# 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): October 11, 2007**

# NILE THERAPEUTICS, INC.
**(Exact name of Registrant as Specified in its Charter)**

| **Delaware** | **333-55166** | **88-0363465** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

**2850 Telegraph Avenue Suite #310**
**Berkeley, CA 94705**
**(Address of Principal Executive Offices)**

**(510) 281-7700**
**(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 October 11, 2007, Nile Therapeutics, Inc. ("Nile"), a Delaware corporation, issued a press release announcing results from a Phase 1a clinical study of CD-NP, Nile's selective NPR-B agonist being developed for the treatment of heart failure. A copy of the press release attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

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, 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 October 11, 2007. |

**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: October 15, 2007

NILE THERAPEUTICS, INC.

By: /s/ Peter M. Strumph
Name: Peter M. Strumph
Title: Chief Executive Officer

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of Nile Therapeutics, Inc. dated October 11, 2007. |

**EXHIBIT 99.1**

**Nile Therapeutics Announces Positive Phase 1a Results of CD-NP, a Selective NPR-B Agonist in Clinical Development for the Treatment of Heart Failure**

BERKELEY, Calif., Oct. 11 /PRNewswire-FirstCall/ — Nile Therapeutics, Inc. (BULLETIN BOARD: NILT), today announced results from a Phase 1a clinical study of CD-NP, Nile's selective NPR-B agonist being developed for the treatment of heart failure. The results of this study will be included in the Company's presentation today at the BIO Investor Forum in San Francisco, CA.

"The development of a peptide that has natriuretic and renal effects, with relatively little effect on blood pressure, is a potentially important achievement. The results of this trial in healthy volunteers have confirmed some of the hypotheses developed during the pre-clinical studies. We were particularly interested to see a clear, dose dependent increase in cGMP, which suggests the molecule activates the NPR receptors," commented Dr. Barry M. Massie, Professor of Medicine, University of California, San Francisco, Chief, Cardiology Section, San Francisco VA Hospital, and member of Nile's scientific advisory board.

Study Design

The Phase 1a study was conducted to investigate the safety, tolerability, pharmacokinetics and pharmacodynamic profile of various doses of CD-NP compared to placebo over a four-hour infusion in 22 healthy volunteers. The study evaluated several pharmacodynamic variables which may translate into safety and efficacy in the heart failure population. Nile measured the effect of CD-NP on systemic blood pressure, urinary flow rate, urinary sodium excretion, serum potassium, renal function and cGMP, a secondary messenger of the target receptor and indicator of in-vivo activity.

Study Results

CD-NP was well tolerated with no serious adverse events and all subjects completed the four-hour infusion of placebo, 10, 17.5 or 25 ng/kg/min of CD-NP.

With respect to clinical and biomarker assessments, CD-NP (placebo, 10, 17.5 and 25 ng/kg/min) increased urine flow rate versus baseline (125%, 53%, 30% and 230% average change, respectively), increased sodium excretion versus baseline (28%, 138%, 55% and 158% average change, respectively) and increased plasma cGMP versus baseline (4%, 202%, 378% and 691% average change, respectively).

With respect to safety assessments, CD-NP (placebo, 10, 17.5 and 25 ng/kg/min) had no effect on mean arterial pressure versus baseline (-5%, 6%, -6%, -8% average change, respectively), had no effect on serum potassium levels versus baseline (0%, -2%, 3%, 3% average change, respectively), and had no effect on renal function as measured by GFR versus baseline (1%, 8%, 3%, 4% average change, respectively).

The four-hour infusion of CD-NP was well tolerated in all subjects at all dose levels tested. At the highest dose (25 ng/kg/min) of CD-NP, after completing the four-hour infusion, in response to an orthostatic challenge, some subjects exhibited transient symptoms consistent with volume depletion and/or vasodilatation including dizziness, asymptomatic tachycardia and orthostatic hypotension. These events are indicative of a practical limit of pharmacologic activity in normal healthy subjects, and Nile intends to investigate higher doses in upcoming Phase 1b studies of CD-NP infusions in heart failure patients.

"In this trial in healthy subjects, we demonstrated that CD-NP can be safely administered and elicits pharmacological and clinical effects which are consistent with the proposed mechanism of action. We are planning additional phase 1 trials in heart failure patients with the goals of determining the therapeutic dose range for diuresis, natriuresis, and cardiac filling pressure reducing effects, while maintaining systemic blood pressure and preserving renal function," commented Peter Strumph, Chief Executive Officer of Nile.

About CD-NP

CD-NP is a rationally-designed synthetic peptide designed to incorporate the optimal components of naturally occurring natriuretic peptides, creating a novel compound with unique actions in vivo. CD-NP is a selective NPR-B agonist with potent renal enhancement and cardiac unloading properties, but with minimal hypotensive effects.

About Heart Failure

Heart failure is a chronic condition in which the heart cannot effectively pump enough blood to the body's other organs. Heart failure is the fastest- growing clinical cardiac disease in the United States, affecting 5 million Americans. In the U.S., more than $30 billion is spent each year to treat heart failure. Approximately 1 million patients in the U.S. each year are hospitalized with acute decompensated heart failure (ADHF). These ADHF patients face high rates of morbidly and mortally following hospital discharge, with 6-month hospital re-admission and mortality rates of 50% and 33%, respectively.

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 need. Nile is initially focusing its efforts on developing its lead compound, CD-NP, a novel chimeric peptide in Phase I studies for the treatment of heart failure, and 2NTX-99, a small molecule, pre-clinical, anti-atherothrombotic agent with nitric oxide donating properties. 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 www.nilethera.com.

Contact:

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Safe Harbor Statement

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 our strategy, future operations, outlook, milestones, the success of Nile's product development, future financial position, future financial results, plans and objectives of management are forward-looking statements. We may not actually achieve these plans, intentions or expectations and Nile cautions investors not to place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Various important factors that could cause actual results or events to differ materially from the forward-looking statements that we make are described in greater detail in the reports we file with Securities and Exchange Commission, including the "Risk Factors" section of our latest Form 8-K, which was filed with the Securities and Exchange Commission on September 21, 2007. 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.

Source: Nile Therapeutics, Inc.

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