,500)	\$ (53,889,769)
	\$ 1,578,426	

See accompanying notes to unaudited consolidated financial statements

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE ENTERPRISE)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 1998  
(UNAUDITED)

1. CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated balance sheets as of September 30, 1998 and December 31, 1997 and the accompanying consolidated statements of operations and cash flows for the three and nine

months ended September 30, 1998 and 1997 and for the period from October 17, 1986 (inception) to September 30, 1998, have been prepared by Sheffield Pharmaceuticals, Inc. (the "Company") 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, and cash flows at September 30, 1998 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, as amended, for the year ended December 31, 1997. The results of operations for the three and nine months ended September 30, 1998 and 1997 are not necessarily indicative of the operating results for the full years.

Sheffield Medical Technologies Inc. ("Sheffield") was incorporated on October 17, 1986. The Company's wholly-owned subsidiary, U-Tech Medical Corporation ("U-Tech") was incorporated on January 13, 1992 and was liquidated on June 30, 1997. On January 26, 1995, the Company's shareholders approved the proposal to reincorporate Sheffield in Delaware, which was effected on June 13, 1995. On January 10, 1996, Ion Pharmaceuticals, Inc. ("Ion"), was formed as a wholly-owned subsidiary of the Company. At that time, Ion acquired the Company's rights to certain early-stage biomedical technologies. On April 17, 1997, CP Pharmaceuticals, Inc. ("CP") was formed for the purpose of acquiring Camelot Pharmacal, L.L.C., a privately held pharmaceutical development company, which acquisition was consummated on April 25, 1997. On June 26, 1997, the Company's shareholders approved the proposal to change Sheffield's name from Sheffield Medical Technologies Inc. to Sheffield Pharmaceuticals, Inc. As part of an agreement with Elan Corporation, plc, on June 30, 1998, Systemic Pulmonary Delivery, Ltd. ("SPD") was formed as a wholly-owned subsidiary of the Company. At that time, SPD acquired the Company's rights to the systemic applications of the Metered Solution Inhaler ("MSI") and acquired Elan's rights to certain pulmonary delivery technologies. Unless the context requires otherwise, Sheffield, U-Tech, Ion, CP and SPD are referred herein to as "the Company." All significant intercompany transactions are eliminated in consolidation.

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 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 has the ability to meet its obligations as they become due and to continue as a going concern through December 1998.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE ENTERPRISE)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 1998  
(UNAUDITED)

2. LOSS PER COMMON SHARE

In 1997, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 128, Earnings Per Share. SFAS No. 128 replaced the previously reported primary and fully diluted earnings per share with basic and diluted earnings per share. Unlike primary earnings per share, basic earnings per share excludes any dilutive effects of options, warrants and convertible securities. Diluted earnings per share is very similar to the previously reported fully diluted earnings per share. Basic net loss per share is based upon the weighted average Common Stock outstanding during each year. Options, warrants and convertible securities are not included as their effect is antidilutive. The effect of adoption of SFAS No. 128 had no financial impact, and accordingly, no restatement of loss per share for prior periods was necessary.

3. IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS

On January 1, 1998 the Company adopted SFAS No. 130, "Reporting Comprehensive Income" ("SFAS No. 130"). SFAS No. 130 establishes standards for the reporting and display of comprehensive income and its components and is applied to all enterprises. The adoption of SFAS No. 130 had no impact on the Company's consolidated results of operations, financial position or cash flows.

In June 1997, the FASB issued SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS No. 131"). SFAS No. 131 establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports issued to stockholders. It also establishes standards for related disclosures about products and services, geographic areas, and major customers. SFAS No. 131 is effective for financial statements for fiscal years beginning after December 15, 1997. The Company will adopt the new requirements in conjunction with its 1998 Form 10-K. The adoption of SFAS No. 131 will have no significant impact on the Company's financial reporting.

4. SIGNIFICANT TRANSACTIONS

On April 15, 1998, the Company issued 1,250 shares of its Series B Cumulative Convertible Redeemable Preferred Stock in a private placement for an aggregate purchase price of \$1,250,000. On July 31,

1998, all of the Series B Preferred Stock was redeemed for cash by the Company.

On July 15, 1998, the Company acquired from Aeroquip Corporation a new generation metered dose inhaler (MDI) system called the Aerosol Drug Delivery System (ADDS) for \$825,000 cash. Part of the purchase price was made in the form of an option payment made during the quarter ended June 30, 1998. The remainder has been expensed during the quarter ended September 30, 1998 as acquired R&D in-process technology because the assets acquired, which consist solely of intellectual property related to ADDS, have not demonstrated technological feasibility and have no alternative future uses. SPD holds the rights to all systemic disease applications of the ADDS technology while Sheffield retains the rights to develop the respiratory disease applications of ADDS.

On September 29, 1998, the Company received \$500,000 from an affiliate of Elan Corporation, plc. Such funds were borrowed under the terms of a convertible promissory note that provides Sheffield with the right to borrow up to \$2 million, subject to satisfying certain conditions. No more than \$500,000 may be drawn under this note in any calendar quarter and at least one-half of the proceeds must be used to fund SPD's development activities. The principal outstanding under this note draws interest at the prime rate plus 1% and, if not previously converted, matures on June 30, 2005. Prior to repayment, Elan has the right to convert all principal and accrued interest into shares of Sheffield common stock at a conversion price of \$1.75 per share.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE ENTERPRISE)

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, INCLUDING WITHOUT LIMITATION, THE SUCCESSFUL DEVELOPMENT AND LICENSING OF THE COMPANY'S TECHNOLOGIES AND THE SUCCESSFUL COMPLETION OF PLANNED FINANCINGS. 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. 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 opportunities, particularly those utilizing unique pulmonary delivery technologies over a range of therapeutic areas. The Company is focusing its resources on the development and commercialization of pharmaceutical products whose utility and commercial potential can be exploited or enhanced by delivery in one of the Company's proprietary pulmonary delivery systems. The Company has established strategic alliances with Siemens AG, Zambon Group SpA, and Elan Corporation, plc for the development of these systems. The Company, through its wholly-owned subsidiary, Systemic Pulmonary Delivery, Ltd. ("SPD"), has expanded its portfolio of proprietary pulmonary delivery technologies with the recent acquisitions of the UPDAS(TM) and Enhancing Technology from Elan Corporation, plc and the ADDS system from Aeroquip Corporation. The Company will seek to acquire additional novel platform drug delivery systems and technologies.

#### LIQUIDITY AND CAPITAL RESOURCES

The Company's cash available for funding its operations as of September 30, 1998 was \$2,585,013. As of such date, the Company had trade payables of \$526,654 and current research obligations of \$449,805. At September 30, 1998, the Company had \$1.5 million available to be borrowed under the terms of a \$2.0 million convertible promissory note from an affiliate of Elan Corporation plc. No more than \$500,000 may be drawn under this note in any calendar quarter and at least one-half of the proceeds must be used to fund SPD's development activities. In addition, under the terms of its agreement with Zambon Group, SpA, the Company will be entitled to receive two separate \$1.0 million interest-free advances against future milestone payments upon the demonstration of certain technical capabilities related to the performance of the Metered Solution Inhaler (MSI) during the initial stage of the development program for respiratory drugs in the MSI.

As a result of its development and growth plans, the Company will need to obtain additional funds for its business through operations or equity or debt financings, collaborative arrangements with corporate partners or from other resources. No assurance can be given that these funds will be available for the Company to finance its development and growth on acceptable terms, if at all. If adequate funds are not available from operations or additional sources of funding, the Company's business will suffer a material adverse effect.

#### SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE)

The Company's operations to date have consumed substantial and increasing amounts of cash. The negative cash flow from operations is expected to continue in the foreseeable future. The Company has not yet begun to generate revenues from the sale of products. The Company's products will require significant additional development, clinical testing and investment prior to commercialization. The Company does not expect regulatory approval for commercial sales of any of its products in the immediate future. There can be no assurance that such products will be successfully developed, proven to be safe and efficacious in clinical trials, able to meet applicable regulatory standards, able to obtain required regulatory approvals, or produced in commercial quantities at reasonable costs or be successfully commercialized and marketed.

The owners and licensors of the technology rights acquired by the Company are entitled to receive a certain percentage of all royalties and payments in lieu of royalties received by the Company from commercialization, if any, of products in respect of which the Company holds licenses. Accordingly, in addition to its substantial investment in product development, the Company will be required to make substantial payments to others in connection with revenues derived from commercialization of products, if any, developed under licenses the Company holds. Consequently, the Company will not receive the full amount of any revenues that may be derived from commercialization of products to fund ongoing operations.

Under the terms of existing agreements, the Company is obligated to make certain payments to its licensors. In the event that the Company defaults on the payment of an installment under the terms of an existing licensing agreement, its rights thereunder could be forfeited. As a consequence, the Company could lose all rights under a license agreement to the related licensed technology, notwithstanding the total investment made through the date of the default. There can be no assurance that unforeseen obligations or contingencies will not deplete the Company's financial resources and, accordingly, sufficient resources may not be available to fulfill the Company's commitments.

## RESULTS OF OPERATIONS

The Company, a development stage enterprise, has incurred a net loss in each of the fiscal years since its inception and has had to rely on outside sources of funds to maintain its liquidity. Additional operating losses are expected to be incurred for the next few years as the Company expends its resources for product acquisition, research and development and preclinical and clinical testing.

As a development stage company without significant revenues, the Company has financed its development activities and operations primarily through public and private offerings of securities, from which it has raised an aggregate of approximately \$52.2 million through September 30, 1998.

### Revenues:

From inception through the period ended September 30, 1998, the Company has earned sub-license revenue of \$1,360,000 relative to various early-stage technologies. The Company earned no sub-license revenue for the quarter ended September 30, 1998.

From inception through the period ended September 30, 1998, the Company has earned interest income of \$489,792 and had an extraordinary item from gain on early extinguishment of debt of \$42,787. 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 or other arrangements.

Interest income for the three months ended September 30, 1998 was \$32,450 compared to \$9,391 for the same period ended September 30, 1997. The increase in interest earned is attributable to an increase in cash available for investment during the period ended September 30, 1998. Except for the sub-license revenue mentioned above, interest income represented all of the Company's income in each of the prior periods.



SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES  
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Operating Expenses:

From inception through the period ended September 30, 1998, the Company incurred \$55,678,948 of operating expenses. Of the total operating expenses for that period, \$21,266,557 were costs of research and development for the Company's technologies and \$14,891,745 for the acquisition of R & D in-process technology. The remainder of expenses for the same period were incurred principally as consulting costs, costs of management, legal and other professional fees and expenses relating to the Company's technologies, and for the cost of completing its financings. Research and development costs are expected to remain high as the Company develops its current technologies and acquires additional technologies. Such costs will continue to be expensed for financial reporting purposes.

Operating expenses for the three months ended September 30, 1998, were \$2,174,860 compared to \$1,898,226 for the same period ended September 30, 1997. Of the total operating expenses for the period ended September 30, 1998, \$218,063 were costs of research and development for the Company's technologies and \$741,745 for the acquisition of R & D in-process technology related to the ADDS system. General and administrative expenses for the three months ended September 30, 1998 were \$1,039,390 compared to \$1,325,874 for the same period ended September 30, 1997. The reduction in general and administrative expenses is primarily due to the relocation of the Company's headquarters to St. Louis, Missouri. Interest expense for the three months ended September 30, 1998 were \$175,662 compared to \$2,183 for the same period ended September 30, 1997. The increase in interest expense is attributable to the redemption of the Company's Series B cumulative convertible redeemable preferred stock.

The Company's direct research and development expenses were \$794,822 and \$32,002,860 for the three months ended September 30, 1998 and from the Company's inception to September 30, 1998, respectively. The Company's committed direct research and development funding after September 30, 1998 is currently \$2.0 million and relates primarily to the development of certain pulmonary delivery technologies by SPD (i.e., systemic applications of the MSI, UPDAS(TM), Enhancing Technology, and ADDS technologies). The Company anticipates funding the development costs associated with the respiratory applications of the UPDAS(TM) and ADDS technologies, the anticipated costs of which have not been determined at the time of this filing. The Company continues to out-license the early-stage technologies remaining in its portfolio, seeking organizations having the interest and resources to continue development accordingly.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE ENTERPRISE)

PART II: OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES.

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The following unregistered securities were issued by the Company during the quarter ended September 30, 1998:

Sale/Issuance	Date of Securities Issued	Description	Options or Warrants	Number of Shares Sold/Issued /Subject to Price Per Share (\$)	Offering/Exercise Purchaser Or Class
June 1998	Common Stock	150,000	\$1.6875	Warrants	Originated and Repaid during the period
July 1998	Common Stock	187,500	\$1.025 - \$3.50	Warrants	Advisors in lieu of cash consideration
August 1998	Common Stock	620,000	\$1.2375 - \$3.125	Options	Issuance to employees pursuant to 1993 Stock Option Plan
August 1998	Common Stock	Options	325,000	\$1.75	Employees
September 1998	Common Stock	25,000	\$1.4375	Options	Issuance to eligible Directors pursuant to the 1996 Directors Stock Option Plan
September 1998	Common Stock	Warrants	100,000	\$1.125	Originated during the period
September 1998	Common Stock	35,000	\$1.375		Advisors in lieu of cash consideration
September 1998	Common Stock	175,000	\$1.688		Advisors in lieu 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 July 15, 1998. All management's nominees for director, as listed in the Proxy Statement for the Annual Meeting were elected. Listed below are the matters voted on by stockholders and the number of votes cast at the Annual Meeting:

(a) ELECTION OF MEMBERS OF THE BOARD OF DIRECTORS.

Name	Voted For	Voted Against	Votes Withheld	Broker Non-Votes And Abstentions
Loren G. Peterson	15,386,075	0	92,985	0
Thomas M. Fitzgerald	15,379,375	0	99,685	0
John M. Bailey	15,382,975	0	96,085	0
Digby W. Barrios	15,382,975	0	96,085	0

(B) AMENDMENT TO THE COMPANY'S 1993 STOCK OPTION PLAN TO INCREASE THE NUMBER OF SHARES OF THE COMPANY'S COMMON STOCK AVAILABLE FOR ISSUANCE THEREUNDER FROM 3,000,000 TO 4,000,000 SHARES.

Voted For: 15,105,464  
Voted Against: 334,110  
Voted Abstained: 39,486  
Broker Non-Votes: 0

(C) RATIFICATION OF ERNST & YOUNG LLP AS INDEPENDENT PUBLIC ACCOUNTANT FOR FISCAL YEAR ENDING DECEMBER 31, 1998.

Voted For: 14,428,770  
Voted Against: 446,343  
Voted Abstained: 603,947  
Broker Non-Votes: 0

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

(a) EXHIBITS

NO.	DESCRIPTION
27	Financial Data Schedule.

(b) REPORTS ON FORM 8-K

The Company filed a current Report on Form 8-K with the Securities and Exchange Commission on July 16, 1998 relating to the Company's consummation of a license and financing transaction with Elan International Services, Ltd. (an affiliate of Elan Corporation plc) in accordance with the terms of the binding letter of intent dated June 3, 1998.

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

SHEFFIELD PHARMACEUTICALS, INC.

Dated: November 13, 1998        /S/ LOREN G. PETERSON  
-----  
Loren G. Peterson  
President & Chief Executive Officer

Dated: November 13, 1998        /S/ JUDY ROESKE BULLOCK  
-----  
Judy Roeske Bullock  
Vice President & Chief Financial Officer  
(Principal Financial and Accounting Officer)

EX-27  
2  
ARTICLE 5 FDS

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THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE  
CONDENSED FINANCIAL STATEMENTS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 1998 AND  
IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH STATEMENTS.

_____	
_____	3-MOS
_____	DEC-31-1998
_____	SEP-30-1998
_____	2,585,013
_____	200,500
_____	0
_____	0
_____	0
_____	2,892,483
_____	384,360
_____	227,639
_____	3,054,885
_____	976,459
_____	500,000
_____	0
_____	115
_____	270,584
_____	1,578,426

3,054,885  
0  
32,450  
0  
0  
2,174,860  
0  
175,662  
(2,142,410)  
0  
(2,142,410)  
0  
0  
0  
(2,142,410)  
(0.08)  
(0.08)

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