Nile Therapeutics, Inc.
Form 10QSB
November 14, 2007
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

# FORM 10-QSB

(Mark One)

**x** **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2007

¨ **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: 333-55166

# NILE THERAPEUTICS, INC.

**(Exact Name Of Registrant As Specified In Its Charter)**

| **Delaware** | **88-0363465** |
|---|---|
| **(State of Incorporation)** | **(I.R.S. Employer Identification No.)** |

**2850 Telegraph Avenue, Suite #310, Berkeley, California 94705**

**(Address of principal executive offices)**

**(510) 281-7700**

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

**SMI Products, Inc.**

**122 Ocean Park Blvd., Suite 307**

**Santa Monica, California 90405**

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

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of October 31, 2007, there were 24,099,716 shares of the issuer s common stock, par value $.001 per share, issued and outstanding.

Transitional Small Business Disclosure Format (Check one): Yes ¨ No x

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**PART I FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED BALANCE SHEET (unaudited)

| | September 30, 2007 |
|---|---|
| **ASSETS** | |
| Current assets | |
| Cash and cash equivalents | $ 18,039,345 |
| Prepaid expenses and other current assets | 368,685 |
| Total current assets | 18,408,030 |
| Property and equipment, net of accumulated depreciation of $8,182 | 58,325 |
| Intangible assets, net of accumulated amortization of $2,420 | 127,354 |
| Other non-current assets | 29,000 |
| Total assets | $ 18,622,709 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | |
| Current liabilities | |
| Accounts payable | $ 572,962 |
| Accrued expenses and other current liabilities | 618,901 |
| Due to related party | 165,038 |
| Total current liabilities | 1,356,901 |
| Commitments and contingencies | |
| Stockholders equity (deficit) | |
| Preferred stock, $0.001 par value, 10,000,000 shares authorized | |
| Common stock, $0.001 par value, 100,000,000 shares authorized 24,099,716 shares issued and outstanding | 24,100 |
| Additional paid-in capital | 27,619,952 |
| Deficit accumulated during the development stage | (10,378,244) |
| Total stockholders equity | 17,265,808 |
| Total liabilities and stockholders equity | $ 18,622,709 |

See accompanying notes to condensed financial statements

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS (unaudited)

| | Three months ended September 30, | | Nine months ended September 30, | | Period from August 1, 2005 (inception) to September 30, 2007 |
|---|---|---|---|---|---|
| | 2007 | 2006 | 2007 | 2006 | |
| Grant income | $ 101,400 | $ | $ 101,400 | $ | $ 482,235 |
| Operating expenses | | | | | |
| Research and development | 2,175,558 | 774,772 | 3,596,835 | 1,856,940 | 6,306,241 |
| General and administrative | 2,562,891 | 10,309 | 3,284,387 | 75,229 | 3,464,244 |
| Total operating expenses | 4,738,449 | 785,081 | 6,881,222 | 1,932,169 | 9,770,485 |
| Loss from operations | (4,637,049) | (785,081) | (6,779,822) | (1,932,169) | (9,288,250) |
| Other income (expense) | | | | | |
| Interest income | 58,975 | 31,889 | 82,937 | 73,526 | 182,802 |
| Interest expense | (970,330) | (60,493) | (1,089,344) | (122,959) | (1,272,796) |
| Total other income (expense) | (911,355) | (28,604) | (1,006,407) | (49,433) | (1,089,994) |
| Net loss | $ (5,548,404) | $ (813,685) | $ (7,786,229) | $ (1,981,602) | $ (10,378,244) |
| Basic and diluted loss per share | $ (0.35) | $ (0.06) | $ (0.54) | $ (0.14) | $ (0.74) |
| Weighted average common shares outstanding | 15,977,936 | 13,794,132 | 14,532,772 | 13,794,132 | 14,099,931 |

See accompanying notes to condensed financial statements

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT) (unaudited)

| | COMMON STOCK | | | | |
|---|---|---|---|---|---|
| | SHARES | AMOUNT | ADDITIONAL PAID-IN CAPITAL | DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE | TOTAL STOCKHOLDERS EQUITY (DEFICIT) |
| Issuance of common shares to founders | 13,794,132 | $ 13,794 | $ (8,794) | $ | $ 5,000 |
| Founders shares returned to treasury | (1,379,413) | | | | |
| Issuance of common shares pursuant to licensing agreement | 1,379,413 | | 500 | | 500 |
| Issuance of stock options for services | | | 10,000 | | 10,000 |
| Net loss | | | | (2,592,015) | (2,592,015) |
| Balance at December 31, 2006 | 13,794,132 | 13,794 | 1,706 | (2,592,015) | (2,576,515) |
| Cancellation of stock options issued for services | | | (3,333) | | (3,333) |
| Issuance of common shares pursuant to licensing agreement | 63,478 | 64 | 182,172 | | 182,236 |
| Issuance of common shares pursuant to licensing agreement | 350,107 | 350 | 999,650 | | 1,000,000 |
| Common shares sold in private placement, net of issuance costs of $102,000 | 6,957,914 | 6,958 | 19,865,789 | | 19,872,747 |
| Conversion of notes payable upon event of merger | 1,684,085 | 1,684 | 4,349,481 | | 4,351,165 |
| Discount arising from beneficial conversion feature | | | 483,463 | | 483,463 |
| Warrants issued in connection with note conversion | | | 288,000 | | 288,000 |
| Reverse merger transaction | | | | | |
| Elimination of accumulated deficit | | | (234,218) | | (234,218) |
| Previously issued SMI stock | 1,250,000 | 1,250 | 232,968 | | 234,218 |
| Employee stock based compensation | | | 1,454,274 | | 1,454,274 |
| Net loss | | | | (7,786,229) | (7,786,229) |
| Balance at September 30, 2007 | 24,099,716 | $ 24,100 | $ 27,619,952 | $ (10,378,244) | $ 17,265,808 |

See accompanying notes to condensed financial statements

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF CASH FLOWS (unaudited)

| | Nine months ended September 30. 2007 | Period from August 1, 2005 (inception) to September 30, 2007 |
|---|---|---|
| Cash flows from operating activities | | |
| Net loss | $ (7,786,229) | $ (10,378,244) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization | 10,249 | 10,602 |
| Employee stock-based compensation | 1,454,274 | 1,454,274 |
| Non-employee stock-based compensation | 1,178,903 | 1,189,403 |
| Warrants issued to noteholders | 288,000 | 288,000 |
| Note discount arising from beneficial conversion feature | 483,463 | 483,463 |
| Non-cash interest expense | 167,713 | 351,165 |
| Changes in operating assets and liabilities | | |
| Prepaid expenses and other current assets | (382,685) | (397,685) |
| Accounts payable | 212,349 | 572,962 |
| Accrued expenses and other current liabilities | 501,221 | 618,901 |
| Due to related party | 159,389 | 165,038 |
| Net cash used in operating activities | (3,713,353) | (5,642,121) |
| Cash flows from investing activities | | |
| Purchase of property and equipment | (49,644) | (66,507) |
| Purchase of intangible assets | (92,639) | (129,774) |
| Net cash used in investing activities | (142,283) | (196,281) |
| Cash flows from financing activities | | |
| Proceeds from issuance of notes payable | 1,500,000 | 5,500,000 |
| Repayment of notes payable | (1,500,000) | (1,500,000) |
| Proceeds from sale of common stock to founders | | 5,000 |
| Proceeds from sale of common stock in private placement | 19,872,747 | 19,872,747 |
| Net cash provided by financing activities | 19,872,747 | 23,877,747 |
| Net increase in cash and cash equivalents | 16,017,111 | 18,039,345 |
| Cash and cash equivalents at beginning of period | 2,022,234 | |
| Cash and cash equivalents at end of period | $ 18,039,345 | $ 18,039,345 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for interest | $ 150,000 | $ 150,000 |
| Supplemental schedule of non-cash investing and financing activities: | | |
| Conversion of notes payable and interest to common stock | $ 4,351,165 | $ 4,351,165 |
| Common shares of SMI issued in reverse merger transaction | $ 1,250 | $ |

See accompanying notes to condensed financial statements

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2007

Unaudited

**1. DESCRIPTION OF BUSINESS**

Nile Therapeutics, Inc. ( we , Nile or the Company ) commercially develops innovative products for the treatment of cardiovascular and metabolic diseases. Nile s lead compound is CD-NP, a chimeric natriuretic peptide currently in Phase I clinical studies for the treatment of heart failure. The Company is also developing 2NTX-99, a pre-clinical, small molecule, anti-atherothrombotic agent with nitric oxide (NO) donating properties.

The Company was incorporated in the State of Nevada on June 17, 1996 and reincorporated in Delaware on February 9, 2007, at which time its name was SMI Products, Inc. ( SMI ). On September 17, 2007, the Company completed a merger transaction whereby Nile Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of SMI, merged with and into Nile Therapeutics, Inc., a privately held Delaware corporation ( Old Nile ), with Old Nile becoming a wholly-owned subsidiary of SMI. Immediately following the merger described above, the Company filed a Certificate of Ownership with the Secretary of State of the State of Delaware pursuant to which the Company merged Old Nile with and into the Company, with the Company remaining as the surviving corporation to that merger. In connection with that short-form merger, and as set forth in the Certificate of Ownership, the Company changed its name to Nile Therapeutics, Inc. These two transactions are hereinafter referred to as the Merger . All costs incurred in connection with the Merger have been expensed. Upon completion of the Merger, the Company adopted Old Nile s business plan.

**2. BASIS OF PRESENTATION**

The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-QSB adopted under the Securities Exchange Act of 1934, as amended. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of Nile s management, the accompanying condensed financial statements contain all adjustments (consisting of normal recurring accruals and adjustments) necessary to present fairly the financial position, results of operations and cash flows of the Company at the dates and for the periods indicated. The interim results for the period ended September 30, 2007 are not necessarily indicative of results for the full 2007 fiscal year or any other future interim periods. Because the Merger was accounted for as a reverse acquisition under generally accepted accounting principles, the financial statements for periods prior to September 17, 2007 reflect only the operations of Old Nile. These statements should be read in conjunction with the audited financial statements for Nile Therapeutics, Inc. and notes thereto for the six months ended June 30, 2007, included in the Company s Form SB-2 filed on October 22, 2007.

The accompanying unaudited condensed financial statements have been prepared assuming that the Company will continue as a going concern. Total cash resources as of September 30, 2007 were $18,039,345, compared to $2,022,234 at December 31, 2006. The Company s continued operations will depend on whether it is able to raise additional funds through various potential sources, such as equity and debt financing. Through September 30, 2007, a significant portion of the Company s financing has been through private placements of common stock and debt financing. The Company will continue to fund operations from cash on hand and through the similar sources of capital previously described. The Company can not assure that it will be able to secure such additional financing, or if available, it will be sufficient to meet its needs. Based on its resources at September 30, 2007, and the current plan of expenditure on continuing development of current products, the Company believes that it has sufficient capital to fund its operations through 2009, and will need additional financing in the future until it can achieve profitability, if ever.

**3. THE MERGER**

**(a) Description of the Merger and Private Placement Offering**

On September 17, 2007, the Company completed the Merger. In accordance with the terms of the Merger, each share of common stock of Old Nile that was outstanding immediately prior to the Merger was exchanged for 2.758838 shares of the Company s common stock, and one share of Old Nile common stock was issued to SMI. In addition, all securities convertible into or exercisable for shares of Old Nile common stock outstanding immediately prior to the Merger were cancelled, and the holders thereof received similar securities convertible into or exercisable for the purchase of an aggregate of 3,572,350 shares of the Company s common stock. In consideration for their shares of the Company s pre-merger common stock, the Company s shareholders received an aggregate of 22,849,716 shares of SMI common stock. Immediately prior to the effective time of the Merger, 755,100 shares of SMI s common stock were issued and outstanding.

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2007

Unaudited

In addition, prior to the effective time of the Merger, 56,364 shares of SMI s common stock were issued to Fountainhead Capital Partners Limited and 438,536 shares of SMI s common stock were issued to Ko Zen Asset Management, Inc. upon the conversion of convertible promissory notes and accrued interest. Upon completion of the Merger, the Old Nile shareholders owned approximately 95% of the Company s issued and outstanding common stock, assuming the exercise of all of the issued and outstanding common stock options and warrants.

Following the Merger, the business conducted by the Company is the business conducted by Old Nile prior to the Merger. In addition, the directors and officers of SMI were replaced by the directors and officers of Old Nile.

As a condition to the closing of the Merger, on September 11, 2007, Old Nile completed a financing whereby it received gross proceeds of $19,974,747 through the sale of 6,957,914 shares of common stock in a private placement to certain qualified investors (the Financing ). Contemporaneously with the Financing, the Company converted $4,351,165 of convertible debt and interest into 1,684,085 shares of common stock and five-year warrants to purchase an aggregate of 168,337 shares of common stock at an exercise price of $2.71 per share.

All references to share and per share amounts in this Quarterly Report have been restated to retroactively reflect the number of common shares of Nile common stock issued pursuant to the Merger.

**(b) Accounting Treatment of the Merger; Financial Statement Presentation**

The Merger was accounted for as a reverse acquisition pursuant to the guidance in Appendix B of SEC Accounting Disclosure Rules and Practices Official Text, which provides that the merger of a private operating company into a non-operating public shell corporation with nominal net assets typically results in the owners and management of the private company having actual or effective operating control of the combined company after the transaction, with the shareholders of the former public shell continuing only as passive investors. These transactions are considered by the Securities and Exchange Commission to be capital transactions in substance, rather than business combinations. That is, the transaction is equivalent to the issuance of stock by the private company for the net monetary assets of the shell corporation, accompanied by a recapitalization. Accordingly, the Merger has been accounted for as a recapitalization, and, for accounting purposes, Old Nile is considered the acquirer in a reverse acquisition. The historical financial statements in this Quarterly Report are those of Old Nile.

SMI s historical accumulated deficit for periods prior to September 17, 2007, in the amount of $234,218, was eliminated against additional-paid-in-capital, and the accompanying financial statements present the previously issued shares of SMI common stock as having been issued pursuant to the Merger on September 17, 2007. The shares of common stock of the Company issued to the Old Nile stockholders in the Merger are presented as having been outstanding since August, 2005 (the month when Old Nile first sold its equity securities).

**4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**(a) Development Stage Company**

For the period from inception (August 1, 2005) to date, the Company has been a development stage enterprise, and, accordingly, the Company s operations have been directed primarily toward developing its licensed technologies. The Company has experienced net losses since its inception and had an accumulated deficit of $10,378,244 at September 30, 2007. Such losses and accumulated deficit resulted from the Company s absence of revenue and significant costs incurred in the acquisition and development of the Company s licensed technologies. The Company expects to incur substantial and increasing losses as it expands its technology portfolio and engages in further research and development activities, particularly the conducting of preclinical and clinical trials.

**(b) Estimates**

The preparation of financial statements in conformity with generally accepted accounting principles requires that management make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and assumptions principally relate to services performed by third parties but not yet invoiced, estimates of the fair value and forfeiture rates of stock options issued to employees and consultants, and estimates of the probability and potential magnitude of contingent liabilities. Actual results could differ from those estimates.

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2007

Unaudited

**(c) Cash Equivalents**

The Company considers all highly liquid investments with a remaining maturity of three months or less at the time of acquisition to be cash equivalents. The Company deposits cash and cash equivalents with high credit quality financial institutions and is insured to the maximum limitations. Balances in these accounts may exceed federally insured limits at times.

**(d) Property and Equipment**

Property and equipment consists primarily of furnishings and fixtures, and computer equipment and is recorded at cost. Repairs and maintenance costs are expensed in the period incurred.

Depreciation of property and equipment is provided for by the straight-line method over the estimated useful lives of the related assets.

| Description | Estimated Useful Life |
|---|---|
| Office equipment and furniture | 5 to 7 years |
| Computer Equipment | 3 years |

**(e) Intangible Assets and Intellectual Property**

Intangible assets consist of costs related to acquiring patents and to prosecuting and maintaining intellectual property rights, and are amortized using the straight-line method over the estimated useful lives, generally 20 years. The costs of acquiring intellectual property rights to be used in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred.

**(f) Impairment or Disposal of Long-lived Assets**

The Company evaluates its long-lived assets, primarily its intellectual property, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets or intangibles may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less cost to sell. To date, the Company has not recorded any impairment charges.

**(g) Research and Development**

Research and development costs are charged to expense as incurred. Research and development includes fees associated with operational consultants, contract clinical research organizations, contract manufacturing organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated executive, human resources and facilities expenses.

**(h) Grant income**

Grant income is recorded when funding is received and qualifying expenses are incurred.

**(i) Share-Based Compensation**

Effective August 1, 2005, the Company adopted Statement of Financial Accounting Standards No. 123(R), Share-Based Payment, (SFAS No. 123R) which requires the Company to record as an expense in its financial statements the fair value of all stock-based compensation awards. The terms and vesting schedules for stock-based awards vary by type of grant. Generally, the awards vest based on time-based or performance-based conditions. Performance-based vesting conditions generally include the attainment of goals related to the Company s development performance.

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**(a development stage company)**

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**(j) Loss per Common Share**

The Company calculates loss per share in accordance with SFAS No. 128, Earnings per Share. Basic loss per share is computed by dividing the loss available to common shareholders by the weighted-average number of common shares outstanding. Diluted loss per share is computed similarly to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive.

For all periods presented, potentially dilutive securities are excluded from the computation of fully diluted net loss per share as their effect is anti-dilutive.

Potentially dilutive securities include:

| | September 30, 2007 | September 30, 2006 |
|---|---|---|
| Warrants to purchase common stock | 168,337 | |
| Options to purchase common stock | 3,404,013 | 206,910 |
| Total potentially dilutive securities | 3,572,350 | 206,910 |

**(k) Income Taxes**

The Company accounts for income taxes in accordance with SFAS No. 109, Accounting for Income Taxes, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the period in which the differences are expected to affect taxable income. The Company provides a valuation allowance when it appears more likely than not that some or all of the net deferred tax assets will not be realized.

**(l) Reclassifications**

Certain prior period amounts have been reclassified in order to conform to current period presentation.

**5. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY**

**Patents**

At September 30, 2007, intangible assets consisted of patents and patent applications acquired from third parties for the CD-NP and 2NTX-99 compounds. Amortization expense was $613 and $0 for the three months ended September 30, 2007 and 2006, respectively, $2,420 and $0 for the nine months ended September 30, 2007 and 2006, respectively, and $2,420 for the period from inception to September 30, 2007.

**License Agreements**

CD-NP

On January 20, 2006, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the Mayo License Agreement, with Mayo Foundation for Medical Education and Research ( Mayo ) for the rights to issued patents, patent applications and know-how relating to the use of CD-NP in all therapeutic uses. The Company also holds the rights to improvements to CD-NP that arise out of the laboratory of Dr. John Burnett, the inventor of CD-NP, until January 20, 2009. Under the terms of the Mayo License Agreement, the Company paid Mayo an up-front cash payment and reimbursed it for past patent expenses. In addition, the Company issued 1,379,413 shares of common stock to Mayo. Mayo will receive performance-based cash payments upon successful completion of clinical and regulatory milestones relating to CD-NP. The next milestone payment to Mayo will be made when the first patient is dosed in the first Company-sponsored Phase II clinical trial of CD-NP. The Company will also pay substantial milestone payments to Mayo upon the receipt of regulatory approval for each additional indication of CD-NP, as well as for additional compounds or analogues contained in the intellectual property. Pursuant to the Mayo License Agreement, the Company will pay Mayo an annual maintenance fee and a percentage of net sales of licensed products, as well as $50,000 per year for the consulting services of Dr. Burnett while serving as chairman of the Company s Scientific Advisory Board.

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2007

Unaudited

In addition to the potential milestone payments discussed above, the Mayo License Agreement requires the Company to issue shares of common stock to Mayo for an equivalent dollar amount of grants received in excess of $300,000, but not to exceed $575,000. For the period from August 1, 2005 (inception) through September 30, 2007, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares of common stock.

2NTX-99

On August 6, 2007, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the 2NTX-99 License Agreement, with Dr. Cesare Casagrande for the rights to the intellectual property and know-how relating to 2NTX-99, and all of its human therapeutic or veterinary uses. The intellectual property portfolio for 2NTX-99 includes an issued U.S. patent and a pending European Patent Cooperative Treaty submission relating to its composition of matter, multiple methods of manufacturing, and method of use in treating a variety of atherosclerotic-thrombotic pathological conditions.

Under the 2NTX-99 License Agreement, the Company made an up-front cash payment to Dr. Casagrande and reimbursed him for past patent expenses. The Company also issued to Dr. Casagrande 350,107 shares of common stock. Additionally, the agreement provides for cumulative performance-based milestone payments to Dr. Casagrande upon completion of clinical and regulatory milestones relating to 2NTX-99 in the U.S., Europe and Japan. The Company will also be required to make certain milestones payments to Dr. Casagrande upon regulatory approval for each additional indication of 2NTX-99 and upon achieving certain annual sales milestones. The first milestone payment will be due when the first patient is dosed in the first Company-sponsored Phase I clinical trial of 2NTX-99 in the U.S. or the European Union. The Company will also be required to make quarterly royalty payments to Dr. Casagrande based on a percentage of net sales of licensed products by the Company and any future sub-licensees.

**6. CONVERTIBLE AND OTHER NOTES PAYABLE**

During March 2006, the Company completed a private placement offering for $4,000,000 aggregate principal amount of 6% convertible promissory notes (the Notes ), due on March 28, 2008. The aggregate principal amount and accrued but unpaid interest on the Notes, which totaled $4,351,165, automatically converted upon the closing of the Financing into 1,684,085 shares of common stock at a conversion price equal to $2.58, which was 90% of the per share price of the Financing. Due to the beneficial conversion feature resulting from the discounted conversion price, a discount of $483,463 was recorded as interest expense with a corresponding credit to additional paid-in capital. In addition, in conjunction with the conversion of the convertible debt, the Company issued warrants to purchase 168,337 shares of common stock. The warrants were valued at $288,000 using the Black-Scholes option-pricing model and the following assumptions: exercise price $2.71, a 3.98% risk-free interest rate, a 5 year contractual term, a dividend rate of 0%, and 68% expected volatility. The warrants were recorded as interest expense with a corresponding credit to additional paid-in capital.

On July 24, 2007, the Company issued an 8% promissory note to an investor in the amount of $1,500,000. The note was due and payable on November 24, 2007. An upfront fee of $30,000 was netted against the gross proceeds. The note was paid in full on September 11, 2007, along with an additional fee of $120,000. The upfront and additional fees were charged to interest expense in the period ended September 30, 2007.

**7. STOCKHOLDERS EQUITY**

**(a) Common Stock**

In August 2005, the Company issued an aggregate 13,794,132 shares of common stock to its founders for $5,000. The founders subsequently returned 1,379,413 of these shares to the Company for issuance to Mayo. In January 2006 the Company issued 1,379,413 shares of common stock to Mayo, pursuant to the terms of the licensing agreement. The fair value of these shares of $500 was recorded as stock-based compensation and is included in research and development expense in the accompanying Statements of Operations.

In September 2007, also pursuant to the terms of the Mayo License Agreement, the Company issued 63,478 shares of common stock to Mayo. The fair value of the shares of $182,236 was recorded as research and development expense in the accompanying Statements of Operations.

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2007

Unaudited

In August 2007, pursuant to the terms of the 2NTX-99 License Agreement, the Company issued 350,107 shares of common stock to Dr. Casagrande. The fair value of the shares was $1,000,000 and was recorded as research and development expense in the accompanying Statements of Operations.

As a condition to the closing of the Merger, on September 11, 2007, Old Nile completed a financing whereby it received gross proceeds of $19,974,747 through the sale of 6,957,914 shares of common stock in a private placement to certain qualified investors (the Financing ). Issuance costs related to the Financing were $102,000.

Contemporaneously with the Financing, the Company converted $4,351,165 of convertible debt and interest into 1,684,085 shares of common stock.

1,250,000 shares of common stock that were held by the original stockholders of SMI prior to the Merger are reflected in the Company s common stock outstanding in the accompanying condensed Balance Sheet.

**(b) Warrants**

In conjunction with the conversion of the Notes, the Company issued warrants to purchase 168,337 shares of common stock. The fair value of the warrants was determined to be $288,000.

**8. STOCK OPTION PLAN**

The Company s 2005 Stock Option Plan (the Plan ) was adopted by the Board of Directors on August 10, 2005 and approved by its shareholders on August 11, 2005. The Plan authorizes a total of 2,000,000 shares of common stock for issuance. Under the Plan, incentives may be granted to officers, employees, directors, consultants, and advisors. Incentives under the Plan may be granted in any one or a combination of the following forms: (a) incentive stock options and non-statutory stock options; (b) stock appreciation rights (c) stock awards; (d) restricted stock and (e) performance shares.

On September 17, 2007, pursuant to the Merger, the Plan was amended and each share of common stock then subject to the Plan was substituted with 2.758838 shares of common stock, for aggregate of 5,517,676 shares.

The Plan is administered by the Board of Directors, or a committee appointed by the Board of Directors, which determines recipients and types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. The term of stock options granted under the Plan cannot exceed ten years. Currently, stock options are granted with an exercise price equal to the closing price of the Company s common stock on the date of grant, and generally vest over a period of three to four years.

The Company records compensation expense associated with stock options and other forms of equity compensation in accordance with SFAS 123(R), Share-Based Payment , as interpreted by Staff Accounting Bulletin No. 107 ( SAB 107 ). Under the fair value recognition provisions of this statement, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the vesting period. The Company estimated the fair value of each option award using the Black-Scholes option-pricing model and the following assumptions:

| | |
|---|---|
| Expected volatility | 68% |
| Expected terms | 5.75 to 6.25 years |
| Dividend yield | 0% |
| Risk-free interest rates | 4.21% to 4.28% |

As allowed by SFAS 123(R) for companies with a short period of publicly traded stock history, management s estimate of expected volatility is based on the average expected volatilities of a sampling of five companies with similar attributes to the Company, including: industry, stage of life cycle, size and financial leverage. As the Company has so far only awarded plain vanilla options as defined by SAB 107, the Company used the simplified method for determining the expected life of the options granted.

The Company has no historical basis for determining expected forfeitures and as such, compensation expense for stock-based awards does not include an estimate for forfeitures. The Company adjusts share-based compensation on a quarterly basis for changes to the estimate of expected equity award forfeitures based on a review of recent forfeiture activity and expected future employee turnover.

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2007

Unaudited

Employee stock compensation costs for the cumulative period from August 1, 2005 (inception) to September 30, 2007 totaled $1,454,274 of which $1,446,884 was included in general and administrative expense and $7,390 was included in research and development expense.

At September 30, 2007, the total outstanding, and the total exercisable, options under the Plan were as follows:

| | Number Outstanding | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Total outstanding options | 3,404,413 | $ 2.71 | 8.82 years | $ 5,772,770 |
| Total exercisable options | 731,683 | $ 2.60 | 4.66 years | $ 1,524,694 |

The Company accounts for stock-based compensation arrangements for non-employees under SFAS 123, Accounting for Stock-Based Compensation ( SFAS 123 ) and Emerging Issues Task Force ( EITF ) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. As such, those transactions are measured at the fair value of the equity instruments or the consideration received, whichever is more reliably measurable.

In February 2006, the Company granted options to purchase 206,910 shares of common stock with an exercise price of $0.09 to three of its advisors. A fair value of $10,000 assigned to the options was based on the Black-Scholes option-pricing model. In June 2007, 68,970 of these options were cancelled. Stock-based compensation expense incurred in connection with these non-employee grants was included in research and development expense.

**9. RELATED PARTIES**

On occasion, some of the Company s expenses are paid by Two River Group Holdings, LLC ( Two River ), a company owned by several of the Company s directors and founders. No interest is charged by Two River on any outstanding balance owed by the Company. For the nine months ended September 30, 2007, reimbursable expenses totaled $93,817. In addition, the Company was billed by Two River for consulting and due diligence efforts related to the licensing of 2NTX-99 in the amount of $70,745. As of September 30, 2007 the Company owed Two River $165,038.

The Company utilized the services of Riverbank Capital Securities, Inc. ( Riverbank ), an entity owned by several of the Company s officers, directors, and founders, for investment banking and other investment advisory services in connection with the Financing. Fees charged by Riverbank totaled $100,000 and have been paid in full. There are no amounts outstanding to Riverbank as of September 30, 2007.

The financial condition and results of operations of the Company, as reported, are not necessarily indicative of results that would have been reported had the Company operated completely independently.

**10. COMMITMENTS AND CONTINGENCIES**

The Company leases a single office facility in Berkeley, California under a non-cancelable operating lease that expires in April 2010. Total future lease payments under this lease at September 30, 2007 were $197,085, plus annual operating cost escalations.

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2007

Unaudited

A former executive of the Company terminated his employment agreement with the Company on May 21, 2007. On August 10, 2007, the Company entered into a Separation Agreement and General Release (the Separation Agreement ) with the executive. Pursuant to the terms of the Separation Agreement, the Company will continue to pay the executive s base salary, performance bonus, and benefits until May 21, 2008. As of September 30, 2007, the Company has accrued expenses of $332,840 related to these payments. In addition, the Company issued an option to purchase 593,743 shares of the Company s common stock immediately following the closing of the Financing. The executive was provided with limited piggy-back registration rights and was reimbursed for approximately $12,000 in attorney s fees.

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**Item 2. Management s Discussion and Analysis or Plan of Operation.**

***Note Regarding Forward Looking Statements***

The following discussion of the financial condition and results of operations should read in conjunction with the financial statements and the related notes included in this Form 10-QSB. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under the section entitled *Risk Factors* included in our Form SB-2 filed on October 22, 2007.

***Overview***

We are a development stage biopharmaceutical company that commercially develops innovative products for the treatment of cardiovascular and metabolic disease. To date, our efforts and resources have been focused on acquiring and developing our pharmaceutical product candidates, raising capital and recruiting personnel. Our lead compound is CD-NP, a chimeric natriuretic peptide in Phase I clinical studies for the treatment of heart failure. We believe CD-NP may be useful in several cardiovascular and renal indications, and is initially being developed as a treatment for heart failure. We are also developing 2NTX-99, a pre-clinical small molecule, anti-atherothrombotic agent with nitric oxide (NO)-donating properties.

We have had no product sales to date nor will we have any product sales unless we receive approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates, which we cannot guarantee. Developing pharmaceutical products, however, is a lengthy and very expensive process. Currently, a large portion of our development expenses are related to our lead product candidate, CD-NP. As we proceed with the clinical development of CD-NP and as we further develop 2NTX-99, our second product candidate, our research and development expenses will further increase. To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance further research and development will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products. Our major sources of working capital have been proceeds from various private financings, primarily private sales of common stock and other equity securities and debt financings.

The development of biomedical product candidates like ours is subject to high levels of risk, including risks presented by subsequent developments that are unforeseen or unforeseeable, as well as risks that are entirely outside of our control, including the risk of unfavorable results in any of our ongoing or planned preclinical and clinical studies. We have not yet received clearance from the FDA, or any comparable foreign regulatory agencies, to begin any of our upcoming clinical trials. We thus face the risk that the FDA, and/or comparable foreign regulatory agencies, will deny, or impose burdensome conditions on, our requests to begin any of our proposed clinical studies, or require us to conduct additional studies. We cannot guarantee that we will be able to complete any of our projected milestone events, or that any of them that we do achieve will be on time or on budget.

***Current Portfolio***

Our current portfolio consists of two products, CD-NP, in clinical development for the treatment of heart failure, and 2NTX-99, in pre-clinical development for atherosclerotic, thrombotic, and microvascular diseases.

*CD-NP Program* - CD-NP is a rationally-designed synthetic peptide developed by researchers at Mayo Foundation of Medical Education and Research. CD-NP was designed to incorporate the optimal components of two naturally occurring natriuretic peptides. The compound is a selective NPRB agonist that has demonstrated potent renal enhancement and cardiac unloading properties in vivo, but with minimal hypotensive effects compared with competitive products. In multiple preclinical studies, including a large animal model of congestive heart failure, CD-NP demonstrated potent therapeutic activity compared to Natrecor®, a drug produced by Scios Inc. (a Johnson & Johnson company) currently used to treat acute heart failure, producing less hypotension and improvement in fluid unloading at equimolar doses.

We recently completed a Phase I study in healthy volunteers to examine the safety and pharmacodynamic effects of various doses of CD-NP. The study placed particular emphasis on the effects of CD-NP on blood pressure and renal function, and identifying a dose for use in later stage studies. Data from this first in-human study confirmed several preclinical findings, including that CD-NP potently activated its target receptor in humans, preserved renal function and caused increases in natriuresis (sodium excretion) and diuresis (urine excretion) at doses associated with a minimal effect on mean arterial pressure. Additional comprehensive Phase I studies to assess the safety and pharmacodynamic profile of CD-NP in heart failure patients are planned for initiation in the fourth quarter of 2007.

2NTX-99 Program - 2NTX-99 is a novel small molecule that has been shown in vivo and in vitro to inhibit the synthesis and action of thromboxane (TXA2), enhance the production of prostacyclin (PGI2) and supply pharmacological amounts of NO to the vasculature. TXA2,

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produced by activated platelets, has prothrombotic properties, stimulating activation of new platelets as well as increasing platelet aggregation. TXA2 is implicated in a number of inflammatory and thrombotic conditions, particularly in diabetic populations. PGI2 reverses many of these inflammatory and thrombotic processes, and acts chiefly to prevent platelet formation and clumping involved in blood clotting, and is also an effective vasodilator. NO-donation is hypothesized to act synergistically with PGI2 in vivo to relax the vasculature and protect against atherosclerotic conditions.

We believe that the unique activity profile of 2NTX-99 has potential utility in a range of atherosclerotic, thrombotic, and microvascular diseases, including intermittent claudication and diabetic nephropathy. We initiated manufacturing activities for 2NTX-99 in the third quarter of 2007, we intend to initiate pre-clinical toxicology for 2NTX-99 in the fourth quarter of 2007, and we plan to file an IND and enter human testing by the end of 2009.

***Liquidity and Capital Resources***

For the nine months ended September 30, 2007, we had a net loss of $7,786,229. From inception to September 30, 2007, we have incurred an aggregate net loss of $10,378,244, primarily through a combination of research and development activities related to the licensed technologies under our control and expenses supporting those activities. We expect to incur additional losses in the future as we increase our research and development and clinical development activities.

We have not generated any revenue from operations to date, and we do not expect to generate revenue for several years, if ever. We have financed our operations since inception primarily through debt and equity financings. During the nine months ended September 30, 2007, we experienced an increase in cash and cash equivalents of $16,017,111. This increase primarily resulted from net cash provided by financing activities of $19,872,747, net of issuance costs, from the sale of 6,957,914 shares of common stock in a private placement to certain qualified investors with gross proceeds of $19,974,747.

Total cash resources as of September 30, 2007 were $18,039,345, compared to $2,022,234 at December 31, 2006. As our business does not generate any cash flow, we will need to raise additional capital after we exhaust our current cash resources in order to continue to fund our research and development, including our long-term plans for clinical trials and new product development, as well as to fund operations generally. Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing. Through September 30, 2007, a significant portion of our financing has been through private placements of common stock and debt financing. We will continue to fund operations from cash on hand and through the similar sources of capital previously described, or through other sources that may be dilutive to existing stockholders. We can give no assurances that we will be able to secure such additional financing, or if available, it will be sufficient to meet our needs. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors including the changes in the focus and direction of our research and development programs, including the acquisition and pursuit of development of new product candidates; competitive and technical advances; costs of commercializing any of the product candidates; and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights. Based on our resources at September 30, 2007, and our current plan of expenditure on continuing development of our current products, we believe that we have sufficient capital to fund our operations through 2009, and will need additional financing until we can achieve profitability, if ever. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, or we could be required to delay, scale back or eliminate some or all our research and development programs. Each of these alternatives would likely have a material adverse effect on the prospects of our business.

***Research and Development Expenses***

Research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for preclinical, clinical, and manufacturing development, legal expenses resulting from intellectual property due diligence and organizational affairs and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our research and development costs as they are incurred.

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development and general legal activities.

***Plant and Equipment***

We have no plans to purchase or sell any plant or significant equipment.

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***Employees***

As of the date of this Quarterly Report, we have four employees, all of whom are full-time. We retain several consultants who serve in various operational and administrative capacities, and we utilize clinical research organizations, and third parties to perform our pre-clinical studies, clinical studies and manufacturing.

As part of our planned expansion, we expect to hire additional research and development staff in support of our existing product development, as well as additional general and administrative staff.

***Off Balance Sheet Arrangements***

There were no off-balance sheet arrangements as of September 30, 2007.

**Item 3. Controls and Procedures.**

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company s reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission s rules and forms and that such information is accumulated and communicated to the Company s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Commission Rule 13a-15(b), the Company carried out an evaluation, under the supervision and with the participation of the Company s management, including the Company s Chief Executive Officer and the Company s Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, the Company s Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in the Company s internal controls over financial reporting during the Company s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company s internal controls over financial reporting.

The Company is not an accelerated filer for the 2007 fiscal year because it remains qualified as a small business issuer. Hence, under current law, the internal controls certification and attestation requirements of Section 404 of the Sarbanes-Oxley act will not apply to the Company until the fiscal year ending December 31, 2008. Notwithstanding the fact that these internal control requirements do not apply to the Company at this time, management has begun reviewing the Company s internal control procedures to facilitate compliance with those requirements when they become applicable.

## PART II OTHER INFORMATION

**Item 1. Legal Proceedings.**

The Company is not a party to any material pending legal proceedings.

**Item 2. Unregistered Sales of Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Submission of Matters to a Vote of Security Holders.**

None.

**Item 5. Other Information.**

None.

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**Item 6. Exhibits**

| Exhibit No. | Exhibit Description |
|---|---|
| 31.1 | Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

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**SIGNATURES**

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

**NILE THERAPEUTICS, INC.**

Date: November 14, 2007

By: /s/ Peter Strumph
Peter Strumph

Chief Executive Officer

(Principal Executive Officer)

Date: November 14, 2007

By: /s/ Daron Evans
Daron Evans

Chief Financial Officer

(Principal Financial and Accounting Officer)

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**EXHIBIT INDEX**

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