

NORTHFIELD LABORATORIES INC /DE/

Form 10-Q

January 09, 2009

Table of Contents

**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, 2008
OR**

**TRANSITION REPORT PURSUANT 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 a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller Reporting Company
(Do not check if a smaller reporting company)

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 under the Exchange Act) Yes No

As of November 30, 2008 Registrant had 26,958,516 shares of common stock outstanding.

TABLE OF CONTENTS

<u>CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION</u>	1
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	2
<u>PART I</u>	
<u>ITEM 1. FINANCIAL STATEMENTS</u>	
<u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	11
<u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	15
<u>ITEM 4. CONTROLS AND PROCEDURES</u>	15
<u>Part II</u>	
<u>ITEM 1. Legal Proceedings</u>	15
<u>ITEM 1A. Risk Factors</u>	15
<u>ITEM 2. Submission of Matters to a Vote of Security Holders</u>	16
<u>SIGNATURES</u>	17
<u>EX-15</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	

Table of Contents

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, forecasts, 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 for our fiscal year ended May 31, 2008 which is filed with the Securities and Exchange Commission, and those matters discussed under Legal Proceedings and Risk Factors in this Quarterly Report. 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.

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders

Northfield Laboratories Inc.:

We have reviewed the balance sheet of Northfield Laboratories Inc. (a company in the development stage) as of November 30, 2008, the related statements of operations for the three-month periods ended November 30, 2008 and November 30, 2007, and the statements of operations and cash flows for the six-month periods ended November 30, 2008 and November 30, 2007 and for the period from June 19, 1985 (inception) through November 30, 2008. We have also reviewed the statements of shareholders' equity (deficit) for the six-month period ended November 30, 2008 and for the period from June 19, 1985 (inception) through November 30, 2008. These financial statements are the responsibility of the Company's management.

We conducted our review in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures 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 Accounting 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 U.S. generally accepted accounting principles.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheet of Northfield Laboratories Inc. as of May 31, 2008, 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, 2008 (not presented herein); and in our report dated August 14, 2008, 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, 2008 and in the accompanying statements of operations, cash flows and shareholders' equity (deficit) for the period from June 19, 1985 (inception) through May 31, 2008 is fairly stated, in all material respects, in relation to the statements from which it has been derived.

Note 1 of the Company's audited financial statements as of May 31, 2008, and for the year then ended, discloses that the Company has suffered recurring losses from operations and has insufficient capital resources to fund its continuing operations. Our auditors' report on those financial statements dated August 14, 2008, includes an explanatory paragraph referring to the matters in note 1 of those financial statements, and indicating that these matters raised substantial doubt about the Company's ability to continue as a going concern. As indicated in note 2 of the Company's unaudited interim financial statements as of November 30, 2008, and for the three and six-months then ended, the Company continues to suffer recurring losses from operations and has insufficient capital resources to fund its continuing operations. The accompanying interim financial information does not include any adjustments that might result from the outcome of this uncertainty.

(signed) KPMG LLP

Chicago, IL

January 9, 2009

Table of Contents**NORTHFIELD LABORATORIES INC.**

(a company in the development stage)

Balance Sheets

November 30, 2008 and May 31, 2008

	November 30, 2008	May 31, 2008
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,029,721	12,746,540
Restricted cash	77,125	301,292
Marketable securities	4,997,683	7,979,830
Prepaid expenses	466,087	696,253
Other current assets	305,948	
Total current assets	10,876,564	21,723,915
Property, plant, and equipment	20,271,112	19,747,948
Accumulated depreciation	(11,834,879)	(11,506,730)
Net property, plant, and equipment	8,436,233	8,241,218
Other assets	19,550	19,550
	\$ 19,332,347	29,984,683
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable	\$ 1,654,539	1,917,260
Accrued expenses	71,549	111,637
Government grant liability	77,125	301,292
Accrued compensation and benefits	709,914	658,012
Other current liabilities	305,948	
Total current liabilities	2,819,075	2,988,201
Other liabilities	15,478	14,392
Total liabilities	2,834,553	3,002,593
Shareholders equity:		
Preferred stock, \$.01 par value. Authorized 5,000,000 shares; none issued and outstanding		
Common stock, \$.01 par value. Authorized 60,000,000 shares; issued 26,960,233 at November 30, 2008 and 26,960,233 at May 31, 2008	269,602	269,602
Additional paid-in capital	247,985,630	246,954,375
Deficit accumulated during the development stage	(231,732,045)	(220,216,494)

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	16,523,187	27,007,483
Less cost of common shares in treasury; 1,717 shares and 1,717 shares, respectively	(25,393)	(25,393)
Total shareholders' equity	16,497,794	26,982,090
	\$ 19,332,347	29,984,683

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

3

Table of Contents**NORTHFIELD LABORATORIES INC.**

(a company in the development stage)

Statement of Operations

Three and six months ended November 30, 2008 and November 30, 2007 and for the period from June 19, 1985 (inception) through November 30, 2008

	Three months ended		Six months ended		Cumulative
	November 30,		November 30,		from
	2008	2007	2008	2007	June 19, 1985
	(unaudited)	(unaudited)	(unaudited)	(unaudited)	through
					November 30,
					2008
					(unaudited)
Revenues license income	\$				3,000,000
Costs and expenses:					
Research and development	4,270,510	3,940,402	8,652,400	7,717,904	193,409,357
General and administrative	1,377,326	1,481,547	2,999,411	2,991,830	73,462,157
	5,647,836	5,421,949	11,651,811	10,709,734	266,871,514
Other income and expense:					
Interest income	54,006	401,241	136,260	883,569	32,297,624
Interest expense					83,234
	\$ 54,006	401,241	136,260	883,569	32,214,390
Net loss before cumulative effect of change in accounting principle	(5,593,830)	(5,020,708)	(11,515,551)	(9,826,165)	(231,657,124)
Cumulative effect of change in accounting principle					74,921
Net loss	\$ (5,593,830)	(5,020,708)	(11,515,551)	(9,826,165)	(231,732,045)
Net loss per share basic and diluted	\$ (0.21)	(0.19)	(0.43)	(0.36)	(17.52)
Shares used in calculation of per share data basic and diluted	26,958,516	26,938,461	26,958,516	26,925,310	13,225,137

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

Table of Contents

NORTHFIELD LABORATORIES INC.

(a company in the development stage)

Statements of Shareholders' Equity (Deficit)

Six months ended November 30, 2008 and the cumulative period
from June 19, 1985 (inception) through November 30, 2008

Preferred stock Aggregate Number of shares	Common stock		Series A convertible preferred stock		Series B convertible preferred stock		Additional paid-in capital	Deficit accumulated during the development stage	Deferred compensation shares	Treasury shares
	Number	Aggregate amount	Number	Aggregate amount	Number	Aggregate amount				
	3,500,000	\$ 35,000					\$ (28,000)	\$		
			250,000	250,000			670,850	(607,688)		
	3,500,000	\$ 35,000	250,000	\$ 250,000			\$ 642,850	\$ (607,688)		
								(2,429,953)		
							2,340,000			(2,340,000)
										720,000
	3,500,000	35,000	250,000	\$ 250,000			\$ 2,982,850	\$ (3,037,641)		\$ (1,620,000)
					\$ 200,633	200,633	6,882,502			

									(3,057,254)
									566,136
\$	3,500,000	\$ 35,000	250,000	\$ 250,000	200,633	200,633	\$	9,865,352	\$ (6,094,895) \$ (1,053,864)
	413,020	4,130						9,749,870	
	1,250,000	12,500	(250,000)	(250,000)				237,500	
	1,003,165	10,032			(200,633)	(200,633)		190,601	
	47,115	471						93,759	
	175,525	1,755						4,976,855	
	87,760	878						2,488,356	

							(7,006,495)		
									254,025
\$	6,566,585	\$ 65,666	\$		\$	\$ 36,930,714	\$ (22,962,862)	\$	(399,739)
	15,000	150				106,890			
	374,370	3,744				5,663,710	(8,066,609)		
									254,025
\$	6,955,955	\$ 69,560	\$		\$	\$ 42,701,314	\$ (31,029,471)	\$	(145,714)
							(7,363,810)		
	2,500,000	25,000				14,163,851			
						(85,400)			85,400
									267
\$	9,455,955	\$ 94,560	\$		\$	\$ 56,779,765	\$ (38,393,281)	\$	(60,047)
	375,000	3,750				2,261,250	(7,439,013)		

10,000	100			71,300	
187,570	1,875			373,264	
				(106,750)	106,750
					(67,892)
\$ 10,028,525	\$ 100,285	\$	\$	\$ 59,378,829	\$ (45,832,294) \$ (21,189)
					(4,778,875)
2,925,000	29,250			48,324,374	
438,750	4,388			7,360,187	
182,380	1,824			362,937	
1,500	15			9,555	
10,000	100			71,300	
				(80,062)	80,062

(62,726)

\$ 13,586,155 \$ 135,862 \$ \$ \$ 115,427,120 \$ (50,611,169) \$ (3,853)
See accompanying notes to financial statements and accountants review report.

5

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at \$8.00 per share									
Balance at May 31, 1999	\$	14,239,875	\$ 142,399	\$	\$	\$ 117,185,514	\$ (68,156,573)	\$	\$ 49,171,340
Net loss							(9,167,070)		(9,167,070)
Non-cash compensation						57,112			57,112
Exercise of stock options at \$13.38 per share		2,500	25			33,425			33,450
Balance at May 31, 2000	\$	14,242,375	\$ 142,424	\$	\$	\$ 117,276,051	\$ (77,323,643)	\$	\$ 40,094,832
Net loss							(10,174,609)		(10,174,609)
Non-cash compensation									
Exercise of stock options at \$6.38 per share		6,000	60			38,220			38,280
Exercise of stock options at \$10.81 per share		17,500	175			189,000			189,175
Balance at May 31, 2001	\$	14,265,875	\$ 142,659	\$	\$	\$ 117,503,271	\$ (87,498,252)	\$	\$ 30,147,678
Net loss							(10,717,360)		(10,717,360)
Balance at May 31, 2002	\$	14,265,875	\$ 142,659	\$	\$	\$ 117,503,271	\$ (98,215,612)	\$	\$ 19,430,318
Net loss							(12,250,145)		(12,250,145)
Balance at May 31, 2003	\$	14,265,875	142,659	\$	\$	\$ 117,503,271	\$ (110,465,757)	\$	\$ 7,180,173
Issuance of common stock at \$5.60 per share on July 28, 2003 net of costs of issuance of (\$909,229)		1,892,857	18,928			9,671,843			9,690,771
Issuance of common stock to directors at \$6.08 per share on October 30, 2003		12,335	123			74,877			75,000
		25,500	255			190,995	(191,250)		

Deferred compensation related to stock grants								
Amortization of deferred compensation						35,630		35,630
Issuance of common stock at \$5.80 per share on January 29, 2004 (net of costs of issuance of \$1,126,104)	2,585,965	25,860		13,846,633				13,872,493
Issuance of common stock at \$5.80 per share on February 18, 2004 (net of costs of issuance of \$116,423)	237,008	2,370		1,255,853				1,258,223
Issuance of common stock at \$5.80 per share on April 5, 2004 (net of costs of issuance of \$192,242)	409,483	4,095		2,178,664				2,182,759
Issuance of common stock at \$12.00 per share on May 8, 2004 (net of costs of issuance of \$1,716,831.36)	1,954,416	19,544		21,716,616				21,736,160
Exercise of stock options at \$6.38 per share	15,000	150		95,550				95,700
Net loss						(14,573,798)		(14,573,798)
Balance at May 31, 2004	\$ 21,398,439	\$ 213,984	\$	\$ 166,534,302	\$ (125,039,555)	\$ (155,620)	\$	\$ 41,553,111
Deferred compensation related to stock	5,500	55		71,055		(71,110)		

grants									
Amortization of deferred compensation						122,121			122,121
Exercise of stock options between \$5.08 and \$14.17 per share	167,875	1,679		1,739,585					1,741,264
Cost of shares in treasury, 717 shares							(25,393)		(25,393)
Issuance of common stock to directors at \$12.66 per share on September 21, 2004	5,925	59		74,941					75,000
Issuance of common stock at \$15.00 per share on February 9, 2005 (net of costs of \$4,995,689)	5,175,000	51,750		72,577,561					72,629,311
Net loss						(20,321,456)			(20,321,456)
Balance at May 31, 2005	\$ 26,752,739	\$ 267,527	\$	\$ 240,997,444	\$ (145,361,011)	\$ (104,609)	\$ (25,393)	\$	\$ 95,773,958
Amortization of deferred compensation						95,550			95,550
Exercise of stock options at \$7.13 and \$10.66 per share	2,875	29		29,295					29,324
Issuance of common stock to directors at \$13.05 per share on September 29, 2005	5,750	57		74,943					75,000
Issuance of common stock to director at \$13.21 per	1,135	12		14,988					15,000

Share on October 3, 2005									
Issuance of common stock to director at \$10.67 per share on February 24, 2006	1,406	14		14,986					15,000
Exercise of stock options at \$10.66, \$5.15 and \$11.09 per share	8,000	80		65,075					65,155
Exercise of stock options at \$10.66 and \$7.13 per share	2,750	28		26,640					26,668
Exercise of stock options at \$5.15 and \$7.13 per share	3,000	30		16,905					16,935
Net loss						(26,775,418)			(26,775,418)
Balance at May 31, 2006	\$ 26,777,655	\$ 267,777	\$	\$ 241,240,276	\$ (172,136,429)	\$	(9,059)	\$ (25,393)	\$ 69,337,172
Eliminate remaining deferred compensation				(9,059)			9,059		
Exercise of stock options at \$5.15 and \$7.13 per share	2,750	28		17,105					17,133
Exercise of stock options at \$7.13 per share	750	7		5,348					5,355
Issuance of common stock to directors at \$13.03 per share on September 20, 2006	6,912	69		89,931					90,000
Exercise of stock options at \$11.44 per share	10,000	100		114,300					114,400
Exercise of stock options at	3,125	31		24,646					24,677

at \$5.15, \$11.92 and \$13.21 per share									
Exercise of stock options at \$5.08 and \$6.08 per share	15,000	150		81,050					81,200
Exercise of stock options at \$5.15 per share	3,000	30		15,420					15,450
Exercise of stock options at \$11.92 per share	375	4		4,466					4,470
Exercise of warrants at \$6.88 per share	96,974	969		666,211					667,180
Share-based compensation				2,655,849					2,655,849
Net loss							(27,671,177)		(27,671,177)
Balance at May 31, 2007	\$ 26,916,541	\$ 269,165	\$	\$ 244,905,543	\$ (199,807,606)	\$	\$ (25,393)	\$	\$ 45,341,709
Issuance of common stock to directors at \$2.06 per share on September 25, 2007	43,692	437		89,563					90,000
Share-based compensation				1,959,269					1,959,269
Net loss							(20,408,888)		(20,408,888)
Balance at May 31, 2008	\$ 26,960,233	\$ 269,602	\$	\$ 246,954,375	\$ (220,216,494)	\$	\$ (25,393)	\$	\$ 26,982,090
Share-based compensation				1,031,255					1,031,255
Net loss							(11,515,551)		(11,515,551)
Balance at November 30, 2008	\$ 26,960,233	\$ 269,602	\$	\$ 247,985,630	\$ (231,732,045)	\$	\$ (25,393)	\$	\$ 16,497,794

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

Table of Contents**NORTHFIELD LABORATORIES INC.**

(a company in the development stage)

Statements of Cash Flows

Six months ended November 30, 2008 and November 30, 2007

and the cumulative period from June 19, 1985

(inception) through November 30, 2008

	Six months ended		Cumulative
	November 30,	November	from
	2008	30, 2007	June 19, 1985
	(unaudited)	(unaudited)	through
			November 30,
			2008
			(unaudited)
Cash flows from operating activities:			
Net loss	\$ (11,515,551)	(9,826,165)	(231,732,045)
Adjustments to reconcile net loss to net cash used in operating activities:			
Marketable security amortization	(99,010)	(335,685)	(4,132,024)
Depreciation and amortization	337,419	324,954	20,411,561
Share-based compensation	1,031,255	1,176,218	9,887,397
Loss of sale of equipment	3,397		91,908
Changes in assets and liabilities:			
Restricted cash	224,167	(1,155,470)	982,379
Prepaid expenses	230,166	69,737	(675,298)
Other current assets	(305,948)	148,016	(2,202,199)
Other assets			55,791
Accounts payable	(445,611)	(2,259,895)	1,471,649
Accrued expenses	(40,088)	21,773	71,549
Government grant liability	(224,167)	1,155,470	(982,379)
Accrued compensation and benefits	51,902	95,220	709,914
Other current liabilities	305,948		313,379
Other liabilities	1,086	4,466	8,047
Net cash used in operating activities	(10,445,035)	(10,581,361)	(205,720,371)
Cash flows from investing activities:			
Purchase of property, plant, equipment, and capitalized engineering costs	(352,941)	(213,227)	(28,615,064)
Proceeds from sale of land and equipment			1,863,023
Proceeds from matured marketable securities	16,000,000	35,946,753	777,808,105
Proceeds from sale of marketable securities			7,141,656
Purchase of marketable securities	(12,918,843)	(28,865,348)	(785,821,200)
Net cash provided by (used in) investing activities	2,728,216	6,868,178	(27,623,480)

Cash flows from financing activities:			
Proceeds from issuance of common stock			237,055,000
Payment of common stock issuance costs			(14,128,531)
Proceeds from issuance of preferred stock			6,644,953
Proceeds from sale of stock options to purchase common shares			7,443,118
Proceeds from issuance of notes payable			1,500,000
Repayment of notes payable			(140,968)

Net cash provided by financing activities			238,373,572
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Net increase (decrease) in cash	(7,716,819)	(3,713,183)	5,029,721
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Cash at beginning of period	12,746,540	23,224,026	
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Cash at end of period	\$ 5,029,721	19,510,843	5,029,721
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Supplemental Schedule of Noncash Financing Activities

:

Exercise of stock option, 5,000 shares in exchange for 1,717 treasury shares.	\$	25,393
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See accompanying notes to financial statements and accountants review report.

Table of Contents

Northfield Laboratories Inc.
(a company in the development stage)
Notes to the Financial Statements
November 30, 2008
(unaudited)

(1) BASIS OF PRESENTATION

The accompanying interim financial statements of Northfield Laboratories, Inc. (the Company) 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, results of operations and cash flows 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 full fiscal years. The interim financial statements should be read in connection with the audited financial statements for the year ended May 31, 2008.

(2) 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 a going concern because it expects to experience significant future losses and currently has insufficient capital resources to fund its continuing operations. As of November 30, 2008, we had cash and cash equivalents, restricted cash and short term marketable securities of approximately \$10.1 million. We are currently utilizing our cash resources at a rate of approximately \$21.6 million per year, and we expect to maintain this rate of cash utilization through our third fiscal quarter. Based on our current estimates, we anticipate that our existing financial resources will be adequate to permit us to continue to conduct our business only for approximately 5 to 6 months from November 30, 2008. To continue operations beyond this point, we will either need to severely restrict our spending or raise additional capital. Our future capital requirements will depend on many factors, including the timing and outcome of regulatory reviews, administrative and legal expenses, the status of competitive products, the establishment of manufacturing capacity and the establishment of collaborative relationships. We cannot ensure that additional funding will be available or, if it is available, that it can be obtained on terms and conditions we will deem acceptable. Any additional funding derived from the sale of equity securities will result in significant dilution to our existing stockholders.

There can be no assurance that the Company will have adequate capital resources to continue to operate through the remainder of our fiscal year, which ends on May 31, 2009. The Company's inability to raise sufficient levels of capital could materially delay or prevent the commercialization of its PolyHeme 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.

(3) 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.

(4) 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 where their effect is dilutive. Because we reported net losses for all periods presented, basic and diluted per share amounts are the same. As of November 30, 2008, we had 2,052,625 options and 58,632 warrants that were excluded from the net loss per share calculation because their inclusion would have been anti-dilutive.

(5) SHARE-BASED COMPENSATION

The Company's Nonqualified Stock Option Plan for Outside Directors (the Directors Plan) lapsed on May 31, 2004. Following the termination of the plan, all options outstanding prior to plan termination may be exercised in

accordance with their terms. As of

Table of Contents

November 30, 2008, options to purchase a total of 45,000 shares of the Company's common stock at prices between \$4.09 and \$11.18 per share were outstanding under this plan. These options expire between 2011 and 2012, ten years after the date of grant.

With an effective date of October 1, 1996, the Company established the Northfield Laboratories Inc. 1996 Stock Option Plan (the "1996 Option Plan"). This plan provides for the granting of stock options to the Company's directors, officers, key employees, and consultants. Stock options to purchase a total of 500,000 shares of common stock are available under the 1996 Option Plan. As of November 30, 2008, options to purchase a total of 105,500 shares of the Company's common stock at prices between \$10.66 and \$15.41 were outstanding under this plan. These options expire between 2009 and 2010, ten years after the date of grant.

With an effective date of June 1, 1999, the Company established the Northfield Laboratories Inc. 1999 Stock Option Plan (the "1999 Option Plan"). This plan provides for the granting of stock options to the Company's directors, officers, key employees, and consultants. Stock options to purchase a total of 500,000 shares of common stock are available under the 1999 Option Plan. As of November 30, 2008, options to purchase a total of 275,625 shares of the Company's common stock at prices between \$3.62 and \$14.17 per share were outstanding under this plan. These options expire between 2011 and 2013, ten years after the date of grant.

With an effective date of January 1, 2003, the Company established the New Employee Stock Option Plan (the "New Employee Plan"). This plan provides for the granting of stock options to the Company's new employees. Stock options to purchase a total of 350,000 shares are available under the New Employee Plan. As of November 30, 2008, options to purchase a total of 50,000 shares of the Company's common stock at prices between \$3.62 and \$18.55 per share were outstanding under this plan. These options expire between 2013 and 2016, ten years after the date of grant.

With an effective date of September 17, 2003, the Company established and shareholders approved the 2003 Equity Compensation Plan with 750,000 available share awards. This plan provides for the granting of stock, stock options and various other types of equity compensation to the Company's employees, non-employee directors and consultants. On September 29, 2005, the number of available share awards was increased to 2,250,000 by shareholder approval. At November 30, 2008, options to purchase a total of 1,576,500 shares of the Company's common stock at prices between \$0.38 and \$18.55 were outstanding under this plan. These options expire between 2013 and 2018, ten years after the date of grant.

The service period for option plans is generally four years, with shares vesting at a rate of 25% each year. The 475,000 options granted to the Company officers on July 12, 2007 have a two year vesting period with shares vesting at a rate of 50% each year.

The Company issues shares from authorized but un-issued common shares upon share option exercises and restricted stock grants.

Compensation expense is measured based on the fair value of the award at the grant date and is recognized on a straight-line basis over the vesting term for share-based payments expected to vest. We estimate forfeitures at the date of grant based on our historical experience and future expectations.

The Company does not recognize a tax benefit related to share-based compensation due to the historical net operating loss and related valuation allowance.

The impact of the share-based compensation expenses on basic earnings per share for the three and six months ended November 30, 2008 was \$0.01 and \$0.04, respectively, and the related charge associated with share-based compensation expense recognized in the Statement of Operations for the three and six months ended November 30, 2008 was \$388,000 and \$1,031,000, respectively.

As of November 30, 2008, there was approximately \$944,000 of total unrecognized compensation cost related to non-vested share-based compensation awards granted under the incentive plans. That cost is expected to be recognized over a weighted-average period of 0.98 years.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The table below outlines the weighted average assumptions for options granted during the three and six months ended November 30, 2008 and November 30, 2007.

Three Months Ended**Six Months Ended**

	November 30, 2008	November 30, 2007	November 30, 2008	November 30, 2007
Fair Value	\$ 6,354	\$ 98,800	\$ 6,354	\$ 681,500
Expected volatility	108.93%	96.47%	108.93%	95.9%
Risk-free interest rate	2.76%	4.22%	2.76%	4.82%
Dividend yield				
Expected lives	6.1 years	6.2 years	6.1 years	6.29 years

Table of Contents

The expected term of the options represents the estimated period of time until exercise and is based on historical experience of similar awards, giving consideration to the contractual terms, vesting schedules and expectations of future employee behavior. Expected stock price volatility is based on historical volatility of the Company's stock. The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with equivalent remaining term.

On October 27, 2008, the Company issued 20,000 options to purchase shares of common stock to one employee at a price of \$0.38 per share under the 2003 Equity Compensation Plan. The Company will expense the fair value of this share-based award over the vesting period of the options which is two years from the grant date.

The weighted average grant-date fair value of options granted during the three months ended November 30, 2008 and November 30, 2007 was \$0.32 per share and \$1.65 per share, respectively. The weighted average grant-date fair value of options granted during the six months ended November 30, 2008 and November 30, 2007 was \$0.32 per share and \$1.16 per share, respectively.

The following table summarizes the Company's option activity during the six months ended November 30, 2008:

	Shares	Range of Exercise Prices	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at May 31, 2008	2,090,125	\$ 1.36 \$18.55	\$ 8.32		
Granted at Fair Value	0				
Exercised	0				
Expired	0				
Cancelled	0				
Outstanding at August 31, 2008	2,090,125	\$ 1.36 \$18.55	\$ 8.32	6.52	\$ 0
Exercisable at August 31, 2008	1,553,500	\$ 1.36 \$18.55	\$ 8.72	6.00	\$ 0
Granted at Fair Value	20,000	\$ 0.38	\$ 0.38		
Exercised	0				
Expired	0				
Cancelled	57,500	\$ 1.36 \$13.42	\$ 3.80		
Outstanding at November 30, 2008	2,052,625	\$ 0.38 \$18.55	\$ 8.37	6.25	\$ 6,400
Exercisable at November 30, 2008	1,562,875	\$ 1.36 \$18.55	\$ 8.88	5.73	\$ 0

The aggregate intrinsic value in the table above is before taxes and based on a weighted average exercise price of \$8.37 for options outstanding at November 30, 2008 and \$8.88 for options exercisable at November 30, 2008. The total intrinsic value of options exercised during the six months ended November 30, 2008 and November 30, 2007 was \$0 and \$0, respectively. The total fair value of options vested during the three months ended November 30, 2008 and November 30, 2007 was \$298,047 and \$494,522, respectively. The total fair value of options vested during the six months ended November 30, 2008 and November 30, 2007 was \$707,467 and \$623,851, respectively.

(6) RESTRICTED CASH

As of November 30, 2008, the Company had \$77,125 in restricted cash from a government grant. All funds are used in accordance with the terms of the grant. The Company accounts for the lapse in restriction when grant expenditures are incurred. The Company recognizes the funds as a contra-expense or a reduction in the asset carrying value based on the type of grant expenditure incurred.

For the three-month period ended November 30, 2008 and November 30, 2007, \$59,728 and \$743,519 of restricted cash from a government grant was recognized as a contra-expense, respectively, and \$83,700 and \$2,732 was recognized as a reduction in the asset carrying value, respectively.

For the six-month period ended November 30, 2008 and November 30, 2007, \$70,899 and \$1,736,190 of restricted cash from a government grant was recognized as a contra-expense, respectively, and \$153,541 and \$186,771 was recognized as a reduction in the asset carrying value, respectively.

(7) MARKETABLE SECURITIES

The Company, at November 30, 2008, was invested in high grade commercial paper and short term certificates of deposit. The Company has the intent and ability to hold these securities until maturity and all securities have a maturity of three months or less.

The fair market value of the Company's marketable securities was \$4,996,770 at November 30, 2008, which included gross unrealized holding losses of \$913. The fair market value of the Company's marketable securities was \$7,979,440 at May 31, 2008, which included gross unrealized holding losses of \$390. All of these marketable securities are scheduled to mature in less than three months.

Table of Contents

(8) MISCELLANEOUS RECEIVABLE

For the second quarter ended November 30, 2008, the Company recorded a miscellaneous receivable in the amount of \$305,948 to reflect proceeds from an insurance claim made in November 2008 for legal expenses incurred in relation to a putative class action lawsuit that was initiated in September 2006. This receivable offsets a corresponding liability in the amount of \$305,948 that has been recorded to reflect the amount due to the Company's legal counsel.

(9) PROPERTY, PLANT & EQUIPMENT

Property, plant and equipment are recorded at cost and are depreciated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized using the straight-line method over the lesser of the life of the asset or the term of the lease, generally five years.

At November 30, 2008, there was \$183,000 of property, plant and equipment that was placed in service for which payment had not yet been made and was recorded in accounts payable. This item represents a non-cash investing activity for statement of cash flow purposes.

(10) INCOME TAXES

The Company adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109 (FIN 48) in the first quarter of fiscal 2008. At the adoption date and as of November 30, 2008, the Company had no material unrecognized tax benefits and no adjustments to liabilities, retained earnings, loss from continuing operations, or net loss were required. It is the Company's policy to include interest and/or penalties related to uncertain tax positions in income tax expense. No interest and/or penalties were recognized upon FIN 48 adoption. Tax years 1993 through 2006 remain open to examination by the major taxing jurisdictions to which the Company reports. The adoption of FIN 48 had no effect on the Company's basic and diluted earnings per share.

(11) LEGAL PROCEEDINGS

Between March 17, 2006 and May 15, 2006, ten separate complaints were filed, each purporting to be on behalf of a class of the Company's shareholders, against the Company and Dr. Steven A. Gould, the Company's Chief Executive Officer, and Richard DeWoskin, the Company's former Chief Executive Officer. Those putative class actions were consolidated in a case pending in the United States District Court for the Northern District of Illinois Eastern Division. The Consolidated Amended Class Action Complaint was filed on September 8, 2006, and alleged, among other things, that during the period from March 19, 2001 through March 20, 2006, the named defendants made or caused to be made a series of materially false or misleading statements and omissions about the Company's elective surgery clinical trial and business prospects in violation of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated there under and Section 20(a) of the Exchange Act. Plaintiffs alleged that those allegedly false and misleading statements and omissions caused the purported class to purchase the Company's common stock at artificially inflated prices. As relief, the complaint sought, among other things, a declaration that the action be certified as a proper class action, unspecified compensatory damages (including interest) and payment of costs and expenses (including fees for legal counsel and experts). The Company and the individual defendants filed a motion to dismiss the complaint, and on September 25, 2007, the court granted that motion, finding that the plaintiffs failed to state a claim. The court dismissed the complaint without prejudice, and on November 20, 2007, the plaintiffs filed a Consolidated Second Amended Class Action Complaint. On January 22, 2008, the Company and the individual defendants filed a motion to dismiss, and the briefing of that motion was completed on June 26, 2008. On September 23, 2008, the Court denied the motion to dismiss, and on December 5, 2008, the Company and the individual defendants answered the Consolidated Second Amended Class Action Complaint. Plaintiffs have advised that they intend to file a motion seeking certification of a class. Accordingly, the case has proceeded into discovery and briefing of class certification issues. The putative class action is at an early stage and it is not possible to predict the outcome or to estimate the amount of liability, if any, of the Company.

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

RECENT DEVELOPMENTS

On December 30, 2008, Northfield announced that the Food and Drug Administration, or FDA, has accepted for filing its Biologics License Application, or BLA, for PolyHeme®, the Company's investigative human

hemoglobin-based red cell substitute for the treatment of life-threatening red blood cell loss when an oxygen-carrying fluid is required and red blood cells are not available. FDA has designated the submission for Priority Review with a review goal date of April 30, 2009.

RESULTS OF OPERATIONS

We reported no revenues for the three and six month periods ended November 30, 2008 and 2007. From Northfield's inception through November 30, 2008, we have reported total revenues of \$3,000,000, all of which were derived from licensing fees.

Table of Contents

OPERATING EXPENSES

Operating expenses for our second quarter ended November 30, 2008 totaled \$5,648,000, an increase of \$226,000 from the \$5,422,000 reported in the second quarter of fiscal 2008. Measured on a percentage basis, second quarter fiscal 2009 expenses exceeded the second fiscal quarter of 2008 by 4.2%. Increased expenses were incurred in BLA production, preparation for a manufacturing site audit by FDA and for expenses in connection with our annual meeting of stockholders.

Operating expenses for the six months ended November 30, 2008 totaled \$11,652,000 which was an increase of \$942,000, or 8.8%, from the \$10,710,000 incurred in the comparable prior year period. The incurred expenses primarily related to BLA preparation and to documentation in anticipation of a facility audit by FDA.

Research and development expenses during the second fiscal quarter ended November 30, 2008 equaled \$4,271,000. This level of expense exceeded the prior year's comparable period by \$330,000, or 8.4%. The current quarter's efforts were focused on final edits and data processing tasks to complete our BLA. These efforts required the purchasing of additional technical and professional services to complete the tasks on an expedited basis.

For the six month period ended November 30, 2008, research and development expense of \$8,652,000 exceeded the research and development expenses for the six month period ended November 30, 2007 by \$934,000, or 12.1%. Purchased validation services, used to define and document the current manufacturing and quality routines applied in the production of PolyHeme, was the single largest contributor to the increase in expense for research and development.

We anticipate research and development expenses in the third fiscal quarter will remain steady. Bonus payments will be made in connection with the filing of our BLA and site audit preparations will continue. We anticipate a decrease in research and development expenses in the fourth fiscal quarter of 2009. Depending on the date of an FDA review and the outcome of that review, the extent of clinical and regulatory documentation support for the manufacturing process should diminish. We are currently preparing for a potential Blood Product Advisory Committee review in our fourth fiscal quarter of 2009. The preparation expenses related to this review will largely occur in the third fiscal quarter of 2009.

General and administration expenses for the second fiscal quarter of 2009 totaled \$1,377,000, a decrease of \$105,000, or 7.1%, from the \$1,482,000 incurred in the second quarter of fiscal 2008. The decrease was achieved despite the expenses of \$174,000 incurred in connection with our annual shareholder meeting held in October 2008.

For the six month period ended November 30, 2008, general and other administrative expenses totaled \$2,999,000, which was 0.25% higher than the comparable prior year period.

During the third fiscal quarter of 2009, we will be incurring compensation expenses in connection with employee bonuses that were contingent upon FDA filing of our BLA and FDA granting the filing a priority review, and expect to make a payment of approximately \$110,000 related to the termination of our corporate office lease in Evanston, Illinois. In the first quarter of fiscal 2010 (beginning in June 2009), we will be consolidating our operations at our owned Mt. Prospect, Illinois facility. We do not anticipate adding any significant administrative programs over the balance of the current fiscal year.

INTEREST INCOME

Interest income for the second quarter ended November 30, 2008 totaled \$54,000, a decrease of \$347,000, or 86.5%, from the second quarter of fiscal 2007. Available cash, restricted cash, and short-term marketable securities as of November 30, 2008 totaled \$10,105,000. We had \$31,385,000 in available cash restricted cash, and short-term marketable securities as of November 30, 2007. Along with lower available investment balances, interest rates on marketable securities have also markedly declined. A year ago, our commercial paper investments were yielding an average of 5.17%. During our third fiscal quarter of 2009, we moved the majority of our investment balances to government insured certificates of deposit and a money market fund investing in treasuries. This change comes at a cost of lower yield. Currently, annual interest rates on short term CDs are yielding approximately 2% and investments in money market funds are yielding an average of 0.5% per year.

For the six month period ended November 30, 2008, investment income amounted to \$136,000, a decrease of \$748,000, or 84.6%, from the \$884,000 reported for the six months ended November 30, 2007. Lower investment balances and lower yields on investments accounted for the difference.

With declining available cash resources, we anticipate that interest income will decline over the balance of fiscal 2009 in the absence of a significant cash infusion. A one percent rate change yields a \$10,000 change in interest income on a \$1,000,000 investment over a 12 month period.

Table of Contents

NET LOSS

The net loss for our three month period ended November 30, 2008 was \$5,594,000, or \$0.21 per share, compared to a net loss of \$5,021,000, or \$0.19 per share, for the three month period ended November 30, 2007. An increase in the period's operating expenses related to the filing of our BLA and continued preparations for a FDA facility audit combined with a significant reduction in other income caused our increased net loss.

For the six month period ended November 30, 2008, Northfield's net loss amounted to \$11,516,000, or \$0.43 per share, compared to a net loss of \$9,826,000, or \$0.36 per share, for the comparable prior year period. Higher expenses and lower interest income in fiscal 2009 accounted for the increased net losses in the fiscal 2009 period.

LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through November 30, 2008, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of \$234,335,000. For the six month periods ended November 30, 2008 and 2007, these cash expenditures totaled \$10,798,000 and \$10,795,000, respectively.

We have financed our research and development and other activities to date through the public and private sale of equity securities and, to a very limited extent, through the license of product rights. As of November 30, 2008, we had cash and cash equivalents, restricted cash and short term marketable securities totaling \$10,105,000. As previously reported, we were successful in securing a \$1.4 million federal appropriation as part of the Defense Appropriation Bill in 2005 and a \$3.5 million federal appropriation as part of the Fiscal 2006 Defense Appropriation Bill. As of November 30, 2008, \$77,000 of these funds remain available.

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 a going concern because it expects to experience significant future losses and currently has insufficient capital resources to fund its continuing operations. We are currently utilizing our cash resources at a rate of approximately \$21.6 million per year. We expect the rate at which we utilize our cash resources will remain consistent in the third quarter and decline in the fourth quarter in order to conserve available cash resources unless additional funding is secured. Based on our current estimates, we believe our existing cash resources will be sufficient to permit us to conduct our operations for approximately 5 to 6 months from November 30, 2008, which should allow for the completion of the FDA's priority review of our BLA. To continue operations beyond this point, we will either have to severely restrict our spending or raise additional capital.

There can be no assurance that the Company will have adequate capital resources through May 31, 2009. The Company's inability to raise sufficient levels of capital could materially delay or prevent the commercialization of its PolyHeme 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.

We cannot ensure that we will be able to achieve product revenues or profitability on a sustained basis or at all. As a result, our independent accountants have included an explanatory paragraph in their audit opinion for the year ended May 31, 2008 based on uncertainty regarding our ability to continue as a going concern. 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.

We may in the future issue additional equity or debt securities or enter into collaborative arrangements with strategic partners, which could provide us with additional funds 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 status of the FDA review of our BLA submission, as well as general conditions in the business and financial markets.

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 policies reflect our more significant judgments

and estimates used in the preparation of our financial statements.

SHARE-BASED COMPENSATION

Effective June 1, 2006, we adopted SFAS No. 123R, Share-Based Payment. We elected to use the modified prospective application of SFAS No. 123R for awards issued prior to June 1, 2006. Income from continuing operations before income tax for the years ended May 31, 2007 and 2008, includes total expense recognized for all of our stock-based payment plans.

The fair value of stock options granted under the stock incentive plans is estimated on the date of grant based on the Black-Scholes option pricing model. We utilize our own historical stock price movement as the basis for our calculated expected volatility factor. We use historical data to estimate stock option exercise and employee departure behavior used in the Black-Scholes option pricing model. The expected term of stock options granted represents the period of time that stock options granted are expected to be

Table of Contents

outstanding. The risk-free rate for the period within the contractual term of the stock option is based on the U.S. Treasury yield curve in effect at the time of grant.

NET DEFERRED TAX ASSETS VALUATION

We record our net deferred tax assets in the amount that we expect to realize based on projected future taxable income. In assessing the appropriateness of our valuation, assumptions and estimates are required, such as our ability to generate future taxable income. As of May 31, 2008, we have recorded a 100% percent valuation allowance against our net deferred tax assets. 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.

CONTRACTUAL OBLIGATIONS

The following table reflects a summary of our contractual cash obligations as of November 30, 2008:

Contractual Obligations	Total	Less than One Year	1 3 Years
Lease Obligations (1)	\$ 294,871	\$ 294,871	
Other Obligations (2)	\$2,852,535	\$2,852,535	
Total Contractual Cash Obligations	\$3,147,406	\$3,147,406	

(1) The lease for our Evanston headquarters is cancelable with six months notice combined with a termination payment equal to three months base rent at any time after February 14, 2009. If the lease is cancelled as of February 15, 2009, unamortized broker commissions of \$17,470 would also be due.

During the third fiscal quarter of 2009, we expect

to make a payment of approximately \$110,000 to terminate the lease for our corporate office in Evanston, Illinois. In the first quarter of fiscal 2010 (June 2009), we will be consolidating our operations at our owned Mt. Prospect, Illinois facility.

- (2) Represents payments required to be made upon termination of employment of our officers. Figures shown represent compensation payable upon the termination of the employment of these officers for reasons other than death, disability, cause or voluntary termination of employment by the officers other than for good reason. Additional payments may be required in connection with a termination of employment of certain executive

officers
following a
change in
control of
Northfield.

RECENT ACCOUNTING PRONOUNCEMENTS

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) 159, The Fair Value Option for Financial Assets and Financial Liabilities. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value at specified election dates. Under SFAS 159, a business entity is required to report unrealized gains and losses on items for which the fair value option has been elected in earnings (or another performance indicator if the business entity does not report earnings) at each subsequent reporting date. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 159 did not have a material effect on our financial statements.

In September 2006, the FASB issued SFAS 157, Fair Value Measurements. SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The requirements of SFAS 157 are effective for financial statements issued for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157, which provides a one year deferral of the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. In accordance with FSP FAS No. 157-2, we only adopted the provisions for SFAS No. 157 with respect to our financial assets and liabilities that are measured at fair value within the financial statements as of June 1, 2008. The adoption of SFAS 157 did not have a material effect on our financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations. This Statement will replace SFAS No. 141, Business Combinations. This Statement establishes principles and requirements for how the acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed and any non-controlling interest in the acquiree; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This Statement applies prospectively to business combinations for which the acquisition date is on or after the

Table of Contents

beginning of the first annual reporting period beginning on or after December 15, 2008. We plan to adopt this Statement on June 1, 2009. We do not believe that adoption of SFAS 141 will have a material effect on our financial statements.

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. We also invest in commercial paper which is shown as marketable securities. 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 in the interest rate received on our cash and marketable securities of \$10,105,000 at November 30, 2008 would decrease interest income by \$101,000 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 of Administration 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 1. Legal Proceedings.

Between March 17, 2006 and May 15, 2006, ten separate complaints were filed, each purporting to be on behalf of a class of the Company's shareholders, against the Company and Dr. Steven A. Gould, the Company's Chief Executive Officer, and Richard DeWoskin, the Company's former Chief Executive Officer. Those putative class actions were consolidated in a case pending in the United States District Court for the Northern District of Illinois Eastern Division. The Consolidated Amended Class Action Complaint was filed on September 8, 2006, and alleged, among other things, that during the period from March 19, 2001 through March 20, 2006, the named defendants made or caused to be made a series of materially false or misleading statements and omissions about the Company's elective surgery clinical trial and business prospects in violation of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated there under and Section 20(a) of the Exchange Act. Plaintiffs alleged that those allegedly false and misleading statements and omissions caused the purported class to purchase the Company's common stock at artificially inflated prices. As relief, the complaint sought, among other things, a declaration that the action be certified as a proper class action, unspecified compensatory damages (including interest) and payment of costs and expenses (including fees for legal counsel and experts). The Company and the individual defendants filed a motion to dismiss the complaint, and on September 25, 2007, the court granted that motion, finding that the plaintiffs failed to state a claim. The court dismissed the complaint without prejudice, and on November 20, 2007, the plaintiffs filed a Consolidated Second Amended Class Action Complaint. On January 22, 2008, the Company and the individual defendants filed a motion to dismiss, and the briefing of that motion was completed on June 26, 2008. On September 23, 2008, the Court denied the motion to dismiss, and on December 5, 2008, the Company and the individual defendants answered the Consolidated Second Amended Class Action Complaint. Plaintiffs have advised that they intend to file a motion seeking certification of a class. Accordingly, the case has proceeded into discovery and briefing of class certification issues. The putative class action is at an early stage and it is not possible to predict the outcome.

Item 1A. Risk Factors.

The following risk factor should be read in conjunction with our Annual Report on Form 10-K for the fiscal year ended May 31, 2008, including the other risk factors identified within the Annual Report.

Our financial resources are limited and we will need to raise additional capital in the future to continue our business.

Table of Contents

As of November 30, 2008, we had cash and cash equivalents and marketable securities of approximately \$10.1 million. We are currently utilizing our cash resources at a rate of approximately \$21.6 million per year, and we expect to maintain this rate of cash utilization through our third fiscal quarter of 2009. Based on our current estimates, we anticipate that our existing financial resources will be adequate to permit us to continue to conduct our business only for approximately 5 to 6 months from November 30, 2008. We will need to raise additional capital to continue our business after this period. Our future capital requirements will depend on many factors, including the timing and outcome of regulatory reviews, administrative and legal expenses, the status of competitive products, the establishment of manufacturing capacity and the establishment of collaborative relationships. We cannot ensure that additional funding will be available or, if it is available, that it can be obtained on terms and conditions we will deem acceptable. Any additional funding derived from the sale of equity securities is likely to result in significant dilution to our existing stockholders. Any additional funding derived from financing our owned manufacturing facility will be subject to prevailing conditions in the commercial real estate market, which may be adverse and may not permit us to derive full value from our facility. The opinion of our independent accountants with respect to our audited financial statements includes an explanatory paragraph regarding the continuation of our company as a going concern. We are also subject to a putative class action lawsuit alleging violations of the federal securities laws. In addition, we have received notice from the Nasdaq Stock Market that our common stock may be delisted from the Nasdaq Global Market if we fail to achieve compliance with Nasdaq's \$1.00 minimum bid price per share. These matters involve risks and uncertainties that may prevent us from raising additional capital or may cause the terms upon which we raise additional capital, if additional capital is available, to be less favorable to us than would otherwise be the case.

Item 2. Submission of Matters to a Vote of Security Holders

Our annual meeting of stockholders was held on October 2, 2008. Proxies for the meeting were solicited pursuant to Section 14(a) of the Securities Exchange Act of 1934 and there was not solicitation in opposition to management's solicitation. Each of the management's nominees for directors, as listed in the proxy statement, was elected with the number of votes set forth below.

Nominee	For	Withheld
Steven A. Gould, M.D.	21,263,700	3,129,674
John F. Bierbaum	21,329,858	3,063,516
Bruce S. Chelberg	21,346,789	3,046,585
Alan L. Heller	21,408,592	2,984,782
Paul M. Ness, M.D.	20,211,927	4,181,447
David A. Savner	21,478,486	2,914,888
Edward C. Wood, Jr.	21,513,802	2,879,572

The aforesaid nominees were elected as Directors.

The results of other matters voted upon at the annual meeting were as follows:

Proposal	For	Against	Abstain	Non-Votes
The proposal to ratify the appointment of KPMG LLP as the independent registered public accounting firm for the Company to serve for the Company's 2009 fiscal year was approved.	22,605,950	1,392,550	394,874	0
The proposal to amend the 2003 Equity Compensation Plan to increase the number of common stock awards available under the plan and increase the annual limits on the number of shares that may be awarded to participants was not approved.	9,243,960	5,577,121	144,864	9,427,429

The proposal to amend the Company's restated certificate of incorporation to effect a reverse split of the outstanding shares of the Company's common stock was not approved.

18,340,001

5,912,817

140,556

0

16

Table of Contents

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 9, 2009.

Signature	Title
/s/ Steven A. Gould Steven A. Gould, M.D.	Chairman of the Board and Chief Executive Officer
/s/ Jack Kogut Jack Kogut	Senior Vice President of Administration