Nile Therapeutics, Inc.
Form 10-Q
August 14, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2012

.. **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 13, 2012, there were 43,062,231 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:

- our ability to obtain adequate financing;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- the development of our product candidates;
- the regulatory approval of our product candidates;
- our use of clinical research centers and other contractors;
- 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; 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, 2011 (“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, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets		
Cash and cash equivalents	$ 777,182	$ 1,039,190
Prepaid expenses and other current assets	164,665	271,298
Total current assets	941,847	1,310,488
Property and equipment, net	6,387	9,744
Other noncurrent assets	51,938	51,938
Total assets	$ 1,000,172	$ 1,372,170
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 121,719	$ 437,837
Accrued expenses and other current liabilities	108,888	64,718
Due to related party	36,448	38,892
Total current liabilities	267,055	541,447
Warrant liability	190,863	-
Total liabilities	457,918	541,447
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, 43,062,231 and 39,712,231 shares issued and outstanding	43,062	39,712

Additional paid-in capital	46,438,985	45,605,991
Deficit accumulated during the development stage	(45,939,793)	(44,814,980)
Total stockholders' equity	542,254	830,723
Total liabilities and stockholders' equity	$ 1,000,172	$ 1,372,170

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 (incpetion) through
	2012	2011	2012	2011	June 30, 2012
Income:					
Grant income	$ -	$ -	$ -	$ -	$ 482,235
Collaboration income	-	346,000	195,500	346,000	1,550,000
Total income	-	346,000	195,500	346,000	2,032,235
Operating expenses:					
Research and development	332,450	702,930	797,803	1,325,262	30,793,694
General and administrative	441,970	523,305	941,990	1,098,583	17,268,150
Total operating expenses	774,420	1,226,235	1,739,793	2,423,845	48,061,844
Loss from operations	(774,420)	(880,235)	(1,544,293)	(2,077,845)	(46,029,609)
Other income (expense):					
Interest income	596	1,046	840	3,032	794,805
Interest expense	-	-	-	-	(1,273,734)
Other income (expense)	420,890	(1,341)	418,640	(1,509)	568,745
Total other income (expense)	421,486	(295)	419,480	1,523	89,816
Net loss	$ (352,934)	$ (880,530)	$ (1,124,813)	$ (2,076,322)	$ (45,939,793)
Basic and diluted loss per share	$ (0.01)	$ (0.03)	$ (0.03)	$ (0.06)	
Weighted-average common shares outstanding	42,951,791	35,091,653	41,332,011	34,882,947	

See accompanying notes to the unaudited condensed financial statements.

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

PERIOD FROM AUGUST 1, 2005 (INCEPTION) TO JUNE 30, 2012

(unaudited)

	COMMON STOCK		ADDITIONAL PAID-IN	DEFICIT ACCUMULATED DURING THE DEVELOPMENT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	CAPITAL	STAGE	(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	-	-	785,587	-	785,587
Non-employee stock-based compensation	-	-	20,740	-	20,740
Stock option and warrant exercises	82,437	82	13,666	-	13,748
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	-	-	-	(4,884,786)	(4,884,786)
Balance at December 31, 2011	39,712,231	39,712	45,605,991	(44,814,980)	830,723
Employee stock-based compensation	-	-	254,033	-	254,033
Units sold in private placement, net of issuance costs of $145,793	3,350,000	3,350	1,190,857	-	1,194,207
Warrants issued in connection with offering	-	-	(611,896)	-	(611,896)
Net loss	-	-	-	(1,124,813)	(1,124,813)
Balance at June 30, 2012	43,062,231	$ 43,062	$ 46,438,985	$ (45,939,793)	$ 542,254

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, 2012
	2012	2011	
Cash flows from operating activities			
Net loss	$ (1,124,813)	$ (2,076,322)	$ (45,939,793)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	3,357	4,067	324,005
Stock-based compensation	254,033	437,715	10,559,493
Warrant liability	(421,033)	-	(421,033)
Write-off of intangible assets	-	-	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	-	-	36,724
Noncash interest expense	-	-	351,165
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	106,633	(160,782)	(164,665)
Other non-current assets	-	-	(51,938)
Accounts payable	(316,118)	(94,620)	121,719
Accrued expenses and other current liabilities	44,170	(491,132)	108,888
Due to related party	(2,444)	(47,059)	36,448
Net cash used in operating activities	(1,456,215)	(2,428,133)	(34,160,694)
Cash flows from investing activities			
Purchase of property and equipment	-	-	(130,855)
Proceeds from sale of assets	-	-	2,500
Cash paid for intangible assets	-	-	(345,591)
Net cash used in investing activities	-	-	(473,946)
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	237,428
Proceeds from sale of common stock to founders	-	-	5,000

Proceeds from sale of common stock in private placement, net	1,194,207	2,298,566	31,169,394
Net cash provided by financing activities	1,194,207	2,309,813	35,411,822
Net (decrease) increase in cash and cash equivalents	(262,008)	(118,320)	777,182
Cash and cash equivalents at beginning of period	1,039,190	3,378,155	-
Cash and cash equivalents at end of period	$ 777,182	$ 3,259,835	$ 777,182
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 placements		$ 1,083,700	$ 5,721,000
Warrants issued to investors in connection with offering	$ 611,896	$ -	$ 611,896
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, 2012

(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 development for the treatment of heart failure patients in the post-acute period. 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, 2012, its efforts have been principally devoted to developing its licensed technologies, 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 ("GAAP") 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, 2012 are not necessarily indicative of results for the full 2012 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, 2011 filed with the Securities and Exchange Commission.

The preparation of financial statements in conformity with GAAP 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 income 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, 2012

(unaudited)

Collaboration Income

In February 2011, the Company entered into a collaboration agreement whereby the Company was reimbursed for work performed on behalf of the collaborator upon the achievement of certain milestones. The Company recorded all of these expenses as research and development expenses and the reimbursements upon the achievement of the milestones as income (Note 5).

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.

Fair Value of Financial Instruments

The Company measures fair value in accordance with generally accepted accounting principles. Fair value measurements are applied under other accounting pronouncements that require or permit fair value measurements. Financial instruments included in the Company's balance sheets consist of cash and cash equivalents, accounts payable, accrued expenses due to related parties, and warrant liability. The carrying amounts of these instruments reasonably approximate their fair values due to their short-term maturities.

Warrant Liability

The Company accounts for the warrants issued in connection with the April 2012 financing (Note 7) in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that the Company classifies the warrant instrument as a liability at its fair value and adjusts the instrument to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income or expense. The fair value of warrants issued by the Company, in connection with offerings of securities, has been estimated by management using a binomial options pricing model. The binomial option pricing model is a generally accepted valuation model used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company's future expected stock prices, and their resulting probabilistic valuation.

3. LIQUIDITY, CAPITAL RESOURCES AND MANAGEMENT'S PLANS

The Company has experienced net losses since its inception and has an accumulated deficit of approximately $45.9 million at June 30, 2012. 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.

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

June 30, 2012

(unaudited)

Cash resources as of June 30, 2012 were approximately $0.8 million, compared to $1.0 million as of December 31, 2011. Based on its resources at June 30, 2012, the Company believes that it has sufficient capital to fund its current operating expenditures into the fourth quarter of 2012. Such expenditures are expected to consist largely of general and administrative items, such as salaries and professional and consulting fees. The Company does not currently have sufficient capital to further the clinical development of its product candidates, and will need to raise additional capital in order to initiate the next clinical trial of cenderitide, which is expected to be a Phase 2 trial. Additionally, the Company will need substantial additional financing in the future until it can achieve profitability, if ever. The Company's continued operations will depend on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its product candidates to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot assure that it will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs.

The success of the Company depends on its ability to 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 rights to 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 obtains 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, 2012	June 30, 2011
Warrants to purchase common stock	-	2,750,000
Options to purchase common stock	-	3,041,000
Total potentially dilutive securities	-	5,791,000

For the three months ended June 30, 2012 and 2011, warrants and options to purchase 19,599,318 and 11,300,285 shares, respectively, have been excluded from the above computation of potentially dilutive securities, respectively, as their exercise prices are greater than the average market price per common share for the three months ended June 30, 2012 and June 30, 2011, respectively.

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS

June 30, 2012

(unaudited)

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 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, until January 19, 2009.

Under the terms of the Cenderitide License Agreement, the Company paid Mayo an up-front cash payment, reimbursed it for past patent expenses and issued to Mayo 1,379,419 shares of common stock. Additionally, 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 July 2008, the Company made a milestone payment of $400,000 to Mayo upon the dosing of the first patient in a Phase 2 trial. Based on the current stage of research the Company does not expect to make any milestone payments for the year ending December 31, 2012. Pursuant to the Cenderitide License Agreement, the Company will pay Mayo an annual maintenance fee and a percentage of net sales of licensed products, as well as $50,000 per year for the consulting services of Dr. Burnett while serving as chairman of the Company's Scientific Advisory Board.

In addition to the potential milestone payments discussed above, the 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 June 30, 2012, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares (representing $182,235) of common stock. No such grant income has been received or shares issued since the year ended December 31, 2008.

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 was also entitled to 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, until 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. Based on the current stage of research the Company does not expect to make any milestone payments for the year ending December 31, 2012. Pursuant to the agreement, the Company must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

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

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The CU-NP License Agreement, unless earlier terminated, will continue in full force and effect until June 13, 2028. However, to the extent any patent covered by the license is issued with an expiration date beyond June 13, 2028, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for the Company's material breach of the agreement that remains uncured after 90 days written notice, (ii) the Company's insolvency or bankruptcy, (iii) if the Company 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

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic, Inc. Pursuant to the agreement, Medtronic provided the funding and 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.

Under the agreement, the Company 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. The final database was delivered to Medtronic on November 19, 2011.

The agreement also provided that intellectual property conceived in or otherwise resulting from the performance of the Phase 1 clinical trial shall be jointly owned by the Nile and Medtronic (the "Joint Intellectual Property"), and that Nile 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 provided 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. As of May 2012, three filed patent applications are considered Joint Intellectual Property.

Pursuant to its terms, the agreement expired in February 2012, following the completion of the Phase 1 clinical trial and the delivery of data and reports related to the study. The Company received the final reimbursement of $195,500 in February 2012 and a total of $1,550,000 over the life of the agreement. All amounts are recorded as income in the Company's Condensed Statement of Operations.

6. FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company defines fair value as the amount at which an asset (or liability) could be bought (or incurred) or sold (or settled) in a current transaction between willing parties, that is, other than in a forced or liquidation sale. The fair value estimates presented in the table below are based on information available to the Company as of June 30, 2012.

The accounting standard regarding fair value measurements discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The standard utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

- Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

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The Company has determined the fair value of certain liabilities using the market approach: the following table presents the Company's fair value hierarchy for these assets measured at fair value on a recurring basis as of June 30, 2012:

	Fair Value June 30, 2012	Quoted Market Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities				
Warrant liability	$ 190,863	$ -	$ -	$ 190,863

The fair value of the warrant liability relating to the warrants issued in conjunction with the April 2012 financing (Note 7b) was estimated by management using a binomial option pricing model. The binomial option pricing model is a generally accepted valuation model used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company's future expected stock prices, and their resulting probabilistic valuation. The changes in the fair value of the warrant liability are recorded in other income (expense) on the statement of operations.

The following table provides a summary of changes in fair value of the Company's liabilities, as well as the portion of losses included in income attributable to unrealized appreciation that relate to those liabilities held at June 30, 2012:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Warrant Liability
Balance at January 1, 2012	$ -
Purchases, sales and settlements	

Warrants issued		611,896
Total gains or losses		
Unrealized depreciation		(421,033)
Balance at June 30, 2012	$	190,863

7. STOCKHOLDERS' EQUITY

(a) Common Stock

On April 4, 2012, the Company closed an offering with certain purchasers pursuant to which it sold an aggregate of 3,350,000 shares of the Company's common stock to such purchasers for a purchase price of $0.40 per share. In addition, for each share purchased, each purchaser also received three-fourths of a five-year warrant to purchase an additional share of common stock at an exercise price of $0.50 per share, which resulted in the issuance of warrants to purchase an aggregate of 2,512,500 shares of the Company's common stock. The warrants contain non-standard anti-dilution features (Note 7b) and as result will be classified as a liability on the Company's balance sheet.

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The total gross proceeds from the offering were $1.34 million, before deducting selling commissions and other offering expenses of approximately $0.14 million. In connection with the offering, the Company engaged Roth Capital Partners, LLC, or Roth, to serve as placement agent. Pursuant to the terms of the placement agent agreement, the Company paid Roth a cash fee equal to seven percent of the gross proceeds received by the Company, or approximately $0.1 million, plus a non-accountable expense allowance of $35,000. Richard B. Brewer, the Company's Executive Chairman, Joshua A. Kazam, the Company's former President and Chief Executive Officer and a director, Daron Evans, the Company's Chief Financial Officer, and Hsiao Lieu, M.D., the Company's former Executive VP of Clinical Development, participated in the offering on the same terms as the unaffiliated purchasers, and collectively purchased 275,000 shares of common stock and warrants to purchase 206,250 shares of common stock for an aggregate purchase price of $110,000.

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 former 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.

(b) Warrants

In connection with the April 2012 financing, as discussed above, the Company issued a total of 2,512,500 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 $0.50 per share. The warrants contain non-standard anti-dilution features, such that, in the event the Company issues common shares at a price below the current exercise price of the warrants, the exercise price of the warrants will be adjusted based on the lower issuance price. Because of this anti-dilution provision and the inherent uncertainty as to the probability of future common share issuances, the Black-Scholes option pricing model the Company uses for valuing stock options could not be used. Management used a binomial option pricing model to determine the warrant liability to be approximately $0.6 million on the date of issuance and $0.1 million at June 30, 2012. The binomial option pricing model is a generally accepted valuation model used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company’s future expected stock prices, and their resulting probabilistic valuation. This valuation will be revised on a quarterly basis until the warrants are exercised or they expire with the changes in fair value recorded in other expense on the statement of operations.

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Significant assumptions used at June 30, 2012 for the warrants included a weighted average term of 4.75 years, volatility of 101%, and a risk-free interest rate of 0.72%.

In connection with the 2011 Offering as 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.

Below is a table that summarizes all outstanding warrants to purchase shares of the Company's common stock as of June 30, 2012.

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
4/4/2012	2,512,500	$ 0.50	$ 0.50	4/3/2017	-	2,512,500
	11,179,984		$ 1.05		5,000	11,174,984

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

For the three and six months ended June 30, 2012, the Company did not issue any employee stock options. In previous periods, 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:

	Three Months Ended	Six Months Ended
	June 30, 2011	June 30, 2011
Price of Nile stock on date of grants	$0.69-0.78	$0.56-0.78
Expected volatility	97%	97%
Expected term	3 years	3 & 5 years
Dividend yield	0%	0%
Risk-free interest rate	0.9-1.2%	0.9-2.2%

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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.

- Risk free interest rate – The risk free interest rate is the rate of interest on a U.S. Treasury note with a term similar to the expect term of the option.

A summary of the status of the options issued under the Plan at June 30, 2012, 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, 2012	1,217,984	7,890,584	$ 1.43	
Options granted under the Plan	-	-	$ -	

Options exercised	-	-	$ -	
Options forfeited	60,000	(60,000)	$ 0.56	
Balance at June 30, 2012	1,277,984	7,830,584	$ 1.43	$ -
Exercisable at June 30, 2012		6,993,916	$ 1.54	$ -

The following table summarizes information about stock options outstanding at June 30, 2012:

	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 $0.57	3,036,533	7.25	$ 0.37	2,286,533	$ 0.38
$0.68 to $0.93	1,680,923	5.98	$ 0.82	1,680,923	$ 0.82
$1.14 to $2.71	2,476,779	4.08	$ 2.33	2,390,111	$ 2.36
$4.45 to $5.75	636,349	5.11	$ 4.54	636,349	$ 4.54
Total	7,830,584	5.80	$ 1.43	6,993,916	$ 1.54

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.

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Employee stock-based compensation costs for the three and six months ended June 30, 2012 and 2011 and for the cumulative period from August 1, 2005 (inception) through June 30, 2012 are as follows:

	Three months ended June 30,		Six months ended June 30,		Period from August 1, 2005 (inception)
	2012	2011	2012	2011	through June 30, 2012
General and administrative	$ 75,030	$ 143,522	$ 186,747	$ 225,049	$ 6,749,293
Research and development	7,188	27,019	67,286	212,666	1,551,203
Total	$ 82,218	$ 170,541	$ 254,033	$ 437,715	$ 8,300,496

The fair value of shares vested under the Plan for the three and six months ended June 30, 2012 and 2011 and for the period from August 1, 2005 (inception) through June 30, 2012 were $307,850, $408,859, $75,015, $404,612, and $7,363,861 respectively.

At June 30, 2012, total unrecognized estimated employee (including directors) compensation cost related to stock options granted prior to that date was $73,432, which is expected to be recognized over a weighted-average vesting period of 0.9 years.

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 any options issued to non-employees is recorded as expense over the applicable service periods.

The Company did not incur stock-based compensation costs for services by non-employees for the three and six months ended June 30, 2012 and 2011, and has expensed a total of $498,095 for the cumulative period from August 1, 2005 (inception) through June 30, 2012. These amounts were included in research and development and general and administrative expenses in the accompanying Condensed Statements of Operations. As of June 30, 2012 all non-employee based options outstanding were fully vested.

9. RELATED PARTIES

On June 24, 2009, the Company entered into a services agreement with Two River Consulting, LLC ("TRC") to provide various clinical development, operational and administrative services to the Company, including the part-time services of Joshua A. Kazam as the Company's President and Chief Executive Officer, for a period of one year. Mr. Kazam and Arie S. Belldegrun are each directors of the Company and 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 had 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. In August 2010, the Company and TRC amended the services agreement to extend its term on a month-to-month basis and to provide for 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 $82,200 that was expensed on the date of grant. In March 2011, the Company and TRC further amended the services agreement to reduce the level of services to be provided by TRC and to reduce the monthly cash fee payable to TRC to $31,702, which monthly fee was then reduced to $30,082 in July 2011 and to $28,600 in April 2012 when certain services were eliminated. On August 1, 2012, the Company and TRC agreed that, upon the appointment of a full-time President and Chief Executive Officer (see Note 10, "Subsequent Events," below), the monthly fee payable under the services agreement would be reduced to $6,600 to reflect the termination of Mr. Kazam's services as President and Chief Executive Officer. Additional operational and clinical development services may be provided by TRC, and billed to the Company, on an hourly basis. The Special Committee reviewed and approved the August 2010, March 2011, and August 2012 amendments to the services agreement.

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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 six months ended June 30, 2012 and 2011 and for the period from August 1, 2005 (inception) through June 30, 2012, total cash services and reimbursed expenses totaled $93,468, $191,940, $112,699, $326,300 and $2,038,030 respectively. As of June 30, 2012 the Company had a payable to TRC of $36,448 which was paid in full in July 2012.

In connection with the 2011 Offering (Note 7), the Company engaged Riverbank to serve as placement agent. Mr. Kazam and Peter M. Kash, a director of the Company, are each officers of Riverbank.

10. SUBSEQUENT EVENTS

Appointment of President and Chief Executive Officer

On August 3, 2012, the Company entered into a letter agreement (the "Agreement") with Darlene Horton, M.D., pursuant to which Dr. Horton will be employed as the Company's President and Chief Executive Officer, effective August 6, 2012. The Agreement provides that Dr. Horton's employment with the Company will continue for an indefinite term. Pursuant to the Agreement, Dr. Horton was also appointed to serve as a member of the Company's Board of Directors, effective August 6, 2012. If Dr. Horton's employment as President and Chief Executive Officer is terminated at any time, whether by her or the Company, the Agreement provides that she will be deemed to have resigned as a director of the Company, effective as of the date of such termination.

The Agreement provides that Dr. Horton will receive an initial monthly base salary of $28,314, and if she remains employed with the Company as of the date of a "compensation adjustment event," then (i) her annualized base salary shall be increased to $400,000, (ii) she will become eligible to receive an annual performance cash bonus in an amount up to 30% of her annualized base salary, and (iii) she will be granted a 10-year stock option to purchase a number of shares of the Company's common stock equal to 5% of the then issued and outstanding shares of common

stock at an exercise price equal to the current market price of the common stock on the date of grant. The stock option, which will vest ratably over a three-year period with respect to 50% of the underlying shares and over a three-year period upon the achievement of specified performance criteria with respect to the remaining 50% of the shares, will be awarded pursuant to the Company's Amended and Restated 2005 Stock Option Plan, as amended (the "Plan"), and be evidenced by a stock option agreement in the Company's standard form of agreement for use under the Plan. For purposes of the Agreement, the term "compensation adjustment event" means the date on which the Company secures sufficient capital, whether by a financing or strategic transaction (or any combination thereof) or another means, in order to enable the Company to initiate and fund to completion a Phase 2 clinical trial of the Company's cenderitide product candidate.

The Agreement further provides that if the Company terminates Dr. Horton's employment without "cause" at any time after the date of a compensation adjustment event, then she will be entitled to continue receiving her then current annualized base salary and medical benefits (the "Severance Benefits") for a period of six months following such termination; provided, however, that if such termination occurs more than one year after the compensation adjustment event, then Dr. Horton will be entitled to receive the Severance Benefits for one year following such termination. For purposes of the Agreement, the term "cause" means the following conduct or actions taken by Dr. Horton: (i) breach of any material term of the Agreement or the confidentiality, non-competition and invention assignment agreement executed by Dr. Horton as a condition of her employment under the Agreement; (ii) conviction of any felony or other crime of moral turpitude; (iii) any act of fraud or dishonesty injurious to the Company or its reputation; (iv) continual failure or refusal to perform her employment duties; (v) any act or omission that, in the Company's reasonable determination, indicates alcohol or drug abuse by Dr. Horton; or (vi) engagement in any form of harassment prohibited by law.

In addition, the Agreement provides that if the Company completes a Change of Control Transaction (as defined in the Agreement) prior to the date of a compensation adjustment event, and Dr. Horton's employment is terminated by the Company (or any successor entity) without cause during the period beginning on the effective date of the Change of Control Transaction and ending on the six-month anniversary of such effective date, then she will be entitled to receive a cash payment equal to 5% of the applicable Change of Control Proceeds (as defined in the Agreement).

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Prior to her appointment as President and Chief Executive Officer, Dr. Horton served as the Company's Chief Medical Officer pursuant to the terms of a Consulting Agreement dated June 18, 2012 (the "Consulting Agreement"). The Consulting Agreement was terminated upon Dr. Horton's appointment as President and Chief Executive Officer.

Resignation of President and Chief Executive Officer

On August 6, 2012, effective as of the appointment of Dr. Horton, Joshua A. Kazam resigned as the Company's President and Chief Executive Officer. Mr. Kazam, who had served in such offices on a part-time basis since June 2009, will continue to serve as a director of the Company.

Option Termination Agreement with Former Chief Executive Officer

On August 3, 2012, the Company entered into an Option Termination Agreement with Peter M. Strumph, who served as the Company's Chief Executive Officer and as a director of the Company from June 2007 to June 2009, pursuant to which the Company paid Mr. Strumph $2,000 in exchange for the forfeiture and termination of options to purchase an aggregate of 1,232,054 shares of the Company's common stock at an exercise price of $2.71, which stock options had previously been granted to Mr. Strumph pursuant to the Plan. As a result of this forfeiture and termination, the number of shares available for future awards under the Plan increased from 1,277,984 as of June 30, 2012, to 2,510,038 as of August 3, 2012.

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. In October 2011, we completed a Phase 1 clinical trial in collaboration with Medtronic, Inc. The next step is a Phase 2 clinical trial to test the safety and tolerability of cenderitide when administered to patients for up to 90 days following admission for ADHF. In addition to safety, we will collect a number of secondary endpoint that are surrogates for re-hospitalization and mortality, which are the proposed end-points for a registration trial.

- ***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 activities 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 June 30, 2012 and 2011 were approximately $0.4 million and $0.5 million, respectively. The decrease in G&A expenses compared to the same period in 2011 is primarily due to a decrease of approximately $0.1 million in stock compensation costs.

G&A expenses for the six months ended June 30, 2012 and 2011 were approximately $0.9 million and $1.1 million, respectively. The decrease in G&A expenses compared to the same period in 2011 is primarily due to decreases in the use of professional investor relations services and reduced fees from no longer being listed on the NASDAQ, as well as from reduced stock compensation costs.

Research and Development Expenses. R&D expenses for the three months ended June 30, 2012 and 2011 were approximately $0.3 million and $0.7 million, respectively. The decrease in R&D expenses in 2012 compared to the same period in 2011 is primarily due to a decrease of approximately $0.2 million relating to the Phase 1 trial of cenderitide conducted in collaboration with Medtronic that was completed in the first quarter of 2012. This trial was ongoing during the three months ended June 30, 2011, but was completed by the start of the three month period ended June 30, 2012. Additionally, there was a decrease of approximately $0.1 million related to toxicology studies being conducted on cenderitide in 2011.

R&D expenses for the six months ended June 30, 2012 and 2011 were approximately $0.8 million and $1.3 million, respectively. The decrease in R&D expenses in 2012 compared to the same period in 2011 is primarily due to decreased stock compensation costs and reduced use of outside consultants of approximately $0.3 million. Additionally, there was a decrease of approximately $0.1 million in regulatory costs relating to cenderitide, as well as a decrease of approximately $0.2 million relating to the Phase 1 trial of cenderitide conducted in collaboration with Medtronic that was completed in the first quarter of 2012.

Cenderitide. Although the development of cenderitide is still in its early stages, we believe that it has potential applications to treat heart failure. Subject to our ability to raise additional capital from either a financing transaction or collaboration or other strategic agreement, we plan to initiate a Phase 2 clinical trial of cenderitide in 2012.

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 June 30, 2012. 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 June 30, 2012 and 2011 was approximately $596 and $1,046, respectively. Interest income for the six months ended June 30, 2012 and 2011 was approximately $840 and $3,032, respectively. This decrease in interest income over 2011 is due to lower interest rates earned on cash in bank accounts and lower average cash balances in 2012 than 2011 levels.

Collaboration Income. As a result of our February 2011 collaboration agreement with Medtronic pursuant to which Medtronic reimbursed us for R&D expenditures that we made in connection with our Phase 1 trial of cenderitide, we recognized income of $0.2 million for the three and six months ended June 30, 2012 compared to $0.3 million during the same periods in 2011. All amounts due under the agreement were paid as of February 2012 at which time the agreement expired.

Other Income (Expense). Other income for the three months ended June 30, 2012 was approximately $0.4 million compared to other expense of approximately $0.0 million for the same period of 2011. This increase in other income of approximately $0.4 million is primarily due to an approximately $0.4 million noncash adjustment to the warrant liability during the three months ended June 30, 2012, with no such charge in 2011 as the warrants were not issued until April 2012. Other income for the six months ended June 30, 2012 was approximately $0.4 million compared to other expense of approximately $0.0 million for the same period of 2011. This increase in other income of approximately $0.4 million is primarily due to an approximately $0.4 million noncash adjustment to the warrant liability during the six months ended June 30, 2012, with no such charge in 2011 as the warrants were not issued until April 2012.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of June 30, 2012 and December 31, 2011 and our net decrease in cash and cash equivalents for the six months ended June 30, 2012 and 2011 (the amounts stated are expressed in thousands):

Liquidity and capital resources	June 30, 2012	December 31,2011
Cash and cash equivalents	$ 777	$ 1,039
Working Capital	$ 675	$ 769
Stockholders' equity	$ 542	$ 831

	Six Months Ended June 30,	
Cash flow data	2012	2011
Cash used in:		
Operating activities	$ (1,456)	$ (2,428)
Investing activities	-	-
Cash provided by:		
Financing activities	1,194	2,310
Net decrease in cash and cash equivalents	$ (262)	$ (118)

Our total cash resources as of June 30, 2012 were $0.8 million compared to $1.0 million as of December 31, 2011. As of June 30, 2012, we had approximately $0.5 million in liabilities (of which, approximately $0.2 million represented a non-cash warrant liability) and $0.7 million in net working capital. We incurred a net loss of $1.1 million and had negative cash flow from operating activities of $1.5 million for the six months ended June 30, 2012. Since August 1, 2005 (inception) through June 30, 2012, we have incurred an aggregate net loss of approximately $45.9 million, while negative cash flow from operating activities has amounted to $34.2 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 June 30, 2012, 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 our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs.

Based on our resources at June 30, 2012, we believe that we have sufficient capital to fund our current operating expenditures into the fourth quarter of 2012. Such expenditures are expected to consist largely of general and administrative items, such as salaries and professional and consulting fees. We do not currently have sufficient capital to further the clinical development of our product candidates, and will need to raise additional capital in order to initiate the next clinical trial of cenderitide, which is expected to be a Phase 2 trial. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors, including the changes in the focus and direction of our research and development programs, including the acquisition and pursuit of development of new product candidates; competitive and technical advances; costs of commercializing any of the product candidates; and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, we could be required to delay, scale back or eliminate some or all our research and development programs and we may need to wind down our operations altogether. Each of these alternatives would likely have a material adverse effect on our business.

Until we have secured additional capital, we only have sufficient capital to fund our ongoing G&A expenses until the fourth quarter of 2012. 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 of cenderitide. 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 fourth 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.

April 2012 Financing

On April 4, 2012, we closed an offering with certain purchasers pursuant to which we sold an aggregate of 3,350,000 shares of our common stock to such purchasers for a purchase price of $0.40 per share. In addition, for each share purchased, each purchaser also received three-fourths of a five-year warrant to purchase an additional share of common stock at an exercise price of $0.50 per share, which resulted in the issuance of warrants to purchase an aggregate of 2,512,500 shares of our common stock. The total gross proceeds from the offering were $1.34 million, before deducting selling commissions and other offering expenses of approximately $0.2 million. In connection with the offering, we engaged Roth Capital Partners, LLC, or Roth, to serve as placement agent. Pursuant to the terms of the placement agent agreement, we paid Roth a cash fee equal to seven percent of the gross proceeds received by us, or approximately $0.1 million, plus a non-accountable expense allowance of $35,000. Richard B. Brewer, our Executive Chairman, Joshua A. Kazam, our former President and Chief Executive Officer and a director, Daron Evans, our Chief Financial Officer, and Hsiao Lieu, M.D., our former Executive VP of Clinical Development, participated in the offering on the same terms as the unaffiliated purchasers, and collectively purchased 275,000 shares of common stock and warrants to purchase 206,250 shares of common stock for an aggregate purchase price of $110,000.

The offer and sale of the shares and warrants was made pursuant to our shelf registration statement on Form S-3 (SEC File No. 333-165167), which became effective on March 12, 2010. Pursuant to the subscription agreements that we entered into with the purchasers in the April 2012 financing, we agreed to file, within 15 business days after the closing of the offering, a registration statement covering the issuance of the shares of our common stock upon exercise of the warrants and the subsequent resale of such shares (the "Additional Registration Statement"), and to cause such registration statement to be declared effective within 90 days following the closing of the offering. In the event the Additional Registration Statement was not declared effective by the SEC within such 90-day period, we agreed to pay liquidated damages to each purchaser in the amount of 1% of such purchaser's aggregate investment amount for each 30-day period until the Additional Registration Statement is declared effective, subject to an aggregate limit of 12% of such purchaser's aggregate investment amount. The Additional Registration Statement was filed on April 25, 2012 and was declared effective by the SEC on May 7, 2012.

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 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 securities purchase agreement that we entered into with the investors in the June 2011 offering, we agreed to file a registration statement with the SEC seeking to register the resale of the shares of common stock sold in the offering, including the shares issuable upon exercise of warrants. 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 former 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.

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 had 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 us 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 provided 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.

Under the agreement, we 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. The final database was delivered to Medtronic on November 19, 2011.

The agreement also provided that intellectual property conceived in or otherwise resulting from the performance of the Phase I clinical trial shall be jointly owned by the 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 provided 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. As of May 2012, three filed patent applications are considered Joint Intellectual Property.

Pursuant to its terms, the agreement expired in February 2012, following the completion of the Phase 1 clinical trial and the delivery of data and reports related to such study. We received the final reimbursement of $195,500 in February 2012 and a total of $1,550,000 over the life of the agreement. All amounts are recorded as income in our Condensed Statement of Operations.

Off -Balance Sheet Arrangements

There were no off-balance sheet arrangements as of June 30, 2012.

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

In February 2011, we entered into a collaboration agreement whereby we were reimbursed for work performed on behalf of the collaborator upon the achievement of certain milestones. We recorded 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 our 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.

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 our Scientific Advisory Board) issued as consideration for goods or services received by us 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 June 30, 2012, our portfolio consisted primarily of bank savings accounts and we did not have any investments with significant exposure to the subprime mortgage market issues. Based on our investment portfolio and interest rates at June 30, 2012, 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 $0.8 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.

We are 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, 2011 ("2011 Annual Report") under the caption "Item 1A. Risk Factors." If any of the risks described below or in our 2011 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 2011 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 in order to continue our business operations and the further development of our product candidates. If we are unable to obtain such additional capital, we will be forced to delay, reduce or eliminate our product development programs and may be forced to cease our operations altogether.

As of June 30, 2012, we only had approximately $0.8 million in cash and cash resources, and net working capital of approximately $0.7 million. During the six months ended June 30, 2012, had negative cash flow from operating activities of $1.5 million, and we expect our negative cash flows from operations to continue for the foreseeable future. We believe that our currently available cash resources are only sufficient to fund our current operating expenditures, which are expected to consist largely of general and administrative items, such as salaries and professional and consulting fees, into the fourth quarter of 2012. As a result, our financial statements reflect substantial uncertainty about our ability to continue as a going concern. Accordingly, we are in immediate need of additional capital to fund our general corporate activities.

Further, beyond funding our basic corporate activities, we 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 of cenderitide. We are pursuing discussions with different strategic partners about potentially collaborating on the future development of cenderitide, including our planned Phase 2 trial; however, we do not have any agreement or

commitment from any collaboration partner, and there is no assurance we will be able to reach any such agreement. If we are unable to reach an agreement with a collaboration partner, we will be required to fund the entire costs of the planned Phase 2 trial on our own, which we estimate may cost approximately $15 million to $20 million and take approximately 30 months to complete. There can be no assurance that we will be able to secure the capital needed to fund this clinical trial.

Since we do not currently generate any revenue from operations, nor do we expect to for the foreseeable future, we expect to finance future cash needs, including the cash needed to fund our general corporate activities and the more substantial capital needed to fund our planned Phase 2 clinical trial of cenderitide, through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. Such 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. In addition, we could be forced to discontinue product development, reduce or forego attractive business opportunities and even cease our operations altogether. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience 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.

Our forecasts regarding the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in this “Risk Factors” section and in our 2011 Annual Report. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

Y the scope, rate of progress, cost and results of our research and development activities, especially our planned Phase 2 clinical trial of cenderitide;

- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit No.	Exhibit Description
10.1	Consulting Agreement between Nile Therapeutics, Inc. and Darlene Horton, M.D., dated June 18, 2012.
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 June 30, 2012, formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Balance Sheets as of June 30, 2012 and December 31, 2011, (ii) Condensed Statements of Operations for the three and six months ended June 30, 2012 and June 30, 2011, and for the period from August 1, 2005 (inception) through June 30, 2012, (iii) Condensed Statement of Stockholders' Equity for the period from August 1, 2005 (inception) through June 30, 2012, (iv) Condensed Statements of Cash Flows for the six months ended June 30, 2012 and June 30, 2011, and for the period from August 1, 2005 (inception) through June 30, 2012, and (v) Notes to Condensed Financial Statements.*

* To be furnished by amendment pursuant to Rule 405(a)(2)(ii) of Regulation S-T.

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: August 14, 2012 By: /s/ Darlene Horton, M.D.
Darlene Horton, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2012 By: /s/ Daron Evans
Daron Evans
Chief Financial Officer
(Principal Financial and Accounting Officer)

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