NORTHFIELD LABORATORIES INC /DE/
Form 8-K
January 20, 2005

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

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

DATE OF REPORT: JANUARY 19, 2005

NORTHFIELD LABORATORIES INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Delaware	000-24050	36-3378733
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(COMMISSION FILE NO.)	(IRS EMPLOYER IDENTIFICATION NUMBER)

1560 Sherman Avenue
Suite 1000
Evanston, Illinois 60201-4800
(847) 864-3500
(ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER
INCLUDING AREA CODE OF REGISTRANT'S
PRINCIPAL EXECUTIVE OFFICES)

N/A
(FORMER NAME OR FORMER ADDRESS, IF CHANGED SINCE LAST REPORT)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

INFORMATION TO BE INCLUDED IN THE REPORT

ITEM 8.01. OTHER EVENTS

The following includes information that is contained in a prospectus supplement filed today by Northfield Laboratories Inc. in connection with a proposed public offering of its common stock and is being filed for the purpose of updating, supplementing and, where appropriate, superseding prior disclosures filed by Northfield under the Securities Exchange Act of 1934. See Exhibit 99.1.

BUSINESS OVERVIEW

Northfield Laboratories Inc. is a leader in the development of a safe and effective alternative to transfused blood for use in the treatment of acute blood loss. We are presently conducting a pivotal Phase III trial of our human hemoglobin-based blood substitute, PolyHeme(R). We believe PolyHeme has the potential to improve survival in critically injured patients and to thereby transform the treatment of trauma.

We are presently developing PolyHeme for a unique indication: the early treatment of urgent, life-threatening blood loss following trauma when donated blood may not be immediately available. We believe that this indication addresses a critical unmet medical need, since some trauma patients bleed to death before they have access to blood.

We are pursuing a unique regulatory strategy in order to seek Food and Drug Administration, or FDA, approval of PolyHeme. We are conducting the first-ever pivotal Phase III trial in the United States in which a human blood substitute is being used to treat severely injured and bleeding patients, beginning at the scene of injury and continuing during transport to the hospital and the early period of hospitalization. Because of the life-saving potential of PolyHeme, our trial is being conducted under a federal regulation, 21 CFR 50.24, that permits certain types of emergency research using an exception from the requirement for prospective informed consent by individual patients. Our current trial is based on our experience in prior clinical trials documenting the potential life-sustaining capability of PolyHeme when given in rapid, massive infusions to critically injured patients in the hospital.

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

As part of our trial protocol, an Independent Data Monitoring Committee, or IDMC, consisting of independent medical and biostatistical experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to continuation or modification of the trial protocol to minimize any identified risks to patients. The IDMC has completed its first two reviews of data on mortality and serious adverse events in the first 120 patients enrolled in the trial and has recommended that the trial continue without modification. This is the first time that a trial of a human blood substitute has passed this patient evaluation milestone in a high risk trauma population.

We believe that PolyHeme ultimately represents a substantial global market

opportunity, based on the need for a universally compatible, immediately available oxygen carrying product and PolyHeme's potential for eventual approval for multiple indications.

As of the date of this prospectus supplement, 16 clinical sites in the United States were enrolling patients in our pivotal Phase III trial and two other sites had received final Institutional Review Board, or IRB, approval and were preparing to begin patient enrollment. Nine additional sites were engaged in the pre-trial public disclosure and community consultation process. Each of the sites participating in the trial is designated as a Level I trauma center, indicating its capacity to treat the most severely injured trauma patients. We anticipate that a total of 25 or more clinical sites across the United States will eventually participate in the trial. The trial has an expected enrollment of 720 patients.

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

In July 2004, the IDMC recommended that our trial continue without modification based on the committee's initial review of blinded data on mortality and serious adverse events from the first 60 patients enrolled in the trial. In October 2004, the IDMC again recommended continuation of the trial without modification based on its review of data following enrollment of the first 120 patients in our trial. The length of time for completion of the IDMC review after each enrollment target is reached is expected to become longer as the number of enrolled patients increases. Enrollment in the trial continues during the period of 30-day follow-up, data preparation and analysis and meetings of the IDMC, so the disclosure of the IDMC recommendation does not correspond to the current status of patient enrollment. We anticipate that the IDMC will complete its third review of trial data on the first 250 patients enrolled in our trial and make a recommendation to us in the second calendar quarter of 2005.

Our current goal is to complete the patient enrollment phase of our trial by the end of calendar 2005. Our ability to achieve this goal will depend, in part, on the number of clinical sites participating in our trial and the ability of these sites to enroll patients at the projected rates.

TRIAL DESIGN AND CLINICAL ENDPOINTS

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

Our pivotal Phase III trial is being conducted under a federal regulation that permits research to be conducted in certain emergent, life-threatening

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

Before enrollment can begin, the regulation requires public disclosure of information 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 participating in our current trial has completed the required public disclosure and community consultation procedures and received IRB approval to enroll patients in accordance with the trial protocol.

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

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

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

THE MARKET OPPORTUNITY

Transfused blood represents a multi-billion dollar market in the United States. We estimate that approximately 14 million units of blood are transfused in the

United States each year. The transfusion market in the United States consists of two principal segments. The acute blood loss segment, which we estimate comprises approximately 60% of the transfusion market, includes transfusions required in connection with trauma, surgery and unexpected blood loss. The chronic blood loss segment, which we believe represents approximately 40% of the transfusion market, includes transfusions in connection with general medical applications and chronic anemias.

We believe that PolyHeme will be most useful in the treatment of acute blood loss. The principal clinical settings in which patients experience acute blood loss are unplanned blood loss in trauma, emergency surgery and other causes of urgent hemorrhage, and planned blood loss in elective surgery. For trauma and emergency surgical procedures, the immediate availability and universal compatibility of PolyHeme may provide significant advantages over transfused blood by avoiding the delay and opportunities for error associated with blood typing. In elective surgery, PolyHeme has the potential to increase transfusion safety for patients and health care professionals.

In addition to the foregoing applications for which blood is currently used, there exist potential sources of demand for which blood is not currently used and for which PolyHeme may be suitable. These include applications in which the required blood type is not immediately available or in which transfusions are desirable but not given for fear of a transfusion reaction due to difficulty in identifying

compatible blood. For example, we believe PolyHeme may be used by Emergency Medical Technicians at the scene of injury and during transport to the hospital by ground or air ambulance. Emergicenters and surgicenters also both experience events where PolyHeme may be useful. In addition, the United States military has expressed interest in the use of blood substitutes for the treatment of battlefield casualties. There may also be potential market opportunities for PolyHeme in novel areas such as ischemia and oncology.

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

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

OUR STRATEGY

Our strategy is to achieve sustainable profitability and growth by developing, marketing and selling an effective alternative to transfused blood for use in the treatment of acute blood loss. To reach these goals we are focusing on the following objectives:

- complete our pivotal Phase III trial;
- prepare and submit a Biologics License Application to FDA for the approval of PolyHeme;
- expand our current manufacturing capabilities to support the commercial launch of PolyHeme; and
- build sales, marketing and distribution capabilities in support of the commercialization of PolyHeme.

OUR CORPORATE INFORMATION

We were incorporated in Delaware in 1985. Our principal executive offices are located at 1560 Sherman Avenue, Suite 1000, Evanston, Illinois 60201-4800, and our telephone number is (847) 864-3500. We maintain an Internet website at www.northfieldlabs.com. We have not incorporated by reference into this prospectus supplement or the accompanying prospectus the information in, or that can be accessed through, our website, and you should not consider it to be a part of this prospectus supplement or the accompanying prospectus.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors that supplement the risk factors described in our Annual Report on Form 10-K for the year ended May 31, 2004 as well as other information contained in our other filings with the Securities and Exchange Commission. If any of the following risks actually occurs, our business, financial condition and results of operations could materially suffer. As a result, the trading price of our common stock could decline, and you might lose all or part of your investment.

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

From our inception through November 30, 2004, we have incurred net operating losses totaling $134,838,000. We will require substantial additional expenditures to complete clinical trials, to pursue regulatory approval for PolyHeme, to establish commercial scale manufacturing processes and facilities, and to establish marketing, sales and administrative capabilities. These expenditures are expected to result in substantial losses for at least the next few years and are expected to substantially exceed our currently available capital resources. The expense and the time required to realize any product revenues or profitability are highly uncertain. We cannot ensure that we will be able to achieve product revenues or profitability on a sustained basis or at all.

WE ARE REQUIRED TO COMPLETE OUR CURRENT CLINICAL TRIAL BEFORE WE MAY SELL POLYHEME COMMERCIALLY AND WE MAY BE REQUIRED TO CONDUCT ADDITIONAL CLINICAL TRIALS IN THE FUTURE.

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

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

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

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

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

Two clinical sites did not receive IRB approval for their participation in our pivotal Phase III trial. It is possible the other prospective clinical sites may decide not to participate in our trial or may fail to obtain IRB approval for their participation in the trial. One or more of the clinical sites currently enrolling patients may also discontinue their participation in our trial in the future. Our projections relating to completion of the enrollment phase of our trial are based, in part, on assumptions regarding the number of clinical sites enrolling patients in our trial. If we are unable to include additional clinical sites in our trial or our current clinical sites discontinue their participation in our trial, the trial may be significantly delayed and we may be unable to complete the trial.

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

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

As part of our trial protocol, an Independent Data Monitoring Committee, or IDMC, consisting of independent medical and biostatistical experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any identified risks to patients. The IDMC focuses its reviews on mortality and serious adverse events and evaluates all safety data as

the trial continues. We anticipate that the IDMC will complete its third review of trial data on the first 250 patients enrolled in our trial and make a recommendation to us in the second calendar quarter of 2005. If the IDMC believes the data from our trial give rise to safety concerns, the IDMC could recommend that our trial be halted or substantially modified. A recommendation of this type could significantly delay the completion of our trial and could prevent us from completing the trial.

THE MARKET MAY NOT ACCEPT OUR PRODUCT.

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

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

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

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

We do not have the ability to conduct our clinical trials independently. We rely and will continue to rely on clinical investigators, third-party clinical research organizations and consultants to perform some or all of the functions associated with clinical trials. In particular, as part of our trial protocol, an Independent Data Monitoring Committee consisting of independent medical and biostatistical

experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any identified risks to patients.

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

- these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines;
- these third parties need to be replaced; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to our clinical protocol or regulatory requirements or for other reasons.

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

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

Our research, development, testing, manufacturing, marketing and distribution of

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

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

Further, discovery of previously unknown problems with PolyHeme or unanticipated problems with our manufacturing facilities, even after FDA approval of PolyHeme for commercial sale, may result in the imposition of significant restrictions, including withdrawal of PolyHeme from the market or restrictions on approved indications. Additional laws and regulations may also be enacted which could prevent or delay regulatory approval of PolyHeme, including laws or regulations relating to the price or cost-effectiveness of medical products. Other laws and regulations may be enacted that could require us to comply with post-marketing requirements for PolyHeme that may be time-consuming and expensive. Any delay or failure to achieve regulatory approval of commercial sales of PolyHeme or to

maintain compliance with current or future laws and regulations is likely to have a material adverse effect on our financial condition.

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

The lack of established criteria for evaluating the safety and effectiveness of

blood substitute products could also delay or prevent FDA approval. In October 2004, FDA published for comment a draft guidance document indicating suggested criteria for testing the safety and efficacy of oxygen therapeutics as substitutes for human red blood cells and providing guidance on the design of clinical trials to assess the risks and benefits associated with the use of such products. The draft guidance document was based in part on a conference on blood substitute products convened at National Institutes of Health in 1999. The draft guidance will not be finalized and implemented until completion of a public comment process. We cannot be certain when the definitive guidance will be issued by FDA or what effect, if any, the definitive guidance may have on our clinical trial. It is possible that, as a result of the definitive guidance, we may be required to undertake additional pre-clinical or clinical trials or modify the way data from our trial are analyzed or presented. FDA's definitive guidance relating to the evaluation of the effectiveness of blood substitute products could delay or prevent FDA regulatory approval of PolyHeme. In addition, delay or rejection could be caused by other future changes in FDA policies and regulations.

WE MAY NEED TO RAISE ADDITIONAL CAPITAL TO CONTINUE OUR BUSINESS.

We currently believe we have sufficient capital resources to complete the enrollment phase of our clinical trials. As more fully described under "Use of Proceeds," we intend to use the proceeds of this offering to fund our post-enrollment activities in our clinical trial, to prepare and submit a BLA application to FDA, to construct a 75,000 unit per year manufacturing facility to produce PolyHeme for commercial sale, to build sales, marketing and distribution capabilities and for other general corporate purposes. We may be required to raise capital, in addition to the proceeds of this offering, to continue our business. Our future capital requirements will depend on many factors, including the scope and results of our clinical trials, the timing and outcome of regulatory reviews, administrative and legal expenses, the status of competitive products, the establishment of manufacturing capacity and the establishment of collaborative relationships. We cannot ensure that additional funding will be available or, if it is available, that it can be obtained on terms and conditions we will deem acceptable. Any additional funding derived from the sale of equity securities may result in significant dilution to our existing stockholders, including purchasers in this offering.

WE CURRENTLY MANUFACTURE POLYHEME AT A SINGLE LOCATION AND, IF WE WERE UNABLE TO UTILIZE THIS FACILITY, OUR ABILITY TO MANUFACTURE POLYHEME WILL BE SIGNIFICANTLY AFFECTED, AND WE WILL BE DELAYED OR PREVENTED FROM COMPLETING OUR CLINICAL TRIALS AND COMMERCIALIZING POLYHEME.

We currently manufacture PolyHeme at a single location and we have no alternative manufacturing capacity in place at this time. Damage to this manufacturing facility due to fire, contamination, natural

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

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

Currently, we have a manufacturing capacity of approximately 10,000 units of PolyHeme per year. Commercial-scale manufacturing of PolyHeme will require the construction of a manufacturing facility significantly larger than that

currently being used to produce PolyHeme for our clinical trials. 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.

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

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

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

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

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

The Financial Accounting Standards Board recently issued its Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (Statement 123R), which addresses the accounting for employee stock options. Statement 123R requires that the cost of all employee stock options, as well as other equity-based compensation arrangements, be reflected in financial statements based on the estimated fair value of the awards. We expect to adopt SFAS 123R for the period ending November 30, 2005. We will assess the impact of the transition to this new accounting standard during the upcoming months. Upon our implementation of Statement 123R, we could be required to recognize significant additional compensation expense.

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

Beginning with our annual report for our fiscal year ending May 31, 2005, Section 404 of the Sarbanes-Oxley Act of 2002 will require us to include a report by our management on our internal controls over financial reporting. This report must contain an assessment by management of the effectiveness of our internal controls over financial reporting as of the end of our fiscal year and a statement as to whether or not our internal controls are effective. The report must also contain a statement that our independent auditors have issued an attestation report on management's assessment of such internal controls.

In order to achieve timely compliance with Section 404, we have begun a process to document and evaluate our internal controls over financial reporting. Our efforts to comply with Section 404 have resulted in, and are likely to continue to result in, significant costs, the commitment of time and

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

Our success depends in part on our ability to obtain and maintain intellectual property protection for PolyHeme as well as our technology and know-how. Our policy is to seek to protect PolyHeme and our technologies by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of PolyHeme. The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective patent claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in the issuance of any patents. Our issued patents and those that may issue in the future may be challenged, invalidated, rendered unenforceable or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for PolyHeme. Our United States patents have expiration dates that extend to 2017. The broadest of our issued patents expires in May 2006. Although we expect to be granted an extension of this patent to 2011, we cannot ensure that an extension will not be for less than five years or that it will be granted at all. In addition, the rights granted under any issued patents may not provide us with

competitive advantages against competitors with similar compounds or technologies. Furthermore, our competitors may independently 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.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(c) Exhibits

Exhibit 99.1 Northfield Laboratories Inc. Press Release dated January 19, 2005.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Northfield Laboratories Inc.

Date: January 19, 2005 By: /s/ Jack J. Kogut

Jack J. Kogut
Senior Vice President and Chief Financial Officer

INDEX TO EXHIBITS

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
99.1	Northfield Laboratories Inc. Press Release dated January 19, 2005.