Edgar Filing: NEUROLOGIX INC/DE - Form 8-K

NEUROLOGIX INC/DE Form 8-K January 24, 2008

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

January 23, 2008

Date of Report (Date of Earliest Event Reported)

Neurologix, Inc. (Exact name of Registrant as Specified in its Charter)

Delaware 000-13347 06-1582875

(State or other Jurisdiction (Commission File Number) (I.R.S. Employer Identification No.)

of Incorporation or Organization)

One Bridge Plaza, Fort Lee, New Jersey 07024 (Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (201) 592-6451

(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))

Edgar Filing: NEUROLOGIX INC/DE - Form 8-K

Item 8.01. Other Events.

Plan of Operation -- Epilepsy

As a result of recent comments from, and discussions with, the Food and Drug Administration ("FDA") with respect to the Investigational New Drug ("IND") application filed by Neurologix, Inc. (the "Company") for a Phase I clinical trial in temporal lobe epilepsy, the Company has decided to conduct an additional preclinical study in non-human primates. Such study will be designed to confirm the safety of the administration and use of the adeno-associated virus expressing Neuropeptide Y (rAAV1-NPY).

The Company plans to work closely with the FDA to design a protocol with respect to this additional preclinical study, and until such protocol is agreed upon, the Company is unable to estimate the total time or costs involved in conducting such trial. In this regard, the commencement of its Phase I clinical trial will depend on the successful completion of this additional preclinical study. At the present time, the Company does not, however, expect that the study will result in significant changes to the protocol submitted by it to the FDA for the Phase I clinical trial. (See "Risk Factors – The Company Cannot Ensure that it Can Pursue Subsequent Trials for its Product Candidates or the Timing of any such Trials"; "Risk Factors – The Company is Subject to Stringent Regulation; FDA Approvals"; and "Risk Factors – The Company Will Need to Conduct Significant Additional Research and Testing Before Conducting Clinical Trials Involving Future Product Candidates" in the Company's 2006 Form 10-KSB).

Edgar Filing: NEUROLOGIX INC/DE - Form 8-K

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto, duly authorized.

NEUROLOGIX, INC.

Date: January 23, 2008 By: /s/ Marc L. Panoff

Name: Marc L. Panoff

Title: Chief Financial Officer, Secretary and Treasurer