NORTHFIELD LABORATORIES INC /DE/
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progress promise

NORTHFIELD LABORATORIES INC

ANNUAL REPORT AND FORM 10K FOR THE YEAR ENDED MAY 31, 2006

NORTHFIELD LABORATORIES INC.
POLYSH-P INJECTION
CAUTION: NEW DRUG LIMITED BY FEDERAL LAW TO INVESTIGATION USE.

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® 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 twelve months.

Identifying the need. Accepting the challenge

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There is a critical, unmet need for a safe and effective alternative to blood when blood is not available.

Efforts to develop a clinically viable oxygen-carrying red blood cell substitute began decades ago, as a project of the U.S. Army following the Vietnam war.

At that time, the objective was to develop a preparation that could be infused rapidly and in massive quantities to injured battlefield combatants in far-forward areas and mobile surgical theaters before the injured could be evacuated to more sophisticated field hospitals for definitive care.

Northfield s scientific founders accepted the challenge and led the effort. Accordingly, the development of PolyHeme® has focused on the treatment of urgent, life-threatening hemorrhage when red blood cells are not immediately available.

Today, there are many circumstances under which blood may not be immediately available:

At the scene of injury During transport In the ER In the OR In rural hospitals In cases of religious objection In cases of blood shortage

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Charting the course. Marking significant progress.

Over the past two years we conducted the first and only rigorously controlled U.S. study a human hemoglobin-based product beginning in the pre-hospital setting. For the first time treatment with an alternative that carries oxygen, like blood, began at the scene of injury and continued during transport and the early hospital period.

One hundred fifty physician investigators, 3,750 EMTs, 1,500 laboratory staffers, and thousands of allied hospital personnel combined their efforts to bring the study to completion at 32 distinguished Level 1 trauma centers throughout the country.

Seven hundred twenty patients were enrolled.

Perhaps most importantly, the Independent Data Monitoring Committee (IDMC) responsible for overseeing patient safety, on four occasions, after 60, 120, 250 and 500 patients had been enrolled, evaluated all safety data and four times recommended that the study continue without modification. After its final review, the committee stated:

Regarding the final assessment of the interim data, including 500 randomized patients, there were no statistically significant trends or safety issues identified to warrant modification or other changes in the current protocol and patient recruitment. The IDMC conclusion is that completion of the trial is appropriate with completion of datasets and final analysis indicated.

PolyHeme® represents a potential life-saving resource sustain lives that otherwise might be lost.
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Moving from the clinic to commercialization.

As our pivotal Phase III study progressed toward completion, we set our course on commercialization planning.

We upsized our plans for our first commercial facility for the manufacture of PolyHeme®. We anticipate that the facility will have the capacity to produce 100,000 units or more PolyHeme® each year.

We engaged the Jacobs Engineering Group Inc. and kicked off size optimization and engineering activities for the planned facility in Mt. Prospect, IL.

We purchased the building we formerly leased to provide us with the autonomy and flexibility we need to meet the anticipated market demand for PolyHeme®.

Because of confidence in the market demand for PolyHeme we are upsizing our first commercial facility.

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Dear Shareholders:

In 2006, our Company made significant progress toward accomplishing our ultimate goal of bringing the life-saving potential of PolyHeme® to realization. We passed a number of milestones along the way. Most importantly, we completed enrollment in our landmark pivotal Phase III PolyHeme trial. This was the first study in the U.S to evaluate the safety and efficacy of an oxgen-carrying red blood cell substitute beginning at the scene of injury and continuing during transport and in the early hospital period. We believe PolyHeme has the potential to have a positive impact on the thousands of lives at risk every year due to massive blood loss from trauma-related injury.

Thirty-two Level I trauma centers across the U.S. participated in this study following review and approval of the study protocol by each site s Institutional Review Board. We are now engaged in preparing the data for analysis in anticipation of reporting top-line results from the study later this fall.

A key event that occurred during the year was receiving the final recommendation from the Independent Data Monitoring Committee (IDMC) for the study. The IDMC completed its fourth and final review of safety data from the initial 500 patients enrolled in the study in November 2005 and recommended that the trial continue without modification to completion of patient enrollment. That was the first time a hemoglobin-based oxygen-carrier had passed that patient evaluation milestone in the high-risk trauma population.

We recently announced we are seeking Fast Track designation for PolyHeme for treatment of urgent, life-threatening blood loss when ultimate red blood cells are not available. Fast Track is a feature of the FDA Modernization Act of 1997 and is intended to facilitate the development and expedite the review of products intended for the treatment of serious or life-threatening conditions and which demonstrate the potential to address an unmet medical need for such a condition. We believe PolyHeme qualifies for Fast Track based on its potential to improve patient survival, and we hope to be eligible for priority review when we submit our Biologics License Application (BLA) to the Food and Drug Administration.

As the study gained visibility throughout the year, the exception from informed consent review provision attracted the attention of members of the media, representatives of the ethics community, and others and stimulated much dialogue. Northfield responded and issued a number of news releases and statements clarifying and correcting inaccuracies and misconceptions. In what became a very challenging environment, enrollment continued to completion, thanks to the dedication and commitment of the investigators, their institutions and the EMS providers, and all individuals participating in the this study.

We reached another key milestone this year with the announcement by Senator Richard Durbin of Illinois that Northfield would receive $3.5 million in the 2006 Defense Appropriations budget almost double the funds allocated the previous year. This brings our total appropriations to $4.9 million. Senator Durbin, the Assistant Democratic

Leader and a member of the Senate Appropriations Committee, visited our manufacturing facility in Mt. Prospect to make the announcement.

Due to our belief in the market potential for PolyHeme, we made the decision to upsize the planned capacity of our first commercial facility from 75,000 units annually to 100,000 units or more. Subsequently, we engaged the Jacobs Engineering Group Inc. and have kicked off the first phase: size optimization and updating of engineering for the facility. Just after the close of our fiscal year, we announced we purchased the building we previously occupied as lessee. Owing the space provides us the autonomy and flexibility needed to meet the anticipated market demand for PolyHeme.

In an effort to further understand the market opportunity for PolyHeme, we have initiated pharmacoeconomic research designed to support policy and reimbursement strategies for the commercialization of PolyHeme. This will supplement our prior market research. We continue our research with community leaders, hospitals and emergency response teams to identify issues and opportunities associated with the adoption of PolyHeme in the treatement of life-threatening blood loss when red blood cells are not available. During the course of our Phase III study, we worked closely with many of the key opinion leaders at the leading Level I trauma centers throughout the country. We are hopefully that this extensive first-hand experience with PolyHeme will be helpful in the initial adoption of PolyHeme once approved.

We announced a number of administrative and organizational developments. John Hinds will be joining us as Vice President Finance. He will serve as Northfield s principal financial and accounting officer. John brings more than 18 years of experience in finance and accounting in both public and private companies, as well as extensive experience in the financial control of rapid growth companies, to his new position at Northfield. Jack Kogut will assume the title of Senior Vice we Administration and will continue to serve as Secretary of the Board.

Early in the year, Alan L. Heller, a healthcare industry veteran, was appointed to our Board of Directors Al s long and distinguished career in the healthcare industry will be valuable as we continue to plan for the market launch of PolyHeme. Jack Olshansky, long-time member of the Board, is not standing for reelection this year. Instead, he will become a director emeritus in recognition of his service to the Company. We thank Jack for his many contributions over the years.

The Company continued its outreach to investors by presenting at a number of institutional investor conferences this past year, including the BIO Investor and the BIO CEO and Investor conferences, the Rodman & Renshaw Techvest 7th Annual Healthcare conference, the SC Cowen Global Pharmaceuticals and Global Health Care conferences, and the UBS Global Pharmaceuticals and Specialty Pharmaceuticals conferences. Notably, we presented at the BioCentury Future Leaders in Biotechnology conference the second time we have participated in this prestigious gathering of biotechnology investors. We also hosted our first-ever meeting for financial analysts and institutional investors last summer. Because this event was so successful, we held another analyst event on August 8. This year s theme was Delivering Trauma Care Today and Tomorrow, and once again we were joined by a panel of distinguished experts.

As we look forward to the future, we believe we ve made significant progress toward delivering on the promise of PolyHeme. We look forward to completing the data analysis and to reporting the top-line results. We await the FDA s decision on Fast Track designation for PolyHeme

On behalf of the Board of Directors and the management team, I would like to thank all of our hard-working employees, dedicated research partners, and loyal shareholders for your continued support of our efforts to bring PolyHeme to market.

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

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OFFICERS

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

Jack. J. Koqut Senior Vice President and Chief Financial Officer

Robert L. McGinnis Senior Vice President Operations

Marc D. Doubleday Chief Technical Officer

Eva C. Essiq, Ph.D. Vice President Regulatory Affairs and Quality

George A. Hides Vice President Clinical Operations

Laurel A. Omert, M.D. Chief Medical Officer

Sophia H. Twaddell Vice President Corporate Communications

BOARD OF DIRECTORS

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Jack Olshansky Independent Consultant to the Healthcare Industry

David A. Savner Senior Vice President and General Counsel General Dynamics Corporation

Edward C. Woods, Jr. Chief Executive Officer Summit Roundtable

SHAREHOLDER INFORMATION

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

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For investor kits, press releases, stock quotes, and product information, please visit the Company website at www.northfieldlabs.com

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