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): September 22, 2020

BioSig Technologies, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38659**	**26-4333375**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

54 Wilton Road, 2nd Floor **Westport, Connecticut**	**06880**
(Address of principal executive offices)	(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:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
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 7.01 Regulation FD Disclosure.

On September 22, 2020, BioSig Technologies, Inc. (the "Company") issued a press release, attached hereto as Exhibit 99.1, announcing that the Company's majority-owned subsidiary, ViralClear Pharmaceuticals, Inc. ("ViralClear") conducted an investor update call on ViralClear's merimepodib drug development program for the treatment of COVID-19. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the 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 it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing. Furthermore, the furnishing of information under Item 7.01 of this Current Report on Form 8-K is not intended to constitute a determination by the Company that the information contained herein, including the exhibits hereto, is material or that the dissemination of such information is required by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated September 22, 2020
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: September 23, 2020

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

ViralClear Expands Ongoing Phase 2 Trial Size for its Oral Anti-Viral for the Treatment of COVID-19, Expands Trial Locations and Appoints Contract Manufacturing Organization to Manufacture Phase 3 Supplies of Merimepodib Oral Solution

Westport, CT, Sept. 22, 2020 (GLOBE NEWSWIRE) --

- **Size of ongoing Phase 2 trial of merimepodib in combination with remdesivir increased from 40 to 80 subjects, with focus on hospitalized patients requiring non-invasive ventilation/high flow oxygen devices**
- **Added 2 new Principal Investigators for the ongoing Phase 2 trial expanding the total number of locations to 10**
- **Contract Manufacturing Organization (CMO) appointed to manufacture Phase 3 supplies of merimepodib oral solution**
- **Merimepodib monotherapy trial to be conducted in the outpatient setting after current combination trial completes**

BioSig Technologies, Inc. (Nasdaq: BSGM) ("BioSig" or the "Company") and its majority owned subsidiary, ViralClear Pharmaceuticals, Inc. (ViralClear), today conducted an investor update call on Viral Clear's merimepodib drug development program for the treatment of COVID-19.

The size of the ongoing randomized, double-blind, placebo-controlled Phase 2 trial of merimepodib in combination with remdesivir is being increased from 40 to 80 subjects. When the trial was first initiated, it was thought that COVID-19 patients with National Institute of Allergy and Infectious Disease (NIAID) 8-point ordinal scores of 3 and 4 (i.e., hospitalized patients who require non-invasive ventilation and patients who require high flow oxygen devices and supplemental oxygen, respectively) would have similar outcomes in terms of their disease. However, based on a review of blinded data from the ongoing trial, subjects with scores of 3 and 4 are showing distinct differences. All subjects who were admitted with a score of 4 have had an uneventful course of disease and were rapidly discharged from the hospital due to improvement in clinical condition. The subjects who were admitted with a score of 3 fared differently: one group of subjects improved and were discharged from the hospital and are doing well at long-term follow-up, while others have not improved.

Based on the above and the small numbers of subjects in each NIAID group, ViralClear decided to increase the enrollment in the current study to 80 subjects, with a focus on subjects with an NIAID score of 3 at entry. The decision to increase the subject number in the trial was also based on advice from industry experts and discussions with government agencies and non-governmental organizations. Once additional subjects are enrolled and further clinical data is obtained, the team will discuss with the FDA the appropriate size for a Phase 3 trial.

Two additional Principal Investigators were added to the ongoing Phase 2 trial to improve the enrollment rate, increasing the total number of locations to 10.

ViralClear has contracted with a US-based Contract Manufacturing Organization (CMO) to manufacture the registration stability batches [required for the New Drug Application (NDA) filing] of the merimepodib oral solutions (drug product) that will also serve as clinical trial supplies for the Phase 3 trial. In July 2020, Viralclear previously announced an agreement with another US-based CMO, AMRI, to produce the registration stability batches of the merimepodib (active pharmaceutical ingredient).

The merimepodib monotherapy trial to be conducted in the outpatient setting will be initiated after the completion of the current Phase 2 combination trial. The Emergency Use Authorizations (EUAs) for remdesivir and convalescent plasma, as well as the increasing use of dexamethasone as a standard of care in hospitalized COVID-19 patients, has precluded an evaluation of merimepodib monotherapy in this setting (i.e., hospitalized patients).

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 and ViralClear
BioSig's Technologies, Inc (Nasdaq: BSGM) subsidiary, ViralClear Pharmaceuticals, Inc. (ViralClear), is seeking to develop a novel pharmaceutical called merimepodib to treat patients with COVID-19. Merimepodib is intended to be orally administered, and has demonstrated broad-spectrum in vitro antiviral activity, including strong activity against SARS-CoV-2 in cell cultures. Merimepodib was previously in development as a treatment for chronic hepatitis C and psoriasis by Vertex Pharmaceuticals Incorporated (Vertex), with 12 clinical trials (7 in phase 1 and 5 in phase 2) with over 400 subjects and patients and an extensive preclinical safety package was 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 as a corresponding author. This article highlights pre-clinical data generated under contract with Galveston National Laboratory at The University of Texas Medical Branch.

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.

Andrew Ballou
BioSig Technologies, Inc.
Vice President, Investor Relations
54 Wilton Road, 2nd floor
Westport, CT 06880
aballou@biosigtech.com
203-409-5444, x133