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): March 9, 2021

BRAIN SCIENTIFIC INC.

(Exact Name of Registrant as Specified in Charter)

Nevada	333-209325	81-0876714
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

125 Wilbur Place, Suite 170
Bohemia, NY 11716
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (917) 388-1578

(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 (*see* General Instruction A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Not applicable	Not applicable	Not applicable

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 March 9, 2021, Brain Scientific Inc. issued a press release announcing that it received U.S. Food and Drug Administration (FDA) 510(k) clearance for its next generation NeuroCap™ device. NeuroCap™ is an advanced Electroencephalogram (EEG) electrode array used to obtain rapid EEGs in routine clinical and research settings where recording of STAT EEGs is desired.

The press release furnished as Exhibit 99.1 to this Current Report on Form 8-K is incorporated herein by reference. The information in this Item 7.01 and in Exhibit 99.1 of Item 9.01 is being furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. This report will not be deemed an admission as to the materiality of any information in this Item 7.01 or Exhibit 99.1 of Item 9.01.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release

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 thereunto duly authorized.

Date: March 9, 2021

BRAIN SCIENTIFIC INC.

By: /s/ Boris Goldstein
Name: Boris Goldstein
Title: Chairman of the Board, Secretary and Executive Vice President

Exhibit 99.1

Brain Scientific Announces FDA Clearance for Next-Gen NeuroCap™ EEG Headset

NEW YORK, March 9, 2021 -- Brain Scientific Inc. (OTCQB: BRSF), a neurology-focused medical device and software company, announced today it received U.S. Food and Drug Administration (FDA) 510(k) clearance for its next generation NeuroCap™ device. NeuroCap™ is an advanced Electroencephalogram (EEG) electrode array used to obtain rapid EEGs in routine clinical and research settings where recording of STAT EEGs is desired.

"We are constantly working on new products for the EEG market. In the new version of NeuroCap™, we added velcro strips for better adhesion. We also expanded the size range by adding an XS (extra small) size. And now this device is designed for broader use - in addition to intensive care units and ERs," **said Irina Nazarova, Marketing Director at Brain Scientific.**

NeuroCap™ is a disposable pre-gelled EEG headset with 22 electrodes and 19 active EEG channels located in accordance with the 10-20 system. Pre-gelled, fixed electrode locations eliminate time consuming tasks of head measurement and electrode placement. The cap is FDA-cleared to stay on a patient's head for up to 4 hours. NeuroCap™ is compatible with most encephalographs on the market and can be applied in just 5 minutes.

Brain Scientific wants to improve patient access to neurological care. The Company's data implies that only 30% of U.S. hospitals have equipment for routine EEGs due to cost and space constraints. The global pandemic is still raging and some studies show that more than 80% of hospitalized COVID-19 patients have neurological symptoms, which could require EEG testing. Additionally, there is an urgent need to limit contact between EEG technicians and patients.

About Brain Scientific

Brain Scientific is a commercial-stage healthcare company with two FDA-cleared products, providing next-gen solutions to the neurology market. The Company's smart diagnostic devices and sensors simplify administration, shorten scan time and cut costs, allowing clinicians to make rapid decisions and bridge the widening gap in access to neurological care.

To learn more about our corporate strategy, devices or for investor relations, please visit: www.brainscientific.com or email us at info@brainscientific.com

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Forward-looking statements, which involve assumptions and describe our future plans, strategies and expectations, are generally identifiable by use of the words "may," "should," "would," "will," "could," "scheduled," "expect," "anticipate," "estimate," "believe," "intend," "seek" or "project" or the negative of these words or other variations on these words or comparable terminology. Such forward-looking statements are not meant to predict or guarantee actual results, performance, events or circumstances, and may not be realized because they are based upon the Company's current projections, plans, objectives, beliefs, expectations, estimates, and assumptions, and are subject to several risks and uncertainties and other influences, many of which the Company has no control. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation, the Company's inability to obtain additional financing, the significant length of time and resources associated with the development of our products and related insufficient cash flows and resulting illiquidity, the Company's inability to expand its business, significant government regulation of medical devices and the healthcare industry, lack of product diversification, volatility in the price of the Company's raw materials and the Company's failure to implement the Company's business plans or strategies. These and other factors are identified and described in more detail in the Company's filings with the SEC. The Company does not undertake to update these forward-looking statements.