Nile Therapeutics, Inc. Form 10-Q August 14, 2013
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q
(Mark One)
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE $^{\rm x}{\rm ACT}$ OF 1934
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 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

(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 August 13, 2013, there were 43,520,563 shares of common stock, par value \$0.001 per share, of Nile Therapeutics, Inc. issued and outstanding.

Index

		Page
PART I	FINANCIAL INFORMATION	
Item 1.	Financial Statements	
	Condensed Balance Sheets (unaudited)	4
	Condensed Statements of Operations (unaudited)	5
	Condensed Statement of Stockholders' Equity (unaudited)	6
	Condensed Statements of Cash Flows (unaudited)	7
	Notes to Condensed Financial Statements (unaudited)	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	28
Item 4.	Controls and Procedures	28
PART I	IOTHER INFORMATION	
Item 1.	Legal Proceedings	29
Item 1A.	. Risk Factors	29
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	29
Item 3.	Defaults Upon Senior Securities	29
Item 4.	Mine Safety Disclosures	29
Item 5.	Other Information	30
Item 6.	Exhibits	31
	Signatures	31
	Exhibit Index	32

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 complete our planned merger with Capricor, Inc.;
 - 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.

3

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED BALANCE SHEETS

	June 30, 2013 (unaudited)	December 31, 2012
ASSETS		
Current assets		
Cash and cash equivalents	\$229,205	\$ 46,716
Prepaid expenses and other current assets	60,088	124,912
Total current assets	289,293	171,628
Property and equipment, net	994	3,488
Other noncurrent assets	4,535	51,938
	,	,
Total assets	\$294,822	\$ 227,054
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities Accounts payable Accrued expenses and other current liabilities Notes payable, net of unamortized discount of \$191,486 Due to related party	\$397,577 346,295 258,514 13,200	\$ 182,916 131,928 - 16,139
Total current liabilities	1,015,586	330,983
Warrant liability	512,087	63,384
Total liabilities	1,527,673	394,367
Commitments and contingencies (Note 11)		
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	- 43,062	- 43,062
shares issued and outstanding		

Additional paid-in capital Deficit accumulated during the development stage	46,512,487 (47,788,400)	46,497,642 (46,708,017)
Total stockholders' deficit	(1,232,851)	(167,313)
Total liabilities and stockholders' deficit	\$294,822	\$ 227,054	

See accompanying notes to the unaudited condensed financial statements.

4

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three months ended June 30,		Six months 6	ended June 30,	Period from August 1, 2005 (inception)	
	2013	2012	2013	2012	through June 30, 2013	
Income: Grant income Collaboration income	\$ - -	\$ - -	\$- -	\$- 195,500	\$ 482,235 1,550,000	
Total income	-	-	-	195,500	2,032,235	
Operating expenses: Research and development General and administrative	36,513 384,621	332,450 441,970	99,119 647,095	797,803 941,990	31,118,939 18,584,966	
Total operating expenses	421,134	774,420	746,214	1,739,793	49,703,905	
Loss from operations	(421,134) (774,420	(746,214) (1,544,293)	(47,671,670)
Other income (expense): Interest income Interest expense Other income (expense)	104 (74,046 (102,545	596) -) 420,890	144 (87,064 (247,249	840) -) 418,640	795,336 (1,360,798 448,732)
Total other income (expense)	(176,487) 421,486	(334,169) 419,480	(116,730)
Net loss	\$(597,621) \$(352,934	\$(1,080,383) \$(1,124,813)	\$ (47,788,400))
Basic and diluted loss per share	\$(0.01) \$(0.01	\$(0.03) \$(0.03)	
Weighted-average common shares outstanding	43,062,231	42,951,791	43,062,231	41,332,011		

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 JUNE 30, 2013

(unaudited)

	COMMON S	ТОСК	ADDITIONA PAID-IN	L	DEFICIT ACCUMULAT DURING THE DEVELOPMEN		TOTAL STOCKHOLDE EQUITY	ERS'
	SHARES	AMOUNT	CAPITAL		STAGE	11	(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			(224.210				(224.210	,
Elimination of accumulated deficit	1 250 000	1.050	(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