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NORTHFIELD LABORATORIES INC /DE/
Form DEFA14A
August 20, 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.

[] Soliciting material pursuant to Section 240.14a-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):

(4) Proposed maximum aggregate value of transaction:

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Fee paid previously with preliminary materials.

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:

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

(3) Filing Party:

(4) Date Filed:

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ISS MEETING
AUGUST 20, 2002

[PICTURE]

August 20, 2002

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NORTHFIELD LABORATORIES INC

HIGHLIGHTS

- 1ST BLA FOR BLOOD SUBSTITUTE
- Extraordinary survival benefit
- Patent portfolio strengthened

- Manufacturing progress
- Addressing greatest need
- Substantial market opportunity

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HUMAN POLYMERIZED HEMOGLOBIN

[POLYHEME (TM) GRAPH]

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HUMAN POLYMERIZED HEMOGLOBIN

1 UNIT POLYHEME

- Equivalent to blood
- 50 grams Hb
- Free of tetramer
- Unique product

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IDEAL RESUSCITATIVE FLUID

POLYHEME

- SUPPORTS LIFE WITHOUT RBCs

- Immediate availability
- Universal compatibility
- No transfusion reactions
- No disease transmission
- Shelf-life more than 1 year
- Rapid, massive infusion

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POLYHEME RESUSCITATION

[GRAPH]

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DEVELOPMENT OF POLYHEME

CLINICAL TRIALS

- Urgent use, 20 units
- Elective use, 6 units
- Compassionate use

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DEVELOPMENT OF POLYHEME

FOCUS

- Life-threatening blood loss
- Potential unavailability of RBCs
- Clinical benefit = (increase in) survival

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UNAVAILABILITY SITUATIONS

- Military or civilian
- Remote or urban locations
- Prehospital or hospital settings
- Unplanned "elective" hemorrhage
- Multiple simultaneous injuries
- Incompatibility
- Inventory imbalance
- Religious objection

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URGENT BLOOD LOSS

PROTOCOL

- Primarily trauma
- Massive hemorrhage
- PolyHeme in lieu of RBCs
- Infusions up to 20 units
- Life-threatening RBC [Hb]
- Mortality vs. historical data

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URGENT BLOOD LOSS

LIFE-THREATENING
RBC [Hb]

- Historical survival <20%
- Observed survival = 75%
- Dramatic improvement

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MORTALITY COMPARISON

[LINE GRAPH]

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ASSESSMENT OF POLYHEME

CONCLUSIONS

- (increase in) Survival at low RBC [Hb]
- Safe during rapid, massive infusion
- Resolves unavailability of RBCs

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THE REGULATORY CHALLENGE

BLOOD SUBSTITUTES

- Innovative therapy
- History of safety concerns
- Multiple sponsors, products and clinical experiences
- Evolving requirements for approval

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NORTHFIELD REGULATORY STATUS

POLYHEME

- Compelling, life-saving benefit
- Critical, unmet medical need
- Substantial evidence of safety and efficacy
- Sufficient for submission of BLA

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NORTHFIELD REGULATORY STATUS

THE EVENTS

- BLA submitted August 2001

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- RTF received November 2001

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NORTHFIELD REGULATORY STATUS

FDA CONCERNS

- Broad nature of indication
- Validity of controls
- Trial design

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NORTHFIELD REGULATORY STATUS

PROGRESS

- Meetings
- Telephone conferences
- Optimistic will achieve consensus

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NORTHFIELD COMMERCIAL DEVELOPMENT

ISSUES

- Manufacturing expansion
- Patent position

- Marketing strategy
- Financial information

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MANUFACTURING EXPANSION

STRATEGY

- 10,000 units/year at present
- 75,000 units/year next step
- 16-20 months
- \$28-32 MM

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NORTHFIELD PATENT POSITION

STATUS

- Additional U.S. patent issued
- Substantial portfolio
- Protection in U.S. until 2017
- Additional U.S. and international applications pending

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MARKETING STRATEGY

POTENTIAL POLYHEME MARKET

- Life-saving therapy
- No alternatives available
- Addresses greatest need
- Premium pricing
- Substantial opportunity

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FINANCIAL INFORMATION

CASH POSITION

Cash (5/31/02) \$18.4 MM

Sufficient Cash 18-20 months

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CORPORATE GOVERNANCE

DEVELOPMENTS

- Board initiated management change
- Code of business conduct
- Audit committee changes
- Nominating committee

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BOARD OF DIRECTORS

PRESENT MEMBERS

- Steven A. Gould, M.D.
- Gerald S. Moss, M.D.
- David A. Savner
- Bruce Chelberg
- Jack Olshansky

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BOARD OF DIRECTORS

PROPOSED MEMBERS

- John F. Bierbaum
- Paul M. Ness, M.D.

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AGENDA

- Resolve regulatory status
- Raise additional capital
- Secure pharmaceutical partner
- Enhance public profile

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