
**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): July 25, 2017

Neuralstem, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-33672

(Commission File Number)

52-2007292

(I.R.S. Employer Identification Number)

2071 Goldenrod Lane, 2nd Floor, Germantown, Maryland 20876

(Address of Principal Executive Offices) (Zip Code)

301-366-4960

(Registrant's telephone number, including area code)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On July 25, 2017, Neuralstem, Inc. (the “Company”) announced top-line results from its exploratory Phase 2 clinical trial examining the efficacy of NSI-189 for the treatment of major depressive disorder. The study did not meet its primary efficacy endpoint. However, of the two secondary efficacy endpoints analyzed so far, the study achieved statistical significance of the patient-rated symptoms of depression questionnaire. A copy of the press release is attached to this report as Exhibit 99.01.

The information contained in this Item 7.01 to this Current Report on Form 8-K and the exhibit attached hereto pertaining to this item shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information or such exhibits be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The information set forth in the exhibits to this Form 8-K relating to this item 7.01 shall not be deemed an admission as to the materiality of any information in this report that is required to be disclosed solely to satisfy the requirements of Regulation FD.

Item 9.01. Financial Statements and Exhibits.

Exhibit

No.	Description
99.01	Press Release dated July 25, 2017

SIGNATURE

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.

Neuralstem, Inc.

Date: July 25, 2017

By: /s/ Richard Daly
Richard Daly
Chief Executive Officer

INDEX OF EXHIBITS

Exhibit

No.

[99.01](#)

Description

Press Release dated July 25, 2017

Neuralstem Announces Top-line Phase 2 Data of NSI-189 for Major Depressive Disorder

GERMANTOWN, Md., July 25, 2017 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company developing novel treatments for nervous system diseases, today announced top-line results from its exploratory Phase 2 clinical trial examining the efficacy of NSI-189 at 40 mg once daily (QD) and 40 mg twice daily (BID) compared to placebo for the treatment of major depressive disorder (MDD). The study, which utilized the two-staged sequential parallel comparison design (SPCD), did not meet its primary efficacy endpoint of a statistically significant reduction in depression symptoms on the Montgomery-Asberg Depression Rating Scale (MADRS). However, the 40 mg QD dose was directionally positive on the MADRS.

Of two secondary efficacy endpoints analyzed so far, the patient-rated Symptoms of Depression Questionnaire (SDQ) achieved statistical significance ($p=0.044$) with NSI-189 40 mg QD compared to placebo in the overall SPCD analysis. Results were also directionally positive on the Hamilton Depression Rating Scale (HAM-D17) at both doses. Both the 40 mg QD and 40 mg BID doses were well-tolerated with no serious adverse events reported.

“Depression is an important and complex area of clinical development,” said Maurizio Fava, MD, Director of the Division of Clinical Research and Executive Vice Chair, Department of Psychiatry at Massachusetts General Hospital, and the principle investigator of the trial. “NSI-189 is a novel small molecule that has shown a potential signal of efficacy in this trial. We are encouraged by its emerging clinical profile, and continuing the clinical evaluation of NSI-189 to pursue its full potential is warranted.”

The 12-week randomized, double-blind, placebo controlled, SPCD study evaluated 220 subjects diagnosed with recurrent MDD and a minimum MADRS score of 20. The mean baseline MADRS score was approximately 32. The study was conducted in two sequential six weeks stages with SPCD. Placebo non-responders from Stage 1 were re-randomized to either NSI-189 (40 mg QD or 40 mg BID) or placebo in Stage 2. Subjects received treatment at the beginning of each period. The results of Stage 1 and Stage 2 were pooled for statistical endpoints.

“I would like to thank the team at Neuralstem for their seamless execution of the Phase 2 trial, and thank the investigators and patients for their participation,” said Rich Daly, chairman and CEO, Neuralstem. “The directionally positive signals across multiple depression scales are encouraging and we look forward to further evaluation of the full dataset in the coming months.”

About Neuralstem

Neuralstem is a clinical-stage biopharmaceutical company developing novel treatments for nervous system diseases of high unmet medical need. NSI-189 is the lead compound in Neuralstem’s neurogenic small molecule program. NSI-566 is a stem cell therapy being tested in stroke, chronic spinal cord injury (cSCI) and Amyotrophic Lateral Sclerosis (ALS). Neuralstem’s diversified portfolio of product candidates is based on its proprietary neural stem cell technology.

Cautionary Statement Regarding Forward Looking Information

This news release contains “forward-looking statements” made pursuant to the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements relate to future, not past, events and may often be identified by words such as “expect,” “anticipate,” “intend,” “plan,” “believe,” “seek” or “will.” Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Specific risks and uncertainties that could cause our actual results to differ materially from those expressed in our forward-looking statements include risks inherent in the development and commercialization of potential products, uncertainty of clinical trial results or regulatory approvals or clearances, need for future capital, dependence upon collaborators and maintenance of our intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements. Additional information on potential factors that could affect our results and other risks and uncertainties are detailed from time to time in Neuralstem’s periodic reports, including the Annual Report on Form 10-K for the year ended December 31, 2016, and Form 10-Q for the three months ended March 31, 2017, filed with the Securities and Exchange Commission (SEC), and in other reports filed with the SEC. We do not assume any obligation to update any forward-looking statements.

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