Nile Therapeutics, Inc.
Form 10-Q
November 13, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

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

As of November 13, 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

	September 30, 2008 (unaudited)	December 31, 2007
ASSETS		
Current assets		
Cash and cash equivalents	$ 7,363,926	$ 16,233,464
Prepaid expenses and other current assets	641,247	526,303
Total current assets	8,005,173	16,759,767
Property and equipment, net	79,849	62,838
Intangible assets, net	217,771	252,723
Other noncurrent assets	106,109	14,000
Total assets	$ 8,408,902	$ 17,089,328
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	$ 558,522	$ 658,773
Accrued expenses and other current liabilities	355,514	915,419
Due to related party	4,112	315,204
Total current liabilities	918,148	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	30,518,341	28,070,642
Deficit accumulated during the development stage	(23,051,737)	(12,894,810)
Total stockholders equity	7,490,754	15,199,932
Total liabilities and stockholders equity	$ 8,408,902	$ 17,089,328

See accompanying notes to unaudited condensed financial statements.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from August 1, 2005 (date of inception) to September 30, 2008
	2008	2007	2008	2007	
Grant income	$	$ 101,400	$	$ 101,400	$ 482,235
Operating expenses					
Research and development	2,556,900	2,175,558	7,423,738	3,596,835	15,257,436
General and administrative	818,761	2,562,891	2,977,263	3,284,387	7,634,687
Total operating expenses	3,375,661	4,738,449	10,401,001	6,881,222	22,892,123
Loss from operations	(3,375,661)	(4,637,049)	(10,401,001)	(6,779,822)	(22,409,888)
Other income (expense)					
Interest income	58,451	58,975	290,734	82,937	678,407
Interest expense		(970,330)	(137)	(1,089,344)	(1,272,934)
Other expense	(3,679)		(46,523)		(47,322)
Total other income (expense)	54,772	(911,355)	244,074	(1,006,407)	(641,849)
Net loss	$ (3,320,889)	$ (5,548,404)	$ (10,156,927)	$ (7,786,229)	$ (23,051,737)
Basic and diluted loss per share	$ (0.14)	$ (0.35)	$ (0.42)	$ (0.54)	
Weighted-average common shares outstanding	24,149,405	15,977,936	24,118,645	14,532,772	

See accompanying notes to unaudited condensed financial statements.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENT OF STOCKHOLDERS EQUITY

PERIOD FROM AUGUST 1, 2005 (DATE OF INCEPTION) TO SEPTEMBER 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			1,808,374		1,808,374
Non-employee stock-based compensation			54,383		54,383
Issuance of common shares pursuant to licensing agreement	49,689	50	249,950		250,000
Net loss				(10,156,927)	(10,156,927)
Balance at September 30, 2008	24,149,405	$ 24,150	$ 30,518,341	$ (23,051,737)	$ 7,490,754

See accompanying notes to unaudited condensed financial statements

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,		Period from August 1, 2005 (date of inception) to September 30, 2008
	2008	2007	
Cash flows from operating activities			
Net loss	$ (10,156,927)	$ (7,786,229)	$ (23,051,737)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	83,963	10,249	111,301
Stock-based compensation	2,447,749	2,633,177	5,542,116
Warrants issued to noteholders		288,000	288,000
Note discount due to beneficial conversion feature		483,463	483,463
Loss on disposal of assets	11,654		11,654
Non-cash interest expense		167,713	351,165
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	(114,944)	(368,685)	(641,247)
Other noncurrent assets	(92,109)	(14,000)	(106,109)
Accounts payable	(100,251)	212,349	558,522
Accrued expenses and other current liabilities	(559,905)	501,221	355,514
Due to related party	(311,092)	159,389	4,112
Net cash used in operating activities	(8,791,862)	(3,713,353)	(16,093,246)
Cash flows from investing activities			
Purchase of property and equipment	(45,314)	(49,644)	(122,241)
Cash paid for intangible assets	(32,362)	(92,639)	(298,334)
Net cash used in investing activities	(77,676)	(142,283)	(420,575)
Cash flows from financing activities			
Proceeds from issuance of notes payable		1,500,000	5,500,000
Repayment of notes payable		(1,500,000)	(1,500,000)
Proceeds from sale of common stock to founders			5,000
Proceeds from sale of common stock in private placement		19,872,747	19,872,747
Net cash provided by financing activities		19,872,747	23,877,747
Net (decrease) increase in cash and cash equivalents	(8,869,538)	16,017,111	7,363,926
Cash and cash equivalents at beginning of period	16,233,464	2,022,234	
Cash and cash equivalents at end of period	$ 7,363,926	$ 18,039,345	$ 7,363,926
Cash paid for interest	$	$ 150,000	$ 150,000
Supplemental schedule of non-cash investing and financing activities:			
Warrants issued in sastisfaction of accrued liability	$ 334,992	$	$ 334,992

Conversion of notes payable and interest to common stock	$	$ 4,351,165	$ 4,351,165
Common shares of SMI issued in reverse merger transaction	$	$ 1,250	$ 1,250

See accompanying notes to unaudited condensed financial statements.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 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 AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through September 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 September 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 accompanying Condensed 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.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2008

(unaudited)

Recently Issued Accounting Pronouncements

In June 2008, the Financial Accounting Standards Board, (FASB), issued FASB Staff Position, (FSP) Emerging Issuers Task Force (EITF) 03-6-1, *Determining Whether Instruments Granted in Share-Based Transactions Are Participating Securities*. This standard provides guidance in determining whether unvested instruments granted under share-based payment transactions are participating securities and, therefore, should be included in earnings per share calculations under the two-class method provided under SFAS No. 128, *Earnings per Share*. FSP EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company does not expect that the adoption of FSP EITF 03-6-1 will have a significant impact on its financial statements.

In April 2008, the FASB issued FSP FAS 142-3, *Determination of the Useful Life of Intangible Assets.* FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. FSP FAS 142-3 aims to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141(R) and other applicable accounting literature. FSP FAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and must be applied prospectively to intangible assets acquired after the effective date. The Company does not expect that the adoption of FSP FAS 142-3 will have a significant impact on its financial statements.

3. LIQUIDITY AND CAPITAL RESOURCES

For the nine months ended September 30, 2008, the Company reported a net loss of $10,156,927 and a net loss of $23,051,737 from the date of inception, August 1, 2005, to September 30, 2008. Total cash and cash equivalents were $7,363,926 as of September 30, 2008 compared to $16,233,464 as of December 31, 2007. Through September 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 September 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 into the second quarter 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 funds.

The recent economic downturn and market instability has made the business climate more volatile and more costly. If the current equity and credit markets deteriorate further, or do not improve, it may make necessary debt or equity financing more difficult, more costly, and more

dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on the Company s growth strategy, financial performance and stock price and could require the delay of new product development and clinical trial plans.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

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(unaudited)

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:

	September 30, 2008	September 30, 2007
Warrants to purchase common stock	375,249	168,337
Options to purchase common stock	4,391,519	3,404,019
Total potentially dilutive securities	4,766,768	3,572,356

5. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

Patents

Intangible assets consist of costs related to acquiring, prosecuting, and maintaining 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 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 September 30, 2008, intangible assets consisted of patents and patent applications acquired from third parties for the CD-NP, CU-NP and 2NTX-99 compounds. Amortization expense was $24,496 and $613 for the three months ended September 30, 2008 and 2007, respectively, $67,314 and $2,420 for the nine months ended September 30, 2008 and 2007, respectively, and $80,563 from the date of inception, August 1, 2005 to September 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 (date of inception) through September 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.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2008

(unaudited)

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 methods 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 intellectual property and to develop commercially CU-NP for all therapeutic indications. The Company also holds the rights to improvements to CU-NP that arise out of the laboratory of Drs. John Burnett and Candace Lee, the inventors of CU-NP, until June 13, 2011.

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 be made upon the occurrence of 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 unaudited Condensed Statements 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 unaudited 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.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2008

(unaudited)

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 unaudited 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 unaudited 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 unaudited 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 unaudited 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.

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.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2008

(unaudited)

A summary of the status of the options issued under the Plan at September 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	972,588	$ 4.68		
Options forfeited	(87,500)	$ 4.45		
Balance at September 30, 2008	3,797,769	$ 3.18	8.86	$ 3,985,042
Exercisable at September 30, 2008	919,561	$ 2.51	8.01	$ 1,454,718

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 granted to employees using the Black-Scholes option-pricing model and the following assumptions for the nine months ended September 30, 2008 and 2007:

	September 30, 2008	September 30, 2007
Expected volatility	75% to 89%	68%
Expected term	6.25 years	5.75 to 6.25 years
Dividend yield	0%	0%
Risk-free interest rates	1.98% to 3.44%	4.21% to 4.25%

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.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2008

(unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period from August 1, 2005 (date of inception) to September 30, 2008
	2008	2007	2008	2007	
Research and development expense	$ 168,861	$ 7,390	$ 351,824	$ 7,390	$ 391,668
General and administrative expense	455,368	1,446,884	1,456,550	1,446,884	3,319,004
Total stock-based compensation expense	$ 624,229	$ 1,454,274	$ 1,808,374	$ 1,454,274	$ 3,710,672

At September 30, 2008, total unrecognized estimated employee compensation cost related to stock options granted prior to that date was $5,335,406, which is expected to be recognized over a weighted-average period of 2.36 years.

In addition to the options issued under the Plan, in September 2007, 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 $783,750 as of September 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 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 $54,383 in connection with these options in the nine months ending September 30, 2008, and $57,049 from inception to September 30, 2008.

8. RELATED PARTIES

On occasion, some of the Company s expenses are paid by Two River, a company controlled by several of the Company s directors and founders. No interest is charged by Two River on any outstanding balance owed by the Company. As of September 30, 2008, reimbursable expenses totaled $4,112, which was paid in full in October 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.

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.

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NILE THERAPEUTICS, INC.

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(unaudited)

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 $27,000 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 approximately $55,000 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 approximately $55,000 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 in the accompanying unaudited Condensed Balance Sheets.

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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, or CNP, and the N- and C-termini of Urodilatin, or 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, most 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 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, or SFAS, No. 123(R), *Share-Based Payment,* or SFAS 123R. 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 condensed 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.

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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, or 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, 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.

In October 2008, we announced interim results of an ongoing Phase IIa study of CD-NP. Results from the first cohort of patients in the study suggested that CD-NP was associated with a statistically significant reduction in pulmonary capillary wedge pressure, a statistically significant increase in diuresis, a trend toward reduction in right atrial pressure, and a trend toward increase in cardiac output at dose levels where patients did not experience symptomatic hypotension or an observed change in serum creatinine.

2NTX-99 Program - 2NTX-99 is a small molecule anti-platelet, anti-atherothrombotic agent with nitric oxide, or NO, donating properties currently in pre-clinical development. Mechanistically, 2NTX-99 is believed to inhibit the synthesis and action of thromboxane and enhance 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. Indications could include intermittent claudication, diabetic nephropathy or pulmonary arterial hypertension. We initiated pre-clinical toxicology and manufacturing activities for 2NTX-99 in 2007.

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 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 dosing the Phase Ib and IIa trials in the fourth quarter of 2008.

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.

In the first half of 2009, we expect to initiate a Phase IIb trial to study CD-NP in patients with acute decompensated heart failure.

For 2NTX-99, we are progressing with IND-enabling development and pharmacological studies that could facilitate entering human testing in 2009.

For CU-NP, we have initiated the pre-clinical development program pharmacology studies which should continue into 2009.

Results of Operations for the Three and Nine Months Ended September 30, 2008 as compared to the Three and Nine Months Ended September 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 nine months ended September 30, 2008 and 2007 as none of our product candidates have been approved for commercialization.

Research and Development Expenses. Research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for 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.

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Research and development expenses for the three months ended September 30, 2008 increased $0.4 million, or 18%, as compared to the same quarter in 2007. This increase was due primarily to an increase in clinical trial expenses of $0.7 million and manufacturing expenses of $0.3 million, both associated with CD-NP. In addition, salaries and related expenses increased $0.3 million, due to increase in research and development personnel. These increases were partially offset by a decrease of $1.0 million in licensing and milestone expenses.

Research and development expenses for the nine months ended September 30, 2008 increased $3.8 million, or 106%, as compared to the same period in 2007. The increase is primarily due to an increase of $1.3 million in manufacturing expenses and $1.9 million in clinical development expenses. Manufacturing expenses, including formulation development and drug product manufacturing increased due to the increase in manufacturing activities for both CD-NP and 2NTX-99. Clinical development expenses increased in relation to sponsored clinical trial expenses. Also, 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.

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 September 30, 2008 decreased by $1.7 million, or 68%, as compared to the same quarter in 2007. The decrease was due primarily to a decrease in stock-based compensation of $1.0 million, and a decrease of $0.7 million in professional fees related primarily to the merger and private sale of common stock in September 2007.

General and administrative expenses for the nine months ended September 30, 2008 decreased by $0.3 million, or 9%, as compared to the same period in 2007 as a result of merger costs incurred in the nine months ended September 30, 2007 of $0.5 million offset by increased costs for insurance, rent and other related office expense, and audit and accounting fees.

Interest Income. Interest income for the three months ended September 30, 2008 and 2007 was approximately $59,000 and $58,000, respectively, and for the nine months ended September 30, 2008 and 2007 was approximately $291,000 and $83,000, respectively. The increase is due to higher cash balances in 2008 resulting from the raising of $20 million in the third quarter of 2007.

Interest Expense. Interest expense for the three months ended September 30, 2008 and 2007 was $0 and $1.0 million, respectively, and for the nine months ended September 30, 2008 and 2007 was $0 and $1.1 million, 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 million.

Off-Balance Sheet Arrangements

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

License Agreement Commitments

Pursuant to our license agreement with Mayo for CD-NP, in July 2008 we 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 to Dr. Casagrande. 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 the 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 be made upon the occurrence upon other events. Pursuant to the agreement, we must also pay

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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.

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 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 nine months ended September 30, 2008, we incurred a net loss of $10.2 million. From inception to September 30, 2008, we have incurred an aggregate net loss of $23.1 million, primarily through a combination of research and development activities related to the licensed technologies under our control and expenses supporting those activities. We expect to incur additional losses in the future as we increase our research and development and clinical development activities.

We have not generated any revenue from operations to date, and we do not expect to generate revenue for several years, if ever. We have financed our operations since inception primarily through debt and equity financings. During the nine months ended September 30, 2008, we experienced a decrease in cash and cash equivalents of approximately $8.9 million. This decrease primarily resulted from net cash used in operating activities.

Total cash resources as of September 30, 2008 were $7.4 million compared to $16.2 million 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 September 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 September 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 into the second quarter 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 of our research and development programs. Each of these alternatives would likely have a material adverse effect on the prospects of our business.

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The recent economic downturn and market instability has made the business climate more volatile and more costly. Our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon new product development and clinical trial plans.

Critical Accounting Policies and Estimates

Our unaudited 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 including clinical trial accruals and stock-based compensation estimates. 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 have issued stock options to employees, directors, consultants and Scientific Advisory Board members under the Amended and Restated 2005 Stock Option Plan.

We account for employee stock-based compensation in accordance with SFAS 123R which 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 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.

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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.
Not applicable

Item 5. Other Information.
Not applicable.

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Item 6. Exhibits

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

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SIGNATURES

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

NILE THERAPEUTICS, INC.

Date November 13, 2008

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

Date November 13, 2008

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

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