Nile Therapeutics, Inc.
Form 10-Q
June 21, 2013

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 MARCH 31, 2013

.. **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.)

63 Bovet Rd., Suite 421, San Mateo, CA 94402

(Address of principal executive offices)(Zip Code)

(650) 918-7489

(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 June 19, 2013, 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, 2012 (“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 THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED BALANCE SHEETS

	March 31, 2013 (unaudited)	December 31, 2012
ASSETS		
Current assets		
Cash and cash equivalents	$285,032	$46,716
Prepaid expenses and other current assets	112,743	124,912
Deferred financing fees	6,506	-
Total current assets	404,281	171,628
Property and equipment, net	1,159	3,488
Other noncurrent assets	9,868	51,938
Total assets	$415,308	$227,054
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$249,351	$182,916
Accrued expenses and other current liabilities	202,203	131,928
Notes payable, net of unamortized discount of $259,026	190,974	-
Due to related party	6,600	16,139
Total current liabilities	649,128	330,983
Warrant liability	408,842	63,384
Total liabilities	1,057,970	394,367
Commitments and contingencies		
Stockholders' (deficit) 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 shares issued and outstanding	43,062	43,062
Additional paid-in capital	46,505,056	46,497,642

Deficit accumulated during the development stage	(47,190,780)	(46,708,017)
Total stockholders' (deficit) equity	(642,662)	(167,313)
Total liabilities and stockholders' equity	$415,308	$227,054

See accompanying notes to the unaudited condensed financial statements.

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three months ended March 31,		Period from August 1, 2005 (inception) through March 31, 2013
	2013	2012	
Income:			
Grant income	$-	$-	$ 482,235
Collaboration income	-	195,500	1,550,000
Total income	-	195,500	2,032,235
Operating expenses:			
Research and development	62,605	465,353	31,082,425
General and administrative	262,475	500,020	18,200,346
Total operating expenses	325,080	965,373	49,282,771
Loss from operations	(325,080)	(769,873)	(47,250,536)
Other income (expense):			
Interest income	40	244	795,232
Interest expense	(13,018)	-	(1,286,752)
Other income (expense)	(144,705)	(2,250)	551,276
Total other income (expense)	(157,683)	(2,006)	59,756
Net loss	$(482,763)	$(771,879)	$ (47,190,780)
Basic and diluted loss per share	$(0.01)	$(0.02)	
Weighted-average common shares outstanding	43,062,231	39,712,231	

See accompanying notes to the unaudited condensed financial statements.

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENT OF STOCKHOLDERS' (DEFICIT) EQUITY

PERIOD FROM AUGUST 1, 2005 (INCEPTION) TO MARCH 31, 2013

(unaudited)

	COMMON STOCK		ADDITIONAL PAID-IN	DEFICIT ACCUMULATED DURING THE DEVELOPMENT	TOTAL STOCKHOLDERS' (DEFICIT)
	SHARES	AMOUNT	CAPITAL	STAGE	EQUITY
Issuance of common shares to found\ers	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	-	-	312,690	-	312,690
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	-	-	-	(1,893,037)	(1,893,037)
Balance at December 31, 2012	43,062,231	43,062	46,497,642	(46,708,017)	(167,313)
Employee stock-based compensation	-	-	7,414	-	7,414

Net loss	-	-	-	(482,763)	(482,763)
Balance at March 31, 2013	43,062,231	$ 43,062	$ 46,505,056	$ (47,190,780)	$ (642,662)

See accompanying notes to the unaudited condensed financial statements.

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Three months ended March 31,		Period from August 1, 2005 (inception) through
	2013	2012	March 31, 2013
Cash flows from operating activities			
Net loss	$(482,763)	$(771,879)	(47,190,780)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	1,022	1,793	327,926
Stock-based compensation	7,414	171,815	10,625,564
Warrant liability	142,058	-	(406,454)
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	1,307	-	38,031
Noncash interest expense	13,018	-	364,183
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	4,519	50,911	(120,393)
Other non-current assets	42,070	-	(9,868)
Accounts payable	66,435	(110,683)	249,351
Accrued expenses and other current liabilities	70,275	(4,816)	202,203
Due to related party	(9,539)	59,399	6,600
Net cash used in operating activities	(144,184)	(603,460)	(35,035,344)
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	382,500	-	5,882,500
Repayment of notes payable	-	-	(1,500,000)
Proceeds from exercise of stock options and warrants	-	-	237,428

Proceeds from sale of common stock to founders	-	-	5,000
Proceeds from sale of common stock in private placement, net	-	-	31,169,394
Net cash provided by financing activities	382,500	-	35,794,322
Net increase (decrease) in cash and cash equivalents	238,316	(603,460)	285,032
Cash and cash equivalents at beginning of period	46,716	1,039,190	-
Cash and cash equivalents at end of period	$285,032	$435,730	$ 285,032
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		$-	$ 5,721,000
Warrants issued to investors in connection with registered direct offering	$-	$-	$ 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 Financial Statements

1. DESCRIPTION OF BUSINESS

Nile Therapeutics, Inc. ("Nile" or the "Company") engages in research and development of 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 March 31, 2013, 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 March 31, 2013 are not necessarily indicative of results for the full 2013 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, 2012 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.

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.

Nile Therapeutics, Inc

(A Development Stage Company)

Notes to Financial Statements

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. 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 March 2013 convertible note issuance (Note 6) and the April 2012 financing (Note 8) 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 adjust 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 the April 2012 financing, have 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. In connection with the March 2013 convertible note issuance, the Company estimated the fair value of the embedded derivative warrant liability by using the Black-Scholes option-pricing model.

3. LIQUIDITY, CAPITAL RESOURCES AND MANAGEMENT'S PLANS

The Company has experienced net losses since its inception and has an accumulated deficit of approximately $47.2 million at March 31, 2013. Cash resources as of March 31, 2013 were approximately $0.3 million, compared to $0.05 million as of December 31, 2012. Based on its currently available cash resources, the Company believes that it only has sufficient capital to fund its minimal operating expenses until the end of the second quarter of 2013. The Company will need to raise additional capital to fund any clinical development and to otherwise continue operations beyond the second quarter of 2013. 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 and avoid the need to cease operations.

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.

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Nile Therapeutics, Inc

(A Development Stage Company)

Notes to Financial Statements

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:

	March 31, 2013	March 31, 2012
Warrants to purchase common stock	-	-
Options to purchase common stock	-	2,750,000
Total potentially dilutive securities	-	2,750,000

For the three months ended March 31, 2013 and 2012, warrants and options to purchase 15,080,741 and 14,336,818 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 March 31, 2013 and March 31, 2012, respectively.

5. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

License Agreements

Cenderitide

On January 20, 2006, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the Cenderitide License Agreement, with 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, 2013. 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 March 31, 2013, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares 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.

As of March 31, 2013, the Company was not in compliance with several terms of the Cenderitide License Agreement, including, but not limited to, provisions requiring the Company to pay the Mayo Foundation an annual maintenance fee and actively pursue the development of cenderitide. The Company is in discussions with the Mayo Foundation to amend the agreement, but the Company cannot guarantee that it will be able to reach an agreement with Mayo that allows the Company to maintain its rights to cenderitide. The Company currently owes Mayo approximately $154,100 in fees and expense reimbursements related to the Cenderitide License Agreement, all of which is included in accounts payable.

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Nile Therapeutics, Inc

(A Development Stage Company)

Notes to Financial Statements

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, 2013. 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 Condensed Statements of Operations.

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.

As of March 31, 2013, the Company was not in compliance with several terms of the CU-NP License Agreement, including, but not limited to, provisions requiring the Company to pay the Mayo Foundation an annual maintenance fee and actively pursue the development of CU-NP. The Company is in discussions with the Mayo Foundation to amend the agreement, but the Company cannot guarantee that it will be able to reach an agreement with Mayo that allows the Company to maintain its rights to CU-NP. As of March 31, 2013, the Company owed Mayo approximately $39,300 in fees and expense reimbursements related to the CU-NP License Agreement, all of which is included in accounts payable.

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 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 collaboration income in the Company's Condensed Statement of Operations.

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6. CONVERTIBLE NOTES PAYABLE

On March 15, 2013, the Company entered into a convertible note purchase agreement with certain accredited investors pursuant to which the Company agreed to sell an aggregate principal amount of up to $500,000 of secured convertible promissory notes (the “2013 Notes”) for an aggregate original issue price of $425,000, representing a 15% original issue discount. The closing of the private placement also occurred on March 15, 2013, and resulted in the sale of the 2013 Notes in the aggregate principal amount of $450,000 for an aggregate original issue price of $382,500. The original issue discount is $67,500 and is being amortized to interest expense over the term of the 2013 Notes. As of March 31, 2013, the unamortized balance of this original issue discount is $64,542.

The 2013 Notes, which have a maturity date of March 15, 2014, do not bear interest and may be prepaid without penalty upon 30 days’ written notice, on the terms set forth in the Notes. The 2013 Notes are secured by a blanket lien on our assets pursuant to a security agreement dated March 15, 2013.

The 2013 Notes contain an optional conversion feature that enables the Holder to convert all outstanding shares into shares of the Company's common stock at a conversion price per share equal to the average daily Closing Price over the ten consecutive trading days preceding the date of such prepayment notice. The optional conversion feature goes into effect only if the Company chooses to prepay the Notes in whole or in part without penalty upon 30 days' prior written notice to the Holder (and conversion must occur within this 30 day period).

Upon a Change of Control (as defined in the 2013 Notes) in which either (i) the outstanding shares of the Company’s common stock are exchanged for securities of another corporation, or (ii) the Company issues shares of common stock, with no securities or other consideration paid or payable to holders of our common stock (e.g., a merger transaction in which the Company acquires another corporation in exchange for shares of our common stock), then (A) the entire unpaid principal under the applicable 2013 Note shall automatically convert, as of immediately prior to the effective time of the Change of Control, into shares of the Company’s common stock at a conversion price per share equal to the Closing Price (as defined in the Notes) on the effective date of the Change of Control, and (B) the Company shall also issue to each 2013 Note holder a five-year warrant entitling the holder to purchase, at an exercise price equal to the Closing Price on the effective date of the Change of Control, that number of shares of our common stock obtained by dividing (a) the sum of the outstanding principal under the applicable Note by (b) the Closing Price on the effective date of the Change of Control.

The warrants issuable upon a Change of Control are considered an embedded derivative and were bifurcated from the notes and accounted for separately at fair value. The fair value of the warrants was $203,400 on the March 15, 2013, date of issuance and were recorded as additional debt discount (see Note 7). Management used the following assumptions for the Black-Scholes valuation of the 2013 Notes on March 15, 2013:

Stock Price :	$0.09
Strike Price :	$0.09
Risk-free Rate:	0.84%
Volatility	148%
Term	5 years
Probability of issuance:	50%

The discount is being amortized to interest expense over the one year term of the 2013 Notes. As of March 31, 2013, the unamortized balance of this note discount is $194,484. The Company will revalue the warrants on a quarterly basis until the warrants are issued or the 2013 Notes are repaid in full. As of March 31, 2013, there was no material change to the fair value of the warrants from the date of issuance.

Upon a Change of Control other than as described in the preceding paragraph, the Company shall pay to each 2013 Note holder an amount in cash equal to 175% of the principal amount then outstanding under the applicable Note. Upon payment of such amount to the 2013 Note holders, all of the obligations under the Notes shall be deemed paid and satisfied in full.

7. 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 March 31, 2013.

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.

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 March 31, 2013:

	Fair Value March 31, 2013	Quoted Market Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities				
Warrant liability - April 2012 issuance	$205,442	$ -	$ -	$ 205,442
Warrant liability - 2013 Notes	203,400	-	-	203,400
Total	$408,842	$ -	$ -	$ 408,842

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The fair value of the warrant liability relating to the 2013 Notes (Note 6) was estimated by management using the Black-Scholes option-pricing model. The changes in the fair value of the warrant liability are recorded in other income (expense) on the Condensed Statements of Operations.

The fair value of the warrant liability relating to the warrants issued in conjunction with the April 2012 financing (Note 8b) 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 Condensed Statements 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 March 31, 2013:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
	Warrant Liability
Balance at January 1, 2013	$ 63,384
Purchases, sales and settlements:	
Derivatives issued	203,400
Total gains or losses	
Unrealized appreciation	142,058
Balance at March 31, 2013	$ 408,842

8. 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 8b) and as result will be classified as a liability on the Company's Condensed Balance Sheet.

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 $0.11 million, plus a non-accountable expense allowance of $35,000. Richard B. Brewer, the Company's former 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.

(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 $0.2 million at March 31, 2013. 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 income (expense) on the Condensed Statements of Operations.

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Significant assumptions used at March 31, 2013 for the warrants included a weighted average term of 4.00 years, volatility of 148%, and a risk-free interest rate of 0.77%.

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 March 31, 2013.

Grant Date	Warrants Issued	Exercise Price Range	Weighted Average Exercise Price	Expiration Date	Exercised	Warrants Outstanding
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
	10,804,695		$ 0.99		5,000	10,799,695

9. 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 months ended March 31, 2013 and March 31, 2012, the Company did not issue any employee stock options.

A summary of the status of the options issued under the Plan at March 31, 2013, 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, 2013	4,537,522	4,571,046	$ 1.24	
Options granted under the Plan	-	-	$ -	
Options exercised	-	-	$ -	
Options forfeited	290,000	(290,000)	$ 2.33	
Balance at March 31, 2013	4,827,522	4,281,046	$ 1.25	$ -
Exercisable at March 31, 2013		4,243,546	$ 1.26	$ -

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The following table summarizes information about stock options outstanding at March 31, 2013:

	Outstanding			**Exercisable**	
Range of Exercise Prices	Shares	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Total Shares	Weighted-Average Exercise Price
$0.09 to $0.57	1,506,533	5.68	$ 0.40	1,469,033	$ 0.40
$0.68 to $0.93	1,469,820	4.87	$ 0.82	1,469,820	$ 0.82
$1.46 to $2.71	974,693	5.29	$ 2.12	974,693	$ 2.12
$4.45	330,000	4.50	$ 4.50	330,000	$ 4.50
Total	4,281,046	5.20	$ 1.25	4,243,546	$ 1.26

Share-based compensation is recognized only for those awards that are ultimately expected to vest, therefore, the Company has applied an estimated forfeiture rate to unvested awards for the purpose of calculating compensation cost. These estimates will be revised, if necessary, in future periods if actual forfeitures differ from estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

Employee stock-based compensation costs for the three months ended March 31, 2013 and 2012 and for the cumulative period from August 1, 2005 (inception) through March 31, 2013 are as follows:

	Three months ended March 31,		Period from August 1, 2005 (inception) through March 31, 2013
	2013	2012	
General and administrative	$7,414	$111,717	$ 6,815,364
Research and development	-	60,098	1,551,203
Total	$7,414	$171,815	$ 8,366,567

The fair value of shares vested under the Plan for the three months ended March 31, 2013 and 2012 and for the period from August 1, 2005 (inception) through March 31, 2013 were $7,431, $101,009, and $7,633,723 respectively.

At March 31, 2013, total unrecognized estimated employee (including directors) compensation cost related to stock options granted prior to that date was $14,810, which is expected to be recognized over a weighted-average vesting period of 0.25 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.

Stock-based compensation costs incurred for services by non-employees for the three months ended March 31, 2013 and 2012, and for the cumulative period from August 1, 2005 (inception) through March 31, 2013 totaled $0, $0, and $498,095, respectively. These amounts were included in research and development and general and administrative expenses in the accompanying Condensed Statements of Operations. As of March 31, 2013 all non-employee based options outstanding were fully vested.

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10. 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