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**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

# FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2008

☐ **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: 001-34058

# NILE THERAPEUTICS, INC.

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

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

**115 Sansome Street, Suite #310, San Francisco, CA 94104**
**(Address of principal executive offices)(Zip Code)**

**(415) 875-7880**
**(Registrant's telephone number, including area code)**

**(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 Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated file, accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

| 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 August 14, 2008, there were 24,149,405 shares of common stock, par value $0.001 per share, of Nile Therapeutics Inc. issued and outstanding.

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**PART I — FINANCIAL INFORMATION**

**Item 1. Condensed Financial Statements.**

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED BALANCE SHEETS

| | June 30, 2008 (unaudited) | December 31, 2007 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 10,347,757 | $ 16,233,464 |
| Prepaid expenses and other current assets | 415,944 | 526,303 |
| Total current assets | 10,763,701 | 16,759,767 |
| Property and equipment, net | 86,000 | 62,838 |
| Intangible assets, net | 234,286 | 252,723 |
| Other noncurrent assets | 105,623 | 14,000 |
| Total assets | $ 11,189,610 | $ 17,089,328 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 695,905 | $ 658,773 |
| Accrued expenses and other current liabilities | 300,355 | 915,419 |
| Due to related party | 3,282 | 315,204 |
| Total current liabilities | 999,542 | 1,889,396 |
| Commitments and contingencies | | |
| Stockholders' equity | | |
| Preferred stock, $0.001 par value, 10,000,000 shares authorized, none issued and outstanding | — | — |
| Common stock, $0.001 par value, 100,000,000 shares authorized, 24,149,405 and 24,099,716 shares issued and outstanding | 24,150 | 24,100 |
| Additional paid-in capital | 29,896,766 | 28,070,642 |
| Deficit accumulated during the development stage | (19,730,848) | (12,894,810) |
| Total stockholders' equity | 10,190,068 | 15,199,932 |
| Total liabilities and stockholders' equity | $ 11,189,610 | $ 17,089,328 |

See accompanying notes to unaudited condensed financial statements.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENTS OF OPERATIONS
(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | | Period from August 1, 2005 (date of inception) to June 30, 2008 |
|---|---|---|---|---|---|
| | 2008 | 2007 | 2008 | 2007 | |
| Grant income | $ — | $ — | $ — | $ — | $ 482,235 |
| Operating expenses | | | | | |
| Research and development | 2,888,654 | 863,029 | 4,866,838 | 1,421,277 | 12,700,536 |
| General and administrative | 960,164 | 564,816 | 2,158,503 | 721,496 | 6,815,927 |
| Total operating expenses | 3,848,818 | 1,427,845 | 7,025,341 | 2,142,773 | 19,516,463 |
| Loss from operations | (3,848,818) | (1,427,845) | (7,025,341) | (2,142,773) | (19,034,228) |
| Other income (expense) | | | | | |
| Interest income | 82,848 | 7,274 | 232,284 | 23,962 | 619,956 |
| Interest expense | — | (59,836) | (137) | (119,014) | (1,272,934) |
| Other expense | (11,131) | — | (42,844) | — | (43,642) |
| Total other income (expense) | 71,717 | (52,562) | 189,303 | (95,052) | (696,620) |
| Net loss | $ (3,777,101) | $ (1,480,407) | $ (6,836,038) | $ (2,237,825) | $ (19,730,848) |
| Basic and diluted loss per share | $ (0.16) | $ (0.11) | $ (0.28) | $ (0.16) | |
| Weighted-average common shares outstanding | 24,106,341 | 13,794,132 | 24,103,010 | 13,794,132 | |

See accompanying notes to unaudited condensed financial statements.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY
PERIOD FROM AUGUST 1, 2005 (DATE OF INCEPTION) TO JUNE 30, 2008
(unaudited)

| | Common Stock | | | | |
|---|---|---|---|---|---|
| | Shares | Amount | Additional Paid-in Capital | Deficit Accumulated during Development Stage | Total Stockholders' Equity |
| Issuance of common shares to founders | 13,794,132 | $ 13,794 | $ (8,794) | $ — | $ 5,000 |
| Founders shares returned to treasury | (1,379,419) | | | | — |
| Net loss | | | | (10,043) | (10,043) |
| Balance at December 31, 2005 | 12,414,713 | $ 13,794 | $ (8,794) | $ (10,043) | $ (5,043) |
| Issuance of common shares pursuant to licensing agreement | 1,379,419 | | 500 | | 500 |
| Issuance of stock options for services | | | 10,000 | | 10,000 |
| Net loss | | | | (2,581,972) | (2,581,972) |
| Balance at December 31, 2006 | 13,794,132 | $ 13,794 | $ 1,706 | $ (2,592,015) | $ (2,576,515) |
| 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 note conversion | | | 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 | | | 1,902,298 | | 1,902,298 |
| Non-employee stock-based compensation | | | (667) | | (667) |
| Net loss | | | | (10,302,795) | (10,302,795) |
| Balance at December 31, 2007 | 24,099,716 | $ 24,100 | $ 28,070,642 | $ (12,894,810) | $ 15,199,932 |
| Warrants issued in satisfaction of accrued liabilities | | | 334,992 | | 334,992 |
| Employee stock-based compensation | | | 1,184,145 | | 1,184,145 |
| Non-employee stock-based compensation | | | 57,037 | | 57,037 |
| Issuance of common shares pursuant to licensing agreement | 49,689 | 50 | 249,950 | | 250,000 |
| Net loss | | | | (6,836,038) | (6,836,038) |
| Balance at June 30, 2008 | 24,149,405 | $ 24,150 | $ 29,896,766 | $ (19,730,848) | $ 10,190,068 |

See accompanying notes to unaudited condensed financial statements.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)

| | Six Months Ended June 30, | | Period from August 1, 2005 (date of inception) to June 30, 2008 |
|---|---|---|---|
| | 2008 | 2007 | |
| Cash flows from operating activities | | | |
| Net loss | $ (6,836,038) | $(2,237,825) | $ (19,730,848) |
| Adjustments to reconcile net loss to net cash used in operating activities | | | |
| Depreciation and amortization | 53,316 | 6,230 | 80,654 |
| Stock-based compensation | 1,826,174 | (3,333) | 4,920,541 |
| Warrants issued to noteholders | — | — | 288,000 |
| Note discount due to beneficial conversion feature | — | — | 483,463 |
| Loss on disposal of assets | 11,654 | — | 11,654 |
| Non cash interest expense | — | — | 351,165 |
| Changes in operating assets and liabilities | | | |
| Prepaid expenses and other current assets | 110,359 | (26,760) | (415,944) |
| Other noncurrent assets | (91,623) | (65,076) | (105,623) |
| Accounts payable | 37,132 | (174,984) | 695,905 |
| Accrued expenses and other current liabilities | (615,064) | 620,198 | 300,355 |
| Due to related parties | (311,922) | 78,280 | 3,282 |
| Net cash used in operating activities | (5,816,012) | (1,803,270) | (13,117,396) |
| Cash flows from investing activities | | | |
| Purchase of property and equipment | (45,314) | (47,585) | (122,241) |
| Cash paid for intangible assets | (24,381) | (6,185) | (290,353) |
| Net cash used in investing activities | (69,695) | (53,770) | (412,594) |
| Cash flows from financing activities | | | |
| Proceeds from issuance of notes payable | — | — | 5,500,000 |
| Repayment of notes payable | — | — | (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 |
| Net cash provided by financing activities | — | — | 23,877,747 |
| | | — | |
| Net (decrease) increase in cash and cash equivalents | (5,885,707) | (1,857,040) | 10,347,757 |
| Cash and cash equivalents at beginning of period | 16,233,464 | 2,022,234 | — |
| Cash and cash equivalents at end of period | $10,347,757 | $ 165,194 | $ 10,347,757 |
| Cash paid for interest | $ — | $ — | $ 150,000 |
| Supplemental schedule of non-cash investing and financing activities: | | | |
| Warrants issued in satisfaction of accrued liability | $ 334,992 | $ — | $ 334,992 |
| Conversion of notes payable and interest to common stock | $ — | $ — | $ 4,351,165 |
| Common shares of SMI issued in reverse merger transaction | $ — | $ — | $ 1,250 |

See accompanying notes to unaudited condensed financial statements.

**NILE THERAPEUTICS, INC.**
**(A Development Stage Company)**
**NOTES TO CONDENSED FINANCIAL STATEMENTS**
June 30, 2008
(unaudited)

## 1. DESCRIPTION OF BUSINESS

Nile Therapeutics, Inc. ("Nile" or "the Company") commercially develops innovative products for the treatment of cardiovascular diseases. Nile's lead compound is CD-NP, a chimeric natriuretic peptide currently in Phase II 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, and CU-NP, a pre-clinical rationally designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type Natriuretic Peptide ("CNP") and the N- and C-termini of Urodilatin ("URO").

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 were expensed. Upon completion of the Merger, the Company adopted Old Nile's business plan.

## 2. BASIS OF PRESENTATION

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through June 30, 2008, its efforts have been principally devoted to developing its licensed technologies, recruiting personnel, establishing office facilities, and raising capital. Accordingly, the accompanying unaudited Condensed Financial Statements have been prepared in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 7, *"Accounting and Reporting by Development Stage Enterprises*."

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-Q 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 June 30, 2008 are not necessarily indicative of results for the full 2008 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 unaudited Condensed Financial Statements have been prepared by management and should be read in conjunction with the Financial Statements and notes thereto included in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2007 filed with the Securities and Exchange Commission.

Pursuant to 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. All share and per share information in the condensed interim financial statements has been restated to retroactively reflect the conversion ratio of 2.758838. As further explained in Note 3(a) in the 2007 Form 10-KSB, upon completion of the Merger and certain related transactions, the Company's stockholders owned 95% of the capital stock of the merged company and the Merger was accounted for as a reverse acquisition.

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. The Company does not believe that any recently issued, but not yet effective accounting pronouncements, if currently adopted, would have a material effect on the accompanying Condensed Financial Statements.

**NILE THERAPEUTICS, INC.**
**(A Development Stage Company)**
**NOTES TO CONDENSED FINANCIAL STATEMENTS**
June 30, 2008
(unaudited)

**3. LIQUIDITY AND CAPITAL RESOURCES**

For the six months ended June 30, 2008, the Company reported a net loss of $6,836,038 and a net loss of $19,730,848 from the date of inception, August 1, 2005, to June 30, 2008. Total cash and cash equivalents were $10,347,757 as of June 30, 2008 compared to $16,233,464 as of December 31, 2007. Through June 30, 2008, a significant portion of the Company's financing has been through private placements of common stock and debt financing. During 2007, the Company raised approximately $20,000,000 through a private placement of common stock. The Company expects to incur substantial and increasing losses and have negative net cash flows from operating activities as it expands its technology portfolio and engages in further research and development activities, particularly the conducting of pre-clinical and clinical trials.

Based on its resources at June 30, 2008 and the current plan of expenditure on continuing development of current products, the Company believes that it has sufficient capital to fund its operations to the middle of 2009 and will need additional financing in the future until it can achieve profitability, if ever. The Company plans to continue to fund its operations from cash on hand and through similar sources of capital as previously described, or through other sources that may be dilutive to existing stockholders. The Company can give no assurances that it will be able to secure such additional financing, or if available that it will be sufficient to meet its needs. Actual cash requirements may vary materially from those now planned, however, because of a number of factors including a change in the focus and direction of the Company's research and development programs; 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. The success of the Company depends on its ability to discover and develop its products to the point of Food and Drug Administration ("FDA") approval and subsequent revenue generation and, accordingly, to raise enough capital to finance these developmental efforts. Management plans to raise additional equity capital to finance the continued operating and capital requirements of the Company. Amounts raised will be used to further develop the Company's products, acquire additional product licenses and for other working capital purposes. While the Company will extend its best efforts to raise additional capital to fund its ongoing operations, management can provide no assurances that the Company will be able to raise such sufficient funds.

**4. BASIC AND DILUTED LOSS PER SHARE**

The Company calculates basic and diluted 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:

| | June 30, 2008 | June 30, 2007 |
|---|---|---|
| Warrants to purchase common stock | 375,249 | — |
| Options to purchase common stock | 4,376,519 | 137,940 |
| Total potentially dilutive securities | 4,751,768 | 137,940 |

**5. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY**

**Patents**

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. Beginning in 2008, the Company changed its estimate of the expected useful life of its recorded intangibles from twenty years to three years. The Company believes that a three year useful life

**NILE THERAPEUTICS, INC.**
**(A Development Stage Company)**
**NOTES TO CONDENSED FINANCIAL STATEMENTS**
June 30, 2008
(unaudited)

better reflects the uncertainty of the future benefit of the patent assets. The change in the useful life of the Company's patent assets did not have a material affect on the Company's financial position or results of operations. 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.

At June 30, 2008, intangible assets consisted of patents and patent applications acquired from third parties for the CD-NP and 2NTX-99 compounds. Amortization expense was $20,195 and $332 for the three months ended June 30, 2008 and 2007, respectively, $42,818 and $1,808 for the six months ended June 30, 2008 and 2007, respectively, and $56,067 from the date of inception, August 1, 2005 to June 30, 2008.

**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 1,379,419 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. In July 2008, the Company made a milestone payment of $400,000 to Mayo upon the dosing of the first patient in a Phase II trial. 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.

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 August 1, 2005 (inception) through June 30, 2008, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares, representing $182,235 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 having a fair market value as of August 6, 2007 equal to $1,000,000. Additionally, the agreement provides for 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 milestone 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.

CU-NP

Effective as of June 13, 2008, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the CU-NP Mayo License Agreement, with Mayo for the rights to commercially develop CU-NP for all therapeutic indications. The Company also holds the rights to improvements to CU-NP that arise out of the laboratory of Dr. John Burnett and Candace Lee, the inventors of CU-NP, until June 13, 2011.

**NILE THERAPEUTICS, INC.**
**(A Development Stage Company)**
**NOTES TO CONDENSED FINANCIAL STATEMENTS**
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(unaudited)

Under the terms of the CU-NP Mayo License Agreement, the Company paid Mayo an up-front cash payment. Additionally, Mayo will receive performance-based cash payments upon successful completion of clinical and regulatory milestones relating to CU-NP, including a milestone payment due in connection with the initiation of the first Phase II clinical trial of a product. Additional milestone payments will occur upon certain other events. Pursuant to the agreement, Nile must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

In addition to the cash payments described above with respect to the CU-NP Mayo License Agreement, the Company has also agreed to issue certain amounts and types of equity to Mayo. In June 2008, the Company issued 49,689 shares of common stock to Mayo having a fair market value as of June 13, 2008 equal to $250,000. This amount has been recorded in research and development expenses in the accompanying Condensed Statement of Operations. Additionally, Dr. Burnett has applied for funding through Mayo's Discovery-Translation Program. In the event Dr. Burnett is awarded funding through this program, and the funding is used for the development of the licensed product based on the patent applications, the Company has agreed to grant to Mayo an equivalent dollar value in stock warrants to purchase the Company's common stock. The number of warrants will be calculated using the Black-Scholes option-pricing model and will include a cashless exercise provision with language to be negotiated in good faith between the parties.

## 6. 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 1,379,419 of these shares to the Company for issuance to Mayo. In January 2006, the Company issued 1,379,419 shares of common stock to Mayo, pursuant to the terms of the Mayo 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 Condensed Statements of Operations.

As a condition to the closing of the Merger, on September 11, 2007, the Company 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 on the accompanying Condensed Balance Sheets.

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 on August 6, 2008 was $1,000,000 and was recorded as research and development expense in the accompanying Condensed 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 on September 17, 2007 was $182,236 and was recorded as research and development expense in the accompanying Condensed Statements of Operations.

In June 2008, pursuant to the CU-NP Mayo License Agreement, the Company issued 49,689 shares of common stock to Mayo. The fair value of the shares on June 13, 2008 was $250,000 and was recorded as research and development expense in the accompanying Condensed Statements of Operations.

### (b) Warrants

In conjunction with the conversion of the convertible promissory 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.

In 2007, as consideration for the performance of consulting and due diligence efforts related to the licensing of 2NTX-99, the Company granted and accrued for fully vested warrants to purchase 206,912 shares of its common stock. The warrants were valued at $334,992 using the Black-Scholes option-pricing model and the following assumptions: exercise price $2.71, a 4.02% risk-free interest rate, a 5 year contractual term, a dividend rate of 0%, and 68% expected volatility. Of the total warrants granted, 137,567 warrants with an aggregate value of $222,770, were granted to employees of Two River Group Holdings, LLC ("Two River"), a related party (note 8). The remaining warrants were granted to outside consultants. The warrants were recorded as an expense and a liability during the year ended December 31, 2007. In March 2008, these warrants were issued in satisfaction of the accrued liability.

**NILE THERAPEUTICS, INC.**
**(A Development Stage Company)**
**NOTES TO CONDENSED FINANCIAL STATEMENTS**
June 30, 2008
(unaudited)

**7. STOCK OPTION PLAN**

The Company's 2005 Stock Option Plan (the "Plan") was adopted by the Board of Directors on August 10, 2005. The Plan authorized 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, increasing the aggregate number of shares authorized under the Plan to 5,517,676 shares.

The Plan is administered by the Board of Directors, or a committee appointed by the Board, 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. Options shall not have an exercise price less than the fair market value of the Company's common stock on the grant date, and generally vest over a period of three to four years.

A summary of the status of the options issued under the Plan at June 30, 2008, and information with respect to the changes in options outstanding is as follows:

| | Options Outstanding | | | |
|---|---|---|---|---|
| | Outstanding Stock Options | Weighted-Average Exercise Price | Weighted-Average Contractual Term | Aggregate Intrinsic Value |
| Balance at December 31, 2007 | 2,912,681 | $ 2.72 | | |
| Options granted under the Plan | 957,588 | $ 4.68 | | |
| Options forfeited | (87,500) | $ 4.45 | | |
| Balance at June 30, 2008 | 3,782,769 | $ 3.17 | 9.02 | $7,880,456 |
| Exercisable at June 30, 2008 | 782,092 | $ 2.30 | 8.06 | $2,307,077 |

The Company records compensation expense associated with stock options and other forms of equity compensation in accordance with SFAS No. 123(R), *Share-Based Payment*," ("SFAS 123R"), as interpreted by Staff Accounting Bulletin 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 value of the award and is recognized as expense over the required service period, which is generally equal to the vesting period. The Company estimated the fair value of each option award using the Black-Scholes option valuation model and the following assumptions for the six months ended June 30, 2008 (no options were granted during the six months ended June 30, 2007):

| | |
|---|---|
| Expected volatility | 75% to 89% |
| Expected term | 5.75 to 6.25 years |
| Dividend yield | 0% |
| Risk-free interest rates | 1.98% to 3.44% |

**NILE THERAPEUTICS, INC.**
**(A Development Stage Company)**
**NOTES TO CONDENSED FINANCIAL STATEMENTS**
June 30, 2008
(unaudited)

As allowed by SFAS 123R 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. The Company calculates the estimated life of stock options using the "simplified" method as permitted by SAB 107.

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.

Total employee stock-based compensation recognized by the Company in the three and six months ended June 30, 2008 and 2007 and from the date of inception, August 1, 2005, to June 30, 2008 was as follows:

| | Three Months Ended June 30, | | Six Months Ended June 30, | | Period from August 1, 2005 (date of inception) to June 30, 2008 |
|---|---|---|---|---|---|
| | 2008 | 2007 | 2008 | 2007 | |
| Research and development expense | 128,675 | — | 182,963 | — | 222,807 |
| General and administrative expense | 434,098 | — | 1,001,182 | — | 2,863,636 |
| Total stock-based compensation expense | 562,773 | — | 1,184,145 | — | 3,086,443 |

At June 30, 2008, total unrecognized estimated employee compensation cost related to stock options granted prior to that date was $5,534,280, which is expected to be recognized over a weighted-average period of 2.5 years.

In addition to the options issued under the Plan, the Company issued fully vested options to purchase 593,750 shares outside of the Plan to a former executive of the Company pursuant to his separation agreement. The options were issued at an exercise price of $2.71 and had an intrinsic value of $1,508,125 as of June 30, 2008. The options expire on September 17, 2012. The former executive was provided with limited "piggy-back" registration rights and was reimbursed for approximately $12,000 in attorney's fees. The fair value of the options on the grant date was $1.62 per share.

The Company accounts for stock-based compensation arrangements for non-employees under SFAS 123, "*Accounting for Stock-Based Compensation*," 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 December 2007, the Company granted 30,000 options to purchase common stock to an advisor. The options vest monthly over 36 months and have an exercise price of $5.75. The Company revalues the options monthly and has expensed $57,037 in connection with these options in the six months ending June 30, 2008, and $66,370 from inception to June 30, 2008.

**8. RELATED PARTIES**

On occasion, some of the Company's expenses have been paid by Two River Group Holdings, LLC ("Two River"), a company controlled by several of our directors and founders. No interest is charged by Two River on any outstanding balance owed by the Company. As of June 30, 2008, reimbursable expenses totaled $3,282, which was paid in full in July 2008.

In 2007, as consideration for the performance of consulting and due diligence efforts related to the licensing of 2NTX-99, the Company granted fully vested warrants to purchase 206,912 shares of its common stock at an exercise price of $2.71. Of the total amount of the warrants granted 137,567 were granted to employees of Two River. The remaining warrants were granted to outside consultants.

**NILE THERAPEUTICS, INC.**
**(A Development Stage Company)**
**NOTES TO CONDENSED FINANCIAL STATEMENTS**
June 30, 2008
(unaudited)

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.

**9. COMMITMENTS AND CONTINGENCIES**

The Company relocated its principal offices effective April 1, 2008 from Berkeley, California to San Francisco, California. The Berkeley, California office was under a non-cancelable operating lease that expires in April 2010. The total undiscounted future lease payments due under this lease as of March 31, 2008 were approximately $162,000. The Company recorded a loss liability of approximately $138,500, which was equal to the total future lease payments through the end of the lease, discounted at 16%. In June 2008, the Company entered into a lease termination and surrender of premises agreement with the landlord, under which the Company paid $57,000 and surrendered the $14,000 security deposit to terminate the lease.

In March 2008, the Company entered into a non-cancelable office lease agreement for office space in San Francisco, California. The lease expires in March 2011. Future minimum lease payments under the lease are approximately $82,395 in 2008, $112,000 in 2009, $116,000 in 2010, and $29,000 in 2011, not including annual operating cost escalations. In connection with this lease, the Company delivered an irrevocable stand-by and unconditional letter of credit in the amount of $54,929 as a security deposit, with the landlord as the beneficiary in case of default or failure to comply with the lease requirements. In order to fund the letter of credit, the Company deposited a compensating balance of $54,929 into a certificate of deposit with a financial institution which shall be restricted for the entire period of the three year lease agreement. Restricted cash is included in other noncurrent assets on the accompanying Condensed Balance Sheets.

**10. SUBSEQUENT EVENTS**

In July 2008, pursuant to the Mayo License agreement, the Company made a milestone payment of $400,000 to Mayo upon the dosing of the first patient in a Phase II trial.

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

***Note Regarding Forward Looking Statements***

*This Quarterly Report on Form 10-Q contains forward-looking statements based on our current expectations. The forward-looking statements are contained principally in this section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations". Words such as "expect," "anticipate," "target," "goal," "project," "intend," "plan," "could," "should," "might," "believe," "seek," "estimate," "continue," "may," variations of such words, and similar expressions are intended to identify such forward-looking statements. In addition, any statements that refer to projections of our future financial performance, anticipated trends in our businesses, and other characterizations of future events or circumstances are forward-looking statements. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those set forth under the section entitled "Risk Factors" included in our 10-KSB filed with the Securities and Exchange Commission on March 27, 2008. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. Except as required under federal securities laws and the rules and regulations of the Securities and Exchange Commission, we do not undertake any obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise. In evaluating our business, you should carefully consider the risks described in the section entitled "Risk Factors" included in our 10-KSB filed with the Securities and Exchange Commission on March 27, 2008. Any of the risks could materially and adversely affect our business, results of operations and financial condition.*

***Overview***

We are a development stage biopharmaceutical company in the business of commercially developing innovative products for the treatment of cardiovascular diseases. Our lead compound is CD-NP, a chimeric natriuretic peptide currently in Phase II clinical studies for the treatment of heart failure. We believe CD-NP may be useful in several cardiovascular and renal indications. We are initially developing CD-NP 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, and CU-NP, a pre-clinical rationally designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type Natriuretic Peptide ("CNP"), and the N- and C-termini of Urodilatin ("URO").

We have no product sales to date and we will not generate any product revenue until we receive approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical product candidates. Developing pharmaceutical products is a lengthy and very expensive process. Assuming we do not encounter any unforeseen safety issues during the course of developing our product candidates, we do not expect to complete the development of a product candidate for several years, if ever. Currently, nearly all of our development expenses have 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 and CU-NP, our second and third product candidates, 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 private sales of our common stock and other debt financings.

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants. We account for stock-based compensation in accordance with Statement of Financial Accounting Standards ("SFAS") 123(R), "*Share-Based Payment.*" SFAS 123R requires us to expense the fair value of stock options over the vesting period. We determine the fair value of stock options using the Black-Scholes option- pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial and development performance. Stock-based compensation expense is included in the respective categories of expense in the statements of operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

***Our Product Candidates***

We currently have three product candidates: CD-NP, in clinical development for the treatment of heart failure; 2NTX-99, which is in pre-clinical development and has potential utility in atherosclerotic, thrombotic, and microvascular diseases; and CU-NP which is in pre-clinical development and has potential utility in a number of cardiovascular and renal indications.

*CD-NP Program* - CD-NP is a novel chimeric natriuretic peptide in clinical development for an initial indication of acute decompensated heart failure ("ADHF"). CD-NP was rationally designed by scientists at the Mayo Clinic's cardio-renal research labs. Current therapies for ADHF, including B-type natriuretic peptide, have been associated with favorable pharmacologic effects, but have also been associated with hypotension and decreased renal function which limit their utility in clinical practice. CD-NP was designed to preserve the favorable effects of current therapies while eliminating or attenuating the hypotensive response, and enhancing or preserving renal function. In addition to an initial indication for ADHF, CD-NP has potential utility in other indications which include preservation of cardiac function subsequent to acute myocardial infarction ("AMI"), and prevention of renal damage subsequent to cardiac surgery.

In 2007, we completed a Phase Ia dose-escalation 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. Data from the completed Phase Ia study in healthy volunteers was consistent with several pre-clinical findings, including that CD-NP was associated with increased levels of plasma cGMP, a secondary messenger of the target receptor, preserved renal function, increased natriuresis and diuresis and had a minimal effect on mean arterial pressure.

*2NTX-99 Program* - 2NTX-99 is a small molecule anti-platelet, anti-atherothrombotic agent with nitric oxide ("NO") donating properties currently in pre-clinical development. Mechanistically, 2NTX-99 is believed to inhibit the synthesis and action of thromboxane and enhances prostacyclin production. Prostacyclin and NO work together to inhibit platelet adhesion and aggregation, induce vasodilation and protect the vascular wall from atherogenic stimuli.

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 pre-clinical toxicology and manufacturing activities for 2NTX-99 in the third quarter of 2007, and we are on track to file an IND and enter human testing in 2009.

*CU-NP Program* – CU-NP is a novel natriuretic peptide rationally designed by scientists at the Mayo Clinic's cardio-renal research labs. CU-NP was designed to combine the favorable hemodynamic venodilating effects of CNP generated via NPR-B receptor agonism, with the beneficial renal effects of Urodilatin generated via NPR-A receptor agonism. In animal models, CU-NP was shown to increase natriuresis, diuresis, and glomerular filtration rate ("GFR") in a dose dependent manner; and to decrease cardiac filling pressure, and inhibit the renin-angiotensin system without inducing significant hypotension.

***Research and Development Plan***

In the first quarter of 2008, we initiated a Phase Ib dose-escalation study to assess the safety and pharmacodynamic profile of CD-NP in stable heart failure patients. In early July 2008, we dosed the first patient in a Phase IIa dose-escalation study to assess the safety and pharmacodynamic profile of CD-NP in acute heart failure patients. We expect to complete our two dose-escalation studies in the second half of 2008. Also in the second half of 2008, we expect to initiate a clinical trial to study CD-NP in patients with AMI.

In addition to our own studies, in July 2008, Mayo dosed the first patient in a Phase Ib study, under an investigator-sponsored IND, to better understand CD-NP's renal properties.

During 2008, we intend to complete the IND-enabling development program for 2NTX-99 to enable entering human testing in 2009.

For CU-NP, we have initiated the pre-clinical development program, and will be performing early pre-clinical studies and pharmacology studies in the second half of 2008.

***Results of Operations for the Three and Six Months Ended June 30, 2008 as compared to the Three and Six Months Ended June 30, 2007***

The following analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and notes contained elsewhere in this Form 10-Q.

*Revenue.* We had no revenue during the three and six months ended June 30, 2008 and 2007 as none of our product candidates have been approved for commercialization.

*Research and Development Expenses.* Research and development expenses for the three months ended June 30, 2008 and 2007 were $2,888,654 and $863,029, respectively. Research and development expenses for the six months ended June 30, 2008 and 2007 were $4,866,838 and $1,421,277, respectively. Research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates. The increase of approximately $3.4 million in the first six months of 2008 over 2007 is primarily due to an increase of approximately $1.2 million in manufacturing expenses and $1.0 million in clinical development expenses. Manufacturing expenses, including formulation development and drug product manufacturing increased due to the increase in manufacturing activities for CD-NP and the addition of manufacturing activities for 2NTX-99. Clinical development expenses increased in relation to sponsored clinical trial expenses. In June 2008, we incurred a one time expense of $0.5 million, including a mixture of issued stock and cash, pursuant to the CU-NP Mayo licensing agreement. The remaining increases resulted from an increase in salaries and related expenses resulting from the hiring of additional research and development personnel. We expense all research and development costs as incurred.

*General and Administrative Expenses.* General and administrative expenses for the three months ended June 30, 2008 and 2007 were $960,164 and $564,816, respectively and for the six months ended June 30, 2008 and 2007 were $2,158,506 and $721,496, respectively. 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. General and administrative personnel expenses in the first six months of 2008 were approximately $1.4 million higher than in the same period in 2007 due to an increase in salaries and related expenses of approximately $0.9 million, including non-cash stock-based compensation. Legal and accounting and other professional services increased approximately $0.4 million due primarily to the Company's public filing requirements in the first six months of 2008 that had no comparable expense in the first six months of 2007.

*Interest Income.* Interest income for the three months ended June 30, 2008 and 2007 was $82,848 and $7,274, respectively and for the six months ended June 30, 2008 and 2007 was $232,284 and $23,962 respectively. The increase is due to an increase in cash and cash equivalents resulting from the raising of approximately $20 million in the third quarter of 2007.

*Interest Expense.* Interest expense for the three months ended June 30, 2008 and 2007 was $0 and $59,836, respectively, and for the six months ended June 30, 2008 and 2007 was $137 and $119,014, respectively. The decrease is attributable to the conversion of 6% convertible promissory notes in September 2007 that were issued in March 2006 and had an aggregate principal amount of $4,000,000.

***Off-Balance Sheet Arrangements***

There were no off-balance sheet arrangements as of June 30, 2008.

***License Agreement Commitments***

Pursuant to our license agreement with Mayo for CD-NP, in July 2008 the Company made a milestone payment of $400,000 to Mayo upon the dosing of the first patient in a Phase II trial. Subsequent milestones achieved will require us to make additional milestone payments to Mayo.

Pursuant to our license agreement with Dr. Casagrande, upon achieving the next milestone, dosing of the first patient in a Phase I trial, we will make a milestone payment of either $250,000 or $150,000 to Dr. Casagrande, depending on the regulatory jurisdiction of the trial. We estimate that this payment will be made in the first half of 2009. Achievement of subsequent milestones will require us to make additional milestone payments to Dr. Casagrande.

Effective June 13, 2008, we entered into the CU-NP Mayo License Agreement with Mayo. Under the terms of the agreement, Mayo granted to us a worldwide, exclusive license for the rights to commercially develop CU-NP for all therapeutic indications. We also have the rights to improvements to CU-NP and know-how that arise out of the laboratory of Dr. John Burnett and Dr. Candace Lee, the inventors of CU-NP, until June 16, 2011. In consideration for the CU-NP Mayo License Agreement, we agreed to expend reasonable amounts to conduct a research and commercial development program to commercialize a product developed from the patent, to pursue diligently worldwide regulatory approval of a product, and to commence marketing within six months following regulatory approval of the product in the United States. In addition, under the terms of the agreement, we made an up-front cash payment to Mayo. Additionally, Mayo will receive performance-based cash payments upon successful completion of clinical and regulatory milestones relating to CU-NP, including a milestone payment due in connection with the initiation of the first Phase II clinical trial of a product. Additional milestone payments will occur upon other events. Pursuant to the agreement, we must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

In addition to the cash payments described above with respect to the CU-NP Mayo License Agreement, we have also agreed to issue certain amounts and types of equity to Mayo. Initially, we have agreed to issue a number of shares of Nile's common stock having a fair market value as of June 13, 2008 equal to $250,000. The shares issued to Mayo are not subject to anti-dilution protection and, like all of our shares of common stock, will be diluted over time if we issue additional shares. Additionally, Dr. Burnett has applied for funding through Mayo's Discovery-Translation Program. In the event Dr. Burnett is awarded funding through this program, and the funding is used for the development of the licensed product, we have agreed to grant to Mayo an equivalent dollar value in stock warrants to purchase our common stock. The number of warrants will be calculated using the Black-Scholes option-pricing model. The warrants will include a cashless exercise provision with language to be negotiated in good faith between the parties.

***Warrant Grant***

In 2007, as consideration for the performance of consulting and due diligence efforts related to the licensing of 2NTX-99, we granted and accrued for fully vested warrants to purchase 206,912 shares of our common stock at an exercise price of $2.71. Of the total amount of the warrants granted, 137,567 were granted to employees of Two River Group, a related party. The remaining warrants were granted to outside consultants. In March 2008, we issued these warrants in satisfaction of the accrued liability.

***Employees***

As of the date of this Quarterly Report, we have eight 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. We may hire additional research and development staff, as required, to support our product development.

***Liquidity and Capital Resources***

For the six months ended June 30, 2008, we had a net loss of $6,836,038. From inception to June 30, 2008, we have incurred an aggregate net loss of $19,730,848 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 six months ended June 30, 2008, we experienced a decrease in cash and cash equivalents of approximately $5.9 million. This decrease primarily resulted from net cash used in operating activities.

Total cash and cash equivalents as of June 30, 2008 were $10,347,757 compared to $16,233,464 at December 31, 2007. 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 June 30, 2008, 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 June 30, 2008, 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 the middle of 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.

***Critical Accounting Policies and Estimates***

Our unaudited Condensed Financial Statements are prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis including clinical trial accruals and stock-based compensation. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates. We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

***Research and Development Expenses and Accruals***

Research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Our cost accruals for clinical trials and other research and development activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and contract research organizations. In the normal course of business we contract with third parties to perform various research and development activities in the on-going development of our product candidates. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other research and development activities are recognized based on our estimate of the degree of completion of the event or events specified in the specific contract.

***Stock-Based Compensation***

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants. We issued stock options to employees, directors and consultants under the 2005 Stock Option Plan beginning in 2006.

We account for employee stock-based compensation in accordance with SFAS 123R, "*Share-Based Payments*". SFAS 123R requires us to expense the fair value of stock options over the vesting period on a straight-line basis. We determine the fair value of stock options using the Black-Scholes option-pricing model. This valuation model requires us to make assumptions and judgments about the variables used in the calculation. These variables and assumptions include the weighted-average period of time that the options granted are expected to be outstanding, the volatility of our common stock, the risk-free interest rate and the estimated rate of forfeitures of unvested stock options. Additional information on the variables and assumptions used in our stock-based compensation are described in Note 7 of the accompanying notes to our unaudited Condensed Financial Statements.

Stock options or other equity instruments to non-employees (including consultants and all members of the Company's Scientific Advisory Board) issued as consideration for goods or services received by the Company are accounted for under SFAS 123, "*Accounting for Stock-Based Compensation*," 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*", based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model and is periodically remeasured as the underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial and development performance. Stock-based compensation expense is included in the respective categories of expense in the statements of operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

As a smaller reporting company, the Company is not required to provide the information required by this Item 3 of Part I.

**Item 4T. 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 Securities and Exchange 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 was not an "accelerated filer" for the 2007 fiscal year because it was 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 ended December 31, 2009. 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 1A. Risk Factors.**

As a smaller reporting company, the Company is not required to provide the information required by this Item 1A of Part II.

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

Not applicable.

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

Not applicable.

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

The 2008 Annual Meeting of Stockholders of the Company was held pursuant to notice on Thursday, May 29, 2008 at 9:30 a.m., Eastern Daylight Time, at One Liberty Plaza, 165 Broadway, 50th Floor, New York, New York. There were present at the meeting, in person or represented by proxy, the holders of 15,216,385 shares of the Company's common stock. The matters voted on at the meeting and the votes cast were as follows:

(a) The nominees listed below were elected to our Board of Directors at the meeting:

| NAME OF NOMINEE | NO. OF COMMON VOTES IN FAVOR | NO. OF COMMON VOTES WITHHELD |
|---|---|---|
| Pedro Granadillo | 15,205,350 | 11,035 |
| Peter M. Kash | 15,205,350 | 11,035 |
| Joshua A. Kazam | 15,205,350 | 11,035 |
| Paul A. Mieyal, Ph.D. | 15,205,350 | 11,035 |
| Gregory W. Schafer | 15,205,350 | 11,035 |
| Peter M. Strumph | 15,205,350 | 11,035 |
| David M. Tanen | 15,205,350 | 11,035 |

(b) The appointment of Hays & Company LLP as the Company's independent accountants for the fiscal year ending December 31, 2008 was ratified. There were 15,119,826 shares of the Company's common stock voting in favor, 0 shares of common stock voting against and 96,559 shares of common stock abstaining

**Item 5. Other Information.**

Not applicable.

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**Item 6. Exhibits**

| Exhibit No. | Exhibit Description |
|---|---|
| 10.1* | Technology License Agreement, by and between Nile Therapeutics, Inc., a Delaware corporation, and Mayo Foundation for Medical Education and Research, a Minnesota charitable corporation, effective as of June 17, 2008. |
| 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. |

* Confidential treatment requested for certain portions.

**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 August 14, 2008

By: /s/ Peter Strumph
Peter Strumph
Chief Executive Officer
(Principal Executive Officer)

Date August 14, 2008

By: /s/ Daron Evans
Daron Evans
Chief Financial Officer
(Principal Financial and Accounting Officer)

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## EXHIBIT INDEX

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**CONFIDENTIAL TREATMENT REQUESTED**

EXHIBIT 10.1

# TECHNOLOGY LICENSE AGREEMENT

This license agreement ("Agreement") is by and between:

**MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH**, a Minnesota charitable corporation, located at 200 First Street SW, Rochester, Minnesota 55905-0001 ("MAYO"); and

**NILE THERAPEUTICS, INC.**, a Delaware corporation, located at 115 Sansome St., Suite 310, San Francisco, California 94104 ("NILE"), each a "Party," and collectively, "Parties."

WHEREAS, MAYO possesses certain intellectual property and know-how relating to a novel synthetic natriuretic compound, named CU-NP, based on the ring structure of human CNP and both C- and N-termini of urodilatin (the "INVENTION"), which was invented at MAYO by Dr. John Burnett and Dr. Candace Lee;

WHEREAS, MAYO desires to make such intellectual property and know-how available for the development and commercialization of products for public use and benefit; and

WHEREAS, MAYO is willing to grant, and NILE is willing to accept, an exclusive license under certain intellectual property and know-how described herein for the purpose of developing and commercializing such products, as set forth below; and

WHEREAS, NILE will be responsible for designing, developing, marketing, sublicensing and selling any products in accordance with the grant of rights hereunder.

NOW THEREFORE, in consideration of the foregoing and their mutual covenants set forth below, the Parties agree as follows:

## Article 1 - Definitions

For purposes of this Agreement, each term defined in this Article will have the meaning specified for it below and will be applicable both to the singular and plural forms:

**1.01 "Affiliate"** means:

(a) with respect to MAYO, any corporation or other entity within the same "controlled group of

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corporations" as MAYO or its parent Mayo Foundation. For purposes of this definition, the term "controlled group of corporations" shall have the same definition as Section 1563 of the Internal Revenue Code as of November 10, 1998, but shall include corporations or other entities that, if not a stock corporation, more than 50% of the board of directors or other governing body of such corporation or other entity is controlled by a corporation within the controlled group of corporations of MAYO or Mayo Foundation. MAYO's Affiliates include, but are not limited to: Mayo Clinic; Mayo Collaborative Services; Inc., Rochester Methodist Hospital; Saint Mary's Hospital; Mayo Clinic Rochester; Mayo Clinic Jacksonville; St. Luke's Hospital Association; Mayo Clinic Arizona; and its Mayo Health System entities.

(b) with respect to NILE means any corporation or other person controlling, controlled by or under common control with NILE.

(c) The term "control" means the ability, directly or indirectly, to direct the management and policies of a corporation or person, whether through the ownership of voting securities, by contract or otherwise. Control shall be deemed to exist in the case of the ownership, directly or indirectly, of 50% or more of the equity interests in any such corporation.

**1.02 "Change of Control"** shall mean (a) the acquisition of NILE by another person or entity by means of any transaction or series of related transactions (including any stock transfer or series of transfers, reorganization, merger or consolidation) that results in the transfer of 50% or more of the outstanding voting power of NILE, or (b) a sale of all or substantially all of the assets of NILE to which this Agreement relates.

**1.03 "Commercialization"** means all steps that must be taken to put a Product on the market in the Territory after all necessary regulatory approvals have been obtained, including, without limitation, the manufacturing, marketing, distribution and/or sublicensing of such Product.

**1.04 "Common Stock"** shall mean the shares of common stock of the LICNESEE, par value $0.001 per share.

**1.05 "Development"** means the process of creating and assembling the data and files necessary to obtain regulatory approval for a Product including, without limitation, all preclinical and clinical research and trials on such Product.

**1.06 "Effective Date"** means June 13,2008.

**1.07 "FDA"** means the Food and Drug Administration within the Department of Health and Human Services of the United States.

**1.08 "Field"** means all therapeutic indications.

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**1.09 "Government Rights"** means rights, if any, of the United States Government to the Patents under Public Law 96-517 and Public Law 98-620, as amended or augmented by other similar laws.

**1.10 "Improvements"** means any and all new developments relating solely to Products made by or arising out of the laboratories of Drs. John Burnett and Candace Lee during the three (3) year period following the Effective Date of this Agreement, including improved methods of manufacture and production techniques, and shall include, but not be limited to, additional therapeutic indications and developments intended to enhance the safety and efficacy of the Product; provided, however, that this provision shall remain in effect only for so long as Drs. Burnett or Lee remain employed by MAYO, respectively.

**1.11 "Know-How"** means all technical information and data, whether or not patented, presently known or learned, invented, or developed by Drs. John Burnett and Candace Lee that is useful in the Development and Commercialization of a Product and is disclosed to NILE, to the extent that such technical information and data are helpful for the use or practice of the Patents or Know-How as permitted herein.

**1.12 "License Quarter"** begins on the Effective Date, and thereafter begins on the first day of each January, April, July, and October during the Term

**1.13 "License Year"** begins on the Effective Date, and thereafter begins on the first day of each January during the Term.

**1.14 "Net Sales"** means the amount invoiced by NILE, its Affiliates or Sublicensee for sale of a Product in the Territory to a third party, less the following:

(a) sales, tariff duties, excise or use taxes directly imposed and with reference to particular sales;

(b) credits for defective or returned Products;

(c) regular trade and discount allowances; and

(d) bad debt deductions actually written off during the accounting period;

Leasing, lending, consigning or any other activity by means of which a third party acquires the right to possession or use of a Product will be considered a sale for the purpose of determining Net Sales.

**1.15 "NDA"** shall mean an application for approval to market a new drug filed with the FDA pursuant to 21 C.F.R. §314.

**1.16 "Patent"** or **"Patents"** means the issued United States and foreign patents and the pending applications set forth in Exhibit A, together with any and all substitutions, extensions, divisionals, continuations, continuations-in-part (to the extent that the subject matter is disclosed and enabled in the parents), or foreign counterparts of such patent applications and patents which issue thereon any where in the world, including reexamined and reissued patents.

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**1.17 "Phase II"** means a human clinical trial, the principal purpose of which is to evaluate the effectiveness of the Product for a particular indication in patients with the disease and to determine the common short-term side effects and risks associated with the Product as required in 21 C.F.R. §312. A Phase II study shall be deemed to have been initiated when the first patient has been dosed with the drug substance.

**1.18 "Phase III"** means expanded controlled and uncontrolled human clinical trials performed after Phase II evidence suggesting effectiveness of the Product has been obtained, and is intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the Product and to provide an adequate basis for physician labeling, as required in 21 C.F.R. §312. A Phase III study shall also include any other human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of an approvable NDA (such as a combined Phase II/Phase III study, or any Phase III study in lieu of a Phase II study) (a "Pivotal Study"), whether or not such study is a traditional Phase III study. A Phase III study shall be deemed to have been initiated when the first patient has been dosed with the drug substance.

**1.19 "Product"** means any method, service or product within the Field, the manufacture, use, offer for sale or sale of which would infringe the Patents.

**1.10 "Reasonable Commercial Efforts"** means efforts consistent with those used by comparable biotechnology companies in the United States in research and development projects for therapeutic methods or compositions deemed to have commercial value comparable to the Product.

**1.21 "Reports"** means written summaries for each Product generally describing NILE's efforts with respect to Development and Commercialization of the Product, including:

(a) tests and research completed;

(b) any filings made with any regulatory authorities;

(c) any regulatory approvals received;

(d) a response to any comments that MAYO has made to any earlier Report, including NILE's rationale for rejecting any suggestion contained in such comments;

(e) reports or minutes of any formal meetings with regulatory authorities, whether convened in person or otherwise; and

(f) any other major regulatory event, including but not limited to, placement of a "clinical hold" on a trial.

**1.22 "Sublicensee"** means any third party to whom NILE or a sublicensee of NILE conveys rights or the forbearance of suit under the Patents and Know-How pursuant to Section 3.01.

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**1.23 "Successful Completion"** of a Phase III clinical trial shall mean a clinical trial that yields data that is sufficiently statistically significant to permit NILE to file a NDA.

**1.24 "Valid Claim"** means an issued claim of any unexpired patent or claim of any pending patent application included among the Patents, which has not been held unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, which has not been rendered unenforceable through disclaimer or otherwise, and which has not been lost through an interference proceeding or abandoned.

**1.25 "VWAP"** is the volume weighted average price of a security that is a measure of the average price that a security has traded at over a given trading period. VWAP is calculated by adding the total dollars traded for every transaction (price multiplied by number of shares traded) and then dividing by the total shares traded for the trading period for which the VWAP is being calculated.

**1.26 "Territory"** means world-wide.

**Article 2 - Development and Commercialization**

**2.01 Agreements of Nile.** NILE agrees to use its commercially reasonable efforts to implement a program of Development and Commercialization of the Product as soon as practically possible. To achieve this goal, NILE agrees to:

(a) conduct a reasonable research and commercial development program to develop a Product;

(b) expend reasonable amounts towards the research and development of such Products;

(c) diligently pursue worldwide regulatory approval of a Product;

(d) commence marketing of a Product within [***] following regulatory approval in the United States.

(e) comply with all applicable laws in performing its obligations under this Agreement, including in connection with obtaining the regulatory approvals; and

(f) perform in good faith all of its obligations under this Agreement.

**2.02 Development Plans and Reports.** NILE agrees to provide MAYO with the Reports semi-annually, within 30 days of June 30$^{h}$ and December 31$^{st}$ , with the first report due by January 30, 2009. Such Reports shall be in sufficient detail for MAYO to among other things:

(a) determine whether NILE is using Reasonable Commercial Efforts to pursue the regulatory approvals;

(b) determine whether NILE is using Reasonable Commercial Efforts to develop a Development plan; and

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(c) determine whether a Development plan, once developed and implemented, establishes that NILE is using its Reasonable Commercial Efforts for Commercialization of a Product.

**2.03 Consultation Regarding Reports.** MAYO shall review the Reports and promptly inform NILE if MAYO reasonably believes that the Development or Commercialization plans presented in the Reports are not adequate for a Product. NILE and MAYO will mutually confer, provided, however, notwithstanding anything to the contrary herein, NILE has the final decision-making authority.

**2.04 Receipt of Regulatory Approval.** NILE shall notify MAYO within five (5) business days of receiving official notice of any regulatory approval for any Product.

**Article 3 - Grant of Rights**

**3.01 Grant of Rights.** MAYO grants to NILE an exclusive, world-wide, royalty-bearing license, with the right to sublicense pursuant to Section 3.06, under the Patents and Improvements, and a nonexclusive right under the Know-How to develop, make, have made, use, sell, import, offer to sell and commercialize Products within the Territory and within the Field.

**3.02 Reservation of Rights.** All rights herein are subject to: (a) the rights and obligations to and requirements of the U.S. government, if any have arisen or may arise, regarding the Patents, including as set forth in 35 U.S.C. §§200 et al., 37 C.F.R. Part 401 et al. ("Bayh-Dole Act"); and (b) MAYO's and its Affiliates' reserved, irrevocable right to practice and have practiced the Patents in connection with MAYO's and its Affiliates' educational, research and non-human clinical programs. NILE agrees to comply with the provisions of the Bayh-Dole Act, including promptly providing to MAYO with information requested to enable MAYO to meet its compliance requirements and substantially manufacturing Product in the U.S.

**3.03 All Other Rights Reserved.** Except as granted in Section 3.01, or as otherwise expressly granted herein, no other license is granted by MAYO under any intellectual property rights owned or controlled by MAYO, including any patents, know-how, copyrights, proprietary information, and trademarks. All such rights are expressly reserved by MAYO. Except as provided herein, NILE acknowledges that in no event will this Agreement be construed as an assignment by MAYO to NILE of any intellectual property rights.

**3.04 Confidentiality.** During the Term, and for a period of five (5) years thereafter, each Party hereto agrees to keep confidential by not disclosing to any third party any information (i) relating to this Agreement, including the terms and conditions thereof, or (ii) disclosed by one Party (the "Disclosing Party") to the other (the "Receiving Party"). The Parties may use this information solely as necessary for complying with the terms and conditions of this Agreement. The obligations of non-disclosure and non-use will not apply when and to the extent such information:

(a) becomes part of the public domain through no action or fault of the Receiving Party; or

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(b) was in the Receiving Party's possession before disclosure by the Disclosing Party, as demonstrated by written records, and was not acquired, directly or indirectly, from the Disclosing Party; or

(c) was received by the Receiving Party from a third party having a legal right to transmit such information.

At MAYO's request, NILE will cooperate fully with MAYO, except financially, in any legal actions taken by MAYO to protect its rights in the Patents and Know-how disclosed hereunder.

For avoidance of doubt, any violation of the obligations stated in this Section 3.04 constitutes a material breach of this Agreement.

**3.05 Availability of Product to MAYO**. Once a Product becomes commercially available, to the extent permitted by law and applicable regulations, NILE will provide Products to MAYO and their Affiliates solely for it and their use for internal research and education programs in the Field at most favored nation pricing (*i.e.* no more than the lowest price available to NILE's commercial customers for the Products for use in the Field).

**3.06 Sublicensee Actions.** NILE may enter into sublicensing agreements relating to the Patents, Improvements and Know-how. Nile agrees that any sublicense agreement shall (i) contain provisions at least as favorable to MAYO for the protection of MAYO's rights and the limitation of MAYO's liability exposure as the terms of this Agreement, including without limitation with respect to name use, limitation of liability and indemnification, and development and commercialization obligations commensurate in scope as those set forth for Nile in this Agreement, (ii) to the fullest extent applicable, contain all rights and obligations due to MAYO contained in this Agreement, and (iii) name MAYO as a third party beneficiary. NILE shall (i) be and remain responsible for the performance by such Sublicensee with the terms of this Agreement, and any action by a Sublicensee that would, if conducted by NILE, be a breach of this Agreement, shall be deemed a breach of this Agreement by NILE, and (ii) ascertain, calculate, audit and collect all royalties that become payable by such Sublicensee hereunder and take appropriate enforcement action against such Sublicensee for any failure to pay or to properly calculate payments. Any purported sublicense in violation of this Section 3.06 shall be voidable.

Nile shall furnish to MAYO a true and complete copy of each sublicense agreement and each amendment thereto, within thirty (30) days after the sublicense or amendment has been executed, which copy shall be the Confidential Information of Nile.

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**Article 4 - Consideration and Royalties**

**4.01 Initial Consideration.**

(a) Upon execution of this Agreement, NILE will pay MAYO an up-front payment of [***] as consideration for entering into the Agreement. This initial payment is nonrefundable and is not an advance or creditable against any royalties otherwise due under this Agreement.

(b) Upon the Effective Date, NILE shall issue to MAYO a number of shares of Common Stock having a fair market value as of the Effective Date equal to TWO HUNDRED FIFTY THOUSAND DOLLARS (US $250,000) based on a 20-day VWAP. NILE shall deliver, or cause to be delivered, to MAYO a stock certificate, duly signed by appropriate officers of NILE and issued in MAYO'S name, representing all of the shares of Common Stock required to be issued to MAYO under this Article 4.

(c) By accepting the shares of Common Stock, MAYO hereby consents to the placement of a legend on any certificate or other document evidencing the shares of Common Stock that such shares of Common Stock have not been registered under the Securities Act of 1933 or any state securities or "blue sky" laws and setting forth or referring to the restrictions on transferability and sale thereof contained in this Agreement. MAYO is aware that NILE will make a notation in its appropriate records with respect to the restrictions on the transferability of such shares of Common Stock. The legend to be placed on each certificate shall be in form substantially similar to the following:

"THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE UNITED STATES SECURITIES ACT OF 1933, AS AMENDED (THE "ACT") OR ANY STATE SECURITIES OR "BLUE SKY LAWS", AND MAY NOT BE OFFERED, SOLD, TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED ABSENT AN EFFECTIVE REGISTRATION THEREOF UNDER SUCH ACT OR COMPLIANCE WITH RULE 144 PROMULGATED UNDER SUCH ACT, OR UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL, REASONABLY SATISFACTORY TO THE COMPANY AND ITS COUNSEL, THAT SUCH REGISTRATION IS NOT REQUIRED."

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**4.02 Milestone Payments.** NILE or its Sublicensee shall make the following one-time milestone payments to MAYO:

| Milestone | Milestone Payment |
|---|---|
| Initiation of the first company sponsored Phase II clinical trial of a Product | [***] |
| Initiation of the first U.S. company sponsored Phase III clinical trial of a Product | [***] |
| Successful completion of a U.S. company sponsored Phase III clinical trial of a Product | [***] |
| Acceptance by the FDA of the first New Drug Application ("NDA") for a Product | [***] |
| Approval by the FDA of the first NDA for a Product | [***] |
| Approval by the FDA of an NDA for the first Product in each additional therapeutic indication | [***] |
| Approval by the FDA of an NDA for each additional Product | [***] |

**4.03 Funding from Mayo's Discovery-Translation Program.** Dr. Burnett has applied for funding through MAYO's Discovery-Translation Program. In the event Dr. Burnett is awarded funding through this program, and the funding is used for the Development of a Product, MAYO shall be granted the equivalent dollar value in stock warrants of NILE. The number of warrants will be calculated using the Black-Scholes option-pricing model and the following assumptions: the market price of NLTX on the Effective Date, the market yield on a 5-year constant maturity U.S. Treasury security on the Effective Date, a 5 year contractual term, a dividend rate of 0%, and an 89% expected volatility. The warrants shall include a cashless exercise provision with language to be negotiated in good faith between the parties.

**4.04 Earned Royalties**. NILE or its Sublicensee will pay MAYO [***] of the Net Sales of Products in the Territory for use in the Field covered by at least one Valid Claim. The Earned Royalties are payable as described in Section 5.01.

**4.05 License Maintenance Royalties.** In order for NILE to maintain its exclusive license, NILE will pay MAYO a License Maintenance Royalty of [***] in License Year 1 and 2 and a License Maintenance Royalty of [***] in each License Year thereafter. Such License Maintenance Royalties are fully creditable against the Milestone Payments described in Section 4.02 hereto. For the avoidance of doubt the License Milestone Royalty for License Year 1 shall be due on or before 13 June 2009. Failure to make License Maintenance Payments shall be considered a material breach of this Agreement.

**4.06 Interest.** Any payment that is not made on or before the date when due under this Agreement shall accrue interest thereon from and including such date and until but excluding the date of payment at the rate of one-half percent (0.5%) per month, or, if such rate is in excess of the rate then permitted by applicable laws, at the highest rate so permitted.

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**4.07 Taxes.** NILE is responsible for all applicable taxes (other than net income taxes), duties, import deposits, assessments, and other governmental charges, however designated, that are now or hereafter will be imposed by any authority in or for the Territory, based on or relating to:

(a) the Product or use of the Patents by NILE and/or NILE's Sublicensees; or

(b) the import of the Product into the Territory by NILE and/or NILE's Sublicensees.

Notwithstanding the foregoing, NILE shall not be responsible for any taxes arising from transactions to which MAYO or any of their Affiliates may be parties exclusive of transactions with NILE.

**4.08 No Deductions for Taxes.** Except as otherwise stated herein, or unless otherwise agreed to in writing by MAYO and NILE, all payments to be made by NILE to MAYO under this Agreement represent net amounts MAYO is entitled to receive, and shall not be subject to any deductions or offsets by NILE for any reason whatsoever. NILE, however, is not responsible for any payments, including income tax, required to be paid by MAYO on funds received from or on behalf of NILE.

**4.09 U.S. Currency.** All payments to MAYO under this Agreement will be made by draft drawn on a United States bank, and payable in United States dollars.

**4.10 Overdue Payments.** If overdue, the payments due under this Agreement shall bear interest until paid at a per annum rate 2% above the prime rate in effect at Citibank on the due date and MAYO shall be entitled to recover, in addition to all other remedies, reasonable attorneys' fees and costs related to the administration or enforcement of this Agreement, including collection of payments, following such failure to pay. The acceptance of any payment, including of such interest shall not foreclose MAYO from exercising any other right or seeking any other remedy that it may have as a consequence of the failure of NILE to make any payment when due.

**4.11 Material Breach.** It shall be a material breach of this Agreement if NILE shall fail to make any payment pursuant to Article 4 of this Agreement when such payment is due or by the end of any applicable cure period.

**Article 5 - Accounting and Reports**

**5.01 Royalty Reports and Payments.** NILE will, after Commercialization of at least one Product, deliver to MAYO on or before 1 June, 1 September, 1 December and 1 March a written report for the previous License Quarter stating, for each Product and for each country in the Territory in which there are Net Sales:

(a) the number of Products sold during the period covered by the written report;

(b) a description of all deductions from gross receipts applied to determine Net Sales;

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(c) amount of royalty due thereupon for the period covered by the written report; and

(d) exchange rates used to calculate the royalties due.

Each such report shall be accompanied by the royalty payment due for such License Quarter, in accordance with this Article 5.

**5.02 Audit Rights.** NILE agrees to maintain the Records and to require any permitted Sublicensees to maintain the Records. "Records" mean complete and accurate records showing clearly all transactions that are relevant to any sales, costs, expenses and payments under this Agreement, to be kept in a manner consistent with generally accepted accounting principles and standard operating procedures. MAYO shall have the right, at its expense, through a certified public accountant or like person reasonably acceptable to NILE, to examine the records of NILE and its Sublicensees during regular business hours before the Termination or expiration of this Agreement and for three (3) years thereafter, provided that such examination shall not take place more often than once a year and shall be limited to a report on the accuracy of royalty statements and payments. If the audit report for any License Year discloses an underpayment discrepancy in royalties owed by NILE and royalties paid by NILE to MAYO that exceeds [***] of total Net Sales or Sublicense Revenue made until the date of completion of the audit, NILE shall pay the reasonable expense of the audit and pay to MAYO the entire amount of the discrepancy plus interest within thirty (30) days from the date upon which MAYO notified NILE of the discrepancy. Interest shall be computed at the rate which is the prime rate of Citibank N.A. (N.Y.) in effect at 9:00 a.m. on the day that MAYO notifies NILE of the discrepancy. Discrepancies in royalty payments for a License Year identified by the audit report amounting to less than [***] shall be paid by the end of the License Quarter in which the audit was made.

**Article 6 – Representations, Warranties and Indemnification**

**6.01** Representations and Warranties. MAYO hereby represents and warrants to the best of its counsel's knowledge the following:

(a) MAYO has the full right and power to perform the obligations and grant the License set forth in this Agreement;

(b) There are no outstanding agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement.

(c) Subject to Section 3.02, MAYO owns or possesses all right, title and interest in and to the Patents free and clear of all liens, charges, encumbrances or other restrictions or limitations of any kind whatsoever.

(d) Subject to Section 3.02, there are no licenses, options, restriction, liens, rights of third parties, disputes, royalty obligations, proceedings or claims relating to, affecting, or limiting its rights or the rights of NILE under this Agreement, which imposes obligations upon MAYO or gives any rights to MAYO which, in either case, would adversely affect the rights of NILE or the obligations of MAYO under this Agreement.

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(e) There is no claim, pending or threatened, of infringement, interference or invalidity regarding, any part or all of the Patents and their use as contemplated in the underlying patent applications as presently drafted or as contemplated under this Agreement.

(f) MAYO has provided a copy of all pending patents and applications, filed as of the Effective Date, for which Dr. Burnett and Dr. Lee are co- inventors .

**6.02 No Warranties.** Notwithstanding the foregoing, nothing in this Agreement will be construed as:

(a) a warranty or representation by MAYO as to the validity or scope of any of the Patents; or

(b) an obligation to bring or to prosecute actions against third parties for infringement of the Patents; or

(c) a warranty or representation that the manufacture, use, sale, offer for sale or importation of any Product or the use or practice of any of the Patents are free from infringement or misappropriation of a third party's intellectual property rights.

**6.03 Disclaimer.** MAYO HAS NOT MADE AND PRESENTLY MAKES NO PROMISES, GUARANTEES, REPRESENTATIONS OR WARRANTIES OF ANY NATURE, DIRECTLY OR INDIRECTLY, EXPRESS OR IMPLIED, REGARDING THE MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT FOR THE PRODUCTS OR PATENTS. THE KNOW-HOW AND PATENTS PROVIDED OR LICENSED UNDER THIS AGREEMENT ARE PROVIDED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS".

NILE is solely responsible for determining whether the Patents and Know-How provided or licensed hereunder have applicability or utility in NILE's manufacturing and design activities. NILE assumes all risk and liability in connection with such determination.

**6.04 Indemnification by NILE.** NILE will defend, indemnify, and hold harmless MAYO and MAYO's Affiliates from any and all claims, actions, demands, judgments, losses, costs, expenses, damages and liabilities (including but not limited to reasonable attorneys fees and other out-of-pocket expenses incurred in litigation) (collectively, "Claims"), regardless of the legal theory asserted, arising out of or connected with: (a) use by NILE of Patents or Know-How furnished or licensed under this Agreement; (b) development, design, manufacture, distribution, use, sale, or other disposition of products, including Products, by NILE or its transferees or Mayo and/or it Affiliates; and (c) any clinical trial funded or conducted by NILE, unless such Claims are judicially determined to have arisen out of the gross negligence or willful misconduct of MAYO or its Affiliates. As used herein, MAYO and its Affiliates include the trustees, officers, agents, and employees of MAYO and its Affiliates. NILE will, during the Term, carry occurrence-based liability insurance, including products

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liability and contractual liability, in an amount and for a time period sufficient to cover the liability assumed by NILE hereunder, such amount being at least [***], provided that a lesser amount shall be acceptable to MAYO until such time as the Product enters into human clinical trials. In addition, such policy will name MAYO as an additional-named insured party.

**6.05 Additional Waivers.** IN NO EVENT WILL MAYO'S LIABILITY OF ANY KIND INCLUDE ANY SPECIAL, INDIRECT, INCIDENTAL, OR FUTURE DAMAGES, EVEN IF MAYO HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO CASE WILL MAYO'S LIABILITY OF ANY KIND EXCEED THE TOTAL AMOUNTS WHICH HAVE ACTUALLY BEEN PAID TO MAYO BY NILE AS OF THE DATE OF FILING OF THE ACTION AGAINST MAYO WHICH RESULTS IN THE SETTLEMENT OR AWARD OF DAMAGES.

**6.06 Prohibition Against Inconsistent Statements**. NILE shall not make any statements, representations or warranties, or accept any liabilities or responsibilities whatsoever which are inconsistent with any disclaimer or limitation included in this section or any other provision of this Agreement. NILE shall not settle any matter that will incur liability for MAYO or require MAYO to make any admission of liability without MAYO's prior written consent.

**Article 7 - Term and Termination**

**7.01 Term.** Unless sooner terminated, this Agreement shall continue in full force and effect until the later of (a) the expiration of the last to expire Valid Claim contained in the Patents and (b) the 20th anniversary of this Agreement.

**7.02 Material Breach.** MAYO shall be entitled to terminate this Agreement at any time based upon material breach if NILE has failed to cure such material breach within ninety (90) days of receipt of notice by NILE from MAYO that NILE is in breach.

**7.03 Termination for Other than Material Breach.** NILE may terminate the Agreement without cause upon ninety (90) days prior written notice.

**7.04 Termination for Cessation of Development.** NILE agrees to notify MAYO within thirty (30) days if NILE determines that all Development efforts have been terminated for all Products. Upon receipt of such notification, MAYO may terminate this Agreement and the licenses granted hereunder.

**7.05 Termination for Challenge**. MAYO may terminate this Agreement by transmitting a notice of termination to NILE in the event NILE challenges the validity or enforceability of any of the Patent Rights in any manner.

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**7.06 Insolvency of Company.** MAYO may terminate this Agreement by transmitting a notice of termination to NILE in the event NILE ceases conducting business in the normal course, becomes insolvent or bankrupt, makes a general assignment for the benefit of creditors, admits in writing its inability to pay its debts as they are due, permits the appointment of a receiver for its business or assets, or avails itself of or becomes subject to any proceeding under any statute of any governing authority relating to insolvency or the protection of rights of creditors.

**7.07 Effect of Termination.** Upon termination of this Agreement, all rights granted herein will immediately revert to MAYO with no further notice or action required on the MAYO's behalf. NILE agrees to negotiate in good faith for an agreement, which shall be on commercially reasonable terms, under which NILE would provide and grant to MAYO the rights to use full and complete copies of all toxicity, efficacy, and other data generated solely by NILE (including by contractors or agents on their behalf, specifically excluding MAYO) in the course of NILE's efforts to develop Products or obtain governmental approval for the sale of Products, for use in connection with the development and commercialization of Products.

**7.08 Survival.** The following obligations survive the expiration or termination of this Agreement:

(a) NILE's obligation to supply reports covering the time period up to the date of termination or expiration;

(b) MAYO' right to receive payments, fees, and royalties accrued or accruable from payment at the time of any termination or expiration;

(c) NILE's obligation to maintain records, and MAYO' right to have those records inspected;

(d) any cause of action or claim of MAYO, accrued or to accrue, because of any action or omission by NILE;

(e) NILE's obligations stated in Section 2.03 for data developed prior to termination or expiration, Sections 3.04 and 3.06; the applicable sections of Article 6; Sections 7.07, 7.09 and 7.010; and Article 10; and

(f) MAYO' obligations stated in Section 3.04 and 10.01, and the applicable sections of Articles 6 and 10.

**7.09 Inventory.** NILE shall notify MAYO within thirty (30) days of the effective date of termination of this Agreement the amounts, if any, of Product that NILE, its Sublicensees and distributors then have in inventory in each country. At MAYO' election, NILE, its Sublicensees and distributors may sell the Product in that country if NILE pays royalties thereon in accordance with Sections 4.04 and 5.01. In the event that MAYO does not permit the sale of the inventory, MAYO will direct NILE to return the inventory to MAYO or to destroy the inventory, at the cost of MAYO.

**7.10 Return of Confidential Information.** Within thirty (30) days of the effective date of termination of this Agreement, each of the Parties shall return all of the other Party's Confidential Information, including all copies thereof; provided, however, that each Party shall be entitled to retain one copy of all such Confidential Information in its legal department so that any continuing obligations of confidentiality may be determined.

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**Article 8 - Patent Filing, Prosecution and Maintenance**

**8.01 Patent Filing, Prosecution and Maintenance.** Following execution of this Agreement, NILE shall be responsible for the prosecution and maintenance of all Patents and Patent applications, at NILE's expense, using counsel reasonably acceptable to MAYO, and shall keep MAYO informed of prosecution

**8.02 Patent Term Extension.** MAYO will have the sole right to decide on which Patent(s) to obtain a patent term extension; provided that MAYO will consider NILE's input on the matter. NILE agrees to do all things which MAYO determines are necessary to ensure the timely and complete filing and prosecution of any application for a patent term extension with the United States Patent and Trademark Office for any Product. NILE's duties shall include, but not be limited to, providing MAYO with any information and notifications reasonably necessary for obtaining a patent term extension.

**Article 9 - Patent Rights Enforcement**

**9.01 Third Party Litigation**. In the event a third party institutes a suit against NILE for patent infringement involving a Product, NILE will promptly inform MAYO and keep MAYO regularly informed of the proceedings. In the event the third party sues or joins MAYO, MAYO will have the right to control the defense of the suit. Each Party will bear its own costs of the suit and any recovery will be shared equally by the Parties.

**9.02 Infringement by Third Party.** NILE and MAYO will promptly inform the other Party in writing of any alleged infringement of any Patent and provide the other Party with available evidence of such infringement, and MAYO and NILE will have the right to institute an action for infringement of the Patents consistent with the following:

(a) If MAYO and NILE agree to institute suit jointly, then the suit will be brought in the names of both Parties. NILE will exercise control over such action, provided, however, that MAYO may, if it so desires, be represented by counsel of its own selection, and at its own expense.

(b) In the absence of an agreement to institute a suit jointly, MAYO may institute suit and, at its option, join NILE as a plaintiff. MAYO will bear the entire cost of such litigation, including attorneys' fees. NILE will cooperate reasonably with MAYO, except financially, in such litigation. MAYO will not settle or enter into a voluntary disposition of the action without NILE's prior written consent.

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(c) In the absence of an agreement to institute a suit jointly, and if MAYO determines not to institute a suit, as provided in paragraph (b) of this Section 9.02, then NILE may institute suit and, at its option, join MAYO if MAYO is a necessary party to the litigation. NILE will bear the entire cost of such litigation, including attorneys' fees. MAYO will cooperate reasonably with NILE, except financially, in such litigation. NILE will not settle or enter into a voluntary disposition of the action without MAYO's prior written consent.

(d) Absent an agreement to the contrary, any costs under (a) above will be borne equally by the Parties and any recoveries will be shared in proportion to the economic damages suffered by each Party. Otherwise, each Party will bear its own expenses and any recovery will be applied as follows:

(i) first, to reimburse the Party bringing the action;

(ii) second, to reimburse the expenses of the other Party in connection with such action; and

(iii) third, [***] ([***]%) to MAYO and [***] ([***]%) to NILE.

(e) If either Party institutes a suit under this Section 9.02 and then decides to abandon the suit, it will first provide timely written notice to the other Party of its intention to abandon the suit, and the other Party, if it wishes, may continue prosecution of such suit, provided, however, that the sharing of expenses and of any recovery in such suit will be agreed-upon separately by the Parties.

**9.03 Patent Marking.** To the extent commercially feasible and customary in the trade, NILE will mark all Products that are manufactured or sold under this Agreement with the number of each issued patent within the Patents that cover such Product(s). Any such marking will be in conformance with the patent laws and other laws of the country of manufacture or sale.

**Article 10 - General Provisions**

**10.01 Name Use.** This Agreement does not convey any right to use any of the other Party's names or logos other than where required by law, rule or regulation. Neither Party may use publicly for publicity, promotion, or otherwise, any logo, name, trade name, service mark or trademark of the other Party or its Affiliates, or any simulation, abbreviation or adaptation of the same, or the name of any of the other Party's employee or agent without such other Party's prior, written, express consent other than where required by law, rule or regulation. MAYO's marks include, but are not limited to, the terms "MAYO®" and "MAYO CLINIC®." Any violation of this Section 10.01 constitutes a material breach of this Agreement.

**10.02 Assignment.** Nile may assign its rights and obligations under this Agreement to a third party in conjunction with a Change of Control without Mayo's prior written consent; provided that Nile shall remain responsible for the performance of its assignee, the assignee agrees to assume and be

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bound by the provisions of this Agreement in writing and Nile promptly notifies Mayo of such assignment. Mayo's written consent, which shall not be unreasonably withheld, shall be required prior to any other assignment of Nile's rights or obligations hereunder. Any other purported assignment is void.

**10.03 Waiver.** The failure of a Party to complain of any default by another Party or to enforce any of such Party's rights, no matter how long such failure may continue, will not constitute a waiver of the Party's rights under this Agreement. The waiver by a Party of any breach of any provision of this Agreement shall not be construed as a waiver of any subsequent breach of the same or any other provision. No part of this Agreement may be waived except by the further written agreement of the Parties.

**10.04 Governing Law and Jurisdiction.** This Agreement is made and performed in Minnesota. It is governed by Minnesota law, but specifically not including Article 2 of the Uniform Commercial Code as enacted in Minnesota. This is not an Agreement for the sale of goods. In addition, no Minnesota conflicts-of-law or choice-of-laws provisions apply to this Agreement. To the extent the substantive and procedural law of the United States would apply to this Agreement, it supersedes the application of Minnesota law. The exclusive fora for actions between the Parties in connection with this Agreement are the State District Court sitting in Olmsted County, Minnesota, or the United States Court for the District of Minnesota. NILE agrees unconditionally that it is personally subject to the jurisdiction of such court.

**10.05 Headings.** The headings of articles and sections used in this document are for convenience of reference only, and shall not affect the meaning or interpretation of this Agreement.

**10.06 Notices.** All notices and other business communications between the Parties related to this Agreement shall be in writing, sent by certified mail, addressed as follows:

If to MAYO:

Mayo Foundation for Medical Education and Research
200 First Street SW
Rochester, Minnesota 55905-0001

Attn: Susan L. Stoddard, Ph.D.
Office of Intellectual Property
Mayo Clinic Health Solutions
Telephone: 507-293-3900
Facsimile: 507-284-5410
Email: sstoddard@mayo.edu and
patents@mayo.edu

COPY TO:
Mayo Legal
Attn: General Counsel
Telephone: 507-284-2650
Facsimile: 507-284-0929

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If to NILE:

Nile Therapeutics, Inc.

115 Sansome St., Suite #310
San Francisco, CA 94104

| | |
|---|---|
| Attn: | Daron Evans |
| Telephone: | 415-875-7880 |
| Facsimile: | 415-875-7075 |
| Email: | devans@nilethera.com |

Notices sent by certified mail shall be deemed delivered on the third day following the date of mailing. A Party may change its address or facsimile number by giving written notice in compliance with this section.

**10.07 Limitation of Rights Created.** This Agreement is intended only to benefit the Parties hereto and is not intended to confer upon any other person any rights or remedies hereunder.

**10.08 Independent Contractors.** It is mutually understood and agreed that the relationship between the Parties is that of independent contractors. No Party is the agent, employee, or servant of the other. Except as specifically set forth herein, no Party shall have or exercise any control or direction over the methods by which the other Party performs work or obligations under this Agreement. Further, nothing in this Agreement is intended to create any partnership, joint venture, or lease, expressly or by implication, between the Parties.

**10.09 Entire Agreement.** This Agreement constitutes the final, complete and exclusive agreement between the Parties with respect to its subject matter and supersedes all past and contemporaneous agreements, promises, and understandings, whether oral or written, between the Parties.

**10.10 Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the Parties, their heirs, legal representatives, successors and assigns.

**10.11 Severability.** In the event any provision of this Agreement is held to be invalid or unenforceable, the remainder of this Agreement shall remain in full force and effect as if the invalid or unenforceable provision had never been a part of the Agreement.

**10.12 Amendments.** This Agreement may not be amended or modified except by a writing signed by the Parties and identified as an amendment to this Agreement.

**10.13 Construction.** The Parties agree to all of the terms of this Agreement. The Parties execute this Agreement only after reviewing it thoroughly. That one Party or another may have drafted all or a part of this Agreement will not cause this Agreement to be read more strictly against the drafting Party. This Agreement, and any changes to it, will be interpreted on the basis that the Parties contributed equally to the drafting of all of its parts.

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**10.14 Registration Of Licenses.** NILE will register and give required notice concerning this Agreement, at its expense, in each country in the Territory where an obligation under law exists to so register or give notice.

**10.15 Export Control.** MAYO is subject to U.S. laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and other commodities that may require a license from the applicable agency of the United States government and/or may require written assurances by NILE that it will not export data or commodities to certain foreign countries without prior approval of such agency. MAYO neither represents that a license is required, nor that, if required, it will be issued.

**10.16 Nondisclosure.** Except as permitted herein, neither Party will disclose any of the terms of this Agreement without the express, prior, written consent of the other Party, or unless required by law or a regulatory authority.

**10.17 Counterparts.** This Agreement shall become binding as of the Effective Date when any one or more counterparts hereof, individually or taken together, shall bear the signatures of each of the Parties hereto. This Agreement may be executed in any number of counterparts, each of which shall be an original as against any Party whose signature appears thereon but all of which together shall constitute but one and the same instrument.

***[Remainder of page intentionally left blank]***

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**IN WITNESS WHEREOF,** MAYO and NILE have caused this Agreement to be signed as of the Effective Date by their respective representatives.

**MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH:**

| | |
|---|---|
| /s/ Steven VanNurden | June 17, 2008 |
| *NAME: STEVEN P. VANNURDEN* | *DATE* |
| *TITLE: ASSISTANT TREASURER* | |

*READ, UNDERSTOOD AND AGREED:*

| | |
|---|---|
| /s/ John Burnett | June 17, 2008 |
| *JOHN C. BURNETT, M.D.* | *DATE* |
| /s/ Candace Lee | June 17, 2008 |
| *CANDACE LEE, M.D., PH.D.* | *DATE* |

**NILE THERAPEUTICS, INC:**

| | |
|---|---|
| /s/ Peter Strumph | June 13, 2008 |
| *NAME:* | *DATE* |
| *TITLE:* | |

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**EXHIBIT A**
**PATENTS**

US Patent Application Number 60951117 filed on 20 July 2007;

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EXHIBIT 31.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

I, Peter Strumph, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Nile Therapeutics, Inc. (the "**Company**");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: August 14, 2008

/s/ Peter Strumph
Name: Peter Strumph
Title: Chief Executive Officer

EXHIBIT 31.2

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

I, Daron Evans, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Nile Therapeutics, Inc. (the "**Company**");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: August 14, 2008

/s/ Daron Evans
Name: Daron Evans
Title: Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Nile Therapeutics, Inc. (the "**Company**") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2008 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2008

/s/ Peter Strumph
Name: Peter Strumph
Title: Chief Executive Officer

THIS CERTIFICATION "ACCOMPANIES" THE REPORT, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE REPORT), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Nile Therapeutics, Inc. (the "**Company**") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2008 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2008

/s/ Daron Evans
Name: Daron Evans
Title: Chief Financial Officer

THIS CERTIFICATION "ACCOMPANIES" THE REPORT, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE REPORT), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.