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, 2003

☐ 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	**04-2836871**
(State of Incorporation)	(IRS Employer Identification Number)
11 Hurley Street, Cambridge, Massachusetts	**02141**
(Address of principal executive offices)	(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 30, 2003 was:

Class A Common Stock, $.01 par value	39,393,800
Class B Common Stock, $1.00 par value	117.7

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BIOPURE CORPORATION

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

	April 30, 2003	October 31, 2002
Assets:		
Current assets:		
Cash and cash equivalents	$ 15,101	$ 19,710
Accounts receivable, net	372	89
Inventories, net	8,021	8,028
Other current assets	1,054	709
Total current assets	24,548	28,536
Property, plant and equipment, net	37,295	38,769
Other assets	10,947	10,972
Total assets	$ 72,790	$ 78,277
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	$ 1,628	$ 2,163
Accrued expenses	3,806	4,026
Total current liabilities	5,434	6,189
Long-term debt	9,847	9,847
Deferred compensation	142	184
Total long-term liabilities	9,989	10,031
Stockholders' equity:		
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, 37,424,043 shares outstanding at April 30, 2003 and 30,353,370 at October 31, 2002	374	304
Class B, $1.00 par value, 179 shares authorized, 117.7 shares outstanding	—	—
Capital in excess of par value	437,040	419,065
Contributed capital	24,574	24,574
Notes receivable	(256)	(255)
Accumulated deficit	(404,365)	(381,631)
Total stockholders' equity	57,367	62,057
Total liabilities and stockholders' equity	$ 72,790	$ 78,277

Note: The balance sheet at October 31, 2002 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 share and per share data)
(Unaudited)

	Three Months Ended		Six Months Ended	
	April 30, 2003	April 30, 2002	April 30, 2003	April 30, 2002
Revenues:				
Oxyglobin	$ 1,961	$ 928	$ 1,982	$ 1,656
Total revenues	1,961	928	1,982	1,656
Cost of revenues	5,973	958	10,821	1,820
Gross loss	(4,012)	(30)	(8,839)	(164)
Operating expenses:				
Research and development	2,536	8,153	5,082	15,125
Sales and marketing	1,606	576	2,622	1,004
General and administrative	3,526	4,129	6,253	6,734
Total operating expenses	7,668	12,858	13,957	22,863
Loss from operations	(11,680)	(12,888)	(22,796)	(23,027)
Other income, net	28	161	62	611
Net loss	$(11,652)	$(12,727)	$(22,734)	$(22,416)
Per share data:				
Basic and diluted net loss per common share	$ (0.35)	$ (0.49)	$ (0.71)	$ (0.87)
Weighted-average shares used in computing basic and diluted net loss per common share	33,351	25,993	31,920	25,692

See accompanying notes.

BIOPURE CORPORATION

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

	Six Months Ended	
	April 30, 2003	April 30, 2002
Operating activities:		
Net loss	$(22,734)	$(22,416)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,658	2,095
Equity compensation	208	(132)
Deferred compensation	(42)	(19)
Accrued interest on stockholders' notes receivable	(1)	(36)
Changes in assets and liabilities:		
Accounts receivable	(283)	88
Inventories	7	1,806
Other current assets	(345)	40
Accounts payable	(535)	274
Accrued expenses	(220)	189
Net cash used in operating activities	(21,287)	(18,111)
Investing activities:		
Purchase of property, plant and equipment	(1,156)	(3,976)
Other assets	(3)	(115)
Net cash used in investing activities	(1,159)	(4,091)
Financing activities:		
Net proceeds from sales of common stock	17,837	26,935
Payment of notes receivable from stockholders	—	80
Proceeds from exercise of options and warrants	—	41
Net cash provided by financing activities	17,837	27,056
Net increase (decrease) in cash and cash equivalents	(4,609)	4,854
Cash and cash equivalents at beginning of period	19,710	36,089
Cash and cash equivalents at end of period	$ 15,101	$ 40,943
Non-cash transactions:		
New facility construction financed through capital lease (classified as long-term debt)	$ —	$ 4,220

See accompanying notes.

BIOPURE CORPORATION

Notes to Condensed Consolidated Financial Statements
April 30, 2003
(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 accounting principles generally accepted in the United States 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 month periods ended April 30, 2003 are not necessarily indicative of the results that may be expected for the year ending October 31, 2003.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended October 31, 2002 filed with the SEC on January 29, 2003.

The Company has financed operations from inception primarily through sales of equity securities, development and license agreement payments, interest income and debt. The Company has not been profitable since inception and had an accumulated deficit of $404,365,000 as of April 30, 2003. Management expects that the Company will continue to generate losses from operations for the next several years. The Company is exploring opportunities to raise capital through sales of securities and joint venture, leasing or licensing arrangements, but the Company cannot assure that sufficient funds will be available to it on terms that the Company deems acceptable, if they are available at all.

At April 30, 2003, the Company had $15,101,000 in cash and cash equivalents. In May and June 2003, the Company raised approximately $10,187,000 in additional funding (See Note 9 Subsequent Events). The Company expects this funding, in addition to the cash and cash equivalents at April 30, 2003, will be sufficient to fund operations until November 2003 under the Company's current operating plan.

2. Net Loss per Share

Basic net loss per common share is computed based on the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed based upon the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of the Company's common stock equivalents, including the shares issuable upon the conversion of Class B Common Stock outstanding and the exercise of common stock options and warrants determined based upon the average market price of common stock for the period. Basic and diluted net loss per common share is computed the same for all periods presented as the Company had losses for all periods presented and, consequently, the effect of Class B Common Stock, options and warrants is anti-dilutive.

Dilutive weighted average shares outstanding do not include 8,651,480 common-equivalent shares for the three and six months ended April 30, 2003 and 4,788,001 common-equivalent shares for the three and six months ended April 30, 2002 as their effect would have been anti-dilutive.

3. Stock Based Compensation

The Company applies Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees,* and related interpretations, in accounting for its stock-based compensation plans. Accordingly, no compensation expense has been recognized for stock-based compensation plans. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123* (SFAS No. 148); therefore, no compensation expense was recognized for the Company's stock option plans. Had compensation expense for the Company's stock option plans been determined based on the fair value at the grant date for awards under these plans, consistent with the methodology prescribed under SFAS No. 148, the Company's net loss and net loss per share would have approximated the pro forma amounts indicated below:

	Three Months Ended		Six Months Ended	
	April 30, 2003	April 30, 2002	April 30, 2003	April 30, 2002
Net loss, as reported	$(11,652)	$(12,727)	$(22,734)	$(22,416)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(1,153)	(882)	(2,175)	(1,696)
Pro forma net loss	$(12,805)	$(13,609)	$(24,909)	$(24,112)
Net loss per share:				
Basic and diluted - as reported	$ (0.35)	$ (0.49)	$ (0.71)	$ (0.87)
Basic and diluted - pro forma	$ (0.38)	$ (0.52)	$ (0.78)	$ (0.94)

The weighted average fair value of each stock option included in the preceding pro forma amounts was estimated using the Black-Scholes option-pricing model and is amortized over the vesting period of the underlying options. The assumptions used to calculate the SFAS No. 148 pro forma disclosure and the weighted average information are as follows:

	Three Months Ended		Six Months Ended	
	April 30, 2003	April 30, 2002	April 30, 2003	April 30, 2002
Risk-free interest rate	4.88%	5.80%	4.88%	5.75%
Expected dividend yield	—	—	—	—
Expected lives	7 years	7 years	7 years	7 years
Expected volatility	80%	77%	80%	61%

4. Inventories

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

In thousands	April 30, 2003	October 31, 2002
Raw materials	$1,480	$2,122
Work-in-process	1,401	676
Finished goods-Oxyglobin	1,476	1,992
Finished goods-Hemopure	3,664	3,238
	$8,021	$8,028

5. Accrued Expenses

Accrued expenses consisted of the following:

In thousands	April 30, 2003	October 31, 2002
Accrued payroll and related employee expenses	$ 502	$ 562
Accrued vacation	709	651
Accrued legal and audit fees	251	301
Accrued health and dental premiums	358	190
Financing fees	358	—
South Carolina Project	—	551
Other	1,628	1,771
	$3,806	$4,026

6. Commitments

Guarantee

In July 1994, the Company acquired a 50% general partnership interest in Eleven Hurley Street Associates (EHSA), a real estate partnership, which owns the Company's principal office and research and development facility. The Company accounts for its investment in EHSA under the equity method of accounting. In the event EHSA became insolvent or was unable to pay its obligations, the Company, as a general partner, would be liable for all partnership obligations. EHSA's liabilities as of April 30, 2003 consist of a promissory note to a bank with a balance of $1,136,000. The note accrues interest at 8.63% and matures on January 30, 2006. As of April 30, 2003, the maximum potential amount of future payments the Company would be required to make under its guarantee would be $1,388,000. The note is secured by the office and research and development facility which the Company believes would satisfy the current promissory note balance. Biopure currently leases this facility from EHSA for $262,000

annually under an operating lease expiring in December 2007 that is included as an operating lease commitment in our Annual Report on Form 10-K for the fiscal year ended October 31, 2002.

Sumter Realty

In December 2001, the Company signed an amended letter of intent with Sumter Realty Group, LLC for the construction and financing of a manufacturing plant in South Carolina, which is designed to produce 500,000 Hemopure units per year and expected to cost approximately $120,000,000. Sumter Realty Group, LLC accepted a letter of commitment from a potential investor for the full $120,000,000 required to finance construction of the new manufacturing facility in South Carolina and in December 2002, Biopure signed a lease agreement, which was amended in March 2003, with Sumter Realty Group, LLC (as amended, the Lease). The terms of the Lease were subject to financial closing and construction by April 1, 2003. The lease expired because the financing was not completed. Sumter Realty Group remains in discussions with investors, but a closing schedule has not been determined. Terms of any new lease are expected to be similar to those of the Lease, as follows: lease payments would start at substantial completion of the facility, expected to be in fiscal 2005. The annual lease payments would be $13,750,000 per year for the first two years and $17,158,000 per year for the balance of the 25-year term. At the conclusion of the 25-year term, the Company would own the facility. In addition, the Company would expect to issue to the potential investor a warrant to purchase up to 2,500,000 shares of Class A Common Stock at $0.01 per share. The Company is committed to pay a finder's fee, of approximately 2 percent of the net amount financed, to CB Richard Ellis, a real estate consulting firm, when financing for the facility is completed.

As of April 30, 2003, $13,287,000 has been included in property, plant and equipment and $9,847,000 in long-term debt reflecting expenses to date for the engineering and design costs of the planned manufacturing facility in Sumter, S.C. Through the second fiscal quarter of 2003, the Company incurred an additional $530,000 of costs for detailed engineering work, including shop drawings for major equipment and steel fabrication, to maintain the timeline for a validated, FDA-approved plant in fiscal 2006. The total $13,440,000 of expenditures by the Company would be returned as described below.

During fiscal 2001 and 2002, Biopure funded $10,000,000 in project costs for the new facility. Biopure expects this amount to be refunded within twelve months of FDA approval for Hemopure and if a final lease agreement has been executed. The $10,000,000 has been accounted for as a deposit in long-term assets as of April 30, 2003. If FDA approval is not received, the $10,000,000 expenditure will not be returned to the Company and will be treated as a capital expenditure, and as a capital expenditure will be subject to immediate impairment review pursuant to SFAS No. 144. Under the terms of the Lease, Sumter Realty Group, LLC would refund the $3,440,000 of additional spending by the Company within six months after financing is completed.

Research Agreement

On March 4, 2003, the Company entered into a Cooperative Research and Development Agreement (CRADA) with the United States Naval Medical Research Center (NMRC). The CRADA will support a pivotal, randomized, standard therapy controlled trial of Hemopure in pre-hospital resuscitation of patients with severe hemorrhagic shock (acute blood loss). Under the terms of the CRADA, the NMRC will contribute $4,000,000 and the Company is committed to contribute $8,753,000 exclusive of internal costs through 2006. These amounts are estimates based upon a preliminary assessment of the current trial protocol. The Company will provide at least $643,000 during the first year of the arrangement. Completion of this pivotal trauma trial is contingent upon further funding.

7. Financing Activities

On March 25, 2003, the Company raised $12,946,000 in net proceeds from the sale of 5,548,480 shares of its Class A Common Stock at a price of $2.42 per share. The Company also issued, to these same investors, warrants to acquire 1,109,696 shares of its Class A Common Stock at an exercise price of $3.63 per share

On April 16, 2003, the Company raised $3,036,000 in net proceeds from the sale of 1,000,000 shares of its Class A Common Stock at a price of $3.13 per share. The Company also issued, to these same investors, warrants to acquire 500,000 shares of its Class A Common Stock at an exercise price of $3.75 per share.

On April 16, 2003 the Company entered into a Standby Equity Distribution Agreement with Bank of New York Capital Markets, Inc. ("CMI") under which the Company may issue and sell up to $10,000,000 of its Class A Common Stock from time to time through CMI.

8. Reclassifications

Certain reclassifications have been made to prior period financial statements presented to conform to the current periods' presentation.

9. Subsequent Events

On May 2, 2003, the Company raised $3,150,000 in net proceeds from the sale of 882,353 shares of its Class A Common Stock at a price of $3.57 per share. The Company also issued, to these same investors, warrants to acquire 176,471 shares of its Class A Common Stock at an exercise price of $3.93 per share.

On May 6, 2003, the Company raised $3,000,000 in net proceeds from the sale of 833,334 shares of its Class A Common Stock at a price of $3.60 per share. The Company also issued, to these same investors, warrants to acquire 166,667 shares of its Class A Common Stock at an exercise price of $3.96 per share.

In May and June 2003, the Company raised $3,887,000, net, from the sale of 707,060 shares of its Class A Common Stock with an average price of $5.50 per share through sales into the market (see Note 7) and $150,000 from the exercise of certain warrants.

10. Recently Issued Accounting Standards

FASB Interpretation No. 45, *"Guarantor Accounting,"* has significantly changed current practice in the accounting for, and disclosure of, guarantees. Most guarantees are to be recognized and initially measured at fair value, which is a change from previous practice. In addition, guarantors are required to make significant new disclosures, even when the likelihood of the guarantor making payments under the guarantee is remote. In general, the Interpretation applies to contracts or indemnification agreements that contingently require the guarantor to make payments to the guaranteed party based on changes in an underlying that is related to an asset, liability, or an equity security of the guaranteed party. The Interpretation's disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002, while the initial recognition and initial measurement provisions are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The Company's adoption of this statement has not had a material impact on its results of operations or financial position.

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, (FIN 46) to clarify the conditions under which assets, liabilities, and activities of another entity should be consolidated into the financial statements of a company. FIN 46 requires the consolidation of a variable-interest entity by a company that bears the majority of the risk of loss from the variable interest entity's activities, is entitled to receive a majority of the variable-interest entity's residual returns or both. The provisions of FIN 46 are required to be adopted by the Company in fiscal 2003. The Company is currently evaluating whether it has any variable-interest entities under FIN 46. However, the Company believes the adoption of FIN 46 will not have a material adverse impact on its overall financial position or results of operations.

On May 15, 2003, the FASB issued Statement of Financial Accounting Standards No. 150 (SFAS 150), "*Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*." SFAS 150 requires certain financial instruments that embody obligations of the issuer and have characteristics of both liabilities and equity to be classified as liabilities. Many of these instruments previously were classified as equity or temporary equity and as such, SFAS 150 represents a significant change in practice in the accounting for a number of financial instruments, including mandatorily redeemable equity instruments and certain equity derivatives that frequently are used in connection with share repurchase programs. SFAS 150 is effective for public companies for all financial instruments created or modified after May 31, 2003, and to other instruments at the beginning of the first interim period beginning after June 15, 2003. The Company is currently evaluating whether it has any financial instruments under SFAS 150. However, the Company believes the adoption of SFAS 150 will not have a material impact on its overall financial position or results of operations.

Cautionary Statement Regarding Forward-Looking Information

The following discussion of our financial condition and results of operations should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included elsewhere in this report. Except for strictly historical information contained herein, matters discussed in this report constitute forward-looking statements. When used herein, the words "expects," "estimates," "intends," "plans," "should," "anticipates" and similar expressions are intended to identify such forward-looking statements. Actual results could differ materially from those set forth in the forward-looking statements. There can be no assurance that Biopure will be able to commercially develop Hemopure, that necessary regulatory approvals will be obtained, that anticipated milestones will be met in the expected timetable, that any clinical trials will be successful, or that any approved product will attain market acceptance and be manufactured and sold in the quantities anticipated. Actual results may differ from those projected in forward-looking statements due to risks and uncertainties that exist in the Company's operations and business environment. These risks include, without limitation, the availability of sufficient financing to support operations, the Company's stage of product development, history of operating losses, accumulated deficit, and uncertainties and possible delays related to clinical trials and regulatory approvals, possible healthcare reform, manufacturing capability, market acceptance and competition. 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. The Company undertakes no obligation to release publicly the results of revisions to these forward-looking statements to reflect events or circumstances after the date hereof. Reference is made in particular to the risk factors and the discussions set forth below in this report under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Overview

Biopure is a leading developer, manufacturer and supplier of pharmaceuticals called oxygen therapeutics. Using our patented and proprietary technology, we have developed and manufacture two products. Hemopure is a first-in-class product for human use that is approved in South Africa for the treatment of acutely anemic surgical patients and to eliminate, delay or reduce red blood cell transfusions in these patients. On July 31, 2002, we submitted a biologic license application (BLA) to the U.S. Food and Drug Administration (FDA) seeking regulatory approval to market Hemopure in the United States for a similar indication in patients undergoing orthopedic surgery. The FDA has accepted this application and has advised us that it will complete its review and act on the application by August 29, 2003. We also continue to develop Hemopure for potential use in trauma and other medical applications. Our veterinary product, Oxyglobin, is the only product of its kind approved in the United States and the European Union, where it is indicated for the treatment of anemia in dogs.

Since inception, we have devoted substantially all of our resources to our research and development programs and manufacturing. We have been dependent upon funding from debt and equity financings, strategic alliances and interest income. We have not been profitable since inception and had an accumulated deficit of $404,365,000 as of April 30, 2003. We expect to incur additional operating losses over the next several years in connection with clinical trials, preparation of a marketing application for Hemopure in Europe and other markets and pre-marketing expenditures for Hemopure. We began generating revenue from the sale of Oxyglobin in fiscal 1998.

We believe our cash and cash equivalents, as of April 30, 2003, in addition to amounts raised from financing transactions in May and June 2003, are sufficient to fund the Company's planned operations until November 2003. For the balance of fiscal 2003, our objectives are to produce Hemopure and Oxyglobin at higher capacity levels in our manufacturing facility in Cambridge, Massachusetts, expand marketing and sales activities for Hemopure, support sales and marketing expenses for Oxyglobin in the United States and Europe and continue clinical development of additional Hemopure indications. Because the Company's funds on hand at January 27, 2003 and forecast sales were not sufficient to fund our plan into fiscal 2004, the audit report of Ernst & Young LLP, the Company's independent auditor, on our fiscal 2002 financial statements includes a going concern modification. In order for us to remain a going concern, we will require significant funding. We are exploring opportunities to raise capital through equity offerings, strategic alliances and other financing vehicles. However, additional financing or strategic alliances may not be available when needed, or, if available, may not be on favorable terms.

Critical Accounting Policies

The Company's significant accounting policies are described in the Notes to the Consolidated Financial Statements, as disclosed in our Form 10-K for the fiscal year ended October 31, 2002. The application of our critical accounting policies is particularly important to the accurate portrayal of the Company's financial position and results of operations. These critical accounting policies require the Company to make subjective judgements in determining estimates about the effect of matters that are inherently uncertain. The following critical accounting policies are considered most significant:

Inventories

Inventories are stated at the lower of cost (determined using the first-in, first-out method) or market. Inventories consist of raw material, work-in-process and Hemopure and Oxyglobin finished goods and are reviewed periodically for slow-moving or obsolete status based on sales activity, both projected and historical. Inventories are also reviewed periodically to determine items that are under quality compliance investigations. Reserves are established for inventory that falls into these categories.

Long-Lived Assets

SFAS 144 requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Our investments in property and equipment, including construction in progress and the new facility construction; real property license rights related to the source, supply and initial processing of our major raw material; and the asset related to the planned South Carolina manufacturing facility costs are the principal long-lived assets that could be subject to such a review. The events or changes in circumstances, among others, that may result in an impairment of these assets are a significant delay in U.S. regulatory approval for our human product, a change in the source of supply of the major raw material, the inability to obtain financing for the South Carolina facility, or lack of adequate demand for our products. In the event of an impairment, the Company would write down the asset to the fair market value, thereby incurring a charge to the statement of operations. Management believes that no such indicators of impairment of its long-lived assets existed at April 30, 2003.

Revenue Recognition

The Company recognizes revenue from sales of Oxyglobin upon shipment provided that there is evidence of an agreement, there are no uncertainties surrounding acceptance, collectibility is probable, the price is fixed and only perfunctory Company obligations, if any, included in the arrangement remain to be completed. The Company sells Oxyglobin to veterinarians in the United States through veterinary product distributors, who purchase product for immediate and direct resale to veterinary practices. The Company sells Oxyglobin to a distributor in the United Kingdom that sells product in selected European countries through local veterinary distributors in Germany, France and the UK. Collectibility is reasonably assured once pricing arrangements are established, as these agreements establish the distributor's intent to pay. The Company's customers do not have a right to return product. The Company and its distributors have an ongoing business relationship, and the Company monitors creditworthiness on a regular basis. The Company believes collectibility of product revenues is reasonably assured at the time of sale.

Research and Development

Since its founding in 1984, Biopure has been primarily a research and development company focused on developing Hemopure, our oxygen therapeutic for human use, and obtaining regulatory approval in the United States. Our research and development expenses have been devoted to basic research, product development, process development, pre-clinical studies, clinical trials and filing a BLA with the FDA. In addition, our development expenses historically have included the design, construction, validation and maintenance of a large-scale pilot manufacturing plant. The existing pilot plant was completed in 1995.

Such a facility is a necessary part of developing a product like Hemopure. Hemopure is classified by the FDA as a biologic, because it is made from animal-source material. Unlike drugs that are chemical compounds, biologics are defined by their manufacturing process as well as composition. Any small change in the manufacturing process could be considered, under FDA regulations, to produce an altered, possibly different product. Therefore, demonstration of manufacturing capability at greater than laboratory scale is necessary for an application for regulatory approval of a biologic to be accepted for review. This requirement results in high manufacturing research and development costs in the development of a biologic relative to other types of drugs.

The only product made in our plant prior to 1998 was product for use in pre-clinical and clinical trials. As an offshoot of the research and development for Hemopure, Oxyglobin, a similar product, gained approval for veterinary use in 1998. This product was then produced for sale in the pilot manufacturing plant built and maintained for the development of Hemopure. Consequently, costs of production of Oxyglobin for sale and an allocation of overhead based on capacity used for Oxyglobin are charged to inventory and to cost of revenues. The remaining costs of the pilot plant continued to be included in research and development expenses through May 2002.

Beginning in May 2002, when we began to make Hemopure for sale under our regulatory approval in South Africa, the primary function of the pilot plant changed from support of the development of Hemopure to production of goods for sale. Since then, all costs of maintaining and operating the pilot plant have been charged to inventory and cost of revenues. Any actual future use of the facility for research and development activities will be expensed; in addition, clinical trial materials taken from inventory for use in research and development are charged to research and development.

Results of Operations

Three months ended April 30, 2003 compared to three months ended April 30, 2002

Total revenues, consisting entirely of Oxyglobin sales, were $1,961,000 for the second quarter of fiscal 2003, compared with $928,000 for the corresponding period in 2002. These sales revenues for Oxyglobin, our veterinary product, increased due to the current quarter's resumption of shipments of Oxyglobin from our expanded manufacturing facilities. The Company shipped over 16,800 units of Oxyglobin consisting of approximately $1,300,000 in backorders and approximately $661,000 in new orders. European sales increased 56% to $97,000 for the second quarter of fiscal 2003 compared to the same period last year.

Cost of revenues was $5,973,000 for the second quarter of fiscal 2003, compared to $958,000 for the corresponding period in 2002. Cost of revenues includes costs of both Oxyglobin and Hemopure, although Hemopure is not currently being sold. Oxyglobin cost of revenues was $2,708,000 for the second quarter of fiscal 2003 compared to $958,000 in 2002. This increase was primarily attributable to the increased Oxyglobin sales. Because of fixed manufacturing costs, the Company expects that costs to produce Oxyglobin will exceed Oxyglobin revenues until the Company more fully utilizes its manufacturing capacity. Cost of revenues for Hemopure was $554,000 lower the second quarter of fiscal 2003 than the comparable $3,819,000, charged to research and development (not cost of revenues) during the same period in 2002. This 15% decrease in cost of revenues for Hemopure is primarily attributable to capitalizing a portion of the unabsorbed fixed manufacturing costs to inventory in 2003, since it is anticipated that the units produced in this period will be sold.

Research and development expenses include product and process development and engineering, pre-clinical studies, clinical trials, clinical trial materials and, through May 2002, an allocation of unabsorbed fixed costs of manufacturing. Our research and development expenses have continued to be primarily for our one major project —Hemopure development for use in patients undergoing surgery.

The completed Phase III orthopedic surgery trial cost approximately $37,000,000 over the four years from protocol development to final report. These trial costs include costs incurred at nearly 50 hospitals, trial site monitoring, data management, regulatory consulting, statistical analysis, medical writing and clinical materials and supplies as well as Company personnel engaged in these activities. Costs incurred in filing the BLA include Company personnel and payments to third parties for manufacturing process documentation, medical consultants, regulatory consultants, integrating the safety and efficacy databases for all clinical trials and pre-clinical studies. Research and development expenses continue to include amounts for support of the BLA review process. These BLA support costs were $2,339,000 for the second fiscal quarter of 2003 and are expected to continue at approximately the same level

until August 29, 2003, when the Company expects the FDA to act on the BLA. If the FDA were to grant a marketing license at that time, this major project could be substantially complete for orthopedic surgery. Further, any FDA action in August could consist of requests for additional information rather than product approval, including a requirement to conduct additional pre-clinical or clinical trials. Moreover, an approval could be conditioned on the Company's agreement to conduct a "Phase IV", or post-marketing trial to collect additional data. Consequently, the amount of further expenditures on this major project after an FDA response cannot be estimated until we receive the response.

If the FDA grants marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004. We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure, the timing of the construction of additional capacity and other factors that may affect our ability to generate a profit from our research and development of Hemopure.

Research and development expenses were $2,536,000 for the second quarter of fiscal 2003, compared to $8,153,000 for the same period in 2002. Of the second quarter fiscal 2003 expenses, $2,339,000 were for BLA support costs and the balance for various expenditures not allocable to any major project. In the corresponding quarter of fiscal 2002, expenditures included $3,148,000 in preparation of filing our BLA, $828,000 for data organization and analyses for the Phase III orthopedic surgery trial of Hemopure and $3,819,000 in unabsorbed fixed manufacturing costs.

Sales and marketing expenses were $1,606,000 for the second quarter of fiscal 2003, compared to $576,000 for the same period in 2002. Hemopure-related sales and marketing expenses were $754,000 for the second quarter of fiscal 2003, compared to $1,739,000 charged to general and administrative expenses for the same period in 2002. This decrease is primarily attributable to expenses related to the shipment of $1,252,000 of product to South Africa in 2002 for use in a pre-launch medical education program, which did not recur in 2003, offset by an increase in education and pre-launch marketing activities in the U.S. in 2003. Oxyglobin-related sales and marketing expenses were $852,000 for the second quarter of fiscal 2003 compared to $576,000 for the same period in 2002. This increase was due to the increased volume of shipments associated with the resumption of shipments of Oxyglobin during the second quarter of 2003, including commissions and increased planning-related activities in Europe.

General and administrative expenses were $3,526,000 for the second quarter of fiscal 2003, compared to $4,129,000 for the same period in 2002. Excluding the $1,739,000 charge described above for Hemopure-related sales and marketing expenses, general and administrative expenses increased $1,136,000 due to higher insurance premiums, financing fees, a non-cash charge associated with the purchase of common stock by directors during the quarter and increased general and administrative payroll-related expenses.

Other income, net, was $28,000 for the second quarter of fiscal 2003, compared to $161,000 for the second quarter of fiscal 2002. This decrease reflects the Company's reduced cash balance and lower interest rates.

Six months ended April 30, 2003 compared to six months ended April 30, 2002

Total revenues increased 20% to $1,982,000 for the first six months of fiscal 2003, compared with the corresponding period in 2002. Domestic sales increased 22% to $1,865,000 for the first six months of fiscal 2003 compared to the same period last year due to the current quarter's resumption of shipments of Oxyglobin from our expanded manufacturing facilities. The Company shipped over 16,000 Oxyglobin units in the United States during the first half of fiscal 2003. Oxyglobin sales in Europe were $117,000 for the first six months of fiscal 2003 and remained relatively unchanged compared to the same period in 2002.

Cost of revenues was $10,821,000 in the first six months of fiscal 2003 compared to $1,820,000 for the corresponding period last year. Cost of revenues includes costs of both Oxyglobin and Hemopure, although Hemopure is not currently being sold. Oxyglobin cost of revenues was $3,441,000 for the second quarter of fiscal 2003 compared to $1,820,000 in 2002. This increase was primarily attributable to the increased Oxyglobin sales. Because of fixed manufacturing costs, the Company expects that costs to produce Oxyglobin will exceed Oxyglobin revenues until the Company more fully utilizes its manufacturing capacity. Cost of revenues for Hemopure was $118,000 lower in the second quarter of fiscal 2003 than the comparable $7,498,000, charged to research and development (not cost of revenues) during the same period in 2002. This decrease in cost of revenues for Hemopure is primarily attributable to capitalizing a portion of the unabsorbed fixed manufacturing costs to inventory in 2003, since it is anticipated that the units produced in this period will be sold.

Research and development expenses include product and process development and engineering, pre-clinical studies, clinical trials, clinical trial materials and, through May 2002, an allocation of unabsorbed fixed costs of manufacturing. Our research and development expenses have continued to be primarily for our one major project —Hemopure development for use in patients undergoing surgery.

The completed Phase III orthopedic surgery trial cost approximately $37,000,000 over the four years from protocol development to final report. These trial costs include costs incurred at nearly 50 hospitals, trial site monitoring, data management, regulatory consulting, statistical analysis, medical writing and clinical materials and supplies as well as Company personnel engaged in these activities. Costs incurred in filing the BLA include Company personnel and payments to third parties for manufacturing process documentation, medical consultants, regulatory consultants, integrating the safety and efficacy data bases for all clinical trials and pre-clinical studies. Research and development expenses continue to include amounts for support of the BLA review process. These BLA support costs were $4,724,000 for the first half of fiscal 2003 and are expected to continue at approximately the same level until August 29, 2003, when the Company expects the FDA to act on the BLA. If the FDA were to grant a marketing license at that time, this major project could be substantially complete for orthopedic surgery. Further, any FDA action in August could consist of requests for additional information rather than product approval, including a requirement to conduct additional pre-clinical or clinical trials. Moreover, an approval could be conditioned on the Company's agreement to conduct a "Phase IV", or post-marketing trial to collect additional data. Consequently, the amount of further expenditures on this major project after an FDA response cannot be estimated until we receive the response.

If the FDA grants marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004. We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure, the

timing of the construction of additional capacity and other factors that may affect our ability to generate a profit from our research and development of Hemopure.

Research and development expenses were $5,082,000 for the first six months of fiscal 2003 compared to $15,125,00 for the same period last year. Of the first half fiscal 2003 expenses, $4,724,000 were for BLA support costs and the balance for various expenditures not allocable to any major project. In the corresponding period of fiscal 2002, expenditures included $5,773,000 in preparation of filing our BLA, $1,379,000 for data organization and analyses for the Phase III orthopedic surgery trial of Hemopure and $7,498,000 in unabsorbed fixed manufacturing costs.

Sales and marketing expenses were $2,622,000 for the first six months of fiscal 2003, compared to $1,004,000 for the same period in 2002. Hemopure-related sales and marketing expenses were $1,413,000 for the first half of fiscal 2003, compared to $2,070,000 charged to general and administrative expenses for the same period in 2002. This decrease is primarily attributable to expenses related to the shipment of $1,252,000 of product to South Africa in 2002 for use in a pre-launch medical education program, which did not recur in 2003, offset by an increase in education and pre-launch marketing activities in the U.S. in 2003. Oxyglobin-related sales and marketing expenses were $1,209,000 for the first six months of fiscal 2003 compared to $1,004,000 for the same period in 2002. This increase was due to the increased volume of shipments associated with the resumption of shipments of Oxyglobin during the second quarter of 2003, including commissions and increased planning-related activities in Europe.

General and administrative expenses were $6,253,000 for the first six months of fiscal 2003, compared to $6,734,000 for the same period in 2002. Excluding the $2,070,000 charge described above for Hemopure-related sales and marketing expenses, general and administrative expenses increased $1,589,000 due to higher insurance premiums, financing fees, a non-cash charge associated with the purchase of common stock by directors during the quarter and increased general and administrative payroll-related expenses.

Other income, net, was $62,000 for the first six months of fiscal 2003, compared to $611,000 for the first six months of fiscal 2002. This decrease reflects the Company's reduced cash balance and lower interest rates. Also included in other income for the first six months of 2002 was $238,000 received as a contingent payment for a 1998 intellectual property transfer not related to Hemopure or Oxyglobin.

Liquidity and Capital Resources

At April 30, 2003, we had $15,101,000 in cash and cash equivalents. We raised $17,837,000 in net proceeds through the sales of equity securities in the first half of fiscal 2003, as discussed below. In May and June 2003, we raised an additional $6,150,000 in net proceeds from sales of registered shares, $3,887,000 in net proceeds from sales of common stock into the market and $150,000 from the exercise of warrants. In order to fund our planned operations through April 30, 2004, the end of the second quarter of our 2004 fiscal year, we estimate that we will need to raise approximately $32,000,000 to attain production of Hemopure and Oxyglobin at higher capacity at our expanded Cambridge manufacturing facility, expand marketing and sales activities for Hemopure, support sales and marketing expenses for Oxyglobin in the United States and Europe and continue clinical development for additional Hemopure indications. We believe our cash and cash equivalents at April 30, 2003 and the amounts raised in May and June 2003 are sufficient to fund operations until November 2003 under the Company's current operating plan. Because the Company's funds on hand at October 31, 2002 and forecast sales were not sufficient to fund our operations into fiscal 2004, the audit report of Ernst & Young LLP, the Company's independent auditor, on our fiscal 2002 financial statements includes a going concern modification. In order for us to remain a going concern we will require significant funding. We are exploring opportunities to raise capital through equity offerings, strategic alliances and other financing vehicles. However, additional financing or strategic alliances may not be available when needed, or, if available, may not be on favorable terms.

On December 31, 2002, we raised $1,855,000 in net proceeds from the sale of our Class A Common Stock in a private placement. On March 25, 2003, the Company raised net proceeds of $12,946,000 from a sale of registered shares and warrants. We realized an additional $3,036,000 in net proceeds from another sale of registered shares and warrants on April 16, 2003.

In December 2001, the Company signed an amended letter of intent with Sumter Realty Group, LLC for the construction and financing of a manufacturing plant in South Carolina, which is designed to produce 500,000 Hemopure units per year and expected to cost approximately $120,000,000. Sumter Realty Group, LLC accepted a letter of commitment from a potential investor for the full $120,000,000 required to finance construction of the new manufacturing facility in South Carolina and in December 2002, Biopure signed a lease agreement, which was amended in March 2003, with Sumter Realty Group, LLC (as amended, the Lease). The terms of the Lease were subject to financial closing and construction by April 1, 2003. The lease expired because the financing was not completed. Sumter Realty Group remains in discussions with investors, but a closing schedule has not been determined. Terms of any new lease are expected to be similar to those of the Lease, as follows: lease payments would start at substantial completion of the facility, expected to be in fiscal 2005. The annual lease payments would be $13,750,000 per year for the first two years and $17,158,000 per year for the balance of the 25-year term. At the conclusion of the 25-year term, the Company would own the facility. In addition, the Company would expect to issue to the potential investor a warrant to purchase up to 2,500,000 shares of Class A Common Stock at $0.01 per share. The Company is committed to pay a finder's fee, of approximately 2 percent of the net amount financed, to CB Richard Ellis, a real estate consulting firm, when financing for the facility is completed.

As of April 30, 2003, $13,287,000 has been included in property, plant and equipment and $9,847,000 in long-term debt reflecting expenses to date for the engineering and design costs of the planned manufacturing facility in Sumter, S.C. Through the second fiscal quarter of 2003, the Company incurred an additional $530,000 of costs for detailed engineering work, including shop drawings for major equipment and steel fabrication, to maintain the timeline for a validated, FDA-approved plant in fiscal 2006. The total $13,440,000 of expenditures by the Company would be returned as described below.

During fiscal 2001 and 2002, Biopure funded $10,000,000 in project costs for the new facility. Biopure expects this amount to be refunded within twelve months of FDA approval for Hemopure and if a final lease agreement has been executed. The $10,000,000 has been accounted for as a deposit in long-term assets as of April 30, 2003. If FDA approval is not received, the $10,000,000 expenditure will not be returned to the Company and will be treated as a capital expenditure, and as a capital expenditure will be subject to immediate impairment review pursuant to SFAS No. 144. Under the terms of the Lease, Sumter Realty Group, LLC would refund the $3,440,000 of additional spending by the Company within six months after financing is completed.

We expect to continue financing our operations, until we are profitable, through sales of securities and joint venture, leasing or licensing arrangements. We will also explore partnering arrangements where appropriate. We have not been profitable since inception and had an accumulated deficit of $404,365,000 as of April 30, 2003. We will continue to generate losses for the next several years.

We plan to spend approximately $4,300,000 for the remainder of fiscal 2003 and fiscal 2004 on capital projects for our existing facilities. The fiscal 2003 planned expenditures of $1,954,000 are included in the cash requirements identified above.

As of October 31, 2002, we had net operating loss carryforwards of approximately $225,600,000 to offset future federal and state taxable income through 2022. 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 April 30, 2003. Utilization of such losses in future years may be limited under the change of stock ownership rules of the Internal Revenue Service.

Recently Issued Accounting Standards

FASB Interpretation No. 45, *"Guarantor Accounting,"* has significantly changed current practice in the accounting for, and disclosure of, guarantees. Most guarantees are to be recognized and initially measured at fair value, which is a change from previous practice. In addition, guarantors are required to make significant new disclosures, even when the likelihood of the guarantor making payments under the guarantee is remote. In general, the Interpretation applies to contracts or indemnification agreements that contingently require the guarantor to make payments to the guaranteed party based on changes in an underlying that is related to an asset, liability, or an equity security of the guaranteed party. The Interpretation's disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002, while the initial recognition and initial measurement provisions are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The Company's adoption of this statement has not had a material impact on its results of operations or financial position.

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, (FIN 46) to clarify the conditions under which assets, liabilities, and activities of another entity should be consolidated into the financial statements of a company. FIN 46 requires the consolidation of a variable-interest entity by a company that bears the majority of the risk of loss from the variable interest entity's activities, is entitled to receive a majority of the variable-interest entity's residual returns or both. The provisions of FIN 46 are required to be adopted by the Company in fiscal 2003. The Company is currently evaluating whether it has any variable-interest entities under FIN 46. However, the Company believes the adoption of FIN 46 will not have a material adverse impact on its overall financial position or results of operations.

On May 15, 2003, the FASB issued Statement of Financial Accounting Standards No. 150 (SFAS 150), "*Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*." SFAS 150 requires certain financial instruments that embody obligations of the issuer and have characteristics of both liabilities and equity to be classified as liabilities. Many of these instruments previously were classified as equity or temporary equity and as such, SFAS 150 represents a significant change in practice in the accounting for a number of financial instruments, including mandatorily redeemable equity instruments and certain equity derivatives that frequently are used in connection with share repurchase programs. SFAS 150 is effective for public companies for all financial instruments created or modified after May 31, 2003, and to other instruments at the beginning of the first interim period beginning after June 15, 2003. The Company is currently evaluating whether it has any financial instruments under SFAS 150. However, the Company believes the adoption of SFAS 150 will not have a material impact on its overall financial position or results of operations.

Quantitative and Qualitative Disclosure About Market Risk

The Company currently does not have any foreign currency exchange risks, with the exception of negligible exchange fluctuations associated with expenses for marketing and regulatory activities outside of the United States. Biopure sells Oxyglobin to its European distributors and plans to sell Hemopure to a South African distributor in U.S. dollars. The customers bear the risk of foreign currency exchange fluctuation. Dramatic fluctuations in exchange rates could result in either increases or decreases in unit sales as the effective unit price to the customer varies. 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.

Controls and Procedures

(a) Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) within 90 days of the filing date of this Quarterly Report on Form 10-Q (the "Evaluation Date"). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded as of the Evaluation Date that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

(b) There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the Evaluation Date, including any corrective actions with regard to significant deficiencies and material weaknesses.

BIOPURE CORPORATION
Part II — Other Information
April 30, 2003

Item 1. Legal Proceedings

None

Item 2. Changes in Securities and Use of Proceeds

On March 27, 2003 and April 16, 2003, the Company issued warrants to purchase 196,454 shares of Class A Common Stock to Shoreline Pacific, LLC. The warrants were issued in settlement of amounts owing under an agreement. The warrants are exercisable for five years at prices of $3.03 and $3.34, respectively, per share. The Company relied on the exemption from registration in Section 4(2) of the Securities Act of 1933.

On April 16, 2003, the Company issued warrants to purchase 50,000 shares of Class A Common Stock to BNY Capital Markets, Inc. The warrants were issued in consideration for the execution and delivery of a Standby Equity Agreement dated April 17, 2003. The warrants are exercisable for five years at a price of $3.45 per share. The Company relied on the exemption from registration in Section 4(2) of the Securities Act of 1933.

Item 3. Defaults Upon Senior Securities

None

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

(a) The Company held its 2003 annual meeting on April 2, 2003.

(b) C. Everett Koop, M.D. and Thomas A. Moore were elected as directors at the meeting. The other directors whose terms of office continued after the meeting are J. Richard Crout, M.D., Daniel P. Harrington, David N. Judelson, Carl W. Rausch and Charles A. Sanders, M.D.

(c) The shares voted were:

	For	Withheld
C. Everett Koop, M.D.	24,394,949	2,426,229
Thomas A. Moore	25,280,654	1,540,524

(d) An amendment to the 2002 Omnibus Securities and Incentive Plan was approved and the shares voted were as follows:

For	Against	Abstain
23,574,904	2,697,262	549,012

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

Item 5. Other Information

Risk Factors

These risks and uncertainties are not the only ones we face. Others that we do not know about now, or that we do not now think are important, may impair our business or the trading price of our securities.

Company Risks

We May Not Be Able To Continue as A Going Concern, as Our Funds Are Sufficient to Fund Operations Only Until November 2003

Ernst & Young LLP, our independent auditors, have included a going concern modification in their audit opinion on our consolidated financial statements for the fiscal year ended October 31, 2002, which states that "the Company's recurring losses from operations and the current lack of sufficient funds to sustain its operations through the second quarter of fiscal 2003 raise substantial doubt about its ability to continue as a going concern."

We expect our cash position to fund operations until November 2003 per our current operating plan. We are exploring opportunities to raise additional capital through equity offerings, strategic alliances and other financing vehicles, but we cannot assure you that sufficient funds will be available to us on terms that we deem acceptable, if they are available at all. The inclusion of a going concern modification in Ernst & Young LLP's audit opinion may materially and adversely affect our ability to raise new capital.

Our financial statements have been prepared on the basis of a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have not made any adjustments to our financial statements as a result of the going concern opinion. If we cannot continue as a going concern, we may have to liquidate our assets and we may receive significantly less than the values at which they are carried on our financial statements. Any shortfall in the proceeds from the liquidation of our assets would directly reduce the amounts that holders of our common stock would receive, if anything, in liquidation.

Failure to Raise Additional Funds in the Future May Affect the Development, Manufacture and Sale of Our Products

We require substantial working capital to develop, manufacture and sell our products and to finance our operations until such time (if ever) as we are able to generate positive operating cash flow. We will need additional funding for, among other things, additional pre-clinical and clinical studies to support expanded indications for Hemopure, the commercial launch of Hemopure (subject to approval by the FDA in the United States or other regulatory authorities elsewhere) and manufacturing capacity. In order to fund our planned operations through April 30, 2004, the end of the second quarter of our 2004 fiscal year, we estimate that we will need to raise approximately $32,000,000.

If additional financing is not available when needed or is not available on acceptable terms, we may be unable to develop products, build manufacturing capacity or fulfill other important goals. A sustained period in which financing is not available could force us to go out of business.

We have an arrangement whereby we can sell our common stock at the market through an agency agreement permitting us to sell up to $10,000,000 in common stock. A balance of more than $6,000,000 remains under this agreement.

If We Fail to Obtain FDA Approval We Cannot Market Hemopure in the United States

We will not be able to market Hemopure in the United States unless and until we receive FDA approval. We have filed an application for approval with the FDA, and the application was accepted for review on October 1, 2002. The FDA has advised that it will have completed its review and take action on the application by August 29, 2003. We believe that our completed pivotal Phase III clinical trials are consistent with the FDA's most recent guidance on the design and efficacy and safety endpoints required for approval of products such as Hemopure for use in surgical indications. However, the FDA could change its view, require a change in study design or require additional data or even further clinical trials, including trials for indications other than those for which the pending application seeks approval, prior to approval of Hemopure. The FDA could refuse to grant a marketing authorization. Trials are expensive and time-consuming. Obtaining FDA approval generally takes years and consumes substantial capital resources with no assurance of ultimate success.

If We Fail to Obtain Regulatory Approvals in Foreign Jurisdictions We Will Not Be Able to Market Hemopure Abroad

We also intend to market our products in international markets, including Europe. We must obtain separate regulatory approvals in order to market our products in Europe and many other foreign jurisdictions. The regulatory approval processes differ among these jurisdictions. Approval in any one jurisdiction does not ensure approval in a different jurisdiction. As a result, obtaining foreign approvals will require additional expenditures and significant amounts of time.

We Cannot Expand Indications for Our Products Unless We Receive FDA Approval for Each Proposed Indication

The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its perioperative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's indications. To do so, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully. We cannot guarantee that the FDA will approve Hemopure for any indication. We can only promote Hemopure in the United States for indications that have been approved by the FDA. The FDA may require a label cautioning against Hemopure's use for indications for which it has not been approved.

The FDA has approved the use of our veterinary product, Oxyglobin, for the treatment of anemia in dogs, regardless of the cause of the anemia. Supplemental approvals are required to market Oxyglobin for any new indications or additional species. We cannot guarantee that we will receive such approvals.

If We Cannot Find Appropriate Marketing Partners, We May Not Be Able to Market and Distribute Hemopure Effectively

Our success depends, in part, on our ability to market and distribute Hemopure effectively. We have no experience in the sale or marketing of medical products for humans. In the event that we obtain FDA approval of Hemopure, we may require the assistance of one or more experienced pharmaceutical companies to market and distribute Hemopure effectively.

If we seek an alliance with an experienced pharmaceutical company:

- we may be unable to find a collaborative partner, enter into an alliance on favorable terms, or enter into an alliance that will be successful;
- any partner to an alliance might, at its discretion, limit the amount and timing of resources it devotes to marketing Hemopure; and
- any marketing partner or licensee might terminate its agreement with us and abandon our products at any time without significant payments, whether or not permitted by the applicable agreement.

If we do not enter into alliances to market and distribute our products, we may not be successful in entering into alternative arrangements, whether engaging independent distributors, or recruiting, training and retaining a marketing staff and sales force of our own.

If We Cannot Generate Adequate, Profitable Sales of Hemopure, We Will Not Be Successful

To succeed as a company, we must develop Hemopure commercially and sell adequate quantities of Hemopure at a high enough price to generate a profit. We may not accomplish either of these objectives. To date, we have focused our efforts on developing our products and establishing their safety and efficacy. Uncertainty exists regarding the potential size of the market for Hemopure and the price that we can charge for it. Additionally, the size of the market will be greatly reduced if reimbursement for the cost of Hemopure is not available.

If We Cannot Obtain Market Acceptance of Hemopure, We Will Not Be Able to Generate Adequate, Profitable Sales

Even if we succeed in obtaining marketing approval for Hemopure, a number of factors may affect future sales of our product. These factors include:

- whether and how quickly physicians accept Hemopure as a cost-effective and therapeutic alternative to other products, in particular, donated human blood. It may take longer than we anticipate to obtain market acceptance; and

- whether medical care providers or the public accept the use of a bovine-derived protein in transfusions, particularly in light of public perceptions in Europe and elsewhere about the risk of "mad cow disease", notwithstanding the certification of the product's safety with regard to agents causing this category of disease by the European Directorate for the Quality of Medicines.

If We Fail to Comply with Good Manufacturing Practices, We May Not Be Able to Sell Our Products

To obtain FDA approval to sell our products, we must demonstrate to the FDA that we can manufacture our products in compliance with the FDA's good manufacturing practices, commonly known as GMPs. GMPs are stringent requirements that apply to all aspects of the manufacturing process. We are subject to periodic FDA inspections to determine whether we are in compliance with the GMP requirements. If we fail to manufacture in compliance with GMPs, the FDA may refuse to approve our products or take other enforcement action with respect to products that we are distributing commercially.

Because the Manufacturing Process for Our Products is Complicated and Time-Consuming, We May Experience Problems That Would Limit Our Ability to Manufacture and Sell Our Products

As with any manufactured product, problems can occur during our production processes. These problems can result in increased production scrap, which can reduce operating margins. These problems could also require us to delay shipments, recall previously shipped product or be unable to supply product for a period of time, all of which could negatively impact our results of operations. Contamination or defects could result in a material recall in the future, which could adversely affect our results of operations.

We Manufacture Our Products at a Single Location and, if We Were Unable to Utilize This Facility, We Would Not Be Able to Manufacture and Sell These Products for An Extended Period of Time

We manufacture our products at a single location located in Massachusetts with ancillary facilities in Pennsylvania and New Hampshire. Damage to any of these manufacturing facilities due to fire, contamination, natural disaster, power loss, riots, unauthorized entry or other events could cause us to cease the manufacturing of our products. If our Massachusetts manufacturing facility were destroyed, it could take approximately two years or more to rebuild and qualify it. Our proposed new manufacturing facility is expected to take 30 months or more to build. In the reconstruction period, we would not be able to sell our products, exclusive of finished goods in inventory.

We Are Dependent on Third Parties to Finance Expansion of Our Manufacturing Capacity, and Failure to Increase Manufacturing Capacity May Impair Hemopure's Market Acceptance and Prevent Us From Achieving Profitability

We will need to construct additional manufacturing facilities to meet annual demand in excess of our current capacity. If Hemopure receives market acceptance, we may experience difficulty manufacturing enough of the product to meet demand. If we cannot manufacture sufficient quantities of Hemopure, we may not be able to operate profitably. In addition, if we cannot fill orders for Hemopure, customers might turn to alternative products and may choose not to use Hemopure, even after we have addressed our capacity shortage.

We will face risks, including the risk of scale-up of our processes, in any new construction, and in turn could encounter delays, higher than usual rejects, additional reviews and tests of units produced and other costs attendant to an inability to manufacture saleable product.

The construction of our proposed new manufacturing facility in Sumter, South Carolina is dependent upon financing from third parties. Groundbreaking for this facility has been delayed and could be delayed further as a result of delays in obtaining such financing. We cannot assure you that sufficient financing for this facility will be available, or if available, will be on terms that are acceptable to us. The completion of this facility or the addition of comparable manufacturing capacity is a key milestone in our plan for future operations. The later the date of completion of additional manufacturing capacity, the more financing we will need for working capital.

Our Lack of Operating History Makes Evaluating Our Business Difficult

Licensing fees, proceeds from the sales of equity securities and payments to fund our research and development activities comprise almost all of our funding to date. We have no operating history of selling our products in large quantities upon which to base an evaluation of our business and our prospects. Consequently, we have no experience on which to predict future commercial success.

We Have a History of Losses and Expect Future Losses

We have had annual losses from operations since our inception in 1984. In the fiscal years ended October 31, 2000, 2001 and 2002, we had losses from operations of $40,434,000, $52,957,000 and $46,657,000, respectively, and we had an accumulated deficit of $381,631,000 as of October 31, 2002. We expect to continue to incur losses from operations until we are able to develop Hemopure commercially and generate a profit. We cannot assure you that we will ever be able to achieve profitable operations.

If We Are Not Able to Protect Our Intellectual Property, Competition Could Force Us to Lower Our Prices, Which Might Reduce Profitability

We believe that our patents, trademarks and other intellectual property rights, including our proprietary know-how, will be important to our success. Our business position will depend, in part, upon our ability to defend our existing patents and engage in our business free of claims of infringement by third parties. We will need to obtain additional patents for our products, the processes utilized to make our products and our product uses. We cannot guarantee that additional products or processes will achieve patent protection. In addition, third parties may successfully challenge our patents.

We have not filed patent applications in every country. In certain countries, obtaining patents for our products, processes and uses may be difficult or impossible. Patents issued in regions other than the United States and Europe may be harder to enforce than, and may not provide the same protection as, patents obtained in the United States and Europe.

Failure to Avoid Infringement of Others' Intellectual Property Rights Could Impair Our Ability to Manufacture and Market Our Products

We cannot guarantee that our products and manufacturing process will be free of claims by third parties alleging that we have

infringed their patents. Any such claim could be expensive and time-consuming to defend, and an adverse litigation result or a settlement of litigation could require us either to obtain a license from the complaining party or to change our manufacturing process. Either result could be expensive or result in a protracted plant shutdown, in turn adversely affecting our ability to make a profit.

A third party could also allege that our products are used in a manner that violates a use patent. Such a claim, if valid, would also be expensive to defend, and either an adverse litigation result or a settlement could limit or preclude us from marketing our product for the patented use and, in turn, adversely affect our sales revenues.

Our Profitability Will Be Affected If We Incur Product Liability Claims in Excess of Our Insurance Coverage

The testing and marketing of medical products, even after FDA approval, have an inherent risk of product liability. We maintain limited product liability insurance coverage in the total amount of $20,000,000. However, our profitability will be adversely affected by a successful product liability claim in excess of our insurance coverage. We cannot guarantee that product liability insurance will be available in the future or be available on reasonable terms.

Replacing Our Sole Source Suppliers for Key Materials Could Result in Unexpected Delays and Expenses

We obtain some key materials, including membranes and chemicals, and services from sole source suppliers. All of these materials are commercially available elsewhere. If such materials or services were no longer available at a reasonable cost from our existing suppliers, we would need to purchase substitute materials from new suppliers. If we need to locate a new supplier, the substitute or replacement materials or facilities will most likely be tested for equivalency. Such equivalency tests could significantly delay development of a product, delay or limit commercial sales of an FDA-approved product and cause us to incur additional expense.

Provisions of Our Restated Certificate of Incorporation and By-Laws Could Impair or Delay Shareholders' Ability to Replace or Remove Our Management and Could Discourage Takeover Transactions that a Stockholder Might Consider to Be in Its Best Interest

Provisions of our Restated Certificate of Incorporation and by-laws, as well as our stockholders rights plan, could impede attempts by shareholders to remove or replace our management or could discourage others from initiating a potential merger, takeover or other change of control transaction, including a potential transaction at a premium over market price that a stockholder might consider to be in its best interest. In particular:

- Our restated Certificate of Incorporation does not permit stockholders to take action by written consent and provides for a classified Board of Directors, and our by-laws provide that stockholders who wish to bring business before an annual meeting of shareholders or to nominate candidates for election of directors at an annual meeting of stockholders must deliver advance notice of their proposals to us before the meeting. These provisions could make it more difficult for a party to replace our board of directors by requiring two annual stockholder meetings to replace a majority of the directors, making it impossible to remove or elect directors by written consent in lieu of a meeting and making it more difficult to introduce business at meetings.

- Our shareholder rights plan may have the effect of discouraging any person or group that wishes to acquire more than 20% of our class A common stock from doing so without obtaining our agreement to redeem the rights; if our agreement to redeem the rights is not obtained, the acquiring person or group would suffer substantial dilution.

- Our restated Certificate of Incorporation provides that until July 31, 2003, two-thirds of our voting power, rather than a majority, is necessary to approve any merger, consolidation or sale of all or substantially all of our assets.

Industry Risks

Intense Competition Could Harm Our Financial Performance

The biotechnology and pharmaceutical industries are highly competitive. There are a number of companies, universities and research organizations actively engaged in research and development of products that may be similar to or alternatives to Hemopure.

We are aware of three competitors that make periodic disclosures to the public. Northfield Laboratories Inc. and Hemosol Inc. are in advanced stages of developing hemoglobin-based oxygen carriers produced from expired human blood. Baxter International Inc. has announced that it is developing a recombinant hemoglobin-based oxygen carrier. Northfield's product is in advanced clinical trials. The products being developed by all three of these companies are intended for use in humans and as such could compete, if approved by regulatory authorities, with Hemopure.

Increased competition could diminish our ability to become profitable or affect our profitability in the future. Our existing and potential competitors:

- are conducting clinical trials of their products;

- may have substantially greater resources than we do and may be better equipped to develop, manufacture and market their products;

- may have their products approved for marketing prior to Hemopure; and

- may develop superior technologies or products rendering our technology and products non-competitive or obsolete.

Stringent, Ongoing Government Regulation and Inspection of Our Products Could Lead to Delays in the Manufacture, Marketing and Sale of Our Products

The FDA continues to review products even after they receive FDA approval. If and when the FDA approves Hemopure, its manufacture and marketing will be subject to ongoing regulation, including compliance with current good manufacturing practices, adverse event reporting requirements and the FDA's general prohibitions against promoting products for unapproved or "off-label" uses. We are also subject to inspection and market surveillance by the FDA for compliance with these and other requirements. Any enforcement action resulting from failure, even by inadvertence, to comply with these requirements could affect the manufacture and marketing of Hemopure. In addition, the FDA could withdraw a previously approved product from the market upon receipt of newly

discovered information. Furthermore, the FDA could require us to conduct additional, and potentially expensive, studies in areas outside our approved indications.

We will be subject to a variety of regulations governing clinical trials and sales of our products outside the United States. Whether or not FDA approval has been obtained, we must secure approval of a product by the comparable non-U.S. regulatory authorities prior to the commencement of marketing of the product in a country. The approval process varies from country to country and the time needed to secure additional approvals may be longer than that required for FDA approval. These applications may require the completion of additional preclinical and clinical studies and disclosure of information relating to manufacturing and controls. Unanticipated changes in existing regulations or the adoption of new regulations could affect the manufacture and marketing of our products.

Health Care Reform and Controls on Health Care Spending May Limit the Price We Can Charge for Hemopure and the Amount We Can Sell

The federal government and private insurers have considered ways to change, and have changed, the manner in which health care services are provided in the United States. Potential approaches and changes in recent years include controls on health care spending and the creation of large purchasing groups. In the future, it is possible that the government may institute price controls and limits on Medicare and Medicaid spending. These controls and limits might affect the payments we collect from sales of our products. Assuming we succeed in bringing Hemopure to market, uncertainties regarding future health care reform and private market practices could affect our ability to sell Hemopure in large quantities at profitable pricing.

Uncertainty of Third-Party Reimbursement Could Affect Our Profitability

Sales of medical products largely depend on the reimbursement of patients' medical expenses by governmental health care programs and private health insurers. There is no guarantee that governmental health care programs or private health insurers will reimburse our sales of Hemopure, or permit us to sell our product at high enough prices to generate a profit.

Investment Risks

Potential for Dilution and Decline of the Price of Our Shares

Our cash on hand is estimated to be sufficient to continue operations until November 2003 under our current operating plan. We will need additional funds to operate beyond this point and are exploring opportunities to raise capital through equity offerings, licensing arrangements and strategic alliances and other financing vehicles that could include an equity component.

Any additional sale of shares may have a dilutive effect on our existing stockholders. Subsequent sales of these shares in the open market could also have the effect of lowering our stock price, thereby increasing the number of shares we may need to issue in the future to raise the same dollar amount and consequently further diluting our outstanding shares. These future sales could also have an adverse effect on the market price of our shares and could result in additional dilution to the holders of our shares.

The perceived risk associated with the possible sale of a large number of shares could cause some of our stockholders to sell their stock, thus causing the price of our stock to decline. In addition, actual or anticipated downward pressure on our stock price due to actual or anticipated sales of stock could cause some institutions or individuals to engage in short sales of our common stock, which may itself cause the price of our stock to decline.

If our stock price declines, we may be unable to raise additional capital. A sustained inability to raise capital could force us to go out of business. Significant declines in the price of our common stock could also impede our ability to attract and retain qualified employees, reduce the liquidity of our common stock and result in the delisting of our common stock from The Nasdaq Stock Market.

Shares Eligible for Future Sale May Cause the Market Price for Our Common Stock to Drop Significantly, Even if Our Business is Doing Well

We cannot predict the effect, if any, that future sales of our common stock or the availability of shares for future sale will have on the market price of our common stock from time to time. Substantially all of our outstanding shares of class A common stock are either freely tradable in the public market, unless acquired by our affiliates, or are "restricted securities" as that term is defined in Rule 144 under the Securities Act of 1933 and eligible for immediate sale in the public market pursuant to Rule 144, subject to certain volume and manner of sale limitations. Other shares of our common stock issued in the future, including shares issued upon exercise of outstanding options and warrants, may become available for resale in the public market from time to time, and the market price of shares of our common stock could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them.

Our Stock Price Has Been and May Continue to Be Highly Volatile, Which May Adversely Affect Holders of Our Stock and Our Ability to Raise Capital

The trading price of our common stock has been and is likely to continue to be extremely volatile. During the period from November 1, 2000 through April 30, 2003, our stock price has ranged from a low of $2.18 per share (on January 29, 2003) to a high of $32.70 per share (on May 9, 2001). Further information regarding the trading price of our common stock is included on page 17 of our Annual Report on Form 10-K for the fiscal year ended October 31, 2002. Our stock price and trading volume could be subject to wide fluctuations in response to a variety of factors, including the following:

- actual or potential clinical trial results relating to products under development by us or our competitors;
- delays in our testing and development schedules;
- events or announcements relating to our relationships with others, including the status of potential transactions with investors, licensees and other parties;
- announcements of technological innovations or new products by our competitors;

- developments or disputes concerning patents or proprietary rights;
- regulatory developments in the United States and foreign countries;
- FDA approval of Hemopure or competitors' products;
- economic and other factors, as well as period-to-period fluctuations in our financial results;
- market conditions for pharmaceutical and biotechnology stocks; and
- publicity regarding actual or potential medical results relating to products under development by us or our competitors.

External factors may also adversely affect the market price for our common stock. Our common stock currently trades on The Nasdaq Stock Market. The price and liquidity of our common stock may be significantly affected by the overall trading activity and market factors on The Nasdaq Stock Market.

Item 6. Exhibits and Reports on Form 8-K

(a) The exhibits are listed in the accompanying Exhibit Index.

(b) A report on Form 8-K was filed on March 13, 2003, reporting required Regulation FD disclosure that a financing lease relating to a proposed manufacturing facility had been signed.

A report on Form 8-K was filed on March 25, 2003, relating to an offering of up to 5,548,480 shares of Class A Common Stock and warrants to purchase up to 1,109,696 shares for gross proceeds, before expenses, of up to $13,427,321.

A report on Form 8-K was filed on April 17, 2003, reporting on the sale of 1,000,000 shares of Class A Common Stock and warrants to purchase 500,000 shares for gross proceeds, before expenses, of $3,130,000.

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.

BIOPURE CORPORATION

Date: June 16, 2003

By: /s/ Ronald F. Richards

Ronald F. Richards
Duly authorized officer of the Registrant and
Chief Financial Officer

I, Thomas A. Moore, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Biopure Corporation;

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 or not 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: June 16, 2003

/s/ Thomas A. Moore

Thomas A. Moore
Chief Executive Officer

CERTIFICATIONS

I, Ronald F. Richards, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Biopure Corporation;

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 or not 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: June 16, 2003

/s/ Ronald F. Richards

Ronald F. Richards
Chief Financial Officer

EXHIBIT INDEX

Number	Description
4.1	Warrant
4.2	Warrant
10.1	Amended and Restated 2002 Omnibus Securities and Incentive Plan
99.1	Certification of Thomas A. Moore pursuant to 18 U.S.C. Section 1350
99.2	Certification of Ronald F. Richards pursuant to 18 U.S.C. Section 1350