UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K	
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CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) March 27, 2019

NEURONETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-38546 (Commission File Number) 33-1051425 (I.R.S. Employer Identification No.)

3222 Phoenixville Pike, Malvern, PA (Address of principal executive offices)

19355 (Zip Code)

Registrant's telephone number, including area code (610) 640-4202

(Former name or former address, if changed since last report.) Not applicable.

ck 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 owing 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))
cate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the urities Exchange Act of 1934.
Emerging growth company 🗵
n emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

Neuronetics, Inc. issued a press release on March 27, 2019 announcing that Japan's Central Social Insurance Medical Council (Chuikyo) has approved the recommendation by Japan's Ministry of Health, Labour and Welfare expert review panel to provide reimbursement for NeuroStar® Advanced Therapy for the treatment of Major Depressive Disorder in adults. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number

Description

99.1 <u>Press Release, dated March 27, 2019, of Neuronetics, Inc.</u>

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.

NEURONETICS, INC.

(Registrant)

Date: March 27, 2019 By: /s/ Peter Donato

Name: Peter Donato

Title: VP, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)



NeuroStar® Advanced Therapy to Receive Reimbursement Approval in Japan

Proven, breakthrough non-drug treatment for depression provides safe and effective option to the country's critical public health issue

MALVERN, Pa, March 27, 2019 – Neuronetics, Inc. (NASDAQ: STIM), a commercial stage medical technology company focused on designing, developing and marketing products that improve the quality of life for patients who suffer from psychiatric disorders, announced today that Japan's Central Social Insurance Medical Council (Chuikyo) has approved the recommendation by Japan's Ministry of Health, Labour and Welfare (MHLW) expert review panel to provide reimbursement for NeuroStar Advanced Therapy for the treatment of Major Depressive Disorder (MDD) in adults. The reimbursement is expected to go into effect on or about June 1, 2019.

The initial reimbursement approval for NeuroStar Advanced Therapy is expected to cover patients who are treated in the largest inpatient and outpatient psychiatric facilities in Japan and be at the rate of JPY12,000 per treatment session. The reimbursement approval of this market leading treatment means greater access and affordability for MDD patients who do not see relief from antidepressant medications. MHLW's Pharmaceuticals and Medical Devices Agency (PMDA) approved the marketing and sale of the NeuroStar Advanced Therapy System in September 2017. The NeuroStar Advanced Therapy System is exclusively distributed in Japan by Teijin Pharma Limited.

There are approximately 2.4 million people in Japan diagnosed with MDD and the country faces one of the highest suicide rates in the world. In Japan, many patients suffering from MDD are treated as inpatients in psychiatric hospitals. The average length of stay for such inpatient treatment is over 120 days. As a new treatment alternative, NeuroStar Advanced Therapy may advance MHLW's initiative called Mental Health Reform that seeks to reduce the length of inpatient treatment for psychiatric diseases.

"Obtaining reimbursement approval in Japan, a single-payor healthcare system, is a critical milestone to facilitate psychiatrists and facilities implementing NeuroStar Advanced Therapy into their treatment continuum to provide a much needed and affordable treatment alternative for MDD patients," said Chris Thatcher, President and CEO of Neuronetics. "MDD is a growing public health issue impacting more than 300 million people worldwide, and we are thrilled to increase patient access to this proven, transformative treatment in Japan to help people find relief from their depression."

About Neurostar Advanced Therapy

With more than 2.3 million treatments delivered to an estimated 62,900 patients worldwide, NeuroStar Advanced Therapy is a proven and effective treatment that uses magnetic pulses to stimulate areas of the brain that are underactive in depression. In an open-label clinical trial, 58% of patients significantly responded to treatment, and 37% achieved remission of their depression symptoms with NeuroStar Advanced Therapy. Additionally, NeuroStar's advanced technology offers doctors real-time feedback and delivers reliable and consistent treatment — allowing for the right treatment dose to be delivered to the right location every time, giving patients the best possible chance for long-term remission. It is

¹ Carpenter LL, et al. *Depress Anxiety*, (2012)

typically administered daily in a doctor's office for four to six weeks, with treatment sessions performed in approximately 37 minutes. Unlike electroconvulsive therapy (ECT), NeuroStar is non-invasive and allows patients to resume daily activities immediately following sessions. NeuroStar Advanced Therapy is commercially available in Japan and the United States as well as the Middle East and Asia regions. NeuroStar Advanced Therapy is also CE marked.

About Neuronetics

Neuronetics, Inc. is a commercial-stage medical technology company focused on designing, developing, and marketing products that improve the quality of life for patients who suffer from psychiatric disorders. Our first commercial product, the NeuroStar® Advanced Therapy System, is a non-invasive and non-systemic office-based treatment that uses transcranial magnetic stimulation, or TMS, to create a pulsed, MRI-strength magnetic field that induces electrical currents designed to stimulate specific areas of the brain associated with mood. The system is cleared by the United States Food and Drug Administration, or FDA for the treatment of major depressive disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Additional information can be found at www.neuronetics.com.

Forward-Looking Statements

Statements in the press regarding Neuronetics, Inc. (the "Company") that are not historical facts constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may be identified by terms such as "outlook," "potential," "believe," "expect," "plan," "anticipate," "predict," "may," "will," "could," "would" and "should" as well as the negative of these terms and similar expressions. These statements include those relating to: the anticipated effective date of reimbursement for NeuroStar Advanced Therapy in Japan; expectations regarding NeuroStar Advanced Therapy treatment by psychiatrists and facilities in Japan, the ability of NeuroStar Advanced Therapy to reduce length of inpatient treatment for psychiatric diseases,; the Company's expectations regarding growth opportunities and the build out of its NeuroStar Advanced Therapy System platform; expectations or beliefs regarding future events, potential markets or market size, and technological developments; and any statements of assumptions underlying any of the foregoing items. These statements are subject to significant risks and uncertainties and actual results could differ materially from those projected. The Company cautions investors not to place undue reliance on the forwardlooking statements contained in this release. These risks and uncertainties include, without limitation, risks and uncertainties related to: availability of coverage and reimbursement from third-party payors for treatments using the Company's products; physician and patient demand for treatments using the Company's products; developments in respect of competing technologies and therapies for the indications that the Company's products treat; product defects; the Company's ability to obtain and maintain intellectual property protection for its technology; and developments in regulation in the United States, Japan and other applicable jurisdictions. For a discussion of these and other related risks, please refer to the Company's recent SEC filings which are available on the SEC's website at www.sec.gov. These forward-looking statements are based on the Company's expectations and assumptions as of the date of this press release. Except as required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information, future events or changes in the Company's expectations.

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