

Nile Therapeutics, Inc.  
Form 8-K  
March 03, 2011

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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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

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

|   |  |   |
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| Delaware<br>(State or other jurisdiction<br>of incorporation) | 001-34058<br>(Commission<br>File Number) | 88-0363465<br>(I.R.S. Employer<br>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))

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

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