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 SEPTEMBER 30, 2011

☐ **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.)**

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 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 November 11, 2011, there were 39,707,764 shares of common stock, par value $0.001 per share, of Nile Therapeutics, Inc. issued and outstanding.

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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 claim 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, 2010 (“Form 10-K”), 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 our Form 10-K and 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

	September 30, 2011 (unaudited)	December 31, 2010
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,607,336	$ 3,378,155
Prepaid expenses and other current assets	420,653	219,095
Total current assets	3,027,989	3,597,250
Property and equipment, net	10,886	16,765
Other noncurrent assets	51,938	51,938
Total assets	$ 3,090,813	$ 3,665,953
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 504,333	$ 332,380
Accrued expenses and other current liabilities	177,317	652,275
Due to related party	36,167	84,430
Total current liabilities	717,817	1,069,085
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, 39,707,764 and 34,629,794 shares issued and outstanding	39,708	34,630
Additional paid-in capital	45,483,878	42,492,432
Deficit accumulated during the development stage	(43,150,590)	(39,930,194)
Total stockholders' equity	2,372,996	2,596,868
Total liabilities and stockholders' equity	$ 3,090,813	$ 3,665,953

See accompanying notes to the unaudited condensed financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from August 1, 2005 (inception) through September 30, 2011
	2011	2010	2011	2010	
Income					
Grant income	$ -	$ -	$ -	$ -	$ 482,235
Collaboration income	813,000	-	1,159,000	-	1,159,000
Total income	813,000	-	1,159,000	-	1,641,235
Operating expenses:					
Research and development	1,470,091	1,148,641	2,795,354	3,517,822	28,654,293
General and administrative	499,273	664,095	1,597,855	1,732,745	15,807,287
Total operating expenses	1,969,364	1,812,736	4,393,209	5,250,567	44,461,580
Loss from operations	(1,156,364)	(1,812,736)	(3,234,209)	(5,250,567)	(42,820,345)
Other income (expense):					
Interest income	1,880	5,954	4,912	17,526	792,871
Interest expense	-	-	-	-	(1,273,734)
Other income (expense)	10,411	(2,711)	8,901	(2,793)	150,618
Total other income (expense)	12,291	3,243	13,813	14,733	(330,245)
Net loss	$ (1,144,073)	$ (1,809,493)	$ (3,220,396)	$ (5,235,834)	$ (43,150,590)
Basic and diluted loss per share	$ (0.03)	$ (0.05)	$ (0.09)	$ (0.17)	
Weighted-average common shares outstanding	39,707,764	34,563,073	36,526,346	31,338,963	

See accompanying notes to the unaudited condensed financial statements.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)
PERIOD FROM AUGUST 1, 2005 (INCEPTION) TO SEPTEMBER 30, 2011
(unaudited)

	COMMON STOCK			DEFICIT ACCUMULATED	
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	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
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
Units sold in private placement, net of issuance costs of $282,773	2,691,394	2,691	3,284,484	-	3,287,175
Stock option and warrant exercises	245,025	245	217,228	-	217,473
Net loss	-	-	-	(7,872,297)	(7,872,297)
Balance at December 31, 2009	27,085,824	27,086	36,853,767	(33,898,703)	2,982,150
Employee stock-based compensation			1,142,552	-	1,142,552
Non-employee stock-based compensation	-	-	(19,249)	-	(19,249)
Units sold in private placement, net of issuance costs of $715,801	7,475,000	7,475	4,509,224	-	4,516,699
Stock option and warrant exercises	68,970	69	6,138	-	6,207
Net loss	-	-	-	(6,031,491)	(6,031,491)
Balance at December 31, 2010	34,629,794	34,630	42,492,432	(39,930,194)	2,596,868
Employee stock-based compensation			686,711	-	686,711
Stock option and warrant exercises	77,970	78	11,169	-	11,247
Units sold in private placement, net of issuance costs of $201,434	5,000,000	5,000	2,293,566	-	2,298,566

Net loss	-	-	-	(3,220,396)	(3,220,396)
Balance at September 30, 2011	39,707,764	$ 39,708	$ 45,483,878	$ (43,150,590)	$ 2,372,996

See accompanying notes to the unaudited condensed financial statements.

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

	Nine Months Ended September 30,		Period from August 1, 2005 (inception) through September 30, 2011
	2011	2010	
Cash flows from operating activities			
Net loss	$ (3,220,396)	$ (5,235,834)	$ (43,150,590)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	5,879	10,709	319,020
Stock-based compensation	686,711	1,034,654	10,185,844
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
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	(201,558)	(46,344)	(420,653)
Other non-current assets	-	-	(51,938)
Accounts payable	171,953	440,925	504,333
Accrued expenses and other current liabilities	(474,958)	435,185	177,317
Due to related party	(48,263)	(8,916)	36,167
Net cash used in operating activities	(3,080,632)	(3,262,791)	(31,135,819)
Cash flows from investing activities			
Purchase of property and equipment	-	-	(128,868)
Proceeds from sale of assets	-	-	2,500
Cash paid for intangible assets	-	-	(345,591)
Net cash used in investing activities	-	-	(471,959)
Cash flows from financing activities			
Proceeds from issuance of notes payable	-	-	5,500,000
Repayment of notes payable	-	-	(1,500,000)
Proceeds from exercise of stock options and warrants	11,247	6,207	234,927
Proceeds from sale of common stock to founders	-	-	5,000
Proceeds from sale of common stock in private placement	2,298,566	4,516,699	29,975,187
Net cash provided by financing activities	2,309,813	4,522,906	34,215,114
Net (decrease) increase in cash and cash equivalents	(770,819)	1,260,115	2,607,336
Cash and cash equivalents at beginning of period	3,378,155	3,175,718	-
Cash and cash equivalents at end of period	$ 2,607,336	$ 4,435,833	$ 2,607,336
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	$ 1,083,700	$ 1,765,300	$ 5,721,000
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 the unaudited condensed financial statements.

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 cenderitide, a chimeric natriuretic peptide currently in clinical development 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 September 30, 2011, 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 Accounting Standards Codification ("ASC") 915, "Development Stage Entities."

The accompanying unaudited Condensed Financial Statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q adopted under the Securities Exchange Act of 1934, as amended. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of Nile's management, the accompanying Condensed Financial Statements contain all adjustments (consisting of normal recurring accruals and adjustments) necessary to present fairly the financial position, results of operations and cash flows of the Company at the dates and for the periods indicated. The interim results for the period ended September 30, 2011 are not necessarily indicative of results for the full 2011 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, 2010 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.

Collaboration Income

The Company has entered into a collaboration agreement under which the Company is reimbursed for development work performed on behalf of the collaborator upon the achievement of certain milestones. The Company records all of these expenses as research and development expenses and the reimbursements upon the achievement of the milestones as income. See Note 5 for further details.

The Company recognizes milestone payments as income upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, the Company defers the milestone payment and recognizes it as income over the remaining estimated period of performance under the contract as the Company completes its performance obligations.

Research and development

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

3. LIQUIDITY, CAPITAL RESOURCES AND MANAGEMENT'S PLANS

The Company has experienced net losses since its inception and has an accumulated deficit of approximately $43.2 million at September 30, 2011. 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.

Cash resources as of September 30, 2011 were approximately $2.6 million, compared to $3.4 million as of December 31, 2010. Based on its resources at September 30, 2011 and the current plan of expenditure for continued development of the Company's current product candidates, which includes the completion of its Phase 1 clinical trial of cenderitide administered with Medtronic's pump technology, the Company believes that it only has sufficient capital to fund its operations into the second quarter of 2012. The Company will need to raise additional capital to complete the next clinical trial of cenderitide, which is expected to be a Phase 2 trial to be initiated in 2012. 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. If the Company is unable to raise additional funds when needed, the Company may not be able to continue the clinical and regulatory development of its products, and could be required to delay, scale back or eliminate some or all of its research and development programs or potentially wind down our operations altogether. Each of these alternatives would likely have a material adverse effect on the Company's business.

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.

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 significant additional 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 factors raise substantial doubt about the Company's ability to continue as a going concern. 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 financial statements do not include any adjustments that might result from the inability of the Company to continue as a going concern.

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, potentially dilutive securities are excluded from the computation of fully diluted loss per share as their effect is anti-dilutive.Potentially dilutive securities include:

	September 30, 2011	September 30, 2010
Warrants to purchase common stock	2,750,000	-
Options to purchase common stock	3,041,000	2,568,970
Total potentially dilutive securities	5,791,000	2,568,970

For the three months ended September 30, 2011 and 2010, warrants and options to purchase 11,300,285 and 10,976,043 shares, respectively, have been excluded from the above computation of potentially dilutive securities, respectively, as their exercise prices are greater than the 100 day moving average market price per common share as of October 31, 2011 and November 1, 2010, respectively.

5. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

License Agreements

Cenderitide

On January 20, 2006, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, referred to as the Cenderitide License Agreement, with the Mayo Foundation for Medical Education and Research ("Mayo") for the rights to issued patents, patent applications and know-how relating to the use of cenderitide in all therapeutic indications. The Company was also entitled to rights to improvements to cenderitide that arose out of the laboratory of Dr. John Burnett, the co-inventor of cenderitide, prior to January 19, 2009.

Under the terms of the Cenderitide 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 cenderitide. This aggregate amount is subject to increase upon the receipt of regulatory approval for each additional indication of cenderitide as well as for additional compounds or analogues contained in the intellectual property.

In addition to the potential milestone payments discussed above, the Cenderitide 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, 2007, the Company received $482,235 in grant income for which the Company has issued to Mayo 63,478 shares (representing $182,236) of common stock. The Company has not received grant income since 2007.

The Cenderitide 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 challenges 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 arose out of the laboratory of Dr. John Burnett and Dr. Candace Lee, the inventors of CU-NP, prior to June 12, 2011.

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 2 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 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) upon the Company's insolvency or bankruptcy, (iii) if the Company challenges 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.

Collaboration Agreement

On February 25, 2011, the Company entered into a Clinical Trial Funding Agreement (the "Collaboration Agreement") with Medtronic, Inc. Pursuant to the Collaboration Agreement, Medtronic agreed to provide the equipment necessary for the Company to conduct a Phase 1 clinical trial to assess the pharmacokinetics and pharmacodynamics of cenderitide when delivered to heart failure patients through continuous subcutaneous infusion using Medtronic's diabetes pump technology. Pursuant to the Collaboration Agreement, Medtronic also agreed to reimburse the Company for certain external expenses related to the Phase 1 clinical trial and make other payments upon the achievement of certain milestones as defined in the Collaboration Agreement. Any budget overages will be reviewed by the Company and Medtronic and may result in additional reimbursement. As of September 30, 2011, the Company has received approximately $1.2 million in reimbursements from Medtronic, all of which amounts are recorded as income on the Company's Condensed Statements of Operations.

Under the Collaboration Agreement, the Company has agreed not to enter into an agreement with another third party to develop or commercialize cenderitide or any drug/device combination developed under the agreement until the earlier of: (i) three months following delivery to Medtronic of a final database with respect to the Phase 1 trial; and (ii) 15 months after the date of the Collaboration Agreement. The Company expects to deliver the final database in November 2011. Therefore, the period in which the Company would not be able to sign an agreement with another third party would expire in February 2012.

The Collaboration Agreement provides that intellectual property conceived in or otherwise resulting from the performance of the Phase 1 clinical trial shall be jointly owned by the Company and Medtronic (the "Joint Intellectual Property"), and that the Company shall pay royalties to Medtronic based on the net sales of any Nile product, of which the manufacture, use or sale is covered or claimed in one or more issued patents constituting Joint Intellectual Property. The Collaboration Agreement further provides that, if the parties fail to enter into a definitive commercial license agreement with respect to cenderitide, then each party shall have a right of first negotiation to license exclusive rights to any Joint Intellectual Property.

The Collaboration Agreement will remain in effect until the completion of the Phase 1 clinical trial, including delivery to Medtronic of a final database and a final study report with respect to the Phase 1 trial, unless terminated earlier by either party (i) if the other has materially breached its obligations thereunder, (ii) if the other party becomes subject to a bankruptcy or similar proceeding, (iii) for reasons related to the safety, efficacy, toxicity or formulation of cenderitide, or (iv) for a failure of the study to meet its endpoints. Also, Medtronic may terminate the agreement without cause at any time upon 90 days' written notice to the Company, in which event Medtronic shall be obligated to pay for any non-cancelable costs incurred by the Company prior to such termination.

6. STOCKHOLDERS' EQUITY

(a) Common Stock

On June 20, 2011, the Company entered into a securities purchase agreement (the "Purchase Agreement") with certain investors pursuant to which it sold 5,000,000 units of its securities (the "Units"), each Unit consisting of (i) one share of common stock (collectively, the "Shares") and (ii) a five-year warrant (collectively, the "Warrants") to purchase one-half share of common stock (collectively, the "Warrant Shares") at an exercise price of $0.60 per share, for a purchase price of $0.50 per Unit (the "2011 Offering"). The Warrants may be exercised immediately and are redeemable by the Company, at a redemption price of $0.001 per Warrant Share, upon 30 days' notice, if at any time, the volume weighted average price of the common stock for any 20 consecutive business days is equal to or greater than 250% of the then applicable exercise price of the Warrants. The gross proceeds from the 2011 Offering were $2,500,000, before deducting selling commissions and expenses, which were $201,434. The closing of the private placement occurred on June 23, 2011.

Pursuant to the Purchase Agreement, the Company agreed to file a registration statement with the Securities and Exchange Commission seeking to register the resale of the Shares and Warrant Shares. In the event the Company did not file the registration statement within 30 days following the closing of the 2011 Offering, the Company agreed to pay liquidated damages to the investors in the amount of 1% of such investor's aggregate investment amount each month until the registration statement is filed. The registration statement was filed on July 22, 2011.

In connection with the 2011 Offering, the Company engaged Riverbank Capital Securities, Inc. ("Riverbank") to serve as placement agent, and Ladenburg Thalmann & Co. Inc. served as a sub-placement agent (together with Riverbank, the "Placement Agents"). The Company agreed to pay the Placement Agents a cash fee equal to 7% of the gross proceeds resulting from the private placement, plus issue a five-year warrant (the "Placement Warrants") to purchase a number of shares equal to 5% of the Shares sold in the private placement. Pursuant to such terms, the Company paid the Placement Agents a cash fee of $175,000 and issued Placement Warrants to purchase 250,000 shares of common stock valued at $93,000. The Placement Warrants are in substantially the same form as the Warrants issued to the purchasers, except that the Placement Warrants include provisions allowing for cashless exercise.

Peter M. Kash, a director of the Company, and Joshua A. Kazam, the Company's President and Chief Executive Officer and a director of the Company, are each officers of Riverbank. Mr. Kash was allocated a portion of the Placement Warrants issuable to the Placement Agents. In light of the relationship between Messrs. Kash and Kazam and Riverbank, the selection of Riverbank as a placement agent and the terms of the engagement were reviewed and approved by a special committee of the Company's Board consisting of disinterested directors with no affiliation to Riverbank or its affiliates.

On April 21, 2010, the Company entered into an underwriting agreement (the "Underwriting Agreement"), providing for the offer and sale in a firm commitment underwritten public offering (the "2010 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). The 2010 Offering closed on April 27, 2010. 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. 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. Each unit sold in the 2010 Offering consisted of one share of the Company's common stock and 0.30 warrants to purchase common stock (the "Unit Warrants"). Each whole 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 were issued separately. 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. Along with the Company's common stock, trading of the Unit Warrants was suspended as of the opening of business on May 12, 2011, and the Company's securities were formally delisted from the Nasdaq Capital Market in July 2011.

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. 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, which had a fair value of $271,900 and was accounted for as a cost of the offering and charged to stockholders' equity.

The net proceeds to the Company from the sale of all units, after deducting underwriting discounts, commissions and professional fees of $715,801, was $4,516,699.

(b) Warrants

In connection with the 2011 Offering discussed above, the Company issued a total of 2,500,000 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 $0.60 per share. In addition, the Company issued the Placement Agents a five-year warrant to purchase 250,000 shares of the Company's common stock at an exercise price of $0.60 per share.

In connection with the 2010 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.

Below is a table that summarizes all outstanding warrants to purchase shares of the Company's common stock as of September 30, 2011.

Grant Date	Warrants Issued	Exercise Price Range	Weighted Average Exercise Price	Expiration Date	Exercised	Warrants Outstanding
9/11/2007	168,377	$ 2.71	$ 2.71	9/11/2012	-	168,377
3/26/2008	206,912	$ 2.71	$ 2.71	9/11/2012	-	206,912
7/15/2009	2,909,695	$ 1.25-2.28	$ 1.64	7/14/2014	5,000	2,904,695
4/21/2010	2,632,500	$ 0.94	$ 0.94	4/20/2015	-	2,632,500
6/20/2011	2,750,000	$ 0.60	$ 0.60	6/19/2016	-	2,750,000
	8,667,484		**$ 1.50**		**5,000**	**8,662,484**

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. On July 26, 2010, the Company's stockholders approved an amendment to the Plan increasing the total number of shares authorized for issuance thereunder to 9,500,000. Under the Plan, incentives may be granted to officers, employees, directors, consultants, and advisors. Incentives under the Plan may be granted in any one or a combination of the following forms: (a) incentive stock options and non-statutory stock options, (b) stock appreciation rights, (c) stock awards, (d) restricted stock and (e) performance shares. The Plan is administered by the Board of Directors, or a committee appointed by the Board, which determines the recipients and types of awards to be granted, as well as the number of shares subject to the awards, the exercise price and the vesting schedule. The term of stock options granted under the Plan cannot exceed ten years. Currently, stock options are granted with an exercise price equal to closing price of the Company's common stock on the date of grant, and generally vest over a period of one to four years.

For the nine months ended September 30, 2011, the Company estimated the fair value of each option award granted using the Black-Scholes option-pricing model. The following assumptions were used for the nine months ended September 30, 2011 and the three and nine months ended September 30, 2010, respectively (no options were issued during the three months ended September 30, 2011):

	Nine Months Ended September 30, 2011	Three Months Ended September 30, 2010	Nine Months Ended September 30, 2010
Expected volatility	97%	90% to 98%	90% to 98%
Expected term	3 - 5 years	3 years	3 years
Dividend yield	0%	0%	0%
Risk-free interest rates	0.9 - 2.2%	0.9% - 1%	0.9% - 1%

The valuation assumptions were determined as follows:

- Expected volatility – The expected volatility is calculated from the 260 day volatility of the Company's stock price.

- Expected term – The expected term of the awards represents the period of time that the awards are expected to be outstanding. Management considered historical data and expectations for the future to estimate employee exercise and post vest termination behavior. Consultant options are assigned an expected term equal to the maximum term of the option grant.

- Dividend yield – The estimate for annual dividends is zero, because the Company has not historically paid dividends and does not intend to in the foreseeable future.

A summary of the status of the options issued under the Plan at September 30, 2011, and information with respect to the changes in options outstanding is as follows:

	Shares Available for Grant	Outstanding Stock Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Balance at January 1, 2011	2,267,851	6,923,154	$ 1.52	
Options granted under the Plan	(1,050,000)	1,050,000	$ 0.68	
Options exercised	-	(77,970)	$ 0.14	
Options forfeited	60,133	(60,133)	$ 0.93	
Balance at September 30, 2011	1,277,984	7,835,051	$ 1.43	$ 776,700
Exercisable at September 30, 2011		5,943,657	$ 1.67	$ 495,020

The following table summarizes information about stock options outstanding at September 30, 2011:

	Outstanding			Exercisable	
Range of Exercise Prices	Shares	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Total Shares	Weighted-Average Exercise Price
$0.30 to $0.93	4,721,923	7.54	$ 0.53	2,971,923	$ 0.54
$1.14 to $2.71	2,476,779	4.84	$ 2.33	2,390,111	$ 2.36
$4.45 to $5.75	636,349	5.86	$ 4.54	581,623	$ 4.55
Total	7,835,051	6.55	$ 1.43	5,943,657	$ 1.67

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.

Employee stock-based compensation costs for the three and nine months ended September 30, 2011 and 2010 and for the cumulative period from August 1, 2005 (inception) through September 30, 2011 are as follows:

	Three months ended September 30,		Nine months ended September 30,		Period from August 1, 2005 (inception) through September 30, 2011
	2011	2010	2011	2010	
General and administrative	$ 126,897	$ 248,886	$ 351,946	$ 731,146	$ 6,662,653
Research and development	122,099	65,978	211,087	217,601	1,284,933
Total	$ 248,996	$ 314,864	$ 563,033	$ 948,747	$ 7,947,586

The fair value of shares vested under the Plan for the three and nine months ended September 30, 2011 and 2010 and for the period from August 1, 2005 (inception) through September 30, 2011 were $290,879, $695,491, $907,271, $1,425,226, and $6,357,032 respectively.

At September 30, 2011, total unrecognized estimated employee (including directors) compensation cost related to stock options granted prior to that date was $431,764, which is expected to be recognized over a weighted-average vesting period of 1.3 years. This unrecognized estimated employee compensation cost does not include any expenses relating to 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 August 12, 2010, in conjunction with an amended services agreement, the Company issued to named employees of Two River Consulting ("TRC") stock options to purchase 250,000 shares of the Company's common stock that were fully vested on issuance and had an estimated fair value of $82,200.

Stock-based compensation costs incurred for services by non-employees for the three and nine months ended September 30, 2011 and 2010, and for the cumulative period from August 1, 2005 (inception) through September 30, 2011 totaled $0, $123,679, $69,638, $85,905 and $698,773 respectively. These amounts were included in research and development and general and administrative expenses in the accompanying Condensed Statements of Operations. As of September 30, 2011 all non-employee based options were fully vested.

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 (the "Special Committee"). 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. Twenty-five percent of the stock options vested immediately and the remaining 75% were scheduled to vest pursuant to the achievement of certain milestones relating to the clinical development of cenderitide. On January 5, 2011, the final block of stock options vested. Of the 750,000 original stock options issued, 535,172 stock options vested with a total fair value of $353,976. On August 12, 2010, the Special Committee approved an extension of the services agreement with TRC to provide for a month-to-month term and the issuance of fully-vested and immediately-exercisable stock options to purchase 250,000 shares of the Company's common stock at an exercise price of $0.38 per share, which had an estimated fair value of $82,000, was expensed on the date of grant. On March 17, 2011, the Special Committee approved an amendment of the services agreement, pursuant to which the level of services to be provided by TRC was reduced and the monthly cash fee payable to TRC was reduced to $31,702. Additional operational and clinical development services may be provided by TRC, and billed to the Company, on an hourly basis.

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 and nine months ended September 30, 2011 and 2010 and for the period from August 1, 2005 (inception) through September 30, 2011, total cash services and reimbursed expenses totaled $99,990, $326,300, $205,239, $619,602, and $1,743,162 respectively. As of September 30, 2011 the Company had a payable to TRC of $36,167 which was paid in full during October 2011.

In connection with the 2011 Offering, the Company engaged Riverbank Capital Securities, Inc. ("Riverbank") to serve as placement agent. Mr. Kazam and Peter M. Kash, a director of the Company, are each officers of Riverbank. See Note 6 for further details.

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:

- ***Cenderitide****,* our lead product candidate, is a chimeric natriuretic peptide that we are developing for the treatment of heart failure. We plan to develop cenderitide for the treatment of patients for up to 90 days following admission for acutely decompensated heart failure, or ADHF. We also believe cenderitide may be useful in several other cardiovascular and renal indications. We recently completed dosing subjects in a Phase 1 clinical trial in collaboration with Medtronic, Inc. Pursuant to an agreement with Medtronic, we are reimbursed for a portion of the costs incurred to conduct this Phase 1 trial. We expect to complete the remaining activities of this Phase 1 trial, which include analysis of the study data and preparation of a study report, during the first quarter of 2012.

- ***CU-NP***, is a pre-clinical rationally designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. We are currently evaluating the potential for the chronic dosing of CU-NP, which could be used to treat a number of cardiovascular and renal diseases.

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, cenderitide. As we proceed with the clinical development of cenderitide 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 September 30, 2011 and 2010 were approximately $0.5 million and $0.7 million, respectively. G&A expenses for the nine months ended September 30, 2011 and 2010 were approximately $1.6 million and $1.7 million, respectively. The small decrease in G&A expenses from 2010 is primarily due to an approximately $0.1 million decrease in stock compensation expense in 2011. Additionally, during the three months ended September 30, 2010, the Company incurred one-time charges for the listing of additional shares on the NASDAQ, with no such charges during the same period in 2011.

Research and Development Expenses. R&D expenses for the three months ended September 30, 2011 and 2010 were approximately $1.5 million and $1.1 million, respectively. The approximately $0.4 million increase in 2011 R&D expenses over 2010 is primarily due to approximately $0.2 million in preclinical toxicology studies conducted on cenderitide, with no such activities during the same period in 2010. Additionally, there was an increase of $0.2 million in clinical costs primarily due to the Phase 1 trial of cenderitide conducted in collaboration with Medtronic that began in 2011 and therefore, no such expenses for the same period in 2010.

R&D expenses for the nine months ended September 30, 2011 and 2010 were approximately $2.8 million and $3.5 million, respectively. The decrease in R&D expenses in 2011 over the respective period in 2010 is primarily due to the completion of our Phase 2 clinical study of cenderitide during the fourth quarter of 2010, offset partially by expenses related to the Phase 1 clinical trial of cenderitide in collaboration with Medtronic which began in 2011.

Cenderitide. Although the development of cenderitide is still in its early stages, we believe that it has potential applications to treat heart failure. In addition to the Phase 1 clinical trial costs being reimbursed by Medtronic pursuant to our collaboration agreement, we expect to spend $0.5 million in external development costs in the remainder of fiscal 2011. We completed dosing the Phase 1 trial in October 2011, having enrolled 58 patients in the trial. Our strategy for further development of cenderitide in 2012 will depend to a large degree on the final analysis of the data from this clinical trial. Subject to such data, we plan to initiate a larger Phase 2 clinical trial in 2012, 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 September 30, 2011. 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 cenderitide 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 September 30, 2011 and 2010 was approximately $1,880 and $5,954, respectively. Interest income for the nine months ended September 30, 2011 and 2010 was approximately $4,912 and $17,526, respectively. This decrease in interest income over 2010 is due to lower interest rates earned on cash in bank accounts and lower average cash balances in 2011 than 2010 levels.

Collaboration Income. As a result of our February 2011 collaboration agreement with Medtronic, pursuant to which Medtronic agreed to reimburse us for our R&D expenditures in connection with our Phase 1 trial of cenderitide, we recognized income of approximately $0.8 million and $1.2 million in the three and nine month periods ended September 30, 2011, respectively, compared to no such income during the corresponding periods in 2010. We expect to recognize approximately $0.2 million of income relating to the reimbursement of expenses from our Phase 1 trial through the remainder of 2011, and another $0.2 million in the first half of 2012.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2011 and December 31, 2010 and our net decrease in cash and cash equivalents for the nine months ended September 30, 2011 and 2010 (the amounts stated are expressed in thousands):

Liquidity and capital resources	September 30, 2011	December 31, 2010
Cash and cash equivalents	$ 2,607	$ 3,378
Working Capital	$ 2,310	$ 2,528
Stockholders' equity	$ 2,373	$ 2,597

	Nine Months Ended September 30,	
Cash flow data	2011	2010
Cash used in:		
Operating activities	$ (3,081)	$ (3,263)
Investing activities	-	-
Cash provided by:		
Financing activities	2,310	4,523
Net (decrease) increase in cash and cash equivalents	$ (771)	$ 1,260

Our total cash resources as of September 30, 2011 were $2.6 million compared to $3.4 million as of December 31, 2010. As of September 30, 2011, we had approximately $0.7 million in current liabilities, and $2.3 million in net working capital. We incurred a net loss of $3.2 million and had negative cash flow from operating activities of $3.1 million for the nine months ended September 30, 2011. Since August 1, 2005 (inception) through September 30, 2011, we have incurred an aggregate net loss of approximately $43.2 million, while negative cash flow from operating activities has amounted to $31.1 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 September 30, 2011, we have financed our operations through public and 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 or 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 September 30, 2011 and the current plan of expenditure on continuing development of current product candidates, which includes the completion of our Phase 1 clinical trial of cenderitide administered with Medtronic's pump technology, we believe that we only have sufficient capital to fund our operations into the second quarter of 2012. We would need substantial additional capital in order to initiate and fund the next clinical study of cenderitide, which is expected to be a Phase 2 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 continue the clinical and regulatory development of our products, and could be required to delay, scale back or eliminate some or all our research and development programs or potentially wind down our operations altogether. Each of these alternatives would likely have a material adverse effect on our business and may result in the entire loss of your investment in our common stock.

Our forecasted average monthly cash expenditures for the next six months, net of funding from Medtronic, are approximately $0.3 million. Following the completion of our Phase 1 trial, we will need substantial additional capital, whether from a financing or a strategic partnership, in order to initiate and complete our next planned study, a Phase 2 clinical trial.

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 estimates 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 significant additional 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 the second quarter of 2012 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.

June 2011 Financing

On June 20, 2011, we sold in a private placement offering a total of 5,000,000 units of our securities at an offering price of $0.50 per unit. Each unit contained one share of common stock and 0.50 warrants to purchase one share of common stock at an exercise price of $0.60 per share. We may call the warrants for redemption upon 30 days notice if the volume weighted average price of the common stock for any 20 consecutive business days is equal to or greater than $1.50 per share. The total gross proceeds from the 2011 Offering were $2.5 million, before deducting selling commissions and expenses, which were approximately $0.2 million. The closing of the private placement occurred on June 23, 2011.

Pursuant to the Purchase Agreement, the Company agreed to file a registration statement with the Securities and Exchange Commission seeking to register the resale of the Shares and Warrant Shares. The registration statement was filed on July 22, 2011.

In connection with the private placement offering, we engaged Riverbank Capital Securities, Inc. (or “Riverbank”) to serve as placement agent, and Ladenburg Thalmann & Co. Inc. served as a sub-placement agent. Pursuant to the terms of the engagement agreement, we paid the placement agents a cash fee of $175,000 and issued warrants to purchase 250,000 shares of common stock, valued at $93,000.

Peter M. Kash, a director, and Joshua A. Kazam, our President and Chief Executive Officer and a director, are each officers of Riverbank. Mr. Kash was allocated a portion of the warrants issuable to the placement agents. In light of the relationship between Messrs. Kash and Kazam and Riverbank, the selection of Riverbank as a placement agent and the terms of the engagement were reviewed and approved by a special committee of the our Board consisting of disinterested directors with no affiliation to Riverbank or its affiliates.

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. The sale of these 6,500,000 units closed on April 27, 2010. 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. We may call the warrants for redemption 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 were approved for trading on the Nasdaq Capital Market under the symbol "NLTXW" and began trading on April 22, 2010. Along with our common stock, trading of the warrants was suspended as of the opening of business on May 12, 2011, and our securities were formally delisted from the Nasdaq Capital Market in July 2011.

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 underwriters 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.

License Agreement Commitments

Cenderitide License Agreement

Pursuant to our license agreement with the Mayo Foundation for Medical Education and Research ("Mayo") for cenderitide, in July 2008 we made a milestone payment of $400,000 to Mayo upon the dosing of the first patient in a Phase 2 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 cenderitide. This aggregate amount is subject to increase upon the receipt of regulatory approval for each additional indication of cenderitide as well as for additional compounds or analogues contained in the intellectual property.

The cenderitide 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 arose out of the laboratory of Dr. John Burnett and Dr. Candace Lee, the inventors of CU-NP and employees of the Mayo Clinic, prior to 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 2 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, 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.

Collaboration Agreement

In February 2011, we entered into a Clinical Trial Funding Agreement with Medtronic, Inc. Pursuant to the agreement, Medtronic agreed to provide the funding and equipment necessary for us to conduct a Phase 1 clinical trial to assess the pharmacokinetics and pharmacodynamics of cenderitide when delivered to heart failure patients through continuous subcutaneous infusion using Medtronic's diabetes pump technology. In accordance with the agreement, Medtronic also agreed to reimburse to us the costs necessary to conduct the Phase 1clinical trial and to supply the pumps and related equipment for use therein. As of September 30, 2011, Nile has received approximately $1.2 million in funding from Medtronic.

Under our agreement with Medtronic, we have agreed not to enter into an agreement with a third party to develop or commercialize cenderitide or any drug/device combination developed under the agreement until the earlier of: (i) three months following delivery to Medtronic of a final database with respect to the Phase 1 trial; and (ii) 15 months after the date of the agreement. We expect to deliver the final database in November 2011. Therefore, we expect that the period in which we would not be able to sign an agreement with another third party would end in February 2012.

The agreement provides that intellectual property conceived in or otherwise resulting from the performance of the Phase 1 clinical trial shall be jointly owned by us and Medtronic (the "Joint Intellectual Property"), and that we shall pay royalties to Medtronic based on the net sales of any Nile product, the manufacture, use or sale of which is covered or claimed in one or more issued patents constituting Joint Intellectual Property. The agreement further provides that, if the parties fail to enter into a definitive commercial license agreement with respect to cenderitide, then each party shall have a right of first negotiation to license exclusive rights to any Joint Intellectual Property.

The agreement will remain in effect until the completion of the Phase 1 clinical trial, including delivery to Medtronic of a final database and a final study report with respect to the Phase 1 trial, unless terminated earlier by either party (i) if the other has materially breached its obligations thereunder, (ii) if the other party becomes subject to a bankruptcy or similar proceeding, (iii) for reasons related to the safety, efficacy, toxicity or formulation of cenderitide, or (iv) for a failure of the study to meet its endpoints. Also, Medtronic may terminate the agreement without cause at any time upon 90 days' written notice to us, in which event Medtronic shall be obligated to pay for any non-cancelable costs incurred by us prior to such termination.

Off -Balance Sheet Arrangements

There were no off-balance sheet arrangements as of September 30, 2011.

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.

Collaboration Income

We have entered into a collaboration agreement whereby we are reimbursed for work performed on behalf of the collaborator upon the achievement of certain milestones. We record all of these expenses as research and development expenses and the reimbursements upon the achievement of the milestones as income.

We recognize milestone payments as income upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as income over the remaining estimated period of performance under the contract as we complete its performance obligations.

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 CROs 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.

We have entered into a collaboration agreement with Medtronic, Inc. relating to our Phase 1 clinical trial of cenderitide. Under this agreement, we are reimbursed for certain costs of the Phase 1 trial. We record all of these expenses as research and development expense and the reimbursements from Medtronic as income.

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 September 30, 2011, 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 September 30, 2011, 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 $2.6 million.

Item 4. 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 control over financial reporting during the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control 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.

An investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factor, together with the other information appearing elsewhere in this report, before making an investment decision regarding our common stock. You should also consider the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2010 ("2010 Annual Report") under the caption "Item 1A. Risk Factors." If any of the risks described below or in our 2010 Annual Report actually occur, our business, financial conditions, results of operation and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below and in our 2010 Annual Report are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

We need substantial additional funding before we can complete the development of our product candidates, including cenderitide, our lead product candidate. If we are unable to raise additional capital, we will be forced to delay, reduce or eliminate our product development programs and may not have the capital required to otherwise operate our business.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue to develop cenderitide, our lead product candidate, and initiate clinical development of CU-NP, our second product candidate. In addition, our expenses could increase beyond expectations if the U.S. Food and Drug Administration, or FDA, requires that we perform additional studies to those that we currently anticipate, and the timing of any potential product approval may be delayed. Other than our cash on hand, we currently have no commitments or arrangements for any additional financing to fund the research and development of our product candidates. We have not generated any product revenues, and do not expect to generate any revenues until, and only if, we receive approval to sell our drug candidates from the FDA and other regulatory authorities for our product candidates. As of September 30, 2011, we had cash and cash equivalents totaling $2.6 million. During the fiscal year ended December 31, 2010 and the nine months ended September 30, 2011, we used net cash totaling $4.3 million and $3.1 million, respectively, in operating activities. We expect our negative cash flows from operations to continue for the foreseeable future and beyond potential regulatory approval and any product launch. Based on our current development plans, including the completion of our Phase 1 PK/PD study of cenderitide, we anticipate that our current resources will only be sufficient to fund our operations into the second quarter of 2012. We will need substantial additional capital in order to complete the next stage of development of cenderitide, which we anticipate will be a Phase 2 double-blind, placebo-controlled, dose ranging clinical study.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. In addition, we could be forced to discontinue product development and reduce or forego attractive business opportunities, or even cease business altogether. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, 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. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. However, even though we have to date been successful in securing the capital needed to fund our business, there is no assurance that we will continue to secure such capital in the future.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. **[Removed and Reserved.]**

Item 5. **Other Information.**

None.

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.
101	The following financial information from Nile Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2011, formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Balance Sheets as of September 30, 2011 and December 31, 2010, (ii) Condensed Statements of Operations for the three and nine months ended September 30, 2011 and September 30, 2010, and for the period from August 1, 2005 (inception) through September 30, 2011, (iii) Condensed Statement of Stockholders' Equity for the period from August 1, 2005 (inception) through September 30, 2011, (iv) Condensed Statements of Cash Flows for the nine months ended September 30, 2011 and September 30, 2010, and for the period from August 1, 2005 (inception) through September 30, 2011, and (v) Notes to Condensed Financial Statements.*

*Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 to this Quarterly Report on Form 10-Q shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be deemed part of a registration statement, prospectus or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filings.

SIGNATURES

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

NILE THERAPEUTICS, INC.

Date: November 14, 2011

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

Date: November 14, 2011

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

EXHIBIT INDEX

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EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Joshua Kazam, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Nile Therapeutics, Inc.;

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 registrant as of, and for, the periods presented in this report;

4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant'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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: November 14, 2011

/s/ Joshua Kazam
Name: Joshua Kazam
Title: Chief Executive Officer

EXHIBIT 31.2

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.;

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 registrant as of, and for, the periods presented in this report;

4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant'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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: November 14, 2011

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

EXHIBIT 32.1

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 September 30, 2011 (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: November 14, 2011

/s/ Joshua Kazam
Name: Joshua Kazam
Title: Chief Executive Officer

EXHIBIT 32.2

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 September 30, 2011 (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: November 14, 2011

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