
**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): April 17, 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)

26-4333375
(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 7.01 Regulation FD Disclosure.

On April 17, 2020, BioSig Technologies, Inc. (the “Company”) issued a letter to shareholders (the “April 2020 Shareholder Letter”), which is attached hereto as Exhibit 99.1. 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 8.01 Other Events

On April 17, 2020, the Company issued a press release announcing that it has issued the April 2020 Shareholder Letter. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	<u>Shareholder, dated April 17, 2020 (furnished herewith pursuant to Item 7.01)</u>
99.2	<u>Press Release, dated April 17, 2020</u>

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: April 17, 2020

By: /s/ Kenneth L. Londoner

Name: Kenneth L. Londoner

Title: Executive Chairman



LETTER TO SHAREHOLDERS

April 2020

Dear BioSig Shareholder

As the pulse of the world beats as one to overcome the COVID-19 pandemic, we hope that this letter finds you and your families safe and healthy. With the situation unfolding so quickly around us, changing the way we live and impacting every sector of the global economy, we feel it is important to provide a business update, share recent accomplishments and highlight our continued commitment to shareholder value creation through new business opportunities.

Since the onset of the pandemic, we have taken a proactive approach to continue business operations in this downturn. Accordingly, we have done the following:

- Put health and safety first and imposed a work-from-home rule for all employees
- Strengthened our balance sheet through closing a \$10 million common stock placement in February
- Preserved valuable resources through a laser focus on core initiatives that are essential to our business
- Continued consistent engagement with our clients via remote product demonstrations and training

We also were excited to announce the acquisition of the rights to develop the novel pharmaceutical candidate Vicromax™ by our subsidiary, ViralClear Pharmaceuticals, Inc. (ViralClear). Before we speak on BioSig's progress and the advancement of the PURE EP™ System, we will provide some information on ViralClear, and the value we believe that it will create for BioSig shareholders.

DEVELOPING A SOLUTION FOR COVID-19

Vicromax™ (merimepodib) has already undergone extensive animal testing as well as a total of 13 Phase I and Phase II human clinical trials for other indications. Most notably, it has also demonstrated strong activity against COVID-19 cell cultures by reducing the viral production by over 98% in in-vitro laboratory tests conducted at the Galveston National Laboratory at the University of Texas Medical Branch. We are currently working vigorously toward advancing this product candidate into FDA-approved clinical trials and in cooperation with Mayo Foundation for Medical Education and Research under the terms of the recently disclosed know-how license agreement.

In just under 30 days, our exceptional team consisting of top industry talent ran extensive laboratory tests, published first data, developed protocols, secured clinical trial support and established a supply chain to help facilitate the commencement of human trials. Once approved by the FDA, a Phase II clinical trial is planned to commence at Mayo Clinic. We are optimistic that we will be submitting an IND (Investigational New Drug) application with the FDA shortly with the goal of commencing human trials within the next several weeks if our IND is approved. We are confident that our efforts will bring significant value to the communities we serve and to our shareholders.

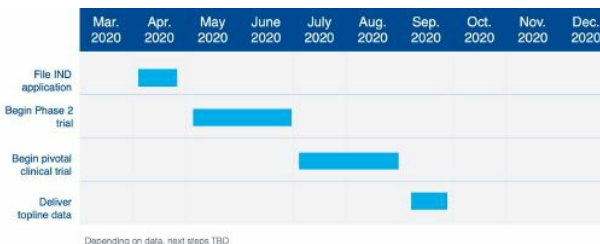
The Phase II clinical trial, upon receipt of FDA approval, is expected to be conducted under the leadership of Andrew D. Badley, M.D., Professor and Chair of Department of Molecular Medicine and the Enterprise Chair of COVID-19 Task Force. The study will be a randomized, placebo-controlled trial. We expect to

announce the data from the planned Phase II trial within three months of its commencement. To quote Dr. Badley, this trial is a part of our commitment to accelerate discoveries related to the SARS-CoV-2 virus and the disease it causes, COVID-19.

We also recently hosted a telebriefing that addressed a number of important questions regarding the product potency, its positioning in the competitive landscape and our overall strategy with our subsidiary. If you did not attend the call, we encourage you to read the full transcript of the briefing which is available on our website under www.ir.biosig.com.

Vicromax™ is being designed as an orally administered broad-spectrum anti-viral. It is intended to be used alone or potentially in combination with other anti-virals or immune modulators. We envision an easy-to-swallow softgel capsule formulation provided in blister packaging with doses labeled for the days of the week, facilitating a high degree of compliance.

Vicromax™ is a small-molecule drug candidate, which we believe can rapidly scale to pandemic quantities. Extensive product development has already been completed for other indications. We believe that Vicromax™ is ready for Phase II human trials and has been tested in more than 300 treated patients for other indications.



Our product candidate is a novel inhibitor of inosine monophosphate dehydrogenase (IMPDH), an enzyme that is responsible for stimulating the production of lymphocytes.

ViralClear's experienced management team is led by Nick Spring, who serves as the Company's CEO. Among other roles, Nick spent over 5 years at Merck & Co., leading teams that developed vaccine initiatives as well as the prelaunch of a billion-dollar HPV vaccine. Additionally, Nick served as the CEO and founder of Topaz Pharmaceuticals Inc., which was acquired by Sanofi for \$200+ million. Serving ViralClear as Executive Chairman is Jerome Zeldis, M.D., Ph.D. Dr. Zeldis served as the CEO of Celgene Global Health and Chief Medical Officer of Celgene Corporation, a fully integrated biopharmaceutical company, where he was employed for nearly 20 years, starting in 1997. Celgene Corporation was acquired by Bristol Myers-Squibb (NYSE: BMY) in a cash and stock deal valued at \$74 billion.

COMMERCIALIZATION OF PURE EP SYSTEM

Now on to BioSig's core business of the commercial implementation PURE EP™ System and associated technologies. As we stated in our November 2020 Shareholder Letter, our main goal for this year is a targeted market release for our platform technology. We had an extraordinary first quarter, during which we generated vast amounts of clinical data, initiated new installations and commenced first commercial discussions. Included in this letter is a recent article from *EP Lab Digest* titled, "Shaping the Future of EP

Through Advanced Signal Processing and Analysis "highlighting the PURE EP™ System and the value proposition that the PURE EP™ System brings to doctors and EP labs performing cardiac ablations.

RECENT HIGHLIGHTS INCLUDE:

- Receiving new commercial units of PURE EP™, which are being allocated to leading centers of excellence across the country
- Conducting over 50 patient enrollments into our first clinical trial at Texas Cardiac Arrhythmia Institute at St. David's Medical Center and Mayo Clinic Florida Campus
- Being formally invited to be featured in live cases during EPLive 2020
- Finalizing protocols for upcoming installations at new medical centers

In the current environment of lockdowns throughout our nation, all elective procedures, including cardiac ablations, are currently being postponed. We are proud to say that our clinical team was performing cases for as long as it was permitted, and we would like to extend our sincere thanks to everyone on our clinical team and all respective physician teams at Mayo Clinic and Texas Cardiac Arrhythmia Institute for putting patients' interests first during this critical time.

Despite the current slowdown in clinical cases, we remain committed to expanding our clinical footprint this year. We received Institutional Review Board (IRB) approvals at a number of medical centers of excellence, which will receive PURE EP™ Systems as soon as practical once current restrictions begin to lift. All centers targeted by our initial market release are high-volume clinical sites that are widely regarded for their work with new technologies.

Inventory to meet planned commercial placement requirements in 2020 is sufficient, and our supply chain remains intact. As we stated previously, our commercial activity is intended to be strongly supported by growing clinical validation and educational and training programs, including establishing training hubs at our early hospital partners' facilities.

Recently, we received a number of requests for commercial proposals, and we are optimistic that several of these requests can be converted to commercial sales.

ADVANCING CLINICAL DATA COLLECTION STRATEGY

Our first clinical trial commenced in November 2019, and to date we enrolled 53 patients at Texas Cardiac Arrhythmia Institute and Mayo Clinic Florida Campus under the leadership of 11 physician investigators.

We collected over 400 clinical data samples, which are currently undergoing deep analysis. This data is being used for a number of strategic initiatives, from abstract submissions to leading peer-reviewed publications to supporting physician education efforts to establishing economic benefits of the PURE EP™ System.

As a next step in our ongoing physician engagement, we plan to host our first Independent Investigators Meeting via a video conference in early May. Fourteen independent investigators have accepted the invitation to discuss our publication strategy, review current data, discuss key findings and provide input on a number of advanced product development initiatives currently in our R&D pipeline.

We have begun sharing some of the most notable signal examples in our public collaterals, and we plan to regularly update our website with this information. We encourage you to visit www.biosig.com/pure-ep/our-solution for more information.

GROWING INDUSTRY PRESENCE

We began 2020 on a very strong note by participating in the *25th Annual International AF Symposium* that took place in Washington, D.C. from January 23-25, 2020. This event was attended by over 1,500 key industry partners. In addition to the booth presentations and technology demonstrations by six members of our commercial team, our PURE EP™ System was presented in a Spotlight Session by Andrea Natale, M.D., of Texas Cardiac Arrhythmia Institute on the first day of the symposium.

We are also proud to report that we have been formally invited to participate in EPLive 2020, which is due to take place at St. David's Medical Center in Austin, Texas from September 17-18, 2020. EPLive Austin is a 2-day intensive educational meeting targeting practicing electrophysiologists, EP fellows in training and other EP professionals. The meeting consists of four sections: AF ablation, VT ablation, devices and new technologies. PURE EP™ System is confirmed for two live cases scheduled to be broadcast during this event.

Very recently, PURE EP™ System was featured in an interview with Andrea Natale, M.D., and Matthew Dare, CEPS (Research and Technology Coordinator), of Texas Cardiac Arrhythmia Institute. This interview was conducted by *EP Lab Digest*, one of the leading publications in our industry. The interview, titled "Shaping the Future of EP Through Advanced Signal Processing and Analysis," is a thorough overview of current challenges and recent developments in treatments of complex cardiac arrhythmias according to Dr. Natale, and his team's experience with PURE EP™ System. We thought that you might appreciate a copy of this interview and have enclosed it for your convenience.



SUMMARY

This is an extraordinary time and it has required an extraordinary response. It was encouraging to see how the entire healthcare community came together to address the pandemic, and we are committed to playing our part in getting physicians back to their patients.

Despite the challenging circumstances, our commitment to the Company and our mission is as strong as ever. The increasing interest in PURE EP™ is a stark testimony to the strong commercial strategy we began executing in 2019 and the quality of our team. Add to this the rapid acquisition of Vicromax™ and the steady advancement of ViralClear to seek to bring Vicromax™ into FDA-approved clinical trials is a testament to our team's dedication. It is an honor to see this Company rally to the cause, support its core business and to be a part of our BioSig family while witnessing and spearheading the launch of ViralClear.

Although these are testing times for the global economies, it also is a crucial time for you, your families and your friends. Please stay healthy and ensure that your well-being as well as the well-being of those close to you, remains your number one priority.

We sincerely appreciate your continued support and encouragement. With best wishes,



Kenneth L. Londoner, Chairman & CEO

SAFE HARBOR DISCLOSURE

This Shareholder Letter 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.



BioSig Issues April 2020 Shareholder Update Letter

- **Information on the progress of our subsidiary ViralClear Pharmaceuticals and Vicromax(tm) – a broad-spectrum orally administered anti-viral candidate for COVID-19**
- **Upon receipt of FDA approval, Phase II clinical trial is planned to be conducted at Mayo Clinic and is set to commence within the next several weeks under the leadership of Andrew D. Badley, M.D., Chair of the COVID-19 Task Force**
- **Update on the PURE EP(tm) System commercial implementation at leading centers across the country and patient enrollments into first clinical trials**

Westport, CT, April 17, 2020 /GLOBE NEWSWIRE/ — BioSig Technologies, Inc. (NASDAQ: BSGM) (“BioSig” or the “Company”), a medical technology Company commercializing a proprietary biomedical signal processing platform, today announced that the Company has issued an April 2020 Letter to Shareholders providing highlights on the Company’s recent developments and updates.

Recent Company Highlights include:

- The Company’s recent acquisition of the rights to develop Vicromax(tm), an anti-viral candidate which has demonstrated strong activity against COVID-19 cell cultures by reducing the viral production by over 98% in in-vitro laboratory tests, and is seeking to commence FDA-approved clinical trials
- Updates on BioSig’s core business in the commercial implementation of the PURE EP(tm) System that has generated vast amounts of clinical data, initiated new installations, and commenced its first commercial discussions
- BioSig’s growing industry presence through its participation in the 23rd Annual International AF Symposium attended by over 1,500 key industry partners and a Spotlight Session by Andrea Natale, M.D., Executive Medical Director, Texas Cardiac Arrhythmia Institute at St. David’s Medical Center
- Strengthened balance sheet through closing a \$10 million common stock placement in February.

“There are many extremely exciting developments that have occurred within the past several weeks in addition to the accomplishments of our core business in the first quarter,” stated Kenneth L. Londoner, Founder, Chairman and CEO of BioSig Technologies, Inc. “Our shareholder letter provides important updates on our early commercialization efforts, progress with our ongoing and planned clinical trials, sets out plans for the rest of the year and provides an update on the progress with our subsidiary, ViralClear Pharmaceuticals. Despite the challenges experienced by global economies as a result of the current pandemic, we believe that BioSig is well-positioned for success, and the core values of our entire Company continue to serve as a foundation for creating the potential for future growth”.

To view the Company’s Shareholder Letter in its entirety, please visit <https://ir.biosig.com>

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 ViralClear

BioSig’s subsidiary ViralClear Pharmaceuticals, Inc., is seeking to develop a novel pharmaceutical to treat COVID-19. Vicromax(tm) is intended to be an orally administered, broad-spectrum anti-viral agent that has demonstrated strong activity against COVID-19 in cell cultures in laboratory testing. The product candidate has completed Phase I and three Phase II trials in other indications.

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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