

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Nile Therapeutics

Form: 8-K

Date Filed: 2009-01-22

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): January 16, 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 1.02. Termination of Material Definitive Agreement.

Nile Therapeutics, Inc., a Delaware corporation, or Nile, is a party that certain Exclusive License Agreement, or the License Agreement, dated August 6, 2007, by and between Nile and Dr. Cesare Casagrande. The License Agreement provides Nile with the rights to issued patents, patent applications and know-how relating to 2NTX-99, and all of its human therapeutic or veterinary uses. The intellectual property portfolio for 2NTX-99 includes an issued United States patent and an issued European patent relating to its composition of matter, multiple methods of manufacturing, and method of use in treating a variety of atherothrombotic pathological conditions. The License Agreement was filed as Exhibit 10.7 to Nile's Quarterly Report on Form 8-K filed September 21, 2007.

On January 16, 2009, Nile provided notice to Dr. Casagrande that it was terminating the License Agreement effective 90 days from the date of the notice. Nile determined to end the 2NTX-99 program and to focus its resources on the development of its other natriuretic peptides, including CD-NP, which is in Phase II development for acute heart failure, and CU-NP, which is a pre-clinical compound. Following the effectiveness of the termination, all rights to 2NTX-99 will revert to Dr. Casagrande.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 16, 2009, the Board of Directors of Nile approved the annual base salary levels of the officers of Nile, effective as of January 1, 2009, and also approved certain incentive cash bonuses and stock options grants to such officers, as indicated below, after providing such officers the choice of receiving a combination of cash and options or all options. The stock options were immediately vested and exercisable at an exercise price of \$0.88 per share, which is equal to the closing price of Nile's Common Stock as reported on NASDAQ on the date of grant. In addition, the Board of Directors certified the achievement of certain corporate objectives and individual performance targets of each of the officers for the year ended December 31, 2008, or a pro rata portion of the year for Hsiao Dee Lieu and Jane Moffitt, each of whom started employment with Nile in 2008. As a result of the determination of the Board of Directors, a number of shares of common stock set forth below, which were subject to certain stock options granted to these officers that vest based on the achievement of certain targets and goals, vested and are now immediately exercisable.

Officer	Annual Base Salary	Cash Bonus	Stock Options Granted	Number of Shares Vested Pursuant to Performance Stock Options
Peter M. Strumph <i>Chief Executive Officer</i>	\$ 320,000	—	149,148	103,474
Daron Evans <i>Chief Financial Officer</i>	\$ 200,000	—	49,020	43,269
Hsiao Dee Lieu, M.D., F.A.C.C. <i>Vice President of Clinical Research</i>	\$ 250,000	\$13,685.00	31,103	9,123
Jane Moffitt, J.D., LL.M. <i>Vice President of Regulatory Affairs</i>	\$ 250,000	—	59,367	6,966

Item 7.01. Regulation FD Disclosure

On January 20, 2009, Nile issued a press release announcing the termination of the License Agreement. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Nile Therapeutics, Inc. dated January 20, 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: January 22, 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 January 20, 2009.

Nile Therapeutics Announces Focus on CD-NP for Acute Heart Failure and Termination of 2NTX-99 Program

SAN FRANCISCO, Jan. 20 — Nile Therapeutics, Inc. (Nasdaq: NLTX), today announced that it will focus resources on the development of its natriuretic peptide franchise, including CD-NP which is in Phase II development for acute heart failure, and CU-NP which is a pre-clinical compound. Nile will suspend the further development of 2NTX-99 and return license rights for the compound to Dr. Cesare Casagrande.

“We are disappointed that we are unable to continue to pursue the development of 2NTX-99,” stated Peter Strumph, Chief Executive Officer of Nile. “We have decided to terminate this program in order to focus our resources on our core natriuretic peptide program, which is showing great promise as a potential treatment for cardiovascular and renal disease.”

Results from two completed Phase I studies and the ongoing open-label Phase IIa study support advancing the CD-NP development program into a Phase IIb clinical study. Current development plans include initiating a 30 patient placebo-controlled clinical study of acute heart failure patients with renal impairment. This study is designed to assess safety and efficacy of early administration of CD-NP in this patient population and may provide additional evidence to support the hypothesis that CD-NP enhances renal function. Such results would build upon the recently completed Phase Ib study in which CD-NP demonstrated diuretic effects comparable to furosemide and produced statistically significant changes on biomarkers consistent with enhanced renal function.

“Another study showing that CD-NP enhances renal function will go a long way towards establishing that CD-NP has differentiated and favorable renal properties relative to current and development treatments for acute heart failure,” commented Peter Strumph. “In addition, this study, which can be completed with our current balance sheet, will provide Nile with the opportunity to continue strategic discussions while building value from a meaningful clinical study.”

About CD-NP

CD-NP is a novel chimeric natriuretic peptide in clinical development for the treatment of acute heart failure. Current therapies for acute heart failure, 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 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 acute heart failure. 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, and prevention of renal damage subsequent to cardiac surgery.

About 2NTX-99

2NTX-99 is a small molecule anti-platelet, anti-atherothrombotic agent with nitric oxide donating properties. Mechanistically, 2NTX-99 is believed to inhibit the synthesis and action of thromboxane and enhance prostacyclin production. Prostacyclin and NO work together to inhibit platelet adhesion and aggregation, induce vasodilation and protect the vascular wall from atherogenic stimuli. The unique activity profile of 2NTX-99 suggests potential utility in a range of atherosclerotic, thrombotic, and microvascular diseases, including intermittent claudication, diabetic nephropathy and pulmonary arterial hypertension.

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, and CU-NP, a novel rationally designed natriuretic peptide. 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 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.