Boston Scientific Announces Expanded Investment and Exclusive Acquisition Option Agreement with Farapulse, Inc.

Agreement expands company's access to pulsed field ablation technology

MARLBOROUGH, Mass., Sept. 21, 2020 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has signed an investment agreement with an exclusive option to acquire Farapulse, Inc., a privately-held company developing a pulsed field ablation (PFA) system for the treatment of atrial fibrillation (AF) and other cardiac arrhythmias. This PFA system - comprising a sheath, generator and catheters - is intended to ablate heart tissue via the creation of a therapeutic electric field instead of using thermal energy sources such as radiofrequency ablation or cryoablation.

Patients with AF, a common heart rhythm disorder that affects more than 33 million people globally, are often treated with anti-arrhythmic drugs as well as cardiac ablation. Ablation therapy is the process of delivering energy to areas of the heart muscle responsible for creating an abnormal heart rhythm. The Farapulse platform employs an ablation modality based on pulsed electric fields, also referred to as irreversible electroporation, that generates zones of ablated cardiac tissue to interrupt the irregular electrical signals that can cause AF. This technology is designed for physicians to precisely ablate tissue and, in turn, spare nearby tissue from unintentional ablation.

"The tissue-selective Farapulse PFA technology is a promising energy source for cardiac ablation – including pulmonary vein isolation - with recent study results demonstrating the effectiveness of the ultra-rapid approach," said Allan Zingeler, president and chief executive officer, Farapulse, Inc. "This next chapter in our collaborative relationship with Boston Scientific will further accelerate our progress towards regulatory approval so we can bring this pioneering system to market."

Farapulse is pursuing regulatory approval in the U.S. and received FDA Breakthrough Designation for its endocardial ablation system in May 2019 - a designation intended to help patients receive more timely access to products that may provide a substantial improvement over existing therapies. The company intends to initiate a pivotal IDE trial in the U.S. and is pursuing CE Mark approval in Europe.

"Our expanded investment in this technology, combined with our recent CE Marked cryoablation and contact force catheters with local impedance technology, affirms our commitment to offer physicians an innovative and comprehensive portfolio of electrophysiology products and services," said Scott Olson, senior vice president and president, Rhythm Management, Boston Scientific.

*The Farapulse platform is an investigational device and not available for sale.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for 40 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding the financial and business impact of the transaction, product launches and product performance and impact. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; the closing and integration of acquisitions; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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ⁱ Chugh SS, et al. Worldwide epidemiology of atrial fibrillation: a global burden of disease 2010 study. Circulation 2014;129:837–847. doi: https://doi.org/10.1161/CIRCULATIONAHA.113.005119.

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