

Nile Therapeutics, Inc.  
Form 10-Q  
May 15, 2008  
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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 MARCH 31, 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)

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**Delaware**  
(State of Incorporation)

**88-0363465**

(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)

**2850 Telegraph Avenue, Suite #310**

**Berkeley, CA 94705**

(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 filer, 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 May 8, 2008, there were 24,099,716 shares of common stock, par value \$0.001 per share, of Nile Therapeutics Inc. issued and outstanding.

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

	March 31, 2008 (unaudited)	December 31, 2007
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 13,659,576	\$ 16,233,464
Prepaid expenses and other current assets	384,554	526,303
<b>Total current assets</b>	<b>14,044,130</b>	<b>16,759,767</b>
Property and equipment, net	88,042	62,838
Intangible assets, net	235,602	252,723
Other non-current assets	118,867	14,000
<b>Total assets</b>	<b>\$ 14,486,641</b>	<b>\$ 17,089,328</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities		
Accounts payable	\$ 815,851	\$ 658,773
Accrued expenses and other current liabilities	332,002	915,419
Due to related party	92,379	315,204
Accrued lease obligation	70,932	
<b>Total current liabilities</b>	<b>1,311,164</b>	<b>1,889,396</b>
Long-term portion of accrued lease obligation	67,575	
<b>Total liabilities</b>	<b>1,378,739</b>	<b>1,889,396</b>
Commitments and contingencies		
Stockholders' equity (deficit)		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized		
Common stock, \$0.001 par value, 100,000,000 shares authorized 24,099,716 shares issued and outstanding	24,100	24,100
Additional paid-in capital	29,037,549	28,070,642
Deficit accumulated during the development stage	(15,953,747)	(12,894,810)
<b>Total stockholders' equity</b>	<b>13,107,902</b>	<b>15,199,932</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 14,486,641</b>	<b>\$ 17,089,328</b>

See accompanying notes to condensed financial statements.



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

	Three Months Ended March 31,		Cumulative Period from August 1, 2005 (date of inception) to March 31, 2008
	2008	2007	
Grant income	\$	\$	\$ 482,235
Operating expenses			
Research and development	1,978,184	558,248	9,811,882
General and administrative	1,198,339	156,680	5,855,763
<b>Total operating expense</b>	<b>3,176,523</b>	<b>714,928</b>	<b>15,667,645</b>
Loss from operations	(3,176,523)	(714,928)	(15,185,410)
Other income (expense)			
Interest income	149,436	16,688	537,109
Interest expense	(137)	(59,178)	(1,272,934)
Other expense	(31,713)		(32,512)
<b>Total other income (expense)</b>	<b>117,586</b>	<b>(42,490)</b>	<b>(768,337)</b>
Net loss	\$ (3,058,937)	\$ (757,418)	\$ (15,953,747)
Basic and diluted loss per share	\$ (0.13)	\$ (0.05)	
Weighted average common shares outstanding	24,099,716	13,794,132	

See accompanying notes to condensed financial statements.

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## NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

## STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)

PERIOD FROM AUGUST 1, 2005 (DATE OF INCEPTION) TO MARCH 31, 2008

(unaudited)

	Common Stock		Additional Paid-in Capital	Deficit Accumulated during Development Stage	Total Stockholders Equity (Deficit)
	Shares	Amount			
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 settlement of accrued liabilities			334,992		334,992
Employee stock based compensation			621,372		621,372
Non-employee stock based compensation			10,543		10,543
Net loss				(3,058,937)	(3,058,937)
Balance at March 31, 2008	24,099,716	\$ 24,100	\$ 29,037,549	\$ (15,953,747)	\$ 13,107,902

See accompanying notes to condensed financial statements.

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

	Three Months Ended March 31,		Cumulative Period from August 1, 2005 (date of inception) to March 31, 2008
	2008	2007	
<b>Cash flows from operating activities</b>			
Net loss	\$ (3,058,937)	\$ (757,418)	\$ (15,953,747)
<b>Adjustments to reconcile net loss to net cash used in operating activities</b>			
Depreciation and amortization	24,411	3,017	51,748
Stock-based compensation	966,907		4,061,274
Warrants issued to noteholders			288,000
Note discount due to beneficial conversion feature			483,463
Non cash interest expense			351,165
<b>Changes in operating assets and liabilities</b>			
Prepaid expenses and other current assets	141,749	(37,692)	(384,554)
Other noncurrent assets	(104,868)	(66,623)	(118,867)
Accounts payable	157,078	(273,815)	815,851
Accrued expenses and other current liabilities	(583,416)	120,207	332,002
Accrued lease obligation	138,507		138,507
Due to related parties	(222,825)	44,217	92,379
Net cash used in operating activities	(2,541,394)	(968,107)	(9,842,779)
<b>Cash flows from investing activities</b>			
Purchase of property and equipment	(26,992)	(19,132)	(103,919)
Cash paid for intangible assets	(5,502)	(3,073)	(271,473)
Net cash used in investing activities	(32,494)	(22,205)	(375,392)
<b>Cash flows from financing activities</b>			
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 increase (decrease) in cash and cash equivalents	(2,573,888)	(990,312)	13,659,576
Cash and cash equivalents at beginning of period	16,233,464	2,022,234	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 13,659,576</b>	<b>\$ 1,031,922</b>	<b>\$ 13,659,576</b>
<b>Cash paid for interest</b>	<b>\$</b>	<b>\$</b>	<b>\$ 150,000</b>



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**Supplemental schedule of non-cash investing and financing activities:**

Warrants issued in settlement 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 condensed financial statements.

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

March 31, 2008

(unaudited)

**1. DESCRIPTION OF BUSINESS**

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

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

**2. BASIS OF PRESENTATION**

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through March 31, 2008, its efforts have been principally devoted to developing its licensed technologies, recruiting personnel, establishing office facilities, and raising capital. Accordingly, the accompanying 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 March 31, 2008 and 2007 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 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.

**3. LIQUIDITY AND CAPITAL RESOURCES**

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For the three months ended March 31, 2008, the Company reported a net loss of \$3,058,937, and the net loss from the date of inception, August 1, 2005 to March 31, 2008 was \$15,953,747. Total cash balance as of March 31, 2008 was \$13,659,576 compared to \$16,233,464 at December 31, 2007.

Through March 31, 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 private placements of common stock and debt financing. 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.

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

March 31, 2008

(unaudited)

The Company plans to continue to fund operations from its existing cash balances and additional funds raised through various sources, such as equity and debt financing. Based on its resources at March 31, 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 success of the Company depends on its ability to discover and develop new products to the point of 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 all operations for the next 12 to 24 months, management can provide no assurances that the Company will be able to raise such sufficient funds.

**4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**(a) Use of Estimates**

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

**(b) Cash and Cash Equivalents**

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

**(c) Restricted Cash**

In February 2008, the Company entered into an office lease agreement. This lease agreement required us to issue a security deposit in the amount of \$54,929. To satisfy this obligation, we opened a \$54,929 line of credit, with the landlord as the beneficiary in case of default or failure to comply with the lease requirements. In order to fund the line of credit, we were required to deposit a compensating balance of \$54,929 into a certificate of deposit with our financial institution. This compensating balance for the line of credit will be restricted for the entire period of the three year lease agreement. It is included in other non-current assets on the balance sheet.

**(d) Prepaid Expenses**

Prepaid expenses consist of payments made in advance to vendors relating to service contracts and insurance policies. These advanced payments are amortized to expense either as services are performed or over the relevant service period under the straight line method.

**(e) Property and Equipment**

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

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

<b>Description</b>	<b>Estimated Useful Life</b>
Office equipment and furniture	5 to 7 years
Leasehold improvements	3 years
Computer equipment	3 years

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

March 31, 2008

(unaudited)

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

Intangible assets consist of costs related to acquiring patents and to prosecuting and maintaining intellectual property rights, and are amortized using the straight-line method over the estimated useful lives. 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 better reflects the uncertainty of the future benefit of the patent assets. The change in the useful life of the Company's patent assets resulted in a net increase in expense of approximately \$19,200 for the quarter ended March 31, 2008. 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.

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

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

**(h) Fair Value of Financial Instruments**

Financial instruments included in the Company's balance sheets consist of cash and cash equivalents and accounts payable. The carrying amounts of these instruments reasonably approximate their fair values due to their short maturities.

**(i) Concentration of Credit Risk**

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents. The Company deposits cash and cash equivalents with high credit quality financial institutions and is insured to the maximum limitations. Balances in these accounts may exceed federally insured limits, which exposes us to institutional risk.

**(j) Research and Development**

Research and development costs are charged to expense as incurred. Research and development includes fees associated with operational consultants, contract clinical research organizations, contract manufacturing organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated executive, human resources and facilities expenses. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in the period when actual costs become known. Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development costs.

**(k) Grant income**

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

**(l) Stock-Based Compensation**

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

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

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March 31, 2008

(unaudited)

**(m) Loss per Common Share**

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

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

Potentially dilutive securities include:

	March 31, 2008	March 31, 2007
Warrants to purchase common stock	375,249	
Options to purchase common stock	4,126,512	206,910
<b>Total potentially dilutive securities</b>	<b>4,501,761</b>	<b>206,910</b>

**(n) Comprehensive Loss**

We have no components of other comprehensive loss other than our net loss, and accordingly, comprehensive loss is equal to net loss for all periods presented.

**(o) Income Taxes**

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

**(p) Recently Issued Accounting Standards**

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141R), which replaces SFAS 141. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS 141R is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The Company does not anticipate that the adoption of this new standard will have a



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material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an Amendment of Accounting Research Bulletin No. 51* (SFAS 160), which establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The Company does not anticipate that the adoption of this new standard will have a material impact on its financial statements.

### **(q) Reclassifications**

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

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

March 31, 2008

(unaudited)

**5. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY**

**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. The next milestone payment to Mayo will be made when the first patient is dosed in the first Company-sponsored Phase II clinical trial of CD-NP. The Company will also pay substantial milestone payments to Mayo upon the receipt of regulatory approval for each additional indication of CD-NP, as well as for additional compounds or analogues contained in the intellectual property. Pursuant to the Mayo License Agreement, the Company will pay Mayo an annual maintenance fee and a percentage of net sales of licensed products, as well as \$50,000 per year for the consulting services of Dr. Burnett while serving as chairman of the Company's Scientific Advisory Board.

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 March 31, 2008, the Company received \$482,235 in grant income for which it has issued to Mayo 63,478 shares, representing \$182,236 of common stock.

**2NTX-99**

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

Under the 2NTX-99 License Agreement, the Company made an up-front cash payment to Dr. Casagrande and reimbursed him for past patent expenses. The Company also issued to Dr. Casagrande 350,107 shares of common stock. Additionally, the agreement provides for cumulative performance-based milestone payments to Dr. Casagrande upon completion of clinical and regulatory milestones relating to 2NTX-99 in the U.S., Europe and Japan. The Company will also be required to make certain 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.

**6. STOCKHOLDERS EQUITY**

**(a) Common Stock**

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In August 2005, the Company issued an aggregate 13,794,132 shares of common stock to its founders for \$5,000. The founders subsequently returned 1,379,413 of these shares to the Company for issuance to Mayo. In January 2006 the Company issued 1,379,413 shares of common stock to Mayo, pursuant to the terms of the 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.

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

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

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(unaudited)

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

As a condition to the closing of the Merger, on September 11, 2007, 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.

**(b) Warrants**

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

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, we issued these warrants in settlement of the accrued liability.

**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 authorizes a total of 2,000,000 shares of common stock for issuance. Under the Plan, incentives may be granted to officers, employees, directors, consultants, and advisors. Incentives under the Plan may be granted in any one or a combination of the following forms: (a) incentive stock options and non-statutory stock options; (b) stock appreciation rights (c) stock awards; (d) restricted stock and (e) performance shares.

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

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The Company records compensation expense associated with stock options and other forms of equity compensation in accordance with SFAS 123(R), 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:

Expected volatility	68% to 89%
Expected terms	5.00 to 6.25 years
Dividend yield	0%
Risk-free interest rates	2.00% to 4.28%

**Table of Contents****NILE THERAPEUTICS, INC.****(a development stage company)****NOTES TO CONDENSED FINANCIAL STATEMENTS**

March 31, 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 SEC Staff Accounting Bulletin No. 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.

Employee stock compensation costs for the cumulative period from August 1, 2005 (inception) to March 31, 2008 totaled \$2,543,704 of which \$2,429,695 was included in general and administrative expense and \$114,009 was included in research and development expense. For the quarters ended March 31, 2008 and 2007, the Company recorded stock-based compensation of \$621,372 and \$0, respectively.

At March 31, 2008, the total outstanding, and the total exercisable, options under the Plan were as follows:

	Number Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Total outstanding options	3,532,769	\$ 3.05	9.29 years	\$ 5,627,710
Total exercisable options	449,735	\$ 1.99	6.82 years	\$ 1,180,521

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

In December 2007, 30,000 options for common stock with an exercise price of \$5.75 that vest monthly over 36 months were granted to an advisor. The Company has expensed \$10,543 in connection with these options in the first quarter of 2008.

Activity with respect to options granted under the Plan is summarized as follows:

**For the Quarter  
Ended  
March 31, 2008**

**For the Quarter Ended  
March 31, 2007**

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	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	2,912,681	\$ 2.72	206,910	\$ 0.09
Granted in the quarter	657,588	4.49		
Exercised				
Surrendered/cancelled				
Forfeited	37,500	2.71		
Outstanding at March 31, 2008 and 2007, respectively	3,532,769	\$ 3.05	206,910	\$ 0.09
Exercisable at March 31, 2008 and 2007, respectively	449,735	\$ 1.99	206,910	\$ 0.09

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**NILE THERAPEUTICS, INC.**

**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

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(unaudited)

**8. RELATED PARTIES**

On occasion, some of the Company's expenses are 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. At March 31, 2008, reimbursable expenses totaled \$92,379, which was paid in full in May 2008.

The Company utilized the services of Riverbank Capital Securities, Inc. ( Riverbank ), an entity owned by several of the Company's officers, directors, and founders, for investment banking and other investment advisory services in connection with the Financing. We paid \$100,000 nonaccountable expense allowance to Riverbank for these services and are not obligated to them for any future payments.

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 Group. The remaining warrants were granted to outside consultants. In March 2008, the Company issued these warrants in settlement of the accrued liability.

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 principle offices effective April 1, 2008 from Berkeley, California to San Francisco, California. The Company leased a single office facility in Berkeley, California under a non-cancelable operating lease that expires in April 2010. The total undiscounted future lease payments under this lease as of March 31, 2008 was approximately \$162,000. The Company is attempting to sublease this office space. As the Company may not be able to sub-lease the vacated office space, the Company has recorded a loss liability of approximately \$138,500, which is equal to the total future lease payments through the end of the lease, discounted at 16%.

The Company's office lease in San Francisco, California expires in March 2011. Future non-cancelable minimum lease payments under this 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 made a cash deposit of approximately \$55,000.

A former executive of the Company terminated his employment agreement with the Company on May 21, 2007. On August 10, 2007, the Company entered into a Separation Agreement and General Release (the Separation Agreement ) with the executive. Pursuant to the terms of the Separation Agreement, the Company will continue to pay the executive's base salary, performance bonus, and benefits until May 21, 2008. As of December 31, the Company had accrued expenses of approximately \$302,000 related to these payments. Payment in full was made in January 2008. In addition, the Company issued an option to purchase 593,743 shares of the Company's common stock immediately following the closing of the Financing. The options expire on September 17, 2012. The executive was provided with limited piggy-back registration rights and was reimbursed for approximately \$12,000 in attorney's fees.

**10. SUBSEQUENT EVENTS**

On May 13, 2008, the Company's shares began trading on the Nasdaq Capital Market under the trading symbol NLTX.





**Table of Contents****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 and Risk Factors. 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, our 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 I 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, antiatherothrombotic agent with nitric oxide (NO) donating properties.

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 candidates. Developing pharmaceutical products, however, 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, our second product candidate, our research and development expenses will further increase. To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance further research and development will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products. Our major sources of working capital have been proceeds from private sales of Old Nile 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 123(R), *Share-Based Payment*, or SFAS 123R. SFAS 123R requires us to expense the fair value of stock options and warrants over the vesting period. We determine the fair value of stock options using the Black-Scholes options 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 two product candidates, CD-NP, in clinical development for the treatment of heart failure, and 2NTX-99, which is in pre-clinical development and has potential utility in atherosclerotic, thrombotic, and microvascular diseases.

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*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 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 plasma cGMP, a secondary messenger of the target receptor, preserved renal function, increased natriuresis and diuresis and 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 inhibits 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.

***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 the second quarter of 2008, we expect to initiate 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 acute myocardial infarction.

In addition to our own studies, Mayo will initiate 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.

***Results of Operations for the Three Months Ended March 31, 2008 as compared to the Three Months Ended March 31, 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 revenues during the three months ended March 31, 2008 and 2007 because we do not have any commercial products.

*Research and Development Expenses.* Research and development expenses for the three months ended March 31, 2008 and 2007 were \$1,978,184 and \$558,248, respectively. These expenses include cash and non-cash expenses relating to the development of our clinical and pre-clinical programs. Clinical development expenses in the first quarter of 2008 were \$428,429 higher than in the first quarter of 2007 due to an increase in sponsored clinical trial expenses. Manufacturing expenses in the first quarter of 2008 were \$567,610 higher than in the first quarter of 2007 due to an increase in manufacturing activities for CD-NP and the addition of manufacturing activities for 2NTX-99. The remainder of the increase were due to an increase in research and development personnel and the addition of other, non-manufacturing expenses supporting the 2NTX-99 program. 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 and organizational affairs, and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our research and development costs as they are incurred.

*General and Administrative Expenses.* General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development and general legal activities. General and administrative expenses for the three months ended March 31, 2008 and 2007 were

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\$1,198,339 and \$156,680, respectively. General and administrative personnel expenses in the first quarter of 2008 increased by \$717,169 due to an increase in general and administrative personnel. The remainder of increase was due to an increase in leased office space, and an increase in the use of legal and accounting professional services.

*Interest Income.* Interest income for the three months ended March 31, 2008 and 2007 was \$149,436 and \$16,668, respectively. The increase of \$132,768 was attributed to having more cash to invest from the financing on September 11, 2007, whereby we received gross proceeds of \$19,974,747, which has been offset by declining interest rates.

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*Interest Expense.* Interest expense for the three months ended March 31, 2008 and 2007 was \$137 and \$59,178, respectively. The decrease of \$59,041 is primarily attributable to the conversion of 6% convertible promissory notes that we issued in March 2006, which had an aggregate principal amount and outstanding interest equal to \$4,351,165 and which automatically converted upon the closing of the Financing into 1,684,085 shares of our common stock at a conversion price of \$2.58.

Due to the factors mentioned above, the net loss for the three months ended March 31, 2008 was \$3,058,937, or a loss of \$0.13 per share of common stock, basic and diluted, as compared to a loss of \$757,418 for the three months ended March 31, 2007, or a loss of \$0.05 per common share, basic and diluted.

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

There were no off-balance sheet arrangements as of March 31, 2008.

### ***License Agreement Commitments***

Per our license agreement with Mayo for CD-NP, upon achieving the next milestone, dosing of the first patient in a Phase II trial, we will remit a milestone payment of \$400,000 to Mayo. We estimate that this payment will be made in the second quarter of 2008. Subsequent milestones will require us to remit additional milestone payments to Mayo.

Per our license agreement with Dr. Casagrande, upon achieving the next milestone, dosing of the first patient in a Phase I trial, we will remit 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 quarter of 2009. Subsequent milestones will require us to remit additional milestone payments to Dr. Casagrande.

### ***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 settlement of the accrued liability.

### ***Plant and Equipment***

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

### ***Employees***

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

As part of our planned expansion, we have hired a VP of Regulatory as reported by an 8-K filed with the SEC on May 1, 2008. We may hire additional research and development staff, as required, to support our product development.

### ***Liquidity and Capital Resources***

For the three months ended March 31, 2008, we had a net loss of \$3,058,937. From inception to March 31, 2008, we have incurred an aggregate net loss of \$15,953,747, primarily through a combination of research and development activities related to the licensed technology 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 three months ended March 31, 2008, we experienced a decrease in cash and cash equivalents of \$2,573,888. This decrease primarily resulted from net cash used on operating activities.



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Total cash resources as of March 31, 2008 were \$13,659,576 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 March 31, 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 March 31, 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 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***

Our condensed financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these condensed 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. 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 that the assumptions and estimates associated with stock-based compensation have the greatest potential impact on our condensed financial statements. Therefore, we consider these to be our critical accounting policies and estimates. For further information on all of our significant accounting policies, please see Note 4 of the accompanying notes to our condensed financial statements.

### ***Stock-based compensation***

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants. The Company 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 Statement of Financial Accounting Standards 123(R), *Share-Based Payment* (SFAS 123R). 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 options 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 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, in accordance with the provisions of SFAS 123, and EITF No. 96-18, 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.

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***Recently Issued Accounting Standards***

In December 2007, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 141 (revised 2007), *Business Combinations*, or SFAS 141R, which replaces SFAS 141. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS 141R is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We do not anticipate that the adoption of this new standard will have a material impact on our financial statements.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an Amendment of Accounting Research Bulletin No. 51*, or SFAS 160, which establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not anticipate that the adoption of this new standard will have a material impact on our financial statements.

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

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings.**



## Edgar Filing: Nile Therapeutics, Inc. - Form 10-Q

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.

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

Not applicable.

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

Not applicable.

**Item 5. Other Information.**

Not applicable.

**Item 6. Exhibits**

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

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**SIGNATURES**

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

**NILE THERAPEUTICS, INC.**

Date: May 15, 2008

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

Date: May 15, 2008

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

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