NORTHFIELD LABORATORIES INC /DE/
Form DEFA14A
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SCHEDULE 14A

PROXY STATEMENT PURSUANT TO SECTION 14(a) OF THE SECURITIES EXCHANGE ACT OF 1934 (AMENDMENT NO.)

Filed by the registrant [X]

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Check the appropriate box:

[ ] Preliminary proxy statement. [ ] Confidential, for use of the Commission only (as permitted by Rule 14a-6(e)(2)).

[ ] Definitive proxy statement.

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NORTHFIELD LABORATORIES, INC.

(Name of Registrant as Specified in Its Charter)

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TO OUR SHAREHOLDERS

The past 12 months were characterized by great accomplishments and significant challenges for Northfield Laboratories. I am honored to have the opportunity to lead Northfield as we embark on the most critical, yet exciting period in the Company's history. I will be searching for both a President and an individual as head of medical affairs to join our management team, and anticipate identifying individuals that will bring additional skill and expertise to our organization. We have great expectations for the next year. I would like to update you on our current status, our ongoing efforts to commercialize our PolyHeme(TM) blood substitute product, and my plans that are designed to increase shareholder value over the long term.

ABOUT POLYHEME

We believe PolyHeme represents an ideal oxygen-carrying resuscitative fluid for use in the treatment of urgent, life threatening blood loss. PolyHeme is the only blood substitute that has been rapidly and safely infused in sufficiently massive quantities to be considered useful in the treatment of large volume blood loss in trauma and surgical settings. PolyHeme provides temporary life-sustaining oxygen carrying capacity and avoids dangerously low hemoglobin levels until adequate red blood cell levels can be restored safely. We have infused PolyHeme in doses of up to 20 units, which is twice the total normal adult blood volume, in as brief a period of 20 minutes in situations of massive blood loss. We have experienced survival rates of 75% in patients with such substantial blood loss, which is a dramatic improvement over the historical survival rate of just 20%. This represents an extraordinary accomplishment, and it is the reason we believe PolyHeme addresses a critical unmet medical need by providing life-saving therapy in situations where no alternative currently exists.

PolyHeme has several other important advantages. It is immediately available and universally compatible with all blood types, eliminating the need for costly and time-consuming compatibility testing before blood can be infused into a patient. Our manufacturing process destroys or eliminates viruses that

might transmit disease, and its extended shelf life of over 12 months compared with a 42-day maximum for donated red blood cells helps make PolyHeme perfectly suited for use in the treatment of urgent and unplanned hemorrhage. We have conducted clinical trials in three areas -- trauma, elective surgery, and compassionate use in life-threatening circumstances. At present, our only active trials are the continuing enrollment of patients on a case by case basis in situations of compassionate use. We are pleased to provide this life-saving benefit in cases of immunologic incompatibility with the available blood supplies or religious objection to donated blood. We will continue this support on an ongoing basis.

POTENTIAL POLYHEME OPPORTUNITY

The extraordinary events of September 11, 2001 demonstrated the unpredictable nature of the blood supply. Had there been a large number of injured patients requiring blood, the available supplies might not have been adequate. As the country responded with a remarkable increase in blood donations, we were faced with the unexpected situation of considerable loss due to outdating of the blood after 42 days. The availability of a supply of an alternative oxygen-carrier such as PolyHeme, with its universal compatibility, immediate availability and long term storage capability, would have been most helpful in avoiding such difficulties. The deployment of our military to Afghanistan has shown the need for resuscitation in areas far removed from medical care. It is likely that PolyHeme would be useful in this environment also. Although these situations are fortunately rare, they do occur and serve to emphasize the potential benefit of PolyHeme in urgent, unplanned blood loss when there is no available alternative treatment.

As we have stated previously, the actual market potential of PolyHeme is difficult to accurately project because of the many factors that will influence the eventual role the product plays in transfusion therapy. However, we anticipate that the major early opportunity will be in situations when blood is unavailable. We believe that the potential benefits of PolyHeme in this setting will appropriately lead to premium pricing and a substantial business opportunity.

REGULATORY STATUS

In August 2001, we submitted our Biologics License Application to the Food and Drug Administration seeking approval to market PolyHeme for use in the treatment of urgent, life-threatening blood loss. This was a significant milestone for Northfield, representing the culmination of 16 years of product development, clinical studies and data analysis. It was also a landmark event for the industry, because it was the first BLA for a blood substitute for human use in the United States. The decision to submit the BLA was based on the demonstration that PolyHeme supported life in seriously injured, bleeding patients and significantly improved survival in situations when blood could not be used. We were aware that despite the compelling outcomes, there would be regulatory hurdles. PolyHeme is an innovative product, with no precedent to provide guidance for the FDA. The history of safety concerns for other blood substitutes as well as other highly visible product recalls added a considered and understandable degree of caution. However, we felt the BLA submission was appropriate.

In November 2001, the FDA issued a refusal to file letter with respect to our BLA filing. Based on our discussions with the FDA, we have learned that many of the agency's concerns are focused on the perceived broad nature of the proposed indication for the use of the product, the validity of the historical control group and the actual trial design itself. These concerns reflect the fact that our studies were not designed as a classical registration trial using a randomized, prospective, double-blinded design, but rather a trial under

conditions involving real life, unplanned, life-threatening blood loss simulating situations in which no alternative treatment is available. The ethical and logistic considerations involved in this environment did not allow us to use a traditional approach to trial design. The endpoint in the trial was patient survival, and the use of PolyHeme led to a dramatic improvement over the predicted survival based on historical data. We believe the strength of the data justified our BLA submission.

We have had numerous recent meetings and follow-on discussions with the FDA. We have described in great detail the patients and settings in which PolyHeme would and would not be used. We have presented additional information regarding the historical controls, and have also submitted other data that we believe validate the control group. We have also discussed the challenges of the traditional trial design for our proposed indication. Our dialogue has been instructive and encouraging, although it is possible that additional trials will still be necessary. We are striving to reach a consensus as quickly as possible in order to move forward to regulatory approval for PolyHeme and resolve the uncertainty that currently exists.

FUNDING

It is clear that we will need additional funding in the future. Clarity and certainty regarding our regulatory status are essential to positioning ourselves to move rapidly and effectively to raise money in the capital funds markets when the climate on Wall Street becomes more favorable. This has been a tumultuous year for the market, but we want to be poised to access new capital when the market normalizes. In the meantime, we have $18.4 million in available cash, which should support our on-going operations for at least the next 18 months.

PARTNERSHIP

Over the course of PolyHeme's development, we have had discussions with several large pharmaceutical companies that have expressed strong interest in partnering with Northfield. We believe a partner with experience in the surgical and critical care areas would be an excellent strategic fit. The right partner would add expertise in the areas of marketing, regulatory affairs and manufacturing and enhance the likelihood of successful commercialization of PolyHeme. As is the case with fund raising, clarity and certainty regarding our regulatory status are essential in order to secure a world-class partner on attractive terms for our shareholders.

SCIENTIFIC AND INVESTOR PRESENTATIONS

As we have done previously, we made several public presentations in a variety of forums. In October 2001 we presented data confirming PolyHeme's life-sustaining capacity in massive blood loss at the American College of Surgeons annual meeting in New Orleans. This is notable since this conference represents the largest surgical meeting in the United States covering all surgical specialties. In May of this year, we once again presented at the Deutsche Bank Alex. Brown Health Care Conference. Also in May, we presented at the American Association of Blood Bank's symposium on Oxygen Therapeutics and Transfusion Alternatives.

In the April 4, 2002 issue of The New England Journal of Medicine, a report appeared describing the successful use of PolyHeme on an emergency basis in a case of life-threatening hemorrhage. In the July 2002 issue of Transfusion, another case report describing the successful use of PolyHeme in life-threatening anemia in a patient with sickle cell anemia will appear. In the October 2002 issue of the Journal of the American College of Surgeons, the manuscript describing the use of PolyHeme in trauma and urgent blood loss will be published in its entirety. These are all significant, since acceptance of

such work for publication following peer review represents validation of our results within the medical and scientific communities and is further evidence of the significance of our work.

In September of this year, there will be several additional important presentations. On September 10, 2002 we will be presenting an update to the military at the Advanced Technology Applications for Combat Casualty Care (ATACCC). On September 27, 2002, a paper from the University of Colorado will be presented at the American Association for the Surgery of Trauma describing the benefits of PolyHeme compared to blood in modulating the immune response in critically injured trauma patients.

CHANGES IN MANAGEMENT

As I write this letter, only a few days have passed since Richard DeWoskin, one of the Company's founders and former Chairman, decided to transfer the leadership of Northfield. Richard has devoted his professional career to the development of a human blood substitute and has spearheaded the efforts that have brought PolyHeme to its current stage of development. Richard's decision to step down reflected his belief that it was an appropriate time for Northfield to continue its development with a different perspective. This orderly transition is an indication of the growth and maturity of our organization. I am delighted that we will continue to benefit from his counsel and support. We are grateful for all of Richard's efforts, and wish him well in his future endeavors.

CORPORATE GOVERNANCE INITIATIVES

In view of the recent focus on corporate governance issues, we have made a number of important changes at Northfield. We have expanded our Board of Directors and nominated two new directors for election at our upcoming annual meeting. The seven director nominees proposed by Northfield include four independent directors. We also created a new nominating committee with responsibility for evaluating and recommending potential director candidates. The nominating committee joins our audit and compensation committees in being comprised fully of independent directors.

We have also recently amended the charter for our audit committee to delegate to the committee the sole power to appoint and replace our independent auditors and to determine what, if any, non-audit services are to be provided by our auditors. In addition, we adopted a written code of business conduct that includes policies applicable to our directors, officers and employees relating to compliance with law, conflicts of interest, protection of confidential information, accuracy and integrity of books and records and similar matters.

ANNUAL MEETING

Our 2002 Annual Meeting of stockholders will be held on Friday, September 13, 2002 at 10:00 a.m. (CDT) at our executive offices in Evanston, Illinois. This year the entire meeting, including the official portion of the meeting, the annual business update and the question and answer session, will be broadcast live on the

Internet. You may visit either Northfield's website at www.northfieldlabs.com or www.tfprn.com to access the presentation. Either site should be accessed at least 15 minutes before the start time to download any software that may be required. Shareholders without Internet access will be able to listen to the report by calling a toll free number. The call-in number will be made available approximately two weeks prior to the presentation and will be announced in a press release and posted on our website. The replay will be available for 30 days on the Internet and for seven days by telephone.

SUMMARY

We believe that the next year will be a pivotal one for Northfield. We intend to aggressively pursue the goals that are essential for our future success and that will increase shareholder value over the long term:

- Resolve our regulatory status with the FDA as quickly as possible;

- Raise additional capital;

- Secure a partnership with a major pharmaceutical company; and

- Increase Northfield's profile in the scientific and investment communities.

We will strive to expand our communications with our current shareholders as well as potential new investors, and to keep you informed of our progress in a timely and open fashion. I anticipate a smooth transition with our management changes, and look forward to the continuing support of our dedicated and loyal employees and investors. I hope this review conveys the sense of optimism regarding our expectations for the next year. I thank you for your continued support as we work to make these goals a reality.

Sincerely,

/s/ Steven A. Gould
Steven A. Gould, M.D.
Chairman of the Board and
Chief Executive Officer