NORTHFIELD LABORATORIES INC /DE/
Form DEFA14A
August 14, 2008

SCHEDULE 14A
(RULE 14a-101)
INFORMATION REQUIRED IN PROXY STATEMENT
SCHEDULE 14A INFORMATION
PROXY STATEMENT PURSUANT TO SECTION 14(a) OF THE SECURITIES EXCHANGE ACT OF 1934 (AMENDMENT NO.)

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Check the appropriate box:
o Preliminary proxy statement.
o Confidential, for use of the Commission only (as permitted by Rule 14a-6(e)(2)).
o Definitive proxy statement.
þ Definitive additional materials.
o Soliciting material pursuant to Rule 14a-12

NORTHFIELD LABORATORIES INC.

(Name of Registrant as Specified in Its Charter)

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To My Fellow Shareholders:

Fiscal 2008 presented many challenges and opportunities for Northfield as we worked to complete our Biologics License Application (BLA) for PolyHeme®. The focus of fiscal 2009, perhaps the most important year in Northfield s history, will be the successful submission and filing of the BLA with a designation of priority review, with the potential to culminate with a marketing approval for the sale of PolyHeme. We believe strongly in PolyHeme s potential to save lives, and are dedicated to making our product available for patients with life threatening hemoglobin levels when blood is not available.

The year began with a pre-BLA meeting with FDA last summer. The meeting was informative and constructive. Although the challenge of preparing the BLA has required considerably more time than anticipated, we believe that the resulting application will make a strong case for the approval of PolyHeme, which is our ultimate goal.

The BLA consists of three sections: clinical, preclinical, and chemistry, manufacturing and controls (CMC). While the key clinical data are the results of our multicenter Phase III trial, the clinical section includes information from all studies in humans, starting with our Phase I volunteer experience. 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.

We have also reviewed and reanalyzed all of the preclinical reports that have been previously submitted in order to provide the most meaningful interpretation of those data. Completing the CMC section continues to be one of the most time consuming parts of the process. The current Good Manufacturing Practices (cGMP) requirements for commercial manufacturing have evolved considerably over the past two decades since our pilot facility was first opened. Since our plan is to seek FDA approval using this site as our first commercial facility, we have made multiple improvements and updates, all of which required subsequent validation, in order to confirm cGMP compliance.

Based on these activities, we now anticipate the final BLA will be submitted in the fourth calendar quarter of 2008. The submission triggers a number of important events. FDA has a 60 day period to conduct its initial review and make a decision on the filing of the BLA and the designation of priority review. We continue to believe that PolyHeme satisfies the stated criteria for priority review based on its potential to address an unmet medical need. The stated time for priority review under the Prescription Drug User Fee Act is six months. It is likely that our BLA would be considered at a meeting of the Blood Products Advisory Committee (BPAC). The Committee is comprised of independent experts who would review Northfield s data and raise questions for the Company at a public meeting. At the end of that meeting, BPAC members would have the opportunity to vote on the safety and efficacy of PolyHeme for the proposed indication. While the decisions of the Advisory Committee are not binding, FDA carefully considers the recommendations of these expert committees. These are all milestone events for Northfield in fiscal 2009.

We had many opportunities to disseminate the results of the Phase III trial. In October the data were presented at the American College of Surgeons, and the presentation formed the basis for a paper which has been submitted to a peer-reviewed journal for publication. The study results were also presented at a plenary session at the XI International Symposium on Blood Substitutes in Beijing. We have also continued to work with our investigators as they complete the process of final public disclosure at their individual sites.

There has been considerable interest in the field of hemoglobin-based oxygen carriers, or HBOCs, this year. In April, FDA and NIH jointly sponsored a two-day public workshop entitled *Hemoglobin-Based Oxygen Carriers: Current Status and Future Directions.* 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 with nitric oxide. At this meeting we also had the opportunity to present new data on cardiac events in the Phase III trial as classified in a blinded analysis by the Cardiac Subcommittee of the Independent Data Monitoring Committee that monitored our Phase III trial. The results, based on uniformly applied objective criteria, indicated that more than half of the patients in both the PolyHeme and the control groups had some evidence of myocardial infarction, or MI, confirming the difficulty of diagnosing MI in trauma patients.

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. Northfield has begun to collaborate with investigators in the field of nitric oxide biology to explore some of these issues and how their findings might relate to PolyHeme

We participated in a number of important meetings related to the advancement of trauma care, including the Endpoint Initiative Meeting in Dallas in February hosted by the National Trauma Institute, and the Decision Gate in Progress Review at Fort Detrick in March. The latter is held each year to brief the Commander of the U.S. Army Medical Research and Materiel Command on the progress of the many different research programs designed to bring forward products that will be useful to the military, and to begin considering the designation of funding for acquisition purposes. We were invited to attend and to discuss the progress we have made with the development of PolyHeme. This is an exciting opportunity for Northfield.

Based on our funds available as of May 31, 2008, we believe we have sufficient financial resources to support the BLA submission and review process, including a pre-approval inspection of our manufacturing facility, for approximately the next year. We are hopeful a successful submission and filing of the BLA with priority review will lead to opportunities to secure the additional funding needed to move PolyHeme into commercialization. Our annual report includes additional information regarding our financial position and our plans relating to Northfield s future.

Our proxy statement this year includes two important proposals that are part of our plan to secure additional funding and to continue to retain and attract the talented employees critical to achieving our objectives. These proposals are unanimously supported by our Board of Directors and I strongly urge you to review the information in our proxy statement and vote for each of these proposals at our upcoming annual meeting of stockholders.

As I stated at the outset, our focus for fiscal 2009 is the successful submission and filing of the BLA with a designation of priority review. I hope you now have a better understanding of the enormity of the task. We believe our clinical data demonstrate PolyHeme has the potential to provide life-sustaining capability to bleeding patients when blood is not immediately available, and to thereby address a critical unmet medical need. We believe PolyHeme has a favorable benefit-to-risk profile for this indication. In addition, there are multiple logistic benefits of PolyHeme that add to the compelling basis for the use of PolyHeme in those clinical settings. This is our case to FDA.

Once more I wish to take this opportunity to thank you, our shareholders, for your loyal support of our efforts to bring PolyHeme to commercial reality. I look forward to reporting our progress as the year proceeds.

Sincerely,
Steven A. Gould, M.D.
Chairman and Chief Executive Officer