

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

NORTHFIELD LABORATORIES INC /DE/
Form 10-Q
January 11, 2002

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 NOVEMBER 30, 2001

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 0-24050

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

DELAWARE
(State or other jurisdiction
of incorporation or organization)

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

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

60201-4800
(Zip Code)

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

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

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

YES X NO
--- ---

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

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

AS OF NOVEMBER 30, 2001, REGISTRANT HAD 14,265,875 SHARES OF COMMON STOCK
OUTSTANDING

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

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 November 30, 2001, and the related statements of operations for the three-month period ended November 30, 2001 and November 30, 2000, and statements of operations and cash flows for the six-month periods ended November 30, 2001 and November 30, 2000 and for the period from June 19, 1985 (inception) through November 30, 2001. We have also reviewed the statements of shareholders' equity (deficit) for the six-month period ended November 30, 2001 and for the period from June 19, 1985 (inception) through November 30, 2001. 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, 2001, 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, 2001 (not presented herein); and in our report dated July 2, 2001, 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, 2001 and in the accompanying statement of shareholders' equity (deficit) is fairly stated, in all material respects, in relation to the statement from which it has been derived.

/s/ KPMG LLP

Chicago, Illinois
December 14, 2001

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

Balance Sheets

November 30, 2001 and May 31, 2001

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

ASSETS	NOVEMBER 30, 2001	MAY 31, 2001
	-----	-----
Current assets:		
Cash	\$ 6,401,835	6,435,54
Marketable securities	16,582,942	22,262,84
Prepaid expenses	330,542	378,14
Other current assets	268,963	455,86
	-----	-----
Total current assets	23,584,282	29,532,38
Property, plant, and equipment, net	2,531,027	2,847,33
Other assets	72,916	122,52
	-----	-----
	\$ 26,188,225	32,502,23
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 801,680	1,772,58
Accrued expenses	102,111	153,90
Accrued compensation and benefits	320,038	261,21
	-----	-----
Total current liabilities	1,223,829	2,187,70
Other liabilities	172,994	166,86
	-----	-----
Total liabilities	1,396,823	2,354,56
	-----	-----
Shareholders' equity:		
Preferred stock, \$.01 par value. Authorized 5,000,000 shares; none issued and outstanding	--	--
Common stock, \$.01 par value. Authorized 30,000,000 shares; issued and outstanding 14,265,875 and 14,265,875 shares at November 30, 2001 and May 31, 2001, respectively	142,659	142,65
Additional paid-in capital	117,503,271	117,503,27
Deficit accumulated during the development stage	(92,854,528)	(87,498,25
	-----	-----
Total shareholders' equity	24,791,402	30,147,67
	-----	-----
	\$ 26,188,225	32,502,23
	=====	=====

See accompanying notes to financial statements.

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

Statements of Operations

Three and six months ended November 30, 2001 and 2000 and for the period
from June 19, 1985 (inception) through November 30, 2001

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

	THREE MONTHS ENDED NOVEMBER 30,		SIX MONTHS ENDED NOVEMBER 30,	
	2001	2000	2001	2000
Revenues - license income	\$ --	--	--	--
Costs and expenses:				
Research and development	1,910,675	2,237,122	4,559,349	4,559,349
General and administrative	524,809	557,627	1,367,769	1,367,769
	2,435,484	2,794,749	5,927,118	5,927,118
Other income and expense:				
Interest income	269,780	551,418	570,842	570,842
Interest expense	--	--	--	--
	269,780	551,418	570,842	570,842
Net loss	\$ (2,165,704)	(2,243,331)	(5,356,276)	(5,356,276)
Net loss per share - basic and diluted	\$ (0.15)	(0.16)	(0.38)	(0.38)
Shares used in calculation of per share data - basic and diluted	14,265,875	14,242,375	14,265,875	14,242,375

See accompanying notes to financial statements.

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

Statements of Shareholders' Equity (Deficit)

Six months ended November 30, 2001 and for the
period from June 19, 1985 (inception) through November 30, 2001

Common stock			
Number of shares	Aggregate amount	Number of shares	Aggregate amount

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

Issuance of common stock on August 27, 1985	--	\$ --	3,500,000	\$
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	--	--	3,500,000	
Net loss	--	--	--	
Deferred compensation relating to grant of stock options	--	--	--	
Amortization of deferred compensation	--	--	--	
Balance at May 31, 1987	--	--	3,500,000	
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	--	--	3,500,000	
Issuance of common stock at \$24.21 per share on June 7, 1988 (net of costs of issuance of \$246,000)	--	--	413,020	
Conversion of Series A convertible preferred stock to common stock on June 7, 1988	--	--	1,250,000	
Conversion of Series B convertible preferred stock to common stock on June 7, 1988	--	--	1,003,165	
Exercise of stock options at \$2.00 per share	--	--	47,115	
Issuance of common stock at \$28.49 per share on March 6, 1989 (net of costs of issuance of \$21,395)	--	--	175,525	
Issuance of common stock at \$28.49 per share on March 30, 1989 (net of costs of issuance of \$10,697)	--	--	87,760	
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	--	--	6,476,585	
Net loss	--	--	--	
Deferred compensation relating to grant of stock options	--	--	--	
Amortization of deferred compensation	--	--	--	
Balance at May 31, 1990	--	--	6,476,585	
Net loss	--	--	--	
Amortization of deferred compensation	--	--	--	
Balance at May 31, 1991	--	--	6,476,585	
Exercise of stock warrants at \$5.60 per share	--	--	90,000	
Net loss	--	--	--	
Amortization of deferred compensation	--	--	--	
Balance at May 31, 1992	--	--	6,566,585	
Exercise of stock warrants at \$7.14 per share	--	--	15,000	

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

Issuance of common stock at \$15.19 per share on April 19, 1993 (net of costs of issuance of \$20,724)	--	--	374,370	
Net loss	--	--	--	
Amortization of deferred compensation	--	--	--	
	----	-----	-----	-----
Balance at May 31, 1993	--	\$ --	6,955,955	\$
	----	-----	-----	-----

(Continued)

	Series B convertible preferred stock		Additional	D
	Number of shares	Aggregate amount	paid-in capital	acc dur dev
	-----	-----	-----	---
Issuance of common stock on August 27, 1985	--	\$ --	(28,000)	
Issuance of Series A convertible preferred stock at \$4.00 per share on August 27, 1985 (net of costs of issuance of \$79,150)	--	--	670,850	
Net loss	--	--	--	
	-----	-----	-----	-----
Balance at May 31, 1986	--	--	642,850	
Net loss	--	--	--	(2
Deferred compensation relating to grant of stock options	--	--	2,340,000	
Amortization of deferred compensation	--	--	--	
	-----	-----	-----	-----
Balance at May 31, 1987	--	--	2,982,850	(3
Issuance of Series B convertible preferred stock at \$35.68 per share on August 14, 1987 (net of costs of issuance of \$75,450)	200,633	200,633	6,882,502	
Net loss	--	--	--	(3
Amortization of deferred compensation	--	--	--	
	-----	-----	-----	-----
Balance at May 31, 1988	200,633	200,633	9,865,352	(6
Issuance of common stock at \$24.21 per share on June 7, 1988 (net of costs of issuance of \$246,000)	--	--	9,749,870	
Conversion of Series A convertible preferred stock to common stock on June 7, 1988	--	--	237,500	
Conversion of Series B convertible preferred stock to common stock on June 7, 1988	(200,633)	(200,633)	190,601	
Exercise of stock options at \$2.00 per share	--	--	93,759	
Issuance of common stock at \$28.49 per share on March 6, 1989 (net of costs of issuance of \$21,395)	--	--	4,976,855	
Issuance of common stock at \$28.49 per share on March 30, 1989 (net of costs of issuance of \$10,697)	--	--	2,488,356	
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)	--	--	7,443,118	
Net loss	--	--	--	
Deferred compensation relating to grant of stock options	--	--	683,040	

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

Amortization of deferred compensation	--	--	--
Balance at May 31, 1989	--	--	35,728,451 (6)
Net loss	--	--	-- (3)
Deferred compensation relating to grant of stock options	--	--	699,163
Amortization of deferred compensation	--	--	--
Balance at May 31, 1990	--	--	36,427,614 (10)
Net loss	--	--	-- (5)
Amortization of deferred compensation	--	--	--
Balance at May 31, 1991	--	--	36,427,614 (15)
Exercise of stock warrants at \$5.60 per share	--	--	503,100
Net loss	--	--	-- (7)
Amortization of deferred compensation	--	--	--
Balance at May 31, 1992	--	--	36,930,714 (22)
Exercise of stock warrants at \$7.14 per share	--	--	106,890
Issuance of common stock at \$15.19 per share on April 19, 1993 (net of costs of issuance of \$20,724)	--	--	5,663,710
Net loss	--	--	-- (8)
Amortization of deferred compensation	--	--	--
Balance at May 31, 1993	--	\$ --	42,701,314 (31)

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

Statements of Shareholders' Equity (Deficit)

Six months ended November 30, 2001 and for
the period from June 19, 1985 (inception) through November 30, 2001

	PREFERRED STOCK		COMMON
	NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES
Net loss	--	\$ --	--
Issuance of common stock at \$6.50 per share on May 26, 1994 (net of costs of issuance of \$2,061,149)	--	--	2,500,000
Cancellation of stock options	--	--	--
Amortization of deferred compensation	--	--	--
Balance at May 31, 1994	--	--	9,455,955
Net loss	--	--	--

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

Issuance of common stock at \$6.50 per share on June 20, 1994 (net of issuance costs of \$172,500)	--	--	375,000
Exercise of stock options at \$7.14 per share	--	--	10,000
Exercise of stock options at \$2.00 per share	--	--	187,570
Cancellation of stock options	--	--	--
Amortization of deferred compensation	--	--	--
	-----	-----	-----
Balance at May 31, 1995	--	--	10,028,525
Net loss	--	--	--
Issuance of common stock at \$17.75 per share on August 9, 1995 (net of issuance costs of \$3,565,125)	--	--	2,925,000
Issuance of common stock at \$17.75 per share on September 11, 1995 (net of issuance costs of \$423,238)	--	--	438,750
Exercise of stock options at \$2.00 per share	--	--	182,380
Exercise of stock options at \$6.38 per share	--	--	1,500
Exercise of stock options at \$7.14 per share	--	--	10,000
Cancellation of stock options	--	--	--
Amortization of deferred compensation	--	--	--
	-----	-----	-----
Balance at May 31, 1996	--	--	13,586,155
Net loss	--	--	--
Exercise of stock options at \$0.20 per share	--	--	263,285
Exercise of stock options at \$2.00 per share	--	--	232,935
Exercise of stock options at \$7.14 per share	--	--	10,000
Amortization of deferred compensation	--	--	--
	-----	-----	-----
Balance at May 31, 1997	--	--	14,092,375
Net loss	--	--	--
Exercise of stock options at \$7.14 per share	--	--	5,000
Amortization of deferred compensation	--	--	--
	-----	-----	-----
Balance at May 31, 1998	--	--	14,097,375
Net loss	--	--	--
Non-cash compensation	--	--	--
Exercise of stock options at \$7.14 per share	--	--	17,500
Exercise of stock warrants at \$8.00 per share	--	--	125,000
	-----	-----	-----
Balance at May 31, 1999	--	--	14,239,875
Net loss	--	--	--
Non-cash compensation	--	--	--
Exercise of stock options at \$13.38 per share	--	--	2,500
	-----	-----	-----
Balance at May 31, 2000	--	--	14,242,375
Net loss	--	--	--
Non-cash compensation	--	--	--
Exercise of stock options at \$6.38 per share	--	--	6,000
Exercise of stock options at \$10.81 per share	--	--	17,500
	-----	-----	-----
Balance at May 31, 2001	--	\$ --	14,265,875
Net loss	--	--	--
	-----	-----	-----
Balance at November 30, 2001	--	\$ --	14,265,875
	=====	=====	=====

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

(Continued)

	SERIES B CONVERTIBLE PREFERRED STOCK		ADDITIONAL PAID-IN CAPITAL	DEFERRED ACCUMULATED DURING PERIOD DEVELOPED STOCK
	NUMBER OF SHARES	AGGREGATE AMOUNT		
Net loss	--	\$ --	--	(7,3
Issuance of common stock at \$6.50 per share on May 26, 1994 (net of costs of issuance of \$2,061,149)	--	--	14,163,851	
Cancellation of stock options	--	--	(85,400)	
Amortization of deferred compensation	--	--	--	
Balance at May 31, 1994	--	--	56,779,765	(38,3
Net loss	--	--	--	(7,4
Issuance of common stock at \$6.50 per share on June 20, 1994 (net of issuance costs of \$172,500)	--	--	2,261,250	
Exercise of stock options at \$7.14 per share	--	--	71,300	
Exercise of stock options at \$2.00 per share	--	--	373,264	
Cancellation of stock options	--	--	(106,750)	
Amortization of deferred compensation	--	--	--	
Balance at May 31, 1995	--	--	59,378,829	(45,8
Net loss	--	--	--	(4,7
Issuance of common stock at \$17.75 per share on August 9, 1995 (net of issuance costs of \$3,565,125)	--	--	48,324,374	
Issuance of common stock at \$17.75 per share on September 11, 1995 (net of issuance costs of \$423,238)	--	--	7,360,187	
Exercise of stock options at \$2.00 per share	--	--	362,937	
Exercise of stock options at \$6.38 per share	--	--	9,555	
Exercise of stock options at \$7.14 per share	--	--	71,300	
Cancellation of stock options	--	--	(80,062)	
Amortization of deferred compensation	--	--	--	
Balance at May 31, 1996	--	--	115,427,120	(50,6
Net loss	--	--	--	(4,2
Exercise of stock options at \$0.20 per share	--	--	50,025	
Exercise of stock options at \$2.00 per share	--	--	463,540	
Exercise of stock options at \$7.14 per share	--	--	71,300	
Amortization of deferred compensation	--	--	--	
Balance at May 31, 1997	--	--	116,011,985	(54,8
Net loss	--	--	--	(5,8
Exercise of stock options at \$7.14 per share	--	--	35,650	
Amortization of deferred compensation	--	--	--	
Balance at May 31, 1998	--	--	116,047,635	(60,7
Net loss	--	--	--	(7,4
Non-cash compensation	--	--	14,354	

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

Exercise of stock options at \$7.14 per share	--	--	124,775	
Exercise of stock warrants at \$8.00 per share	--	--	998,750	
	-----	-----	-----	-----
Balance at May 31, 1999	--	--	117,185,514	(68,1
Net loss	--	--	--	(9,1
Non-cash compensation	--	--	57,112	
Exercise of stock options at \$13.38 per share	--	--	33,425	
	-----	-----	-----	-----
Balance at May 31, 2000	--	--	117,276,051	(77,3
Net loss	--	--	--	(10,1
Non-cash compensation	--	--	--	
Exercise of stock options at \$6.38 per share	--	--	38,220	
Exercise of stock options at \$10.81 per share	--	--	189,000	
	-----	-----	-----	-----
Balance at May 31, 2001	--	\$ --	\$117,503,271	(87,4
	-----	-----	-----	-----
Net loss	--	--	--	(5,3
	-----	-----	-----	-----
Balance at November 30, 2001	--	\$ --	\$117,503,271	(92,8
	=====	=====	=====	=====

See accompanying notes to financial statements

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

Statements of Cash Flows

Six months ended November 30, 2001 and 2000
and the cumulative period from June 19, 1985
(inception) through November 30, 2001

	SIX MONTHS ENDED NOVEMBER 30	
	2001	2000
	-----	-----
Cash flows from operating activities:		
Net loss	\$ (5,356,276)	(4,761,2
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	431,905	247,0
Non-cash compensation	--	
Loss on sale of equipment	--	
Changes in assets and liabilities:		

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

Prepaid expenses	47,600	135,9
Other current assets	186,897	(26,7
Other assets	49,101	(49,2
Accounts payable	(970,902)	153,0
Accrued expenses	(51,794)	(82,6
Accrued compensation and benefits	58,825	16,6
Other liabilities	6,134	13,0
	-----	-----
Net cash used in operating activities	(5,598,510)	(4,354,0
	-----	-----
Cash flows from investing activities:		
Purchase of property, plant, equipment, and capitalized engineering costs	(115,094)	(599,7
Proceeds from sale of land and equipment	--	
Proceeds from matured marketable securities	10,679,200	5,774,5
Proceeds from sale of marketable securities	--	
Purchase of marketable securities	(4,999,301)	(6,416,2
	-----	-----
Net cash provided by (used in) investing activities	5,564,805	(1,241,4
	-----	-----
Cash flows from financing activities:		
Proceeds from issuance of common stock	--	
Payment of common stock issuance costs	--	
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	--	
	-----	-----
Net (decrease) increase in cash	(33,705)	(5,595,5
Cash at beginning of period	6,435,540	15,154,2
	-----	-----
Cash at end of period	\$ 6,401,835	9,558,7
	=====	=====

See accompanying notes to financial statements.

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

Notes to Financial Statements

November 30, 2001

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

(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 period presented are not necessarily indicative of the results to be expected for the year ending May 31, 2002. The interim financial statements should be read in connection with the audited financial statements for the year ended May 31, 2001.

(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.

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

Since Northfield's incorporation in 1985, we have devoted substantially all of our efforts and resources to the research, development and clinical testing of our potential product, PolyHeme(TM). We have incurred operating losses during each year of our operations since inception and expect to incur substantial additional operating losses for the next several years. From Northfield's inception through November 30, 2001, we have incurred operating losses totaling \$92,855,000.

Our success will depend on several factors, including our ability to obtain Food and Drug Administration ("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, and enforce our patent positions. 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.

We anticipate that research and development expenses will increase during the foreseeable future. These expected increases are attributable to additional clinical trials to expand the indications for which PolyHeme may be marketed, monitoring and reporting the results of these trials and continuing process development associated with improving our manufacturing capacity to permit commercial-scale production of PolyHeme. We expect that general and administrative expenses will increase over the foreseeable future as a result of increased costs relating to the expansion of our organization in support of anticipated commercial operations.

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

RESULTS OF OPERATIONS

We reported no revenues for either of the three-month periods ended November 30, 2001 or 2000. From Northfield's inception through November 30, 2001, we have reported total revenues of \$3,000,000, all of which were derived from licensing fees.

OPERATING EXPENSES

Operating expenses for our second fiscal quarter ended November 30, 2001 totaled \$2,435,000, a decrease of \$360,000 from the \$2,795,000 reported in the second quarter of the prior year. Measured on a percentage basis, operating expenses in the second quarter of fiscal 2002 decreased by 12.9%. Expenses incurred in the prior fiscal year for conducting, monitoring and reporting clinical trials have been significantly reduced as the trials then in progress have been completed. Except for the infusion of PolyHeme in individual compassionate use cases, Northfield is not currently enrolling additional patients in clinical trials.

Operating expenses for the six-month period ended November 30, 2001 totaled \$5,927,000 an increase of \$25,000, or 0.4%, from the \$5,902,000 incurred in the six-month period ended November 30, 2000.

Research and development expenses for the second quarter of the current fiscal year totaled \$1,911,000, a decrease of \$326,000, or 14.6%, from the \$2,237,000 reported in the second quarter of the prior fiscal year. This expense reduction was directly related to the completion of clinical trials and the subsequent monitoring, data analysis and report preparation.

Research and development expenses for the six-month period ended November 30, 2001 totaled \$4,559,000, an increase of \$84,000, or 1.9%, from the \$4,475,000 reported in the comparable prior year period. Increases in compensation and scientific consulting expenses were offset by expense reductions relating to our clinical trials.

We anticipate that our research and development expenses for the third quarter of fiscal 2002 will approximate those reported for the second quarter. In August 2001, we filed a Biologics License Application for PolyHeme with the FDA following the completion of our most recent clinical trials. In November 2001, we announced that we had received comments from the FDA on our BLA filing and that the agency was seeking additional information before accepting our application for filing. Since then, we have been in the process of addressing these issues. We do not expect to conduct additional clinical trials of PolyHeme until we reach an understanding with the FDA regarding the status of our BLA filing. We anticipate that our research and development expenses will remain at approximately the current level until that time.

General and administration expenses in the second quarter of fiscal 2002 totaled \$525,000 compared to \$558,000 for second quarter of fiscal 2001. This decrease of \$33,000, or 5.9%, was primarily the result of reduced professional fees.

General and administration expenses for the six-month period ended

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

November 30, 2001 totaled \$1,368,000, which represents a decrease of \$60,000, or 4.2%, from the \$1,428,000 in

general and administrative expenses incurred during the six-month period ended November 30, 2000. This decrease was primarily the result of reduced professional fees in the current fiscal year.

Over the balance of the current fiscal year, we anticipate that general and administrative expenses will post only modest increases. We plan to limit significant increases in our general and administrative expenses until we reach an understanding with the FDA regarding the status of our BLA filing for PolyHeme.

INTEREST INCOME

Interest income in the second quarter of fiscal 2002 totaled \$270,000, or a \$281,000 decrease from the \$551,000 in interest income reported in the second quarter of fiscal 2001. Significantly lower interest rates in fiscal 2002 along with lower available investment balances accounted for the decrease. Maturing investments which were yielding in excess of 6% are now being reinvested at 2 to 3%. In the absence of a major cash infusion, interest income will continue to be significantly below prior year levels.

Interest income for the six-month period ended November 30, 2001 totaled \$571,000, or a \$570,000 decrease from the \$1,141,000 in interest income earned in the comparable prior year period. From November 30, 2000 through November 30, 2001, available investment balances decreased by \$10,345,000. This investment balance decrease combined with a reduction in

short-term interest rates of 300 to 400 basis points combined to cause interest income to decline.

NET LOSS

Our net loss for the second quarter ended November 30, 2001 was \$2,166,000, or \$.15 per share, compared to a net loss of \$2,243,000, or \$.16 per share, for the second quarter ended November 30, 2000. The decrease in the loss per share is primarily the result of a decrease in clinical trial expenses.

For the six-month period ended November 30, 2001, Northfield reported a loss of \$5,356,000, or \$.38 per share, compared to a loss of \$4,761,000, or \$.33 per share, in the comparable prior year period. The increased loss was primarily due to the significant reduction in interest income.

LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through November 30, 2001, we have used cash for operating activities and for the purchase of property, plant, equipment and engineering services in the amount of \$93,003,000. For the six-month periods ended November 30, 2001 and 2000, these cash expenditures totaled \$5,713,000 and \$4,954,000, respectively. The increased cash outlay for the first six-months of fiscal 2002 compared to the comparable prior year period is reflective of increased operating losses and a reduction in accounts payable balances.

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

We have financed our research and development and other activities to date primarily through the public and private sale of equity securities and, to a more limited extent, through the licensing of product rights. As of November 30, 2001, we had cash and marketable securities totaling \$22,985,000.

We believe our existing capital resources will be adequate to satisfy our operating capital requirements and maintain our existing pilot manufacturing plant and office facilities for approximately the next 24 months. Thereafter, we are likely to require substantial additional capital to continue our operations. Our requirements for and ability to obtain additional capital are likely to be significantly affected by the outcome of our discussions with the FDA regarding the status of our BLA filing for PolyHeme.

We are currently unable to fund the construction of a large-scale greenfield manufacturing facility, which is estimated to cost approximately \$50 million, without raising substantial additional capital. Currently, we have manufacturing capacity of approximately 10,000 units. Initial engineering on the leased space adjacent to our existing manufacturing facility is completed. This engineering indicates an additional capacity of 75,000 units could be developed in approximately 16 to 20 months at a cost of \$26 to \$30 million. Like a large-scale greenfield manufacturing facility, significant additional funding will be required before the smaller scale expansion facility could be completed. Northfield has not yet committed to the build-out. We view the smaller facility as financially prudent yet large enough for commercial viability. We estimate that we will require at

least \$40 million in additional funding to build a smaller scale expansion facility (75,000 unit), fund the subsequent working capital needs and support an expanded manufacturing and marketing organization.

We may issue additional equity or debt securities to the public 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. Any one or a combination of these sources may be utilized to raise the required funding. Business or market conditions may not be favorable, which would cause a delay in the commercialization of our product.

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

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

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

liability is changed at the end of each period to reflect the passage of time and changes in the estimated future cash flows underlying the initial fair value measurement. Adoption of FASB Statement No. 143 is required for fiscal years beginning after June 15, 2002. We do not expect the adoption of the provisions of FASB Statement No. 143 to have a material impact on the financial position or the results of operations of the Company.

In October 2001, the FASB issued FASB Statement No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This Statement supersedes FASB Statement No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of, and the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations--Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business (as previously defined in that Opinion), and also amends ARB No. 51, Consolidated Financial Statements, to eliminate the exception to consolidation for a subsidiary for which control is likely to be temporary. FASB Statement No. 144 retains a majority of the provisions of FASB Statement No. 121 while establishing a single accounting model, based on the framework established in FASB Statement No. 121, for long-lived assets to be disposed of by sale. FASB Statement No. 144 also resolves significant implementation issues related to FASB Statement No. 121. Adoption of FASB Statement No. 144 is required for fiscal years beginning after December 15, 2001. We do not expect the adoption of the provisions of FASB Statement No. 144 to have a material impact on the financial position or the results of operations of the Company.

PART II. OTHER INFORMATION

Item 6. Exhibits

- a) Exhibit 15 - Acknowledgement of Independent Certified Public Accountants
- b) None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this January 11, 2002.

NORTHFIELD LABORATORIES INC.

By: /s/ RICHARD E. DEWOSKIN

Richard E. DeWoskin
Chairman of the Board and
Chief Executive Officer

By: /s/ JACK J. KOGUT

Jack J. Kogut
Secretary and Treasurer
(principal financial officer and
principal accounting officer)