NORTHFIELD LABORATORIES INC /DE/
Form 10-K
August 03, 2001
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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, 2001

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

COMMISSION FILE NUMBER 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. [ ]

As of July 30, 2001, 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 July 30, 2001) held by non-affiliates of the Registrant was $230,941,934 (12,416,233 shares at $18.60 per share).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2001 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 Annual Report 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 a lot of 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. believes it 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(TM) blood substitute product is a solution of chemically modified hemoglobin derived from human blood. 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. Our method of manufacturing PolyHeme is designed to eliminate the risk of transmission of diseases such as AIDS or hepatitis.

Clinical studies to date indicate that PolyHeme is universally compatible and accordingly should not require blood typing prior to infusion. Therefore, PolyHeme should be available for immediate use in emergency situations. In addition, PolyHeme has an extended shelf life compared to blood.

We are presently conducting clinical trials of PolyHeme at multiple locations in the United States. Our clinical trials include the infusion of PolyHeme in trauma and emergency surgical applications as well as in elective surgical procedures. The observations in the trials continue to demonstrate the potential clinical utility of PolyHeme in the treatment of urgent blood loss. Both our trauma trials and elective surgery trials involve 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 worldwide clinical need and has the greatest market opportunity. We believe we are the only company in our field with an oxygen-carrying blood substitute being rapidly infused at high dosage -- as much as 20 units (1000 grams) or twice the blood volume of the average adult.

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 12 million units of blood were transfused in the United States in 2000, of which approximately 7.2 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 12 million units of blood were transfused in the United States in 2000, of which approximately 7.2 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 2000 for the treatment of acute blood loss exceed $2 billion. 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

We are presently conducting clinical trials of PolyHeme at multiple locations in the United States. Our clinical trials include the infusion of PolyHeme in trauma and emergency surgical applications as well as in elective surgical procedures. In addition, we continue to make PolyHeme available on a compassionate use basis in life-threatening situations when blood cannot be used. The observations in the trials continue to demonstrate the potential clinical utility of PolyHeme in the treatment of urgent blood loss. Both our trauma trials and elective surgery trials involve 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 worldwide clinical need, provides the greatest patient benefit, and has the greatest market opportunity. We believe we are the only company in our field with an oxygen-carrying blood substitute being rapidly infused at high dosage -- as much as 20 units (1000 grams) or twice the blood volume of the average adult.

We have engaged an international contract research organization to independently administer the collection of patient data generated by test sites participating in our trials. The purpose of independent administration is to ensure that data collected as part of these trials is free from any inaccuracy or bias that might result from interactions between the testing sites and the trial sponsor.

TRAUMA AND EMERGENCY SURGICAL APPLICATIONS

We are conducting clinical trials of PolyHeme in trauma and emergency surgical applications at multiple hospitals in the United States, including both civilian and military institutions. These continuing clinical trials are 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 have been infused with up to 20 units (1000 grams) of PolyHeme. This unprecedented dose is equivalent to twice the blood volume of an average adult.

The protocol has allowed us to assess the life-sustaining capacity of PolyHeme following massive blood loss when blood is not used for resuscitation and the red blood cell hemoglobin level falls 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

continues to be 75%. This improvement demonstrates the ability of PolyHeme to effectively transport oxygen. The important safety observations are that none of the toxicities historically associated with other hemoglobin solutions have been identified in our clinical experience.

We have been analyzing the data from our trauma trials and are continuing to consider our regulatory position based on our findings. We are pleased with the results from these trials, which demonstrate 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 elective surgical procedures. We are planning to file the Biologic License Application, or BLA, with the Food and Drug Administration in the near future.

ELECTIVE SURGICAL APPLICATIONS

We are also conducting clinical trials of PolyHeme in elective surgical applications at multiple locations in the United States. Our clinical protocol for these trials is a randomized controlled study in which elective surgical patients are 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 is the same as that for trauma -- high dose, rapid infusion for acute blood loss -- the clinical endpoint for these trials is the elimination of the use of

banked blood. We believe these trials are producing important results. Due to the complexity of the clinical protocol, however, patient accrual is progressing slowly, as previously reported. As a result, we are considering instituting additional elective surgery trials with different protocols to more broadly and rapidly confirm PolyHeme's capability as an alternative to blood in critical care situations. We intend to terminate our current elective surgery protocol after the BLA is filed and focus on these additional trials. We believe our clinical trials may continue throughout the regulatory review process.

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 will supply us with 82,500 units per year of packed red cells, the source material for PolyHeme, over a three year period. 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.

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 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. Many 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. During the past year, a bovine-source hemoglobin-based oxygen-carrier was approved for human use in South Africa and an application for marketing approval for one human-source hemoglobin-based oxygen-carrier was filed in Canada and the United Kingdom.

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, the 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 the FDA of an Investigational New Drug application, clinical trials in humans to establish the safety and effectiveness of the product, the submission to the FDA of a Biologic License Application, or 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 filed there is an initial review by the FDA to be sure that all of the required elements are included in the filing. There can be no assurance that the filing will be accepted or that the FDA may not issue a refusal to file, or RTF. If the filing is accepted 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 the 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 the FDA from time to time throughout the trial process. In addition, before approval for the commercial sale of a product can be obtained, results of the preclinical and clinical studies must be submitted to the 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. The 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 the 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 five 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 its 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.

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 2001, 2000 and 1999, our research and development expenses totaled $9,437,000, $9,193,000 and $7,661,000, 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, 2001, we had 58 employees, of whom 50 were involved in research and development and eight were responsible for financial and other administrative matters. We also had consulting arrangements with eight 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 MAY BE REQUIRED TO CONDUCT EXTENSIVE ADDITIONAL CLINICAL TRIALS IN THE FUTURE

The results of our clinical trials may not be sufficient at present to demonstrate adequately the safety and effectiveness of PolyHeme in order to receive product approval once our Biologic License Application is filed with the FDA. We believe clinical trials may continue throughout the regulatory review process. If extensive additional trials are necessary, they will be expensive and time-consuming. The timing of the 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 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 the 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 the FDA and its foreign counterparts. 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. Similar delays or rejections may also be encountered in foreign countries. We cannot ensure that, even after extensive clinical trials, regulatory approval will ever be obtained for PolyHeme. Under FDA guidelines, the FDA may comment upon the acceptability of a BLA following its submission. After a BLA is filed there is an initial review by the FDA to be sure that all of the required elements are included in the filing. There can be no assurance that the BLA filing will be accepted or that the FDA may not issue a refusal to file, or RTF. If the BLA filing is accepted, there can be no assurance that the full review will result in approval of PolyHeme for manufacture and sale. 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.

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 WILL NEED TO RAISE SUBSTANTIAL ADDITIONAL CAPITAL TO CONTINUE OUR BUSINESS

We will be required to raise substantial additional capital to achieve

commercial production of PolyHeme. Our future capital requirements will depend on many factors, including the scope and results of 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. 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 manufacturing capabilities will have a material adverse effect on the completion of our clinical trials and therefore on the commercial manufacture and sale 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 the 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 82,500 units per year of packed red cells, the source material for PolyHeme, over a three year period. 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.

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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. Many 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. During the past year, a bovine-source hemoglobin-based oxygen-carrier was approved for human use in South Africa, and an application for marketing approval for one human-source hemoglobin-based oxygen-carrier was filed in Canada and the United Kingdom.

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.

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

From Northfield's inception through May 31, 2001, we have incurred net operating losses totaling $87,498,000. 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. 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.

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.

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.

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 2001 fiscal year was $810,000. 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 $26 to $30 million.

ITEM 3. LEGAL PROCEEDINGS.

As of May 31, 2001, 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, 1998	17.25	9.50
August 31, 1998	18.13	10.13
November 30, 1998	15.63	9.13
February 28, 1999	16.38	10.94
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 (through July 30, 2001)	18.72	12.70

HOLDERS OF RECORD

As of May 31, 2001, there were approximately 500 holders of record and approximately 11,600 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, 2001 and for the period from June 19, 1985 (inception) through May 31, 2001 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
	2001	2000	1999	1998	1997	MAY 31, 2001
	(IN THOUSANDS, EXCEPT PER SHARE DATA)					
STATEMENT OF OPERATIONS DATA:						
Revenues:						
License income	$ --	--	--	--	--	3,000
Costs and expenses:						
Research and development	9,437	9,193	7,661	6,675	5,188	78,577
General and administrative	2,786	2,260	2,311	2,338	2,317	34,257
Interest income (net)	2,048	2,286	2,556	3,130	3,259	22,336
Net loss	$(10,175)	(9,167)	(7,416)	(5,883)	(4,246)	(87,498)
Net loss per share basic and diluted	$ (0.71)	(0.64)	(0.53)	(0.42)	(0.30)	(9.40)
Shares used in calculation of per Share data(1)	14,253	14,241	14,115	14,097	13,961	9,305

	MAY 31,				
	2001	2000	1999	1998	1997
	(IN THOUSANDS)				
BALANCE SHEET DATA:					
Cash and marketable securities	$ 28,698	$ 38,284	$ 47,561	$ 53,504	$ 60,294
Total assets	32,502	41,728	50,963	56,919	62,343
Total liabilities	2,355	1,634	1,791	1,471	1,048
Deficit accumulated during Development stage	(87,498)	(77,324)	(68,157)	(60,740)	(54,857)
Total shareholders' equity(2)	30,148	40,095	49,171	55,448	61,295

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

(2) Excludes 640,500 shares reserved for issuance upon the exercise of stock options outstanding as of May 31, 2001. Additional stock options for a total of 446,500 shares and 170,000 shares, respectively, were available for grant as of May 31, 2001 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, 2001, we have incurred operating losses totaling $87,498,000.

Our success will depend on several factors, including our ability to obtain Food and Drug Administration 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, and enforce our patent positions. 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.

We anticipate that research and development expenses will increase during the foreseeable future. These expected increases are attributable to anticipated future clinical trials, monitoring and reporting the results of these trials and continuing process development associated with improving our manufacturing capacity to permit commercial-scale production of PolyHeme. We expect that general and administrative expenses will increase over the foreseeable future due to increased expenses relating to the expansion of our organization in support of launching commercial operations.

RESULTS OF OPERATIONS

We reported no revenues for the fiscal years ended May 31, 2001, 2000 or 1999. From Northfield's inception through May 31, 2001, 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, 2001, 2000 and 1999 totaled $12,222,000, $11,453,000 and 9,972,000, respectively. Measured on a percentage basis, fiscal 2001 operating expenses exceeded fiscal 2000 expenses by 6.7%, while fiscal 2000 operating expenses exceeded fiscal 1999 expenses by 14.9%.

For the year ended May 31, 2001, research and development expenses totaled $9,437,000, representing an increase of $244,000, or 2.7%, from the year ended May 31, 2000. The composition of the expenditures has changed as higher manufacturing employment levels and salary increases have pushed labor costs up, partially offset by reductions in purchased services related to clinical trial field work.

For the year ended May 31, 2000, research and development expenses totaled $9,193,000, representing an increase of $1,532,000, or 20.0%, from the year ended May 31, 1999. The year over year difference is due to increased expenses for clinical trials, expansion of our manufacturing organization, validation services and amortization of previously capitalized engineering costs.

We anticipate that research and development expenses will continue to increase for the foreseeable future. Increased costs are being planned for additional multi-center clinical trials, third party clinical monitoring, biostatistical analysis and report preparation and production.

General and administrative expenses for fiscal 2001 totaled $2,786,000 compared to expenses of $2,260,000 for fiscal 2000, representing an increase of $526,000, or 23.3%. The increase is due primarily to increased professional fees.

General and administrative expenses for fiscal 2000 totaled $2,260,000 compared to expenses of $2,311,000 for fiscal 1999, representing a decrease of $51,000, or 2.2%. The decrease was primarily due to lower non-cash expenses as the depreciation stream on our corporate leasehold improvements ended.

We anticipate that general and administration expenses will likely increase over the next several quarters as the expense of the development of sales, marketing and distribution capabilities will be incurred.

INTEREST INCOME

Interest income in fiscal 2001 equaled $2,048,000, or a $238,000 decrease from the $2,286,000 in interest income reported in fiscal 2000. Higher interest rates early in fiscal 2001 partially offset lower available investment balances to account for the decrease. Currently available short-term interest rates are yielding over 2.5 percentage points less than the rates available for the comparable prior year period.

Interest income in fiscal 2000 equaled $2,286,000, or a $270,000 decrease from the $2,556,000 in interest income reported in fiscal 1999. Lower available investment balances were the primary reason for the decrease in interest income.

Without additional cash inflows, interest income will decline significantly over the next several quarters. If we were to spend at current rates and earn interest at current short-term money rates, interest income in fiscal 2002 would decline by approximately 50% compared to fiscal 2001.

NET LOSS

The net loss for the year ended May 31, 2001 was $10,175,000, or $.71 per basic share, compared to a net loss of $9,167,000, or $.64 per basic share, for the year ended May 31, 2000. The increase in the loss per basic share is primarily the result of higher professional fees which increased over the course of the year as well as increased labor costs.

The net loss for the year ended May 31, 2000 was $9,167,000, or $.64 per basic share, compared to a net loss of $7,416,000, or $.53 per basic share, for the year ended May 31, 1999. The increase in the loss per basic share was the result of the increased expense of conducting our clinical trials, increased expenditures for validation services combined with the expansion of our manufacturing organization and facilities.

LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through May 31, 2001, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of $87,289,000. For the years ended May 31, 2001 and 2000, these cash expenditures totaled $9,813,000 and $11,097,000, respectively. The year over year decrease is due primarily to the prior year expansion of our manufacturing facilities.

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, 2001, we had cash

and marketable securities totaling $28,698,000.

We believe our existing capital resources will be adequate to satisfy our operating capital requirements and maintain our existing manufacturing plant and office facilities for approximately the next 24-30 months. Thereafter, we are likely to require substantial additional capital to continue our operations. We are currently unable to fund the construction of a large-scale greenfield manufacturing facility, which is estimated to cost approximately $45 million, without raising substantial additional capital. Currently, we have manufacturing capacity of approximately 10,000 units. Initial engineering on the leased space adjacent to our existing manufacturing facility is completed. This engineering indicates an additional capacity of 75,000 units could be developed in approximately 16-20 months at a cost of $26-30 million. Like a large-scale greenfield manufacturing facility, significant additional funding will be required before the smaller scale expansion facility could be completed. Northfield has not yet committed to the build-out of a smaller scale expansion facility. We view the smaller scale expansion facility as financially prudent yet large enough for commercial viability.

After filing for product approval with the FDA, Northfield will focus on raising additional capital. We estimate that we will require at least $40 million in additional funding to build a smaller scale expansion

facility (75,000 unit), fund the subsequent working capital needs and support an expanded manufacturing and marketing organization.

We may issue additional equity or debt securities to the public 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. Any one or a combination of these sources may be utilized to raise the required funding. Business or market conditions may not be favorable which would cause a delay in the commercialization of our product.

Our capital requirements may vary materially from those now anticipated because of the 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.

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 $28.7 million would decrease interest income by $287,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See the index to Financial Statements on page 20. See footnote 10 to the Financial Statements on page 35 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 2001, 2000 or 1999 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 2001, pursuant to Regulation 14A, a definitive proxy statement which will contain the information required to be included in Items 10 through 13 of Form 10-K.

PART IV

ITEM 14. 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 Index to Financial Statements on page 20.

(3) See Description of Exhibits on page 36.

b) None.

c) See Description of Exhibits on page 36.

d) None.

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FINANCIAL STATEMENTS
INDEX TO FINANCIAL STATEMENTS

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INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders
Northfield Laboratories Inc.:

We have audited the accompanying balance sheets of Northfield Laboratories Inc. (a company in the development stage) as of May 31, 2001 and 2000 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, 2001 and for the cumulative period from June 19, 1985 (inception) through May 31, 2001. 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, 2001 and 2000, and the results of its operations and its cash flows for each of the years in the three-year period ended May 31, 2001 and for the cumulative period from June 19, 1985 (inception) through May 31, 2001 in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

July 2, 2001
Chicago, Illinois

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

BALANCE SHEETS
MAY 31, 2001 AND 2000

	2001	2000
ASSETS		
Current assets:		
Cash	$ 6,435,540	15,154,295
Short-term marketable securities	22,262,841	23,129,324
Prepaid expenses	378,142	409,270
Other current assets	455,860	505,572
Total current assets	29,532,383	39,198,461
Property, plant, and equipment, net	2,847,333	2,455,701
Other assets	122,522	74,333
	$ 32,502,238	41,728,495

LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,772,582	1,061,367
Accrued expenses	153,905	174,009
Accrued compensation and benefits	261,213	250,570
Total current liabilities	2,187,700	1,485,946
Other liabilities	166,860	147,717
Total liabilities	2,354,560	1,633,663
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 and 14,242,375 shares in 2001 and 2000, respectively	142,659	142,424
Additional paid-in capital	117,503,271	117,276,051
Deficit accumulated during the development stage	(87,498,252)	(77,323,643)
Total shareholders' equity	30,147,678	40,094,832
	$ 32,502,238	41,728,495

See accompanying notes to financial statements.

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

STATEMENTS OF OPERATIONS
YEARS ENDED MAY 31, 2001, 2000, AND 1999
AND THE CUMULATIVE PERIOD FROM JUNE 19, 1985
(INCEPTION) THROUGH MAY 31, 2001

	YEARS ENDED MAY 31,			CUMULAT FROM JUNE 19, THROU
	2001	2000	1999	MAY 31,
Revenues -- license income	$ --	--	--	3,000
Costs and expenses:				
Research and development	9,436,992	9,192,833	7,660,763	78,577
General and administrative	2,785,500	2,260,488	2,311,365	34,256
	12,222,492	11,453,321	9,972,128	112,834
Other income and expense:				
Interest income	2,047,883	2,286,251	2,555,795	22,419
Interest expense	--	--	--	83
	2,047,883	2,286,251	2,555,795	22,335

Net loss	$(10,174,609)	(9,167,070)	(7,416,333)	(87,498
Net loss per share -- basic and diluted	$ (0.71)	(0.64)	(0.53)	(
Shares used in calculation of per share data -- basic and diluted	14,253,385	14,240,749	14,114,676	9,304

See accompanying notes to financial statements.

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NORTHFIELD LABORATORIES INC.
(A COMPANY IN THE DEVELOPMENT STAGE)
STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
YEARS ENDED MAY 31, 2001, 2000, AND 1999 AND THE CUMULATIVE
PERIOD FROM JUNE 19, 1985 (INCEPTION) THROUGH MAY 31, 2001

	NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHAR	CO
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

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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	SHA (
--	$ --	--	$ --	(28,000)	--	--	
250,000	250,000	--	--	670,850	--	--	
--	--	--	--	--	(607,688)	--	
250,000	250,000	--	--	642,850	(607,688)	--	--
--	--	--	--	--	(2,429,953)	--	(2
--	--	--	--	2,340,000	--	(2,340,000)	
--	--	--	--	--	--	720,000	
250,000	250,000	--	--	2,982,850	(3,037,641)	(1,620,000)	(1
--	--	200,633	200,633	6,882,502	--	--	7
--	--	--	--	--	(3,057,254)	--	(3
--	--	--	--	--	--	566,136	
250,000	250,000	200,633	200,633	9,865,352	(6,094,895)	(1,053,864)	3
--	--	--	--	9,749,870	--	--	9
(250,000)	(250,000)	--	--	237,500	--	--	
--	--	(200,633)	(200,633)	190,601	--	--	
--	--	--	--	93,759	--	--	
--	--	--	--	4,976,855	--	--	4

--	--	--	--	2,488,356	--	--	2
--	--	--	--	7,443,118	--	--	7
--	--	--	--	--	(791,206)	--	
--	--	--	--	683,040	--	(683,040)	
--	--	--	--	--	--	800,729	
--	--	--	--	35,728,451	(6,886,101)	(936,175)	27
--	--	--	--	--	(3,490,394)	--	(3
--	--	--	--	699,163	--	(699,163)	
--	--	--	--	--	--	546,278	
--	--	--	--	36,427,614	(10,376,495)	(1,089,060)	25
--	--	--	--	--	(5,579,872)	--	(5
--	--	--	--	--	--	435,296	
--	--	--	--	36,427,614	(15,956,367)	(653,764)	19
--	--	--	--	503,100	--	--	
--	--	--	--	--	(7,006,495)	--	(7
--	--	--	--	--	--	254,025	
--	--	--	--	36,930,714	(22,962,862)	(399,739)	13
--	--	--	--	106,890	--	--	
--	--	--	--	5,663,710	--	--	5
--	--	--	--	--	(8,066,609)	--	(8
--	--	--	--	--	--	254,025	
--	$ --	--	$ --	42,701,314	(31,029,471)	(145,714)	11

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

STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
YEARS ENDED MAY 31, 2001, 2000, AND 1999 AND THE CUMULATIVE
PERIOD FROM JUNE 19, 1985 (INCEPTION) THROUGH MAY 31, 2001

	PREFERRED STOCK		CO
	NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBE OF SHAR
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,

See accompanying notes to financial statements.

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

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

STATEMENTS OF CASH FLOWS
YEARS ENDED MAY 31, 2001, 2000, AND 1999
AND THE CUMULATIVE PERIOD FROM JUNE 19, 1985
(INCEPTION) THROUGH MAY 31, 2001

	YEARS ENDED MAY 31,			CUMULATIV FROM JUNE 19, 1 THROUGH
	2001	2000	1999	MAY 31, 20
Cash flows from operating activities:				
Net loss	$(10,174,609)	(9,167,070)	(7,416,333)	(87,498,2
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	819,828	790,563	489,773	15,468,4
Non-cash compensation	--	88,378	14,354	3,552,7
Loss on sale of equipment	--	--	--	66,3
Changes in assets and liabilities:				
Prepaid expenses	31,128	(107,030)	21,811	(587,3
Other current assets	49,712	(237,142)	(259,940)	(2,352,1
Other assets	(49,201)	--	--	(42,2
Accounts payable	711,215	(263,663)	287,763	1,772,5
Accrued expenses	(20,104)	53,385	39,102	153,9
Accrued compensation and benefits	10,643	29,570	(32,345)	261,2
Other liabilities	19,143	23,015	25,726	166,8
Net cash used in operating activities	(8,602,245)	(8,789,994)	(6,830,089)	(69,037,8
Cash flows from investing activities:				
Purchase of property, plant, equipment, and capitalized engineering costs	(1,210,448)	(2,307,390)	(238,223)	(18,251,2
Proceeds from sale of land and equipment	--	1,786,436	--	1,863,0
Proceeds from matured marketable securities	24,148,171	21,549,200	49,049,200	379,538,1
Proceeds from sale of marketable securities	--	--	--	7,141,6
Purchase of marketable securities	(23,281,688)	(22,973,075)	(43,723,747)	(408,942,6
Net cash provided by (used in) investing activities	(343,965)	(1,944,829)	5,087,230	(38,651,0
Cash flows from financing activities:				
Proceeds from issuance of common stock	227,455	33,450	1,124,950	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	33,450	1,124,950	114,124,4
Net (decrease) increase in cash	(8,718,755)	(10,701,373)	(617,909)	6,435,5

Cash at beginning of period.....	15,154,295	25,855,668	26,473,577	
Cash at end of period.....	$ 6,435,540	15,154,295	25,855,668	6,435,5

See accompanying notes to financial statements.

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

NOTES TO FINANCIAL STATEMENTS
MAY 31, 2001 AND 2000

(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.

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 2001 and 2000 the Company capitalized $0 and $359,649, of such engineering costs, respectively. These costs are being amortized over a three year period, the expected period of benefit. For the years ended May 31, 2001 and 2000, and 1999, total amortization cost recorded was $120,000, and $379,674, and 185,544 respectively.

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 effect of unexercised common equivalent shares, if their inclusion is not antidilutive. Because the Company reported a net loss for the years ended May 31, 2001, 2000, and 1999 and the cumulative period from June 19, 1985 (inception) through May 31, 2001, basic and diluted per share amounts are the same.

Had the Company reported net earnings for the years ended May 31, 2001, 2000, and 1999 and the cumulative period from June 19, 1985 (inception) through May 31, 2001, the weighted average number of

shares outstanding would have been diluted by the following common equivalent securities (not assuming the effects of applying the treasury stock method):

	2001	2000	1999	CUMULATIVE FROM JUNE 19, 1985 THROUGH MAY 31, 2001
Stock options	603,000	594,350	539,250	571,848
Warrants	--	--	118,836	76,250
	603,000	594,250	658,086	648,098

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.

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, 2001 and 2000.

(2) MARKETABLE SECURITIES

The fair market value of the Company's marketable securities was $22,464,045 at May 31, 2001, which included gross unrealized holding gains of $201,204. The fair market value of the Company's marketable securities was $23,022,457 at May 31, 2000, which included gross unrealized holding losses of $106,867.

At May 31, 2001, 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, 2001 and 2000:

	USEFUL LIFE	2001	2000
Manufacturing equipment	5 years	$ 9,331,865	9,257,650
Laboratory equipment	5 years	1,330,425	1,330,425
Office furniture and equipment	7 years	671,778	671,778
Computer equipment	3 years	87,515	187,160
Leasehold improvements	Lease term	1,621,332	1,596,927
Capitalized engineering costs	3 years	924,867	924,867
		13,967,782	13,968,807
Less accumulated depreciation and amortization		11,120,449	11,513,106
		$ 2,847,333	2,455,701

Depreciation and amortization expense amounted to $818,816, $789,551, and $479,595 for the years ended May 31, 2001, 2000, and 1999, respectively. During the fiscal year ended May 31, 2001, the Company disposed of $1,211,473 of fully depreciated capital equipment.

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(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 (note 7).

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 (note 7).

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, 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, 2001, the Company had net operating loss carryforwards for income tax purposes of approximately $88,000,000, which are available to offset future taxable income, if any, through 2002 to 2021. Deferred tax assets primarily resulted from net operating loss carryforwards and differences in the recognition of research and development, compensatory stock options, and depreciation expenses and the tax benefit from the exercise of stock options. Additionally, the Company had approximately $2,500,000 of research and experimentation tax credits and investment tax credits available to reduce future income taxes through 2021.

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, 2001 and 2000 are summarized as follows:

	2001	2000
Deferred tax assets:		
Net operating loss carryforwards	$ 34,200,000	30,400,000
Tax credit carryforwards	2,500,000	2,200,000
Deferred compensation	--	1,400,000
Other	900,000	800,000
	37,600,000	34,800,000
Valuation allowance	(37,600,000)	(34,800,000)
Net deferred tax asset	$ --	--

The net change in the valuation allowance during fiscal 2001, 2000, and 1999 was an increase of $2,800,000, $4,400,000, and $2,600,000, 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, 2000, 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.

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 year ended May 31, 2001, the Company granted 64,000 options to purchase shares of common stock at $10.66 and $15.41 per share. During the year ended May 31, 2000, the Company granted 15,000 options to purchase shares of

common stock at $12.88 per share, which was below the fair market value of a

share of common stock at $15.69 at the date of grant. The above mentioned options expire ten years after the date of grant.

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, 2001, the Company granted 60,000 options to purchase shares of common stock at $10.88 per share. These options expire in 2011, ten years after the date of the grant. During the year ended May 31, 2000, the Company did not grant any options under this plan.

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, 2001, the Company granted 15,000 options to purchase shares of common stock at $11.18 per share. These shares expire in 2011. During the year ended May 31, 2000, the Company granted no options to purchase shares of common stock.

The Company applies the intrinsic value method to account 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, the Company's net loss and net loss per share would have been the pro forma amounts indicated below:

	2001	2000	1999
Net loss as reported.....	$(10,174,609)	(9,167,070)	(7,416,333)
Pro forma.....	(10,854,076)	(9,727,924)	(8,175,218)
Net loss per share as reported.....	(0.71)	(0.64)	(0.53)
Pro forma.....	(0.76)	(0.68)	(0.58)

For purposes of calculating the compensation cost consistent with using the fair value method, 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 2001, 2000, and 1999:

	2001	2000	1999
Expected volatility.....	67.0%	60.2%	58.5%
Risk-free interest rate.....	5.4%	5.3%	5.9%
Dividend yield.....	--	--	--
Expected lives.....	7.0 years	6.7 years	6.7 years

Additional information on shares subject to options is as follows:

	2001		2000		19
	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS
Outstanding at beg of year.....	565,500	$11.64	623,000	$11.41	455,500
Granted.....	139,000	11.97	15,000	12.88	185,000
Exercised.....	23,500	9.68	2,500	13.38	17,500
Canceled.....	40,500	13.82	70,000	9.76	--
Outstanding at end of year.....	640,500	$11.65	565,500	$11.64	623,000
Options exercisable at year end.....	423,250	$11.56	404,250	$11.66	338,000
Weighted-average fair value of options granted during the year.....	$ 8.27		$ 10.62		$ 6.86

The following table summarizes information about stock options outstanding at May 31, 2001:

	OPTIONS OUTSTANDING			OPTION
RANGE OF EXERCISE PRICES	NUMBER OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	OPTION EXERCISA AT MAY 3 2001
$ 6.38 -- 10.81.....	354,000	6.55	$10.43	262,00
10.88 -- 15.41.....	286,500	7.16	13.17	161,25

(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 (note 4).

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 (note 4).

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 (note 4).

(8) LEASES

Rent expense amounted to $809,721, $747,055, and $499,491 for the years ended May 31, 2001, 2000, and 1999, respectively.

The Company has renewed the lease for its corporate facility which now expires in February 2006. The terms of the renewed lease are substantially the same as the original lease. The Company has the option to cancel the lease after February 15, 2002, upon giving written notice at least six months prior to termination, as well as paying a penalty equal to six months rent of $144,375 at February 15, 2002.

The Company has renewed the lease for its research and manufacturing facility which now expires in August 2004. The terms of the renewed lease are substantially the same as the original lease. The lease is collateralized by a $49,200 security deposit as of May 31, 2001.

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At May 31, 2001, future minimum lease payments under the operating leases are as follows:

YEARS ENDING MAY 31,	AMOUNT
2002	$ 554,986
2003	578,588
2004	588,234
2005	382,957
2006 and thereafter	226,188
	$2,330,953

(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, 2001, 2000, and 1999 amounted to $145,051, $129,496, and $118,167, respectively.

(10) QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table shows our quarterly unaudited financial information for the eight quarters ended May 31, 2001. 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				
	AUG. 31, 1999	NOV. 30, 1999	FEB. 29, 2000	MAY 31, 2000	AUG. 31, 2000
Revenues	$ --	--	--	--	--
Costs and Expenses:					
Research and Development	2,124	2,362	2,365	2,342	2,238
General and Administrative	485	524	657	594	870
	2,609	2,886	3,022	2,936	3,108
Other income and expense:					
Interest Income	570	579	558	579	590
Interest Expense	--	--	--	--	--
Net loss	$(2,039)	(2,307)	(2,464)	(2,357)	(2,518)
Net loss per share - basic and diluted	$ (0.14)	(0.16)	(0.17)	(0.17)	(0.18)
Shares used in calculation of per share data - basic and diluted	14,240	14,240	14,241	14,242	14,242

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 "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 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 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 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 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 Registration Statement)
10.8*	Northfield Laboratories Inc. 401(K) Plan (incorporated herein by reference to Exhibit 10.14 to the 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*	Employment Agreement dated as of January 1, 2001 between the Registrant and Richard E. DeWoskin (incorporated herein by reference to Exhibit 10.15 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001)
10.13*	Employment Agreement dated as of January 1, 2001 between the Registrant and Steven A. Gould, M.D. (incorporated herein by reference to Exhibit 10.16 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001)

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NUMBER	DESCRIPTION
10.14*	Employment Agreement dated as of January 1, 2001 between the Registrant and Jack Kogut (incorporated herein by reference to Exhibit 10.17 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001)
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

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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 3, 2001.

NORTHFIELD LABORATORIES INC.

By: /s/ RICHARD E. DEWOSKIN

Richard E. DeWoskin
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 3, 2001.

SIGNATURE	TITLE
/s/ RICHARD E. DEWOSKIN Richard E. DeWoskin	Chairman of the Board and Chief Executive Officer (principal executive officer)
/s/ STEVEN A. GOULD, M.D. Steven A. Gould	President and Director
/s/ JACK J. KOGUT Jack J. Kogut	Vice President - Finance, Secretary and Treasurer (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