

NORTHFIELD LABORATORIES INC /DE/

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August 17, 2007

**NORTHFIELD  
LABORATORIES INC  
ANNUAL REPORT AND FORM 10K  
FOR THE YEAR ENDED MAY 31, 2007**

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Northfield is a leader in developing an oxygen-carrying red blood cell substitute for the treatment of life-threatening blood loss when an oxygen-carrying fluid is required and red blood cells are not available. PolyHeme<sup>®</sup> is a solution of chemically modified human hemoglobin that requires no cross-matching and is therefore compatible with all blood types. It has a shelf life in excess of twelve months.

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To Our Fellow Shareholders:

Fiscal year 2007 was a challenging period for Northfield as we continued our quest to bring the life-saving potential of PolyHeme® to commercial reality. We achieved full enrollment in our landmark pivotal Phase III trial. We completed the initial analysis of the study data. We prepared and submitted a detailed summary of the data to FDA. This was followed by a recent pre-BLA meeting with the Agency in anticipation of our planned submission of a BLA for PolyHeme during the first half of calendar 2008.

Our singular focus this year is the successful submission of the BLA. We are presently preparing the application and a request for priority review. We believe PolyHeme satisfies the stated criteria for priority review based on its potential to address an unmet medical need. Given our strong belief in PolyHeme's potential to save lives, we are dedicated to making our product available for patients with urgent, life-threatening blood loss when blood is not available. Every officer, every manager, and every employee is committed to doing whatever it takes to accomplish this goal.

Much of last year was devoted to supporting our clinical sites through the completion of enrollment in our Phase III trial in a very difficult environment. There was heightened public scrutiny of the 1996 federal regulation that allows patients to be enrolled in emergency research studies with an exception from the requirement for informed consent, and considerable debate regarding our study protocol in particular. Responding to multiple constituencies and defending the protocol required significant management and research partner time and effort. Much credit is due to our investigators, their institutions, and the Emergency Medical Services units that participated in the study. They believed in the importance of this research, and their commitment and dedication culminated in the completion of the planned enrollment of 720 patients in July 2006.

We devoted significant time to analyzing the data from the study. The primary efficacy endpoint was a dual superiority-noninferiority assessment of mortality at 30 days after injury. Although the results fell just outside the agreed upon statistical boundary for this endpoint in the primary analysis population, a number of key observations were made about the potential role of PolyHeme in the early care of the injured patient. Day 30 mortality was also a primary safety endpoint. Importantly, there was no statistically significant difference in mortality at 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 transfusion, upon arrival at the hospital. We believe the results of this study extend and confirm our prior published observations in hospitalized trauma patients regarding the potential clinical utility of PolyHeme when blood is not available.

The results are best understood in the context of bleeding patients who do not have early access to blood transfusion, as did the patients in our study. Since blood is not typically carried in ambulances, trauma patients in this country do not have access to blood until they reach a trauma center or hospital. There are 47 million Americans who live more than an hour away from a trauma center. The clinical literature documents that increased Emergency Medical Services response time, time on the scene, and distance to the scene are associated with higher trauma mortality rates. Beyond the civilian trauma settings, the threat of mass casualty disasters and ongoing military operations under austere conditions in remote locations also represent potential situations where blood may be unavailable for an extended period of time. It was recognized at the outset that mortality rates in these scenarios would be considerably higher than those observed in the control

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patients in the largely urban setting of our trial, where transit times were relatively short and access to blood was rapid. We believe that when our observed data are extrapolated to those patients who need an oxygen carrier and have delayed access to blood, PolyHeme can play an important role in saving lives.

The safety analysis revealed some confounding findings, but we believe the safety profile observed is within an acceptable risk-benefit profile for bleeding patients at risk of dying when blood is not available. A higher incidence of myocardial infarction was reported in the PolyHeme patients. At the same time, there was a considerable disparity between the low number of reported myocardial infarctions and the high incidence of abnormal electrocardiograms and elevated cardiac enzymes, the traditional markers of myocardial ischemia, in both the treatment and control groups. An independent panel of cardiac experts is currently conducting a blinded review of the cardiac profiles of all 720 randomized patients to help elucidate these findings.

We are committed to publishing the results of our study in a peer-reviewed scientific journal and have already begun this process. Dr. Ernest E. Gene Moore, the lead investigator, is the chairman of the publications committee of the investigators and a manuscript is in preparation. We will be meeting with our investigators at the American Association for the Surgery of Trauma meeting in September to review the data together. In October, Dr. Moore will give the first formal presentation of the study results, entitled *Postinjury Resuscitation with Human Polymerized Hemoglobin: The USA Multicenter Trial*, at the 93rd Annual Clinical Congress of the American College of Surgeons in New Orleans. I will also be presenting the study results at the XI International Symposium on Blood Substitutes in Beijing in October. Later this fall, study investigators will complete the public disclosure of the study results to their communities, as required by the regulation governing studies conducted with an exception from the requirement for informed consent.

We will continue our investor outreach and presently have plans to report on our progress at the Thomas Weisel Partners Healthcare Conference and the UBS Global Life Sciences Conference in September, and the BIO Investor Conference in October.

We continue to believe that there is a considerable market opportunity for PolyHeme. In an effort to further understand the commercial potential, we initiated pharmacoeconomic research designed to better understand and develop policy and reimbursement strategies for the commercialization of PolyHeme. This work will continue during the current fiscal year. We will step up our work with the trauma community, the military, and other stakeholders to identify key issues and opportunities as we prepare for the introduction of PolyHeme to the market.

We have much to accomplish in our 2008 fiscal year. I believe we will succeed because we have the right product, the right people, and the right strategies in place. All of us at Northfield appreciate your support and belief in the promise of PolyHeme. We will do our best to make that promise a reality.

Sincerely,

**Steven A. Gould, M.D.**

Chairman and Chief Executive Officer

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Summit Roundtable

SHAREHOLDER INFORMATION

**Headquarters**

Northfield Laboratories Inc.

1560 Sherman Avenue, Suite 1000

Evanston, IL 60201-4800

847.864.3500

**Transfer Agent**

Computershare Investor Services, LLC  
P.O. Box 43036  
Providence, RI 02940-3036  
1.312.588.4225  
www.computershare.com

**Common Stock**

Northfield Laboratories Inc. is listed on  
Nasdaq under the symbol NFLD

**Independent Auditors**

KPMG, LLP  
Chicago, IL

**Contact Information**

Sophia H. Twaddell  
Vice President  
Corporate Communications  
847.864.3500  
investor\_relations@northfieldlabs.com  
For investor kits, press releases, stock  
quotes, and product information, please  
visit the Company website at  
www.northfieldlabs.com

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**NORTHFIELD  
LABORATORIES INC**

Northfield Laboratories Inc. 1560 Sherman Avenue, Suite 1000 Evanston, IL 60201-4800 847.864.3500  
**[www.northfieldlabs.com](http://www.northfieldlabs.com)**