NORTHFIELD LABORATORIES INC /DE/
Form 10-K
August 14, 2008

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, 2008

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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company x

(Do not check if a smaller reporting company)

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, 2007, 26,960,233 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, 2007 held by non-affiliates of the Registrant was $28,349,365 (26,249,412 shares at $1.08 per share).

As of July 31, 2008, there were 26,960,233 shares of the Registrant s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement for its 2008 Annual Meeting are incorporated by reference into Part III of this Form 10-K. The Registrant maintains an Internet website at *www.northfieldlabs.com*. None of the information contained on this website is incorporated by reference into this Form 10-K or into any other document filed by the Registrant with the Securities and Exchange Commission.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

This Annual Report contains forward-looking statements concerning, among other things, our prospects, clinical and regulatory developments affecting our potential product and our business strategies. These forward- looking statements are identified by the use of such terms as intends, expects, plans, estimates, anticipates, forecasts, believes and similar terms.

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

All subsequent written and oral forward-looking statements attributable to Northfield or any person acting on our behalf are qualified by 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.

PART I

ITEM 1. ***Business.***

Northfield Laboratories Inc. is a leader in developing a hemoglobin-based oxygen-carrying red blood cell substitute. The initial indication we are seeking for our product, PolyHeme®, is the treatment of life-threatening hemoglobin levels when blood transfusion is indicated but red blood cells may not be available, appropriate or acceptable. We believe that this indication addresses a critical unmet medical need in multiple civilian and military clinical settings, including:

at the scene of injury

during transport to the hospital via ground or air ambulance

unplanned hemorrhage in the operating room

lack of compatible blood

depletion of the available blood supply due to multiple, simultaneous injured patients

limited blood inventory in remote or rural hospitals

religious objection to blood transfusion

periodic blood shortages

We believe that in such settings PolyHeme has the potential to improve survival in critically ill 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 multicenter 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, following approval of the trial protocol by the Institutional Review Board, or IRB, at each institution. The trial had an enrollment of 720 patients.

We reported the data from the study in May 2007, and subsequently announced the results of an independent cardiac analysis in April 2008. 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. Mortality rates in that scenario would be considerably higher than those observed in the control patients in our trial, where transit times were relatively short. We believe that when our data are extrapolated to patients who need an oxygen carrier and have delayed access to blood, where the expected mortality would be high without oxygen-carrying replacement, 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. We anticipate the final BLA will be submitted in the fourth

calendar quarter of 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 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. Other potential hazards of transfusion include mistransfusion, transfusion-related lung acute injury, transfusion-associated circulatory overload, and transfusion-related immunomodulation and its consequences. There is no commercially available hemoglobin-based oxygen-carrying red blood cell substitute in this country which addresses these problems.

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.

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 following approval of the trial protocol by the Institutional Review Board, or IRB, at each institution. 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 were enrolled at 31 of the sites.

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 did not have access to the trial data reviewed by the IDMC until the database of information concerning patients enrolled in the trial 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.

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- 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.

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. There were six patients enrolled who received no treatment. The modified intent to treat, or MITT, population is comprised of all 714 patients both

randomized and treated. In the primary MITT analysis population, patients were analyzed *as randomized*, and not based on the actual treatment they received. There were 41 randomized patients in the study who received the incorrect treatment. Therefore, 21 patients randomized to PolyHeme who did not receive any PolyHeme were

analyzed in the PolyHeme group. Two of these patients died. Similarly, 20 patients randomized to control who received PolyHeme 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 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*. 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.

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		**Control Group**		
	(Deaths/Number of Patients)	**Mortality Rate (%)**	**(Deaths/Number of Patients)**	**Mortality Rate (%)**	**Upper Limit (%)**
MITT	47/350	13	35/364	10	7.65%
As Treated	46/349	13	36/365	10	7.06%
Per Protocol	31/279	11	29/311	9	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 43% than the control group at 52% ($p<0.001$). There was no statistically significant difference between PolyHeme and control patients for the other efficacy endpoints.

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. 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), ($p=0.041$). 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

pneumonia, multiple organ failure, hemorrhagic shock 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% (16 patients) in the control group ($p>0.05$). The overall incidence of MI in the study as reported by investigators was 2% (14 patients): eleven PolyHeme patients and three control patients ($p<0.05$). Three PolyHeme patients and one control patient died.

IDMC Cardiac Subcommittee Analysis

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 biomarkers Troponin I and CK-MB, both of which

can be altered by direct trauma. Approximately 75% of the patients in our Phase III study had abnormal electrocardiograms or elevated cardiac biomarkers. Because of the disparity between the low number of reported MIs and the high incidence of abnormal electrocardiograms and elevated cardiac biomarkers, Northfield established an expert Cardiac Subcommittee of the IDMC to review the cardiac profiles of all 720 randomized patients in a blinded fashion. This committee was established and the criteria agreed upon prior to unblinding the study. The Cardiac Subcommittee used objective criteria based on biomarkers and electrocardiograms to classify the MIs in the study as possible, probable, indeterminate, and absent. More than half of the patients in both study groups had some evidenc of myocardial infarction. The classifications developed by the Cardiac Subcommittee are summarized in the following table.

IDMC Cardiac Subcommittee MI Analysis

	PolyHeme (n=349)	Control (n=365)
Probable MI	43 (12%)	30 (8%)
Possible MI	150 (43%)	160 (44%)
Total Possible or Probable MI	193 (55%)	190 (52%)
Indeterminate	72 (21%)	111 (30%)
Absent MI	84 (24%)	64 (18%)

BIOLOGICS LICENSE APPLICATION

We are presently preparing a BLA for PolyHeme for submission to FDA. A BLA includes material related to clinical, preclinical, and CMC, or chemistry, manufacturing and controls, information.

The clinical section of the BLA will include the results of the Phase III trial discussed above. We have submitted a detailed summary of our Phase III trial data to FDA and have participated in a pre-BLA meeting with the agency. The clinical section of the BLA will also include information from all studies in humans, starting with our Phase I volunteer experience. The process has taken longer than we planned. As we have reviewed and reanalyzed the results of our clinical studies, we have expanded the number of data sets we believe should be included. This has required the generation of multiple additional tables, listings, figures, and graphs, and the subsequent additional analyses of this information in order to provide the most comprehensive summary and interpretation of the totality of our clinical data. That process continues as we finalize the portions of the BLA that address the important integrated summaries of efficacy and safety, the risk-benefit analysis, and the product labeling.

Preclinical testing includes extensive in-vitro and in-vivo studies of PolyHeme to assess product pharmacology and toxicology. These studies have varied greatly with regard to animal species, protocol and product dosing, concomitant study drugs, and the timing and nature of the observations and measurements. Some of these studies have shown species dependent abnormalities in certain laboratory findings, including increases in aspartate aminotransferase, bilirubin, blood urea nitrogen, chromaturia, glucose, and troponin, and certain abnormal microscopic findings, including renal tubular proteinosis, Kupffer cell hypertrophy, karyomegaly, histiocytosis, cellular degeneration, and inflammation in organs such as the kidney, liver, or heart. These abnormalities were largely reversible and there was no evidence of organ failure. The clinical relevance of these findings is unclear when extrapolated to the human setting. As with the clinical section, preparing the preclinical data for inclusion in the BLA allows Northfield to review all of the reports that have been previously submitted to the IND and provide a more meaningful and comprehensive summary and interpretation of the totality of the preclinical data.

The BLA also addresses CMC issues. Completing the CMC section of our BLA has for a number of reasons also consumed and continues to consume considerably more time than anticipated. Our pilot manufacturing facility was first opened in 1990 with a design capacity to produce up to 10,000 units of PolyHeme per year. At the time it was Northfield s plan to use the pilot facility for research and development purposes and the manufacture of clinical supplies under the appropriate current Good Manufacturing Practices, or cGMP, with future commercial scale manufacturing being performed in a new facility. Our current plan is to seek FDA approval for use of the pilot plant as our initial commercial manufacturing site, to be followed by expansion at a later date. The cGMP requirements

for commercial manufacturing have evolved considerably over the past two decades and we have made multiple improvements and updates to our pilot facility, all of which required subsequent validation, in order to confirm cGMP compliance. These upgrades have consumed and continue to consume considerable time, effort and expense. We anticipate that the final capacity of this pilot facility will be approximately 5,000 to 7,500 units per year. As with the clinical and preclinical sections, the facility modification and revalidation effort has required considerably more time that initially projected, but it is essential in order to provide the most meaningful and comprehensive summary and characterization of our product and our manufacturing process to FDA.

Based on all of these activities, we anticipate the final BLA will be submitted during the fourth calendar quarter of 2008. We also plan to request priority review of our BLA. We continue to believe PolyHeme satisfies the stated criteria for priority review based on its potential to address an unmet medical need.

RECENT DEVELOPMENTS

There has been considerable public interest this year in the entire field of hemoglobin-based oxygen carriers, or HBOCs. In April 2008, a paper was published in the *Journal of the American Medical Association* describing a statistical assessment called meta analysis that pooled data from multiple clinical trials with multiple different HBOC products used in a variety of clinical settings. Although meta analysis is not designed to assess individual treatments, the authors concluded that all current HBOCs had unacceptable safety profiles and that no further clinical trials should be conducted. Another paper was published in April 2008 in *Circulation* assessing the interaction of hemoglobin and nitric oxide in both small and large animals. The authors concluded that some of the vasoactive or hemodynamic effects observed with certain HBOCs could be ameliorated by the inhalation of nitric oxide prior to and during infusion. Lastly, there was a two day public Workshop sponsored by FDA and National Institutes of Health, or NIH, in April 2008 to discuss the safety and future development of HBOCs. The program included presentations of clinical data by all sponsors developing HBOCs, including Northfield, as well as discussions of the basic science of hemoglobin, and the interactions of hemoglobin and nitric oxide. There was also interest in the potential role of nitric oxide donors, such as nitrite infusions, inhaled nitric oxide, or s-nitrosylation of hemoglobin, when administered with HBOCs. Northfield has begun to collaborate with investigators in the field of nitric oxide biology to explore some of these issues with regard to PolyHeme.

A number of key scientific papers were published during the year addressing the safety of blood as well as HBOCs. Several of these studies reported that many of the cardiovascular adverse events experienced in HBOC trials also occur in patients who receive blood transfusions. In fact, the role of nitric oxide for both blood and HBOCs, and the significance of the age of stored blood in relation to safety, are now of great interest to the transfusion medicine community.

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. Ambulatory surgery centers and emergicenters may also experience circumstances of unplanned hemorrhage in which 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 assessment performed for Northfield by an independent market analysis firm of the potential market opportunity for PolyHeme, using a variety of primary and secondary sources along with original research, indicated a potential market opportunity in the United States for PolyHeme s initial indication of unavailability in excess of 350,000 units per year, representing an estimated market value of $400 to $500 million. In addition, the global opportunity for our initial indication, as well as multiple other potential indications, is estimated to be six to seven times the U.S. unavailability projection, or $2 to $3 billion.

MANUFACTURING AND MATERIAL SUPPLY

We use a proprietary process of separation, filtration, chemical modification, purification and formulation to produce PolyHeme. We have produced PolyHeme for use in our clinical trials in our pilot manufacturing facility in Mt. Prospect, Illinois. Our pilot manufacturing facility was first opened in 1990 with a design capacity to produce up to 10,000 units of PolyHeme per year. At the time, it was Northfield s plan to use the pilot facility for research and development purposes and the manufacture of clinical supplies under the appropriate current Good Manufacturing Practices, or cGMP, with future commercial scale manufacturing being performed in a new facility. Our current plan is to seek FDA approval for use of the pilot plant as our initial commercial manufacturing site, to be followed by expansion at a later date. The cGMP requirements for commercial manufacturing have evolved considerably over the past two decades and we have made multiple improvements and updates to our pilot facility in an effort to maintain compliance. These upgrades have consumed and continue to consume considerable time, effort and expense. We anticipate that the final capacity of this pilot facility will be approximately 5,000 to 7,500 units per year.

Upon approval for the commercial sale of PolyHeme we presently plan 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 expect to construct our expanded commercial manufacturing facility at this site. In addition to manufacturing operations, we expect that the facility will also house 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 KABIVITRUM AB, a Swedish corporation which was later acquired by 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. Following an update from Northfield and internal analysis, Pfizer has communicated that the product does not fit within their corporate strategies and that Pfizer would not participate in any clinical or commercialization activities. We are currently finalizing the termination of the license issued to Pfizer. Northfield does not anticipate any significant cash needs to terminate this license.

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

Our present plans with respect to the marketing and distribution of PolyHeme in the United States and overseas may change significantly based on the FDA regulatory process, the establishment of relationships with strategic partners, changes in the scale, timing and cost of our commercial manufacturing facility, competitive and technological advances, 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 when blood is not available 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 in June 2008 the Naval Medical Research Center submitted a new protocol for a Phase II clinical trial for resuscitation of operational casualties with severe traumatic hemorrhagic shock without availability of blood transfusions in comparison with Hextend. Subjects will sign an informed consent prospectively. Biopure announced in July it has also proposed to study use of Hemopure in patients suffering from Acute Myelogenous Leukemia (AML) who refuse transfusion with blood components.

As of July 1, 2008, Synthetic Blood International, Inc., changed its name to Oxygen Biotherapeutics Inc. They are developing a protocol for a Phase II-b clinical trial of Oxycyte in Traumatic Brain Injury. Oxycyte is a perfluorocarbon.

Sangart, Inc., a private company, has completed enrollment two parallel European Phase III trails 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 outcome of the 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

FDA Approval of Biological Products

The commercial 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 biological products, which includes PolyHeme. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act governs the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and 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 (1) preclinical testing, (2) submission to FDA of an Investigational New Drug application, (3) conduct of clinical trials in humans to establish the safety and effectiveness of the product, (4) submission to FDA of a BLA relating to the product and the manufacturing facilities to be used to produce the product for commercial sale, and (5) FDA approval of the BLA. We have completed steps (1) through (3) of this process, and are currently in the process of preparing a BLA in support of PolyHeme.

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. Typically, trial design protocols, trial endpoints, and the broad concepts for clinical indications those endpoints would support if reached are established in consultation with FDA. At the sponsor s request, FDA may reach agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in a BLA. This agreement is called Special Protocol Assessment or SPA.

We reached such an agreement with FDA regarding our Phase III study described above, but this does not guarantee that PolyHeme will be approved. Instead, it reflects agreement that the agency will not later alter its perspectives on the issues of design, execution, or analysis, unless previously unrecognized public health concerns come to light, other new scientific concerns regarding product safety or efficacy arise, FDA determines that we failed to comply with the protocol agreed upon, or data, assumptions, or information forming the basis of the agreement are determined to be inaccurate. In other words, assuming no unexpected change in circumstances, the agreement means that if the trial is conducted as planned *and is successful* it will provide evidence in support of product approval. Even after an SPA agreement is finalized, it may be changed by the sponsor or FDA on written agreement of both parties. Further, FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study subject to it.

As described previously, our Phase III trial did not reach the efficacy endpoints established in our SPA agreement. However, we believe that approval may still be possible based on extrapolation of the Phase III data to treatment settings that more accurately reflect our proposed indication, which is for use of PolyHeme when red blood cells are unavailable. There can be no assurance, however, that FDA will agree.

The results of preclinical and clinical testing are submitted to FDA from time to time throughout the trial process, and are then compiled for submission in support of a BLA, along with the details of the manufacturing process and product characterization. The BLA must also include various certifications, including a statement that applicable clinical trials were appropriately registered in the public database maintained by the National Institutes of Health (NIH), and were conducted in accordance with federal human subject protections. Each of the clinical sites that participated in our trials received IRB approval on the basis of satisfaction of applicable requirements for emergency research. Additionally, our clinical trials were appropriately registered on the NIH database. Accordingly, we do not anticipate difficulty with these components of the BLA submission. FDA has in recent years increased its scrutiny of clinical data, particularly with respect to compliance with good clinical practice standards. Although we monitored the sites where our Phase III study was conducted, FDA could review their practices and our data with potential negative consequences for our BLA.

After the BLA is submitted, FDA will engage in an initial review to determine whether all of the required elements are included; this is not a complete review of the merits of the application, but rather a threshold determination as to whether the information submitted to support licensure is sufficiently complete to permit a substantive and meaningful review. We will not submit our BLA unless we believe it to be complete, but there can be no assurance that the submission will be accepted for filing. If FDA deems the submission to be inadequate for review, as it did for our 2001 PolyHeme BLA, it will issue a refusal to file letter, or RTF, generally within 60 days of receiving the application. If an RTF is issued, there is opportunity for discussion with the agency to resolve all concerns, and it may be necessary to submit supplemental information. There can be no assurance that such discussion will be successful in leading to the filing of the BLA, however. Further, even if the submission is filed, there can be no assurance that full review will result in product approval.

During the filing review, FDA will also decide whether to categorize the BLA as standard or eligible for priority review. We intend to seek priority review status, which may be granted to products that are safe and effective where no alternative therapy exists, or that offer major advances in treatment. We believe that PolyHeme satisfies the criteria for this designation based on its potential to improve patient survival in circumstances where red blood cells are unavailable. FDA has committed to review and act on 90% of priority BLA submissions within 6 months of receipt, as opposed to 10 months for standard review applications. However, these timeframes are not binding on FDA. Amendments to the application may alter the review schedule, even when required by FDA, and the 6 or 10 month goal is only for a complete response to the application, in which the agency may approve the product, or simply request additional information. We cannot guarantee that the agency will grant priority review and cannot predict what impact, if any, priority review will have on the review schedule for PolyHeme. Further, priority review does not ensure that FDA will ultimately approve PolyHeme.

Ultimately, we will need to satisfy FDA that PolyHeme is safe, pure, and potent (*i.e.*, safe and effective) for the proposed use. 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. 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. We cannot be certain when the definitive guidance will be issued by FDA or what effect, if any, the guidance will have on approval of PolyHeme. It is possible that, as a result of more 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, delaying or preventing approval of our BLA.

In addition to the submission of adequate study data, part of meeting the standard for approval of biological products involves satisfying FDA that manufacturing procedures and quality controls conform to statutory and regulatory requirements. Prior to granting approval, FDA generally conducts an inspection of the facilities, including outsourced facilities that will be involved in the manufacture, production, packaging, testing and control

of the product for compliance with current Good Manufacturing Practices, or cGMP. FDA will not approve the application unless cGMP compliance is satisfactory. Once the product is approved, domestic manufacturing facilities are also subject to biennial FDA inspections, and foreign manufacturing facilities are subject to periodic FDA inspections or inspections by foreign regulatory authorities with reciprocal inspection agreements with FDA.

Additional preclinical studies, clinical trials, or manufacturing data may be requested during the FDA review process, which may significantly delay, or preclude, product approval. Further, when deciding whether to approve the PolyHeme BLA, FDA will likely seek the opinion of an advisory committee comprised of outside experts. Advisory committees vote on specific questions posed by the agency about scientific or medical questions raised by potential new products, like PolyHeme. Although advisory committees do not bind FDA, the agency generally follows committee recommendations.

Once FDA has completed its review, it may approve the BLA and license the product for marketing for a specific use. Alternatively, as noted above, if it determines that it will not approve the application in its present form, the agency may issue a complete response letter describing all the deficiencies it has identified, as well as actions the applicant can take to repair the BLA. Upon receipt of a complete response letter, the applicant must either resubmit the application addressing all identified deficiencies or withdraw the application. We cannot predict what deficiencies the agency may identify in our BLA for PolyHeme, or whether the necessary remedial actions will be feasible or acceptable to the company.

As a condition of approval, the agency may require post-approval testing and surveillance to monitor the product s safety or efficacy and may impose other conditions, including labeling and distribution restrictions, which can involve significant expense and materially impact the product s potential market and profitability. Once granted, product approvals may be withdrawn or restricted if compliance with regulatory standards, including those related to manufacturing, record keeping, safety reporting, and marketing, is not maintained, or if problems with the product are subsequently identified. Should a sponsor seek to market the product for a new use, a new BLA, and supportive clinical trials, will be required.

The Food and Drug Administration Amendments Act of 2007

As part of a sweeping initiative aimed at improving the safety of medical products regulated by FDA, Congress enacted the Food and Drug Administration Amendments Act of 2007, or FDAAA, in September 2007. Among other things, FDAAA imposed the following changes:

Clinical Trial Registration and Results Posting. Certain information about clinical trials must be submitted to NIH, including a description of the trial, participation criteria, location of trial sites, and contact information. In September 2008, the law will require that certain results information be submitted. Because our clinical trials conducted to date were completed in 2006, they are not subject to the new law, although they were registered under a pre-existing statute governing registration of controlled trials testing treatments for serious or life-threatening conditions. Future trials conducted in the course of developing PolyHeme will be subject to FDAAA s more burdensome registration and results posting requirements. Compliance must be documented in various agency submissions, including the currently planned BLA. Failure to comply may result in significant civil penalties.

Postmarketing Studies and Clinical Trials. Before or after approving a BLA, FDA may require the conduct of post-approval studies or clinical trials to investigate a known serious risk, assess signals of serious risk, or identify an unexpected serious risk when data indicate the potential for such risk. Post-approval requirements under the new law may be based on information about other products that are chemically or pharmacologically related, but if imposed after approval, must be based on new safety information, broadly defined to include

new analyses of existing information. Further, a post-approval study may be required only if FDA determines that the new active postmarket risk identification system (also created by FDAAA) and the existing passive adverse event reporting system are inadequate. In light of the fact that we are seeking approval of PolyHeme on the basis of a single pivotal efficacy study, it is possible that FDA will require one or more post-approval studies or trials, which may require substantial expense. Significant civil fines may be imposed for noncompliance.

Risk Evaluation and Mitigation Strategies (REMS). FDAAA authorizes FDA, before or after approving a BLA, to require submission of a REMS if necessary to ensure that the benefits of the product outweigh the

risks. A REMS may include a medication guide to provide better information to consumers about the product s risks and benefits, a plan for communication with healthcare providers, restrictions on a product s distribution, or a safety registry. Sponsors of products subject to a REMS are required to submit periodic assessments of the strategy at specified intervals, and again, face significant penalties for failure to comply. FDA s REMS authority supplements the agency s previous authority to negotiate risk minimization action plans (RiskMAPs) to minimize known and preventable safety risks or otherwise impose burdens, such as limits on prescribing, distribution, or direct-to-consumer advertising, on an applicant s ability to commercialize its product. A REMS could significantly impact the marketability of PolyHeme.

Best Pharmaceuticals for Children Act/Pediatric Research Equity Act. FDAAA reauthorized FDA to require pediatric testing of certain drugs. PolyHeme was not tested in pediatric patients, and, under FDAAA, we could be required to conduct post-marketing studies in pediatric patients.

Foreign Approvals

We are also exploring the potential to seek regulatory approval of PolyHeme outside the United States, where we would be subject to foreign regulatory requirements governing clinical trials, marketing approval, and reimbursement for medical products. This may involve licensing or other arrangements with other foreign or domestic companies. To date, we have not conducted any foreign clinical trials of PolyHeme.

Foreign requirements applicable to the licensure, marketing, and pricing of PolyHeme may differ substantially from those imposed and enforced by FDA. Approval of PolyHeme by FDA does not guarantee approval abroad.

PATENTS AND PROPRIETARY RIGHTS

Seven of our United States patents, including our broadest United States patent, have expired. With the issuance in 2007 of two new patents, we now own five 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 2008. Earlier this year, however, PTO reversed its previous decision on the basis that PolyHeme was no longer under continuous development in light of the length of time that had expired without product approval after FDA s original Refusal to File decision in 2001. In fact, during the intervening period, we conducted a Phase III pivotal study to address the identified deficiencies, and are currently preparing a BLA submission for 2008. We believe that this constitutes the requisite due diligence in seeking regulatory approval necessary to retain eligibility for interim patent term extension, and are currently evaluating our options to appeal PTO s determination. We cannot ensure that we will be successful in recovering this patent protection, however, and if we are, we cannot be certain that any additional extensions will be granted. In any event, no extensions of this patent 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.

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 2008 and 2007, our research and development expenses totaled $15,916,000 and $21,060,000, respectively. We anticipate that our research and development expenses will decrease significantly once our BLA is submitted to FDA.

HUMAN RESOURCES

As of August 1, 2008, we had 91 employees, of whom 78 were involved in research and development and thirteen 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, 2008 we have incurred net operating losses totaling $220,216,000. 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.

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

As of May 31, 2008, we had cash and cash equivalents of approximately $21 million. We are currently utilizing our cash resources at a rate of approximately $20 million per year, and we expect to maintain this rate of cash utilization through the submission of our BLA to FDA. We anticipate that our existing financial resources will be adequate to permit us to continue to conduct our business only for the next 11 to 13 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 is likely to result in significant dilution to our existing stockholders. The opinion of our independent accountants with respect to our audited financial statements for our fiscal year ended May 31, 2008 includes an explanatory paragraph regarding the continuation of our company as a going concern. In addition, we are subject to a putative class action lawsuit alleging violations of the federal securities laws. This matter involves 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.

We anticipate submitting our BLA to FDA in the fourth calendar quarter of 2008. Our BLA will include information related to our clinical and preclinical studies as well as information relating to the chemistry, manufacturing and controls, or CMC, involved in the manufacture of PolyHeme. The preparation of a BLA is a complex and time-consuming process; we have already experienced delays 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 review, and potential approval for commercial sale, will also be delayed.

We intend to seek priority review of our BLA, but there can be no assurance that FDA will classify the application as priority. In fact, there can be no assurance that the submission will be accepted for filing. FDA may issue a refusal to file letter, or RTF, if it believes the filing is inadequate or incomplete. FDA previously issued an RTF for our BLA submitted in 2001, which was based on data from our prior Phase II trauma trials in the hospital setting only. Subsequent discussion with FDA resulted in the mutual decision to proceed with our pivotal Phase III trial, which FDA agreed would satisfy the standards for approval of PolyHeme, if successful. That agreement, reached as part of a special protocol assessment, or SPA, is not a guarantee of approval, however, since new concerns about safety and efficacy have arisen, as described below.

The clinical section of the BLA will include the results of our Phase III trial and the results of our prior clinical trials of PolyHeme. The primary efficacy endpoint of the Phase III trial was a dual superiority-noninferiority assessment of mortality at 30 days after injury. The results did not achieve the primary efficacy endpoint in the primary patient population as specified in the protocol. Further, although there was no statistically significant difference between the

PolyHeme and control group for any of the primary safety endpoints for our trial, statistically significant differences favoring the standard of care were observed with respect to certain secondary safety endpoints, including the incidence of myocardial infarction. Based on these results, there can be no assurance that the data will be sufficient to demonstrate the safety and effectiveness of PolyHeme for purposes of obtaining FDA approval.

Preclinical testing included extensive in-vitro and in-vivo studies of PolyHeme to assess product pharmacology and toxicology. These studies varied greatly with regard to animal species, protocol and product dosing, concomitant study drugs, and the timing and nature of the observations and measurements. Some of these studies have shown species dependent abnormalities in certain laboratory findings, including increases in aspartate aminotransferase, bilirubin, blood urea nitrogen, chromaturia, glucose, and troponin, and certain abnormal microscopic findings, including renal tubular proteinosis, Kupffer cell hypertrophy, karyomegaly, histiocytosis, cellular degeneration, and inflammation in organs such as the kidney, liver, or heart. These abnormalities were largely reversible and there was no evidence of organ failure. The clinical relevance of these findings is unclear when extrapolated to the human setting. There can be no assurance that these preclinical data will be considered sufficient for FDA approval.

The BLA also addresses CMC issues. Our pilot manufacturing facility was first opened in 1990 with a design capacity to produce up to 10,000 units of PolyHeme per year. At the time it was Northfield s plan to use the pilot facility for research and development purposes and the manufacture of clinical supplies under the appropriate current Good Manufacturing Practices, or cGMP, with future commercial scale manufacturing being performed in a new facility. Our current plan is to seek FDA approval for use of the pilot plant as our initial commercial manufacturing site, to be followed by expansion at a later date. The cGMP requirements for commercial manufacturing have evolved considerably over the past two decades and we have made multiple improvements and updates to our pilot facility, all of which required subsequent validation, in order to confirm cGMP compliance. These upgrades have consumed and continue to consume considerable time, effort and expense. We anticipate that the final capacity of this pilot facility will be approximately 5,000 to 7,500 units per year. There can be no assurance that the pilot facility will be considered to be in compliance with cGMP requirements.

FDA review includes a balance of risks and benefits, but the current regulatory climate is shaped by heightened pressure on FDA from the public and Congress following high profile safety concerns about certain pharmaceutical products. FDA has become increasingly risk-averse, requiring even more substantial benefits to outweigh potential safety concerns. We believe that PolyHeme could offer substantial benefits to patients in the absence of red blood cells for transfusion. If approved, PolyHeme would be the first hemoglobin-based oxygen carrier for human use to receive FDA approval. We recognize, however, that our Phase III study did not fully reflect the patient population for whom PolyHeme may be most appropriate and that the data are therefore susceptible to varying interpretations. As a result, there is no guarantee that an agency focused more heavily on product safety risks will be willing to extrapolate an acceptable risk-benefit profile from the urban setting of our pivotal clinical trial, particularly in light of potential safety signals.

FDA may accordingly refuse to approve PolyHeme for commercial sale, and may require us to conduct additional clinical trials of PolyHeme in order to obtain approval. Alternatively, FDA may be willing to approve PolyHeme on the basis of available evidence, but may significantly limit the indication for which it may be marketed, impose additional restrictions through a Risk Evaluation and Mitigation Strategy, or REMS, or require substantial postmarketing commitments to evaluate the use of PolyHeme in additional settings where it may be used or in additional patient populations, such as children . Any of these alternatives could impede access, raise costs and reduce the ability of Northfield to recoup investments. Additionally, in order to market PolyHeme for any additional uses in the United States, we will be required to obtain approval of a separate BLA, which will require the design and conduct of additional clinical trials, and will involve all of the uncertainties described above.

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. Even if we submit our BLA during the fourth calendar quarter of 2008, FDA s increasing focus on drug safety may lead to a substantial delay in obtaining FDA approval of PolyHeme. A 2007 study conducted by an independent research organization found that product approvals have been increasingly delayed by FDA requests for additional safety and other data. FDA also

faces an increased workload following many new responsibilities imposed by the Food and Drug Administration Amendments Act of 2007, and these factors have combined to result in longer periods of time to approve new products. In this environment, we anticipate that PolyHeme s approval, if it occurs at all, may take significantly longer than the six month goal established by FDA for priority review products.

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.

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 (as well as that of our collaborators) are, and will continue to be, subject to extensive regulation, monitoring, and approval by FDA and other government agencies, potentially in ways that we cannot currently predict. 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 resources.

We have taken advantage of Special Protocol Assessment, or SPA. 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 come 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.

Before we can market PolyHeme for any use in the United States, and for each subsequent indication, we must submit a BLA. Once we have prepared an application that we believe satisfies the statutory and regulatory standards for approval, there are many junctures at which the application may be delayed or fail. FDA may refuse to file the application, may refuse to designate the application for priority review, or may not be satisfied that PolyHeme is safe, pure, and potent, as a result of inadequate support from clinical trials, or concerns about our manufacturing facilities. The timing of each of these decisions is uncertain, and even after extensive clinical trials, there is no assurance that regulatory approval will ever be obtained for PolyHeme, particularly in light of FDA s current conservative approach to risk.

Moreover, if regulatory approval of PolyHeme is granted, it may be heavily constrained by FDA s focus on drug safety, and the authorities granted FDA by the Food and Drug Administration Amendments Act. Approval may be authorized only for a narrow indication, which will limit the ability to market PolyHeme, and FDA may also require post-approval studies or REMS in order to protect patients, further limiting access and requiring substantial investments of company time and resources. If these studies, clinical experience and required adverse event reporting, additional trials to support new indications, or even meta-analyses made possible through FDAAA s clinical trial disclosure requirements, demonstrate new risks, FDA may further restrict the approval of PolyHeme, or withdraw approval altogether. Additional laws and regulations may also be enacted which could prevent or delay regulatory approval of PolyHeme, and/or negatively impact post-approval marketing, including laws or regulations relating to the price or cost-effectiveness of medical products. Any of these scenarios are likely to have a material adverse effect on our financial condition.

Further, the manufacturing, testing, distribution, labeling, packaging, storage, advertising, promotion, reporting and record-keeping related to PolyHeme will also be subject to extensive ongoing regulatory requirements following approval. Among other things, we will be required to comply with current good manufacturing practices, adverse event reporting requirements, and FDA s general prohibitions against promoting products for unapproved or off-label uses. We are also subject to inspection and market surveillance by FDA for compliance with these and other requirements. Any enforcement action resulting from failure, even by inadvertence, to comply with these requirements, or those imposed in the future, could negatively affect the manufacture and marketing of 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. Although we have made substantial ongoing investments in the maintenance of our manufacturing facility, there can be no assurance that the we will not experience disruptions in our use of the facility due to age or condition of our facility. In addition, 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, destroyed or becomes inoperable 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.

Our pilot manufacturing facility was first opened in 1990 with a design capacity to produce up to 10,000 units of PolyHeme per year. At the time it was Northfield s plan to use the pilot facility for research and development purposes and the manufacture of clinical supplies under the appropriate current Good Manufacturing Practices, or cGMP, with future commercial scale manufacturing being performed in a new facility. Our current plan is to seek FDA approval for use of the pilot plant as our initial commercial manufacturing site, to be followed by expansion at a later date. The cGMP requirements for commercial manufacturing have evolved considerably over the past two decades and we have made multiple improvements and updates to our pilot facility in an effort to confirm compliance. These upgrades have consumed and continue to consume considerable time, effort and expense. We anticipate that the final capacity of this pilot facility will be approximately 5,000 to 7,500 units 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 an expanded commercial manufacturing facility at this site if FDA approval for the marketing of PolyHeme is received. 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 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.

Further, the regulatory climate for follow-on or generic versions of biological products approved under a BLA in the United States remains uncertain. Currently, there is no established statutory or regulatory pathway for the abbreviated approval of follow-on versions of biological products approved under a BLA, meaning that even after our intellectual property protections expire, a company seeking to market a copy of PolyHeme would have to conduct its own clinical trials and submit a completely independent BLA. However, members of Congress have expressed increasing interest in legislation to establish a statutory path for follow-on biological products. At this time, we cannot know with certainty when any such process may be adopted, or how it might affect our intellectual property rights, but any such process has the potential to have a material effect on PolyHeme s commercial success.

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, which are subject to significant regulations not applicable to the sale and marketing of other types of goods and services. PolyHeme may only be marketed and promoted for its approved use(s), and our sales force will be subject to a variety of regulatory and industry restrictions on their ability to aggressively pursue potential customers. If our sales and marketing teams fail to comply with these restrictions, we could be subject to significant liability.

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 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 have historically provided incentive compensation to our officers and employees in part

through grants of stock options and restricted stock under our equity compensation plans. Decreases in the trading price of our common stock, however, have substantially reduced the value of equity compensation awards made to our officers and employees in prior years. Our ability to provide competitive compensation to our officers and employees may also be adversely affected by our limited capital resources and anticipated need to raise substantial additional capital to continue our business. We cannot ensure that we will be

able to retain existing employees or to attract and retain additional skilled personnel on acceptable terms as a result of these factors as well as 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 with Pfizer Inc. and Hemocare Ltd., an Israeli corporation, to develop, manufacture and distribute PolyHeme in certain European, Middle Eastern and African countries. Following an update from Northfield and internal analysis, Pfizer has communicated that the product does not fit within their corporate strategies and that Pfizer would not participate in any clinical or commercialization activities. We are currently finalizing the termination of the license issued to Pfizer. Northfield does not anticipate any significant cash needs to terminate this license.

The license agreements permit Hemocare to sell PolyHeme in return for the payment of royalties based upon sales of PolyHeme in the licensed territories. In order for 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.

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.

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, 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.

We and Dr. Steven A. Gould, Northfield s Chief Executive Officer, and Richard De Woskin, Northfield s previous 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 March 19, 2001 to March 20, 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 is ultimately resolved in favor of Northfield, Northfield still may incur substantial legal fees and expenses in defending the lawsuit.

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 was extended by the United States Patent Office to 2007. Earlier this year, however, PTO reversed its decision on the basis that PolyHeme was no longer under continuous development in light of the length of time that had expired without product approval after FDA s original Refusal to File decision in 2001. During the intervening period, we conducted our pivotal Phase III trial, and are currently preparing a BLA submission for 2008. We believe that this constitutes the requisite due diligence in seeking regulatory approval necessary to retain eligibility for interim patent term extension, and are currently evaluating our options to appeal PTO s determination. We cannot ensure that we will be successful in recovering this patent protection, and if we are, we cannot be certain that any additional extensions will be granted. In any event, no extensions for this patent are possible beyond 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 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.

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.

We have received notice that our common stock may be delisted from the Nasdaq Global Market unless we are able to achieve compliance with Nasdaq s minimum bid requirement.

Our common stock currently trades on the Nasdaq Global Market. In June 2008, we received notice from the Nasdaq Stock Market that for 30 consecutive business days our share price had closed below the minimum $1.00 per share requirement for continued inclusion under Marketplace Rule 4450(a)(5). In accordance with Marketplace Rule 4450(e)(2), we have until December 8, 2008 to regain compliance. The Nasdaq notice stated that if, at any time before December 8, 2008 the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, or such longer period as may be required under Market Place Rule 4450(e)(2), the Nasdaq staff would provide written notification that we had achieved compliance with the minimum bid requirement. Through August 14, 2008, we have not achieved compliance with the minimum bid requirement and there can be no assurance that we will be able to achieve compliance before December 8, 2008.

The Nasdaq notice also indicated that if we do not regain compliance by December 8, 2008, the Nasdaq staff will provide written notification that our common stock will be delisted from the Nasdaq Global Market. At that time, we may appeal the staff s determination to the Nasdaq Listing Qualifications Panel. Alternatively, we would be permitted to apply to transfer our common stock to the Nasdaq Capital Market if we satisfy the requirements for initial inclusion set forth in Marketplace Rule 4310(c), other than the minimum bid price requirement, at that time. If our application is approved, we would be afforded an additional period of up to 180 calendar days in which to regain compliance while our common stock is traded on the Nasdaq Capital Market. If we fail to achieve compliance during this period while our common stock is traded on the Nasdaq Capital Market, Nasdaq may fully delist our common stock. Following full delisting, our common stock would trade on an over-the-counter basis and would not be listed or traded on any securities exchange.

The delisting of our common stock from the Nasdaq Global Market is likely to reduce the trading volume and liquidity in our shares and may lead to further decreases in the trading price of our shares. Similar reductions in trading volume, liquidity and trading price are likely to occur if our shares are fully delisted from Nasdaq and begin trading in the over-the-counter market. The delisting of our shares may also prevent investors from purchasing shares of our common stock using margin loans provided by brokers or other financial institutions.

Our ability to raise additional equity capital, which is critical to the continuation of our business, would also likely to be adversely affected by the delisting of our common stock from the Nasdaq Global Market or the Nasdaq Capital Market.

Our board of directors may consider possible actions, such as a reverse stock split, combination of shares, or other recapitalization transaction, in order to increase the trading price of our common stock to achieve compliance with Nasdaq s minimum bid requirement. At our annual meeting of stockholders to be held on October 2, 2008, it is expected that our stockholders will be asked to consider and approve a resolution authorizing our board of directors to amend our certificate of incorporation to effect a reverse split of our common stock. If the proposal is approved by our stockholders, our board of directors would be authorized to effect a reverse split of our common stock in a range of

between three and seven pre-split shares for each post-split share. Our board of directors would be given the discretion whether to implement the reverse stock split and, if implemented, to determine the number of pre-split shares, within the foregoing range, to be combined into each post-split share. There can be no assurance that our stockholders will approve the proposal to effect a reverse split of our common stock or, if approved by our stockholders, that our board of directors will determine that it is advisable to effect such a split. If a reverse stock split is completed, there can also be no assurance that the trading price of our common stock will increase as a result of the split or that the split will permit us to achieve compliance with Nasdaq s minimum bid requirements.

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.

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 2008 fiscal year was $442,959.

We currently operate a pilot manufacturing facility in Mt. Prospect, Illinois. If we receive FDA approval for the commercial sale of PolyHeme we presently plan 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, we expect that the facility will also house 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.***

Between March 17, 2006 and May 15, 2006, ten separate complaints were filed, each purporting to be on behalf of a class of the Company s shareholders, against the Company and Dr. Steven A. Gould, the Company s Chief Executive Officer, and Richard DeWoskin, the Company s former Chief Executive Officer. Those putative class actions were 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 on September 8, 2006, and alleged, among other things, that during the period from March 19, 2001 through March 20, 2006, the named defendants made or caused to be made a series of materially false or misleading statements and omissions about the Company 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 there under, and Section 20(a) of the Exchange Act. Plaintiffs alleged that those allegedly false and misleading statements and omissions caused the purported class to purchase the Company s common stock at artificially inflated prices. As relief, the complaint sought, 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 Company and the individual defendants filed a motion to dismiss the complaint, and on September 25, 2007, the court granted that motion, finding that the plaintiffs

failed to state a claim. The court dismissed the complaint without prejudice, and on November 20, 2007, the plaintiffs filed a Consolidated Second Amended Class Action Complaint. On January 22, 2008, the Company filed a motion to dismiss, and the briefing of that motion was completed on June 26, 2008. The fully briefed motion to dismiss currently is pending before the court. The putative class action is at an early stage and it is not possible to predict the outcome.

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

None.

PART II

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

MARKET INFORMATION

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 28, 2006	$ 14.45	$ 8.86
May 31, 2006	11.30	8.62
August 31, 2006	13.10	8.06
November 30, 2006	16.36	10.29
February 28, 2007	17.94	3.73
May 31, 2007	5.93	1.36
August 31, 2007	1.76	1.00
November 30, 2007	3.08	.75
February 29, 2008	1.35	.95
May 31, 2008	1.20	.76
August 31, 2008 (through July 31, 2008)	.96	.37

STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total return on our common stock from May 31, 2003 through May 31, 2008 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, 2003, 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, 2003, 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.

HOLDERS OF RECORD

As of August 1, 2008, there were approximately 500 holders of record and approximately 16,000 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, 2008.

RECENT SALES OF UNREGISTERED SECURITIES

We did not make any unregistered sales of our common stock during our 2008 fiscal year.

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, 2008 and for the cumulative period from June 19, 1985 (inception) through May 31, 2008 were derived from Northfield s financial statements.

	Years Ended May 31,					Cumulative June 19, 1985 through May 31,
	2008	2007	2006	2005	2004	2008
	(In thousands, except per share data)					
Statement of Operations Data:						
Revenues:						
License income	$					$ 3,000
Costs and expenses:						
Research and development	$ 15,916	$ 21,060	$ 24,165	$ 16,600	$ 10,777	$ 184,757
General and administrative	5,812	9,374	5,832	4,990	3,854	70,463
Interest income (net)	1,320	2,763	3,222	1,268	131	32,078
Net loss	$ (20,409)	$ (27,671)	$ (26,775)	$ (20,322)	$ (14,574)	$ (220,216)
Net loss per share basic and	$ (.76)	$ (1.03)	$ (1.00)	$ (0.88)	$ (0.86)	$ (16.67)
Shares used in calculation of per share data(1)	26,955	26,906	26,770	23,069	16,932	13,214
Balance Sheet Data:						
Cash and marketable securities	$ 20,726	$ 40,158	$ 72,984	$ 98,131	$ 42,487	
Total assets	29,985	50,119	75,871	100,002	44,179	
Total liabilities	3,003	4,777	6,534	4,228	2,626	
Deficit accumulated during development stage	(220,216)	(199,808)	(172,136)	(145,361)	(125,040)	
Total shareholders equity	26,982	45,342	69,337	95,774	41,553	

(1) Computed on the basis described in Note 1 of the Notes to Financial Statements. Excludes 2,090,125 shares reserved for issuance upon the exercise of stock options and 115,418 shares reserved for issuance for stock warrants as of May 31, 2008. Additional stock options for a total of 526,000 were available for grant as of May 31, 2008 under our employee stock option plans.

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

RECENT DEVELOPMENTS

We are presently preparing a Biologics License Application, or BLA, for our PolyHeme red blood cell substitute, for submission to the Food and Drug Administration, or FDA. We anticipate submitting our BLA to FDA during the

fourth calendar quarter of 2008. We also plan to submit a request for 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.

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, 2008, we have incurred operating losses totaling approximately $220,216,000.

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, 2008 or 2007. From Northfield s inception through May 31, 2008, 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, 2008 and 2007 totaled $21,729,000, and $30,434,000, respectively. Measured on a percentage basis, fiscal 2008 operating expenses decreased from fiscal 2007 expenses by 28.6%.

During fiscal 2008, research and development expenses totaled $15,916,000, a decrease of $5,144,000, or 24.4%, from fiscal 2007 expenses of $21,060,000. During fiscal 2007, we concluded enrollment in our pivotal Phase III trial. While clinical costs associated with the trial decreased during fiscal 2008, our efforts to prepare our BLA for PolyHeme to be submitted to FDA and to ready our manufacturing facility, increased, which offset a portion of the decline. The reduction in research and development costs was also driven by $3,500,000 in federal grant funding that was used to offset operating expenses at our manufacturing facility throughout the fiscal year.

We anticipate a continued high level of research and development spending in fiscal 2009. Preparing our BLA for PolyHeme to be submitted to FDA will continue through fiscal 2009. 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 maintain the use of external resources to complete these tasks in a timely manner.

General and administrative expenses for the 2008 fiscal year totaled $5,812,000, a decrease of $3,562,000, or 38.0%, from the expenses incurred in the prior fiscal year. We experienced a significant decrease in professional fees following the completion of our response to voluntary requests for information received for the Securities and Exchange Commission and Senate Finance Committee in March 2006. Northfield also saw a reduction in public relations expense during fiscal 2008. Additionally there was a decrease in share based compensation expense in fiscal 2008 compared to fiscal 2007. Executive compensation decreased because there were no bonuses paid during fiscal 2008. We anticipate our general and administrative expenses will remain consistent in fiscal 2009.

INTEREST INCOME

Interest income in fiscal 2008 equaled $1,320,000 compared to $2,763,000 in fiscal 2007. 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 5.2% for money-market investments and 5.2% for high quality one year securities. Money market rates in May 2008 were approximately 1.98% and high quality three-month securities were also around 2.03%. As our current investments mature, they will be rolled over until the funds are required for our business.

With declining available cash resources we anticipate that in the absence of a major cash infusion, interest income will decline in fiscal 2009. 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, 2008 was $20,409,000, or $.76 per share, compared to a net loss of $27,671,000, or $1.03 per share, for the fiscal year ended May 31, 2007. The decrease in net loss was primarily driven by a reduction in outside clinical expenses of $3,900,000. The reduction in net loss was also driven by $3,500,000 in federal grant funding that was used to offset operating expenses at our manufacturing facility throughout the year. 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 decrease in net loss was further driven by a decrease in share based compensation expenses and professional service fees.

LIQUIDITY AND CAPITAL RESOURCES

From Northfield s inception through May 31, 2008, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of $223,537,000. For the fiscal years ended May 31, 2008 and 2007, these cash expenditures totaled $19,953,000 and $34,969,000, respectively. The fiscal 2008 decrease in cash utilization is due to the purchase of our manufacturing facility in fiscal 2007 for $6,700,000. The decrease in cash utilization was also driven by a reduction in payments of outside clinical expenses.

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, 2008, we had cash and marketable securities totaling $20,726,000. 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, 2008, we have received all of these funds.

We are currently utilizing our cash resources at a rate of approximately $20 million per year. We expect the rate at which we utilize our cash resources will remain constant in fiscal 2009 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 11 to 13 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 status of the FDA review of our BLA submission, as well as general conditions in the business and financial markets.

We cannot ensure that we will be able to achieve product revenues or profitability on a sustained basis or at all. As a result, our independent accountants have included an explanatory paragraph in their audit opinion based on uncertainty regarding our ability to continue as a going concern. Our capital requirements may vary materially from those now anticipated because of the timing and results of our clinical testing of PolyHeme, the establishment of relationships with strategic partners, changes in the scale, timing or cost of our 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.

SHARE-BASED COMPENSATION

Effective June 1, 2006, we adopted SFAS No. 123R, Share-Based Payment. We elected to use the modified prospective application of SFAS No. 123R for awards issued prior to June 1, 2006. Income from continuing

operations before income tax for the years ended May 31, 2007 and 2008, includes total expense recognized for all of our stock-based payment plans.

The fair value of stock options granted under the stock incentive plans is estimated on the date of grant based on the Black-Scholes option pricing model. We utilize our own historical stock price movement as its basis for our calculated expected volatility factor. We use historical data to estimate stock option exercise and employee departure behavior used in the Black-Scholes option pricing model. The expected term of stock options granted represents the period of time that stock options granted are expected to be outstanding. The risk-free rate for the period within the contractual term of the stock option is based on the U.S. Treasury yield curve in effect at the time of grant.

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. As of May 31, 2008, we have recorded a 100% percent valuation allowance against our net deferred tax assets. 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.

CONTRACTUAL OBLIGATIONS

The following table reflects a summary of our contractual cash obligations as of May 31, 2008:

Contractual Obligations	Total	Less than One Year	1-3 Years
Lease Obligations(1)	$ 367,248	$ 367,248	
Other Obligations(2)	1,776,900	1,776,900	
Total Contractual Cash Obligations	$ 2,144,148	$ 2,144,148	

(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 three 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 Statement of Financial Accounting Standards (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. In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157,* which provides a one year deferral of the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. In accordance with FSP FAS No. 157-2, we will only adopt the provisions for SFAS No. 157 with respect to our financial assets and liabilities that are measured at fair value within the financial statements as of June 1, 2008.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations.* This Statement will replace SFAS No. 141, *Business combinations.* This Statement establishes principles and requirements for how the acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed and any non-controlling interest in the acquiree; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We plan to adopt this Statement on June 1, 2009. We do not believe that adoption of SFAS 157 will have a material effect on our 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 was effective for fiscal years beginning after December 15, 2006. We adopted this interpretation as required on June 1, 2007 (See note 5 to the consolidated 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 $20,726,000 at May 31, 2008 would decrease interest income by $207,000.

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

See the Table of Contents to Financial Statements on Page 38. See Note 10 to the Financial Statements on Page 57 for the Unaudited Supplementary Quarterly Data. These Financial Statements are incorporated by reference into this document.

ITEM 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.***

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, 2008 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, 2008. 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, 2008, 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.

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.

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, 2008, 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 38.

(3) See Description of Exhibits on page 59.

(b) See Description of Exhibits on page 59.

(c) None.

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

TABLE OF CONTENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors
Northfield Laboratories Inc.:

We have audited the accompanying balance sheets of Northfield Laboratories Inc. (a company in the development stage) as of May 31, 2008 and 2007, and the related statements of operations, shareholders equity (deficit), and cash flows for each of the years in the two-year period ended May 31, 2008, and for the cumulative period from June 19, 1985 (inception) through May 31, 2008. 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 generally accepted auditing standards as established by the Auditing Standards Board (United States) and in accordance with the auditing 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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, 2008 and 2007, and the results of its operations and its cash flows for each of the years in the two-year period ended May 31, 2008 and for the cumulative period from June 19, 1985 (inception) through May 31, 2008, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 1 to the financial statements, the Company has suffered recurring losses from operations and has insufficient capital resources to fund its continuing operations that raise substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

August 14, 2008

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

BALANCE SHEETS
May 31, 2008 and May 31, 2007

	May 31, 2008	May 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,746,540	23,224,026
Restricted cash	301,292	529,752
Marketable securities	7,979,830	16,934,204
Prepaid expenses	696,253	673,192
Other current assets		212,854
Total current assets	21,723,915	41,574,028
Property, plant, and equipment	19,747,948	19,588,246
Accumulated depreciation	(11,506,730)	(11,063,080)
Net property, plant, and equipment	8,241,218	8,525,166
Other assets	19,550	19,550
	$ 29,984,683	50,118,744
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,917,260	3,573,025
Accrued expenses	111,637	101,118
Government grant liability	301,292	529,752
Accrued compensation and benefits	658,012	565,709
Total current liabilities	2,988,201	4,769,604
Other liabilities	14,392	7,431
Total liabilities	3,002,593	4,777,035
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 26,960,233 at May 31, 2008 and 26,916,541 at May 31, 2007	269,602	269,165
Additional paid-in capital	246,954,375	244,905,543
Deficit accumulated during the development stage	(220,216,494)	(199,807,606)

		27,007,483	45,367,102
Less cost of common shares in treasury; 1,717 shares and 1,717 shares, respectively		(25,393)	(25,393)
Total shareholders equity		26,982,090	45,341,709
	$	29,984,683	50,118,744

See accompanying notes to financial statements.

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

STATEMENTS OF OPERATIONS
Years ended May 31, 2008 and 2007 and
the cumulative period from June 19, 1985
(inception) through May 31, 2008

	Years Ended May 31, 2008	2007	Cumulative from June 19, 1985 through May 31, 2008
Revenues license income	$		3,000,000
Costs and expenses:			
Research and development	15,916,141	21,059,618	184,756,957
General and administrative	5,812,451	9,374,395	70,462,746
	21,728,592	30,434,013	255,219,703
Other income and expense:			
Interest income	1,319,704	2,762,836	32,161,364
Interest expense			83,234
	1,319,704	2,762,836	32,078,130
Net loss before cumulative effect of change in accounting principle	(20,408,888)	(27,671,177)	(220,141,573)
Cumulative effect of change in accounting principle			74,921
Net loss	$ (20,408,888)	(27,671,177)	(220,216,494)
Net loss per share basic and diluted	$ (0.76)	(1.03)	(16.67)
Shares used in calculation of per share data basic and diluted	26,954,530	26,906,407	13,214,051

See accompanying notes to financial statements.

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

STATEMENTS OF SHAREHOLDERS EQUITY (DEFICIT)
Years ended May 31, 2008 and 2007 and the cumulative period from June 19, 1985 (inception) through May 31, 2008

	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.

Series A convertible preferred stock		Series B convertible preferred stock		Additional paid-in capital	Deficit accumulated during the development stage	Deferred compensation	Treasury shares	Total shareholders equity (deficit)
Number of shares	Aggregate amount	Number of shares	Aggregate amount					
	$		$	$ (28,000)	$	$		$ 7,000
250,000	250,000			670,850				920,850
					(607,688)			(607,688)
250,000	250,000			642,850	(607,688)			320,162
					(2,429,953)			(2,429,953)
				2,340,000		(2,340,000)		
						720,000		720,000
250,000	250,000			2,982,850	(3,037,641)	(1,620,000)		(1,389,791)
		200,633	200,633	6,882,502				7,083,135
					(3,057,254)			(3,057,254)
						566,136		566,136
250,000	250,000	200,633	200,633	9,865,352	(6,094,895)	(1,053,864)		3,202,226
				9,749,870				9,754,000
(250,000)	(250,000)			237,500				
		(200,633)	(200,633)	190,601				
				93,759				94,230
				4,976,855				4,978,610
				2,488,356				2,489,234
				7,443,118				7,443,118
					(791,206)			(791,206)
				683,040		(683,040)		
						800,729		800,729