TRANSFORMING *medicine* BY DELIVERING

lifesaving oxygen

BIOPURE CORPORATION

ANNUAL REPORT 2002

COMPANY PROFILE

BIOPURE CORPORATION'S mission is to introduce revolutionary new drugs that deliver lifesaving oxygen. The company has pioneered the development and manufacture of oxygen therapeutics, a new class of intravenously administered pharmaceuticals that deliver oxygen to the body's tissues. Biopure's products represent a new Oxygen Bridge™ treatment approach for managing patients' oxygen requirements in a broad range of potential medical applications, including as a treatment for acute anemia in surgery and trauma patients, as an adjunct to cancer therapy and as a means of preventing tissue damage and organ dysfunction in ischemic conditions such as heart attack and stroke. Hemopure® [hemoglobin glutamer – 250 (bovine)], Biopure's first-in-class product for human use, is approved in South Africa to treat acutely anemic surgery patients, and to eliminate, reduce or delay the need for allogeneic red blood cells in these patients. In October 2002, the U.S. Food and Drug Administration (FDA) accepted for review Biopure's application to market Hemopure in the United States for a similar indication in orthopedic surgery patients. Oxyglobin® [hemoglobin glutamer – 200 (bovine)], the company's veterinary product for the treatment of anemia in dogs, is the only oxygen therapeutic approved by the FDA and the European Commission.

INVESTMENT HIGHLIGHTS

- World's first approved hemoglobin-based oxygen therapeutics for use in human and veterinary medicine
- U.S. marketing application for Hemopure accepted and undergoing FDA review
- Only company with two completed Phase III clinical trials of an oxygen therapeutic
- Largest validated manufacturing capacity for hemoglobin-derived oxygen therapeutics
- 100 percent ownership of rights to patented products and manufacturing technology
- Multi-billion dollar global market opportunity

APPROVED PRODUCTS	2
HEMOPURE CLINICAL TRIALS	>20
HEMOPURE PATIENTS	>800
HEMOPURE COMPASSIONATE USE CASES	>40
PRECLINICAL STUDIES	>180
OXYGLOBIN UNITS SOLD	>115K
U.S. PATENTS	>20

MILESTONES

1984
Company founded and began business at Tufts New England Enzyme Center in Boston, Mass. 1984 to 1989: $14.4M raised (net)

1986
Oxyglobin: investigational new animal drug (INAD) application filed with U.S. Food and Drug Administration (FDA)

1987
Manufacturing support facility established in Dover, N.H.

1988
Hemopure: Original investigational new drug (IND) application filed with U.S. FDA

1990
1990-1991: Pilot manufacturing facility constructed in Cambridge, Mass.

1990-1999: $242 million raised (net) prior to Biopure's initial public offering

1991
Boston manufacturing operations transferred to Cambridge, Mass. facility

Hemopure: First Phase I clinical trial initiated (frozen formulation)

1992
Two U.S. patents issued

1993
Hemopure: 1993-1994: Four Phase I clinical trials of Hemopure (room temperature formulation)

Oxyglobin: Pivotal clinical trial

1994
1994-1996: Front-end manufacturing facility constructed in Souderton, Pa.

Two U.S. patents issued

Hemopure: 1994-1998: 12 Phase I/II and 2 Phase II clinical trials (11 surgical, 3 non-surgical) conducted in the United States and Europe

1995
Corporate offices relocated to Cambridge, Mass.

Oxyglobin: 1995-1996: Phased submission of new animal drug application (NADA) filed with U.S. FDA

1998
Five U.S. patents issued

Hemopure: Phase II double-blind cardiac surgery trial presented at American Heart Association annual meeting

Oxyglobin: U.S. FDA approval of Oxyglobin for the treatment of anemia in dogs; Veterinary marketing application filed with the European Medicines Evaluation Agency (EMEA)

2000
Follow-On Public Offering (Net $83.7 million)

One U.S. patent issued

Hemopure: Phase II vascular surgery trial published in *Journal of Vascular Surgery*

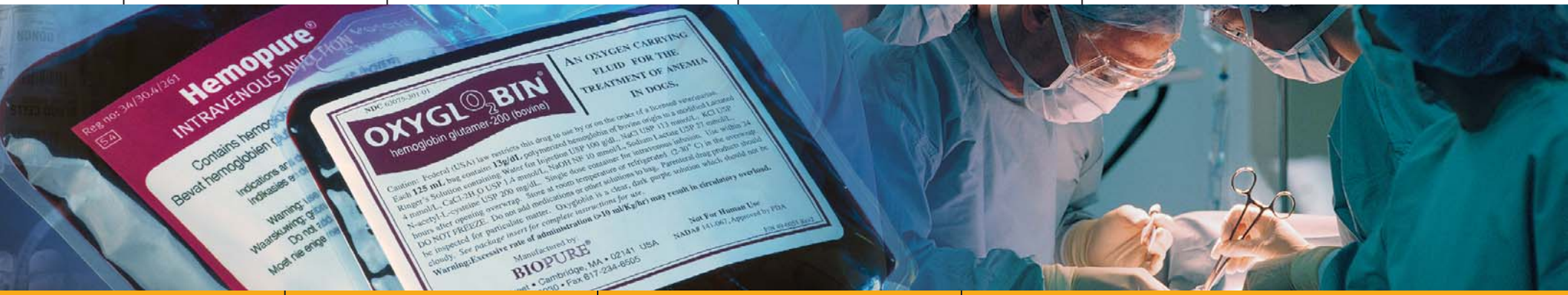
Oxyglobin: Flexible dose range approved by U.S. FDA; U.S. expiration date extended to three years

2002
$35.5 million raised (net)

Hemopure: Biologic license application (BLA) filed with and accepted for review by U.S. FDA; U.S. Army trauma research grant awarded

Manufacturing facilities in Mass. and Pa. expanded

Biopure South Africa Ltd. established



1997
Four U.S. patents issued

Hemopure: 1997-1999: Phase III general non-cardiac surgery trial in South Africa and Europe

Oxyglobin: U.S. FDA inspection of manufacturing facilities

1999
Initial Public Offering (Net $37.7 million)

Four U.S. patents issued

Hemopure: marketing application filed with South Africa's Medicines Control Council (MCC); U.S. Phase III orthopedic surgery trial initiated

Oxyglobin: European Commission (EC) approval of Oxyglobin for the treatment of anemia in dogs

2001
Engineering begun for new manufacturing facility in Sumter, S.C.

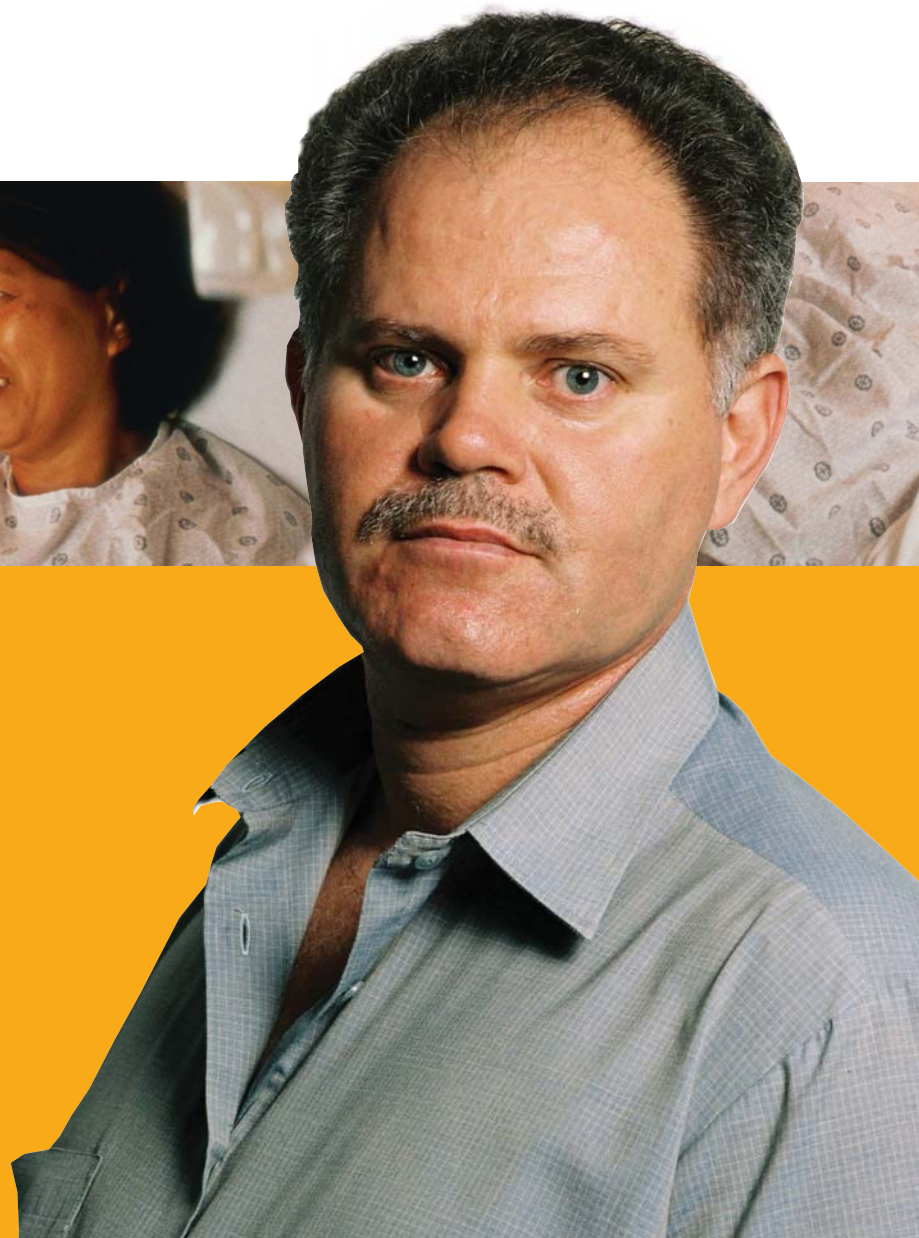
Two U.S. patents issued

Hemopure: Approved by South Africa's MCC for the treatment of acute anemia in adult surgery patients; Primary study endpoints met in U.S. Phase III orthopedic surgery trial

Oxyglobin: European launch of Oxyglobin; Flexible dose range approved by EC; European expiration date extended to three years

THE OXYGEN BRIDGE™

The purpose of intravenous oxygen-carrying support is to help stabilize the patient and prevent tissue damage or organ dysfunction associated with oxygen deprivation. When Hemopure or Oxyglobin is infused into the bloodstream, its chemically stabilized hemoglobin molecules carry oxygen in the plasma (the fluid part of blood) and facilitate the release of oxygen from red blood cells, increasing diffusion of oxygen to tissues. If necessary, this effect can be extended over time by repeat dosing to provide a continuous Oxygen Bridge until anemic patients can recover. Since treatment protocols for managing patients' oxygen requirements are historically based on the use of blood, our challenge at Biopure is to educate medical providers on the unique physiology of Hemopure and how to use the Oxygen Bridge approach to achieve better treatment regimens and patient outcomes.



"We've found Hemopure to be very effective and safe to use in two Phase III surgery trials and in post-approval use in South Africa. We continue to utilize it for postoperative anemia, and envision utilizing it in the future in other conditions where tissue hypoxia plays a major pathophysiological role."

R. Van Rooyen, M.D.
Pretoria Heart Hospital, South Africa

CHANGING GEARS FOR THE FUTURE

DEAR FELLOW SHAREHOLDERS: Shortly after I began as Biopure's CEO in mid 2002, we realized the tremendous achievement of filing our electronic biologic license application (BLA) for Hemopure® with the U.S. Food and Drug Administration. It was incredibly exciting to see more than 500,000 pages of clinical and preclinical data, chemistry, manufacturing and controls data, and supporting materials make its way down to Washington, D.C. on July 31st. By my "mid-term", the FDA had accepted the application for review—an unprecedented event for a hemoglobin-based oxygen therapeutic. We anticipate that the agency will complete its review of our BLA by mid 2003.

The FDA's acceptance of our U.S. marketing application marked our fourth significant regulatory achievement—the previous three being the approvals of Oxyglobin® in the United States and the European Union for veterinary use and the approval of Hemopure in South Africa for human use. Competitive products have not achieved any regulatory approvals. Biopure's unique accomplishment, in what has historically been one of the most difficult areas of science and medicine, reflects the tremendous efforts of the company's co-founder Carl Rausch and its talented and truly dedicated employees. It is an honor to work with them.

Thomas A. Moore
President and Chief Executive Officer

As the agency's evaluation of our BLA progresses, we at Biopure are "changing gears". We have now turned to the challenge of our future and the commercialization of this revolutionary, first-in-class product.

Our preparations for the future traverse every part of the organization. In manufacturing, we expanded our annual production capacity up to 75,000 Hemopure units, and installed the equipment necessary to reach a 100,000-unit capacity. While the plant shutdown associated with this expansion resulted in a temporary reduction in Oxyglobin-related revenues in the short term, it was essential to making Biopure a viable commercial company over the long term.

We now have the largest validated manufacturing capacity in the world for a hemoglobin-based oxygen therapeutic.

Making our product in large quantities at the lowest possible cost is paramount to our future success. To improve our efficiency and prepare for the construction of a 500,000-unit plant in Sumter, S.C., we've restructured managerial responsibilities and created a new department that groups our engineering, process development and quality control disciplines. These changes will serve us well as we evolve from research and development to a fully commercialized, pharmaceutical manufacturing company. We've signed the Sumter lease agreement and anticipate the financial closing will be completed by Spring 2003.

BUSINESS STRATEGY

- Successfully launch Hemopure under an orthopedic surgery indication in the United States
- Clinically develop Hemopure for trauma, ischemia, and adjunctive cancer therapy indications
- Increase production capacity and lower production costs to reach profitability no later than fiscal 2006
- Strengthen cash position through strategic alliances and/or sales of equity and debt securities

CHANGING GEARS FOR THE FUTURE

We're also working to expand Hemopure's clinical use beyond the treatment of acutely anemic surgical patients. Our first clinical priority is to demonstrate the product's utility in stabilizing trauma patients in the emergency room and the pre-hospital, or ambulance, setting. Our extensive preclinical work in animals and a limited sample of trauma-related surgeries in our Phase III clinical trial database strongly support the pursuit of this indication.

In September 2002 the U.S. Department of the Army awarded Biopure a research grant to fund a Phase II trauma trial of Hemopure, and we expect to receive further Army funding for trauma research in 2003.* We have been working with the Army, Navy and Air Force to field a clinical program that, with additional support from the Department of Defense, will meet both civilian and military needs. We expect to begin trauma trials this year in the United States and South Africa.

Finally, we're completing the U.S. marketing plan for the introduction of Hemopure under our proposed orthopedic surgery indication. This initial U.S. market is more than adequate to absorb our projected production capacity over the next three years, but it will not develop overnight. Hemopure represents a new treatment approach, and the introduction of any change in surgical procedures requires a carefully executed marketing and education program.

Grant DAMD17-02-1-0697. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office.

CHANGING GEARS FOR THE FUTURE

The basic need for Hemopure is clear. Many patients refuse blood transfusions on religious grounds, are alloimmunized, or simply prefer to avoid allogeneic blood transfusions. Media coverage of emerging infectious agents and blood handling errors will only increase this population. Meanwhile, blood-intensive medical procedures are likely to increase sharply as the baby boomer generation ages.

In addition, according to the National Blood Data Resource Center the percentage of hospitals canceling elective surgeries due to blood shortages increased from 7.4 percent in 1999 to 12.7 percent in 2001.

Our plan is to introduce Hemopure into a market already receptive to blood avoidance techniques: orthopedic surgeries are among the most sensitive to blood shortage issues, and orthopedics is a leading specialty in the practice of allogeneic blood avoidance techniques such as autologous donation, cell salvage, and the use of erythropoietin.

Enabling confident usage of Hemopure in the orthopedic field could also lead to broader acceptance in other potential applications: our next targeted indication is trauma, and an estimated 35 percent of orthopedic surgeons specialize in trauma surgery.

SOUTH AFRICA EXPERIENCE In South Africa, where Hemopure is approved for use in acutely anemic surgical patients, we have established a wholly-owned subsidiary under the name Biopure South Africa Ltd. Commercial sales have been delayed as we are learning how to best introduce the product to medical providers and payors. As part of this process, we've transitioned our medical education program from group seminars to a hospital-by-hospital approach where a product specialist team conducts in-house training.

The information we're obtaining about how doctors perceive and use Hemopure is extremely valuable in refining the marketing model for the United States and Europe. In addition, clinical use of the product in South Africa in surgical patients suggests that, with additional research, we may be able to define and document advantages in healing and recovery—key therapeutic benefits regardless of the availability or lack of availability of allogeneic blood.

The practical experience we have gained in South Africa to date and will obtain in the future provides a unique competitive advantage that cannot be overemphasized. In the coming year, we will start realizing product sales and see the beginnings of an active scientific exchange program where South African doctors will share their clinical experiences using Hemopure with the medical community worldwide.

CHANGING GEARS FOR THE FUTURE

ACCELERATING OUR PROGRESS During 2002, we succeeded in our primary objective of filing our BLA for Hemopure and gaining FDA acceptance for its review. However, in almost every other respect our plans moved more slowly than expected. The slow pace of our progress, and investor awareness of the historical difficulties in securing regulatory approval for an oxygen therapeutic, undoubtedly contributed to the decline in Biopure's market valuation. We do not believe the current stock price represents the company's inherent value today, never mind its potential future value, and we are dedicated to accelerating our progress and realizing value for all our shareholders.

During 2003, we'll grow our organization with new faces and new structure, and we'll start building the necessary manufacturing capacity to produce our products at prices and in quantities that will provide substantial profitability. We'll work to establish alliances that generate significant shareholder benefit without risking our intellectual property. We'll also begin clinically developing Hemopure for trauma applications, and we plan to start at least one clinical trial in cancer (adjunctive use with radiation and/or chemotherapy) and/or ischemia (reduced blood circulation). But most of all, we'll maintain our focus on becoming a fully commercialized company that

successfully markets the world's first oxygen therapeutics for human and veterinary use in the United States and abroad.

I cannot close without addressing our independent auditors' "going concern" note in the enclosed Form 10-K. In my opinion, we have more than adequate access to the resources needed to develop, manufacture and market our products long-term. When the Board of Directors views the company as undervalued, we will reduce cash on hand to limit dilution and protect shareholder value. Until we reach our projected profitability in 2006, we plan to fund operations through a combination of sales revenues, strategic alliances and licensing agreements, as well as sales of equity and debt securities.

On behalf of Biopure, I thank all of our shareholders for your support. I also thank my fellow employees for your dedication in making this tremendous medical advance a commercial reality. Together we can make 2003 the company's breakthrough year!

Sincerely,

Thomas A. Moore
President and Chief Executive Officer, Biopure Corporation
February 4, 2003

BUSINESS DEVELOPMENT
SOUTH AFRICA

As the first country to grant regulatory approval of Hemopure for human use, South Africa has a head start on the rest of the world in learning how oxygen therapeutics can revolutionize medicine. We at Biopure South Africa Ltd. look forward in 2003 to beginning product sales and integrating this new class of drug into the unusual environment that is South African healthcare. While we are focused on the initial surgery market for Hemopure, we are also preparing to expand Biopure's clinical development program in trauma into South Africa, which to our regret is often considered the trauma capital of the world. Juxtaposed within this developing nation is a country struggling to deliver basic primary healthcare to rural communities while simultaneously providing a level of sophisticated medical service in urban centers that is unparalleled in most of the world. Understanding the key drivers within this setting is critical to gaining acceptance and widespread use of Hemopure as a revolutionary product and new treatment paradigm. While positioning the product as an alternative to blood makes sense, simply placing it on the shelf and saying that the clinicians now have a "blood substitute" does not do justice to the product's unique characteristics.

Therefore, we at Biopure South Africa are facing the challenge of introducing an innovative, but relatively expensive new pharmaceutical product into the South African market by identifying its overall cost benefits and therapeutic value as an oxygen therapeutic. To that end we are building a pharmacoeconomic model for payors, a medical readiness model for mining groups and the military, and a clinical applications model for a broad range of medical specialties.

South African doctors relish the idea of having a treatment alternative for the management of surgical anemia, and they are beginning to realize that Hemopure's ability to transport oxygen to the microcirculation via the plasma suggests much broader applications for the product. Improved wound healing, greater tumor penetration, reduced reconstructive flap problems, reduced hospital stays, improved graft behavior and faster ventilator weaning are being thought about, talked about and observed! One of our goals for 2003 is to have South African doctors begin sharing these experiences with the worldwide medical community in appropriate medical forums.

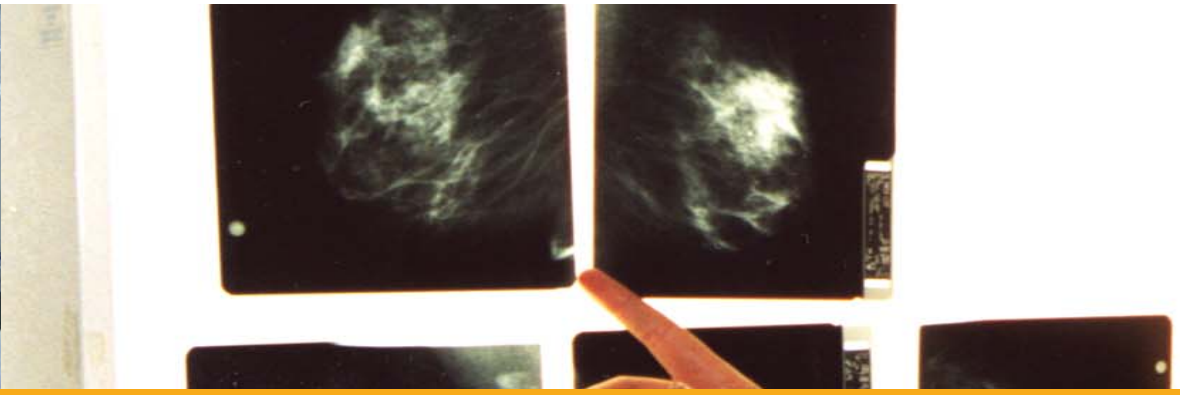
Charl van Loggerenberg, M.D.
Managing Director
Biopure South Africa Ltd.

CLINICAL EXPERIENCE
SOUTH AFRICA

My clinical experience and impressions of Hemopure during the past year have been extremely positive. The ability to safely enhance oxygen delivery to tissues at the microvascular level has suggested significant improvement in patient outcomes and local tissue morbidity and has elevated the quality of surgical care we can offer patients undergoing breast cancer surgery.

Dr. Gereth Edwards and I have reported on the first intraoperative use of Hemopure, outside of a clinical trial, in 25 patients to manage acute blood loss during major surgery aimed at curing malignancy. Our report focuses on the use of Hemopure in breast cancer patients undergoing mastectomy and immediate breast reconstruction, without blood usage, to reduce or eliminate the immune modulation effects associated with conventional blood products.

The results—an extremely low wound complication rate and 100 percent flap healing—are impressive and suggest that Hemopure could potentially eliminate wound complications and normal blood requirements, thereby contributing to the establishment of a new standard of care in South African breast cancer patients.



Gereth Edwards, M.D.
Plastic and
Reconstructive Surgeon
Milpark Hospital

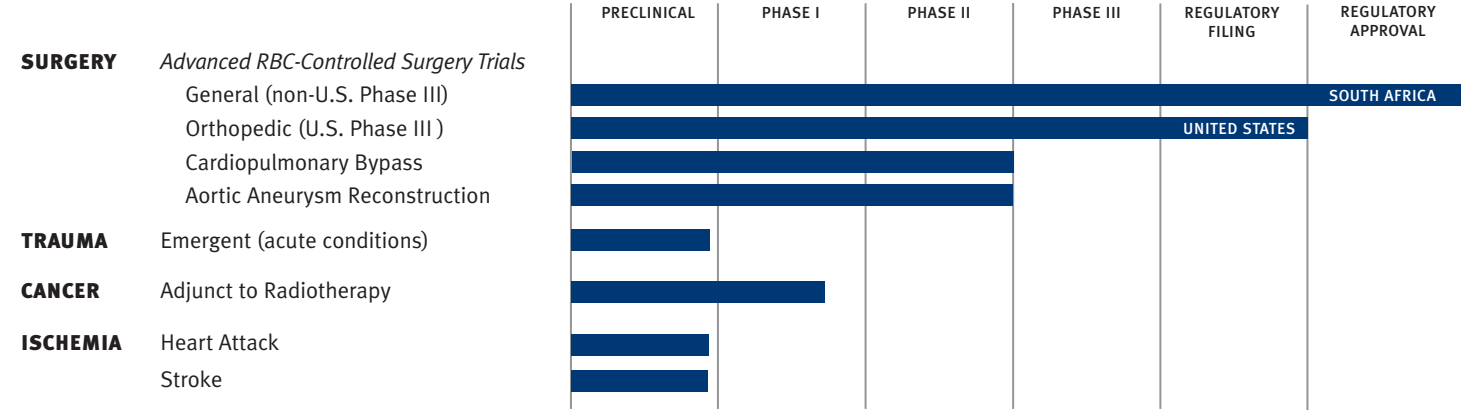
"Without Hemopure, my patients would be exposed to high-risk blood transfusions and, in my opinion, longer recuperation periods and slower wound healing."

We concluded that these results were achieved by eliminating the immune modulation effects associated with blood transfusion and by improving tissue oxygen delivery with Hemopure—an absolute delight for both the surgeon and the patient.

Carol Benn, M.D.
General Surgeon and Breast Cancer Specialist
Milpark Hospital, Johannesburg, South Africa

The South Africa package insert for Hemopure is available online at http:www.biopure.com/hemopurepi/rsa or per request by calling (617)234-6863

HEMOPURE®
CLINICAL DEVELOPMENT



PRODUCT CHARACTERISTICS

CHARACTERISTICS	BIOPURE'S OXYGEN THERAPEUTICS	RED BLOOD CELLS
STORAGE	*Room temperature (2˚ to 30˚ C)*	Refrigerated
SHELF LIFE	*36 months*	42 days
PREPARATION	*Ready to use*	Testing, typing and crossmatching
COMPATIBILITY	*Universal*	Type specific
EFFECTIVENESS	*Immediate oxygen delivery*	Dependant on length of storage
PURITY	*Processed to remove all potential contaminants*	Tested and screened for specific infectious agents
RAW MATERIAL	*Bovine hemoglobin - abundant, controlled source*	Human blood - limited availability, not controlled

HEMOPURE®
CLINICAL DEVELOPMENT

The surrounding tables describe our 22 clinical trials of Hemopure, the status of our target applications, and key product characteristics as compared to allogeneic red blood cells. We began testing Hemopure in healthy volunteers 11 years ago and have progressed through Phase I, II and III clinical trials focusing primarily on surgical patient populations, which constitute 14 of the trials in the table below.

On October 1, 2002, the FDA accepted for review our biologic license application to market Hemopure in the United States for the treatment of the signs and symptoms of acute anemia in adult patients undergoing elective orthopedic surgery, and for the purpose of eliminating or reducing the need for allogeneic red blood cells in these patients. Based on FDA performance goals and guidelines in the Prescription Drug User Fee Act (PDUFA), we anticipate that the agency will complete its review and act on our BLA in mid 2003.

The clinical section of the BLA is based on four major, red blood cell controlled surgery trials—a Phase II study in cardiac surgery, a Phase II study in vascular surgery, a non-U.S. Phase III study in non-cardiac general surgery, and a U.S. Phase III orthopedic surgery study that, to

HEMOPURE®
CLINICAL TRIALS

# STUDIES	TYPE	HEMOPURE SUBJECTS (n)	CONTROL SUBJECTS (n)	MAXIMUM TOTAL DOSE (grams of hemoglobin)
4	Healthy Volunteers	64	29	45 - 140
4	Non-Surgery	34	14	43 - 1080
3	Surgery with ANH*	31	36	36 - 98
7	General Surgery	146	95	27 - 300
4	Major Surgery Trials	531	487	120 - 300
22		806**	661	27 - 1080

* ANH = Acute Normovolemic Hemodilution
** Total does not include compassionate use patients treated under emergency INDs

HEMOPURE®
CLINICAL DEVELOPMENT

our knowledge, is the only U.S. Phase III trial of a hemoglobin solution ever completed. The BLA is also based on an integrated database for all of our trials, which includes more than 1400 total subjects of whom more than 800 were administered Hemopure.

During the past 18 years more than 180 preclinical animal and laboratory studies have been conducted with Biopure's oxygen therapeutics. These studies include the standard battery of toxicology tests required to support Biopure's application. They also include pharmacology studies investigating the kinetics of oxygen onloading and offloading, tissue oxygenation and the product's effects in various animal models of physiologic stress, including hemorrhagic shock and trauma.

MILITARY SUPPORT FOR TRAUMA TRIALS In March 2002, Biopure Vice Chairman and Chief Technology Officer Carl W. Rausch was invited to testify before a Congressional Armed Services Subcommittee at a hearing on innovative technologies that support homeland defense and the war on terrorism. Because Hemopure can be stockpiled, positioned abroad, and carried or stored in remote locations for

immediate use when red blood cells are not readily available, it could potentially enhance medical readiness and improve treatment in critical care conditions and in emergency situations on the battlefield.

In September 2002, the U.S. Army awarded Biopure a $908,900 grant, funded by the Defense Appropriations Act of 2002, for a randomized, standard therapy-controlled, Phase II clinical trial of Hemopure in consenting trauma patients as a precursor to broader trauma trials. In November 2002, a committee of military and civilian trauma experts reviewed data from the Phase III orthopedic surgery trial and the integrated safety database of all Hemopure trials. During this meeting, the committee recommended broadening the proposed Phase II trauma program to include more severely injured and unstable patients in emergency room and pre-hospital settings. We expect to receive up to $4 million in additional funding for this trauma program from monies in the Defense Appropriations Act of 2003.

In addition, Biopure and the Naval Medical Research Center (NMRC) have tentatively agreed to the terms of a Cooperative Research and Development Agreement (CRADA) for a multicenter Phase III trauma trial of Hemopure. Biopure and NMRC are also cooperating on preclinical studies using Hemopure in the development of next-generation hemoglobin-based oxygen carriers under the Navy's already funded Hematomimetics Program.

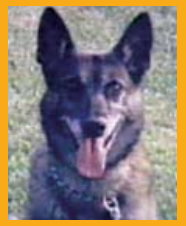
OXYGLOBIN®

Since Oxyglobin was approved by the FDA in 1998 and the European Commission in 1999, we have sold more than 115,000 units for the treatment of canine anemia regardless of the cause, which includes blood loss, disease and ineffective red blood cell production. This veterinary experience provides a compelling proof of concept for the valuable role oxygen therapeutics may soon play in human medicine.

While our manufacturing plant expansion and revalidation created a backorder situation for our veterinary customers in 2002, in early 2003 we received FDA approval of our expanded facilities and promptly filled backorders in excess of 11,000 units. We are continuing to manufacture new product and are committed to providing an uninterrupted supply of product now that shipments have resumed.

Our goals are to restore and expand Oxyglobin sales by launching new marketing and medical education initiatives and by introducing a 60-milliliter bag that will give veterinarians greater flexibility in matching the dose to the patient's oxygen requirements, particularly in smaller dogs. Internationally, we will gradually expand Oxyglobin's availability in the European Union and target Japan as a future veterinary market.

INJURED POLICE DOG TREATED WITH OXYGLOBIN



On August, 22, 2002, Fresno Police Department K-9 Officer Saxon was shot at point blank range with a shotgun blast from a felony suspect. The gunshot nearly proved fatal to K-9 Saxon as it punctured his lungs, broke two legs, and ripped open his entire left side. Conversations between members of my staff and veterinarian Dr. Roger Gfeller leave no doubt about the pivotal role that Oxyglobin played in saving K-9 Saxon's life.

The enormous boost to the morale of the K-9 Unit, the Fresno Police Department, and the community at large when it was announced that K-9 Saxon would recover was evident in the events that followed: school children writing get well cards; citizens sending in cards and donations on K-9 Saxon's behalf; other law enforcement agencies' K-9's coming to the aid of our agency.

I would be honored if you would pass along my sincerest thanks to all of Biopure Corporation's employees who have made Oxyglobin the life saving product that it is. Thank you again for your role in giving K-9 Saxon back to a grateful community.

Jerry Dyer
Chief of Police, Fresno, California
November 26, 2002

SHAREHOLDER INFORMATION

Biopure Corporation
11 Hurley Street
Cambridge, MA 02141
Tel: (617) 234-6500
Fax: (617) 234-6505
Internet: www.biopure.com
E-mail: IR@biopure.com

Stock Listing: Nasdaq: BPUR

Annual Meeting: April 2, 2003

Transfer Agent and Registrar:
American Stock Transfer & Trust Co.
40 Wall Street - 46th Floor
New York, NY 10005
212-936-5100

The company's annual report on form 10-K for the fiscal year ended October 31, 2002 is included herein. The exhibits accompanying the report are filed with the U.S. Securities and Exchange Commission and can be accessed in the EDGAR database at the SEC Web site, www.sec.gov, or through the Investor section of Biopure's Web site, www.biopure.com. The Company will provide these items to stockholders upon request. Requests for any such exhibits should be made to:

Biopure Corporation
Corporate Communications
11 Hurley Street
Cambridge, MA 02141

BOARD OF DIRECTORS

- **Charles A. Sanders, M.D.**
  Chairman
  Former Chairman and Chief Executive Officer, Glaxo, Inc.
- **David N. Judelson**
  Vice Chairman, Co-founder
  Co-founder, Gulf & Western (Paramount Corp.)
- **Carl W. Rausch**
  Vice Chairman, Co-founder
  Chief Technology Officer
- **J. Richard Crout, M.D.**
  President, Crout Consulting
  Former Vice President, Medical Scientific Affairs, Boehringer Manheim Pharmaceuticals
- **Daniel P. Harrington**
  President, HTV Industries, Inc.
- **C. Everett Koop, M.D.**
  Former U.S. Surgeon General
- **Thomas A. Moore**
  President and Chief Executive Officer

OFFICERS

- **Thomas A. Moore**
  President and Chief Executive Officer
- **Carl W. Rausch**
  Chief Technology Officer
- **Ronald F. Richards**
  Chief Financial Officer and Senior Vice President, Business Development
- **Maria S. Gawryl, Ph.D.**
  Senior Vice President, Research and Development
- **Jane Kober**
  Senior Vice President, General Counsel and Secretary
- **Francis H. Murphy**
  Senior Vice President, Engineering and Process Technology
- **Howard P. Richman, D.P.M.**
  Senior Vice President, Regulatory and Operations
- **William A. Eudailey, Pharm.D.**
  Vice President, Marketing
- **Geoffrey J. Filbey**
  Vice President, Engineering
- **Carolyn R. Fuchs**
  Vice President, Human Resources
- **Douglas M. Hansell, M.D.**
  Vice President, Medical Affairs
- **W. Richard Light, Ph.D.**
  Vice President, Process Technology
- **Barry Scott**
  Vice President, International Business Development

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended October 31, 2002

or

☐ **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 or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
11 Hurley Street, Cambridge, MA	**02141**
(Address of principal executive offices)	*(Zip Code)*

Registrant's telephone number, including area code: (617) 234-6500
Securities registered pursuant to Section 12(b) of the Act:
NONE

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.01 par value per share
Preferred Stock Purchase Rights
(Title of Class)

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 ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☑ No ☐

Based on assumptions relating to the privately held non-voting Class B Common Stock, the aggregate market value of the voting and non-voting common equity held by nonaffiliates of the registrant on April 30, 2002 was $327,418,870.

The number of shares outstanding of the registrant's Class A Common Stock was 30,875,563 on January 17, 2003; the number of shares of the Class B Common Stock as of such date was 117.7.

Documents Incorporated By Reference

Location in Form 10-K	Incorporated Document
Part III	Specifically identified portions of the registrant's definitive proxy statement to be filed in connection with the registrant's Annual Meeting to be held on April 2, 2003.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

This report contains forward-looking statements concerning, among other things, possible applications for marketing approval and other regulatory matters, clinical trials, plans for the development of Hemopure and business strategies. These forward-looking statements are identified by the use of such terms as "intends," "expects," "plans," "estimates," "anticipates," "should" and "believes."

These forward-looking statements involve risks and uncertainties. Actual results may differ materially from those predicted by the forward-looking statements because of various factors and possible events. Company risks include lack of FDA or any other regulatory approval for our human product in a major market, the difficulty and uncertainty in obtaining regulatory approvals, uncertainty about future physician and market acceptance of our product, our limited manufacturing capacity and capital resources and our lack of commercial experience as a pharmaceutical company. In addition, we are subject to industry risks such as: our industry is highly regulated, keenly competitive and subject to uncertainty of pricing because of controls on health care spending and uncertainty of third-party reimbursement.

PART I

Item 1. *Business*

Biopure develops, manufactures and markets oxygen therapeutics, a new class of pharmaceuticals that are administered intravenously into the circulatory system to increase oxygen transport to the body's tissues. Using its patented and proprietary technology, the Company has developed and manufactures two products: Hemopure [hemoglobin glutamer — 250 (bovine), or HBOC-201] for human use, and Oxyglobin [hemoglobin glutamer — 200 (bovine), or HBOC-301] for veterinary use.

Hemopure is a first-in-class product that is approved in South Africa for the treatment of adult surgical patients who are acutely anemic, and for the purpose of eliminating, delaying or reducing the need for allogenic red blood cells in these patients. On July 31, 2002, Biopure submitted a biologic license application (BLA) to the U.S. Food and Drug Administration seeking regulatory approval to market Hemopure in the United States for a similar indication in patients undergoing orthopedic surgery. The FDA has accepted and is reviewing this application.

Biopure is also developing Hemopure for potential use in trauma and other medical applications. In September 2002, the U.S. Department of the Army awarded Biopure a $908,900 grant for a standard therapy controlled, Phase II clinical trial evaluating the safety and tolerability of the product in trauma patients. The Company has identified trauma as its next clinical development priority and is working with a committee of independent civilian and military trauma experts to broaden its trauma program.

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, regardless of the cause of the anemia.

During 2002 Biopure also completed plant expansions designed to increase the Company's design capacity to approximately 75,000 Hemopure units or 262,000 Oxyglobin units. Upon future validation and regulatory approval of a newly installed product fill process, these expanded facilities will be designed to produce up to approximately 100,000 Hemopure units or 350,000 Oxyglobin units per year, or any combination of the two products. Biopure also signed a lease, contingent upon financing, in December 2002 for a proposed manufacturing facility that, when constructed, is designed to produce up to 500,000 Hemopure units per year.

Biopure was incorporated in Delaware in 1984. Biopure maintains a website at the following Internet address: www.biopure.com. Through a link to a third-party content provider, this corporate website provides free access to Biopure's annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after electronic filing with the Securities and Exchange Commission.

Biopure®, Hemopure®, and Oxyglobin® are registered trademarks of Biopure.

Scientific Overview

Oxygen is indispensable to the life of all of the body's tissues. Hemoglobin, a protein normally contained within red blood cells, is the molecule responsible for carrying and releasing oxygen to the body's tissues. Hemoglobin's protein structure is similar in many different animal species, including humans. Under normal conditions, hemoglobin contained within red blood cells carries approximately 98 percent of the body's oxygen and the remaining two percent is dissolved in the plasma, the fluid part of blood.

As the heart pumps blood, hemoglobin within red blood cells takes up oxygen in the lungs and carries it to various parts of the body. Blood travels through progressively smaller blood vessels to the capillaries, some of which are so narrow that red blood cells can only pass through in single file. Most of the oxygen release occurs in the capillaries. Blood then returns to the lungs to reload the red blood cells with oxygen. Adequate blood pressure and red blood cell counts are crucial to this process. Oxygen deprivation, even for several minutes, can result in cell damage, organ dysfunction and, if prolonged, death.

The causes of inadequate tissue oxygenation generally can be classified into three categories:

- *anemia* — insufficient hemoglobin, reducing the oxygen-carrying capacity of the blood. Blood loss from injury, surgery or disorders that affect red blood cell production or maintenance, such as bone marrow disease, can cause anemia;
- *ischemia* — localized, inadequate red blood cell flow. Obstructed or constricted blood vessels can result in ischemia. Ischemia can lead to stroke, heart attack or other organ or tissue dysfunction; and
- *cardiopulmonary failure* — impaired function of the heart or lungs. The heart's inability to pump sufficient quantities of blood to meet the needs of the tissues or the failure of the lungs to oxygenate blood adequately can cause tissue damage.

A red blood cell transfusion is the standard therapy for anemia resulting from blood loss. Sources of red blood cells for transfusions include stored supplies of donated blood or of the recipient's own pre-donated blood. Health care professionals also may use medications that stimulate red blood cell production if anemia is anticipated, for example, as a result of planned surgery.

Red blood cell transfusions have certain risks and limitations. As HIV, hepatitis, West Nile Virus and other pathogens have contaminated portions of the world's blood supply, the need for a purified, pharmaceutical quality blood product has become increasingly apparent. There is currently no 100 percent effective method for detecting blood-borne diseases or for sterilizing donated blood. As a result, the risk of disease transmission from donated blood is an ongoing concern to physicians and patients. Handling errors in typing and cross-matching blood, as well as the inadvertent introduction of pathogens, can also have significant medical consequences. Blood typing and handling requirements, particularly refrigeration, limit the feasibility of using red blood cell transfusions in pre-hospital emergency treatment situations. Shortages of certain types of blood can occur due to seasonal factors or disasters. Donated red blood cells are available for use in transfusions for only 42 days after collection and this limitation affects the ability to stockpile red blood cell supplies. Although freezing can extend the life of red blood cells, the freezing and thawing processes require chemical treatment of the red blood cells and reduce the efficacy of those red blood cells. Finally, the longer red blood cells are stored, the longer it takes them to reach their maximum oxygen-releasing capacity and the more they break down, limiting their effectiveness in delivering oxygen. Red blood cells lose approximately 75 percent of their immediate oxygen-releasing ability after eight days of storage. Blood banks generally release the longest stored blood first to prevent outdating after 42 days.

Red blood cell transfusions generally are not effective for ischemic conditions caused by blockage. In such situations, an obstructed or constricted blood vessel that is too narrow to permit the normal passage of red blood cells can prevent oxygen from reaching the body's tissues. Similarly, red blood cell transfusions are generally not effective in overcoming poor oxygenation due to impaired heart or lung function.

In trauma situations, victims may experience massive bleeding resulting in rapid loss of blood volume and oxygen-carrying capacity. Existing alternatives to red blood cell transfusions are limited. In an effort to stabilize trauma patients, emergency caregivers typically administer commonly used intravenous fluids, such

as Ringer's lactate or saline. Ringer's lactate consists of water and electrolytes and generally is administered to patients who have lost substantial amounts of bodily fluids as a result of bleeding, vomiting or diarrhea. Both Ringer's lactate and saline restore blood volume, but do not carry oxygen.

For anemia in non-acute situations, there are currently two biological products on the market. Both of these products are formulations of a protein called erythropoietin. Erythropoietin stimulates the body's ability to produce red blood cells. In a surgical setting, these products are administered in anticipation of blood loss during surgery, thereby potentially reducing the need for red blood cell transfusions. However, erythropoietin does not deliver oxygen to the body's tissues and does not act as a blood volume expander. As a result, these products are not effective in treating acute blood loss and are generally not used in cases of unplanned surgeries or emergency need. In addition, the labels on these products caution against their use in patients undergoing cardiac surgery.

Biopure's Oxygenation Technology

Biopure has two proprietary oxygen therapeutic products that are identical except for their molecular size distributions. Biopure defines its products as therapeutics because they remediate oxygen deprived tissues. One administers these products intravenously. Biopure's products are made from hemoglobin that has been extracted from bovine red blood cells and then purified, chemically modified and cross-linked for stability. The resulting hemoglobin solutions do not contain red blood cells and are formulated in a balanced salt solution similar to Ringer's lactate for the final product.

The average Hemopure molecule is less than 1/1000th the size of a red blood cell. Once infused into a patient, the Hemopure molecules disperse throughout the entire plasma space and are in continuous contact with the blood vessel wall where oxygen transport to tissues takes place.

Upon infusion into the bloodstream, Hemopure immediately turns the plasma into an oxygen-delivering substance. Plasma containing Hemopure flows everywhere that blood ordinarily flows and can also bypass partial blockages or pass through constricted vessels that impede the normal passage of red blood cells.

In addition, introducing Hemopure into the bloodstream may enable red blood cells to release more oxygen to the tissues than they otherwise would. In addition to delivering oxygen to tissues, Hemopure also acts as a blood volume expander and may support the body's ability to produce red blood cells.

Hemopure molecules hold the same amount of oxygen as the hemoglobin molecules in red blood cells on a gram-for-gram basis. Hemopure molecules, however, are chemically modified to have less affinity for oxygen than red blood cells, enabling Hemopure to take up oxygen from the lungs and release it to tissues more efficiently than red blood cells. Human hemoglobin, unlike bovine hemoglobin, depends on the action of 2,3 diphosphoglycerate, or 2,3 DPG, a substance found in high concentrations only within the red blood cell, for optimal onloading and offloading of oxygen to tissues. The 2,3 DPG breaks down rapidly in stored blood causing red blood cells to lose approximately 75 percent of their ability to immediately release oxygen after eight days of storage. The 2,3 DPG breakdown reduces the oxygen offloading efficiency of transfused red blood cells until 2,3 DPG levels are restored, a process that can require hours. Biopure's bovine hemoglobin permits the efficient offloading of oxygen in the absence of 2,3 DPG, thereby allowing Hemopure to be at its optimal oxygen offloading effectiveness immediately upon infusion.

Hemoglobin molecules in different species have demonstrated low antigenicity, which means that they do not readily elicit an immune or allergic response. Biopure has confirmed Hemopure's low antigenicity, as indicated by the absence of certain effects, through studies in the laboratory, not involving living beings, and in living animals and humans.

The following chart lists Hemopure's characteristics in comparison to transfused red blood cells:

Characteristic	Hemopure	Transfused Stored Red Blood Cells
Onset of action	Immediate — not 2,3 DPG-dependent	Initially limited — 2,3 DPG-dependent
Oxygen affinity	More efficient oxygen release to tissues	Less efficient oxygen release to tissues
Oxygen transport	Red blood cells and Hemopure molecules in plasma	Red blood cells; plasma a minor contributor
Risk of disease transmission	Product purity maintained through raw material controls and a reproducible and controllable pharmaceutical manufacturing process that is validated to remove potential pathogens; no leukocyte, or white blood cell, exposure	Risk minimized by testing, donor selection and administration protocols and ongoing surveillance for emerging pathogens; leukocyte exposure
Storage	Room temperature; no loss of efficacy	Refrigeration required; loss of efficacy
Shelf life	36 months	42 days
Compatibility	Universal	Type-specific
Preparation	Ready-to-use	Requires typing and cross-matching
Viscosity	Low	High
Raw material source	Controlled	Not controlled
Duration of action (time the product remains active in the body)	One to three days, depending on dose	Estimated 60 to 90 days

In addition to Hemopure's use as an alternative to red blood cell transfusions in surgery, human clinical testing and preclinical studies suggest that Hemopure also could be a readily available therapeutic with other potential applications. These applications may include the treatment of trauma and ischemic conditions, such as stroke and heart attack. Hemopure may also improve the effectiveness of radiation and chemotherapy against malignant hypoxic tumors.

Hemopure has a 36-month shelf life without refrigeration (2° to 30° centigrade), is universally compatible and can be stocked well in advance of anticipated use. Consequently, when blood is not available, Hemopure could be used to maintain a patient until the needed type and quantity of red blood cells arrive, until the patient can be transported to a hospital or until a patient's body replenishes its own red blood cells. We refer to use in these contexts as an Oxygen Bridge™. Hemopure may be particularly well suited for this Oxygen Bridge function because the duration of action of an infusion of a single unit is between one and two days with 50 percent of the Hemopure molecules retained in the circulatory system for 19 to 24 hours following administration. In clinical trial data, Biopure observed that dosing with more than one unit or the redosing of Hemopure over several days can prolong Hemopure's "Oxygen Bridge" effect.

Transfused red blood cells have some advantages when compared to Hemopure. Transfused red blood cells have a longer duration of action and can persist in the body for an estimated 60 to 90 days. Hemopure, on the other hand, has a half-life of up to one day and, depending on the amount infused, may require repeat administration. In addition, it is anticipated that Hemopure will be more expensive to use than transfused red blood cells.

Strategy

Biopure intends to develop, manufacture and market oxygen therapeutics through the following strategy:

- *Develop and Commercialize Hemopure as a Treatment for Acute Anemia in Patients Undergoing Surgery.* Biopure's advanced clinical trials have demonstrated Hemopure's efficacy as an alternative to red blood cell transfusions in the treatment of acute anemia in patients undergoing elective

orthopedic surgery. While Biopure does not anticipate that Hemopure will replace all red blood cell transfusions, the Company believes that Hemopure's use in orthopedic surgery and its use in other types of surgery in South Africa demonstrates the product to be a safe and effective oxygen therapeutic.

- *Pursue Marketing Approvals.* Biopure will seek to register its oxygen therapeutics internationally.
- *Pursue Approvals of Hemopure for Additional Therapeutic Applications.* Because of Hemopure's unique physical and clinical characteristics, Biopure intends to develop it for multiple medical applications, including trauma, ischemic conditions such as stroke and heart attack, and as an adjunct therapy for malignant hypoxic tumors.
- *Increase Market Awareness of Hemopure.* Biopure intends to increase market awareness of Hemopure by identifying the issues and benefits of oxygen therapeutics in patient management and implementing professional education programs targeted at the medical community.

Biopure's Products

Our two products are oxygen therapeutics. Hemopure is our product for human use. In fiscal year 2002, we filed an application with the FDA seeking regulatory approval to market Hemopure in the United States for the treatment of the signs and symptoms of acute anemia in adult patients undergoing orthopedic surgery, and for the purpose of eliminating or reducing the need for red blood cells in these patients. The FDA and the European Commission have approved the use of Oxyglobin, our veterinary product, for the treatment of anemia in dogs, regardless of cause. Oxyglobin is marketed and sold to veterinary hospitals in the United States and Europe. We have tested Hemopure in clinical trials involving more than 1450 humans, of whom more than 800 were administered Hemopure. On a "compassionate use" basis, Hemopure has been administered as an Oxygen Bridge to more than 40 human patients with life threatening anemia when compatible red blood cells were unavailable or unacceptable. Hemopure and Oxyglobin have been tested in 180 completed preclinical studies involving animals from 10 species. Commercial sales of Oxyglobin have resulted in thousands of administrations in animals. The overall incidence of adverse events reported in the United States and Europe for Oxyglobin is less than 0.05 percent.

Hemopure

We believe Hemopure can be developed for several indications. As described below, the first indication we are seeking is for the treatment of acute anemia in surgery patients undergoing orthopedic surgery, as an alternative to red blood cell transfusions. Preclinical studies and observations from completed trials show that general surgery, trauma, ischemic conditions such as stroke and heart attack, and malignant hypoxic tumors might be possible additional indications for clinical development.

Red Blood Cell Transfusion Alternative

Hemopure serves as an alternative to red blood cell transfusions by providing a temporary Oxygen Bridge until suitable red blood cells become available or are produced by the body. We do not expect Hemopure to replace all red blood cell transfusions. However, Hemopure's oxygen-carrying properties, storage and infusion advantages address many of the limitations associated with red blood cell transfusions.

Biopure's clinical trials have demonstrated Hemopure's efficacy as an alternative to red blood cell transfusions in patients undergoing elective orthopedic surgery as measured by the avoidance of red blood cell transfusions. In all of Biopure's advanced clinical trials, Hemopure's efficacy as an oxygen therapeutic was evaluated by determining, within the context of a written set of guidelines known as a protocol, the percentage of patients given Hemopure who did not require a subsequent transfusion of red blood cells. In these trials, Hemopure was administered only to patients who needed a red blood cell transfusion. Trial design limited the amount of Hemopure that could be infused and the number of post-operative days during which it could be infused. Under this protocol, Hemopure's clinical trials that have been completed and analyzed demonstrate clinically significant elimination of red blood cell transfusions. Elimination was deemed to occur if the patient

did not require a subsequent red blood cell transfusion. Elimination was deemed not to occur if the patient was administered a red blood cell transfusion for any reason.

The following chart summarizes the advanced clinical trials that Biopure has completed for Hemopure as an alternative to red blood cell transfusions. The column labeled "Results" lists efficacy results.

Type of Surgery	Development Status	Dosing: Grams Hemoglobin (Units Hemopure)	No. of Total Patients/No. of Patients Treated with Hemopure	Results
Elective orthopedic surgery	Phase III trial completed in U.S., Canada, Europe and South Africa	Up to 300 grams (10 units) over 6 days before, during or after surgery	688/350	59% elimination of red blood cell transfusions in the intent-to-treat population
Non-cardiac elective surgery	Phase III trial completed in Europe and South Africa, the basis for filing in South Africa in July 1999	Up to 210 grams (7 units) over 6 days before, during or after surgery	160/83	43% elimination of red blood cell transfusions in the intent-to-treat population
Post cardiopulmonary bypass surgery	Phase II trial completed in the U.S.; supportive trial for the South African July 1999 filing	Up to 120 grams (4 units) over 3 days post-surgery	98/50	34% elimination of red blood cell transfusions
Aortic aneurysm reconstruction surgery	Phase II trial completed in the U.S. and Europe; supportive trial for the South African July 1999 filing	Up to 150 grams (5 units) over 4 days; first dose administered during or after surgery	72/48	27% elimination of red blood cell transfusions

U.S. Phase III Orthopedic Surgery Trial. Biopure's application to the FDA for approval to market Hemopure includes two Phase III trials. The U.S. Phase III trial was in elective orthopedic surgery. Elective orthopedic surgery includes non-emergency surgery involving bones and joints, including spinal surgery and the repair of orthopedic fractures in stabilized trauma patients. The primary efficacy objective of this trial was the avoidance of red blood cell transfusions for six weeks after orthopedic surgery. The safety objective of the U.S. Phase III trial is that patients treated with Hemopure have outcomes no worse than patients treated with red blood cells per the statistical methodology defined in the study analysis plan. Biopure designed this randomized, red blood cell controlled, multi-center study to enroll a total of 640 patients in the United States, Europe, Canada and South Africa, of whom approximately one-half would be in the Hemopure treatment group and the other half would receive red blood cells. Final enrollment was 688 patients. Up to 300 grams of hemoglobin, or ten units of Hemopure, could be infused before, during or after surgery for a total of up to six treatment days. The efficacy objective of this trial, the elimination of red blood cell transfusions in at least 35 percent of the patients who received Hemopure, was achieved.

Non-U.S. Phase III Non-cardiac Surgery Trial. Biopure completed a Phase III trial in Europe and South Africa in 1998 in non-cardiac surgery. Non-cardiac surgery refers to surgery that does not involve the heart and can include surgery of the digestive or urinary tract as well as orthopedic surgery. The primary objective of this trial was the avoidance of red blood cell transfusions for 28 days after non-cardiac surgery. This randomized, red blood cell controlled, multi-center study enrolled 160 patients, 83 of whom were infused with Hemopure. Up to 210 grams of hemoglobin, or seven units of Hemopure, were permitted during a six-day treatment period. The trial resulted in the clinically significant elimination of red blood cell transfusions in 43 percent of the patients who received Hemopure in the intent-to-treat population.

U.S. Phase II Post-Cardiopulmonary Bypass Surgery Trial. A randomized, double-blind, red blood cell controlled, multi-center study in post-cardiopulmonary bypass surgery patients was completed in 1997. During cardiopulmonary bypass surgery, patients are connected to a heart and lung machine that replaces functions of the heart and lungs during surgery. The primary objective of this trial was the avoidance of red blood cell transfusions for 28 days after surgery. The study treated 98 patients, 50 of whom were infused with Hemopure. Up to 120 grams of hemoglobin, or four units of Hemopure, were administered over a three-day treatment period following surgery. The trial resulted in the clinically significant elimination of red blood cell transfusions in 34 percent of the patients that received Hemopure. In this study, 100 percent of the patients who received Hemopure did not require any red blood cells during the day of surgery.

Additionally, we observed that the hematocrit, which is a measure of the packed red blood cell volume as a percentage of total blood volume, of the patients treated with Hemopure recovered to a degree that was similar to the red blood cell treated patients at both six and 28 days post-surgery. This trial was reported in the *Journal of Thoracic and Cardiovascular Surgery*, July 2002.

U.S. Phase II Aortic Aneurysm Reconstruction Surgery Trial. In 1998, Biopure completed a randomized, red blood cell controlled, multi-center trial in abdominal aortic aneurysm reconstruction surgery. Aortic aneurysm reconstruction surgery involves repairing a damaged segment of the aorta, the body's principal artery. This study treated 72 patients, 48 of whom were infused with Hemopure. The maximum dosage was 150 grams of hemoglobin, 30 grams more than the post cardiopulmonary bypass trial. Usually aortic aneurysm reconstruction surgery involves much more blood loss than post cardiopulmonary bypass surgery. In this trial, Hemopure was used during the surgery in contrast to the post cardiopulmonary bypass trial, where use began after surgery. The trial resulted in the clinically significant elimination of red blood cell transfusions in 27 percent of the patients that received Hemopure. The trial was reported in the *Journal of Vascular Surgery*, February 2000.

In these four red blood cell controlled trials, adverse events that occurred in the Hemopure-treated group of patients (n=531) at greater than or equal to 5 percent increased incidence versus the control group (n=487) were anemia (low red blood cell count), abdominal pain, dysphagia (difficulty swallowing), nausea, vomiting, jaundice (transient yellow skin discoloration not generally associated with liver dysfunction), increased lipase (metabolic enzyme), oliguria (low urine output), hypertension (mild to moderate increase in blood pressure) and tachycardia (rapid heart rate).

Trauma

We believe that Hemopure could be infused at the site of a crash, potentially extending the time that a trauma patient could be supported awaiting hospital care. Hemopure is also a blood volume expander, a common therapy used to stabilize trauma patients. To facilitate a clinical development program for Hemopure in trauma, we conducted a Phase II trial in non-cardiac surgery patients. This 51-patient trial was conducted at the University of Texas at San Antonio Health Service Center, Brooke Army Medical Center and Wilford Hall Air Force Hospital. In this controlled and randomized study, investigators infused patients on a randomized basis with Hemopure, or Ringer's lactate, the control treatment, based on the estimated amount of blood the patient had lost. Biopure has convened a panel of experts, including experts in the U.S. military, to advise us in the design of a trauma program and study.

Preclinical animal studies performed in academic and military research laboratories have shown the benefit of using Hemopure in situations involving severe trauma, hemorrhagic shock, hemorrhagic shock with tissue injury and resuscitation from cardiac arrest resulting from severe hemorrhage.

An abstract published in the *The Journal of Trauma* in January 2000 and presented at the 30th Annual Scientific Meeting of the Western Trauma Association on March 1, 2000 described a preclinical study using a pre-hospital hemorrhagic shock model designed to simulate what happens to humans after an accident. The

study demonstrated that resuscitation using small volumes of Hemopure can restore and sustain brain oxygenation, blood pressure and cardiac output following severe hemorrhagic shock.

Ischemia

The ability of Hemopure molecules to circumvent partial occlusions could potentially benefit patients suffering from ischemic conditions by supplying oxygen to tissues that are receiving inadequate numbers of red blood cells. Inadequate tissue oxygenation due to partial vessel blockage or constriction can cause heart attack, angina and transient ischemic attack, which is a precursor to stroke. In these situations, treatment with red blood cell transfusions would not be effective because red blood cells are too large to navigate around blockages. Biopure has completed preclinical studies with results supporting these potential indications. One preclinical study demonstrated that Hemopure sustained heart tissue oxygenation and heart function during 90 percent constriction of a coronary artery.

Cancer Therapy Adjunct

Radiation therapy and many types of chemotherapy depend on the adequate oxygenation of tumors to kill cancer cells. Malignant cancer tumors, such as brain, breast, prostate and other solid tumors, are dense tumors which often outgrow their blood supply, leaving much of the tumor without oxygen. Consequently, they resist chemotherapy and radiation treatment. We collaborated with the Dana-Farber Cancer Institute in Boston to develop a patented method for oxygenating oxygen deficient tumor cells, referred to as "hypoxic" that potentially could increase the tumor-killing effects of radiation and chemotherapy. Studies in animals have shown the feasibility of this application. In 1999, Biopure initiated clinical development of this indication, specifically the treatment of brain tumor (glioblastoma). Enrollment in a Phase I clinical trial of patients diagnosed with glioblastoma was completed in 2001. Biopure has identified further cancer trials as its next priority after trauma.

Oxyglobin

Oxyglobin is identical to Hemopure except for its molecular size distribution. The FDA Center for Veterinary Medicine approved Oxyglobin in 1998 and the European Commission approved Oxyglobin in 1999, in both cases for the treatment of canine anemia, regardless of the cause of the anemia. Anemia in dogs often results from blood loss, disease or ineffective red blood cell production. Oxyglobin sales were $2.0 million in fiscal 2002, $3.5 million in fiscal 2001 and $3.1 million in fiscal 2000. The decline in 2002 sales is attributable to the Company's expansion of manufacturing capacity and resultant need for regulatory approval to ship product manufactured at its facilities post-expansion.

As of December 31, 2002, we had $1.3 million in backorders, believed to be firm, for Oxyglobin. There was no backlog as of December 31, 2001. All of the backlog is expected to be filled in fiscal year 2003.

Manufacturing

We use proprietary and patented purification and polymerization processes in the manufacture of our oxygen therapeutic products. Biopure's scientific and engineering team has designed and built much of its large-scale critical equipment. Proprietary computer logic controls operate and monitor most aspects of this process. Biopure has produced both Hemopure and Oxyglobin since 1991.

Raw Material Source

Our products consist of bovine hemoglobin that has been purified, chemically modified and cross-linked for stability. Controlled herds of U.S. cattle raised for meat provide the raw material, bovine hemoglobin, used in our products. Cattle must meet the requirements of a herd management program we have in place to confirm origin, health, feed and quality of the cattle to be used as a raw material source. These safety standards are not and cannot be established for donated human blood. Suppliers to Biopure contract to maintain traceable records on animal origin, health, feed and care to assure the use of known, healthy animals.

The U.S. Department of Agriculture, or USDA, deems the United States to be free of pathogens associated with "mad cow disease."

Raw Material Collection

We collect bovine whole blood into individual presanitized containers at an abattoir. We then transport the containers to a separation facility. Prior to collection, the animals undergo live inspection. Then, following blood collection, the animal carcass undergoes USDA inspection for use as beef for human consumption. If an animal carcass is retained for further inspection for final disposition by the USDA veterinarian, we reject the corresponding container of whole blood.

Safety

Our patented purification and manufacturing process has been validated to remove potential pathogens, if present, including bacteria, viruses such as those leading to hepatitis and AIDS, and the transmissible spongiform encephalopathies (TSE) that cause rare neurological disorders such as "mad cow disease" and its human equivalent. Health and regulatory authorities have given guidance directed at three factors to control these diseases: source of animals, nature of tissue used and manufacturing process. We comply with, and believe we exceed, all current guidelines regarding such risks for human pharmaceutical products. Our source is controlled, U.S. source bovine red blood cells do not carry BSE and our process has been shown to remove all measurable quantities of prions, were they present. Bovine red blood cells do not contain prions, the proteins necessary for transmissible spongiform encephalopathies. In addition, in fiscal 2001 the European Directorate for the Quality of Medicines (EDQM) granted a "Certification of Suitability of Monographs of the European Pharmacopoeia" for our veterinary product, Oxyglobin. This certification is required for all human and veterinary medicinal products that are manufactured from ruminant materials and marketed in the European Union, and it represents the Council of Europe's official acknowledgment of the acceptability of Oxyglobin with regard to transmissible spongiform encephalopathy agents.

Manufacturing Processes

A cell washing filtration process removes plasma proteins in the bovine blood. Washed cells are next placed in a centrifuge that separates the red blood cells from other, remaining blood components. The hemoglobin is extracted from the red blood cells and is then diafiltered to remove red blood cell wall debris and other contaminants. The resulting material is a cell-free hemoglobin intermediate. A semi-continuous purification process involving a high performance liquid chromatography process purifies the hemoglobin intermediate. Next, the purified hemoglobin is polymerized, or linked, by the addition of a cross-linking agent. Polymerized and stabilized material is placed into a physiologic solution, then fractionated if required, and concentrated. The final product is filtered into sterilized batch holding tanks until it is sterile filled into bags.

Marketing

Hemopure

Biopure expects to market Hemopure initially to hospitals. Biopure recognizes that it is crucial to establish a core understanding among opinion leaders that Hemopure fills an important medical need and that systematic development of opinion leader advocacy is necessary for capturing and maintaining a leadership position. Biopure expects to use publications and educational forums, such as seminars and presentations at meetings of medical specialists. Biopure has engaged a distributor for sales in South Africa. Biopure has trained approximately 400 doctors and nurses in South Africa in the use of the product and is continuing to train individuals there who wish to use it.

Biopure will explore various means of selling Hemopure elsewhere. Among other options, the Company may seek to enter into licensing or co-marketing agreements for parts or all of the world. Alternatively, it could engage "contract" sales organizations from vendors, contract pharmaceutical companies that supply sales services or recruit and train its own marketing and sales force.

Oxyglobin

Biopure estimates that there are at least 15,000 small animal veterinary practices in the United States, another 4,000 mixed animal practices treating small and large animals in the United States and approximately 22,000 small animal practices in Europe. Biopure believes that the average veterinary practice treats only a small percentage of canine anemia cases with a red blood cell transfusion. The remainder receive either cage rest or a minimally effective treatment such as fluid administration, iron supplements, nutritional supplements or inspired oxygen.

Biopure sells Oxyglobin to veterinarians in the United States through veterinary product distributors — one national and seven regional. Orders are drop shipped by Biopure directly. In Europe, Oxyglobin is imported by a pharmaceutical company that releases each lot through its quality assurance personnel. It is then purchased by distributors and wholesalers and resold to veterinarians.

Marketing programs in both the United States and Europe have included advertising, direct mail, educational seminars, conference calls, lectures at congresses and attendance at trade shows. Biopure has established a core group of veterinary practices in the United States and Europe that use the product regularly. These veterinarians are effective advocates of the product when interacting with other veterinarians.

Competition

Hemopure will compete with traditional therapies and with other oxygen delivery pharmaceuticals. Comparisons with traditional therapies, including red blood cell transfusions, are described under "— Scientific Overview," "— Biopure's Oxygenating Technology" and "— Biopure's Products." In addition, cost may be a competitive factor in traditional therapies.

Oxygen therapeutics under development fall into two categories:

- *hemoglobin-based oxygen carriers*, including Hemopure and Oxyglobin, consist of natural hemoglobin from an animal or human or genetically engineered source that has been modified to improve stability, efficacy and safety; and
- *perfluorocarbon emulsions* are chemicals administered intravenously. Perfluorocarbon emulsions are effective principally under conditions of high oxygen partial pressure to assist in oxygen delivery by forcing dissolved oxygen into the plasma space.

We believe that the competitive factors for our oxygen therapeutics will be efficacy, safety, ease of use and cost. We believe that we have significant advantages as compared to our competitors' pharmaceuticals, including:

- patents covering our processes, our products and their uses;
- larger molecule size than competitor's hemoglobin based oxygen carriers, resulting in longer duration of action than some other products under development;
- long-term room temperature stability;
- operational large-scale manufacturing facility;
- ample, controlled raw material source;
- marketing approval in South Africa;
- FDA acceptance for review of a marketing application; and
- FDA and European Commission approvals of Oxyglobin and the facilities that produce it and usage by veterinarians.

Some of our competitors and potential competitors have greater financial and other resources to develop, manufacture and market their products. Existing competitors in the development of hemoglobin-based oxygen therapeutics use outdated human red blood cells or recombinant human hemoglobin as their raw material. We

are aware of two human hemoglobin-based products currently in a pivotal, U.S. Phase III clinical trial or with applications for approval pending. We are not aware of any competitor that has completed a pivotal, U.S. Phase III clinical trial of a product as an alternative to red blood cell transfusions in surgery. Biopure believes that its use of bovine red blood cells is an advantage over products made from outdated donated human red blood cells because of the availability, abundance, ability to control source, cost and relative safety of bovine red blood cells. However, the use of bovine derived blood products may encounter resistance from physicians and patients. Among other things, public perceptions about the risk of "mad cow disease" may affect market acceptance of Hemopure. We also believe that competitors may find it difficult to make or offer a hemoglobin-based oxygen carrier product having the product characteristics of Hemopure without infringing on one or more of our patents. In addition, the relatively low viscosity of Hemopure is a potential advantage for patients with low blood pressure resulting from blood loss.

Biopure knows of no companies developing oxygen products intended to compete with Oxyglobin in the veterinary market.

Intellectual Property

Patents, trademarks, trade secrets, technological know-how and other proprietary rights are important to Biopure's business. We actively seek patent protection both in the United States and abroad. We filed our initial patent in 1986 in the United States. Five U.S. patents have been issued from this filing. These patents describe and claim ultra-pure semi-synthetic blood substitutes and methods for their preparation.

In total, we have 21 U.S. patents granted and 11 applications pending relating to our oxygen therapeutics. Our granted U.S. patents include:

- three patents covering an ultra-purification process for hemoglobin solutions, regardless of the source of hemoglobin, two of which expire in 2006 and one of which expires in 2014; two patents covering the ultra-pure oxygen therapeutic solutions produced by this process expiring in 2009; and one patent covering the chromatography purification of the hemoglobin solution, expiring in 2015;
- three patents regarding compositions having improved stability, of which two expire in 2015 and the third expires in 2016, and one patent covering processes for producing these compositions which expires in 2016;
- three patents, two of which expire in 2015 and one of which expires in 2016, covering improvements in preservation of such hemoglobin solutions;
- two patents, which expire in 2015 and 2016, covering improved methods for separating polymerized from unpolymerized hemoglobin;
- one patent, which expires in 2015, covering methods of oxygenating tissue affected by inadequate red blood cell flow;
- one patent, which expires in 2016, covering the removal of pathogens, if present, from Biopure's source material; and
- three patents, which expire in 2011, 2014 and 2015, covering methods for treating tumors; and
- one patent, which expires in 2010, covering a sample valve for sterile processing.

We believe that it is not economically practicable to determine in advance whether our products, product components, manufacturing processes or the uses of our products infringe the patent rights of others. It is likely that, from time to time, we will receive notices from others of claims or potential claims of intellectual property infringement or we may be called upon to defend a customer, vendee or licensee against such third-party claims. Responding to these kinds of claims, regardless of merit, could consume valuable time, result in costly litigation, which in turn could harm our business. Responding to these claims also could require us to enter into royalty or licensing agreements with the third parties claiming infringement. Such royalty or licensing agreements, if available, may not be available on terms acceptable to us.

Employees

As of January 9, 2003, we employed 249 persons. None of our employees are covered by a collective bargaining agreement. We believe our relations with our employees are good.

Government Regulation

New Drug or Biologic Approval for Human Use

Governmental authorities in the United States and other countries extensively regulate the testing, manufacturing, labeling, advertising, promotion, export and marketing, among other things, of Biopure's oxygen therapeutic products. Any oxygen therapeutic product administered to human patients is regulated as a drug or a biologic drug and requires regulatory approval before it may be commercialized.

In the United States, Hemopure is regulated as a human biologic.

The steps required before approval of a biologic for marketing in the United States generally include:

- preclinical laboratory tests and animal tests;
- the submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing, which must become effective before human clinical trials may lawfully commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
- the submission to the FDA of a biologic license application;
- FDA review of the biologic license application; and
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with current good manufacturing practices, which include elaborate testing, control, documentation and other quality assurance procedures.

The testing and approval process requires substantial time, effort and financial resources. After approval is obtained, a supplemental approval generally is required for each proposed new indication, often accompanied by data similar to that submitted with the original biologic license application.

Preclinical studies include laboratory evaluation of the product and animal studies to assess the safety and potential efficacy of the product. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND. The IND automatically becomes effective in 30 days unless the FDA, before that time, raises concerns or questions and imposes a "clinical hold." In such a case, the IND sponsor, in our case Biopure, and the FDA must resolve any outstanding concerns before the trial can proceed. Once trials have commenced, the FDA may stop the trials, or particular types of trials, by imposing a clinical hold because of concerns about, for example, the safety of the product being tested or the adequacy of the trial design.

Clinical trials involve the administration of investigational products to healthy volunteers or patients under the supervision of a qualified principal investigator consistent with an informed consent. An independent institutional review board, or IRB, or ethics committee must review and approve each clinical trial at each institution at which the study will be conducted. The IRB or ethics committee will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the drug into human subjects, the drug is usually tested for safety or adverse effects, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics. Phase II clinical trials usually involve studies in a limited patient population to evaluate the efficacy of the drug for specific, targeted indications, determine dosage tolerance and optimal dosage and identify possible adverse effects and safety risks. Phase III clinical trials generally further evaluate clinical efficacy and test further for safety within an expanded patient population and at multiple clinical sites. Phase IV clinical trials are conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication. If

the FDA approves a product, additional clinical trials may be necessary. A company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. These clinical trials are often referred to as Phase III/IV post-approval clinical trials.

We believe that our completed Phase III clinical trials are consistent with the FDA's guidance on the design and efficacy and safety endpoints required for approval of products such as Hemopure. However, the FDA could change its view or require additional data or even further clinical trials prior to approval of Hemopure.

The results of the preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the FDA in the application requesting approval to market the product. Before approving a biologic license application, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility is in compliance with current good manufacturing practices. The FDA may delay or deny approval of a biologic license application if applicable regulatory criteria are not satisfied or may require additional testing or information, and/or require postmarketing testing and surveillance to monitor safety, purity or potency of a product. It may also limit the indicated uses for which an approval is given.

New Drug Approval for Veterinary Use

New drugs for companion animals must receive New Animal Drug Application, or NADA, approval prior to being marketed in the United States. The requirements for approval are similar to those for new human drugs. Obtaining NADA approval requires preclinical studies and clinical field trials and the submission of an Investigational New Animal Drug Application, which becomes effective upon acceptance for filing.

Pervasive and Continuing Regulation

Any product approvals that are granted remain subject to continual FDA review, and newly discovered or developed safety or efficacy data may result in withdrawal of products from the market. Moreover, if and when FDA approval is obtained, the manufacture and marketing of our products remain subject to extensive regulatory requirements administered by the FDA and other regulatory bodies, including continuing 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 subject to inspection and market surveillance by the FDA for compliance with these requirements. Failure to comply with the requirements can, among other things, result in warning letters, product seizures, recalls, fines, injunctions, suspensions or withdrawals of regulatory approvals, operating restrictions and criminal prosecutions. Any such enforcement action could have a material adverse effect on us. Unanticipated changes in existing regulations or the adoption of new requirements also could have a material adverse effect on us.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substance disposal.

Foreign Regulation

We will be subject to a variety of regulations governing clinical trials and sales of our products outside the United States and are currently subject to requirements of law in South Africa. We must obtain approval of our products by the comparable non-U.S. regulatory authorities prior to the commencement of product marketing in the country whether or not we have obtained FDA approval. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. These applications require the completion of extensive preclinical and clinical studies and manufacturing and controls information.

Reimbursement

Biopure's ability to successfully commercialize its human product will depend in significant part on the extent to which reimbursement of the cost of such product and related treatment will be available from government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and there can be no assurance that adequate third-party coverage will be available to enable Biopure to maintain price levels sufficient for realization of an appropriate return on its investment in product development. The public and the federal government have recently focused significant attention on reforming the health care system in the United States. A number of health care reform measures have been suggested, including price controls on therapeutics. Public discussion of such measures is likely to continue, and concerns about the potential effects of different possible proposals have been reflected in the volatility of the stock prices of companies in the health care and related industries.

Item 2. ***Properties***

Biopure has manufacturing facilities in Pennsylvania for the collection and separation of blood and in Cambridge, Massachusetts, where processing is completed. In connection with Biopure's application for marketing approval for Oxyglobin, and again following the Company's 2002 plant expansion, the FDA inspected these facilities for compliance with good manufacturing practices. The Medicines Control Agency, on behalf of the European Medicines Evaluation Agency, also inspected Biopure's facilities prior to granting marketing approval for Oxyglobin.

Biopure manufactures separation materials in a 10,000 square foot plant in New Hampshire. The current annual lease payment for this facility is $56,000. The lease expires on March 31, 2005. Biopure has an option to extend this lease for an additional five years.

Biopure leases two facilities for office and research space in Massachusetts. One lease covers 24,000 square feet, and its current annual lease payment is $262,000. This lease expires on December 31, 2007. Biopure has an option to extend this lease for ten five-year periods, or an additional 50 years. The other lease, of office space, covers 14,000 square feet. This lease expires on February 29, 2008, and annual lease payments are $329,000.

Biopure leases 33,000 square feet of manufacturing space under four leases in Massachusetts. The current annual lease payments for these facilities is $283,000. The leases expire on November 30, 2005. Biopure has an option to extend these leases for four five-year periods, or an additional 20 years, with an exclusive right to negotiate for an additional 25 years. Biopure owns 18,000 square feet of manufacturing space in Pennsylvania. It also leases warehouse space in New Hampshire.

Biopure's current process is designed to be scalable, such that additional capacity can be obtained by adding duplicate equipment and additional raw material including power and water. In fiscal 2002, Biopure completed construction of a 1,700 square foot building abutting the existing research and manufacturing building and added utilities to maximize production in Cambridge. The Cambridge facilities as enlarged currently have the design capacity to produce approximately 75,000 units of Hemopure or 262,500 units of Oxyglobin per year, operating continuously. This plant is designed to attain capacity to produce approximately 100,000 units of Hemopure or 350,000 units of Oxyglobin per year, operating continuously, following additional validation of new product-fill equipment that was installed during the plant expansion. This capacity can be used for any combination of Oxyglobin and Hemopure units.

Biopure has purchased land and completed engineering work sufficient to support the start of construction of a new plant with a designed annual capacity of 500,000 units of Hemopure. In December 2002 Biopure signed a lease for this facility, which will be effective once financing has been completed. The site will accommodate the additional construction of a plant to supply another 500,000 units of Hemopure. Biopure believes that the engineering from this plant will be applicable to any future new plants.

Item 3. ***Legal Proceedings***

Neither the Company nor any of its subsidiaries is a party to, and none of their properties are the subject of, any pending legal proceedings.

Biopure and its former Chairman and Chief Executive Officer were named as defendants in a purported class action (resulting from the consolidation of five actions, the first of which was filed on February 5, 2002) in the U.S. District Court for the District of Massachusetts (the "Court") by alleged purchasers of Biopure's common stock and subsequently amended (the "complaints"). The complaints claimed that Biopure violated the federal securities laws by publicly disseminating materially false and misleading statements regarding the anticipated time of a biologic license application Biopure expected to make to the FDA and that Biopure failed to disclose materially adverse information regarding the data Biopure gathered in the Phase III clinical trials in support of its FDA application, resulting in the artificial inflation of Biopure's common stock price during the purported class period of May 8, 2001 through March 21, 2002. By Memorandum And Order dated September 4, 2002, the Court granted defendants' motion to dismiss in its entirety, dismissing all of plaintiffs' claims with prejudice. The plaintiffs appealed the decision but withdrew their appeal and dismissed with prejudice in return for a mutual general release, including any claim of Biopure for the recovery of Biopure's attorneys' fees.

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

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this report.

Executive Officers of the Company

The executive officers of Biopure are as follows:

Name	Age	Title
Thomas A. Moore	53	President and Chief Executive Officer
Carl W. Rausch	54	Vice Chairman and Chief Technical Officer
Maria S. Gawryl, Ph.D.	49	Senior Vice President, Research and Development
Jane Kober	59	Senior Vice President, General Counsel and Secretary
Francis H. Murphy	64	Chief Financial Officer
William A. Eudailey	58	Vice President, Marketing
Geoffrey J. Filbey	59	Vice President, Engineering
Carolyn R. Fuchs	50	Vice President, Human Resources
Douglas M. Hansell, M.D.	43	Vice President, Medical Affairs
Alain Massot	56	Vice President, International Marketing
Howard P. Richman, D.P.M.	51	Vice President, Regulatory Affairs and Compliance
Barry L. Scott	53	Vice President, International Business Development

Thomas A. Moore has been President of Biopure since July 2002. From 1996 to 2002 he was President and Chief Executive Officer of Nelson Communications, Inc., a leading medical communications company. From 1973 to 1996, he held various positions with The Procter & Gamble Company, the last of which was Group Vice President of The Procter & Gamble Company and President of Health Care Products Worldwide. He holds a B.A. degree from Princeton University. Mr. Moore is chairman of the Institute for Cancer Prevention and serves as a director of Interleukin Genetics Inc., which develops gene-based diagnostics, and of Alteon, Inc., a developer of drugs to reverse certain effects of aging.

Carl W. Rausch is a co-founder of Biopure and has served as Vice Chairman and Chief Technical Officer of Biopure since July 2002. From 1997 until 1999, Mr. Rausch was President of Biopure, and from 1984 until 2002 was Chairman and Chief Executive Officer. He holds an M.S. degree in chemical engineering from the

Massachusetts Institute of Technology and holds an M.S. degree in medical engineering and a B.S. degree in chemical engineering from Tufts University.

Maria S. Gawryl, Ph.D. has been Senior Vice President, Research and Development of Biopure since 1999. From September 1990 to April 1999, she was Vice President, Research and Development. Dr. Gawryl holds a Ph.D. in immunology from the University of Connecticut. She did post-doctoral work at the University of Connecticut Health Center and Rush Presbyterian, St. Luke's Medical Center. She holds a B.S. degree in math and chemistry from Antioch College.

Jane Kober has been Senior Vice President, General Counsel and Secretary of Biopure since 1998. From June 1989 to April 1998, she was a partner in LeBoeuf, Lamb, Greene & MacRae, L.L.P. Ms. Kober holds a J.D. degree from Case Western Reserve University, an M.A. degree from the University of Chicago and a B.A. in English from the Pennsylvania State University. She serves as a director of HTV Industries, Inc.

Francis H. Murphy has been Chief Financial Officer of Biopure since 1999. Previously, Mr. Murphy had been International Vice President and business manager for Japan, Latin America and Asia Pacific for the Corning Science Product Division of Corning Incorporated. He holds an M.B.A. degree from Boston University and a B.S. degree in industrial engineering and a B.A. degree from Rutgers University.

William A. Eudailey became Vice President, Marketing, in February 2000. From 1996 through 1999, Mr. Eudailey was Vice President of Separations Business of Corning Incorporated, and from 1995 to 1996 he was Vice President Worldwide Marketing for the Science Products Division of Corning Incorporated. He holds a Pharm.D. degree and a B.S. in pharmacy from the University of Tennessee College of Pharmacy.

Geoffrey J. Filbey joined Biopure in 1985 and has served as Vice President, Engineering since 1995. Mr. Filbey holds a B.Sc. degree in engineering from the City University in London, England.

Carolyn R. Fuchs has served as Vice President, Human Resources since 1998. From October 1996 to June 1998, she was an independent consultant. From May 1991 to October 1996, she worked at National Medical Care. Ms. Fuchs holds a M.Ed. degree in counseling and a B.S. degree in psychology from the University of Massachusetts at Amherst.

Douglas M. Hansell joined Biopure as Vice President, Medical Affairs, in January 2003. From February 2001 until joining Biopure he was a visiting physician and assistant anesthetist at Massachusetts General Hospital, Harvard University, where he was engaged in fellow, resident and medical student education and evaluation. From 1999 to 2000 he was Chief Medical Officer and Vice President for Medical Affairs of the Emerson Health System, a hospital and affiliated entities in Concord, Massachusetts. From 1992 to 1999 he was a visiting physician and assistant anesthetist at Massachusetts General Hospital, Harvard University. He holds the B.S. and M.D. degrees from the University of Illinois and a Master of Public Health degree from Harvard University.

Alain Massot joined Biopure as Vice President, International Marketing in 2000. From 1995 to 2000, Mr. Massot was a consultant in international market development to biotechnology and high technology companies. From 1993 to 1996, Mr. Massot was Senior Vice President, International PerSeptive Biosystems, Inc. Mr. Massot holds an M.S. in chemical engineering from the Sorbonne University and holds degrees in computer programming.

Howard P. Richman joined Biopure as Vice President, Regulatory Affairs and Compliance in 2001. From 1998 to 2001, Dr. Richman worked for MacroChem, where he was Senior Director of Regulatory Affairs, Quality Assurance, and Chemistry Manufacturing and Controls. From January 1998 to June 1998, Dr. Richman was Senior Director of Clinical and Regulatory Affairs at Synsorb Biotech. From 1993 to 1998, he was Director of Regulatory Affairs, Regulatory Compliance, and Business Development at Covance Clinical and Periapproval Services, Inc. From 1991 to 1993, Dr. Richman served as a pharmaceutical consultant to the FDA. He holds a D.P.M. degree from New York College of Podiatric Medicine and a B.S. degree in chemistry and biology from St. John's University.

Barry L. Scott has been Vice President, International Business Development since June, 2002. From 1998 until 2002 Mr. Scott worked for Bristol-Myers Squibb Company, most recently as Vice President,

International Business Development, Europe. From 1996 until 1998 he was the general manager of Bristol-Myers Squibb, Ltd., South Africa. Mr. Scott holds the Diploma in Education from the University of Rhodesia and the Diploma in Marketing Management from the Institute of Marketing Management, South Africa.

PART II

Item 5. ***Market for Registrant's Common Equity and Related Stockholder Matters***

(a) *Market Information.* The Company's Class A Common Stock is traded on The NASDAQ Stock Market under the trading symbol "BPUR." There is no established public trading market for the Class B Common Stock.

The following table sets forth the high and low sale prices for the Class A Common Stock for each of the quarters in the two years ended October 31, 2002, as reported by The NASDAQ Stock Market.

	High	Low
Year Ended October 31, 2001		
First Quarter	$28.25	$17.25
Second Quarter	27.48	10.63
Third Quarter	32.70	19.46
Fourth Quarter	26.50	16.25
Year Ended October 31, 2002		
First Quarter	20.30	8.75
Second Quarter	13.26	6.14
Third Quarter	8.95	4.95
Fourth Quarter	8.00	3.20

(b) *Holders.* As of December 31, 2002 there were 648 holders of record of the Class A Common Stock.

(c) *Dividends.* The Company did not pay dividends on its Class A Common Stock during the two fiscal years ended October 31, 2002 and does not plan to pay dividends on its Class A Common Stock in the foreseeable future. The Class B Common Stock is not entitled to dividends.

Item 6. ***Selected Financial Data***

Set forth below is selected financial data for the five years ended October 31, 2002.

	Fiscal Year Ended October 31,				
	2002	2001	2000	1999	1998
	(In thousands, except per share data)				
Statements of Operations Data:					
Total revenues	$ 1,989	$ 3,489	$ 3,063	$ 2,866	$ 1,131
Cost of revenues	7,401	3,665	4,778	6,814	1,543
Gross profit (loss)	(5,412)	(176)	(1,715)	(3,948)	(412)
Operating expenses:					
Research and development	25,982	34,609	26,378	24,166	22,950
Sales and marketing	3,028	2,807	2,463	2,922	2,444
General and administrative	12,235	15,365	9,878	5,266	4,660
Total operating expenses	41,245	52,781	38,719	32,354	30,054
Loss from operations	(46,657)	(52,957)	(40,434)	(36,302)	(30,466)
Total other income, net	874	3,538	4,356	772	419
Net loss	(45,783)	(49,419)	(36,078)	(35,530)	(30,047)
Stock dividends on preferred stock	—	—	—	(17,915)	—
Net loss applicable to common stockholders	$(45,783)	$(49,419)	$(36,078)	$(53,445)	$(30,047)
Basic net loss per common share	$ (1.66)	$ (1.97)	$ (1.51)	$ (3.61)	$ (2.41)
Weighted-average common shares outstanding	27,582	25,066	23,947	14,813	12,460
Pro forma basic net loss per common share				$ (2.62)	$ (1.65)
Pro forma weighted-average common shares outstanding				20,369	18,237

	At October 31,				
	2002	2001	2000	1999	1998
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$19,710	$36,089	$88,828	$30,778	$6,063
Total current assets	28,536	42,249	95,920	38,277	13,175
Working capital	22,347	35,952	84,928	27,872	1,986
Net property and equipment	38,769	30,162	25,061	27,447	29,606
Total assets	78,277	84,187	121,287	66,230	44,848
Long-term debt (including current portion)	9,847	5,205	—	—	6,000
Common stock to be repurchased	—	—	—	—	6,300
Total stockholders' equity	62,057	70,893	108,510	54,037	21,449

The following is a summary of quarterly (unaudited) financial results:

	4Q '02	3Q '02	2Q '02	1Q '02	4Q '01	3Q '01	2Q '01	1Q '01
	(In thousands, except per share data)							
Statements of Operations Data:								
Total revenues	$ 73	$ 260	$ 928	$ 728	$ 970	$ 946	$ 838	$ 735
Gross profit (loss)	(3,023)	(2,299)	9	(99)	(108)	43	(76)	(35)
Operating expenses:								
Research and development	3,794	7,063	8,153	6,972	7,123	10,297	9,002	8,187
Sales and marketing	1,075	875	615	463	737	784	664	622
General and administration	2,932	2,569	4,129	2,605	2,001	1,538	8,753	3,073
Total operating expenses	7,801	10,507	12,897	10,040	9,861	12,619	18,419	11,882
Loss from operations	(10,824)	(12,806)	(12,888)	(10,139)	(9,969)	(12,576)	(18,495)	(11,917)
Other income, net	53	210	161	450	578	654	990	1,316
Net loss	$(10,771)	$(12,596)	$(12,727)	$ (9,689)	$(9,391)	$(11,922)	$(17,505)	$(10,601)
Per share data:								
Basic net loss per common share	$ (0.36)	$ (0.43)	$ (0.49)	$ (0.38)	$ (0.37)	$ (0.47)	$ (0.70)	$ (0.42)
Weighted-average shares used in computing basic net loss per common share	29,742	29,141	25,993	25,401	25,208	25,134	24,958	24,960

In the third quarter of fiscal 2001, research and development expenses include a one-time expense of $1,604,000, of which $1,511,000 is non-cash, for intellectual property and pre-clinical studies related to the acquisition of Reperfusion Systems, Inc., an inactive company 26% owned by Biopure.

General and administrative expenses include non-cash compensation expense for stock options and warrants granted to certain consultants and directors. This non-cash compensation must be accounted for at fair value, per SFAS 123 and EITF 96-18, and be amortized over the vesting period and revalued each quarter based on the closing stock price. The quarterly expenses/(credits) to operations for fiscal 2002 were $16,000, $55,000, $13,000 and ($145,000) for the fourth, third, second and first quarters, respectively. The quarterly expenses/(credits) to operations for fiscal 2001 were ($80,000), ($793,000), $6,370,000 and $1,347,000 for the fourth, third, second and first quarters, respectively.

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

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 its oxygen therapeutic products, 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, accumulating deficits, 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 set forth in Exhibit 99.1 to this report 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 as an alternative to red blood cell transfusion. On July 31, 2002, we submitted a biologic license application (BLA) to the FDA seeking regulatory approval to market Hemopure in the United States for a similar indication in patients undergoing orthopedic surgery. The FDA has accepted and is reviewing this application. We are also developing 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 Europe Union, where it is indicated for the treatment of anemia in dogs.

During 2002 we completed the expansion of our existing manufacturing facilities, and in December 2002 we signed a lease for a proposed manufacturing facility that, when constructed, will further expand the Company's production capacity.

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 $381.6 million as of October 31, 2002. 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 January 27, 2003, are sufficient to fund our fiscal 2003 operating plan through more than half of the second quarter of fiscal 2003. Under this plan, our operations for the balance of fiscal 2003 will be to fund the ramp up of production of Hemopure and Oxyglobin at our manufacturing facility in Cambridge, Massachusetts, market development for Hemopure, sales and marketing expenses for Oxyglobin in the United States and Europe and continuation of clinical development for additional Hemopure indications. Additional expenditures not included in our fiscal 2003 operating plan, including the costs of increasing personnel and clinical development of additional indications for Hemopure, will be deferred until sufficient funds, in addition to those on hand, are available. Because the Company's funds on hand at January 27, 2003 and forecast sales are 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, the issuance of debt securities, strategic alliances and other financing vehicles.

Critical Accounting Policies

The Company's significant accounting policies are described in the Notes to the Consolidated Financial Statements. The application of our critical accounting policies is particularly important to the 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 meet these characteristics and 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 121 (and SFAS 144, applicable in fiscal 2003) require 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 or impairment of its long-lived assets existed at October 31, 2002.

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, which 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. Sales of Hemopure to South Africa are expected to begin in fiscal 2003 and also will be through an importer/distributor. 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.

Results of Operations

Fiscal Years Ended October 31, 2002 and 2001

Total revenues, almost entirely from Oxyglobin sales, were $2.0 million compared to $3.5 million in fiscal 2001. The decrease in Oxyglobin sales is due to our having an insufficient supply of inventory resulting from the expansion and revalidation of Biopure's manufacturing facilities. We have been allocating Oxyglobin produced before the expansion to our largest customers, and as of October 31, 2002, had backorders of more than 9,000 units, or approximately $1.0 million in anticipated revenue. We expect to fill backorders in fiscal 2003 following regulatory clearance to ship product manufactured at the revalidated facilities.

Cost of revenues totaled $7.4 million compared to $3.7 million in fiscal 2001. The increase is due to costs associated with the shut-down of our Cambridge manufacturing facility in November 2001 for capacity expansion. During the six-month shutdown, we had negative gross margins for Oxyglobin sales resulting from an allocation of unabsorbed manufacturing costs. The remainder of these fixed costs were allocated to research and development. The above allocations were based on current and expected production levels and annual production capacities and required management judgment. When production resumed in May 2002, because we began producing Hemopure for sale to South Africa, the allocation of unabsorbed fixed manufacturing costs to research and development stopped and all costs were charged to cost of revenues or inventory. Cost of revenues for the last half of fiscal 2002 reflects manufacturing inefficiencies during ramp-up of the expanded facilities. Unit production costs that exceeded the net realizable value were charged to cost of revenues.

Inventory reserves were increased by $1.2 million at October 31, 2002 above our usual allowances for slow-moving and obsolete inventory to cover:

- production lots that are not rejected but are undergoing additional review;
- product in inventory at October 31, 2002 that was subsequently rejected per the Company's pre-release quality control procedures; and
- the possibility that delays in shipping could affect the saleability of product in inventory.

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 efforts have focused on developing and gaining regulatory approval of Hemopure, our product for use in humans. In fiscal 2002, we completed data analysis and filed our biologic license application for Hemopure with the FDA. The development and approval of Oxyglobin, our veterinary product, was a result of the development of Hemopure. Hemopure is approved for use in South Africa. Failure to gain one or more additional regulatory approvals during the next several years would make it difficult for the Company to continue its development efforts.

Research and development expenses decreased 24.9% to $26.0 million in fiscal 2002 from fiscal 2001. This decrease was due to a $6.7 million reduction in expenses for activities associated with data organization and analyses for the Phase III orthopedic surgery trial of Hemopure, a $1.6 million reduction in expenses for preclinical studies, and a $2.2 million reduction in the allocation of unabsorbed fixed manufacturing costs, as described above. Expenses in 2001 also included a one-time expense of $1.6 million, of which $1.5 million was non-cash, for research and preclinical studies related to the acquisition in May 2001 of the balance of an inactive company previously 26% owned by Biopure. The decrease in expenses was partially offset by an increase of approximately $3.4 million for preparing the BLA for Hemopure that was submitted to the FDA on July 31, 2002.

Sales and marketing expenses increased 7.9% to $3.0 million in fiscal 2002. Initial market development expenses for Hemopure were classified as general and administrative expenses for the first half of fiscal 2002. Hemopure marketing expenses of $1.0 million are included in sales and marketing expenses for the second half of fiscal 2002, because Hemopure is approved for sale in South Africa. Oxyglobin sales and marketing expenses decreased $781,000 to $2.0 million for fiscal 2002, in line with the decrease in sales volume. This decrease is primarily due to reductions in veterinary educational programs in fiscal 2002.

General and administrative expenses decreased 20.4% to $12.2 million in fiscal 2002. This decrease is due largely to fiscal 2001 non-cash charges of $6.8 million for stock options and warrants issued to non-employees that vested fully in fiscal 2001. This non-cash compensation was accounted for at fair value, per SFAS 123 and EITF 96-18. Excluding the effects of the non-cash compensation charges, expenses for fiscal 2002 increased by $3.8 million primarily due to an expense of $1.3 million for product shipped to South Africa for use in a pre-launch medical education program and increased information technology and consulting expenses compared to fiscal 2001.

Total other income, net, consists of interest income and other non-product related income partially offset by interest expense. Included in other income, net, for fiscal 2002 is $238,000 received as a contingent payment for a 1998 intellectual property transfer not related to Hemopure or Oxyglobin. Total other income, net, was $874,000 in fiscal 2002 compared to $3.5 million in fiscal 2001. This decrease was attributable to the Company's decreased cash balance and lower interest rates. We anticipate a decrease in other income in fiscal 2003.

Basic and diluted net loss per common share for fiscal 2002 decreased to $1.66 from $1.97 per share in 2001. For fiscal 2002, non-cash compensation expense for stock options and warrants previously issued to non-employees was a credit of $61,000 compared to an expense of $6.8 million, or $0.27 per share for fiscal 2001. Shares used to calculate these losses were the actual weighted-average number of common shares outstanding during 2002 of 27,582,301 and 25,066,132 for 2001. Diluted net losses per share equals basic earnings per share because the Company had losses from all periods.

Fiscal Years Ended October 31, 2001 and 2000

Total revenues, almost entirely from Oxyglobin sales, increased 13.9% to $3.5 million in fiscal 2001. Revenues in fiscal 2001 included the launch of Oxyglobin in Europe resulting in $173,000 in sales to our European distributors. Domestic sales increased 8.2% resulting from a 1.5% increase in unit sales and an increase in the average selling price per unit of 6.6%.

Cost of revenues totaled $3.7 million in fiscal 2001, a decrease of 23.3% from fiscal 2000. The decrease is due to increased manufacturing activity associated with the development of Hemopure and the resulting decrease in manufacturing expenses allocated to Oxyglobin. Cost of revenues in fiscal 2001 and 2000 reflects the direct costs associated with the production of Oxyglobin plus an allocation of a portion of the unabsorbed fixed costs of manufacturing. An allocation of these unabsorbed costs was also made to Hemopure units in finished goods inventory. The remainder of these fixed costs and the direct costs of production of clinical trial materials were allocated to research and development. The above allocations are based on current and expected production levels and annual production capacities and require management judgment. Our Cambridge manufacturing facility was shut down in November 2001 for a capacity upgrade.

Research and development expenses include product and process development and engineering, pre-clinical studies, clinical trials, clinical trial materials and an allocation of unabsorbed fixed costs of manufacturing. Our research and development efforts have been focused on developing and gaining regulatory approval of Hemopure, our product for use in humans. The development and approval of Oxyglobin, our veterinary product, was a result of the development of Hemopure. Hemopure is approved for use in South Africa. Failure to gain one or more additional regulatory approvals during the next several years would make it difficult for the Company to continue its development efforts.

Research and development expenses increased 31.2% to $34.6 million in fiscal 2001. The increase was due to activities associated with data organization and analyses for the pivotal Phase III clinical trial of Hemopure, preparation for the filing of an electronic U.S. marketing application, ongoing research and development and an increase in the allocation of fixed costs of unused production capacity. Expenses in 2001 also included a one-time non-cash expense of $1.5 million for research and pre-clinical studies related to the acquisition in May of Reperfusion Systems, Inc., an inactive company previously 26% owned by Biopure, for approximately 67,000 shares of Biopure common stock and $55,000 in cash.

Sales and marketing expenses, consisting of Oxyglobin expenses, increased to $2.8 million, or 14.0% in fiscal 2001. This increase was primarily due to selling, marketing and distribution expenses associated with the launch of Oxyglobin in Europe during 2001.

General and administrative expenses increased 55.6% to $15.4 million in fiscal 2001. This increase is primarily due to a $3.1 million increase in non-cash compensation expense for stock options and warrants granted to our South African distributor, consultants and two directors. This non-cash compensation was accounted for at fair value, per SFAS 123 and EITF 96-18. Prelaunch expenses for Hemopure, increased premiums for insurance and increased spending on corporate communications also contributed to the increase in 2001.

Total other income consists primarily of interest income and other non-product related income partially offset by interest expense. Total other income was $3.5 million in fiscal 2001 compared to $4.4 million in fiscal 2000. This decrease was attributable to the Company's decreased cash balance and lower interest rates.

Basic and diluted net loss per common share for fiscal 2001 increased to $1.97 from $1.51 per share in 2000. Shares used to calculate these losses were the actual weighted-average number of common shares outstanding during 2001 of 25,066,132 and 23,947,251 for 2000. Diluted net losses per share are not presented because the Company had losses from all periods.

Liquidity and Capital Resources

At October 31, 2002, we had $19.7 million in cash and cash equivalents and from November 1, 2002 through January 27, 2003, we have raised $1.9 million through the sale of equity as discussed below. Based on

our fiscal 2003 operating plan, we require approximately $55 million to attain production of Hemopure and Oxyglobin at full-capacity at our expanded Cambridge manufacturing facility, market development for Hemopure, sales and marketing expenses for Oxyglobin in the United States and Europe and continuation of clinical development for additional Hemopure indications. We believe our cash and cash equivalents at January 27, 2003, are only sufficient to fund operations according to our fiscal 2003 operating plan through more than half of the second quarter of fiscal 2003. External cash requirements are expected to be lower during the last half of fiscal 2003 because of anticipated Hemopure product sales. Additional expenditures not included in our fiscal 2003 operating plan, including the costs of personnel and clinical development of additional indications for Hemopure, will be deferred until sufficient funds, in addition to those on hand, are available. Because the Company's funds on hand at January 27, 2003 and forecast sales are not sufficient to fund its 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, the issuance of debt securities, 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.

We raised $35.5 million through sales of Class A Common Stock in fiscal 2002. In the first quarter of fiscal 2002, we drew net proceeds of $6.6 million under an equity line stock purchase agreement with Societe Generale as further described below. On April 23, 2002, the Company raised net proceeds of $19.7 million from a sale of registered shares. We realized an additional $4.9 million in net proceeds from another sale of registered shares on May 9, 2002. On September 19, 2002, we raised net proceeds of $4.3 million from a sale of registered shares. On December 31, 2002, we raised $1.9 million in a private placement.

We used $44.1 million of cash in operating activities in fiscal 2002. The principal uses of cash in fiscal 2002 were to fund our net loss of $45.8 million and the increase of Oxyglobin and Hemopure inventory of $3.4 million, partially offset by $4.6 million of depreciation and amortization.

We used $7.6 million of cash in investing activities in fiscal 2002. The principal uses for this purpose were to purchase property, plant and equipment, $2.8 million to complete the Cambridge manufacturing expansion and $2.9 million for detailed engineering work for the planned manufacturing facility in South Carolina.

In December 2001, the Company signed an amended letter of intent with Sumter Realty Group, LLC for the construction and financing of a 500,000-unit Hemopure plant in South Carolina expected to cost $120 million. Sumter Realty Group, LLC has accepted a letter of commitment from a potential investor for the full $120 million required to finance construction of the new manufacturing facility in South Carolina. In December 2002, Biopure signed a lease agreement with Sumter Realty Group, LLC (the Lease). In addition, the Company also expects to issue a warrant to purchase up to 2.5 million shares of Class A Common Stock at $0.01 per share, exercisable five years from the start of construction and is committed to pay a finder's fee, of approximately 2 percent of the net amount financed, to a consultant when financing for the facility is completed. Under the terms of the Lease, minimum lease payments will start at substantial completion of the facility, which the Company expects to be in the beginning of fiscal 2005. The annual lease payments will be $13.8 million per year for the first two years and $17.2 million per year for the balance of the 25-year term. At the conclusion of the 25-year term, the Company will own the facility. The terms of the Lease are subject to financial closing and construction beginning within 75 days of the date of the lease. The Company can cancel the lease if the definitive financing documentation is not acceptable or based on the outcome of continuing site assessment. The lease will be void if the financing is not completed. Subject to diligence and definitive documentation, closing and start of construction could occur in early calendar year 2003.

As of October 31, 2002, $12.8 million has been included in property, plant and equipment and $9.8 million in long-term debt reflecting expenses to date for the engineering and design costs of the planned manufacturing facility in Sumter, S.C. Through December 2002, the Company incurred an additional $500,000 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 2005. The total $13.3 million of expenditures by the Company will be returned as described below.

During fiscal 2001, we paid $10 million, Biopure's initial contribution to the cost of the facility, into an escrow account to fund certain initial expenditures related to the construction of the new facility. Under the proposed agreement for the construction and financing of the new plant, the $10 million in project cost funded by Biopure is expected to be refunded upon receipt of FDA approval for Hemopure and if a final lease agreement has been executed. The $10 million has been accounted for as a deposit in long-term assets as of October 31, 2002. If FDA approval is not received, the $10 million deposit 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. 121 (and SFAS No. 144, applicable in fiscal 2003). Under the terms of the Lease, Sumter Realty Group, LLC will refund the $3.3 million of additional spending by the Company in fiscal 2003 once financing is completed.

Biopure is a party to a $75 million equity line stock purchase agreement with Societe Generale. Under this agreement, Biopure would have the option of drawing up to a remaining balance of $67.8 until June 2003, if conditions under the agreement were met, in exchange for the issuance of Biopure common stock. As of January 27, 2003, the Company had drawn net proceeds of $6.6 million, all in the first quarter of fiscal 2002, under this agreement. The Company is currently unable to raise funds through this agreement because its recent stock prices have been below the minimum price of $13 per share specified in the agreement.

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 licensing and partnering arrangements where appropriate. We have not been profitable since inception and had an accumulated deficit of $381.6 million as of October 31, 2002. We will continue to generate losses for the next several years.

We plan to spend approximately $5.0 million in the period fiscal 2003 to fiscal 2004 on capital projects for our existing facilities. The fiscal 2003 planned expenditures are included in the cash requirements identified above.

The following table summarizes the Company's significant contractual obligations at October 31, 2002:

	Payments Due by Period			
	Less than 1 year	1-3 years	4-5 years	Total
	(In thousands)			
Operating leases	$1,023	$2,612	$745	$4,380

As of October 31, 2002, we had net operating loss carryforwards of approximately $225.6 million 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 October 31, 2002. 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

In August 2001, the FASB issued SFAS No. 144, "*Accounting for the Impairment or Disposal of Long-Lived Assets*." This statement supercedes SFAS No. 121, "*Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*," and certain accounting and reporting provisions of Accounting Principles Board (APB) Opinion No. 30, "*Reporting the Results of Operations — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*." Statement 144 requires that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and it broadens the presentation of discontinued operations to include more disposal transactions. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption permitted. We do not believe the adoption of this statement will have a material impact on our results of operations or financial position.

SFAS No. 146, "*Accounting for Costs Associated with Exit or Disposal Activities*", issued in July 2002, addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies

EITF Issue No. 94-3, "*Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*." The principal difference between Statement 146 and Issue 94-3 relates to Statement 146's requirements for recognition of a liability for a cost associated with an exit or disposal activity. Statement 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit costs as generally defined in Issue 94-3 was recognized at the date of an entity's commitment to an exit plan. Therefore, this Statement eliminates the definition and requirements for recognition of exit costs in Issue 94-3. This Statement also established that fair value is the objective for initial measurement of the liability. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. We do not believe the adoption of this statement will have a material impact on our results of operations or financial position.

FASB Interpretation No. 45, "*Guarantor Accounting,*" will significantly change 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 current practice. In addition, guarantors will be 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. We do not believe the adoption of this statement will have a material impact on our results of operations or financial position.

At the November 21, 2002 meeting, the Energy Issues Task Force reached a consensus on Issue 00-21, *"Accounting for Revenue Arrangements with Multiple Deliverables,"* which addresses how to account for arrangements that may involve the delivery or performance of multiple products, services, and/or rights to use assets. The final consensus will be applicable to agreements entered into in fiscal periods beginning after June 15, 2003 with early adoption permitted. Additionally, companies will be permitted to apply the consensus guidance to all existing arrangements as the cumulative effect of a change in accounting principle in accordance with APB Opinion No. 20, Accounting Changes. Following is a brief summary of the final model approved by the Task Force.

Revenue arrangements with multiple deliverables should be divided into separate units of accounting if the deliverables in the arrangement meet the following criteria:

- The delivered item(s) has value to the customer on a standalone basis. That item(s) has value on a standalone basis if it is sold separately by any vendor or the customer could resell the deliverable on a standalone basis. In the context of a customer's ability to resell the deliverable, the Task Force observed that this criterion does not require the existence of an observable market.

- There is objective and reliable evidence of the fair value of the undelivered item(s).

- If the arrangement includes a general right of return, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the vendor.

- Arrangement consideration should be allocated among the separate units of accounting based on their relative fair values. The amount allocated to the delivered item(s) is limited to the amount that is not contingent on the delivery of additional items or meeting other specified performance conditions.

- Applicable revenue recognition criteria should be considered separately for separate units of accounting.

The Company does not believe the adoption of EITF 00-21 will have a material impact on its results of operations or financial position.

Item 7A. ***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 clinical trial and regulatory activities outside of the United States. Biopure sells Oxyglobin to its European distributors and plans to sell Hemopure to its 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.

Item 8. ***Financial Statements and Supplementary Data***

The response to this item is submitted as a separate section of this report commencing on Page F-1.

Schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable, and therefore have been omitted.

Item 9. ***Changes In and Disagreements With Accountants on Accounting and Financial Disclosure***

Not applicable.

PART III

The information required by Item 10 — Directors and Executive Officers of the Registrant; Item 11 — Executive Compensation; Item 12 — Security Ownership of Certain Beneficial Owners and Management; and Item 13 — Certain Relationships and Related Transactions is incorporated into Part III of this Annual Report on Form 10-K by reference to the Company's Proxy Statement for the Annual Meeting of Stockholders scheduled to be held on April 2, 2003.

Item 14. ***Controls and Procedures***

We currently have in place systems relating to disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) of the Securities Exchange Act of 1934). The Company's principal executive officer and its principal financial officer evaluated the effectiveness of these disclosure controls and procedures in connection with the preparation of this annual report. They concluded that the controls and procedures are effective and adequate at this time. There were no significant changes in the Company's internal controls or in other factors that could significantly affect the controls subsequent to the date of their evaluation.

Item 15. ***Exhibits, Financial Statement Schedules, and Reports on Form 8-K***

(a)(1) and (2). The response to this portion of Item 15 is submitted as a separate section of this report commencing on page F-1.

(a)(3) The exhibits are set forth in the exhibit index. Following are the management contracts, compensatory plans and arrangements filed as exhibits:

Ex. 10.5	Promissory Note dated July 31, 1995, from Maria Gawryl.
Ex. 10.6	Amended and Restated Stock Purchase Agreement between Biopure and Maria Gawryl.
Ex. 10.7	Employment Agreement dated as of June 25, 2002 between Biopure and Thomas A. Moore.
Ex. 10.14	Option dated as of June 25, 2002, in favor of Thomas A. Moore.
Ex. 10.15	Employment Agreement dated as of July 29, 2002, between Biopure and Carl W. Rausch.
Ex. 10.16	Promissory Note dated July 29, 2002, from Carl Rausch.
Ex. 10.17	1998 Stock Option Plan.
Ex. 10.18	Agreement re: Loan dated July 29, 2002, between Biopure and Carl Rausch.
Ex. 10.20	Deferred Compensation Agreement dated July 29, 2002 between Biopure and Carl Rausch.

(b) The Company filed no reports during the fourth quarter of fiscal 2002.

(c) Exhibits are set forth on the following exhibit index.

(d) Not applicable.

EXHIBIT INDEX

Exhibit No.	Description	Location
3.1(1)	Restated Certificate of Incorporation of Biopure	***
3(ii)	By-laws of Biopure, as amended	*
10.1	Lease Agreement dated as of December 24, 2002, between Biopure and Sumter Realty Group, LLC	#
10.2	Agreement between Biopure and Moyer Packing Company dated October 21, 1994	*
10.3	Agency Agreement between Biopure and The Butler Company dated March 29, 1999	*
10.4	2002 Omnibus Securities and Incentive Plan	*##
10.5	Promissory Note dated July 31, 2000, from Maria Gawryl in favor of Biopure	#
10.6	Amended and Restated Stock Purchase Agreement between Biopure and Maria Gawryl dated as of May 1, 1999	##
10.7	Employment Agreement dated as of June 25, 2002 between Biopure and Thomas A. Moore	*###
10.8	Lease Agreement dated October 12, 1990, between Biopure and Tarvis Realty Trust	*
10.9	Sublease between Cendant Operations, Inc. and Biopure Corporation dated June 20, 2001	**##
10.10	License Agreement for Waste Disposal System between Moyer Packing Company and Biopure Corporation dated June 12, 2001	**##
10.11	Lease Agreement dated August 29, 1994, between Biopure and Eleven Hurley Street Associates	*
10.12	Lease Agreement dated May 10, 1994, between Biopure and Tarvis Realty Trust	*
10.13	Lease Agreement dated August 23, 1994, between Biopure and Tarvis Realty Trust	*
10.14	Option dated as of June 25, 2002, in favor of Thomas A. Moore	*###
10.15	Employment Agreement with Carl Rausch dated as of July 29, 2002	*###
10.16	Promissory Note dated July 29, 2002 from Carl Rausch	*###
10.17	1998 Stock Option Plan	*
10.18	Agreement re loan dated July 29, 2002 between the Company and Carl Rausch	*###
10.19	Amended and Restated Equity Line Financing Agreement dated October 23, 2001, by and between Biopure Corporation and Société Generale	*#
10.20	Deferred Compensation Agreement dated July 29, 2002 between Biopure and Carl Rausch	*###
10.21	Employment Agreement Concerning Protection of Company Property and the Arbitration of Legal Disputes	*
10.22	Rights Agreement between Biopure and American Stock Transfer& Trust Company dated September 21, 1999	**
10.23	Amended and Restated 1999 Omnibus Securities and Incentive Plan dated as of February 14, 2000	***
10.24	License Agreement for Spur Facility between Moyer Packing Company and Biopure Corporation dated June 12, 2001	**##
10.25	Assignment and Assumption of Deed of Easement between Moyer Packing Company and Biopure Corporation dated June 12, 2001	**##
10.26	Distribution Agreement between the Company and Network Healthcare Holdings Limited	**#
10.27	Amendment to [Distribution] Agreement between the Company, Network Healthcare Holdings Limited and Tshepo Pharmaceuticals (Pty) Limited	**#
10.28	Letter Agreement between the Company and Network Healthcare Holdings Limited	**#

Exhibit No.	Description	Location
10.29	Letter Agreement between the Company and Scanix Six (Pty) Ltd.	**#
23	Consent of Independent Auditors	#
99.1	Factors to Consider in Connection with Forward-Looking Statements	#
99.2	Certification of Thomas A. Moore pursuant to 18 U.S.C. Section 1350	#
99.3	Certification of Francis H. Murphy pursuant to 18 U.S.C. Section 1350	#

#	Filed herewith.
##	Previously filed as an exhibit to the Company's report on Form 10-K for the year ended October 31, 2000.
###	Previously filed as an exhibit to the Company's report on Form 8-K dated June 21, 2001 and incorporated herein by reference thereto.
*	Previously filed as an exhibit to the Company's Registration Statement on Form S-1 (File No. 333-78829) and incorporated herein by reference thereto.
**	Previously filed as an exhibit to the Company's Report on Form 8-A dated November 4, 1999 and incorporated herein by reference thereto.
***	Previously filed as an exhibit to the Company's Registration Statement on Form S-1 (File No. 333-30382) and incorporated herein by reference thereto.
*#	Previously filed as an exhibit to the Company's Registration Statement on Form S-3 (File No. 333-66464) and incorporated herein by reference thereto.
**#	Previously filed as an exhibit to the Company's report on Form 10-Q for the quarter ended April 30, 2001.
**##	Previously filed as an exhibit to the Company's report on Form 10-Q for the quarter ended July 31, 2001.
*##	Previously filed as an exhibit to the Company's report on Form 10-Q for the quarter ended April 30, 2002.
*###	Previously filed as an exhibit to the Company's report on Form 10-Q for the quarter ended July 31, 2002.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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

By: /s/ FRANCIS H. MURPHY
Francis H. Murphy
Chief Financial Officer

Dated: January 29, 2003

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ CHARLES A. SANDERS, M.D. Charles A. Sanders, M.D.	Director, Chairman of the Board	January 29, 2003
/s/ DAVID N. JUDELSON David N. Judelson	Director, Vice Chairman	January 29, 2003
/s/ CARL W. RAUSCH Carl W. Rausch	Director, Vice Chairman	January 29, 2003
/s/ THOMAS A. MOORE Thomas A. Moore	Director, President (Chief Executive Officer)	January 29, 2003
/s/ DANIEL P. HARRINGTON Daniel P. Harrington	Director	January 29, 2003
/s/ C. EVERETT KOOP, M.D. C. Everett Koop, M.D.	Director	January 29, 2003
/s/ J. RICHARD CROUT, M.D. J. Richard Crout, M.D.	Director	January 29, 2003
/s/ FRANCIS H. MURPHY Francis H. Murphy	Chief Financial Officer, Principal Accounting Officer	January 29, 2003

CERTIFICATIONS

I, Thomas A. Moore, certify that:

1. I have reviewed this annual report on Form 10-K of Biopure Corporation;

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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 annual 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 annual report (the "Evaluation Date"); and

c) presented in this annual 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 annual 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: January 29, 2003

/s/ THOMAS A. MOORE

Thomas A. Moore
Chief Executive Officer

I, Francis H. Murphy, certify that:

1. I have reviewed this annual report on Form 10-K of Biopure Corporation;

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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 annual 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 annual report (the "Evaluation Date"); and

c) presented in this annual 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 annual 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: January 29, 2003

/s/ Francis H. Murphy

Francis H. Murphy
Chief Financial Officer

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

Board of Directors and Stockholders
Biopure Corporation

We have audited the accompanying consolidated balance sheets of Biopure Corporation (the Company) as of October 31, 2002 and 2001, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended October 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Biopure Corporation as of October 31, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended October 31, 2002, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 to the consolidated financial statements, 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. Management's plans as to these matters are described in Note 1. The 2002 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Boston, Massachusetts
December 9, 2002, except for
Note 12, as to which the date
is December 31, 2002

BIOPURE CORPORATION
CONSOLIDATED BALANCE SHEETS

	October 31, 2002	October 31, 2001
	(In thousands, except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,710	$ 36,089
Accounts receivable, less allowance of $8 and $40 at October 31, 2002 and 2001, respectively	89	724
Inventories, net	8,028	4,665
Other current assets	709	771
Total current assets	28,536	42,249
Property, plant and equipment:		
Land	401	262
Equipment	36,436	30,252
Leasehold improvements	15,884	14,207
Furniture and fixtures	1,025	973
Construction in progress	500	2,976
New facility construction	12,757	5,205
	67,003	53,875
Accumulated depreciation and amortization	(28,234)	(23,713)
Net property, plant and equipment	38,769	30,162
Investment in affiliate	—	32
Deposit on new facility	10,000	10,000
Other assets	972	1,744
Total assets	$ 78,277	$ 84,187
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,163	$ 1,348
Accrued expenses	4,026	4,949
Total current liabilities	6,189	6,297
Long-term liabilities:		
Long-term debt	9,847	5,205
Deferred compensation	184	1,792
Total long-term liabilities	10,031	6,997
Commitments and contingencies, Notes 7 and 11.		
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, 30,353,370 and 25,225,083 shares issued and outstanding at October 31, 2002 and 2001, respectively	304	252
Class B, $1.00 par value, 179 shares authorized, 117.7 shares issued and outstanding	—	—
Capital in excess of par value	419,065	383,570
Contributed capital	24,574	24,574
Notes receivable from stockholders	(255)	(1,655)
Accumulated deficit	(381,631)	(335,848)
Total stockholders' equity	62,057	70,893
Total liabilities and stockholders' equity	$ 78,277	$ 84,187

See accompanying notes

BIOPURE CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended October 31,		
	2002	2001	2000
	(In thousands, except share and per share data)		
Revenues:			
Oxyglobin	$ 1,988	$ 3,482	$ 3,058
Other	1	7	5
Total revenues	1,989	3,489	3,063
Cost of revenues	7,401	3,665	4,778
Gross profit (loss)	(5,412)	(176)	(1,715)
Operating expenses:			
Research and development	25,982	34,609	26,378
Sales and marketing	3,028	2,807	2,463
General and administration	12,235	15,365	9,878
Total operating expenses	41,245	52,781	38,719
Loss from operations	(46,657)	(52,957)	(40,434)
Other income (expense):			
Interest income	679	3,609	4,424
Interest expense	(47)	(71)	(68)
Other	242	—	—
Total other income, net	874	3,538	4,356
Net loss	$ (45,783)	$ (49,419)	$ (36,078)
Per share data:			
Basic and diluted net loss per common share	$ (1.66)	$ (1.97)	$ (1.51)
Weighted-average shares used in computing basic and diluted net loss per common share	27,582,301	25,066,132	23,947,251

See accompanying notes.

BIOPURE CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock				Capital in Excess of Par Value	Contributed Capital	Notes Receivable	Accumulated Deficit	Total Stockholders' Equity
	Class A		Class B						
	Shares	Amount	Shares	Amount					
	(In thousands, except share and per share data)								
Balance at October 31, 1999	22,280,867	223	117.7	—	282,054	24,574	(2,463)	(250,351)	54,037
Exercise of stock options and warrants	92,128				577				577
Sale of common stock	2,565,000	26			83,725				83,751
Equity compensation					3,681				3,681
Payment of discount plus interest on "non-lapse" restricted shares					2,112				2,112
Payment of notes receivable from shareholders							556		556
Accrued interest							(126)		(126)
Net loss								(36,078)	(36,078)
Balance at October 31, 2000	24,937,995	249	117.7	—	372,149	24,574	(2,033)	(286,429)	108,510
Exercise of stock options and warrants	226,550	2			1,929				1,931
Stock issued for acquisition of research and development information	67,270				1,511				1,511
Land acquired upon exercise of stock option	80,000	1			1,004				1,005
Retirement of treasury stock that resulted from payment of "non-lapse" restricted shares	(86,732)	—			—				
Equity compensation					6,844				6,844
Payment of discount plus interest on "non-lapse" restricted shares					133				133
Payment of notes receivable from shareholders							468		468
Accrued interest							(90)		(90)
Net loss								(49,419)	(49,419)
Balance at October 31, 2001	25,225,083	$252	117.7	—	$383,570	$24,574	$(1,655)	$(335,848)	$ 70,893
Exercise of stock options and warrants	2,842	—			40				40
Sale of common stock	5,121,297	52			35,382				35,434
Adjustment for stock issued for acquisition of research and development information	(3,852)	—							—
Land acquired upon exercise of stock option	8,000	—			134				134
Equity compensation					(61)				(61)
Payment of notes receivable from shareholders							80		80
Settlement of note receivable and accrued interest from shareholder							1,601		1,601
Amended note receivable to shareholder							(233)		(233)
Accrued interest							(48)		(48)
Net loss								(45,783)	(45,783)
Balance at October 31, 2002	30,353,370	$304	117.7	$ —	$419,065	$24,574	$ (255)	$(381,631)	$ 62,057

See accompanying notes.

BIOPURE CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended October 31,		
	2002	2001	2000
		(In thousands)	
Operating activities:			
Net loss	$(45,783)	$(49,419)	$(36,078)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,577	3,643	4,107
Disposition of obsolete fixed assets	—	—	331
Equity compensation	(61)	6,844	3,681
Deferred compensation	(7)	7	(3)
Accrued interest on notes receivable from stockholders	(48)	(90)	(126)
Acquired research and development information	—	1,511	—
Equity in affiliate's operations	32	34	35
Changes in assets and liabilities:			
Accounts receivable	635	(246)	(157)
Inventories	(3,363)	(1,939)	456
Other current assets	62	(391)	108
Accounts payable	815	(416)	1,023
Accrued expenses	(923)	(771)	(436)
Net cash used in operating activities	(44,064)	(41,233)	(27,059)
Investing activities:			
Purchases of property, plant and equipment	(8,352)	(3,265)	(2,052)
Escrow for new facility	—	(10,000)	—
Other assets	716	(98)	165
Net cash used in investing activities	(7,636)	(13,363)	(1,887)
Financing activities:			
Net proceeds from sales of common stock	35,466	—	83,751
Expenses related to equity line	(32)	(675)	—
Proceeds from exercise of stock options, warrants and restricted stock	40	2,064	2,689
Payment of notes receivable from stockholders	80	468	556
Amendment of note receivable from stockholder	(233)	—	—
Net cash provided by financing activities	35,321	1,857	86,996
Increase (decrease) in cash and cash equivalents	(16,379)	(52,739)	58,050
Cash and cash equivalents at beginning of the year	36,089	88,828	30,778
Cash and cash equivalents at end of the year	$ 19,710	$ 36,089	$ 88,828
Supplemental Disclosure of Non Cash Investing Activities:			
Land and license rights acquired upon exercise of stock option	$ 134	$ 1,005	$ —
New facility construction financed through capital lease (classified as long-term debt)	$ 4,642	$ 5,205	$ —
Supplemental Disclosure of Non Cash Financing Activities:			
Settlement of deferred compensation and accrued interest	$ (1,601)	$ —	$ —
Settlement of note receivable and accrued interest	$ 1,601	$ —	$ —

See accompanying notes.

1. The Company

Nature of Business and Organization

Biopure Corporation (Biopure, or the Company) is a leading developer, manufacturer and supplier of a new class of pharmaceuticals, called oxygen therapeutics, which are intravenously administered to deliver oxygen to the body's tissues. Its products are Oxyglobin, for veterinary use, and Hemopure, for human use.

During 1998, the Company began selling Oxyglobin in the United States for the treatment of anemia in dogs. Initially, sales were made on a limited basis directly to emergency and specialty veterinary practices. In October 1998, the Company began selling Oxyglobin nationwide through several veterinary distributors, who purchase product for immediate and direct resale to veterinary practices. In April 2001, the Company began selling Oxyglobin to a distributor in the United Kingdom. Oxyglobin is now available to veterinarians in selected European countries through established local veterinary distributors in Germany, France and the United Kingdom. In fiscal 2001, Hemopure was approved in South Africa for use in adult surgery patients to treat acute anemia and eliminate, reduce or delay red blood cell transfusion.

During fiscal 2002, the Company continued activities associated with data organization and analyses for the pivotal Phase III clinical trial of Hemopure. In July 2002 the Company filed a marketing application for Hemopure in the United States, for perioperative use of the product in patients undergoing elective orthopedic surgery. The application was accepted for review by the FDA in October 2002. These activities are significant factors relating to the Company's operating losses. Although there cannot be any assurance that Hemopure will be approved for sale in additional countries, the trials to date have produced results that have allowed the Company to continue clinical progress. The product also is being developed for use in trauma, cancer and ischemic events such as heart attack and stroke.

Going Concern Uncertainty

The financial statements of the Company have been presented on the basis of a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. However, the Company may not be able to continue its operations because it has experienced significant operating losses, which it expects will continue and has insufficient sources of funding its operations. In order for the Company to remain a going concern it will require significant additional funding in the near term. The Company is exploring opportunities to raise capital through equity offerings, the issuance of debt securities, strategic alliances and other financing vehicles. However, there can be no assurance that any such additional financing will be available to the Company on the terms that it deems acceptable, if at all. The financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. In December 2002, the Company raised approximately $1.9 million, of additional funding from the sale of Class A Common Stock (See Note 12, Subsequent Events). The Company expects this funding, in addition to the cash and cash equivalents at October 31, 2002, will be sufficient to fund operations according to its current plan through more than half of the second quarter of fiscal 2003. External cash requirements are expected to be lower during the last half of fiscal 2003 because of anticipated revenues from product sales. Expenditures, including the costs of personnel and clinical development of additional indications for Hemopure, will be deferred until sufficient funds, in addition to those on hand, are available. Should management's plans not develop as anticipated, the Company will restrict additional planned activities and operations, as necessary, to sustain operations and conserve cash resources.

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements reflect the accounts of the Company and its subsidiaries. All intercompany accounts and transactions have been eliminated.

Risks and Uncertainties

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

In addition to the risks and uncertainties discussed in Note 1, concerning the uncertainty of our continuing as a going concern, the Company is subject to a number of risks associated with companies in the biotechnology industry. Principal among these are the risks associated with the Company's dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with the FDA and other governmental regulations and approval requirements, as well as the ability to grow the Company's business and to obtain adequate financing to fund this growth.

We obtain some key materials, including membranes and chemicals, from sole source suppliers. If such materials were no longer available at a reasonable cost from our existing suppliers, we would need to obtain supply contracts with new suppliers for substitute materials. If we need to locate a new supplier, the substitute or replacement materials will most likely be tested for equivalency. Such evaluations could delay development of a product, limit commercial sales of an FDA-approved product and cause us to incur additional expense. In addition, the time expended for such tests could delay the marketing or sale of an FDA-approved product.

Cash Equivalents

The Company considers highly liquid instruments with original maturities of 90 days or less at the time of purchase to be cash equivalents. Cash equivalents are carried at cost, which approximate their fair market value. As of October 31, 2002, cash equivalents principally consisted of money market funds. As of October 31, 2001, cash equivalents principally consisted of money market funds and high-grade commercial paper.

Inventories

Inventories are stated at the lower of cost (determined using the first-in, first-out method) or market. Inventories are reviewed periodically for slow-moving or obsolete status based on sales activity, both projected and historical. Inventories are also reviewed periodically for materials or product under quality compliance investigations. Reserves are established for inventory that falls into these categories.

Property and Equipment

Property and equipment are recorded at cost and depreciated over the estimated useful lives of the assets using the straight-line method. The estimated useful lives are as follows:

Major equipment	10-12 years
Equipment	5-7 years
Leasehold improvements	Shorter of useful life or life of the lease
Furniture and fixtures	5 years
Computer equipment	3 years

Included in property, plant and equipment for the fiscal years ended October 31, 2002 and 2001 is $12,757,000 and $5,205,000, respectively, reflecting expenditures made by Biopure for the engineering and design costs of a new 500,000 unit Hemopure plant to be constructed in South Carolina. The new plant is expected to cost $120,000,000 and is to be financed through a capital lease. As such, the financial statements also include $9,847,000 and $5,205,000 in long-term debt for the fiscal years 2002 and 2001, respectively. See Note 7 for more information.

Other Assets

Acquired licenses, stated at amortized cost of $675,000 as of October 31, 2002, are included in other assets. Amortization is calculated using the straight-line method over the estimated useful life of the amortized assets, which is 13 years.

Long-Lived Assets

In accordance with Financial Accounting Standards Board Statement (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets,* the Company recognizes impairment losses on long-lived assets when indicators of impairment are present and future undiscounted cash flows are insufficient to support the assets' recovery. Management believes that no such indicators of impairment of its long-lived assets exist at October 31, 2002.

Revenue Recognition

The Company recognizes revenue from product sales upon shipment provided that there is evidence of a final arrangement, there are no uncertainties surrounding acceptance, collectibility is probable, the price is fixed and only perfunctory company obligations included in the arrangement, if any, remain to be completed.

Research and Development Costs

Research and development costs are expensed as they are incurred. These costs include product and process development and engineering, pre-clinical studies, clinical trials, costs of product used in trials and tests and an allocation of a portion of the unabsorbed fixed costs of manufacturing.

Stock-Based Compensation

The Company generally grants stock options for a fixed number of shares, with an exercise price equal to the market value of the shares at the date of grant. The Company has elected to follow Accounting Principles Board Opinion No. 25, *"Accounting for Stock Issued to Employees"* (APB 25), and related interpretations, in accounting for its stock-based compensation plans, rather than the alternative fair value accounting method provided under SFAS 123, *"Accounting for Stock-Based Compensation."* Under APB 25, when the exercise price of options granted to employees equals the market price of the underlying stock on the date of grant, no compensation expense is required.

The Company applies SFAS 123 and EITF 96-18 *"Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services"* with respect to options issued to nonemployees.

Net Loss Per Common 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 year, adjusted for the dilutive effect 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 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 does not include 4,199,178, 3,252,627 and 2,726,222 common stock equivalents for the years ended October 31, 2002, 2001 and 2000 respectively, as their effects would be anti-dilutive.

Concentration of Credit Risk and Significant Customers

SFAS No. 105, *"Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk,"* requires disclosure of any significant off-balance-sheet risks and credit risk concentrations. The Company has no significant off-balance-sheet risk. Financial instruments, which subject the Company to credit risk, principally consist of cash, cash equivalents, accounts receivable and notes receivable from two officers. The Company maintains the majority of its cash balances with high quality financial institutions. Three customers represented 68% of total accounts receivable at October 31, 2002 while two customers represented 65% of total accounts receivable on October 31, 2001 and four customers represented 87% of total accounts receivable on October 31, 2000. The Company derived revenue from five unrelated parties in 2002 individually accounting for a total of 37%, 15%, 13%, 13% and 11% of total revenues. The Company derived revenue from four unrelated parties in 2001 individually accounting for a total of 42%, 20%, 11% and 11% of total revenues. The Company derived revenue from three unrelated parties in 2000 individually accounting for a total of 45%, 16%, and 11% of total revenues.

Fair Value of Financial Instruments

SFAS No. 107, *"Disclosures about Fair Value of Financial Instruments,"* requires disclosure of the fair value of financial instruments. The Company has estimated the fair value of financial instruments using available market information and appropriate valuation methodologies. The carrying value of cash, cash equivalents, accounts receivable, notes receivable from two officers and accounts payable approximate fair value due to the short-term nature of these financial instruments. The carrying value of the Company's long-term debt also approximates fair value based on comparable market terms and conditions.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in net assets of the Company during a period from transactions generated from non-owner sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners. The Company had no other components of comprehensive loss other than its net loss for all periods presented.

Segment Information

SFAS No. 131, *"Disclosures About Segments of an Enterprise and Related Information,"* establishes standards for reporting information regarding operating segments and for related disclosures about products and services and geographical areas.

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions regarding resource allocation and assessing performance. To date the Company has viewed its operations and manages its business as principally one operating segment, which is developing, manufacturing and supplying a new class of pharmaceuticals, called oxygen therapeutics, which are intravenously administered to deliver oxygen to the body's tissues. As of October 31, 2002 most of the Company's assets are

located in the United States. For the fiscal year ended October 31, 2002, customers in the United States and the United Kingdom accounted for 87% and 13% of the Company's revenue recognized, respectively. For the fiscal year ended October 31, 2001 customers in the United States and the United Kingdom accounted for 95% and 5% of the Company's revenue recognized, respectively. For the fiscal year ended October 31, 2000, all revenue recognized was derived from customers within the United States.

Recently Issued Accounting Standards

In August 2001, the FASB issued SFAS No. 144, *"Accounting for the Impairment or Disposal of Long-Lived Assets."* This statement supercedes SFAS No. 121, *"Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of,"* and certain accounting and reporting provisions of Accounting Principles Board (APB) Opinion No. 30, *"Reporting the Results of Operations — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions."* Statement 144 requires that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and it broadens the presentation of discontinued operations to include more disposal transactions. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption permitted. The Company does not believe the adoption of this statement will have a material impact on its results of operations or financial position.

SFAS No. 146, *"Accounting for Costs Associated with Exit or Disposal Activities,"* issued in July 2002, addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, *"Liability Recognition for Certain Employee Termination* Benefits *and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*." The principal difference between Statement 146 and Issue 94-3 relates to Statement 146's requirements for recognition of a liability for a cost associated with an exit or disposal activity. Statement 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit costs as generally defined in Issue 94-3 was recognized at the date of an entity's commitment to an exit plan. Therefore, this Statement eliminates the definition and requirements for recognition of exit costs in Issue 94-3. This Statement also established that fair value is the objective for initial measurement of the liability. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The Company does not believe the adoption of this statement will have a material impact on its results of operations or financial position.

FASB Interpretation No. 45, *"Guarantor Accounting,"* will significantly change 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 current practice. In addition, guarantors will be 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 does not believe the adoption of this statement will have a material impact on its results of operations or financial position.

At the November 21, 2002 meeting, the Task Force reached a consensus on Issue 00-21, *"Accounting for Revenue Arrangements with Multiple Deliverables,"* which addresses how to account for arrangements that may involve the delivery or performance of multiple products, services, and/or rights to use assets. The final consensus will be applicable to agreements entered into in fiscal periods beginning after June 15, 2003 with early adoption permitted. Additionally, companies will be permitted to apply the consensus guidance to all

existing arrangements as the cumulative effect of a change in accounting principle in accordance with APB Opinion No. 20, *Accounting Changes*. Following is a brief summary of the final model approved by the Task Force.

- Revenue arrangements with multiple deliverables should be divided into separate units of accounting if the deliverables in the arrangement meet the following criteria:
  - The delivered item(s) has value to the customer on a standalone basis. That item(s) has value on a standalone basis if it is sold separately by any vendor or the customer could resell the deliverable on a standalone basis. In the context of a customer's ability to resell the deliverable, the Task Force observed that this criterion does not require the existence of an observable market.
  - There is objective and reliable evidence of the fair value of the undelivered item(s).
  - If the arrangement includes a general right of return, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the vendor.
  - Arrangement consideration should be allocated among the separate units of accounting based on their relative fair values. The amount allocated to the delivered item(s) is limited to the amount that is not contingent on the delivery of additional items or meeting other specified performance conditions.
  - Applicable revenue recognition criteria should be considered separately for separate units of accounting.

The Company does not believe the adoption of EITF 00-21 will have a material impact on its results of operations or financial position.

3. Transactions with Related Parties

In August 1990, the Company made loans to certain directors and officers to allow them to purchase Class A Common Stock. The principal and interest for the loan that remains outstanding, not including the loan made to Carl Rausch, the Company's Vice Chairman and Chief Technology Officer, is approximately $22,000 and was due on October 31, 2002. The principal balance continues to bear interest until all principal and interest are paid. The note receivable for the loan bears interest at the prime rate (4.75% at October 31, 2002) and is included in stockholders' equity in the accompanying consolidated financial statements. The Company is currently negotiating a payment agreement with the officer in regards to this note.

In August 1990, the Company awarded deferred compensation of $700,000 to Carl Rausch, then Chairman and Chief Executive Officer. The deferred amount with interest was to be paid on July 31, 2003. The Company also made a loan of $700,000 to Mr. Rausch in August 1990, the proceeds of which were used to purchase shares of the Company's Class A Common Stock. On July 29, 2002, Mr. Rausch settled the interest accrued on his deferred compensation and the Company settled the interest due on the loan which were both $901,000. Biopure accelerated the deferred compensation payment of $700,000 to Mr. Rausch, of which $233,100 was withheld for taxes and the balance of $466,900 was paid on the loan, leaving a principal loan balance of $233,100. This remaining loan balance bears interest at the prime rate (4.75% at October 31, 2002) and is included in stockholders' equity as notes receivable in the accompanying consolidated financial statements. Interest payments are made on a current basis and the principal on the loan is due on July 31, 2007.

On May 24, 2001 the Company acquired by merger the 74% of Reperfusion Systems, Inc., a Delaware corporation, it did not already own. Reperfusion was formed in 1993 to investigate a device for resuscitation to be used with Hemopure or other oxygen carrying fluids. Related to this acquisition, the Company issued 67,270 shares of Class A Common Stock and paid $55,000 to the Reperfusion shareholders. A one-time

expense of $1,604,000, of which $1,511,000 is non-cash, was recorded as research and development for intellectual property and pre-clinical studies.

4. Inventories

Inventories, net of reserves, consisted of the following:

	October 31,	
	2002	2001
	(In thousands)	
Raw materials	$2,122	$ 771
Work-in-process	676	243
Finished goods — Oxyglobin	1,992	1,886
Finished goods — Hemopure	3,238	1,765
	$8,028	$4,665

5. Investment in Affiliate

The Company accounts for its investments in affiliated companies under the equity method of accounting. 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 facilities. The Company's lease with EHSA requires annual rental payments of $239,000 through 2002 and $262,000 from 2003 through 2007. The partnership's income was not significant for any of the periods presented. In fiscal 2002 the Company received a $35,000 distribution which reduced the remaining investment of $31,500 to zero and the remainder is recorded in other income on the consolidated statements of operations for the fiscal year ended October 31, 2002.

6. Accrued Expenses

Accrued expenses consisted of the following:

	October 31,	
	2002	2001
	(In thousands)	
Clinical trials	27	662
Preparation of biologic license application	186	306
Accrued payroll and related employee expenses	562	1,365
Accrued vacation	651	398
Accrued legal and audit fees	301	257
South Carolina capital project	551	—
Other	1,748	1,961
	$4,026	$4,949

7. Long-Term Debt

In December 2001, the Company signed an amended letter of intent with Sumter Realty Group, LLC for the construction and financing of a 500,000-unit Hemopure plant in South Carolina expected to cost $120 million. Sumter Realty Group, LLC has accepted a letter of commitment from a potential investor for the full $120 million required to finance construction of the new manufacturing facility in South Carolina. In December 2002, Biopure signed a lease agreement with Sumter Realty Group, LLC (the Lease). In addition,

the Company also expects to issue a warrant to purchase up to 2.5 million shares of Class A Common Stock at $0.01 per share, exercisable five years from the start of construction and is committed to pay a finder's fee, of approximately 2 percent of the net amount financed, to a consultant when financing for the facility is completed. Under the terms of the Lease, minimum lease payments will start at substantial completion of the facility, which the Company expects to be in the beginning of fiscal 2005. The annual lease payments will be $13.8 million per year for the first two years and $17.2 million per year for the balance of the 25-year term. At the conclusion of the 25-year term, the Company will own the facility. The terms of the Lease are subject to financial closing and construction beginning within 75 days of the date of the lease. The Company can cancel the lease if the definitive financing documentation is not acceptable or based on the outcome of continuing site assessment. The lease will be void if the financing is not completed. Subject to diligence and definitive documentation, closing and start of construction could occur in early calendar year 2003.

As of October 31, 2002, $12.8 million has been included in property, plant and equipment and $9.8 million in long-term debt reflecting expenses to date for the engineering and design costs of the planned manufacturing facility in Sumter, S.C. Through December 2002, the Company incurred an additional $500,000 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 2005. The total $13.3 million of expenditures by the Company will be returned as described below.

During fiscal 2001, the Company paid $10 million, Biopure's initial contribution to the cost of the facility, into an escrow account to fund certain initial expenditures related to the construction of the new facility. Under the proposed agreement for the construction and financing of the new plant, the $10 million in project cost funded by Biopure is expected to be refunded upon receipt of FDA approval for Hemopure and if a final lease agreement has been executed. The $10 million has been accounted for as a deposit in long-term assets as of October 31, 2002. If FDA approval is not received, the $10 million deposit 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. 121 (and SFAS No. 144, applicable in fiscal 2003). Under the terms of the Lease, Sumter Realty Group, LLC will refund the $3.3 million of additional spending by the Company in fiscal 2003 once financing is completed.

8. Stockholders' Equity

Equity Line Stock Purchase Agreement

Biopure is a party to an equity line stock purchase agreement with Société Générale. In December 2001 and January 2002, the Company drew a total of $7,250,000 in exchange for 516,531 shares of Class A Common Stock under this agreement. The agreement will terminate in June 2003. The Company is currently unable to raise funds through this agreement because its recent stock prices have been below the minimum price ($13) specified in the agreement

Stock Issuances

On March 11, 2002, the Company filed a common stock shelf registration statement with the SEC. On April 23, 2002, the Company sold 2,766,665 of these registered shares. The Company received proceeds of $19,863,000 before expenses of $174,000 and recorded an increase in stockholders' equity of $19,689,000. On May 9, 2002, the Company sold an additional 690,000 shares for proceeds of $4,916,000 before expenses of $21,000 and recorded an increase in stockholders' equity of $4,895,000. On September 19, 2002 the Company sold an additional 1,148,101 shares for proceeds of $4,340,000 before expenses of $34,000 and recorded an increase in stockholders' equity of $4,306,000.

On March 24, 2000, the Company completed a public offering of 2,565,000 shares of Class A Common Stock. The Company received proceeds of $84,388,000 before expenses of $637,000 and recorded an increase in stockholders' equity of $83,751,000.

In fiscal 1994, one of the Company's vendors was granted options to acquire 80,000 shares and in fiscal 2000 it was granted an option for an additional 8,000 shares of Class A Common Stock in exchange for certain land and real property lease and license rights. In 2001 and 2002, the vendor exercised its option to acquire 80,000 and 8,000 shares, respectively, of Class A Common Stock for consideration consisting of land and real property lease and license rights valued at $1,138,500, $396,000 of which was recorded as land and $742,500 was recorded as other assets.

Common Stock

The holder of Class B Common Stock is not entitled to vote or receive dividends. The Class B Common Stock is convertible into shares of Class A Common Stock according to a formula that is based upon a future fair market value of the Company and is conditioned upon the Company achieving U.S. FDA approval for Hemopure. The number of shares of Class A Common Stock to be issued in exchange for the Class B Common Stock will be determined based upon an independent valuation of the Company, after FDA approval of the Company's human oxygen therapeutic product. The valuation is then divided by 13,635,525 shares to arrive at a fair value per share of Class A Common Stock. The total investment in the Company, $142.3 million, divided by such per share fair value of Class A Common Stock, results in the number of shares of Class A Common Stock the holder will receive, limited to a maximum of 1,272,119 shares.

Of the Company's currently outstanding Class A Common Stock, 1,000,052 shares are restricted from transfer by a restriction that can only be removed upon payment to the Company, in cash of Class A Common Stock, of $7.92 per restricted share.

Dividends

At this time, the Company does not intend to pay dividends.

Contributed Capital

The Company recorded as contributed capital research and development costs incurred by the holder of the Class B Common Stock on behalf of the Company. Upon conversion of the Class B Common Stock, the cumulative amount of contributed capital will be treated as consideration for the Class A Common Stock issued in the conversion.

Stock Options and Warrants

The Company has options outstanding under three plans, the 2002 Omnibus Securities and Incentive Plan (the 2002 Plan), the 1999 Omnibus Securities and Incentive Plan (the 1999 Plan) the 1998 Stock Option Plan (the 1998 Plan), under which key employees, directors and consultants may be granted options to purchase Class A Common Stock at the average of the high and low trading price on the date of grant. Under most of the option grants the options become exercisable over a four-year period and expire ten years from date of grant.

Presented below is a summary of transactions under the stock option plans during 2002, 2001 and 2000:

	Year Ended October 31,					
	2002		2001		2000	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Options outstanding at beginning of year	2,079,538	$15.28	2,179,600	$14.98	1,945,161	$13.84
Granted	1,049,950	7.66	87,500	17.46	435,200	18.94
Exercised	(2,776)	14.15	(162,715)	12.52	(34,816)	11.90
Forfeited	(161,254)	16.46	(24,847)	14.30	(165,945)	12.65
Expired	(5,134)	13.50	—	—	—	—
Options outstanding at end of year	2,960,324	$12.50	2,079,538	$15.28	2,179,600	$14.98
Options exercisable	1,872,793		1,352,406		748,000	

The following table summarizes information about options outstanding at October 31, 2002:

	Options Outstanding			Options Exercisable	
Exercise Price	Shares	Weighted Average Remaining Contractual Life (Yrs.)	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
$5.40-$11.81	1,123,383	9.4	$ 7.75	359,166	$ 8.22
$12.00-$13.50	1,077,391	6.8	12.00	922,052	12.00
$16.69-$22.50	679,550	6.1	18.83	551,575	19.05
$26.10-$35.69	80,000	7.8	32.09	40,000	32.09
	2,960,324	7.7	$12.50	1,872,793	$13.78

During 1998, the Company's 1988 Stock Option Plan expired. In March 1998, the Board of Directors approved the adoption of the 1998 Plan to provide for the granting of options for up to 98,293 shares of Class A Common Stock, the number of shares remaining in the expired 1988 plan.

In June 1999, the Company established the 1999 Plan, which provides for the granting of incentive stock options, non-qualified stock options, restricted stock awards, deferred stock awards, unrestricted stock awards, performance share awards, distribution equivalent rights, or any combination of the foregoing to key management, employees and directors. The maximum number of shares of Class A Common Stock reserved for issuance under the 1999 Plan is 1,866,666.

In April 2002, the Company established the 2002 Plan, which provides for the granting of incentive stock options, non-qualified stock options, restricted stock awards, deferred stock awards, unrestricted stock awards, performance share awards, distribution equivalent rights, or any combination of the foregoing to key management, employees and directors. The maximum number of shares of Class A Common Stock reserved for issuance under the 2002 Plan is 1,200,000.

At October 31, 2002, there were 501,846 shares available for future grants under stock option plans.

During fiscal 2001, Biopure granted to unrelated parties an aggregate of 400,000 warrants at an exercise price of $19.30 per share and 350,000 warrants with an exercise price of $35.00 per share. Both warrants vested in April 2001 and expire three years from the date of grant. The Company recorded $4,174,500 as a one-time

compensation expense in April 2001. The weighted-average fair value per warrant was $5.57. In November 1999, the Company granted 25,000 warrants to consultants at an exercise price of $12.00 per share. The warrants vested immediately and expire five years from the date of grant. The related compensation expense was recorded on the grant date and was not significant. At October 31, 2002, all such warrants were outstanding.

During fiscal 2002, Biopure granted a total of 85,700 warrants to unrelated parties in connection with the sale of the registered shares mentioned above. On April 23, 2002, 65,000 shares were granted, at an exercise price of $7.53 per share, which vested immediately and expire four years from the date of grant. On May 9, 2002, 20,700 shares were granted, at an exercise price of $7.67 per share, which vested immediately and expire three years from the date of grant.

SFAS No. 123 Disclosures

The Company has adopted the disclosure provisions only of SFAS No. 123. The fair value of options and warrants granted was estimated at the date of grant using the Black-Scholes option pricing model for 2002, 2001 and 2000, with the following assumptions: risk-free interest rates ranging from 4.20% to 6.32%; dividend yield of 0% and an expected life between one and seven years. For 2002, 2001 and 2000 a volatility factor of the expected market price of the Company's Common Stock of .80 was used. If the compensation cost for options and warrants granted had been determined based on the fair value of the options and warrants at the date of grant, the SFAS No. 123 pro forma net loss applicable to common stockholders for 2002, 2001, and 2000 would have been $47,371,000, $53,692,000 and $38,901,000, respectively.

The SFAS No. 123 pro forma net loss per share for 2002, 2001 and 2000 would have been $(1.72), $(2.14) and $(1.62), respectively. Compensation expense under SFAS No. 123 for 2002, 2001 and 2000 is not representative of future expense, as it includes only four, three and two years of grants, respectively. In future years, the effect of determining compensation cost using the fair value method will include additional vesting and associated expense.

The weighted-average fair value per option and warrant for grants during 2002, 2001 and 2000 was $5.66, $7.73 and $13.89, respectively.

Reserved Shares

At October 31, 2002, there were 6,524,484 shares of Class A Common Stock reserved for issuance under the stock option plans, stock option agreements and warrants and upon conversion of Class B Common Stock. In addition at October 31, 2002 there were 4,483,469 shares of Class A Common Stock reserved for issuance in connection with the Societe General equity line mentioned above.

Rights Agreement

Each holder of Class A Common Stock has a preferred stock purchase right for each share owned. The rights entitle the holders to acquire preferred stock following an acquisition of more than 20% of the Company's Class A Common Stock by any person or group, if the board of directors does not redeem the rights. If the rights were not redeemed, their exercise would cause substantial dilution to the acquiring person or group.

9. Employee Benefit Plan

The Company has a defined contribution plan, the Biopure Corporation Capital Accumulation Plan, qualified under the provisions of Internal Revenue Code section 401(k). Employees are eligible for enrollment upon becoming employed and for discretionary matching after one year of service. The Company's

discretionary contribution vests after a period of three years from the date of employment. In 2002, 2001 and 2000, the Company contributed $279,000, $223,000, and $225,000 respectively, to the plan.

10. Income Taxes

At October 31, 2002, the Company had available for the reduction of future years' federal taxable income and income taxes, net operating loss carryforwards of approximately $225,560,000, expiring from the year ended October 31, 2004 through 2022, along with research and development and investment tax credits of approximately $5,602,000, expiring from the year ended October 31, 2002 through 2022. Since the Company has incurred only losses since inception and due to the degree of uncertainty with respect to future profitability, the Company believes at this time that it is more likely than not that sufficient taxable income will not be earned to allow for realization of the tax loss and credit carryforwards and other deferred tax assets. Accordingly, the tax benefit of these items has been fully reserved.

Upon subsequent recognition of any tax benefit relating to the valuation allowance of deferred tax assets, approximately $3,090,000, as of October 31, 2002 would be reported in additional paid in capital.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities as of October 31, 2002 and 2001 were as follows:

	2002	2001
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforward	$ 85,166	$ 75,522
Capitalized research and development	46,565	39,644
Accruals and reserves	2,828	2,368
Tax credit carryforwards	8,041	7,442
Total deferred tax assets	142,600	124,976
Deferred tax liabilities:		
Depreciation	1,977	2,169
Total deferred tax liabilities	1,977	2,169
Net deferred tax assets	140,623	122,807
Valuation allowance for deferred tax assets	(140,623)	(122,807)
Net deferred tax assets	$ —	$ —

In 2002, the valuation allowance increased by $17,816,000 due primarily to the increase in net operating losses, capitalized research and development costs, and research and development tax credits.

11. Commitments

In 1997, the Company entered into an agreement with B. Braun Melsungen A.G. (Braun) to repurchase shares of the Company's common stock. This agreement was terminated in 1999 and resulted in a requirement that the Company pay Braun a royalty of two percent of the Company's revenues from human product sales and license fees in a certain European region. Payments must be made on a quarterly basis until such amounts aggregate $7,500,000. In exchange for this royalty commitment, the rights to manufacture and market specified products in Braun's territory were reacquired by the Company. No payments have been required or made as of October 31, 2002.

If the Company is unable to draw down additional funds through the equity line stock purchase agreement explained in Note 8 the Company will be subject to a penalty of $537,500.

Future minimum lease payments under operating leases for the Company's various office, laboratory, warehouse and processing facilities at October 31, 2002 are as follows:

2003	$1,023,385
2004	1,003,051
2005	945,720
2006	662,889
2007	591,150
Thereafter	153,324
	$4,379,519

Rent expense was approximately $1,093,000, $977,000 and $992,000 in 2002, 2001 and 2000, respectively.

12. Subsequent Events

On December 24, 2002, the Company signed a lease with Sumter Realty Group, LLC. Under the terms of the lease, Sumter Realty Group, LLC will refund the $3.5 million of additional spending by the Company in fiscal 2003 (see Note 7). The lease payments will start at substantial completion of the facility, which the Company expects to be in the beginning of fiscal 2005. The annual lease payments will be $13,750,000 per year for years one and two and $17,150,000 per year thereafter. The Company will own the facility at the end of the lease term. These terms are subject to financing closing and construction to begin within 75 days of the signing of the lease. The Company can cancel the agreement if due diligence on the suitability of the site and financing documentation is not favorable to the Company.

On December 31, 2002, the Company sold to an investor 522,193 shares of its Class A Common Stock at a price of $3.83 per share and warrants to acquire 522,193 shares of its Class A Common Stock at an exercise price of $4.84 per share. The aggregate proceeds to the Company, before expenses, were approximately $2,000,000.

13. Quarterly Financial Information (Unaudited)

The following is a summary of quarterly financial results for the fiscal years 2002 and 2001:

	4Q '02	3Q '02	2Q '02	1Q '02
	(In thousands, except per share data)			
Statements of Operations Data:				
Total revenues	$ 73	$ 260	$ 928	$ 728
Gross profit (loss)	(3,023)	(2,299)	9	(99)
Operating expenses:				
Research & development	3,794	7,063	8,153	6,972
Sales and marketing	1,075	875	615	463
General & administration	2,932	2,569	4,129	2,605
Total operating expenses	7,801	10,507	12,897	10,040
Loss from operations	(10,824)	(12,806)	(12,888)	(10,139)
Other income, net	53	210	161	450
Net loss	$(10,771)	$(12,596)	$(12,727)	$ (9,689)
Per share data:				
Basic net loss per common share	$ (0.36)	$ (0.43)	$ (0.49)	$ (0.38)
Weighted-average shares used in computing basic net loss per common share	29,742	29,141	25,993	25,401

	4Q '01	3Q '01	2Q '01	1Q '01
	(In thousands, except per share data)			
Statements of Operations Data:				
Total revenues	$ 970	$ 946	$ 838	$ 735
Gross profit (loss)	(108)	43	(76)	(35)
Operating expenses:				
Research & development	7,123	10,297	9,002	8,187
Sales and marketing	737	784	664	622
General & administration	2,001	1,538	8,753	3,073
Total operating expenses	9,861	12,619	18,419	11,882
Loss from operations	(9,969)	(12,576)	(18,495)	(11,917)
Other income, net	578	654	990	1,316
Net loss	$ (9,391)	$(11,922)	$(17,505)	$(10,601)
Per share data:				
Basic net loss per common share	$ (0.37)	$ (0.47)	$ (0.70)	$ (0.42)
Weighted-average shares used in computing basic net loss per common share	25,208	25,134	24,958	24,960

In the third quarter of fiscal 2001, research and development expenses include a one-time expense of $1,604,000, of which $1,511,000 is non-cash, for intellectual property and pre-clinical studies related to the acquisition of Reperfusion Systems, Inc., an inactive company previously 26% owned by Biopure.

General and administrative expenses include non-cash compensation expense for stock options and warrants granted to certain consultants and directors. This non-cash compensation must be accounted for at fair value, per SFAS 123 and EITF 96-18, and be amortized over the vesting period and revalued each quarter based on the closing stock price. The quarterly expenses/(credits) to operations for fiscal 2002 were $16,000, $55,000, $13,000 and ($145,000) for the fourth, third, second and first quarters, respectively. The quarterly expenses/(credits) to operations for fiscal 2001 were ($80,000), ($793,000), $6,370,000 and $1,347,000 for the fourth, third, second and first quarters, respectively.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

The content of this report does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred. The Navy-Biopure collaborative clinical development program for Hemopure in trauma is contigent upon funding. This report contains forward-looking statements concerning, among other things, possible applications for marketing approval and other regulatory matters, clinical trials, plans for the development of Hemopure and business strategies. These forward-looking statements are identified by the use of such terms as "intends," "expects," "plans," "estimates," "anticipates," "should" and "believes."

These forward-looking statements involve risks and uncertainties. Actual results may differ materially from those predicted by the forward-looking statements because of various factors and possible events. Company risks include lack of FDA or any other regulatory approval for our human product in a major market, the difficulty and uncertainty in obtaining regulatory approvals, uncertainty about future physician and market acceptance of our product, our limited manufacturing capacity and capital resources, availability of financing to support operations, history of losses, and our lack of commercial experience as a pharmaceutical company. In addition, we are subject to industry risks such as: our industry is highly regulated, keenly competitive and subject to uncertainty of pricing because of controls on health care spending and uncertainty of third-party reimbursement. Risk factors are set forth in Exhibit 99 to the Form 10-K report.

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