

Nile Therapeutics, Inc.  
Form 10-Q  
May 14, 2010

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2010

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  
(State of Incorporation)

88-0363465  
(I.R.S. Employer Identification No.)

4 West 4th Ave., Suite 400, San Mateo, CA 94402  
(Address of principal executive offices)(Zip Code)

(650) 458-2670  
(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  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

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

company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

As of May 13, 2010, there were 34,560,824 shares of common stock, par value \$0.001 per share, of Nile Therapeutics, Inc. issued and outstanding.

---

## Index

	Page
<b>PART I FINANCIAL INFORMATION</b>	<b>4</b>
Item 1. Financial Statements	4
Condensed Balance Sheets (unaudited)	4
Condensed Statements of Operations (unaudited)	5
Condensed Statement of Stockholders' Equity (unaudited)	6
Condensed Statements of Cash Flows (unaudited)	7
Notes to Condensed Financial Statements (unaudited)	8
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4T. Controls and Procedures	24
<b>PART II OTHER INFORMATION</b>	<b>25</b>
Item 1. Legal Proceedings	25
Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	25
Item 3. Defaults Upon Senior Securities	26
Item 4. [Removed and Reserved]	26
Item 5. Other Information	26
Item 6. Exhibits	26
Signatures	27
Exhibit Index	28

Forward-Looking Statements

This Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These forward-looking statements include, but are not limited to, statements about:

- the development of our product candidates;
- the regulatory approval of our product candidates;
- our use of clinical research centers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- acceptance of our products by doctors, patients or payors;
- our ability to market any of our product candidates;
- our history of operating losses;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our ability to attract and retain key personnel;
- availability of reimbursement for our product candidates;
- the effect of potential strategic transactions on our business;
- our ability to obtain adequate financing; and
- the volatility of our stock price.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. For such statements, we are afforded the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report on Form 10-Q are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Quarterly Report on Form 10-Q was filed with the Securities and Exchange Commission, or SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Discussions containing these forward-looking statements may be found throughout this report, including Part I, the section entitled “Item 2: Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in our Annual Report on Form 10-K for the year ended December 31, 2009, that could cause our actual results to differ materially from those in the forward-looking statements. Except as required by law, we undertake no obligation to publicly revise our forward-looking statements to reflect events or

circumstances that arise after the filing of this report or documents incorporated by reference herein that include forward-looking statements. The risks discussed in this report should be considered in evaluating our prospects and future financial performance.

In addition, past financial or operating performance is not necessarily a reliable indicator of future performance and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition.

References to the “Company,” “Nile,” the “Registrant,” “we,” “us,” or “our” in this report refer to Nile Therapeutics, Inc., a Delaware corporation, unless the context indicates otherwise.

## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements.

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

	March 31, 2010 (unaudited)	December 31, 2009
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 2,013,394	\$ 3,175,718
Prepaid expenses and other current assets	282,945	257,732
<b>Total current assets</b>	<b>2,296,339</b>	<b>3,433,450</b>
Property and equipment, net	23,486	27,486
Intangible assets, net	-	106,830
Other noncurrent assets	51,938	51,938
<b>Total assets</b>	<b>\$ 2,371,763</b>	<b>\$ 3,619,704</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 164,545	\$ 150,628
Accrued expenses and other current liabilities	649,205	402,772
Due to related party	75,462	84,154
<b>Total current liabilities</b>	<b>889,212</b>	<b>637,554</b>
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, 27,085,824 shares issued and outstanding	27,086	27,086
Additional paid-in capital	37,285,990	36,853,767
Deficit accumulated during the development stage	(35,830,525)	(33,898,703)
<b>Total stockholders' equity</b>	<b>1,482,551</b>	<b>2,982,150</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 2,371,763</b>	<b>\$ 3,619,704</b>

See accompanying notes to condensed financial statements.



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

	Three months ended March 31, 2010		Period from August 1, 2005 (inception) through March 31, 2010
Grant income	\$ -	\$ -	\$ 482,235
Operating expenses:			
Research and development	1,313,423	1,324,603	23,091,479
General and administrative	623,202	462,468	12,619,964
Total operating expenses	1,936,625	1,787,071	35,711,443
Loss from operations	(1,936,625)	(1,787,071)	(35,229,208)
Other income (expense):			
Interest income	4,846	14,686	772,428
Interest expense	-	-	(1,273,734)
Other expense	(43)	(6,423)	(100,011)
Total other income (expense)	4,803	8,263	(601,317)
Net loss	\$ (1,931,822)	\$ (1,778,808)	\$ (35,830,525)
Basic and diluted loss per share	\$ (0.07)	\$ (0.07)	
Weighted-average common shares outstanding	27,085,824	24,149,405	

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 (INCEPTION) TO MARCH 31, 2010  
(unaudited)

	COMMON SHARES	STOCK AMOUNT	ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE 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

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

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	-	-	1,772,597	-	1,772,597
Non-employee stock-based compensation	-	-	473,584	-	473,584
Common shares sold in private placement, net of issuance costs of \$282,773	2,691,394	2,691	3,083,284	-	3,085,975
Warrants issued to placement agent in connection with private placement	-	-	201,200	-	201,200
Stock option and warrant exercises	245,025	245	217,228	-	217,473
Net loss	-	-	-	(7,872,297)	(7,872,297)

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

Balance at December 31, 2009	27,085,824	27,086	36,853,767	(33,898,703)	2,982,150
Employee stock-based compensation	-	-	351,478	-	351,478
Non-employee stock-based compensation	-	-	80,745	-	80,745
Stock option and warrant exercises	-	-	-	-	-
Net loss	-	-	-	(1,931,822)	(1,931,822)
Balance at March 31, 2010	27,085,824	\$ 27,086	\$ 37,285,990	\$ (35,830,525)	\$ 1,482,551

See accompanying notes to condensed financial statements.

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

	Period from		
	Three months ended March 31,		August 1, 2005 (inception)
	2010	2009	through March 31, 2010
<b>Cash flows from operating activities</b>			
Net loss	\$ (1,931,822)	\$ (1,778,808)	\$ (35,830,525)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	4,000	75,969	304,215
Stock-based compensation	432,223	159,594	8,808,053
Write-off of intangible assets	106,830	-	106,830
Warrants issued in connection with note conversion	-	-	288,000
Note discount arising from beneficial conversion feature	-	-	483,463
Loss on disposal of assets	-	-	35,223
Noncash interest expense	-	-	351,165
<b>Changes in operating assets and liabilities</b>			
Prepaid expenses and other current assets	(25,213)	206,260	(282,945)
Other non-current assets	-	(327)	(51,938)
Accounts payable	13,917	(285,804)	164,545
Accrued expenses and other current liabilities	246,433	(264,045)	649,205
Due to related party	(8,692)	(3,588)	75,462
Net cash used in operating activities	(1,162,324)	(1,890,749)	(24,899,247)
<b>Cash flows from investing activities</b>			
Purchase of property and equipment	-	-	(126,663)
Proceeds from sale of assets	-	-	2,500
Cash paid for intangible assets	-	(2,739)	(345,591)
Net cash used in investing activities	-	(2,739)	(469,754)
<b>Cash flows from financing activities</b>			
Proceeds from issuance of notes payable	-	-	5,500,000
Repayment of notes payable	-	-	(1,500,000)
Proceeds from exercise of stock options and warrants	-	-	217,473
Proceeds from sale of common stock to founders	-	-	5,000
Proceeds from sale of common stock in private placement	-	-	23,159,922
Net cash provided by financing activities	-	-	27,382,395
Net (decrease) increase in cash and cash equivalents	(1,162,324)	(1,893,488)	2,013,394
Cash and cash equivalents at beginning of period	3,175,718	5,500,790	-

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

Cash and cash equivalents at end of period	\$	2,013,394	\$	3,607,302	\$	2,013,394
--	----	-----------	----	-----------	----	-----------

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
--	----	---	----	---	----	---------

Warrants issued to placement agent and investors, in connection with private placement	\$	-	\$	-	\$	2,872,200
--	----	---	----	---	----	-----------

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, 2010

(unaudited)

1. DESCRIPTION OF BUSINESS

Nile Therapeutics, Inc. (“Nile” or the “Company”) 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 March 31, 2010, its efforts have been principally devoted to developing its licensed technologies, recruiting personnel, establishing office facilities, and raising capital. Accordingly, the accompanying condensed financial statements have been prepared in accordance with the provisions of ASC 915, “Development Stage Entities.” The Company’s condensed 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 \$35.8 million at March 31, 2010. The Company expects to incur substantial and increasing losses and to 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, 2010 are not necessarily indicative of results for the full 2010 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, 2009 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.

NILE THERAPEUTICS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS  
March 31, 2010  
(unaudited)

### 3. LIQUIDITY AND CAPITAL RESOURCES

Cash resources as of March 31, 2010 were approximately \$2.0 million, compared to \$3.2 million as of December 31, 2009. Based on its resources at March 31, 2010, together with the net proceeds from the Company's April 2010 underwritten public offering (see note 6), and the current plan of expenditure for continued development of the Company's current product candidates, including the potential dosing of additional cohorts in the ongoing Phase II study of CD-NP, the Company believes that it has sufficient capital to fund its operations through to the second half of 2011. However, the Company will need to raise additional capital to complete the next clinical study of CD-NP, which is expected to be a Phase IIb trial. Additionally, the Company will need substantial additional financing in the future until it can achieve profitability, if ever. The Company's continued operations will depend on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its product candidates to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot assure that it will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs.

The success of the Company depends on its ability to discover and develop new products to the point of FDA approval and subsequent revenue generation and, accordingly, to raise enough capital to finance these developmental efforts. Management plans to raise additional equity capital or license one or more of its products to finance the continued operating and capital requirements of the Company. Amounts raised will be used to further develop the Company's product candidates, acquire additional product licenses and for other working capital purposes. While the Company will extend its best efforts to raise additional capital to fund all operations for the next 12 to 24 months, management can provide no assurances that the Company will be able to raise sufficient funds. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

In addition, to the extent that the Company raises additional funds by issuing shares of its common stock or other securities convertible or exchangeable for shares of common stock, stockholders may experience additional significant dilution. In the event the Company raises additional capital through debt financings, the Company may incur significant interest expense and become subject to covenants in the related transaction documentation that may affect the manner in which the Company conducts its business. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its 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 Company's business.

### 4. BASIC AND DILUTED LOSS 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, all potentially dilutive securities are excluded from the computation of fully diluted loss per share as their effect is anti-dilutive.





NILE THERAPEUTICS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 2010

(unaudited)

Potentially dilutive securities include:

	March 31, 2010	March 31, 2009
Warrants to purchase common stock	3,279,984	375,249
Options to purchase common stock	4,901,499	4,626,953
Total potentially dilutive securities	8,181,483	5,002,202

## 5. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

### Patents

As of January 1, 2010, the Company revised its estimate for the useful lives of its patent and patent applications to zero. As a result of this change in estimates, the Company recorded an impairment of approximately \$106,830 to research and development expense, which was the net book value of its intangible assets as of December 31, 2009. Management believes this revised estimate better reflects the tremendous uncertainty surrounding drug product development. Management does not believe that the change in this estimate will have a material impact on its financial statements.

### License Agreements

#### CD-NP

On January 20, 2006, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the CD-NP 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 indications. The Company was also entitled to rights to improvements to CD-NP that arise out of the laboratory of Dr. John Burnett, the co-inventor of CD-NP, until January 19, 2009.

Under the terms of the CD-NP License Agreement, the Company agreed to make contingent cash payments up to an aggregate of \$31.9 million upon successful completion of specified clinical and regulatory milestones relating to CD-NP. This aggregate amount is subject to increase 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.

In addition to the potential milestone payments discussed above, the CD-NP 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 December 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.

The CD-NP License Agreement, unless earlier terminated, will continue in full force and effect until January 20, 2026. However, to the extent any patent covered by the license is issued with an expiration date beyond January 20, 2026, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i)

for the Company's material breach of the agreement that remains uncured after 90 days' written notice, (ii) the Company's insolvency or bankruptcy, or (iii) if the Company challenge the validity or enforceability of any of the patents in any manner. The Company may terminate the agreement without cause upon 90 days' written notice.

#### CU-NP

On June 13, 2008, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the CU-NP 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 12, 2011.

NILE THERAPEUTICS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 2010

(unaudited)

Under the terms of the CU-NP License Agreement, the Company made an up-front cash payment to Mayo and agreed to make future contingent cash payments up to an aggregate of \$24.3 million upon achievement of specific 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. This aggregate amount of \$24.3 million is subject to increase upon the receipt of regulatory approval for each additional indication of CU-NP, as well as for additional compounds or analogues contained in the intellectual property. Pursuant to the agreement, the Company must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

Payments payable with pursuant to the CU-NP License Agreement, are recorded as 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 agreed to grant to Mayo an equivalent dollar value in warrants to purchase shares of the Company's common stock. The number of shares purchasable under these warrants will be calculated using the Black-Scholes option-pricing model and the warrants will include a cashless exercise provision with language to be negotiated in good faith between the parties.

The CU-NP License Agreement, unless earlier terminated, will continue in full force and effect until June 13, 2028. However, to the extent any patent covered by the license is issued with an expiration date beyond June 13, 2028, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for the Company's material breach of the agreement that remains uncured after 90 days written notice, (ii) the Company's insolvency or bankruptcy, (iii) if the Company challenge the validity or enforceability of any of the patents in any manner, or (iv) or upon receipt of notice from the Company that it has terminated all development efforts under the agreement. The Company may terminate the agreement without cause upon 90 days' written notice.

## 6. STOCKHOLDERS' EQUITY

### (a) Common Stock

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 in exchange for an aggregate gross purchase price of \$3,368,748. Each unit included one share of common stock and one warrant to purchase a share of common stock. See Note 6(b). Issuance costs related to the financing were \$282,773, including 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 issuance and sale of the units pursuant to the Securities Purchase Agreement was completed on July 15, 2009.

The Company agreed to file a registration statement with the SEC within 60 days 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. The Company filed such registration statement with the SEC on August 13, 2009.

As a subsequent event on April 21, 2010, the Company entered into an underwriting agreement to sell 6,500,000 units of its securities at a public offering price of \$0.70 per unit (less an underwriting discount). On May 6, 2010 the underwriters exercised an option to purchase an additional 975,000 units to cover over-allotments, which purchase was completed on May 10, 2010. Each unit consisted of one share of the Company's common stock and 0.30 warrants to purchase common stock, each whole warrant representing the right to purchase one share of common stock at an exercise price of \$0.94 per share (the "Unit Warrants"). In total, the Company sold 7,475,000 units under the terms of the underwriting agreement, consisting of an aggregate of 7,475,000 shares of common stock and 2,242,500 Unit Warrants. The net proceeds to the Company were \$4.6 million. See note 9 for additional information.

(b) Warrants

In connection with its July 2009 private placement, as discussed above, 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:

NILE THERAPEUTICS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 2010

(unaudited)

- Warrants to purchase 672,849 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 672,848 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 1,345,697 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 private placement are redeemable by the Company 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 applicable exercise price of each warrant.

As consideration for its services as placement agent in connection with the July 2009 private placement, 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, which is equal to 110% of the per unit purchase price paid by investors, and have a cashless (net) exercise provision. See Note 8.

Below is a table that summarizes all outstanding warrants to purchase shares of the Company's common stock as of March 31, 2010.

Grant Date	Warrants Issued	Exercise Price	Weighted Average Exercise Price	Expiration Date	Exercised	Warrants Outstanding
9/11/2007	168,377	2.71		9/11/2012	-	168,377
3/26/2008	206,912	2.71		9/11/2012	-	206,912
7/15/2009	672,849	1.25		7/14/2014	5,000	667,849
7/15/2009	672,849	1.71		7/14/2014	-	672,849
7/15/2009	1,345,697	2.28		7/14/2014	-	1,345,697
7/15/2009	218,300	1.38		7/14/2014	-	218,300
	3,284,984		\$ 1.94		5,000	3,279,984

In connection with the public offering discussed above, the Company issued a total of 2,242,500 Unit Warrants, each of which has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of \$0.94 per share. In addition, the Company issued the underwriters a five-year warrant to purchase 390,000 shares of the Company's common stock at an exercise price of \$0.94 per share. The fair value of this warrant is \$271,900, and is allocated for as an expense of the offering resulting in a charge to stockholder's equity. See note 9 for additional information.

## 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 the closing price of the Company's common stock on the date of grant, and generally vest over a period of one to four years.

A summary of the status of the options issued under the Plan at March 31, 2010, and information with respect to the changes in options outstanding is as follows:

NILE THERAPEUTICS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 2010

(unaudited)

	Shares Available for Grant	Outstanding Stock Options	Weighted- Average Exercise Price	Aggregate Intrinsic Value
		4		
Balance at January 1, 2010	836,249	,441,402	\$ 2.22	
Options granted under the Plan	-	-	\$ -	
Options exercised		-	\$ -	
Options forfeited	133,653	(133,653)	\$ 1.87	
		4		
Balance at March 31, 2010	969,902	,307,749	\$ 2.10	\$ -
Exercisable at March 31, 2010		3,172,189	\$ 2.27	\$ -

The following table summarizes information about stock options outstanding at March 31, 2010:

Range of Exercise Prices	Shares	Outstanding		Exercisable	
		Weighted- Average Remaining Contractual Life	Weighted-Average Exercise Price	Total Shares	Weighted- Average Exercise Price
\$0.09 to \$0.93	1,184,313	8.73	\$ 0.80	971,813	\$ 0.78
\$1.14 to \$2.71	2,487,087	8.10	\$ 2.33	1,819,587	\$ 2.59
\$4.45 to \$5.75	636,349	7.87	\$ 4.54	380,789	\$ 4.56
Total	4,307,749	8.24	\$ 2.23	3,172,189	\$ 2.27

Share-based compensation is recognized only for those awards that are ultimately expected to vest, therefore, 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, 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.

Employee stock-based compensation costs for the three months ended March 31, 2010 and 2009 and for the cumulative period from August 1, 2005 (inception) through March 31, 2010 are as follows:



NILE THERAPEUTICS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 2010

(unaudited)

	Three months ended March 31, 2010	2009	Period from August 1, 2005 (inception) through March 31, 2010
General and administrative	\$ 263,530	\$ (47,288)	\$ 5,624,518
Research and development	87,948	95,209	845,283
Total	\$ 351,478	\$ 47,921	\$ 6,469,801

The fair value of shares vested under the Plan for the three months ended March 31, 2010 and 2009 and for the period from August 1, 2005 (inception) through March 31, 2010 were \$475,818, \$588,243, and \$4,587,212 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, subsequent to March 31, 2009 decided to estimate forfeiture rates on performance-based stock options for future periods. For the cumulative period from August 1, 2005 (inception) through March 31, 2010, employees forfeited 379,617 shares related to performance-based options, which had a fair value of \$643,094. Based on these forfeiture rates, the Company estimates that an additional 13,682 options will be forfeited in the future. This estimated compensation cost of these forfeited shares is \$46,120.

At March 31, 2010, total unrecognized estimated employee (including directors) compensation cost related to stock options granted prior to that date was \$1,007,507, 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 \$46,120 in management estimated forfeitures of performance-based stock options.

Common stock, stock options or other equity instruments issued to non-employees (including consultants and all members of the Company's Scientific Advisory Board) 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 three months ended March 31, 2010, the Company recorded an expense of \$81,546 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 months ended March 31, 2010 and 2009, and for the cumulative period from August 1, 2005 (inception) through March 31, 2010 totaled \$80,745, (\$5,899), and \$570,705, respectively. These amounts were included in research and development and general and administrative expenses in the accompanying Condensed Statements of Operations.



NILE THERAPEUTICS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 2010

(unaudited)

8. RELATED PARTIES

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. Joshua A. Kazam, the Company's President and Chief Executive Officer and director, and Arie S. Belldegrun, who was appointed to serve as a member of the Company's Board of Directors on September 24, 2009, are each partners of TRC. David M. Tanen, who served as the Company's Secretary and director until his resignation from both positions on September 24, 2009, is also a partner 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 compensation for the services contemplated by the services agreement, the Company agreed to 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 stock options 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. On occasion, some of the Company's expenses are paid by TRC. No interest is charged by TRC on any outstanding balance owed by the Company. For the three months ended March 31, 2010 and 2009 and for the period from August 1, 2005 (inception) through March 31, 2010, total cash services and reimbursed expenses totaled \$205,461, \$0 and \$688,301, respectively. As of March 31, 2010 the Company has a payable to TRC of \$75,462.

As discussed in Notes 6(a) and 6(b), pursuant to a Securities Purchase Agreement dated July 7, 2009 between the Company and certain qualified investors identified therein, the Company engaged Riverbank to serve as its placement agent. Riverbank was not paid a cash commission for its services, however, the Company issued to designees of Riverbank five-year warrants to purchase 218,300 shares of the Company's common stock with an aggregate fair value of \$201,200 and an expense allowance of \$50,000 to cover expenses incurred during the financing. These costs were incurred in connection with the private placement of units resulting in a charge to stockholder's equity.

Peter M. Kash, the Chairman of the Company's Board of Directors, Joshua A. Kazam, the Company's President and Chief Executive Officer and director, and David M. Tanen, a director of the Company until September 24, 2009, are each officers of and collectively control Riverbank. In light of the relationship between Messrs. Kash, Kazam and Tanen and 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 had any interest or other relationship in Riverbank or its affiliates.

9. SUBSEQUENT EVENTS

On April 21, 2010, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Maxim Group LLC (the "Representative"), as representative of the several underwriters named in the Underwriting Agreement (collectively, the "Underwriters"), providing for the offer and sale in a firm commitment underwritten public offering (the "Offering") of 6,500,000 units of its securities at a public offering price of \$0.70 per unit (less an underwriting discount of \$0.063 per unit). Pursuant to the Underwriting Agreement, the Company granted the Underwriters an option for a period of 45 days to purchase up to an additional 975,000 units to cover over-allotments, if any. Each unit consisted of one share of the Company's common stock and 0.30 warrants to purchase common stock. Each Unit

Warrant has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of \$0.94 per share. The units separated immediately and the common stock and Unit Warrants will be issued separately. American Stock Transfer & Trust Company, LLC ("AST") will act as warrant agent for the Unit Warrants. Among other terms and conditions of the Unit Warrants, the agreement provides that, in the event the closing sale price of the Company's common stock is at least \$3.00 per share for any 20 trading days within a period of 30 consecutive trading days, the Company may call the Unit Warrants for redemption, at a redemption price of \$0.01 per Unit Warrant, by providing at least 30 days notice to each Unit Warrant holder. The Unit Warrants were approved for trading on the Nasdaq Capital Market under the symbol "NLTXW" and began trading on April 22, 2010. The Offering closed on April 27, 2010.

In addition, the Company issued the Underwriters a Representative Warrant, which is a five-year warrant to purchase 390,000 shares of the Company's common stock at an exercise price of \$0.94 per share.

On May 6, 2010, the Underwriters exercised their option to purchase the maximum amount of 975,000 over-allotment units. The sale of the over-allotment units closed on May 10, 2010.

The net proceeds to the Company from the sale of all units, after deducting underwriting discounts and commissions, was approximately \$4.6 million. In connection with the Offering, certain of the Company's officers, directors and significant stockholders entered into 90-day "lock-up" agreements pursuant to which such persons agreed not to sell or transfer shares of the Company's common stock owned by them, subject to customary exceptions.

NILE THERAPEUTICS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 2010

(unaudited)

The Offering was made pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-165167) previously filed with and declared effective by the Securities and Exchange Commission (the "SEC") on March 12, 2010, and a final prospectus supplement filed with the SEC on April 22, 2010.

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

Overview

We are a development stage biopharmaceutical company in the business of commercially developing innovative products for the treatment of cardiovascular diseases. We currently have rights to develop and commercialize two product candidates, described as follows:

- **CD-NP** – 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 currently developing CD-NP for an initial indication of acute decompensated heart failure, or ADHF. In July 2009, we began enrolling patients in an open-label Phase II study of CD-NP in patients with ADHF and mild to moderate renal dysfunction. In May 2010, we reached our maximum tolerated dose in this population. We have identified two doses that appear to have an attractive safety and activity profile. We plan to enroll one additional cohort at each of the two doses to expand the number of patients exposed at these doses, and confirm safety prior to proceeding to our next Phase II study. To date, we have dosed 60 of approximately 75 patients anticipated in the study; full data is expected in late 2010. Following the completion of the ongoing Phase II study, and subject to its results, we plan to initiate a Phase IIb study in a large 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.
- **CU-NP** – 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 C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. In 2009, in partnership with the Mayo Clinic, we progressed toward the development of formulations to enable the chronic administration of CU-NP. In 2010, we expect to initiate and complete multiple in vivo pharmacological studies with chronic formulations of CU-NP.

We have no product sales to date and we will not generate any product revenue until we receive approval from the U.S. Food and Drug Administration, or 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 and public sales of our common stock, and debt financings.

Research and development, or R&D, 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. We expense our R&D costs as they are incurred.

General and administrative, or G&A, expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, personnel recruiting fees, accounting, legal and other professional fees, business development expenses, rent, business insurance and other corporate expenses.

Our results include non-cash compensation expense as a result of the issuance of stock, stock options, and warrants. We 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 performance and product development. 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.

## Results of Operations

**General and Administrative Expenses.** G&A expenses for the three months ended March 31, 2010 and 2009 were approximately \$0.6 million and \$0.5 million, respectively. The increase of approximately \$0.1 million over 2009 is primarily due to reduced forfeiture of management's performance-related options, offset by decreases in salaries due to a decrease in employees.

**Research and Development Expenses.** R&D expenses for the three months ended March 31, 2010 and 2009 were approximately \$1.3 million and \$1.3 million, respectively. We incurred increased expenses in the quarter ended March 31, 2010 of approximately \$0.1 million relating to our CD-NP program as a result of our ongoing Phase II clinical trial. However, this increase was effectively offset by reduced expenses resulting from the discontinued 2NTX-99 program and dose finding studies in non-acute heart failure patients for CD-NP.

**CD-NP.** Although the development of CD-NP is still in its early stages, we believe that it has potential applications to treat heart failure. We expect to spend an additional \$1.7 to \$2.0 million in external development costs in 2010 in order to complete the ongoing Phase II clinical trial and analyze its data. We have completed four cohorts to date in the on-going clinical trial, and expect enroll a total of six cohorts in the trial. Our strategy for further development of CD-NP in 2010 will depend to a large degree on the outcome of this ongoing clinical trial. If the data from the ongoing Phase II trial is positive, we may then initiate a larger Phase IIb clinical trial in 2011, which will require significant additional capital to fund.

**CU-NP.** Since acquiring our rights to CU-NP in June 2008, we have incurred total research and development expenses of approximately \$0.6 million through March 31, 2010. CU-NP has only undergone preclinical studies and has yet to be studied in humans. Based on our current development plans for CU-NP, we anticipate that we will expend a minimal amount on external development costs until we have obtained significant additional capital.

Our expenditures on current and future clinical development programs, particularly our CD-NP program, are expected to be substantial, particularly in relation to our available capital resources, and to increase. However, these planned expenditures are subject to many uncertainties, including the results of clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our drug candidates; and
- the costs, requirements, timing of, and the ability to secure regulatory approvals.

**Interest Income.** Interest income for the three months ended March 31, 2010 and 2009 were approximately \$4,846 and \$14,686, respectively. This decrease in interest income over 2009 is due to lower interest rates earned on cash in bank accounts, and lower average cash balances in 2010 than 2009 levels.

## Liquidity and Capital Resources



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

The following table summarizes our liquidity and capital resources as of March 31, 2010 and December 31, 2009 and our net decrease in cash and cash equivalents for the three months ended March 31, 2010 and 2009 (the amounts stated are expressed in thousands):

Liquidity and capital resources	March 31, 2010	December 31, 2009
Cash and cash equivalents	\$ 2,013	\$ 3,176
Working Capital	1,407	2,796
Stockholders' equity	1,483	2,982

Cash flow data	Three Months Ended 31,	
	2010	2009
Cash used in:		
Operating activities	\$ (1,162)	\$ (1,891)
Investing activities	-	(2)
Financing activities	-	-
Net decrease in cash and cash equivalents	\$ (1,162)	\$ (1,893)

Our total cash resources as of March 31, 2010 were \$2.0 million compared to \$3.2 million as of December 31, 2009. As of March 31, 2010, we had approximately \$0.9 million in liabilities, and \$1.4 million in net working capital. We incurred a net loss of \$1.9 million and had negative cash flow from operating activities of \$1.2 million for the three months ended March 31, 2010. Since August 1, 2005 (inception) through March 31, 2010, we have incurred an aggregate net loss of approximately \$35.8 million, while negative cash flow from operating activities has amounted to \$24.9 million. As we continue to develop our product candidates, we expect to continue to incur substantial and increasing losses, which will continue to generate 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.

From inception through March 31, 2010, we have financed our operations through private sales of our equity and debt securities. 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 through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs.

Based on our resources at March 31, 2010, together with the net proceeds from our April 2010 public offering, and our current plan of expenditure on continuing development of current product candidates which includes the potential dosing of additional cohorts in the ongoing Phase II study, we believe that we have sufficient capital to fund our operations through to the second half of 2011. Pending results of our ongoing Phase II clinical trial of CD-NP, however, 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. 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.

Our forecasted average monthly cash expenditures for the next six months are approximately \$0.4 million, which is consistent with our average monthly expenses from the previous six months. Because our plan includes the potential for dosing additional cohorts in the ongoing current Phase II study, we raised additional capital to complete the study activities, and fund operations into 2011. Following the completion of our ongoing Phase II study, we will need substantial additional capital, whether from a financing or a strategic partnership, in order to initiate and complete the next clinical study of CD-NP.

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

The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;

- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- the cost involved in prosecuting and enforcing patent claims and other intellectual property rights; and the cost and timing of regulatory approvals.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs and the opportunities presented by such programs and allocate our resources in the manner most prudent.

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 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, on acceptable terms or even at all, will increase our liabilities and future cash commitments.

#### Financing Activities

**April 2010 Financing.** On April 21, 2010, we sold in an underwritten public offering a total of 6,500,000 units of our securities at a public offering price of \$0.70 per unit. Each unit contained one share of common stock and 0.30 warrants to purchase common stock, each whole warrant representing the right to purchase one share of common stock at an exercise price of \$0.94 per share. The warrants are redeemable by us upon 30 days notice if the price of our common stock is at least \$3.00 per share for any 20 trading days within a period of 30 consecutive trading days. The units separated immediately and the common stock and warrants were issued separately. The warrants are approved for trading on the Nasdaq Capital Market under the symbol "NLTXW" and began trading on April 22, 2010. The sale of these 6,500,000 units closed on April 27, 2010.

Pursuant to the terms of the underwriting agreement, we granted the underwriters an option for a period of 45 days to purchase up to an additional 975,000 units to cover over-allotments, if any. We also issued the underwrites a five-year warrant to purchase 390,000 shares of our common stock at an exercise price of \$0.94 per share.

On May 6, 2010, the underwriters exercised their option to purchase the maximum amount of 975,000 over-allotment units. The sale of the over-allotment units closed on May 10, 2010.

The net proceeds to us from the sale of the units, after deducting underwriting discounts and commissions, was approximately \$4.6 million when including the proceeds from the sale of the 975,00 over-allotment units.

July 2009 Financing. On July 7, 2009, we entered into a securities purchase agreement with various accredited investors pursuant to which we agreed to sell in a private placement an aggregate of 2,691,394 shares of our common stock and five-year warrants to purchase an equal number of additional shares of common stock. The purchase price for each unit of one share of common stock and one warrant was \$1.25. The sale of the shares and warrants resulted in aggregate gross proceeds of approximately \$3.37 million, before deducting expenses. The issuance and sale of the units pursuant to the securities purchase agreement was completed on July 15, 2009.

In accordance with the terms of the securities purchase agreement, the warrants issued to the investors are evidenced by three separate certificates, which collectively represented at issuance the right to purchase a number of shares of common stock equal to the number of shares purchased by such investor in the private placement, as follows:

- A warrant representing the right to purchase 25% of the warrant shares at an exercise price equal to \$1.25, which represented 110% of the \$1.14 consolidated closing bid price of our common stock on the date of the securities purchase agreement;
- A warrant representing the right to purchase 25% of the warrant shares at an exercise price equal to \$1.71, which represented 150% of the closing bid price of our common stock on the date of the securities purchase agreement; and
- A warrant representing the right to purchase 50% of the warrant shares at an exercise price equal to \$2.28, which represented 200% of the closing bid price of our common stock on the date of the securities purchase agreement.

These warrants are redeemable by us, at a redemption price of \$0.001 per warrant share, upon 30 days' notice, if at any time, the volume weighted average price of our common stock for any 20 consecutive business days is equal to or greater than 200% of the then applicable exercise price of the warrants.

Issuance costs related to the financing were \$282,773, including the issuance of warrants to purchase 218,300 shares of common stock to designees of Riverbank Capital Securities, Inc., or Riverbank, which served as our placement agent in connection with the private placement. Certain of our officers and directors are principals of Riverbank.

#### License Agreement Commitments

##### CD-NP License Agreement

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. We agreed to make contingent cash payments up to an aggregate of \$31.9 million upon successful completion of specified clinical and regulatory milestones relating to CD-NP. This aggregate amount is subject to increase 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.

The CD-NP license agreement, unless earlier terminated, will continue in full force and effect until January 20, 2026. However, to the extent any patent covered by the license is issued with an expiration date beyond January 20, 2026, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, or (iii) if we challenge the validity or enforceability of any of the patents in any manner. We may terminate the agreement without cause upon 90 days' written notice.

##### CU-NP License Agreement

On June 13, 2008, we entered into a second license agreement with Mayo pursuant to which we acquired the rights to CU-NP. 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 and employees of the Mayo Clinic, until June 12, 2011.

Under the terms of the CU-NP license agreement, we made an up-front cash payment to Mayo and agreed to make future contingent cash payments up to an aggregate of \$24.3 million upon achievement of specific 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. This aggregate amount of \$24.25 million is subject to increase upon

the receipt of regulatory approval for each additional indication of CU-NP, as well as for additional compounds or analogues contained in the intellectual property. Pursuant to the agreement, we must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

The CU-NP License Agreement, unless earlier terminated, will continue in full force and effect until June 13, 2028. However, to the extent any patent covered by the license is issued with an expiration date beyond June 13, 2028, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, (iii) if we challenge the validity or enforceability of any of the patents in any manner, or (iv) or upon receipt of notice from the Company that we have terminated all development efforts under the agreement. We may terminate the agreement without cause upon 90 days' written notice.

#### Off -Balance Sheet Arrangements

There were no off-balance sheet arrangements as of March 31, 2010.

## 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

R&D 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. Except for capitalized patent expenses, R&D 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 R&D 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 R&D 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 R&D 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 R&D 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 expense the fair value of stock-based compensation 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. 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.

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.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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, 2010, 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, 2010, 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 \$2.0 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 the end of the quarter covered by this report. 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 at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

The Company is not a party to any material pending legal proceedings.

Item 1A. Risk Factors.

Not applicable.

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

Not applicable.

25

---

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. [Removed and Reserved.]

Item 5. Other Information.

On May 10, 2010, the Company issued a press release announcing that the underwriters in its previously announced public offering had exercised their over-allotment option to purchase an additional 975,000 units of the Company's securities. A copy of such press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

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.
99.1	Press release dated May 10, 2010.

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, 2010

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

Date: May 14, 2010

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

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.
99.1	Press release dated May 10, 2010.