NORTHFIELD LABORATORIES INC /DE/
Form DEFA14A
August 03, 2001
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SCHEDULE 14A
(RULE 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT
SCHEDULE 14A INFORMATION

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.

[ ] Soliciting material pursuant to Rule 14a-12

NORTHFIELD LABORATORIES, INC.

(Name of Registrant as Specified in Its Charter)

(Name of Person(s) Filing Proxy Statement if Other Than the Registrant)

Payment of filing fee (check the appropriate box):

[X] No fee required.

[ ] Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

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[ ] Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the form or schedule and the date of its filing.

(1) Amount Previously Paid:

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(2) Form, Schedule or Registration Statement No.:

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TO OUR SHAREHOLDERS

This past year has been both rewarding and exciting for Northfield Laboratories in our efforts to complete the successful development of PolyHeme(TM) as the first blood substitute to be commercially available for human use in this country. We believe that we have achieved a unique status in the field of blood substitutes based on our impressive clinical experience that has demonstrated a remarkable survival benefit using PolyHeme in lieu of blood in the treatment of urgent, life-threatening blood loss. We believe we are addressing the clinical setting of greatest need for a blood substitute and one that will provide us with a key market opportunity. We remain confident, optimistic and have high expectations for the successful completion of our clinical development.

ABOUT POLYHEME

We believe PolyHeme represents an ideal oxygen-carrying resuscitative fluid for use in the treatment of urgent, life-threatening blood loss. Our on-going clinical trials continue to demonstrate that PolyHeme will support life in human patients in the virtual absence of any remaining red blood cells. 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 believe PolyHeme therefore addresses a critical, unmet medical need by providing life-saving therapy in situations where no alternative currently exists. In addition, PolyHeme's other attributes such as immediate availability, universal compatibility, lack of transfusion reactions, lack of

disease transmission, and its extended shelf-life make this solution perfectly suited for use in the urgent treatment of substantial hemorrhage. PolyHeme's most essential characteristic is its ability to be safely infused in rapid and massive fashion. In fact, PolyHeme was specifically designed during its product development to avoid the adverse effects of other hemoglobin-based oxygen-carriers that would preclude such rapid, massive infusions. No other blood substitute has achieved this goal.

POTENTIAL POLYHEME OPPORTUNITY

The potential clinical role of PolyHeme as a novel oxygen-carrier can be best assessed in relation to the present pattern of blood use. The current market for blood in the United States is estimated to be in the multiple billions of dollars. There are approximately 12 million units of blood transfused each year into approximately four million recipients. Sixty percent of this blood is used for acute blood loss and 40% for chronic blood loss. Acute blood loss refers to an abrupt onset of bleeding, usually involving major surgery. Our focus has always been the treatment of acute blood loss because of the potential benefits of PolyHeme in this setting.

There are two categories of acute blood loss, urgent use and elective use. Approximately 2.5 million units of blood per year are used in urgent use, consisting of both trauma and non-trauma settings. The larger category in acute blood loss is that of elective surgery where approximately 4.7 million units of blood are used each year. These are two different and distinct clinical settings, with different issues, different potential patient benefits, and different regulatory considerations.

As stated above, we believe the most important and appropriate setting for PolyHeme is for the treatment of urgent blood loss. Urgent blood loss is unplanned, unscheduled hemorrhage. It usually occurs during nights and weekends and places considerable stress on the available resources. The volume of hemorrhage tends to be rapid and substantial. It is most often life-threatening, and importantly, there are currently no alternatives to donated blood in this setting. Of more significance, however, is the fact that frequently there is no donated blood available. In these situations, the delay until blood is available may place the patient at extreme risk. The potential benefit of PolyHeme in this setting is that it addresses the greatest clinical need for an alternative oxygen-carrier because of the urgency and difficulties of the situation. Our data demonstrate that PolyHeme saves lives in this setting and thereby provides a remarkable clinical benefit.

The issues in elective blood loss are quite different. Blood loss in elective surgery is primarily planned hemorrhage. The bleeding tends to be slow and more modest in volume, usually not life-threatening. Perhaps

the most important observation is that a number of alternatives to donated blood for use in elective surgery are presently available, including preoperative autologous donation, cell-saver techniques, acute normovolemic hemodilution, recombinant erythropoetin, and even the possibility of rescheduling such elective operations. The potential benefit of PolyHeme or any alternative oxygen-carrier in these situations is the avoidance of donated blood. While this is important, in view of the current safety of the blood supply this is a more modest clinical benefit.

The actual market potential of PolyHeme is difficult to accurately project but it will depend on a number of factors. There may certainly be some penetration of the current blood market. However, we anticipate that the major early opportunity will be in the use of PolyHeme when blood is not available. We therefore anticipate premium pricing to blood based on the potential benefits of PolyHeme and believe that this will create a substantial business opportunity.

CLINICAL STATUS

Our trials continue in three different areas. Our primary focus remains the trials in urgent blood loss at a dose of up to 20 units, equivalent to two complete blood volumes. The other trials in elective surgery at a dose of six units, and compassionate use for life-saving therapy also continue. The important safety observations are that none of the adverse effects historically associated with other hemoglobin solutions have been identified by our clinical studies. Furthermore, the demonstration of life-sustaining benefits and improved survival in the urgent setting provides a simultaneous demonstration of efficacy and safety. Based on the published literature, the anticipated survival rate at life-threatening red blood cell hemoglobin levels is less than 20%. The observed survival rate in our patients with similar hemoglobin levels continues to be 75%. This dramatic improvement unequivocally demonstrates the ability of PolyHeme to effectively transport oxygen. We are pleased with the response of both scientific and lay audiences to these results.

There are numerous efforts underway by others to develop both hemoglobin-based and perfluorochemical oxygen-carriers. To our knowledge, all other trials are occurring in only elective surgery at low doses and slow infusions where the blood loss is relatively moderate. The endpoint for efficacy in those trials is a reduction in the use of donated blood, with no survival benefit. Although such observations are useful, and similar to our own experience in elective surgery, we believe this benefit is less compelling than our experiences in urgent blood loss.

THE REGULATORY CHALLENGE

The major unresolved issue at present is the regulatory challenge. It is indeed a real challenge. PolyHeme is an innovative product with no precedent to provide guidance for the FDA. A history of safety concerns for other blood substitutes as well as other recent highly visible product recalls have added a considerable degree of caution to all current FDA reviews. In the field of blood substitutes, the presence of multiple sponsors, multiple products, and varying clinical experiences has resulted in the current evolving requirements for approval of such a product. Additionally, the potentially helpful guidance to be issued following the FDA Workshop in the fall of 1999 is still being finalized so it is not presently available. We continue to believe that we are addressing all of the important areas that will be of concern to the regulatory authorities. Our experience in both trauma and elective surgery, in stressed and stable patients, with high doses and rapid infusions, focusing on a survival endpoint in trauma are appropriate because that is how we believe PolyHeme should and will be used. Furthermore, it is the strength and robustness of our data that we believe should provide the relevant basis for product approval.

PolyHeme is unique in that it is the only product under development that is equivalent in oxygen-carrying capacity to a unit of blood. We believe our clinical program is unique in addressing both trauma and elective surgery. Our protocol of rapid, massive infusion provides a unique safety experience, and the survival benefit demonstrated in our trials represents the only formal protocol in urgent blood loss that is addressing this end-point.

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We are enthusiastic about our progress. We are in the final stages of the preparation of our Biologic License Application for PolyHeme. In fact, we are planning to file our BLA with the FDA in the very near future. We remain confident about the prospects for the approval and subsequent marketing of PolyHeme.

MANUFACTURING

Last year we described the expansion of our manufacturing capacity of PolyHeme to our current capability to produce 10,000 units annually. We also leased space adjacent to our current facility that will allow a further expansion of an additional 75,000 units of capacity per year as our next step. We view this approach as financially prudent, yet large enough for commercial viability. We remain in discussion with several potential manufacturing, marketing-distribution and source supply partners.

SCIENTIFIC AND INVESTOR PRESENTATIONS

As in prior years, we have continued to make formal, public presentations in a variety of forums. Last year we presented at the Prudential Vector Securities HealthCare Conference in November, and the Deutsche Banc Alex Brown Conference in May, as well as the Illinois Bio Market Place 2000 Conference in October.

We also made presentations at the post-graduate course on Pre and Post Operative Care at the Annual Meeting of the American College of Surgeons, at a NATO conference on Combat Fluid Resuscitation, and at the Illinois Society of Anesthesiologists. This fall we will be participating in the American Association of Blood Bank educational symposium on the potential role of blood substitutes in trauma, and most importantly, we will be presenting the results of our trials in urgent blood loss and trauma at the Papers Sessions at the Annual Meeting of the American College of Surgeons in October in New Orleans. This is a particularly important forum since this is the largest surgical meeting covering all specialties in the United States each year.

RUSSELL 3000(R) INDEX

We were notified in June that we were selected for inclusion in the Russell 3000(R) Index for the next year. Selection for inclusion in the Russell 3000(R) identifies Northfield as one of the 3,000 largest publicly traded U.S. companies based on total market capitalization.

ANNUAL MEETING FORMAT

We will once again be using the Internet to provide information simultaneously to all of our shareholders following the conclusion of our annual meeting. The meeting will convene at 2:00 pm (CDT) on Friday, August 31, 2001. The meeting will adjourn after the completion of the official business matters and the annual business update, including responses to frequently asked questions, and will be broadcast on the Internet only beginning at 4:30 pm (CDT). The update will be broadcast by Video News Wire, a partner of PRNewswire. You may visit either Northfield's website at www.northfieldlabs.com or www.videonewswire.com to access the presentation. 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 before 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.

In summary, we continue to appreciate the support of our shareholders, and the dedication and diligent efforts of our loyal employees. We hope this review conveys our sense of excitement and enthusiasm. We are gratified at your ongoing support through the many challenges of the past. We believe the future will continue to bring further good news. We remain optimistic with high expectations for the next year.

Sincerely,

-s- Richard DeWoskin
Richard DeWoskin
Chairman & Chief Executive Officer

-s- Steven A. Gould
Steven A. Gould, M.D.
President & Chief Operating Officer