

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

NORTHFIELD LABORATORIES INC /DE/  
Form 10-Q  
January 10, 2005

=====

UNITED STATES  
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 QUARTERLY PERIOD ENDED NOVEMBER 30, 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

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 NOVEMBER 30, 2004, REGISTRANT HAD 21,551,364 SHARES OF COMMON STOCK  
OUTSTANDING

=====

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING  
INFORMATION

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

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," "forecasts," "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.

### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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 November 30, 2004, and the related statements of operations for the three-month periods ended November 30, 2004 and 2003, and the statements of operations and cash flows for the six-month periods ended November 30, 2004 and November 30, 2003, and for the period from June 19, 1985 (inception) through November 30, 2004. We have also reviewed the statements of shareholders' equity (deficit) for the six-month period ended November 30, 2004 and for the period from June 19, 1985 (inception) through November 30, 2004. These financial statements are the responsibility of the Company's management.

We conducted our review in accordance with standards of the Public Company Accounting Oversight Board (United States). 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 the standards of the Public Company Oversight Board (United States), 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 standards of the Public Company Accounting Oversight Board (United States), the balance sheet of Northfield Laboratories Inc. as of May 31, 2004, 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, 2004 (not presented herein); and in our report dated July 12, 2004, we expressed an unqualified

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

opinion on those financial statements. In our opinion, the information set forth in the accompanying balance sheet as of May 31, 2004 and in the accompanying statements 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  
January 7, 2005

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

#### Balance Sheets

November 30, 2004 and May 31, 2004

	NOVEMBER 30, 2004	MAY 31, 2004
	-----	-----
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash	\$ 18,896,961	39,040,000
Marketable securities	14,956,822	3,440,000
Prepaid expenses	681,351	61,000
Other current assets	118,532	
	-----	-----
Total current assets	34,653,666	43,100,000
Property, plant, and equipment	14,629,792	14,520,000
Accumulated depreciation	(13,833,526)	(13,510,000)
	-----	-----
Net	796,266	1,000,000
	-----	-----
Other assets	69,884	7,000
	-----	-----
	\$ 35,519,816	44,170,000
	=====	=====
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,036,813	1,830,000
Accrued expenses	313,345	110,000
Accrued compensation and benefits	483,531	410,000
	-----	-----

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

Total current liabilities	1,833,689	2,37
Other liabilities	251,728	25
	-----	-----
Total liabilities	2,085,417	2,62
	-----	-----
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 21,551,364 at November 30, 2004 and 21,398,439 at May 31, 2004	215,513	21
Additional paid-in capital	168,227,128	166,53
Deficit accumulated during the development stage	(134,838,223)	(125,03
Deferred compensation	(170,019)	(15
	-----	-----
Total shareholders' equity	33,434,399	41,55
	-----	-----
	\$ 35,519,816	44,17
	=====	=====

See accompanying notes to financial statements and accountants' review report.

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

Statements of Operations

Three and six months ended November 30, 2004 and November 30, 2003 and for the period from June 19, 1985 (inception) through November 30, 2004

	THREE MONTHS ENDED		SIX MONTHS EN
	NOVEMBER 30,	NOVEMBER 30,	NOVEMBER 30, N
	-----	-----	-----
	2004	2003	2004
	-----	-----	-----
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Revenues - license income	\$ --	--	--
	-----	-----	-----
Costs and expenses:			
Research and development	4,177,450	2,558,012	8,215,886
General and administrative	910,063	1,021,644	1,858,788
	-----	-----	-----
	5,087,513	3,579,656	10,074,674
	-----	-----	-----
Other income and expense:			
Interest income	155,814	25,046	276,006

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

Interest expense	--	--	--
	-----	-----	-----
	155,814	25,046	276,006
	-----	-----	-----
Cumulative effect of change in accounting principle	--	--	--
	-----	-----	-----
Net loss	\$ (4,931,699)	(3,554,610)	(9,798,668)
	=====	=====	=====
Net loss per share - basic and diluted	\$ (0.23)	(0.22)	(0.46)
	=====	=====	=====
Shares used in calculation of per share data - basic and diluted	21,440,357	16,162,934	21,422,267
	=====	=====	=====

See accompanying notes to financial statements and accountants' review report.

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

Statements of Shareholders' Equity (Deficit)

Six months ended November 30, 2004 and for the period  
from June 19, 1985 (inception) through November 30, 2004

	PREFERRED STOCK	
	NUMBER OF SHARES	AGGREGATE 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	--	
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	--	
	-----	-----

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

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	---	
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	---	\$

See accompanying notes to financial statements and accountants' review report.

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)
--	--	--	--	--	--
--	--	--	--	36,427,614	(15,956,367)
--	--	--	--	503,100	--
--	--	--	--	--	(7,006,495)

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

--	--	--	--	--	--	--
-----	-----	-----	-----	-----	-----	-----
--	--	--	--	--	36,930,714	(22,962,862)
--	--	--	--	--	106,890	--
--	--	--	--	--	5,663,710	--
--	--	--	--	--	--	(8,066,609)
--	--	--	--	--	--	--
-----	-----	-----	-----	-----	-----	-----
--	--	--	--	--	42,701,314	(31,029,471)
--	--	--	--	--	--	(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)

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

Statements of Shareholders' Equity (Deficit)

Six months ended November 30, 2004 and for the period  
from June 19, 1985 (inception) through November 30, 2004

	PREFERRED STOCK	
	NUMBER OF SHARES	AGGREGATE AMOUNT
	-----	-----
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	--	--

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

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, 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)	--	--
Issuance of common stock at \$5.80 per share on April 15, 2004 (net of costs of issuance of \$192,242)	--	--
Issuance of common stock at \$12.00 per share on May 18, 2004 (net of costs of issuance of \$1,716,831.36)	--	--
Exercise of stock options at \$6.38 per share	--	--
Net loss	--	--
	-----	-----
Balance at May 31, 2004	--	--
Exercise of stock options at \$6.38 per share	--	--
Deferred compensation related to stock grants	--	--
Amortization of deferred compensation	--	--
Exercise of stock options at \$7.83 per share	--	--
Exercise of stock options at \$13.38 per share	--	--
Exercise of stock options at \$10.88 per share	--	--
Exercise of stock options at \$10.81 per share	--	--
Issuance of common stock to directors at \$12.66 per share on September 21, 2004	--	--
Net loss	--	--
	-----	-----

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

Balance at November 30, 2004 (unaudited)

\$

See accompanying notes to financial statements and accountants' review report.

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

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

-----	-----	-----	-----	-----	-----	-----
--	--	--	--	--	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	--
--	--	--	--	--	2,178,664	--
--	--	--	--	--	21,716,616	--
--	--	--	--	--	95,550	--
--	--	--	--	--	--	(14,573,798)
-----	-----	-----	-----	-----	-----	-----
--	--	--	--	--	166,534,302	(125,039,555)
--	--	--	--	--	38,220	--
--	--	--	--	--	71,055	--
--	--	--	--	--	--	--
--	--	--	--	--	19,550	--
--	--	--	--	--	267,400	--
--	--	--	--	--	195,660	--
--	--	--	--	--	1,026,000	--
--	--	--	--	--	74,941	--
--	--	--	--	--	--	(9,798,668)
-----	-----	-----	-----	-----	-----	-----
--	\$	--	\$	--	\$ 168,227,128	\$ (134,838,223)

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

Statements of Cash Flows

Six months ended November 30, 2004 and 2003  
and for the period from June 19, 1985  
(inception) through November 30, 2004

SIX MONTHS ENDED NOVEMBER 30,

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

	2004	2003
	-----	-----
	(unaudited)	(unaudited)
Cash flows from operating activities:		
Net loss	\$ (9,798,668)	(6,487,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	370,838	345,000
Non-cash compensation	131,711	75,000
Loss on sale of equipment	--	--
Changes in assets and liabilities:		
Prepaid expenses	(66,687)	215,000
Other current assets	(117,450)	--
Other assets	--	(15,000)
Accounts payable	(800,838)	(995,000)
Accrued expenses	196,338	1,000
Accrued compensation and benefits	64,718	32,000
Other liabilities	(1,028)	93,000
	-----	-----
Net cash used in operating activities	(10,021,066)	(6,735,000)
	-----	-----
Cash flows from investing activities:		
Purchase of property, plant, equipment, and capitalized engineering costs	(108,237)	(43,000)
Proceeds from sale of land and equipment	--	--
Proceeds from matured marketable securities	6,450,000	2,000,000
Proceeds from sale of marketable securities	--	--
Purchase of marketable securities	(18,014,865)	--
	-----	-----
Net cash provided by (used in) investing activities	(11,673,102)	1,957,000
	-----	-----
Cash flows from financing activities:		
Proceeds from issuance of common stock	1,548,245	10,600,000
Payment of common stock issuance costs	--	(909,000)
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	1,548,245	9,691,000
	-----	-----
Net (decrease) increase in cash	(20,145,923)	4,912,000
	-----	-----
Cash at beginning of period	39,042,884	4,897,000
	-----	-----
Cash at end of period	\$ 18,896,961	9,810,000
	=====	=====

See accompanying notes to financial statements and accountants' review report.

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

NORTHFIELD LABORATORIES INC.  
(A COMPANY IN THE DEVELOPMENT CHANGE)  
NOTES TO FINANCIAL STATEMENTS  
NOVEMBER 30, 2004  
(UNAUDITED)

### (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, 2005. The interim financial statements should be read in connection with the audited financial statements for the year ended May 31, 2004.

### (2) USE OF ESTIMATES

Our management has made a number of estimates and assumptions relating to the reporting of assets and liabilities and the disclosure of contingent assets and liabilities to prepare these financial statements in conformity with accounting principles generally accepted in the United States of America. Actual results could differ from those estimates.

### (3) 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 we reported a net loss for all periods presented, basic and diluted per share amounts are the same. As of November 30, 2004, we have 1,206,500 options and 212,392 warrants that were excluded from the net loss per share calculation because their inclusion would have been antidilutive.

### (4) ASSET RETIREMENT OBLIGATIONS

We 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 to the adoption of SFAS No. 143.

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

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

Quarter Ended November 30, 2004

-----	
	(unaudited)
Obligation at May 31, 2004	\$210,066
Accretion	9,452
	-----
Obligation at November 30, 2004	\$219,518
=====	

If the change in accounting had been applied retroactively, our pro forma net loss for the six months ended November 30, 2003 would have been \$6,413,064, with a \$0.01 decrease in loss per share.

(5) STOCK OPTIONS

We account for our 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.

The following table illustrates the effect on net loss if we had applied the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) 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	
	November 30, 2004	November 30, 2003
	----- (unaudited)	----- (unaudited)
Net loss as reported	\$ (4,931,699)	(3,554,610)
Add: Stock based compensation expense included in statements of operations	107,870	75,000
Deduct: Total stock based compensation expense determined under the fair value method for all awards, net of related tax effects	(639,175)	(275,962)
	----- (5,463,004) =====	----- (3,755,572) =====

Basic and diluted loss per share:

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

As reported	(0.23)	(0.22)
Pro forma	(0.25)	(0.24)
	=====	=====

### Recently Issued Accounting Standards

- (6) In December 2004, Statement of Financial Accounting Standards (SFAS) No. 123 (Revised 2004), "Share-Based Payment: an amendment of FASB Statements No. 123 and 95", was issued. This Statement amends SFAS No. 123, "Accounting for Stock-Based Compensation", and requires companies to recognize in the income statement the grant-date fair value of stock options and other equity-based compensation issued to employees. The Statement is effective for public companies with interim or annual periods beginning after June 15, 2005. The Company will adopt SFAS 123(R) for the period ended November 30, 2005. The Company will assess the impact of the transition to this new accounting standard during the upcoming months.

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

### RECENT DEVELOPMENTS

We are currently enrolling patients in a pivotal Phase III trial in which PolyHeme is being used for the first time in civilian, urban trauma settings to treat severely injured patients in hemorrhagic shock before they reach the hospital. Under this protocol, treatment with PolyHeme begins at the scene of the injury or in the ambulance and continues during transport and the initial 12 hour post-injury period in the hospital. Since blood is not presently carried in ambulances, the use of PolyHeme in this setting has the potential to improve survival and address a critical, unmet medical need.

As of January 10, 2005, 16 clinical sites in the United States were enrolling patients in our pivotal Phase III trial and two other sites had received final Institutional Review Board approval and were preparing to begin patient enrollment. Eight additional sites were engaged in the pre-trial public disclosure and community consultation process. Each of the sites participating in the trial is designated as a Level I trauma center because of its capacity to treat the most severely injured trauma patients. We anticipate that a total of approximately 25 or more clinical sites across the United States will eventually participate in the trial. The trial has an expected enrollment of 720 patients.

As part of our trial protocol, an independent data monitoring committee, or IDMC, consisting of independent medical and biostatistical experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any identified risks to patients. The protocol includes four planned evaluations by the IDMC that occur after 60, 120, 250 and 500 patients have been enrolled and monitored for a 30-day follow up period. The IDMC will focus its initial review on mortality and serious adverse events and will review all safety data as the trial continues. We will receive a recommendation from the IDMC after each review, but we will not have access to the trial data reviewed by the IDMC until the trial is completed.

In July 2004, the IDMC recommended that our trial continue without modification based on the committee's initial review of blinded data on mortality and serious adverse events from the evaluation of the first 60

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

patients enrolled in the trial. The IDMC again recommended continuation of the trial without modification in October 2004 based on its review of data following enrollment of the first 120 patients. The length of time for completion of the IDMC review after each enrollment target is reached is expected to become longer as the number of enrolled patients increases. Enrollment in the trial continues during the period of 30 day follow-up, the data preparation and analysis, and the actual IDMC meeting, so the disclosure of the IDMC recommendation does not correspond to the current status of patient enrollment. We anticipate that the IDMC will complete its third review of trial data on the first 250 patients enrolled in our trial in the second calendar quarter of 2005. Northfield's current goal is to complete the patient enrollment phase of our trial by the end of calendar 2005. Our ability to achieve this goal will depend, in part, on the number of clinical sites participating in our trial, and the ability of these sites to enroll patients at the projected rates.

The progress of our pivotal Phase III trial and the timing and outcome of the FDA review process are subject to significant risks and uncertainties, many of which are outside of our control. We urge you review the "Risk Factors" section in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission for a discuss of certain of these risks and uncertainties.

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(R). 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 November 30, 2004, we have incurred operating losses totaling \$134,838,000.

We will be required to complete our pivotal Phase III trial and obtain regulatory approval from Food and Drug Administration 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. The costs incurred by Northfield to date and during each period presented below in connection with our development of PolyHeme are described in the Statements of Operations in our financial statements.

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 and six-month periods ended November 30, 2004 or 2003. From Northfield's inception through November 30, 2004, we have reported total revenues of \$3,000,000, all of which were derived from licensing fees.

### OPERATING EXPENSES

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

Operating expenses for our second fiscal quarter ended November 30, 2004 totaled \$5,088,000, an increase of \$1,508,000 from the \$3,580,000 reported in the second quarter of fiscal 2004. Measured on a percentage basis, fiscal 2005 operating expenses exceeded fiscal 2004 expenses by 42.1%. As expected, significant increases in operating expenses were incurred to conduct, expand, report and support our pivotal Phase III trial.

Research and development expense during the second quarter of fiscal 2005 totaled \$4,177,000, an increase of \$1,619,000, or 63.3%, from the \$2,558,000 reported in the second quarter of fiscal 2004. Our pivotal Phase III trial is enrolling patients and we continue to actively pursue additional Level I trauma sites to participate. As of November 30, 2004, 16 sites had full Institutional Review Board approval and were enrolling patients. Work continues to achieve our goal of having 20 to 25 sites enrolling patients by Spring 2005. Included in the second quarter of fiscal 2005 research and development expense was an increase of \$1,385,000 for clinical site charges and for data accumulation, data monitoring and analysis compared to the second quarter of fiscal 2004. We anticipate that these expenses will continue to grow consistent with the rate of patient enrollment and site initiation. Also included in the second quarter research and development expenses was an increased use of science consultants to prepare for the reporting to FDA.

General and administrative expenses in the second quarter of fiscal 2005 totaled \$910,000, which is a decrease of \$112,000, or 11.0%, from the general and administrative expenses reported in the second quarter of fiscal 2004 of \$1,022,000. The decreased expense in the second quarter of fiscal 2005 compared to the second quarter of fiscal year 2004 was due to a reduced use of professional services and administrative consulting. We anticipate modest increases in general and administrative expenses over the balance of fiscal 2005. Our new Internet Web site was launched in September 2004 and an expansion of business development activities is planned. Successfully completing our pivotal Phase III trial remains our primary focus.

For the six-month period ended November 30, 2004, operating expenses of \$10,075,000 exceeded the operating expenses of \$6,462,000 incurred in the six-month period ended November 30, 2003. The dollar increase was \$3,613,000 and the percentage increase equaled 55.9%. The increases can primarily be attributed to the planning, preparation, execution, analysis and reporting of our pivotal Phase III trial.

Research and development expenses for the six-month period ended November 30, 2004 totaled \$8,216,000, which represents a \$3,459,000, or 72.7%, increase from the comparable expenses incurred in the six-month period ended November 30, 2003. During the current fiscal year, increased expense totalling \$2,744,000 was reported for sites in monitoring related activities. Additional expenses were also recorded to manufacture increased quantities of clinical material. The cost of additional personnel and higher benefit costs also added to the current year expenses.

General and administrative expenses for the six-month period ended November 30, 2004 totaled \$1,859,000, which is an increase of \$155,000, or 9.1%, from the general and administrative expenses reported for the six-month period ended November 30, 2003 of \$1,704,000. The increased expenses this fiscal year are

due to taxes payable on our increased market capitalization and expenses related

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

to preparing for commercialization. We anticipate modest increases in general and administrative expenses over the balance of fiscal 2005 as successfully completing our pivotal Phase III trial remains our primary focus.

### INTEREST INCOME

Interest income for the three-month period ended November 30, 2004 totaled \$156,000, an increase of \$131,000 from the \$25,000 in interest income reported in the three-month period ended November 30, 2003. Following three successful fund raising efforts in fiscal 2004, Northfield started the fiscal year 2005 with \$42,487,000 in available cash resources. This compares to available cash resources at the beginning of fiscal 2004 of \$6,890,000. The significant increase in cash balances and a modest increase in available short-term interest rates caused interest income to increase.

Interest income for the six-month period ended November 30, 2004 totaled \$276,000, an increase of \$228,000 from the \$48,000 in interest income reported in the six-month period ended November 30, 2003. The increase in cash balances and a modest increase in available short-term interest rates caused interest income to increase. We continue to invest our funds only in high grade, short-term instruments.

### NET LOSS

The net loss for the three-month period ended November 30, 2004 totaled \$4,932,000, or \$0.23 per share, compared to a net loss of \$3,555,000, or \$0.22 per share, for the three-month period ended November 30,

2003. In dollar terms the loss increased by 38.7%, primarily from the expense of conducting our pivotal Phase III trial. However, on a per share basis the additional 5,277,000 shares outstanding in the current year mitigated the loss per share increase to 4.5%.

On a fiscal year to date basis, we reported a loss of \$9,799,000 or \$0.46 per share compared to a prior year six-month loss of \$6,488,000 or \$0.42 per share. The increased net loss of \$3,311,000, primarily from the expense of conducting our pivotal Phase III trial in the first six-months of the current fiscal year as compared to the same period in the prior year was mitigated by the increased number of shares outstanding in the current fiscal year.

### LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through November 30, 2004, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of \$132,525,000. For the six-months ended November 30, 2004 and 2003, these cash expenditures totaled \$10,129,000 and \$6,779,000, respectively. The six-month increase in cash utilization is due primarily to expenses related to our pivotal Phase III trial.

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. As of November 30, 2004, we had cash and marketable securities totaling \$33,854,000. It should be noted that in this fiscal year lobbying efforts have been successful in securing a \$1.4 million federal appropriation as part of the 2005 Defense Appropriation Bill. As of November 30, 2004 we have not yet received the funds.

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

We believe our existing capital resources will be adequate to satisfy our operating capital requirements, including patient enrollment and the initial data accumulation for our pivotal Phase III trial, and maintain our existing manufacturing plant and office facilities for approximately the next 15 to 18 months. Thereafter, we will require substantial additional funding to pursue FDA regulatory approval for Polyheme, to expand our commercial manufacturing and marketing capabilities and to continue our ongoing operations.

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 additional 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 or enter into a collaborative arrangement with a strategic partner will depend primarily on the results of our clinical trial, as well as general conditions in the business and financial markets. An inability to raise sufficient levels of capital could materially delay or prevent the commercialization of PolyHeme, even if approved by FDA.

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 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 November 30, 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 November 30, 2004:

CONTRACTUAL CASH OBLIGATIONS	TOTAL	LESS THAN ONE YEAR	1-3 YEARS	4-5 YEARS
-----	-----	-----	-----	-----

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

Lease Obligations(1) .....	\$2,825,031	\$ 858,656	\$1,587,466	\$378,909
Other Obligations .....	639,045	591,962	47,083	--
	-----	-----	-----	-----
Total Contractual Cash Obligations ...	\$3,464,076	\$1,450,618	\$1,634,549	\$378,909
	=====	=====	=====	=====

-----  
(1) The lease for our Evanston headquarters is cancelable with six months notice combined with a termination payment equal to six months base rent. At November 30, 2004, this penalty would have amounted to \$156,750.

Recently Issued Accounting Standards

In December 2004, Statement of Financial Accounting Standards (SFAS) No. 123 (Revised 2004), "Share-Based Payment: an amendment of FASB Statements No. 123 and 95", was issued. This Statement amends SFAS No. 123, "Accounting for Stock-Based Compensation", and requires companies to recognize in the income statement the grant-date fair value of stock options and other equity-based compensation issued to employees. The Statement is effective for public companies with interim or annual periods beginning after June 15, 2005. The Company will adopt SFAS 123(R) for the period ended November 30, 2005. The Company will assess the impact of the transition to this new accounting standard during the upcoming months.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES 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 our cash and marketable securities of \$33.8 million at November 30, 2004 would decrease interest income by \$338,000 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.

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

## PART II. OTHER INFORMATION

### Item 6. Exhibits

- a) Exhibit 10.1 - Form of restricted stock grant to officers and employees pursuant the Northfield Laboratories Inc. 2003 Equity Compensation Plan
  - Exhibit 10.2 - Form of stock option grant to officers and employees pursuant the Northfield Laboratories Inc. 2003 Equity Compensation Plan
  - Exhibit 10.3 - Form of stock option grant to directors pursuant the Northfield Laboratories Inc. 2003 Equity Compensation Plan.
  - Exhibit 10.4 - Form of stock option grant pursuant the Northfield Laboratories Inc. Stock Option Plan for New Employees
  - Exhibit 15 - Acknowledgment of Independent Registered Public Accounting Firm Regarding Accountants' Review Report
  - Exhibit 31.1 - Certification of Steven A. Gould, M.D., pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934
  - Exhibit 31.2 - Certification of Jack J. Kogut, pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934
  - 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) None

## 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 January 7, 2005.

SIGNATURE

TITLE

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

/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