

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

NORTHFIELD LABORATORIES INC /DE/  
Form 10-Q  
April 14, 2004

=====

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 29, 2004

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  NO

INDICATE BY CHECK MARK WHETHER THE REGISTRANT IS AN ACCELERATED FILER (AS  
DEFINED IN RULE 12b-2 OF THE EXCHANGE ACT).

YES  NO

AS OF APRIL 12, 2004, REGISTRANT HAD 19,019,540 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 undue 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 29, 2004, and the related statements of operations for the three and nine month periods and cash flows for the nine month periods ended February 29, 2004 and February 28, 2003, and for the period from June 19, 1985 (inception) through February 29, 2004. We have also reviewed the statements of shareholders' equity (deficit) for the nine-month period ended February 29, 2004 and for the period from June 19, 1985 (inception) through February 29, 2004. 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 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, 2003, and the related statements of operations,

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

shareholders' equity (deficit), and cash flows for the year then ended and for the period from June 19, 1985 (inception) through May 31, 2003 (not presented herein); and in our report dated July 28, 2003, 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, 2003 and in the accompanying statement of shareholders' equity (deficit) is fairly stated, in all material respects, in relation to the statements from which it has been derived.

As discussed in note 4 to the financial statements, the Company adopted Statement of Financial Accounting Standards No. 143, "Accounting for Asset Retirement Obligations", as of June 1, 2003.

/s/ KPMG LLP

Chicago, Illinois  
April 5, 2004

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

Balance Sheets

February 29, 2004 and May 31, 2003

ASSETS	FEBRUARY 29, 2004	MAY 31, 2003
	-----	-----
Current assets:		
Cash	\$ 18,699,170	4,897,
Marketable securities	3,074,808	1,992,
Prepaid expenses	263,064	688,
Other current assets	29,367	
	-----	-----
Total current assets	22,066,409	7,579,
Property, plant, and equipment, net	1,138,430	1,596,
Other assets	86,306	71,
	-----	-----
Total assets	\$ 23,291,145	9,246,
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 556,286	1,462,
Accrued expenses	35,611	61,
Accrued compensation and benefits	324,063	377,
	-----	-----

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

Total current liabilities	915,960	1,901,
Other liabilities	259,164	165,
	-----	-----
Total liabilities	1,175,124	2,066,
	-----	-----
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 19,019,540 at February 29, 2004 and 14,265,875 at May 31, 2003	190,195	142,
Additional paid-in capital	142,543,472	117,503,
Deficit accumulated during the development stage	(120,438,163)	(110,465,
Deferred compensation	(179,483)	
	-----	-----
Total shareholders' equity	22,116,021	7,180,
	-----	-----
Total liabilities and shareholders' equity	\$ 23,291,145	9,246,
	=====	=====

See accompanying notes to financial statements.

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

Statements of Operations

Three and nine months ended February 29, 2004 and February 28, 2003 and for the period from June 19, 1985 (inception) through February 29, 2004

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	FEBRUARY 29, ----- 2004 ----- (unaudited) -----	FEBRUARY 28, ----- 2003 ----- (unaudited) -----	FEBRUARY 29, ----- 2004 ----- (unaudited) -----	FEBRUARY 28, ----- 2003 ----- (unaudited) -----
Revenues - license income	\$ --	--	--	--
Costs and expenses:				
Research and development	2,630,388	2,203,047	7,387,751	6,
General and administrative	882,913	745,528	2,587,086	2,
	-----	-----	-----	-----

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

	3,513,301	2,948,575	9,974,837	9,
	-----	-----	-----	-----
Other income and expense:				
Interest income	28,880	43,673	77,352	
Interest expense	--	--	--	
	-----	-----	-----	-----
	28,880	43,673	77,352	
	-----	-----	-----	-----
Cumulative effect of change in accounting principle	--	--	74,921	
	-----	-----	-----	-----
Net loss	\$ (3,484,421)	(2,904,902)	(9,972,406)	(8,
	=====	=====	=====	=====
Net loss per share - basic and diluted	\$ (0.20)	(0.20)	(0.62)	
	=====	=====	=====	=====
Shares used in calculation of per share data - basic and diluted	17,092,979	14,265,875	16,069,729	14,
	=====	=====	=====	=====

See accompanying notes to financial statements.

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

Statements of Shareholders' Equity (Deficit)

Nine months ended February 29, 2004 and for the period from June 19, 1985  
(inception) through February 29, 2004

	NUMBER OF SHARES	AGGREG AMOUNT
	-----	-----
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	--	

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

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 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.

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

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		
--	\$ --	--	\$ --	\$ (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)
--	--	--	--	--	--

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

--	--	--	--	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)
-----	-----	-----	-----	-----	-----

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

Statements of Shareholders' Equity (Deficit)

Nine months ended February 29, 2004 and for the period  
from June 19, 1985 (inception) through February 29, 2004

	PREFERRED STOCK	
	NUMBER OF SHARES	AGGREGATE 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,	--	--



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

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	--	--
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 May 31, 2003	--	--
Issuance of common stock at \$5.60 per share on July 28, 2003 (net of costs of issuance of \$909,229)	--	--
Issuance of common stock to directors at \$6.08 per share on October 30, 2003	--	--
Deferred compensation related to stock grants	--	--
Amortization of deferred compensation	--	--
Issuance of common stock at \$5.80 per share on January 29,		

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

2004 (net of costs of issuance of \$1,126,104)	--	--
Issuance of common stock at \$5.80 per share on February 18,		
2004 (net of costs of issuance of \$116,423)	--	--
Net loss	--	--
	-----	-----
Balance at February 29, 2004		\$
	=====	=====

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	--
--	--	--	--	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	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----

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

--	--	--	--	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)
--	--	--	--	--	(12,250,145)
-----	-----	-----	-----	-----	-----
--	--	--	--	117,503,271	(110,465,757)
--	--	--	--	9,671,843	--
--	--	--	--	74,877	--
--	--	--	--	190,995	--
--	--	--	--	--	--
--	--	--	--	13,846,633	--
--	--	--	--	1,255,853	--
--	--	--	--	--	(9,972,406)
-----	-----	-----	-----	-----	-----
--	\$	--	\$	\$ 142,543,472	(120,438,163)
=====	=====	=====	=====	=====	=====

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

Statements of Cash Flows

Nine months ended February 29, 2004 and February 28, 2003  
and for the period from June 19, 1985  
(inception) through February 29, 2004

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

	NINE MONTHS ENDED	
	FEBRUARY 29, 2004	FEBRUARY 28, 2003
Cash flows from operating activities:		
Net loss	\$ (9,972,406)	(8,926,352)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	519,850	604,762
Non-cash compensation	86,767	--
Loss on sale of equipment	--	--
Changes in assets and liabilities:		
Prepaid expenses	425,691	246,787
Other current assets	(29,367)	(14,845)
Other assets	(14,907)	--
Accounts payable	(906,300)	(622,865)
Accrued expenses	(25,908)	(48,510)
Accrued compensation and benefits	(53,054)	14,136
Other liabilities	94,120	(8,839)
Net cash used in operating activities	(9,875,514)	(8,755,726)
Cash flows from investing activities:		
Purchase of property, plant, equipment, and capitalized engineering costs	(72,505)	(172,863)
Proceeds from sale of land and equipment	--	--
Proceeds from matured marketable securities	2,000,000	--
Proceeds from sale of marketable securities	--	--
Purchase of marketable securities	(3,072,260)	(1,953,138)
Net cash used in investing activities	(1,144,765)	(2,126,001)
Cash flows from financing activities:		
Proceeds from issuance of common stock	26,973,243	--
Payment of common stock issuance costs	(2,151,756)	--
Proceeds from issuance of preferred stock	--	--
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	24,821,487	--
Net (decrease) increase in cash	13,801,208	(10,881,727)
Cash at beginning of period	4,897,962	17,668,687
Cash at end of period	\$ 18,699,170	6,786,960

See accompanying notes to financial statements.

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

NORTHFIELD LABORATORIES INC.

(A COMPANY IN THE DEVELOPMENT STAGE)

NOTES TO FINANCIAL STATEMENTS

FEBRUARY 29, 2004

## (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, 2004. The interim financial statements should be read in connection with the audited financial statements for the year ended May 31, 2003.

## (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. Of the total options outstanding as of February 29, 2004, the Company has 1,033,500 options with an exercise price less than the market price and 181,000 options with an exercise price greater than the market price that were excluded from the earnings per share calculation.

## (3) GOING CONCERN UNCERTAINTY

The financial statements of the Company have been presented based on the assumption that the Company will continue as a going concern. The Company, however, may not be able to continue as going concern because it expects to experience significant future losses and currently has insufficient capital resources to fund its continuing operations. The Company believes its existing capital resources will be adequate to satisfy its operating capital requirements and maintain its existing manufacturing plant and office facilities for nine to twelve months. In addition, the Company expects its existing capital resources will be sufficient to support expenditures incurred in connection with the Company's ongoing Phase III clinical trials during this period. Thereafter, the Company will require substantial additional funding to continue its operations and complete its planned clinical trials.

In July 2003, the Company raised \$10,600,000 in gross proceeds through an offering of its common stock. In January 2004, the Company raised \$14,998,597 in gross proceeds through an offering of its common stock and in February 2004, the Company raised an additional \$1,374,646 in gross proceeds through the issuance of additional shares to existing shareholders from the Company's January

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

offering. The Company may issue additional equity or debt securities or 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. The Company is also pursuing potential sources of government funding. Any one or a combination of these sources may be utilized to raise additional capital. We believe our ability to raise additional capital will depend primarily on the progress we make toward the commercialization of our potential product, as well as general conditions in the business and financial markets. There can be no assurance that the Company will be successful in raising additional capital. The Company's inability to raise

sufficient levels of capital could materially delay or prevent the commercialization of its PolyHeme(R) blood substitute product and could result in the cessation of the Company's business. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### (4) ASSET RETIREMENT OBLIGATIONS

The Company adopted Statement of Financial Accounting Standards, SFAS No. 143 - "Accounting for Asset Retirement Obligations" as of June 1, 2003. The cumulative effect of the change in accounting principle upon implementation was to recognize a net asset of \$17,800, an increase in liabilities of \$92,721 and an increase in net loss of \$74,921, or \$0.01 per share.

The obligation relates to the restoration of a leased manufacturing facility to its original condition. A liability of \$100,000 had been recorded in a prior period.

The Company's asset retirement obligations are included in other liabilities. The balances and changes thereto are summarized below:

	QUARTER ENDED FEBRUARY 29, 2004
Obligation at June 1, 2003	\$192,721
Accretion	13,008
Obligation at February 29, 2004	\$205,729

If the change in accounting had been applied retroactively, the Company's pro forma net loss for the three and nine months ended February 28, 2003 would have been \$2,909,592 and \$8,996,582. The Company's pro forma liability at February 28, 2003 would have been \$188,742.

### (5) STOCK OPTIONS

The Company accounts for its fixed plan stock options under the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for options granted to directors, officers, and key employees under the plans. As such, compensation expense is recorded on the date of grant and amortized over the period of service only if the current market value of the underlying stock exceeded the exercise price. No stock-based employee compensation cost is reflected in net loss, as each option granted under these plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

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

The following table illustrates the effect on net loss if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock Based Compensation", to the measurement of stock-based employee compensation, including a straight-line recognition of compensation costs over the related vesting periods for fixed awards:

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	FEB 29, 2004	FEB. 28, 2003	FEB. 29, 2004	FEB. 28, 2003
	----- (unaudited)	----- (unaudited)	----- (unaudited)	----- (unaudited)
Net loss as reported	\$ (3,484,421)	(2,904,902)	(9,972,406)	(8,926,
Add: stock-based employee compensation expense included in reported net earnings (loss), net of related tax effects	11,767	0	86,767	
Deduct: total stock based compensation expense determined under the fair value method for all awards, net of related tax effects	(156,098)	(169,808)	(590,712)	(509,
	----- (3,628,752)	----- (3,074,710)	----- (10,476,351)	----- (9,435,
	=====	=====	=====	=====
Basic and diluted loss per share:				
As reported	\$ (0.20)	(0.20)	(0.62)	(0
Pro forma	\$ (0.21)	(0.22)	(0.65)	(0
	=====	=====	=====	=====

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

As of February 29, 2004, Northfield Laboratories Inc. ("Northfield") had available cash balances of \$21,774,000. This balance represents an increase of \$11,964,000 from the \$9,810,000 we reported as of November 30, 2003. The increase in cash is the result of successful offering transactions completed on January 29, 2004 and February 18, 2004 in which we sold a combined 2,823,000 shares of our common stock and raised \$16,373,000 in gross proceeds. The offerings were made pursuant to a shelf registration statement, which allows us to issue up to \$50.0 million in securities. To date, we have issued approximately \$27.0 million in securities under this registration statement.

We forecast that this \$21,774,000 will be sufficient to fund current operational costs and third party costs for our Phase III pre-hospital trauma trial of our PolyHeme(R) blood substitute product for approximately the next 9 to 12 months.

As we have previously announced, our goal is to have at least 20 Level I trauma centers, the most sophisticated sites for trauma care, participate in

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

our trial. As of February 29, 2004, there were 22 institutions in 18 cities that had publicly disclosed their intent to participate in our clinical trial. As of that date, five of the institutions were already enrolling patients and the other 17 were actively engaged in the community consultation that is required prior to initiating enrollment as mandated in the federal regulation that permits certain trials to be performed with an exception from the requirement for informed consent. We are also in dialogue with a number of additional potential sites that have not yet publicly disclosed their intent to participate in the trial.

We plan to obtain as large a network of institutions as possible to allow enrollment to be completed at the earliest possible date. We are seeking to use sites that have the potential to enroll approximately one patient per week based on prior experience documented in the trauma registry at each institution. If that goal is achieved, once 20 sites are open it would take approximately 36 weeks to complete enrollment in our trial if there were no unanticipated challenges. Since we are still ramping up to the 20 or more sites, we believe it will require approximately one year to complete enrollment in our trial. Since the first site was only initiated in late December 2003, however, we believe it is still too early to be certain about the accuracy of this planned timetable. The anticipated third party costs to complete enrollment has been previously estimated to be \$15 million, although our experience to date suggests that these costs may approximate \$16.5 million. These costs are in addition to our ongoing operational costs.

We expect that we will need to raise additional capital to fund operations through the completion of enrollment in our Phase III pre-hospital trauma trial. We may issue additional equity or debt securities, or utilize other financing vehicles, to provide additional capital. During April 2004, existing shareholders from our January offering may purchase an additional 409,000 shares of our common stock at \$5.80 per share, which will generate gross proceeds of approximately \$2.4 million. We believe our ability to raise additional capital will depend primarily on the progress we make toward the commercialization of PolyHeme, as well as general conditions in the business and financial markets. Our inability to raise sufficient levels of capital would severely impair our current operations and would raise significant doubt about our ability to continue as a going concern.

The post-enrollment stage of our trial will include the monitoring and source verification of the collected data, locking the database, the complete analysis of the data, and the preparation of the final study report. Once the study report is completed, it must be included with the full clinical,

preclinical and manufacturing components that will comprise a final Biologics License Application, or BLA, to be submitted to FDA for review. A number of months will be required after completion of enrollment in our trial to first complete the final study report and to then complete the final BLA. We will require additional funds to support these specific post-enrollment activities, as well as the ongoing operations for Northfield that will include the necessary tasks to prepare for the commercialization of PolyHeme.

Since Northfield's incorporation in 1985, we have devoted substantially all of our efforts and resources to the research, development and clinical testing of PolyHeme. 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 29, 2004, we have incurred operating losses totaling \$120,438,000.



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

We will be required to successfully complete our Phase III pre-hospital trauma trial to obtain FDA regulatory approval before PolyHeme can be sold commercially. The FDA regulatory process is subject to significant risks and uncertainties, including those described under "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission. We therefore cannot at this time reasonably estimate the timing of any future revenues from the commercial sale of PolyHeme.

Our success will depend on several factors, including our ability to obtain FDA regulatory approval of PolyHeme and our manufacturing facilities, our ability to obtain sufficient quantities of blood to manufacture PolyHeme in commercial quantities, our ability to manufacture and distribute PolyHeme in a cost-effective manner, our ability to enforce our patent positions and the availability of 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 the three and nine-month periods ended February 29, 2004 and February 28, 2003. From Northfield's inception through February 29, 2004, 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 29, 2004 totaled \$3,513,000, an increase of \$564,000, or 19.1%, from the \$2,949,000 reported in the third quarter of fiscal 2003. The difference was primarily due to increased costs associated with initiating and adding sites in our Phase III pre-hospital trauma trial.

Research and development expenses for the third quarter of fiscal 2004 totaled \$2,630,000, an increase of \$427,000, or 19.4%, from the \$2,203,000 reported in the third quarter of fiscal 2003. Higher expenses were recognized during the third quarter of fiscal 2004 related to launch and ramp up costs for our Phase III pre-hospital trauma trial. These costs included site qualification visits, costs incurred for community consultation and public disclosure as required under our FDA-approved clinical trial protocol, site training for logistics and data recording, and training for analyzing patient blood samples. As of February 29, 2004, 22 clinical sites have been authorized by their Institutional Review Boards to conduct community consultation regarding their

participation in the pre-hospital trial. Of these, five sites are enrolling patients and 17 are actively engaged in various stages of community consultation and public disclosures. In addition, Northfield is actively working with multiple other sites that are evaluating participation in our trial.

We anticipate that research and development expenses will increase significantly from current levels during the fourth quarter of our fiscal year. Additional costs are anticipated for community disclosure, multi-center patient payments, clinical monitoring, database preparation, biostatistical analysis,

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

independent safety appraisal and project management. Multiple additional sites are planning to enroll patients during the fourth quarter. We continue to plan for 20 or more enrolling sites before calendar year end.

General and administrative expenses in the third quarter of fiscal 2004 totaled \$883,000 compared to expenses of \$746,000 in the third quarter of 2003, representing an increase of \$137,000, or 18.4%. This increase was due primarily to higher insurance costs, higher professional service costs relating to intellectual property and enhancing our visibility with governmental entities.

We anticipate an increase in general and administrative expenses, specifically for market analysis and research, over the balance of the fiscal year. Our focus is centered on successfully executing our Phase III pre-hospital trauma trial. An effort, however, will be initiated to enhance our assessment of the potential market and begin to develop plans for the commercial launch of PolyHeme.

For the nine-month period ended February 29, 2004, operating expenses of \$9,975,000 exceeded the operating expenses of \$9,108,000 incurred in the nine-month period ended

February 28, 2003. The dollar increase was \$867,000 and the percentage increase equaled 9.5%. The increases can primarily be attributed to the required work for our Phase III pre-hospital trauma trial. For the nine-month period ending February 29, 2004, research and development costs were 74.1% of total operating expenses. In the comparable prior fiscal year nine-month period, research and development costs equaled 71.1% of total operating expenses.

Research and development expenses for the nine-month period ended February 29, 2004 totaled \$7,388,000, which represents a \$916,000, or 14.2%, increase from the comparable expenses incurred of \$6,472,000 in the nine-month period ended February 28, 2003. During the current fiscal year, our most important activity was the launch of our Phase III pre-hospital trauma trial. This was accomplished by obtaining the required regulatory approvals, preparing site required documentation for both community consultation and institutional review board approval, and formalizing, communicating and conducting site training for logistical and data issues. These efforts and executing the trial are the sources of the increased expenses.

General and administrative expenses for the nine-month period ended February 29, 2004 totaled \$2,587,000, which represents a decrease of \$48,000, or 1.8%, from the expense incurred of \$2,635,000 in the comparable prior year period. The decrease is primarily the result of a reduction in our use of outside professional services.

### INTEREST INCOME

Interest income in the third quarter of fiscal 2004 totaled \$29,000, or a \$15,000 decrease from the \$44,000 in interest income reported in the third quarter of fiscal 2003. Lower yielding investment options accounted for the decrease in interest income. Our sales of common stock

during the current fiscal year have raised investment fund levels to the point that even in today's very low interest rate market, fourth quarter interest

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

income in fiscal 2004 should moderately exceed the interest income earned in the comparable prior year period.

On a fiscal year to date basis, interest income of \$77,000 was \$104,000 lower than in the comparable prior year period. Lower yielding investment options caused the decrease in interest income. In spite of higher available cash balances for the fourth quarter of the current fiscal year, we anticipate total year interest income will be significantly less than was earned in the prior fiscal year.

### NET LOSS

The net loss for the third quarter ended February 29, 2004 was \$3,484,000, or \$0.20 per share, compared to a net loss of \$2,905,000, or \$0.20 per share, for the third quarter ended February 28, 2003. The \$579,000 increased net loss in the current quarter compared to the third quarter of the prior year was primarily the result of increased research and development spending. On a per share basis, the increased net loss was diluted by the additional shares outstanding from successful fund raising efforts this fiscal year and resulted in the loss per share being the same in both reporting periods.

On a fiscal year to date basis, we reported a loss of \$9,972,000, or \$0.62 per share compared to a prior period loss of \$8,926,000, or \$0.63 per share. The increased net loss of \$1,046,000 in the first nine-months of the current fiscal year compared to the same period in the

prior year is diluted by the increased number of shares outstanding in the current fiscal year and caused the nine-month loss per share in the current year to decrease by \$.01.

### LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through February 29, 2004, we have used cash for operating activities and for the purchase of property, plant, equipment and engineering services in the amount of \$119,084,000. For the nine-month periods ended February 29, 2004 and February 28, 2003, these cash expenditures totaled \$9,948,000 and \$8,929,000, respectively. The increased cash outlay for the first nine-month period of fiscal 2004 compared to the comparable period in the prior year is the result of a higher level of research and development expenses related to our Phase III pre-hospital trauma trial in the current year.

We have financed our research and development and other activities to date through the public and private sale of equity securities and, to a more limited extent, through the license of product rights. In the current fiscal year, we sold 4,715,830 shares of our common stock in two registered direct offering transactions that generated gross proceeds before expenses of \$26,973,000. Net proceeds from these offerings were approximately \$24.8 million. As of February 29, 2004, we had cash and marketable securities totaling \$21,774,000.

We believe our existing capital resources will be adequate to satisfy our operating capital requirements and maintain our existing manufacturing plant and office facilities for approximately the next 9 to 12 months. In addition, our existing capital resources are expected to be sufficient to support expenditures incurred in connection with the expansion and execution of the

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

enrollment phase of our Phase III pre-hospital trauma trials during this period. Thereafter, we will require substantial additional funding to continue our operations and report our data to FDA. Our inability to raise sufficient levels of capital would severely impair our current operations and raise significant doubt about our ability to continue as a going concern.

We may issue additional equity or debt securities or enter into collaborative arrangements with strategic partners, which could provide us with additional funding or absorb expenses we would otherwise be required to pay. We are also pursuing potential sources of government funding. Any one or a combination of these sources may be utilized to raise additional capital. During April 2004, existing shareholders from our January offering may purchase an additional 409,000 shares of our common stock at \$5.80 per share, which will generate gross proceeds of approximately \$2.4 million. We believe our ability to raise additional capital will depend primarily on the progress we make toward the commercialization of PolyHeme, as well as general conditions in the business and financial markets. Our inability to raise sufficient levels of capital could materially delay or prevent the commercialization of PolyHeme, even if it is approved by FDA. We cannot ensure that we will be able to achieve product revenues or profitability on a sustained basis or at all.

Our capital requirements may vary materially from those now anticipated because of the timing and results of our clinical testing of PolyHeme, the establishment of relationships with strategic partners, changes in the scale, timing or cost of our planned 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 reflects our more significant judgments and estimates used in the preparation of our 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 Northfield's ability to generate future taxable income. In the event we were to determine that it was more likely than not we would be able to realize our deferred tax assets in the future in excess of their carrying value, an adjustment to recognize the deferred tax assets would increase income in the period such determination was made. As of February 29, 2004, we have recorded a 100 percent valuation allowance against our net deferred tax assets.

### CONTRACTUAL OBLIGATIONS

The following table reflects a summary of our contractual cash obligations as of February 29, 2004:

CONTRACTUAL CASH OBLIGATIONS	TOTAL	LESS THAN ONE YEAR	1-3 YEARS	4 YEARS
-----	-----	-----	-----	-----
Lease Obligations (1)	\$3,559,784	864,897	1,380,082	1,050,000

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

Other Obligations (2)	1,305,453	834,620	470,833	
	-----	-----	-----	
Total Contractual Cash Obligations	\$4,865,237	1,699,517	1,850,915	1,05
	=====	=====	=====	=====

(1) The lease for our Evanston headquarters may be canceled 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. The Mt. Prospect lease for our manufacturing facility has been renewed through August 2009.

(2) Includes payments required under employment agreements for Steven A. Gould, M.D., our Chairman and Chief Executive Officer, and Jack J. Kogut, our Senior Vice President and Chief Financial Officer, and obligations under a consulting agreement. The employment agreements provide for a minimum of one-year severance and additional payments under certain circumstances.

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 asset (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. We adopted this standard as of June 1, 2003. Upon adoption, the cumulative effect of the change in accounting principle was to recognize a net asset of \$17,800, an increase in liabilities of \$92,721 and an increase in net loss of \$74,921, or \$.01 per share.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liability and Equity. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It also requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, except for certain mandatorily redeemable financial instruments. For certain mandatorily redeemable financial instruments the Statement will be effective on January 1, 2005. The effective date has been deferred indefinitely for certain other types of mandatorily redeemable financial instruments. The adoption of SFAS No. 150 did not have a significant impact on our consolidated financial position, results of operations, or cash flows.

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

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK.

We currently do not have any foreign currency exchange risk. We invest our cash and cash equivalents in government securities, certificates of deposit and money market funds. These investments are subject to interest rate risk. However, due to the nature of our short-term investments, we believe that the financial market risk exposure is not material. A one percentage point decrease on an investment balance of \$21.7 million would decrease interest income by \$217,000 on an annual basis.

### ITEM 4. CONTROLS AND PROCEDURES.

Based on their evaluation as of the end of the period covered by this report, our Chief Executive Officer and Senior Vice President and Chief Financial Officer have concluded that Northfield's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 6. Exhibits

- a) Exhibit 15 - Acknowledgment of Independent Certified Public Accountants
- Exhibit 31.1 - Certification of Steven A. Gould, M.D., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 31.2 - Certification of Jack J. Kogut, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.1 - Certification of Steven A. Gould, M.D., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.2 - Certification of Jack J. Kogut, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- b) On January 26, 2004 the Registrant filed Form 8-K relating to a registered direct offering registered on Form S-3.

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

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 13, 2004.

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