ISSUERDIRECT

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Nile Therapeutics

Form: 10-Q

Date Filed: 2009-05-14

Corporate Issuer CIK: 1133869
Symbol: NLTX

© Copyright 2014, Issuer Direct Corporation. All Right Reserved. Distribution of this document is strictly prohibited, subject to the terms of use.

Table of Contents

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 MARCH 31, 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 than the registrant was required to submit and post such files). ☐ Yes ☐ No

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

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company 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 May 13, 2009, there were 24,149,405 shares of common stock, par value $0.001 per share, of Nile Therapeutics, Inc. issued and outstanding.

Index

		Page
PART I	**FINANCIAL INFORMATION**	3
Item 1.	Financial Statements	3
	Condensed Balance Sheets (unaudited)	3
	Condensed Statements of Operations (unaudited)	4
	Condensed Statement of Stockholders' Equity (unaudited)	5
	Condensed Statements of Cash Flows (unaudited)	6
	Notes to Condensed Financial Statements (unaudited)	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	20
Item 4T.	Controls and Procedures	20
PART II	**OTHER INFORMATION**	22
Item 1.	Legal Proceedings	22
Item 1A.	Risk Factors	22
Item 2.	Unregistered Sales of Securities and Use of Proceeds	22
Item 3.	Defaults Upon Senior Securities	23
Item 4.	Submission of Matters to a Vote of Security Holders	23
Item 5.	Other Information	23
Item 6.	Exhibits	23
	Signatures	24
	Exhibit Index	

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2009 (unaudited)	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,607,302	$ 5,500,790
Prepaid expenses and other current assets	338,574	544,834
Total current assets	3,945,876	6,045,624
Property and equipment, net	66,278	73,699
Intangible assets, net	143,740	209,549
Other noncurrent assets	106,924	106,597
Total assets	$ 4,262,818	$ 6,435,469
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 453,091	$ 738,895
Accrued expenses and other current liabilities	322,211	586,256
Due to related party	3,112	6,700
Total current liabilities	778,414	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	31,265,468	31,105,874
Deficit accumulated during the development stage	(27,805,214)	(26,026,406)
Total stockholders' equity	3,484,404	5,103,618
Total liabilities and stockholders' equity	$ 4,262,818	$ 6,435,469

See accompanying notes to condensed financial statements.

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

	Three months ended March 31,		Period from August 1, 2005 (inception) through March 31, 2009
	2009	2008	
Grant income	$ —	$ —	$ 482,235
Operating expenses:			
Research and development	1,324,603	1,978,184	18,636,124
General and administrative	462,468	1,198,339	9,042,056
Total operating expenses	1,787,071	3,176,523	27,678,180
Loss from operations	(1,787,071)	(3,176,523)	(27,195,945)
Other income (expense):			
Interest income	14,686	149,436	735,074
Interest expense	—	(137)	(1,272,934)
Other expense	(6,423)	(31,713)	(71,409)
Total other income (expense)	8,263	117,586	(609,269)
Net loss	$ (1,778,808)	$ (3,058,937)	$ (27,805,214)
Basic and diluted loss per share	$ (0.07)	$ (0.13)	
Weighted-average common shares outstanding	24,149,405	24,099,716	

See accompanying notes to condensed financial statements.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)
PERIOD FROM AUGUST 1, 2005 (DATE OF INCEPTION) TO MARCH 31, 2009
(unaudited)

	Common Stock		Additional paid-in capital	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Shares	Amount			
Issuance of common shares to founders	13,794,132	$13,794	$ (8,794)	$ —	$ 5,000
Founders shares returned to treasury	(1,379,419)	—	—	—	—
Net loss	—	—	—	(10,043)	(10,043)
Balance at December 31, 2005	12,414,713	13,794	(8,794)	(10,043)	(5,043)
Issuance of common shares pursuant to licensing agreement	1,379,419	—	500	—	500
Issuance of stock options for services	—	—	10,000	—	10,000
Net loss	—	—	—	(2,581,972)	(2,581,972)
Balance at December 31, 2006	13,794,132	13,794	1,706	(2,592,015)	(2,576,515)
Issuance of common shares pursuant to licensing agreement	63,478	64	182,172	—	182,236
Issuance of common shares pursuant to licensing agreement	350,107	350	999,650	—	1,000,000
Common shares sold in private placement, net of issuance costs of $102,000	6,957,914	6,958	19,865,789	—	19,872,747
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	—	—	165,493	—	165,493
Non-employee stock-based compensation	—	—	(5,899)	—	(5,899)
Net loss	—	—	—	(1,778,808)	(1,778,808)
Balance at March 31, 2009	24,149,405	$24,150	$31,265,468	$(27,805,214)	$ 3,484,404

See accompanying notes to condensed financial statements.

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

	Three months ended March 31,		Period from August 1, 2005 (inception) through March 31, 2009
	2009	2008	
Cash flows from operating activities			
Net loss	$(1,778,808)	$ (3,058,937)	$ (27,805,214)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	75,969	24,411	216,595
Stock-based compensation	159,594	966,907	6,289,243
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
Noncash interest expense	—	—	351,165
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	206,260	141,749	(338,574)
Other non-current assets	(327)	(104,868)	(106,924)
Accounts payable	(285,804)	157,078	453,091
Accrued expenses and other current liabilities	(264,045)	(583,416)	322,211
Accrued lease obligation		138,507	—
Due to related party	(3,588)	(222,825)	3,112
Net cash used in operating activities	(1,890,749)	(2,541,394)	(19,832,178)
Cash flows from investing activities			
Purchase of property and equipment	—	(26,992)	(122,241)
Cash paid for intangible assets	(2,739)	(5,502)	(316,026)
Net cash used in investing activities	(2,739)	(32,494)	(438,267)
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	(1,893,488)	(2,573,888)	3,607,302
Cash and cash equivalents at beginning of period	5,500,790	16,233,464	—
Cash and cash equivalents at end of period	$ 3,607,302	$13,659,576	$ 3,607,302
Supplemental schedule of cash flows information:			
Cash paid for interest	$ —	$ —	$ 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
Common shares of SMI issued in reverse merger transaction	$ —	$ —	$ 1,250

See accompanying notes to condensed financial statements.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2009
(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 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 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 March 31, 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 $28 million at March 31, 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 March 31, 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.

Pursuant to the Merger, each share of common stock of Old Nile that was outstanding immediately prior to the Merger was exchanged for 2.758838 shares of the Company's common stock, and one share of Old Nile common stock was issued to SMI. All share and per share information in the Condensed Financial Statements has been restated to retroactively reflect the conversion ratio of 2.758838. As further explained in Note 3(a) in the Form 10-K filed for the year ended December 31, 2008, upon completion of the Merger and certain related transactions, Old Nile's stockholders owned approximately 95% of the capital stock of the merged company and the Merger was accounted for as a reverse acquisition.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2009
(unaudited)

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.

Reclassifications

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

3. LIQUIDITY AND CAPITAL RESOURCES

Cash resources as of March 31, 2009 were $3.6 million, compared to $5.5 million as of December 31, 2008. Based on our resources at March 31, 2009, the planned cost savings measures, and the current plan of expenditure on continuing development of current products, the Company believes that there is sufficient capital to fund operations through the third quarter of 2009, depending largely on patient enrollment rates. Potential costs savings measures could include a further reduction of staff and the increased use of part-time consultants, which could add additional risk to the Company's operational plans. 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; 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 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 our operations altogether. Each of these alternatives would likely have a material adverse effect on our business.

In addition, to the extent that the Company raises additional funds by issuing equity or convertible or non-convertible debt securities, the Company's 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 product candidates, or grant licenses on terms that may not be favorable to the Company. These things may have a material adverse effect on the business.

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies continuing into 2009. As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have lead to a decrease in spending by businesses and consumers alike, and a corresponding decrease in global infrastructure spending. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business and consumer spending may adversely affect the Company's liquidity and financial condition, and the liquidity and financial condition of the Company's customers, including the ability to refinance maturing liabilities and access the capital markets to meet liquidity needs.

There is substantial doubt about the Company's ability to continue as a going concern as the continuation of the Company's business is dependent upon obtaining further long-term financing, the successful development of the Company's 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 is likely to result in a significant dilution in the equity interests of the Company's 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.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2009
(unaudited)

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:

	March 31, 2009	March 31, 2008
Warrants to purchase common stock	375,249	375,249
Options to purchase common stock	4,626,953	4,126,512
Total potentially dilutive securities	5,002,202	4,501,761

5. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

Patents

At March 31, 2009, intangible assets consisted of patents and patent applications acquired from third parties for the CD-NP and CU-NP compounds. Amortization expense was $20,100 and $22,600 for the three months ended March 31, 2009 and 2008, respectively. In addition, there was a onetime charge of $48,500 in the three months ended March 31, 2009 for the impairment of patents and patent applications associated with 2NTX-99. Amortization expense of $172,300 has been recorded for the period from August 1, 2005 (inception) through March 31, 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 arose 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 March 31, 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.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2009
(unaudited)

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.

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 included an issued United States patent and an issued European patent relating to its composition of matter, multiple methods of manufacturing, and method of use in treating a variety of atherothrombotic pathological conditions. Patent applications were filed in other major markets around the world.

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.

On January 16, 2009, the Company announced that it will focus 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. The Company terminated the 2NTX-99 program and returned the rights to the molecule to Dr. Cesare Casagrande, effective April 16, 2009. As such, the Company recorded an impairment charge of $48,479 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 of $182,236 was recorded as research and development expense in the accompanying Statements of Operations.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2009
(unaudited)

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.

(b) Warrants

In conjunction with the conversion of the Notes, the Company issued fully vested warrants to purchase 168,337 shares of common stock to the holders of the Notes. 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. No warrants have been exercised to date.

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 (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

(a) 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, resulting in an aggregate of 5,517,676 shares available under the Plan.

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.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2009
(unaudited)

A summary of the status of the options issued under the Plan at March 31, 2009, and information with respect to the changes in options outstanding is as follows:

		Options Outstanding		
	Options Available for Grant	Outstanding Stock Options	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	(320,148)	320,148	$ 0.88	
Options forfeited	264,714	(264,714)	$ 2.86	
Balance at March 31, 2009	1,484,473	4,033,203	$ 2.92	
Exercisable at March 31, 2009		1,633,659	$ 2.40	

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 only options granted to employees during the three months ended March 31, 2009 were granted in exchange for accrued performance cash bonuses. 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 were expensed in the first quarter as a result of this incremental incentive to preserve the Company's cash.

The fair value of options granted during the three months ended March 31, 2008 was estimated using the Black-Scholes option-pricing model using an expected volatility of 89%, expected terms from 5.75 to 6.25 years, a dividend yield of 0% and risk-free interest rates from 2% to 3%.

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.

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.

In the quarter ending March 31, 2009, with two years of employee performance and forfeiture history, the Company began to estimate forfeitures of performance-based stock options. Prior to December 31, 2008, the Company did not include an estimate for forfeitures in 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.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2009
(unaudited)

Employee stock-based compensation costs for the three months ended March 31, 2009 and 2008 and for the cumulative period from August 1, 2005 (inception) through March 31, 2009 are as follows:

	Three months ended March 31,		Period from August 1, 2005 (inception) through March 31,
	2009	2008	2009
General and administrative	$(47,288)	$567,084	$3,805,604
Research and development	95,209	54,288	698,970
Total	$ 47,921	$621,372	$4,504,574

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, adjusted estimated forfeiture rates on performance-based stock options for future periods. For the cumulative period from August 1, 2005 (inception) through March 31, 2009, employees forfeited 302,214 shares related to performance-based options, which had a fair value of $560,798. Based on these forfeiture rates, the Company estimates that an additional 306,336 options will be forfeited in the future. The estimated compensation cost of these forfeited shares is $604,585.

At March 31, 2009, total unrecognized estimated employee (including directors) compensation cost related to stock options granted prior to that date was $4,745,218, which is expected to be recognized over a weighted-average vesting period of 1.61 years. This unrecognized estimated employee compensation cost does not include $604,585 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.

Stock-based compensation costs incurred for services by non-employees for the three months ended March 31, 2009 and 2008, and for the cumulative period from August 1, 2005 (inception) through March 31, 2009 totaled ($5,899), $10,543 and $17,121, respectively. These amounts were included in research and development expense in the accompanying Condensed Statements of Operations.

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

8. RELATED PARTIES

On occasion, some of the Company's expenses are paid by Two River, a company owned by several of the Company's directors and founders. No interest is charged by Two River on any outstanding balance owed by the Company. For the three months ended March 31, 2009 and 2008 and for the period from August 1, 2005 (inception) through March 31, 2009, reimbursable expenses totaled $3,112, $6,700, and $157,912, 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 March 31, 2009 the Company has a payable to Two River of $3,112.

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. The warrants were recorded as an expense and a liability during the year ended December 31, 2007. In March 2008, these warrants were issued in satisfaction of the accrued liability.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2009
(unaudited)

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.

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 $87,000 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

As part of the Company’s planned cost saving measures, as of May 8, 2009, the Company has laid-off administrative and development employees. As part of the lay-offs, Jennifer Hodge, Vice President, Development, was informed on May 7, 2009, that her employment would be terminated as of May 31, 2009. As a result of the lay-offs, unvested employee and performance-based options for 471,466 shares were cancelled, with a fair value of $1,444,268.

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

Note Regarding Forward Looking Statements

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Item 1A of the Annual Report filed on March 12, 2009, and amended on April 23, 2009, our actual results may differ materially from those anticipated in these forward-looking statements.

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 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 123R. SFAS 123R 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.

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. 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.

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.

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 March 2009, the US Food and Drug Administration or FDA placed a clinical hold on our 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 and expects a response from the FDA by the end of May.

Shortly following the FDA's release from clinical hold, Nile intends to initiate a 30-patient single-blind, placebo-controlled Phase 2 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. The dosing of this 30-patient study is expected to be completed by the end of 2009.

CU-NP Program – CU-NP is a novel natriuretic peptide rationally designed by scientists at the Mayo Clinic's cardio-renal research labs. CU-NP was designed to combine the favorable hemodynamic venodilating effects of CNP generated via NPR-B receptor agonism, with the beneficial renal effects of Urodilatin generated via NPR-A receptor agonism. In animal models, CU-NP was shown to increase natriuresis, diuresis, and glomerular filtration rate 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 – On January 16, 2009, we provided notice to Dr. Casagrande that we were terminating the 2NTX-99 License Agreement effective 90 days from the date of the notice. We decided to end the 2NTX-99 program and to focus our resources on the development of our natriuretic peptides. Following the effectiveness of the termination, all rights to 2NTX-99 will revert to Dr. Casagrande.

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 the 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 the 2008 10-K.

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 the second half of 2009, if the FDA releases CD-NP from clinical hold, we expect to initiate a 30 patient, open-label Phase IIb study of CD-NP in patients with acute decompensated heart failure and renal function insufficiency. Depending on the timing of the release of the clinical hold, we may require additional funds to complete the trial. Following the 30 patient study, we plan to initiate another 330 patient Phase IIb study, which, if successful, would serve as the basis for dose selection for a Phase III program.

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.

Revenue. We had no product revenue during the three months ended March 31, 2009 and 2008 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.

Research and development expenses for the three months ended March 31, 2009 decreased approximately $654,000, or 33%, as compared to the same period in 2008. The change is primarily due to a decrease of approximately $488,400 in manufacturing expense, reductions primarily relating to our CD-NP program, and a decrease of approximately $146,400 in toxicology expenses, reductions primarily relating to our 2NTX-99 program. For the three months ended March 31, 2008, we incurred clinical expenses from closing out our Phase Ib and IIa clinical trials and from start-up activities for our Phase IIb trial. For the three months ended March 31, 2009, we incurred a comparable amount of clinical expenses from start-up activities relating to our Phase Ib and IIa.

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 March 31, 2009 decreased by approximately $736,000, or 61%, as compared to the same period in 2008. This decrease is primarily due to a decrease in stock based compensation of approximately $612,000, a decrease in professional fees of approximately $67,000 and a decrease in occupancy costs of approximately $68,000.

Interest Income. Interest income for the three months ended March 31, 2009 and 2008 was approximately $15,000 and approximately $149,000, respectively. Cash balances in 2009 have decreased substantially, as we produce no revenue and have not raised any additional capital.

Liquidity and Capital Resources

Cash and cash flow

For the three months ended March 31, 2009 and 2008, we had a net loss of approximately $1.8 million and $3.1 million, respectively. From August 1, 2005 (inception) through March 31, 2009, we have incurred an aggregate net loss of approximately $27.8 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 March 31, 2009 were $3.6 million compared to $5.5 million as of December 31, 2008. As of March 31, 2009, we had approximately $0.8 million in liabilities, and $3.2 million in net working capital. Our forecasted average monthly cash expenditures for the next six months are approximately $0.5 million, which is a decrease from our average monthly expenses from the previous six months.

From inception through March 31, 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 before 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. We are seeking 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.

Based on our resources at March 31, 2009, the planned cost savings measures, and the current plan of expenditure on continuing development of current products, we believe that we have sufficient capital to fund our operations through the third quarter of 2009, depending largely on patient enrollment rates. Potential costs savings measures could include a further reduction of staff and the increased use of part-time consultants, which could add additional risk to our operational plans. 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.

In addition, 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.

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies continuing into 2009. As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have lead to a decrease in spending by businesses and consumers alike, and a corresponding decrease in global infrastructure spending. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business and consumer spending may adversely affect our liquidity and financial condition, and the liquidity and financial condition of our customers, including our ability to refinance maturing liabilities and access the capital markets to meet liquidity needs.

There is substantial doubt about our ability to continue as a going concern as the continuation of our business 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 is likely to result in a significant dilution in the equity interests of our 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 March 31, 2009.

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 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.

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 $87,000 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.

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 March 31, 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 March 31, 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 $3.6 million.

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 is not an "accelerated filer" because it is qualified as a smaller reporting company. 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.

On May 7, 2009, the Company informed Jennifer Hodge, its Vice President, Development, that it was terminating her employment with the Company effective as of May 31, 2009. The decision to terminate Ms. Hodge's employment was made as part of a number of other measures the Company has taken to substantially reduce its ongoing expenses in order to focus its available resources toward its CD-NP development program.

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.

SIGNATURES

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

NILE THERAPEUTICS, INC.

Date: May 14, 2009

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

Date: May 14, 2009

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

Table of Contents

EXHIBIT INDEX

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.

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Peter Strumph, certify that:

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

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

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

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

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

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

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

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

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

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

Date: May 14, 2009

/s/ Peter Strumph

Name: Peter Strumph
Title: Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Daron Evans, certify that:

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

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

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

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

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

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

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

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

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

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

Date: May 14, 2009

/s/ Daron Evans

Name: Daron Evans
Title: Chief Financial Officer

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

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

(1) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2009 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: May 14, 2009

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

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

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

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

(1) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2009 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: May 14, 2009

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

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