NORTHFIELD LABORATORIES INC /DE/
Form ARS
August 15, 2005

Transforming the treatment of trauma ANNUAL REPORT FOR THE YEAR ENDED MAY 31, 2005

18 people die every hour from injuries.* Many trauma patients bleed to death before they have access to blood. *Centers for Disease Control (CDC); +JAMA, June 1, 2005, Volume 293, No. 21; **American College of Surgeons, ATLS Handbook

Trauma is the leading cause of death in Americans under the age of 45. 47 million Americans live more than an hour away from a trauma center.[+] Trauma-related costs exceed $400 billion annually in the U.S.[**] Medical costs alone are estimated at $117 billion.[*] PolyHeme® may address a critical, unmet medical need: the unavailability of blood in urgent, life-threatening blood loss.

Transforming the treatment of trauma Northfield passed a number of key milestones in fiscal 2005. Our most notable progress occurred in our pivotal Phase III trial with PolyHeme,® now underway at Level I trauma centers throughout the nation. We have successfully passed the halfway mark of the study and look forward to completing enrollment in early 2006. We also raised $77.6 million through an underwritten public offering to support the initial commercialization of PolyHeme. I am pleased to have this opportunity to provide the details of these and our other accomplishments during the past 12 months. Our principal focus in 2005 was on ramping up our Phase III trial.This landmark study is the first in the U.S. to evaluate the use of a hemoglobin-based oxygen-carrying resuscitative fluid beginning at the scene of injury. In June 2004, 11 Level I trauma centers were open for enrollment. As I write this letter in early August, the number has almost doubled, to 21 active centers. Six additional sites have full Institutional Review Board approval and are expected to begin enrollment shortly. Interest in participating in the PolyHeme study remains high, as evidenced by the number of other sites completing the community consultation process required before study initiation. We anticipate meeting our goal of 25 or more open sites by September 30. Patient enrollment is progressing well. As of June 30, approximately 400 patients had been enrolled in the study, or more than half the planned 720 patients. Based on present enrollment rates at currently active sites, we estimate that approximately 600 patients will be enrolled by the end of calendar 2005. We will provide quarterly updates on patient accrual until the study reaches full enrollment. We were particularly pleased to announce the successful completion of three of the four planned interim analyses of the trial data. We received three positive recommendations from an Independent Data Monitoring Committee (IDMC) to continue the study without modification after reviewing blinded data from the first 60, 120, and 250 patients enrolled. No other hemoglobin-based oxygen carrier has passed this patient evaluation milestone in the high-risk trauma population. As part of its third interim analysis, the IDMC also analyzed the planned sample size of the study and concluded that no increase in the number of patients to be enrolled would be required. The fourth, final interim analysis is scheduled to occur after 500 patients have been enrolled, and we anticipate being able to announce that milestone before the end of calendar 2005. Laurel A. Omert, M.D., a noted trauma and critical-care surgeon, joined Northfield in January as Chief Medical Officer. Dr. Omert is skilled in the clinical care of trauma patients and in conducting clinical research in trauma, and has extensive hands-on experience working with urban and rural Emergency Medical Systems. Her expertise has been of great value to us and we are delighted to have her on our senior management team. Northfield has never been stronger financially. Early in February, we raised $77.6 million in an underwritten public offering. We also received a $1.4 million appropriation in the 2005 Defense Appropriations budget. As of May 31, we had $98.1 million in cash and marketable securities on our balance sheet, providing us with a welcome level of financial security going forward. This year we initiated a number of activities in preparation for the commercialization of PolyHeme. We commissioned an independent assessment of the potential market opportunity for PolyHeme, specifically focused on the initial indication we are seeking: urgent, life-threatening blood loss when blood or red blood cells are not immediately available. We believe this indication addresses a critical, unmet medical need and represents a substantial business opportunity.The study estimated the U.S. m arket for the unavailability indication to be in excess of 350,000 units annually, valued at $400 million to $500 million.The global market opportunity for PolyHeme, including additional indications, was estimated at six to seven times the U.S. unavailability projection, or $2 billion to $3 billion.

We also began preconstruction activities for our planned expansion of manufacturing capacity for PolyHeme. We are developing a request for proposal that we intend to issue this fall. After reviewing bids, we will select the contractor, negotiate and award the final contract, and begin final engineering. Our regular program of investor outreach continues to bear fruit, as evidenced by the expanded interest in Northfield in many areas. Participation in our quarterly conference calls and webcasts has increased significantly. Over the course of the year, we presented at seven institutional investor conferences in the U.S. and in Europe that were also webcast for the public. Each of these conferences represents an additional opportunity to tell our story. We have already received multiple invitations to present at upcoming conferences. Additionally, four firms initiated research coverage on Northfield during the year: Cathay Financial, SG Cowen, Harris Nesbitt, and UBS. In early July, we hosted our first-ever meeting for financial analysts and institutional investors. It was a highly successful event.The program, The Emerging Role of Hemoglobin-Based Oxygen Carriers, included presentations by leading experts and was also made available to our shareholders and the public by webcast. Dr. Omert spoke on the current care of the injured patient. Ernest E. Moore, M.D., Chief of Surgery and Trauma Services at Denver Health Medical Center and lead investigator for our PolyHeme trial, reviewed his extensive clinical and laboratory experience with PolyHeme and described the emerging role of hemoglobin-based oxygen carriers in the care of injured patients. Jay Menitove, M.D., Executive Director and Medical Director of the Community Blood Center of Kansas City, reviewed the many implications of the availability of a hemoglobin-based oxygen carrier on the blood supply. Corporate governance initiatives were a focus for the Board of Directors and senior management. Northfield was among the many companies required to achieve compliance with new federal requirements relating to internal financial controls by the end of our 2005 fiscal year.This costly and complicated process is now complete, thanks to the diligence of our Chief Financial Officer, Jack Kogut, and his staff. In addition, the Board of Directors formalized and adopted new Corporate Governance Guidelines, which are now available on our website. In recognition of our evolution toward commercialization, Edward C. Wood, Jr., a seasoned healthcare industry executive with extensive experience in the transfusion and blood products markets, has been nominated to serve on Northfield s Board of Directors. The nominating committee of the Board reviewed the credentials of a number of individuals and felt that Ed s expertise would be of considerable value to the Company as we move forward. Northfield made steady progress toward the commercialization of PolyHeme this year. We successfully passed the halfway mark in our pivotal Phase III trial. Our balance sheet has never been stronger. We believe we are closer than ever to bringing PolyHeme to market, with the potential to transform the treatment of trauma in the U.S. and throughout the world. Our progress would not have been possible without the dedication of Northfield s employees, the guidance of the Board of Directors, and the continued support of our loyal shareholders. I am most appreciative of your collective efforts and support. We have high expectations for the coming year. We anticipate that our trial will reach full enrollment early in 2006.The data will be analyzed and reported. Our BLA preparation and manufacturing expansion will be well underway. I look forward to continued progress toward realizing the promise of PolyHeme. STEVEN A. GOULD, M.D. Chairman of the Board and Chief Executive Officer

Transforming the treatment of trauma Northfield Laboratories is a leader in developing an oxygen-carrying resuscitative fluid for the treatment of urgent, large volume blood loss in trauma and resultant surgical settings. PolyHeme® 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 of over 12 months.

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