NORTHFIELD LABORATORIES INC /DE/
Form DEFA14A
August 16, 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)

Northfield Laboratories Inc.

(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:

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

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(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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(4) Proposed maximum aggregate value of transaction:

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(5) Total fee paid:

[ ] 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:

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(2) Form, schedule or registration statement no.:

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(3) Filing party:

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(4) Date filed:

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PRESS RELEASE

NORTHFIELD INTENDS TO SUBMIT FDA APPLICATION BEFORE LABOR DAY; DATA ANALYSIS FOR APPLICATION COMPLETE

EVANSTON, Ill., Aug. 16 - Northfield Laboratories Inc. (Nasdaq: NFLD), a leading developer of an oxygen-carrying blood substitute, reported today that it has completed preparation of all of the components of its Biologics License Application (BLA), including collection and analysis of its clinical trial data for PolyHeme. The company now is completing the final clerical compilation and preparation of the document for submission to the Food and Drug Administration (FDA). Northfield intends to submit the application before Labor Day.

"We are pleased with the results from our clinical studies and believe the safety and efficacy data that we will present to the FDA are compelling," said Richard DeWoskin, chairman and chief executive officer. "We have begun the administrative challenge of compiling the application, which involves approximately 40 volumes of information, spanning more than 16,000 pages. Once the BLA has been submitted to the FDA, we will announce that milestone to our shareholders."

The company noted that while recent reports have suggested that other blood substitute sponsors are experiencing problems in elective surgery trials, Northfield's focus always has been in the trauma, or urgent, acute blood loss market.

The company will provide more detail on its regulatory progress in its annual business update on August 31, 2001. This presentation will be webcast after the close of the market, at 4:30 p.m. central time, that day. Anyone interested in accessing the presentation should log on to www.northfieldlabs.com or www.videonewswire.com, or for those without Internet access, you may dial in to 888-413-4411 to listen to the call. A replay of the webcast will be available for 30 days after the presentation. The telephonic replay will be available for seven days by dialing 888-266-2086 and providing the passcode, 5458560.

Northfield's annual meeting will take place earlier that day at 2:00 p.m. central time to vote on business matters as outlined in its August 3rd proxy statement. Only questions related to those business matters will be taken at the meeting. The business update will not be webcast at corporate headquarters.

ABOUT THE COMPANY

Northfield Laboratories, founded in 1985, is a leading developer of an oxygen-carrying blood substitute. Its product, PolyHeme, is the only blood substitute undergoing clinical trials that has been tested at large enough dosages to be considered a substitute for acute blood loss in trauma and surgical settings. As a result of the process used to manufacture the blood substitute,

essentially a solution of polymerized hemoglobin, PolyHeme has a longer shelf life than blood, requires no cross matching and does not transmit disease.

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 filing with the Securities and Exchange Commission.

Visit the Northfield website at: www.northfieldlabs.com.