NORTHFIELD LABORATORIES INC /DE/
Form DEFA14A
August 30, 2002

SCHEDULE 14A

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

Filed by the registrant [X]

Filed by a party other than the registrant [ ]

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.

[X] Definitive additional materials.

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NORTHFIELD LABORATORIES INC.

(Name of Registrant as Specified in Its Charter)

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(4) Date Filed:

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FOR IMMEDIATE RELEASE
FRIDAY, AUGUST 30, 2002

NORTHFIELD SENDS CEO LETTER TO SHAREHOLDERS

EVANSTON, ILLINOIS, AUGUST 30, 2002 - NORTHFIELD LABORATORIES INC. (NASDAQ/NMS: NFLD), a leading developer of an oxygen-carrying blood substitute for trauma and elective surgery situations, today distributed the following letter to shareholders from Dr. Steven A. Gould, Northfield's Chairman and Chief Executive Officer:

Dear Fellow Shareholder:

Part of my mandate, upon assuming the office of Chief Executive Officer, was to ensure that Northfield shareholders were informed about, and had the opportunity to participate in, our vision of the company. As you know, we have sent you a number of mailings in connection with our Annual Meeting. Since I became CEO, I have also been engaged in a large number of personal conversations with many of our loyal but frustrated shareholders. The essential question I have been asked again and again is, "Why should I vote for you and the other Board nominees, and what will you do to enhance shareholder value?"

The future success of Northfield is entirely dependent upon our ability to bring PolyHeme(TM) to market. FIRST AND FOREMOST WE MUST RESOLVE OUR REGULATORY SITUATION WITH THE FDA. Once the FDA and Northfield have reached a consensus

about the appropriate next steps, the company can aggressively move forward to raise additional funds and secure a strategic partnership. IT IS NAIVE AND UNREALISTIC TO BELIEVE THAT A POTENTIAL PARTNER WHO COULD ADD VALUE TO NORTHFIELD WOULD BE WILLING TO COMMIT TO A MAJOR BUSINESS COMBINATION BEFORE RESOLUTION OF OUR FUTURE REGULATORY PATH.

I would like to take this opportunity to again detail the important facts about the status of PolyHeme and its implications for Northfield which previously appeared in our Annual Report. I believe that this will help you understand why it is so important to support your Board and its nominees at this critical juncture.

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, as of May 31, 2002 we had $18.4 million in available cash, which should support our on-going operations for at least 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.

In summary, we have been engaged in what we believe is a constructive dialogue about exactly what information the FDA will require and how Northfield should provide it. We hope to reach a consensus with the FDA in the near future.

In the meantime, I am fully committed to making Northfield accessible and responsive to all current and future shareholders. We will continue to keep you apprised of important developments as they occur. I am asking you for your vote on the BLUE proxy card to help us realize Northfield's potential.

Thank you for your continued support.

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

REMEMBER--ONLY YOUR LATEST DATED PROXY COUNTS!

If you have already voted a White proxy card in error, you have every legal right to change your vote by signing and returning a later-dated BLUE proxy card today.

To ensure that your vote is counted for Northfield's director nominees, do NOT sign any White proxy card sent to you by C. Robert Coates, even to withhold your support for the Coates nominees. Simply discard the White card.

If you have any questions or need assistance in voting your shares, please call:

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Statements in this release that are not strictly historical are "forward-looking" statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve known and unknown risks, which may cause the company's actual results in the future to differ materially from expected results. These risks include, among others: competition from other blood substitute products; the company's ability to obtain regulatory approval to market PolyHeme commercially; the company's and/or its representative's ability to successfully market and sell PolyHeme; the company's ability to manufacture PolyHeme in sufficient quantities; the company's ability to obtain an adequate supply of raw materials; the company's ability to maintain intellectual property protection for its proprietary product and to defend its existing intellectual property rights from challenges by third parties; the availability of capital to finance planned growth; and the extent to which the hospitals and physicians using PolyHeme are able to obtain third-party reimbursement, as described in the company's filings with the Securities and Exchange Commission.