NORTHFIELD LABORATORIES INC /DE/
Form 10-K
August 13, 2003

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 period ended May 31, 2003

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

COMMISSION FILE NUMBER 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). [ ] Yes [X] No

As of November 29, 2002, 14,265,875 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 29, 2002) held by non-affiliates of the Registrant was $45,764,148 (11,556,603 shares at $3.96 per share).

As of July 31, 2003, there were 16,158,732 shares of the Registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2003 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 prospects, clinical and regulatory developments affecting our potential product and our business strategies. These forward-looking statements are identified by the use of such terms as "intends," "expects," "plans," "estimates," "anticipates," "should" and "believes" and are in certain cases followed by a cross reference to "Risk Factors."

These forward-looking statements involve risks and uncertainties. Actual results may differ materially from those predicted by the forward-looking statements because of various factors and possible events, including those discussed under "Risk Factors." Because these forward-looking statements involve risks and uncertainties, actual results may differ significantly from those predicted in these forward-looking statements. You should not place undue weight on these statements. These 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.

All subsequent written and oral forward-looking statements attributable to Northfield or any person acting on our behalf are qualified by the cautionary statements in this section. We will have no obligation to revise these forward-looking statements.

PART I

ITEM 1. DESCRIPTION OF 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(R) 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 safely infused in clinical trials in sufficient quantities to be useful in 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 have received clearance from the U.S. Food and Drug Administration, or FDA, to proceed with a pivotal Phase III trial in which PolyHeme will be 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 will begin at the scene of the injury or in the ambulance and continue 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 thereby address a critical, unmet medical need.

We also recently received a response from FDA on our request for Special Protocol Assessment, or SPA, for our urban ambulance trial, confirming that agreement had been reached on the primary endpoints for the protocol and the broad concepts for clinical indications those endpoints would support. The response also provided comments and recommendations regarding the collection and analysis of the trial data. We are implementing these steps before enrollment begins to ensure that the results of the trial will be appropriate to support a marketing application for product approval. Agreements that are part of an SPA become part of the administrative record and may only be changed by mutual agreement of the parties, or if FDA identifies a substantial scientific issue relevant to safety or efficacy after the trial has begun.

We are currently in contact with over 40 potential clinical sites in an effort to complete the trial at the earliest possible date. We anticipate that approximately 20 Level I trauma centers throughout the United States will eventually participate in the PolyHeme trial, which has an expected enrollment of 720 patients. The process of public disclosure and community consultation required under the regulations is underway at a number of potential trial sites across the country.

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 as life-saving therapy in situations of compassionate use. The observations in these trials have demonstrated the potential clinical utility of PolyHeme in the treatment of urgent blood loss and life-threatening hemoglobin levels. In these trials in hospitalized trauma patients, 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 and has the greatest market opportunity. We believe we are the only company in our field with an oxygen-carrying blood substitute that has been rapidly infused at such high doses -- as much as 20 units (1,000 grams) or twice the blood volume of the average adult.

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 refuse to file letter relating to our BLA. We subsequently had numerous meetings with FDA and were successful in reaching consensus with FDA on our current clinical development plan for PolyHeme.

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,

8-Ks and other documents that we file with or furnish to the Securities and Exchange Commission 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.

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 were transfused in the United States in 2002, of which approximately 8.4 million units were 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 and chemical modification to produce PolyHeme. Hemoglobin is first extracted from red blood cells and filtered to remove impurities. The purified 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 demonstrate the 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 and clinical 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 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 were transfused in the United States in 2002, of which approximately 8.4 million units were administered to patients suffering the effects of acute blood loss. Patient charges for the units of blood used in the United States in 2002 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.

PolyHeme is intended for use in the treatment of acute blood loss. The two principal clinical settings in which patients experience acute blood loss are urgent use in trauma, emergency surgery and other unexpected blood loss, and elective use in planned surgery. For trauma and emergency surgical procedures, the immediate availability and universal compatibility of PolyHeme are expected to provide significant advantages over transfused blood by avoiding the delay and opportunities for error associated with blood typing. The major benefit of PolyHeme in elective surgery is expected to be increased transfusion safety for patients and health care professionals.

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 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

In March 2003, we received FDA approval to initiate a pivotal Phase III trial in which PolyHeme will be 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 will begin at the scene of the injury or in the ambulance and continue 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 thereby address a critical, unmet medical need.

In June 2003, we received a response from FDA on our request for Special Protocol Assessment, or SPA, for our urban ambulance trial, confirming that agreement had been reached on the primary endpoints for the

protocol and the broad concepts for clinical indications those endpoints would support. The response also provided comments and recommendations regarding the collection and analysis of the trial data. We are implementing these steps before enrollment begins to ensure that the results of the trial will be appropriate to support a marketing application for product approval. Agreements that are part of an SPA become part of the administrative record and may only be changed by mutual agreement of the parties, or if FDA identifies a substantial scientific issue relevant to safety or efficacy after the trial has begun.

We are currently in contact with over 40 potential clinical sites in an effort to complete the trial at the earliest possible date. We anticipate that approximately 20 Level I trauma centers throughout the United States will eventually participate in the PolyHeme trial, which has an expected enrollment of 720 patients. The process of public disclosure and community consultation required under the regulations is underway at a number of potential trial sites across the country.

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 refuse to file letter relating to our BLA. We subsequently had numerous meetings with FDA and were successful in reaching consensus with FDA on our current clinical development plan for PolyHeme.

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 occur in our patients is less than 20% based on the published literature. The observed survival rate in our 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.

We analyzed the data from our trauma trials and considered our regulatory position based on our findings. We were pleased with the results from these trials, which demonstrated 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. We submitted our BLA to FDA in August 2001 based on the strength of these data.

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. We anticipate other potential trials in elective surgery in the future.

COMPASSIONATE USE

We continue to enroll patients on a case by case basis in situations of compassionate use on an emergent basis in life-threatening situations. We provide PolyHeme as life-saving treatment in situations of immunologic incompatibility with the available supply of blood, or religious objection to donated blood. Each case is reviewed to be certain that the use of PolyHeme may be beneficial in treating a patient who would otherwise have a high risk of mortality. We will continue this support on an on-going basis.

MANUFACTURING AND MATERIAL SUPPLY

We use a proprietary process of separation, filtration and chemical modification 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 are also considering 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. 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 intend to market PolyHeme with our own sales force in the United States. We intend to recruit and train a specialty sales force of approximately 20 individuals to introduce PolyHeme in selected markets. The selling effort will target approximately 500 hospitals which utilize over 70% of the nation's blood supply. We believe the most important marketing activities will be educating, stimulating use by and servicing health care professionals. If we secure a partnership with a pharmaceutical company with expertise in marketing this strategy will change.

We may pursue licenses or other arrangements for the manufacture and distribution of PolyHeme both inside and outside the United States. We have entered into license agreements with Pharmacia Corporation, now Pfizer Inc., and Hemocare Ltd., an Israeli corporation, to develop, manufacture and distribute PolyHeme in certain European, Middle Eastern and African countries. The license agreements permit Pharmacia 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 Pharmacia 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, Pharmacia has the right, upon consultation with us, to promote and sell PolyHeme in the licensed territory under its own trademark. The license agreement with Pharmacia 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 Pharmacia'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 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 other new technologies or products. We also cannot ensure that the price of PolyHeme, in light of PolyHeme's potential advantages, will be competitive with the price of established therapies or other new technologies or products.

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. Some of these companies 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 and products which will be 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 noncompetitive. A bovine-source hemoglobin-based oxygen-carrier has been approved for human use in South Africa and a BLA was submitted to FDA for its use in the United States.

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 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 filing 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.

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 effectiveness of the product in the setting of its intended use. The results of preclinical and clinical testing are submitted to 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 or clinical trials may be requested during the FDA review process and may delay product approval. After FDA approval for its initial indications, 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 arrange for testing and 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 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 expire in 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 have also contracted for the preliminary engineering necessary to assess the production of PolyHeme in commercial quantities.

In fiscal 2003, 2002 and 2001, our research and development expenses totaled $8,819,000, $8,843,000 and $9,437,000, 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, 2003, we had 63 employees, of whom 55 were involved in research and development and eight were responsible for financial and other administrative matters. We also had consulting arrangements with 13 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 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 preparing to commence enrollment in a pivotal Phase III trial in which PolyHeme will 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 will begin at the scene of the injury and continue during transport to the hospital by ambulance. This trial is likely to 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 clinical trials successfully or obtain FDA approval of PolyHeme, or that FDA approval, if obtained, will not include 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 planned clinical trials or a failure to achieve FDA approval of 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 clinical trials at any time if it is believed that the subjects participating in such trials 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 file 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 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, OUR FUTURE PROFITABILITY IS UNCERTAIN AND OUR FINANCIAL STATEMENTS ARE SUBJECT TO A GOING CONCERN EXPLANATORY PARAGRAPH BY OUR INDEPENDENT ACCOUNTANTS.

From Northfield's inception through May 31, 2003, we have incurred net operating losses totaling $110,466,000. 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. As a result of these factors, our independent accountants have included an explanatory paragraph in their audit opinion based on uncertainty regarding our ability to continue as a going concern.

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. Our independent accountants have included an explanatory paragraph in their audit opinion based on uncertainty regarding our ability to continue as a going concern. A statement of this type may interfere with our ability to issue our securities to the public or in private transactions. Any additional funding derived from the sale of equity securities may result in significant dilution to our existing stockholders.

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 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. A bovine-source hemoglobin-based oxygen-carrier has been approved for human use in South Africa and a BLA is under review by FDA for its use in the United States.

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. Patent applications in the United States are maintained in secrecy until patents are issued. 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.

PART II

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 2004 and February 2006, respectively. We have the option to extend the existing lease for two additional five-year periods for the manufacturing facility. Rent expense for our 2003 fiscal year was $821,760. 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, 2003, we were not a party to any material pending legal proceedings.

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

None.

PART III

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

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, 1999	15.00	10.50
August 31, 1999	13.88	11.00
November 30, 1999	15.25	11.25
February 29, 2000	23.31	10.00
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
(through July 31, 2003)	9.84	5.95

HOLDERS OF RECORD

As of May 31, 2003, there were approximately 450 holders of record and approximately 11,000 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, 2003 and for the period from June 19, 1985 (inception) through May 31, 2003 were derived from Northfield's financial statements, which financial statements have been audited by KPMG LLP, independent certified public accountants.

	YEARS ENDED MAY 31,					CUMULATIVE FROM JUNE 19, 1985 THROUGH
	2003	2002	2001	2000	1999	MAY 31, 2003
	(IN THOUSANDS, EXCEPT PER SHARE DATA)					
STATEMENT OF OPERATIONS DATA:						
Revenues:						
License income	$ --	--	--	--	--	3,000
Costs and expenses:						
Research and development	8,819	8,843	9,437	9,193	7,661	96,240
General and administrative	3,643	2,700	2,786	2,260	2,311	40,600
Interest income (net)	212	826	2,048	2,286	2,556	23,374
Net loss	$(12,250)	(10,717)	(10,175)	(9,167)	(7,416)	(110,466)
Net loss per share basic and diluted	$ (0.86)	(0.75)	(0.71)	(0.64)	(0.53)	(11.20)
Shares used in calculation of per share data(1)	14,266	14,266	14,253	14,241	14,115	9,863

	2003	2002	2001	2000	1999
BALANCE SHEET DATA:					
Cash and marketable securities	$ 6,890	$18,389	$28,698	$38,284	$47,561
Total assets	9,246	21,235	32,502	41,728	50,963
Total liabilities	2,066	1,804	2,355	1,634	1,791
Deficit accumulated during development stage	(110,466)	(98,216)	(87,498)	(77,324)	(68,157)
Total shareholders' equity(2)	7,180	19,430	30,148	40,095	49,171

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

(2) Excludes 959,000 shares reserved for issuance upon the exercise of stock options outstanding as of May 31, 2003. Additional stock options for a total

of 493,000 shares and 140,000 shares, respectively, were available for grant as of May 31, 2003 under our employee 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, 2003, we have incurred operating losses totaling $110,466,000.

We will be required to complete our planned Phase III clinical trials 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 and in note 10 of 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, 2003, 2002 or 2001. From Northfield's inception through May 31, 2003, 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, 2003, 2002 and 2001 totaled $12,462,000, $11,543,000 and $12,222,000, respectively. Measured on a percentage basis, fiscal 2003 operating expenses exceeded fiscal 2002 expenses by 8.0%, while fiscal 2002 operating expenses were lower than fiscal 2001 expenses by 5.6%.

For our 2003 fiscal year, research and development expenses totaled $8,819,000, representing a decrease of $24,000, or 0.2%, from the prior fiscal year. Lower clinical trials expense was partially offset by increased manufacturing costs as we built inventory for our upcoming clinical trials.

We are planning for a significant increase in research activity and related expense in fiscal 2004. Preparation for our Phase III prehospital trial is nearing completion and patient enrollment is forecasted to start in the fourth quarter of the calendar year. Expenses directly related to the trial for fiscal year 2004 is estimated at $10,000,000. These expenses include per patient

charges by the participating trial sites for the 720 enrollees as well as expenses for data gathering, analysis and audit, project management, lab analysis and interim reporting. Northfield is also planning a modest employment expansion in support of the trial.

For our 2002 fiscal year, research and development expenses totaled $8,843,000, representing a decrease of $594,000, or 6.3%, from the 2001 fiscal year. During fiscal 2002, Northfield closed all of its then current clinical trials, except those relating to compassionate use. The elimination of these expenses caused fiscal 2002 research and development expenses to be less than those incurred in fiscal 2001.

General and administrative expenses for fiscal 2003 totaled $3,643,000 compared to expenses of $2,700,000 for fiscal 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 increased costs associated with our increased public relations focus.

General and administrative expenses for fiscal 2002 totaled $2,700,000 compared to expenses of $2,786,000 for fiscal 2001, representing a decrease of $86,000, or 3.1%. The decrease was due primarily to reduced professional fees.

We anticipate that general and administrative expenses will likely increase in fiscal 2004. The cost of directors and officers liability insurance has increased by $140,000 and we expect to incur additional expenses in expanding the organization in support of planning for the commercialization of PolyHeme.

INTEREST INCOME

Interest income in fiscal 2003 equaled $212,000, representing a decrease of $614,000, or 74.4%, from the $826,000 in interest income reported in fiscal 2002. Interest income in fiscal 2002 equaled $826,000, representing a decrease of $1,222,000, or 59.7%, from the $2,048,000 in interest income reported in fiscal 2001. Significantly lower interest rates and lower available investment balances accounted for the decrease. Significantly lower interest rates and lower available investment balances account for the decrease. Currently available short-term interest rates are yielding less than 1.00%.

Interest rates for short-term high grade investments are at near record lows. Money market rates range from 0.4% to 0.9%, one-year certificates of deposit are quoted at 1.1% and other investment types provide similar returns. The combination of extremely low available rates and the accelerating use of cash will combine to cause fiscal 2004 interest income to be significantly below fiscal 2003 interest income.

NET LOSS

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 is primarily the result of the reduction in interest income, expenses relating to our 2002 annual meeting of stockholders and increased professional services.

The net loss for our fiscal year ended May 31, 2002 was $10,717,000, or $.75 per share, compared to a net loss of $10,175,000, or $.71 per share, for the fiscal year ended May 31, 2001. The increase in the loss per share is primarily the result of the reduction in interest income. Fiscal 2002 operating expenses were $679,000 less than those incurred in fiscal 2001, while interest income in fiscal 2002 was $1,222,000 less than the interest income earned in

fiscal 2001.

LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through May 31, 2003, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of $110,466,000. For the fiscal years ended May 31, 2003, 2002 and 2001, these cash expenditures totaled $11,538,000, $10,310,000 and $9,813,000, respectively. The fiscal 2003 increase in cash utilization is due primarily to lower interest income, expenses related to our 2002 annual meeting of stockholders, professional services for investor relations and expense associated with our directors and officers liability insurance.

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, 2003, we had cash and marketable securities totaling $6,890,000. In July 2003, we sold 1,892,857 shares of our common stock in an offering transaction that generated gross proceeds before expenses of $10,600,000. Net proceeds from this offering were approximately $9.8 million.

We believe our existing capital resources will be adequate to satisfy our operating capital requirements and maintain our existing manufacturing plant and office facilities through March 1, 2004. In addition, our existing capital resources are expected to be sufficient to support expenditures incurred in connection with our planned Phase III clinical trials during this period. Thereafter, we will require substantial additional funding to continue our operations and complete our planned clinical trials.

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 planned clinical trials 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.

We cannot ensure that we will be able to achieve product revenues or profitability on a sustained basis or at all. As a result, our independent accountants have included an explanatory paragraph in their audit opinion based on uncertainty regarding our ability to continue as a going concern.

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

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 consolidated 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, 2003, we have recorded a 100% 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, 2003:

CONTRACTUAL CASH OBLIGATIONS	TOTAL	LESS THAN ONE YEAR	1-3 YEARS	4-5 YEARS
Lease obligations(1)	$1,578,938	857,502	721,436	--
Other obligations	1,406,861	888,544	518,317	--
Total contractual cash obligations	$2,985,799	1,746,046	1,239,753	--

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(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, 2003, this penalty would have amounted to $148,500.

RECENT ACCOUNTING PRONOUNCEMENTS

In August 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 143, Accounting for Asset Retirement Obligations, (SFAS 143) which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and for the associated asset retirement

costs. SFAS 143 requires an enterprise to record the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of tangible long-lived assets that result from the acquisition, construction, development and/or normal use of the assets. The enterprise also is to record a corresponding increase to the carrying amount of the related long-lived assets (i.e., the associated asset retirement costs) and to depreciate that cost over the life of the assets. The liability is changed at the end of each period to reflect the passage of time and changes in the estimated future cash flows underlying the initial fair value measurement. Adoption of SFAS 143 is required for fiscal years beginning after June 15, 2002. Upon adoption of this statement we expect to record an additional liability of approximately $138,000, as the additional costs required to restore our leased manufacturing facility back to its move in condition.

In December 2002, the FASB released SFAS No. 148, Accounting for Stock-Based Compensation -- Transition and Disclosure, an amendment of FASB Statement No. 123 (SFAS 148). This Statement amends SFAS 123, to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements. The provisions of SFAS 148 related to transition from the intrinsic-value to the fair-value method and annual disclosures are effective for fiscal years ending after December 15, 2002. The provisions of the Statement related to interim disclosures are effective in financial reports containing financial statements for interim periods beginning after December 31, 2002. The annual disclosures are included in the notes to these financial statements.

On May 15, 2003 the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity (SFAS 150). The provisions of the Statement will change the classification of certain freestanding financial instruments that are now classified as equity. Generally, the Statement is effective for financial instrument arrangements entered into or modified after May 31, 2003. As of May 31, 2003, the adoption of SFAS 150 does not have a material effect on the financial position, results of operations, or cash flows of the Company. The Company is currently evaluating the impact of SFAS 150 subsequent to May 31, 2003.

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

The Company currently does not have any foreign currency exchange risk. The Company invests its cash and cash equivalents in government securities, certificates of deposit and money market funds. These investments are subject to interest rate risk. However, due to the nature of the Company's short-term investments, it believes that the financial market risk exposure is not material. A one percentage point decrease on an investable balance of $6.9 million would decrease interest income by $69,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See the Table of Contents to Financial Statements on page 22. See Note 10 to the Financial Statements on page 38 for Supplementary Quarterly Data. These Financial Statements are incorporated by reference into this document.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON A 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 2003, 2002 or 2001 fiscal years.

PART III

ITEMS 10 THROUGH 13.

The information specified in Items 10 through 13 of Form 10-K has been omitted in accordance with instructions to Form 10-K. We expect to file with the Commission in August 2003, pursuant to Regula-

tion 14A, a definitive proxy statement which will contain the information required to be included in Items 10 through 13 of Form 10-K.

ITEM 14. 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.

ITEM 15. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

During fiscal 2003, we paid KPMG LLP, our independent accountants, the following fees:

Audit Fees. For professional services rendered for the audit of our fiscal year 2003 consolidated financial statements and the review of the financial statements included in our fiscal year 2003 Forms 10-Q, KPMG billed us a total of $74,000.

Financial Information System Design and Implementation Fees. KPMG provided no professional services to us of the nature described in Paragraph (c)(4)(ii) of Rule 2-01 of Regulation S-X during the fiscal year ended May 31, 2003.

All Other Fees. In addition to the fees described above, KPMG billed us an aggregate of $21,500 for all other services rendered during fiscal year 2003, including $4,500 for audit related services concerning the filing of a registration statement relating to an employee stock option plan and $17,000 for tax compliance and consultation services.

The audit committee of our board of directors considered whether the non-audit services rendered by KPMG were compatible with maintaining KPMG's independence as auditors of our consolidated financial statements, and concluded that they were.

PART IV

ITEM 16. 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 22.

(3) See Description of Exhibits on page 40.

b) None.

c) See Description of Exhibits on page 40.

d) None.

TABLE OF CONTENTS

INDEPENDENT AUDITORS' REPORT

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, 2003 and 2002, 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, 2003 and for the cumulative period from June 19, 1985 (inception) through May 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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, 2003 and 2002, and the results of its operations and its cash flows for each of the years in the three-year period ended May 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that Northfield Laboratories Inc. will continue as a going concern. As more fully described in Note 1, the Company has experienced recurring operating losses and has an accumulated deficit of $110,466,000 at May 31, 2003. In addition, the Company expects to experience significant future losses and currently has insufficient capital resources to fund its continuing operations. These

conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

KPMG LLP

Chicago, Illinois
July 28, 2003

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

BALANCE SHEETS
MAY 31, 2003 AND 2002

	2003	2002
ASSETS		
Current assets:		
Cash	$ 4,897,962	17,668,687
Marketable securities	1,992,297	720,000
Prepaid expenses	688,755	540,003
Other current assets	--	1,437
Total current assets	7,579,014	18,930,127
Property, plant, and equipment, net	1,596,026	2,232,204
Other assets	71,399	72,410
	$ 9,246,439	21,234,741
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,462,586	1,077,712
Accrued expenses	61,519	210,109
Accrued compensation and benefits	377,117	338,849
Total current liabilities	1,901,222	1,626,670
Other liabilities	165,044	177,753
Total liabilities	2,066,266	1,804,423
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 14,265,875 at May 31, 2003 and 2002 respectively	142,659	142,659
Additional paid-in capital	117,503,271	117,503,271
Deficit accumulated during the development stage	(110,465,757)	(98,215,612)
Total shareholders' equity	7,180,173	19,430,318
	$ 9,246,439	21,234,741

See accompanying notes to financial statements

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

STATEMENTS OF OPERATIONS
YEARS ENDED MAY 31, 2003, 2002, AND 2001
AND THE CUMULATIVE PERIOD FROM JUNE 19, 1985
(INCEPTION) THROUGH MAY 31, 2003

	YEARS ENDED MAY 31,			CUMULAT FROM JUNE 19, THROU
	2003	2002	2001	MAY 31,
Revenues -- license income.....	$ --	--	--	3,000
Costs and expenses:				
Research and development.....	8,819,016	8,843,115	9,436,992	96,239
General and administrative.....	3,643,318	2,700,183	2,785,500	40,600
	12,462,334	11,543,298	12,222,492	136,839
Other income and expense:				
Interest income.....	212,189	825,938	2,047,883	23,457
Interest expense.....	--	--	--	83
	212,189	825,938	2,047,883	23,373
Net loss.....	$(12,250,145)	(10,717,360)	(10,174,609)	(110,465
Net loss per share -- basic and diluted.....	$ (0.86)	(0.75)	(0.71)	(1
Shares used in calculation of per share data -- basic and diluted.....	14,265,875	14,265,875	14,253,385	9,863

See accompanying notes to financial statements

NORTHFIELD LABORATORIES INC.
(A COMPANY IN THE DEVELOPMENT STAGE)
STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
YEARS ENDED MAY 31, 2003, 2002, AND 2001 AND THE CUMULATIVE
PERIOD FROM JUNE 19, 1985 (INCEPTION) THROUGH MAY 31, 2003

	NUMBER OF SHARES	AGGREGATE AMOUNT	CO NUMBER OF SHAR
Issuance of common stock on August 27, 1985	--	$ --	3,500,0
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	--	--	3,500,0
Net loss	--	--	
Deferred compensation relating to grant of stock options	--	--	
Amortization of deferred compensation	--	--	
Balance at May 31, 1987	--	--	3,500,0
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	--	--	3,500,0
Issuance of common stock at $24.21 per share on June 7, 1988 (net of costs of issuance of $246,000)	--	--	413,0
Conversion of Series A convertible preferred stock to common stock on June 7, 1988	--	--	1,250,0
Conversion of Series B convertible preferred stock to common stock on June 7, 1988	--	--	1,003,1
Exercise of stock options at $2.00 per share	--	--	47,1
Issuance of common stock at $28.49 per share on March 6, 1989 (net of costs of issuance of $21,395)	--	--	175,5
Issuance of common stock at $28.49 per share on March 30, 1989 (net of costs of issuance of $10,697)	--	--	87,7
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	--	--	6,476,5
Net loss	--	--	
Deferred compensation relating to grant of stock options	--	--	
Amortization of deferred compensation	--	--	
Balance at May 31, 1990	--	--	6,476,5
Net loss	--	--	
Amortization of deferred compensation	--	--	
Balance at May 31, 1991	--	--	6,476,5
Exercise of stock warrants at $5.60 per share	--	--	90,0
Net loss	--	--	
Amortization of deferred compensation	--	--	
Balance at May 31, 1992	--	--	6,566,5
Exercise of stock warrants at $7.14 per share	--	--	15,0
Issuance of common stock at $15.19 per share on April 19, 1993 (net of costs of issuance of $20,724)	--	--	374,3
Net loss	--	--	

Amortization of deferred compensation.....	--	--	
Balance at May 31, 1993.....	--	$ --	6,955,9

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)

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

STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
YEARS ENDED MAY 31, 2003, 2002, AND 2001
AND THE CUMULATIVE PERIOD FROM JUNE 19, 1985 (INCEPTION) THROUGH MAY 31, 2003

	PREFERRED STOCK		CO
	NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER SHARE
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,
Cancellation of stock options.....	--	--	
Amortization of deferred compensation.....	--	--	
Balance at May 31, 1994.....	--	--	9,455,
Net loss.....	--	--	
Issuance of common stock at $6.50 per share on June 20, 1994 (net of issuance costs of $172,500).....	--	--	375,
Exercise of stock options at $7.14 per share.....	--	--	10,
Exercise of stock options at $2.00 per share.....	--	--	187,
Cancellation of stock options.....	--	--	
Amortization of deferred compensation.....	--	--	
Balance at May 31, 1995.....	--	--	10,028,
Net loss.....	--	--	
Issuance of common stock at $17.75 per share on August 9, 1995 (net of issuance costs of $3,565,125).....	--	--	2,925,
Issuance of common stock at $17.75 per share on September 11, 1995 (net of issuance costs of $423,238).....	--	--	438,
Exercise of stock options at $2.00 per share.....	--	--	182,
Exercise of stock options at $6.38 per share.....	--	--	1,
Exercise of stock options at $7.14 per share.....	--	--	10,
Cancellation of stock options.....	--	--	
Amortization of deferred compensation.....	--	--	
Balance at May 31, 1996.....	--	--	13,586,
Net loss.....	--	--	
Exercise of stock options at $0.20 per share.....	--	--	263,
Exercise of stock options at $2.00 per share.....	--	--	232,
Exercise of stock options at $7.14 per share.....	--	--	10,
Amortization of deferred compensation.....	--	--	
Balance at May 31, 1997.....	--	--	14,092,

Net loss	--	--	
Exercise of stock options at $7.14 per share	--	--	5,
Amortization of deferred compensation	--	--	
Balance at May 31, 1998	--	--	14,097,
Net loss	--	--	
Non-cash compensation	--	--	
Exercise of stock options at $7.14 per share	--	--	17,
Exercise of stock warrants at $8.00 per share	--	--	125,
Balance at May 31, 1999	--	--	14,239,
Net loss	--	--	
Non-cash compensation	--	--	
Exercise of stock options at $13.38 per share	--	--	2,
Balance at May 31, 2000	--	--	14,242,
Net loss	--	--	
Exercise of stock options at $6.38 per share	--	--	6,
Exercise of stock options at $10.81 per share	--	--	17,
Balance at May 31, 2001	--	--	14,265,
Net loss	--	--	
Balance at May 31, 2002	--	--	14,265,
Net loss	--	--	
Balance at May 31, 2003	--	$ --	14,265,

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
--	$ --	--	$ --	$ --	$ (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)
--	--	--	--	--	(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)	$ --

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

STATEMENTS OF CASH FLOWS
YEARS ENDED MAY 31, 2003, 2002, AND 2001
AND THE CUMULATIVE PERIOD FROM JUNE 19, 1985
(INCEPTION) THROUGH MAY 31, 2003

	YEARS ENDED MAY 31,			CUMULATIV FROM JUNE 19, 1 THROUGH
	2003	2002	2001	MAY 31, 20

Cash flows from operating activities:				
Net loss	$(12,250,145)	(10,717,360)	(10,174,609)	(110,465,7
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	812,356	822,257	819,828	17,103,0
Non-cash compensation	--	--	--	3,552,7
Loss on sale of equipment	--	--	--	66,3
Changes in assets and liabilities:				
Prepaid expenses	(148,752)	(161,861)	31,128	(897,9
Other current assets	1,437	454,423	49,712	(1,896,2
Other assets	--	49,099	(49,201)	6,8
Accounts payable	384,874	(694,870)	711,215	1,462,5
Accrued expenses	(148,590)	56,204	(20,104)	61,5
Accrued compensation and benefits	38,268	77,636	10,643	377,1
Other liabilities	(12,709)	10,893	19,143	165,0
Net cash used in operating activities	(11,323,261)	(10,103,579)	(8,602,245)	(90,464,7
Cash flows from investing activities:				
Purchase of property, plant, equipment, and capitalized engineering costs	(214,326)	(206,115)	(1,210,448)	(18,671,6
Proceeds from sale of land and equipment	--	--	--	1,863,0
Proceeds from matured marketable securities	720,000	29,279,200	24,148,171	409,537,3
Proceeds from sale of marketable securities	--	--	--	7,141,6
Purchase of marketable securities	(1,953,138)	(7,736,359)	(23,281,688)	(418,632,1
Net cash provided by (used in) investing activities	(1,447,464)	21,336,726	(343,965)	(18,761,8
Cash flows from financing activities:				
Proceeds from issuance of common stock	--	--	227,455	103,749,3
Payment of common stock issuance costs	--	--	--	(5,072,0
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	--	--	227,455	114,124,4
Net (decrease) increase in cash	(12,770,725)	11,233,147	(8,718,755)	4,897,9
Cash at beginning of period	17,668,687	6,435,540	15,154,295	
Cash at end of period	$ 4,897,962	17,668,687	6,435,540	4,897,9

See accompanying notes to financial statements

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

NOTES TO FINANCIAL STATEMENTS
MAY 31, 2003 AND 2002

(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.

GOING CONCERN UNCERTAINTY

The financial statements of the Company have been presented based on the assumption that the Company will continue as a going concern. The Company, however, may not be able to continue as going concern because it expects to experience significant future losses and currently has insufficient capital resources to fund its continuing operations. The Company believes its existing capital resources will be adequate to satisfy its operating capital requirements and maintain its existing manufacturing plant and office facilities through March 1, 2004. In addition, the Company expects its existing capital resources will be sufficient to support expenditures incurred in connection with the Company's planned Phase III clinical trials during this period. Thereafter, the Company will require substantial additional funding to continue its operations and complete its planned clinical trials.

The Company raised $10,600,000 in gross proceeds through an offering of its common stock in July 2003. See Note 11, Subsequent Events. The Company may issue additional equity or debt securities or enter into collaborative arrangements with strategic partners, which could provide the Company with additional funding or absorb expenses the Company would otherwise be required to pay. The Company is also pursuing potential sources of government funding. Any one or a combination of these sources may be utilized to raise additional capital. The Company believes its ability to raise additional capital or enter into a collaborative arrangement with a strategic partner will depend primarily on the results of its planned clinical trials as well as general conditions in the business and financial markets. There can be no assurance that the Company will be successful in raising additional capital. The Company's inability to raise sufficient levels of capital could materially delay or prevent the commercialization of its PolyHeme blood substitute product and could result in the cessation of the Company's business. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

MARKETABLE SECURITIES

Marketable securities consist of government securities, corporate notes, and 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 eight to ten years.

CAPITALIZED ENGINEERING COSTS

Capitalized engineering costs include design and other initial engineering studies relating to a commercial scale facility. During fiscal 2003 and 2002, the Company capitalized no engineering costs. Capitalized engineering costs are being amortized over a three-year period. For the years ended May 31, 2003, 2002 and 2001 amortization cost recorded was $119,649, $120,000 and $120,000, respectively. As of May 31, 2003 all capitalized engineering costs have been amortized. The net book value as of May 31, 2003 is zero.

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, 2003, 2002, and 2001 and the cumulative period from June 19, 1985 (inception) through May 31, 2003, 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.

	2003	2002	2001	CUMULATIVE FROM JUNE 19, 1985 THROUGH MAY 31, 2003
Stock options	826,500	667,250	603,000	600,142
Warrants	--	--	--	67,778
	826,500	667,250	603,000	667,920

Of the total options outstanding as of May 31, 2003, the Company has 331,000 options in-the-money and 628,000 options out-of-the-money that were

excluded from the EPS 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 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:

	2003	2002	2001
Net loss as reported	$(12,250,145)	(10,717,360)	(10,174,609)
Deduct: Total stock based compensation expense determined under the fair value method for all awards, net of related tax effects	(600,616)	(859,923)	(679,467)
Pro forma net loss	(12,850,761)	(11,577,283)	(10,854,076)
Basic and diluted earnings per share:			
As reported	(0.86)	(0.75)	(0.71)
Pro forma	(0.90)	(0.81)	(0.76)

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 2003, 2002, and 2001:

	2003	2002	2001
Expected volatility	68.6%	66.3%	67.0%
Risk-free interest rate	3.1%	4.8%	5.4%
Dividend yield	--	--	--
Expected lives	8.0 years	7.0 years	7.0 years

FINANCIAL INSTRUMENTS

The fair values of financial instruments, which consist of marketable securities (note 2), were not materially different from their carrying values at May 31, 2003 and 2002.

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.

RECENT ACCOUNTING PRONOUNCEMENTS

In August 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 143, Accounting for Asset Retirement Obligations, (SFAS 143) which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and for the associated asset retirement costs. SFAS 143 requires an enterprise to record the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of tangible long-lived assets that result from the acquisition, construction, development and/or normal use of the assets. The enterprise also is to record a corresponding increase to the carrying amount of the related long-lived assets (i.e., the associated asset retirement costs) and to depreciate that cost over the life of the assets. The liability is changed at the end of each period to reflect the passage of time and changes in the estimated future cash flows underlying the initial fair value measurement. Adoption of SFAS 143 is required for fiscal years beginning after June 15, 2002. Upon adoption of this statement we expect to record an additional liability of approximately $138,000, as the additional costs required to restore our leased manufacturing facility back to its move in condition.

In December 2002, the FASB released SFAS No. 148, Accounting for Stock-Based Compensation -- Transition and Disclosure, an amendment of FASB Statement No. 123 (SFAS 148). This Statement amends SFAS 123, to provide alternative methods of transition for a voluntary change to the fair value method of

accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements. The provisions of SFAS 148 related to transition from the intrinsic-value to the fair-value method and annual disclosures are effective for fiscal years ending after December 15, 2002. The provisions of the Statement related to interim disclosures are effective in financial reports containing financial statements for interim periods beginning after December 31, 2002. The annual disclosures are included in the notes to these financial statements.

On May 15, 2003 the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity (SFAS 150). The provisions of the Statement will change the classification of certain freestanding financial instruments that are now classified as equity. Generally, the Statement is effective for financial instrument arrangements entered into or modified after May 31, 2003. As of May 31, 2003, the adoption of SFAS 150 does not have a material effect on the financial position, results of operations, or cash flows of the Company. The Company is currently evaluating the impact of SFAS 150 subsequent to May 31, 2003.

(2) MARKETABLE SECURITIES

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. The fair market value of the Company's marketable securities was $715,360 at May 31, 2002, which included gross unrealized holding losses of $4,640.

At May 31, 2003, all of the Company's 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, 2003 and 2002:

	USEFUL LIFE	2003	2002
Manufacturing equipment	5 years	$ 9,694,205	9,482,870
Laboratory equipment	5 years	1,330,425	1,330,425
Office furniture and equipment	7 years	677,362	680,008
Computer equipment	3 years	109,917	104,280
Leasehold improvements	Lease term	1,651,447	1,651,447
Capitalized engineering costs	3 years	924,867	924,867
		14,388,223	14,173,897
Less accumulated depreciation and amortization		(12,792,197)	(11,941,693)
		$ 1,596,026	2,232,204

Depreciation and amortization expense related to property, plant and equipment amounted to $856,199, $821,244, and $818,816, for the years ended May 31, 2003, 2002, and 2001, respectively.

(4) 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 7). 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.

5) INCOME TAXES

As a result of losses incurred to date, the Company has not provided for income taxes. As of May 31, 2003, the Company has net operating loss carryforwards for income tax purposes of approximately $110,000,000, which are available to offset future taxable income, if any, from 2004 to 2023. 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 $3,300,000 of research and experimentation tax credits and investment tax credits available to reduce future income taxes through 2023.

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, 2003 and 2002 are summarized as follows:

	2003	2002
Deferred tax assets:		
Net operating loss carryforwards	$44,900,000	40,700,000
Tax credit carryforwards	3,300,000	2,900,000
Other	900,000	700,000
	49,100,000	44,300,000
Valuation allowance	(49,100,000)	(44,300,000)
Net deferred tax assets	$ --	--

The net change in the valuation allowance for the fiscal years ended May 31, during fiscal 2003, 2002 and 2001 was an increase of $4,800,000, $6,700,000, and $2,800,000, respectively.

(6) 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, 2003, options to purchase a total of 77,000 shares of the Company's common stock at prices of $6.38 and $15.19 per share were outstanding under the Employee Stock Option Plan. These options expire in 2003 and 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, 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, 2003 and May 31, 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, 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 the date of grant.

With an effective date of January 1, 2003, the Company established 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, 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.

Additional information on shares subject to options is as follows:

	2003		2002		2001	
	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEI AVE EXE PR
Outstanding at beginning of year	694,000	$11.81	640,500	$11.65	565,500	$1
Granted	305,000	4.48	54,500	13.59	139,000	1
Exercised	--	--	--	--	23,500	
Canceled	40,000	8.43	1,000	10.66	40,500	1
Outstanding at end of year	959,000	$ 9.62	694,000	$11.81	640,500	$1
Options exercisable at year end	622,125	$11.46	519,500	$11.62	423,250	$1
Weighted-average fair value of options granted during the year	$ 3.51		$ 9.23		$ 8.27	

The following table summarizes information about stock options outstanding

at May 31, 2003:

	OPTIONS OUTSTANDING			OPTIONS
RANGE OF EXERCISE PRICES	NUMBER OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS EXERCISAB AT MAY 31, 2003
$ 3.62 -- 5.15	277,000	9.49	$ 4.40	15,000
6.09 -- 9.56	45,000	3.25	7.25	38,250
10.66 -- 15.41	637,000	5.70	12.05	568,875

(7) 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.

(8) LEASES/COMMITMENTS

Rent expense amounted to $821,760, $835,661, and $809,721 for the years ended May 31, 2003, 2002, and 2001, respectively.

The Company lease for its research and manufacturing facility expires August 30, 2004 and includes the option to renew the lease for (2) successive 5-year terms. The lease is collateralized by a $49,200 security deposit as of May 31, 2003.

The Company lease for its corporate facility expires February 14, 2006. The Company has the option to cancel the lease upon giving written notice 6 months prior to termination as well as paying a penalty equal to 6 months rent calculated at the rate payable on the date of notice. As of May 31, 2003, this penalty would have amounted to $148,500. The lease is secured by a security deposit of $19,250 as of May 31, 2003.

At May 31, 2003, future minimum lease payments under the operating leases are as follows:

YEARS ENDING

MAY 31,	AMOUNT
2004	$ 857,502
2005	473,404
2006	248,032
	$1,578,938

(9) 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, 2003, 2002, and 2001 amounted to $145,307, $157,294 and $145,051, respectively.

(10) QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table shows our quarterly unaudited financial information for the eight quarters ended May 31, 2003. 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, 2003	FEB. 28, 2003	NOV. 30, 2002	AUG. 31, 2002	MAY 31, 2002	FEB. 200
Revenues	$ --	--	--	--	--	
Costs and Expenses						
Research and Development	2,347	2,203	2,243	2,026	2,108	2,1
General and Administrative	1,008	746	961	929	749	5
	3,355	2,949	3,204	2,955	2,857	2,7
Other Income and Expense						
Interest Income	31	44	60	77	87	1
Interest Expense	--	--	--	--	--	
Net Loss	$(3,324)	(2,905)	(3,144)	(2,878)	(2,770)	(2,5
Net Loss Per share -- Basic and Diluted	$ (0.23)	(0.20)	(0.22)	(0.20)	(0.19)	(0.
Shares used in calculation	14,266	14,266	14,266	14,266	14,266	14,2

(11) SUBSEQUENT EVENT

On July 28, 2003, the Company issued 1,892,857 shares of registered common stock for gross proceeds of $10,600,000. The transaction includes a 60-day option period for investors to purchase an additional 567,857 shares of common stock at a per share price of $5.60. If the option is fully exercised this would generate additional gross proceeds to the Company of $3,180,000. As part of the transaction, the Company issued a warrant to the placement agent in the amount of 3% of the shares issued. The warrant has a five-year life and is exercisable anytime between the first and fifth anniversary of the transaction. The warrant exercise price is $7.75 per share.

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	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)
10.7	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)
10.8*	Northfield Laboratories Inc. 401(K) Plan (incorporated herein by reference to Exhibit 10.14 to the S-1 Registration Statement)
10.9*	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)
10.10*	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)
10.11*	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)
10.12*	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")
10.13*	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)

NUMBER	DESCRIPTION
10.14*	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)
10.15	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)
10.16	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)
10.17	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 KPMG LLP
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

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* 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 8, 2003.

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 8, 2003.

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/ GERALD S. MOSS, M.D. Gerald S. Moss, M.D.	Director
/s/ BRUCE S. CHELBERG Bruce S. Chelberg	Director
/s/ JACK OLSHANSKY Jack Olshansky	Director
/s/ DAVID A. SAVNER David A. Savner	Director
/s/ JOHN F. BIERBAUM John F. Bierbaum	Director
/s/ PAUL M. NESS, M.D. Paul M. Ness, M.D.	Director

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