

NORTHFIELD LABORATORIES INC /DE/

Form 10-Q

April 09, 2009

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**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 FEBRUARY 28, 2009  
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 February 28, 2009 Registrant had 27,038,497 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.

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**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 February 28, 2009, the related statements of operations for the three-month periods ended February 28, 2009 and February 29, 2008, and the statements of operations and cash flows for the nine-month periods ended February 28, 2009 and February 29, 2008 and for the period from June 19, 1985 (inception) through February 28, 2009. We have also reviewed the statements of shareholders' equity (deficit) for the nine-month period ended February 28, 2009 and for the period from June 19, 1985 (inception) through February 28, 2009. 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 February 28, 2009, and for the three and nine-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

April 9, 2009

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(a company in the development stage)

Balance Sheets

February 28, 2009 and May 31, 2008

|  | <b>February 28<br/>2009</b> | <b>May 31,<br/>2008</b> |
|--|-----------------------------|-------------------------|
|  | (unaudited)                 |                         |
| <b>Assets</b>  |                             |                         |
| Current assets:  |                             |                         |
| Cash and cash equivalents  | \$ 2,893,830                | 12,746,540              |
| Restricted cash  | 77,165                      | 301,292                 |
| Marketable securities  | 1,743,771                   | 7,979,830               |
| Prepaid expenses   | 308,621                     | 696,253                 |
| Other current assets   | 833,772                     |                         |
| Total current assets   | 5,857,159                   | 21,723,915              |
| Property, plant, and equipment   | 20,446,985                  | 19,747,948              |
| Accumulated depreciation   | (12,008,572)                | (11,506,730)            |
| Net property, plant, and equipment   | 8,438,413                   | 8,241,218               |
| Other assets   | 19,550                      | 19,550                  |
|  | \$ 14,315,122               | 29,984,683              |
| <b>Liabilities and Shareholders Equity</b>   |                             |                         |
| Current liabilities:   |                             |                         |
| Accounts payable   | \$ 1,768,039                | 1,917,260               |
| Accrued expenses   | 165,248                     | 111,637                 |
| Government grant liability   | 77,165                      | 301,292                 |
| Accrued compensation and benefits  | 756,318                     | 658,012                 |
| Other current liabilities  | 730,094                     |                         |
| Total current liabilities  | 3,496,864                   | 2,988,201               |
| Other liabilities  | 11,003                      | 14,392                  |
| Total liabilities  | 3,507,867                   | 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 27,038,497 at February 28, 2009 and 26,960,233 at May 31, 2008 | 270,385                     | 269,602                 |
| Additional paid-in capital   | 248,544,853                 | 246,954,375             |
| Deficit accumulated during the development stage   | (237,982,590)               | (220,216,494)           |

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|   |               |            |
|---|---------------|------------|
|   | 10,832,648    | 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   | 10,807,255    | 26,982,090 |
|   | \$ 14,315,122 | 29,984,683 |

See accompanying notes to financial statements and accountants review report.

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(a company in the development stage)

## Statement of Operations

Three and nine months ended February 28, 2009 and February 29, 2008 and for the period from June 19, 1985 (inception) through February 28, 2009

|   | <b>Three months ended</b> |                     | <b>Nine months ended</b> |                     | <b>Cumulative</b>    |
|---|---------------------------|---------------------|--------------------------|---------------------|----------------------|
|   | <b>February</b>           | <b>February 29,</b> | <b>February</b>          | <b>February 29,</b> | <b>from</b>          |
|   | <b>28, 2009</b>           | <b>2008</b>         | <b>28, 2009</b>          | <b>2008</b>         | <b>June 19, 1985</b> |
|   | (unaudited)               | (unaudited)         | (unaudited)              | (unaudited)         | <b>through</b>       |
|   |                           |                     |                          |                     | <b>February 28,</b>  |
|   |                           |                     |                          |                     | <b>2009</b>          |
|   |                           |                     |                          |                     | (unaudited)          |
| Revenues license income \$  |                           |                     |                          |                     | 3,000,000            |
| Costs and expenses:   |                           |                     |                          |                     |                      |
| Research and development  | 4,745,642                 | 3,669,678           | 13,398,042               | 11,387,582          | 198,154,999          |
| General and administrative  | 1,516,836                 | 1,480,860           | 4,516,247                | 4,472,690           | 74,978,993           |
|   | 6,262,478                 | 5,150,538           | 17,914,289               | 15,860,272          | 273,133,992          |
| Other income and expense:   |                           |                     |                          |                     |                      |
| Interest income   | 11,932                    | 319,318             | 148,193                  | 1,202,887           | 32,309,556           |
| Interest expense  |                           |                     |                          |                     | 83,234               |
|   | \$ 11,932                 | 319,318             | 148,193                  | 1,202,887           | 32,226,322           |
| Net loss before cumulative effect of change in accounting principle | (6,250,546)               | (4,831,220)         | (17,766,096)             | (14,657,385)        | (237,907,670)        |
| Cumulative effect of change in accounting principle                 |                           |                     |                          |                     | 74,921               |
| Net loss  | \$ (6,250,546)            | (4,831,220)         | (17,766,096)             | (14,657,385)        | (237,982,591)        |
| Net loss per share basic and diluted                                | \$ (0.23)                 | (0.18)              | (0.66)                   | (0.54)              | (17.71)              |
|   | 27,008,953                | 26,958,516          | 26,975,144               | 26,939,859          | 13,438,569           |



Shares used in calculation  
of per share data basic  
and diluted

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

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**NORTHFIELD LABORATORIES INC.**

(a company in the development stage)

Statements of Shareholders' Equity (Deficit)

Nine months ended February 28, 2009 and the cumulative period from June 19, 1985 (inception) through February 28, 2009

| Preferred stock | Common stock | Series A convertible | Series B convertible | Additional | Deficit     | Deferred       | Treasury       |
|-----------------|--------------|----------------------|----------------------|------------|-------------|----------------|----------------|
|                 |              |                      |                      |            |             |                |                |
| of              | of           | of                   | of                   | capital    | during the  | sation         |                |
| shares          | shares       | shares               | shares               |            | development |                |                |
| Number          | Number       | Number               | Number               |            | stage       |                |                |
| Aggregate       | Aggregate    | Aggregate            | Aggregate            |            |             |                |                |
| amount          | amount       | amount               | amount               |            |             |                |                |
|                 |              |                      |                      |            |             |                |                |
| \$              | 3,500,000    | \$ 35,000            |                      |            |             |                |                |
|                 |              |                      |                      |            |             |                |                |
|                 |              |                      | 250,000              | 250,000    |             |                |                |
|                 |              |                      |                      |            | 670,850     |                |                |
|                 |              |                      |                      |            |             | (607,688)      |                |
| \$              | 3,500,000    | \$ 35,000            | 250,000              | \$ 250,000 | \$          | \$ (607,688)   | \$             |
|                 |              |                      |                      |            |             | (2,429,953)    |                |
|                 |              |                      |                      |            |             |                |                |
|                 |              |                      |                      |            | 2,340,000   |                | (2,340,000)    |
|                 |              |                      |                      |            |             |                | 720,000        |
| \$              | 3,500,000    | 35,000               | 250,000              | \$ 250,000 | \$          | \$ (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  
87,760 878

4,976,855  
2,488,356

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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)

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)

(7,439,013)

375,000 3,750

2,261,250

|    |            |            |    |    |               |                 |             |
|----|------------|------------|----|----|---------------|-----------------|-------------|
|    | 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.

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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 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 grants  | 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<br>October 3,<br>2005   |               |            |    |                |                  |              |         |             |               |
| Issuance of<br>common stock<br>to director at<br>\$10.67 per<br>share on<br>February 24,<br>2006   | 1,406         | 14         |    | 14,986         |                  |              |         |             | 15,000        |
| Exercise of<br>stock options at<br>\$10.66, \$5.15<br>and \$11.09 per<br>share                     | 8,000         | 80         |    | 65,075         |                  |              |         |             | 65,155        |
| Exercise of<br>stock options at<br>\$10.66 and<br>\$7.13 per share                                 | 2,750         | 28         |    | 26,640         |                  |              |         |             | 26,668        |
| Exercise of<br>stock options at<br>\$5.15 and<br>\$7.13 per share                                  | 3,000         | 30         |    | 16,905         |                  |              |         |             | 16,935        |
| Net loss   |               |            |    |                |                  | (26,775,418) |         |             | (26,775,418)  |
| Balance at<br>May 31, 2006   | \$ 26,777,655 | \$ 267,777 | \$ | \$ 241,240,276 | \$ (172,136,429) | \$           | (9,059) | \$ (25,393) | \$ 69,337,172 |
| Eliminate<br>remaining<br>deferred<br>compensation   |               |            |    | (9,059)        |                  |              | 9,059   |             |               |
| Exercise of<br>stock options at<br>\$5.15 and<br>\$7.13 per share                                  | 2,750         | 28         |    | 17,105         |                  |              |         |             | 17,133        |
| Exercise of<br>stock options at<br>\$7.13 per share  | 750           | 7          |    | 5,348          |                  |              |         |             | 5,355         |
| Issuance of<br>common stock<br>to directors at<br>\$13.03 per<br>share on<br>September 20,<br>2006 | 6,912         | 69         |    | 89,931         |                  |              |         |             | 90,000        |
| Exercise of<br>stock options at<br>\$11.44 per<br>share  | 10,000        | 100        |    | 114,300        |                  |              |         |             | 114,400       |
| Exercise of<br>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 |
| Issuance of common stock to directors at \$1.15 per share on January 2, 2009    | 78,264        | 783        |    | 89,217         |                  |    |              |    | 90,000        |
| Share-based compensation  |               |            |    | 1,501,261      |                  |    |              |    | 1,501,261     |
| Net loss  |               |            |    |                |                  |    | (17,766,096) |    | (17,766,096)  |
| Balance at February 28, 2009  | \$ 27,038,497 | \$ 270,385 | \$ | \$ 248,544,853 | \$ (237,982,590) | \$ | \$ (25,393)  | \$ | \$ 10,807,255 |

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

Nine months ended February 28, 2009 and February 29, 2008

and the cumulative period from June 19, 1985

(inception) through February 28, 2009

**Other current assets**

|   | <b>Nine months ended</b> |                 | <b>Cumulative</b>    |
|---|--------------------------|-----------------|----------------------|
|   | <b>February</b>          | <b>February</b> | <b>from</b>          |
|   | <b>28, 2009</b>          | <b>29, 2008</b> | <b>June 19, 1985</b> |
|   | (unaudited)              | (unaudited)     | <b>through</b>       |
|   |                          |                 | <b>February 28,</b>  |
|   |                          |                 | <b>2009</b>          |
|   |                          |                 | (unaudited)          |
| Cash flows from operating activities:                                       |                          |                 |                      |
| Net loss  | \$ (17,766,096)          | (14,657,385)    | (237,982,590)        |
| Adjustments to reconcile net loss to net cash used in operating activities: |                          |                 |                      |
| Marketable security amortization  | (106,250)                | (448,158)       | (4,139,264)          |
| Depreciation and amortization   | 511,112                  | 477,495         | 20,585,254           |
| Share-based compensation  | 1,591,261                | 1,628,127       | 10,447,403           |
| Loss of sale of equipment   | 3,397                    |                 | 91,908               |
| Changes in assets and liabilities:  |                          |                 |                      |
| Restricted cash   | 224,127                  | (59,562)        | 982,339              |
| Prepaid expenses  | 387,632                  | 345,325         | (517,832)            |
| Other current assets  | (833,772)                | 212,854         | (2,730,023)          |
| Other assets  |                          |                 | 55,791               |
| Accounts payable  | (149,221)                | (1,810,221)     | 1,768,039            |
| Accrued expenses  | 53,611                   | 87,208          | 165,248              |
| Government grant liability  | (224,127)                | 59,562          | (982,339)            |
| Accrued compensation and benefits   | 98,306                   | 276,964         | 756,318              |
| Other current liabilities   | 730,094                  |                 | 737,525              |
| Other liabilities   | (3,389)                  | 6,417           | 3,572                |
| <br>  |                          |                 |                      |
| Net cash used in operating activities                                       | (15,483,315)             | (13,881,374)    | (210,758,651)        |
| <br>  |                          |                 |                      |
| Cash flows from investing activities:                                       |                          |                 |                      |
| Purchase of property, plant, equipment, and capitalized engineering costs   | (711,704)                | (235,950)       | (28,973,827)         |
| Proceeds from sale of land and equipment                                    |                          |                 | 1,863,023            |
| Proceeds from matured marketable securities                                 | 21,000,000               | 48,161,753      | 782,808,105          |
| Proceeds from sale of marketable securities                                 |                          |                 | 7,141,656            |
| Purchase of marketable securities   | (14,657,691)             | (40,742,415)    | (787,560,048)        |
| <br>  |                          |                 |                      |
| Net cash provided by (used in) investing activities                         | 5,630,605                | 7,183,388       | (24,721,091)         |

|   |  |  |              |
|---|--|--|--------------|
| 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 (decrease) increase in cash | (9,852,710) | (6,697,986) | 2,893,830 |
|---------------------------------|-------------|-------------|-----------|

|                             |            |            |  |
|-----------------------------|------------|------------|--|
| Cash at beginning of period | 12,746,540 | 23,224,026 |  |
|-----------------------------|------------|------------|--|

|                       |              |            |           |
|-----------------------|--------------|------------|-----------|
| Cash at end of period | \$ 2,893,830 | 16,526,040 | 2,893,830 |
|-----------------------|--------------|------------|-----------|

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.



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**Northfield Laboratories Inc.**  
**(a company in the development stage)**  
**Notes to the Financial Statements**  
**February 28, 2009**  
**(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 February 28, 2009, we had cash and cash equivalents, restricted cash, and marketable securities of approximately \$4.7 million. From the beginning of our current fiscal year on June 1, 2008 through February 28, 2009, we estimate that we have utilized our cash resources at an average rate of approximately \$1.8 million per month. Based on recently announced reductions in the total number of our employees, the placement of certain employees on part-time status and our other cost-reduction initiatives, we believe we will be able to reduce the utilization of our cash resources to an average of approximately \$1.4 million per month, excluding severance and other costs relating to our staff reductions. Based on our current estimates, we anticipate that our existing financial resources, including the proceeds from an offering of shares of our convertible preferred stock in March 2009, will be adequate to permit us to continue to conduct our business through at least April 30, 2009. We will need to raise substantial 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 will result in significant dilution to our existing stockholders. Our inability to raise sufficient levels of capital could materially delay or prevent the commercialization of our 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 February 28, 2009, we had 2,660,625 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

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February 28, 2009, 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 February 28, 2009, 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 February 28, 2009, 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 February 28, 2009, 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 February 28, 2009, options to purchase a total of 2,184,500 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. In addition, the 450,000 options granted to the Company officers on January 2, 2009 have a two year vesting period with shares vesting at a rate of 50% each year. The 60,000 options granted to the Company board members on January 2, 2009 were 100% vested on the date of the grant.

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 nine months ended February 28, 2009 was \$0.02 and \$0.06, respectively, and the related charge associated with share-based compensation expense recognized in the Statement of Operations for the three and nine months ended February 28, 2009 was \$560,000 and \$1,591,000, respectively.

As of February 28, 2009, there was approximately \$1,054,000 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 1.27 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 nine months ended February 28, 2009 and February 29, 2008.

|                         | <b>Three Months Ended</b>        |                                  | <b>Nine Months Ended</b>         |                                  |
|-------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
|                         | <b>February<br/>28,<br/>2009</b> | <b>February<br/>29,<br/>2008</b> | <b>February<br/>28,<br/>2009</b> | <b>February<br/>29,<br/>2008</b> |
| Fair Value              | \$ 578,951                       | \$                               | \$ 585,333                       | \$ 679,560                       |
| Expected volatility     | 108.24%                          |                                  | 108.27%                          | 95.9%                            |
| Risk-free interest rate | 1.62%                            |                                  | 1.65%                            | 4.8%                             |
| Dividend yield          |                                  |                                  |                                  |                                  |
| Expected lives          | 6.0 years                        |                                  | 6.0 years                        | 6.3 years                        |

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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.

On January 2, 2009, the Company issued 60,000 options to purchase shares of common stock to its directors, 450,000 options to purchase shares of common stock to its officers, and 100,000 options to purchase shares of common stock to eight key employees at a price of \$1.15 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. On January 2, 2009, the Company issued 78,264 share grants to its officers at \$1.15 per share.

The weighted average grant-date fair value of options granted during the three months ended February 28, 2009 was \$0.95 per share. There were no options granted during the three months ended February 29, 2008. The weighted average grant-date fair value of options granted during the nine months ended February 28, 2009 and February 29, 2008 was \$0.93 per share and \$1.16 per share, respectively.

The following table summarizes the Company's option activity during the nine months ended February 28, 2009:

|                                  | Shares    | Range of<br>Exercise<br>Prices | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(years) | Aggregate<br>Intrinsic<br>Value |
|----------------------------------|-----------|--------------------------------|--|--|---------------------------------|
| Outstanding at May 31, 2008      | 2,090,125 | \$ 1.36 \$18.55                | \$ 8.32                                  |  |                                 |
| Granted                          | 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                          | 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                            |

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|                                     |           |    |               |    |       |      |          |
|-------------------------------------|-----------|----|---------------|----|-------|------|----------|
| Granted                             | 610,000   | \$ | \$1.15        | \$ | 1.15  |      |          |
| Exercised                           | 0         |    |               |    |       |      |          |
| Expired                             | 0         |    |               |    |       |      |          |
| Cancelled                           | 2,000     | \$ | 10.94 \$11.92 | \$ | 11.43 |      |          |
| Outstanding at February 28,<br>2009 | 2,660,625 | \$ | 0.38 \$18.55  | \$ | 6.71  | 6.88 | \$ 7,000 |
| Exercisable at February 28,<br>2009 | 1,732,875 | \$ | 1.36 \$18.55  | \$ | 9.04  | 5.69 | \$ 0     |

The aggregate intrinsic value in the table above is before taxes and based on a weighted average exercise price of \$6.71 for options outstanding at February 28, 2009 and \$9.04 for options exercisable at February 28, 2009. The total fair value of options vested during the three months ended February 28, 2009 and February 29, 2008 was \$1,307,589 and \$1,499,421, respectively. The total fair value of options vested during the nine months ended February 28, 2009 and February 29, 2008 was \$2,015,057 and \$2,103,068, respectively.

**Table of Contents****(6) RESTRICTED CASH**

As of February 28, 2009, the Company had \$77,165 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 months ended February 28, 2009 and February 29, 2008, \$0 and \$1,096,000 of restricted cash from a government grant was recognized as a contra-expense, respectively.

For the nine months ended February 28, 2009 and February 29, 2008, \$71,000 and \$2,832,000 of restricted cash from a government grant was recognized as a contra-expense, respectively, and \$154,000 and \$187,000 was recognized as a reduction in the asset carrying value, respectively.

**(7) MARKETABLE SECURITIES**

The Company, at February 28, 2009, was invested in 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 one month or less.

The fair market value of the Company's marketable securities was \$1,743,809 at February 28, 2009, which included gross unrealized holding losses of \$38. 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.

**(8) MISCELLANEOUS RECEIVABLE**

For the third quarter ended February 28, 2009, the Company recorded a miscellaneous receivable in the amount of \$730,094 to reflect proceeds from an insurance claim made in February 2009 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 \$730,094 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.

**(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 February 28, 2009, 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 2007 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.

**(12) SUBSEQUENT EVENTS**

On March 16, 2009, we announced that we had completed the sale of 5,404,652 shares of convertible preferred stock pursuant to a registered direct offering to a single institutional investor, representing gross proceeds of approximately \$1.4 million. The preferred stock is convertible into 5,404,652 shares of Northfield's common stock at the option of the investor at a price of \$0.265 per share. Northfield also issued warrants to purchase 5,404,652 shares of common stock at an exercise price of \$0.53 per share in connection with the offering.



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**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, had accepted for filing its Biologics License Application, or BLA, for PolyHeme<sup>®</sup>, 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 Prescription Drug Users Fee Act, or PDUFA, review goal date of April 30, 2009.

From January 1 through October 31, 2008, data published by FDA indicate that approximately 20% of the PDUFA review date goals were missed. Furthermore, the impact of the implementation of the FDA Amendment Act, or FDAAA, and the planned implementation of the FDA's 21st Century Review Process has increased the potential for missed PDUFA review dates, particularly in the case of Priority Reviews, because of the difficulty of successfully completing all the required activities, including a discussion of the applicable product at a FDA advisory committee meeting, within the target review period. FDAAA authority to require post-marketing studies and Risk Evaluation and Mitigation Strategies, or REMS, only came into effect in March 2008, but the experience suggests that REMS may prolong review times. It is therefore possible that FDA will not be able to complete its review of our BLA within the review period prescribed under PDUFA. For these reasons, we are not able to predict whether FDA will comply with the April 30, 2009 review goal date for our BLA or, if FDA does not comply with this review goal date, when the agency will complete its review of our BLA.

Under FDA's review process, the agency generally convenes a meeting of its Blood Products Advisory Committee, or BPAC, to discuss BLAs relating to new blood products. BPAC is an independent advisory committee comprised of researchers, physicians and other experts in the field of blood products as well as community representatives. BPAC most recently met on April 1, 2009 and our BLA was not discussed at that meeting. We therefore do not believe our BLA will be discussed by BPAC prior to FDA's April 30, 2009 review goal date for our BLA. It is not certain whether and when our BLA for PolyHeme will be discussed by BPAC or what effect, if any, the timing of the discussion of our BLA by BPAC may have on the ability of FDA to achieve its review goal date for our BLA.

Since the submission of our BLA in October 2008, there has been considerable activity. We have received multiple requests from FDA for data clarification and supplementation. To address these requests, we have provided several amendments to our original BLA. The process of FDA site inspection and audit has begun at a number of the 32 institutions that participated in our Phase III trial. FDA has also conducted a Pre-License Inspection of our manufacturing facility.

The manuscript describing the results of our Multicenter Phase III trial, entitled *Human Polymerized Hemoglobin for the Treatment of Hemorrhagic Shock when Blood Is Unavailable: The USA Multicenter Trial*, was published in the January 2009 print edition of the Journal of the American College of Surgeons.

On March 5, 2009, we announced that researchers from the University of Colorado at Denver/Denver Health Medical Center, Bonfils Blood Center in Denver, and University of Texas Southwestern Medical Center at Dallas had demonstrated that the use of PolyHeme significantly reduces metastases and primary tumor growth in a mouse model of pancreatic cancer.

We have recently implemented a number of measures to reduce our cash burn in order to preserve our available cash resources for ongoing operations. We have eliminated staff positions at our manufacturing facility in Mount Prospect, Illinois, and have reduced hours for our remaining staff. In addition, we are closing our corporate offices in Evanston, Illinois and relocating staff to our owned Mount Prospect facility to further reduce operating costs. Following the completion of FDA's Pre-License Inspection of our manufacturing facility, we believe these actions can be taken while still maintaining our capability to address manufacturing, regulatory and licensing issues. In addition, on March 6, 2009, we issued a Worker Adjustment and Retraining Notification as advance notice of facility closing dependent on future fundraising success and future regulatory actions.

On March 16, 2009, we announced that we had completed the sale of 5,404,652 shares of convertible preferred stock pursuant to a registered direct offering to a single institutional investor, representing gross proceeds of approximately \$1.4 million. The preferred stock is convertible into 5,404,652 shares of Northfield's common stock at

the option of the investor at a price of \$0.265 per share. Northfield also issued warrants to purchase 5,404,652 shares of common stock at an exercise price of \$0.53 per share in connection with the offering.

### **RESULTS OF OPERATIONS**

We reported no revenue for the three and nine month periods ended February 28, 2009 and February 29, 2008. From Northfield's inception through February 28, 2009, we have reported total revenue of \$3,000,000, all of which were derived from licensing fees.

### **OPERATING EXPENSES**

Operating expenses for our third quarter ended February 28, 2009 totaled \$6,262,000, an increase of \$1,111,000 from the \$5,151,000 reported in the third quarter of fiscal 2008. Measured on a percentage basis, third quarter fiscal 2009 expenses exceeded the third fiscal quarter of 2008 by 21.6%. Expenses in the third fiscal quarter were higher when compared to the same prior year period as a result of higher levels of professional services, equipment maintenance and overtime expenses incurred in connection with the preparation for and the conduct of the Pre-License Inspection of our manufacturing facility by FDA. In addition, we incurred higher levels of accounting and legal expenses related to our pursuit of additional financing. Also contributing to the increase in operating expenses were expenses relating to annual equity awards made to directors and officers, which were deferred from the second fiscal quarter until after Northfield had announced that FDA had accepted our BLA and granted Priority Review to our filing.

Operating expenses for the nine months ended February 28, 2009 totaled \$17,914,000 which was an increase of \$2,054,000, or 13.0%, from the \$15,860,000 incurred in the comparable prior year period. The incurred expenses primarily related to BLA preparation and documentation in anticipation of Pre-License Inspection by FDA, proxy solicitation services incurred in connection with our annual shareholder meeting, and expenses incurred as a result of our pursuit of additional financing.

Research and development expenses during the third fiscal quarter ended February 28, 2009 equaled \$4,746,000. This level of expense exceeded the prior year's comparable period by \$1,076,000, or 29.4%. The key events in the quarter were BLA filing with Priority Review and FDA Pre-License Inspection of Northfield's manufacturing site. Preparation for the inspection involved a mock audit, additional manufacturing facility maintenance work, and a renewed focus on procedures.

For the nine month period ended February 28, 2009, research and development expense of \$13,398,000 exceeded the \$11,388,000 of research and development expenses for the nine month period ended February 29, 2008 by \$2,010,000, or 17.7%. During the current fiscal year, the BLA was prepared, internally audited, submitted and accepted with Priority Review by FDA. Much work and

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use of professional support services was required in this effort. Also of note, \$2,832,000 of government grant money was utilized to offset expenses or reduce asset carrying values during the nine month period ended February 29, 2008, compared to \$71,000 during the nine month period ended February 28, 2009. In addition to the BLA submission, preparation for and conduct of FDA's Pre-License Inspection occurred during the period as discussed previously and preparation for a meeting with FDA's Blood Products Advisory Committee began.

General and administration expenses for the third fiscal quarter of 2009 totaled \$1,517,000, an increase of \$36,000, or 2.5%, from the \$1,481,000 incurred in the third quarter of fiscal 2008. General and Administrative expenditures have been limited to maintaining existing levels of support to the organization and outside stakeholders. No new or enhanced programs have been undertaken this fiscal year. During the quarter Northfield cancelled the lease on its corporate office space and paid a one-time cancellation fee of \$114,000.

For the nine month period ended February 28, 2009, general and other administrative expenses totaled \$4,516,000, which was 1.0% higher than the comparable prior year period.

**INTEREST INCOME**

Interest income for the third quarter ended February 28, 2009 totaled \$12,000, a decrease of \$307,000, or 96.2%, from the third quarter of fiscal 2008. At February 29, 2008, we held approximately \$9,963,000 in marketable securities yielding between 2.7% and 5.1%. At February 28, 2009, we held approximately \$1,744,000 in marketable securities earning between 2.0% and 2.15%. Total cash including marketable securities, restricted cash, and money market funds at February 28, 2009 of \$4,715,000 was \$22,363,000 less than the \$27,078,000 available on February 29, 2008. The combination of lower available cash balances and lower interest rates caused interest income to fall.

For the nine month period ended February 28, 2009, investment income amounted to \$148,000, a decrease of \$1,055,000, or 87.7%, from the \$1,203,000 reported for the nine months ended February 29, 2008. 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.

**NET LOSS**

The net loss for our three month period ended February 28, 2009 was \$6,251,000, or \$0.23 per share, compared to a net loss of \$4,831,000, or \$0.18 per share, for the three month period ended February 29, 2008. An increase in the period's operating expenses related to the filing of our BLA and continued preparations for a FDA Pre-License Inspection combined with a significant reduction in other income caused our increased net loss.

For the nine month period ended February 28, 2009, Northfield's net loss amounted to \$17,766,000, or \$0.66 per share, compared to a net loss of \$14,657,000, or \$0.54 per share, for the comparable prior year period. Higher research and development expenses and lower interest income in fiscal 2009 accounted for the increased net loss in the fiscal 2009 period.

**LIQUIDITY AND CAPITAL RESOURCES**

From Northfield's inception through February 28, 2009, we have used cash in operating activities and for the purchase of property, plant, equipment and engineering services in the amount of \$239,732,000. For the nine month periods ended February 28, 2009 and February 29, 2008, these cash expenditures totaled \$16,195,000 and \$14,117,000, 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 February 28, 2009, we had cash and cash equivalents, restricted cash and short term marketable securities totaling \$4,715,000. 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 February 28, 2009, \$77,000 of these funds remain available. We also reported that on March 16, 2009 we completed the sale of shares of convertible preferred stock with gross proceeds to Northfield of \$1.4 million.

From the beginning of our current fiscal year on June 1, 2008 through February 28, 2009, we estimate that we have utilized our cash resources at an average rate of approximately \$1.8 million per month. Based on recently announced

reductions in the total number of our employees, the placement of certain employees on part-time status and our other cost-reduction initiatives, we believe we will be able to reduce the utilization of our cash resources to an average of approximately \$1.4 million per month, excluding severance and other costs relating to our staff reductions. Based on our current estimates, we anticipate that our existing financial resources, including the proceeds from an offering of our convertible preferred stock in March 2009, will be adequate to permit us to continue to conduct our business through at least April 30, 2009. We will need to raise substantial additional capital to continue our business after this period. We anticipate having sufficient resources to allow for the completion of FDA Priority Review of our BLA, which has a target completion date of April 30, 2009. To continue operations beyond this point, we will either have to severely restrict our spending or raise additional capital.

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There can be no assurance that we will have adequate capital resources beyond April 30, 2009. Our inability to raise sufficient levels of capital could materially delay or prevent the commercialization of our PolyHeme blood substitute product and could result in the cessation of our business. Our 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 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 February 28, 2009:

| <b>Contractual Obligations</b> | <b>Total</b> | <b>Less than<br/>One Year</b> | <b>1 3<br/>Years</b> |
|--------------------------------|--------------|-------------------------------|----------------------|
| Lease Obligations (1)          | \$ 123,915   | \$ 123,915                    |                      |
| Other Obligations (2)          | \$2,852,535  | \$2,852,535                   |                      |

|   |                    |                    |
|---|--------------------|--------------------|
| <b>Total Contractual Cash Obligations</b> | <b>\$2,976,450</b> | <b>\$2,976,450</b> |
|---|--------------------|--------------------|

(1) During the third fiscal quarter of 2009, we terminated our lease for our corporate office in Evanston, Illinois. In connection with the termination, we made a payment of approximately \$114,000 to cancel the lease effective June 30, 2009. In the first quarter of fiscal 2010 (June 2009), we will be consolidating our operations at our owned Mount Prospect, Illinois facility.

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(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 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(R) 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, restricted cash, and marketable securities of \$4,715,000 at February 28, 2009 would decrease interest income by \$47,000 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



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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.***

As of February 28, 2009, we had cash and cash equivalents and marketable securities of approximately \$4.7 million. From the beginning of our current fiscal year on June 1, 2008 through February 28, 2009, we estimate that we have utilized our cash resources at an average rate of approximately \$1.8 million per month. Based on recently announced reductions in the total number of our employees, the placement of certain employees on part-time status and our other cost-reduction initiatives, we believe we will be able to reduce the utilization of our cash resources to an average of approximately \$1.4 million per month, excluding severance and other costs relating to our staff reductions.

Based on our current estimates, we anticipate that our existing financial resources, including the proceeds from an offering of our convertible preferred stock in March 2009, will be adequate to permit us to continue to conduct our business through at least April 30, 2009. We will need to raise substantial additional capital to continue our business after this period. If we are unable to raise substantial additional capital, we will not be able to continue our business and we anticipate that we will terminate the employment of most or all of our remaining employees and use our remaining cash resources to pay severance and other employee-related costs, make payments to extend our directors and officers liability insurance coverage and satisfy outstanding obligations to our vendors, consultants and professional advisors. We do not expect that there will be material cash available for distribution to our stockholders if we are unable to continue our business. It is highly likely in this event that our shares will lose all or substantially all of their market value.

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. In view of Northfield's financial condition and business prospects, combined with current adverse conditions in the financial and securities markets, debt or equity financing on acceptable terms may not be available to Northfield for the foreseeable future. If funding becomes available in the future, 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 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. 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.

***We are required to receive FDA approval before we may sell PolyHeme commercially, data from our clinical trials to date may not be adequate to obtain FDA approval, and we may be required to conduct additional clinical trials in the future.***

We submitted our BLA for PolyHeme to FDA on October 29, 2008. On December 30, 2008, we announced that FDA had accepted for filing our BLA and had granted Priority Review of our application with a Prescription Drug Users Fee Act, or PDUFA, review goal date of April 30, 2009.

From January 1 through October 31, 2008, data published by FDA indicate that approximately 20% of the PDUFA review date goals were missed. Furthermore, the impact of the implementation of the FDA Amendment Act, or FDAAA, and the planned implementation of the FDA's 21st Century Review Process has increased the potential for missed PDUFA review dates, particularly in the case of Priority Reviews, because of the difficulty of successfully completing all the required activities, including a discussion of the applicable product at a FDA advisory committee meeting, within the target review period. FDAAA authority to require post-marketing studies and Risk Evaluation and Mitigation Strategies, or REMS, only came into effect in March 2008, but the experience suggests that REMS may prolong review times. It is therefore possible that FDA will not be able to complete its review of our BLA within the review period prescribed under PDUFA. For these reasons, we are not able to predict whether FDA will comply with the April 30, 2009 review goal date for our BLA or, if FDA does not comply with this review goal date, when the agency will complete its review of our BLA.

Under FDA's review process, the agency generally convenes a meeting of its Blood Products Advisory Committee, or BPAC, to discuss BLAs relating to new blood products. BPAC is an independent advisory committee comprised of researchers, physicians and other experts in the field of blood products as well as community representatives. BPAC most recently met on April 1, 2009 and our BLA was not discussed at that meeting. We therefore do not believe our BLA will be discussed by BPAC prior to FDA's April 30,

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2009 review goal date for our BLA. It is not certain whether and when our BLA for PolyHeme will be discussed by BPAC or what effect, if any, the timing of the discussion of our BLA by BPAC may have on the ability of FDA to achieve its review goal date for our BLA.

The publicly available data regarding recent applications to FDA for approval of new molecular entities, or NMEs, indicates that in the five years from 2003 to 2007, approximately 68% of Priority Review applications were approved by FDA in the first review cycle. For those applications that the agency does not approve in the first review cycle, FDA can request that the sponsor provide additional information, conduct additional preclinical or clinical tests or take other actions as a condition to license approval. It is therefore possible that FDA may refuse to approve our BLA or may require us to take additional actions as a condition to approval. If our BLA is not approved in the first review cycle, we cannot predict what additional actions FDA might require us to take to obtain approval of our BLA or the time or costs that may be required for us to complete such actions. Because of our limited capital resources, we may not have sufficient funds available to continue our operations for a period that would enable us to satisfy potential additional requirements imposed by FDA as a condition to granting approval of our BLA.

The primary efficacy endpoint of our most recent Phase III trial, in which patient enrollment was completed in July 2006, was a dual superiority-noninferiority assessment of mortality at 30 days after injury. The results did not achieve the primary efficacy endpoint in the primary patient population as specified in the protocol. Further, although there was no statistically significant difference between the PolyHeme and control group for any of the primary safety endpoints for our trial, statistically significant differences favoring the standard of care were observed with respect to certain safety parameters, including the incidence of myocardial infarction as reported by investigators. Based on these results, there can be no assurance that the data will be sufficient to demonstrate the safety and effectiveness of PolyHeme for purposes of obtaining FDA approval.

Preclinical testing included extensive in-vitro and in-vivo studies of PolyHeme to assess product pharmacology and toxicology. These studies varied greatly with regard to animal species, protocol and product dosing, concomitant study drugs, and the timing and nature of the observations and measurements. Some of these studies have shown species dependent abnormalities in certain laboratory findings, including increases in aspartate aminotransferase, bilirubin, blood urea nitrogen, chromaturia, glucose, and troponin, and certain abnormal microscopic findings, including renal tubular proteinosis, Kupffer cell hypertrophy, karyomegaly, histiocytosis, cellular degeneration, and inflammation in organs such as the kidney, liver, or heart. These abnormalities were largely reversible and there was no evidence of organ failure. The clinical relevance of these findings is unclear when extrapolated to the human setting. There can be no assurance that these preclinical data will be considered sufficient for FDA approval.

Our BLA also addressed chemistry, manufacturing and controls, or CMC, issues. 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, all of which required subsequent validation, in order to confirm cGMP 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. There can be no assurance that the pilot facility will be considered to be in compliance with cGMP requirements.

FDA review includes a balance of risks and benefits, but the current regulatory climate is shaped by heightened pressure on FDA from the public and Congress following high profile safety concerns about certain pharmaceutical products. FDA has become increasingly risk-averse, requiring even more substantial benefits to outweigh potential safety concerns. We believe that PolyHeme could offer substantial benefits to patients in the absence of red blood cells for transfusion. If approved, PolyHeme would be the first hemoglobin-based oxygen carrier for human use to receive FDA approval. We recognize, however, that our Phase III study did not fully reflect the patient population for whom PolyHeme may be most appropriate and that the data are therefore susceptible to varying interpretations. As a result, there is no guarantee that an agency focused more heavily on product safety risks will be willing to extrapolate

an acceptable risk-benefit profile from the urban setting of our pivotal clinical trial, particularly in light of potential safety signals.

FDA may accordingly refuse to approve PolyHeme for commercial sale, and may require us to conduct additional clinical trials of PolyHeme in order to obtain approval. Alternatively, FDA may be willing to approve PolyHeme on the basis of available evidence, but may significantly limit the indication for which it may be marketed, impose additional restrictions through a Risk Evaluation and Mitigation Strategy, or REMS, or require substantial postmarketing commitments to evaluate the use of PolyHeme in additional settings where it may be used or in additional patient populations, such as children. Any of these alternatives could impede access, raise costs and reduce the ability of Northfield to recoup investments. Additionally, in order to market PolyHeme for any additional uses in the United States, we will be required to obtain approval of a separate BLA, which will require the design and conduct of additional clinical trials, and will involve all of the uncertainties described above.

Our business, financial condition and results of operations are critically dependent on receiving FDA approval of PolyHeme. A delay in achieving, or failure to achieve, FDA approval for commercial sales of PolyHeme would have a material adverse effect on us and could result in the cessation of our business.

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***We depend on the services of a limited number of key personnel.***

Our success is highly dependent on the continued services of a limited number of skilled managers and scientists. The loss of any of these individuals could have a material adverse effect on us. In addition, our success will depend, among other factors, on the recruitment and retention of additional highly skilled and experienced management and technical personnel. Recent reductions in our staff and the placement of certain employees on part-time status may increase the difficulty in retaining and recruiting qualified employees. We have historically provided incentive compensation to our officers and employees in part through grants of stock options and restricted stock under our equity compensation plans. Decreases in the trading price of our common stock, however, have substantially reduced the value of equity compensation awards made to our officers and employees in prior years and such awards may not provide adequate compensation to retain such individuals. Our ability to provide competitive compensation to our officers and employees may also be adversely affected by our limited capital resources and anticipated need to raise substantial additional capital to continue our business. We cannot ensure that we will be able to retain existing officers employees or attract and retain additional skilled personnel on acceptable terms as a result of these factors as well as competition for such personnel from numerous large and well-funded pharmaceutical and health care companies, universities and non-profit research institutions.

***We have significant severance and other obligations under agreements with our officers and employees and we may agree to satisfy these obligations from the proceeds of a future loan, sale, sale-leaseback, lease or similar transaction involving our owned manufacturing facility.***

We have entered into employment and severance protection agreements with each of our officers and certain of our key employees. These agreements provide for cash severance payments and the continuation of health insurance and other benefits for a specified period if the employment of the officer or employee is terminated by Northfield without cause or terminates under certain other circumstances, including a change in control of Northfield. Our aggregate contractual obligation under these agreements, determined as of February 28, 2009, was approximately \$2.9 million. Our existing cash resources are not expected to be adequate to permit us to satisfy these severance obligations in full if we cease to conduct business and the employment of all or substantially all of these officers and key employees is terminated. We may accordingly enter into agreements with our officers and key employees that modify their severance arrangements. These modified arrangements may include an agreement that our severance obligations, should they become payable, may be deferred and satisfied in whole or in part from the proceeds of a future loan, sale, sale-leaseback, lease or similar transaction involving our owned manufacturing facility located in Mount Prospect, Illinois. If we enter into an arrangement of this type, the proceeds from a possible transaction involving our manufacturing facility would not be available to fund our ongoing operations to permit us to continue our business. Northfield's contractual responsibility for these severance and other benefit obligations may therefore cause us to cease or curtail our operations at an earlier date than would otherwise be the case if we were not required to satisfy these obligations.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company in the capacities indicated on April 9, 2009.

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