NORTHFIELD LABORATORIES INC /DE/
Form 10-K
August 16, 2004

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

FORM 10-K

FOR ANNUAL AND TRANSITION
REPORTS PURSUANT TO SECTION 13 OR
15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended May 31, 2004

[ ] 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 0-24050

NORTHFIELD LABORATORIES INC.
(Exact name of Registrant as Specified in Its Charter)

DELAWARE	36-3378733
(State of Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
1560 SHERMAN AVENUE, SUITE 1000, EVANSTON, ILLINOIS	60201-4800
(Address of Principal Executive Offices)	(Zip Code)

(847) 864-3500
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

COMMON STOCK, PAR VALUE $.01 PER SHARE

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. [X] Yes [ ] No

Indicate by check mark 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 the Registrant's knowledge, in the definitive proxy or information statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). [X] Yes [ ] No

As of November 28, 2003, 16,171,067 shares of the Registrant's common stock, par value $.01 per share, were outstanding. On that date, the aggregate market value of voting stock (based upon the closing price of the Registrant's common stock on November 28, 2003) held by non-affiliates of the Registrant was $81,412,872 (14,060,945 shares at $5.79 per share).

As of July 31, 2004, there were 21,404,439 shares of the Registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2004 Annual Meeting are incorporated by reference into Part III of this Form 10-K. The Registrant maintains an Internet Web site at www.northfieldlabs.com. None of the information contained on this Web site is incorporated by reference into this Form 10-K or into any other document filed by the Registrant with the Securities and Exchange Commission.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

This document contains forward-looking statements concerning, among other things, our future business plans and strategies and clinical and regulatory developments affecting our PolyHeme(R) blood substitute product. These forward-looking statements are identified by the use of such terms as "intends," "expects," "plans," "estimates," "anticipates," "should," "believes" and similar terms. These forward-looking statements involve inherent risks and uncertainties. Our actual results may therefore differ materially from those predicted by the forward-looking statements because of various factors and possible events, including those discussed below under "Risk Factors." These forward-looking statements speak only as of the date of this document or, in the case of any document incorporated by reference, the date of that document. We do not undertake any obligation to update or publicly release any revisions to forward-looking statements to reflect events, circumstances or changes in expectations after the date such statements are made. All subsequent written and oral forward-looking statements attributable to Northfield or any person acting on our behalf are qualified by this cautionary statement.

PART I

ITEM 1. BUSINESS.

Northfield Laboratories Inc. is a leader in the development of a safe and effective alternative to transfused blood for use in the treatment of acute blood loss. Our PolyHeme blood substitute product is a solution of chemically modified hemoglobin derived from human blood. PolyHeme simultaneously restores lost blood volume and hemoglobin levels and is designed for rapid, massive infusion. PolyHeme requires no cross-matching, and is therefore immediately available and compatible with all blood types. PolyHeme has an extended shelf life compared to blood. We believe PolyHeme is the only blood substitute in development that has been well tolerated when infused in patients in clinical trials in sufficient quantities for the treatment of urgent, large volume blood loss in trauma and surgical settings, with a particular focus on situations where donated blood is not immediately available.

We are currently enrolling patients in a Pivotal Phase III Prehospital Trial in which PolyHeme is being used for the first time in civilian, urban trauma settings to treat severely injured patients in hemorrhagic shock before

they reach the hospital. Under this protocol, treatment with PolyHeme begins at the scene of the injury or in the ambulance and continues during transport and the initial 12 hour post-injury period in the hospital. Since blood is not presently carried in ambulances, the use of PolyHeme in this setting has the potential to improve survival and address a critical, unmet medical need.

As of August 14, 2004, 12 clinical sites in the United States were enrolling patients in our Pivotal Phase III Prehospital Trial. Each of these sites is designated as a Level I trauma center because of its capacity to treat the most severely injured trauma patients. We anticipate that a total of approximately 25 or more clinical sites across the United States will eventually participate in the trial. The trial has an expected enrollment of 720 patients.

As part of our trial protocol, an independent data monitoring committee, or IDMC, consisting of independent medical and biostatistical experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any identified risks to patients. The protocol includes four planned evaluations by the IDMC that occur after predefined numbers of patients have been enrolled and monitored for a 30-day follow up period. The IDMC will focus its initial review on mortality and serious adverse events and will review all safety data as the trial continues. We will receive a recommendation from the IDMC after each review, but we will not have access to the trial data reviewed by the IDMC until the trial is completed.

In July 2004, the IDMC recommended that our Pivotal Phase III Prehospital Trial continue without modification based on the committee's initial review of blinded data on mortality and serious adverse events from the first predefined evaluation of the patients enrolled in the trial.

We have previously conducted Phase II and Phase III clinical trials of PolyHeme at multiple locations in the United States in trauma and emergency surgical applications, in elective surgical procedures, and in situations of compassionate use in life-threatening situations. The observations in these trials have indicated the potential clinical utility of PolyHeme in the treatment of urgent blood loss and life-threatening hemoglobin levels. In a trial of hospitalized trauma patients, an analysis of the data revealed that PolyHeme significantly improved survival compared to historical control patients who did not receive blood. Our trials have involved high dosage and rapid infusion of PolyHeme in situations that are life-threatening and where massive blood loss routinely occurs. We believe that this application addresses the largest world-wide clinical need for this type of product and represents the greatest potential market opportunity. We believe we are the only company in our field with an oxygen-carrying blood substitute that has been rapidly infused at doses as high as 20 units (1,000 grams) or twice the blood volume of the average adult.

Our principal executive offices are located at 1560 Sherman Avenue, Suite 1000, Evanston, Illinois 60201-4800, and our telephone number is (847) 864-3500. We maintain an Internet Web site at www.northfieldlabs.com. We make available free of charge on our Web site our Form 10-Ks, Form 10-Qs, Form 8-Ks and other documents that we file with or furnish to the Securities and Exchange Commission, or "SEC" as soon as reasonably practicable after filing with the SEC. The information contained on our Web

site, or on other Web sites linked to our Web site, is not a part of this document. We have adopted a written code of business conduct and ethics that applies to all Northfield directors, officers and employees. Our code of business conduct and ethics is available on our Web site. In the event that we make changes in, or provide waivers from, the provisions of our code of business

conduct and ethics that the SEC requires us to disclose, we intend to disclose these events on our Web site to the extent permitted under the listing requirements of the Nasdaq Stock Market.

BACKGROUND

The principal function of human blood is to transport oxygen throughout the body. The lack of an adequate supply of oxygen as a result of blood loss can lead to organ dysfunction or death. The transfusion of human blood is presently the only effective means of immediately restoring diminished oxygen-carrying capacity resulting from blood loss. We estimate that approximately 14 million units of blood are transfused in the United States each year, of which approximately 8.4 million units are administered to patients suffering the effects of acute blood loss.

The use of donated blood in transfusion therapy, while effective in restoring an adequate supply of oxygen in the body of the recipient, has several limitations. Although testing procedures exist to detect the presence of certain diseases in blood, these procedures cannot eliminate completely the risk of blood-borne disease. Transfused blood also can be used only in recipients having a blood type compatible with that of the donor. Delays in treatment, resulting from the necessity of blood typing prior to transfusion, together with the limited shelf-life of blood and the limited availability of certain blood types, impose constraints on the immediate availability of compatible blood for transfusion. There is no commercially available blood substitute in this country which addresses these problems.

Our scientific research team has been responsible for the original concept, the early development and evaluation and clinical testing of PolyHeme, and has authored over 100 publications in the scientific literature relating to human blood substitute research and development. Members of our scientific research team have been involved in development of national transfusion policy through their participation in the activities of the National Heart Lung Blood Institute, the National Blood Resource Education Panel, the Department of Defense, the American Association of Blood Banks, the American Blood Commission, the American College of Surgeons and the American Red Cross.

THE PRODUCT

PolyHeme is a solution of chemically modified hemoglobin derived from human blood. Hemoglobin is the oxygen-carrying component of the human red blood cell. We purchase indated and outdated blood from The American Red Cross and Blood Centers of America for use as the starting material for PolyHeme. We use a proprietary process of separation, filtration, chemical modification, purification and formulation to produce PolyHeme. Hemoglobin is first extracted from red blood cells and filtered to remove impurities. The hemoglobin is next chemically modified using a multi-step process to create a polymerized form of hemoglobin designed to avoid the undesirable effects historically associated with hemoglobin-based blood substitutes, including vasoconstriction, kidney dysfunction, liver dysfunction and gastrointestinal distress. The modified hemoglobin is then incorporated into a solution which can be administered as an alternative to transfused blood. One unit of PolyHeme contains 50 grams of modified hemoglobin, approximately the same amount of hemoglobin delivered by one unit of transfused blood.

PolyHeme is intended for use in the treatment of acute blood loss. Clinical studies to date indicate that PolyHeme carries as much oxygen, and loads and unloads oxygen in the same manner as transfused blood. Infusion of PolyHeme also restores blood volume. Therefore, PolyHeme should be effective as an oxygen-carrying resuscitative fluid in the treatment of hemorrhagic shock resulting from extensive blood loss. Clinical studies to date suggest the potential life-sustaining capacity of PolyHeme when used as treatment for massive,

life-threatening blood loss in lieu of blood.

In addition to its utility as an oxygen carrier and blood volume expander, we believe PolyHeme will have the following additional benefits:

Impact on Disease Transmission. We believe, and laboratory tests have thus far indicated, that the manufacturing process used to produce PolyHeme greatly reduces the concentration of infectious agents known to be responsible for the transmission of blood-borne diseases. There are no currently approved methods in this country to reduce the quantity of such infectious agents in red cells.

Universal Compatibility. Clinical studies to date indicate that PolyHeme is universally compatible and accordingly should not require blood typing prior to use. The potential benefits of universal compatibility include the ability to use PolyHeme immediately, the elimination of transfusion reactions due to mistakes in blood typing, and the reduction of the inventory burden associated with maintaining sufficient quantities of all blood types.

Extended Shelf-life. We believe PolyHeme has a shelf-life well in excess of the 28 to 42 days currently permitted for blood. We estimate that PolyHeme has a shelf-life in excess of 12 months under refrigerated conditions.

THE MARKET

We estimate that approximately 14 million units of blood are transfused in the United States each year, of which approximately 8.4 million units are administered to patients suffering the effects of acute blood loss. Patient charges for the units of blood used in the United States each year for the treatment of acute blood loss represent a multi-billion dollar market. The transfusion market in the United States consists of two principal segments. The acute blood loss segment, which comprises approximately 60% of the transfusion market, includes transfusions required in connection with trauma, surgery and unexpected blood loss. The chronic blood loss segment represents approximately 40% of the transfusion market and includes transfusions in connection with general medical applications and chronic anemias.

We believe the most appropriate use for PolyHeme is in the treatment of acute blood loss. The principal clinical settings in which patients experience acute blood loss are unplanned blood loss in trauma, emergency surgery, and other causes of urgent hemorrhage, and planned blood loss in elective surgery. For trauma and emergency surgical procedures, the immediate availability and universal compatibility of PolyHeme may provide significant advantages over transfused blood by avoiding the delay and opportunities for error associated with blood typing. In elective surgery, PolyHeme has the potential to increase transfusion safety for patients and health care professionals. The initial indication for use we are seeking for PolyHeme is for the treatment of urgent, life-threatening blood loss in trauma and resultant surgical settings where blood may not be immediately available. This indication has the potential to improve survival and address a critical, unmet medical need.

In addition to the foregoing applications for which blood is currently used, there exist potential sources of demand for which blood is not currently utilized and for which PolyHeme may be suitable. These include applications in which the required blood type is not immediately available or in which transfusions are desirable but not given for fear of a transfusion reaction due to difficulty in identifying compatible blood. For example, we believe emergicenters and surgicenters both experience events where an oxygen-carrying volume expander may be eventually useful. We also believe PolyHeme may be used by Emergency Medical Technicians in ambulances, medical helicopters and other

prehospital settings. In addition, the military has expressed a high level of interest in oxygen-carrying products for the resuscitation of battlefield casualties.

CLINICAL TRIALS

We are currently enrolling patients in a Pivotal Phase III Prehospital Trial in which PolyHeme is being used for the first time in civilian, urban trauma settings to treat severely injured patients in hemorrhagic shock before they reach the hospital. Under this protocol, treatment with PolyHeme begins at the scene of the injury or in the ambulance and continues during transport and the initial 12 hour post-injury period in the hospital.

Since blood is not presently carried in ambulances, the use of PolyHeme in this setting has the potential to improve survival and address a critical, unmet medical need.

As of August 14, 2004, 12 clinical sites in the United States were enrolling patients in our Pivotal Phase III Prehospital Trial. Each of these sites is designated as a Level I trauma center because of its capacity to treat the most severely injured trauma patients. We anticipate that a total of approximately 25 or more clinical sites across the United States will eventually participate in the trial. The trial has an expected enrollment of 720 patients.

As part of our trial protocol, an independent data monitoring committee, or IDMC, consisting of independent medical and biostatistical experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any identified risks to patients. The protocol includes four planned evaluations by the IDMC that occur after predefined numbers of patients have been enrolled and monitored for a 30-day follow up period. The IDMC will focus its initial review on mortality and serious adverse events and will review all safety data as the trial continues. We will receive a recommendation from the IDMC after each review, but we will not have access to the trial data reviewed by the IDMC until the trial is completed.

In July 2004, the IDMC recommended that our Pivotal Phase III Prehospital Trial continue without modification based on the committee's initial review of blinded data on mortality and serious adverse events from the first predefined evaluation of the patients enrolled in the trial.

Our Pivotal Phase III Prehospital Trial is being conducted under federal regulations that allow research to be conducted in certain emergent, life-threatening situations using an exception from the requirement for informed patient consent. Participation by each clinical trial site is overseen by a local Institutional Review Board, or IRB. The IRB is an independent body composed of medical, scientific and nonscientific members whose responsibility is to ensure the protection of the rights, safety and well-being of patients enrolled in clinical trials. Under the applicable federal regulations, an IRB may give approval for patient enrollment in trials in emergency situations without requiring individual informed consent provided specific criteria are met. The patients must be in a life-threatening situation and the experimental therapy being evaluated must offer patients the potential for direct clinical benefit in the form of increased survival. Before enrollment can begin, the regulations require public disclosure of information about the trial, including the potential risks and expected benefits. Consultation must also occur with representatives of the community where the study will be conducted and from which the study population will be drawn. The process is individualized and must be tailored to the specific community and patient population involved. Each of

the clinical sites participating in our current trial has completed the required public disclosure and community consultation procedures and received local IRB approval to enroll patients in accordance with the trial protocol.

We have reached agreement with FDA on Special Protocol Assessment, or SPA, for our Pivotal Phase III Prehospital Trial. SPA is an agreement between FDA and a trial sponsor confirming the primary endpoints for the trial protocol and the broad concepts for clinical indications those endpoints would support in a marketing application. FDA's response to our request for SPA also provided comments and recommendations regarding the collection and analysis of the trial data. We have implemented these steps in an effort to ensure that the results of our trial will be appropriate to support a marketing application for product approval.

TRAUMA AND EMERGENCY SURGICAL APPLICATIONS

We have previously conducted clinical trials of PolyHeme in trauma and emergency surgical applications at multiple hospitals in the United States, including both civilian and military institutions. These clinical trials were designed to assess the safety and effectiveness of PolyHeme in treating acute blood loss and hemorrhagic shock in trauma and emergency surgical patients. Patients participating in these trials were infused with up to 20 units (1000 grams) of PolyHeme. This unprecedented dose is equivalent to twice the blood volume of an average adult.

Our clinical protocol allowed us to assess the life-sustaining capacity of PolyHeme following massive blood loss when blood was not used for resuscitation and the red blood cell hemoglobin level fell to life-

threatening levels. The anticipated survival rate at the life-threatening red blood cell hemoglobin levels that occurred in these patients was less than 20% based on the published literature. The observed survival rate in patients receiving PolyHeme was 75%. This improvement demonstrates the ability of PolyHeme to effectively transport oxygen. The important safety observations were that none of the toxicities historically associated with other hemoglobin solutions have been identified in our clinical experience to date.

We analyzed the data from our trauma trials and considered our regulatory position based on our findings. We believe the results from these trials indicate a potential life-saving benefit from the use of PolyHeme in urgent, acute blood loss settings, including trauma, emergency surgery and unexpected life-threatening blood loss during surgical procedures. Based on the strength of these data, in August 2001 we submitted a Biologics License Application, or BLA, to FDA seeking approval to market PolyHeme for use in the treatment of urgent, life-threatening blood loss. In November 2001, FDA issued a refusal to file letter relating to our BLA. We subsequently had numerous meetings with FDA and were successful in reaching consensus with FDA on our Phase III study with PolyHeme.

ELECTIVE SURGICAL APPLICATIONS

We have also conducted clinical trials of PolyHeme in elective surgical applications at multiple locations in the United States. Our clinical protocol for these trials was a randomized controlled study in which elective surgical patients were infused with up to six units of PolyHeme (three liters containing 300 grams of hemoglobin). The majority of elective surgical procedures require the infusion of six units or less of blood.

While the use of PolyHeme in our elective surgery trials was the same as

that for trauma -- high dose, rapid infusion for acute blood loss -- the clinical endpoint for these trials was the elimination of the use of banked blood. Due to the complexity of the clinical protocol, however, patient accrual progressed slowly. As a result, we closed the elective surgery protocol after our BLA was submitted in August 2001. We anticipate other potential trials in elective surgery in the future.

COMPASSIONATE USE

We have enrolled patients on a case by case basis in situations of compassionate use in life-threatening situations. We have provided PolyHeme as treatment in situations of immunologic incompatibility with the available supply of blood, or religious objection to donated blood. Each case was reviewed to be certain that the use of PolyHeme might be beneficial in treating a patient who would otherwise have a high risk of mortality.

MANUFACTURING AND MATERIAL SUPPLY

We use a proprietary process of separation, filtration, chemical modification, purification and formulation to produce PolyHeme. Since 1990, we have produced PolyHeme in our manufacturing facility. We believe this facility is capable of producing sufficient quantities of PolyHeme for all of our clinical trials in the United States. Our current manufacturing capability for PolyHeme is to produce 10,000 units annually. We have leased space adjacent to our current facility that will allow a further expansion of an additional 75,000 units of capacity per year as our next step. Our independent engineering consultants and we believe that our existing manufacturing process may be scaled up without substantial modification to produce commercial quantities of PolyHeme in larger facilities.

If FDA approval of PolyHeme is received, we presently intend to manufacture PolyHeme for commercial sale in the United States using our own facilities. We currently have licensing arrangements for the manufacture of PolyHeme in certain countries outside the United States. We may also consider entering into other collaborative relationships with strategic partners which could involve arrangements relating to the manufacture of PolyHeme.

The successful commercial introduction of PolyHeme will also depend on an adequate supply of blood to be used as a starting material. We believe that an adequate supply of blood is obtainable through the voluntary blood services sector. We have had extensive discussions with existing blood collection agencies, including The

American Red Cross and Blood Centers of America, regarding sourcing of blood. We currently have short-term purchasing contracts with each of these agencies. We have also entered into an agreement with hemerica, Inc., a subsidiary of Blood Centers of America, under which hemerica would supply us with up to 160,000 units per year of packed red cells, the source material for PolyHeme. This quantity of blood would permit us to operate a manufacturing facility producing approximately 75,000 units of PolyHeme per year. We have not purchased any blood supplies under this agreement to date. We will continue to pursue long-term supply contracts with such agencies and other potential sources, although we cannot ensure that we will be able to obtain sufficient quantities of blood from the voluntary blood services sector to enable us to produce commercial quantities of PolyHeme if FDA approval is received.

MARKETING STRATEGIES

If FDA approval of PolyHeme is received, we presently intend to market PolyHeme with our own sales force in the United States. We have retained a

consulting firm to evaluate the potential market and assist us in developing an effective sales and marketing plan for PolyHeme. We may also consider entering into collaborative relationships with strategic partners which could involve arrangements relating to the sale and marketing of PolyHeme.

We have entered into license agreements with Pfizer Inc., formerly known as Pharmacia Corporation, and Hemocare Ltd., an Israeli corporation, to develop, manufacture and distribute PolyHeme in certain European, Middle Eastern and African countries. The license agreements permit Pfizer and Hemocare to utilize PolyHeme and related manufacturing technology in return for the payment of royalties based upon sales of PolyHeme in the licensed territories.

In March 1989, we granted Pfizer an exclusive license to manufacture, promote and sell PolyHeme in a territory encompassing the United Kingdom, Germany, the Scandinavian countries and certain countries in the Middle East. Under the terms of the license agreement, Pfizer has the right, upon consultation with us, to promote and sell PolyHeme in the licensed territory under its own trademark. The license agreement with Pfizer provides for a nonrefundable initial fee, two additional nonrefundable fees based upon achievement of certain regulatory milestones, and ongoing royalty payments based upon net sales of PolyHeme in the licensed territory. The license agreement further provides for a reduction of royalty payments upon the occurrence of certain events. In addition, under the terms of the agreement, we have the right under certain circumstances to direct Pfizer's clinical testing of PolyHeme in the licensed territory.

In July 1990, we granted Hemocare an exclusive license to manufacture, promote and sell PolyHeme in a territory encompassing Israel, Cyprus, Ivory Coast, Jordan, Kenya, Lebanon, Liberia, Nigeria and Zaire. Under the terms of the license agreement, Hemocare has the right, upon consultation with us, to promote and sell PolyHeme in the licensed territory under its own trademark. The license agreement with Hemocare provides for royalty payments based on net sales of PolyHeme in the licensed territory. In addition, under the terms of the license agreement, we have the right under certain circumstances to direct Hemocare's clinical testing of PolyHeme in the licensed territory.

Our present plans with respect to the marketing and distribution of PolyHeme in the United States and overseas may change significantly based on the results of the clinical testing of PolyHeme, the establishment of relationships with strategic partners, changes in the scale, timing and cost of our commercial manufacturing facility, competitive and technological advances, the FDA regulatory process, the availability of additional funding and other factors.

COMPETITION

If approved for commercial sale, PolyHeme will compete directly with established therapies for acute blood loss and may compete with other technologies currently under development. We believe that the treatment of urgent blood loss is the setting most likely to lead to FDA approval and the application which presents the greatest market opportunity. However, several companies have developed or are in the process of developing technologies which are, or in the future may be, the basis for products which will compete with

PolyHeme. Certain of these companies are pursuing different approaches or means of accomplishing the therapeutic effects sought to be achieved through the use of PolyHeme.

Sangart, Inc. has announced that it has received regulatory approval to conduct a Phase II clinical trial in Sweden of a hemoglobin-based blood substitute intended for use in elective and emergency orthopedic surgical

applications. Synthetic Blood International, Inc., which is developing a perfluorocarbon-based blood substitute, has announced plans to begin Phase II clinical trials of its product in surgical patients. Biopure Corporation, which is developing a bovine-source blood substitute product, filed a BLA with FDA in 2002 relating to the use of its product in orthopedic surgical applications. Biopure announced in December 2003 that FDA had raised a number of questions regarding the safety and efficacy of its product and that it had been requested to conduct additional animal studies to address FDA's concerns. Biopure also announced recently that it was initiating a Phase II clinical trial of its product in South Africa. Alliance Pharmaceutical Corp., Baxter International Inc. and Hemosol Corporation have announced that they have suspended clinical trials of their blood substitute products.

We believe that important competitive factors in the market for blood substitute products will include the relative speed with which competitors can develop their respective products, complete the clinical testing and regulatory approval process and supply commercial quantities of their products to the market. In addition to these factors, competition is expected to be based on the effectiveness of blood substitute products and the scope of the intended uses for which they are approved, the scope and enforceability of patent or other proprietary rights, product price, product supply and marketing and sales capability. We believe that our competitive position will be significantly influenced by the timing of the clinical testing and regulatory filings for PolyHeme, our ability to expand our manufacturing capability to permit commercial production of PolyHeme, if approved, and our ability to maintain and enforce our proprietary rights covering PolyHeme and its manufacturing process.

GOVERNMENT REGULATION

The commercial manufacture and distribution of PolyHeme and the operation of our manufacturing facilities will require the approval of United States government authorities as well as those of foreign countries. In the United States, FDA regulates medical products, including the category known as "biologicals" which includes PolyHeme. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of PolyHeme. In addition to FDA regulations, we are also subject to other federal and state regulations, such as the Occupational Safety and Health Act and the Environmental Protection Act. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial funds.

The steps required before a biological product may be sold commercially in the United States include preclinical testing, the submission to FDA of an Investigational New Drug application, clinical trials in humans to establish the safety and effectiveness of the product, the submission to FDA of a BLA relating to the product and the manufacturing facilities to be used to produce the product for commercial sale, and FDA approval of a BLA. After a BLA is submitted there is an initial review by FDA to be sure that all of the required elements are included in the submission. There can be no assurance that the submission will be accepted for filing or that FDA may not issue a refusal to file, or RTF. If a RTF is issued, there is opportunity for dialogue between the sponsor and FDA in an effort to resolve all concerns. There can be no assurance that such a dialogue will be successful in leading to the filing of the BLA. If the submission is filed, there can be no assurance that the full review will result in product approval.

Preclinical tests include evaluation of product chemistry and studies to assess the safety and effectiveness of the product and its formulation. The results of the preclinical tests are submitted to FDA as part of the Investigational New Drug application. The goal of clinical testing is the demonstration in adequate and well-controlled studies of substantial evidence of

the safety and efficacy of the product in the setting of its intended use. The results of preclinical and clinical testing are submitted to the FDA from time to time throughout the trial process. In addition, before approval for the commercial sale of a product can be obtained, results of the

preclinical and clinical studies must be submitted to FDA in the form of a BLA. The testing and approval process requires substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, including the severity of the condition being treated, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional preclinical studies, clinical trials or manufacturing data may be requested during the FDA review process and may delay product approval. After FDA approval for its initial indication(s), further clinical trials may be necessary to gain approval for the use of a product for additional indications. FDA may also require post-marketing testing, which can involve significant expense, to monitor for adverse effects.

Among the conditions for BLA approval is the requirement that the prospective manufacturer's quality controls and manufacturing procedures conform to FDA requirements. In addition, domestic manufacturing facilities are subject to biennial FDA inspections and foreign manufacturing facilities are subject to periodic FDA inspections or inspections by the foreign regulatory authorities with reciprocal inspection agreements with FDA. Outside the United States, we are also subject to foreign regulatory requirements governing clinical trials and marketing approval for medical products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country.

Our regulatory strategy is to pursue clinical testing and FDA approval of PolyHeme in the United States. We intend to seek regulatory approval of PolyHeme outside the United States through licensing or other arrangements with other foreign or domestic companies. To date, we have not conducted any clinical trials of PolyHeme outside of the United States.

PATENTS AND PROPRIETARY RIGHTS

We own eight United States patents and several pending U.S. patent applications, relating to PolyHeme, its uses and certain of our manufacturing processes. We have obtained counterpart patents and have additional patent applications pending in Canada, Israel and various European Union countries. Our United States patents have expiration dates that extend to 2017. We have a policy of seeking patents covering the important techniques, processes and applications developed from our research and all modifications and improvements thereto. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We will continue to seek appropriate protection for our proprietary technology.

We cannot ensure that our patents or other proprietary rights will be determined to be valid or enforceable if challenged in court or administrative proceedings or that we will not become involved in disputes with respect to the patents or proprietary rights of third parties. An adverse outcome from these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to stop using our technology, any of which would result in a material adverse effect on our results of operations and our financial position.

RESEARCH AND DEVELOPMENT

The principal focus of our research and development effort is the support of the clinical trials necessary for regulatory approval of PolyHeme. We also continue to assess our manufacturing processes for improvements and in preparation for FDA's required pre-approval inspection.

In fiscal 2004, 2003 and 2002, our research and development expenses totaled $10,777,000, $8,819,000 and $8,843,000, respectively. We anticipate that these expenses will continue to increase as we fund the further clinical testing of PolyHeme and prepare for production of PolyHeme in commercial quantities.

HUMAN RESOURCES

As of May 31, 2004, we had 63 employees, of whom 55 were involved in research and development and 8 were responsible for financial and other administrative matters. We also had consulting arrangements with 19 individuals as of that date. None of our employees are represented by labor unions, and we are not aware of

any organizational efforts on behalf of any labor unions involving our employees. We consider our relations with our employees to be excellent.

RISK FACTORS

You should consider the following matters when reviewing the information contained in this document. You also should consider the other information incorporated by reference in this document.

WE ARE REQUIRED TO COMPLETE OUR CURRENT CLINICAL TRIAL BEFORE WE MAY SELL POLYHEME COMMERCIALLY AND WE MAY BE REQUIRED TO CONDUCT ADDITIONAL CLINICAL TRIALS IN THE FUTURE.

The results of our clinical trials conducted to date are not sufficient to demonstrate adequately the safety and effectiveness of PolyHeme in order to obtain approval from FDA for the commercial sale of PolyHeme. We are currently conducting a Pivotal Phase III Prehospital Trial in which PolyHeme is being be used for the first time in civilian trauma applications to treat severely injured patients before they reach the hospital. Under this protocol, treatment with PolyHeme begins at the scene of the injury,continues during transport to the hospital by ambulance and further in the hospital. This trial will be expensive and time-consuming and the timing of FDA review process is uncertain. We cannot ensure that we will be able to complete our current clinical trial successfully or that FDA will not require us to conduct additional clinical trials of PolyHeme in the future. If FDA approval for the commercial sale of PolyHeme is obtained, it may include significant limitations on the indicated uses for which PolyHeme may be marketed. Our business, financial condition and results of operations are critically dependent on receiving FDA approval of PolyHeme. A significant delay in our clinical trial or a failure to achieve FDA approval for commercial sales of PolyHeme would have a material adverse effect on us and could result in the cessation of our business. We or FDA may in the future suspend our clinical trial at any time if it is believed that the subjects participating in the trial are being exposed to unacceptable health risks.

OUR ACTIVITIES ARE AND WILL CONTINUE TO BE SUBJECT TO EXTENSIVE GOVERNMENT REGULATION.

Our research, development, testing, manufacturing, marketing and distribution of PolyHeme are, and will continue to be, subject to extensive regulation, monitoring and approval by FDA. The regulatory approval process to establish the safety and effectiveness of PolyHeme and the safety and

reliability of our manufacturing process has already consumed several years and considerable expenditures. The data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA regulatory approval. The lack of established criteria for evaluating the effectiveness of blood substitute products could also delay or prevent FDA regulatory approval. In addition, delay or rejection could be caused by changes in FDA policies and regulations. We cannot ensure that, even after extensive clinical trials, regulatory approval will ever be obtained for PolyHeme.

We will be required to submit a Biologics License Application, or BLA, with FDA in order to obtain regulatory approval for the commercial sale of PolyHeme in the United States. Under FDA guidelines, FDA may comment upon the acceptability of a BLA following its submission. After a BLA is submitted there is an initial review by FDA to be sure that all of the required elements are included in the submission. There can be no assurance that the submission will be accepted for filing or that FDA may not issue a refusal to file, or RTF. If an RTF is issued, there is opportunity for dialogue between the sponsor and FDA in an effort to resolve all concerns. There can be no assurance that such a dialogue will be successful in leading to the filing of the BLA. If the submission is filed, there can be no assurance that the full review will result in product approval. Moreover, if regulatory approval of PolyHeme is granted, the approval may include limitations on the indicated uses for which PolyHeme may be marketed.

Further, even if such regulatory approval is obtained, we do not presently have manufacturing facilities sufficient to profitably produce commercial quantities of PolyHeme. In order to seek FDA approval of the sale of PolyHeme produced at its first commercial manufacturing facility we may be required to conduct a portion of our clinical trials with product manufactured at that facility. Discovery of previously unknown problems with PolyHeme or unanticipated problems with our manufacturing facilities, even after FDA approval of

PolyHeme for commercial sale, may result in the imposition of significant restrictions, including withdrawal of PolyHeme from the market. Additional laws and regulations may also be enacted which could prevent or delay regulatory approval of PolyHeme, including laws or regulations relating to the price or cost-effectiveness of medical products. Any delay or failure to achieve regulatory approval of commercial sales of PolyHeme is likely to have a material adverse effect on our financial condition.

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

WE ARE A DEVELOPMENT STAGE COMPANY WITHOUT REVENUES OR PROFITS.

Northfield was founded in 1985 and is a development stage company. Since 1985, we have been engaged primarily in the development and clinical testing of PolyHeme. No revenues have been generated to date from commercial sales of PolyHeme. Our revenues to date have consisted solely of license fees. We cannot

ensure that our clinical testing will be successful, that regulatory approval of PolyHeme will be obtained, that we will be able to manufacture PolyHeme at an acceptable cost and in appropriate quantities or that we will be able to successfully market and sell PolyHeme. We also cannot ensure that we will not encounter unexpected difficulties which will have a material adverse effect on us, our operations or our properties.

WE HAVE A HISTORY OF LOSSES AND OUR FUTURE PROFITABILITY IS UNCERTAIN.

From Northfield's inception through May 31, 2004, we have incurred net operating losses totaling $125,040,000. We will require substantial additional expenditures to complete clinical trials, to pursue regulatory approval for PolyHeme, to establish commercial scale manufacturing processes and facilities, and to establish marketing, sales and administrative capabilities. These expenditures are expected to result in substantial losses for at least the next several years and are expected to substantially exceed our available capital resources. The expense and the time required to realize any product revenues or profitability are highly uncertain. We cannot ensure that we will be able to achieve product revenues or profitability on a sustained basis or at all.

WE WILL NEED TO RAISE ADDITIONAL CAPITAL TO CONTINUE OUR BUSINESS.

We will be required to raise additional capital to achieve commercial production of PolyHeme. Our future capital requirements will depend on many factors, including the scope and results of our clinical trials, the timing and outcome of regulatory reviews, administrative and legal expenses, the status of competitive products, the establishment of manufacturing capacity and the establishment of collaborative relationships. We cannot ensure that this additional funding will be available or, if it is available, that it can be obtained on terms and conditions we will deem acceptable.

WE ARE DEVELOPING A SINGLE PRODUCT THAT IS SUBJECT TO A HIGH LEVEL OF TECHNOLOGICAL RISK.

Our operations have to date consisted primarily of the development and clinical testing of PolyHeme. We do not expect to realize product revenues unless we successfully develop and achieve commercial introduction of PolyHeme. We expect that such revenues, if any, will be derived solely from sales of PolyHeme. We also expect the use of PolyHeme to be limited primarily to the acute blood loss segment of the transfusion market. The biomedical field has undergone rapid and significant technological changes. Technological developments may result in PolyHeme becoming obsolete or non-competitive before we are able to recover any portion of

the research and development and other expenses we have incurred to develop and clinically test PolyHeme. Any such occurrence would have a material adverse effect on us and our operations.

WE ARE NOT CERTAIN THAT WE WILL BE ABLE TO MANUFACTURE POLYHEME COMMERCIALLY.

Commercial-scale manufacturing of PolyHeme will require the construction of a manufacturing facility significantly larger than that currently being used to produce PolyHeme for our clinical trials. We have no experience in commercial-scale manufacturing, and there can be no assurance that we can achieve commercial-scale manufacturing capacity. It is also possible that we may incur substantial cost overruns and delays compared to existing estimates in building and equipping a commercial-scale manufacturing facility. Moreover, in order to seek FDA approval of the sale of PolyHeme produced at our first commercial manufacturing facility, we may be required to conduct a portion of

our clinical trials with product manufactured at that facility. Accordingly, a delay in achieving scale-up of commercial manufacturing capabilities will have a material adverse effect on sales of PolyHeme. Additionally, the manufacture of PolyHeme will be subject to extensive government regulation. Among the conditions for marketing approval is that our quality control and manufacturing procedures conform to FDA's good manufacturing practice regulations. We cannot ensure that we will be able to obtain the necessary regulatory clearances or approvals to manufacture PolyHeme on a timely basis or at all.

THERE MAY BE LIMITATIONS IN THE SUPPLY OF THE STARTING MATERIAL FOR POLYHEME.

We currently purchase donated blood from The American Red Cross and Blood Centers of America for use as the starting material for PolyHeme. We have also entered into an agreement with hemerica, Inc., a subsidiary of Blood Centers of America, under which hemerica would supply us with up to 160,000 units per year of packed red cells, the source material for PolyHeme. We have not purchased any blood supplies under this agreement to date. We have plans to enter long-term supply arrangements with other blood collectors. We cannot ensure that we will be able to enter into satisfactory long-term arrangements with blood bank operators, that the price we may be required to pay for starting material will permit us to price PolyHeme competitively or that we will be able to obtain an adequate supply of starting material. Additional demand for blood may arise from competing blood substitute products, some of which are derived from human blood, thereby limiting our available supply of starting material.

THERE ARE SIGNIFICANT COMPETITORS DEVELOPING SIMILAR PRODUCTS.

If approved for commercial sale, PolyHeme will compete directly with established therapies for acute blood loss and may compete with other technologies currently under development. We cannot ensure that PolyHeme will have advantages which will be significant enough to cause medical professionals to adopt it rather than continue to use established therapies or to adopt other new technologies or products. We also cannot ensure that the cost of PolyHeme will be competitive with the cost of established therapies or other new technologies or products. The development of blood substitute products is a rapidly evolving field. Competition is intense and expected to increase. Several companies have developed or are in the process of developing technologies which are, or in the future may be, the basis for products which will compete with PolyHeme. Certain of these companies are pursuing different approaches or means of accomplishing the therapeutic effects sought to be achieved through the use of PolyHeme. Some of these companies may have substantially greater financial resources, larger research and development staffs, more extensive facilities and more experience than Northfield in testing, manufacturing, marketing and distributing medical products. We cannot ensure that one or more other companies will not succeed in developing technologies or products which will become available for commercial use prior to PolyHeme, which will be more effective or less costly than PolyHeme or which would otherwise render PolyHeme obsolete or non-competitive.

WE DO NOT HAVE EXPERIENCE IN THE SALE AND MARKETING OF MEDICAL PRODUCTS.

If approved for commercial sale, we intend to market PolyHeme in the United States using our own sales force. We have no experience in the sale or marketing of medical products. Our ability to implement our sales and marketing strategy for the United States will depend on our ability to recruit, train and retain a marketing

staff and sales force with sufficient technical expertise. We cannot ensure that we will be able to establish an effective marketing staff and sales force, that the cost of establishing such a marketing staff and sales force will not exceed

revenues from the sale of PolyHeme or that our marketing and sales efforts will be successful.

THE MARKET MAY NOT ACCEPT OUR PRODUCT.

We anticipate that the market price for PolyHeme, if FDA approval is received, will exceed the cost of transfused blood. Competitors may also develop new technologies or products which are more effective or less costly than PolyHeme. We cannot ensure that the price of PolyHeme, considered in relation to PolyHeme's expected benefits, will be perceived by health care providers and third party payors as cost-effective, or that the price of PolyHeme will be competitive with transfused blood or with other new technologies or products. Our results of operations may be adversely affected if the price of PolyHeme is not considered cost-effective or if PolyHeme does not otherwise receive market acceptance.

OUR PATENTS AND OTHER PROPRIETARY RIGHTS MAY NOT PROTECT OUR TECHNOLOGY.

Our ability to compete effectively with other companies will depend, in part, on our ability to protect and maintain the proprietary nature of our technology. We cannot be certain as to the degree of protection offered by our patents or as to the likelihood that additional patents in the United States and certain other countries will be issued based upon pending patent applications. We cannot be certain that we were the first creator of the inventions covered by our patents or pending patent applications or that we were the first to file patent applications for our inventions. The high costs of enforcing patent and other proprietary rights may also limit the degree of protection afforded to us. We also rely on unpatented proprietary technology, and we cannot ensure that others may not independently develop the same or similar technology or otherwise obtain access to our proprietary technology. We cannot ensure that our patents or other proprietary rights will be determined to be valid or enforceable if challenged in court or administrative proceedings or that we will not become involved in disputes with respect to the patents or proprietary rights of third parties. An adverse outcome from these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to stop using this technology, any of which would result in a material adverse effect on our results of operations.

OUR PROFITABILITY WILL BE AFFECTED IF WE INCUR PRODUCT LIABILITY CLAIMS IN EXCESS OF OUR INSURANCE COVERAGE.

The testing and marketing of medical products, even after FDA approval, have an inherent risk of product liability. We maintain limited product liability insurance coverage for our clinical trials in the total amount of $10 million. However, our profitability will be adversely affected by a successful product liability claim in excess of our insurance coverage. We cannot guarantee that product liability insurance will be available in the future or be available on reasonable terms.

WE DEPEND ON THE SERVICES OF A LIMITED NUMBER OF KEY PERSONNEL.

Our success is highly dependent on the continued services of a limited number of skilled managers and scientists. The loss of any of these individuals could have a material adverse effect on us. In addition, our success will depend, among other factors, on the recruitment and retention of additional highly skilled and experienced management and technical personnel. We cannot ensure that we will be able to retain existing employees or to attract and retain additional skilled personnel on acceptable terms given the competition for such personnel among numerous large and well-funded pharmaceutical and health care companies, universities and non-profit research institutions.

HEALTH CARE REFORM AND CONTROLS ON HEALTH CARE SPENDING MAY LIMIT THE PRICE WE CAN CHARGE FOR POLYHEME AND THE AMOUNT WE CAN SELL.

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

UNCERTAINTY OF THIRD-PARTY REIMBURSEMENT COULD AFFECT OUR PROFITABILITY.

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

THE MARKET PRICE OF OUR COMMON STOCK HAS EXPERIENCED SIGNIFICANT VOLATILITY AND COULD FLUCTUATE IN THE FUTURE.

The market price of our common stock has fluctuated significantly in response to a number of factors, many are which are beyond our control, including:

- regulatory developments relating to our PolyHeme blood substitute product;
- announcements by us relating to the results of our clinical trials of PolyHeme;
- developments relating to our efforts to obtain additional financing to fund our operations;
- announcements by us regarding transactions with potential strategic partners;
- announcements relating to blood substitute products being developed by our competitors;
- changes in industry trends or conditions;
- our issuance of additional debt or equity securities; and
- sales of significant amounts of our common stock or other securities in the market.

In addition, the stock market in general, and the Nasdaq National Market and the biotechnology industry market in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, securities class action litigation has often been instituted following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities and the

diversion of our management's attention and resources.

ANTI-TAKEOVER PROVISIONS CONTAINED IN OUR CHARTER AND BYLAWS COULD DISCOURAGE POTENTIAL TAKEOVER ATTEMPTS.

Our certificate of incorporation contains a "fair price" provision which requires approval of the holders of at least 80% of our voting stock, excluding shares held by certain interested stockholders and their affiliates, as a condition to mergers or certain other business combinations with, or proposed by, any holder of 15% or more of our voting stock, except in cases where approval of our disinterested directors is obtained or certain minimum price criteria and other procedural requirements are satisfied. In addition, our board of directors has the authority, without further action by our stockholders, to fix the rights and preferences and issue shares of preferred stock. These provisions, and other provisions of our certificate of incorporation and bylaws and Delaware law, may have the effect of deterring hostile takeovers or delaying or preventing changes in our

control or management, including transactions in which stockholders might otherwise receive a premium for their shares over the then prevailing market prices.

ITEM 2. PROPERTIES.

We currently lease a manufacturing facility located in Mt. Prospect, Illinois, and maintain our principal executive offices in Evanston, Illinois. The leases for our manufacturing facility and executive offices extend through August 2009 and February 2006, respectively. We have the option to extend the existing lease for three additional five-year periods for the manufacturing facility. Rent expense for our 2004 fiscal year was $915,752. We believe our present manufacturing facility is capable of producing sufficient quantities of PolyHeme for all of our clinical trials in the United States.

Currently, we have a manufacturing capacity of approximately 10,000 units of PolyHeme per year. We have leased additional space adjacent to our existing manufacturing facility but have not yet committed to the buildout of this space. The initial engineering studies on the additional space have been completed and indicate that an additional capacity of 75,000 units of PolyHeme per year could be developed in approximately 16 to 20 months at a cost of $30 to $35 million.

ITEM 3. LEGAL PROCEEDINGS.

As of May 31, 2004, we were not a party to any material pending legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

MARKET INFORMATION

The following table sets forth, for the periods indicated, the range of high and low sales prices for our common stock on the Nasdaq National Market. These prices do not include retail markups, markdowns or commissions.

FISCAL QUARTER ENDED	HIGH	LOW
May 31, 2000	41.50	11.00
August 31, 2000	18.00	11.00
November 30, 2000	16.25	8.50
February 28, 2001	17.50	9.00
May 31, 2001	17.00	8.41
August 31, 2001	21.25	12.70
November 30, 2001	17.75	9.00
February 28, 2002	10.20	7.12
May 31, 2002	8.98	3.91
August 31, 2002	5.66	3.00
November 29, 2002	5.86	3.75
February 28, 2003	6.63	3.30
May 31, 2003	8.85	4.95
August 31, 2003	9.84	5.95
November 30, 2003	7.81	5.50

FISCAL QUARTER ENDED	HIGH	LOW
February 29, 2004	12.14	4.96
May 31, 2004	19.74	11.34
(through July 31, 2004)	15.28	10.17

No purchases of our equity securities were made by or on behalf of Northfield or any affiliated purchaser during our fiscal year ended May 31, 2004.

HOLDERS OF RECORD

As of May 31, 2004, there were approximately 500 holders of record and approximately 18,000 beneficial owners of our common stock. There were as of that date no issued and outstanding shares of our preferred stock.

DIVIDENDS

We have never declared or paid dividends on our capital stock and do not anticipate declaring or paying any dividends in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA.

The selected financial data set forth below for, and as of the end of, each of the years in the five-year period ended May 31, 2004 and for the cumulative period from June 19, 1985 (inception) through May 31, 2004 were derived from Northfield's financial statements, which financial statements have been audited by KPMG LLP, independent registered public accounting firm.

CUMULATIVE

	YEARS ENDED MAY 31,					JUNE 19, 1985 THROUGH
	2004	2003	2002	2001	2000	MAY 31, 2004
	(IN THOUSANDS, EXCEPT PER SHARE DATA)					
STATEMENT OF OPERATIONS DATA:						
Revenues:						
License income	$ --	--	--	--	--	3,000
COSTS AND EXPENSES:						
Research and development	10,777	8,819	8,843	9,437	9,193	107,016
General and administrative	3,854	3,643	2,700	2,786	2,260	44,454
Interest income (net)	131	212	826	2,048	2,286	23,505
Net loss	$(14,574)	(12,250)	(10,717)	(10,175)	(9,167)	(125,040)
Net loss per share basic and diluted	$ (0.86)	(0.86)	(0.75)	(0.71)	(0.64)	(12.21)
Shares used in calculation of per share data(1)	16,932	14,266	14,266	14,253	14,241	10,241
BALANCE SHEET DATA:						
Cash and marketable securities	$ 42,487	6,890	18,389	28,698	38,284	
Total assets	44,179	9,246	21,235	32,502	41,728	
Total liabilities	2,626	2,066	1,804	2,355	1,634	
Deficit accumulated during development stage	(125,040)	(110,466)	(98,216)	(87,498)	(77,324)	
Total shareholders' equity(2)	41,553	7,180	19,430	30,148	40,095	

---

(1) Computed on the basis described in Note 1 of the Notes to Financial Statements.

(2) Excludes 1,203,500 shares reserved for issuance upon the exercise of stock options, 25,500 shares reserved for issuance for restricted share grants outstanding, and 212,392 shares reserved for issuance for stock warrants as of May 31, 2004. Additional stock options for a total of 1,024,665 were available for grant as of May 31, 2004 under our employees stock option plans and stock option plan for outside directors.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Since Northfield's incorporation in 1985, we have devoted substantially all of our efforts and resources to the research, development and clinical testing of our potential product, PolyHeme. We have incurred operating losses during each year of our operations since inception and expect to incur substantial additional operating losses for the next several years. From Northfield's inception through May 31, 2004, we have incurred operating losses totaling $125,040,000.

We will be required to complete our Pivotal Phase III Prehospital Trial and obtain FDA regulatory approval before PolyHeme can be sold commercially. The FDA regulatory process is subject to significant risks and uncertainties, including those described above under "Risk Factors." We therefore cannot at this time reasonably estimate the timing of any future revenues from the commercial sale of PolyHeme. The costs incurred by Northfield to date and during each period

presented below in connection with our development of PolyHeme are described in the Statements of Operations included in this report and in Note 11 of the notes to our financial statements.

Our success will depend on several factors, including our ability to obtain FDA regulatory approval of PolyHeme and our manufacturing facilities, obtain sufficient quantities of blood to manufacture PolyHeme in commercial quantities, manufacture and distribute PolyHeme in a cost-effective manner, enforce our patent positions and raise sufficient capital to fund these activities. We have experienced significant delays in the development and clinical testing of PolyHeme. We cannot ensure that we will be able to achieve these goals or that we will be able to realize product revenues or profitability on a sustained basis or at all.

RESULTS OF OPERATIONS

We reported no revenues for the fiscal years ended May 31, 2004, 2003 or 2002. From Northfield's inception through May 31, 2004, we have reported total revenues of $3,000,000, all of which were derived from licensing fees.

OPERATING EXPENSES

Operating expenses for our fiscal years ended May 31, 2004, 2003 and 2002 totaled $14,630,000, $12,462,000 and $11,543,000, respectively. Measured on a percentage basis, fiscal 2004 operating expenses exceeded fiscal 2003 expenses by 17.4%, while fiscal 2003 operating expenses exceeded fiscal 2002 expenses by 8.0%.

During fiscal 2004, research and development expenses totaled $10,777,000, an increase of $1,958,000, or 22.2%, from fiscal 2003 expenses of $8,819,000. During fiscal 2004, we began enrolling patients in our Pivotal Phase III Prehospital Trial. In December 2003, the first trial site was initiated and by May 31, the number of sites enrolling patients had grown to 11. The expense of site training, initiation and monitoring along with patient study costs are the sources of the increased costs.

We anticipate and are planning for significant increases in research and development spending in fiscal 2005. Available funding is being used to add new clinical sites and expand patient enrollment. Support for this effort will include increased patient monitoring, expanded laboratory analyses, sophisticated data analysis and the manufacture of additional units of PolyHeme. We are also expending considerable effort and resources in reviewing, and modifying when necessary, all current plant operations in anticipation of a required FDA pre-approval inspection.

For our 2003 fiscal year, research and development expenses totaled $8,819,000, representing a decrease of $24,000, or 0.3%, from the prior fiscal year. During 2003, lower clinical trials expense was partially offset by increased manufacturing expenses as we stocked PolyHeme for our current clinical trial.

General and administrative expenses for the fiscal year ended May 31, 2004, totaled $3,854,000, an increase of $211,000, or 5.8%, from the expenses incurred in the comparable prior year period. During our 2004 fiscal year, we pursued significant administrative initiatives to expand and further protect our intellectual property portfolio and to conduct market research on the commercial potential of PolyHeme. Expenses in connection with these initiatives accounted for all of the increases in fiscal 2004. While we have begun the process of planning for commercialization of PolyHeme, our priority and focus remain

centered on successfully executing our Pivotal Phase III Prehospital Trial.

General and administrative expenses for the year ended May 31, 2003, totaled $3,643,000 compared to expenses of $2,700,000 for the year ended May 31, 2002, representing an increase of $943,000, or 34.9%. The increase was due primarily to costs associated with a proxy contest in connection with our 2002 annual meeting of stockholders, as well as costs associated with our increased public relations focus.

We anticipate modest increases in general and administrative expenses in fiscal 2005. Business taxes based on the capitalization of the Company will increase by more than $100,000 in fiscal 2005 as a result of our successful fundraising efforts in fiscal 2004. We also anticipate increased expenses related to the development of a new Web site and expansion of business development activities. We anticipate no other significant administrative initiatives in fiscal 2005.

INTEREST INCOME

Interest income in fiscal 2004 equaled $131,000, representing a decrease of $81,000, or 38.2%, from the $212,000 in interest income reported in fiscal 2003. Lower available investment balances and lower interest rates caused the decrease. Interest income in fiscal 2003 equaled $212,000, representing a decrease of $614,000, or 74.3%, from the $826,000 in interest income reported in fiscal 2002. Significantly lower interest rates and lower available investment balances accounted for the decrease.

Following our successful fundraising efforts in fiscal 2004, we now anticipate interest income will increase substantially in fiscal 2005. Interest rates, however, for short-term high-grade investments remain at historically low levels. Current money market rates range between .4% and 1.0% and one-year investments yield in the 2% range. We remain invested at the short-end of the yield curve with modest expectations for yield improvement over the course of the year. A 1% rate increase yields $10,000 in additional interest income on a $1,000,000 investment over a 12-month period.

NET LOSS

The net loss for our fiscal year ended May 31, 2004 was $14,574,000, or $0.86 per share, compared to a net loss of $12,250,000, or $0.86 per share, for the fiscal year ended May 31, 2003. The increased net loss was primarily due to higher research and development costs associated with our Pivotal Phase III Prehospital Trial. The net loss per share was the same for both fiscal years because the average number of shares outstanding in the current fiscal year increased as a result of our recent fundraising efforts and diluted the increased dollar loss in the current fiscal year.

The net loss for our fiscal year ended May 31, 2003 was $12,250,000, or $0.86 per share, compared to a net loss of $10,717,000, or $0.75 per share, for the fiscal year ended May 31, 2002. The increase in the loss per share for fiscal 2003 was primarily the result of the reduction in interest income, expenses relating to our 2002 annual meeting of stockholders and increased professional services.

LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through May 31, 2004, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of $122,395,000. For the fiscal years ended

May 31, 2004, 2003 and 2002, these cash expenditures totaled $13,259,000, $11,538,000 and $10,310,000, respectively. The fiscal 2004 increase in cash utilization is due primarily to expenses related to our Pivotal Phase III Prehospital Trial.

We have financed our research and development and other activities to date through the public and private sale of equity securities and, to a more limited extent, through the license of product rights. As of May 31, 2004, we had cash and marketable securities totaling $42,487,000.

We believe our existing capital resources will be adequate to satisfy our operating capital requirements, including the expenses we expect will be incurred in connection with our Pivotal Phase III Prehospital Trial and the operation of our existing manufacturing plant and office facilities, for approximately the next 18 to 24 months. Thereafter, we will require substantial additional funding to continue our operations.

We may issue additional equity or debt securities or enter into collaborative arrangements with strategic partners, which could provide us with additional funding or absorb expenses we would otherwise be required to pay. We are also pursuing potential sources of government funding. Any one or a combination of these sources may be utilized to raise additional capital. We believe our ability to raise additional capital or enter into a collaborative arrangement with a strategic partner will depend primarily on the results of our clinical trial, as well as general conditions in the business and financial markets. Our inability to raise sufficient levels of capital could materially delay or prevent the commercialization of PolyHeme, even if it is approved by FDA.

Our capital requirements may vary materially from those now anticipated because of the timing and results of our clinical testing of PolyHeme, the establishment of relationships with strategic partners, changes in the scale, timing or cost of our commercial manufacturing facility, competitive and technological advances, the FDA regulatory process, changes in our marketing and distribution strategy and other factors.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements requires management to make estimates and assumptions that affect amounts reported therein. We believe the following critical accounting policy reflects our more significant judgments and estimates used in the preparation of our financial statements.

NET DEFERRED TAX ASSETS VALUATION

We record our net deferred tax assets in the amount that we expect to realize based on projected future taxable income. In assessing the appropriateness of our valuation, assumptions and estimates are required, such as Northfield's ability to generate future taxable income. In the event we were to determine that it was more likely than not we would be able to realize our deferred tax assets in the future in excess of their carrying value, an adjustment to recognize the deferred tax assets would increase income in the period such determination was made. As of May 31, 2004, we have recorded a 100% percent valuation allowance against our net deferred tax assets.

CONTRACTUAL OBLIGATIONS

The following table reflects a summary of our contractual cash obligations as of May 31, 2004:

CONTRACTUAL CASH OBLIGATIONS	TOTAL	LESS THAN ONE YEAR	1-3 YEARS	4-5 YEARS	6 + YEARS
Lease Obligations(1).....	$3,252,135	$ 855,229	$1,260,178	$1,010,425	$126,303
Other Obligations.....	1,083,317	753,734	329,583	--	--
Total Contractual Cash Obligations.....	$4,335,452	$1,608,963	$1,589,761	$1,010,425	$126,303

---

(1) The lease for our Evanston headquarters is cancelable with six months notice combined with a termination payment equal to six months base rent. At May 31, 2004, this penalty would have amounted to $152,625.

ITEM 7(A). QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK.

We currently do not have any foreign currency exchange risk. We may invest our cash and cash equivalents in government agency securities, corporate debt, certificates of deposit and money market funds. These investments are subject to interest rate risk. However, due to the nature of our short-term investments, we believe that the financial market risk exposure is not material. A one percentage point decrease on our cash and marketable securities balance of $42.5 million at May 31, 2004, would decrease annual interest income by $425,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See the Table of Contents to Financial Statements on page 23. See Note 11 to the Financial Statements on page 41 for Supplementary Quarterly Data. These Financial Statements are incorporated by reference into this document.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

We have not had a disagreement on any matter of accounting principles or financial statement disclosure with our independent accountants during our 2004, 2003 or 2002 fiscal years.

ITEM 9A. CONTROLS AND PROCEDURES.

Based on their evaluation as of the end of the period covered by this report, our Chief Executive Officer and Senior Vice President and Chief Financial Officer have concluded that Northfield's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. There were no significant changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART III

ITEMS 10 THROUGH 14.

The information specified in Items 10 through 14 of Form 10-K has been omitted in accordance with instructions to Form 10-K. We expect to file with the SEC in August 2004, pursuant to Regulation 14A, a definitive proxy statement which will contain the information required to be included in Items 10 through 14 of Form 10-K.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a) The following documents are filed as part of this report:

(1) and (2). See the Table of Contents to Financial Statements on page 23.

(3) See Description of Exhibits on page 42.

(b) On May 14, 2004, the Company filed a form 8-K dated May 12, 2004 relating to a registered direct offering of its common stock (Item 5,7).

(c) See Description of Exhibits on page 42.

(d) None.

NORTHFIELD LABORATORIES INC.
(A COMPANY IN THE DEVELOPMENT STAGE)

TABLE OF CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Northfield Laboratories Inc.:

We have audited the accompanying balance sheets of Northfield Laboratories Inc. (a company in the development stage) as of May 31, 2004 and 2003, and the related statements of operations, shareholders' equity (deficit), and cash flows for each of the years in the three-year period ended May 31, 2004 and for the cumulative period from June 19, 1985 (inception) through May 31, 2004. 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 the standards of the Public Company Accounting Oversight Board (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 financial position of Northfield Laboratories Inc. (a company in the development stage) as of May 31, 2004 and 2003, and the results of its operations and its cash flows for each of the years in the three-year period ended May 31, 2004 and for the cumulative period from June 19, 1985 (inception) through May 31, 2004, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 4 to the financial statements, the Company adopted Statement of Financial Accounting Standards No. 143, "Accounting for Asset Retirement Obligations," as of June 1, 2003.

KPMG LLP

Chicago, Illinois
July 12, 2004

NORTHFIELD LABORATORIES INC.
(A COMPANY IN THE DEVELOPMENT STAGE)

BALANCE SHEETS
MAY 31, 2004 AND 2003

	2004	2003
ASSETS		
Current assets:		
Cash	$ 39,042,884	4,897,962
Marketable securities	3,443,825	1,992,297
Prepaid expenses	614,664	688,755
Other current assets	1,082	--
Total current assets	43,102,455	7,579,014
Property, plant, and equipment, net	1,006,494	1,596,026

Other assets	70,389	71,399
	$ 44,179,338	9,246,439
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,837,651	1,462,586
Accrued expenses	117,007	61,519
Accrued compensation and benefits	418,813	377,117
Total current liabilities	2,373,471	1,901,222
Other liabilities	252,756	165,044
Total liabilities	2,626,227	2,066,266
Shareholders' equity:		
Preferred stock, $.01 par value. Authorized 5,000,000 shares; none issued and outstanding	--	--
Common stock, $.01 par value. Authorized 30,000,000 shares; issued and outstanding 21,398,439 at May 31, 2004 and 14,265,875 at May 31, 2003	213,984	142,659
Additional paid-in capital	166,534,302	117,503,271
Deficit accumulated during the development stage	(125,039,555)	(110,465,757)
Deferred compensation	(155,620)	--
Total shareholders' equity	41,553,111	7,180,173
	$ 44,179,338	9,246,439

See accompanying notes to financial statements.

NORTHFIELD LABORATORIES INC.
(A COMPANY IN THE DEVELOPMENT STAGE)

STATEMENTS OF OPERATIONS
YEARS ENDED MAY 31, 2004, 2003, AND 2002
AND THE CUMULATIVE PERIOD FROM JUNE 19, 1985
(INCEPTION) THROUGH MAY 31, 2004

	YEARS ENDED MAY 31,			CUMULAT FROM JUNE 19, THROU
	2004	2003	2002	MAY 31,
Revenues -- license income	$ --	--	--	3,000
Costs and expenses:				
Research and development	10,776,519	8,819,016	8,843,115	107,016
General and administrative	3,853,769	3,643,318	2,700,183	44,453
	14,630,288	12,462,334	11,543,298	151,470
Other income and expense:				

Interest income	131,411	212,189	825,938	23,588
Interest expense	--	--	--	83
	131,411	212,189	825,938	23,505
Net loss before cumulative effect of change in accounting principle	(14,498,877)	--	--	(124,964
Cumulative effect of change in accounting principle	74,921	--	--	74
Net loss	$(14,573,798)	(12,250,145)	(10,717,360)	(125,039
Net loss per share -- basic and diluted	$ (0.86)	(0.86)	(0.75)	(1
Shares used in calculation of per share data -- basic and diluted	16,932,301	14,265,875	14,265,875	10,240

See accompanying notes to financial statements.

(This page intentionally left blank)

NORTHFIELD LABORATORIES INC.
(A COMPANY IN THE DEVELOPMENT STAGE)
STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
YEARS ENDED MAY 31, 2004, 2003 AND 2002 AND THE CUMULATIVE PERIOD
FROM JUNE 19, 1985 (INCEPTION) THROUGH MAY 31, 2004

	PREFERRED STOCK		COMMO
	NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES
Issuance of common stock on August 27, 1985	--	$ --	3,500,000
Issuance of Series A convertible preferred stock at $4.00 per share on August 27, 1985 (net of costs of issuance of $79,150)	--	--	--
Net loss	--	--	--
Balance at May 31, 1986	--	--	3,500,000
Net loss	--	--	--
Deferred compensation relating to grant of stock options	--	--	--
Amortization of deferred compensation	--	--	--
Balance at May 31, 1987	--	--	3,500,000
Issuance of Series B convertible preferred stock at $35.68 per share on August 14, 1987 (net of costs of issuance of $75,450)	--	--	--
Net loss	--	--	--
Amortization of deferred compensation	--	--	--

Balance at May 31, 1988	--	--	3,500,000
Issuance of common stock at $24.21 per share on June 7, 1988 (net of costs of issuance of $246,000)	--	--	413,020
Conversion of Series A convertible preferred stock to common stock on June 7, 1988	--	--	1,250,000
Conversion of Series B convertible preferred stock to common stock on June 7, 1988	--	--	1,003,165
Exercise of stock options at $2.00 per share	--	--	47,115
Issuance of common stock at $28.49 per share on March 6, 1989 (net of costs of issuance of $21,395)	--	--	175,525
Issuance of common stock at $28.49 per share on March 30, 1989 (net of costs of issuance of $10,697)	--	--	87,760
Sale of options at $28.29 per share to purchase common stock at $.20 per share on March 30, 1989 (net of costs of issuance of $4,162)	--	--	--
Net loss	--	--	--
Deferred compensation relating to grant of stock options	--	--	--
Amortization of deferred compensation	--	--	--
Balance at May 31, 1989	--	--	6,476,585
Net loss	--	--	--
Deferred compensation relating to grant of stock options	--	--	--
Amortization of deferred compensation	--	--	--
Balance at May 31, 1990	--	--	6,476,585
Net loss	--	--	--
Amortization of deferred compensation	--	--	--
Balance at May 31, 1991	--	--	6,476,585
Exercise of stock warrants at $5.60 per share	--	--	90,000
Net loss	--	--	--
Amortization of deferred compensation	--	--	--
Balance at May 31, 1992	--	--	6,566,585
Exercise of stock warrants at $7.14 per share	--	--	15,000
Issuance of common stock at $15.19 per share on April 19, 1993 (net of costs of issuance of $20,724)	--	--	374,370
Net loss	--	--	--
Amortization of deferred compensation	--	--	--
Balance at May 31, 1993	--	--	6,955,955
Net loss	--	--	--
Issuance of common stock at $6.50 per share on May 26, 1994 (net of costs of issuance of $2,061,149)	--	--	2,500,000
Cancellation of stock options	--	--	--
Amortization of deferred compensation	--	--	--
Balance at May 31, 1994	--	--	9,455,955
Net loss	--	--	--
Issuance of common stock at $6.50 per share on June 20, 1994 (net of costs of issuance of $172,500)	--	--	375,000
Exercise of stock options at $7.14 per share	--	--	10,000
Exercise of stock options at $2.00 per share	--	--	187,570
Cancellation of stock options	--	--	--
Amortization of deferred compensation	--	--	--
Balance at May 31, 1995	--	$ --	10,028,525

See accompanying notes to financial statements.

SERIES A CONVERTIBLE PREFERRED STOCK		SERIES B CONVERTIBLE PREFERRED STOCK					S
NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES	AGGREGATE AMOUNT	ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	DEFERRED COMPENSATION	
--.....	$ --	--	$ --	$ (28,000)	$ --	$ --	
250,000..	250,000	--	--	670,850	--	--	
--.....	--	--	--	--	(607,688)	--	
250,000..	250,000	--	--	642,850	(607,688)	--	
--.....	--	--	--	--	(2,429,953)	--	
--.....	--	--	--	2,340,000	--	(2,340,000)	
--.....	--	--	--	--	--	720,000	
250,000..	250,000	--	--	2,982,850	(3,037,641)	(1,620,000)	
--.....	--	200,633	200,633	6,882,502	--	--	
--.....	--	--	--	--	(3,057,254)	--	
--.....	--	--	--	--	--	566,136	
250,000..	250,000	200,633	200,633	9,865,352	(6,094,895)	(1,053,864)	
--.....	--	--	--	9,749,870	--	--	
(250,000)	(250,000)	--	--	237,500	--	--	
--.....	--	(200,633)	(200,633)	190,601	--	--	
--.....	--	--	--	93,759	--	--	
--.....	--	--	--	4,976,855	--	--	
--.....	--	--	--	2,488,356	--	--	
--.....	--	--	--	7,443,118	--	--	
--.....	--	--	--	--	(791,206)	--	
--.....	--	--	--	683,040	--	(683,040)	
--.....	--	--	--	--	--	800,729	
--.....	--	--	--	35,728,451	(6,886,101)	(936,175)	
--.....	--	--	--	--	(3,490,394)	--	
--.....	--	--	--	699,163	--	(699,163)	
--.....	--	--	--	--	--	546,278	
--.....	--	--	--	36,427,614	(10,376,495)	(1,089,060)	
--.....	--	--	--	--	(5,579,872)	--	
--.....	--	--	--	--	--	435,296	
--.....	--	--	--	36,427,614	(15,956,367)	(653,764)	
--.....	--	--	--	503,100	--	--	
--.....	--	--	--	--	(7,006,495)	--	
--.....	--	--	--	--	--	254,025	
--.....	--	--	--	36,930,714	(22,962,862)	(399,739)	
--.....	--	--	--	106,890	--	--	
--.....	--	--	--	5,663,710	--	--	
--.....	--	--	--	--	(8,066,609)	--	
--.....	--	--	--	--	--	254,025	
--.....	--	--	--	42,701,314	(31,029,471)	(145,714)	
--.....	--	--	--	--	(7,363,810)	--	
--.....	--	--	--	14,163,851	--	--	
--.....	--	--	--	(85,400)	--	85,400	

--.....	--	--	--	--	--	267
--------	---------	--------	---------	----------	----------	----------
--.....	--	--	--	56,779,765	(38,393,281)	(60,047)
--.....	--	--	--	--	(7,439,013)	--
--.....	--	--	--	2,261,250	--	--
--.....	--	--	--	71,300	--	--
--.....	--	--	--	373,264	--	--
--.....	--	--	--	(106,750)	--	106,750
--.....	--	--	--	--	--	(67,892)
--------	---------	--------	---------	----------	----------	----------
--.....	$ --	--	$ --	$59,378,829	$(45,832,294)	$ (21,189)
========	=========	========	=========	==========	==========	==========

NORTHFIELD LABORATORIES INC.
(A COMPANY IN THE DEVELOPMENT STAGE)

STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
YEARS ENDED MAY 31, 2004, 2003, AND 2002 AND THE CUMULATIVE PERIOD
FROM JUNE 19, 1985 (INCEPTION) THROUGH MAY 31, 2004

	PREFERRED STOCK		COMMON
	NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES
Net loss.....	--	$ --	--
Issuance of common stock at $17.75 per share on August 9, 1995 (net of costs of issuance of $3,565,125).....	--	--	2,925,000
Issuance of common stock at $17.75 per share on September 11, 1995 (net of costs of issuance of $423,238).....	--	--	438,750
Exercise of stock options at $2.00 per share.....	--	--	182,380
Exercise of stock options at $6.38 per share.....	--	--	1,500
Exercise of stock options at $7.14 per share.....	--	--	10,000
Cancellation of stock options.....	--	--	--
Amortization of deferred compensation.....	--	--	--
Balance at May 31, 1996.....	--	--	13,586,155
Net loss.....	--	--	--
Exercise of stock options at $0.20 per share.....	--	--	263,285
Exercise of stock options at $2.00 per share.....	--	--	232,935
Exercise of stock options at $7.14 per share.....	--	--	10,000
Amortization of deferred compensation.....	--	--	--
Balance at May 31, 1997.....	--	--	14,092,375
Net loss.....	--	--	--
Exercise of stock options at $7.14 per share.....	--	--	5,000
Amortization of deferred compensation.....	--	--	--
Balance at May 31, 1998.....	--	--	14,097,375
Net loss.....	--	--	--
Non-cash compensation.....		--	--
Exercise of stock options at $7.14 per share.....	--	--	17,500
Exercise of stock warrants at $8.00 per share.....	--	--	125,000
Balance at May 31, 1999.....	--	--	14,239,875

Net loss	--	--	--
Non-cash compensation	--	--	--
Exercise of stock options at $13.38 per share	--	--	2,500
Balance at May 31, 2000	--	--	14,242,375
Net loss	--	--	--
Non-cash compensation	--	--	--
Exercise of stock options at $6.38 per share	--	--	6,000
Exercise of stock options at $10.81 per share	--	--	17,500
Balance at May 31, 2001	--	--	14,265,875
Net loss	--	--	--
Balance at May 31, 2002	--	--	14,265,875
Net loss	--	--	--
Balance at May 31, 2003	--	--	14,265,875
Issuance of common stock at $5.60 per share on July 28, 2003 (net of costs of issuance of $909,229)	--	--	1,892,857
Issuance of common stock to directors at $6.08 per share on October 30, 2003	--	--	12,335
Deferred compensation related to stock grants	--	--	25,500
Amortization of deferred compensation	--	--	--
Issuance of common stock at $5.80 per share on January 29, 2004 (net of costs of issuance of $1,126,104)	--	--	2,585,965
Issuance of common stock at $5.80 per share on February 18, 2004 (net of costs of issuance of $116,423)	--	--	237,008
Issuance of common stock at $5.80 per share on April 15, 2004 (net of costs of issuance of $192,242)	--	--	409,483
Issuance of common stock at $12.00 per share on May 18, 2004 (net of costs of issuance of $1,716,831)	--	--	1,954,416
Exercise of stock options at $6.38 per share	--	--	15,000
Net loss	--	--	--
Balance at May 31, 2004		$	$21,398,439

See accompanying notes to financial statements.

SERIES A CONVERTIBLE PREFERRED STOCK		SERIES B CONVERTIBLE PREFERRED STOCK				
NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES	AGGREGATE AMOUNT	ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	DEFERRED COMPENSATION
--	$ --	--	$ --	$ --	$ (4,778,875)	$ --
--	--	--	--	48,324,374	--	--
--	--	--	--	7,360,187	--	--
--	--	--	--	362,937	--	--
--	--	--	--	9,555	--	--
--	--	--	--	71,300	--	--
--	--	--	--	(80,062)	--	80,062
--	--	--	--	--	--	(62,726)
--	--	--	--	115,427,120	(50,611,169)	(3,853)

--	--	--	--	--	(4,245,693)	--
--	--	--	--	50,025	--	--
--	--	--	--	463,540	--	--
--	--	--	--	71,300	--	--
--	--	--	--	--	--	2,569
--	--	--	--	116,011,985	(54,856,862)	(1,284)
--	--	--	--	--	(5,883,378)	--
--	--	--	--	35,650	--	--
--	--	--	--	--	--	1,284
--	--	--	--	116,047,635	(60,740,240)	--
--	--	--	--	--	(7,416,333)	--
--	--	--	--	14,354	--	--
--	--	--	--	124,775	--	--
--	--	--	--	998,750	--	--
--	--	--	--	117,185,514	(68,156,573)	--
--	--	--	--	--	(9,167,070)	--
--	--	--	--	57,112	--	--
--	--	--	--	33,425	--	--
--	--	--	--	117,276,051	(77,323,643)	--
--	--	--	--	--	(10,174,609)	--
--	--	--	--	--	--	--
--	--	--	--	38,220	--	--
--	--	--	--	189,000	--	--
--	--	--	--	117,503,271	(87,498,252)	--
--	--	--	--	--	(10,717,360)	--
--	--	--	--	117,503,271	(98,215,612)	--
--	--	--	--	--	(12,250,145)	--
--	--	--	--	117,503,271	(110,465,757)	--
--	--	--	--	9,671,843	--	--
--	--	--	--	74,877	--	--
--	--	--	--	190,995	--	(191,250)
--	--	--	--	--	--	35,630
--	--	--	--	13,846,633	--	--
--	--	--	--	1,255,853	--	--
--	--	--	--	2,178,664	--	--
--	--	--	--	21,716,616	--	--
--	--	--	--	95,550	--	--
--	--	--	--	--	(14,573,798)	--
--	$ --	--	$ --	$166,534,302	$(125,039,555)	$(155,620)

NORTHFIELD LABORATORIES INC.
(A COMPANY IN THE DEVELOPMENT STAGE)

STATEMENTS OF CASH FLOWS
YEARS ENDED MAY 31, 2004, 2003, AND 2002
AND THE CUMULATIVE PERIOD FROM JUNE 19, 1985
(INCEPTION) THROUGH MAY 31, 2004

	YEARS ENDED MAY 31,			CUMULATIV FROM JUNE 19, 1 THROUGH
	2004	2003	2002	MAY 31, 20
Cash flows from operating activities:				
Net loss	$(14,573,798)	(12,250,145)	(10,717,360)	(125,039,5
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	661,887	812,356	822,257	17,764,9
Non-cash compensation	110,630	--	--	3,663,3
Loss on sale of equipment	--	--	--	66,3
Changes in assets and liabilities:				
Prepaid expenses	74,091	(148,752)	(161,861)	(823,8
Other current assets	(1,082)	1,437	454,423	(1,897,3
Other assets	--	--	49,099	6,8
Accounts payable	375,065	384,874	(694,870)	1,837,6
Accrued expenses	55,488	(148,590)	56,204	117,0
Accrued compensation and benefits	41,696	38,268	77,636	418,8
Other liabilities	87,712	(12,709)	10,893	252,7
Net cash used in operating activities	(13,168,311)	(11,323,261)	(10,103,579)	(103,633,0
Cash flows from investing activities:				
Purchase of property, plant, equipment, and capitalized engineering costs	(90,613)	(214,326)	(206,115)	(18,762,3
Proceeds from sale of land and equipment	--	--	--	1,863,0
Proceeds from matured marketable securities	2,000,000	720,000	29,279,200	411,537,3
Proceeds from sale of marketable securities	--	--	--	7,141,6
Purchase of marketable securities	(3,432,260)	(1,953,138)	(7,736,359)	(422,064,4
Net cash provided by (used in) investing activities	(1,522,873)	(1,447,464)	21,336,726	(20,284,6
Cash flows from financing activities:				
Proceeds from issuance of common stock	52,896,936	--	--	156,646,3
Payment of common stock issuance costs	(4,060,830)	--	--	(9,132,8
Proceeds from issuance of preferred stock	--	--	--	6,644,9
Proceeds from sale of stock options to purchase common shares	--	--	--	7,443,1
Proceeds from issuance of notes payable	--	--	--	1,500,0
Repayment of notes payable	--	--	--	(140,9
Net cash provided by financing activities	48,836,106	--	--	162,960,5
Net (decrease) increase in cash	34,144,922	(12,770,725)	11,233,147	39,042,8
Cash at beginning of period	4,897,962	17,668,687	6,435,540	

Cash at end of period.....	$ 39,042,884	4,897,962	17,668,687	39,042,8

See accompanying notes to financial statements.

NORTHFIELD LABORATORIES INC.
(A COMPANY IN THE DEVELOPMENT STAGE)

NOTES TO FINANCIAL STATEMENTS
MAY 31, 2004 AND 2003

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

DESCRIPTION OF OPERATIONS IN THE DEVELOPMENT STAGE

Northfield Laboratories Inc. (the Company), a Delaware corporation, was incorporated on June 19, 1985 to research, develop, test, manufacture, market, and distribute a hemoglobin-based blood substitute product. The Company is continuing its research and development activities.

BASIS OF PRESENTATION

The financial statements have been prepared in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 7, "Accounting and Reporting by Development Stage Enterprises", which requires development stage companies to employ the same generally accepted accounting principles as operating companies.

During the year ended May 31, 2004, Northfield raised $52.8 million in gross proceeds through common stock offerings. The Company ended the fiscal year with cash and marketable securities of $42.5 million. Existing capital resources will be adequate to satisfy operating capital requirements, including the expenditures the Company expects will be incurred in connection with its Phase III clinical trial for a period of greater than one year. Thereafter, the Company will require substantial additional funding to continue its operations.

MARKETABLE SECURITIES

Marketable securities consist of certificates of deposit with maturities of less than one year. The Company classifies its investment securities as held-to-maturity. Held-to-maturity securities are those securities which the Company has the ability and intent to hold until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related instrument as an adjustment to yield using the straight-line method, which approximates the effective interest method. Interest income is recognized when earned.

PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment are recorded at cost and are depreciated using the straight-line method over the estimated useful lives of the respective assets, generally five to seven years. Leasehold improvements are amortized using the straight-line method over the lesser of the life of the asset or the term of the lease, generally five years.

CAPITALIZED ENGINEERING COSTS

Capitalized engineering costs include design and other initial engineering studies relating to a commercial scale facility. During fiscal 2004 and 2003, the Company capitalized no engineering costs. Capitalized engineering costs are being amortized over a three-year period. For the years ended May 31, 2004, 2003 and 2002 amortization cost recorded was $0, $119,649, and $120,000, respectively. As of May 31, 2003 all capitalized engineering costs have been amortized.

COMPUTATION OF NET LOSS PER SHARE

Basic earnings per share is based on the weighted average number of shares outstanding and excludes the dilutive effect of unexercised common equivalent shares. Diluted earnings per share is based on the weighted average number of shares outstanding and includes the dilutive effect of unexercised common equivalent

shares as long as their inclusion is not anti-dilutive. Because the Company reported a net loss for the years ended May 31, 2004, 2003, and 2002 and the cumulative period from June 19, 1985 (inception) through May 31, 2004, basic and diluted per share amounts are the same.

The following potential common share instruments have been excluded from the computation of per share amounts for all periods presented as their effect on per share calculations is anti-dilutive. The share amounts represent an average annual balance of all outstanding options and warrants.

	2004	2003	2002	CUMULATIVE FROM JUNE 19, 1985 THROUGH MAY 31, 2004
Stock options	1,081,250	826,500	667,250	631,898
Warrants	106,196	--	--	75,389
	1,187,446	826,500	667,250	707,287

Of the total options and warrants outstanding as of May 31, 2004, the Company has 1,048,500 options in-the-money, 155,000 options out-of-the-money, and 212,392 warrants that were in-the-money, that were excluded from the net loss per share calculation.

EMPLOYEE STOCK COMPENSATION

The Company applies the intrinsic value method of APB Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations in accounting for options granted to directors, officers, and key employees under the plans. Accordingly, compensation cost is recorded on the date of grant only if the current market price of the underlying stock exceeds the exercise price. Had compensation cost for the Company's stock option plans been determined using the fair value method prescribed by SFAS No. 123, "Accounting for Stock Based Compensation" (SFAS 123) the Company's net loss and net loss per share would have been the pro forma amounts indicated below:

	2004	2003	2002
Net loss as reported	$(14,573,798)	(12,250,145)	(10,717,360)
Add: Stock based compensation expense included in statements of operations	110,630	--	--
Deduct: Total stock based compensation expense determined under the fair value method for all awards, net of related tax effects	(760,239)	(600,616)	(859,923)
Pro forma net loss	$(15,223,407)	(12,850,761)	(11,577,283)
Basic and diluted earnings per share:			
As reported	(0.86)	(0.86)	(0.75)
Pro forma	(0.90)	(0.90)	(0.81)

For purposes of calculating the compensation cost consistent with SFAS 123, the fair value of each option grant is estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants in fiscal 2004, 2003, and 2002:

	2004	2003	2002
Expected volatility	68.8%	68.6%	66.3%
Risk-free interest rate	3.2%	3.1%	4.8%
Dividend yield	--	--	--
Expected lives	7.9 years	8.0 years	7.0 years

FINANCIAL INSTRUMENTS

The fair market values of financial instruments, which consist of marketable securities (note 2), were not materially different from their carrying values at May 31, 2004 and 2003.

USE OF ESTIMATES

Management of the Company has made a number of estimates and assumptions relating to the reporting of assets and liabilities and the disclosure of contingent assets and liabilities to prepare these financial statements in conformity with accounting principles generally accepted in the United States of America. Actual results could differ from those estimates.

(2) MARKETABLE SECURITIES

The fair market value of the Company's marketable securities was $3,441,669 at May 31, 2004, which included gross unrealized holding losses of $2,156. The fair market value of the Company's marketable securities was $1,992,860 at May 31, 2003, which included gross unrealized holding gains of $563.

At May 31, 2004, the Company held only certificates of deposit. All of these marketable securities were scheduled to mature in less than one year.

(3) PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment, at cost, less accumulated depreciation and amortization, is summarized as follows as of May 31, 2004 and 2003:

	USEFUL LIFE	2004	2003
Manufacturing equipment	5 years	$ 9,734,378	9,694,205
Laboratory equipment	5 years	1,340,440	1,330,425
Office furniture and equipment	7 years	699,186	677,362
Computer equipment	3 years	109,917	109,917
Leasehold improvements and asset retirement obligations	Lease term	1,712,768	1,651,447
Capitalized engineering costs	3 years	924,867	924,867
		14,521,556	14,388,223
Less accumulated depreciation and amortization		(13,515,062)	(12,792,197)
		$ 1,006,494	1,596,026

Depreciation and amortization expense related to property, plant and equipment amounted to $682,992, $856,199, and $821,244, for the years ended May 31, 2004, 2003, and 2002, respectively.

(4) ASSET RETIREMENT OBLIGATIONS

The Company adopted Statement of Financial Accounting Standards, SFAS No. 143, "Accounting for Asset Retirement Obligations" as of June 1, 2003. The cumulative effect of the change in accounting principle upon implementation was to recognize a net asset of $17,800, an increase in liabilities of $92,721 and an increase in net loss of $74,921, or $0.01 per share.

The obligation relates to the restoration of a leased manufacturing facility to its original condition. A liability of $100,000 had been recorded in a prior period.

The Company's asset retirement obligations are included in other liabilities.

The balances and changes thereto are summarized below:

	YEAR ENDED MAY 31, 2004
Obligation at June 1, 2003	$192,721
Accretion	17,345

Obligation at May 31, 2004.....	$210,066

If the change in accounting had been applied retroactively, the Company's pro forma net loss for the years ended May 31, 2004, 2003 and 2002 would have been $14,498,877, $12,268,906 and $10,734,807, respectively with no impact on loss per share for any of the periods. For the cumulative period from June 19, 1985 (inception) through May 31, 2004 the pro forma net loss would have been $125,134,669 with a $0.01 increase in loss per share.

(5) SHAREHOLDERS' EQUITY

On June 19, 1985, the date of incorporation, the Company authorized 5,500,000 shares of $.10 par value common stock. On August 12, 1985, an amendment to the Certificate of Incorporation was approved increasing the authorized number of common shares to 8,750,000 and changing the par value to $.01.

On June 7, 1988, the Company issued 413,020 additional shares of common stock for net proceeds of $9,754,000. In conjunction with this transaction, all outstanding shares of Series A and Series B convertible preferred stock were converted to common stock and the Series B warrants were converted to common stock warrants (note 8). In conjunction with this transaction, options for 47,115 common shares were exercised at $2.00 per share.

On March 6, 1989, the Company issued 175,525 additional shares of common stock for net proceeds of $4,978,610.

On March 30, 1989, the Company issued 87,760 additional shares of common stock for net proceeds of $2,489,234. Also on this date, the Company sold an option to purchase 263,285 shares of common stock for net proceeds of $7,443,118. The option exercise price was $.20 per share. On July 8, 1996, the option was exercised and the Company issued all 263,285 shares of common stock.

On September 30, 1991, the Company issued 90,000 additional shares of common stock for net proceeds of $504,000. These shares were issued as a result of the exercise of common stock warrants.

On June 29, 1992, the Company issued 15,000 additional shares of common stock for net proceeds of $107,040. These shares were issued as a result of the exercise of common stock warrants.

On April 19, 1993, the Company issued 374,370 additional shares of common stock for net proceeds of $5,667,454.

On May 5, 1994, the Company filed an amended and restated Certificate of Incorporation effecting a five-for-one stock split of the Company's common stock. All common share and per share amounts have been adjusted retroactively to give effect to the stock split. Additionally, the amended and restated Certificate of Incorporation effected an increase in the number of authorized shares of common stock to 20,000,000 and authorized 5,000,000 shares of preferred stock.

On May 26, 1994, the Company issued 2,500,000 additional shares of common stock for net proceeds of $14,188,851. The proceeds were received by the Company on June 3, 1994.

On June 20, 1994, the Company issued 375,000 additional shares of common stock for net proceeds of $2,265,000.

During the year ended May 31, 1995, the Company issued 197,570 additional shares of common stock upon the exercise of stock options for cash at $2.00 and $7.14 per share for net proceeds of $446,539.

On August 9, 1995, the Company issued 2,925,000 additional shares of common stock for net proceeds of $48,353,624.

On September 11, 1995, the Company issued 438,750 additional shares of common stock for net proceeds of $7,364,575.

During the year ended May 31, 1996, the Company issued 193,880 additional shares of common stock upon the exercise of stock options for cash at $2.00, $6.38, and $7.14 per share for net proceeds of $445,731.

During the year ended May 31, 1997, the Company issued 506,220 additional shares of common stock upon the exercise of stock options for cash at $0.20, $2.00, and $7.14 per share for net proceeds of $589,927.

During the year ended May 31, 1998, the Company issued 5,000 additional shares of common stock upon the exercise of stock options for cash at $7.14 per share for net proceeds of $35,700.

During the year ended May 31, 1999, the Company issued 142,500 additional shares of common stock upon the exercise of warrants and stock options for cash at $8.00 and $7.14 per share, respectively, for net proceeds of $1,124,950.

During the year ended May 31, 2000, the Company issued 2,500 additional shares of common stock upon the exercise of stock options for cash at $13.38 per share, for net proceeds of $33,450.

During the year ended May 31, 2001, the Company issued 23,500 additional shares of common stock upon the exercise of stock options for cash at $6.38 and $10.81 per share, respectively, for net proceeds of $227,455.

On July 28, 2003, the Company issued 1,892,857 additional shares of common stock for net proceeds of $9,690,771.

On October 30, 2003, the Company issued 12,335 additional shares of common stock to directors in the form of stock grants.

On January 16, 2004, the Company issued 25,500 additional restricted shares of common stock to officers in the form of stock grants.

On January 29, 2004, the Company issued 2,585,965 additional shares of common stock for net proceeds of $13,872,493.

On February 18, 2004, the Company issued 237,008 additional shares of common stock for net proceeds of $1,258,223.

On April 15, 2004, the Company issued 409,483 additional shares of common stock for net proceeds of $2,182,759.

On May 18, 2004, the Company issued 1,954,416 additional shares of common stock for net proceeds of $21,736,160.

On May 26, 2004, the Company issued 15,000 additional shares of common stock upon the exercise of a stock option for cash at $6.38 per share for net proceeds of $95,700.

(6) INCOME TAXES

As a result of losses incurred to date, the Company has not provided for income taxes. As of May 31, 2004, the Company has net operating loss carryforwards for income tax purposes of approximately $122,000,000, which are available to offset future taxable income, if any, from 2005 to 2024. Deferred tax assets primarily resulted from net operating loss carryforwards and differences in the recognition of research and development and depreciation expenses. Additionally, the Company has approximately $3,600,000 of research and experimentation tax credits and investment tax credits available to reduce future income taxes through 2024.

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

The net deferred tax assets as of May 31, 2004 and 2003 are summarized as follows:

	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	$ 50,100,000	44,900,000
Tax credit carryforwards	3,600,000	3,300,000
Other	1,000,000	900,000
	54,700,000	49,100,000
Valuation allowance	(54,700,000)	(49,100,000)
Net deferred tax assets	$ --	--

The net change in the valuation allowance for the fiscal years ended May 31, during fiscal 2004, 2003 and 2002 was an increase of $5,600,000, $4,800,000, and $6,700,000, respectively.

(7) STOCK OPTION PLAN

The Company's Restated Nonqualified Stock Option Plan (the Employee Stock Option Plan) lapsed on September 30, 1996. Following the termination of the plan, all options outstanding prior to the plan termination may be exercised in accordance with their terms. As of May 31, 2004, options to purchase a total of 6,000 shares of the Company's common stock at $6.38 per share were outstanding under the Employee Stock Option Plan. These options expire in 2004, ten years after the date of grant.

In September 1994, the Company adopted the Nonqualified Stock Option Plan for Outside Directors (Directors Plan) which provides for the granting of nonqualified stock options to directors of the Company who are neither employees of nor consultants to the Company and who were not directors of the Company prior to June 1, 1994. Stock options to purchase a total of 200,000 shares of common stock are available under the Directors Plan. During the year ended May 31, 2004 the Company did not grant any options to purchase shares of common stock. During the year ended May 31, 2003 the Company granted 30,000 options to

purchase shares of common stock at $4.09 per share. These options expire in 2012 or ten years after the date of grant. During the year ended May 31, 2002, the Company did not grant any options to purchase shares of common stock.

With an effective date of October 1, 1996, the Company established the Northfield Laboratories Inc. 1996 Stock Option Plan (the 1996 Option Plan). This plan provides for the granting of stock options to the Company's directors, officers, key employees, and consultants. Stock options to purchase a total of 500,000 shares of common stock are available under the 1996 Option Plan. During the years ended May 31, 2004, 2003 and 2002 the Company did not grant any options from this plan.

With an effective date of June 1, 1999, the Company established the Northfield Laboratories Inc. 1999 Stock Option Plan (the 1999 Option Plan). This plan provides for the granting of stock options to the Company's directors, officers, key employees, and consultants. Stock options to purchase a total of 500,000 shares of common stock are available under the 1999 Option Plan. During the year ended May 31, 2004, the Company granted 23,000 options to purchase shares of common stock at $7.13 per share. These options expire in 2013, ten years after the date of grant. During the year ended May 31, 2003, the Company granted 265,000 options to purchase shares of common stock between $3.62 and $7.14 per share. These options expire in 2012 and 2013, ten years after the date of the grant. During the year ended May 31, 2002, the Company granted 54,500 options to purchase shares of common stock at $7.83 and $14.17 per share. These options expire in 2011 and 2012, ten years after date of grant.

With an effective date of January 1, 2003, the Company established the New Employee Stock Option Plan (the "New Employee Plan"). This plan provides for the granting of stock options to the Company's new

employees. Stock options to purchase a total of 350,000 shares are available under the New Employee Plan. During the year ended May 31, 2004, the Company granted 75,000 options to purchase shares of common stock at prices of $7.43 and $7.57. These options expire in 2013 or ten years after date of grant. During the year ended May 31, 2003, the Company granted 10,000 options to purchase shares of common stock at $3.62 per share. These options expire in 2013 or ten years after the date of grant.

With an effective date of September 17, 2003, the Company established 2003 Equity Compensation Plan. This plan provides for the granting of stock, stock options and various other types of equity compensation to the Company's employees, non-employee directors and consultants. Stock options to purchase a total of 750,000 shares are available under the 2003 Equity Compensation Plan. During the year ended May 31, 2004, the Company granted 261,500 options to purchase shares of common stock at prices between $5.94 and $15.15. These options expire in 2013 and 2014 or ten years after date of grant. During the year ended May 31, 2004, the Company granted and issued 12,335 common shares to directors and the Company granted 25,500 restricted common shares to employees. These shares have a two-year vesting period. Restricted stock grants in January 2004 totaled 25,500 shares. At May 31, 2004, the amount of related deferred compensation reflected in shareholders' equity was $155,620. The amortization of deferred compensation for the year ended May 31, 2004, was $35,630.

Additional information on shares subject to options is as follows:

	2004	2003	2002

	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEI AVE EXE PR
Outstanding at beginning of year	959,000	$ 9.62	694,000	$11.81	640,500	$1
Granted	359,500	7.22	305,000	4.48	54,500	1
Exercised	15,000	6.38	--	--	--	
Canceled	100,000	11.67	40,000	8.43	1,000	1
Outstanding at end of year	1,203,500	$ 8.64	959,000	$ 9.62	694,000	$1
Options exercisable at year end	638,250	$10.33	622,125	$11.46	519,500	$1
Weighted-average fair value of options granted during the year	$ 5.10		$ 3.51		$ 9.23	

The following table summarizes information about stock options outstanding at May 31, 2004:

	OPTIONS OUTSTANDING			OPTIO
RANGE OF EXERCISE PRICES	NUMBER OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	OPTIO EXERCIS AT MAY 3 2004
$ 3.62 -- 5.94	325,000	8.63	$ 4.63	87,5
6.08 -- 9.56	329,500	9.09	7.38	44,2
10.66 -- 15.41	549,000	4.65	11.78	506,5

(8) STOCK WARRANTS

In connection with demand notes dated September 23, 1986, the Company issued warrants to purchase a total of 90,000 shares of common stock at $5.60 per share. The warrants were exercised on September 30, 1991.

In connection with a demand note dated July 2, 1987, the Company issued warrants to purchase a total of 3,000 shares of Series B convertible preferred stock at $35.68 per share. On June 7, 1988, these warrants were converted to common stock warrants to purchase 15,000 shares of common stock at $7.14 per share. The warrants were exercised on June 29, 1992.

On March 13, 1993, the Company granted warrants to purchase 125,000 shares of common stock of the Company at $13.00 per share. These warrants were canceled on August 3, 1994 and were reissued at $8.00 per share. These warrants were exercised on May 13, 1999.

In connection with a share offering dated July 28, 2003, the Company issued a warrant to purchase 56,786 shares of common stock at $7.75 per share. The warrant becomes exercisable on July 28, 2004 and expires on July 29, 2008. The Black-Scholes fair value of this warrant is $282,794. The assumptions used to calculate the Black-Scholes value were as follows: the risk-free interest rate was 3.1%, the expected life was five years and the expected volatility was 82.9%.

In connection with a share offering dated January 29, 2004, the Company issued a warrant to purchase 96,974 shares of common stock at $6.88 per share. The warrant becomes exercisable on January 29, 2005 and expires on January 30, 2009. The Black-Scholes fair value of this warrant is $414,079. The assumptions used to calculate the Black-Scholes value were as follows: the risk-free interest rate was 3.2%, the expected life was five years and the expected volatility was 74.4%.

In connection with a share offering dated May 18, 2004, the Company issued a warrant to purchase 58,632 shares of common stock at $13.73 per share. The warrant becomes exercisable on May 18, 2005 and expires on May 17, 2009. The Black-Scholes fair value of this warrant is $484,887. The assumptions used to calculate the Black-Scholes value were as follows: the risk-free interest rate was 4.4%, the expected life was five years and the expected volatility was 77.8%.

(9) LEASES/COMMITMENTS

Rent expense amounted to $915,752, $821,760, and $835,661 for the years ended May 31, 2004, 2003, and 2002, respectively.

The Company lease for its research and manufacturing facility expires August 30, 2009 and includes the option to renew the lease for three successive five-year terms. The lease is collateralized by a $49,200 security deposit as of May 31, 2004.

The Company lease for its corporate facility expires February 14, 2006. The Company has the option to cancel the lease upon giving written notice six months prior to termination as well as paying a penalty equal to six months rent calculated at the rate payable on the date of notice. As of May 31, 2004, this penalty would have amounted to $152,625. The lease is secured by a security deposit of $19,250 as of May 31, 2004.

At May 31, 2004, future minimum lease payments under the operating leases are as follows:

YEARS ENDING MAY 31,	AMOUNT
2005	$ 855,229
2006	756,361
2007	503,817
2008	505,213
2009	505,212
Thereafter	126,303
	$3,252,135

(10) EMPLOYEE BENEFIT PLAN

Effective January 1, 1994, the Company established a defined contribution 401(k) savings plan covering each employee of the Company satisfying certain minimum length of service requirements. Matching contributions to the accounts of plan participants are made by the Company in an amount equal to 33% of each plan participant's before-tax contribution, subject to certain maximum contribution limitations, and are made at the discretion of the Company. Expenses incurred under this plan for Company contributions for the years ended May 31, 2004, 2003, and 2002 amounted to $169,758, $145,307 and $157,294, respectively.

(11) QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table shows our quarterly unaudited financial information for the eight quarters ended May 31, 2004. We have prepared this information on the same basis as the annual information presented in other sections of this report. In management's opinion this information reflects fairly, in all material respects, the results of its operations. You should not rely on the operating results for any quarter to predict the results for any subsequent period or for the entire fiscal year. You should be aware of possible variances in our future quarterly results. See "Risk Factors" in the body of this document.

	QUARTER ENDED					
	(IN THOUSANDS EXCEPT PER SHARE DATA)					
	MAY 31, 2004	FEB. 29, 2004	NOV. 30, 2003	AUG. 31, 2003	MAY 31, 2003	FEB. 200
Revenues	$ --	--	--	--	--	
Costs and Expenses:						
Research and Development	3,389	2,630	2,558	2,199	2,347	2,2
General and Administrative	1,266	883	1,022	683	1,008	7
	4,655	3,513	3,580	2,882	3,355	2,9
Other Income and Expense:						
Interest Income	54	29	25	23	31	
Interest Expense	--	--	--	--	--	
Cumulative effect of change in accounting principle	--	--	--	75	--	
Net Loss	$(4,601)	(3,484)	(3,555)	(2,934)	(3,324)	(2,9
Net Loss Per share -- Basic and Diluted	$ (0.24)	(0.20)	(0.22)	(0.20)	(0.23)	(0.
Shares used in calculation	19,501	17,093	16,163	14,965	14,266	14,2

EXHIBITS

NUMBER	DESCRIPTION
3.1	Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on March 25, 1994, File No. 33-76856 (the "S-1 Registration Statement"))
3.2	Certificate of Amendment to Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1999)
3.3	Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.4 to the S-1 Registration Statement)
10.1	Office Sublease dated as of April 20, 1993 between the Registrant and First Illinois Bank of Evanston, N.A., as Trustee (incorporated herein by reference to Exhibit 10.1 to the S-1 Registration Statement)
10.2	Amendment to Lease dated as of January 7, 1998 between the Registrant and First Illinois Bank of Evanston, N.A. (incorporated herein by reference to Exhibit 10.1.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 1998)
10.3	Lease dated as of June 8, 1989 between the Registrant and OTR (incorporated by reference to Exhibit 10.2 to the S-1 Registration Statement)
10.4	Amendment to Lease dated as of May 6, 1998 between the Registrant and OTR (incorporated herein by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the Registrant's fiscal year ended May 31, 1998)
10.5	Third Amendment to Lease dated as of September 16, 1999 between the Registrant and OTR (incorporated be reference to Exhibit 10.4.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1999)
10.6	Fourth Amendment to Lease dated as of September 22, 2003 between the Registrant and OTR (incorporated by reference to Exhibit 10.18 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended August 31, 2003).
10.7	License Agreement dated as of March 6, 1989 between the Registrant and KabiVitrum AB (predecessor of Pharmacia & Upjohn Inc.) (incorporated herein by reference to Exhibit 10.6 to the S-1 Registration Statement)
10.8	License Agreement dated as of July 20, 1990 between the Registrant and Eriphyle BV (incorporated herein by reference to Exhibit 10.7 to the S-1 Registration Statement)
10.9*	Northfield Laboratories Inc. 401(K) Plan (incorporated herein by reference to Exhibit 10.14 to the S-1 Registration Statement)
10.10*	Northfield Laboratories Inc. Nonqualified Stock Option Plan for Outside Directors (incorporated herein by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K for the Registrant's fiscal year ended May 31, 1994)
10.11*	Northfield Laboratories Inc. 1996 Stock Option Plan (incorporated herein by reference to Exhibit 10.5.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1997)
10.12*	Northfield Laboratories Inc. 1999 Stock Option Plan (incorporated herein by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the Registrant's fiscal year ended May 31, 1999)

10.13*	Northfield Stock Option Plan for New Employees (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on June 27, 2003, File No. 333-106615 the "S-3 Registration Statement")

NUMBER	DESCRIPTION
10.14*	Northfield Laboratories Inc. 2003 Equity Compensation Plan (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on October 30, 2003, File No. 333-110110.)
10.15*	Employment Agreement dated as of January 1, 2003 between the Registrant and Steven A. Gould, M.D. (incorporated herein by reference to Exhibit 10.13 to the S-3 Registration Statement)
10.16*	Employment Agreement dated as of January 1, 2003 between the Registrant and Jack J. Kogut (incorporated herein by reference to Exhibit 10.14 to the S-3 Registration Statement)
10.17	Form of Indemnification Agreement -- Director and Executive Officer (incorporated herein by reference to Exhibit 10.18 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001)
10.18	Form of Indemnification Agreement -- Director (incorporated herein by reference to Exhibit 10.19 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001)
10.19	Form of Indemnification Agreement -- Executive Officer (incorporated herein by reference to Exhibit 10.20 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001)
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Rule 13a-14(a)/15d-14(a)
31.2	Certification Pursuant to Rule 13a-14(a)/15d-14(a)
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

---

* Indicates a management contract or compensatory plan or arrangement required to be filed as an exhibit to Form 10-K pursuant to Item 14(c).

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this August 13, 2004.

NORTHFIELD LABORATORIES INC.

By: /s/ STEVEN A. GOULD, M.D.

Steven A. Gould, M.D.
Chairman of the Board and
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company in the capacities indicated on August 13, 2004.

SIGNATURE	TITLE
/s/ STEVEN A. GOULD, M.D. Steven A. Gould, M.D.	Chairman of the Board and Chief Executive Officer (principal executive officer)
/s/ JACK J. KOGUT Jack J. Kogut	Senior Vice President and Chief Financial Officer (principal financial and accounting officer)
/s/ JOHN F. BIERBAUM John F. Bierbaum	Director
/s/ BRUCE S. CHELBERG Bruce S. Chelberg	Director
/s/ PAUL M. NESS, M.D. Paul M. Ness, M.D.	Director
/s/ JACK OLSHANSKY Jack Olshansky	Director
/s/ DAVID A. SAVNER	

David A. Savner	Director