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QUARTERLY REPORT ENDED 6/30/00

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTER ENDED JUNE 30, 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.

☒ Yes ☐ No

The number of shares outstanding of the Registrant's Common Stock is 28,105,293 shares as of August 11, 2000.

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

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

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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, 2000 | December 31, 1999 |
|--|------------------|----------------------|
| | ----- | ----- |
| | (unaudited) | |
| <hr/> | | |
| Current assets: | | |
| — Cash and cash equivalents | \$ 1,846,056 | \$ 3,874,437 |
| — Marketable equity securities | 1,140,950 | 519,387 |
| — Prepaid expenses and other current assets | 476,082 | 145,237 |
| | ----- | ----- |
| — Total current assets | 3,463,088 | 4,539,061 |
| | ----- | ----- |
| Property and equipment: | | |
| — Laboratory equipment | 415,704 | 407,624 |
| — Office equipment | 208,347 | 178,797 |
| — Leasehold improvements | 18,320 | 15,000 |
| | ----- | ----- |
| — Total at cost | 642,371 | 601,421 |
| — Less accumulated depreciation and amortization | (364,708) | (311,752) |
| | ----- | ----- |
| — Property and equipment, net | 277,663 | 289,669 |
| | ----- | ----- |
| Patent costs, net of accumulated amortization of \$10,467 and \$0, respectively .. | 182,868 | 204,283 |
| Other assets | 15,830 | 15,642 |
| | ----- | ----- |
| — Total assets | \$ 3,939,449 | \$ 5,048,655 |
| | ===== | ===== |

LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

| | | |
|--|------------|------------|
| Current liabilities: | | |
| — Accounts payable and accrued liabilities | \$ 508,698 | \$ 773,206 |
| — Sponsored research payable | 348,629 | 421,681 |
| | ----- | ----- |
| — Total current liabilities | 857,327 | 1,194,887 |
| | ----- | ----- |
| Convertible promissory note | 2,000,000 | 2,000,000 |
| Unearned revenue | 1,000,000 | 1,000,000 |
| Other long-term liabilities | 283,287 | 182,695 |
| Commitments and contingencies | ----- | ----- |
| | ----- | ----- |

| | | |
|-------------------------|-----------|-----------|
| Total liabilities | 4,140,614 | 4,377,582 |
|-------------------------|-----------|-----------|

| | | |
|---------------------------------------|--|--|
| Minority interest in subsidiary | | |
|---------------------------------------|--|--|

Stockholders' equity (net capital deficiency):

—Preferred stock, \$.01 par value, authorized 3,000,000 shares:

—Series C cumulative convertible preferred stock, authorized 23,000

—shares; 13,236 and 12,780 shares issued and outstanding at June 30,

| | | |
|--|-----|-----|
| 2000 and December 31, 1999, respectively | 132 | 128 |
|--|-----|-----|

—Series D cumulative convertible exchangeable preferred stock, authorized

—21,000 shares; 12,435 and 12,015 issued and outstanding at June 30,

| | | |
|--|-----|-----|
| 2000 and December 31, 1999, respectively | 124 | 120 |
|--|-----|-----|

—Series F convertible non-exchangeable preferred stock, 5,000 shares

—authorized; 5,000 shares issued and outstanding at June 30, 2000 and

| | | |
|-------------------------|----|----|
| December 31, 1999 | 50 | 50 |
|-------------------------|----|----|

—Common stock, \$.01 par value, authorized 60,000,000 shares; issued and

—outstanding 28,080,293 and 27,308,846 shares at June 30, 2000 and

| | | |
|---------------------------------------|---------|---------|
| December 31, 1999, respectively | 280,803 | 273,088 |
|---------------------------------------|---------|---------|

| | | |
|----------------------------------|------------|------------|
| Additional paid-in capital | 75,836,293 | 73,638,128 |
|----------------------------------|------------|------------|

| | | |
|----------------------------------|---------|---------|
| Other comprehensive income | 808,955 | 169,387 |
|----------------------------------|---------|---------|

| | | |
|--|--------------|--------------|
| Deficit accumulated during development stage | (77,127,522) | (73,409,828) |
|--|--------------|--------------|

| | | |
|---|-----------|---------|
| Total stockholders' equity (net capital deficiency) | (201,165) | 671,073 |
|---|-----------|---------|

| | | |
|---|--------------|--------------|
| Total liabilities and stockholders' equity (net capital deficiency) | \$ 3,939,449 | \$ 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 Six Months Ended June 30, 2000 and 1999 and
for the Period from October 17, 1986 (inception) to
June 30, 2000
(Unaudited)

| Three Months Ended | | Six Months Ended | | October 17, 1986 |
|--------------------|------|------------------|------|------------------|
| June 30, | | June 30, | | (inception) to |
| | | | | June 30, |
| 2000 | 1999 | 2000 | 1999 | 2000 |

Revenues:

| | | | | | |
|----------------------------------|------------|-----------|------------|-----------|------------|
| —Contract research revenue | \$ 124,505 | \$ 67,709 | \$ 245,675 | \$ 93,709 | \$ 645,053 |
| —Sublicense revenue | | | | 1,360,000 | |

| | | | | | |
|---|---------------------------|---------------------------|---------------------------|---------------------------|----------------------------|
| Total revenues..... | 124,505 | 67,709 | 245,675 | 93,709 | 2,005,053 |
| Expenses: | | | | | |
| — Acquisition of research and development | | | | | |
| — in-process technology..... | -- | -- | -- | -- | 29,975,000 |
| Research and development..... | 882,755 | 903,684 | 1,784,778 | 1,584,663 | 26,810,202 |
| General and administrative..... | 691,421 | 632,693 | 1,386,145 | 1,132,356 | 22,903,695 |
| Total expenses..... | 1,574,176 | 1,536,377 | 3,170,923 | 2,717,019 | 79,688,897 |
| Loss from operations..... | (1,449,671) | (1,468,668) | (2,925,248) | (2,623,310) | (77,683,844) |
| Interest income..... | 41,991 | 17,476 | 94,492 | 39,353 | 700,533 |
| Interest expense..... | (57,124) | (35,818) | (107,157) | (65,709) | (680,512) |
| Realized gain (loss) on sale of | | | | | |
| — marketable securities..... | 52,614 | -- | 52,614 | -- | (272,301) |
| Minority interest in loss of subsidiary... | 28,380 | -- | 44,399 | -- | 3,029,399 |
| Loss before extraordinary item..... | (1,383,810) | (1,487,010) | (2,840,900) | (2,649,666) | (74,906,725) |
| Extraordinary item..... | -- | -- | -- | -- | 42,787 |
| Net loss..... | \$ (1,383,810) | \$ (1,487,010) | \$ (2,840,900) | \$ (2,649,666) | \$ (74,863,938) |
| Accretion of mandatorily redeemable | | | | | |
| — preferred stock..... | -- | -- | -- | -- | (103,400) |
| Net loss - attributable to common shares.. | \$ (1,383,810) | \$ (1,487,010) | \$ (2,840,900) | \$ (2,649,666) | \$ (74,967,338) |
| Weighted average common shares | | | | | |
| — outstanding-basic and diluted..... | 27,975,234 | 27,276,405 | 27,781,815 | 27,175,887 | 8,640,140 |
| Net loss per share of common stock— | | | | | |
| — basic and diluted: | | | | | |
| — Loss before extraordinary item..... | \$ (0.05) | \$ (0.05) | \$ (0.10) | \$ (0.10) | \$ (8.68) |
| — Extraordinary item..... | -- | -- | -- | -- | -- |
| — Net loss per share..... | \$ (0.05) | \$ (0.05) | \$ (0.10) | \$ (0.10) | \$ (8.68) |

See notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)
For the Period from October 17, 1986 (Inception) to June 30, 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 | -- | 8,625 | -- | 1,569,450 |
| Repurchase and retirement of common stock | -- | (910) | -- | (312,279) |
| Series C preferred stock dividends | 4 | -- | -- | 455,996 |
| Series D preferred stock dividends | 4 | -- | -- | 419,996 |
| Common stock warrants issued | -- | -- | -- | 65,002 |
| Comprehensive income (loss): | | | | |
| — Unrealized gain on marketable securities | -- | -- | -- | -- |
| — Net loss | -- | -- | -- | -- |
| — Comprehensive income (loss) | -- | -- | -- | -- |
| <hr/> | | | | |
| Balance at June 30, 2000 | \$ 306 | \$ 280,803 | \$ -- | \$ 75,836,293 |

| | Deficit | Total |
|---|--------------------------------------|---|
| Other comprehensive income (loss) | accumulated during development stage | stockholders' equity (net capital deficiency) |
| <hr/> | | |
| Balance at October 17, 1986 | \$ -- | \$ -- |
| Common stock issued | -- | 29,444,483 |
| Reincorporation in Delaware at \$.01 par value | -- | -- |
| Issuance of common stock in connection with | | |
| — acquisition of Camelot Pharmacal, L.L.C. | -- | 1,650,000 |
| Common stock options issued | -- | 240,868 |
| Common stock options extended | -- | 215,188 |
| Accretion of issuance costs for Series A preferred | | |
| — stock | (79,500) | (79,500) |
| Common stock subscribed | -- | (110,000) |
| Comprehensive income (loss): | | |
| — Net loss | (36,077,790) | -- |
| — Comprehensive income (loss) | -- | (36,077,790) |
| <hr/> | | |
| Balance at December 31, 1997 | -- (36,157,290) | (4,716,751) |
| <hr/> | | |
| Common stock issued | -- | 12,679,655 |
| Series C preferred stock issued | -- | 11,500,000 |
| Series C preferred stock dividends | -- (415,112) | (1,112) |
| Accretion of issuance costs for Series A preferred | | |
| — stock | (23,900) | (23,900) |
| Comprehensive income (loss): | | |
| — Unrealized loss on marketable securities | (222,226) | -- |
| — Net loss | (18,560,461) | -- |
| — Comprehensive income (loss) | -- | (18,782,687) |
| <hr/> | | |
| Balance at December 31, 1998 | (222,226) | (55,156,763) |
| <hr/> | | |
| Common stock issued | -- | 101,563 |
| Series C preferred stock dividends | -- (868,277) | (2,277) |
| Series D preferred stock issued | -- | 12,015,000 |
| Series F preferred stock issued | -- | 4,691,305 |
| Common stock warrants issued | -- | 203,452 |

| | | | |
|---|--------------|----------------|--------------|
| Comprehensive income (loss): | | | |
| Unrealized gain on marketable securities | 391,613 | | |
| Net loss | (17,384,788) | | |
| Comprehensive income (loss) | | (16,993,175) | |
| <hr/> | | | |
| Balance at December 31, 1999 | 169,387 | (73,409,828) | 671,073 |
| <hr/> | | | |
| Common stock issued | | 1,578,075 | |
| Repurchase and retirement of common stock | | (313,189) | |
| Series C preferred stock dividends | (456,269) | (269) | |
| Series D preferred stock dividends | (420,525) | (525) | |
| Common stock warrants issued | | 65,002 | |
| <hr/> | | | |
| Comprehensive income (loss): | | | |
| Unrealized gain on marketable securities | 639,568 | | |
| Net loss | (2,840,900) | | |
| Comprehensive income (loss) | | (2,201,332) | |
| <hr/> | | | |
| Balance at June 30, 2000 | \$ 808,955 | \$(77,127,522) | \$ (201,165) |
| <hr/> | | | |

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

| | Six Months Ended | | October 17, |
|---|------------------|----------------|-----------------|
| | June 30, | | 1986 |
| | | | (inception) to |
| | 2000 | 1999 | June 30, |
| | | | 2000 |
| <hr/> | | | |
| Cash outflows from operating activities: | | | |
| Net loss..... | \$ (2,840,900) | \$ (2,649,666) | \$ (74,863,938) |
| Adjustments to reconcile net loss to net cash used by | | | |
| —development stage activities: | | | |
| —Issuance of common stock, stock options/warrants for | | | |
| services..... | 77,002 | 105,642 | 2,562,427 |
| —Non-cash acquisition of research and development | | | |
| in-process technology..... | | | 1,650,000 |
| —Depreciation and amortization..... | 63,423 | 42,143 | 542,983 |

| | | | |
|---|-----------|-----------|-----------|
| — (Gain) loss realized on sale of marketable securities.. | (52,614) | -- | 272,301 |
| — Increase in prepaid expenses & other current assets.... | (330,845) | (85,779) | (535,123) |
| — Decrease (increase) in other assets..... | 10,760 | (15,642) | (150,124) |
| — Decrease in accounts payable and accrued liabilities... | (220,723) | (83,991) | (34,857) |
| — (Decrease) increase in sponsored research payable..... | (73,052) | -- | 925,699 |
| — Increase in unearned revenue..... | -- | 1,000,000 | 1,000,000 |
| — Other..... | 59,116 | 60,457 | 297,191 |

Net cash used by development stage activities..... (3,307,833) (1,626,836) (68,333,441)

Cash flows from investing activities:

| | | | |
|--|----------|----------|-----------|
| — Proceeds on sale of marketable securities..... | 70,618 | -- | 245,703 |
| — Acquisition of laboratory and office equipment, and — leasehold improvements..... | (40,950) | (47,992) | (626,662) |
| — Other..... | -- | 10,000 | (57,087) |

Net cash provided (used) by investing activities..... 29,668 (37,992) (438,046)

Cash flows from financing activities:

| | | | |
|---|-----------|-----------|------------|
| — Payments on debt and capital leases..... | (3,102) | (2,670) | (839,276) |
| — Net proceeds from issuance of: | | | |
| — Debt..... | -- | 500,000 | 5,050,000 |
| — Common stock..... | -- | -- | 21,418,035 |
| — Preferred stock..... | -- | -- | 32,741,117 |
| — Proceeds from exercise of warrants/stock options..... | 1,566,075 | 74,375 | 13,059,796 |
| — Repurchase and retirement of common stock..... | (313,189) | -- | (313,189) |
| — Other..... | -- | (104,145) | (500,024) |

Net cash provided by financing activities..... \$ 1,249,784 467,560 70,616,459

Net (decrease) increase in cash and cash equivalents..... (2,028,381) (1,197,268) 1,844,972

Cash and cash equivalents at beginning of period..... 3,874,437 2,456,290 1,084

Cash and cash equivalents at end of period..... \$ 1,846,056 \$ 1,259,022 \$ 1,846,056

Noncash investing and financing activities:

| | | | |
|---|-----------|------------|--------------|
| — Common stock, stock options/warrants issued for — services..... | \$ 77,002 | \$ 105,642 | \$ 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..... | 876,000 | 422,987 | 2,522,824 |

Supplemental disclosure of cash flow information:

— Interest paid..... \$ 1,070 \$ 4,152 \$ 277,390

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, 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 June 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 six months ended June 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.

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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%). 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 by the Company. 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.

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 second quarter of 2000 and 1999 were \$124,505 and \$67,709, respectively. For the first six months of 2000 and 1999, contract research revenues were \$245,675 and \$93,709, respectively. The increase for both the second quarter and first half of 2000 relates to three additional respiratory programs in development in 2000 as compared to 1999. 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 \$882,755 and \$903,684 for the second quarter of 2000 and 1999, respectively. For the six months ended June 30, 2000 and 1999, R&D costs were \$1,784,778 and \$1,584,663, respectively. The decrease of \$20,929 in the second quarter of 2000 was primarily due to lower development costs on the Company's two systemic programs, partially offset by higher expenses related to (1) the development by RSD of three steroid products initiated during the fourth quarter of 1999, (2) costs associated with increased contract research revenue as discussed above, and (3) formulation work begun during 2000 on an undisclosed respiratory product to be delivered via the ADDS. The increase for the first half of 2000 was \$200,115 primarily reflecting 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 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 \$691,421 and 632,693 for the quarters ended June 30, 2000, and 1999, respectively, and \$1,386,145 and \$1,132,356 for the first half of 2000 and 1999, respectively. The increase for both the second quarter and the first six months of 2000 was primarily due to higher consulting costs and legal fees associated with expanded business development activity.

Interest

Interest income was \$41,991 and \$17,476 for the quarter ended June 30, 2000 and 1999, respectively, and \$94,492 and \$39,353 for the first six months of 2000 and 1999, respectively. The increase in interest income for both the second quarter and first six months of 2000 was primarily due to larger balances of cash available for investment and higher average yields on those investments.

Interest expense was \$57,124 and \$35,818 for the second quarter of 2000, and 1999, respectively, and \$107,157 and \$65,709 for the first half of 2000 and 1999, respectively. The increase in both the second quarter and first half 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 June 30, 2000, the Company had \$1,846,056 in cash and cash equivalents compared to \$3,874,437 at December 31, 1999. The decrease of \$2,028,381 primarily reflects \$3,307,833 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 \$1,566,075 in net proceeds from the exercise of common stock options and warrants.

During the second quarter of 2000, the Company sold 30,000 shares of its investment in Lorus Therapeutics, Inc. ("Lorus") for proceeds of \$70,618, resulting in a gain of \$52,614. At June 30, 2000, the value of the Company's remaining Lorus investment of 553,188 shares was \$1,140,950.

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 will be utilized for general operating purposes. As part of the agreement, Elan also committed to purchase, on a drawdown basis, up to an additional \$4,000,000 of the Company's Series E Cumulative Convertible Preferred Stock ("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 June 30, 2000, no purchases of Series E Preferred Stock have been made.

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 proceeds from this advance are not restricted as to their use by the Company. 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 \$72.3 million through June 30, 2000, of which approximately \$30.0 million has been spent to acquire certain in-process research and development technologies, and \$26.8 million has been incurred to fund certain ongoing technology research projects. The Company expects to incur additional costs in the future, including costs relating to its ongoing research and development activities, and preclinical and clinical testing of its product candidates. The Company may also bear considerable costs in connection with filing, prosecuting, defending and/or enforcing its patent and other intellectual property claims. Therefore, the Company will need substantial additional capital before it will recognize significant cash flow from operations, which is contingent on the successful commercialization of the Company's technologies. There can be no assurance that any of the technologies to which the Company currently has or may acquire rights can or will be commercialized or that any revenues generated from such commercialization will be sufficient to fund existing and future research and development activities.

Because the Company does not expect to generate significant cash flows from operations for at least the next few years, the Company believes it will require additional funds to meet future costs. 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) to continue to fund its operations, the Company may not be able to obtain additional financing on acceptable terms, or at all, 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 terms acceptable to the Company; (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 will be able to 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.

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

An annual Meeting of Stockholders was held on May 9, 2000. All management's nominees for director, as listed in the Proxy Statement for the Annual Meeting, were elected. Listed below are the matters voted on by Stockholders and the number of votes cast at the Annual Meeting.

(a) Election of members of the Board of Directors.

| Name | Voted for | Voted Against | Broker Non-Votes | |
|----------------------|------------|---------------|------------------|-----------------|
| | | | Votes Withheld | and Abstentions |
| Thomas M. Fitzgerald | 23,878,371 | | 43,725 | |
| Loren G. Peterson | 23,863,371 | | 58,725 | |
| John M. Bailey | 23,878,371 | | 43,725 | |
| Digby W. Barrios | 23,878,371 | | 43,725 | |
| Todd C. Davis | 23,878,371 | | 43,725 | |
| Roberto Rettani | 23,878,371 | | 43,725 | |

(b) Ratification of Ernst & Young LLP as independent public accountant for fiscal year ending December 31, 2000.

Voted For: 23,210,678
Voted Against: 506,300
Votes Abstained: 205,118
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, 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: August 11, 2000 _____ /s/ Loren G. Peterson

Loren G. Peterson

President & Chief Executive Officer

Dated: August 11, 2000 _____ /s/ Scott A. Hoffmann

Scott A. Hoffmann

Vice President & Chief Financial Officer

(Principal Financial and Accounting Officer)