Nile Therapeutics, Inc.
Form 10-Q
August 15, 2011

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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 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 x No ¨

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of August 12, 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 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

	June 30, 2011 (unaudited)	December 31, 2010
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,259,835	$ 3,378,155
Prepaid expenses and other current assets	379,877	219,095
Total current assets	3,639,712	3,597,250
Property and equipment, net	12,698	16,765
Other noncurrent assets	51,938	51,938
Total assets	$ 3,704,348	$ 3,665,953
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 237,760	$ 332,380
Accrued expenses and other current liabilities	161,143	652,275
Due to related party	37,371	84,430
Total current liabilities	436,274	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	45,234,882	42,492,432
Deficit accumulated during the development stage	(42,006,516)	(39,930,194)
Total stockholders' equity	3,268,074	2,596,868
Total liabilities and stockholders' equity	$ 3,704,348	$ 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 June 30,		Six Months Ended June 30,		Period from August 1, 2005 (inception) through June 30, 2011
	2011	2010	2011	2010	
Income					
Grant income	$ -	$ -	$ -	$ -	$ 482,235
Collaboration income	346,000	-	346,000	-	346,000
Total income	346,000	-	346,000	-	828,235
Operating expenses:					
Research and development	702,930	1,055,759	1,325,262	2,369,181	27,184,202
General and administrative	523,305	445,448	1,098,583	1,068,650	15,308,014
Total operating expenses	1,226,235	1,501,207	2,423,845	3,437,831	42,492,216
Loss from operations	(880,235)	(1,501,207)	(2,077,845)	(3,437,831)	(41,663,981)
Other income (expense):					
Interest income	1,046	6,726	3,032	11,572	790,991
Interest expense	-	-	-	-	(1,273,734)
Other income (expense)	(1,341)	(40)	(1,509)	(82)	140,208
Total other income (expense)	(295)	6,686	1,523	11,490	(342,535)
Net loss	$ (880,530)	$ (1,494,521)	$ (2,076,322)	$ (3,426,341)	$ (42,006,516)
Basic and diluted loss per share	$ (0.03)	$ (0.05)	$ (0.06)	$ (0.12)	
Weighted-average common shares outstanding	35,091,653	32,285,824	34,882,947	29,700,189	

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 JUNE 30, 2011
(unaudited)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	TOTAL STOCKHOLDERS ' EQUITY (DEFICIT)
	SHARES	AMOUNT			
Issuance of common shares to founders	13,794,132	$13,794	$ (8,794)	$ -	$ 5,000
Founders shares returned to treasury	(1,379,419)	-	-	-	-
Net loss	-	-	-	(10,043)	(10,043)
Balance at December 31, 2005	12,414,713	13,794	(8,794)	(10,043)	(5,043)
Issuance of common shares pursuant to licensing agreement	1,379,419	-	500	-	500
Issuance of stock options for services	-	-	10,000	-	10,000
Net loss	-	-	-	(2,581,972)	(2,581,972)
Balance at December 31, 2006	13,794,132	13,794	1,706	(2,592,015)	(2,576,515)
Issuance of common shares pursuant to licensing agreement	63,478	64	182,172	-	182,236
Issuance of common shares pursuant to licensing agreement	350,107	350	999,650	-	1,000,000
Common shares sold in private placement, net of issuance costs of $102,000	6,957,914	6,958	19,865,789	-	19,872,747
Warrants issued in connection with note conversion	-	-	288,000	-	288,000
Conversion of notes payable upon event of merger	1,684,085	1,684	4,349,481	-	4,351,165
Note discount arising from beneficial conversion feature	-	-	483,463	-	483,463

Reverse merger transaction					
Elimination of accumulated deficit	-	-	(234,218)	-	(234,218)
Previously issued SMI stock	1,250,000	1,250	232,968	-	234,218
Employee stock-based compensation	-	-	1,902,298	-	1,902,298
Non-employee stock-based compensation	-	-	(667)	-	(667)
Net loss	-	-	-	(10,302,795)	(10,302,795)
Balance at December 31, 2007	24,099,716	24,100	28,070,642	(12,894,810)	15,199,932
Warrants issued in satisfaction of accrued liabilities	-	-	334,992	-	334,992
Employee stock-based compensation	-	-	2,436,603	-	2,436,603
Non-employee stock-based compensation	-	-	13,687	-	13,687
Issuance of common shares pursuant to licensing agreement	49,689	50	249,950	-	250,000
Net loss	-	-	-	(13,131,596)	(13,131,596)
Balance at December 31, 2008	24,149,405	24,150	31,105,874	(26,026,406)	$ 5,103,618
Employee stock-based compensation	-	-	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			437,715	-	437,715
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	-	-	-	(2,076,322)	(2,076,322)
Balance at June 30, 2011	39,707,764	$39,708	$ 45,234,882	$ (42,006,516)	$ 3,268,074

See accompanying notes to the unaudited condensed financial statements.

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

	Six Months Ended June 30,		Period from August 1, 2005 (inception) through June 30, 2011
	2011	2010	
Cash flows from operating activities			
Net loss	$(2,076,322)	$(3,426,341)	$ (42,006,516)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	4,067	7,631	317,208
Stock-based compensation	437,715	650,152	9,936,848
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	(160,782)	20,545	(379,877)
Other non-current assets	-	-	(51,938)
Accounts payable	(94,620)	3,400	237,760
Accrued expenses and other current liabilities	(491,132)	514,036	161,143
Due to related party	(47,059)	(5,252)	37,371
Net cash used in operating activities	(2,428,133)	(2,128,999)	(30,483,320)
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	-	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	4,516,699	34,215,114
Net (decrease) increase in cash and cash equivalents	(118,320)	2,387,700	3,259,835
Cash and cash equivalents at beginning of period	3,378,155	3,175,718	-
Cash and cash equivalents at end of period	$3,259,835	$5,563,418	$ 3,259,835

Supplemental schedule of cash flows information:			
Cash paid for interest	$-	$-	$ 150,000
Supplemental schedule of non-cash investing and financing activities:			
Warrants issued in sastisfaction of accrued liability	$-	$-	$ 334,992
Warrants issued to placement agents and investors, in connection with financings	$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.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONDENSED FINANCIAL STATEMENTS
June 30, 2011
(unaudited)

1. DESCRIPTION OF BUSINESS

Nile Therapeutics, Inc. ("Nile" or the "Company") develops innovative products for the treatment of cardiovascular diseases. Nile's lead compound is cenderitide, a chimeric natriuretic peptide currently in a Phase I clinical study for the treatment of heart failure. The Company is also developing CU-NP, a pre-clinical rationally designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type Natriuretic Peptide ("CNP") and the N- and C-termini of Urodilatin ("URO").

The Company was incorporated in the State of Nevada on June 17, 1996 and reincorporated in Delaware on February 9, 2007, at which time its name was SMI Products, Inc. ("SMI"). On September 17, 2007, the Company completed a merger transaction whereby Nile Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of SMI, merged with and into Nile Therapeutics, Inc., a privately held Delaware corporation ("Old Nile"), with Old Nile becoming a wholly-owned subsidiary of SMI. Immediately following the merger described above, Old Nile was merged with and into the Company, with the Company remaining as the surviving corporation to that merger. In connection with that short-form merger, the Company changed its name to "Nile Therapeutics, Inc." These two merger transactions are hereinafter collectively referred to as the "Merger." All costs incurred in connection with the Merger have been expensed. Upon completion of the Merger, the Company adopted Old Nile's business plan.

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through June 30, 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 June 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.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONDENSED FINANCIAL STATEMENTS
June 30, 2011
(unaudited)

Collaboration Income

The Company has entered into a collaboration agreement whereby the Company is reimbursed for 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 $42.0 million at June 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 June 30, 2011 were approximately $3.3 million, compared to $3.4 million as of December 31, 2010. Based on its resources at June 30, 2011 and the current plan of expenditure for continued development of the Company's current product candidates, which includes the enrollment of a Phase I clinical trial of cenderitide administered with Medtronic's pump technology, the Company believes that it 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 IIb 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.

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.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONDENSED FINANCIAL STATEMENTS
June 30, 2011
(unaudited)

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:

	June 30, 2011	June 30, 2010
Warrants to purchase common stock	2,750,000	-
Options to purchase common stock	3,091,000	137,940
Total potentially dilutive securities	5,841,000	137,940

For the three months ended June 30, 2011 and 2010, warrants and options to purchase 11,250,285 and 10,676,043 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 August 1, 2011 and July 29, 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, or 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.

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONDENSED FINANCIAL STATEMENTS
June 30, 2011
(unaudited)

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, 2009, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares (representing $182,236) of common stock.

The 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 II clinical trial of the licensed product. This aggregate amount of $24.3 million is subject to increase upon the receipt of regulatory approval for each additional indication of CU-NP, as well as for additional compounds or analogues contained in the intellectual property. Pursuant to the agreement, the Company must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

Payments payable 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 will provide the equipment necessary for the Company to conduct its ongoing Phase I 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. The Collaboration Agreement provides that Medtronic will reimburse the Company for certain external expenses related to the Phase I 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 June 30, 2011, the Company has received $346,000 in reimbursements from Medtronic, all of which amounts are recorded as income on the Company's Statements of Operations.

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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 I trial; and (ii) 15 months after the date of the Collaboration Agreement.

The Collaboration Agreement provides that intellectual property conceived in or otherwise resulting from the performance of the Phase I 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 I clinical 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 $2.5 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. 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.

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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 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 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 June 30, 2011.

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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 three and six months ended June 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 three and six months ended June 30, 2011 (no options were issued during the three and six months ended June 30, 2010):

	Three Months Ended June 30, 2011	Six Months Ended June 30, 2011
Expected volatility	97%	97%
Expected term	3 years	3 - 5 years
Dividend yield	0%	0%
Risk-free interest rates	0.9 - 1.2%	0.9 - 2.2%

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.

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A summary of the status of the options issued under the Plan at June 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 June 30, 2011	1,277,984	7,835,051	$ 1.43	$ 1,271,720
Exercisable at June 30, 2011		5,094,491	$ 1.86	$ 494,520

The following table summarizes information about stock options outstanding at June 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	7.89	$ 0.53		