NORTHFIELD LABORATORIES INC /DE/
Form 10-Q
October 10, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE QUARTERLY PERIOD ENDED August 31, 2008

OR

o **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	36-3378733
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1560 SHERMAN AVENUE, SUITE 1000, EVANSTON, ILLINOIS	60201-4800
(Address of principal executive offices)	(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 þ No o
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 o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company þ

(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 Yes o No þ

As of August 31, 2008, Registrant had 26,958,516 shares of common stock outstanding.

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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.

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 August 31, 2008, the related statements of operations and cash flows for the three-month periods ended August 31, 2008 and August 31, 2007, and for the period from June 19, 1985 (inception) through August 31, 2008. We have also reviewed the statements of shareholders equity (deficit) for the three-month period ended August 31, 2008 and for the period from June 19, 1985 (inception) through August 31, 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 August 31, 2008, and for the three-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
October 10, 2008

NORTHFIELD LABORATORIES INC.
(a company in the development stage)
Balance Sheets
August 31, 2008 and May 31, 2008

	August 31, 2008 (unaudited)	May 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 7,329,990	12,746,540
Restricted cash	220,462	301,292
Marketable securities	7,993,424	7,979,830
Prepaid expenses	630,860	696,253
Total current assets	16,174,736	21,723,915
Property, plant, and equipment	19,863,322	19,747,948
Accumulated depreciation	(11,671,559)	(11,506,730)
Net property, plant, and equipment	8,191,763	8,241,218
Other assets	19,550	19,550
	$ 24,386,049	29,984,683
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable	$ 1,561,542	1,917,260
Accrued expenses	84,545	111,637
Government grant liability	220,462	301,292
Accrued compensation and benefits	800,631	658,012
Total current liabilities	2,667,180	2,988,201
Other liabilities	14,935	14,392
Total liabilities	2,682,115	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 August 31, 2008 and 26,960,233 at May 31, 2008	269,602	269,602
Additional paid-in capital	247,597,939	246,954,375
Deficit accumulated during the development stage	(226,138,214)	(220,216,494)
	21,729,327	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	21,703,934	26,982,090
	$ 24,386,049	29,984,683

See accompanying notes to financial statements and accountants review report.

NORTHFIELD LABORATORIES INC.
(a company in the development stage)
Statements of Operations
Three months ended August 31, 2008 and August 31, 2007 and for the period
from June 19, 1985 (inception) through August 31, 2008

	Three months ended		Cumulative from June 19, 1985 through
	August 31, 2008 (unaudited)	August 31, 2007 (unaudited)	August 31, 2008 (unaudited)
Revenues license income	$		3,000,000
Costs and expenses:			
Research and development	4,381,890	3,777,501	189,138,847
General and administrative	1,622,085	1,510,284	72,084,831
	6,003,975	5,287,785	261,223,678
Other income and expense:			
Interest income	82,255	482,328	32,243,619
Interest expense			83,234
	$ 82,255	482,328	32,160,385
Net loss before cumulative effect of change in accounting principle	(5,921,720)	(4,805,457)	(226,063,293)
Cumulative effect of change in accounting principle			74,921
Net loss	$ (5,921,720)	(4,805,457)	(226,138,214)
Net loss per share basic and diluted	$ (0.22)	(0.18)	(17.47)
Shares used in calculation of per share data basic and diluted	26,958,516	26,914,814	12,944,301

See accompanying notes to financial statements and accountants review report.

NORTHFIELD LABORATORIES INC.
(a company in the development stage)
Statements of Shareholders Equity (Deficit)
Three months ended August 31, 2008 and the cumulative period
from June 19, 1985 (inception) through August 31, 2008

Preferred stock Number of shares	Preferred stock Aggregate amount	Common stock Number of shares	Common stock Aggregate amount	Series A convertible preferred stock Number of shares	Series A convertible preferred stock Aggregate amount	Series B convertible preferred stock Number of shares	Series B convertible preferred stock Aggregate amount	Additional paid-in capital	Deficit accumulated during the development stage	Deferred compen-sation	Treasur shares
k ,											
	$	3,500,000	$ 35,000		$		$	$ (28,000)	$	$	$
ck											
				250,000	250,000			670,850	(607,688)		
6	$	3,500,000	$ 35,000	250,000	$ 250,000		$	$ 642,850	$ (607,688)		$
									(2,429,953)		
n											
k											
								2,340,000		(2,340,000)	
n										720,000	
7	$	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			
ck											

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

					7,443,118	(791,206)			
					683,040		(683,040)		
							800,729		
$	6,476,585	$ 64,766	$	$	$ 35,728,451	$ (6,886,101)	$ (936,175)	$	
						(3,490,394)			
					699,163		(699,163)		
							546,278		
$	6,476,585	$ 64,766	$	$	$ 36,427,614	$ (10,376,495)	$ (1,089,060)	$	
						(5,579,872)			
							435,296		
$	6,476,585	$ 64,766	$	$	$ 36,427,614	$ (15,956,367)	$ (653,764)	$	
	90,000	900			503,100				

						(7,006,495)		
n							254,025	
2	$ 6,566,585	$ 65,666	$	$	$ 36,930,714	$ (22,962,862)	$ (399,739)	$
ts								
	15,000	150			106,890			
k								
3 of								
	374,370	3,744			5,663,710	(8,066,609)		
n							254,025	
3	$ 6,955,955	$ 69,560	$	$	$ 42,701,314	$ (31,029,471)	$ (145,714)	$
						(7,363,810)		
k								
4 of								
	2,500,000	25,000			14,163,851			
					(85,400)		85,400	
n							267	
4	$ 9,455,955	$ 94,560	$	$	$ 56,779,765	$ (38,393,281)	$ (60,047)	$
						(7,439,013)		
	375,000	3,750			2,261,250			
k								
4								

s								
	10,000	100			71,300			
	187,570	1,875			373,264			
					(106,750)		106,750	
n							(67,892)	
5	$ 10,028,525	$ 100,285	$	$	$ 59,378,829	$ (45,832,294) (4,778,875)	$ (21,189)	$
k								
s 5)	2,925,000	29,250			48,324,374			
k								
l,								
s	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	

n								(62,726)
6	$ 13,586,155	$ 135,862	$	$	$ 115,427,120	$ (50,611,169)	$ (3,853)	$

See accompanying notes to financial statements and accountants review report

NORTHFIELD LABORATORIES INC.
(a company in the development stage)
Statements of Shareholders Equity (Deficit)
Three months ended August 31, 2008 and the cumulative period
from June 19, 1985 (inception) through August 31, 2008

	Preferred stock Number of shares	Preferred stock Aggregate amount	Common stock Number of shares	Common stock Aggregate amount	Series A convertible preferred stock Number of shares	Series A convertible preferred stock Aggregate amount	Series B convertible preferred stock Number of shares	Series B convertible preferred stock Aggregate amount	Additional paid-in capital	Deficit accumulated during the development stage	Deferred compen-sation	Treasury shares	Total share-holders equity (deficit)
Net loss		$		$		$		$	$	(4,245,693)	$	$	$ (4,245,693)
Exercise of stock options at $0.20 per share			263,285	2,633					50,025				52,658
Exercise of stock options at $2.00 per share			232,935	2,329					463,540				465,869
Exercise of stock options at $7.14 per share			10,000	100					71,300				71,400
Amortization of deferred compensation											2,569		2,569
Balance at May 31, 1997		$	14,092,375	$ 140,924		$		$	$ 116,011,985	$ (54,856,862)	$ (1,284)	$	$ 61,294,763
Net loss										(5,883,378)			(5,883,378)
Exercise of stock options at $7.14 per share			5,000	50					35,650				35,700
Amortization of deferred compensation											1,284		1,284
Balance at May 31, 1998		$	14,097,375	$ 140,974		$		$	$ 116,047,635	$ (60,740,240)	$	$	$ 55,448,369
Net loss										(7,416,333)			(7,416,333
Non-cash compensation									14,354				14,354
Exercise of stock options at $7.14 per share			17,500	175					124,775				124,950
Exercise of stock warrants			125,000	1,250					998,750				1,000,000

t $8.00 per hare								
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 tock options at $13.38 per hare	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 tock options at $6.38 per share	6,000	60			38,220			38,280
Exercise of tock options at $10.81 per hare	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
ssuance of common stock t $5.60 per hare on uly 28, 2003 net of costs of ssuance of $909,229)	1,892,857	18,928			9,671,843			9,690,771
ssuance of common stock o 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 15, 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 18, 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, 1,717 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 issuance 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

hare on October 3, 2005								
ssuance of ommon stock o director at $10.67 per hare on February 24, 2006	1,406	14		14,986				15,000
Exercise of tock options at $10.66, $5.15 nd $11.09 per hare	8,000	80		65,075				65,155
Exercise of tock options at $10.66 and $7.13 per share	2,750	28		26,640				26,668
Exercise of tock 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 emaining deferred ompensation				(9,059)		9,059		
Exercise of tock options at $5.15 and $7.13 per share	2,750	28		17,105				17,133
Exercise of tock options at $7.13 per share	750	7		5,348				5,355
ssuance of ommon stock o directors at $13.03 per hare on September 20, 2006	6,912	69		89,931				90,000
Exercise of tock options at $11.44 per hare	10,000	100		114,300				114,400
Exercise of tock options at	3,125	31		24,646				24,677

$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 compenstion				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 compenstion				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 compenstion				643,564				643,564
Net loss					(5,921,720)			(5,921,720
Balance at August 31, 2008	$ 26,960,233	$ 269,602	$	$ 247,597,939	$ (226,138,214)	$	$ (25,393)	$ 21,703,934

See accompanying notes to financial statements and accountants review report

NORTHFIELD LABORATORIES INC.
(a company in the development stage)
Statements of Cash Flows
Three months ended August 31, 2008 and August 31, 2007
and the cumulative period from June 19, 1985
(inception) through August 31, 2008

	Three months ended		Cumulative from June 19, 1985 through
	August 31, 2008	August 31, 2007	August 31, 2008
	(unaudited)	(unaudited)	(unaudited)
Cash flows from operating activities:			
Net loss	$ (5,921,720)	(4,805,457)	(226,138,214)
Adjustments to reconcile net loss to net cash used in operating activities:			
Marketable security amortization	(53,236)	(228,212)	(4,086,250)
Depreciation and amortization	164,829	164,943	20,238,971
Share-based compensation	643,564	517,439	9,499,706
Loss of sale of equipment			88,511
Changes in assets and liabilities:			
Restricted cash	80,830	(529,752)	839,042
Prepaid expenses	65,393	(11,859)	(840,071)
Other current assets		(433,771)	(1,896,251)
Other assets			55,791
Accounts payable	(355,718)	(1,580,507)	1,561,542
Accrued expenses	(27,092)	75,163	84,545
Government grant liability	(80,830)	529,752	(839,042)
Accrued compensation and benefits	142,619	283,339	800,631
Current other liabilities			7,431
Other liabilities	543	2,233	7,504
Net cash used in operating activities	(5,340,818)	(6,016,689)	(200,616,154)
Cash flows from investing activities:			
Purchase of property, plant, equipment, and capitalized engineering costs	(115,374)	(171,291)	(28,377,497)
Proceeds from sale of land and equipment			1,863,023
Proceeds from matured marketable securities	6,000,000	23,946,753	767,808,105
Proceeds from sale of marketable securities			7,141,656
Purchase of marketable securities	(5,960,358)	(18,745,784)	(778,862,715)
Net cash provided by (used in) investing activities	(75,732)	5,029,678	(30,427,428)

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
Net increase (decrease) in cash	(5,416,550)	(987,011)	7,329,990
Cash at beginning of period	12,746,540	23,224,026	
Cash at end of period	$ 7,329,990	22,237,015	7,329,990
Supplemental Schedule of Noncash Financing Activities :			
Exercise of stock option, 5,000 shares in exchange for 1,717 treasury shares	$		25,393

See accompanying notes to financial statements and accountants review report.

Northfield Laboratories Inc.
(a company in the development stage)
Notes to the Financial Statements
August 31, 2008
(unaudited)

(1) BASIS OF PRESENTATION

The interim financial statements presented are unaudited but, in the opinion of management, have been prepared in conformity with accounting principles generally accepted in the United States of America applied on a basis consistent with those of the annual financial statements. Such interim financial statements reflect all adjustments (consisting of normal recurring accruals) necessary for a fair presentation of the financial position, 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 August 31, 2008, we had cash and cash equivalents, restricted cash and short term marketable securities of approximately $15.5 million. We are currently utilizing our cash resources at a rate of approximately $20 million per year, and we expect to maintain this rate of cash utilization through the submission of our Biologics License Application or BLA and receipt of a decision from the Food and Drug Administration or FDA. We anticipate that our existing financial resources will be adequate to permit us to continue to conduct our business only for approximately 8 to 9 months. To continue operations beyond this point, we will either have 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 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.

(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 net loss per share is based on the weighted average number of shares outstanding and excludes the dilutive effect of unexercised common stock equivalents. Diluted net loss per share is based on the weighted average number of shares outstanding and includes the dilutive effect of unexercised common stock equivalents. Because we reported net losses for all periods presented, basic and diluted per share amounts are the same. As of August 31, 2008, we had 2,090,125 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 August 31, 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. 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 August 31, 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. 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 August 31, 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. 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 August 31, 2008, options to purchase a total of 55,000 shares of the Company s common stock at prices between $3.62 and $18.55 per share were outstanding. 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 August 31, 2008, options to purchase a total of 1,609,000 shares of the Company s common stock at prices between $1.36 and $18.55 were outstanding. These options expire between 2013 and 2017, 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 on July 12, 2007 to Company officers have a two year vesting period with shares vesting at a rate of 50% each year.

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

Compensation expense is recognized on a straight-line basis over the vesting term only 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 months ended August 31, 2008 was $.03 and the related charge associated with share-based compensation expense recognized in the Statement of Operations for the three months ended August 31, 2008 was $644,000.

As of August 31, 2008, there was approximately $1,365,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the incentive plans. That cost is expected to be recognized over a weighted-average period of 1.14 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 months ended August 31, 2008 and August 31, 2007.

	Three Months Ended	
	August 31, 2008	August 31, 2007
Fair value	$	$ 580,250
Expected volatility	%	95.9%
Risk-free interest rate	%	4.9%
Dividend yield		
Expected lives		6.3 years

There were no options granted during the three months ended August 31, 2008. The weighted average grant-date fair value of options granted during the three months ended August 31, 2007 was $1.10 per share.

The following table summarizes the Company s option activity during the three months ended August 31, 2008:

	Shares	Range of Exercise Prices		Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (years)	Aggregate Intrinsic Value
Outstanding at May 31, 2008	2,090,125	$ 1.36	$18.55	$ 8.32		
Granted at Fair Value						
Exercised						
Expired						
Cancelled						
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

The aggregate intrinsic value in the table above is before taxes and based on a weighted average exercise price of $8.32 for options outstanding at August 31, 2008 and $8.72 for options exercisable at August 31, 2008. The total intrinsic value of options exercised during the three months ended August 31, 2008 and August 31, 2007 was $0 and $0, respectively. The total fair value of options vested during the three months ended August 31, 2008 and August 31, 2007 was $426,882 and $190,781, respectively.

(6) RESTRICTED CASH

As of August 31, 2008, the Company had $220,462 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 periods ended August 31, 2008 and 2007, $11,171 and $0 of restricted cash from a government grant was recognized as a contra-expense, respectively, and $69,841 and $0 were recognized as a reduction in the asset carrying value, respectively.

(7) MARKETABLE SECURITIES

The Company, at August 31, 2008, is 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 $7,991,490 at August 31, 2008, which included gross unrealized holding losses of $1,934. 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.

(8) 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.

(9) INCOME TAXES

The Company adopted the provisions of 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 August 31, 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 upon adoption. 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 or in subsequent periods. 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.

(10) 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 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. Plaintiffs have advised that they intend to file a motion seeking certification of a class. Accordingly, the case is expected to proceed 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 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

RECENT DEVELOPMENTS

We are presently preparing a Biologics License Application, or BLA, for our PolyHeme red blood cell substitute, for submission to the Food and Drug Administration, or FDA. We anticipate submitting our BLA to FDA during the fourth calendar quarter of 2008. We also plan to submit a request for priority review of our BLA. We believe PolyHeme satisfies the stated criteria for priority review based on its potential to address an unmet medical need.

Since Northfield s incorporation in 1985, we have devoted substantially all of our efforts and resources to the research, development and clinical testing of PolyHeme. We have incurred operating losses during each year of our operations since inception and expect to incur substantial additional operating losses for the next several years. From Northfield s inception through August 31, 2008, we have incurred operating losses totaling approximately $226,138,000.

We will be required to obtain regulatory approval from FDA before PolyHeme can be sold commercially. The FDA regulatory process is subject to significant risks and uncertainties. We therefore cannot at this time reasonably estimate the timing of any future revenues from the commercial sale of PolyHeme. The costs incurred by Northfield to date and during each period presented below in connection with our development of PolyHeme are described in the Statements of Operations in our financial statements.

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

RESULTS OF OPERATIONS

We reported no revenues for the three months ended August 31, 2008 or August 31, 2007. From Northfield s inception through August 31, 2008, we have reported total revenues of $3,000,000, all of which were derived from

licensing fees.

OPERATING EXPENSES

Operating expenses for the first fiscal quarter of 2009 and 2008 totaled $6,004,000 and $5,288,000, respectively. Measured on a percentage basis, operating expenses for the three month period ended August 31, 2008 increased from the three month period ended August 31, 2007 by 13.6%.

During the three months ended August 31, 2008, research and development expenses totaled $4,382,000, an increase of $604,000, or 16.0%, from the three month period ended August 31, 2007 expenses of $3,778,000. During the first fiscal quarter of 2009, our efforts to prepare our BLA for PolyHeme to be submitted to FDA and to ready our manufacturing facility increased. The increase in research and development costs was also driven by an increase in validation services and an increase in publishing services in connection with the preparation of our BLA.

We anticipate a continued high level of research and development spending in fiscal 2009. Along with preparing our BLA for PolyHeme, we will be undergoing an extensive process of preparation for FDA s pre-approval inspection of our pilot manufacturing facility. At the same time, we will be preparing for a FDA sponsored advisory committee review of our product. Northfield s internal research and development resources will be focused on these tasks and we expect to continue the use of external resources to complete these tasks in a timely manner.

General and administrative expenses for the first fiscal quarter of 2009 totaled $1,622,000, an increase of $112,000, or 7.5%, from the $1,510,000 of expenses incurred in the first fiscal quarter of 2008. The increase is due to a non-cash charge to share-based compensation expense due to a change in estimated forfeitures for option grants to reflect a better estimate of the Company s forfeiture experience. We anticipate no significant addition to administrative expenses in fiscal 2009.

INTEREST INCOME

Interest income for the three month period ended August 31, 2008 was $82,000 compared to $482,000 in the three month period ended August 31, 2007. The current period decrease is the result of lower available cash resources for investment. Money market rates in August 2008 were approximately 1.94% and high quality three-month securities were also around 2.67%. As our current investments mature, they will be rolled over until the funds are required for our business.

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

NET LOSS

The net loss for our three month period ended August 31, 2008 was $5,922,000, or $.22 per share, compared to a net loss of $4,805,000, or $.18 per share, for the three month period ended August 31, 2007. The increase in net loss was primarily driven by an increase in our efforts to prepare our BLA for PolyHeme to be submitted to FDA and to ready our manufacturing facility for FDA inspection.

LIQUIDITY AND CAPITAL RESOURCES

From Northfield s inception through August 31, 2008, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of $228,994,000. For the three month period ended August 31, 2008 and 2007, these cash expenditures totaled $5,456,000 and $6,188,000, respectively. The decrease in cash utilization was driven by a reduction in payments of professional services.

We have financed our research and development and other activities to date through the public and private sale of equity securities and, to a more limited extent, through the license of product rights. As of August 31, 2008, we had cash and cash equivalents, restricted cash and short term marketable securities totaling $15,544,000. The Company invests in high grade commercial paper and short term certificates of deposit with maturities of three months or less. As of August 31, 2008, the Company has an unrealized holding loss of $1,934. As previously reported, we have been 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 August 31, 2008, we have received all of these funds.

We are currently utilizing our cash resources at a rate of approximately $20 million per year. We expect the rate at which we utilize our cash resources will remain consistent in fiscal 2009 as we prepare to complete and submit a BLA for PolyHeme to FDA, and prepare our manufacturing facility for FDA inspection.

Based on our current estimates, we believe our existing capital resources will be sufficient to permit us to conduct our operations, including the preparation and submission of a BLA to FDA, for approximately 8 to 9 months.

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.

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.

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 its 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 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 August 31, 2008:

Contractual Obligations	Total	Less than One Year	1-3 Years
Lease Obligations(1)	$ 276,001	$ 276,001	
Other Obligations(2)	1,776,900	1,776,900	

Total Contractual Cash Obligations	$2,052,901	$2,052,901

(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.

(2) Represents payments required to be made upon termination of employment agreements with three of our executive officers. The employment contracts renew automatically unless terminated. Figures shown represent compensation payable upon the termination of the employment agreements for reasons other

than death, disability, cause or voluntary termination of employment by the executive officer other than for good reason. Additional payments may be required under the employment agreements in connection with a termination of employment of the executive officer following a change in control of Northfield.

RECENT ACCOUNTING PRONOUNCEMENTS

In February 2007, the Financial Accounting Standards Board 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 nonfinancial 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 will adopt 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.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations (SFAS 141R). 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 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 141R 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 $15,323,414 at August 31, 2008 would decrease interest income by $153,000 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 Vice President Finance 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 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. Plaintiffs have advised that they intend to file a motion seeking certification of a class. Accordingly, the case is expected to proceed 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.

As of August 31, 2008, we had cash and cash equivalents and marketable securities of approximately $15.3 million. We are currently utilizing our cash resources at a rate of approximately $20 million per year, and we expect to maintain this rate of cash utilization through the submission of our BLA to FDA. We anticipate that our existing financial resources will be adequate to permit us to continue to conduct our business only for the next 8 to 9 months. 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. The opinion of our independent accountants with respect to our audited financial statements as of and for the year ended May 31, 2008, 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 requirement by December 8, 2008. 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.

Failure to increase manufacturing capacity may impair PolyHeme s market acceptance and prevent us from achieving profitability.

Our pilot manufacturing facility was first opened in 1990 with a design capacity to produce up to 10,000 units of PolyHeme per year. At the time it was Northfield s plan to use the pilot facility for research and development purposes and the manufacture of clinical supplies under the appropriate current Good Manufacturing Practices, or cGMP, with future commercial scale manufacturing being performed in a new facility. Our current plan is to seek FDA approval for use of the pilot plant as our initial commercial manufacturing site, to be followed by expansion at a later date. The cGMP requirements for commercial manufacturing have evolved considerably over the past two decades and we have made multiple improvements and updates to our pilot facility in an effort to confirm compliance. These upgrades have consumed and continue to consume considerable time, effort and expense. We anticipate that the final capacity of this pilot facility will be approximately 5,000 to 7,500 units per year. At this manufacturing capacity, profitability can not be achieved. In June 2006, we purchased the 106,000 square foot building in Mt. Prospect, Illinois in which our pilot manufacturing facility is located and plan to construct an expanded commercial manufacturing facility at this site if FDA approval for the marketing of PolyHeme is received. We currently do not have sufficient available funds to permit us to begin construction of this facility and we will need to raise additional funds before we are able to proceed with our planned manufacturing expansion. There can be no assurance that we will be able to raise additional funds for this purpose. If we are successful in raising sufficient funds to begin construction of a commercial manufacturing facility, we expect that completion of the facility, including FDA inspection and validation, will require approximately 24 to 30 months. Therefore, even if FDA approval for the marketing of PolyHeme is obtained, we will not be able to produce PolyHeme in sufficient quantities to achieve profitability for a substantial period of time. A commercial-scale manufacturing facility will be subject to FDA inspections and extensive regulation, including compliance with current good manufacturing practices and FDA approval of scale-up changes. Failure to comply may result in enforcement action, which may significantly delay or suspend manufacturing operations. We have no experience in large-scale manufacturing, and there can be no assurance that we can achieve large-scale manufacturing capacity. It is also possible that we may incur substantial cost overruns and delays compared to existing estimates in building and equipping a large-scale manufacturing facility. Moreover, in order to seek FDA approval of the sale of PolyHeme produced at a larger-scale manufacturing facility, we may be required to conduct additional studies with product manufactured at that facility. A significant delay in achieving scale-up of commercial manufacturing capabilities would have a material adverse effect on sales of PolyHeme.

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 October 10, 2008.

Signature	Title
/s/ Steven A. Gould Steven A. Gould, M.D.	Chairman of the Board and Chief Executive Officer
/s/ Donna O Neill-Mulvihill Donna O Neill-Mulvihill	Vice President of Finance