

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended April 30, 2001

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

For the transition period from _____ to _____

Commission File Number 001-15167

BIOPURE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State of Incorporation)

04-2836871

(IRS Employer Identification Number)

11 Hurley Street, Cambridge, Massachusetts

(Address of principal executive offices)

02141

(Zip Code)

(617) 234-6500

(Registrant's telephone number)

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. Yes ☒ No ☐

The number of shares outstanding of each of the issuer's classes of common stock as of May 31, 2001 was:

Class A Common Stock, \$.01 par value	25,121,944
Class B Common Stock, \$1.00 par value	117.7

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BIOPURE CORPORATION

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PART I

ITEM 1

BIOPURE CORPORATION

Condensed Consolidated Balance Sheets (In thousands, except share and per share data) (Unaudited)

	April 30, 2001	October 31, 2000
Assets:		
Current assets:		
Cash and cash equivalents	\$ 71,320	\$ 88,828
Accounts receivable, net	481	478
Inventories, net	3,283	2,726
Current portion of restricted cash	—	3,508
Other current assets	444	380
Total current assets	75,528	95,920
Property, plant and equipment, net	24,624	25,061
Investment in affiliate	66	66
Other assets	250	240
Total assets	<u>\$ 100,468</u>	<u>\$ 121,287</u>
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	\$ 1,263	\$ 1,764
Accrued expenses	7,377	9,228
Total current liabilities	8,640	10,992
Deferred compensation	1,756	1,785
Stockholders' equity:		
Convertible preferred stock, \$0.01 par value, 30,000,000 shares authorized, no shares outstanding	—	—
Common stock:		
Class A, \$0.01 par value, 100,000,000 shares authorized, 25,078,130 shares outstanding at April 30, 2001 and 24,937,995 at October 31, 2000	251	249
Class B, \$1.00 par value, 179 shares authorized, 117.7 shares outstanding	—	—
Capital in excess of par value	381,528	372,149
Contributed capital	24,574	24,574
Notes receivable	(1,746)	(2,033)
Accumulated deficit	(314,535)	(286,429)
Total stockholders' equity	90,072	108,510
Total liabilities and stockholders' equity	<u>\$ 100,468</u>	<u>\$ 121,287</u>

Note: The balance sheet at October 31, 2000 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

See accompanying notes.

BIOPURE CORPORATION

Condensed Consolidated Statements of Operations **(In thousands, except per share data)** **(Unaudited)**

	Three Months Ended		Six Months Ended	
	April 30,	April 29,	April 30,	April 29,
	2001	2000	2001	2000
Revenues:				
Oxyglobin	\$ 837	\$ 710	\$ 1,568	\$ 1,304
Other	1	—	5	3
Total revenues	<u>838</u>	<u>710</u>	<u>1,573</u>	<u>1,307</u>
Cost of revenues	<u>914</u>	<u>1,102</u>	<u>1,684</u>	<u>2,291</u>
Gross profit (loss)	(76)	(392)	(111)	(984)
Operating expenses:				
Research and development	9,002	8,143	17,189	16,402
Sales and marketing	664	569	1,286	1,148
General and administrative	<u>8,753</u>	<u>1,736</u>	<u>11,826</u>	<u>4,848</u>
Total operating expenses	<u>18,419</u>	<u>10,448</u>	<u>30,301</u>	<u>22,398</u>
Loss from operations	(18,495)	(10,840)	(30,412)	(23,382)
Other income	<u>990</u>	<u>933</u>	<u>2,306</u>	<u>1,291</u>
Net loss	<u><u>\$(17,505)</u></u>	<u><u>\$ (9,907)</u></u>	<u><u>\$(28,106)</u></u>	<u><u>\$(22,091)</u></u>
Per share data:				
Basic and diluted net loss per common share	\$ (0.70)	\$ (0.42)	\$ (1.13)	\$ (0.96)
Weighted average shares used in computing basic net loss per common share	24,958	23,580	24,959	22,938

See accompanying notes.

BIOPURE CORPORATION

Condensed Consolidated Statement of Cash Flows (In thousands) (Unaudited)

	Six Months Ended	
	April 30, 2001	April 29, 2000
Operating activities:		
Net loss	\$(28,106)	\$ (22,091)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,103	2,049
Equity compensation	7,717	1,820
Deferred compensation	(29)	(37)
Accrued interest on stockholders' notes receivable	(50)	(86)
Accounts receivable	(3)	(118)
Inventories	(557)	594
Other current assets	(64)	(223)
Accounts payable	(501)	234
Accrued expenses	1,657	1,307
Net cash used in operating activities	(17,833)	(16,551)
Investing activities:		
Purchase of property, plant and equipment	(1,666)	(222)
Other assets	(10)	(36)
Net cash used in investing activities	(1,676)	(258)
Financing activities:		
Net proceeds from sale of common stock	—	83,739
Payment of notes receivable from stockholders	337	556
Proceeds from exercise of options and warrants	1,532	472
Proceeds from exercise of non lapse restricted stock	132	2,112
Net cash provided by financing activities	2,001	86,879
Net increase (decrease) in cash and cash equivalents	(17,508)	70,070
Cash and cash equivalents at beginning of period	88,828	30,778
Cash and cash equivalents at end of period	<u>\$ 71,320</u>	<u>\$100,848</u>

See accompanying notes.

BIOPURE CORPORATION

Notes to Condensed Consolidated Financial Statements April 30, 2001 (Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and six months periods ended April 30, 2001 are not necessarily indicative of the results that may be expected for the year ended October 31, 2001.

For further information, refer to the consolidated financial statements and footnotes thereto for the year ended October 31, 2000, included in the Company's Annual Report on Form 10-K for the year ended October 31, 2000.

2. Net Loss per Share

Basic net loss per share is computed based on the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed based upon the weighted-average number of common shares outstanding during the year, adjusted for the dilutive effect of shares issuable upon the exercise of common stock options and warrants determined based upon the average market price of common stock for the period. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per share are the same.

3. Inventories

Inventories are valued at the lower of cost (determined using the first-in, first-out method) or market. Inventories were as follows:

	April 30, 2001	October 31, 2000
<i>In thousands</i>		
Raw materials	\$1,160	\$ 980
Work-in-process	1,167	476
Finished goods	956	1,270
	<u>\$3,283</u>	<u>\$2,726</u>

BIOPURE CORPORATION

Notes to Condensed Consolidated Financial Statements

April 30, 2001

(Unaudited)

(Continued)

4. Accrued Expenses

Accrued expenses consisted of the following:

	<u>April 30, 2001</u>	<u>October 31, 2000</u>
<i>In thousands</i>		
Settlement	\$ —	\$3,508
Phase III clinical trial	3,116	2,897
BLA	717	—
Accrued Payroll	481	482
Performance Incentive	501	65
Other	<u>2,562</u>	<u>2,276</u>
	<u>\$7,377</u>	<u>\$9,228</u>

5. Stock Option Compensation

In August 1999, Biopure granted 386,680 options to two directors which are assumed to be for services in addition to board activities and must be accounted for at fair value, pursuant to Financial Accounting Standards Board Statement No. 123, Accounting for Stock-Based Compensation (SFAS 123) and EITF 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services. The Company records compensation expense based on a service period adjusted for the fair value of the stock until these options have been earned, as discussed below. In October 2000, January 2001 and April 2001, Biopure granted 30,000, 7,503 and 30,000 options, respectively, to three consultants, which must be accounted for at fair value.

Because the options are assumed to be earned over the service period, the final value of the options (i.e. the compensation expense), will not be determined until the service period is complete. Therefore, at each time interval (i.e. quarterly), the options must be marked to fair value (based on a valuation model such as the Black Scholes option pricing model). Compensation expense based on fair value will continue to be amortized to general and administrative expense on a straight-line basis over the service period. However, the amount charged to expense will be increased or decreased at each point in time based on the then current fair value of the Company's stock. Therefore, during each time interval the Company will be required to record two amounts, the first relating to the current period compensation charge and the second, a cumulative catch-up adjustment for the period based on the fair value of the options at the end of that period.

In April 2001, Biopure granted 750,000 warrants to two contract parties, which also must be accounted for at fair value. The warrants were issued for services completed and as such the non-cash compensation expenses related to these warrants was a one-time charge in the quarter ended April 30, 2001. With respect to these 1,204,183 options and warrants, \$6,370,000 was charged to non-cash compensation expense for the quarter ended April 30, 2001.

BIOPURE CORPORATION

Notes to Condensed Consolidated Financial Statements

April 30, 2001

(Unaudited)

(Continued)

6. Commitment

On January 31, 2001 the Company signed a letter of intent for the construction and financing of an \$85,000,000 state-of-the-art biopharmaceutical facility in Sumter, South Carolina. On May 8, 2001 Biopure placed \$10,000,000 in escrow as its contribution to equity in the project. The Company will enter into a 20-year lease with optional buyout provisions and a bargain purchase option at the end of the term. Lease payments are expected to start in the beginning of fiscal 2004. Financing for the new plant will consist of asset-backed mortgage financing, tax exempt bonds, equipment lease financing, and state and local incentives.

7. Litigation

The Company was a party to litigation initially filed in 1990 arising from certain joint venture agreements for development and distribution of product in Central and South America. Summary judgments were entered against the two plaintiffs in 1994. The plaintiffs each appealed the judgments; one of the appeals was voluntarily dismissed. The other appeal was remanded to the trial court for further findings based on lack of jurisdiction. The trial court made the requisite findings in favor of the Company. The matter was appealed again. By judgment entered March 6, 2001, the U.S. Court of Appeals for the First Circuit affirmed the summary judgments in favor of the Company. In connection with the summary judgments, the Company had agreed to a settlement with a third-party intervenor with claims against one of the plaintiffs. Final payment of the settlement was subject to the outcome of the pending appeal; however, the Company had provided for such settlement in its financial statements. On April 2, 2001, the Company paid out \$3,508,000 from an escrow account in connection with this settlement. This amount had been included in the financial statements as current portion of restricted cash. The related obligation had previously been recorded in accrued liabilities.

BIOPURE CORPORATION

Management's Discussion and Analysis of Financial Condition and Results of Operations April 30, 2001

Except for historical information contained herein, some matters discussed in this report constitute 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. Actual results could differ materially from those projected in the forward-looking statements as a result of the risk factors set forth in this report and in Exhibit 99.0 to the Company's Annual Report on Form 10-K for the year ended October 31, 2000. In light of the substantial risks and uncertainties inherent in all future projections, the inclusion of forward-looking statements in this report should not be regarded as representations by the Company that the objectives or plans of the Company will be achieved. Many factors could cause the Company's actual results, performance or achievements to differ materially from those in the forward-looking statements. Reference is made in particular to the discussions set forth below in this Report under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Business Outlook

We anticipate our sales of Oxyglobin, our veterinary product, will be between \$3,400,000 and \$3,600,000 in fiscal 2001. Operating expenses are anticipated to be between \$49,000,000 and \$50,000,000 excluding actual non-cash compensation expenses of \$7,700,000 in the first six months and an estimate of \$800,000 for the third quarter. No material non-cash compensation expenses are anticipated for the fourth quarter of fiscal 2001. The third quarter non-cash compensation expense can vary widely and will depend on the actual closing share price on July 31, 2001. Interest income is expected to decrease for the second six months of fiscal 2001 because of current lower interest rates and reduced invested cash balances.

Research and development expenses for the third quarter are expected to be approximately 10% higher than for the second quarter of fiscal 2001. This increase is attributable to a one-time expense for research and pre-clinical studies related to the acquisition, in May, of Reperfusion Systems Incorporated, an inactive company 26% owned by Biopure, for approximately 63,000 shares of Biopure Common Stock. We anticipate that the fourth quarter research and development expenses will increase 5% over the levels of the second quarter. Our manufacturing facility in Cambridge is scheduled to be shut down for its capacity upgrade during the fourth quarter and the first quarter of 2002. During this six month shutdown, all costs of our manufacturing facilities will be charged to research and development expenses instead of only a portion of unabsorbed costs as has been done historically. Expenses related to our anticipated electronic BLA filing should decrease from the third quarter to the fourth quarter. We will highlight these shutdown costs when we report on our results of operations.

Selling, general and administrative expenses for the third and fourth quarters, excluding all non-cash compensation expenses, are anticipated to increase by 10% and 40% respectively compared to the actual SG&A expenses, excluding all non-cash compensation charges, for the second quarter of 2001. Marketing activities for the 2002 launch of Hemopure, our product for humans, in South Africa should increase and the cost of the product we will ship to South Africa, in these quarters, will be charged to selling expenses.

This Business Outlook discussion contains, in addition to historical information, forward-looking statements that involve risks and uncertainties. When used herein, the words "expects," "anticipates," "estimates," "intends," "plans" and similar expressions are intended to identify such forward-looking statements. Our actual results could differ materially from the results discussed in these forward-looking statements for the reasons referenced in the first paragraph, above, of this discussion and analysis.

BIOPURE CORPORATION

Management's Discussion and Analysis of Financial Condition and Results of Operations April 30, 2001 (Continued)

Results of Operations

Three months ended April 30, 2001 compared to three months ended April 29, 2000

Total revenues increased 18.0% to \$838,000 in the second quarter of fiscal 2001 from \$710,000 in the second quarter of fiscal 2000. The increase in revenue reflects the first shipments of Oxyglobin, the Company's veterinary drug for the treatment of canine anemia, to customers in Europe and a 12.7% growth in domestic sales.

Cost of revenues decreased 17.1% to \$914,000 in the second quarter of fiscal 2001 from \$1,102,000 in the second quarter of fiscal 2000. This decline is due to increased manufacturing activity associated with the development of Hemopure, the Company's advanced stage Oxygen TherapeuticTM for human use, and the resulting decrease in manufacturing expenses allocated to Oxyglobin.

Research and development expenses increased 10.5% to \$9,002,000 in the second quarter of fiscal 2001 from \$8,143,000 in the second quarter of fiscal 2000. This increase was primarily due to the activities associated with data organization and analyses for the pivotal Phase III trial of Hemopure, preparation for the filing of an electronic U.S. marketing application this year and ongoing research and development. Additionally, the increased manufacturing activity associated with Hemopure and the resulting increase in manufacturing expenses allocated to research and development contributed to the increase.

Sales and marketing expenses increased 16.7% to \$664,000 in the second quarter of fiscal 2001 from \$569,000 in the second quarter of fiscal 2000. This increase was primarily attributable to marketing and selling expenses associated with the launch of Oxyglobin in Europe.

General and administrative expenses were \$8,753,000 in the second quarter of fiscal 2001, up from \$1,736,000 in the second quarter of fiscal 2000. This increase is mostly due to non-cash compensation expense for stock options and warrants issued to certain consultants, directors and contract parties that must be accounted for at fair value, per SFAS 123 and EITF 96-18, and be amortized over the service period and revalued each quarter based on the closing stock price or, if issued for services completed, are recorded as a one-time charge. For the second quarter of fiscal 2001, we recorded \$6,370,000 as compensation expense under these options and warrants versus \$131,000 for the same period last year. Pre-approval marketing expenses for Hemopure and consulting expenses related to our facility to be built in South Carolina increased in the second quarter of fiscal 2001 compared to the same period in 2000.

Total other income was \$990,000 in the second quarter of fiscal 2001 compared to \$933,000 in the second quarter of fiscal 2000. The increase reflects additional interest earned on a higher average cash balance in the second quarter of fiscal 2001.

BIOPURE CORPORATION

Management's Discussion and Analysis of Financial Condition and Results of Operations

April 30, 2001

(Continued)

Six months ended April 30, 2001 compared to six months ended April 29, 2000

Total revenues increased 20.4% to \$1,573,000 in the first six months of fiscal 2001 from \$1,307,000 in the first six months of fiscal 2000. The first six months of fiscal 2001 included our first shipments of Oxyglobin to our customers in Europe and a 17.4% growth in sales to our domestic customers.

Cost of revenues decreased 26.5% to \$1,684,000 in the first six months of fiscal 2001 from \$2,291,000 in the first six months of fiscal 2000. This decline is due to increased manufacturing activity associated with the development of Hemopure and the resulting decrease in manufacturing expenses allocated to Oxyglobin.

Research and development expenses increased 4.8% to \$17,189,000 in the first six months of fiscal 2001 from \$16,402,000 in the first six months of fiscal 2000. This increase was primarily due to the activities associated with the data organization and analyses for the pivotal Phase III trial of Hemopure, preparation for the filing of an electronic U.S. marketing application this year and ongoing research and development. Additionally, the increased manufacturing activity associated with Hemopure and the resulting increase in manufacturing expenses allocated to research and development contributed to the increase.

Sales and marketing expenses increased 12.0% to \$1,286,000 in the first six months of fiscal 2001 from \$1,148,000 in the first six months of fiscal 2000. The increase was primarily due to sales and marketing efforts of introducing Oxyglobin in selected European countries in 2001.

General and administrative expenses increased 143.9% to \$11,826,000 in the first six months of fiscal 2001 from \$4,848,000 in the first six months of fiscal 2000. The increase is primarily due to non-cash compensation expense for stock options and warrants issued to certain consultants, directors and contract parties that must be accounted for at fair value, per SFAS 123 and EITF 96-18, and be amortized over the service period and revalued each quarter based on the closing stock price or, if issued for services completed, are a one-time charge. For the first six months of fiscal 2001, we recorded \$7,717,000 as compensation expense under these options and warrants versus \$1,820,000 in the first six months of fiscal 2000. Increased spending in public and investor relations, pre-approval marketing expenses for Hemopure and consulting expenses related to our facility to be built in South Carolina also contributed to the increase.

Total other income was \$2,306,000 in the first six months of fiscal 2001 compared to \$1,291,000 in the first six months of fiscal 2000. The increase reflects additional interest earned on a higher average cash balance in fiscal 2001.

Liquidity and Capital Resources

At April 30, 2001, we had current assets of \$75,528,000, consisting primarily of \$71,320,000 in cash and cash equivalents and \$3,283,000 in net inventory. At April 30, 2001, current liabilities were \$8,640,000. On April 2, 2001, we paid out \$3,508,000 from an escrow account that had been included in current portion of restricted cash in connection with the settlement described in note 7 to the financial statements included in this report.

BIOPURE CORPORATION

Management's Discussion and Analysis of Financial Condition and Results of Operations April 30, 2001 (Continued)

During the first six months of fiscal 2001, our cash and cash equivalents decreased \$17,508,000 from \$88,828,000 at October 31, 2000 to \$71,320,000 at April 30, 2001. This decrease is primarily due to cash outflows of \$17,833,000 for operating activities.

On January 31, 2001, we signed a letter of intent for the construction and financing of an \$85,000,000 state-of-the-art biopharmaceutical facility in Sumter, South Carolina. On May 8, 2001 Biopure placed \$10,000,000 in escrow as its contribution to equity in the project and will enter into a 20-year lease with optional buyout provisions and a bargain purchase option at the end of the term. Lease payments are expected to start in the beginning of fiscal 2004. Financing for the new plant will consist of asset-backed mortgage financing, tax exempt bonds, equipment lease financing, and state and local incentives.

We have financed operations from inception primarily through sales of equity securities, development and license agreement payments, interest income and debt.

Our primary investment objective is preservation of principal and we currently invest in high-grade commercial paper.

We have not been profitable since inception and had an accumulated deficit of \$314,535,000 as of April 30, 2001. We will continue to generate losses from operations for the foreseeable future. We will explore and are pursuing opportunities to raise capital through sales of equity and debt securities, potential partnerships, bank borrowings or leasing arrangements.

We believe our current cash, cash equivalents and short-term investments should be sufficient to meet our projected operating requirements through the first half of fiscal 2002. Our cash requirements may vary significantly from current projections.

As of October 31, 2000, we had net operating loss carryforwards of approximately \$171,000,000 to offset future federal and state taxable income through 2020. Due to the degree of uncertainty related to the ultimate realization of such prior losses, no benefit has been recognized in our financial statements as of October 31, 2000. Utilization of such losses in future years may be limited under the change of stock ownership rules of the Internal Revenue Service.

Quantitative and Qualitative Disclosure of Market Risk

The Company currently does not have any foreign currency exchange risks with the exception of negligible exchange fluctuations associated with expenses for clinical trial and regulatory activities outside of the United States. The Company invests its cash and cash equivalents in high-grade commercial paper and money market funds. These investments are subject to interest rate risk. However, due to the nature of the Company's short-term investments, it believes that the financial market risk exposure is not material.

BIOPURE CORPORATION

Part II – Other Information April 30, 2001

Item 2 – Changes in Securities and Use of Proceeds

Warrants to purchase 3,611 shares of Class A Common Stock were exercised in the second quarter of fiscal 2001 for aggregate proceeds to the Corporation of \$7,200.00. The Corporation relied on Section 4(2) of the Securities Act of 1933 and Regulation D under the Securities Act of 1933 in issuing shares upon the exercise of warrants.

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

- (a) The Corporation held its 2001 Annual Meeting on April 4, 2001.
- (b) Daniel P. Harrington and Stephen A. Kaplan were elected as directors at the meeting. The other directors whose terms of office continued after the meeting are David N. Judelson, C. Everett Koop, M.D., Paul A. Looney, Carl W. Rausch and Charles A. Sanders, M.D.
- (c) The election of directors was the only matter voted upon at the meeting. The shares voted were:

	For	Withheld
Daniel P. Harrington	21,480,438	93,301
Stephen A. Kaplan	21,477,363	96,376

There were no broker held nonvoted shares represented at the meeting.

Item 6 – Exhibits and Reports on Form 8-K

- (a) The exhibits are listed in the accompanying Exhibit Index.
- (b) No reports on Form 8-K were filed during the quarter for which this report is filed.

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.

Date: June 14, 2001

BIOPURE CORPORATION

By: /s/ Carl W. Rausch

Carl W. Rausch
Chairman of the Board
Chief Executive Officer

Date: June 14, 2001

By: /s/ Francis H. Murphy

Francis H. Murphy
Chief Financial Officer

EXHIBIT INDEX

Number	Description
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10.1	Distribution Agreement between the Company and Network Healthcare Holdings Limited
10.2	Amendment to [Distribution] Agreement between the Company, Network Healthcare Holdings Limited and Tshepo Pharmaceuticals (Pty) Limited
10.3	Letter Agreement between the Company and Network Healthcare Holdings Limited
10.4	Letter Agreement between the Company and Scanix Six (Pty) Ltd.