March 18, 2020

# BioSig Technologies, Inc. (BSGM - \$2.73)

Before a Successful Catheter Ablation, You Need to First Accurately Identify the Abnormal Cardiac Signals

We are transferring research coverage of BSGM to Yale Jen following the departure of the prior covering analyst. We are re-initiating the coverage with Buy rating and 12-month target price of \$13.

- Major value driver, the PURE EP system is a first-to-market and novel signal processing system that could help to improve the efficacy of catheter ablation in arrhythmia patients. The key value proposition of the PURE EP system is to provide electrophysiologists with visualized original and less distorted cardiac signals after the removal most of the noise and artifacts. This enables them more precisely to identify and destroy the diseased sites during the catheter ablation procedure and improve the success rate in treating atrial fibrillation (AFib) and ventricular tachycardia (VT). The use of the PURE EP system could potentially lead to more procedures being performed and translate to more hospital revenue. The PURE EP system was approved [510(k) clearance] in 3Q18. BSGM is conducting a randomized and blinded post-marketing clinical study to potentially demonstrate an improved signal by the PURE EP system vs. the current SOC recording/mapping system. A portion (n=34) of the outcome would be submitted for a publication, likely in 2020. With potential competitors far behind, the PURE EP system is likely to be the leading player in this space.
- A great entry point to own BSGM shares; the company is on the cusp of generating product revenue and expects robust sales growth. BSGM expects to generate product sales revenue starting in 2H20 supported by differentiated product and a seasoned and experienced commercial team. Given the uniqueness and the scarcity of the PURE EP system as situated in a concentrated industry sector, BSGM potentially could be a desirable M&A prospect.
- NeuroClear subsidiary could expand footprint into emerging bioelectronic medicine and is like a free call option for investors. NeuroClear focuses on developing highspeed electroneurogram recordings for accurate and targeted stimulation of specific nerves and implementing self-adjustment enabled effective feedback loop to provide optimal stimulation. It is like a free call option to investors not currently accounted for in BSGM share valuation.
- **Upside remains at the current valuation.** With the PURE EP system at initial stage of commercialization and a positive outlook for its revenue stream, we believe BSGM shares remain undervalued at current levels. Our 12-month \$13 price target is based on our forward P/E and EP space M&A comparable analyses.

Earnings Estimates: (\$ per share)

(June)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-20E</b>	-0.23	-0.23	-0.19	-0.18	-0.82	N.A.
<b>FY-19A</b>	-0.33	-0.38	-0.25	-0.68	-1.67	N.A.
<b>FY-18A</b>	-1.24	-1.24	-1.24	-1.24	-1.25	N.A.
<b>FY-17A</b>	-0.36	-0.31	-0.17	-0.41	-1.24	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology/MedTech

Ticker:	<b>BSGM</b>
Rating:	Buy
Price Target:	\$13.00

#### **Trading Data:**

AA = A
\$2.73
\$9.97
\$2.42
\$80
26.0

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## **Investment Thesis**

Our \$13 price target is supported by forward P/E and EP space M&A comparable analyses.

PURE EP system is to provide visualized original and less distorted electrocardiographic and intracardiac signals after the removal most of the noise and artifacts created by the large workstations interconnected with other lab equipment in electrophysiology (EP) suite.

Together, PURE EP system could be welcomed by both the physicians and hospital administrators.

- We are initiating coverage of BioSig Technologies (BSGM) with a Buy rating and a 12-month price target of \$13. BioSig Technologies is a commercial stage MedTech company with lead product, the PURE EP system in place and the company is on the cusp of generating sales revenue. The PURE EP system is a first-to-market signal processing system that could be used to improve the signal quality recorded during catheter ablation procedure and enable electrophysiologists to perform the procedure with greater precision and achieve better clinical outcome. Catheter ablation is used in treating arrhythmia patients, mainly atrial fibrillation (AFib) and ventricular tachycardia (VT).
  - The PURE EP system is a first-to-market and novel signal processing system that could help to improve the efficacy of catheter ablation in arrhythmia patients while potential competitions are far behind. The PURE EP system is comprised of both hardware and software. The key value proposition of the PURE EP system is to provide visualized original and less distorted electrocardiographic and intracardiac signals after the removal of most of the noise and artifacts created by the large workstations interconnected with other lab equipment electrophysiology (EP) suite. As such, this enables electrophysiologists more precisely to identify and destroy the diseased sites during the catheter ablation procedure. Consequently, it could improve the success rate of catheter ablation, especially in complex arrhythmia patients. Potentially this could result in less need to conduct repeated procedures. In addition, with the aid of the PURE EP system, the time needed for carrying out catheter ablation might be shortened due to the reduction of complexity of maneuvers. This ultimately might lead to more procedures being performed over a given time period, and likely translate to more revenue to the hospital. Together, the PURE EP system could be welcomed by both the physicians and hospital administrators. The PURE EP System is approved in the U.S. with 510(k) clearance issued in August 2018. The PURE EP system is not a replacement of the current recording systems, but a third-party add-on to existing EP recorders that could provide more optimal outcomes. BSGM developed the PURE EP system in collaboration with several academic institutions. The company also recently signed a 10-year collaboration agreement with the Mayo Clinic for long-term development of the PURE EP system and potentially other signal processing bioelectronic medical devices. We view this collaboration a valuable asset for BSGM's long term development. BSGM has conducted 23 preclinical studies with results published. BSGM is conducting a randomized and blinded clinical study (a postmarketing trial) to potentially demonstrated an improved signal derived from the PURE EP system vs. the current standard of care recording/mapping system. A portion (n=34) of the outcome would be submitted for a publication, likely in 2020. Given the PURE EP system

is the only player in town, and while potential competitors are far behind, we believe its commercial outlook is bright.

- A great entry point to own BSGM shares; the company is on the cusp of generating product revenue and expects robust sales growth. Given that the PURE EP system is on the cusp of generating sales revenue (likely to start in 2H20), a promising outlook for ramping up sales in 2021 and beyond, and the current low valuation of BSGM shares, we believe it is a great entry point for investors to start owning BSGM shares. Besides the well differentiated product, we are impressed by BSGM's sales and marketing team, as it comprised of seasoned and experienced members with track records from major EP power houses, like JNJ, BSX and MDT. Management also guided that the PURE EP system could potentially be installed in 4–9 centers in 1H20. Despite the potential short-term impact on sales projections due to the ongoing COVID-19 pandemic infection; we remain confident that the near-term outlook is intact, given the solid fundamentals of the product and the commercial organization. In addition, two other business-related factors could further de-risk the outlook of BSGM shares and the PURE EP system. The first is that the PURE EP system belongs to the 3D mapping and recording subsector, which relatively lacks innovation lately, while innovative product development, such as new catheters, from the remaining subsectors of the EP device market is much more robust. As such, it further showcases the uniqueness and the scarcity of the PURE EP system. The second is that the EP market is very active in M&A, and BSGM could be a M&A prospect, and if so, that could potentially carry additional premium to its valuation.
- NeuroClear subsidiary could expand footprint into emerging bioelectronic medicine and this is like a free call option for investors. NeuroClear Technologies is a subsidiary formed by BSGM in 4Q18 to pursue additional applications of the PURE EP signal processing technology outside of the field of EP. NeuroClear's current focus is to develop highspeed electroneurogram (ENG) recordings for an accurate and targeted stimulation of specific nerves in a nerve bundle and implementing an effective feedback loop that can self-adjust for the optimal amount and timing of stimulation. ENG consists of small, high frequency, low amplitude signals, and they are hard to detect with conventional signal recording systems. The near-term objectives of NeuroClear are focusing on non-invasive vagus nerve stimulation (nVNS) and deep brain stimulation (DBS). On the nVNS side, potential indications to be treated include cognitive disorders, AFib, and chronic pain. On the DBS side, potential indications to be treated include ADHD, eating disorders, Alzheimer's, addiction, epilepsy, dementia, and pain. Bioelectronic medicine (BEM) is a rapidly emerging and highly promising field and we believe NeuroClear's highspeed ENG recording system could afford a unique and differentiated approach in product development. All their developments are in early preclinical stage. Given none of these have been priced in BSGM share value, we view this asset as free call option for investors.
- Valuation is favorable. We believe BSGM shares are undervalued, based on its novel and well differentiated PURE EP system and the scenario that the company is on the cusp of generating product revenue

Pursuing additional applications of the PURE EP signal processing technology outside of the field of EP.

The near-term objectives of NeuroClear are focusing on non-invasive vagus nerve stimulation (nVNS) and deep brain stimulation (DBS).

supported by a very seasoned and capable commercial team. Accordingly, our \$13 price target is supported by forward P/E and EP space M&A comparable analyses. We are recommending BSGM shares to long-term oriented investors with high to modest risk tolerance.

# Anticipated milestones in 2020 and beyond

Program	Indication	Event	Timing	Impacts
		Expand marketing and sales effort at hospitals	2020/2021	***
	Publish first clinical trial results and initiate new studies	2020	****	
PURE EP system	Arrhythmias catheter	Potentially report first clinical trial results	2020	****
	ablations	Potentially initiate additional clinical study	2020	***
		Participate medical and industry events	May and Oct. 2020	***
		Potentially receive EU approval	2021	***

<sup>\*\*\*\* / \*\*\*\*\*</sup> Major catalyst event that could impact share price very significantly while \*\*\* event is more informative

Source: Laidlaw & Company and company presentation.

PURE EP System Is the Leading Signal Processing System that Could Improve Clinical Efficacy of Catheter Ablation in Arrhythmia Patients

# What is PURE (Precise Uninterrupted Real-time evaluation of Electrograms) EP System

BioSig is an emerging MedTech company focusing on bioelectronic medicine and with its PURE (Precise Uninterrupted Real-time evaluation of Electrograms) EP system as lead product. The PURE EP system is a proprietary biomedical signal processing platform that extracts information from physiologic signals to facilitate electrophysiologists for diagnosis or during surgical procedures. More specifically, the PURE EP system serves to acquire, digitize, amplify, filter, measure, calculate, display, record and store original and less distorted electrocardiographic and intracardiac signals from patients undergoing electrophysiological (EP) procedures. As a reminder, EP is a discipline for studying the propagation of electrical impulses throughout different organs, currently mainly in heart but also of other organs, such as neurological systems. As for the PURE EP system, the most relevant uses are for catheter ablation as a treatment in various arrhythmias, mainly atrial fibrillation (AFib) and ventricular tachycardia (VT).

The value proposition of the PURE EP system is trying to resolve certain uncertainties in identifying the sites on the heart from which the arrhythmic signals derive. This is critical given more accurately recognizing these lesions (~0.2 inch) possessing electrical abnormality would increase the success rate of diagnosis and the destruction of the tissue (create a scar) by ablation, especially of complex arrhythmias, like AFib and VT.

Issues in EP lab for successfully achieving catheter ablation in complex arrhythmias. The key to identifying the precise diseased sites is to monitor and record abnormal electrical signals prior to and during ablation. However, significant amounts of noise and artifacts occur during EP procedures making this task more difficult and, often, less accurate in site recognition. The sources of the noise and artifacts are created from the large workstations interconnected with other lab equipment used in the EP suite, and this could overshadow the true small electrophysiological potentials need to be recorded into the surface and intracardiac recording systems. Although many commercially available products all have provided noise and artifacts ameliorating filters (low pass, high pass and notch) and gain settings for improvement, unfortunately it seems that these efforts might not be sufficient. Given the amplitude and morphology of electrocardiogram and intracardiac signals are significantly affected by filters

PURE EP system is a proprietary biomedical signal processing platform that extracts information from physiologic signals to facilitate electrophysiologists for diagnosis or during surgical procedures.

...the most relevant uses are for catheter ablation as a treatment in various arrhythmias, mainly atrial fibrillation (AFib) and ventricular tachycardia (VT). During the surgical procedure, electrophysiologist needs to integrate multiple information streams from monitors and patient responses in real-time and react, such as delivering ablation.

PURE EP system is not a replacement of current recording systems, but a third-party add-on to existing electrophysiology recorders.

PURE EP system received 510(k) clearance by the FDA in August 2018.

The PURE EP system is comprised of both hardware and software

used to remove noise, the current recording systems, therefore, are less effective in preserving the optimal amount of original information contained in the cardiac signals.

In addition, during the surgical procedure, electrophysiologist needs to integrate multiple information streams from monitors and patient responses in real-time and react, such as delivering ablation. This further complicates and potentially extends the time to make decisions, especially if the signal being read is suboptimal. Compounding that, as other parts of equipment for the ablation procedure are further improved (i.e. remote robotic and magnetic navigation systems), the issue of less than optimal signals being recorded could be even more pronounced. the PURE EP system is likely to provide substantial improvements here.

The PURE EP system is not a replacement of current recording systems, but a third-party add-on to existing electrophysiology recorders that could provide much improved and most optimal outcomes. Examples of marketed systems that are compatible to the PURE EP system include CARTO by Biosense Webster (a Johnson & Johnson subsidiary), EnSite Precision by Abbott, and CardioLab by GE Healthcare. The PURE EP system received 510(k) clearance by the FDA in August 2018.

The PURE EP system is comprised of both hardware and software (Figure 1). On the hardware side, it could reduce the excessive use of filtering and enables amplifying the analog to digital conversion for further processing by software. The system also has means to provide defibrillator protection and radiofrequency (RF) noise suppression as both, if active, could generate significantly larger unwanted signals that could create a saturation artifact. Coupling software processing and the use of a proprietary adaptive notch filtering enables it to provide high fidelity unipolar recording signals. Unipolar signals are rather valuable in mapping and ablating arrhythmias, but suffer from higher noise under the conventional recording systems. It also would provide a higher sampling rate and broader dynamic range to facilitate the visualization of both small and large signals with similar resolution. In addition, it offers real-time digital signal processing (DSP) and recording of ECG/IC and provides synchronized multiple display windows with signals filtered in multiple ways.

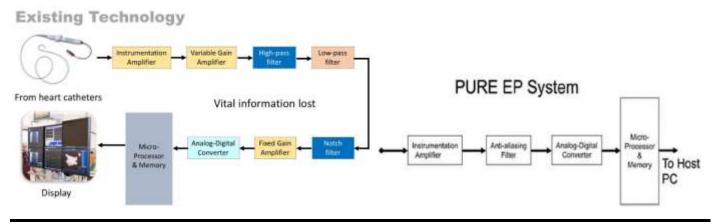
Figure 1: PURE EP system



Source: Company presentation

**Product development recap.** During product development, BSGM initially analyzed different EP recorders and various filters to determine the current status of signal quality (amplitude, morphology and duration) generated from those systems. The company then developed the PURE EP system showing ECG and intracardiac signals with less baseline wander, noise and artifacts compared to conventional EP recorders. In addition, distortions of spaciotemporal aspect of signals also have substantially improved compared to data generated from conventional EP recorders when notch filtering is being used. Figure 2 highlights the differences of processes involved between the current recording and filter system vs. the use of the PURE EP system.

Figure 2: Comparison between current and PURE EP system in mapping lesions to be ablated

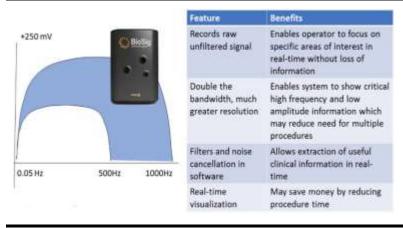


Source: Company presentation

In summary, several product attributes of the PURE EP system afford a number of specific benefits based on clinical practice perspective by electrophysiologists. They are illustrated in Figure 3.

Figure 3: PURE EP system in mapping lesions to be ablated

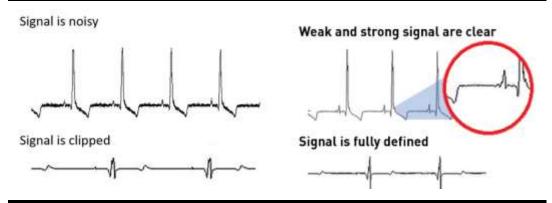
Obtaining higher resolution from doubled bandwidth could help electrophysiologists to gain more information of the high frequency and low amplitude signals enabling them potentially making more correct ablation decisions.



Source: Company presentation

We also highlight that obtaining higher resolution from doubled bandwidth could help electrophysiologists to gain more information of the high frequency and low amplitude signals (especially those temporally situated near the low frequency and high amplitude signals or large high-frequency signals) enabling them potentially making more correct ablation decisions. Figure 4 illustrates that the visualization of ECG wave pattern from a conventional EP recording (either with high noise background or being clipped by physicians) (left panel) compared to the pattern observed after processing by the PURE EP technology (right panel).

Figure 4: Signals showen from regular (I) and PURE PE improved (r) ECG wave



Source: Company presentation

With the advantages provided by the PURE EP system, there are several value propositions to both electrophysiologists and patients:

- Reduce the unnecessary complexity of maneuvers for EP study or ablation target identification of various arrhythmias, ultimately leading to better clinical outcomes. With greater precision in targeting, it is likely to create improved efficacy of catheter ablation, especially in more complicated cases. For example, with the use of conventional recording systems, electrophysiologists sometimes need to perform an exercise called clipping to remove overlapping signals on the display screen to better recognize the different signals if these signals are discrete and separated in time. However, if they are too close in time and too similar in amplitude, the data could be misinterpreted, especially given such scenario cannot be predicted in advance. The PURE EP system might mitigate such a problem given the system is configured with very low hardware gain, high dynamic range, and good noise performance.
- Shorten procedure times possibly creating greater economic benefit to hospital. With the aid of the PURE EP system to facilitates real-time clinical decision-making, surgeons might re-assess signals on the display less frequently and perform the task more accurately, the overall procedure time could be shortened (BSGM estimates it could be up to 20%). This could potentially benefit the hospital as physicians might see more patients and perform more procedures over a same period.
- Ultimately, reduce repeated ablations. With increasingly more accurate and successful initial catheter ablations, the probability of a repeat procedures could decrease. This could lead to further improvement of the efficacy, safety profile and success rate of catheter ablation procedure.

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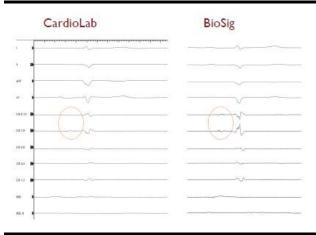
In 1Q17, BSGM signed a 10-year collaboration agreement with Mayo Clinic for a long-term development of the PURE EP system and potentially other signal processing bioelectronic medical devices (particularly in noise removal) that could be used broadly in other indications.

The study illustrates that PURE EP system exhibited better resolution of local, low voltage, fractionated electrograms than CardioLab in AFib patients undergoing ablation.

Collaboration with Mayo Clinic and other medical institutions. After developing the initial PURE EP system in Austin, TX., the company was in collaboration with lab at the University of California at Los Angeles to complete the proof of concept testing. Starting in 2014, BSGM has been in collaboration with Mayo Clinic (mainly at the laboratory of Samuel J. Asirvatham, MD) to further develop and refine the system, including conduct pre-clinical studies with multiple publications. In 1Q17, BSGM signed a 10-year collaboration agreement with Mayo Clinic for long-term development of the PURE EP system and potentially other signal processing bioelectronic medical devices (particularly in noise removal) that could be used broadly in other indications. The collaboration has further expanded recently with four more agreements signed in 2019. Together, we view the long-term collaboration with Mayo a very important piece of BSGM's total value proposition for the company advancing the technology of various product developments into the future. Overall, the BSGM team along with academic collaborators have completed 23 preclinical studies with publications in leading journals. In addition, the company also has performed 21 clinical cases including at the Texas Cardiac Arrhythmia Institute (TCAI) and the University of Indiana with encouraging results as surgeons were impressed with signals read from the PURE EP system.

Of the 23 studies evaluating the PURE EP system, one is done by Dr. Amin Al-Ahmad and colleagues of the Texas Cardiac Arrhythmia Institute in Austin with outcome presented at Venice Arrhythmias 2019 in 3Q19. The study illustrates that the PURE EP system exhibited better resolution of local, low voltage, fractionated electrograms than CardioLab on a side by side, subjective and qualitative comparison of the same signals in AFib patients undergoing ablation (Figure 5).

Figure 5: PURE PE vs. CardioLab of electrogram in the proximal coronary sinus



Source: Al-Ahmad, A., et. al., Poster at Venice Arrhythmias 2019

**Current and the next step developments.** BSGM started (Nov. 2019) the first clinical study (a post-marketing trial) evaluating whether signals harvested from the PURE EP system would be better than the one from the existing recording and mapping system. The study could enroll up to 500 patients and BSGM plans

Results from the first 34 patients will be submitted for a publication at a medical journal, which is expected in 2020 and we estimate could be in 2H20.

BSGM is also seeking potential EU approval for PURE EP system, possibly in late 2021. As such, product launch in EU could slate to early 2022.

to take the results from the first 34 patients and submitted it for a publication at a medical journal, which is expected in 2020 and we estimate that could be in 2H20.

The most recent BSGM update indicated >40 patients were enrolled and they anticipated patient recruitment could be completed in mid-2020. The patients eligible for the study are those receiving an elective cardiac ablation procedure. The indications include atrial fibrillation, atypical atrial flutter, symptomatic premature ventricular contractions (PVCs) or ischemic ventricular tachycardia.

From the patient's perspective, it is a prospective, non-randomized, observational study. The current standard of care recording/mapping system will be used for all patients undergoing surgery; while monitoring and intracardiac electrogram signal will be collected concurrently by the PURE EP system. After the procedures, parallel signal data samples will be harvested, cleaned, and organized, followed by the individual signal samples to be reviewed in a blinded, controlled fashion by a group of independent, unbiased electrophysiologists. Lastly, selected signal sample sets (from the same date and time stamp) will be separated in a survey and arranged in random order. The reviewer will be asked specific and identical questions relevant to each set of signal samples, but the individual samples will be separated and randomized across a full survey containing many different signal samples from many different procedures. In short, the signal comparison and survey part of the study is randomized and blinded.

Although BSGM has not revealed when the topline results would be available, we view the data readout would be an important milestone that could boost the confidences for electrophysiologists and hospital to use and purchase the PURE EP system. Going forward, we believe BSGM could conduct additional clinical studies, potentially associated with clinical outcomes, and that could potentially further increase the buy-in by multiple stakeholders. In addition, BSGM is also seeking potentially EU approval for the PURE EP system, potentially in late 2021. As such, product launch in EU could slate to early 2022.

#### Marketing and sales

Given the PURE EP system already received 510(k) clearance by the FDA in 3Q18, BSGM currently is in the early stage of commercialization in the U.S. Since at the time 510(k) clearance was granted, there were no patient experiences in using the system, BSGM has to conduct in-human clinical studies, first with case studies, followed by larger scale randomized and blinded studies to gain the buy-in from electrophysiologists and hospitals. In addition, BSGM has assembled a strong marketing and sales team with senior management came from EP powerhouses like Johnson & Johnson (Biosense Webster), Medtronic and Boston Scientific. The company guided that the headcounts for the M&S force could reach 12-15 in 2020 and potentially to be doubled in 2021.

One of the venues for products marketing in MedTech space is attending relevant leading medical and industry conferences. One positive example is the recent Annual International AF (AFIB) Symposium held in 01/2020 and management announced that it has generated 41 qualified business leads. In 2020, other

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The immediate goal of BSGM's marketing efforts is to start placing more PURE EP systems in more hospitals so surgeons would have a chance to experience the potential benefit firsthand.

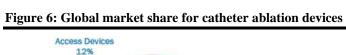
The 3D mapping, recording and others subsector, where the PURE PE system is categorized accounts for 13% or ~\$550MM.

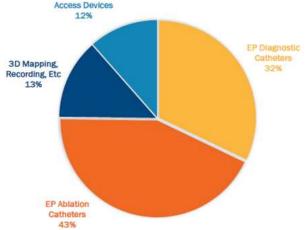
industry events include EPLive 2020 (which might be postponed due to COVID-19 infection) on April 2-3, Heart Rhythm Society meeting on May 6-8, and VT Symposium on Oct. 9-10.

The immediate goal of BSGM's marketing efforts is to start placing more PURE EP systems in more hospitals so surgeons would have a chance to experience the potential benefit firsthand. After a varying time of "try-outs", BSMG would discuss a potential transaction for generating revenue with hospital management. Coupled with factors like capital equipment purchasing cycle and the financial status of different institutions, we believe BSGM would likely to generate revenues starting 2H20. BSGM recently guided that they expect to place PURE EP system in four centers (St. David's Medical Center in Austin, TX., Mayo Clinic, UPenn, and Mass General) by end of 1Q20 and potentially more than nine by mid-2020, possibly reaching 20 by the end of 2020 or early 2021.

As for the types of product revenue from the PURE EP system, BSGM has suggested certain flexibility for the transaction. The product could be sold, leased or rented followed by sales. As such, the range of pricing could be between \$150k and \$200k. In addition, there would be an annual service agreement, which we estimate around \$35,000. Near-term revenue breakdown might be difficult to predict since it remains at a very early stage for revenue generation.

**PURE PE system belongs to an important, albeit smaller portion of the overall catheter ablation device market.** The 2018 catheter ablation device (or more broadly, the electrophysiology device) market, based on market research firm BCC Research analysis as well as several other analyses we have examined, is about \$4.1 billion (Figure 6). Within this market, EP ablation catheter subsector accounts for a majority of 43%, while the 3D mapping, recording and others subsector, where the PURE PE system is categorized accounts for 13% or ~\$550MM.





Source: Company presentation derived from BCC Research (2018, November).

Although the 3D mapping and recording subsector is smaller than treatment or diagnostic catheter subsectors, it is a subsector with many fewer innovations

...these marketed EP recording systems might not necessarily be considered competitors since EP recording systems could be a supplement to be added to the current EP catheter ablation suite as a functionality enhancer.

Four large MedTech companies dominate EP market share: Johnson & Johnson, Abbott Laboratories, Medtronic, and Boston Scientific. The first three account for ~40%, 30% and 20% of the total market share, respectively compared to other subsectors. As such, the PURE PE system could have a rather unique opportunity to be one of the leaders in this arena.

There are other EP recording systems in the marketplace, mainly from the large companies. They are CardioLab Recording System family by GE Healthcare, LabSystem PRO EP Recording System by Boston Scientific, EP-WorkMate Recording System by Abbott Laboratories, and Axiom Sensis XP by Siemens AG. Among them, CardioLab Recording system accounts for the majority of market share. GE Healthcare, Abbott Laboratories and Boston Scientific are major players in this market. Given the added benefits of PURE PE system, these marketed EP recording systems might not necessarily be considered competitors since EP recording systems could be a supplement to be added to the current EP catheter ablation suite as a functionality enhancer.

**Competitors.** There are two potential competitors, both privately-owned companies from Europe. One is CathVision ApS and the second is EPMap-System, GmbH. Denmark-based CathVision developed CathVision Cube, a lownoise signal processing EP recording system that could help better guide ablation therapy through improved EP signal quality. Germany-based EPMap-System, GmbH is developing a suite of technologies focused on EP procedures, including a 3D mapping and navigation system with an integrated signal recording and pacing system, a radiofrequency ablation generator, and an irrigation pump. The EP Map system received a CE Mark in 2016 and is available commercially in Europe. Although there is rather limited information regarding the two companies and their products availability, we believe neither one is close to being a meaningful competitor to BSGM and the PURE PE system. One is still in an early development stage and the other is with limited visibility. By contrast, the PURE PE system is approved in the U.S. with strong backing by multiple KOLs and is in an active marketing and sales stage. Together, we view PURE PE system as the only unique product in the arrhythmias management space in atrial fibrillation and ventricular tachycardia.

**EP market.** The overall electrophysiology device market is expected to grow at a rate of low-teens going forward. Four large MedTech companies dominate EP market share: Johnson & Johnson (Biosense Webster), Abbott Laboratories (after acquisition of St. Jude Medical in 1Q17), Medtronic, and Boston Scientific. The first three account for approximately 40%, 30% and 20% of the total market share, respectively. Their actual market shares have changed slightly over the last few years. All of them provide a comprehensive range of products in cardiac arrhythmias management, including diagnostic and treatment catheters, navigation systems and others. Other major companies also participate in this market include Koninklijke Philips NV and Siemens AG.

Overall, the EP devices market is very competitive and a highly concentrated one, which can be illustrated by the duopoly of top players and high degree of M&A and consolidation activities. Large players constantly contemplate acquiring novel and innovative technology and products to improve and expand their product portfolios, as well as an opportunity to be a first entrant to a niche market

BEM is trying to diagnose and treat disease via manipulate the signal from the neuronal system, either CNS or PNS.

It is important that ~50% of patients with the complex atrial fibrillation and ventricular tachycardia have to return for repeat ablation treatments.

PURE EP system is characterized with a scarcity factor of novel EP products especially in the signal recording and processing subsector. segment. To that end, we believe BSGM could also potentially be on the radar screen of some major EP device players.

Bioelectronic medicine could be the next frontier and BSGM could contribute for resolving some key issues. Given that BSGM's core technology is in providing more optimal signals with greater fidelity, this potential utility could be expanded beyond arrhythmias management into other disease areas. This is in an emerging treatment arena called bioelectronic medicine (BEM). Simply put, BEM tries to diagnose and treat disease via manipulation of the signal from the neuronal system, either CNS or PNS. The basic premise is that in many disorders, dysfunctional neural circuits give rise to dysfunctional organs. As such, the objective of bioelectronic medicine is trying to restore healthy patterns of electrical impulses by changing the concentrations of neurotransmitters traveling through those circuits. One of the key issues that needs to be resolved before BEM becomes a more broadly applicable treatment modality is to clearly decipher the therapeutic- or diagnostic-relevant signals from the background noise enabling the treatment to be effective. To that end, we believe BSGM's core technology could be an important piece in BEM development.

Our take: We believe the PURE EP system is a leading, first-to-market innovative signal processing system that could address one of the major shortcomings in executing catheter ablation in complex arrhythmias like atrial fibrillation and ventricular tachycardia. Given the benefits and improvements demonstrated from multiple preclinical analyses and positive feedback from electrophysiologists and surgeons, such as from the recent AFIB Symposium this January; we anticipate the initial stage of commercialization could be very successful. The ongoing and upcoming clinical studies could further expand the buy-in by physicians as well as hospital decision makers. It is important to know that approximately 50% of patients with the complex AFib and VT have to return for repeat ablation treatments, and the use of the PURE EP system could potentially improve the efficacy of this procedure. The potential of shortening procedure time and affording better clinical performance of the catheter ablation procedure would be important tangible benefits. One of the likely consequences of greater efficiency would be the increased number of procedures carried out by surgeons - a welcome outcome by management for expanding hospital's top- and bottomline. Together, these factors might provide a pull from some users. In addition, we are encouraged that BSGM has a very seasoned commercial team as several of them came from EP powerhouses, like Johnson & Johnson. They are very familiar with selling products in the EP space given their prior experience and relationships with EP units of many hospitals.

As the company is on the cusp of generating revenue at their initial product selling stage and based on the current valuation of BSGM shares, we believe it is a great buying opportunity for investors to own BSGM shares. Given that the risks of product development are in the rear-view mirror now, we view BSGM is a story mainly only bearing commercial risks. There are several factors that could further mitigate risks of BSGM shares, which include: 1) scarcity factor of novel EP products especially in the signal recording and processing subsector; 2) the

Once the infection dies down

(hopefully), we anticipate the

might have some experience

in using PURE EP system and

some could potentially make

transactions (purchase, lease

or rent followed by own) later.

EP units of many hospitals

PURE EP system practically is the first-to-market product; 3) like-minded competitors are still in early product development stage and/or potentially poorly funded; and 4) due to the concentrated nature of the EP device sector and frequent M&A activities, BSGM could be an acquisition prospect given its unique and effective technology platform.

Comments on potential COVID-19 infection impact might have on PURE EP system advancement. Although we do not have any crystal ball regarding the duration and the scope of this infection, it is important for us to speculate on the possible impact the current COVID-19 pandemic infection might have on the near-term development of the PURE EP system. Although some of the medical conferences, such as EPLive 2020, might have been postponed, we believe the rich leads generated from the AFIB Symposium early this year could provide sufficient opportunities to be harvested later in 2020 and beyond by BSGM. In addition, potential turmoil of hospitalizing and treating COVID-19 infected patients might attract the majority of attention of many hospitals possibly into mid-year or even 3Q20. Once the infection dies down (hopefully), we anticipate the EP units of many hospitals might have some experience in using the PURE EP system and some could potentially make transactions (purchase, lease or rent followed by own) later.

# Surgical treatment of the two indications that the PURE EP system could make an immediate positive impact

The two most relevant indications associated with catheter ablation that the PURE EP system could provide improvements are atrial fibrillation and ventricular tachycardia.

**Atrial Fibrillation (AFib).** This is a condition that atria (the upper chambers of the heart) would beat chaotically and irregularly (quiver) and out of sync with that of ventricles (the lower chambers of the heart) due to chaotic electrical signals. Without proper treatment, AFib could potentially lead to heart failure, stroke (due to break off of clots formed in atrium) and heart-related deaths.

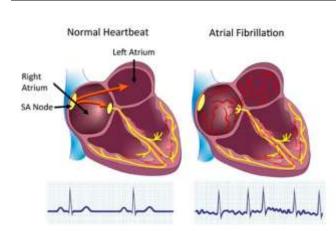


Figure 6: Normal heartbeat and atrial fibrillation (AFib)

Source: Company presentation

In the U.S., nearly 750,000 AFib patients each year were hospitalized with estimated 130,000 deaths. Annual incidences of AFib is about 160,000.

In a healthy heart, heart rhythm is controlled by electrical signal send from sinoatrial (SA) node, then pass through the atrium, atrioventricular (AV) node and into ventricles to contract and pump the blood out. SA node is located on the top of the right atrium. In patients with AFib, the signal sent by the SA node is to multiple locations (especially pulmonary veins in the left atrium) and create an abnormal impulse in the atrium, resulting in chaotically beating in the atrium and much faster beating in ventricles (400 to 600 beats/min) due to the impaired control of the AV node (Figure 6).

AFib is the most common arrhythmia of clinical significance. AFib affects 2.7MM to 6.1MM individuals in the U.S. and 33.5MM globally. In the U.S., nearly 750,000 AFib patients each year were hospitalized with estimated 130,000 deaths. Annual incidences of AFib are about 160,000. Based on the duration of AFib symptoms, AFib could be categorized into several classes: paroxysmal AF, persistent AF, long-standing persistent AF, permanent AF and novalvular AF (Figure 7). Paroxysmal, persistent and permanent each account for approximately one-third of total AF.

Figure 7: Classification of atrial fibrillation

Term	Definition
Paroxysmal AF	AF that terminates spontaneously or with intervention within 7 d of onset.     Episodes may recur with variable frequency.
Persistent AF	<ul> <li>Continuous AF that is sustained &gt;7 d.</li> </ul>
Long-standing persistent AF	<ul> <li>Continuous AF &gt;12 mo in duration.</li> </ul>
Permanent AF	<ul> <li>The term "permanent AF" is used when the patient and clinician make a joint decision to stop further attempts to restore and/or maintain sinus rhythm.</li> <li>Acceptance of AF represents a therapeutic attitude on the part of the patient and clinician rather than an inherent pathophysiological attribute of AF.</li> <li>Acceptance of AF may change as symptoms, efficacy of therapeutic interventions, and patient and clinician preferences evolve.</li> </ul>
Nonvalvular AF	<ul> <li>AF in the absence of rheumatic mitral stenosis, a mechanical or bioprosthetic heart valve, or mitral valve repair.</li> </ul>

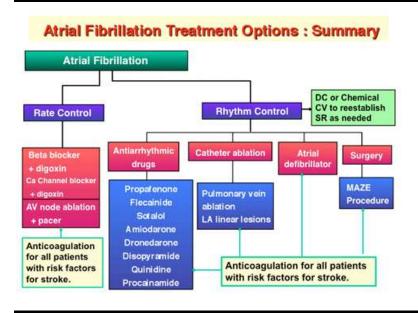
Source: 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation

**Treatment of AFib.** Based on the treatment objective, AFib patients can be treated by medication, catheter ablation, cardioversion, or other methods. Figure 8 illustrates a summary of AFib treatment options based on a presentation from the National Association of Managed Care Physicians.

The process for providing adequate and appropriate ventricular rate that reduces symptoms and enables exercise is called **rate control**. In order to achieve that, a number of medications, such as beta blockers or calcium channel blockers plus digoxin can be used. For acute restoration and maintenance of sinus rhythm (**rhythm control**), patient can be treated with certain antiarrhythmic drugs, such as amiodarone, performing catheter ablation, atrial defibrillator, or surgery. The antiarrhythmic drugs generally are less effective (65%-70% efficacy in one year) and most patients would become refractory and later require different treatment

modalities, commonly with catheter ablation. In symptomatic AFib patients, rhythm control is an important treatment modality for improving their wellbeing. For most AFib patients, preventing stroke due to blood clot formed in left atrium resulting from the accumulation of excess blood which supposed flow into ventricles is important. To achieve that, an **antithrombotic therapy** would be implemented. Although Warfarin or clopidogrel have been used for a long time, several recently developed next generation oral anti-coagulants, such as Eliquis and Xarelto, are being used more commonly nowadays.

Figure 8: AFib treatment summary



Source: National Association of Managed Care Physician

The left atrial appendage (LAA) is a tubular shaped cardiac cavity attached to the left atrium. Given that the LAA is the primary source for thromboembolism in AF patients, exclusion of the LAA, surgically or with devices, is being practiced with the goal of reducing thromboembolism as part of overall AFib management. Two devices have been frequently used: WATCHMAN device by Boston Scientific and Amplatzer cardiac plug sold by Abbott, which initially developed by St. Jude Medical.

Catheter ablation. This is a minimally invasive medical procedure using several flexible catheters insert into either femoral, internal jugular or subclavian vein and advance into the heart to deliver either heat-based (radiofrequency or RF at 50°C–60°C) or tissue-freezing (cryoablation) to destroy the abnormal tissue that caused arrhythmia signal. Catheter ablation is more successful in regular arrhythmias, but less in complex arrhythmias like AFib and ventricular tachycardia (VT). It is estimated that there were 973,000+ catheter ablation procedures done in 2017 and the figure could reach 1.4 million by 2022. Among them, nearly 45% are treating more complex arrhythmias.

The main objectives of catheter ablation procedure in treating AFib are to precisely identify, ablate and eliminate pulmonary vein potentials with the

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technique called pulmonary vein isolation (PVI). The objectives of catheter ablation procedure in treating VT are to map the arrhythmia substrate and precisely identify and ablate the small abnormal potentials. Although catheter ablation is generally effective, it is not considered as a cure for AFib or VT.

Ventricular Tachycardia (VT) This is another type of cardiac arrhythmia but with significantly greater risks. VT is defined as a fast and abnormal heart rate (three or more in a row at a rate greater than 100 beats/min) of the ventricles. This is triggered by electrical conduction signal from the SA node being disorganized, overriding the heart's normal rate and rhythm (Figure 9). The sites that cause the abnormal signals could come from 1) scarring of the heart muscle (monomorphic ventricular tachycardia) which came from previous myocardial infarction; or 2) abnormalities of ventricular muscle repolarization (polymorphic ventricular tachycardia).

Normal Heartbeat

Left Ventricle

SA Node

Right Ventricle

White is a second of the s

Figure 9: Ventricular tachycardia (VT)

Source: Company presentation

VT may result in ventricular fibrillation (VF) and frequently turn into sudden cardiac death. VF is a condition of rapid chaotic heartbeat in the ventricles when the fibrillating muscle would quiver instead of contracting and pumping blood to other organs. VF is the leading cause of sudden cardiac death with  $\sim 325,000$  deaths each year in the U.S. Five to 10 percent of patients presented with acute myocardial infarction (AMI) have VF or VT in the U.S.

**Treatment of VT.** Several therapy options are available for treating VT, which include cardioversion, implantable cardioverter defibrillators (ICDs), medication (such as procainamide or sotalol), or a combination of ablation and an ICD. It is also noted that catheter ablation in VT success rate is determined by the amount of infarct-related scar burden, represented as low-voltage signals; and the experience of the team and center carrying out the procedure.

**PURE EP system in catheter ablation revenue model.** Our model (Figure 10a and b) projects that the PURE EP system could potentially start to generate

revenue in 2H20 in the U.S. We also assume the EU approval and subsequent commercialization could take place in 2022.

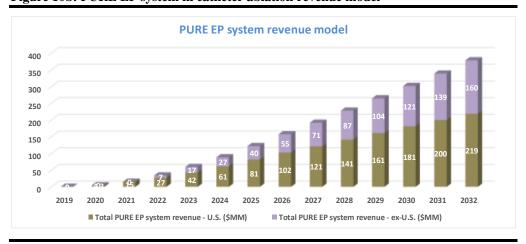
We conservatively priced the PURE EP system at \$160,000, on par with other recording systems sold in the U.S. even though the PURE EP system has unique attributes that other systems do not provide. We also model the annual service fee of \$35,000, which would be a recurrent revenue to BSGM. Together, we estimate the annual sales of the PURE EP system could exceed \$100MM by 2025 and \$200MM by 2028. In addition, the value of potential sales from ROW outsides of the U.S. and EU have not been incorporated into our model.

Figure 10a: PURE EP system in catheter ablation revenue model

PURE EP system revenue mo	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Electrophysiology rooms -U. S.	3,425	3,425	3,476	3,529	3,581	3,635	3,690	3,745	3,801	3,858	3,916	3,975	4,034	4,09
PURE EP system penetration	0.0%	0.7%	2.1%	3.4%	4.9%	6.5%	8.0%	9.2%	9.8%	10.4%	10.8%	11.1%	11.2%	11.19
# of PURE EP system sold	0	22	73	119	175	236	294	344	373	401	422	441	450	45
Price of PURE EP system (\$)	160,000	160,000	160,800	161,604	162,412	163,224	164,040	164,860	165,685	166,513	167,346	168,182	169,023	169,86
Total revenue of PURE EP system sold (\$ MM)	0.00	3.56	11.74	19.27	28.50	38.57	48.30	56.74	61.72	66.81	70.65	74.20	76.03	77.4
Accumulated PURE EP system sold	0	22	95	215	390	626	921	1,265	1,637	2,039	2,461	2,902	3,352	3,80
% use PURE EP system (%)	0.0%	0.7%	2.7%	6.1%	10.9%	17.2%	25.0%	33.8%	43.1%	52.8%	62.8%	73.0%	83.1%	93.0%
Annual maintenance fee (\$)	35,000	35,000	35,175	35,351	35,528	35,705	35,884	36,063	36,244	36,425	36,607	36,790	36,974	37,15
Total annual maintenance fee (\$ MM)	0.00	0.78	3.35	7.58	13.86	22.36	33.04	45.62	59.35	74.26	90.08	106.77	123.93	141.4
Total PURE EP system revenue - U.S. (\$MM)	0	4.3	15	27	42	61	81	102	121	141	161	181	200	21
Electrophysiology rooms - ex-U. S.	3,915	3,915	3,962	4,010	4,058	4,106	4,156	4,205	4,256	4,307	4,359	4,411	4,464	4,51
PURE EP system penetration			0.0%	0.9%	2.0%	2.9%	4.0%	5.0%	5.9%	6.7%	7.4%	7.9%	8.4%	9.09
# of PURE EP system sold			0	36	81	120	166	210	251	289	322	347	374	40
Price of PURE EP system (\$)	156,800	156,800	157,584	158,372	159,164	159,960	160,759	161,563	162,371	163,183	163,999	164,819	165,643	166,47
Total revenue of PURE EP system sold (\$ MM)			0.00	5.71	12.92	19.25	26.72	33.97	40.77	47.09	52.83	57.14	61.89	67.8
Accumulated PURE EP system sold	0	0	0	36	117	238	404	614	865	1,154	1,476	1,823	2,196	2,60
% use PURE EP system (%)			0.0%	0.9%	2.9%	5.8%	9.7%	14.6%	20.3%	26.8%	33.9%	41.3%	49.2%	57.6%
Annual maintenance fee (\$)		33,250	33,416	33,583	33,751	33,920	34,090	34,260	34,431	34,604	34,777	34,950	35,125	35,30
Total annual maintenance fee (\$ MM)			0.00	1.21	3.96	8.06	13.76	21.04	29.79	39.92	51.32	63.70	77.14	91.9
Total PURE EP system revenue - ex-U.S. (\$MM)	0	0	0	7	17	27	40	55	71	87	104	121	139	16
Total PURE EP system revenue - Global (\$MM)	0	4	15	34	59	88	122	157	192	228	265	302	339	37
Total PURE EP system revenue -product (\$MM)	0.0	3.6	11.7	25.0	41.4	57.8	75.0	90.7	102.5	113.9	123.5	131.3	137.9	145.
Total PURE EP system revenue -service (\$MM)	0.00	0.78	3.35	8.80	17.81	30.42	46.80	66.65	89.13	114.18	141.41	170.46	201.07	233.4

Source: Laidlaw & Company estimates

Figure 10b: PURE EP system in catheter ablation revenue model



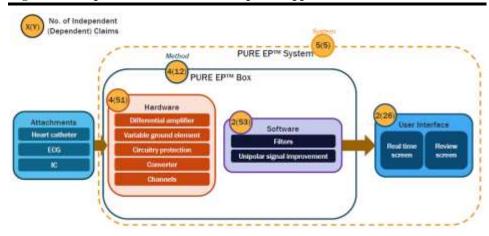
Source: Laidlaw & Company estimates

## Robust IP position

BSGM has a robust IP portfolio that covers most of their core technology in both hardware and software. BSGM filed two "omnibus" hardware and software patent applications in 2Q18 and 2Q19, respectively. The first one includes multiple

claim sets, and several multiple feature-set graphical user interface (GUI) design patents. It covers the core hardware and software technology associated with the PURE EP system, in which technology includes a cardiac signal system that reads cardiac signals and filters such cardiac signals from noise such as non-cardiac signals or other body-generated artifacts. The second one captured innovation in software with Dr. Samuel J. Asirvatham of Mayo Clinic. Figure 11 highlights the features of the first omnibus patent application.

Figure 11: Snap shot of the first omnibus patent application

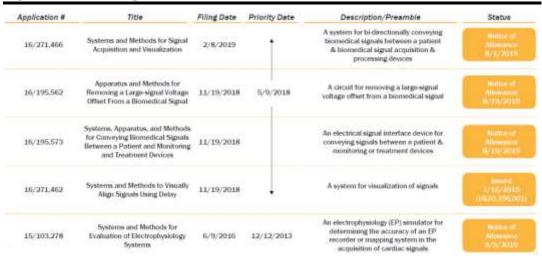


The expiration of BSGM's major patents would not occur until the 2040s.

Source: Company presentation

BSGM's patent portfolio includes five allowed/issued patents. Thirteen pending worldwide utility patent covering various aspects of the PURE EP system for recording, measuring, calculating and displaying of electrocardiograms during cardiac ablation procedures. BSGM also has 21 allowed/issued worldwide design patents, which cover various features of its display screens and graphical user interface for enhanced visualization of biomedical signals. The expiration of BSGM's major patents would not occur until the 2040s.

Figure 12: Five issued patents



Source: Company presentation

# NeuroClear Subsidiary Could Expand BSGM Footprint into Emerging Bioelectronic Medicine

# NeuroClear subsidiary leverages BSGM's signal processing expertise

In 4Q18, BSGM formed a subsidiary called NeuroClear Technologies to pursue additional applications of the PURE EP signal processing technology outside of the field of EP. BSGM is the majority owner of NeuroClear with ~88% of its outstanding common stock.

By recording and analyzing action potentials of the impulses along the membrane of a muscle cell or a nerve cell, NeuroClear's current focus is to develop highspeed electroneurogram (ENG) recordings to address the unmet medical needs in neurological disorders. The major value proposition of NeuroClear is achieving accurate and targeted stimulation of specific nerves in a nerve bundle and implementing an effective feedback loop that can self-adjust for the optimal amount and timing of stimulation – an overall similar aim as the PURE EP system in EP. It is known that the ENGs consist of small, high frequency, low amplitude signals, and they are hard to detect with conventional signal recording systems.

ENG is to visualize the recorded neuronal electrical activities of CNS (brain, spinal cord) or PNS (nerves, ganglions). These impulses and potential manipulation of them could have clinical utility, both in treatment and in diagnosis.

The near-term objectives of NeuroClear are focusing on two areas: non-invasive vagus nerve stimulation (nVNS) and deep brain stimulation (DBS).

Vagus nerve stimulation (VNS) uses a medical device delivering electrical impulses to the vagus nerve, and such a device has been approved by the FDA (such as VNS Therapy System by LivaNova) as an add-on treatment for certain types of intractable epilepsy and treatment-resistant depression in patients over 12 years of age. Other players in the VNS space include Medtronic and Boston Scientific. The vagus nerve provides an extensive innervation in the viscera and plays a key role as an interface between higher CNS circuits and the autonomic control circuitry of the brain stem (Figure 13).

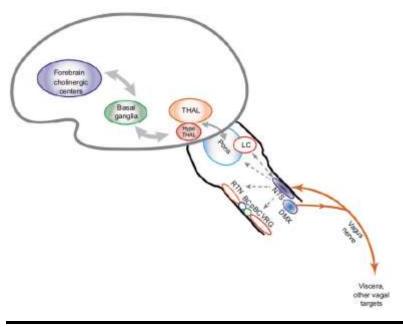
NeuroClear believes that the ENG as part of nVNS could have potential in treating cognitive disorders, AFib, and chronic pain. In addition, as a digital wearable nVNS device, it has potential to target a range of diseases such as epilepsy, chronic refractory depression, migraine, and obesity. NeuroClear views the major differentiation of nVNS vs. other products is nVNS might implement a feedback

The major value proposition of NeuroClear is achieving accurate and targeted stimulation of specific nerves in a nerve bundle and implementing an effective feedback loop that can self-adjust for the optimal amount and timing of stimulation.

Vagus nerve stimulation is an add-on treatment for certain types of intractable epilepsy and treatment-resistant depression in patients over 12 years of age.

loop through a biomedical signal-processing unit, which would self-adjust to provide an appropriate amount of stimulation. NeuroClear plans to develop products in the digital health wearable market and also explore licensing opportunities with consumer electronics market players.

Figure 13: Putative pathways involved in vagus nerve stimulation



Source: Johnson, R. L., et. al., 2018, J Inflammation Res 11: 203-213

Deep brain stimulation (DBS) is by implanting electrodes (leads) within certain areas of the brain to deliver electrical pulses. DBS could provide therapeutic benefits in patients suffering from movement disorders, such as Parkinson's disease, tremors, and dystonia. NeuroClear anticipates ENG can be a new high-speed board-based platform for improving accuracy in lead implantation – an important attribute in the prediction of the activation of axons surrounding the implanted lead. Neurological and psychiatric disorders resulting from dysfunctional neuronal circuitry could be improved by DBS. Other indications that also could be explored include ADHD, eating disorders, Alzheimer's, addiction, epilepsy, dementia, and pain management. Overall, the therapeutic concept of DBS is very similar to that of the heart pacemaker.

DBS market is one of the rapid growing sectors in the neurostimulation market worldwide with annual growth rate of 10.7%. The global market is estimated of ~\$700MM in 2018. According to data from the American Association of Neurological Surgeons (AANS), there are more than 35,000 DBS implants worldwide. Major players include Medtronic, Abbott, and Boston Scientific. In China, Beijing PINS Medical (品独医疗) is a key player. One of the major research areas in improving the current product is improving electrodes to avoid stimulation of adjacent structures (electric field shaping) which are the root cause of unwanted side effects of DBS. Major product offerings in this space include Activa systems by Medtronic, Infinity DBS IPG and Brio Rechargeable IPG by Abbott and Neural Navigator systems by Boston Scientific.

NeuroClear plans to develop products in the digital health wearable market and also explores licensing opportunities with consumer electronics market players.

The global DBS market is estimated of ~\$700MM in 2018 and there are more than 35,000 DBS implants worldwide.

# Financial Projections and Valuation

BSGM currently has ~\$20MM (proforma) cash, including a recently closed offering in Feb. 2020 of 2.5MM shares of common stock at price of \$4.00 per share, resulting in net proceeds of \$9.2MM. As such, we anticipate the company should have sufficient resources to advance their marketing and sales effects to generate sales from the PURE EP system. Laidlaw & Company (UK) Ltd. acted as sole book-running manager for the offering.

Our forward P/E analysis suggests a one-year target value for BSGM of \$13.08 based on 2028 earnings of \$3.11, multiple of 11 and discounted rate of 15%.

Forward P/E analysis

Year earnings based	2028
Earnings	\$3.11
Target Year	2021
Discount period (year)	6.75
Fair value	\$13
Current price	\$2.73
Upsides	382%

			Forw	ard P/E mu	ltiples	
		7	9	11	13	15
	9%	11.98	15.37	18.76	22.15	25.54
(%)	11%	10.60	13.60	16.60	19.60	22.60
ate (	13%	9.40	12.06	14.72	17.38	20.05
i i	15%	8.35	10.72	13.08	15.45	17.81
Discount rate (%)	17%	7.44	9.54	11.65	13.76	15.86
Dis	19%	6.64	8.52	10.39	12.27	14.15
	21%	5.93	7.61	9.29	10.97	12.65

Source: Laidlaw & Company estimates

Given BSGM is a rather unique publicly traded company as a pure play in the EP recording and signal processing space, it might not be fair or practical to use peer comparables to assess its valuation. In addition, given the heavy M&A activities in this space, comparing the current valuation of BSGM with valuations of recently closed M&A transactions in overall similar development would be appropriate. Based on the recent M&A transactions, we believe a fair value of BSGM is ~\$336MM. If we calculate it based on per share base, it would be \$12.85 based on share counts at the end of 2020.

Recent EP space M&A activities compared to current BSGM valuation

Acauiree	Acquirer	Ticker	Proof of Concept	Prototype	Clinical Data	CE Mark	FDA	Sales	Time of transaction	Valuation
EPD Solutions	Koninklijke Philips N.V.	PHG	+	+	+	+		+	06/2018	\$563
nContact	AtriCure	ATRC	+	+	+	+			10/2015	\$149
Cardiolnsight	Medtronic	MDT	+	+	+	+	+	+	06/2015	\$272
Topera Medical	Abbott	ABT	+	+	+	+	+		12/2014	\$350
Endosense SA	St. Jude Medical	STJ	+	+	+	+		+	08/2013	\$331
Bard EP	Boston Scientific	BSX	+	+	+	+	+	+	11/2013	\$275
Rhythmia Medical	Boston Scientific	BSX	+	+	+				10/2012	\$410
									Average =	\$336
BioSig	ı	BSGM	+	+	+		+		Market cap =	\$80

Source: Laidlaw & Company estimates

Together, we assigned our blended 12-month target price for BSGM at \$13. We view our potential valuation of ~\$340MM of BSGM shares a year from now reasonable. At that time BioSig should have achieved some success with revenue from PURE EP system sales, with potentially more robust buy-in from electrophysiologists and hospitals, leading to more aggressive sales growth underway. In addition, we anticipate most of the uncertainty driven by th COVID-19 infection should be much clarified.

# Major Risks

Commercial risks remain difficult to handicap. Although BSGM has started to commercialize the PURE EP system in the U.S., with a promising start, it remains too early to have absolute confidence that product sales could go very smoothly and without significant challenges. Although electrophysiologists user experiences are very positive, the transaction decision is still in a hospital administrator's hand. Budget constraints and the budgeting cycle could potentially limit the pace or whether or not a purchase or lease is carried out. As such, the revenue projection could change materially. Macro factors, such as the U.S. economy and third-party payer attitude toward certain medical procedures could also impact on the revenue outlook of PURE EP system sales. A material change of the PURE EP system sales projection could have substantial impact on BSGM share value.

Competition might not be easy to gauge. Although the PURE EP system is the current leader in signal processing for providing optimal visualized signals to electrophysiologists carrying out catheter ablation, competition might still take place, even if not coming from the two weak European companies mentioned on the report. Major EP players with a suite of product offerings in this space could also try to develop a like-minded or even further improved product that might circumvent the IP protection of the PURE EP system and achieve a similar outcome as the PURE EP system. If so, the commercial outlook as well as BSGM share value could be challenged. Such a competing product could be used inhouse for the developer as part of improved product offering. The company also could sell such product to other companies and create a direct competition for BSGM. If so, this could have substantial impact on BSGM share value.

Additional financings could dilute shareholder value. The company currently has ~ cash ~\$20MM (proforma). BSGM would likely need more financial resources going forward if they have not yet reached cash breakeven or profitability. Unless the company can successfully explore non-dilutive financial sources, additional equity offerings might reduce the value to current shareholders unless the share price increases of any upside created due to greater financial source could offset the dilution of current shareholders.

**COVID-19 pandemic infection could be a wildcard creating significant uncertainties.** As the COVID-19 pandemic infection is just in its early phase in the U.S. and many parts of the world, it is very difficult to gauge its impact on many aspects of the business and personal life. As such, the validity of many projection could be weakened until much greater visibility of the duration and the specific impact on various business sectors by the COVID-19 pandemic infection becomes available.

## Management

**Kenneth L. Londoner – CEO.** Mr. Londoner founded and has served as President and CEO of BioSig Technologies since 2009. Prior to joining BSGM, Mr. Londoner co-founded and served as executive VP of NewCardio from 2007 until 2009. Prior, he co-founded Safe Ports Holdings from 2005 to 2009. Prior, he founded Endicott Management Partners, LLC. Prior, Mr. Londoner founded and managed Red Coat Capital Management from 1996. Prior, he served as Portfolio Manager and later Co-Manager of J. & W. Seligman & Co. from 1991 to 1997. Mr. Londoner received an MBA degree from New York University

**Steve Chaussy – CFO.** Mr. Chaussy has served as CFO of BioSig Technologies since 2018 and as part-time CFO since 2011. Prior, he founded and operated Anna & Co since 2005. Prior, Mr. Chaussy provided services as both a chief financial officer and as a consultant to small publicly traded companies from 2001 to 2005. Prior, Mr. Chaussy served as CFO of Liberski from 1994 to 2000. Prior, he served as Administration Controller of Penske Truck Leasing from 1983 to 1994. Mr. Chaussy received a BS degree from Virginia Polytechnic Institute and State University.

John Kowalski – Vice President, Sales. Mr. Kowalski has served as Vice President, Sales of BioSig Technologies since 2019. Prior to joining BSGM, Mr. Kowalski served as Area Director of Sales & Clinical Support from 2009 till 2019, Regional Business Director from 2001 to 2009, and Territory Sales Manager from 1995 till 2001 of Biosense Webster, a Johnson & Johnson company. Prior to joining in JNJ, he served as Sales Specialist of B. Braun Medical from 1988 to 1995. Mr. Kowalski received a BS degree from University of Maine.

Barry Keenan, Ph.D. – Vice President, Engineering. Dr. Keenan has served as Vice President, Engineering of BioSig Technologies since 2019. Prior to joining BSGM, Mr. Keenan served as an independent medical device consultant from 2016 till 2019. Prior, he served as CTO & VP Research and Development of Alfred Mann Foundation from 2014 to 2016. Prior, he served as Research Director & Technical Fellow and other positions of Medtronic from 2005 till 2014. Prior to joining in Medtronic, he served as Chief Engineer of VivoMetrics from 2001 to 2005. Dr. Keenan received a PhD degree from University of Michigan.

# Yale Jen, Ph.D.

**Income Statement** 

('000 \$)	2017	2018					2019					F2020E	2021E	2022E	2023E	2024E	2025
_			1Q19	2Q19	3Q19	4Q19		1Q20E	2Q20E	3Q20E	4Q20E						
Revenues	0									4.070	0.474	4.044	45.000	00.704	F0 000	00.000	404.0
Product revenues	0	0	-	-	-	-	0	-	-	1,870	2,471	4,341	15,090	33,784	59,232	88,233	121,82
PURE EP system revenue	0	0	- ,		-	-	0	-	-	1,870	2,471	4,341	15,090	33,784	59,232	88,233	121,8
Other revenue	0	0	-		-	-	0	-	-	4.070	- 0.474	0	0	0	0	0	0
Total Revenue COGS	0	0	-	-	-	-	0	-	-	1,870 468	2,471 618	4,341 1,085	15,090 3,773	33,784 8,446	59,232 14,808	88,233 22,058	121,82
Research and development	4,756	4,369	1.489	1,818	1.644	4,788	9,739	1,820	1.856	1,930	1,986	7,592	3,773 8.731	9,691	10,466	10.885	11,32
General and administrative	8,138	12,881	4,379	6,161	3,841	10,430	24,811	3,859	4,091	4,303	4,488	16,741	17,411	18,003	18,615	19,248	19,90
Depreciation and amortization	12	12,001	4,379	10	3,041	10,430	54	3,639	20	4,303	4,400	81	83	84	82	88	93
Operaing expense	12,906	17.262	5.876	7.989	5,503	15,236	34.604	5,697	5,967	6.254	6,497	24,414	26.225	27.778	29,163	30.221	31,31
· • ·		, -	-,	,			- ,			-, -			-, -			,	
Operating incomes (losses)	(12,906)	(17,262)	(5,876)	(7,989)	(5,503)	(15,236)	(34,604)	(5,697)	(5,967)	(4,852)	(4,643)	(21,158)	(14,907)	(2,440)	15,261	35,954	60,05
Gain on change in fair value of derivatives	210	44		20	20	0	0	20	20	40	40	457	404	400	470	400	400
Interest income, net	(12,606)	(17.051)	6 (5.970)	(7.050)	39 (E 464)	48	133	38 (F 650)	39 (5.038)	40	40	157	161	169	178 15.438	186 36.141	196 60.25
Income (loss) before taxes Income tax expense	(12,696)	(17,251)	(5,870)	(7,950)	(5,464)	(15,188)	(34,471)	(5,659)	(5,928)	(4,812)	(4,603)	(21,001)	(14,746)	(2,271)	15,438 (3,860)	36,141 (9,035)	(15,06
•	(12,696)	(17,251)	(5.070)	(7,950)	(5,464)	(45 400)	(24.474)	(5,659)	(5,928)	(4,812)	(4.000)	(04.004)	(44.740)	(0.074)		(9,035) 27,106	
Net income	(12,696)	(17,251)	(5,870)	(7,950)	(5,464)	(15,188)	(34,471)	(5,659)	(5,928)	(4,812)	(4,603)	(21,001)	(14,746)	(2,271)	11,579	27,106	45,187
	4.55	()		(-)			()	4-1			(-)		()	(==)	()	(==)	()
Preferred stock dividend	(120)	(885)	(11)	(5)	(5)	(5)	(25)	(6)	(7)	(8)	(8)	(29)	(29)	(29)	(29)	(29)	(29)
Non-controlling interest					21	395	416	20	21	22	21	84	84	84	84	84	84
Net income attributable to common shareholders	(\$12,816)	(\$18,136)	(\$5,880)	(\$7,954)	(\$5,448)	(\$14,798)	(\$34,080)	(\$5,645)	(\$5,914)	(\$4,798)	(\$4,590)	(\$20,946)	(\$14,691)	(\$2,216)	\$11,634	\$27,161	\$45,24
Net Earnings (Losses) Per Share—Basic/Diluted	(\$1.24)	(\$1.25)	(\$0.33)	(\$0.38)	(\$0.25)	(\$0.68)	(\$1.67)	(\$0.23)	(\$0.23)	(\$0.19)	(\$0.18)	(\$0.82)	(\$0.50)	(\$0.08)	\$0.38	\$0.87	\$1.43
Shares outstanding—basic/diluted	10,220	14,504	17,848	20,671	21,810	22,449	20,695	24,949	25,349	25,749	26,149	25,549	29,549	30,049	30,549	31,049	31,549
Margin Analysis (% of Sales/Revenue)																	
COGS										25%	25%	25%	25%	25%	25%	25%	25%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	103%	80%	175%	58%	29%	18%	12%	9%
G&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	230%	182%	386%	115%	53%	31%	22%	16%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-259%	-188%	-487%	-99%	-7%	26%	41%	49%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	-257%	-186%	-484%	-98%	-7%	26%	41%	49%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	25%	25%	25%	25%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-257%	-186%	-483%	-97%	-7%	20%	31%	37%
Financial Indicator Growth Analysis (YoY%)																	
Total Revenue		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	248%	124%	75%	49%	38%
R&D expenses		-8%	73%	25%	121%	265%	123%	22%	2%	17%	-59%	-22%	15%	11%	8%	4%	4%
General and administrative		58%	147%	43%	60%	138%	93%	-12%	-34%	12%	-57%	-33%	4%	3%	3%	3%	3%
Sales and marketing																7%	6%
Operaing expense		34%	123%	39%	75%	167%	100%	-3%	-25%	14%	-57%	-29%	7%	6%	5%	4%	4%
Operating Incomes (Losses)		34%	123%	39%	75%	167%	100%	-3%	-25%	-12%	-70%	-39%	-30%	-84%	-725%	136%	67%
Pretax Income		36%	123%	38%	73%	167%	100%	-4%	-25%	-12%	-70%	-39%	-30%	-85%	-780%	134%	67%
Net Income		36%	123%	38%	73%	167%	100%	-4%	-25%	-12%	-70%	-39%	-30%	-85%	-610%	134%	67%
EPS - Basic		1%	34%	-12%	16%	95%	33%	-31%	-39%	-25%	-74%	-51%	-39%	-85%	-602%	130%	64%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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Company Est. 1842	

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(000 \$)														
(	2016	2017	2018	1Q19	2Q19	3Q19	4Q19	2019	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E
Assets														
Cash and cash equivalents	1,056	1,548	4,450	10,934	10,334	12,309	12,109	12,109	17,656	15,235	13,292	11,048	11,048	15,469
Cash and cash equivalents	1,056	1,548	4,450	10,934	10,334	12,309	12,109	12,109	17,656	15,235	13,292	11,048	11,048	15,469
Inventory							578	578	580	590	595	608	608	972
Prepaid expenses	134	117	78	157	306	143	141	141	145	148	143	144	144	155
Vendor deposits	0	0	100	0	0	430	0	0	0	0	0	0	0	(
Total Current Assets	1,190	1,665	4,629	11,090	10,640	12,883	12,827	12,827	18,381	15,973	14,030	11,800	11,800	16,596
Property and equipment, net	24	19	44	54	78	102	180	180	140	161	100	107	107	116
Right-to-use assets, net	0	0	0	381	814	732	714	714	231	183	111	140	140	139
Patents, net	0	0	269	324	374	369	365	365	221	169	160	131	131	127
Trademarks	0	0	1	1	1	1	1	1	1	1	1	1	1	1
Prepaid expenses, long term	0	0	0	0	0	32	27	27	15	27	26	29	29	30
Deposits	28	17	54	54	155	102	102	102	102	102	102	102	102	102
Total Assets	1,242	1,700	4,997	11,904	12,062	14,221	14,217	14,217	19,091	16,616	14,530	12,310	12,310	17,110
Liabilities and Stockholders' Equity														
Accounts payable	373	473	955	597	943	724	1.489	1.489	929	907	961	969	969	1,018
Dividends payable	360	448	243	253	119	124	128	128		126	129	122	122	132
Warrant liability	1,937	2,358	0	0	0	0	0	0	0	0	0	0	0	0
Derivative liability	289	686	0	0	0	0	0	0	0	0	0	0	0	0
Lease liability, short term	0	0	0	159	352	365	412	412	379	366	375	276	276	349
Total Current Liabilities	2,959	3,965	1,198	1,009	1.414	1,213	2,030	2,030	1,436	1.400	1.465	1.367	1,367	1,499
Lease liability, long term	0	0	0	227	468	375	311	311	362	376	358	455	455	378
Total long-term Liabilities	o	0	0	227	468	375	311	311	362	376	358	455	455	378
Total Liabilities	2,959	3,965	1,198	1,236	1,882	1,589	2,341	2,341	1,798	1,776	1,824	1,822	1,822	1,876
Series C Preferred Stock	1,070	985	475	475	215	215	215	215	215	215	215	215	215	215
Common stock	23	12	17	20	21	22	23	23	25	25	25	25	25	27
Additional paid-in capital	41,019	53,233	74,039	86,466	94,495	101,484	115,910	115,910	126,504	129,097	130,633	131,955	131,955	148,387
Subscriptions	0	30	0	309	0	501	0	0	290	769	900	1,100	1,100	3,040
Accumulated deficit	(43,829)	(56,525)	(70,732)	(76,601)	(84,551)	(89,995)	(104,787)	(104,812)	(110,431)	(116,345)	(121,143)	(125,733)	(125,733)	(140,424)
Total Stockholders' Equity (Deficits)	(2,787)	(3,250)	3,324	10,193	9,965	12,012	11,147	11,147	16,388	13,546	10,415	7,347	7,347	11,030
Non-controlling interest			0	0	0	406	515	515	690	1,079	2,076	2,925	2,925	3,989
Total equity	(2,787)	(3,250)	3,324	10,193	9,965	12,418	11,661	11,661	17,078	14,625	12,491	10,272	10,272	15,019
Total Liabilities and Stockholders' Deficit	1,242	1,700	4.997	11,904	12,062	14,221	14,217	14,217	19.091	16.616	14,530	12.310	12,310	17,110

Yale Jen, Ph.D. 212-953-4978

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

### **Cash flow Statement**

BioSig Technologies – Cash Flow Statement														
(000 \$)	2016	2017	2018					2019E					2020E	2021E
Cash Flows From Operating Activities:	2010	2017	2010	1Q19	2Q19E	3Q19	4Q19	2013L	1Q20E	2Q20E	3Q20E	4Q20E	2020L	2021L
Net profit (loss)	(11,587)	(12,696)	(17,251)	(5,870)	(7,950)	(5,464)	(15, 188)	(34,471)	(5,659)	(5,928)	(4,812)	(4,603)	(21,001)	(14,746)
Adjustments to reconcile net loss to net cash used in operating activities:														
Depreciation and amortization	10	12	12	8	10	19	18	54	18	20	21	22	81	83
Equity based compensation	6,000	4,749	6,601	2,670	3,057	1,969	7,481	15,178	1,211	1,009	1,311	1,086	4,617	3,287
Fair value of issued warrant to acquire research and development	0	544					3,162	3,162						
Change in fair value of modified options				0	666	0	0	666	0	0	0	0	0	0
Changes in operating assets and liabilities:														
Inventory							(578)	(578)	(2)	(10)	(5)	(13)	(30)	(364)
Vendor deposits	0	0	0	0	0	(330)	430	100	0	0	0	0	0	0
Prepaid expenses	(103)	17	(62)	22	(181)	62	7	(90)	9	(15)	6	(4)	(4)	(12)
Security deposit	0	11	(37)	0	(70)	22	0	(48)	0	0	0	0	0	0
Accounts payable and accrued expenses	150	102	479	(354)	346	(218)	764	537	(559)	(22)	54	8	(520)	49
Lease liability, net	0	0	0	1	2	1	1	6	1	1	1	1	4	5
Deferred rent payable	(0)	(2)	3	0	0	0	0	0	0	0	0	0	0	0
Net Cash Used In Operating Activities	(5,107)	(7,470)	(10,255)	(3,523)	(4,119)	(3,940)	(3,901)	(15,483)	(4,982)	(4,945)	(3,424)	(3,503)	(16,853)	(11,698)
Cash Flows From Investing Activities:														
Proceeds from disposal of equipment							3	3						
Payments of patent costs	0	0	(269)	(58)	(53)	0	0	(111)	0	0	0	0	0	0
Payment of trademark costs	0	0	(1)	(0)	Ô	0	0	(0)	0	0	0	0	0	0
Purchases of property and equipment	(16)	(9)		(14)	(31)	(38)	(94)	(177)	(65)	(69)	(55)	(63)	(252)	(313)
Net Cash Used in Investing Activities	(16)	(9)	(308)	(73)	(84)	(38)	(91)	(286)	(65)	(69)	(55)	(63)	(252)	(313)
Cash Flows From Financing Activities:														
Proceeds from sale of common stock	5,226	6,011	9,140	8,619	0	0	1,388	10,007	9,200	0	0	0	9,200	11,000
Proceeds from sale of subsidiary stock to non-controlling interest	0	0	0	0	0	3,695	1,317	5,011	0	1,090	0	0	1,090	0
Subscription received from subsidiary stock subscription from non-controlling interest	0	0	0	0	0	501	(501)	0	0	0	0	0	0	0
Proceeds from sale of Series D preferred stock	0	1,930					` ,							
Proceeds from sale of Series E preferred stock	0	0	1,493	0	0	0	0	0	0	0	0	0	0	0
Proceeds from exercise of warrants	0	0	2,217	1,460	3,159	1,736	1,116	7,471	1,094	1,141	1,203	1,101	4,539	4,411
Proceeds from exercise of options	0	0	616	0	445	20	473	938	300	362	333	221	1,216	1,021
Net Cash Provided by Financing Activities	5,226	7,971	13,466	10,079	3,604	5,952	3,792	23,427	10,594	2,593	1,536	1,322	16,045	16,432
Net increase (decrease) in cash	103	492	2,903	6,483	(600)	1,975	(200)	7,658	5,547	(2,421)	(1,943)	(2,244)	(1,060)	4,421
Cash at beginning of period	953	1,056	1,548	4,450	10,934	10,334	12,309	4,450	12,109	17,656	15,235	13,292	12,109	11,048
Cash at end of period	1,056	1,548	4,450	10,934	10,334	12,309	12,109	12,109	17,656	15,235	13,292	11,048	11,048	15,469

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

March 18, 2020

March 18, 2020

### **DISCLOSURES:**

#### ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

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#### Additional information available upon request.

‡ Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

## An employee of Laidlaw & Co (UK) Ltd. is a member of the Board of Directors of the subject company.

#### **RATINGS INFORMATION**

Source: Laidlaw & Company

#### **Rating and Price Target Change History**



Created	hv:	Blue-Compass.net

3 Y	ear Rating Chang	ge History	
Date	Rating	Closing Price (\$)	
04/05/2017	Puv/P.)	3.04	

3 Year Price Change History							
Date	Target Price (\$)	Closing Price (\$)					
04/05/2017	10.00**	3.94					
03/29/2018	8.75**	3.93					
02/20/2019	10.50	5.25					
03/18/2020	13.00	2.73*					

<sup>\*</sup> Previous Close 3/17/2020

<sup>\*\*</sup> Split Adjusted

Laidlaw & C	ompany Rating System*	% of Companies Under Coverage	% of Companies for which Laidlaw & Company has performed services for in the last 12 months				
		With This Rating	Investment Banking	Brokerage			
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%			
Buy (B)	Expected to outperform the sector average over 12 months.	46.27%	20.90%	2.99%			
Hold (H)	Expected returns to be in line with the sector average over 12 months.	1.49%	1.49%	0.00%			
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%			

#### ADDITIONAL COMPANIES MENTIONED

Johnson & Johnson (JNJ – Not Rated)
Medtronic (MDT – Not Rated)
Boston Scientific (BSX – Not Rated)
Abbott Laboratories (ABT – Not Rated)
Koninklijke Philips NV (PHG – Not Rated)
Siemens AG (SIEGY - Not Rated)
General Electric (GE – Not Rated)
LivaNova (LIVN– Not Rated)

#### ADDITIONAL DISCLOSURES

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