
**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): May 18, 2020

BioSig Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38659
(Commission File Number)

26-433375
(IRS Employer
Identification No.)

54 Wilton Road, 2nd Floor
Westport, Connecticut
(Address of principal executive offices)

06880
(Zip Code)

(203) 409-5444
(Registrant's telephone number, including area code)

N/A
(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))

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

| <u>Title of each class</u> | <u>Trading Symbol(s)</u> | <u>Name of exchange on which registered</u> |
|---|--------------------------|---|
| Common Stock, par value \$0.001 per share | BSGM | The NASDAQ Capital Market |

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

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 8.01 Other Events

On May 18, 2020, BioSig Technologies, Inc. and its majority owned subsidiary, ViralClear Pharmaceuticals, Inc. (“ViralClear”), announced that the U.S. Food and Drug Administration has completed its review of ViralClear’s Investigational New Drug application. A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---|
| 99.1 | Press Release, dated May 18, 2020 |

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.

Date: May 19, 2020

By: /s/ Kenneth L. Londoner
Name: Kenneth L. Londoner
Title: Executive Chairman



FDA Clears the Investigational New Drug Application to Enable the Phase II Trial of ViralClear's Merimepodib, Oral Solution to Treat Adult Patients with Advanced COVID-19, to Proceed

- **Phase II clinical trial expected to be conducted at multiple centers in the United States, including three Mayo Clinic sites under the leadership of Andrew D. Badley, M.D., Enterprise Chair of COVID-19 Task Force**
- **Randomized, double blind, placebo-controlled clinical trial to be conducted in adults with COVID-19 who are hospitalized and either require supplemental oxygen or are on non-invasive ventilation or high flow oxygen devices**

Westport, CT, May 18, 2020 — BioSig Technologies, Inc. (Nasdaq: BSGM) ("BioSig" or the "Company") and its majority owned subsidiary, ViralClear Pharmaceuticals, Inc. (ViralClear), today announced that the U.S. Food and Drug Administration (FDA) has completed its review of ViralClear's Investigational New Drug (IND) application. The FDA informed ViralClear that it may proceed with a proposed phase II study of merimepodib oral solution in adults with COVID-19 who are hospitalized and either require supplemental oxygen or are on non-invasive ventilation or high flow oxygen devices.

This study will be a randomized, double blind, placebo-controlled trial to evaluate the efficacy and safety of merimepodib as an orally administered treatment. The trial will occur in hospitalized patients who have confirmed infection with SARS-CoV-2 and require supplemental oxygen.

"I'm very pleased to be involved in this planned Phase II study of merimepodib for the treatment of patients with COVID-19 disease," said Andrew D. Badley, M.D., Professor and Chair of Department of Molecular Medicine and the Enterprise Chair of COVID-19 Task Force. "We are grateful to the FDA for their prompt response in helping accelerate opportunities to find treatments for the novel coronavirus. We plan to begin enrollment of this trial as soon as practicable given the importance of finding solutions to this pandemic."

"FDA clearance for our proposed phase II trial to proceed is an important step for the development of merimepodib," commented Jerome B. Zeldis, M.D., Ph.D, Executive Chair, co-founder and acting Chief Medical Officer of ViralClear Pharmaceuticals, Inc. "We intend to conduct Phase II evaluations of our drug both in the hospital and outpatient settings as part of our clinical development plan."

"We thank the Mayo Clinic for collaborating with us to conduct the trials under the leadership of Professor Badley," said Nick Spring, Chief Executive Officer of ViralClear Pharmaceuticals, Inc. "Of the therapies that are currently being evaluated as treatments and can be available in the short term, we believe that a broad-spectrum antiviral that is orally administered and widely available could be very helpful in addressing the COVID-19 pandemic. We further believe it can play a pivotal role in helping manage this type of public health crisis."

About BioSig Technologies

BioSig Technologies is a medical technology company commercializing a proprietary biomedical signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals (www.biosig.com).

The Company's first product, PURE EP(tm) System is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing electrophysiology (EP) procedures in an EP laboratory.

About Merimepodib (MMPD)

Merimepodib, a broad-spectrum anti-viral candidate, that demonstrates strong activity against COVID-19 in cell cultures in laboratory testing and additional antiviral studies are underway. Merimepodib was previously in development as a treatment for chronic hepatitis C and psoriasis by Vertex Pharmaceuticals Incorporated (Vertex), with 12 clinical trials conducted (including 315 chronic hepatitis C patients, 24 psoriasis patients, and 98 healthy volunteers) and an extensive preclinical safety package completed.

A manuscript titled, "The IMPDH inhibitor merimepodib provided in combination with the adenosine analogue remdesivir reduces SARS-CoV-2 replication to undetectable levels in vitro", was submitted to an online peer-reviewed life sciences journal. This manuscript is authored by Natalya Bukreyeva, Rachel A. Sattler, Emily K. Mantlo, John T. Manning, Cheng Huang and Slobodan Paessler of the UTMB Galveston National Laboratory and Dr. Jerome Zeldis of ViralClear Pharmaceuticals, Inc. ("ViralClear") as a corresponding author. This article highlights pre-clinical data generated under contract with Galveston National Laboratory at The University of Texas Medical Branch.

About ViralClear

BioSig's subsidiary ViralClear Pharmaceuticals, Inc., is seeking to develop a novel pharmaceutical to treat COVID-19. Merimepodib is intended to be orally administered, and has demonstrated broad-spectrum in vitro antiviral activity, including strong activity against COVID-19 in cell cultures. Merimepodib has been previously studied in 12 clinical trials, including 5 in patients with hepatitis C (1 Phase 1b, 1 Phase 2, 2 Phase 2a, and 1 Phase 2b), 1 in patients with psoriasis (Phase 2), and six in healthy volunteers (Phase I).

Forward-looking Statements

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) the geographic, social and economic impact of COVID-19 on our ability to conduct our business and raise capital in the future when needed, (ii) our inability to manufacture our products and product candidates on a commercial scale on our own, or in collaboration with third parties; (iii) difficulties in obtaining financing on commercially reasonable terms; (iv) changes in the size and nature of our competition; (v) loss of one or more key executives or scientists; and (vi) difficulties in securing regulatory approval to market our products and product candidates. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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