NORTHFIELD LABORATORIES INC /DE/
Form 10-K
August 14, 2007

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

FORM 10-K

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

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended May 31, 2007

o 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:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $.01 per share	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the Registrant is a well known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933. o Yes x No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. o Yes x No

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

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Securities Exchange Act of 1934.

Large Accelerated Filer o Accelerated Filer x Non-Accelerated Filer o

Indicate by check mark if the Registrant is a shell company (as defined in Rule 12b-2 of their Securities Exchange Act of 1934). o Yes x No

As of November 30, 2006, 26,814,475 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, 2006) held by non-affiliates of the Registrant was $412,674,770 (26,814,475 shares at $15.39 per share).

As of July 31, 2007, there were 26,916,541 shares of the Registrant s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement for its 2007 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.

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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, 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 this cautionary statement. We do not undertake any obligation to update or publicly release any revisions to forward-looking statements to reflect events, circumstances or changes in expectations after the time such statement is made.

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PART I

ITEM 1. *Business.*

Northfield Laboratories Inc. is a leader in developing a hemoglobin-based oxygen-carrying red blood cell substitute 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®, 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 that PolyHeme has the potential to improve survival in critically injured patients who have delayed access to blood and whose expected mortality without oxygen-carrying replacement would be considerably greater.

In July 2006 we announced the completion of patient enrollment in our pivotal Phase III trial with PolyHeme. This was the first study in the United States to evaluate the safety and efficacy of an oxygen-carrying red blood cell substitute beginning at the scene of injury and continuing during transport and in the early hospital period. A total of 32 Level I trauma centers across the country participated in our study. The trial had an enrollment of 720 patients.

We reported the preliminary top-line results of our study in December 2006 and announced additional results from the study in May 2007. The primary efficacy endpoint of the study was a dual superiority-noninferiority assessment of mortality at 30 days after injury. The margin to assess noninferiority, using the upper limit of the confidence interval, was set at 7% more than control. In the primary modified intent to treat population, representing the 714 patients both randomized and treated, the upper limit was 7.65%. These results did not achieve the primary endpoint for efficacy in the primary analysis population as specified in the protocol. In the as treated population, comprised of the same 714 patients, but analyzed in accordance with the treatment the patients actually received, the upper limit was 7.06%. In the per protocol population, which included the 590 patients both appropriately randomized and correctly treated as specified in the trial protocol, the upper limit was 6.21%.

Day 30 mortality was also a primary safety endpoint. There was no statistically significant difference in mortality at 30 days between patients who received PolyHeme beginning at the scene and continuing for up to 12 hours following injury, and control patients who received the standard of care, including early blood.

We believe the results of this study are best understood in the context of bleeding patients who do not have early access to blood transfusion, as did the patients in our trial. Mortality rates in that scenario would be considerably higher than those observed in the control patients in the largely urban setting of our trial, where transit times were relatively short and access to blood was rapid. We believe that when our data are extrapolated to patients who need an oxygen carrier and have delayed access to blood, PolyHeme can play an important role in saving lives.

We are presently preparing a Biologics License Application, or BLA, for PolyHeme for submission to the U.S. Food and Drug Administration, or FDA. We have submitted a detailed summary of our trial data to FDA and have participated in a pre-BLA meeting with the Agency. Our goal is to submit our BLA to FDA during the first half of calendar 2008. We also plan to request priority review of our BLA. We believe PolyHeme satisfies the stated criteria for priority review based on its potential to address an unmet medical need.

We believe that PolyHeme ultimately represents a substantial global market opportunity, based on the need for a universally compatible, immediately available oxygen-carrying product with extended shelf-life 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 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. Transfused blood can be used only in recipients having a blood

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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. In addition, although testing procedures exist to detect the presence of certain diseases in blood, these procedures cannot eliminate completely the risk of blood-borne disease. There is no commercially available hemoglobin-based oxygen-carrying red blood cell substitute in this country which addresses these problems.

Our founding scientific research team was 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 red blood cell substitute in development for the treatment of life-threatening blood loss when an oxygen-carrying fluid is required and red blood cells are not 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.

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 red blood cell substitute in the treatment of hemorrhagic shock resulting from extensive blood loss.

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.

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OUR PIVOTAL PHASE III TRIAL

Patient enrollment in our pivotal Phase III trial, in which PolyHeme was used for the first time to treat severely injured patients in hemorrhagic shock before they reached the hospital, was completed in July 2006. Under this protocol, treatment with PolyHeme began at the scene of the injury or in the ambulance and continued during transport and the initial 12 hour post-injury period in the hospital. The study was based on two potential life-saving benefits. The first was starting infusion of an oxygen-carrying fluid at the scene of injury and continuing during transport to the hospital. Because blood is not routinely carried in ambulances, PolyHeme represented a potential improvement over the current standard of care.

The second opportunity was the potential to improve the outcome associated with the use of donated blood in the early hospital period in critically injured patients. Although blood is the current standard of care, there is a growing body of scientific evidence pointing to the adverse immunomodulatory effects of early blood transfusion in trauma patients, specifically the incidence of multiple organ failure and the resultant associated mortality. There are also published data indicating that these same effects may not occur with PolyHeme. While blood is available in the hospital, PolyHeme was evaluated as a potentially better alternative for the early care of the injured patient.

A total of 32 Level I trauma centers across the United States participated in our study. Each of the sites that participated in the trial is designated as a Level I trauma center, indicating its capacity to treat the most severely injured trauma patients. A total of 720 patients was enrolled.

As part of our trial protocol, an Independent Data Monitoring Committee, or IDMC, consisting of independent medical and biostatistical experts, was 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 included four planned evaluations by the IDMC that occurred after 60, 120, 250 and 500 patients had been enrolled and monitored for a 30-day follow up period. The IDMC focused its reviews on mortality and serious adverse events and evaluated all safety data as the trial continued. We received a recommendation from the IDMC after each review, but we did not have access to the trial data reviewed by the IDMC until enrollment had been completed and the database had been locked.

The IDMC completed all four of the planned reviews of the trial data and, in each case, recommended continuation of the trial without modification through completion of patient enrollment. This was the first time that a trial of a hemoglobin-based oxygen carrier passed this patient evaluation milestone in a high risk trauma population.

As part of its third interim evaluation, 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 remained at 720 patients.

TRIAL DESIGN AND CLINICAL ENDPOINTS

Prior to the launch of our pivotal Phase III trial, we reached agreement with FDA on Special Protocol Assessment, or SPA, for the 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 BLA submitted to FDA. 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 was conducted under a federal regulation, 21 CFR 50.24, 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-

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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, 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 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 that participated in our trial 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 were randomly assigned to either a treatment group or a control group. The treatment group received PolyHeme at the scene of injury or in the ambulance during transport, and continued to receive PolyHeme, if necessary, during the initial 12 hour post-injury period in the hospital. Patients in the treatment group were eligible to receive a maximum of six units of PolyHeme. The control group received crystalloid solution in the field and donated blood, if necessary, in the hospital.

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

Patient enrollment in our trial was 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 are brief, and it was understood that patients in the control group would reach the hospital, where they would have early access to blood, in relatively short periods of time. As a result, it was recognized that the observed outcome in our trial might not demonstrate the expected 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 is often limited. It was therefore understood that the data from our study would be extrapolated to the intended setting and the intended patient population who require transfusion but have delayed access to blood.

PHASE III TRIAL RESULTS

Efficacy Analysis

The primary efficacy endpoint for our pivotal Phase III trial was a dual superiority-noninferiority assessment of mortality at 30 days after injury. A noninferiority endpoint requires the establishment of a relative margin around the control outcome. The margin to assess noninferiority in our study, using the upper limit of the confidence interval, was set at 7% more than control.

The protocol for our trial specified multiple patient populations for analysis. The primary modified intent to treat, or MITT, population is comprised of all 714 patients both randomized and treated. In this population, patients were analyzed *as randomized*, and not based on the actual treatment they received. Overall, 41 randomized patients in the study received the incorrect treatment. There were 21 patients randomized to PolyHeme who did not receive any PolyHeme were analyzed in the PolyHeme group. Two of these patients died. Similarly, there were 20 patients randomized to control who received PolyHeme, and were analyzed in the control group. One of those patients died.

The as treated, or AT, population is also comprised of all 714 patients both randomized and treated. However, in this population all patients were analyzed according to the *treatment they actually received*. Therefore, all patients who received PolyHeme were analyzed in the PolyHeme group, and all patients who did not receive any

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PolyHeme were analyzed in the control group. Although the AT population was pre-specified for safety rather than efficacy, it provides a meaningful opportunity to assess mortality as well.

The per protocol, or PP, population is comprised of the 590 patients both *appropriately randomized and correctly treated* according to the protocol. The PP population does not include 124 patients who had major protocol violations related to eligibility or treatment regimen. Since the PP patients were treated exactly as specified in the protocol, Northfield believes the PP population represents the clearest opportunity to assess a treatment effect of PolyHeme in this setting.

In the primary MITT population, the upper limit of the confidence interval in our pivotal Phase III trial was 7.65%. These results did not achieve the primary endpoint for efficacy in the primary analysis population as specified in the protocol. In the AT population, the upper limit was 7.06%. In the PP population, the upper limit was 6.21%. The data are shown in the following table:

DAY 30 MORTALITY

	PolyHeme Group (Deaths/Number of Patients)	**Mortality Rate (%)**	**Control Group (Deaths/Number of Patients)**	**Mortality Rate (%)**	**Upper Limit (%)**
MITT	47/350	13.4	35/364	9.6	7.65
AT	46/349	13.2	36/365	9.9	7.06
PP	31/279	11.1	29/311	9.1	6.21

Secondary efficacy endpoints of the study included Day 1 mortality, the incidence of multiple organ failure, the use of donated blood through Day 1, and an analysis of mortality by the mechanism of injury (blunt versus penetrating trauma). The incidence of transfusion of donated blood was significantly lower in the PolyHeme group at 41% than the control group at 51% ($p \leq 0.05$). A p-value ≤ 0.05 indicates that the probability the result is due to chance is equal to or less than 5%. There was no statistically significant difference between PolyHeme and control patients for the other efficacy endpoints. The Day 1 mortality data is shown in the following table:

DAY 1 MORTALITY

	PolyHeme Group (Deaths/Number of Patients)	**Mortality Rate (%)**	**Control Group (Deaths/Number of Patients)**	**Mortality Rate (%)**
MITT	34/350	9.7	27/364	7.4
AT	33/349	9.5	28/365	7.7
PP	20/279	7.2	22/311	7.1

Safety Analysis

The primary safety endpoints in the study were Day 1 mortality, Day 30 mortality and durable serious adverse events, or SAEs. Durable SAEs were prospectively defined as SAEs which resulted in a permanently disabling outcome. There were two durable SAEs in each group. There was no statistically significant difference in mortality at Day 1 or Day 30 between patients who received PolyHeme beginning at the scene and continuing for up to 12 hours following injury, and control patients who received the standard of care, including early blood.

In addition to these primary safety endpoints, all adverse events, or AEs, SAEs, cardiac SAEs and myocardial infarction, or MI, were also analyzed. Virtually all patients in the study had adverse events. The overall incidence of AEs in the PolyHeme group of 93% (324 patients) was higher than that in the control group of 88% (322 patients), ($p \leq 0.05$). The most common AEs in both groups were anemia, fever and electrolyte imbalances. The overall incidence of SAEs in the study was 40% (141 patients) in the PolyHeme group and 35% (126 patients) in the control group ($p > 0.05$). The most common SAEs in both groups were shock, pneumonia and respiratory failure.

The incidence of cardiac AEs was 35% (123 patients) in the PolyHeme group and 29% (105 patients) in the control group ($p > 0.05$). The incidence of cardiac SAEs was 7% (23 patients) in the PolyHeme group and 4%

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(16 patients) in the control group (p>0.05). The overall incidence of MI in the study as reported by investigators was 2%: eleven PolyHeme patients and three control patients (p≤0.05). Three PolyHeme patients and one control patient died.

The medical literature documents the difficulty of making an accurate diagnosis of MI in trauma patients for multiple reasons, including direct trauma to the chest. MI and myocardial ischemia are traditionally assessed by electrocardiograms and measurement of the levels of the cardiac enzymes Troponin I and CK-MB, both of which can be altered by direct trauma. Approximately 75% of the patients in this study had abnormal electrocardiograms or elevated cardiac enzymes. Because of the disparity between the low number of reported MIs and the high incidence of abnormal electrocardiograms and elevated cardiac enzymes, Northfield has established an independent panel of cardiac experts to review the cardiac profiles of all 720 randomized patients in a blinded fashion to categorize MIs in the study.

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 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 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 carriers for the treatment of battlefield casualties. There may also be potential market opportunities for PolyHeme in novel areas such as ischemia, oncology, organ preservation, pancreatic islet cell transplantation and sickle cell anemia.

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.

An independent assessment of the potential market opportunity for PolyHeme, using a variety of primary and secondary sources along with original research, 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.

In an effort to further understand the potential market opportunity for PolyHeme, we have initiated pharmacoeconomic research designed to better understand and help develop policy and reimbursement strategies

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for the commercialization of PolyHeme. This work will continue during the current fiscal year. We continue to work with community leaders, hospitals and emergency response teams to identify issues and opportunities associated with the adoption of PolyHeme in the treatment of life threatening blood loss when red blood cells are not available.

MANUFACTURING AND MATERIAL SUPPLY

We use a proprietary process of separation, filtration, chemical modification, purification and formulation to produce PolyHeme. We have produced PolyHeme for use in our clinical trials in our pilot manufacturing facility in Mt. Prospect, Illinois. Our pilot manufacturing facility has the capacity to produce approximately 10,000 units of PolyHeme per year. We plan to submit our BLA based on the use of this facility for our initial product production.

We are presently planning to construct an expanded commercial manufacturing facility with the capacity to produce 100,000 units or more of PolyHeme per year. In June 2006, we purchased the 106,000 square foot building in Mt. Prospect, Illinois in which our pilot manufacturing facility is located and plan to construct our expanded commercial manufacturing facility at this site. In addition to manufacturing operations, the facility houses laboratory, quality control and administrative personnel. We have conducted certain engineering and size optimization activities for the planned facility. We will need to raise additional funds before we are able to proceed with this manufacturing expansion.

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

The successful commercial introduction of PolyHeme will also depend on an adequate supply of blood to be used as a starting material. We believe that an adequate supply of blood is obtainable through the voluntary blood services sector. We have had extensive discussions with existing blood collection agencies, including the American Red Cross and Blood Centers of America, regarding sourcing of blood. We currently have short-term purchasing contracts with each of these agencies. We also have an agreement in place 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.

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. 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

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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.

Biopure Corporation, which is developing a bovine hemoglobin-based oxygen carrier product, has stated that it intends to pursue an indication for cardiovascular ischemia and is conducting trials to explore that indication outside the United States. Biopure has submitted a marketing authorization application to the United Kingdom s Medicines and Healthcare Products Regulatory Agency for its Hemopure product for the treatment of acutely anemic adult orthopedic surgery patients less than 80 years of age and has reported receiving a provisional letter raising questions about its application. Biopure has also reported 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. This proposed study protocol is currently on clinical hold. Synthetic Blood International, Inc., which is developing a perfluorocarbon-based oxygen carrier product, completed an eight patient proof-of-concept study in patients with traumatic brain injury at one center in the United States. Sangart, Inc., a private company, is enrolling patients in two parallel European Phase III trials in elective orthopedic surgery to gauge the ability of its human hemoglobin-based product to prevent and treat hemodynamic instability, especially hypotension, or low blood pressure, during surgery. Hemobiotech, a private company, is developing a bovine hemoglobin-based solution. It has not reported conducting clinical trials in the United States to date.

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 if we expand

overseas. In the United States, FDA regulates medical products, including the category known as biological products, 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

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promotion of PolyHeme. In addition to FDA laws and regulations, we are also subject to other federal and state regulations, such as the Occupational Safety and Health Act and the Environmental Protection Act. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial funds.

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

Preclinical tests include evaluation of product chemistry and studies to assess the safety and effectiveness of the product 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 effectiveness of the product in the setting of its intended use. With a few narrow exceptions, FDA regulations require that patients participating in clinical studies must provide informed consent. Under a federal regulation, 21 CFR 50.24, clinical research can be conducted in certain emergent, life-threatening situations without obtaining prospective informed consent from individual patients. To meet the requirements of this exception from informed consent requirements, 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 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 that participated in our trial completed the required public disclosure and community consultation procedures and received IRB approval to enroll patients in accordance with the trial protocol.

Typically, the trial design protocols and effectiveness endpoints are established in consultation with the FDA. At the sponsor s request, FDA may meet with sponsors for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in a BLA. If an agreement is reached, the FDA will reduce the agreement to writing. This agreement is called a special protocol assessment, or SPA. The SPA agreement, however, is not a guarantee of product approval by FDA or approval of any permissible claims about the product. In particular, it is not binding on the FDA if previously unrecognized public health concerns later come to light, other new scientific concerns regarding product safety or efficacy arise, the sponsor fails to comply with the protocol agreed upon, or FDA s reliance on data, assumptions or information are determined to be wrong. Even after an SPA agreement is finalized, the SPA agreement may be changed by the sponsor company or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

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.

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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, 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 FDA approval of PolyHeme in the United States. We have submitted a detailed summary of our trial data to FDA and have participated in a pre-BLA meeting with the agency. Our goal is to submit our BLA to FDA during the first half of calendar 2008. We intend to request priority review at the time our BLA is submitted to FDA. FDA may grant priority review to products that provide significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of serious or life-threatening disease. We believe PolyHeme satisfies the stated criteria for this designation based on its potential to improve patient survival. Products awarded priority review are given abbreviated review goals by the agency. FDA makes a decision as part of the agency s review of the application for filing. We cannot guarantee that the agency will grant priority review and cannot predict what impact, if any, priority review will have on the review time for PolyHeme. Priority review does not ensure that FDA will ultimately approve PolyHeme. See risk factor section for all additional disclosures.

We are also exploring the potential to seek regulatory approval outside the United States. This may involve licensing or other arrangements with other foreign or domestic companies. To date, we have not conducted any clinical trials of PolyHeme outside of the United States.

PATENTS AND PROPRIETARY RIGHTS

With the expiration in 2006 of five of our United States patents and issuance of two new patents, we now own six United States patents and several pending United States 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, Mexico, Australia, New Zealand, Iceland, Norway, India, the Russian Federation, South Africa, Brazil, various Asian countries and various European Union countries. Our United States patents have various expiration dates; the latest to expire of our United States patents has a term that extends to 2025. Our broadest issued United States patent was originally scheduled to expire in 2006 but has been extended by the United States Patent Office to 2007. A further application for a one-year patent term extension has been filed in the Patent Office. If that extension is granted, that patent will expire in 2008 and a further application for a one-year extension will then be filed with the Patent Office seeking an extension until 2009. No extensions are possible beyond 2011. 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.

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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 2007, 2006 and 2005, our research and development expenses totaled $21,060,000, $24,165,000 and $16,600,000, respectively. We anticipate that our research and development expenses, which include expenses relating to the preparation and submission of our BLA for PolyHeme, will continue during fiscal 2008 at approximately the same level as during our 2007 fiscal year.

HUMAN RESOURCES

As of August 1, 2007, we had 93 employees, of whom 82 were involved in research and development and nine were responsible for financial and other administrative matters. We also had consulting arrangements with 30 individuals and organizations 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.

CORPORATE INFORMATION

We were incorporated under the laws of the State of Delaware in June 1985. 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 soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission, or SEC. Copies of our code of business conduct and ethics and other corporate governance documents are available on our website.

Item 1A. *Risk Factors.*

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

We are 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, 2007, we have incurred net operating losses totaling $199,808,000. We will require substantial additional expenditures to pursue regulatory approval for PolyHeme, to establish expanded 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.

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Our financial resources are limited and we will need to raise additional capital in the future to continue our business.

As of May 31, 2007, we had cash and cash equivalents of approximately $40,688,000. During our 2007 fiscal year, we spent approximately $34,969,000 to operate our business, and we expect to spend approximately the same amount during our 2008 fiscal year. We anticipate that our existing financial resources will be adequate to permit us to continue to conduct our business for the next 18 to 20 months. We will need to raise additional capital to continue our business after this period. Our future capital requirements will depend on many factors, including 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. In addition, we are subject to a putative class action lawsuit alleging violations of the federal securities laws and we also have received separate requests from both the SEC and the Senate Committee on Finance asking us voluntarily to provide certain information. These matters involve risks and uncertainties that may prevent Northfield from raising additional capital or may cause the terms upon which Northfield raises additional capital, if additional capital is available, to be less favorable to Northfield than would otherwise be the case.

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 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 receive FDA approval before we may sell PolyHeme commercially, data from our clinical trials to date may not be adequate to obtain FDA approval, and we may be required to conduct additional clinical trials in the future.

The primary efficacy endpoint of our pivotal Phase III trial was a dual superiority-noninferiority assessment of mortality at 30 days after injury. The results from our trial did not achieve the primary efficacy endpoint in the primary patient population as specified in the protocol. There was no statistically significant difference between the PolyHeme and control group for any of the primary safety endpoints for our trial. There were, however, statistically significant differences observed with respect to certain secondary safety endpoints, including the incidence of myocardial infarction. Based on these results from our trial, there can therefore be no assurance that the data from the trial will be sufficient to demonstrate the safety and effectiveness of our PolyHeme product for purposes of obtaining FDA approval for the commercial sale of the product in the United States.

Our goal is to submit our BLA for PolyHeme to FDA during the first half of calendar year 2008. The preparation of a BLA is a complex and time-consuming process and there can be no assurance that we will be able to submit our BLA within this time period. If the completion of our BLA takes longer than expected, FDA approval for the commercial sale of PolyHeme may be substantially delayed.

Once we submit our BLA, 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 it believes the filing is inadequate or incomplete. FDA previously issued an RTF to us in 2001 when we submitted a BLA based on data from our prior Phase II trauma trials. We intend to seek priority review of our BLA filing. Even if FDA accepts the submission of our BLA, there can also be no assurance that FDA will grant the BLA priority review. There also can be no assurance that FDA will determine that the trial data included in our BLA are sufficient to demonstrate that PolyHeme is safe or that we have achieved the clinical

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endpoints for effectiveness that are part of the trial protocol for our pivotal Phase III trial. FDA may accordingly refuse to approve PolyHeme for commercial sale or may require us to conduct additional clinical trials of PolyHeme in order to obtain approval. Even 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 achieving or 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.

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 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 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 competing therapies.

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 perform data collection and analysis with respect to our clinical trial and to assist in the preparation of our BLA for PolyHeme, which may result in costs and delays that prevent us from successfully commercializing our product.

We do not have the personnel resources to conduct all of the activities relating to the collection and analysis of data from our clinical trial and the preparation and submission of our BLA for PolyHeme. We rely and will continue to rely on clinical investigators, third-party clinical research organizations and consultants to perform many of these functions.

Our BLA may be delayed, suspended or terminated if:

these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines;

these third parties need to be replaced; or

the work performed by these third parties does not satisfy applicable regulatory requirements or is not usable for other reasons.

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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.

We have 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 SPA agreement, however, is not a guarantee of product approval by FDA or approval of any permissible claims about the product. In particular, it is not binding on the FDA if previously unrecognized public health concerns later comes to light, other new scientific concerns regarding product safety or effectiveness arise, the sponsor fails to comply with the protocol agreed upon, or FDA s reliance on data, assumptions or information are determined to be wrong. Even after an SPA agreement is finalized, the SPA agreement may be changed by the sponsor company or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

In addition, the data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA regulatory approval. Even if FDA accepts that our analysis of the Phase III data is sufficient to demonstrate effectiveness, 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 for human use 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 pivotal Phase III trial. When our planned 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 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

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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 effectiveness of oxygen therapeutics 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 plan to request priority review of our BLA by FDA. We believe that PolyHeme satisfies the stated criteria for priority review based on its potential to address an unmet medical need. Products awarded priority review are given abbreviated review goals by the agency. FDA makes a decision as part of the agency s review of the application for filing. There can be no assurance that the agency will grant PolyHeme priority review. If priority review is granted, we also cannot predict what impact, if any, it may have on the review time for PolyHeme. Priority review does not ensure that FDA will ultimately approve PolyHeme.

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 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 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 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. We intend to seek FDA approval of this facility for the commercial production of PolyHeme if and when marketing approval of PolyHeme is obtained. This facility will be subject to FDA inspections and extensive regulation, including compliance with current good manufacturing practices and FDA approval. Failure to comply may result in enforcement action, which may significantly delay or suspend manufacturing operations.

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 in our existing pilot facility. In June 2006, we purchased the 106,000 square foot building in Mt. Prospect, Illinois in which our pilot manufacturing facility is located and plan to construct an expanded commercial manufacturing facility at this site. We currently do not have sufficient available funds to permit us to begin construction of this facility and we will need to raise additional funds before we are able to proceed with our planned manufacturing expansion. There can be no

assurance that we will be able to raise additional funds for this purpose. If we are successful in raising sufficient funds to begin construction of a commercial manufacturing facility, we expect that completion of the facility, including FDA inspection and validation, will require approximately 24 to 30 months. Therefore, even if FDA approval for the marketing of PolyHeme is obtained, we may not be able to produce PolyHeme in commercial

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quantities for a substantial period of time. 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 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 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 was 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

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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.

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 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 Pfizer Inc. and Hemocare Ltd., an Israeli corporation, to develop, manufacture and distribute PolyHeme in certain European, Middle Eastern and African countries. The license agreements permit 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 our 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.

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Failure to maintain effective internal controls over financial reporting could have a material adverse effect on our business, operating results and stock price.

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 SEC. 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 an opinion by our independent auditors with respect to the effectiveness 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 determine that our internal controls are not effective, 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.

We are subject to a putative class action lawsuit and have received requests from both the SEC and the Senate Committee on Finance asking us voluntarily to provide information.

We and Dr. Steven A. Gould, Northfield s Chief Executive Officer, and Richard E. DeWoskin, Northfield s former Chief Executive Officer, are subject to a putative class action pending in the United States District Court for the Northern District of Illinois Eastern Division, purportedly brought on behalf of a class of Northfield s shareholders. The complaint alleges, among other things, that during the period from December 22, 2003 to February 21, 2006, the named defendants made or caused to be made a series of materially false or misleading statements and omissions about Northfield s elective surgery clinical trial and business prospects in violation of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act. Plaintiffs allege that those allegedly false and misleading statements and omissions caused the purported class to purchase Northfield common stock at artificially inflated prices. As relief, the complaint seeks, among other things, a declaration that the action be certified as a proper class action, unspecified compensatory damages (including interest) and payment of costs and expenses (including fees for legal counsel and experts). If the outcome of this lawsuit is unfavorable to Northfield, or Northfield determines that it is advisable to enter into a settlement of the lawsuit, Northfield could be required to pay significant monetary damages or make significant settlement payments to the plaintiffs in the lawsuit.

While Northfield maintains directors and officers liability insurance, there can be no assurance that the proceeds of this insurance will be available with respect to all or part of any damages, costs or expenses that may be incurred by Northfield in connection with the aforementioned putative class action lawsuit. In addition, Northfield is a party to indemnification agreements under which it may be required to indemnify and advance defense costs to its current and former directors and officers in connection with this putative class action lawsuit. Even if this lawsuit

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is ultimately resolved in favor of Northfield, Northfield still may incur substantial legal fees and expenses in defending the lawsuit.

In March 2006, the SEC notified Northfield that it was conducting an informal inquiry, and requested that Northfield voluntarily provide the SEC with certain categories of documents from 1998 to the present primarily relating to our public disclosures concerning the clinical development of PolyHeme. Northfield is cooperating with the SEC and has provided the SEC with certain requested documents and information. While Northfield does not know and cannot predict the ultimate outcome or future of the SEC s inquiry, the SEC has the authority to pursue formal civil enforcement actions, civil penalties, and equitable remedies, including disgorgement of funds and injunctions against future violations of the federal securities laws, and may refer criminal violations of the federal securities laws to the United States Department of Justice for prosecution.

Also in March 2006, Northfield received a letter from Senator Charles E. Grassley, then Chairman of the Senate Committee on Finance, informing Northfield that the Committee was concerned that Northfield s Phase III clinical trauma trial may not have satisfied all of the criteria of the federal regulation that allows a waiver of informed consent in the context of emergency research. While Northfield does not know and cannot predict the ultimate outcome of the Committee s investigation, actions by legislative bodies such as the Senate could prevent or materially delay FDA approval of the commercial sale of PolyHeme.

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 marketing related products or the length of term of patent protection that we may have for PolyHeme. Our United States patents have various expiration dates; the latest to expire of our United States patents has a term that extends to 2025. Our broadest United States patent was originally scheduled to expire in 2006 but has been extended by the United States Patent Office to 2007. A further application for a one-year patent term extension has been filed in the Patent Office. If that extension is granted, that patent will expire in 2008 and a further application for a one-year extension will then be filed seeking an extension until 2009. No extensions are possible beyond 2011. We cannot ensure that any particular extension will be granted or that any extensions that are granted will not result in an expiration date prior to 2011. 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 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

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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 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 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.

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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

Our stock price could be volatile.

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

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

Anti-takeover provisions contained in our charter and bylaws could discourage potential takeover attempts.

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

stockholders might otherwise receive a premium for their shares over the then prevailing market prices.

Item 1B. ***Unresolved Staff Comments.***

We have not received any written comments from the staff of the SEC regarding our periodic or current reports under the Securities Exchange Act of 1934 that remain unresolved.

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Item 2. ***Properties.***

We maintain our principal executive offices in Evanston, Illinois. The lease for our executive offices extends through February 2011. Rent expense for our Evanston offices for our 2007 fiscal year was $401,988.

We currently operate a pilot manufacturing facility in Mt. Prospect, Illinois. We are presently planning to construct an expanded commercial manufacturing facility with the capacity to produce more than 100,000 units of PolyHeme per year. In June 2006, we purchased the 106,000 square foot building in Mt. Prospect, Illinois in which our pilot manufacturing facility is located and plan to construct our expanded commercial manufacturing facility at this site. In addition to manufacturing operations, the facility houses laboratory, quality control and administrative personnel. Engineering and size optimization activities for the planned facility are currently underway. We currently do not have sufficient available funds to permit us to begin construction of this facility and we will need to raise additional funds before we are able to proceed with our planned manufacturing expansion. There can be no assurance that we will be able to raise additional funds for this purpose.

Item 3. ***Legal Proceedings.***

During 2006, ten separate complaints were filed, each purporting to be on behalf of a class of Northfield s shareholders, against Northfield and Dr. Steven A. Gould, Northfield s Chief Executive Officer, and Richard E. DeWoskin, Northfield s former Chief Executive Officer. Those putative class actions have been consolidated in a case pending in the United States District Court for the Northern District of Illinois Eastern Division. The Consolidated Amended Class Action Complaint was filed in July 2006, and alleges, among other things, that during the period from December 22, 2003 to February 21, 2006, the named defendants made or caused to be made a series of materially false or misleading statements and omissions about Northfield s elective surgery clinical trial and business prospects in violation of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act. Plaintiffs allege that those allegedly false and misleading statements and omissions caused the purported class to purchase Northfield common stock at artificially inflated prices. As relief, the complaint seeks, among other things, a declaration that the action be certified as a proper class action, unspecified compensatory damages (including interest) and payment of costs and expenses (including fees for legal counsel and experts). The putative class action is at an early stage and it is not possible at this time to predict the outcome of any of the matters or their potential effect, if any, on Northfield or the clinical development or future commercialization of PolyHeme. Northfield intends to defend vigorously against the allegations stated in the Consolidated Amended Class Action Complaint.

In March 2006, the SEC notified Northfield that it was conducting an informal inquiry, and requested that Northfield voluntarily provide the SEC with certain categories of documents from 1998 to the present primarily relating to Northfield s public disclosures concerning the clinical development of PolyHeme. Since its initial notice, the SEC has sent Northfield additional requests for documents and information. Northfield is cooperating with the SEC and has provided the SEC with certain requested documents and information.

Also in March 2006, Northfield received a letter from Senator Charles E. Grassley, then Chairman of the Senate Committee on Finance, informing Northfield that the Committee was concerned that Northfield s Phase III clinical trauma trial may not have satisfied all of the criteria of the federal regulation that allows a waiver of informed consent in the context of emergency research. In that letter, the Committee requested that Northfield provide certain categories of documents primarily relating to the Phase III clinical trauma trial. Northfield representatives have met with the staff of the Committee and we have provided certain documents and information requested by the Committee.

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

None.

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PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.***

MARKET INFORMATION

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

Fiscal Quarter Ended	High	Low
February 29, 2005	$ 23.85	$ 15.35
May 31, 2005	16.19	10.71
August 31, 2005	15.10	11.32
November 30, 2005	15.50	11.45
February 28, 2006	14.45	8.86
May 31, 2006	11.30	8.62
August 31, 2006	11.00	10.74
November 30, 2006	15.59	15.05
February 28, 2007	3.98	3.81
May 31, 2007	1.55	1.46
August 31, 2007 (through July 31, 2007)	1.46	1.21

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STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total return on our common stock from May 31, 2002 through May 31, 2007 with the CRSP Total Return Index for the Nasdaq Stock Market (U.S. Companies) and the Nasdaq Pharmaceutical Index. The total stockholder return assumes that $100 was invested in our common stock and each of the two indexes on May 31, 2002 and also assumes the reinvestment of any dividends. The return on our common stock is calculated using the closing price for the common stock on May 31, 2002, as quoted on the Nasdaq Stock Market, Inc. Past financial performance may not be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

Comparison of Five Year Cumulative Total Returns
Performance Graph for
Northfield Laboratories, Inc.

The Stock Performance Graph is not deemed to be soliciting material or to be filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, or incorporated by reference in any document so filed.

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HOLDERS OF RECORD

As of August 1, 2007, there were approximately 500 holders of record and approximately 13,000 beneficial owners of our common stock. There were as of that date no issued and outstanding shares of our preferred stock.

DIVIDENDS

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

ISSUER PURCHASES OF EQUITY SECURITIES

We did not repurchase any of our equity securities during the three months ended May 31, 2007.

RECENT SALES OF UNREGISTERED SECURITIES

We did not make any unregistered sales of our common stock during our 2007 fiscal year.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

Information with respect to securities authorized for issuance under equity compensation plans can be found under the caption Securities Authorized for Issuance Under Equity Compensation Plans in our Proxy Statement for our September 25, 2007 Annual Meeting of Shareholders and is incorporated herein by reference.

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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, 2007 and for the cumulative period from June 19, 1985 (inception) through May 31, 2007 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,
	2007	2006	2005	2004	2003	2007
	(In thousands, except per share data)					
Statement of Operations Data:						
Revenues:						
License income	$					3,000
Costs and expenses:						
Research and development	$ 21,060	$ 24,165	16,600	10,777	8,819	168,841
General and administrative	9,374	5,832	4,990	3,854	3,643	64,650
Interest income (net)	2,763	3,222	1,268	131	212	30,841
Net loss	$ (27,671)	$ (26,775)	(20,322)	(14,574)	(12,250)	(199,808)
Net loss per share basic and diluted	$ (1.03)	$ (1.00)	(0.88)	(0.86)	(0.86)	(17.42)
Shares used in calculation of per share data(1)	26,906	26,770	23,069	16,932	14,266	11,470
Balance Sheet Data:						
Cash and marketable securities	$ 40,688	$ 73,910	98,131	42,487	6,890	
Total assets	50,119	75,871	100,002	44,179	9,246	
Total liabilities	4,777	6,534	4,228	2,626	2,066	
Deficit accumulated during development stage	(199,808)	(172,136)	(145,361)	(125,040)	(110,466)	
Total shareholders equity	45,342	69,337	95,774	41,553	7,180	

(1) Computed on the basis described in Note 1 of the Notes to Financial Statements. Excludes 1,681,375 shares reserved for issuance upon the exercise of stock options and 115,418 shares reserved for issuance for stock warrants as of May 31, 2007. Additional stock options for a total of 1,426,500 were available for grant as of May 31, 2007 under our employee stock option plans.

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

RECENT DEVELOPMENTS

In July 2006 we announced the completion of patient enrollment in our pivotal Phase III trial with PolyHeme. This was the first study in the United States to evaluate the safety and efficacy of an oxygen-carrying red blood cell substitute beginning at the scene of injury and continuing during transport and in the early hospital period. We reported the preliminary top-line results of our study in December 2006 and announced additional results from the study in May 2007.

We are presently preparing a Biologics License Application, or BLA, for PolyHeme for submission to the U.S. Food and Drug Administration, or FDA. We have submitted a detailed summary of our trial data to FDA and have participated in a pre-BLA meeting with the Agency. Our goal is to submit our BLA to FDA during the first half of calendar 2008. We also plan to request priority review of our BLA. We believe PolyHeme satisfies the stated criteria for priority review based on its potential to address an unmet medical need.

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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, 2007, we have incurred operating losses totaling $199,808,000.

We will be required to prepare and submit a BLA to FDA 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 described in the Statements of Operations 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, 2007, 2006 or 2005. From Northfield s inception through May 31, 2007, 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, 2007, 2006 and 2005 totaled $30,434,000, $29,998,000 and $21,589,000, respectively. Measured on a percentage basis, fiscal 2007 operating expenses exceeded fiscal 2006 expenses by 1.5%, while fiscal 2006 operating expenses exceeded fiscal 2005 expenses by 38.9%.

During fiscal 2007, research and development expenses totaled $21,060,000, a decrease of $3,105,000, or 12.9%, from fiscal 2006 expenses of $24,165,000. During fiscal 2007, we concluded enrollment in our pivotal Phase III trial. While clinical costs associated with the trial decreased, our efforts to prepare our manufacturing facility and submit our BLA to FDA increased. The direct costs of the trial, hospital site activity and contract research activity totaled $3,186,000 in fiscal 2007, a decrease of $7,510,000, or 70.2%, from fiscal 2006. Additional fiscal 2007 costs were also recorded for science consulting, increased staff, benefit costs and production maintenance.

During fiscal 2006, research and development expenses totaled $24,165,000, an increase of $7,565,000, or 45.6%, from the fiscal 2005 expenses of $16,600,000. During fiscal 2006, an additional 12 trial sites opened 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 totaled $10,696,000 in fiscal 2006, an increase of $4,082,000, or 61.7%, from fiscal 2005. Additional 2006 costs were also recorded for increasing staff, benefit costs, insurance and science consulting.

We anticipate a continued high level of research and development spending in fiscal 2008. Following completion of enrollment in our pivotal Phase III trial in fiscal 2007, we have accelerated the significant task of data audit, assembly, analysis and report preparation. Preparing our BLA for PolyHeme to be submitted to FDA will continue through fiscal 2008. At the same time, we will be undergoing an extensive process of preparation for FDA s pre-approval inspection of our pilot manufacturing facility. Northfield s internal research and development resources will be focused on these

tasks and we expect to expand the use of external resources to complete these tasks in a timely manner.

General and administrative expenses for the 2007 fiscal year totaled $9,374,000, an increase of $3,542,000, or 60.7%, from the expenses incurred in the prior fiscal year. Significant increases in share based compensation

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expense and professional service fees occurred during fiscal 2007. Effective June 1, 2006, we adopted Financial Accounting Standards Board Statement No. 123 (revised), *Share-Based Payment*. Among its provisions, SFAS 123R requires us to recognize compensation expense for equity awards over the vesting period based on their grant-date fair value. We also incurred expenses for professional services in connection with a putative class action lawsuit that was initiated in the fourth quarter of fiscal 2006. In addition, we incurred increased expenses in fiscal 2007 for new software installation and our ongoing efforts to ensure the continued effectiveness of our internal controls over financial reporting as mandated by the Sarbanes-Oxley Act of 2002. We anticipate a reduction in our general and administrative expenses due to an anticipated reduction in share based compensation and professional services fees in fiscal 2008.

General and administrative expense for the 2006 fiscal year totaled $5,832,000, an increase of $842,000, or 16.9%, from the expense incurred in the prior fiscal year. Significant increases in professional service fees and public relations expenses occurred during fiscal 2006. These expenses were mainly incurred in connection with an informal request from the staff of the SEC to voluntarily provide certain information relating to the clinical development of PolyHeme in an elective surgery trial conducted between 1997 and 2001. We also provided similar information to the staff of the Finance Committee of the United States Senate. In addition, we incurred expenses for professional services in connection with a putative class action lawsuit that was initiated in the fourth quarter of fiscal 2006.

We anticipate a decrease in general and administrative expenses in fiscal 2008 compared to the $9,374,000 incurred during fiscal 2007. A reduction in share based compensation, legal expenses and other professional service costs, such as consulting fees and corporate communications, is planned. We are planning for a decrease in general and administrative expenses for fiscal 2008 of approximately 20% to 30% compared with our general and administrative expenses for fiscal 2007.

INTEREST INCOME

Interest income in fiscal 2007 equaled $2,763,000 compared to $3,222,000 in fiscal 2006. The current year decrease is the result of lower available cash resources for investment. Available interest rates at the beginning of the current fiscal year were approximately 4.9% for money-market investments and 5.1% for high quality one year securities. Money market rates in July 2007 were approximately 5.2% and high quality three-month securities were also around 5.2%. As our current investments mature, they will be rolled over until the funds are required for our business.

Interest income in fiscal 2006 equaled $3,222,000 compared to $1,268,000 in fiscal 2005. The increase was the result of larger available cash resources as well as higher interest rates on our short term investments.

With declining available cash resources and short term interest rates perhaps nearing a peak, we anticipate that in the absence of a major cash infusion, interest income will decline in fiscal 2008. A one percent rate decline yields $10,000 less in 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, 2007 was $27,671,000, or $1.03 per share, compared to a net loss of $26,775,000, or $1.00 per share, for the fiscal year ended May 31, 2006. Effective June 1, 2006, we adopted SFAS 123R. Among its provisions, SFAS 123R requires us to recognize compensation expense for equity awards over the vesting period based on their grant-date fair value. The increased net loss was primarily the result of increased share based compensation expenses and professional service fees as well as an increase in science consulting and production maintenance.

The net loss for our fiscal year ended May 31, 2006 was $26,775,000, or $1.00 per share, compared to a net loss of $20,321,000, or $0.88 per share, for the fiscal year ended May 31, 2005. The increased net loss was primarily the result of increased clinical trial expenses and professional service fees.

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LIQUIDITY AND CAPITAL RESOURCES

From Northfield s inception through May 31, 2007, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of $203,585,000. For the fiscal years ended May 31, 2007, 2006 and 2005, these cash expenditures totaled $34,969,000, $26,055,000 and $19,238,000, respectively. The fiscal 2007 increase in cash utilization is due to the purchase of our manufacturing facility for $6,700,000 and to the payment of 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. As of May 31, 2007, we had cash and marketable securities totaling $40,688,000. As previously reported, we have been successful in securing a $1.4 million federal appropriation as part of the Defense Appropriation Bill in 2005 and a $3.5 million federal appropriation as part of the Fiscal 2006 Defense Appropriation Bill. As of May 31, 2007, we have received $1,236,000 of these funds.

We are currently utilizing our cash resources at a rate of approximately $24 million per year. We expect the rate at which we utilize our cash resources will remain constant in fiscal 2008 as we prepare to complete and submit a BLA for PolyHeme to FDA, and upgrade our manufacturing facility for FDA inspection.

Based on our current estimates, we believe our existing capital resources will be sufficient to permit us to conduct our operations, including the preparation and submission of a BLA to FDA, for approximately 18 to 20 months.

We may in the future issue additional equity or debt securities or enter into collaborative arrangements with strategic partners, which could provide us with additional funds or absorb expenses we would otherwise be required to pay. We are also pursuing potential sources of additional 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 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 planned commercial manufacturing facility, competitive and technological advances, the FDA regulatory process, changes in our marketing and distribution strategy and other factors.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements requires management to make estimates and assumptions that affect amounts reported therein. We believe the following critical accounting policy reflects our more significant judgments and estimates used in the preparation of our 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, 2007, we have recorded a 100% percent valuation allowance against our net deferred tax assets.

CONTRACTUAL OBLIGATIONS

The following table reflects a summary of our contractual cash obligations as of May 31, 2007:

Contractual Obligations	Total	Less than One Year	1-3 Years
Lease Obligations(1)	$ 727,447	$ 360,198	$ 367,248
Other Obligations(2)	1,230,000	1,230,000	
Total Contractual Cash Obligations	$ 1,957,447	$ 1,590,198	$ 367,248

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(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 15, 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 February 2007, the Financial Accounting Standards Board issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value at specified election dates. Under SFAS 159, a business entity is required to report unrealized gains and losses on items for which the fair value option has been elected in earnings (or another performance indicator if the business entity does not report earnings) at each subsequent reporting date. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We do not believe that adoption of SFAS 159 will have a material effect on our financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The requirements of SFAS 157 are effective for financial statements issued for fiscal years beginning after November 15, 2007. We do not believe that adoption of SFAS 157 will have a material effect on our financial statements.

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. The intent of SAB 108 is to reduce diversity in practice for the method companies use to quantify financial statement misstatements, including the effect of prior year uncorrected errors. SAB 108 establishes an approach that requires quantification of financial statement errors using both an income statement and a cumulative balance sheet approach. SAB 108 is effective for the fiscal year ending after November 15, 2006. The adoption of SAB 108 did not have an impact on our Consolidated Financial Statements.

In June 2006, the FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes an Interpretation of SFAS 109, Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 developed a two-step process to evaluate a tax position and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. This interpretation is effective for fiscal years beginning after December 15, 2006. We do not believe the adoption of FIN 48 will have a material effect on our financial statements.

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 $40,688,000 at May 31, 2007 would decrease interest income by $407,000.

ITEM 8. ***Financial Statements and Supplemental Data.***

See the Table of Contents to Financial Statements on Page 35. See Note 12 to the Financial Statements on Page 56 for the Unaudited Supplementary Quarterly Data. These Financial Statements are included elsewhere in this document.

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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 Vice President Finance 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 SEC 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, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control 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 the Securities Exchange Act of 1934). Our management assessed the effectiveness of our internal control over financial reporting as of May 31, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework. Our management has concluded that, as of May 31, 2007, 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 opinion on our internal control over financial reporting, which is included herein.

Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Vice President Finance, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors 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.

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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 14, 2007, 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 35.

(3) See Description of Exhibits on page 58.

(b) See Description of Exhibits on page 58.

(c) None.

NORTHFIELD LABORATORIES INC.
(a company in the development stage)

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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, 2007 and 2006, 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, 2007 and for the cumulative period from June 19, 1985 (inception) through May 31, 2007. 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, 2007 and 2006, and the results of its operations and its cash flows for each of the years in the three-year period ended May 31, 2007 and for the cumulative period from June 19, 1985 (inception) through May 31, 2007, 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 control over financial reporting as of May 31, 2007, based on the criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated August 14, 2007, expressed an unqualified opinion on management s assessment of, and the effective operation of, internal control over financial reporting.

As discussed in Note 1 to the financial statements, the Company adopted Statement of Financial Accounting Standards No. 123 (revised), Share-Based Payment, as of June 1, 2006.

/s/ KPMG LLP

Chicago, Illinois
August 14, 2007

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Report of Independent Registered Public Accounting Firm

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, 2007, 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.

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, 2007, 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, 2007, 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, 2007 and 2006, 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,

2007, and for the cumulative period from June 19, 1985 (inception) through May 31, 2007, and our report dated August 14, 2007 expressed an unqualified opinion on those financial statements.

/s/ KPMG LLP

Chicago, Illinois
August 14, 2007

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NORTHFIELD LABORATORIES INC.
(a company in the development stage)

BALANCE SHEETS
May 31, 2007 and May 31, 2006

	May 31, 2007	May 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,224,026	39,304,602
Restricted cash	529,752	926,492
Marketable securities	16,934,204	33,679,022
Prepaid expenses	673,192	813,104
Other current assets	212,854	
Total current assets	41,574,028	74,723,220
Property, plant, and equipment	19,588,246	15,654,049
Accumulated depreciation	(11,063,080)	(14,575,118)
Net property, plant, and equipment	8,525,166	1,078,931
Other assets	19,550	68,941
	$ 50,118,744	75,871,092
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,573,025	4,481,804
Accrued expenses	101,118	134,006
Accrued compensation and benefits	565,709	742,038
Government grant liability	529,752	926,492
Other		249,580
Total current liabilities	4,769,604	6,533,920
Other liabilities	7,431	
Total liabilities	4,777,035	6,533,920
Shareholders equity:		
Preferred stock, $.01 par value. Authorized 5,000,000 shares; none issued and outstanding		
Common stock, $.01 par value. Authorized 60,000,000 shares; issued 26,916,541 at May 31, 2007 and 26,777,655 at May 31, 2006	269,165	267,777
Additional paid-in capital	244,905,543	241,240,276
Deficit accumulated during the development stage	(199,807,606)	(172,136,429)
Deferred compensation		(9,059)

		45,367,102	69,362,565
Less cost of common shares in treasury; 1,717 shares and 1,717 shares, respectively		(25,393)	(25,393)
Total shareholders equity		45,341,709	69,337,172
	$	50,118,744	75,871,092

See accompanying notes to financial statements.

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NORTHFIELD LABORATORIES INC.
(a Company in the development stage)

STATEMENTS OF OPERATIONS
Years ended May 31, 2007, 2006 and 2005 and the cumulative period from June 19, 1985 (inception) through May 31, 2007

	Years Ended May 31,			Cumulative from June 19, 1985 through
	2007	2006	2005	May 31, 2007
Revenues license income	$			3,000,000
Costs and expenses:				
Research and development	21,059,618	24,165,407	16,599,736	168,840,816
General and administrative	9,374,395	5,832,297	4,989,620	64,650,295
	30,434,013	29,997,704	21,589,356	233,491,111
Other income and expense:				
Interest income	2,762,836	3,222,286	1,267,900	30,841,660
Interest expense				83,234
	$ 2,762,836	3,222,286	1,267,900	30,758,426
Net loss before cumulative effect of change in accounting principle	(27,671,177)	(26,775,418)	(20,321,456)	(199,732,685)
Cumulative effect of change in accounting principle				74,921
Net loss	$ (27,671,177)	(26,775,418)	(20,321,456)	(199,807,606)
Net loss per share basic and diluted	$ (1.03)	(1.00)	(0.88)	(17.42)
Shares used in calculation of per share data basic and diluted	26,906,407	26,769,860	23,069,166	11,470,012

See accompanying notes to financial statements.

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NORTHFIELD LABORATORIES INC.
(a company in the development stage)

STATEMENTS OF SHAREHOLDERS EQUITY (DEFICIT)
Years ended May 31, 2007, 2006 and 2005 and the cumulative period from June 19, 1985 (inception) through May 31, 2007

	Preferred stock		Common stock	
	Number of shares	Aggregate amount	Number of shares	Aggregate amount
Issuance of common stock on August 27, 1985		$	3,500,000	$ 35,000
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	35,000
Net loss				
Deferred compensation relating to grant of stock options				
Amortization of deferred compensation				
Balance at May 31, 1987			3,500,000	35,000
Issuance of Series B convertible preferred stock at $35.68 per share on August 14, 1987 (net of costs of issuance of $75,450)				
Net loss				
Amortization of deferred compensation				
Balance at May 31, 1988			3,500,000	35,000
Issuance of common stock at $24.21 per share on June 7, 1988 (net of costs of issuance of $246,000)			413,020	4,130
Conversion of Series A convertible preferred stock to common stock on June 7, 1988			1,250,000	12,500
Conversion of Series B convertible preferred stock to common stock on June 7, 1988			1,003,165	10,032
Exercise of stock options at $2.00 per share			47,115	471
Issuance of common stock at $28.49 per share on March 6, 1989 (net of costs of issuance of $21,395)			175,525	1,755
Issuance of common stock at $28.49 per share on March 30, 1989 (net of costs of issuance of $10,697)			87,760	878
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	64,766

Net loss			
Deferred compensation relating to grant of stock options			
Amortization of deferred compensation			
Balance at May 31, 1990		6,476,585	64,766
Net loss			
Amortization of deferred compensation			
Balance at May 31, 1991		6,476,585	64,766
Exercise of stock warrants at $5.60 per share		90,000	900
Net loss			
Amortization of deferred compensation			
Balance at May 31, 1992		6,566,585	65,666
Exercise of stock warrants at $7.14 per share		15,000	150
Issuance of common stock at $15.19 per share on April 19, 1993 (net of costs of issuance of $20,724)		374,370	3,744
Net loss			
Amortization of deferred compensation			
Balance at May 31, 1993		6,955,955	69,560
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	25,000
Cancellation of stock options			
Amortization of deferred compensation			
Balance at May 31, 1994		9,455,955	94,560
Net loss			
Issuance of common stock at $6.50 per share on June 20, 1994 (net of issuance costs of $172,500)		375,000	3,750
Exercise of stock options at $7.14 per share		10,000	100
Exercise of stock options at $2.00 per share		187,570	1,875
Cancellation of stock options			
Amortization of deferred compensation			
Balance at May 31, 1995		10,028,525	100,285
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	29,250
Issuance of common stock at $17.75 per share on September 11, 1995 (net of issuance costs of $423,238)		438,750	4,388
Exercise of stock options at $2.00 per share		182,380	1,824
Exercise of stock options at $6.38 per share		1,500	15
Exercise of stock options at $7.14 per share		10,000	100
Cancellation of stock options			
Amortization of deferred compensation			
Balance at May 31, 1996	$	13,586,155	$ 135,862

See accompanying notes to financial statements.

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