SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Nile Therapeutics

Form: 8-K

Date Filed: 2009-03-27

Corporate Issuer CIK: 1133869
Symbol: NLTX

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

FORM 8-K

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

Date of report (Date of earliest event reported): March 27, 2009

NILE THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware	**001-34058**	**88-0363465**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

115 Sansome Street, Suite 310
San Francisco, California 94104
(Address of Principal Executive Offices)

(415) 875-7880
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure

On March 27, 2009, Nile Therapeutics, Inc., or Nile, issued a press release announcing that, in the course of reviewing the investigational new drug application materials that Nile submitted to the U.S. Food and Drug Administration, or FDA, to support the start-up of Nile's Phase IIb clinical trial with CD-NP for the treatment of acute heart failure, the FDA has placed CD-NP on clinical hold.

The information in this Item 7.01, including that incorporated herein by reference, is being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including that incorporated herein by reference, shall not be deemed incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Nile Therapeutics, Inc. dated March 27, 2009.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

Date: March 27, 2009

NILE THERAPEUTICS, INC.

By: /s/ Daron Evans
Name: Daron Evans
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Nile Therapeutics, Inc. dated March 27, 2009.

PRESS RELEASE

March 27, 2009

Nile Therapeutics Provides Update on Phase II CD-NP Clinical Trial for Acute Heart Failure

SAN FRANCISCO, CA, Mar. 27 – Nile Therapeutics, Inc. (NASDAQ: NLTX), a leading company in the development of novel therapeutics for heart failure patients, announced today that, in the course of reviewing the investigational new drug application (IND) materials that Nile submitted to the U.S. Food and Drug Administration (FDA) to support the start-up of the Company's Phase IIb clinical trial with CD-NP for the treatment of acute heart failure, the FDA has placed CD-NP on clinical hold. In a letter sent to the Company this week and in a follow-up teleconference with the Company, the FDA requested additional data from the recently completed Phase IIa clinical trial and modifications to CD-NP's Investigator Brochure (IB). The Company is working diligently to respond in a timely manner and expects to be able to provide a complete response to the FDA's requests with recently finalized data from the Phase IIa clinical trial in acute heart failure patients.

About CD-NP

CD-NP is a novel chimeric natriuretic peptide in clinical development for the treatment of acute heart failure. CD-NP was designed to have direct hemodynamic and renal activity to reduce symptoms of dyspnea, be diuretic and natriuretic and preserve or enhance renal function in heart failure patients. In addition to an initial indication for acute heart failure, CD-NP has potential utility in other indications which include preservation of cardiac function subsequent to acute myocardial infarction (AMI), and prevention of renal damage subsequent to cardiac surgery.

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.

Contact:
Daron Evans
Chief Financial Officer
Nile Therapeutics, Inc.
+1-415-875-7880
info@nilethera.com

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 Nile's strategy, future operations, outlook, milestones, the timing and success of Nile's product development, the uncertain, lengthy and expensive clinical development and regulatory process, 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 are described in greater detail in the reports Nile files with Securities and Exchange Commission, including the "Risk Factors" section in Item 1A of the Form 10-K Nile filed with the Securities and Exchange Commission on March 12, 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.