

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

NORTHFIELD LABORATORIES INC /DE/
Form 10-Q
April 14, 2003

=====

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

FOR THE PERIOD ENDED FEBRUARY 28, 2003

OR

TRANSITION REPORT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 0-24050

NORTHFIELD LABORATORIES INC.
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation or organization)

36-3378733
(I.R.S. Employer
Identification Number)

1560 SHERMAN AVENUE, SUITE 1000, EVANSTON, ILLINOIS
(Address of principal executive offices)

60201-4800
(Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (847) 864-3500

FORMER NAME, FORMER ADDRESS AND FORMER FISCAL YEAR, IF CHANGED SINCE LAST
REPORT: NOT APPLICABLE

INDICATE BY CHECK MARK WHETHER THE REGISTRANT (1) HAS FILED ALL REPORTS
REQUIRED TO BE FILED BY SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
1934 DURING THE PRECEDING 12 MONTHS (OR FOR SUCH SHORTER PERIOD THAT THE
REGISTRANT WAS REQUIRED TO FILE SUCH REPORTS), AND (2) HAS BEEN SUBJECT TO SUCH
FILING REQUIREMENTS FOR THE PAST 90 DAYS.

YES X NO
--- ---

APPLICABLE ONLY TO ISSUER INVOLVED IN BANKRUPTCY
PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

INDICATE BY CHECK MARK WHETHER THE REGISTRANT HAS FILED ALL DOCUMENTS AND
REPORTS REQUIRED TO BE FILED BY SECTION 12, 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934 SUBSEQUENT TO THE DISTRIBUTION OF SECURITIES UNDER A PLAN
CONFIRMED BY A COURT. YES NO
--- ---

AS OF FEBRUARY 28, 2003, REGISTRANT HAD 14,265,875 SHARES OF COMMON STOCK
OUTSTANDING

=====

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

This Quarterly Report contains forward-looking statements concerning, among other things, our prospects, clinical and regulatory developments affecting our potential product and our business strategies. These forward-looking statements are identified by the use of such terms as "intends," "expects," "plans," "estimates," "anticipates," "should," "believes" and similar terms.

These forward-looking statements involve risks and uncertainties. Actual results may differ materially from those predicted by the forward-looking statements because of various factors and possible events, including those discussed under "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission. Because these forward-looking statements involve risks and uncertainties, actual results may differ significantly from those predicted in these forward-looking statements. You should not place a lot of weight on these statements. These statements speak only as of the date of this document or, in the case of any document incorporated by reference, the date of that document.

All subsequent written and oral forward-looking statements attributable to Northfield or any person acting on our behalf are qualified by the cautionary statements in this section and in our Annual Report. We will have no obligation to revise these forward-looking statements.

INDEPENDENT ACCOUNTANTS' REVIEW REPORT

The Board of Directors
Northfield Laboratories Inc.:

We have reviewed the balance sheet of Northfield Laboratories Inc. (a company in the development stage) as of February 28, 2003, and the related statements of operations for the three-month periods ended February 28, 2003 and February 28, 2002, and the statements of operations and cash flows for the nine-month periods ended February 28, 2003 and February 28, 2002 and for the period from June 19, 1985 (inception) through February 28, 2003. We have also reviewed the statements of shareholders' equity (deficit) for the nine-month period ended February 28, 2003 and for the period from June 19, 1985 (inception) through February 28, 2003. These financial statements are the responsibility of the Company's management.

We conducted our review in accordance with standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures to financial data and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with auditing standards generally accepted in the United States of America, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the financial statements referred to above for them to be in conformity with accounting principles generally accepted in the United States of

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

America.

We have previously audited, in accordance with auditing standards generally accepted in the United States of America, the balance sheet of Northfield Laboratories Inc. as of May 31, 2002, and the related statements of operations, shareholders' equity (deficit), and cash flows for the year then ended and for the period from June 19, 1985 (inception) through May 31, 2002 (not presented herein); and in our report dated July 16, 2002, we expressed an unqualified opinion on those financial statements. In our opinion, the information set forth in the accompanying balance sheet as of May 31, 2002 and in the accompanying statement of shareholders' equity (deficit) is fairly stated, in all material respects, in relation to the statement from which it has been derived.

/s/ KPMG LLP

Chicago, Illinois
March 20, 2003

NORTHFIELD LABORATORIES INC.
(a company in the development stage)

Balance Sheets

February 28, 2003 and May 31, 2002

ASSETS	FEBRUARY 28, 2003 ----- (UNAUDITED)
Current assets:	
Cash	\$ 6,786,960
Marketable securities	2,700,956
Prepaid expenses	293,216
Other current assets	16,280

Total current assets	9,797,412
Property, plant, and equipment, net	1,773,245
Other assets	71,653

	\$ 11,642,310 =====
LIABILITIES AND SHAREHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	\$ 454,848
Accrued expenses	161,597
Accrued compensation and benefits	352,985

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Total current liabilities	969,430
Other liabilities	168,914

Total liabilities	1,138,344

Shareholders' equity:	
Preferred stock, \$.01 par value. Authorized 5,000,000 shares; none issued and outstanding	--
Common stock, \$.01 par value. Authorized 30,000,000 shares; issued and outstanding 14,265,875 at February 28, 2003 and May 31, 2002	142,659
Additional paid-in capital	117,503,271
Deficit accumulated during the development stage	(107,141,964)

Total shareholders' equity	10,503,966

	\$ 11,642,310
	=====

See accompanying notes to financial statements.

NORTHFIELD LABORATORIES INC.
(a company in the development stage)

Statements of Operations

Three and nine months ended February 28, 2003 and 2002 and for the period
from June 19, 1985 (inception) through February 28, 2003

	THREE MONTHS ENDED FEBRUARY 28,		NINE MONTHS ENDED FEBRUARY 28,	
	2003	2002	2003	2002
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
	-----	-----	-----	-----
Revenues - license income	\$ --	--	--	--
	-----	-----	-----	-----
Costs and expenses:				
Research and development	2,203,047	2,175,834	6,472,161	6,472,161
General and administrative	745,528	582,852	2,635,430	2,635,430
	-----	-----	-----	-----
	2,948,575	2,758,686	9,107,591	9,107,591
	-----	-----	-----	-----

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Other income and expense:			
Interest income	43,673	167,966	181,239
Interest expense	--	--	--
	-----	-----	-----
	43,673	167,966	181,239
	-----	-----	-----
Net loss	\$ (2,904,902)	(2,590,720)	(8,926,352)
	=====	=====	=====
Net loss per share - basic and dilute	\$ (0.20)	(0.18)	(0.63)
	=====	=====	=====
Shares used in calculation of per share data - basic and diluted	14,265,875	14,265,875	14,265,875
	=====	=====	=====

See accompanying notes to financial statements.

NORTHFIELD LABORATORIES INC.
(a company in the development stage)

Statements of Shareholders' Equity (Deficit)

Nine months ended February 28, 2003 and for the period
from June 19, 1985 (inception) through February 28, 2003

	NUMBER OF SHARES	AGGREG AMOU
	-----	-----
Issuance of common stock on August 27, 1985	--	\$ --
Issuance of Series A convertible preferred stock at \$4.00 per share on August 27, 1985 (net of costs of issuance of \$79,150)	--	--
Net loss	--	--
	-----	-----
Balance at May 31, 1986	--	--
Net loss	--	--
Deferred compensation relating to grant of stock options	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1987	--	--
Issuance of Series B convertible preferred stock at \$35.68 per share on August 14, 1987 (net of costs of issuance of \$75,450)	--	--
Net loss	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1988	--	--
Issuance of common stock at \$24.21 per share on June 7, 1988 (net of		

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

costs of issuance of \$246,000)	--	--
Conversion of Series A convertible preferred stock to common stock on June 7, 1988	--	--
Conversion of Series B convertible preferred stock to common stock on June 7, 1988	--	--
Exercise of stock options at \$2.00 per share	--	--
Issuance of common stock at \$28.49 per share on March 6, 1989 (net of costs of issuance of \$21,395)	--	--
Issuance of common stock at \$28.49 per share on March 30, 1989 (net of costs of issuance of \$10,697)	--	--
Sale of options at \$28.29 per share to purchase common stock at \$.20 per share on March 30, 1989 (net of costs of issuance of \$4,162)	--	--
Net loss	--	--
Deferred compensation relating to grant of stock options	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1989	--	--
Net loss	--	--
Deferred compensation relating to grant of stock options	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1990	--	--
Net loss	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1991	--	--
Exercise of stock warrants at \$5.60 per share	--	--
Net loss	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1992	--	--
Exercise of stock warrants at \$7.14 per share	--	--
Issuance of common stock at \$15.19 per share on April 19, 1993 (net of costs of issuance of \$20,724)	--	--
Net loss	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1993	--	\$ --
	-----	-----

See accompanying notes to financial statements.

SERIES A CONVERTIBLE PREFERRED STOCK		SERIES B CONVERTIBLE PREFERRED STOCK		ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE
NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES	AGGREGATE AMOUNT		
-----	-----	-----	-----	-----	-----

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

--	\$ --	--	\$ --	\$ (28,000)	\$ --
250,000	250,000	--	--	670,850	--
--	--	--	--	--	(607,688)
-----	-----	-----	-----	-----	-----
250,000	250,000	--	--	642,850	(607,688)
--	--	--	--	--	(2,429,953)
--	--	--	--	2,340,000	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
250,000	250,000	--	--	2,982,850	(3,037,641)
--	--	200,633	200,633	6,882,502	--
--	--	--	--	--	(3,057,254)
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
250,000	250,000	200,633	200,633	9,865,352	(6,094,895)
--	--	--	--	9,749,870	--
(250,000)	(250,000)	--	--	237,500	--
--	--	(200,633)	(200,633)	190,601	--
--	--	--	--	93,759	--
--	--	--	--	4,976,855	--
--	--	--	--	2,488,356	--
--	--	--	--	7,443,118	--
--	--	--	--	--	(791,206)
--	--	--	--	683,040	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	35,728,451	(6,886,101)
--	--	--	--	--	(3,490,394)
--	--	--	--	699,163	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	36,427,614	(10,376,495)
--	--	--	--	--	(5,579,872)
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	36,427,614	(15,956,367)
--	--	--	--	503,100	--
--	--	--	--	--	(7,006,495)
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	36,930,714	(22,962,862)
--	--	--	--	106,890	--
--	--	--	--	5,663,710	--
--	--	--	--	--	(8,066,609)
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	\$ --	--	\$ --	\$42,701,314	\$ (31,029,471)
-----	-----	-----	-----	-----	-----

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

NORTHFIELD LABORATORIES INC.
(a company in the development stage)

Statements of Shareholders' Equity (Deficit)

Nine months ended February 28, 2003 and for the period
from June 19, 1985 (inception) through February 28, 2003

	PREFERRED STOCK	
	NUMBER OF SHARES	AGGREG AMOUNT
	-----	-----
Net loss	--	\$ --
Issuance of common stock at \$6.50 per share on May 26, 1994 (net of costs of issuance of \$2,061,149)	--	--
Cancellation of stock options	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1994	--	--
Net loss	--	--
Issuance of common stock at \$6.50 per share on June 20, 1994 (net of issuance costs of \$172,500)	--	--
Exercise of stock options at \$7.14 per share	--	--
Exercise of stock options at \$2.00 per share	--	--
Cancellation of stock options	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1995	--	--
Net loss	--	--
Issuance of common stock at \$17.75 per share on August 9, 1995 (net of issuance costs of \$3,565,125)	--	--
Issuance of common stock at \$17.75 per share on September 11, 1995 (net of issuance costs of \$423,238)	--	--
Exercise of stock options at \$2.00 per share	--	--
Exercise of stock options at \$6.38 per share	--	--
Exercise of stock options at \$7.14 per share	--	--
Cancellation of stock options	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1996	--	--
Net loss	--	--
Exercise of stock options at \$0.20 per share	--	--
Exercise of stock options at \$2.00 per share	--	--
Exercise of stock options at \$7.14 per share	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1997	--	--
Net loss	--	--

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Exercise of stock options at \$7.14 per share	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1998	--	--
Net loss	--	--
Non-cash compensation	--	--
Exercise of stock options at \$7.14 per share	--	--
Exercise of stock warrants at \$8.00 per share	--	--
	-----	-----
Balance at May 31, 1999	--	--
Net loss	--	--
Non-cash compensation	--	--
Exercise of stock options at \$13.38 per share	--	--
	-----	-----
Balance at May 31, 2000	--	--
Net loss	--	--
Non-cash compensation	--	--
Exercise of stock options at \$6.38 per share	--	--
Exercise of stock options at \$10.81 per share	--	--
	-----	-----
Balance at May 31, 2001	--	--
Net loss	--	--
	-----	-----
Balance at May 31, 2002	--	--
Net loss	--	--
	-----	-----
Balance at February 28, 2003	--	\$ --
	=====	=====

See accompanying notes to financial statements.

SERIES A CONVERTIBLE PREFERRED STOCK		SERIES B CONVERTIBLE PREFERRED STOCK		ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE
NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES	AGGREGATE AMOUNT		
--	\$ --	--	\$ --	\$ --	\$ (7,363,810)
--	--	--	--	14,163,851	--
--	--	--	--	(85,400)	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	56,779,765	(38,393,281)
--	--	--	--	--	(7,439,013)
--	--	--	--	2,261,250	--

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

--	--	--	--	71,300	--
--	--	--	--	373,264	--
--	--	--	--	(106,750)	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	59,378,829	(45,832,294)
--	--	--	--	--	(4,778,875)
--	--	--	--	48,324,374	--
--	--	--	--	7,360,187	--
--	--	--	--	362,937	--
--	--	--	--	9,555	--
--	--	--	--	71,300	--
--	--	--	--	(80,062)	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	115,427,120	(50,611,169)
--	--	--	--	--	(4,245,693)
--	--	--	--	50,025	--
--	--	--	--	463,540	--
--	--	--	--	71,300	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	116,011,985	(54,856,862)
--	--	--	--	--	(5,883,378)
--	--	--	--	35,650	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	116,047,635	(60,740,240)
--	--	--	--	--	(7,416,333)
--	--	--	--	14,354	--
--	--	--	--	124,775	--
--	--	--	--	998,750	--
-----	-----	-----	-----	-----	-----
--	--	--	--	117,185,514	(68,156,573)
--	--	--	--	--	(9,167,070)
--	--	--	--	57,112	--
--	--	--	--	33,425	--
-----	-----	-----	-----	-----	-----
--	--	--	--	117,276,051	(77,323,643)
--	--	--	--	--	(10,174,609)
--	--	--	--	--	--
--	--	--	--	38,220	--
--	--	--	--	189,000	--
-----	-----	-----	-----	-----	-----
--	--	--	--	117,503,271	(87,498,252)
--	--	--	--	--	(10,717,360)
-----	-----	-----	-----	-----	-----
--	--	--	--	117,503,271	(98,215,612)
--	--	--	--	--	(8,926,352)
-----	-----	-----	-----	-----	-----
--	\$	--	\$	\$117,503,271	\$ (107,141,964)
=====	=====	=====	=====	=====	=====

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

NORTHFIELD LABORATORIES INC.
(a company in the development stage)

Statements of Cash Flows

Nine months ended February 28, 2003 and 2002
and the cumulative period from June 19, 1985
(inception) through February 28, 2003

	Nne months ende

	2003

	(unaudited)
Cash flows from operating activities:	
Net loss	\$ (8,926,352)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	604,762
Non-cash compensation	--
Loss on sale of equipment	--
Changes in assets and liabilities:	
Prepaid expenses	246,787
Other current assets	(14,845)
Other assets	--
Accounts payable	(622,865)
Accrued expenses	(48,510)
Accrued compensation and benefits	14,136
Other liabilities	(8,839)

Net cash used in operating activities	(8,755,726)

Cash flows from investing activities:	
Purchase of property, plant, equipment, and capitalized engineering costs	(172,863)
Proceeds from sale of land and equipment	--
Proceeds from matured marketable securities	--
Proceeds from sale of marketable securities	--
Purchase of marketable securities	(1,953,138)

Net cash provided by (used in) investing activities	(2,126,001)

Cash flows from financing activities:	
Proceeds from issuance of common stock	--
Payment of common stock issuance costs	--
Proceeds from issuance of preferred stock	--

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Proceeds from sale of stock options to purchase common shares	--
Proceeds from issuance of notes payable	--
Repayment of notes payable	--

Net cash provided by financing activities	--

Net (decrease) increase in cash	(10,881,727)
Cash at beginning of period	17,668,687

Cash at end of period	\$ 6,786,960
	=====

See accompanying notes to financial statements.

NORTHFIELD LABORATORIES INC.

(A COMPANY IN THE DEVELOPMENT STAGE)

NOTES TO FINANCIAL STATEMENTS

FEBRUARY 28, 2003

(1) BASIS OF PRESENTATION

The interim financial statements presented are unaudited but, in the opinion of management, have been prepared in conformity with accounting principles generally accepted in the United States of America applied on a basis consistent with those of the annual financial statements. Such interim financial statements reflect all adjustments (consisting of normal recurring accruals) necessary for a fair presentation of the financial position and the results of operations for the interim periods presented. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the year ending May 31, 2003. The interim financial statements should be read in connection with the audited financial statements for the year ended May 31, 2002.

(2) COMPUTATION OF NET LOSS PER SHARE

Basic earnings per share is based on the weighted average number of shares outstanding and excludes the dilutive effect of unexercised common stock equivalents. Diluted earnings per share is based on the weighted average number of shares outstanding and includes the dilutive effect of unexercised common stock equivalents. Because the Company reported a net loss for all periods presented, basic and diluted per share amounts are the same.

(3) LIQUIDITY

The Company has had recurring losses since its inception and expects that significant additional expenditures will be required to successfully commercialize PolyHeme. The Company has financed its

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

research and development and other activities to date primarily through the public and private sale of equity securities and, to a more limited extent, through the licensing of product rights. As of February 28, 2003, the Company had cash and marketable securities totaling \$9,488,000. The Company is actively pursuing additional financing to fund its continued operations. The Company may also enter into collaborative arrangements with strategic partners, which could provide the Company with additional funding or absorb expenses the Company would otherwise be required to pay. Any one or a combination of these sources may be utilized to raise the required funding. Business or market conditions may not be favorable, which could delay or prevent the Company from raising additional capital or entering into a collaborative arrangement. If the Company is unable to obtain additional capital or enter into a collaborative arrangement, the Company may be required to curtail its product development and other activities and the Company may be forced to cease operations.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Since Northfield's incorporation in 1985, we have devoted substantially all of our efforts and resources to the research, development and clinical testing of our potential product, PolyHeme(TM). We have incurred operating losses during each year of our operations since inception and expect to incur substantial additional operating losses for the next several years. From Northfield's inception through February 28, 2003, we have incurred operating losses totaling \$107,142,000.

RECENT EVENTS

On March 5, 2003, we announced that we had received clearance from the Food and Drug Administration to proceed with a pivotal Phase III trial in which PolyHeme will be used for the first time in civilian trauma applications to treat severely injured patients before they reach the hospital. Under this protocol, treatment with PolyHeme will begin at the scene of the injury and continue during transport to the hospital by either ground or air ambulance.

We are currently in contact with over 30 potential clinical sites in an effort to launch the trial at the earliest possible date and ultimately have at least 20 sites open and enrolling patients. The process of initiating sites is elongated due to the compliance requirements allowing for an exception to informed consent. The review process of the institutional review board has begun at a number of sites. We are engaged with a number of sites in coordinating the process of informing the relevant community and seeking their response. This upfront time of obtaining community input as well as institutional review board approval has historically taken between six weeks at the earliest and over six months at the longest before the first patient is enrolled. Once the trial receives local approval, our goal is to enroll one patient per week at each site.

We have also submitted a request for Special Protocol Assessment ("SPA") for our approved civilian trauma trials. SPA represents an acknowledgement and confirmation of a

mutual agreement between the sponsoring company and FDA that successful

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

completion of a clinical trial will form the basis for product approval. If agreement is reached, FDA reduces the agreement to writing and makes it part of the administrative record.

On March 5, 2003, we received additional comment regarding special protocol assessment relating to certain administrative and procedural details. We are currently working to complete the final negotiations for special protocol assessment with FDA to solidify our regulatory program. We also intend to request that PolyHeme be designated as a fast track product. It may then be possible for certain portions of our Biologics License Application to be accepted for review prior to completion of our proposed clinical trial, a so-called "rolling BLA." In parallel with our approved civilian trauma trials, we are currently developing a treatment Investigational New Drug application with the U.S. Army.

The FDA regulatory process is subject to significant risks and uncertainties. The nature, timing and costs of the efforts necessary for us to obtain regulatory approval for PolyHeme, and the timing of any future revenues from the commercial sale of PolyHeme, cannot therefore be reasonably estimated at this time because of the current regulatory status of PolyHeme.

Our success will depend on several factors, including our ability to obtain FDA regulatory approval of PolyHeme and our manufacturing facilities, obtain sufficient quantities of blood to manufacture PolyHeme in commercial quantities, manufacture and distribute PolyHeme in a cost-effective manner, enforce our patent positions and raise sufficient capital to fund these activities. We have experienced significant delays in the development and clinical testing of PolyHeme. We cannot ensure that we will be able to achieve these goals or that we will be able to realize product revenues or profitability on a sustained basis or at all.

RESULTS OF OPERATIONS

We reported no revenues for either of the three-month periods or nine-month periods ended February 28, 2003 or 2002. From Northfield's inception through February 28, 2003, we have reported total revenues of \$3,000,000, all of which were derived from licensing fees.

OPERATING EXPENSES

Operating expenses for our third fiscal quarter ended February 28, 2003 totaled \$2,949,000, an increase of \$190,000 from the \$2,759,000 reported in the third quarter of the fiscal 2002. Measured on a percentage basis, operating expenses in the third quarter of fiscal 2003 increased by 6.9%. The difference was due primarily to higher costs for executive recruiting and scientific consulting services. We are currently seeking to recruit a new vice president of regulatory affairs and vice president of clinical affairs. Until these positions are filled, we expect the duties of these officers will be performed by other Northfield officers and by outside consultants.

For the nine-month period ended February 28, 2003, operating expenses totaled \$9,108,000, or a \$422,000, or 4.9%, increase from the \$8,686,000, of operating expenses incurred during the nine-month period ended February 28, 2002. The majority of the expense increase occurred in the general and administrative category and is attributable to the proxy contest in connection with our 2002 annual meeting of shareholders.

Research and development expenses for the third quarter of fiscal 2003

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

totalled \$2,203,000, an increase of \$27,000, or 1.2%, from the \$2,176,000 reported in the third quarter of fiscal 2002. Higher expenses were recognized during the third quarter of fiscal 2003 for executive recruiting and scientific consulting services.

Research and development expenses for the nine-month period ended February 28, 2003

totalled \$6,472,000, a decrease of \$263,000, or 3.9%, from the \$6,735,000 reported in the comparable prior year period. Increased expense for the purchase of manufacturing supplies were offset by larger decreases in compensation costs and expenses related to clinical trials from those incurred in the prior year period. These additional costs were incurred as we build a supply of PolyHeme for use in our recently approved civilian trauma trial.

We anticipate that research and development expenses will increase moderately in the fourth quarter of fiscal 2003. Additional costs are being planned for our civilian trauma trials, including third party clinical monitoring, biostatistical analysis, report preparation and continued expansion of our manufacturing organization. We are currently soliciting clinical sites to participate in our upcoming trials. Once the sites are cleared to enroll patients, we expect that the related study costs will increase significantly starting in the first and second quarters of fiscal 2004. We estimate that the total study costs for our civilian trauma trials will be approximately \$15,000,000.

General and administrative expenses in the third quarter of fiscal 2003 totalled \$746,000 compared to expenses of \$583,000 in the third quarter of 2002, representing an increase of \$163,000, or 28.0%. This increase was due primarily to increased patent, public relations and directors and officers insurance costs.

General and administrative expenses for the nine-month period ended February 28, 2003 totalled \$2,635,000, representing an increase of \$684,000, or 35.1%, from general and administrative expenses incurred during the nine-month period ended February 28, 2002. Virtually all of the \$684,000 variance is attributable to expenses related to the proxy contest in connection with our 2002 annual meeting and increased expenses for directors and officers insurance.

With the exception of continuing to enhance Northfield's investor relations capabilities, we are not planning any new general and administrative programs over the balance of the current fiscal year. Securing regulatory approval for PolyHeme is our highest priority item. Once there is greater clarity on the probability and timing of approval, general and administrative expenses are expected to increase to support the commercialization of our product.

INTEREST INCOME

Interest income in the third quarter of fiscal 2003 totalled \$44,000, or a \$124,000 decrease from the \$168,000 in interest income reported in the third quarter of fiscal 2002. Short term available interest rates declined in excess of 400 basis points from the third quarter of fiscal 2002, which along with lower available investment balances accounted for the decrease in interest

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

income. In the absence of a major cash infusion, interest income will continue to be significantly below prior year levels.

For the nine-month period ended February 28, 2003, interest income totaled \$181,000, or a \$558,000 decrease in interest income of \$739,000, from the nine-month period ended February 28, 2002. Lower investment balances and lower interest rates combined to cause the decrease.

NET LOSS

Our net loss for the third quarter ended February 28, 2003 was \$2,905,000, or \$0.20 per basic share, compared to a net loss of \$2,591,000, or \$0.18 per basic share, for the third quarter ended February 28, 2002. The increase in the net loss per basic share is primarily the result of costs relating to increased purchases of manufacturing supplies, recruiting costs and lower interest income.

Our nine-month net loss for the period ended February 28, 2003 totaled \$8,926,000, or \$0.63 per basic share, compared to a net loss of \$7,947,000, or \$0.56 per basic share, for the

nine-month period ended February 28, 2002, and is the result of the expenses related to the proxy contest in connection with our 2002 annual meeting of shareholders and lower interest income.

LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through February 28, 2003, we have used cash for operating activities and for the purchase of property, plant, equipment and engineering services in the amount of \$106,527,000. For the nine-month periods ended February 28, 2003 and 2002, these cash expenditures totaled \$8,929,000 and \$7,994,000, respectively. The increased net loss for the first nine months of fiscal 2003 compared to the comparable prior year period resulted in higher cash utilization.

We have had recurring losses since our inception and expect that significant additional expenditures will be required to successfully commercialize PolyHeme. We have financed our research and development and other activities to date primarily through the public and private sale of equity securities and, to a more limited extent, through the licensing of product rights. As of February 28, 2003, we had cash and marketable securities totaling \$9,488,000.

We believe our existing capital resources will be adequate to satisfy our current operating requirements and maintain our existing pilot manufacturing plant and office facilities for approximately the next six to nine months. We will require substantial additional capital to continue our operations beyond the next six to nine months and to conduct our planned clinical trials. Our current cash position therefore raises substantial doubt regarding our ability to continue as a going concern.

Northfield is actively pursuing additional financing to fund our continued operations, including our planned civilian trauma trials. We may issue additional equity or debt securities to the public or in private placement transactions. We may also enter into collaborative arrangements with

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

strategic partners, which could provide us with additional funding or absorb expenses we would otherwise be required to pay. Any one or a combination of these sources may be utilized to raise the required funding. Business or market conditions may not be favorable, which could delay or prevent us from raising additional capital or entering into a collaborative arrangement. If we are unable to obtain additional capital or enter into a collaborative arrangement, we may be required to curtail our product development and other activities and may be forced to cease operations.

As of May 31, 2002, we had net operating loss carry forwards of approximately \$98,000,000 to offset future federal taxable income through 2022. Due to the degree of uncertainty related to the ultimate realization of such prior losses, no benefit has been recognized in our financial statements as of May 31, 2002.

We are currently unable to fund the construction of a large-scale greenfield manufacturing facility, which is estimated to cost approximately \$70 million, without raising substantial additional capital. Currently, we have manufacturing capacity of approximately 10,000 units. Initial engineering on the leased space adjacent to our existing manufacturing facility is completed. This engineering indicates an additional capacity of 75,000 units could be developed in approximately 16 to 20 months at a cost of \$28 to \$32 million. Like a large-scale greenfield manufacturing facility, significant additional funding will be required before the smaller scale expansion facility could be completed. Northfield has not yet committed to the build-out of this facility. We view the smaller facility as financially prudent yet large enough for commercial viability.

Our capital requirements may vary materially from those now anticipated because of the results of our clinical testing of PolyHeme, the establishment of relationships with strategic partners, changes in the scale, timing or cost of our commercial manufacturing facility, competitive and technological advances, the FDA regulatory process, changes in our marketing and distribution strategy and other factors.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements requires management to make estimates and assumptions that affect amounts reported therein. We believe the following critical accounting policy affects our more significant judgments and estimates used in the preparation of our consolidated financial statements.

NET DEFERRED TAX ASSETS VALUATION

We record our net deferred tax assets in the amount that we expect to realize based on projected future taxable income. In assessing the appropriateness of our valuation, assumptions and estimates are required such as our ability to generate future taxable income. In the event that we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount of zero, an adjustment to the deferred tax asset would increase income in the period such determination was made. As of February 28, 2003, we had recorded a 100% valuation allowance against our deferred tax assets.

CONTRACTUAL OBLIGATIONS

The following table reflects a summary of our contractual cash obligations as of February 28, 2003:

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Contractual Cash Obligations	Total	Less Than One Year	1-3 Years	4-5 Years
	-----	-----	-----	-----
Lease Obligations (1)	\$1,788,807	853,524	935,283	--
Other Obligations (2)	1,628,997	888,544	740,453	--
	-----	-----	-----	-----
Total Contractual Cash Obligations	\$3,417,804	1,742,068	1,675,736	--

- (1) Northfield's Evanston lease agreement is cancellable with six months notice combined with a termination payment equal to six months base rent and six months of additional rental payments. If the lease were terminated today the termination payment would be \$315,530.
- (2) Includes payments required under employment agreements for Steven A. Gould, M.D. and Jack J. Kogut and obligations under a consulting agreement.

RECENT ACCOUNTING PRONOUNCEMENTS

In August 2001, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 143, Accounting for Asset Retirement Obligations, which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and for the associated asset retirement costs. FASB Statement No. 143 requires an enterprise to record the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of tangible long-lived assets that result from the acquisition, construction, development and/or normal use of the assets. The enterprise also is to record a corresponding increase to the carrying amount of the related long-lived assets (i.e., the associated asset retirement costs) and to depreciate that cost over the life of the asset. The liability is changed at the end of each period to reflect the passage of time and changes in the estimated future cash flows underlying the initial fair value measurement. Adoption of FASB Statement No. 143 is required for fiscal years beginning after June 15, 2002. Upon adoption of this provision we expect to record an additional liability of approximately \$138,000, as the additional costs required to restore our leased manufacturing facility back to its move in condition.

In July 2002, the FASB released SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities (FAS 146). FAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. This statement also establishes that fair value is the objective for initial measurement of the liability. SFAS No. 146

is effective for exit or disposal activities after December 31, 2002. The adoption did not have a material effect on the Company's financial position or results of operations.

In November 2002, the FASB released FASB Interpretation No. 45 (FIN 45), Guarantor's Accounting and Disclosure Requirements for Guarantees,

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Including Indirect Guarantees of Indebtedness of Others. FIN 45 requires that a guarantor recognize a liability for the fair value of an obligation assumed under a guarantee. This interpretation also discusses additional disclosures to be made in the interim and annual financial statements of the guarantor about obligations under certain guarantees. The initial measurement and recognition requirements of FIN 45 are effective prospectively for guarantees issued or modified after December 31, 2002, regardless of the guarantors' fiscal year-end. The disclosures requirements in this Interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of FIN 45 did not have a material effect on the financial position, results of operations, or cash flows of the Company.

In December 2002, the FASB released SFAS No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure, an amendment of FASB Statement No. 123 (FAS 148). This Statement amends FASB Statement No. 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of Statement No. 123 to require prominent disclosures in both annual and interim financial statements. The provisions of the Statement related to transition from the intrinsic-value to the fair-value method and annual disclosures are effective for fiscal years ending after December 15, 2002. The provisions of the Statement related to interim disclosures are effective in financial reports containing financial statements for interim

periods beginning after December 31, 2002. The adoption of FAS 148 will not have a material effect on the financial position, results of operations, or cash flows of the Company.

QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISKS

Our marketable security investments have been made for investment (as opposed to trading) purposes. Interest rate risk with respect to our investments is not significant as all such investments are in U.S. dollar cash equivalents and short-term investments (with maturities of less than 12 months), which by their nature are less sensitive to interest rate movements. Our investments are generally made in U.S. government and federal agency bonds, high-grade commercial paper, corporate bonds and certificates of deposit. A one percentage point decrease or increase on an investment balance of \$9.5 million would change annual interest income by \$95,000.

CONTROLS AND PROCEDURES

We maintain a set of disclosure controls, procedures and internal controls designed to ensure that information required to be disclosed in our filings under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our principal executive and financial officers have evaluated our disclosure controls and procedures within 90 days prior to the filing of this Quarterly Report on Form 10-Q and have determined that such disclosure controls and procedures are effective.

Subsequent to our evaluation, there were no significant changes in internal controls or other factors that could significantly affect internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

PART II. OTHER INFORMATION

Item 6. Exhibits

- a)
 - Exhibit 15 - Acknowledgment of Independent Certified Public Accountants
 - Exhibit 99.1 - Certification of Chief Executive Officer
 - Exhibit 99.2 - Certification of Chief Financial Officer

b) Report on Form 8-K:

The Company filed a report dated August 9, 2002, in which Steven A. Gould, M.D., Chief Executive Officer and Jack J. Kogut, Chief Financial Officer of Northfield Laboratories Inc., submitted certifications to the Securities and Exchange Commission pursuant to Section 906 of the Sarbanes-Oxley Act.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company in the capacities indicated on April 14, 2003.

SIGNATURE	TITLE
/s/ Steven A. Gould, M.D. ----- Steven A. Gould, M.D.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)
/s/ Jack J. Kogut ----- Jack J. Kogut	Sr. Vice President and Chief Financial Officer

CERTIFICATION

I, Steven A. Gould, M.D., Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Northfield

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Laboratories Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
 - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:
 - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 14, 2003

/s/ Steven A. Gould, M.D.

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

CERTIFICATION

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

I, Jack J. Kogut, Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Northfield Laboratories Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
 - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:
 - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 14, 2003

/s/ Jack J. Kogut

Jack J. Kogut
Chief Financial Officer

