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SHEFFIELD PHARMACEUTICALS, INC. 10-Q/3-31-03

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q
(Mark One)
[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2003

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITY EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 1-12584

SHEFFIELD PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its charter)

DELAWARE	13-3808303
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

3136 WINTON ROAD SOUTH SUITE 201 ROCHESTER, NEW YORK	14623	(585) 292-0310
(Address of Principal executive offices)	(Zip Code)	(Registrant's Telephone Number, Including Area Code)

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 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.
[X]Yes [ ] No

Indicate by check mark whether the Registrant is an accellerated filer (as defined in Rule 12b-2 of the Exchange Act).

[ ] Yes [X] No

The number of outstanding shares of the Registrant's Common Stock was 29,563,712 shares as of April 14, 2003.

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

FORM 10-Q
For the Quarterly Period Ended March 31, 2003

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Item 1. Financial Statements

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

ASSETS	March 31, 2003	December 31, 2002
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 162,811	$ 327,195
Clinical supplies	349,422	349,422
Prepaid expenses and other current assets	61,881	158,697
Total current assets	574,114	835,314
Property and equipment:		
Laboratory equipment	462,949	462,949
Office equipment	75,723	75,723
Leasehold improvements	18,320	18,320
Total at cost	556,992	556,992
Less accumulated depreciation and amortization	(357,464)	(332,721)
Property and equipment, net	199,528	224,271
Patent costs, net of accumulated amortization of $42,791 and $37,232, respectively	462,108	445,850
Other assets	8,234	9,223
Total assets	$ 1,243,984	$ 1,514,658
LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)		
Current liabilities:		
Accounts payable	$2,563,344	$ 2,598,678
Accrued liabilities	565,093	449,251
Current maturities of long-term debt	1,000,000	1,000,000
Note payable	1,305,000	975,000
Total current liabilities	5,433,437	5,022,929
Convertible promissory note	2,000,000	2,000,000
Long-term debt	8,500,000	8,500,000
Other long-term liabilities	1,553,729	1,377,713
Commitments and contingencies	--	--
Total liabilities	17,487,166	16,900,642
Minority interest in subsidiary	--	--

Stockholders' equity (net capital deficiency): Preferred stock, $.01 par value, authorized 3,000,0000 shares:		
Series C cumulative convertible preferred stock, authorized 23,000 shares; issued and outstanding 16,054 and 15,778 shares at March 31, 2003 and December 31, 2002, respectively	161	158
Series D cumulative convertible exchangeable preferred stock, authorized 21,000 shares; issued and outstanding 14,795 shares at March 31, 2003 and December 31, 2002	148	148
Series E cumulative convertible non-exchangeable preferred stock, authorized 9,000 shares; issued and outstanding 3,378 shares at March 31, 2003 and December 31, 2002	34	34
Series F convertible non-exchangeable preferred stock, 5,000 shares authorized; issued and outstanding 5,000 shares at March 31, 2003 and December 31, 2002	50	50
Common stock, $.01 par value, authorized 100,000,000 shares; issued and outstanding 29,563,712 shares at March 31, 2003 and December 31, 2002	295,637	295,637
Additional paid-in capital	88,055,895	87,756,118
Other comprehensive income	--	--
Deficit accumulated during development stage	(104,595,107)	(103,438,129)
Total stockholders' equity (net capital deficiency)	(16,243,182)	(15,385,984)
Total liabilities and stockholders' equity (net capital deficiency)	$ 1,243,984	$ 1,514,658

See notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF OPERATIONS
For the Three Months Ended March 31, 2003 and 2002 and for the Period from October 17, 1986 (inception) to March 31, 2003
(unaudited)

	Three Months Ended March 31,		October 17, 1986 (inception) to March 31,
	2003	2002	2003
Revenues:			
Contract research revenue	$ 75,000	$ --	$ 1,850,045
Sublicense revenue	--	--	1,375,000
Total revenues	75,000	--	3,225,045
Expenses:			
Acquisition of research and development in-process technology	--	--	29,975,000
Research and development	250,250	1,153,790	38,645,240
General and administrative	398,838	1,938,666	33,767,802
Total expenses	649,088	3,092,456	102,388,042
Loss from operations	(574,088)	(3,092,456)	(99,162,997)
Interest income	179	2,662	797,977
Interest expense	(320,110)	(149,831)	(2,138,213)
Realized loss on sale of marketable securities	--	--	(5,580)
Minority interest in loss of subsidiary	13,156	106,042	3,745,042
Net loss	$ (880,863)	$ (3,133,583)	$ (96,763,771)
Preferred stock dividends	(611,033)	(552,663)	(8,701,667)
Accretion of mandatorily redeemable preferred stock	--	--	(103,400)
Net loss - attributable to common shares	$ (1,491,896)	$ (3,686,246)	$ (105,568,838)
Weighted average common shares outstanding-basic and diluted	29,563,712	29,024,008	12,046,725
Net loss per share of common stock - basic and diluted	$ (0.05)	$ (0.13)	$ (8.76)

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 March 31, 2003

	Preferred stock	Common stock	Notes receivable in connection with sale of stock	Additional paid-in capital
Balance at October 17, 1986	$ --	$ --	$ --	$ --
Common stock issued	--	11,503,195	110,000	34,424,316
Reincorporation in Delaware at $.01 par value	--	(11,220,369)	--	11,220,369
Common stock subscribed	--	--	(110,000)	--
Repurchase and retirement of common stock	--	(910)	--	(312,279)
Common stock options and warrants issued	--	--	--	639,522
Issuance of common stock in connection with acquisition of Camelot Pharmacal, L.L.C.	--	6,000	--	1,644,000
Common stock options extended	--	--	--	215,188
Accretion of issuance costs for Series A preferred stock	--	--	--	--
Series C preferred stock issued	115	--	--	11,499,885
Series C preferred stock dividends	22	--	--	2,211,978
Series D preferred stock issued	120	--	--	12,014,880
Series D preferred stock dividends	9	--	--	854,991
Series E preferred stock issued	10	--	--	999,990
Series E preferred stock dividends		--	--	4,000
Series F preferred stock issued	50	--	--	4,691,255
Comprehensive income (loss):				
Unrealized gain on marketable securities	--	--	--	--
Net loss	--	--	--	--
Comprehensive loss	--	--	--	--
Balance at December 31, 2000	326	287,916	--	80,108,095
Common stock issued	--	4,251	--	481,201
Repurchase and retirement of common stock	--	(2,151)	--	(640,691)
Series C preferred stock dividends	10	--	--	995,990
Series D preferred stock dividends	9	--	--	928,991
Series E preferred stock issued	10	--	--	999,990
Series E preferred stock dividends	1	--	--	119,999
Common stock warrants issued	--	--	--	126,741
Comprehensive income (loss):				
Unrealized loss on marketable securities	--	--	--	--
Net loss	--	--	--	--
Comprehensive loss	--	--	--	--
Balance December 31, 2001	356	290,016	--	83,120,316

Common stock issued	--	5,621	--	1,001,379
Series C preferred stock dividends	11	--	--	1,069,989
Series D preferred stock dividends	10	--	--	995,990
Series E preferred stock issued	10	--	--	999,990
Series E preferred stock dividends	3	--	--	253,997
Common stock warrants issued	--	--	--	314,457
Net loss (unaudited)	--	--	--	--
Balance December 31, 2002	$ 390	$ 295,637	$ --	$87,756,118
Series C preferred stock dividends	3	--	--	275,997
Common stock warrants issued	--	--	--	23,780
Net loss (unaudited)	--	--	--	--
Balance March 31, 2003 (unaudited)	$ 393	$ 295,637	$ --	$88,055,895

	Other comprehen-sive income (loss)	Deficit accumulated during development stage	Total stockholders' equity (net capital deficiency)
Balance at October 17, 1986	$ --	$ --	$ --
Common stock issued	--	--	46,037,511
Reincorporation in Delaware at $.01 par value	--	--	--
Common stock subscribed	--	--	(110,000)
Repurchase and retirement of common stock	--	--	(313,189)
Common stock options and warrants issued	--	--	639,522
Issuance of common stock in connection with acquisition of Camelot Pharmacal, L.L.C.	--		1,650,000
Common stock options extended	--	--	215,188
Accretion of issuance costs for Series A preferred stock	--	(103,400)	(103,400)
Series C preferred stock issued	--	--	11,500,000
Series C preferred stock dividends	--	(2,217,434)	(5,434)
Series D preferred stock issued	--	--	12,015,000
Series D preferred stock dividends	--	(855,750)	(750)
Series E preferred stock issued	--	--	1,000,000
Series E preferred stock dividends	--	(4,750)	(750)
Series F preferred stock issued	--	--	4,691,305
Comprehensive income (loss):			
Unrealized gain on marketable securities	157,467	--	--
Net loss	--	(77,786,190)	--
Comprehensive loss	--	--	(77,628,723)
Balance at December 31, 2000	157,467	(80,967,524)	(413,720)
Common stock issued	--	--	485,452
Repurchase and retirement of common stock	--	--	(642,842)
Series C preferred stock dividends	--	(999,278)	(3,278)
Series D preferred stock dividends	--	(929,603)	(603)
Series E preferred stock issued	--	--	1,000,000
Series E preferred stock dividends	--	(121,422)	(1,422)
Common stock warrants issued	--	--	126,741
Comprehensive income (loss):			
Unrealized loss on marketable securities	(157,467)	--	--

Net loss	--	(9,479,137)	--
Comprehensive loss	--	--	(9,636,604)
Balance December 31, 2001	--	(92,496,964)	(9,086,276)
Common stock issued	--		1,007,000
Series C preferred stock dividends	--	(1,071,913)	(1,913)
Series D preferred stock dividends	--	(996,710)	(710)
Series E preferred stock issued	--	--	1,000,000
Series E preferred stock dividends	--	(254,960)	(960)
Common stock warrants issued	--	--	314,457
Net loss	--	(8,617,582)	(8,617,582)
Balance December 31, 2002	$ --	$(103,438,129)	$(15,385,984)
Series C preferred stock dividends	--	(276,115)	(115)
Common stock warrants issued	--	--	23,780
Net loss (unaudited)	--	(880,863)	(880,863)
Balance March 31, 2003 (unaudited)	$ --	$(104,595,107)	$(16,243,182)

See notes to consolidated financial statements.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Three Months Ended March 31, 2003 and 2002 and for the Period from October 17, 1986 (inception) to March 31, 2003
(unaudited)

	Three Months Ended March 31,		October 17, 1986 (inception) to March 31,
	2003	2002	2003
Cash outflows from operating activities:			
Net loss	$(880,863)	$(3,133,583)	$ (96,763,771)
Adjustments to reconcile net loss to net cash used by development stage activities:			
Issuance of common stock, stock options/warrants for services	23,780	221,539	3,157,605
Depreciation and amortization	30,302	39,185	913,320
Non-cash acquisition of research and development in-process technology	--	--	1,650,000
Loss on sale of marketable securities	--	--	5,580

Decrease (increase) in clinical supplies, prepaid expenses & other current assets	96,815	(76,524)	(470,345)
Decrease (increase) in other assets	988	(300)	50,807
(Decrease) increase in accounts payable and accrued liabilities	(30,299)	1,124,040	3,126,826
Increase in sponsored research payable	--	--	577,070
Increase in other long-term liabilities	176,016	236,198	1,612,496
Other	111,459	(193,722)	(566,328)
Net cash used by operating activities	(471,802)	(1,783,167)	(86,706,740)
Cash flows from investing activities:			
Proceeds from sale of marketable securities	--	--	844,420
Acquisition of laboratory and office equipment, and leasehold improvements	--	(31,029)	(903,419)
Acquisition of patents	(21,817)	(3,154)	(504,898)
Other	--	--	(52,337)
Net cash provided (used) by investing activities	(21,817)	(34,183)	(616,234)
Cash flows from financing activities:			
Payments on debt and capital leases	(765)	(2,030)	(859,379)
Net proceeds from issuance of:			
Debt	330,000	1,000,000	15,855,000
Common stock	--	--	23,433,660
Preferred stock	--	1,000,000	35,741,117
Proceeds from exercise of warrants/stock options	--	17,000	14,770,358
Repurchase and retirement of common stock	--	--	(956,031)
Other	--	--	(500,024)
Net cash provided by financing activities	329,235	2,014,970	87,484,701
Net (decrease) increase in cash and cash equivalents	(164,384)	197,620	161,727
Cash and cash equivalents at beginning of period	327,195	859,298	1,084
Cash and cash equivalents at end of period	$ 162,811	$ 1,056,918	$ 162,811
Noncash investing and financing activities:			
Common stock, stock options/warrants issued for services	$ 23,780	$ 221,539	$ 3,157,605
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	276,115	257,390	8,091,372
Supplemental disclosure of cash flow information: Interest paid	$ 1,366	$ 923	$ 294,580

Income taxes paid..	--	--	--

See notes to consolidated financial statements.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2003
(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 U.S. Securities and Exchange Commission and should be read in conjunction with the financial statements and notes thereto included in Sheffield Pharmaceuticals, Inc.'s (the "Company's") Annual Report on Form 10-K for the year ended December 31, 2002. In the opinion of the Company's 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 March 31, 2003 and for all periods presented have been made. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted. The results of operations for the three months ended March 31, 2003 and 2002 are not necessarily indicative of the operating results for the full years. In addition, the preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management of the Company to make estimates and assumptions that affect the amounts reported in the consolidated financial statements. Actual results could differ from these estimates.

The consolidated financial statements include the accounts of the Company 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., ("RSD") and are herein together 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 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 accompanying consolidated financial statements have been prepared on a going concern basis that contemplates the realization of assets

and satisfaction of liabilities and commitments in the normal course of business. 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 of rights to its technology, as well as through equity and debt offerings, to continue to operate its business. Unless the Company is able to raise significant capital ($1 million to $2.5 million) within the next 30-60 days, management believes that it is unlikely that the Company will be able to meet its obligations as they become due and to continue as a going concern. To meet this capital requirement, the Company is evaluating various financing alternatives including, but not limited to, private offerings of its securities, debt financings, collaboration and licensing arrangements with other companies, and the sale of non-strategic assets and/or technologies to third parties. Should the Company be unable to meet its capital requirement through one or more of the above-mentioned financing alternatives, the Company may file for bankruptcy or similar protection under the Federal Bankruptcy Code. In such event, the basis of presentation of the Company's financial statements will be adjusted to reflect a liquidation basis of accounting.

Additionally, 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 intends to 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 of, or that the licensing of such products will be profitable.

2. BASIC LOSS PER COMMON SHARE

Basic net loss per share is calculated in accordance with the Financial Accounting Standard Board's 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. STOCK OPTION PLANS

The Company applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees", and related interpretations in accounting for its stock option plans. Accordingly, no compensation expense has been recognized for its stock option plans. During the first quarter of 2003, the Company adopted the disclosure provisions of SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure". The following table illustrates the effect on net earnings and earnings per share had the Company adopted the fair value based method of accounting for stock-based employee compensation for all

periods presented.

	3 Months Ended March 31, 2003	3 Months Ended March 31, 2002
Net loss, as reported	$(1,491,896)	$(3,686,246)
Pro forma net loss	$(1,494,814)	$(3,824,170)
Earnings per share:		
Basic - as reported	$(.05)	$(.13)
Basic - pro forma.....	$(.05)	$(.13)

4. NOTES PAYABLE

On September 6, 2002, the Company entered into a $.5 million unsecured debt financing with certain shareholders of the Company. The promissory notes issued in connection with such unsecured debt financing provided for interest at the rate of 7% per annum and originally matured on January 1, 2003. Upon maturity, the promissory notes provide for the Company to repay the principal and accrued interest on each note, and at the Company's discretion, either a premium of approximately 14% of the principal amount, or a warrant to purchase the number of shares of the Company's common stock equal to the principal amount of each promissory note. Any warrants to be issued under the promissory notes would have an exercise price equal to $.60 per share, the closing price of the Company's common stock on the closing date of the promissory notes. The outstanding principal balance of the promissory notes at December 31, 2002 was $.5 million. On January 1, 2003, the Company amended and restated the promissory notes ("Amended Notes"). The Amended Notes provide for interest at the rate of 7% per annum and mature on May 15, 2003. Upon maturity of $225,000 of the Amended Notes, the Amended Notes provide for the Company to repay principal and accrued interest on each Amended Note, and at the Company's discretion, either a premium of approximately 14% of the principal amount, or issue warrants to purchase the number of shares of the Company's common stock equal to the principal amount of each Amended Note. Any warrants issued under the Amended Notes will have an exercise price of $.19 per share, the closing price of the Company's common stock on the closing date of the Amended Notes. Upon maturity of $250,000 of the Amended Notes, the Amended Notes provide for the Company to repay principal and accrued interest on each Amended Note, and at the Company's discretion, either a premium of approximately 28% of the principal amount, or issue warrants to purchase an aggregate of 500,000 shares of the Company's common stock, of which 250,000 shares will have an exercise price of $.60 per share, and 250,000 shares will have an exercise price of $.19 per share. Upon amending and restating certain of the promissory notes, the Company issued to certain promissory noteholders warrants to purchase a total of 225,000 of the Company's common stock at an exercise price of $.60 per share.

On February 25, 2003, the Company entered into a $.5 million secured debt financing with certain shareholders of the Company and a third party. The promissory note issued to the third party in connection with such secured debt financing provides up to $.45 million of financing

which the Company, at its option, can draw down in three equal installments. The Company received the first installment on February 25, 2003, the second installment on March 28, 2003, and the third installment on April 29, 2003. The promissory note provides for interest at the rate of 9% per annum and matures on the closing of a licensing transaction for the Unit Dose NanoCrystal(TM) Budesonide drug product being developed through RSD. The promissory note is secured by a priority claim on the Company's interest in the Unit Dose Budesonide product. Upon maturity, promissory note provides for the Company to repay principal and accrued interest on the promissory note, a premium of 100% of the outstanding balance of the promissory note, and a warrant to purchase the number of shares of the Company's common stock equal to the principal amount of the promissory note drawn down by the Company. Any warrants to be issued under the promissory note financing will have an exercise price of $.20 per share. The promissory notes with certain of the shareholders provide an additional $.03 million of financing received upon signing of the notes. These promissory notes include essentially the same terms and conditions as the aforementioned notes with the third party.

5. RECLASSIFICATIONS

Certain amounts in the Company's prior year financial statements and notes have been reclassified to conform to the current year presentation.

Item 2.
Management's Discussion and Analysis of Financial Condition and Results of Operations

The information contained in 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, including, without limitation, statements containing the words "believes," "anticipates," "intends," "plans," "expects" and words of similar import, involve risks and uncertainty. Although Sheffield Pharmaceuticals, Inc. (the "Company," "we," "our" or "us") 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 certain 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. The Company disclaims any obligation to update or revise the information provided in this

report to reflect future events.

OVERVIEW

We provide innovative, cost-effective pharmaceutical therapies by combining state-of-the-art pulmonary drug delivery technologies with existing and emerging therapeutic agents. We are developing a range of products to treat respiratory and systemic diseases in our proprietary Premaire(R) Delivery System ("Premaire") and Tempo(TM) Inhaler ("Tempo"). We are in the development stage and, as such, have been principally engaged in the development of our pulmonary delivery systems.

In 1997, we acquired the Premaire, a portable nebulizer-based pulmonary delivery system, through a worldwide exclusive license and supply arrangement with Siemens AG. During the second half of 1998, we acquired the rights to an additional pulmonary delivery technology, Tempo, from a subsidiary of Aeroquip-Vickers, Inc. The Tempo technology is a new generation propellant-based pulmonary delivery system. Additionally, during 1998, we licensed from Elan Corporation, plc ("Elan") the Ultrasonic Pulmonary Drug Absorption System ("UPDAS(TM)"), 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, we licensed Elan's Nanocrystal(TM) technology to be used in developing certain inhaled steroid products.

Our drug delivery technology includes the Premaire, which is a patented, multi-dose nebulizer delivery system. The pocket-sized inhaled drug delivery system features an ultrasonic nebulizer that emits high-frequency sound waves that turn liquid medication into a fine cloud or soft mist. The Premaire combines the therapeutic benefits of nebulization with the convenience of pressurized metered dose inhalers, or pMDIs, in one patient-friendly device. The Premaire is comprised of a hand-held ultrasonic nebulizer and drug-filled cartridges that are inserted into the inhaler unit. The cartridges provide patients who must take multiple respiratory medications with a single, easy-to-use system. We believe the soft mist created by the Premaire provides multiple drug administration advantages over the high-velocity pMDIs and dry powder inhalers. Furthermore, the Premaire system is fast and portable as compared to conventional tabletop nebulizers, which are large, cumbersome and more time consuming to use. The Premaire system targets younger and older asthma patients, as well as older chronic obstructive pulmonary disease patients who have difficulty using pMDIs and currently depend on tabletop nebulizers for delivery of their medications.

Our Tempo Inhaler is a patented, new generation pMDI that we believe has significant efficiency and performance advantages over standard pMDIs. The Tempo technology utilizes a standard aerosol pMDI canister, encased in a compact device that provides an aerosol flow-control chamber and a synchronized triggering mechanism. The aerosol flow-control chamber allows the patient to inhale through the device at a normal breathing rate, instead of a forced breath. The inspiratory breath establishes flow fields within the device that mix and uniformly disperse the drug in the breath. At the mouthpiece, nearly all the propellant is evaporated leaving only drug particles to be inspired, allowing a significant increase in the amount of drug delivered to the lungs. The Tempo system, like the Premaire system, is designed to reduce patient coordination problems and enhance compliance with the prescribed treatment.

In June 1998, we sublicensed to Zambon Group SpA ("Zambon") worldwide marketing and development rights to respiratory products to be delivered by the Premaire in return for an equity investment in the Company (approximately 10%). From June 1998 to September 2001, Zambon funded the development costs for the respiratory compounds delivered by Premaire. In September 2001, we amended our 1998 agreement with Zambon whereby we regained the rights to the Premaire previously granted to Zambon. As part of the amended agreement, Zambon provided a low-interest, $2.5 million loan to us to progress the development

of the Premaire respiratory program. Upon commercialization, Zambon will be entitled to certain royalties on payments received by us for albuterol, ipratropium and cromolyn sales for specified periods.

Also in 1998, the systemic applications of Premaire and Tempo were licensed to Systemic Pulmonary Delivery, Ltd. ("SPD"), one of our wholly owned subsidiaries. In addition, two Elan technologies, UPDAS(TM) and the Enhancing Technology, were also licensed to SPD. We retained exclusive rights outside of the strategic alliance to respiratory disease applications utilizing the Tempo technology and the two Elan technologies. On August 21, 2002 we ended this strategic alliance with Elan and regained all intellectual property rights to the systemic applications of Premaire and Tempo that were licensed to SPD. In addition, as part of the termination of this alliance, we intend to enter into a separate agreement with Elan to license exclusively the UPDAS(TM) and the Enhancing Technology. We have also granted to Elan an ongoing right to receive royalties on commercialization of two products, morphine delivered by Premaire and ergotamine tartrate delivered by Tempo.

In addition to the above alliance with Elan, in 1999, we 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. Currently, RSD is developing 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 Premaire. On November 8, 2002, as part of an agreement between Elan and RSD, the parties terminated the license for the Elan NanoCrystal technology to RSD. As provided in the 1999 license agreement, upon termination of this license, all intellectual property of RSD was transferred to and jointly owned by Elan and us.

RESULTS OF OPERATIONS

Revenue

Contract research revenues represent revenues earned from a feasibility study with a third party relating to the development of respiratory applications of Tempo. For the first three months of 2003 and 2002, contract research revenues were $75,000 and $0, respectively. The increase was due to our beginning the feasibility work in the first quarter of 2003. Costs of contract research revenue approximated such revenues in 2003 and are included in research and development expenses. Future contract research revenues and expenses are anticipated to fluctuate depending, in part, on our ability to obtain additional collaborative agreements and upon the success of current clinical studies.

Our ability to generate material revenues is contingent on the successful commercialization of our technologies and other technologies and products that we 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 $.3 million and $1.2 million for the first quarter of 2003 and 2002, respectively. The decrease of $.9 million from 2002 was primarily due to lower development expenses related to RSD's unit dose product ($.4 million), lower Premaire development costs as well as reduced formulation work on the Premaire budesonide product ($.3 million), lower Tempo development costs resulting from finalizing the industrialization of the device in the first half of 2002 for Phase I and II trials ($.1 million) and reduced R&D administrative costs ($.1 million).

The following details the status of each of our development programs as of March 31, 2003:

Premaire Respiratory Program:

As a result of our regaining from Zambon the rights to the respiratory applications to the Premaire in September 2001, the sponsorship of the Premaire respiratory development programs was transferred to us from Zambon with the U.S. Food and Drug Administration ("FDA") being notified accordingly. In the fourth quarter of 2001, we reviewed all of the development work completed-to-date and identified a number of deficiencies in the Zambon development program. To address these issues, we made a number of internal management changes and moved the program to a group of highly experienced pulmonary clinical and regulatory experts. The Premaire device is currently in a to-be-marketed form and is fully industrialized. As of March 31, 2003, we had spent $3.9 million on developing the respiratory products discussed below.

Our strategy is to license the U.S. rights to the Premaire respiratory products to a third party. We anticipate concluding a license arrangement sometime in 2003. As a result, we estimate a U.S. commercial launch of our first products in Premaire to occur in the last half of 2005 or first half of 2006. Subject to our obtaining additional financing, we intend to fund the continued development work for the Premaire respiratory products up through the period of outlicensing,

currently estimated at approximately $10 million, after which time we anticipate that the licensee would assume funding responsibility for further development work.

Albuterol Sulfate. Zambon initiated a Phase II clinical trial in December 1999 that compared the Premaire-albuterol sulfate to a

conventional albuterol-pMDI. Findings from Phase II studies indicated that Premaire-albuterol and pMDI-albuterol were comparable in improving lung function in the 24 adult patients. An end of Phase II meeting was held in February 2002 with the FDA where the results of the development activities-to-date, specifically the results of the Phase II trial, were reviewed. We are currently reviewing the FDA's comments and recommendations, integrating the information into the plans for the Phase III trial and NDA submission. Subject to our obtaining additional financing, we anticipate that we will begin pivotal clinical trials for the albuterol sulfate program sometime in 2003.

Budesonide. Preclinical formulation development work is currently underway. A formulation developed by Nanosystems has proven a feasible candidate for delivery in the Premaire. The formulation is dependent on a proprietary nanocrystaline dispersion of budesonide in an aqueous carrier. Two other alternative formulation approaches are also under evaluation. Subject to our obtaining additional financing, upon scale-up and production of clinical batches released under CMC protocol, an Investigational New Drug Application ("IND") will be prepared for filing with the FDA. This is currently planned for sometime in 2003.

Ipratropium Bromide. Zambon initiated a Phase I/II clinical trial in Europe in January 2000 assessing the safety and efficacy compared to a commercially available ipratropium bromide product delivered by a pMDI and placebo in patients with chronic obstructive pulmonary disease ("COPD"). The results of the study indicated that both Premaire-ipratropium bromide and pMDI-ipratropium were tolerated and improved lung function in the COPD patients. An IND was filed by Zambon with the FDA in May 2000. During 2001, the IND was transferred to us. We do not intend to further develop this product on our own as the program has progressed to the point where a potential licensing partner would be in a position to take the product into clinical studies.

Sodium Cromoglycate. An IND was filed by Zambon with the FDA in July 2000. No further development work is anticipated to be completed on this product as the projected market opportunity for sodium cromoglycate is currently deemed by us to be too small to justify further progression.

Premaire Systemic Program:

Through our development alliance with Elan and SPD, we evaluated certain drugs for systemic treatment by pulmonary delivery through Premaire. By identifying a market opportunity for a rapid-acting, non-invasive treatment for breakthrough pain, the first drug to be tested for delivery in Premaire was morphine. In July 1999, we completed a gamma scintigraphy/pharmacokinetic trial comparing morphine delivered using the Premaire to subcutaneous injection. The Premaire demonstrated good pulmonary deposition and very rapid absorption, more rapid peak blood levels vs. subcutaneous injection and low oral and throat deposition. As part of the development alliance with Elan, Elan had the first right of refusal on the development of any product developed by the joint venture. Elan chose not to license this product from the joint venture. In August 2002, we regained all intellectual

property rights to the systemic applications of Premaire from SPD and ended the joint venture relationship with Elan. As such, we now continue to seek to attract a partner for the continued development and commercialization of this product. Upon commercialization, Elan will be entitled to certain royalties on payments received. We have spent $.4 million to date to develop this product and do not anticipate incurring any future costs for further development until such time as a licensing partner is secured.

Tempo Respiratory Program:

In September 2000, we completed a pilot study using the Tempo to deliver an undisclosed, patented respiratory drug used to treat asthma. The study measured the distribution of this respiratory drug delivered by Tempo compared to the distribution of this same drug delivered through a commercially available pMDI in 12 healthy volunteers. Results of this study demonstrated that Tempo significantly increased drug deposition in all regions of the lung. Tempo delivered approximately 200% more drug to the lungs, deposited approximately 75% less drug in the mouth, and increased dosing consistency by approximately 55% compared to the currently marketed form of this same drug. As of March 31, 2003, we had incurred approximately $.9 million to-date on this study. We are using the results of this study as a basis for conducting discussions for feasibility work and/or clinical studies with potential collaboration partners.

Tempo Systemic Program:

The development of systemic drugs using Tempo was conducted as part of our alliance with Elan. The initial product developed was targeted to address migraine headaches. We utilized ergotamine tartrate as a proof-of-principle product. In December 1999, we completed a gamma scintigraphy/pharmacokinetic trial comparing the Tempo to a conventional pMDI. The trial showed successful delivery of the drug to all regions of lung with significantly reduced mouth and throat deposition, and rapid drug absorption. As part of the development alliance with Elan, Elan had the first right of refusal on the development of any product developed by the joint venture. Elan chose not to license this product from the joint venture. In August 2002, we regained all intellectual property rights to the systemic applications of Tempo from SPD and ended the joint venture relationship with Elan. As such, we now seek to attract a partner for the continued development and commercialization of this product. Upon commercialization, Elan will be entitled to certain royalties on payments received. As of March 31, 2003, we had spent $1.0 million to date to develop this product and do not anticipate incurring any future costs for further development until such time as a licensing partner is secured.

As a result of the work performed on the ergotamine product noted above, in April 2002, we announced the initiation of a pulmonary migraine therapy program with Inhale Therapeutic Systems ("Inhale"), a

world-renowned expert in particle design. We will combine Inhale's supercritical fluid technology with our proprietary drug delivery technologies to develop a systemically-acting DHE administered through the pulmonary route. We plan to study DHE in sub-categories of migraine where DHE administered by injection is often used to relieve migraine symptoms. These sub-categories are the more serious forms of migraine and often require either hospitalization or treatment in pain or headache clinics. Under the terms of the agreement, Inhale will supply the particle engineering technology and receive R&D funding, milestone payments, and royalties upon commercialization. We are responsible for all other aspects of clinical development and marketing of the product. As part of this agreement, Inhale will produce DHE particles using Good Manufacturing Practices ("GMP") for clinical development and commercial sale. The treatment of migraine represents a worldwide prescription market estimated at approximately $2.4 billion. As of March 31, 2003, we had incurred-to-date approximately $1.0 million related to this project. Future costs related to this project are dependent upon, among other factors, the timing of securing a development partner. Subject to our obtaining additional financing, we do not estimate incurring any costs related to the development of the DHE project until mid-year of 2003.

Unit Dose Nebulizer Program:

As part of an alliance with Elan, RSD is developing a product for inhalation delivery in a standard commercial tabletop device using the steroid budesonide, formulated using the NanoCrystal technology. A Phase I, double-blind safety and pharmacokinetic study of nebulized nanobudesonide in 16 healthy volunteers was satisfactorily completed at Thomas Jefferson University Hospital in February 2002. This study compared single doses of Pulmicort Respules ("Pulmicort"), our proprietary nanobudesonide in two different single dose strengths and placebo. The study resulted in no significant adverse events with either of our dosage strengths or the Pulmicort reference drug. Data from the study is currently undergoing final data and statistical analysis. After such data has been analyzed, we plan on initiating discussions with potential partners regarding the outlicensing of this opportunity. As of March 31, 2003, we incurred-to-date approximately $3.1 million on this project. On November 8, 2002, as part of an agreement between Elan and RSD, we and Elan terminated the license for the Elan NanoCrystal technology to RSD. As provided in the 1999 license agreement, upon termination of this license, all intellectual property of RSD was transferred to and jointly owned by Elan and us. Use of the property by either party can only made with the applied written consent of the other. It is our intent to continue pursuing licensing partners for this product while we and Elan negotiate the disposition of the use and ownership of the intellectual property. Subject to disposition of the property rights, we do not intend to incur any additional development costs related to this product.

General and Administrative

General and administrative expenses were $.4 million for the first quarter of 2003 as compared to $1.9 million for the first quarter of 2002. The decrease of $1.5 million from 2002 was primarily due to higher consulting costs, legal fees and severance-related costs in the first quarter of 2002 (1.4 million) and cost

reduction efforts to conserve cash while various financing alternatives are evaluated, including reduced administrative headcount ($.1 million). The higher consulting costs and legal fees in 2002 were associated with expanded business development, and merger and acquisition activities in the area of licensing and partnering of our delivery systems, as well as potential acquisitions of complementary pulmonary delivery technologies and companies ($.9 million). The severance costs were associated with the resignation of two executive officers in

the first quarter of 2002 and include the costs incurred pursuant to their respective separation agreements for severance payments and ongoing benefit coverage ($.3 million) and modification of the terms of certain stock options ($.2 million).

Interest

Interest income was $179 and $2,662 for the first quarter of 2003 and 2002, respectively. The decrease in interest income from 2002 was primarily due to less cash available for investment.

Interest expense was $320,110 and $149,831 for the first quarter of 2003 and 2002, respectively. The increase of $170,279 from 2002 resulted primarily from interest associated with three short-term promissory notes and higher borrowings on the August 2001 Note Purchase Agreement with Elan Pharma (borrowings totaled $5 million as of March 31, 2003, compared to total borrowings of $4 million as of March 31, 2002). The short-term promissory notes, totaling $1.3 million as of March 31, 2003, consist of a September 6, 2002 (and amended and restated on January 1, 2003) unsecured debt financing with certain shareholders, a November 8, 2002 unsecured promissory note with Elan Pharma, and a February 25, 2003 secured debt financing with certain shareholders and a third party.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2003, we had $163,000 in cash and cash equivalents compared to $327,000 at December 31, 2002. The decrease of $164,000 reflects cash disbursements of approximately $500,000 used primarily to fund operating activities, partially offset by the receipt of $330,000 from the proceeds of secured promissory notes from certain shareholders and a third party.

Cash available for funding our operations as of March 31, 2003 was $.2 million. As of such date, we had trade payables and accrued liabilities of $3.1 million. As of May 12, 2003, we had cash and equivalents of approximately $.2 million. As of such date, we had trade payables and accrued liabilities of approximately $3.3 million. Unless the Company is able to raise significant capital ($1 million to $2.5 million) within the next 30-60 days, management believes that it is unlikely that the Company will be able to meet its obligations as they become due and to continue as a going concern. To meet this capital requirement, we are evaluating various financing alternatives including, but not limited to, private offerings of our securities, debt financings, collaboration and licensing arrangements with other companies, and the sale of non-strategic assets and/or

technologies to third parties. We are also investigating other business transaction opportunities on an ongoing basis. Should the Company be unable to meet its capital requirement through one or more of the above-mentioned financing alternatives, we may file for bankruptcy or seek similar protection.

Because we do not expect to generate significant cash flows from operations for at least the next few years, we will require additional funds to meet our current obligations and future costs. In an effort to meet both our short- and long-term capital requirements, we are currently evaluating various financing alternatives including, but not limited to, private offerings of our securities, debt financings, and collaboration and licensing arrangements with other companies. There can be no assurance that we will be able to obtain such additional funds or enter into such collaborative and licensing arrangements on terms favorable to us, if at all. Our development programs will cease if future financings are not completed.

On February 25, 2003, we entered into a $.5 million secured debt financing with certain of our shareholders and a third party. The promissory note issued in connection with such unsecured debt financing provides up to $.45 million of financing which we, at our option, can draw down in three equal installments. We received the first installment on February 25, 2003, the second installment on March 28, 2003, and the third installment on April 29, 2003. The promissory note provides for interest at the rate of 9% per annum and matures on the closing of a licensing transaction for the Unit Dose NanoCrystal(TM) Budesonide drug product being developed through RSD. The promissory note is secured by a priority claim on our interest in the Unit Dose Budesonide product. Upon maturity, the promissory note provides for us to repay principal and accrued interest on the promissory note, a premium of 100% of the outstanding balance of the promissory note, and a warrant to purchase the number of shares of our common stock equal to the principal amount of the note drawn down by us. Any warrants to be issued under the note arrangement will have an exercise price of $.20 per share. The promissory notes with certain of the shareholders provides an additional $.03 million of financing received upon signing of the notes. These notes include essentially the same terms and conditions as the aforementioned notes with the third party.

On November 8, 2002 we entered into an agreement with Elan Pharma, whereby among other items, we received proceeds of $.5 million evidenced by an unsecured demand promissory note. The promissory note provides for interest on principal and semi-annually compounded interest at a fixed rate of 10% per annum. Also as part of the agreement, the parties terminated the 1999 license agreement for the Elan NanoCrystal technology made between Elan Pharma and RSD. As provided in the 1999 license agreement, upon termination of this license, all intellectual property of RSD was transferred to and jointly owned by

Elan and us. The outstanding principal balance of the promissory note at March 31, 2003 was $.5 million.

On September 6, 2002, we entered into a $.5 million unsecured debt financing with certain of our shareholders. The promissory notes issued in connection with this financing provide for interest at the rate of 7% per annum and originally

matured on January 1, 2003. Upon maturity, the promissory notes provide for us to repay principal and accrued interest on each promissory note, and at our discretion, either a premium of approximately 14% of the principal amount, or a warrant to purchase the number of shares of our common stock equal to the principal amount of each note. Any warrants to be issued under the promissory notes would have an exercise price equal to $.60 per share, the closing price of our common stock on the closing date of the promissory notes. On January 1, 2003, we amended and restated the promissory notes ("Amended Notes"). The Amended Notes provide for interest at the rate of 7% per annum and mature on May 15, 2003. We are presently in discussions with the holders of the Amended Notes to extend such maturity date. Upon maturity of $225,000 of the Amended Notes, the Amended Notes provide that we will repay principal and accrued interest on each Amended Note, and at our discretion, either a premium of approximately 14% of the principal amount, or issue a warrant to purchase the number of shares of our common stock equal to the principal amount of each Amended Note. Any warrants issued under the Amended Notes will have an exercise price of $.19 per share, the closing price of our common stock on the closing date of the Amended Notes. Upon maturity of $250,000 of the Amended Notes, the Amended Notes provide that we will repay principal and accrued interest on each Amended Note, and at our discretion, either a premium of approximately 28% of the principal amount, or issue warrants to purchase an aggregate of 500,000 shares of our common stock, of which 250,000 shares will have an exercise price of $.60 per share, and 250,000 shares will have an exercise price of $.19 per share. Upon amending and restating certain of these notes, we issued to certain noteholders warrants to purchase a total of 225,000 of Sheffield common stock at an exercise price of $.60 per share. The outstanding principal balance of the promissory notes at March 31, 2003 was $.5 million.

On April 5, 2002, Elan International Services, Ltd. exercised a portion of a warrant that it had received in June 1998 as part of a strategic alliance with us and purchased 495,000 shares of our common stock at $2.00 per share. We received approximately $1.0 million in proceeds as a result of the exercise of a portion of this warrant.

On August 14, 2001, we entered into a Note Purchase Agreement (the "Agreement") with Elan Pharma, pursuant to which Elan Pharma agreed to lend us up to $4 million. On April 4, 2002, we amended the Agreement. Under the terms of the amended Agreement, Elan Pharma agreed to increase the principal amount of the loan available from $4 million to $5 million and extend the maturity date from November 14, 2002 to April 4, 2004. On April 5, 2002, we received proceeds on the loan of $1 million, increasing the total borrowings to $5 million. All borrowings under the Agreement are evidenced by our $5 million unsecured promissory note that provides for interest on principal and semi-annually compounded interest at a fixed rate of 10% per annum. Due to the modification of the maturity date, the borrowings under the Agreement, totaling $5 million at March 31, 2003, have been classified in our balance sheet as long-term debt.

In September 2001, in connection with the amendment of our 1998 agreement with Zambon, we entered into a Loan and Security Agreement ("Loan Agreement") with Zambon, pursuant to which Zambon agreed to lend us $2.5 million. We received $1.0 million upon signing of the Loan Agreement, $1.0 million on January 2, 2002 and $.5 million on April 5, 2002. The Loan Agreement provides for interest on principal and annually compounded interest at a fixed rate of 2% per annum and is secured by certain security interests in respiratory products developed in the Premaire. One third of the principal balance, together with interest, is payable by us upon our execution of an agreement with one or more third parties

to develop, co-promote and/or sell certain products in North America, with all remaining unpaid principal and interest due on December 31, 2005. On October 17, 2001, as part of the amendment of our 1998 agreement with Zambon, we repurchased from Zambon, 214,997 shares of common stock for $3.0233 per share ("Repurchase Price"). In addition, we received an option, expiring December 31, 2002, to repurchase the remaining shares of our common stock held by Zambon at the Repurchase Price. In the event we complete a sublicense for the North American rights or a sublicense for the non-North American rights to certain Premaire respiratory products prior to December 31, 2002, we will repurchase from Zambon 882,051 shares of our common stock on each of the events.

In October 1999, as part of a licensing agreement with Elan, we received gross proceeds of $17,015,000 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, we made an equity investment of $12,015,000 in a joint venture, RSD, representing an initial 80.1% ownership. The remaining proceeds from this 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 $4.0 million of our Series E Preferred Stock. Although only $3 million has been drawn down under the Series E Preferred Stock, as part of the November 8, 2002 Note Agreement with Elan, Elan is no longer obligated to provide us with the remaining $1 million in funding.

In May 1999, in conjunction with the completion of its Phase I/II Premaire-albuterol trial, Zambon provided us with a $1.0 million interest-free advance against future milestone payments. In January 2001, we received an additional $1.0 million

interest-free milestone advance resulting from the demonstration of the technical feasibility of delivering an inhaled steroid formulation in Premaire. The proceeds from these advances are not restricted as to their use by us. As part of the amendment of its 1998 agreement with Zambon, the terms of the milestone advances were modified in that we shall repay $1.0 million of the advance milestone payments upon the earlier of December 31, 2003, or upon the first regulatory approval for either albuterol or an inhaled steroid delivered in the Premaire. The remaining $1.0 million advance is required to be repaid by us on the earlier of December 31, 2005, or the regulatory approval of the second product (albuterol or an inhaled steroid) delivered in the Premaire. Due to the modification in the repayment terms, the advances have been reclassified in our balance sheet as long-term debt.

CERTAIN RISK FACTOR THAT MAY AFFECT FUTURE RESULTS, FINANCIAL CONDITION AND MARKET PRICE OF SECURITIES

The following are some of the factors that could affect our future results. They should be considered in connection with evaluating forward-looking statements contained in this report and otherwise made by us or on our behalf, because these factors could cause actual results and conditions to differ materially from those projected in forward-looking statements.

We need additional financing, which if not available, will prevent us from continuing as a going concern.

Unless we are able to raise significant capital ($1 million to $2.5 million) within the next 30-60 days, management believes that it is unlikely that we will be able to meet our obligations as they become due and to continue as a going concern. To meet this immediate capital requirement, we are evaluating various financing alternatives including, but not limited to, private offerings of our securities, debt financings, collaboration and licensing arrangements with other companies, and the sale of non-strategic assets and/or technologies to third parties. Should we be unable to meet our capital requirement through one or more of the above-mentioned financing alternatives, we may file for bankruptcy or seek similar protection.

Provided immediate funding is secured, we will still need to raise substantial additional capital in the very near-term to fund our operations in an effort to continue to meet our obligations as they become due and to continue as a going concern. The development of our technologies and proposed products will require a commitment of substantial funds to conduct costly and time-consuming research, preclinical and clinical testing, and to bring any such products to market. Our future capital requirements will depend on many factors, including continued progress in developing and out-licensing our pulmonary delivery technologies, our ability to establish and maintain collaborative arrangements with others and to comply with the terms thereof, receipt of payments due from partners under research and development agreements, progress with preclinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technology and the status of competitive products. We are currently seeking such additional funding through collaborative or partnering arrangements, the extension of existing arrangements, or through public or private equity or debt financings. Additional financing may not be available on acceptable terms or at all. If we raise additional funds by issuing equity securities, stockholders may be further diluted and such equity securities might have rights, preferences and privileges senior to those of our current stockholders. If adequate funds are not available over the longer-term, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize. If adequate funds are not available from operations or additional sources of funding, our business will suffer a material adverse effect.

We have experienced significant operating losses throughout our history and expect these losses to continue for the foreseeable future.

Our operations to date have consumed substantial amounts of cash and we have generated to date only limited revenues from contract research and licensing activities. We have incurred approximately $99.2 million of operating losses since our inception, including $.6 million for the three months ended March 31, 2003. Our operating losses and negative cash flow from operations are expected to continue in the foreseeable future. We expect that we will continue to have a high level of operating expenses, negative cash flow from operations and will be required to make significant up-front expenditures in connection with its product development activities. As a result, we anticipate additional operating

losses for the remainder of 2003 and that such losses will continue thereafter until such time, if ever, as we are able to generate sufficient revenues to sustain our operations. The independent auditors' report, dated April 4, 2003, on our consolidated financial statements stated that we have incurred recurring operating losses and have a working capital deficiency and that these conditions raise substantial doubt about our ability to continue as a going concern.

If our common stock is delisted from the American Stock Exchange, the price of our common stock and its liquidity could decline.

Our common stock is listed for trading on the American Stock Exchange, or the AMEX, under the symbol "SHM". We have not for some period of time and do not now satisfy AMEX standards for continued listing, including a standard that a listed company that has sustained losses from continuing operations and/or net losses in its five most recent fiscal years have stockholders' equity of at least $6,000,000. We had a net capital deficiency of $16.2 million at March 31, 2003. We submitted a plan advising the AMEX of the action we will take that will bring us into compliance with continued listing standards. On September 11, 2002, the AMEX notified us that it had accepted our plan of compliance and granted us an extension through the 2002 year-end reporting period to regain compliance with its continued listing standards. We will be subject to periodic review by the AMEX staff during the extension period. Failure to regain compliance with the continued listing standards by the end of the extension period could result in our being delisted from the AMEX. If our common stock were delisted from AMEX, trading of our common stock, if any, would thereafter likely be conducted in the over-the-counter market, unless we were able to list our common stock on The Nasdaq Stock Market or another national securities exchange, which cannot be assured. If our common stock were to trade in the over-the-counter market it may be more difficult for investors to dispose of, or to obtain accurate quotations as to the market value of our common stock. In addition, it may become more difficult for us to raise funds through the sale of our securities.

In the event of the delisting of our common stock from the AMEX and our inability to list our common stock on The Nasdaq Stock Market or another national securities exchange, the regulations of the SEC under the Securities Exchange Act of 1934, as amended, require additional disclosure relating to the market for penny stocks. SEC regulations generally define a penny stock to be an equity security that has a market price of less than $5.00 per share, subject to certain exceptions. A disclosure schedule explaining the penny stock market and the risks associated therewith is required to be delivered to a purchaser and various sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors (generally institutions). In addition, the broker-dealer must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. If our securities become subject to the regulations applicable to penny stocks, the market liquidity for our securities could be severely affected. In such an event, the regulations on penny stocks could limit the ability of broker-dealers to sell our securities.

Our products are still in development and we may be unable to bring our products to market.

We have not yet begun to generate revenues from the sale of products. Our products will require significant additional development, clinical testing and investment prior to their commercialization. We do not expect regulatory approval for commercial sales of any of our products in the immediate future. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. Such reasons include the possibility that products will not be proven to be safe and efficacious in clinical trials, that they will not be able to meet applicable regulatory standards or obtain required regulatory approvals, that they cannot be produced in commercial quantities at reasonable costs or that they fail to be successfully commercialized or fail to achieve market acceptance.

If our products are not accepted by the medical community, our business will suffer.

Commercial sales of our products will substantially depend upon the products' efficacy and on their acceptance by the medical community. Widespread acceptance of our products will require educating the medical community as to the benefits and reliability of the products. Our products may not be accepted and, even if accepted, we are unable to estimate the length of time it would take to gain such acceptance.

We will be required to make royalty payments on products we may develop, reducing the amount of revenues with which we could fund ongoing operations.

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

Our dependence on third parties for rights to technology and the development of our products could harm our business.

Under the terms of existing license agreements, we are obligated to make certain payments to our licensors. In the event that we default on the payment of an installment under the terms of an existing licensing agreement, our rights there under could be forfeited. As a consequence, we could lose all rights under a license agreement to the related licensed technology, notwithstanding the total investment made through the date of the default. Unforeseen obligations or contingencies may deplete our financial resources and, accordingly, sufficient resources may not be available to fulfill our commitments. If we were to lose

our rights to technology, we may be unable to replace the licensed technology or be unable to do so on commercially reasonable terms, which would materially adversely affect our ability to bring products based on that technology to market. In addition, we depend on our licensors for assistance in developing products from licensed technology. If these licensors fail to perform or their performance is not satisfactory, our ability to successfully bring products to market may be delayed or impeded.

We face intense competition and rapid technological changes and our failure to successfully compete or adapt to changing technology could make it difficult to successfully bring products to market.

The medical field is subject to rapid technological change and innovation. Pharmaceutical and biomedical research and product development are rapidly evolving fields in which developments are expected to continue at a rapid pace. Reports of progress and potential breakthroughs are occurring with increasing frequency. Our success will depend upon our ability to develop and maintain a competitive position in the research, development and commercialization of products and technologies in our areas of focus. Competition from pharmaceutical, chemical, biomedical and medical companies, universities, research and other institutions is intense and is expected to increase. All, or substantially all, of these competitors have substantially greater research and development capabilities, experience, and manufacturing, marketing, financial and managerial resources. Further, acquisitions of competing companies by large pharmaceutical or other companies could enhance such competitors' financial, marketing and other capabilities. Developments by others may render our products or technologies obsolete or not commercially viable and we may not be able to keep pace with technological developments.

We are subject to significant government regulation and failure to achieve regulatory approval for our products would severely harm our business.

Our ongoing research and development projects are subject to rigorous FDA approval procedures. The preclinical and clinical testing requirements to demonstrate safety and efficacy in each clinical indication (the specific condition intended to be treated) and regulatory approval processes of the FDA can take a number of years and will require us to expend substantial resources. We may be unable to obtain FDA approval for our products, and even if we do obtain approval, delays in such approval would adversely affect the marketing of products to which we have rights and our ability to receive product revenues or royalties. Moreover, even if FDA approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA, and a later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer. Failure to comply with the applicable regulatory requirements can, among other things, result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. Additional government regulation may be established which could prevent or delay regulatory approval of our products. Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Even if FDA approval has been obtained, approval of a product by comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The time required to obtain such approval may be longer or shorter than that required for FDA approval. We have no experience in manufacturing or marketing in foreign countries nor in matters such as currency regulations, import-export

controls or other trade laws. To date, we have not received final regulatory approval from the FDA or any other comparable foreign regulatory authority for any of our products or technologies.

Our failure to meet product release schedules would make it difficult to predict our quarterly results and may cause our operating results to vary significantly.

Delays in the planned release of our products may adversely affect forecasted revenues and create operational inefficiencies resulting from staffing levels designed to support the forecasted revenues. Our failure to introduce new products on a timely basis could delay or hinder market acceptance and allow competitors to gain greater market share.

If our intellectual property and proprietary rights are infringed, or infringe upon the rights of others, our business will suffer.

Our success will depend in part on our ability to obtain patent protection for our technologies, products and processes and to maintain trade secret protection and operate without infringing the proprietary rights of others. The degree of patent protection

to be afforded to pharmaceutical, biomedical or medical inventions is an uncertain area of the law. In addition, the laws of foreign countries do not protect our proprietary rights to the same extent as do the laws of the United States. We may not develop or receive sublicenses or other rights related to proprietary technology that are patentable, patents that are pending may be not issued, and any issued patents may not provide us with any competitive advantages and may be challenged by third parties. Furthermore, others may independently duplicate or develop similar products or technologies to those developed by or licensed to us. If we are required to defend against charges of patent infringement or to protect our own proprietary rights against third parties, substantial costs will be incurred and we could lose rights to certain products and technologies or be required to enter into costly royalty or licensing agreements.

We do not have any marketing or manufacturing capabilities and will likely rely on third parties for these capabilities in order to bring products to market.

We do not currently have our own sales force or an agreement with another pharmaceutical company to market all of our products that are in development. When appropriate, we may build or otherwise acquire the necessary marketing capabilities to promote our products. However, we may not have the resources available to build or otherwise acquire our own marketing capabilities, and we may be unable to reach agreements with other pharmaceutical companies to market our products on terms acceptable to us, if at all.

In addition, we do not intend to manufacture our own products. While we have already entered into two manufacturing and supply agreements related to the Premaire system and one related to the Tempo, these manufacturing and supply agreements may not be adequate and we may not be able to enter into future manufacturing and supply agreements on acceptable terms, if at all. Our reliance

on independent manufacturers involves a number of risks, including the absence of adequate capacity, the unavailability of, or interruptions in, access to necessary manufacturing processes and reduced control over product quality and delivery schedules. If our manufacturers are unable or unwilling to continue manufacturing our products in required volumes, we will have to identify acceptable alternative manufacturers. The use of a new manufacturer may cause significant interruptions in supply if the new manufacturer has difficulty manufacturing products to our specifications. Further, the introduction of a new manufacturer may increase the variation in the quality of our products.

Healthcare reimbursement policies are uncertain and may adversely impact the sale of our products.

Our ability to commercialize human therapeutic and diagnostic products may depend in part on the extent to which costs for such products and technologies are reimbursed by private health insurance or government health programs. The uncertainty regarding reimbursement may be especially significant in the case of newly approved products. Reimbursement price levels may be insufficient to provide a return to us on our investment in new products and technologies. In the United States, government and other third-party payers have sought to contain healthcare costs by limiting both coverage and the level of reimbursement for new pharmaceutical products approved for marketing by the FDA, including some cases of refusal to cover such approved products. Healthcare reform may increase these cost containment efforts. We believe that managed care organizations may seek to restrict the use of new products, delay authorization to use new products or limit coverage and the level of reimbursement for new products. Internationally, where national healthcare systems are prevalent, little if any funding may be available for new products, and cost containment and cost reduction efforts can be more pronounced than in the United States.

We may become subject to product liability claims and our product liability insurance may be inadequate.

The use of our proposed products and processes during testing, and after approval, may entail inherent risks of adverse effects that could expose us to product liability claims and associated adverse publicity. Although we currently maintain general liability insurance, the coverage limits of our insurance policies may not be adequate. We currently maintain clinical trial product liability insurance of $2.0 million per event for certain clinical trials and intend to obtain insurance for future clinical trials of products under development. However, we may be unable to obtain or maintain insurance for any future clinical trials. Such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. A successful claim brought against us in excess of our insurance coverage would have a material adverse effect upon us and our financial condition. We intend to require our licensees to obtain adequate product liability insurance. However, licensees may be unable to maintain or obtain adequate product liability insurance on acceptable terms and such insurance may not provide adequate coverage against all potential claims.

The price of biotechnology/pharmaceutical company stocks has been volatile which

could result in substantial losses to our stockholders.

The market price of securities of companies in the biotechnology/pharmaceutical industries has tended to be volatile. Announcements of technological innovations by us or our competitors, developments concerning proprietary rights and concerns about safety and other factors may have a material effect on our business or financial condition. The market price of our common stock may be significantly affected by announcements of developments in the medical field generally or our research areas specifically. The stock market has experienced volatility in market prices of companies similar to us that has been unrelated to the operating results of such companies. This volatility may have a material adverse effect on the market price of our common stock.

Our ability to issue "blank check" preferred stock may make it more difficult for a change in our control.

Our certificate of incorporation authorizes the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined from time to time by the Board of Directors, without shareholder approval. In the event of issuance, such preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in our control and preventing shareholders from receiving a premium for their shares in connection with a change of control. We issued Series A and Series B cumulative convertible redeemable preferred stock in connection with private placements in February 1997 and April 1998, respectively. All of the Series A preferred stock was converted into common stock during 1998. On July 31, 1998, all of the Series B Preferred stock was redeemed for cash. We also issued shares of our Series C cumulative convertible preferred stock in connection with the consummation of an agreement with Elan International Services, Ltd. ("Elan International") in June 1998. In October 1999, in conjunction with a licensing agreement with Elan International, we issued shares of our Series D cumulative convertible exchangeable preferred stock and Series F cumulative convertible preferred stock. During 2002, 2001 and 2000, Elan International purchased a total of $3,000,000 of our Series E cumulative convertible non-exchangeable preferred stock. Except for additional shares of Series C, D and E preferred stock that may be payable as dividends to Elan International, as holder of the outstanding Series C, D and E preferred stock, we have no current plans to issue any additional shares of our preferred stock. However, as we are currently attempting to secure additional capital, we may issue additional shares of our preferred stock in the near future.

We are obligated to issue additional securities in the future diluting our stockholders.

As of March 31, 2003, we had reserved approximately 4,215,372 shares of our common stock for issuance upon exercise of outstanding options and warrants convertible into shares of our common stock, including by our officers and directors. In addition, as of March 31, 2003, we had $2,000,000 principal amount of a convertible promissory note, 16,054 shares of our Series C preferred stock, 14,795 shares of our Series D preferred stock, 3,378 shares of our Series E preferred stock and 5,000 shares of our Series F preferred stock outstanding. Each of the convertible securities provides for conversion into shares of our common stock at a premium to the market price at March 31, 2003. Our Series C, D, E and F preferred stock are convertible into 11,385,816 shares, 3,044,239 shares, 868,380 shares and 1,470,588 shares, respectively, of common stock. The convertible promissory note, including accrued interest is convertible into

1,600,527 shares of common stock. The exercise of options and outstanding warrants, the conversion of such other securities and sales of common stock issuable thereunder could have a significant dilutive effect on the market price of our common stock and could materially impair our ability to raise capital through the future sale of our equity securities.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

The Company has no material market risk exposure.

Item 4. Controls and Procedures

(a) Explanation Of Disclosure Controls And Procedures. Our President, Chief Executive Officer and Acting Chief Financial Officer (principal executive officer and principal financial officer), after evaluating the effectiveness of our disclosure controls and procedures (as defined in Securities Exchange Act Rules 13a-14(c) and 15d-14(c)) as of a date within 90 days of the filing date of this Form 10-Q (the "Evaluation Date"), has concluded that as of the Evaluation Date our disclosure controls and procedures were adequate and effective to ensure that material information relating to us would be made known to such officer by others within our company, particularly during the period in which this Form 10-Q was being prepared.

(b) Changes In Internal Controls. There were no significant changes in our internal controls or in other factors that could significantly affect our disclosure controls and procedures subsequent to the Evaluation Date, nor were there any significant deficiencies or material weaknesses in such disclosure controls and procedures requiring corrective action. As a result, no corrective action was taken.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

The Company was named as a defendant in Jeffrey Leston v. Sheffield Pharmaceuticals, Inc., filed on October 16, 2002 in the United States District Court, Southern District of New York. The plaintiff in this action seeks damages of $100,000

for the breach of a contract under which Leston was retained to introduce and facilitate a business alliance between Sheffield and Zambon Corporation. The plaintiff claims that under this contract, Sheffield was obligated, among other things, to pay Leston a fee equal to 4% of any equity purchased by Zambon in Sheffield or other financing by Zambon, including loans. In January 1999, an agreement was entered into amending the original contract in a manner that the Company believes relieved the Company of any of the obligations claimed in the Complaint. In September 2001, Zambon loaned $2.5 million to Sheffield as part of a restructuring of their alliance. This action seeks $100,000, or 4% of the $2.5 million loaned to Sheffield under this restructuring with Zambon. On January 21, 2003, the Company filed an Answer and Counterclaim. The Company denied the plaintiff's allegations and counter-claimed for the return of monies previously paid to the plaintiff. The Company intends to vigorously defend the action and prosecute its counterclaim.

Item 2. Changes in Securities and Use of Proceeds

The following unregistered securities were issued by the Company during the quarter ended March 31, 2003:

Date of Sale/Issuance	Description of Securities Issued	Number of Shares Subject to Options or Warrants	Exercise Price per Share ($)	Purchaser or Class
January 1, 2003	Warrants to purchase Common stock.	225,000	$.60	Holders of promissory notes amended during the period.

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. These securities were issued in connection with the amendment of certain of the Company's promissory notes originally issued on September 6, 2002 and amended on January 1, 2003.

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

(a) Exhibits

See Index to Exhibits on Page 24.

(b) Reports on Form 8-K

(1) A current Report on Form 8-K was filed with the Securities and Exchange Commission on January 28, 2003 to announce the filing of a press release under

Item 5.

(2) A current Report on Form 8-K was filed with the Securities and Exchange Commission on March 7, 2003 to announce the filing of a press release under Item 5.

(3) A current Report on Form 8-K was filed with the Securities and Exchange Commission on March 14, 2003 under Item 4, relating to a change in the Registrant's certifying accountant.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SHEFFIELD PHARMACEUTICALS, INC.

Date: May 12, 2003 /s/ Thomas M. Fitzgerald

Thomas M. Fitzgerald
President, Chief Executive Officer
and Acting Chief Financial Officer

CERTIFICATION

I, Thomas M. Fitzgerald, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sheffield Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements

were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 12, 2003

/s/ Thomas M. Fitzgerald

Thomas M. Fitzgerald
President, Chief Executive Officer and
Acting Chief Financial Officer
(Principal Executive Officer and
Principal Financial Officer)

Index to Exhibits

3.1 Certificate of Incorporation of the Company, as amended (1)

3.2 By-Laws of the Company (2)

4.1 Form of Common Stock Certificate (3)

4.4 Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series C Cumulative Convertible Redeemable Preferred Stock. (1)

4.5 Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series D Cumulative Convertible Exchangeable Preferred Stock. (4)

4.6 Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series E Convertible Non-Exchangeable Preferred Stock. (4)

4.7 Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series F Convertible Non-Exchangeable Preferred Stock. (4)

*10.42 Form of promissory note dated February 25, 2003 with certain shareholders and a third party.

*99.1 Certification of President, Chief Executive Officer and Acting Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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* Filed herewith.

(1) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998 filed with the Securities and Exchange Commission.

(2) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997 filed with the Securities and Exchange Commission.

(3) Incorporated by reference to the Company's Annual Report on Form 10-KSB for its fiscal year ended December 31, 1995 filed with the Securities and Exchange Commission.

(4) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 2, 1999.