

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 18, 2009

NILE THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34058
(Commission
File Number)

88-0363465
(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 8.01. Other Events.

On March 18, 2009, Nile Therapeutics, Inc. (the "Company") issued a press release, in compliance with Nasdaq Marketplace Rule 4350(b)(1)(B), announcing that the independent audit report included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 filed with the Securities and Exchange Commission on March 12, 2009 contained a going concern qualification from its independent registered accounting firm, Hays & Company LLP. A copy of the press release is filed as Exhibit 99.1 to this report.

The information contained in this Item 8.01 and the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|----------------------------------------------------------------|
| 99.1 | Press Release of Nile Therapeutics, Inc. dated March 18, 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 19, 2009

NILE THERAPEUTICS, INC.

By: /s/ Daron Evans

Name: Daron Evans

Title: Chief Financial Officer

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|----------------------------------------------------------------|
| 99.1 | Press Release of Nile Therapeutics, Inc. dated March 18, 2009. |

Press Release**Nile Therapeutics Announces Information in Compliance With NASDAQ Marketplace Rule 4350 and Reiterates 2009 Objectives**

SAN FRANCISCO, March 18 — Nile Therapeutics, Inc. (Nasdaq: NLTX—News), a leading company in the development of novel therapeutics for heart failure patients, today announced that, pursuant to Nasdaq Marketplace Rule 4350(b)(1)(B), its audited financial statements for the fiscal year ended December 31, 2008, included in the Company's Annual Report on Form 10-K, filed on March 12, 2009, contained a going concern qualification from its independent registered public accounting firm, Hays & Company LLP.

This announcement is required by Nasdaq Marketplace Rule 4350(b)(1)(B), which requires separate disclosure of receipt of an audit opinion containing a going concern qualification. This announcement does not represent any change or amendment to the company's financial statements or to its Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

2009 Objectives

Nile is focused on very specific clinical and corporate objectives:

- To complete the dosing of a 30 patient, placebo-controlled Phase 2b study in the 3rd quarter of 2009. This study is designed to provide additional clinical evidence that CD-NP enhances renal function. This finding would favorably differentiate CD-NP from other acute heart failure therapies.
- Through financing, partnering or other strategic alternative, secure the resources necessary to continue development activities beyond the 30 patient Phase 2b study.
- To start enrollment into the 330 patient double-blind, placebo-controlled Phase 2b acute heart failure Proof of Concept study.

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. A key component of the company's strategy is to acquire the global rights to additional compounds to expand its portfolio. More information on Nile can be found at <http://www.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, 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.