

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

NORTHFIELD LABORATORIES INC /DE/
Form 10-K
August 15, 2005

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

FORM 10-K

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

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

For the fiscal year ended May 31, 2005

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. 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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

amendment to this Form 10-K. [X]

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

As of November 30, 2004, 21,551,364 shares of the Registrant's common stock, par value \$.01 per share, were outstanding. On that date, the aggregate market value of voting stock (based upon the closing price of the Registrant's common stock on November 30, 2004) held by non-affiliates of the Registrant was \$378,131,185 (20,220,919 shares at \$18.70 per share).

As of July 31, 2005, there were 26,751,397 shares of the Registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2005 Annual Meeting are incorporated by reference into Part III of this Form 10-K. The Registrant maintains an Internet website at www.northfieldlabs.com. None of the information contained on this website 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," "forecasts," "should," "believes" and similar terms.

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

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. BUSINESS.

Northfield Laboratories Inc. is a leader in developing a hemoglobin-based oxygen-carrying resuscitative fluid for the treatment of urgent, large volume blood loss in trauma and resultant surgical settings. The initial indication we are seeking for our product, PolyHeme(R), is the early treatment of urgent, life-threatening blood loss following trauma when donated blood may not be immediately available. We believe that this indication addresses a critical unmet medical need, since some trauma patients bleed to death before they have access to blood. We believe PolyHeme has the potential to improve survival in critically injured patients and to thereby transform the treatment of trauma.

We are pursuing a unique regulatory strategy in order to seek Food and Drug

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Administration, or FDA, approval of PolyHeme. We are conducting the first-ever pivotal Phase III trial in the United States in which a hemoglobin-based oxygen carrier is being used to treat severely injured and bleeding patients, beginning at the scene of injury and continuing during transport to the hospital and the early period of hospitalization. Our current trial is based on our experience in prior clinical trials documenting the potential life-sustaining capability of PolyHeme when given in rapid, massive infusions to critically injured patients in the hospital. Some of these patients received up to 20 units of PolyHeme, equivalent to twice their normal blood volume. Because of the life-sustaining potential of PolyHeme, our trial is being conducted under a federal regulation, 21 CFR 50.24, that permits certain types of emergency research using an exception from the requirement for prospective informed consent by individual patients.

We have also taken advantage of Special Protocol Assessment, or SPA, one of the features of the Food and Drug Modernization Act of 1997. Our SPA reflects an agreement with FDA on our trial design, the trial endpoints and the broad concepts for clinical indications those endpoints would support in an application for product approval by FDA. The assessment of efficacy in our trial will be based on the data on patient survival at 30 days. A key feature of our SPA is the agreement on dual primary endpoints of superiority and non-inferiority between the treatment and control groups. Either of these endpoints may be used to provide evidence of efficacy.

As part of our trial protocol, an Independent Data Monitoring Committee, or IDMC, consisting of independent medical and biostatistical experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to continuation or modification of the trial protocol to minimize any identified risks to patients. The IDMC has completed the first three of four planned reviews of data from the initial 60, 120 and 250 patients enrolled in the trial and has recommended on each occasion that the trial continue without modification. This is the first time that a trial of a hemoglobin-based oxygen carrier has passed this patient evaluation milestone in a high risk trauma population. The final interim analysis is scheduled to occur after 500 patients have been enrolled, and we anticipate being able to announce that milestone before the end of calendar 2005.

As of June 30, 2005, approximately 400 patients had been enrolled in our trial, or more than half the planned 720 patients. Based on present enrollment at currently active sites, we estimate that approximately 600 patients will be enrolled by the end of calendar 2005. Our current goal is to complete the patient enrollment phase of our trial early in calendar 2006. Our ability to achieve this goal will depend, in part, on the number of clinical sites participating in our trial and the ability of these sites to enroll patients at the projected rates. We will provide quarterly updates on enrollment until full enrollment is reached.

We believe that PolyHeme ultimately represents a substantial global market opportunity, based on the need for a universally compatible, immediately available oxygen carrying product and PolyHeme's potential for eventual approval for multiple indications.

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

diminished oxygen-carrying capacity resulting from blood loss. We estimate that approximately 14 million units of blood are transfused in the United States each year, of which approximately 8.4 million units are administered to patients suffering the effects of acute blood loss.

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

OUR PRODUCT

Our product, PolyHeme, is a human hemoglobin-based oxygen carrying resuscitative fluid in development for the treatment of urgent, large volume blood loss in trauma and resultant surgical settings, with a particular focus on settings where blood is not immediately available.

PolyHeme is a solution of chemically modified human hemoglobin which simultaneously restores lost blood volume and hemoglobin levels. Hemoglobin is the oxygen-carrying component of the red blood cell. PolyHeme is designed for rapid, massive infusion, which is the way blood is transfused in trauma patients.

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

We believe PolyHeme will have the following important benefits:

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Oxygen-Carrying Ability. Our clinical studies indicate that PolyHeme carries as much oxygen and loads and unloads oxygen in a manner similar to transfused blood.

Blood Volume Replacement. Infusion of PolyHeme also restores blood volume. Therefore, PolyHeme should be useful as an oxygen-carrying resuscitative fluid in the treatment of hemorrhagic shock resulting from extensive blood loss.

4

Impact on Disease Transmission. We believe, and laboratory tests have thus far indicated, that the manufacturing process used to produce PolyHeme substantially 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 blood cells.

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

OUR PIVOTAL PHASE III TRIAL

We are currently enrolling patients in a pivotal Phase III trial in which PolyHeme is being used for the first time in the U.S. to treat severely injured patients in hemorrhagic shock before they reach the hospital. Under this protocol, treatment with PolyHeme begins at the scene of the injury or in the ambulance and continues during transport and the initial 12 hour post-injury period in the hospital. Since blood is not presently carried in ambulances, the use of PolyHeme in this setting has the potential to improve survival and address a critical, unmet medical need.

As of August 1, 2005, 21 clinical sites in the United States were enrolling patients in our pivotal Phase III trial and six other sites had received final Institutional Review Board, or IRB, approval and were preparing to begin patient enrollment. Multiple additional sites were engaged in the required public disclosure and community consultation process. Each of the sites participating in the trial is designated as a Level I trauma center, indicating its capacity to treat the most severely injured trauma patients. We anticipate that a total of 25 or more clinical sites across the United States will eventually participate in the trial. The trial has an expected enrollment of 720 patients.

As part of our trial protocol, an Independent Data Monitoring Committee, or IDMC, consisting of independent medical and biostatistical experts, is responsible for periodically evaluating the safety data from the trial and making recommendations relating to continuation or modification of the trial protocol to minimize any identified risks to patients. The protocol includes four planned evaluations by the IDMC that occur after 60, 120, 250 and 500 patients have been enrolled and monitored for a 30-day follow up period. The IDMC focuses its reviews on mortality and serious adverse events and evaluates all safety data as the trial continues. We receive a recommendation from the IDMC after each review, but we will not have access to the trial data reviewed by the IDMC until the trial is complete.

The IDMC has completed three of the four planned reviews of the trial data. In July 2004, the IDMC recommended that our trial continue without modification based on the committee's initial review of blinded data from the first 60 patients enrolled in the trial. In October 2004, the IDMC recommended continuation of the trial without modification based on its review of data following enrollment of the first 120 patients in our trial. In April 2005, the IDMC recommended that our trial continue without modification based on the

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

committee's review of blinded data from the first 250 patients enrolled in the study. This is the first time that a trial of a hemoglobin-based oxygen carrier has passed this patient evaluation milestone in a high risk trauma population.

As part of the third interim analysis, the IDMC also conducted an adaptive sample size determination as specified in the trial protocol. A blinded power analysis was performed to determine if any increase in the sample size of the study was necessary. The assessment was based on a comparison between the mortality rate predicted in the protocol and the observed mortality rate in the trial to date. The IDMC concluded that no adjustment in the number of patients to be enrolled in the study would be required. Therefore, planned enrollment remains at 720 patients.

We anticipate that the IDMC will complete its final review of trial data on the first 500 patients enrolled in our trial and make a recommendation to us in the fourth quarter of calendar year 2005.

As of June 30, 2005, approximately 400 patients had been enrolled in our trial, or more than half the planned 720 patients. Based on present enrollment at currently active sites, we estimate that approximately 600 patients will be enrolled by the end of calendar 2005. Our current goal is to complete the patient

5

enrollment phase of our trial early in calendar 2006. Our ability to achieve this goal will depend, in part, on the number of clinical sites participating in our trial and the ability of these sites to enroll patients at the projected rates. We will provide quarterly updates on enrollment until full enrollment is reached.

TRIAL DESIGN AND CLINICAL ENDPOINTS

We have reached agreement with FDA on Special Protocol Assessment, or SPA, for our pivotal Phase III trial. SPA is designed to facilitate the review and approval of drug and biological products by allowing for FDA evaluation of the trial sponsor's proposed design and size of clinical trials intended to form the primary basis for an efficacy claim in a Biologics License Application, or BLA, submitted to FDA. If agreement is reached between FDA and the trial sponsor, SPA will document the terms and conditions under which the clinical trial will be conducted. Our SPA reflects an agreement with FDA on our trial design, the trial endpoints and the broad concepts for clinical indications those endpoints would support in an application for product approval by FDA.

Our pivotal Phase III trial is being conducted under a federal regulation that permits research to be conducted in certain emergent, life-threatening situations using an exception from the requirement for prospective informed consent by individual patients. Participation by each clinical trial site is overseen by an IRB. Under the applicable federal regulation, an IRB may give approval for patient enrollment in trials in emergency situations without requiring individual informed consent provided specific criteria are met. Patients must be in a life-threatening situation for which available treatments are unproven or unsatisfactory and scientific evidence must be needed to assess the safety and effectiveness of alternative treatments. The experimental therapy being evaluated must also provide patients potential for direct clinical benefit. In addition, medical intervention must be required before informed consent can be obtained and it must be impracticable to conduct the trial using only consenting patients. Where informed consent is feasible, the sponsor's consent procedures and forms must be reviewed and approved by the IRB, and attempts to obtain informed consent must be documented by the sponsor. Before enrollment can begin, the regulation requires public disclosure of information

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

about the trial, including the potential risks and benefits, and the formation of an independent monitoring committee to oversee the trial. Consultation must also occur with representatives of the community where the study will be conducted and from which the study population will be drawn. Each of the clinical sites currently participating in our trial has completed the required public disclosure and community consultation procedures and received IRB approval to enroll patients in accordance with the trial protocol.

Under our trial protocol, patients enrolled in the trial are randomly assigned to either a treatment group or a control group. The treatment group receives PolyHeme at the scene of the injury or in the ambulance during transport and continues to receive PolyHeme, if necessary, during the initial 12 hour post-injury period in the hospital. Patients in the treatment group may receive a maximum of six units of PolyHeme. The control group receives saline solution in the field and donated blood, if necessary, in the hospital.

Evaluation of the efficacy data generated in our pivotal Phase III trial will focus on patient survival at 30 days after the date of injury. The mortality rate observed for patients in the treatment group in our trial will be compared statistically with the mortality rate for patients in the control group. A key feature of our SPA is the agreement on dual primary end points of superiority and non-inferiority between the treatment and control groups. The trial design is unusual in that either of the primary endpoints of superiority or non-inferiority may be used to provide evidence of efficacy.

Our trial is being conducted primarily in urban settings because urban Level I trauma centers have the patient volume, resources and sophistication to conduct a clinical trial of this complexity. In urban areas, however, transit times in the ambulance may be brief, and the control group will reach the hospital, where patients will have access to blood, in relatively short periods of time. The observed outcome in our trial may therefore not demonstrate the expected magnitude of survival benefit that might occur if the trial were being conducted in the rural setting, where more extended transport times are typical and where the availability of blood may be limited. It is therefore possible that the observed survival rate in the treatment group may trend towards the survival rate observed in patients in the control group who have rapid access to blood. This

6

outcome would represent non-inferiority, which would satisfy one of the dual primary endpoints for efficacy in our trial protocol.

THE MARKET OPPORTUNITY

Transfused blood represents a multi-billion dollar market in the United States. We estimate that approximately 14 million units of blood are transfused in the United States each year. The transfusion market in the United States consists of two principal segments. The acute blood loss segment, which we estimate comprises approximately 60% of the transfusion market, includes transfusions required in connection with trauma, surgery and unexpected blood loss. The chronic blood loss segment, which we believe represents approximately 40% of the transfusion market, includes transfusions in connection with general medical applications and chronic anemias.

We believe that PolyHeme will be most useful in the treatment of acute blood loss. The principal clinical settings in which patients experience acute blood loss are unplanned blood loss in trauma, emergency surgery and other causes of urgent hemorrhage, and planned blood loss in elective surgery. For trauma and emergency surgical procedures, the immediate availability and universal compatibility of PolyHeme may provide significant advantages over

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

transfused blood by avoiding the delay and opportunities for error associated with blood typing. In elective surgery, PolyHeme has the potential to increase transfusion safety for patients and health care professionals.

In addition to the foregoing applications for which blood is currently used, there exist potential sources of demand for which blood is not currently used 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 PolyHeme may be used by Emergency Medical Technicians at the scene of injury and during transport to the hospital by ground or air ambulance. Emergicenters and surgicenters also both experience events where PolyHeme may be useful. In addition, the United States military has expressed interest in the use of hemoglobin based oxygen carryings for the treatment of battlefield casualties. There may also be potential market opportunities for PolyHeme in novel areas such as ischemia and oncology.

We believe that the initial indication we are seeking for PolyHeme -- unavailability of red blood cells -- represents the greatest clinical and commercial opportunity for the product since it addresses a critical unmet medical need and has the potential to provide a survival benefit. At present, no adequate alternative to blood exists for the treatment of patients with life-threatening hemorrhage who need replacement of lost oxygen-carrying capacity. PolyHeme is the first hemoglobin-based oxygen carrier to pursue this indication, and our goal is for PolyHeme to be first to the market for this indication.

We recently engaged a national consulting firm to conduct an independent assessment of the potential market opportunity for PolyHeme. Using a variety of primary and secondary sources along with original research, their analysis indicates a potential market opportunity in the United States for PolyHeme's initial indication of unavailability in excess of 350,000 units per year, representing an estimated market value of \$400 to \$500 million. In addition, the global opportunity for our initial indication, as well as multiple other potential indications, is estimated to be six to seven times the U.S. unavailability projection, or \$2 to \$3 billion.

MANUFACTURING AND MATERIAL SUPPLY

We use a proprietary process of separation, filtration, chemical modification, purification and formulation to produce PolyHeme. Since 1990, we have produced PolyHeme in our manufacturing facility. We believe this facility is capable of producing sufficient quantities of PolyHeme for our current clinical trial.

Our current manufacturing facility has the capacity to produce 10,000 units of PolyHeme 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. We have begun preconstruction activities for our planned expansion of manufacturing capacity for Polyheme. We are developing a request for proposal that we intend to

7

issue this fall. After reviewing bids, we will select the contractor, negotiate and award the final contract, and begin final engineering. 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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

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

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

MARKETING STRATEGIES

If FDA approval of PolyHeme is received, we presently intend to market PolyHeme with our own sales force in the United States. We are exploring potential sales, marketing and distribution plans for PolyHeme. We may also consider entering into collaborative relationships with strategic partners which could involve arrangements relating to the sale and marketing of PolyHeme.

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

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

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

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

COMPETITION

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

Sangart, Inc. announced in July 2005 the initiation of a 40 patient Phase II clinical trial in elective surgery with its human hemoglobin-based oxygen carrier. Synthetic Blood International, Inc., which is developing a perfluorocarbon-based oxygen carrier product, is conducting a Phase II study in surgery patients who experience mild to moderate blood loss. Biopure Corporation, which is developing a bovine hemoglobin-based oxygen carrier product, announced that it intends to pursue an indication for myocardial ischemia. Biopure also announced that the Naval Medical Research Center has assumed primary responsibility for submitting an Investigational New Drug application to conduct a clinical trial using Biopure's product for the out-of-hospital treatment of trauma patients. Biopure subsequently announced that FDA placed this proposed study protocol on clinical hold.

We believe that important competitive factors in the market for oxygen carrier 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 oxygen carrier products and the scope of the intended uses for which they are approved, the scope and enforceability of patent or other proprietary rights, product price, product supply and marketing and sales capability. We believe that our competitive position will be significantly influenced by the timing of the clinical testing and regulatory filings for PolyHeme, our ability to expand our manufacturing capability to permit commercial production of PolyHeme, if approved, and our ability to maintain and enforce our proprietary rights covering PolyHeme and its manufacturing process.

GOVERNMENT REGULATION

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Act and the Environmental Protection Act. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial funds.

The steps required before a biological product may be sold commercially in the United States include preclinical testing, the submission to FDA of an Investigational New Drug application, clinical trials in humans to establish the safety and effectiveness of the product, the submission to FDA of a Biologics 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 submitted there is an initial review

9

by FDA to be sure that all of the required elements are included in the submission. There can be no assurance that the submission will be accepted for filing or that FDA may not issue a refusal to file, or RTF. If a RTF is issued, there is opportunity for dialogue between the sponsor and FDA in an effort to resolve all concerns. There can be no assurance that such a dialogue will be successful in leading to the filing of the BLA. If the submission is filed, there can be no assurance that the full review will result in product approval.

Preclinical tests include evaluation of product chemistry and studies to assess the safety and effectiveness of the product and its formulation in animals. The results of the preclinical tests are submitted to FDA as part of the Investigational New Drug application. The goal of clinical testing is the demonstration in adequate and well-controlled studies of substantial evidence of the safety and efficacy of the product in the setting of its intended use. The results of preclinical and clinical testing are submitted to the FDA from time to time throughout the trial process. In addition, before approval for the commercial sale of a product can be obtained, results of the preclinical and clinical studies must be submitted to FDA in the form of a BLA. The testing and approval process requires substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, including the severity of the condition being treated, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional preclinical studies, clinical trials or manufacturing data may be requested during the FDA review process and may delay product approval. After FDA approval for its initial indication(s), further clinical trials may be necessary to gain approval for the use of a product for additional indications. FDA may also require post-marketing testing, which can involve significant expense, to monitor for adverse effects.

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

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

PATENTS AND PROPRIETARY RIGHTS

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

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

10

RESEARCH AND DEVELOPMENT

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

In fiscal 2005, 2004, and 2003, our research and development expenses totaled \$16,600,000, \$10,777,000 and \$8,819,000 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, 2005, we had 69 employees, of whom 61 were involved in research and development and eight were responsible for financial and other administrative matters. We also had consulting arrangements with 20 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.

Our website is www.northfieldlabs.com. We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports of Form 8-K, Forms 3, 4 and 5 filed on behalf of directors and executive officers and any amendments to such reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission (the "SEC").

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.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

WE ARE A DEVELOPMENT STAGE COMPANY WITHOUT REVENUES OR PROFITS.

Northfield was founded in 1985 and is a development stage company. Since 1985, we have been engaged primarily in the development and clinical testing of PolyHeme. No revenues have been generated to date from commercial sales of PolyHeme. Our revenues to date have consisted solely of license fees. We cannot ensure that our clinical testing will be successful, that regulatory approval of PolyHeme will be obtained, that we will be able to manufacture PolyHeme at an acceptable cost and in appropriate quantities or that we will be able to successfully market and sell PolyHeme. We also cannot ensure that we will not encounter unexpected difficulties which will have a material adverse effect on us, our operations or our properties.

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

From our inception through May 31, 2005, we have incurred net operating losses totaling \$145,361,000. 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 few years and are expected to substantially exceed our currently available capital resources. The expense and the time required to realize any product revenues or profitability are highly uncertain. We cannot ensure that we will be able to achieve product revenues or profitability on a sustained basis or at all.

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

To succeed as a company, we must develop PolyHeme commercially and sell adequate quantities of PolyHeme at a high enough price to generate a profit. We may not accomplish either of these objectives. 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

11

PolyHeme. We expect that such revenues, if any, will be derived solely from sales of PolyHeme directly or through licensees. We also expect the use of PolyHeme initially to be limited 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 REQUIRED TO COMPLETE OUR CURRENT CLINICAL TRIAL BEFORE WE MAY SELL POLYHEME COMMERCIALY AND WE MAY BE REQUIRED TO CONDUCT ADDITIONAL CLINICAL TRIALS IN THE FUTURE.

The results of our clinical trials conducted to date are not sufficient to demonstrate adequately the safety and effectiveness of PolyHeme in order to obtain approval from FDA for the commercial sale of PolyHeme. We are currently conducting a pivotal Phase III trial in which PolyHeme is being used for the first time in the U.S. to treat severely injured patients before they reach the hospital. Under this protocol, treatment with PolyHeme begins at the scene of the injury or in the ambulance and continues during transport and the initial 12 hour post-injury period in the hospital. This trial will be expensive and

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

time-consuming and the timing of the FDA review process is uncertain. Our trial may be delayed due to failure to conduct the trial in accordance with regulatory requirements, a lower than anticipated enrollment rate of patients or insufficient supply of product or other materials necessary for the conduct of the trial. We or FDA may in the future suspend our clinical trial at any time if it is believed that the subjects participating in the trial are being exposed to unacceptable health risks.

We cannot ensure that we will be able to complete our current clinical trial successfully or that FDA will not require us to conduct additional clinical trials of PolyHeme in the future. If FDA approval for the commercial sale of PolyHeme is obtained, it may include significant limitations on the indicated uses for which PolyHeme may be marketed. FDA requires a separate approval for each proposed indication for the use of PolyHeme in the United States. If we want to expand PolyHeme's indications, we will have to design additional clinical trials, submit the trial designs to FDA for review and complete those trials successfully.

Our business, financial condition and results of operations are critically dependent on receiving FDA approval of PolyHeme. A significant delay in our clinical trial or a failure to achieve FDA approval for commercial sales of PolyHeme would have a material adverse effect on us and could result in the cessation of our business.

COMPLETION OF OUR PIVOTAL PHASE III CLINICAL TRIAL IS DEPENDENT ON THE NUMBER OF CLINICAL TRIAL SITES PARTICIPATING IN THE TRIAL AND THE RATE AT WHICH WE ARE ABLE TO ENROLL PATIENTS IN THE TRIAL.

As of August 1, 2005, 21 clinical sites were enrolling patients in our pivotal Phase III trial and six additional sites had received IRB approval to begin enrollment. Two clinical sites did not receive IRB approval for their participation in our trial, although the IRB at one of these sites subsequently reconsidered its decision and approved participation in our trial. It is possible the other prospective clinical sites may decide not to participate in our trial or may fail to obtain IRB approval for their participation in the trial. One or more of the clinical sites currently enrolling patients may also discontinue their participation in our trial in the future. Our projections relating to completion of the enrollment phase of our trial are based, in part, on assumptions regarding the number of clinical sites enrolling patients in our trial. If we are unable to include additional clinical sites in our trial or our current clinical sites discontinue their participation in our trial, the trial may be significantly delayed and we may be unable to complete the trial.

Our pivotal Phase III trial is being conducted under a federal regulation that allows research to be conducted in certain emergent, life-threatening situations using an exception from the requirement for prospective informed patient consent. Under our trial protocol, members of the public can take steps to avoid being enrolled in our trial and patients enrolled in our trial are permitted to terminate their participation at any time. Our trial may be delayed, and we may be unable to complete the trial, if a significant number of individuals decline to participate in the trial or if patients enrolled in the trial terminate their participation before the end of the 30-day post-treatment evaluation period required under our trial protocol.

12

SAFETY DATA FROM OUR PIVOTAL PHASE III CLINICAL TRIAL WILL BE REVIEWED BY AN INDEPENDENT COMMITTEE, WHICH COULD RECOMMEND THAT THE TRIAL BE HALTED OR MODIFIED.

As part of our trial protocol, an Independent Data Monitoring Committee, or

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

IDMC, consisting of independent medical and biostatistical experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any identified risks to patients. The IDMC focuses its reviews on mortality and serious adverse events and evaluates all safety data as the trial continues. If the IDMC believes the data from our trial give rise to safety concerns, the IDMC could recommend that our trial be halted or substantially modified. A recommendation of this type could significantly delay the completion of our trial and could prevent us from completing the trial.

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

We currently purchase donated red blood cells from The American Red Cross and Blood Centers of America for use as the starting material for PolyHeme. We have also entered into an agreement with hemerica, Inc., a subsidiary of Blood Centers of America, under which hemerica would supply us with up to 160,000 units per year of packed red cells, the source material for PolyHeme. We have not purchased any blood supplies under this agreement to date. We have plans to enter into 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 human hemoglobin-based oxygen carrier products, thereby limiting our available supply of starting material.

THE MARKET MAY NOT ACCEPT OUR PRODUCT.

Even if PolyHeme is approved for commercial sale by FDA, the degree of market acceptance of PolyHeme by physicians, healthcare professionals and third party payors, and our profitability and growth will depend on a number of factors, including:

- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- effectiveness of our sales and marketing strategy; and
- the price of PolyHeme compared with other hemoglobin-based oxygen carrier products.

In addition, even if PolyHeme does achieve market acceptance, we may not be able to maintain that market acceptance over time if new products are introduced that are more favorably received than PolyHeme or render PolyHeme obsolete.

WE RELY ON THIRD PARTIES TO COORDINATE OUR CLINICAL TRIALS AND PERFORM DATA COLLECTION AND ANALYSIS, WHICH MAY RESULT IN COSTS AND DELAYS THAT PREVENT US FROM SUCCESSFULLY COMMERCIALIZING OUR PRODUCT.

We do not have the ability to conduct our clinical trials independently. We rely and will continue to rely on clinical investigators, third-party clinical research organizations and consultants to perform some or all of the functions associated with clinical trials. In particular, as part of our trial protocol, an Independent Data Monitoring Committee consisting of independent medical and biostatistical experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any identified risks to patients.

Our clinical trial may be delayed, suspended or terminated if:

- these third parties do not successfully carry out their contractual

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

duties or regulatory obligations or meet expected deadlines;

- these third parties need to be replaced; or

13

- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to our clinical protocol or regulatory requirements or for other reasons.

Failure to perform by these third parties may increase our development costs, delay our ability to obtain regulatory approval and prevent the commercialization of our product.

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

Our research, development, testing, manufacturing, marketing and distribution of PolyHeme are, and will continue to be, subject to extensive regulation, monitoring and approval by FDA. The regulatory approval process to establish the safety and effectiveness of PolyHeme and the safety and reliability of our manufacturing process has already consumed considerable time and expenditures. The data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA regulatory approval. Even if we demonstrate evidence of efficacy, our data may not demonstrate safety. We cannot ensure that, even after extensive clinical trials, regulatory approval will ever be obtained for PolyHeme. If PolyHeme is approved, it would be the first hemoglobin-based oxygen carrier ever to receive FDA approval.

We will be required to submit a Biologics License Application, or BLA, with FDA in order to obtain regulatory approval for the commercial sale of PolyHeme in the United States. Under FDA guidelines, FDA may comment upon the acceptability of a BLA following its submission. After a BLA is submitted there is an initial review by FDA to be sure that all of the required elements are included in the submission. There can be no assurance that the submission will be accepted for filing or that FDA may not issue a refusal to file, or RTF. If an RTF is issued, there is opportunity for dialogue between the sponsor and FDA in an effort to resolve all concerns. There can be no assurance that such a dialogue will be successful in leading to the filing of the BLA. We received an RTF from FDA in November 2001 in connection with our submission of a BLA seeking approval to market PolyHeme for use in the treatment of urgent, life-threatening blood loss based on data from patients in the hospital setting only. The subsequent dialogue with FDA resulted in the mutual decision to proceed with our current pivotal Phase III trial, which starts in the prehospital setting. If a new BLA submission is filed, the timing of the FDA review process is uncertain and there can be no assurance that the full review will result in product approval. Moreover, if regulatory approval of PolyHeme is granted, the approval may include limitations on the indicated uses for which PolyHeme may be marketed. Further clinical trials will likely be required to gain approval to promote the use of PolyHeme for any additional indications.

Further, 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 or restrictions on approved indications. 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. Other laws and regulations may be enacted that could require us to comply with post-marketing requirements for PolyHeme that may be

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

time-consuming and expensive. Any delay or failure to achieve regulatory approval of commercial sales of PolyHeme or to maintain compliance with current or future laws and regulations is likely to have a material adverse effect on our financial condition.

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

The lack of established criteria for evaluating the safety and effectiveness of hemoglobin-based oxygen carrying products could also delay or prevent FDA approval. In October 2004, FDA published for comment a draft guidance document indicating suggested criteria for testing the safety and efficacy of oxygen therapeutics

14

as substitutes for human red blood cells and providing guidance on the design of clinical trials to assess the risks and benefits associated with the use of such products. The draft guidance document was based in part on a conference on hemoglobin-based oxygen carrying products convened at National Institutes of Health in 1999. The draft guidance will not be finalized and implemented until completion of a public comment process. We cannot be certain when the definitive guidance will be issued by FDA or what effect, if any, the definitive guidance may have on our clinical trial. It is possible that, as a result of the definitive guidance, we may be required to undertake additional pre-clinical or clinical trials or modify the way data from our trial are analyzed or presented. FDA's definitive guidance relating to the evaluation of the effectiveness of hemoglobin-based oxygen carrying products could delay or prevent FDA regulatory approval of PolyHeme. In addition, delay or rejection could be caused by other future changes in FDA policies and regulations.

WE MAY IN THE FUTURE NEED TO RAISE ADDITIONAL CAPITAL TO CONTINUE OUR BUSINESS.

We may in the future be required to raise additional capital to continue our business. Our future capital requirements will depend on many factors, including the scope and results of our clinical trials, the timing and outcome of regulatory reviews, administrative and legal expenses, the status of competitive products, the establishment of manufacturing capacity and the establishment of collaborative relationships. We cannot ensure that 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 CURRENTLY MANUFACTURE POLYHEME AT A SINGLE LOCATION AND, IF WE WERE UNABLE TO UTILIZE THIS FACILITY, OUR ABILITY TO MANUFACTURE POLYHEME WILL BE SIGNIFICANTLY AFFECTED, AND WE WILL BE DELAYED OR PREVENTED FROM COMPLETING OUR CLINICAL TRIAL AND COMMERCIALIZING POLYHEME.

We currently manufacture PolyHeme at a single location and we have no alternative manufacturing capacity in place at this time. Damage to this

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

manufacturing facility due to fire, contamination, natural disaster, power loss, unauthorized entry or other events could force us to cease the manufacturing of PolyHeme. Any lack of supply could, in turn, delay our clinical trial and any potential commercial sales. In addition, if the facility or the equipment in the facility is significantly damaged or destroyed for any reason, we may not be able to replace our manufacturing capacity for an extended period of time, and our business, financial condition and results of operations will be materially and adversely affected.

FAILURE TO INCREASE MANUFACTURING CAPACITY MAY IMPAIR POLYHEME'S MARKET ACCEPTANCE AND PREVENT US FROM ACHIEVING PROFITABILITY.

Currently, we have a manufacturing capacity of approximately 10,000 units of PolyHeme per year. 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 trial. A commercial-scale manufacturing facility will be subject to FDA inspections and extensive regulation, including compliance with current good manufacturing practices and FDA approval of scale-up changes. Failure to comply may result in enforcement action, which may significantly delay or suspend manufacturing operations. We have no experience in large-scale manufacturing, and there can be no assurance that we can achieve large-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 large-scale manufacturing facility. Moreover, in order to seek FDA approval of the sale of PolyHeme produced at a larger-scale manufacturing facility, we may be required to conduct additional studies with product manufactured at that facility. A significant delay in achieving scale-up of commercial manufacturing capabilities would have a material adverse effect on sales of PolyHeme.

THERE ARE SIGNIFICANT COMPETITORS DEVELOPING SIMILAR PRODUCTS.

We may be unable to compete successfully in developing and marketing our product. 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

15

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 hemoglobin based oxygen carrying products is a continuously evolving field. Competition is intense and may increase. Several companies have developed or are in the process of developing technologies which are, or in the future may be, the basis for products which will compete with PolyHeme. Certain of these companies are pursuing different approaches or means of accomplishing the therapeutic effects sought to be achieved through the use of PolyHeme. Some of these companies may have substantially greater financial resources, larger research and development staffs, more extensive facilities and more experience in testing, manufacturing, marketing and distributing medical products. We cannot ensure that one or more other companies will not succeed in developing technologies or products which will become available for commercial use prior to PolyHeme, which will be more effective or less costly than PolyHeme or which would otherwise render PolyHeme obsolete or non-competitive.

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

If approved for commercial sale, we currently intend to market PolyHeme in

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

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.

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

The testing and marketing of medical products, even after FDA approval, have an inherent risk of product liability. Claims by users of PolyHeme, or by others selling PolyHeme, could expose us to substantial product liability. We maintain limited product liability insurance coverage for our clinical trials in the total amount of \$10 million. However, our profitability would be adversely affected by a successful product liability claim in excess of our insurance coverage. We cannot ensure that product liability insurance will be available in the future or be available on reasonable terms.

Our pivotal Phase III trial is being conducted under a federal regulation that allows research to be conducted in certain emergent, life-threatening situations using an exception from the requirement for informed patient consent. Under the applicable federal regulation, an IRB may give approval for patient enrollment in trials in emergency situations without requiring individual informed consent provided specific criteria are met. Individual informed consent is often a defense raised against product liability claims asserted by patients participating in clinical trials of medical products. We cannot ensure that IRB approval of patient enrollment in our trial, even if given in full compliance with the applicable federal regulations, will provide us with a defense against product liability claims by patients participating in our trial. It is also possible that we may be subject to legal claims by patients objecting to being enrolled in our trial without their individual informed consent, even if the patients do not suffer any injuries in connection with our trial.

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.

16

OUR ABILITY TO GENERATE REVENUE FROM OUR PRODUCT WILL DEPEND ON REIMBURSEMENT AND DRUG PRICING POLICIES AND REGULATIONS.

Our ability to achieve acceptable levels of reimbursement for PolyHeme by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize PolyHeme. We cannot be sure that reimbursement in the United States, Europe or elsewhere will be available for PolyHeme or, if reimbursement should become available, that it will not be decreased or eliminated in the future. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize PolyHeme, and may not be able to obtain a

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

satisfactory financial return on PolyHeme.

Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States and the changes in health insurance programs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including PolyHeme. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could harm our ability to sell PolyHeme. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect this legislation or regulation would have on our business. In the event that governmental authorities enact legislation or adopt regulations which affect third-party coverage and reimbursement, demand for PolyHeme may be reduced, thereby harming our sales and profitability.

FAILURE TO OBTAIN REGULATORY APPROVAL IN FOREIGN JURISDICTIONS WOULD PREVENT OUR PRODUCT FROM BEING MARKETED ABROAD.

We have entered into license agreements with Pfizer Inc., formerly known as Pharmacia Corporation, and Hemocare Ltd., an Israeli corporation, to develop, manufacture and distribute PolyHeme in certain European, Middle Eastern and African countries. The license agreements permit Pfizer and Hemocare to sell PolyHeme in return for the payment of royalties based upon sales of PolyHeme in the licensed territories. In order for Pfizer, Hemocare or anyone else, including us, to market our products in the European Union and many other foreign jurisdictions, we or licensees must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process entails all of the risks associated with obtaining FDA approval. We and our licensees may fail to obtain foreign regulatory approvals on a timely basis, if at all. Approval by FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by FDA. We and our licensees may not be able to file for, and may not receive, necessary regulatory approvals to commercialize our product in any market. If we or our licensees fail to obtain these approvals, our business, financial condition and results of operations could be materially and adversely affected.

OUR FINANCIAL RESULTS COULD BE AFFECTED BY CHANGES IN THE ACCOUNTING RULES GOVERNING THE RECOGNITION OF STOCK-BASED COMPENSATION EXPENSE.

The Financial Accounting Standards Board recently issued its Statement of Financial Accounting Standards No. 123, SFAS 123R (revised 2004), Share-Based Payment (Statement 123R), which addresses the accounting for employee stock options. Statement 123R requires that the cost of all employee stock options, as well as other equity-based compensation arrangements, be reflected in financial statements based on the estimated fair value of the awards. We expect to adopt SFAS 123R for the period ending August 31, 2006. We will assess the impact of the transition to this new accounting standard during the upcoming months. Upon our implementation of Statement 123R, we could be required to recognize additional compensation expense.

17

FAILURE TO MAINTAIN EFFECTIVE INTERNAL CONTROLS OVER FINANCIAL REPORTING COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, OPERATING RESULTS AND STOCK PRICE.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to include a report by our management on our internal controls over financial reporting in our annual reports filed with the Securities and Exchange Commission. This report must contain an assessment by management of the effectiveness of our internal controls over financial reporting as of the end of our fiscal year and a statement as to whether or not our internal controls are effective. The report must also contain a statement that our independent auditors have issued an attestation report on management's assessment of such internal controls.

Our efforts to comply with Section 404 have resulted in, and are likely to continue to result in, significant costs, the commitment of time and operational resources and the diversion of management's attention. If our management identifies one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert our internal controls are effective. If we are unable to assert that our internal controls over financial reporting are effective, or if our independent auditors are unable to attest that our management's report is fairly stated or they are unable to express an opinion on our management's evaluation or on the effectiveness of our internal controls, our business may be harmed. Market perception of our financial condition and the trading price of our stock may be adversely affected and customer perception of our business may suffer.

WE ARE SUBJECT TO A VARIETY OF FEDERAL, STATE AND LOCAL LAWS, RULES AND REGULATIONS RELATED TO THE DISCHARGE OR DISPOSAL OF TOXIC, VOLATILE OR OTHER HAZARDOUS CHEMICALS.

Although we believe that we are in material compliance with these laws, rules and regulations, the failure to comply with present or future regulations could result in fines being imposed on us, suspension of production or cessation of operations. Third parties may also have the right to sue to enforce compliance. Moreover, it is possible that increasingly strict requirements imposed by environmental laws and enforcement policies could require us to make significant capital expenditures. The operation of a manufacturing plant entails the inherent risk of environmental damage or personal injury due to the handling of potentially harmful substances, and there can be no assurance that we will not incur material costs and liabilities in the future because of an accident or other event resulting in personal injury or unauthorized release of such substances to the environment. In addition, we generate hazardous materials and other wastes that are disposed of at various offsite facilities. We may be liable, irrespective of fault, for material cleanup costs or other liabilities incurred at these disposal facilities in the event of a release of hazardous substances by such facilities into the environment.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

OUR SUCCESS DEPENDS UPON OUR ABILITY TO PROTECT OUR INTELLECTUAL PROPERTY AND OUR PROPRIETARY TECHNOLOGY.

Our success depends in part on our ability to obtain and maintain intellectual property protection for PolyHeme as well as our technology and know-how. Our policy is to seek to protect PolyHeme and our technologies by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of PolyHeme. The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective patent claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in the issuance of any patents. Our issued patents and those that may issue in the future may be challenged, invalidated, rendered unenforceable or circumvented, which could limit our ability to stop competitors from

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

marketing related products or the length of term of patent protection that we may have for PolyHeme. Our United States patents have expiration dates that extend to 2017. The broadest of our issued patents expires in May 2006. Although we expect to be granted an extension of this patent to 2011, we cannot ensure that an extension will not be for less than five years or that it will be granted at all. In addition, the rights granted under any issued patents may not provide us with competitive advantages against competitors with similar compounds or technologies. Furthermore, our competitors may independently

18

develop similar technologies or duplicate any technology developed by us in a manner that does not infringe our patents or other intellectual property. Because of the extensive time required for development, testing and regulatory review of PolyHeme, it is possible that, before PolyHeme can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent.

WE RELY ON TRADE SECRETS AND OTHER CONFIDENTIAL INFORMATION TO MAINTAIN OUR PROPRIETARY POSITION.

In addition to patent protection, we also rely on protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we have entered into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also provide that inventions conceived by the individual in the course of rendering services to us will be our exclusive property. Individuals with whom we have these agreements may not comply with their terms. In the event of the unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by others in their work for us, disputes may arise as to the rights in related inventions. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and could have a material adverse effect on our operating results, financial condition and future growth prospects.

WE MAY BE INVOLVED IN LAWSUITS TO PROTECT OR ENFORCE OUR PATENTS, WHICH COULD BE EXPENSIVE AND TIME CONSUMING.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings brought by the United States Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not prevail in any litigation or interference proceeding in which we are involved. Even if we do prevail, these proceedings can be very expensive and distract our management.

THIRD PARTIES MAY OWN OR CONTROL PATENTS OR PATENT APPLICATIONS THAT ARE INFRINGED BY OUR PRODUCT OR TECHNOLOGIES.

Our success depends in part on avoiding the infringement of other parties' patents and proprietary rights. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. As a result, there may be patents of which we are

19

unaware, and avoiding patent infringement may be difficult. We may inadvertently infringe third-party patents or patent applications. These third parties could bring claims against us that, even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of PolyHeme in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with PolyHeme. Even if we were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

We also may be required to pay substantial damages to the patent holder in the event of an infringement. Under some circumstances in the United States, these damages could be triple the actual damages the patent holder incurs. If we have supplied infringing products to third parties for marketing or licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for any damages they may be required to pay to the patent holder and for any losses the third parties may sustain themselves as the result of lost sales or damages paid to the patent holder.

Any successful infringement action brought against us may also adversely affect marketing of PolyHeme in other markets not covered by the infringement action. Furthermore, we may suffer adverse consequences from a successful infringement action against us even if the action is subsequently reversed on appeal, nullified through another action or resolved by settlement with the patent holder. The damages or other remedies awarded, if any, may be significant. As a result, any infringement action against us would likely delay the regulatory approval process, harm our competitive position, be very costly and require significant time and attention of our key management and technical personnel.

RISKS RELATED TO OUR COMMON STOCK

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

OUR STOCK PRICE COULD BE VOLATILE.

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

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

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

20

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

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

ITEM 2. PROPERTIES.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

We currently lease a manufacturing facility located in Mt. Prospect, Illinois, and maintain our principal executive offices in Evanston, Illinois. The leases for our manufacturing facility and executive offices extend through August 2009 and February 2011, respectively. We have the option to extend the existing lease for three additional five-year periods for the manufacturing facility. Rent expense for our 2005 fiscal year was \$800,540. 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 build-out 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 approximately \$40 million.

ITEM 3. LEGAL PROCEEDINGS.

As of May 31, 2005, we were not a party to any material pending legal proceedings.

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

None.

21

PART II

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

MARKET INFORMATION

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

FISCAL QUARTER ENDED	HIGH	LOW
-----	-----	-----
May 31, 2001.....	17.00	8.41
August 31, 2001.....	21.25	12.70
November 30, 2001.....	17.75	9.00
February 28, 2002.....	10.20	7.12
May 31, 2002.....	8.98	3.91
August 31, 2002.....	5.66	3.00
November 29, 2002.....	5.86	3.75
February 28, 2003.....	6.63	3.30
May 31, 2003.....	8.85	4.95
August 31, 2003.....	9.84	5.95
November 30, 2003.....	7.81	5.50
February 29, 2004.....	12.14	4.96
May 31, 2004.....	19.74	11.34
August 31, 2004.....	15.28	8.78
November 30, 2004.....	18.83	12.21
February 29, 2005.....	23.85	15.35
May 31, 2005.....	16.19	10.71

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

August 31, 2005 (through July 31, 2005)..... 15.09 11.30

ISSUER PURCHASES OF EQUITY SECURITIES

PERIOD	(A) TOTAL NUMBER OF SHARES (OR UNITS) PURCHASED	(B) AVERAGE PRICE PAID PER SHARE (OR UNIT)	(C) TOTAL NUMBER OF SHARES (OR UNITS) PURCHASED AS PART OF PUBLICLY ANNOUNCED PLANS OR PROGRAMS	(D) MAXI APPROXIMAT OF SHARES MAY YET BE THE PLAN
March 1 -- March 31, 2005...	--	--	--	
April 1 -- April 30, 2005...	--	--	--	
May 1 -- May 31, 2005.....	1,717 (1)	\$14.79	--	
Total.....	1,717	--	--	

(1) Represents shares surrendered upon exercise of stock option.

HOLDERS OF RECORD

As of May 31, 2005, there were approximately 500 holders of record and approximately 21,000 beneficial owners of our common stock. There were as of that date no issued and outstanding shares of our preferred stock.

22

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, 2005 and for the cumulative period from June 19, 1985 (inception) through May 31, 2005 were derived from Northfield's financial statements, which financial statements have been audited by KPMG LLP, independent registered public accounting firm.

	YEARS ENDED MAY 31,					CUMULATIVE JUNE 19, 1985 THROUGH MAY 31, 2005
	2005	2004	2003	2002	2001	
(IN THOUSANDS, EXCEPT PER SHARE DATA)						
STATEMENT OF OPERATIONS DATA:						
Revenues:						
License income.....	\$ --	--	--	--	--	3,000
COSTS AND EXPENSES:						
Research and development....	16,600	10,777	8,819	8,843	9,437	123,616
General and						

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

administrative.....	4,990	3,854	3,643	2,700	2,786	49,444
Interest income (net).....	1,268	131	212	826	2,048	24,773
Net loss.....	\$ (20,322)	(14,574)	(12,250)	(10,717)	(10,175)	(145,361)
Net loss per share basic and diluted.....	\$ (0.88)	(0.86)	(0.86)	(0.75)	(0.71)	(13.35)
Shares used in calculation of per share data(1).....	23,069	16,932	14,266	14,266	14,253	10,890
BALANCE SHEET DATA:						
Cash and marketable securities.....						
	\$ 98,131	42,487	6,890	18,389	28,698	
Total assets.....	100,002	44,179	9,246	21,235	32,502	
Total liabilities.....	4,228	2,626	2,066	1,804	2,355	
Deficit accumulated during development stage.....						
	(145,361)	(125,040)	(110,466)	(98,216)	(87,498)	
Total shareholders' equity(2).....						
	95,774	41,553	7,180	19,430	30,148	

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

(2) Excludes 1,377,625 shares reserved for issuance upon the exercise of stock options, 18,250 shares reserved for issuance for restricted share grants outstanding, and 212,392 shares reserved for issuance for stock warrants as of May 31, 2005. Additional stock options for a total of 356,740 were available for grant as of May 31, 2005 under our employees stock option plans and stock option plan for outside directors.

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

RECENT DEVELOPMENTS

We are currently enrolling patients in a pivotal Phase III trial in which our PolyHeme human hemoglobin-based oxygen carrier is being used for the first time in the U.S. to treat severely injured patients in hemorrhagic shock before they reach the hospital. Under this protocol, treatment with PolyHeme begins at the scene of the injury or in the ambulance and continues during transport and the initial 12-hour post-injury period in the hospital. Since blood is not presently carried in ambulances, the use of PolyHeme in this setting has the potential to improve survival and address a critical, unmet medical need.

The trial has a planned enrollment of 720 patients. Approximately 400 patients have been enrolled in the trial as of June 30, 2005. At the current enrollment rate, at the presently active sites, Northfield projects

23

enrollment of approximately 600 patients by calendar year-end. Our current goal is to complete the patient enrollment phase of our trial in early calendar 2006. Our ability to achieve this goal will depend, in part, on the number of clinical sites participating in our trial and the ability of these sites to enroll patients at the projected rates.

Since Northfield's incorporation in 1985, we have devoted substantially all of our efforts and resources to the research, development and clinical testing of 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,

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

2005, we have incurred operating losses totaling \$145,361,000.

We will be required to complete our pivotal Phase III trial and obtain regulatory approval from FDA before PolyHeme can be sold commercially. The FDA regulatory process is subject to significant risks and uncertainties. We therefore cannot at this time reasonably estimate the timing of any future revenues from the commercial sale of PolyHeme. The costs incurred by Northfield to date and during each period presented below in connection with our development of PolyHeme are discussed in our financial statements.

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

RESULTS OF OPERATIONS

We reported no revenues for the fiscal years ended May 31, 2005, 2004 or 2003. From Northfield's inception through May 31, 2005, 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, 2005, 2004 and 2003 totaled \$21,589,000, \$14,630,000 and \$12,462,000, respectively. Measured on a percentage basis, fiscal 2005 operating expenses exceeded fiscal 2004 expenses by 47.6%, while fiscal 2004 operating expenses exceeded fiscal 2003 expenses by 17.4%

During fiscal 2005, research and development expenses totaled \$16,600,000, an increase of \$5,823,000, or 54.0%, from fiscal 2004 expenses of \$10,777,000. During fiscal 2005, we significantly expanded our pivotal Phase III trial. Nine additional trial sites were opened during fiscal 2005 with the attendant community consultation, training and trial initiation costs. Patient enrollment likewise accelerated with more clinical sites open and more sites gaining experience with the trial protocol. The direct costs of the trial, hospital site activity and contract research activity increased by \$4,572,000, or 223.9%, in fiscal 2005. Additional 2005 costs were also recorded for increasing staff, benefit costs and science consulting.

We anticipate a continued high level of research and development spending in fiscal 2006. Continued patient enrollment at an expanded number of clinical sites is forecast during fiscal 2006. Following completion of the enrollment stage of the trial, we will begin the significant task of data assembly, analysis and reporting to FDA. Preparing the Biologics License Application for PolyHeme to be filed with FDA will likely continue beyond fiscal 2006. At the same time, we will be manufacturing product for the trial and undergoing an extensive process of preparation for FDA's review of our manufacturing facility. Northfield's internal research and development resources will be focused on these tasks and the use of external resources will be expanded to complete the tasks in a timely manner.

During fiscal 2004, research and development expenses totaled \$10,777,000, an increase of \$1,958,000, or 22.2%, from the fiscal 2003 expenses of \$8,819,000. During fiscal 2004, we began enrolling patients in our

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

pivotal Phase III trial. In December, 2003, the first trial site was initiated and by May 31, 2004, the number of sites enrolling patients had grown to eleven. The expense of site training, initiating and monitoring along with patient study costs were the sources of the increased costs.

General and administrative expenses for the 2005 fiscal year totaled \$4,990,000, an increase of \$1,136,000, or 29.5%, from the expense incurred in the prior fiscal year. The extensive procedure, documentation and testing requirements relating to our internal controls over financial reporting mandated by the Sarbanes-Oxley Act of 2002 were primarily responsible for a \$758,000, or 83.3%, increase in professional services in fiscal 2005 compared to fiscal 2004. Also, state corporate franchise taxes, which are calculated based on Northfield's share capital, significantly increased following our successful public stock offering in February 2005.

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

We anticipate a decrease in general and administrative expenses in fiscal 2006 compared to the \$4,990,000 incurred in fiscal 2005. Ongoing internal controls compliance costs are expected to be reduced in fiscal 2006 and should offset cost increases anticipated for new hires and commercialization planning. Throughout fiscal 2006, the corporate focus will remain centered on successfully executing our pivotal Phase III trial.

INTEREST INCOME

Interest income in fiscal 2005 equaled \$1,268,000 compared to \$131,000 in fiscal 2004. The current year increase is the result of larger available cash resources as well as higher interest rates on our short term investments. In February 2005, we raised \$72,629,000 in net proceeds from an underwritten public stock offering. These funds are currently invested in short term marketable securities. Available interest rates at the beginning of the current fiscal year were between 0.4% and 1.0% for money-market investments and 2% for high quality one year securities. Money market rates in July 2005 were approximately 2.7% to 3.1% and high quality one year securities were approaching 4.0%. As our current investments mature, they will be rolled over into higher yielding securities until the funds are required for our business.

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

Following our successful public offering in February 2005, we anticipate that interest income will increase significantly in fiscal 2006. The extent of the increase will be dependent on the rate of our use of cash in operations and the timing of investment in plant and equipment, as well as available interest rates. A 1% rate increase yields \$10,000 in additional interest income on a \$1,000,000 investment over a 12-month period.

NET LOSS

The net loss for our fiscal year ended May 31, 2005 was \$20,322,000, or \$0.88 per share, compared to a net loss of \$14,574,000, or \$0.86 per share, for

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

the fiscal year ended May 31, 2004. The increased net loss was the result of increased clinical trial expenses and professional service fees. The net loss per share increased by only \$.02 because the average number of shares outstanding in the current fiscal year increased as a result of our recent public offering and diluted the increased dollar loss in the current fiscal year.

The net loss for our fiscal year ended May 31, 2004 was \$14,574,000, or \$0.86 per share, compared to a net loss of \$12,250,000, or \$0.86 per share, for the fiscal year ended May 31, 2003. The increased net loss was primarily due to higher research and development costs associated with our pivotal Phase III trial. The net loss per share was the same for both fiscal years because the average number of shares outstanding in our 2004

25

fiscal year increased as a result of fundraising efforts completed in fiscal 2004 which diluted the increased dollar loss in fiscal 2004.

LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through May 31, 2005, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of \$141,634,000. For the fiscal years ended May 31, 2005, 2004 and 2003, these cash expenditures totaled \$19,238,000, \$13,259,000 and \$11,538,000, respectively. The fiscal 2005 increase in cash utilization is due primarily to expenses related to our pivotal Phase III trial.

We have financed our research and development and other activities to date through the public and private sale of equity securities and, to a more limited extent, through the license of product rights. In February 2005, we raised \$72,629,000 in net proceeds from an underwritten public stock offering. As of May 31, 2005, we had cash and marketable securities totaling \$98,131,000.

We believe our existing capital resources will be adequate to fund the completion of the patient enrollment phase of our pivotal Phase III clinical trial, the preparation and submission of a Biologics License Application for PolyHeme with FDA, our planned construction of a 75,000 unit commercial manufacturing facility, and our operating capital requirements for approximately the next 24 months. Thereafter, we may require substantial additional funding to continue our operations.

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

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

CRITICAL ACCOUNTING POLICIES

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

NET DEFERRED TAX ASSETS VALUATION

We record our net deferred tax assets in the amount that we expect to realize based on projected future taxable income. In assessing the appropriateness of our valuation, assumptions and estimates are required, such as our ability to generate future taxable income. In the event we were to determine that it was more likely than not we would be able to realize our deferred tax assets in the future in excess of their carrying value, an adjustment to recognize the deferred tax assets would increase income in the period such determination was made. As of May 31, 2005, we have recorded a 100% percent valuation allowance against our net deferred tax assets.

26

CONTRACTUAL OBLIGATIONS

The following table reflects a summary of our contractual cash obligations as of May 31, 2005:

CONTRACTUAL OBLIGATIONS -----	TOTAL -----	LESS THAN ONE YEAR -----	1-3 YEARS -----	4-5 YEARS -----
Lease Obligations(1).....	\$3,512,773	\$ 854,302	\$1,683,922	\$974,549
Other Obligations(2).....	1,251,250	1,251,250	--	--
Total Contractual Obligations.....	\$4,764,023 =====	\$2,105,552 =====	\$1,683,922 =====	\$974,549 =====

-
- (1) The lease for our Evanston headquarters is cancelable with six months notice combined with a termination payment equal to three months base rent at any time after February 14, 2009. If the lease is cancelled as of February 14, 2009 unamortized broker commissions of \$17,470 would also be due.
 - (2) Represents payments required to be made upon termination of employment agreements with two of our executive officers. The employment contracts renew automatically unless terminated. Figures shown represent compensation payable upon the termination of the employment agreements for reasons other than death, disability, cause or voluntary termination of employment by the executive officer other than for good reason. Additional payments may be required under the employment agreements in connection with a termination of employment of the executive officer following a change in control of Northfield.

RECENT ACCOUNTING PRONOUNCEMENTS

In December 2004, the FASB issued SFAS 123R which requires the measurement of all employee share-based payments to employees, including grants of employee stock options, using a fair-value-based method and the recording of such expense

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

in our statements of operations. The accounting provisions of SFAS 123R are effective for annual reporting periods beginning after June 15, 2005. We are required to adopt SFAS 123R for the period ended August 31, 2006. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. See Footnote No. 1 -- Stock Based Compensation for the pro forma net loss and net loss per share amounts, for 2003 through 2005, as if we had used a fair-value-based method similar to the methods required under SFAS 123R to measure compensation expense for employee stock incentive awards. Although we have not yet determined whether the adoption of SFAS 123R will result in amounts that are similar to the current pro forma disclosures under SFAS 123, we are evaluating the requirements under SFAS 123R and expect the adoption to have an impact on our statements of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We currently do not have any foreign currency exchange risk. We invest our 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 our short-term investments, we believe that the financial market risk exposure is not material. A one percentage point decrease in the interest rate received over a one year period on our cash and marketable securities of \$98.1 million at May 31, 2005 would decrease interest income by \$981,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA.

See the Table of Contents to Financial Statements on Page 30. See Note 11 to the Financial Statements on Page 51 for the Supplementary Quarterly Data. These Financial Statements are incorporated by reference into this document.

27

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

Based on their evaluation as of the end of the period covered by this report, our Chief Executive Officer and Senior Vice President and Chief Financial Officer have concluded that Northfield's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

CHANGE IN INTERNAL CONTROL OVER FINANCIAL REPORTING

There were no changes in our internal control over financial reporting during the quarter ended May 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

the Securities Exchange Act of 1934, as amended). Our management assessed the effectiveness of our internal control over financial reporting as of May 31, 2005. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") on Internal Control -- Integrated Framework. Our management has concluded that, as of May 31, 2005, our internal control over financial reporting is effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our independent registered public accounting firm, KPMG LLP, has issued an audit report on our assessment of our internal control over financial reporting, which is included herein.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

ITEM 9B. OTHER INFORMATION.

None.

28

PART III

ITEMS 10 THROUGH 14.

The information specified in Items 10 through 14 of Form 10-K has been omitted in accordance with instructions to Form 10-K. We expect to file with the SEC by August 15, 2005, pursuant to Regulation 14A, a definitive proxy statement which will contain the information required to be included in Items 10 through 14 of Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

(1) and (2). See the Table of Contents to Financial Statements on page 30.

(3) See Description of Exhibits on page 52.

(b) See Description of Exhibits on page 52.

(c) None.

29

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

TABLE OF CONTENTS

	PAGE

Report of Independent Registered Public Accounting Firm.....	31
Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting.....	32
Balance Sheets, May 31, 2005 and 2004.....	33
Statements of Operations, Fiscal Years ended May 31, 2005, 2004 and 2003, and the cumulative period from June 19, 1985 (inception) through May 31, 2005.....	34
Statements of Shareholders' Equity (Deficit), Fiscal Years ended May 31, 2005, 2004, and 2003, and the cumulative period from June 19, 1985 (inception) through May 31, 2005.....	36
Statements of Cash Flows, Fiscal Years ended May 31, 2005, 2004, and 2003, and the cumulative period from June 19, 1985 (inception) through May 31, 2005.....	40
Notes to Financial Statements.....	41

30

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Northfield Laboratories Inc.:

We have audited the accompanying balance sheets of Northfield Laboratories Inc. (a company in the development stage) as of May 31, 2005 and 2004, 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, 2005 and for the cumulative period from June 19, 1985 (inception) through May 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Northfield Laboratories Inc. as of May 31, 2005 and 2004, and the results of its operations and its cash flows for each of the years in the three-year period ended May 31, 2005 and for the cumulative period from June 19, 1985 (inception) through May 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Northfield Laboratories Inc.'s internal controls over financial reporting as of May 31, 2005, based on the criteria established in Internal Control-Integrated

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated August 12, 2005, expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

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

/s/ KPMG LLP

Chicago, Illinois
August 12, 2005

31

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Board of Directors and Shareholders
Northfield Laboratories Inc.:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Northfield Laboratories Inc. (a company in the development stage) maintained effective internal control over financial reporting as of May 31, 2005, based on criteria established in Internal Control -- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Northfield Laboratories Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Northfield Laboratories Inc. maintained effective internal control over financial reporting as of May 31, 2005, is fairly stated, in all material respects, based on criteria established in Internal Control -- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, Northfield Laboratories Inc. maintained, in all material respects, effective internal control over financial reporting as of May 31, 2005, based on criteria established in Internal Control -- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Northfield Laboratories Inc. as of May 31, 2005 and 2004, 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, 2005, and for the cumulative period from June 19, 1985 (inception) through May 31, 2005, and our report dated August 12, 2005 expressed an unqualified opinion on those financial statements.

/s/ KPMG LLP

Chicago, Illinois
August 12, 2005

32

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

BALANCE SHEETS MAY 31, 2005 AND 2004

	2005	2004
	----	----
ASSETS		
Current assets:		
Cash and cash equivalents.....	\$ 6,800,405	39,042,884
Marketable securities.....	91,330,289	3,443,825
Prepaid expenses.....	826,741	614,664
Other current assets.....	139,808	1,082
	-----	-----
Total current assets.....	99,097,243	43,102,455
Property, plant, and equipment.....	14,796,631	14,521,555
Accumulated depreciation.....	(13,961,694)	(13,515,061)
	-----	-----
Net property, plant, and equipment.....	834,937	1,006,494
	-----	-----
Other assets.....	69,392	70,389
	-----	-----
	\$ 100,001,572	44,179,338
	=====	=====

LIABILITIES AND SHAREHOLDERS' EQUITY

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Current liabilities:		
Accounts payable.....	\$ 3,325,570	1,837,651
Accrued expenses.....	110,679	117,007
Accrued compensation and benefits.....	539,783	418,813
	-----	-----
Total current liabilities.....	3,976,032	2,373,471
Other liabilities.....	251,582	252,756
	-----	-----
Total liabilities.....	4,227,614	2,626,227
	-----	-----
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 26,752,739 at May 31, 2005 and 21,398,439 at May 31, 2004; 26,751,022 outstanding at May 31, 2005 and 21,398,439 at May 31, 2004.....	267,527	213,984
Additional paid-in capital.....	240,997,444	166,534,302
Deficit accumulated during the development stage.....	(145,361,011)	(125,039,555)
Deferred compensation.....	(104,609)	(155,620)
	-----	-----
	95,799,351	41,553,111
Less cost of common shares in treasury; 1,717 shares and zero shares, respectively.....	(25,393)	--
	-----	-----
Total shareholders' equity.....	95,773,958	41,553,111
	-----	-----
	\$ 100,001,572	44,179,338
	=====	=====

See accompanying notes to financial statements.

33

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

STATEMENTS OF OPERATIONS
YEARS ENDED MAY 31, 2005, 2004, AND 2003
AND THE CUMULATIVE PERIOD FROM JUNE 19, 1985
(INCEPTION) THROUGH MAY 31, 2005

	YEARS ENDED MAY 31,			CUMULATIVE FROM JUNE 19, 1985 THROUGH MAY 31, 2005
	2005	2004	2003	
	-----	-----	-----	-----
Revenues -- license income.....	\$ --	--	--	3,000,000
	-----	-----	-----	-----
Costs and expenses:				
Research and development.....	16,599,736	10,776,519	8,819,016	123,615,791
General and administrative.....	4,989,620	3,853,769	3,643,318	49,443,603
	-----	-----	-----	-----
	21,589,356	14,630,288	12,462,334	173,059,394
	-----	-----	-----	-----
Other income and expense:				

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Interest income.....	1,267,900	131,411	212,189	24,856,538
Interest expense.....	--	--	--	83,234
	-----	-----	-----	-----
	1,267,900	131,411	212,189	24,773,304
	-----	-----	-----	-----
Net loss before cumulative effect of change in accounting principle.....	(20,321,456)	(14,498,877)	(12,250,145)	(145,286,090)
	-----	-----	-----	-----
Cumulative effect of change in accounting principle.....	--	74,921	--	74,921
	-----	-----	-----	-----
Net loss.....	\$(20,321,456)	(14,573,798)	(12,250,145)	(145,361,011)
	=====	=====	=====	=====
Net loss per share -- basic and diluted.....	\$ (0.88)	(0.86)	(0.86)	(13.35)
	=====	=====	=====	=====
Shares used in calculation of per share data -- basic and diluted.....	23,069,166	16,932,301	14,265,875	10,889,531
	=====	=====	=====	=====

See accompanying notes to financial statements.

34

(This page intentionally left blank)

35

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

STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
YEARS ENDED MAY 31, 2005, 2004 AND 2003 AND THE CUMULATIVE PERIOD
FROM JUNE 19, 1985 (INCEPTION) THROUGH MAY 31, 2005

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

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

See accompanying notes to financial statements.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

36

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

--	--	--	--	(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)

37

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

STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
YEARS ENDED MAY 31, 2005, 2004, AND 2003 AND THE CUMULATIVE PERIOD
FROM JUNE 19, 1985 (INCEPTION) THROUGH MAY 31, 2005

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Net loss.....	--	--	--
Non-cash compensation.....	--	--	--
Exercise of stock options at \$13.38 per share.....	--	--	2,500
	-----	-----	-----
Balance at May 31, 2000.....	--	--	14,242,375
Net loss.....	--	--	--
Non-cash compensation.....	--	--	--
Exercise of stock options at \$6.38 per share.....	--	--	6,000
Exercise of stock options at \$10.81 per share.....	--	--	17,500
	-----	-----	-----
Balance at May 31, 2001.....	--	--	14,265,875
Net loss.....	--	--	--
	-----	-----	-----
Balance at May 31, 2002.....	--	--	14,265,875
Net loss.....	--	--	--
	-----	-----	-----
Balance at May 31, 2003.....	--	--	14,265,875
Issuance of common stock at \$5.60 per share on July 28, 2003 (net of costs of issuance of \$909,229).....	--	--	1,892,857
Issuance of common stock to directors at \$6.08 per share on October 30, 2003.....	--	--	12,335
Deferred compensation related to stock grants.....	--	--	25,500
Amortization of deferred compensation.....	--	--	--
Issuance of common stock at \$5.80 per share on January 29, 2004 (net of costs of issuance of \$1,126,104).....	--	--	2,585,965
Issuance of common stock at \$5.80 per share on February 18, 2004 (net of costs of issuance of \$116,423).....	--	--	237,008
Issuance of common stock at \$5.80 per share on April 15, 2004 (net of costs of issuance of \$192,242).....	--	--	409,483
Issuance of common stock at \$12.00 per share on May 18, 2004 (net of costs of issuance of \$1,716,831.36).....	--	--	1,954,416
Exercise of stock options at \$6.38 per share.....	--	--	15,000
Net loss.....	--	--	--
	-----	-----	-----
Balance at May 31, 2004.....	--	--	21,398,439
Deferred compensation related to stock grants.....	--	--	5,500
Amortization of deferred compensation.....	--	--	--
Exercise of stock options between \$5.08 and \$14.17 per share.....	--	--	167,875
Cost of shares in treasury, 1,717 shares.....	--	--	--
Issuance of common stock to directors at \$12.66 per share on September 21, 2004.....	--	--	5,925
Issuance of common stock at \$15.00 per share on February 9, 2005 (net of costs of issuance of \$4,995,689).....	--	--	5,175,000
Net loss.....	--	--	--
	-----	-----	-----
Balance at May 31, 2005.....	--	\$ --	26,752,739
	=====	=====	=====

See accompanying notes to financial statements.

SERIES A CONVERTIBLE PREFERRED STOCK		SERIES B CONVERTIBLE PREFERRED STOCK		ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	DEFERRED COMPENSATION
NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES	AGGREGATE AMOUNT			
-----	-----	-----	-----			

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

	\$			\$		\$	(4,778,875)	\$
					48,324,374			
					7,360,187			
					362,937			
					9,555			
					71,300			
					(80,062)			80,062
					--			(62,726)
					115,427,120	(50,611,169)		(3,853)
					--	(4,245,693)		--
					50,025			--
					463,540			--
					71,300			--
					--			2,569
					116,011,985	(54,856,862)		(1,284)
					--	(5,883,378)		--
					35,650			--
					--			1,284
					116,047,635	(60,740,240)		--
					--	(7,416,333)		--
					14,354			--
					124,775			--
					998,750			--
					117,185,514	(68,156,573)		--
					--	(9,167,070)		--
					57,112			--
					33,425			--
					117,276,051	(77,323,643)		--
					--	(10,174,609)		--
					--			--
					38,220			--
					189,000			--
					117,503,271	(87,498,252)		--
					--	(10,717,360)		--
					117,503,271	(98,215,612)		--
					--	(12,250,145)		--
					117,503,271	(110,465,757)		--
					9,671,843			--
					74,877			--
					190,995			(191,250)
					--			35,630
					13,846,633			--
					1,255,853			--
					2,178,664			--
					21,716,616			--
					95,550			--
					--	(14,573,798)		--
					166,534,302	(125,039,555)		(155,620)
					71,055			(71,110)
					--			122,121
					1,739,585			--

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

--	--	--	--	--	--	--
--	--	--	--	74,941	--	--
--	--	--	--	72,577,561	--	--
--	--	--	--	--	(20,321,456)	--
-----	-----	-----	-----	-----	-----	-----
--	\$ --	--	\$ --	\$240,997,444	\$ (145,361,011)	\$ (104,609)
=====	=====	=====	=====	=====	=====	=====

39

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

STATEMENTS OF CASH FLOWS
YEARS ENDED MAY 31, 2005, 2004, AND 2003
AND THE CUMULATIVE PERIOD FROM JUNE 19, 1985
(INCEPTION) THROUGH MAY 31, 2005

	YEARS ENDED MAY 31,			CUMULATI
	2005	2004	2003	FROM JUNE 19, THROUGH MAY 31, 2
	----	----	----	-----
Cash flows from operating activities:				
Net loss.....	\$ (20,321,456)	(14,573,798)	(12,250,145)	(145,361,
Adjustments to reconcile net loss to net cash used in operating activities:				
Marketable security amortization....	(537,201)	(19,266)	(44,853)	(601,
Depreciation and amortization.....	447,633	681,153	857,209	18,276,
Non-cash compensation.....	197,121	110,630	--	3,860,
Loss on sale of equipment.....	--	--	--	66,
Changes in assets and liabilities:				
Prepaid expenses.....	(212,077)	74,091	(148,752)	(1,035,
Other current assets.....	(138,726)	(1,082)	1,437	(2,036,
Other assets.....	--	--	--	6,
Accounts payable.....	1,487,919	375,065	384,874	3,325,
Accrued expenses.....	(6,328)	55,488	(148,590)	110,
Accrued compensation and benefits.....	120,970	41,696	38,268	539,
Other liabilities.....	(1,174)	87,712	(12,709)	251,
	-----	-----	-----	-----
Net cash used in operating activities.....	(18,963,311)	(13,168,311)	(11,323,261)	(122,596,
	-----	-----	-----	-----
Cash flows from investing activities:				
Purchase of property, plant, equipment, and capitalized engineering costs.....	(275,076)	(90,613)	(214,326)	(19,037,
Proceeds from sale of land and equipment.....	--	--	--	1,863,
Proceeds from matured marketable securities.....	18,315,000	2,000,000	720,000	429,852,
Proceeds from sale of marketable securities.....	--	--	--	7,141,
Purchase of marketable securities.....	(105,664,266)	(3,432,260)	(1,953,138)	(527,728,
	-----	-----	-----	-----
Net cash used in investing				

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

activities.....	(87,624,342)	(1,522,873)	(1,447,464)	(107,909,
Cash flows from financing activities:				
Proceeds from issuance of common stock...	79,340,871	52,896,936	--	235,987,
Payment of common stock issuance costs...	(4,995,689)	(4,060,830)	--	(14,128,
Proceeds from issuance of preferred stock.....	--	--	--	6,644,
Proceeds from sale of stock options to purchase common shares.....	--	--	--	7,443,
Proceeds from issuance of notes payable.....	--	--	--	1,500,
Repayment of notes payable.....	--	--	--	(140,
Net cash provided by financing activities.....	74,345,174	48,836,106	--	237,305,
Net (decrease) increase in cash and cash equivalents.....	(32,242,479)	34,144,922	(12,770,725)	6,800,
Cash and cash equivalents at beginning of period.....	39,042,884	4,897,962	17,668,687	
Cash and cash equivalents at end of period.....	\$ 6,800,405	39,042,884	4,897,962	6,800,
Supplemental Schedule of Noncash Financing Activities:				
Exercise of stock options, 5,000 shares in exchange for 1,717 treasury shares.....	\$ 25,393	--	--	25,

See accompanying notes to financial statements.

40

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

NOTES TO FINANCIAL STATEMENTS
MAY 31, 2005 AND 2004

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

DESCRIPTION OF OPERATIONS IN THE DEVELOPMENT STAGE

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

BASIS OF PRESENTATION

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

During the year ended May 31, 2005, Northfield raised \$77.6 million in gross proceeds through a common stock offering. The Company ended the fiscal year with cash and cash equivalents and marketable securities of \$98.1 million.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Existing capital resources are forecast to be adequate to satisfy operating capital requirements, including the expenditures the Company expects will be incurred in connection with its Phase III clinical trial to fund post-enrollment activities in our clinical trial, to prepare and submit a Biologics License Application to FDA, to prepare for the commercial launch of Polyheme, construction of a 75,000 unit commercial manufacturing facility and for other general corporate purposes. Thereafter, the Company may require additional funding to continue its operations.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents consist of cash on hand, cash in banks, and money market funds.

MARKETABLE SECURITIES

Marketable securities consist of U.S. Treasury Securities, obligations of U.S. government agencies, high grade commercial paper and certificates of deposit, all of which have 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 both the ability and intent to hold until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related instrument as an adjustment to yield using the straight-line method, which approximates the effective interest method. Interest income is recognized when earned.

PROPERTY, PLANT, AND EQUIPMENT

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

CAPITALIZED ENGINEERING COSTS

Capitalized engineering costs include design and other initial engineering studies relating to a commercial scale facility. During fiscal 2005 and 2004, the Company capitalized no engineering costs. Capitalized engineering costs are being amortized over a three-year period. For the years ended May 31, 2005, 2004 and

41

2003, amortization cost recorded was \$0, \$0, and \$119,649, respectively. As of May 31, 2003 all capitalized engineering costs had been amortized.

TREASURY SHARES

The Company intends to hold repurchased shares in treasury for general corporate purposes, including issuances under various employee stock option plans. The Company accounts for treasury shares using the cost method.

COMPUTATION OF NET LOSS PER SHARE

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

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

equivalent shares as long as their inclusion is not anti-dilutive. Because the Company reported a net loss for the years ended May 31, 2005, 2004, and 2003 and the cumulative period from June 19, 1985 (inception) through May 31, 2005, basic and diluted per share amounts are the same.

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

	2005	2004	2003	CUMULATIVE FROM JUNE 19, 1985 THROUGH MAY 31, 2005
	----	----	----	-----
Stock options.....	1,290,563	1,081,250	826,500	669,184
Warrants.....	212,392	106,196	--	82,239
	-----	-----	-----	-----
	1,502,955	1,187,446	826,500	751,423
	=====	=====	=====	=====

Of the total options and warrants outstanding as of May 31, 2005, the Company has 964,125 options in-the-money, 413,500 options out-of-the-money, 153,760 warrants in-the-money, and 58,632 warrants out-of-the money, that were excluded from the net loss per share calculation.

STOCK BASED COMPENSATION

The Company applies the intrinsic value method of APB Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations in accounting for options granted to directors, officers, and key employees under the plans. Accordingly, compensation cost is recorded on the date of grant only if the current market price of the underlying stock exceeds the exercise price. Had compensation cost for the Company's stock option plans been determined using the fair value method prescribed by SFAS No. 123, "Accounting for

42

Stock Based Compensation" (SFAS 123) the Company's net loss and net loss per share would have been the pro forma amounts indicated below:

	2005	2004	2003
	----	----	----
Net loss as reported.....	\$(20,321,456)	(14,573,798)	(12,250,145)
Add: Stock based compensation expense included in statements of operations.....	197,121	110,630	--
Deduct: Total stock based compensation expense determined under the fair value method for all awards.....	(1,659,343)	(760,239)	(600,616)
	-----	-----	-----
Pro forma net loss.....	\$(21,783,678)	(15,223,407)	(12,850,761)
	=====	=====	=====

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Basic and diluted earnings per share:

As reported.....	(0.88)	(0.86)	(0.86)
Pro forma.....	(0.94)	(0.90)	(0.90)
	=====	=====	=====

For purposes of calculating the compensation cost consistent with SFAS 123, the fair value of each option grant is estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants in fiscal 2005, 2004, and 2003:

	2005 ----	2004 ----	2003 ----
Expected volatility.....	71.3%	68.8%	68.6%
Risk-free interest rate.....	4.0%	3.2%	3.1%
Dividend yield.....	--	--	--
Expected lives.....	7.7 years	7.9 years	8.0 years
	=====	=====	=====

In December 2004, the Financial Accounting Standards Board issued a revised SFAS No. 123, (SFAS 123) "Share-Based Payment." The revised SFAS 123 requires that the fair value of stock options be recorded in the results of operations and requires adoption no later than the fiscal year beginning after June 15, 2005. The effect of adopting the new rules on reported income is dependent on the number of options granted in the future and the fair value of those options.

FINANCIAL INSTRUMENTS

The fair market values of financial instruments, which consist of marketable securities (note 2), were not materially different from their carrying values at May 31, 2005 and 2004.

USE OF ESTIMATES

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

(2) MARKETABLE SECURITIES

The Company classifies its investments in marketable securities as "held to maturity" in accordance with the provisions of SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities". Held to maturity securities are 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. Premium 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. Unrealized losses considered to be "other-than-temporary" are recognized currently in earnings. All marketable securities are due within one year.

Marketable securities at May 31, 2005 were as follows:

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

	AMORTIZED COST	FAIR VALUE	GROSS UNREALIZED LOSSES
	-----	-----	-----
Certificates of Deposit.....	\$ 4,972,789	\$ 4,955,938	\$ (16,851)
US Government and agency securities.....	37,747,575	37,695,640	(51,935)
Corporate debt securities.....	48,609,925	48,558,325	(51,600)
	-----	-----	-----
Total.....	\$91,330,289	\$91,209,903	\$ (120,386)
	=====	=====	=====

All investments in the Company's portfolio as of May 31, 2005 have been in place for less than 12 months and will mature within 8 months. These 50 investments include U.S. Government insured certificates of deposit, U.S. Government and agency securities and high grade corporate debt securities. Due to increasing short-term interest rates, the fair-value of existing security positions has declined. However, given the types of securities as well as their short-term maturity, the company expects the investments to repay at par value.

Marketable securities at May 31, 2004 were as follows:

	AMORTIZED COST	FAIR VALUE	GROSS UNREALIZED (LOSSES)
	-----	-----	-----
Certificates of Deposit.....	\$ 3,443,825	\$ 3,441,669	\$ (2,156)

Fair values are based on quoted market prices.

(3) PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment, at cost, less accumulated depreciation and amortization, is summarized as follows as of May 31, 2005 and 2004:

	USEFUL LIFE	2005	2004
	-----	----	----
Manufacturing equipment.....	5 years	\$ 9,953,048	9,734,377
Laboratory equipment.....	5 years	1,340,440	1,340,440
Office furniture and equipment.....	7 years	706,138	699,186
Computer equipment.....	3 years	142,632	109,917
Leasehold improvements and asset retirement obligations.....	Lease term	1,729,506	1,712,768
Capitalized engineering costs.....	3 years	924,867	924,867
		-----	-----
		14,796,631	14,521,555
Less accumulated depreciation and amortization.....		(13,961,694)	(13,515,061)
		-----	-----
		\$ 834,937	1,006,494
		=====	=====

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Depreciation and amortization expense related to property, plant and equipment amounted to \$446,633, \$682,992, and \$856,199, for the years ended May 31, 2005, 2004, and 2003, respectively.

(4) ASSET RETIREMENT OBLIGATIONS

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

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

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

44

The balances and changes thereto are summarized below:

	YEAR ENDED MAY 31, 2005	YEAR ENDED MAY 31, 2004
	-----	-----
Obligation at June 1.....	\$210,066	\$192,721
Accretion.....	18,906	17,345
	-----	-----
Obligation at May 31.....	\$228,972	\$210,066
	=====	=====

If the change in accounting had been applied retroactively, the Company's pro forma net loss for the years ended May 31, 2004 and 2003 would have been \$14,498,877 and \$12,268,906, respectively with no impact on loss per share.

(5) SHAREHOLDERS' EQUITY

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

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

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

On March 30, 1989, the Company issued 87,760 additional shares of common stock for net proceeds of \$2,489,234. Also on this date, the Company sold an

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

option to purchase 263,285 shares of common stock for net proceeds of \$7,443,118. The option exercise price was \$.20 per share. On July 8, 1996, the option was exercised and the Company issued all 263,285 shares of common stock.

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

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

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

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

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

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

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

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

45

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.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

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

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

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

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

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

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

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

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

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

On June 1, 2004 the Company issued 6,000 additional shares of common stock upon the exercise of a stock option for cash at \$6.38 per share for net proceeds of \$38,280.

On September 1, 2004, the Company issued 4,500 additional restricted shares of common stock to officers in the form of stock grants.

On September 17, 2004, the Company issued 2,500 additional shares of common stock upon the exercise of a stock option for cash at \$7.83 per share for net proceeds of \$19,575.

On September 21, 2004, the Company issued 5,925 additional shares of common stock to directors in the form of stock grants.

On October 21, 2004, the Company issued 1,000 additional restricted shares of common stocks to an employee in the form of a stock grant.

46

On November 10, 11 and 12, 2004 the Company issued 84,029 additional shares of common stock upon the exercise of stock options for cash at \$13.38, \$10.88 and \$10.81 per share for net proceeds of \$961,013.

On November 16, 17 and 18, 2004, the Company issued 48,971 additional shares of common stock upon the exercise of stock options for cash at \$10.81 per share for net proceeds of \$529,377.

On December 1, 2004, the Company issued 12,500 additional shares of common stock upon the exercise of stock options for cash at \$7.43 per share for net proceeds of \$92,875.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

On January 14, 2005, the Company issued 375 additional shares of common stock upon the exercise of stock options for cash at \$7.13 per share for net proceeds of \$2,674.

On February 1, 2005, the Company issued 6,000 additional shares of common stock upon the exercise of stock options for cash at \$5.15, \$7.13, \$10.66, and \$14.17 per share for net proceeds of \$59,195.

On February 9, 2005, the Company issued 5,175,000 additional shares of common stock for net proceeds of \$72,629,311.

On April 26, 2005, the Company issued 2,500 additional shares of common stock upon the exercise of stock options for cash at \$5.15 per share for net proceeds of \$12,875.

On May 6, 2005, the Company issued 5,000 additional shares of common stock upon the exercise of stock options at \$5.08 per share for the exchange of 1,717 shares of common stock at a price per share of \$14.79 and cash of \$6.

(6) INCOME TAXES

As a result of losses incurred to date, the Company has not provided for income taxes. As of May 31, 2005, the Company has net operating loss carryforwards for income tax purposes of approximately \$138,000,000, which are available to offset future taxable income, if any, from 2006 to 2025. Deferred tax assets primarily resulted from net operating loss carryforwards and differences in the recognition of research and development and depreciation expense. During the year ended May 31, 2005, net operating loss carryforwards of \$3,100,000 expired. Additionally, the Company has approximately \$4,200,000 of research and experimentation tax credits and investment tax credits available to reduce future income taxes through 2025.

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, 2005 and 2004 are summarized as follows:

	2005 ----	2004 ----
Deferred tax assets:		
Net operating loss carryforwards.....	\$ 53,500,000	\$ 50,100,000
Tax credit carryforwards.....	4,200,000	3,600,000
Other.....	1,400,000	1,000,000
	-----	-----
	59,100,000	54,700,000
Valuation allowance.....	(59,100,000)	(54,700,000)
	-----	-----
Net deferred tax assets.....	\$ --	\$ --
	=====	=====

The net change in the valuation allowance during fiscal 2005, 2004 and 2003 was an increase of \$4,400,000, \$5,600,000, and \$4,800,000, and respectively. Differences between the statutory federal tax rate of 34 percent and effective federal rates are primarily due to the increase in the valuation allowance.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

(7) STOCK OPTION PLAN

The Company's Restated Nonqualified Stock Option Plan (the Employee Stock Option Plan) lapsed on September 30, 1996. Following the termination of the plan, all options outstanding prior to the plan

47

termination may be exercised in accordance with their terms. As of May 31, 2004, options to purchase a total of 6,000 shares of the Company's common stock at \$6.38 per share were outstanding under the Employee Stock Option Plan. These options were exercised in the current fiscal year.

The Company's Nonqualified Stock Option Plan for Outside Directors (Directors Plan) lapsed on May 31, 2004. Following the termination of the plan, all options outstanding prior to plan termination may be exercised in accordance with their terms. During the year ended May 31, 2005 and May 31, 2004, the Company did not grant any options to purchase shares of common stock. During the year ended May 31, 2003 the Company granted 30,000 options to purchase shares of common stock at \$4.09 per share. These options expire in 2012 or ten years after the date of grant. As of May 31, 2005, options to purchase a total of 60,000 shares of the Company's common stock at prices between \$4.09 and \$13.38 per share were outstanding. These options expire between 2008 and 2012, 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 years ended May 31, 2005, 2004 and 2003, the Company did not grant any options from this plan. As of May 31, 2005, options to purchase a total of 308,000 shares of the Company's common stock at prices between \$9.56 and \$15.41 were outstanding.

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, 2005 the Company did not grant any options to purchase shares of common stock. During the year ended May 31, 2004, the Company granted 23,000 options to purchase shares of common stock at \$7.13 per share. These options expire in 2013, ten years after the date of grant. During the year ended May 31, 2003, the Company granted 265,000 options to purchase shares of common stock between \$3.62 and \$7.14 per share. These options expire in 2012 and 2013, ten years after the date of the grant. As of May 31, 2005, options to purchase a total of 328,125 shares of the Company's common stock at prices between \$3.62 and \$14.17 per share were outstanding.

With an effective date of January 1, 2003, the Company established the New Employee Stock Option Plan (the "New Employee Plan"). This plan provides for the granting of stock options to the Company's new employees. Stock options to purchase a total of 350,000 shares are available under the New Employee Plan. During the year ended May 31, 2005, the Company granted 35,000 options to purchase shares of common stock at prices between \$10.41 and \$22.02. These options expire in 2015, ten years after the date of grant. During the year ended May 31, 2004, the Company granted 75,000 options to purchase shares of common stock at prices of \$7.43 and \$7.57. These options expire in 2013 or ten years after date of grant. During the year ended May 31, 2003, the Company granted 10,000 options to purchase shares of common stock at \$3.62 per share. These

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

options expire in 2013 or ten years after the date of grant.

With an effective date of September 17, 2003, the Company established 2003 Equity Compensation Plan. This plan provides for the granting of stock, stock options and various other types of equity compensation to the Company's employees, non-employee directors and consultants. Stock options to purchase a total of 750,000 shares are available under the 2003 Equity Compensation Plan. During the year ended May 31, 2005, the Company granted 356,000 options to purchase shares of common stock at prices between \$11.09 and \$18.55. These options expire between 2014 and 2015 or ten years after date of grant. During the year ended May 31, 2005, the Company granted and issued 5,925 common shares at a price of \$12.66 to directors and the Company granted 5,500 restricted common shares at prices between \$12.90 and \$13.06 to officers. These shares have a two-year vesting period. During the year ended May 31, 2004, the Company granted 261,500 options to purchase shares of common stock at prices between \$5.94 and \$15.15. These options expire in 2013 and 2014 or ten years after date of grant. During the year ended May 31, 2004, the Company granted and

48

issued 12,335 common shares at a price of \$6.08 to directors and the Company granted 25,500 restricted common shares at a price of \$7.50 to officers. These shares have a two-year vesting period. At May 31, 2005 and May 31, 2004 the amount of related deferred compensation reflected in shareholders' equity was \$104,609 and \$155,620, respectively. The amortization of deferred compensation for the years ended May 31, 2005 and May 31, 2004 was \$122,121 and \$35,630, respectively.

Additional information on shares subject to options is as follows:

	2005		2004		2003	
	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
Outstanding at beginning of year.....	1,203,500	\$ 8.64	959,000	\$ 9.62	694,000	\$ 9.62
Granted.....	391,000	16.23	359,500	7.22	305,000	7.22
Exercised.....	167,875	10.37	15,000	6.38	--	--
Canceled.....	49,000	7.85	100,000	11.67	40,000	11.67
Outstanding at end of year...	1,377,625	\$10.61	1,203,500	\$ 8.64	959,000	\$ 8.64
Options exercisable at year end.....	680,125	\$ 9.51	638,250	\$10.33	622,125	\$ 9.51
Weighted-average fair value of options granted during the year.....	\$ 11.76		\$ 5.10		\$ 3.51	

The following table summarizes information about stock options outstanding at May 31, 2005:

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING			OPTIONS
	NUMBER OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	EXERCISAB AT MAY 31, 2005
\$ 3.62 -- 5.94.....	316,000	7.64	\$ 4.62	163,500
6.08 -- 9.56.....	264,625	8.29	7.38	92,500
10.66 -- 15.60.....	572,000	5.34	12.27	424,125
18.55 -- 22.02.....	225,000	9.67	18.63	--
	=====	=====	=====	=====

(8) STOCK WARRANTS

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

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

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

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

49

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

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

(9) LEASES/COMMITMENTS

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

Rent expense amounted to \$800,540, \$915,752, and \$821,760 for the years ended May 31, 2005, 2004, and 2003, respectively.

The Company's lease for its research and manufacturing facility expires August 30, 2009 and includes the option to renew the lease for three successive five-year terms. The lease is collateralized by a \$49,200 security deposit as of May 31, 2005.

The Company's lease for its corporate facility expires February 14, 2011. The lease is cancelable with six months notice combined with a termination payment equal to three months base rent at any time after February 14, 2009. If the lease is cancelled as of February 14, 2009 unamortized broker commissions of \$17,470 would also be due. The lease is secured by a security deposit of \$19,250 as of May 31, 2005.

At May 31, 2005, future minimum lease payments under the operating leases are as follows:

YEARS ENDING MAY 31, -----	AMOUNT -----
2006.....	\$ 854,302
2007.....	837,884
2008.....	846,039
2009.....	853,088
2010.....	121,460
Thereafter.....	0

	\$3,512,773
	=====

(10) EMPLOYEE BENEFIT PLAN

Effective January 1, 1994, the Company established a defined contribution 401(k) savings plan covering each employee of the Company satisfying certain minimum length of service requirements. Matching contributions to the accounts of plan participants are made by the Company in an amount equal to 33% of each plan participant's before-tax contribution, subject to certain maximum contribution limitations, and are made at the discretion of the Company. Expenses incurred under this plan for Company contributions for the years ended May 31, 2005, 2004, and 2003 amounted to \$202,838, \$169,758, and \$145,307, respectively.

50

(11) QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table shows our quarterly unaudited financial information for the eight quarters ended May 31, 2005. The Company has 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.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

	QUARTER ENDED					
	MAY 31, 2005	FEB. 28, 2005	NOV. 30, 2004	AUG. 31, 2004	MAY 31, 2004	FEB. 2004
	(IN THOUSANDS EXCEPT PER SHARE DATA)					
Revenues.....	\$ --	--	--	--	--	--
Costs and Expenses:						
Research and Development.....	4,566	3,818	4,178	4,038	3,389	2,6
General and Administrative.....	1,820	1,311	910	949	1,266	8
	6,386	5,129	5,088	4,987	4,655	3,5
Other Income and Expense:						
Interest Income.....	711	281	156	120	54	
Interest Expense.....	--	--	--	--	--	
Cumulative effect of change in accounting principle.....	--	--	--	--	--	
Net Loss.....	\$ (5,675)	(4,848)	(4,932)	(4,867)	(4,601)	(3,4
Net Loss Per share -- Basic and Diluted.....	\$ (0.21)	(0.21)	(0.23)	(0.23)	(0.24)	(0.
Shares used in calculation....	26,747	22,658	21,440	21,404	19,501	17,0

51

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 (the "Commission") on March 25, 1994, File No. 33-76856 (the "S-1 Registration Statement"))
3.2	Certificate of Amendment to Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1999)
3.3	Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Form 8-K filed by the Registrant with the Commission on August 15, 2005)
10.1	Office Sublease dated as of April 20, 1993 between the Registrant and First Illinois Bank of Evanston, N.A., as Trustee (incorporated herein by reference to Exhibit 10.1 to the S-1 Registration Statement)
10.2	Amendment to Lease dated as of January 7, 1998 between the Registrant and First Illinois Bank of Evanston, N.A. (incorporated herein by reference to Exhibit 10.1.1 to the

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

- Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 1998)
- 10.3 Lease dated as of June 8, 1989 between the Registrant and OTR (incorporated by reference to Exhibit 10.2 to the S-1 Registration Statement)
- 10.4 Amendment to Lease dated as of May 6, 1998 between the Registrant and OTR (incorporated herein by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the Registrant's fiscal year ended May 31, 1998)
- 10.5 Third Amendment to Lease dated as of September 16, 1999 between the Registrant and OTR (incorporated by reference to Exhibit 10.4.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1999)
- 10.6 Fourth Amendment to Lease dated as of September 22, 2003 between the Registrant and OTR (incorporated by reference to Exhibit 10.18 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended August 31, 2003)
- 10.7 Second Amendment to Lease between the Registrant and Rotary International (incorporated by reference to Exhibit 10.1 to the Form 8-K filed by the Registrant with the Commission on March 7, 2005)
- 10.8 License Agreement dated as of March 6, 1989 between the Registrant and KabiVitrum AB (predecessor of Pharmacia & Upjohn Inc.) (incorporated herein by reference to Exhibit 10.6 to the S-1 Registration Statement)
- 10.9 License Agreement dated as of July 20, 1990 between the Registrant and Eriphyle BV (incorporated herein by reference to Exhibit 10.7 to the S-1 Registration Statement)
- 10.10* Northfield Laboratories Inc. 401(K) Plan (incorporated herein by reference to Exhibit 10.14 to the S-1 Registration Statement)
- 10.11* 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)
- 10.12* 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)
- 10.13* 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)
- 10.14* Northfield Stock Option Plan for New Employees (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on June 27, 2003, File No. 333-106615 the "S-3 Registration Statement")

52

NUMBER	DESCRIPTION
-----	-----
10.15*	Northfield Laboratories Inc. 2003 Equity Compensation Plan (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on October 30, 2003,

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

- File No. 333-110110.)
- 10.16* Employment Agreement dated as of January 25, 2005 between the Registrant and Steven A. Gould, M.D. (incorporated herein by reference to Exhibit 99.1 to the Form 8-K filed by the Registrant with the Commission on February 1, 2005)
- 10.17* Employment Agreement dated as of January 25, 2005 between the Registrant and Jack J. Kogut (incorporated herein by reference to Exhibit 99.2 to the Form 8-K filed by the Registrant with the Commission on February 1, 2005)
- 10.18 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)
- 10.19 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)
- 10.20 Form of Indemnification Agreement -- Executive Officer (incorporated herein by reference to Exhibit 10.20 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001)
- 23.1 Consent of Independent Registered Public Accounting Firm
- 31.1 Certification Pursuant to Rule 13a-14(a)/15d-14(a)
- 31.2 Certification Pursuant to Rule 13a-14(a)/15d-14(a)
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this August 15, 2005.

NORTHFIELD LABORATORIES INC.

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

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company in the capacities indicated on August 15, 2005.

SIGNATURE

TITLE

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-K

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