

NEOGEN CORP  
Form 10-Q  
January 06, 2011  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

*(Mark One)*

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended November 30, 2010.

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 0-17988

**Neogen Corporation**

*(Exact name of registrant as specified in its charter)*

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**Michigan**  
*(State or other jurisdiction of  
incorporation or organization)*

**38-2367843**  
*(IRS Employer  
Identification Number)*

**620 Leshar Place**

**Lansing, Michigan 48912**

*(Address of principal executive offices, including zip code)*

**(517) 372-9200**

*(Registrant's telephone number, including area code)*

**N/A**

*(Former name, former address and former fiscal year, if changed since last report)*

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 reports), and (2) has been subject to such filing requirements for the past 90 days. YES  NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (see definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): YES  NO

As of December 1, 2010, there were 23,115,000 shares of Common Stock outstanding.

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**NEOGEN CORPORATION AND SUBSIDIARIES**

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**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Interim Consolidated Financial Statements****NEOGEN CORPORATION AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

|   | November 30,<br>2010<br><i>(In thousands, except share<br/>and per share amounts)</i><br><b>(Unaudited)</b> | May 31,<br>2010<br><i>(Audited)</i> |
|---|---|-------------------------------------|
| <b>ASSETS</b>   |   |                                     |
| <b>CURRENT ASSETS</b>   |   |                                     |
| Cash and cash equivalents   | \$ 44,392   | \$ 22,806                           |
| Accounts receivable, less allowance of \$700 and \$600.                                   | 28,050  | 27,433                              |
| Inventories   | 31,433  | 31,316                              |
| Deferred income taxes   | 774   | 774                                 |
| Prepaid expenses and other current assets   | 3,479   | 3,691                               |
| <b>TOTAL CURRENT ASSETS</b>   | <b>108,128</b>  | <b>86,020</b>                       |
| <b>NET PROPERTY AND EQUIPMENT</b>   | <b>20,739</b>   | <b>19,180</b>                       |
| <b>OTHER ASSETS</b>   |   |                                     |
| Goodwill  | 53,320  | 52,899                              |
| Other non-amortizable intangible assets   | 4,089   | 4,139                               |
| Customer based intangibles, net of accumulated amortization of \$4,779 and \$4,002        | 12,245  | 13,021                              |
| Other non-current assets, net of accumulated amortization of \$2,360 and \$1,822          | 5,154   | 4,974                               |
|   | <b>74,808</b>   | <b>75,033</b>                       |
|   | <b>\$ 203,675</b>   | <b>\$ 180,233</b>                   |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |   |                                     |
| <b>CURRENT LIABILITIES</b>  |   |                                     |
| Accounts payable  | \$ 9,010  | \$ 7,187                            |
| Accrued compensation  | 1,803   | 2,346                               |
| Income taxes  | 4,685   | 2,838                               |
| Other accruals  | 5,799   | 4,662                               |
| <b>TOTAL CURRENT LIABILITIES</b>  | <b>21,297</b>   | <b>17,033</b>                       |
| <b>DEFERRED INCOME TAXES</b>  | <b>5,824</b>  | <b>5,824</b>                        |
| <b>OTHER LONG-TERM LIABILITIES</b>  | <b>4,596</b>  | <b>4,323</b>                        |
|   | <b>10,420</b>   | <b>10,147</b>                       |
| <b>TOTAL LIABILITIES</b>  | <b>31,717</b>   | <b>27,180</b>                       |
| <b>EQUITY</b>   |   |                                     |
| Preferred stock, \$1.00 par value, 100,000 shares authorized, none issued and outstanding |   |                                     |

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|   |            |            |
|---|------------|------------|
| Common stock, \$.16 par value, 30,000,000 shares authorized 23,115,106 shares issued and outstanding at November 30, 2010; 22,625,399 shares issued and outstanding at May 31, 2010 | 3,698      | 3,621      |
| Additional paid-in capital  | 75,584     | 69,550     |
| Accumulated other comprehensive loss  | (817)      | (1,676)    |
| Retained earnings   | 93,137     | 81,170     |
| <br>  |            |            |
| Total Neogen Corporation Stockholders' Equity   | 171,602    | 152,665    |
| Noncontrolling Interest   | 356        | 388        |
| <br>  |            |            |
| TOTAL EQUITY  | 171,958    | 153,053    |
|   | <br>       |            |
|   | \$ 203,675 | \$ 180,233 |

See notes to interim consolidated financial statements

**Table of Contents****NEOGEN CORPORATION AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF INCOME (UNAUDITED)**

|                                   | <b>Three Months Ended</b>                       |                 | <b>Six Months Ended</b> |                 |
|-----------------------------------|---|-----------------|-------------------------|-----------------|
|                                   | <b>November 30</b>                              |                 | <b>November 30</b>      |                 |
|                                   | <b>2010</b>                                     | <b>2009</b>     | <b>2010</b>             | <b>2009</b>     |
|                                   | <i>(In thousands, except per share amounts)</i> |                 |                         |                 |
| Net sales                         | \$ 43,931                                       | \$ 35,251       | \$ 86,853               | \$ 67,598       |
| Cost of goods sold                | 21,443  | 16,729          | 41,598                  | 31,806          |
| <b>GROSS MARGIN</b>               | <b>22,488</b>                                   | <b>18,522</b>   | <b>45,255</b>           | <b>35,792</b>   |
| <b>OPERATING EXPENSES</b>         |   |                 |                         |                 |
| Sales and marketing               | 7,504   | 6,405           | 15,016                  | 12,377          |
| General and administrative        | 3,714   | 3,191           | 7,576                   | 6,082           |
| Research and development          | 1,641   | 1,698           | 3,438                   | 3,161           |
|                                   | 12,859  | 11,294          | 26,030                  | 21,620          |
| <b>OPERATING INCOME</b>           | <b>9,629</b>                                    | <b>7,228</b>    | <b>19,225</b>           | <b>14,172</b>   |
| <b>OTHER INCOME (LOSS)</b>        |   |                 |                         |                 |
| Interest income                   | 28  | 16              | 57                      | 33              |
| Change in purchase consideration  | (100)   |                 | (400)                   |                 |
| Other income (expense)            | (47)  | (34)            | (147)                   | 1               |
|                                   | (119)   | (18)            | (490)                   | 34              |
| <b>INCOME BEFORE INCOME TAXES</b> | <b>9,510</b>                                    | <b>7,210</b>    | <b>18,735</b>           | <b>14,206</b>   |
| <b>INCOME TAXES</b>               | <b>3,400</b>                                    | <b>2,600</b>    | <b>6,800</b>            | <b>5,200</b>    |
| <b>NET INCOME</b>                 | <b>\$ 6,110</b>                                 | <b>\$ 4,610</b> | <b>\$ 11,935</b>        | <b>\$ 9,006</b> |
| <b>NET INCOME PER SHARE</b>       |   |                 |                         |                 |
| Basic                             | \$ .27  | \$ .21          | \$ .52                  | \$ .40          |
| Diluted                           | \$ .26  | \$ .20          | \$ .51                  | \$ .39          |

See notes to interim consolidated financial statements

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## NEOGEN CORPORATION AND SUBSIDIARIES

## CONSOLIDATED STATEMENT OF EQUITY (UNAUDITED)

|  | Common Stock |          | Additional<br>Paid-in<br>Capital | Accumulated<br>Other<br>Comprehensive<br>Income<br>(Loss) | Retained<br>Earnings | Noncontrolling<br>Interest | Total      |
|--|--------------|----------|----------------------------------|---|----------------------|----------------------------|------------|
|  | Shares       | Amount   |                                  | (In thousands)  |                      |                            |            |
| Balance, June 1, 2010  | 22,625       | \$ 3,621 | \$ 69,550                        | \$ (1,676)  | \$ 81,170            | \$ 388                     | \$ 153,053 |
| Issuance of shares of common stock under equity compensation plans, and share based compensation, including \$322 of excess income tax benefit | 481          | 75       | 5,841                            |   |                      |                            | 5,916      |
| Issuance of shares under employee stock purchase plan  | 9            | 2        | 193                              |   |                      |                            | 195        |
| Comprehensive income:  |              |          |                                  |   |                      |                            |            |
| Net income for the six months ended November 30, 2010  |              |          |                                  |   | 11,967               | (32)                       | 11,935     |
| Foreign currency translation adjustments   |              |          |                                  | 859   |                      |                            | 859        |
| Total comprehensive income (\$8,924 in the six months ended November 30, 2009)   |              |          |                                  |   |                      |                            | 12,794     |
| Balance, November 30, 2010   | 23,115       | \$ 3,698 | \$ 75,584                        | \$ (817)  | \$ 93,137            | \$ 356                     | \$ 171,958 |

See notes to interim consolidated financial statements

**Table of Contents****NEOGEN CORPORATION AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

|   | <b>Six Months Ended<br/>November 30,<br/>2010      2009<br/>(In thousands)</b> |                  |
|---|--|------------------|
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                      |  |                  |
| Net income  | \$ 11,935  | \$ 9,006         |
| Adjustments to reconcile net income to net cash provided by operating activities: |  |                  |
| Depreciation and amortization   | 2,584  | 2,027            |
| Share based compensation  | 1,240  | 1,050            |
| Excess income tax benefit from the exercise of stock options                      | (322)  | (596)            |
| Changes in operating assets and liabilities, net of business acquisitions:        |  |                  |
| Accounts receivable   | (215)  | (1,875)          |
| Inventories   | 213  | 1,173            |
| Prepaid expenses and other current assets   | 292  | (65)             |
| Accounts payable and accruals   | 3,832  | 5,777            |
| <b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>                                  | <b>19,559</b>  | <b>16,497</b>    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                      |  |                  |
| Purchases of property and equipment and other assets                              | (3,423)  | (1,522)          |
| <b>NET CASH USED IN INVESTING ACTIVITIES</b>                                      | <b>(3,423)</b>   | <b>(1,522)</b>   |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                      |  |                  |
| Increases in other long-term liabilities  | 257  | 70               |
| Net proceeds from issuance of common stock  | 4,871  | 2,971            |
| Excess income tax benefit from the exercise of stock options                      | 322  | 596              |
| <b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>                                  | <b>5,450</b>   | <b>3,637</b>     |
| <b>INCREASE IN CASH</b>   | <b>21,586</b>  | <b>18,612</b>    |
| <b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>                           | <b>22,806</b>  | <b>13,842</b>    |
| <b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>                                 | <b>\$ 44,392</b>   | <b>\$ 32,454</b> |

See notes to interim consolidated financial statements

**Table of Contents****NEOGEN CORPORATION AND SUBSIDIARIES****NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)****1. BASIS OF PRESENTATION**

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (generally accepted accounting principles) for interim financial information and with the instructions to Form 10-Q and Article 10 Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. The results of operations for the three and six month periods ended November 30, 2010 are not necessarily indicative of the results to be expected for the fiscal year ending May 31, 2011. For more complete financial information, these consolidated financial statements should be read in conjunction with the May 31, 2010 audited consolidated financial statements and the notes thereto included in the Company's annual report on Form 10-K for the year ended May 31, 2010.

**2. INVENTORIES**

Inventories are stated at the lower of cost, determined on the first-in, first-out method, or market. The components of inventories follow:

|                              | November 30,<br>2010  | May 31,<br>2010 |
|------------------------------|-----------------------|-----------------|
|                              | <i>(In thousands)</i> |                 |
| Raw materials                | \$ 12,098             | \$ 11,815       |
| Work-in-process              | 2,057                 | 1,958           |
| Finished and purchased goods | 17,278                | 17,543          |
|                              | \$ 31,433             | \$ 31,316       |

**3. NET INCOME PER SHARE**

The calculation of net income per share follows:

|   | Three Months Ended<br>November 30,<br>2010      |          | Six Months Ended<br>November 30,<br>2010 |          |
|---|---|----------|--|----------|
|   | 2009  |          | 2009                                     |          |
|   | <i>(In thousands, except per share amounts)</i> |          |  |          |
| Numerator for basic and diluted net income per share: |   |          |  |          |
| Net income  | \$ 6,110  | \$ 4,610 | \$ 11,935                                | \$ 9,006 |
| Denominator:  |   |          |  |          |
| Denominator for basic net income per share:           |   |          |  |          |
| Weighted average shares                               | 22,926  | 22,387   | 22,802                                   | 22,281   |
| Effect of dilutive stock options and warrants         | 803   | 663      | 797                                      | 652      |
| Denominator for diluted net income per share          | 23,729  | 23,050   | 23,599                                   | 22,933   |
| Net income per share:                                 |   |          |  |          |
| Basic   | \$ .27  | \$ .21   | \$ .52                                   | \$ .40   |
| Diluted   | \$ .26  | \$ .20   | \$ .51                                   | \$ .39   |



**Table of Contents****4. SEGMENT INFORMATION**

The Company has two reportable segments: Food Safety and Animal Safety. The Food Safety segment produces and markets diagnostic test kits and related products used by food producers and processors to detect harmful natural toxins, foodborne bacteria, allergens and levels of general sanitation. The Animal Safety segment is primarily engaged in the production and marketing of products dedicated to animal health, including a complete line of consumable products marketed to veterinarians and animal health product distributors and provides genetic identification services. Additionally, the Animal Safety segment produces and markets rodenticides and disinfectants to assist in control of rodents and disease in and around agricultural, food production and other facilities.

Segment information as of and for the three months ended November 30, 2010 and 2009 follows:

|                                 | <b>Food<br/>Safety</b> | <b>Animal<br/>Safety</b> | <b>Corporate<br/>and<br/>Eliminations<br/>(1)</b> | <b>Total</b> |
|---------------------------------|------------------------|--------------------------|---|--------------|
|                                 | <i>(In thousands)</i>  |                          |   |              |
| <b>Fiscal 2011</b>              |                        |                          |   |              |
| Net sales to external customers | \$ 21,341              | \$ 22,590                | \$  | \$ 43,931    |
| Operating income (reduction)    | 6,264                  | 3,775                    | (410)   | 9,629        |
| <b>Fiscal 2010</b>              |                        |                          |   |              |
| Net sales to external customers | \$ 18,446              | \$ 16,805                | \$  | \$ 35,251    |
| Operating income (reduction)    | 5,282                  | 2,428                    | (482)   | 7,228        |

Segment information as of and for the six months ended November 30, 2010 and 2009 follows:

|                                 | <b>Food<br/>Safety</b> | <b>Animal<br/>Safety</b> | <b>Corporate<br/>and<br/>Eliminations<br/>(1)</b> | <b>Total</b> |
|---------------------------------|------------------------|--------------------------|---|--------------|
|                                 | <i>(In thousands)</i>  |                          |   |              |
| <b>Fiscal 2011</b>              |                        |                          |   |              |
| Net sales to external customers | \$ 43,593              | \$ 43,260                | \$  | \$ 86,853    |
| Operating income (reduction)    | 13,237                 | 6,886                    | (898)   | 19,225       |
| Total Assets                    | 76,790                 | 87,914                   | 38,971  | 203,675      |
| <b>Fiscal 2010</b>              |                        |                          |   |              |
| Net sales to external customers | \$ 35,921              | \$ 31,677                | \$  | \$ 67,598    |
| Operating income (reduction)    | 10,413                 | 4,645                    | (886)   | 14,172       |
| Total Assets                    | 62,287                 | 68,719                   | 29,907  | 160,913      |

- (1) Includes corporate assets, consisting principally of cash and cash equivalents, deferred assets and overhead expenses not allocated to specific business segments. Also includes the elimination of intersegment transactions.

**Table of Contents****5. EQUITY COMPENSATION PLANS**

Options are generally granted under the employee and director stock option plan for 5 years and become exercisable in varying installments. Certain non-qualified options are granted for 10 year periods. A summary of stock option activity during the six months ended November 30, 2010 follows:

|   | <b>Shares</b>    | <b>Weighted-Average<br/>Exercise Price</b> |
|---|------------------|--|
| Options outstanding at June 1, 2010             | 1,998,000        | \$ 14.14                                   |
| Granted   | 288,000          | 28.29                                      |
| Exercised                                       | (467,000)        | 11.11                                      |
| Forfeited                                       | (5,000)          | 9.53                                       |
| <b>Options outstanding at November 30, 2010</b> | <b>1,814,000</b> | <b>17.18</b>                               |

During the three and six month periods ended November 30, 2010 and 2009 the Company recorded \$564,000 and \$525,000 and \$1,240,000 and \$1,050,000, respectively of compensation expense related to its share-based awards.

The weighted-average fair value of stock options granted during 2011 and 2010, estimated on the date of grant using the Black-Scholes option pricing model was \$8.60 and \$6.35 respectively. The fair value of stock options granted was estimated using the following weighted-average assumptions.

|                                 | <b>2011</b> | <b>2010</b> |
|---------------------------------|-------------|-------------|
| Risk-free interest rate         | 1.7%        | 2.0%        |
| Expected dividend yield         | 0%          | 0%          |
| Expected stock price volatility | 35.8%       | 37.8%       |
| Expected option life            | 4.0 years   | 4.0 years   |

The Company has 11,250 outstanding warrants that are exercisable for common stock. The warrants have lives of 5 years and were expensed at fair value upon issuance.

The Company has an Employee Stock Purchase plan that provides for employee stock purchases at a 5% discount to market. The discount is expensed as of the date of purchase.

**6. NEW ACCOUNTING PRONOUNCEMENTS**

Recent ASU s issued by the FASB and guidance issued by the SEC did not, or are not believed by management to, have a material effect on the Company s present or future consolidated financial statements.

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**7. BUSINESS AND PRODUCT LINE ACQUISITIONS**

On December 1, 2009, the Company purchased the BioKits food safety business of Gen-Probe Incorporated. Consideration for the purchase, which was determined through arms length negotiations, approximated \$6.5 million in cash and the assumption of trade accounts payable of \$175,000. The preliminary allocation of the purchase price included net current assets of \$770,000, fixed assets \$163,000 and intangible assets of \$5,742,000. The acquired business operates as a unit of Neogen's food safety division. Principal products include allergen test kits.

On April 1, 2010, Neogen Corporation acquired GeneSeek, Inc. of Lincoln, Nebraska, a leading commercial agricultural genetic laboratory. GeneSeek's technology employs high-resolution DNA genotyping for identity and trait analysis in a variety of important animal and agricultural plant species. Consideration for the purchase was \$13,800,000 in cash and secondary payment obligations of up to \$7,000,000. The preliminary allocation of the purchase price included accounts receivable of \$1,923,000, inventory of \$1,212,000, fixed assets of \$847,000, current liabilities of \$600,000, deferred tax liabilities of \$2,050,000, secondary payment liabilities of \$3,583,000, based upon future operating results of the GeneSeek business until and is payable yearly over a three year measurement period, and the remainder to goodwill and other intangible assets (with estimated lives of 5-20 years). The secondary payment was measured at fair value, and is considered a level 3 fair value measurement under ASC 820-Fair Value Measurement and Disclosure, as it was based on unobservable inputs and involves management's judgment. The Company recorded a charge within other income (expense) of approximately \$400,000 for the six months ended November 30, 2010, representing the increase in fair value of the secondary payment liability. As of November 30, 2010, the balance of the secondary payment liability recorded was approximately \$3,933,000. The acquisition will be integrated into the Animal Safety segment and is expected to be a strong synergistic fit.

**8. LONG TERM DEBT AND LIABILITIES**

The Company maintains a financing agreement with a bank (no amounts drawn at November 30, 2010 or May 31, 2010) providing for an unsecured revolving line of credit of \$10,000,000. The interest rate is at LIBOR plus 100 basis points (rate under terms of the agreement was 1.25% at November 30, 2010). Financial covenants include maintaining specified levels of tangible net worth, debt service coverage, and funded debt to EBITDA, each of which the Company was in compliance with at November 30, 2010.

**9. COMMITMENTS AND CONTINGENCIES**

The Company is involved in environmental remediation and monitoring activities at its Randolph, Wisconsin manufacturing facility and accrues for related costs when such costs are determined to be probable and estimable. The Company is currently expensing annual costs of remediation of approximately \$90,000. The Company's estimated liability for this expense of \$916,000 at November 30, 2010 and May 31, 2010 is recorded within other long-term liabilities in the consolidated balance sheet.

The Company is subject to certain legal and other proceedings in the normal course of business that, in the opinion of management, will not have a material effect on its future results of operations or financial position.

**10. STOCK PURCHASE**

In December 2008, the Company's Board of Directors authorized a program to purchase, subject to market conditions, up to 750,000 shares of the Company's common stock. As of November 30, 2010, 74,684 cumulative shares had been purchased in negotiated and open market transactions for a total price, including commissions, of approximately \$923,000. There were no purchases in fiscal year 2011 or 2010. Shares purchased under the program were retired.

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**PART I FINANCIAL INFORMATION**

**Item 2. Management's Discussion and Analysis of Financial Conditions and Results of Operations**

The information in this Management's Discussion and Analysis of Financial Condition and Results of Operations contains both historical financial information and forward-looking statements. Neogen does not provide forecasts of future performance. While management is optimistic about the Company's long-term prospects, historical financial information may not be indicative of future financial performance.

**Safe Harbor and Forward-Looking Statements**

Forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, are made throughout this Quarterly Report on Form 10-Q. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "seeks," "estimates," and similar expressions are intended to identify forward-looking statements. There are a number of important factors, including competition, recruitment and dependence on key employees, impact of weather on agriculture and food production, identification and integration of acquisitions, research and development risks, patent and trade secret protection, government regulation and other risks detailed from time to time in the Company's reports on file at the Securities and Exchange Commission, that could cause Neogen Corporation's results to differ materially from those indicated by such forward-looking statements, including those detailed in this Management's Discussion and Analysis of Financial Condition and Results of Operations.

In addition, any forward-looking statements represent management's views only as of the day this Quarterly Report on Form 10-Q was first filed with the Securities and Exchange Commission and should not be relied upon as representing management's views as of any subsequent date. While management may elect to update forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, even if its views change.

**Critical Accounting Policies and Estimates**

The discussion and analysis of the Company's financial condition and results of operations are based on the consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires that management make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates the estimates, including those related to receivable allowances, inventories, accruals and intangible assets. These estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to the critical accounting policies and estimates disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2010.

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**Results of Operations**

**Executive Overview**

Neogen Corporation revenues increased by 25% in the second quarter to \$43.9 million and by 28% to \$86.9 million for the six-month period ended November 30, 2010 when compared to the prior year. Food Safety revenues increased by 16% and 21% in the quarter and in the six-month period ended November 30, 2010, respectively. Animal Safety revenues increased by 34% and 37% in the quarter and in the six-month period ended November 30, 2010, respectively. Exclusive of the revenues from the BioKits and GeneSeek acquisitions, and foreign currency effects overall revenues increased 10% and 13% in the second quarter and year-to-date periods, respectively. Gross margins decreased from 52.5% in the November 2009 quarter to 51.2% in the November 2010 quarter and decreased from 52.9% to 52.1% on a year-to-date basis. The decrease in gross margins was a principally result of less favorable product mix. Operating margins increased in the quarter and six-month periods from 20.5% to 21.9% and from 21.0% to 22.1% respectively. The gains were the result of growth leverage and acquisitions as well as continuing cost control efforts.



|           |       |            |           |            |           |             |             |         |        |           |
|-----------|-------|------------|-----------|------------|-----------|-------------|-------------|---------|--------|-----------|
|           |       |            |           |            | 418,182   | —           | (418,182)   | —       |        |           |
|           | —     | —          | —         | —          | —         | —           | (5,960,907) | —       | —      | —         |
| 1,000,000 | 1,000 | 23,362,396 | 23,362    | 14,289,535 | —         | (7,473,205) | —           | (7,760) | —      | —         |
|           | —     | —          | 27,600    | 27         | 30,073    | —           | —           | —       | —      | —         |
|           | —     | —          | 3,368,952 | 3,369      | 3,358,349 | —           | —           | —       | —      | —         |
| (170,528) | (171) | 1,550,239  | 1,551     | (1,380)    | —         | —           | —           | —       | —      | —         |
| 24,901    | 25    | —          | —         | 281,073    | —         | —           | (282,388)   | —       | —      | —         |
| —         | —     | —          | —         | —          | —         | —           | (585,799)   | 585,799 | —      | —         |
| —         | —     | —          | —         | 125,558    | —         | —           | —           | —       | —      | (120,968) |
| —         | —     | —          | —         | —          | —         | —           | —           | —       | —      | 100,800   |
| —         | —     | —          | —         | —          | —         | —           | —           | —       | 20,997 | —         |

|  |           |        |            |           |               |      |                 |            |           |          |
|--|-----------|--------|------------|-----------|---------------|------|-----------------|------------|-----------|----------|
|  | —         | —      | —          | —         | —             | —    | (5,896,031)     | —          | —         | —        |
|  | 854,373   | 854    | 28,309,187 | 28,309    | 18,083,208    | —    | (13,955,035)    | 303,411    | 13,237    | (20,168) |
|  | —         | —      | 1,000      | 1         | 999           | —    | —               | —          | —         | —        |
|  | —         | —      | 172,433    | 172       | 68,319        | —    | —               | —          | —         | —        |
|  | (154,266) | (154)  | 1,402,409  | 1,403     | (1,249)       | —    | —               | —          | —         | —        |
|  | 23,574    | 24     | —          | —         | 246,436       | —    | —               | (246,906)  | —         | —        |
|  | —         | —      | —          | —         | —             | —    | (127,466)       | 127,466    | —         | —        |
|  | —         | —      | —          | —         | —             | —    | —               | —          | —         | 20,168   |
|  | —         | —      | —          | —         | —             | —    | —               | —          | 3,938     | —        |
|  | —         | —      | —          | —         | —             | —    | (1,426,079)     | —          | —         | —        |
|  | 723,681   | \$ 724 | 29,885,029 | \$ 29,885 | \$ 18,397,713 | \$ — | \$ (15,508,580) | \$ 183,971 | \$ 17,175 | \$ —     |

See accompanying notes to unaudited condensed consolidated financial statements.

**MANHATTAN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

(A Development Stage Company)  
 Condensed Consolidated Statements of Cash Flows  
 (Unaudited)

|  | <b>Three months ended March 31,</b> |                | <b>Cumulative<br/>period from<br/>August 6, 2001<br/>(inception) to<br/>March 31,<br/>2005</b> |
|--|-------------------------------------|----------------|--|
|  | <b>2005</b>                         | <b>2004</b>    |  |
| <b>Cash flows from operating activities:</b>                                       |                                     |                |  |
| Net loss   | \$ (1,426,079)                      | \$ (1,095,348) | \$ (14,377,133)  |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b> |                                     |                |  |
| Common stock issued for license rights   |                                     |                | —  |
|  |                                     |                | —  |
|  |                                     |                | 1,000  |
| Amortization of unearned consulting costs  |                                     |                | 20,168   |
|  |                                     |                | 10,080   |
|  |                                     |                | 181,557  |
| Warrants issued for consulting services  |                                     |                | —  |
|  |                                     |                | —  |
|  |                                     |                | 4,590  |
| Amortization of intangible assets  |                                     |                | —  |
|  |                                     |                | —  |
|  |                                     |                | 145,162  |

Gain on sale of short-term investments

—

—

(71,182

)

Depreciation

12,743

2,452

46,303

Loss on impairment of intangible assets

—

—

1,248,230

Loss on disposition of intangible assets

—

—

1,213,878

Changes in operating assets and liabilities, net of acquisition:

Decrease in prepaid expenses and other current assets

39,786

10,645

57,905

Increase in other assets

—

—

(70,506

)

Increase/(decrease) in accounts payable

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|   |              |
|---|--------------|
| )   | (31,508)     |
| )   | 20,850       |
| )   | 788,360      |
| Increase/(decrease) in accrued expenses   |              |
| )   | 106,387      |
| )   | (229,084)    |
| )   | (381,832)    |
| Net cash used in operating activities     |              |
| )   | (1,278,503)  |
| )   | (1,280,405)  |
| )   | (11,213,668) |
| Cash flows from investing activities:     |              |
| Purchase of property and equipment        |              |
| )   | (20,081)     |
| )   | (33,992)     |
| )   | (164,975)    |
| Cash paid in connection with acquisitions |              |
| )   | (128,233)    |
| )   | —            |
| )   | (161,041)    |
| Purchase of short-term investments        |              |

|  |             |
|--|-------------|
|  | —           |
|  | —           |
| )  |             |
| Proceeds from sales of short-term investments            | (5,000,979) |
|  | 997,067     |
|  | —           |
|  | 1,928,156   |
| Proceeds from sale of license                            |             |
|  | —           |
|  | —           |
|  | 200,001     |
| Net cash provided by (used in) investing activities      |             |
|  | 848,753     |
| )  | (33,992)    |
|  | (3,198,838) |
| )  |             |
| Cash flows from financing activities:                    |             |
| Proceeds from issuances of notes payable to stockholders |             |
|  | —           |
|  | —           |
|  | 233,500     |
| Repayments of notes payable to stockholders              |             |
|  | —           |
|  | —           |
| )  | (233,500)   |
| Proceeds from issuance of note payable to bank           |             |

|   |           |
|---|-----------|
|   | —         |
|   | —         |
|   | 600,000   |
| Repayment of note payable to bank                   |           |
|   | —         |
|   | —         |
|   | (600,000) |
| )   |           |
| Proceeds from subscriptions receivable              |           |
|   | —         |
|   | —         |
|   | 4,000     |
| Payment for fractional shares for stock combination |           |
|   | (446      |
| )   |           |
|   | —         |
|   | (1,436    |
| )   |           |
| Proceeds from sale of common stock, net             |           |
|   | —         |
|   | 3,431,165 |
|   | 5,809,126 |
| Proceeds from sale of preferred stock, net          |           |
|   | —         |
|   | —         |
|   | 9,046,176 |
| Proceeds from exercise of stock options             |           |
|   | 1,000     |

|  |            |
|--|------------|
|  | 12,500     |
|  | 31,100     |
| Proceeds from exercise of warrants                   |            |
|  | 68,491     |
|  | —          |
|  | 68,491     |
| Net cash provided by financing activities            |            |
|  | 69,045     |
|  | 3,443,665  |
|  | 14,957,457 |
| Net increase (decrease) in cash and cash equivalents |            |
| )  | (360,705   |
|  | 2,129,268  |
|  | 544,951    |
| Cash and cash equivalents at beginning of period     |            |
|  | 905,656    |
|  | 7,413,803  |
|  | —          |
| Cash and cash equivalents at end of period           |            |
| \$   | 544,951    |
| \$   | 9,543,071  |
| \$   |            |

544,951

## Supplemental disclosure of cash flow information:

## Interest paid

|    |        |
|----|--------|
| \$ | —      |
| \$ | —      |
| \$ | 26,934 |

## Supplemental disclosure of noncash investing and financing activities:

## Stock options/warrants issued for consulting services

|    |         |
|----|---------|
| \$ | —       |
| \$ | —       |
| \$ | 181,557 |

## Preferred stock dividends accrued

127,466

713,265

## Conversion of preferred stock to common stock

154

325

## Preferred stock dividends paid by issuance of shares

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25

|  |           |
|--|-----------|
|  | 246,436   |
|  | —         |
|  | 528,824   |
| Issuance of common stock for acquisition                           | —         |
|  | —         |
|  | 2,336,242 |
| Short-term investments received in connection with sale of license | —         |
|  | —         |
|  | 359,907   |

See accompanying notes to condensed consolidated financial statements.

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MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
March 31, 2005

(1) BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, the consolidated financial statements do not include all information and footnotes required by accounting principles generally accepted in the United States of America for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of only normal recurring adjustments, considered necessary for a fair presentation. Interim operating results are not necessarily indicative of results that may be expected for the year ending December 31, 2005 or for any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the Annual Report on Form 10-KSB of Manhattan Pharmaceuticals, Inc. and its subsidiaries ("Manhattan" or the "Company") as of and for the year ended December 31, 2004.

(2) LIQUIDITY

The Company reported a net loss of \$1,426,079 and negative cash flows from operating activities of \$1,278,503 for the three months ended March 31, 2005. The net loss from date of inception, August 6, 2001, to March 31, 2005 amounts to \$14,377,133.

Management believes that the Company will continue to incur net losses and negative cash flows from operating activities through at least March 31, 2006. Based on the resources of the Company available at March 31, 2005, management believes that the Company will need additional equity or debt financing or will need to generate revenues during 2005 through licensing of its products or entering into strategic alliances to be able to sustain its operations through 2005 and that it will need additional financing thereafter until it can achieve profitability, if ever. These matters raise substantial doubt about the Company's ability to continue as a going concern.

The Company's continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances and its ability to realize the full potential of its technology in development. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term. Through March 31, 2005, a significant portion of the Company's financing has been through private placements of common and preferred stock. Until and unless the Company's operations generate significant revenues and cash flows from operating activities, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital previously described.

(3) COMPUTATION OF NET LOSS PER COMMON SHARE

Basic net loss per common share is calculated by dividing net loss applicable to common shares by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect because the Company incurred a net loss during each period presented. The amount of potentially dilutive securities excluded from the calculation was 13,575,304 and 15,533,533 as of March 31, 2005 and 2004, respectively.



MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
March 31, 2005

## (4) STOCK OPTIONS

On January 11, 2005, the Company granted directors and employees options to purchase an aggregate of 367,280 shares of common stock under the Company's 2003 Stock Option Plan at an exercise price of \$1.00 per share. 168,030 shares subject to these options vest in three equal annual installments starting on the grant date and continuing each anniversary thereafter, provided the optionee continues in service. 50,000 shares subject to these options vest in two equal annual installments starting on January 3, 2006, provided the optionee continues in service and 149,250 shares subject to these options vest in three equal annual installments starting one year from the grant date, provided the optionee continues in service.

The Company uses the intrinsic value method of accounting for stock options pursuant to the provisions of APB Opinion No. 25. Since all of the options granted by the Company have been at exercise prices that were at least equal to the market value at the date of grant, there were no charges to operations upon issuance. Had compensation costs been determined using the Black-Scholes option pricing model in accordance with the fair value method prescribed by SFAS No. 123 for all options issued to employees and amortized over the vesting period, the Company's net loss applicable to common shares and net loss per common share (basic and diluted) would have been increased to the pro forma amounts indicated below.

|  | <b>Three months ended</b> |                |
|--|---------------------------|----------------|
|  | <b>March 31,</b>          |                |
|  | <b>2005</b>               | <b>2004</b>    |
| Net loss applicable to common shares, as reported  | \$ (1,426,079)            | \$ (1,095,348) |
| Deduct: Total stock-based employee compensation expense determined under fair value method | (167,912)                 | (282,168)      |
| Net loss applicable to common shares, pro forma  | \$ (1,593,991)            | \$ (1,377,516) |
| Net loss per common share – basic  |                           |                |
| As reported  | \$ (0.05)                 | \$ (0.04)      |
| Pro forma  | (0.06)                    | (0.05)         |

As a result of amendments to SFAS No. 123, the Company will be required to expense the fair value of employee stock options over the vesting period, beginning January 1, 2006.

The fair value of each option granted is estimated on the date of the grant using the Black-Scholes option pricing model with the following weighted average assumptions used for the grants in the three months ended March 31, 2005: dividend yield of 0%; expected volatility of 70%; risk-free interest rate of 3.4%; and expected lives of five years. The following assumptions were used for the grants in the three months ended March 31, 2004: dividend yield of 0%; expected volatility of 82%; risk-free interest rate of 3.2%; and expected lives of eight years.

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
March 31, 2005

(5) SUBSEQUENT EVENTS

On April 1, 2005, Manhattan Pharmaceuticals, Inc. (the "Company") entered into an Agreement and Plan of Merger (the "Agreement") with Tarpan Therapeutics, Inc., a Delaware corporation ("Tarpan"), and Tarpan Acquisition Corp., a Delaware corporation and wholly-owned subsidiary of the Company ("TAC"). The Agreement provided that TAC would merge with and into Tarpan, with Tarpan remaining as the surviving corporation and a wholly-owned subsidiary of the Company (the "Merger"). The Merger was completed April 1, 2005. In consideration for their shares of Tarpan capital stock and in accordance with the Agreement, the stockholders of Tarpan received a number of shares of the Company's common stock such that, upon the effective time of the Merger, the Tarpan stockholders collectively received (or are entitled to receive) approximately 20 percent of the Company's outstanding common stock on a fully-diluted basis (i.e., assuming the issuance of common stock underlying outstanding options, warrants and other rights). Based on the number of fully-diluted outstanding shares of the Company's common stock on the date of the Merger, the current stockholders of Tarpan will receive an aggregate of approximately 10,731,052 shares of the Company's common stock in the Merger. At the time of the Merger, Tarpan had outstanding indebtedness of approximately \$648,000 resulting from a series of promissory notes issued to Paramount BioCapital Investments, LLC and Horizon BioMedical Ventures, LLC, both of which are owned or controlled by Dr. Lindsay Rosenwald. The notes were amended at the time of the Merger to provide that one-half of the outstanding indebtedness was payable upon completion of the Merger and the remaining one-half will be payable at such time as the Company raises at least \$5 million in new financing.

The transaction will be accounted for using the purchase method of accounting. Based on management's preliminary purchase price allocation, we believe all or a significant amount of the purchase price will be allocated to in-process research and development. The purchase price was approximately \$11,700,000 and acquisition costs related to the transaction were approximately \$178,000.

Several of Tarpan's former stockholders are directors or significant stockholders of the Company. Dr. Rosenwald and various trusts established for the benefit of Dr. Rosenwald and members of his immediate family collectively beneficially owned approximately 46 percent of Tarpan's common stock and beneficially own approximately 26 percent our common stock. In addition, Joshua Kazam, David Tanen, Dr. Michael Weiser and Timothy McInerney, all of whom are members of the Company's board of directors, collectively owned approximately 13.4 percent of Tarpan's outstanding common stock. Dr. Weiser and Mr. McInerney are also employed by Paramount BioCapital, Inc., an entity owned and controlled by Dr. Rosenwald. As a result of such relationships between the Company and Tarpan, the Company's board of directors established a special committee to consider and approve the Agreement. The special committee consisted of Neil Herskowitz, Malcolm Hoenlein and Richard Steinhart, none of whom had any prior relationship with Tarpan.

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
March 31, 2005

Upon completion of the Merger, Douglas Abel, formerly chief executive officer of Tarpan, was appointed president and chief executive officer of the Company. Pursuant to the Agreement, the Company entered into an Employment Agreement dated April 1, 2005 with Mr. Abel. This agreement has a three-year term commencing on April 1, 2005, which may be extended for additional one (1) year periods thereafter. Under the agreement, Mr. Abel is entitled to an annual salary of \$300,000, in addition to health, disability insurance and other benefits. The annual salary shall be increased to \$325,000 at such time as the Company completes a financing transaction that results in aggregate gross proceeds to the Company of at least \$5,000,000, retroactive to the date of the agreement. In addition, the Company will pay Dr. Abel a cash bonus of \$200,000 in the first year and he may receive a discretionary bonus in the first and subsequent years of up to 50 percent of his base salary. Pursuant to his employment agreement, on April 1, 2005, Mr. Abel was granted an option to purchase an aggregate of 2,923,900 shares of common stock at a price of \$1.50 per share. The option vests in three equal installments, on November 1, 2005, November 1, 2006, and November 1, 2007. Mr. Abel and his dependents are eligible to receive paid medical and long term disability insurance and such other health benefits as we make available to other senior officers and directors. Mr. Abel reports to the Board of Directors of the Company.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

**You should read the following discussion of our results of operations and financial condition in conjunction with our Annual Report on Form 10-KSB for the year ended December 31, 2004 (the "Annual Report"). This discussion includes "forward-looking" statements that reflect our current views with respect to future events and financial performance. We use words such as we "expect," "anticipate," "believe," and "intend" and similar expressions to identify forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties inherent in future events, particularly those risks identified in the "Risk Factors" section of the Annual Report, and should not unduly rely on these forward looking statements.**

### RESULTS OF OPERATIONS

#### THREE-MONTH PERIOD ENDED MARCH 31, 2005 VS 2004

During the quarters ended March 31, 2005 and 2004, we had no revenue. We do not expect to have significant revenues relating to our product candidates in development prior to March 31, 2006.

For the quarter ended March 31, 2005, research and development expense was \$964,040 as compared to \$709,273 for the first quarter of 2004. The increase of \$254,767 is due primarily to an acceleration of pre-clinical development of our Oleoyl-estrone drug candidate.

For the quarter ended March 31, 2005, general and administrative expense was \$493,243 as compared to \$413,238 for the quarter ended March 31, 2004. The increase of \$80,005 is due primarily to increases in investor relations expense and consulting of approximately \$55,000. In addition we had increases in expenses related to rent, telephone, directors' fees and accounting of \$17,000, \$16,000, \$15,000 and \$12,000, respectively. These increases are partially offset by a reduction in legal and other expenses of approximately \$33,000 and \$2,000, respectively.

For the quarter ended March 31, 2005, interest and other income was \$31,204 as compared to \$27,163 for the quarter ended March 31, 2004. The increase of \$4,041 is due primarily to a realized gain on sale of short-term investments during the quarter.

Net loss for the quarter ended March 31, 2005, was \$1,426,079 as compared to \$1,095,348 for the quarter ended March 31, 2004. This increase in net loss is attributable primarily to an increase in research and development expenses of \$254,767 and an increase in general and administrative expenses of \$80,005. These expense increases are partially offset by an increase in interest and other income of \$4,041.

Preferred stock dividends of \$127,466 and \$212,123 reduced earnings per share for the three months ended March 31, 2005 and 2004 by \$0.00 and \$0.01, respectively.

### LIQUIDITY AND CAPITAL RESOURCES

From inception to March 31, 2005, we incurred a deficit during the development stage of \$15,508,580 primarily as a result of losses, and we expect to continue to incur additional losses and negative cash flows from operating activities through March 31, 2006 and for the foreseeable future. These losses have been incurred through a combination of research and development activities related to the various technologies under our control and expenses supporting those activities.

We have financed our operations since inception primarily through equity financing and our licensing and sale of residual royalty rights of CT-3 to Indevus. During the three months ended March 31, 2005, we had a net decrease in cash and cash equivalents of \$360,705. This decrease resulted from net cash used in operating activities of \$1,278,503, partially offset by net cash provided by investing and financing activities of \$848,753 and \$69,045, respectively. Total liquid resources including short term investments as of March 31, 2005 were \$4,066,038 compared to \$5,419,872 at December 31, 2004. In addition, during the three months ended March 31, 2005, we accrued a preferred stock dividend of \$127,466.

Our current liabilities as of March 31, 2005 were \$1,270,584 compared to \$1,195,705 at December 31, 2004, an increase of \$74,879. The increase was primarily due to an increase in expenditures associated with the commencement of our Phase I clinical trial for our Oleoyl-estrone product candidate. As of March 31, 2005, we had working capital of \$2,795,794 compared to \$4,264,293 at December 31, 2004.

Our available working capital and capital requirements will depend upon numerous factors, including progress of our research and development programs, our progress in and the cost of ongoing and planned pre-clinical and clinical testing, the timing and cost of obtaining regulatory approvals, the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, competing technological and market developments, changes in our existing collaborative and licensing relationships, the resources that we devote to developing manufacturing and commercializing capabilities, the status of our competitors, our ability to establish collaborative arrangements with other organizations and our need to purchase additional capital equipment.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing, other collaborative agreements, strategic alliances, and our ability to realize the full potential of our technology in development. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. Through March 31, 2005, a significant portion of our financing has been through private placements of common stock and warrants. Unless our operations generate significant revenues and cash flows from operating activities, we will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. Management believes that we will continue to incur net losses and negative cash flows from operating activities for the foreseeable future. Based on the resources available to us at March 31, 2005, management believes that we will need additional equity or debt financing or will need to generate revenues during 2005 through licensing our products or entering into strategic alliances to be able to sustain our operations through 2005 and we will need additional financing thereafter until we can achieve profitability, if ever.

We have reported net losses of \$1,426,079 and \$1,095,348 for the three months ended March 31, 2005 and 2004, respectively. The net loss from date of inception, excluding preferred stock dividends, August 6, 2001 to March 31, 2005, amounts to \$14,377,133. Management believes that we will continue to incur net losses through at least March 31, 2006 and in the foreseeable future thereafter. Based on the current resources available to us, we will need additional equity or debt or financing or we will need to generate revenues through licensing our products or entering into strategic alliances to be able to sustain our operations until we can achieve profitability, if ever. These matters raise substantial doubt about our ability to continue as a going concern.

## RESEARCH AND DEVELOPMENT PROJECTS

***Oleoyl-estrone.*** In January 2005, The United States Food and Drug Administration (FDA) accepted our filed Investigational New Drug Application (IND) for the human clinical testing of oleoyl estrone. This IND allowance was granted on the preclinical chemistry, manufacturing, and safety data submitted to the FDA by the Company.

In February 2005, we began dosing patients in our first Phase I trial in Basel, Switzerland to evaluate the safety and tolerability of defined doses of orally administered oleoyl-estrone in obese adults, in accordance with FDA guidelines after obtaining formal approval from the Swiss medical regulatory authority, Swissmedic. The objective of this human Phase I dose-escalation study is to determine the pharmacokinetic profile of oleoyl-estrone, as well as its safety and tolerability in obese adult volunteers of both genders. The study is being completed in two parts, Phase Ia and Phase Ib. In May 2005, we concluded Phase Ia, in which 36 obese volunteers were randomized to receive a single dose of either OE or a placebo, in a dose escalating manner, and currently have begun patient dosing in Phase Ib. We are currently reviewing and analyzing the results of the Phase Ia portion of the trial, which will ultimately be used to obtain approval to move forward with Phase II studies. The Phase Ib trial is a repeat-dose, dose escalation trial that will evaluate 24 obese volunteers in four cohorts randomized 2 to 1, active to placebo. Results from this study will also be used, in conjunction with extensive preclinical work, to establish the protocol and obtain approval from the FDA to begin Phase II clinical trials. The trial is being conducted under the IND accepted by the FDA in January 2005. Under our license agreement with Oleoyl-Estrone Developments, we made a \$250,000 milestone payment upon the treatment of the first patient in the Phase I trial. Given the uncertainties inherent in early human clinical trials, it is difficult to predict with accuracy when the Phase I program will be completed.

To date, we have incurred \$4,867,078 of project costs related to our development of oleoyl-estrone, of which \$881,584 and \$251,178 was incurred in the first three months of 2005 and 2004, respectively. Currently, we anticipate that we will need to expend approximately an additional \$1,500,000 to \$2,500,000 in development costs in fiscal 2005. Since oleoyl-estrone is regarded by the FDA as a new entity, it is not realistic to predict the size and the design of the study at this time.

Although we currently have sufficient capital to fund our anticipated 2005 R&D expenditures relating to oleoyl-estrone, we will need to raise additional capital from debt financings or by selling shares of our capital stock in order to complete the anticipated five or six year development program for the product. If we are unable to raise such additional capital, we may have to sublicense our rights to oleoyl-estrone to a third party as a means of continuing development, or much less likely, we may be required to abandon further development efforts altogether, either of which would have a material adverse effect on the prospects of our business.

In addition to raising additional capital, whether we are successful in developing oleoyl-estrone is dependent on numerous other factors, including unforeseen safety issues, lack of effectiveness, significant unforeseen delays in the clinical trial and regulatory approval process, both of which could be extremely costly, and inability to monitor patients adequately before and after treatments. Additional risks and uncertainties are also described in our Annual Report on Form 10-KSB for the year ended December 31, 2004. The existence of any of these factors could increase our development costs or make successful completion of development impractical, which would have a material adverse affect on the prospects of our business.

***Lingual Spray Propofol.*** We are currently working with NovaDel to develop, manufacture and commercialize a propofol lingual spray. In July 2004, we released the results of the first human trial for our proprietary lingual spray formulation of propofol. In January 2005, the FDA accepted our IND for the initiation of the human clinical trials in the United States required for FDA approval of Propofol Lingual Spray (Propofol LS). We continue to pursue FDA approval of Propofol LS under 505(b)2 regulatory pathway. Section 505(b)2 of the U.S. Food, Drug & Cosmetic Act allows the FDA to approve a drug on the basis of existing data in the scientific literature or data used by the FDA in the approval of other drugs. Accordingly, the FDA has indicated to us that we will be able to utilize Section 505(b)2 to proceed directly to a pivotal Phase III trial for lingual spray propofol following completion of Phase 1 trials. We are

actively planning the next steps of the clinical development process for Propofol LS, meeting with scientific advisors and Novadel regarding formulation, reviewing existing data, developing trial design, and evaluating plans to re-enter the clinic in mid-2005.

To date, we have incurred \$2,699,396 of project costs related to our development of propofol lingual spray, of which \$82,456 and \$483,778 was incurred during the first three months of 2005 and 2004, respectively. Currently, we anticipate that we will need to expend approximately an additional \$1,000,000 to \$1,500,000 in development costs in fiscal 2005 and at least an aggregate of approximately \$3,000,000 to \$5,000,000 until we receive FDA approval for propofol, should we opt to continue development until then, including anticipated 2005 costs. As with our development of oleoyl-estrone, we believe we currently have sufficient capital to fund our development activities of propofol lingual spray during 2005. Since our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the product beyond 2005. We expect to raise such additional capital through debt financings or by selling shares of our capital stock. To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to propofol lingual spray or abandon our development efforts altogether, either of which would have a material adverse effect on the prospects of our business.

#### **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements.

#### **Recently Issued Accounting Standards**

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS No. 150 changes the accounting for certain financial instruments with characteristics of both liabilities and equity that, under previous pronouncements, issuers could account for as equity. The new accounting guidance contained in SFAS No. 150 requires that those instruments be classified as liabilities in the balance sheet.

SFAS No. 150 affects the issuer's accounting for three types of freestanding financial instruments. One type is mandatory redeemable shares, which the issuing company is obligated to buy back in exchange for cash or other assets. A second type included put options and forward purchase contracts, which involves instruments that do or may require the issuer to buy back some of its shares in exchange for cash or other assets. The third type of instruments that are liabilities under SFAS No. 150 are obligations that can be settled with shares, the monetary value of which is fixed, tied solely or predominantly to a variable such as market index, or varies inversely with the value of the issuer's shares. SFAS No. 150 does not apply to features embedded in a financial instrument that is not a derivative in its entirety.

Most of the provisions of SFAS No. 150 are consistent with the existing definition of liabilities in FASB Concepts Statement No. 6, "Elements of Financial Statements." The remaining provisions of SFAS No. 150 are consistent with the FASB's proposal to revise that definition to encompass certain obligations that a reporting entity can or must settle by issuing its own shares. SFAS No. 150 was effective for financial instruments entered into or modified after May 31, 2003 and otherwise was effective at the beginning of the first interim period beginning after June 15, 2003. There was no effect on the Company's financial statements from adopting this statement.

In December 2004, the FASB issued SFAS No. 123(R) (revised 2004), "Share-Based Payment", which amends SFAS Statement No. 123 and will be effective for small business issuers for annual periods beginning after December 15, 2005. The new standard will require us to expense employee stock options and other share-based payments over the vesting period. The new standard may be adopted in one of three ways - the modified prospective transition method, a variation of the modified prospective transition method or the modified retrospective transition method. We are currently evaluating how we will adopt the standard and evaluating the effect that the adoption of SFAS 123(R) will have on our financial position and results of operations.

**Item 3. Controls and Procedures**

As of March 31, 2005, we carried out an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in alerting them on a timely basis to material information required to be disclosed in our periodic reports to the Securities and Exchange Commission. During the first quarter of 2005, there were no changes in our internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting subsequent to such evaluation.

As a non-accelerated filer with a fiscal year end of December 31, we must first begin to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 for the fiscal year ending December 31, 2006. We believe that our present internal control program has been effective at a reasonable assurance level to ensure that our financial reporting has not been materially misstated. Nonetheless, during the remaining periods through December 31, 2006, we will review, and where necessary, enhance our internal control design and documentation, management review, and ongoing risk assessment as part of our internal control program, including implementing the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

**PART II - OTHER INFORMATION**

**Item 6. Exhibits**

Exhibit No.    Description

31.1            Certification of Chief Executive Officer

31.2            Certification of Chief Financial Officer

32.1            Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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**SIGNATURES**

In accordance with the requirements of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MANHATTAN PHARMACEUTICALS, INC.

Date: May 16, 2005

By: /s/ Douglas Abel

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Douglas Abel  
President and Chief Executive Officer

Date: May 16, 2005

By: /s/ Nicholas J. Rossettos

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Nicholas J. Rossettos  
Chief Financial Officer and Chief Operating Officer

**Exhibit Index**

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|--------------------|--|
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