Nile Therapeutics, Inc.
Form 10-Q
August 13, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2009

¨ 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)

Not Applicable

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 August 10, 2009, there were 24,215,477 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. Financial Statements.

NILE THERAPUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED BALANCE SHEETS

	June 30, 2009 (unaudited)	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,770,226	$ 5,500,790
Prepaid expenses and other current assets	185,368	544,834
Total current assets	1,955,594	6,045,624
Property and equipment, net	59,810	73,699
Intangible assets, net	131,424	209,549
Other noncurrent assets	107,066	106,597
Total assets	$ 2,253,894	$ 6,435,469
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	$ 200,287	$ 738,895
Accrued expenses and other current liabilities	159,666	586,256
Due to related party	80,437	6,700
Total current liabilities	440,390	1,331,851
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 shares issued and outstanding	24,150	24,150
Additional paid-in capital	32,094,658	31,105,874
Deficit accumulated during the development stage	(30,305,304)	(26,026,406)
Total stockholders equity	1,813,504	5,103,618
Total liabilities and stockholders equity	$ 2,253,894	$ 6,435,469

See accompanying notes to condensed financial statements.

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NILE THERAPUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three months ended June 30,		Six months ended June 30,		Period from August 1, 2005 (inception) through June 30,
	2009	2008	2009	2008	2009
Grant income	$	$		$	$ 482,235
Operating expenses:					
Research and development	1,103,428	2,888,654	2,428,032	4,866,838	19,739,552
General and administrative	1,397,689	960,164	1,860,157	2,158,503	10,439,745
Total operating expenses	2,501,117	3,848,818	4,288,189	7,025,341	30,179,297
Loss from operations	(2,501,117)	(3,848,818)	(4,288,189)	(7,025,341)	(29,697,062)
Other income (expense):					
Interest income	5,886	82,848	20,573	232,284	740,753
Interest expense				(137)	(1,272,934)
Other expense	(4,859)	(11,131)	(11,282)	(42,844)	(76,061)
Total other income (expense)	1,027	71,717	9,291	189,303	(608,242)
Net loss	$ (2,500,090)	$ (3,777,101)	(4,278,898)	$ (6,836,038)	$ (30,305,304)
Basic and diluted loss per share	$ (0.10)	$ (0.16)	(0.18)	$ (0.28)	
Weighted-average common shares outstanding	24,149,405	24,106,341	24,149,405	24,103,010	

See accompanying notes to condensed financial statements.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)

PERIOD FROM AUGUST 1, 2005 (DATE OF INCEPTION) TO JUNE 30, 2009

(unaudited)

	COMMON STOCK			DEFICIT ACCUMULATED DURING THE	
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	DEVELOPMENT STAGE	TOTAL STOCKHOLDERS EQUITY (DEFICIT)
Issuance of common shares to founders	13,794,132	$ 13,794	$ (8,794)	$	$ 5,000
Founders shares returned to treasury	(1,379,419)				
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
Warrants issued in connection with note conversion			288,000		288,000
Conversion of notes payable upon event of merger	1,684,085	1,684	4,349,481		4,351,165
Note discount arising from beneficial conversion feature			483,463		483,463
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			2,436,603		2,436,603
Non-employee stock-based compensation			13,687		13,687
Issuance of common shares pursuant to licensing agreement	49,689	50	249,950		250,000
Net loss				(13,131,596)	(13,131,596)
Balance at December 31, 2008	24,149,405	24,150	31,105,874	(26,026,406)	5,103,618
Employee stock-based compensation			860,412		860,412

Non-employee stock-based compensation			128,372		128,372
Net loss				(4,278,898)	(4,278,898)
Balance at June 30, 2009	24,149,405	$ 24,150	$ 32,094,658	$ (30,305,304)	$ 1,813,504

See accompanying notes to condensed financial statements.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Six months ended June 30,		Period from August 1, 2005 (inception) through June 30, 2009
	2009	2008	
Cash flows from operating activities			
Net loss	$ (4,278,898)	$ (6,836,038)	$ (30,305,304)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	102,838	53,316	243,464
Stock-based compensation	988,784	1,826,174	7,118,433
Warrants issued in connection with note conversion			288,000
Note discount arising from beneficial conversion feature			483,463
Loss on disposal of assets		11,654	11,654
Noncash interest expense			351,165
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	359,466	110,359	(185,368)
Other non-current assets	(469)	(91,623)	(107,066)
Accounts payable	(538,608)	37,132	200,287
Accrued expenses and other current liabilities	(426,590)	(615,064)	159,666
Due to related party	73,737	(311,922)	80,437
Net cash used in operating activities	(3,719,740)	(5,816,012)	(21,661,169)
Cash flows from investing activities			
Purchase of property and equipment		(45,314)	(122,241)
Cash paid for intangible assets	(10,824)	(24,381)	(324,111)
Net cash used in investing activities	(10,824)	(69,695)	(446,352)
Cash flows from financing activities			
Proceeds from issuance of notes payable			5,500,000
Repayment of notes payable			(1,500,000)
Proceeds from sale of common stock to founders			5,000
Proceeds from sale of common stock in private placement			19,872,747
Net cash provided by financing activities			23,877,747
Net (decrease) increase in cash and cash equivalents	(3,730,564)	(5,885,707)	1,770,226
Cash and cash equivalents at beginning of period	5,500,790	16,233,464	
Cash and cash equivalents at end of period	$ 1,770,226	$ 10,347,757	$ 1,770,226

Supplemental schedule of cash flows information:			
Cash paid for interest	$	$	$ 150,000
Supplemental schedule of non-cash investing and financing activities:			
Warrants issued in satisfaction of accrued liability	$	$ 334,992	$ 334,992
Conversion of notes payable and interest to common stock	$	$	$ 4,351,165
Common shares of SMI issued in reverse merger transaction	$	$	$ 1,250

See accompanying notes to condensed financial statements.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

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 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, Old Nile was merged with and into the Company, with the Company remaining as the surviving corporation to that merger. In connection with that short-form merger, the Company changed its name to Nile Therapeutics, Inc. These two merger transactions are hereinafter collectively 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 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 June 30, 2009, 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 Company s financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has experienced net losses since its inception and has an accumulated deficit of approximately $30.3 million at June 30, 2009. 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.

The accompanying unaudited Condensed Financial Statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q adopted under the Securities Exchange Act of 1934, as amended. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of Nile s management, the accompanying Condensed Financial Statements contain all adjustments (consisting of normal recurring accruals and adjustments) necessary to present fairly the financial position, results of operations and cash flows of the Company at the dates and for the periods indicated. The interim results for the period ended June 30, 2009 are not necessarily indicative of results for the full 2009 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-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission.

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 periods. 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.

Recently Issued Accounting Standards

In May, 2009, the Financial Accounting Standards Board (FASB) issued SFAS No. 165, Subsequent Events. SFAS No. 165 prescribes the period after the balance sheet date during which management should evaluate transactions for potential recognition, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date and the required disclosures an entity should make about transactions or events occurring after the balance sheet date. This statement is effective for interim or annual periods ending after June 15, 2009. The adoption of SFAS 165 did not have a material impact on the Company s condensed financial statements. The Company evaluated subsequent events through the date the accompanying financial statements were issued, which was August 13, 2009.

In April 2009, the FASB issued FASB Staff Position No. 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, (FSP FAS 107-1). FSP FAS 107-1 amends FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. FSP FAS 107-1 is effective for interim reporting periods ending after June 15, 2009. The adoption of FSP FAS 107-1 did not have a material impact on the Company s condensed financial statements.

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 UNAUDITED CONDENSED FINANCIAL STATEMENTS

3. LIQUIDITY AND CAPITAL RESOURCES

On July 7, 2009, as a subsequent event to the quarter ending June 30, 3009, the Company entered into a Securities Purchase Agreement with certain investors pursuant to which the Company agreed to sell to such investors in a private placement 2,691,394 units of its securities. Each unit included one share of common stock and one five-year warrant to purchase a share of common stock. See Note 6a, 6b and 8. The private placement was completed on July 15, 2009 and resulted in gross proceeds to the Company of $3,368,750 before deducting expenses.

Cash resources as of June 30, 2009 were $1.8 million, compared to $5.5 million as of December 31, 2008. Based on its resources at June 30, 2009, the planned cost savings measures, the net proceeds from the Company s July 2009 private placement, and the current plan of expenditure on continuing development of current products, the Company believes that it has sufficient capital to fund its operations through 2010. However, pending results of the Company s ongoing Phase II clinical trial of CD-NP, the Company would need substantial additional capital in order to initiate and fund the next clinical study of CD-NP, which is expected to be a Phase IIb clinical trial. Cost savings implemented in the quarter ended June 30, 2009 included a significant staff reduction and the increased use of part-time consultants. 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 research and development programs, including competitive and technical advances; and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights. If the Company is unable to raise additional funds when needed, the Company may not be able to market its products as planned or continue development and regulatory approval of its products, the Company could be required to delay, scale back or eliminate some or all research and development programs and may need to wind down the Company s operations altogether. Each of these alternatives would likely have a material adverse effect on the Company s business.

To the extent that the Company raises additional funds by issuing equity or convertible or non-convertible debt securities, its stockholders may experience additional significant dilution and such financing may involve restrictive covenants. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to the Company s technologies or its product candidates, or grant licenses on terms that may not be favorable to it. These things may have a material adverse effect on the Company s business.

The continuation of the Company s business beyond 2010 is dependent upon obtaining further long-term financing, the successful development of its drug product candidates and related technologies, the successful and sufficient market acceptance of any product offerings that the Company may introduce, and, finally, the achievement of a profitable level of operations. The issuance of additional equity securities by the Company may result in a significant dilution in the equity interests of current stockholders. Obtaining commercial loans, assuming those loans would be available, including on acceptable terms, will increase the Company s liabilities and future cash commitments.

4. BASIC AND DILUTED LOSS PER 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 loss per share as their effect is anti-dilutive.

Potentially dilutive securities include:

	June 30, 2009	June 30, 2008

Warrants to purchase common stock	375,249	375,249
Options to purchase common stock	4,582,682	4,376,519
Total potentially dilutive securities	4,957,931	4,751,768

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

5. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

Patents

At June 30, 2009, intangible assets consisted of patents and patent applications acquired from third parties for the CD-NP and CU-NP compounds. Amortization expense was $20,401 and $20,195 for the three months ended June 30, 2009 and 2008, respectively, $88,949 and $42,818 for the six months ended June 30, 2009 and 2008. There was a onetime charge of $48,500 in the six months ended June 30, 2009 for the impairment of patents and patent applications associated with 2NTX-99. Amortization expense of $192,688 has been recorded for the period from August 1, 2005 (inception) through June 30, 2009.

License Agreements

CD-NP

On January 16, 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 held the rights to improvements to CD-NP that arise out of the laboratory of Dr. John Burnett, the inventor of CD-NP, until January 19, 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 from August 1, 2005 (inception) through June 30, 2009, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares (representing $182,236) of common stock.

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 Dr. John Burnett and Dr. 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 the licensed product. Additional milestone payments will occur upon certain other events. Pursuant to the agreement, Nile must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

In addition to the cash payments described above with respect to the CU-NP Mayo License Agreement, the Company has also agreed to issue certain amounts and types of equity to Mayo. In June 2008, the Company issued 49,689 shares of common stock to Mayo having a fair market value as of June 13, 2008 equal to $250,000. This amount has been recorded in research and development expenses in the accompanying

Condensed 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.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

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. 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. In January 2009, the Company determined to discontinue the 2NTX-99 program so that it could focus its resources on the development of its natriuretic peptide franchise, including CD-NP which is in Phase II development for acute heart failure, and CU-NP which is a pre-clinical compound. Accordingly, the Company terminated the 2NTX-99 License Agreement, returning the rights to the molecule to Dr. Casagrande, effective April 16, 2009. As such, the Company recorded an impairment charge of $48,500 for unamortized patent costs, which is included in research and development expense in the Condensed Statement of Operations.

6. STOCKHOLDERS EQUITY

(a) Common Stock

In August 2005, the Company issued an aggregate of 13,794,132 shares of common stock to its founders for $5,000. The founders subsequently returned 1,379,419 of these shares to the Company for issuance to Mayo. In January 2006 the Company issued 1,379,419 shares of common stock to Mayo, pursuant to the terms of the Mayo Licensing Agreement. The fair value of these shares of $500 was recorded as stock-based compensation and is included in research and development expense in the accompanying Condensed Statements of Operations.

In August 2007, pursuant to the terms of the 2NTX-99 License Agreement, the Company issued 350,107 shares of common stock to Dr. Casagrande. The fair value of the shares was $1,000,000 and was recorded as research and development expense in the accompanying 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, $182,236, was recorded as research and development expense in the accompanying Statements of Operations.

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

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

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

Subsequent to the quarter ended June 30, 2009, on July 7, 2009, the Company entered into a Securities Purchase Agreement with certain qualified investors pursuant to which it agreed to sell 2,691,394 units of its securities in a private placement, resulting in aggregate gross proceeds of $3,368,750. Each unit included one share of common stock and one warrant to purchase a share of common stock. See Note 6b. Issuance costs related to the financing were $73,850, plus the issuance of warrants (Placement Warrants) to purchase 218,300 shares of common stock to designees of Riverbank Capital Securities, Inc. (Riverbank) a FINRA member broker dealer that acted as placement agent for the Company in connection with the private placement. See Note 8.

The Company agreed to file a registration statement with the Securities and Exchange Commission in order to register the resale of the shares of common stock, including shares of common stock issuable pursuant to the exercise of warrants and Placement Warrants, issued in the private placement. In the event the Company does not file the registration statement within 60 days following the closing of the financing, the Company has agreed to pay liquidated damages to the investors in the amount of 1% of such investor s aggregate investment amount each month until the registration statement is filed.

(b) Warrants

In conjunction with the conversion of $4,351,165 of convertible debt prior to the Merger, the Company issued fully vested warrants to purchase 168,337 shares of common stock to the holders of such debt. The warrants were issued with an exercise price of $2.71 and expire in September 2012. The fair value of the warrants was determined to be $288,000. None of these warrants have been exercised to date.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

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: an exercise price of $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, and its affiliates. See 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.

Subsequent to the quarter ended June 30, 2009, as discussed in Note 3 and Note 10, in connection with its July 2009 private placement, the Company issued 2,691,394 shares of common stock and five-year warrants to purchase an additional 2,691,394 shares of common stock. The warrants were issued in three separate tranches, as follows:

- Warrants to purchase 627,849 shares, representing 25% of the total warrant shares issued to investors, have an exercise price equal to $1.25, which represents 110% of the $1.14 consolidated closing bid price of the Company s common stock on July 7, 2009 (the Closing Bid Price);

- Warrants to purchase 627,848 shares, representing 25% of the total warrant shares issued to investors, have an exercise price equal to $1.71, which represents 150% of the Closing Bid Price; and

- Warrants to purchase 1,345,687 shares, representing 50% of the total warrant shares issued to investors, have an exercise price equal to $2.28, which represents 200% of the Closing Bid Price.

The warrants issued to investors in the July 2009 financing are redeemable by the Company, at a redemption price of $0.001 per warrant share, upon 30 days notice, if at any time, the volume weighted average price of the common shares for any 20 consecutive business days is equal to or greater than 200% of the exercise price of each warrant.

As consideration for its services as placement agent in connection with the July 2009 financing, the Company also issued to designees of Riverbank five-year warrants to purchase 218,300 shares of common stock at a price of $1.375 per share. These warrants have an aggregate fair-value of $199,700.

7. STOCK OPTION PLAN

The Company s Amended and Restated 2005 Stock Option Plan (the Plan) was initially 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. 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, resulting in an aggregate of 5,517,676 shares available under the Plan. 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.

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

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A summary of the status of the options issued under the Plan at June 30, 2009, and information with respect to the changes in options outstanding is as follows:

	Options Available for Grant	Options Outstanding Stock Options	Options Outstanding Weighted Average Exercise Price	Aggregate Intrinsic Value
Balance at January 1, 2006	5,310,766	206,910	$ 0.09	
Options granted under the plan	(2,802,329)	2,802,329	$ 2.85	
Options forfeited	96,558	(96,558)	$ 0.84	
Balance at December 31, 2007	2,604,995	2,912,681	$ 2.72	
Options granted under the plan	(1,152,588)	1,152,588	$ 4.09	
Options forfeited	87,500	(87,500)	$ 4.45	
Balance at December 31, 2008	1,539,907	3,977,769	$ 3.08	
Options granted under the plan	(1,170,148)	1,170,148	$ 0.89	
Options forfeited	1,158,985	(1,158,985)	$ 3.45	
Balance at June 30, 2009	1,528,744	3,988,932	$ 2.58	$
Exercisable at June 30, 2009		2,531,496	$ 2.37	

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.

For the three months ended March 31, 2009, the Company granted options in exchange for accrued performance cash bonuses (Cash Bonus Options). Employees received a certain amount of options in exchange for up to 50% of their accrued performance cash bonus. The Company estimated the fair value of these options to be equal to the amount of cash bonus exchanged for the options divided by the number of options granted. The options were 100% vested on the date of the grant, January 16, 2009. In addition, employees were given the option of exchanging the remaining 50% of their performance cash bonus for 50% more options than were exchanged for the first 50% of their performance cash bonus. An additional $23,293 in compensation costs was expensed in the first quarter as a result of this incremental incentive to preserve the Company s cash.

Excluding the Cash Bonus Options, for the six months ended June 30, 2009, 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 six months ended June 30, 2009 and 2008:

	June 30, 2009	June 30, 2008
Expected volatility	117%	75% to 89%

Expected term	3 years	5.75 to 6.25 years
Dividend yield	0%	0%
Risk-free interest rates	1.5% to 1.7%	2.0% to 3.4%

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.

Since share-based compensation under SFAS 123R is recognized only for those awards that are ultimately expected to vest, the Company has applied an estimated forfeiture rate to unvested awards for the purpose of calculating compensation cost. These estimates will be revised, if necessary, in future periods if actual forfeitures differ from estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

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Employee stock-based compensation costs for the three and six months ended June 30, 2009 and 2008 and for the cumulative period from August 1, 2005 (inception) through June 30, 2009 are as follows:

	Three months ended June 30,		Six months ended June 30,		Period from August 1, 2005 (inception) through June 30, 2009
	2009	2008	2009	2008	
General and administrative	$ 882,008	$ 434,098	$ 834,720	$ 1,001,182	$ 4,687,612
Research and development	(69,517)	128,675	25,692	182,963	629,453
Total	$ 812,491	$ 562,773	$ 860,412	$ 1,184,145	$ 5,317,065

The fair value of shares vested under the Plan for the three and six months ended June 30, 2009 and 2008 and for the period from August 1, 2005 through December 31, 2008 were $1,229,846, $1,818,089, $575,930, $1,205,143 and $3,758,557, respectively.

Certain employees have been granted performance-based stock options that are subject to forfeiture based on the failure to achieve specified goals. The Company analyzed two years of annual performance measurements, and, based on that analysis, decided to estimate forfeiture rates on performance-based stock options for future periods. For the cumulative period from August 1, 2005 (inception) through June 30, 2009, employees forfeited 302,214 shares related to performance-based options, which had a fair value of $560,798. During the six months ended June 30, 2009, employment stock options and performance-based stock options relating to 894,271 shares, which had a fair value of $2,182,485, were forfeited as a result of the corporate lay-offs. Based on the forfeiture rates of the performance-based stock options, the Company estimates that options relating to an additional 73,803 shares of common stock will be forfeited in the future. This estimated compensation cost of these forfeited shares is $161,249.

During the six months ended June 30, 2009, in accordance with the terms of the separation agreements of certain former employees, the Company agreed to extend to December 31, 2009 the exercise period relating to vested stock options held by those employees. In total, stock options relating to 177,049 shares of common stock with a weighted average exercise price of $2.93 were affected by such extension. No additional stock-option compensation expense was required to be recorded as a result of the extended exercise period based on the Company s analysis of modifications made to the stock option grants.

In addition, pursuant to the terms of a separation agreement of a former executive dated June 10, 2009, the Company accelerated the vesting of 329,857 shares subject to a stock option, resulting in additional stock compensation expense of approximately $676,000 during the six months ended June 30, 2009. The Company also agreed to extend to June 10, 2014 the exercise period relating to the vested stock options owned by the former executive. This extended exercise period did not result in any incremental stock compensation cost required to be recorded. In total, the former executive has stock options to purchase 1,381,202 shares of common stock at a weighted average exercise price of $2.51 per share.

At June 30, 2009, total unrecognized estimated employee (including directors) compensation cost related to stock options granted prior to that date was $806,134, which is expected to be recognized over a weighted-average vesting period of 1.2 years. This unrecognized estimated employee compensation cost does not include $161,249 in management estimated forfeitures of performance-based stock options.

In accordance with the provisions of SFAS 123, and EITF No. 96-18, common stock, 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 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.

On June 24, 2009, in conjunction with a services agreement, the Company issued to named employees of Two River Consulting, LLC (TRC) stock options to purchase 187,500 shares of common stock that vested on issuance and have a fair-value of $116,309; and stock options to purchase 562,500 shares that vest based on the achievement of certain milestones and have an estimated fair-value of $363,028. TRC is an entity controlled by two of the Company s officers and directors. For the six months ended June 30, 2009, the Company recorded an expense of $124,342 related to these options and will record additional expense in the future as the remaining options are expected to vest.

Stock-based compensation costs incurred for services by non-employees for the three and six months ended June 30, 2009 and 2008, and for the cumulative period from August 1, 2005 (inception) through June 30, 2009 totaled $134,272, $46,494, $128,372, $57,037 and $144,816, respectively. These amounts were included in research and development expense in the accompanying Condensed Statements of Operations.

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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 per share.

8. RELATED PARTIES

On occasion, some of the Company s expenses are paid by Two River Group Holdings, LLC (Two River), a company owned by three of the Company s directors and founders. No interest is charged by Two River on any outstanding balance owed by the Company. For the three months ended June 30, 2009 and 2008 and for the period from August 1, 2005 (inception) through June 30, 2009, reimbursable expenses totaled $15,437, $3,282 and $173,349, respectively. For the six months ended June 30, 2009 and 2008, reimbursable expenses totaled $18,549 and $9,982, respectively. In addition, during 2007 the Company paid $70,245 to Two River for consulting and due diligence efforts performed by Two River employees related to the licensing of 2NTX-99. As of June 30, 2009 the Company has a payable to Two River of $15,437.

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

On June 24, 2009, the Company entered into a services agreement with TRC to provide various clinical development, operational and administrative services to the Company for a period of one year. As compensation for such services, the Company will pay to TRC a monthly cash fee of $65,000 and issued stock options to purchase up to an aggregate of 750,000 shares of the Company s common stock at a price per share equal to $0.89, the closing sale price of the Company s common stock on June 24, 2009. The total estimated fair-value of the option shares is $479,338. Twenty-five percent of the shares subject to the stock option vested immediately and the remaining 75% vest pursuant to the achievement of certain milestones relating to the clinical development of CD-NP. As of June 30, 2009 the Company has a payable to TRC of $65,000. Joshua A. Kazam, the Company s President & CEO, and David M. Tanen, the Company s Secretary, both of whom are also directors of the Company, are each partners of TRC. The terms of the Services Agreement were reviewed and approved by a special committee of the Company s Board of Directors consisting of independent directors. None of the members of the special committee has any interest in TRC or the services agreement.

As discussed in Note 6a and 6b, pursuant to a Securities Purchase Agreement dated July 7, 2009 between the Company and certain qualified investors identified therein, the Company sold 2,691,394 units of its securities resulting in gross proceeds of $3,368,750. The sale of the units was completed on July 15, 2009. The Company engaged Riverbank Capital Securities, Inc. (Riverbank) to serve as its placement agent. Riverbank was not paid a cash commission for its services, however, the Company issued Riverbank (or its designees) five-year warrants to purchase 218,300 shares of the Company s common stock. The warrants are exercisable at a price of $1.375 per share, which is equal to 110% of the per unit purchase price paid by investors, and have a cashless (net) exercise provision. The Company also paid Riverbank an expense allowance of $50,000 to cover expenses incurred during the financing.

Peter M. Kash, the Company s Chairman, Joshua A. Kazam, the Company s President and Chief Executive Officer of the Company, and David Tanen, the Company s Secretary, each of whom also serves on the Board of Directors of the Company, are each officers of and collectively control Riverbank. In light of the relationship between Messrs. Kash, Kazam and Tanen and the Riverbank, the selection and terms of the engagement were reviewed and approved by a special committee of the Company s Board consisting of independent directors, none of whom has any interest or other relationship in Riverbank or its affiliates.

9. COMMITMENTS AND CONTINGENCIES

The Company relocated its principal offices effective April 1, 2008 from Berkeley, California to San Francisco, California. The Company leased its office facility in Berkeley, California under a non-cancelable operating lease that was due to expire 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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On March 3, 2008 the Company signed a non-cancelable operating lease agreement to lease office space in San Francisco, California. The lease expires in March 2011. Future non-cancelable minimum lease payments under this lease are approximately $59,000 for the remainder of 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 Condensed Balance Sheets.

10. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through August 13, 2009, the date on which the financial statements were issued.

On July 7, 2009, as a subsequent event to the quarter ending June 30, 3009, the Company entered into a Securities Purchase Agreement. See Note 3, Note 6 and Note 8.

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

Note Regarding Forward Looking Statements

The Quarterly Report on Form 10-Q, including the following Management s Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements that involve risks and uncertainties. We use words such as may, will, expect, anticipate, estimate, intend, plan, predict, potential, believe, should and similar expressions to identify forward-looking statements. These statements appearing throughout our Form 10-Q are statements regarding our intent, belief, or current expectations, primarily regarding our operations and our efforts to develop our lead product candidate, CD-NP. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this Form 10-Q. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including those set forth under Item 1A Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2008, which was filed with the Securities and Exchange Commission on March 12, 2009. Except as required by law, we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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 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 CNP, and the N- and C-termini of Urodilantin, 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. To date, 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 CU-NP, 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 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 123(R), *Share-Based Payment,* or SFAS 123(R). SFAS 123(R) requires us to expense the fair value of stock options and warrants over the vesting period. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial and development performance. Stock-based compensation expense is included in the respective categories of expense in the statements of operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

Our Product Candidates

We currently have two product candidates: CD-NP, in clinical development for the treatment of heart failure, and CU-NP which is in pre-clinical development and has potential utility in a number of cardiovascular and renal indications. We recently terminated our 2NTX-99 program in order to focus on our natriuretic peptide programs.

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.

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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 2008, we initiated two additional dose-escalation studies to assess the safety and pharmacodynamic profile of CD-NP in heart failure patients. The first study was a Phase Ib study in stable heart failure patients designed to understand the maximum tolerated dose of the product candidate, and the second study was a Phase IIa study in acute heart failure patients designed to better understand the hemodynamic properties of the product candidate.

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. The study dosing was completed at the end of 2008.

In December 2008, we announced preliminary data from the Phase Ib study of CD-NP. Results of this study showed that CD-NP was well tolerated at doses of up to 20 ng/kg/min, blood pressure effects were dose dependent and well characterized, CD-NP demonstrated diuretic effects comparable to furosemide, and CD-NP produced statistically significant changes on biomarkers consistent with enhanced renal function.

We believe that the cumulative final results of the Phase Ib and IIa studies indicate that a) CD-NP was well tolerated at doses of up to 20 ng/kg/min in stable and acute heart failure patients, b) CD-NP blood pressure effects were dose-dependent and well characterized in chronic heart failure patients, c) in the anticipated therapeutic dose range, CD-NP produced a statistically significant reduction in pulmonary capillary wedge pressure, d) CD-NP demonstrated diuretic effects alone, and CD-NP produced a statistically significant increase in diuresis concurrent with furosemide, and e) with a 24 hour infusion, CD-NP produced statistically significant decreases in serum creatinine and cystatin-c, consistent with enhanced renal function.

In addition to our own studies, the Mayo Clinic initiated a Phase Ib study, under an investigator-sponsored investigational new drug application, or IND, to better understand CD-NP s renal properties.

In March 2009, the US Food and Drug Administration, or FDA, placed a clinical hold on the CD-NP program. In a letter sent to us, and in a follow-up teleconference, the FDA requested additional data on our Phase IIa clinical trial, which was finalized in March 2009, and modifications to CD-NP s current Investigator Brochure or IB. Nile submitted a full response to the FDA in April.

On May 15 2009, the FDA released the CD-NP program from clinical hold. Shortly following the release from clinical hold, we initiated a 30-40 patient single-blind, placebo-controlled Phase II study designed to provide additional information on the safety and tolerability of CD-NP when infused for up to 72 hours in patients with acute heart failure and renal function insufficiency. Additionally, the study contains several exploratory efficacy endpoints to provide insight into the potential for CD-NP to enhance renal function in acute heart failure patients. In July 2009, we dosed the first patient in this Phase II study. We expect to announce interim results of the study later this year, with results from the full study available in 2010.

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, decrease cardiac filling pressure, and inhibit the renin-angiotensin system without inducing significant hypotension.

In 2008, we manufactured a supply of CU-NP. In 2009, we plan to complete additional pharmacological studies, to investigate chronic formulations, and, if possible, to initiate pre-clinical toxicology and manufacturing activities.

2NTX-99 Program In January 2009, we discontinued the development of 2NTX-99 and terminated our license to certain patents and other intellectual property relating to that product candidate. We decided to end the 2NTX-99 program in order to focus our resources on the development of our natriuretic peptides.

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Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis, including research and development and 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. Research and development costs are expensed as incurred. 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 CROs, clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CRO s and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in research and development expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed.

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.

No adjustments for material changes in estimates have been recognized in any period presented.

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 our Amended and Restated 2005 Stock Option Plan.

We account for employee stock-based compensation in accordance with SFAS 123(R) which requires us to expense the fair value of stock options over the vesting period on a straight-line basis. When more precise pricing data is unavailable, 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 10 of the accompanying notes to our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2008.

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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.

In the quarter ending March 31, 2009, with two years of employee performance and forfeiture history, we began to estimate forfeitures of performance-based stock options. Prior to December 31, 2008, we did not include an estimate for forfeitures in our compensation expenses on a quarterly basis. Instead, adjustments to the performance-based stock compensation expense for the full year were made in the fourth quarter at the time of performance assessment.

Research and Development Plan

In July 2009, we began enrolling patients in a 30-40 patient open-label Phase II study of CD-NP in patients with ADHF and mild to moderate renal dysfunction. Following the completion of the ongoing Phase II study, we plan to initiate another Phase IIb study of CD-NP in a larger number of patients, which, if successful, would serve as the basis for dose selection for a Phase III program. We would require substantial additional funding to complete the Phase IIb study.

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. We expect Mayo to complete dosing of this trial in 2010.

For CU-NP, we have manufactured CU-NP API and expect to initiate work on pre-clinical pharmacology studies and chronic formulation development in 2009.

Results of Operations

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

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2009 and 2008 were approximately $1.1 million and $2.9 million, respectively. Research and development expenses for the six months ended June 30, 2009 and 2008 were approximately $2.4 million and $4.9 million, respectively. The decrease of approximately $2.4 million in the first six months of 2009 over 2008 is primarily due to an approximately $1 million decrease in clinical expenses in our CD-NP program and to an approximately $1 million reduction in expenses relating to the 2NTX-99 program. The decrease in clinical expenses is primarily the result of having two ongoing clinical trials in the first half of 2008, and being in the start-up process of only one clinical trial in the first half of 2009. The decrease in 2NTX-99 expenses is a result of terminating the program in January 2009.

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, rent and other office expense, and general legal activities.

General and administrative expenses for the three months ended June 30, 2009 and 2008 were approximately $1.4 million and $1.0 million, respectively and for the six months ended June 30, 2009 and 2008 were approximately $1.9 million and $2.2 million, respectively. The decrease in $0.3 million in the first six months of the 2009 over 2008 is primarily due to an approximately $0.3 million decrease in stock based compensation expense as a result of corporate lay-offs.

Interest Income. Interest income for the three months ended June 30, 2009 and 2008 was approximately $5,900 and approximately $83,000 respectively and for the six months ended June 30, 2009 and 2008 was approximately $21,000 and $232,000, respectively. In addition to decreased interest earned on cash in bank accounts, cash balances in 2009 have decreased substantially, as we produce no revenue and, as of

June 30, 2009, have not raised any additional capital.

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Liquidity and Capital Resources

Cash and cash flow

For the six months ended June 30, 2009 and 2008, we had a net loss of approximately $4.3 million and $6.8 million, respectively. From August 1, 2005 (inception) through June 30, 2009, we have incurred an aggregate net loss of approximately $30.3 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 continue to incur substantial and increasing losses, which will continue to have negative net cash flows from operating activities as we expand our technology portfolio and engage in further research and development activities, particularly the conducting of pre-clinical studies and clinical trials.

Our total cash resources as of June 30, 2009 were $1.8 million compared to $5.5 million as of December 31, 2008. As of June 30, 2009, we had approximately $0.4 million in liabilities, and $1.5 million in net working capital. Our forecasted average monthly cash expenditures for the next six months are approximately $0.4 million, which is a decrease from our average monthly expenses from the previous six months.

From inception through June 30, 2009, we have financed our operations through private debt and equity financing. As we have not generated any revenue from operations to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital 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. We may seek to raise additional funds through various potential sources, such as equity and debt financings, or though corporate collaboration and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support or operations, or, if it such funds are available to us, that such additional financing will be sufficient to meet our needs.

On July 7, 2009, as a subsequent event to the quarter ending June 30, 3009, we entered into a Securities Purchase Agreement with certain investors pursuant to which we agreed to sell to such investors in a private placement 2,691,394 units of its securities. Each unit included one share of common stock and one five-year warrant to purchase a share of common stock. The private placement was completed on July 15, 2009 and resulted in gross proceeds of $3,368,750 before deducting expenses.

Based on our resources at June 30, 2009, the planned cost savings measures, proceeds realized from our July 2009 private placement of securities, and the current plan of expenditure on continuing development of current products, we believe we have sufficient capital to fund our operations through 2010. However, pending the results of our ongoing Phase II clinical trial of CD-NP, we would need substantial additional capital in order to initiate and fund the next clinical study of CD-NP, which is expected to be a Phase IIb clinical trial. Cost savings implemented in the quarter ended June 30, 2009 included a significant staff reduction and the increased use of part-time consultants. 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. 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, we could be required to delay, scale back or eliminate some or all our research and development programs and we may need to wind down our operations altogether. Each of these alternatives would likely have a material adverse effect on our business.

To the extent that we raise additional funds by issuing equity or convertible or non-convertible debt securities, our stockholders may experience additional significant dilution and such financing may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us. These things may have a material adverse effect on our business.

The continuation of the our business beyond 2010 is dependent upon obtaining further long-term financing, the successful development of our drug product candidates and related technologies, the successful and sufficient market acceptance of any product offerings that we may introduce, and, finally, the achievement of a profitable level of operations. The issuance of additional equity securities by us may result in a significant dilution in the equity interests of current stockholders. Obtaining commercial loans, assuming those loans would be available, including on acceptable terms, will increase our liabilities and future cash commitments.

Off -Balance Sheet Arrangements

There were no off-balance sheet arrangements as of June 30, 2009.

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Contractual Obligations

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.

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 12, 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 of other events. Pursuant to the agreement, we must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products. In addition to the cash payments described above with respect to the CU-NP Mayo License Agreement, we have also agreed to issue certain amounts and types of equity to Mayo. In June 2008, we issued to Mayo 49,689 shares of 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 as and to the extent 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.

In March 2008, we 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 $59,000 for the remainder of 2009, $116,000 in 2010, and $29,000 in 2011, not including annual operating cost escalations.

Related Party Transactions

As consideration for the performance of consulting and due diligence efforts related to the licensing of 2NTX-99, in 2007 we granted 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, a related party, and its affiliates. The remaining warrants were granted to outside consultants.

On June 24, 2009, we entered into a services agreement with Two River Consulting, LLC, or TRC, to provide us with various clinical development, operational and administrative services for a period of one year. As compensation for such services, we will pay to TRC a monthly cash fee of $65,000 and we issued stock option to purchase up to an aggregate of 750,000 shares of our common stock at a price per share equal to $0.89, the closing sale price of our common stock on June 24, 2009. Shares relating to 25% of this option vested immediately and the remaining shares will vest pursuant to the achievement of certain milestones relating to the development of CD-NP.

Joshua A. Kazam, our President & Chief Executive Officer and David M. Tanen, our Secretary, both of whom are also directors of the Company and TRC. The terms of the services agreement with TRC were reviewed and approved by a special committee of our Board of Directors consisting of Pedro Granadillo, Paul Mieyal and Greg Schafer. None of the members of the special committee has any interest in TRC or the agreement.

In connection with our July 2009 private placement, we engaged Riverbank Capital Securities, Inc. (Riverbank), a FINRA member broker dealer, to serve as placement agent. Riverbank was not paid a cash commission for its services in connection with the financing. However, we issued Riverbank (or its designees) warrants to purchase 218,300 shares of our common stock. The warrants issued to Riverbank have an exercise price of $1.375, which is equal to 110% of the closing price of the units sold to investors, and have a cashless (net) exercise provision. We also paid Riverbank an expense allowance of $50,000 to cover expenses incurred during the financing.

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Peter M. Kash, our Chairman, Joshua A. Kazam, our President and Chief Executive Officer, and David Tanen, our Secretary, each of whom also serves on our Board of Directors, are each officers of and collectively control Riverbank. In light of the relationship between Messrs. Kash, Kazam and Tanen and the Riverbank, the selection and terms of the engagement were reviewed and approved by a special committee of our Board consisting of Pedro Granadillo, Paul Mieyal and Gregory Schaefer, none of whom has any interest or other relationship in Riverbank or its affiliates.

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our exposure to market risk for changes in interest rates relates primarily to our cash and cash equivalents. The goal of our investment policy is to place our investments with highly rated credit issuers and limit the amount of credit exposure to any one issuer. We seek to improve the safety and likelihood of preservation of our invested funds by limiting default risk and market risk. Our policy is to mitigate default risk by investing in high credit quality securities and currently do not hedge interest rate exposure. Due to our policy to only make investments with short-term maturities, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio.

As of June 30, 2009, our portfolio consisted primarily of bank savings accounts and a certificate of deposit associated with our lease obligation, and we did not have any investments with significant exposure to the subprime mortgage market issues. Based on our investment portfolio and interest rates at June 30, 2009, we believe that a decrease in interest rates would not have a significant impact on the fair value of our cash and cash equivalents of approximately $1.8 million.

Item 4T. Controls and Procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our 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 our management, including our 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), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2009. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

There has been no change in our internal controls over financial reporting during the quarter ended June 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act. Hence, under current law, the internal controls certification and attestation requirements of Section 404 of the Sarbanes-Oxley Act will not apply to us until the fiscal year ended December 31, 2009. Notwithstanding the fact that these internal control requirements do not apply to us at this time, management has begun reviewing our internal control procedures to facilitate compliance with those requirements when they become applicable.

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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.

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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.
In July 2009, the Company dosed its first patient in a Phase 2 clinical study of its lead product, CD-NP, for the treatment of acute heart failure. The single-blind, placebo-controlled Phase 2 study is designed to provide additional information on the safety and tolerability of CD-NP when infused for up to 72 hours in patients with acute heart failure and mild to moderate renal insufficiency. Additional exploratory endpoints will include assessments of CD-NP s ability to relieve symptoms of acute heart failure and its effects on biomarkers of heart failure and renal function. The study is expected to enroll approximately 30 to 40 patients in the United States, Germany and Israel and will examine up to 3 doses of CD-NP. The Company expects to announce interim results of the study later this year, with results from the full study available in 2010.

Item 6. Exhibits.

Exhibit No.	Exhibit Description
10.1	Separation Agreement and General Release dated June 10, 2009 between Nile Therapeutics, Inc. and Peter M. Strumph (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on June 12, 2009).
10.2	Services Agreement dated June 24, 2009 between Nile Therapeutics, Inc. and Two River Consulting, LLC.
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: August 13, 2009

By: /s/ Joshua Kazam
Joshua Kazam
Chief Executive Officer
(Principal Executive Officer)

Date: August 13, 2009

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

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INDEX TO EXHIBITS FILED WITH THIS REPORT

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