



## **PRESS RELEASE**

**November 12, 2009**

### **Nile Therapeutics Reports 2009 Third Quarter Financial Results**

**SAN MATEO, CA, November 12, 2009** -- Nile Therapeutics, Inc. (NASDAQ: NLTX), a company focused on the development of novel therapeutics for heart failure patients, today announced its third quarter financial results for 2009.

#### **Financial Results**

For the three months ended September, 30 2009, Nile reported a net loss of approximately \$2.0 million, or \$0.08 per share, compared to a net loss of approximately \$3.3 million, or \$0.14 per share, during the third quarter of 2008. Weighted-average shares outstanding for the quarter were 26.5 million.

Net cash used in operating activities in the third quarter of 2009 was \$1.0 million. As of September 30, 2009, Nile had cash and cash equivalents of approximately \$4.2 million compared to approximately \$5.5 million as of December 31, 2008.

#### **Update on CD-NP**

In August 2009, Nile completed dosing of the first patient in a single-blind, placebo-controlled Phase 2 study designed to provide additional information on the safety and tolerability of CD-NP when infused for up to 72 hours in patients with acute heart failure and mild to moderate renal insufficiency. Additional endpoints will include assessments of CD-NP's ability to relieve symptoms of acute heart failure and its effects on biomarkers of heart failure and renal function. The study is expected to enroll approximately 30 to 40 patients in the United States, Germany and Israel and will evaluate up to 3 dosages of CD-NP. Nile expects to announce results of the study in first half of 2010.

#### **About Nile Therapeutics**

Nile Therapeutics, Inc. is a clinical-stage biopharmaceutical company that develops innovative products for the treatment of cardiovascular disease and other areas of unmet medical needs. Nile is initially focusing its efforts on developing its lead compound, CD-NP, a novel rationally designed chimeric peptide in clinical studies for the treatment of heart failure, and CU-NP, a novel rationally designed natriuretic peptide. More information on Nile can be found at <http://www.nilethera.com>.

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**Safe Harbor Paragraph for Forward-Looking Statements:** This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding the timing, progress and anticipated results of the clinical development, regulatory processes, clinical trial timelines, anticipated benefits of CD-NP, Nile's strategy, future operations, outlook, milestones, the timing and success of Nile's product development, future financial position, future financial results, plans and objectives of management are forward-looking statements. Nile may not actually achieve these plans, intentions or expectations and Nile cautions investors not to place undue reliance on Nile's forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements Nile makes. Various important factors that could cause actual results or events to differ materially from the forward-looking statements that Nile makes include Nile's need to raise additional capital to fund its product development programs to completion, Nile's reliance on third-party researchers to develop its product candidates, and its lack of experience in developing and commercializing pharmaceutical products. Additional risks are described in greater detail in the reports Nile files with Securities and Exchange Commission, including those described under the caption "Risk Factors" in Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission on March 12, 2009 and amended on April 23, 2009. Nile is providing this information as of the date of this press release and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

**Condensed Statement of Operations**

	<u>Three months ended Sept. 30,</u>		<u>Nine months ended Sept. 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Grant income	\$ -	\$ -	-	\$ -
Operating expenses:				
Research and development	1,149,232	2,556,900	3,577,264	7,423,738
General and administrative	869,143	818,761	2,729,300	2,977,263
Total operating expenses	<u>2,018,375</u>	<u>3,375,661</u>	<u>6,306,564</u>	<u>10,401,001</u>
Loss from operations	(2,018,375)	(3,375,661)	(6,306,564)	(10,401,001)
Other income (expense):				
Interest income	15,194	58,451	35,767	290,734
Interest expense	-	-	-	(137)
Other expense	(24,499)	(3,679)	(35,781)	(46,523)
Total other income (expense)	<u>(9,305)</u>	<u>54,772</u>	<u>(14)</u>	<u>244,074</u>
Net loss	\$ <u>(2,027,680)</u>	\$ <u>(3,320,889)</u>	<u>(6,306,578)</u>	\$ <u>(10,156,927)</u>
Basic and diluted loss per share	\$ <u>(0.08)</u>	\$ <u>(0.14)</u>	<u>(0.25)</u>	\$ <u>(0.42)</u>
Weighted-average common shares outstanding	<u>26,491,211</u>	<u>24,149,405</u>	<u>24,930,007</u>	<u>24,118,645</u>

**Summary Balance Sheet Data**  
(in thousands)

	September 30, 2009		December 31, 2008	
Cash and cash equivalents	\$	4,224	\$	5,501
Total assets	\$	4,829	\$	6,435
Stockholders' equity	\$	3,984	\$	5,104