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): December 9, 2008

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 December 9, 2008, Nile Therapeutics, Inc., a Delaware corporation, issued a press release announcing preliminary data from its recently completed multi-center, open-label, ascending-dose Phase 1b clinical study of CD-NP, a novel chimeric natriuretic peptide, in patients with 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 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 December 9, 2008.

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: December 12, 2008

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 December 9, 2008.

EXHIBIT 99.1

Nile Therapeutics Announces Positive Results from Phase 1b Safety and Pharmacodynamics Study of CD-NP in Patients with Heart Failure

SAN FRANCISCO, Dec. 9 — Nile Therapeutics, Inc. (Nasdaq: NLTX), today announced preliminary data from its recently completed multi-center, open-label, ascending-dose Phase 1b clinical study of CD-NP, a novel chimeric natriuretic peptide, in patients with heart failure. Results of this study showed:

- CD-NP was well tolerated at doses of up to 20 ng/kg/min
- Blood pressure effects were dose dependent and well characterized
- CD-NP demonstrated diuretic effects comparable to furosemide
- CD-NP produced statistically significant changes on biomarkers consistent with enhanced renal function

These positive results are supportive of further study to fully validate proof-of-concept of CD-NP in a Phase 2b clinical trial planned to begin in 2009.

About the Study

The objectives of the Phase 1b study were to establish the maximum tolerated dose (MTD) and to assess the pharmacodynamic effects of CD-NP on blood pressure and renal function in stable heart failure patients. Patients with NYHA Class II or Class III heart failure, ejection fraction <40% and current signs of fluid overload were included in the study. In this dose escalation trial, four cohorts were administered a single 24-hour infusion of CD-NP at a dose of either 3 (n=6), 10 (n=6), 20(n=6) or 30 ng/kg/min (n=2). During the infusion of CD-NP, furosemide and vasoactive therapies were withheld.

Effects on Blood Pressure

The effects on blood pressure were dose-dependent. During a 24-hour infusion of CD-NP at doses of 3, 10 and 20 ng/kg/min, mean reductions in Mean Arterial Pressure were 2.2, 8.9 and 13.2 mmHg respectively.

CD-NP was well-tolerated at doses up to an MTD of 20 ng/kg/min. Dose escalation was limited by symptoms of hypotension observed at 30 ng/kg/min, which represents a dose of approximately 3- to 6-fold above the anticipated therapeutic range.

Effects on Renal Function

Enhancement of renal function by CD-NP was observed at doses well below the MTD. Notably, no clinically limiting changes in blood pressure were observed at the doses showing the most favorable renal effects.

Renal function from evaluable patients was assessed via biomarkers including serum creatinine and creatinine clearance, the most frequently used surrogate measure of glomerular filtration rate (GFR) and renal function. CD-NP treatment resulted in a statistically significant reduction of serum creatinine. After a 24-hour infusion of CD-NP at 3 ng/kg/min, serum creatinine was reduced by 10% (p=0.03). Infusions of 10 and 20 ng/kg/min resulted in serum creatinine reductions of 10% and 7%, respectively. These changes translated to a statistically significant increase in creatinine clearance using the Cockcroft-Gault formula, with infusions of CD-NP at 3, 10 and 20 ng/kg/min resulting in increases of 10% (p=0.01), 9% (p=0.02) and 7%, respectively.

Consistent with its effect on creatinine clearance, CD-NP elicited a statistically significant reduction of cystatin C, another biomarker of renal function. Infusions of CD-NP at 3, 10, and 20 ng/kg/min resulted in reductions of cystatin-c of 5% (p=0.05), 9% (p=0.05) and 4%, respectively.

Infusion with CD-NP resulted in diuresis similar to that observed with furosemide, a common diuretic used frequently in the management of heart failure patients. The average total urine volume during the 24-hour infusions of CD-NP at 3, 10 and 20 ng/kg/min was 2,738 ml. By comparison, during the 24-hour period prior to CD-NP infusion in which patients received standard doses of furosemide, the average total urine volume was 2,217 ml.

“Worsening renal function is an independent predictor of morbidity and mortality in heart failure. The data from this study show that administration of CD-NP in heart failure patients resulted in evidence of enhanced renal function as well as diuresis comparable to furosemide,” said Joel Neutal, M.D., Associate Professor of Medicine at University of California in Irving and Medical Director of Clinical Pharmacology at Orange County Research Center. “The unique profile of CD-NP could satisfy an unmet need for the treatment of patients with acute heart failure.”

“We are very pleased with the results of this Phase 1b study which support the hypothesis that the administration of CD-NP in heart failure patients results in diuresis and enhanced renal function with minimal blood pressure effects,” said Peter Strumph, Chief Executive Officer of Nile. “These data, in combination with the recently announced interim Phase 2a data, give us important clinical insight into the activity and tolerability of CD-NP and confirm our belief that CD-NP can provide a novel therapeutic profile for the treatment of heart failure.”

Information regarding this study is available at the U.S. government’s clinical trials database at http://www.clinicaltrials.gov.

About Heart Failure

Heart failure (HF) is a chronic condition in which the heart cannot effectively pump enough blood to the body’s other organs. HF is a major and growing public health problem affecting 5.3 million Americans, with over 650,000 new cases diagnosed every year. The annual mortality rate for heart failure is 19%. Treatment of heart failure generates annual costs of approximately $35 billion, of which approximately $3 billion is spent on drugs and $19 billion is spent in the acute hospital setting. Heart Failure patients frequently suffer episodes of acute decompensated heart failure (ADHF) which require hospitalization. For Americans over 65 years of age, ADHF is the most frequent cause of hospital admission. In recent years, 2.4 million patients in the US were hospitalized with a primary or secondary discharge code of ADHF and an average hospital stay of 4.3 days.

About CD-NP

CD-NP is a novel chimeric natriuretic peptide in clinical development for the treatment of ADHF. CD-NP was rationally designed by scientists at the Mayo Clinic’s Cardiorenal Research Labs. Current therapies for ADHF, including B-type natriuretic peptide, have been associated with favorable pharmacologic effects, but have also been associated with hypotension and decreased renal function which limit their utility in clinical practice. CD-NP was designed to preserve the favorable effects of current therapies while preventing or attenuating the hypotensive response, and enhancing or preserving renal function. The Company believes that these biochemical features, together with preclinical and preliminary clinical data in patients with heart failure, suggest that CD-NP may have a favorable safety and efficacy profile relative to current therapies for ADHF. In addition to an initial indication for ADHF, 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. We expect to initiate a Phase 2b study in patients with acute heart failure in 2009.

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 rationally designed chimeric peptide in clinical studies for the treatment of heart failure; 2NTX-99, a small molecule, pre-clinical, anti-atherothrombotic agent with nitric oxide donating properties; 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.

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 in Item 1 of the Form 10-KSB we filed with the Securities and Exchange Commission on March 27, 2008. 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.