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 14, 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 October 14, 2008, Nile Therapeutics, Inc., a Delaware corporation, issued a press release announcing interim data from its multi-center, open-label Phase 2a clinical study of CD-NP, a novel chimeric natriuretic peptide, in patients hospitalized for acute 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 October 14, 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: October 15, 2008

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 14, 2008.

EXHIBIT 99.1

Nile Therapeutics Announces Positive Interim Data from Phase 2a Study of CD-NP in Patients with Heart Failure

SAN FRANCISCO, Oct. 14 — Nile Therapeutics, Inc. (Nasdaq: NLTX), today announced interim data from its multi-center, open-label Phase 2a clinical study of CD-NP, a novel chimeric natriuretic peptide, in patients hospitalized for acute heart failure.

- Statistically significant reduction in pulmonary capillary wedge pressure
- Statistically significant increase in diuresis
- Trend toward reduction in right atrial pressure
- Trend toward increase in cardiac output
- No hypotension
- No change in serum creatinine

About the Study

The objective of the Phase 2a study is to assess hemodynamic and renal effects of CD-NP in patients with acute heart failure. In this dose escalation trial, stabilized acute heart failure patients receiving standard-of-care heart failure medications were administered an 8-hour infusion of CD-NP at 3 ng/kg/min (n=11), followed by a 14-hour washout period, and then an 8-hour infusion of CD-NP at 10 ng/kg/min (n=9).

Effects on Hemodynamics

Results from the first cohort of patients show a statistically significant reduction in pulmonary capillary wedge pressure (PCWP). Infusion with 3 ng/kg/min of CD-NP resulted in a statistically significant reduction of 2.9 mmHg relative to baseline at eight hours ($p=0.02$). Infusion of 10 ng/kg/min CD-NP following a washout period resulted in a further reduction of PCWP, which reached statistical significance at two hours after initiation ($p=0.02$). In patients who completed both doses of CD-NP, there was a statistically significant overall reduction in PCWP of 5.4 mmHg ($p=0.002$) from the initial baseline PCWP of 23.7 mmHg. The interim results also include an observed trend of decreasing right atrial pressure (RAP) and increasing cardiac output during i.v. infusion of CD-NP; however, these trends did not reach statistical significance in this initial sample of patients.

Importantly, these favorable hemodynamic effects of CD-NP were observed with minimal changes in blood pressure relative to baseline. No hypotension or clinically significant blood pressure reductions were observed during the study.

Effects on Renal Function

Based on the interim data, CD-NP elicited a statistically significant increase in urine output during infusion at both dose levels administered. Notably, the increase by CD-NP represents an increase to the baseline urine outflow established by concurrent infusion of furosemide. During the 3 ng/kg/min infusion of CD-NP, there was an increase in hourly urine output of 48 mL/hr ($p=0.01$) compared to the pre-dose baseline period. Infusion of 10 ng/kg/min CD-NP resulted in an increase in the hourly urine output of 93 mL/hr ($p<0.01$) compared to the pre-dose baseline period. Serum creatinine remained unchanged during the infusion period. These data suggest that CD-NP may preserve renal function in this patient population.

“The rate and magnitude of the reduction in PCWP is suggestive of a potential role for CD-NP in rapid relief of symptoms in acute decompensated heart failure patients,” said Uri Elkayam, M.D., Director of the Heart Failure Program at the University of Southern California. “The reduction in PCWP and RAP combined with minimal blood pressure changes and improved urine flow are supportive of CD-NP’s proposed mechanism of action as a venodilator that will preserve or improve renal function. Renal insufficiency is a major predictor of morbidity and mortality in this patient population, and there is a clear unmet medical need for novel heart failure therapeutics that are renal protective.”

“We are excited to announce data that are consistent with our hypothesis that CD-NP is a best-in-class product with favorable hemodynamic and renal activity,” said Peter Strumph, Chief Executive Officer of Nile. “We believe that the results from this patient population will be predictive of activity in our upcoming Phase 2b study in acute heart failure patients. We look forward to announcing the full results from this Phase 2a study, as well as results from the ongoing phase 1b study in stable heart failure patients.”

Information regarding this study is available at the U.S. government’s clinical trials database athttp://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, either as a result of impaired contractility (systolic heart failure) or impaired relaxation and ventricular filling (diastolic heart failure). 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 with 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 heart failure in 2009 and a Phase 2 study in AMI patients.

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.