

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): February 25, 2011

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.)

4 West 4th Ave., Suite 400
San Mateo, California 94402
(Address of Principal Executive Offices)

(650) 458-2670
(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))
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Item 1.01. Entry into a Material Definitive Agreement

On February 25, 2011, Nile Therapeutics, Inc. (the “Company”) entered into a Clinical Trial Funding Agreement (the “Agreement”) with Medtronic, Inc. (“Medtronic”). Pursuant to the Agreement, the Company will undertake a Phase I clinical trial to assess the pharmacokinetics and pharmacodynamics of the Company’s cenderitide (formerly CD-NP) product candidate when delivered to heart failure patients through continuous subcutaneous infusion using Medtronic’s diabetes pump technology (the “Study”). In accordance with the Agreement, Medtronic will provide the funding necessary to conduct the Study and will supply the pumps and related equipment for use therein.

The Agreement provides that intellectual property conceived in or otherwise resulting from the performance of the Study shall be jointly owned by the parties (the “Joint Intellectual Property”), and that the Company shall pay royalties to Medtronic based on the net sales of any Company product, the manufacture, use or sale of which is covered or claimed in one or more issued patents constituting Joint Intellectual Property. The Agreement further provides that, if the parties fail to enter into a definitive commercial license agreement with respect to cenderitide, then each party shall have a right of first negotiation to license exclusive rights to any Joint Intellectual Property.

Under the Agreement, the Company has agreed not to enter into an agreement with a third party to develop or commercialize cenderitide or any drug/device combination developed under the Agreement until the earlier of: (i) three months following delivery to Medtronic of a final database with respect to the Study; and (ii) 15 months after the date of the Agreement.

The Agreement shall remain in effect until the completion of the Study unless terminated earlier by either party (i) if the other has materially breached its obligations thereunder, (ii) if the other party becomes subject to a bankruptcy or similar proceeding, (iii) for reasons related to the safety, efficacy, toxicity or formulation of cenderitide, or (iv) for a failure of the Study to meet its endpoints. Also, Medtronic may terminate the Agreement without cause at any time upon 90 days written notice to the Company, in which event Medtronic shall be obligated to pay the Company for any non-cancelable costs incurred prior to such termination.

The foregoing description of the Agreement does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the full text of the Agreement that will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ending March 31, 2011.

On February 28, 2011, the Company issued a press release announcing the collaboration with Medtronic. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 8.01. Other Events.

On February 28, 2011, the Company issued a press release announcing plans to pursue a new indication in the field of heart failure. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

In addition, on March 2, 2011, the Company issued a press release announcing that a Nasdaq Listing Qualifications Panel had granted the Company’s request for continued listing on the Nasdaq Capital Market. A copy of the press release is attached hereto as Exhibit 99.3 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated February 28, 2011, announcing collaboration with Medtronic.
99.2	Press release dated February 28, 2011, announcing plans to pursue a new indication in the field of heart failure.
99.3	Press release dated March 2, 2011, announcing positive Nasdaq determination.

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.

NILE THERAPEUTICS, INC.

Date: March 3, 2011

By: /s/ Daron Evans
Daron Evans
Chief Financial Officer

EXHIBIT INDEX

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99.3	Press release dated March 2, 2011, announcing positive Nasdaq determination.

**PRESS RELEASE****February 28, 2011****Nile Therapeutics to Collaborate with Medtronic on Clinical Development of Cenderitide for Heart Failure and Renal Disease**

SAN MATEO, CA, February 28, 2011 -- Nile Therapeutics, Inc. (NASDAQ: NLTX), a company focused on the development of novel therapeutics for heart failure patients, today announced plans to collaborate with Medtronic, Inc. (NYSE:MDT) on the clinical development of Nile's proprietary natriuretic peptide, cenderitide (formerly CD-NP), for heart failure and renal disease applications.

"We are very pleased to partner with Medtronic on cenderitide," said Joshua Kazam, Chief Executive Officer of Nile Therapeutics. "This collaboration will be an important step on our path to developing cenderitide as a potential new therapy for patients with cardiovascular and renal disease following hospitalization for acute heart failure."

Under the terms of the agreement, Medtronic will fund and provide its drug-device expertise as Nile executes on its Phase I clinical trial to assess the pharmacokinetics and pharmacodynamics of cenderitide delivered through Medtronic diabetes pump technology. In the planned clinical trial, cenderitide will be delivered to heart failure patients for up to 24 hours through continuous subcutaneous infusion. Nile expects to complete the trial by the first quarter of 2012. Financial terms were not disclosed.

Following the Phase I study, Nile intends to initiate a larger Phase II double-blind, placebo-controlled, dose ranging study in patients admitted to the hospital for acute heart failure. The planned Phase II study will evaluate the endpoints of cardiac remodeling, renal function, re-hospitalization and mortality in patients following 90 days of continuous therapy via subcutaneous pump. The first 90 days following admission to the hospital is a critical time for heart failure patients who are known to have combined rates of re-admission and mortality as high as 50% during that period. Nile believes that the cardiac unloading and renal preserving properties of cenderitide could have a significant benefit to patients during a critical time in their recovery from acute heart failure.

About Heart Failure

Heart failure is the fastest-growing clinical cardiac disease in the U.S. according to the American Heart Association, affecting over 5 million Americans. Over 1 million patients in the U.S. each year are hospitalized with ADHF, an acute exacerbation of heart failure. This hospitalization rate is almost double the rate seen 15 years ago, and is the most frequent cause of hospital admission in the U.S. for patients older than 65 years, generating annual inpatient costs of more than \$33 billion.

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, cenderitide, 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>.

Contact:

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Chief Financial Officer
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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 plans to develop cenderitide in the post-acute setting, the anticipated benefits of cenderitide for patients in the post-acute setting, and Nile's plans to initiate clinical trials in the post-acute setting, are forward-looking statements. Forward-looking statements also include statements regarding the timing, progress and anticipated results of the clinical development, regulatory processes, clinical trial timelines, expected patient enrollment, anticipated benefits of cenderitide, 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 include Nile's need to raise additional capital to fund its product development programs to completion, Nile's reliance on third-party researchers to develop its product candidates, and its lack of experience in developing and commercializing pharmaceutical products. Additional risks are described in greater detail in the reports Nile files with Securities and Exchange Commission, including those described under the caption "Risk Factors" in Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2009 filed with the Securities and Exchange Commission on March 3, 2010. 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.

**PRESS RELEASE****February 28, 2011****Nile Therapeutics Announces Plans to Pursue a Post-Acute Indication in Heart Failure**

SAN MATEO, CA, February 28, 2011 -- Nile Therapeutics, Inc. (NASDAQ: NLTX), a biopharmaceutical company focused on the development of novel therapeutics for cardiovascular disease, announced plans to pursue a new indication in the field of heart failure. Nile plans to develop cenderitide (formerly CD-NP) as an outpatient therapy to be delivered to acutely decompensated heart failure (ADHF) patients continuously for up to 90 days after discharge from the hospital. This is a novel therapeutic space for natriuretic peptides that has been termed "post-acute."

Within 90 days of admission for ADHF, approximately 40% of patients return to the hospital. Post-acute patients need sustained cardiac and renal function support to prevent a recurrence of their acute symptoms. In multiple clinical trials in both acute and chronic heart failure patients, short-term infusion of cenderitide has been shown to have positive effects on cardiovascular and renal parameters. Nile believes that the continuous and extended infusion of cenderitide through a subcutaneous pump will provide patients with sustained symptomatic relief in the outpatient setting that could contribute to a reduction in post-acute hospitalizations and persistent improvement in cardiorenal functions.

"With over 1 million admissions per year in the U.S., at a cost of over \$33 billion, ADHF is one of our country's most expensive health problems," said Richard B. Brewer, Nile's Executive Chairman. "We believe that cenderitide has an opportunity to address a true unmet need in heart failure, and could help reduce the overall cost of health care."

Nile recently had a productive meeting with the United States Food and Drug Administration (FDA) on the development of cenderitide as an extended subcutaneous therapy for a post-acute indication. Nile will seek a FDA Fast-Track Approval Designation for this post-acute indication. Before the end of the second quarter of 2011, Nile plans to file a new Investigational New Drug (IND) application and to initiate a Phase I pharmacokinetics and pharmacodynamics (PK/PD) clinical trial. Following the PK/PD trial, Nile intends to initiate a Phase II double-blind, placebo-controlled, dose-ranging clinical trial in post-acute heart failure patients in the first half of 2012.

"This new path represents the identification of an opportunity that incorporates the current clinical, scientific, and regulatory perspectives on the development of heart failure therapeutics," said James Young, MD, Professor and Executive Dean, Cleveland Clinic Lerner College of Medicine. "Preclinical and clinical data have shown that the natriuretic peptide class can act on multiple disease processes that play a role in the negative outcomes associated with heart failure. The unique properties of cenderitide provide a sound rationale to support this innovative strategy and could lead to the development of a differentiated product with clinically meaningful benefits."

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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, cenderitide, a novel, rationally designed chimeric peptide for the treatment of heart failure, and CU-NP, a second novel, rationally designed natriuretic peptide.

More information on Nile can be found at <http://www.nilethera.com>.

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PRESS RELEASE

March 2, 2011

Nile Therapeutics Receives Positive Nasdaq Panel Determination

SAN MATEO, Calif., March 2, 2011 -- Nile Therapeutics, Inc. (NASDAQ: NLTX), a company focused on the development of novel therapeutics for heart failure patients, today announced that, on March 1, 2011, the Company received a positive determination from the NASDAQ Listing Qualifications Panel (the "Panel") indicating that the Panel had granted the Company's request for an extension to remain listed on The NASDAQ Stock Market ("NASDAQ"). In accordance with the terms of the Panel's decision, the Company's continued listing on NASDAQ is subject to the Company evidencing compliance with NASDAQ's minimum \$1.00 bid price requirement, as set forth in Listing Rule 5550(a)(2), by May 31, 2011. The Company may evidence compliance with the bid price requirement by evidencing a closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days by May 31, 2011.

As previously disclosed, on November 30, 2010, the Company was notified by NASDAQ that its securities were subject to delisting based upon the Company's failure to satisfy the minimum bid price requirement. The Company subsequently attended a hearing before the Panel at which it presented its plan to regain compliance with the minimum bid price requirement by May 31, 2011. May 31, 2011 constitutes the full extent of the Panel's discretion to grant the Company an extension to remedy the bid price deficiency. While the Company is working to timely satisfy the terms of the Panel's decision, there can be no assurance that it will be able to do so.

About Nile Therapeutics

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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 ability to regain compliance with NASDAQ's listing requirements 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 include whether the price of Nile's common stock will close at or above \$1.00 for at least 10 consecutive business days prior to May 31, 2011, Nile's need to raise additional capital to fund its product development programs to completion, Nile's reliance on third-party researchers to develop its product candidates, and its lack of experience in developing and commercializing pharmaceutical products. Additional risks are described in greater detail in the reports Nile files with the Securities and Exchange Commission, including those described under the caption "Risk Factors" in Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2009 filed with the Securities and Exchange Commission on March 3, 2010. 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.
