

Boston Scientific

Boston Scientific to Acquire Cryterion Medical, Inc.

Company to expand atrial fibrillation ablation therapy offerings with innovative cryoballoon platform

MARLBOROUGH, Mass., July 5, 2018 /[PRNewswire](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced a definitive agreement to acquire Cryterion Medical, Inc., a privately-held company developing a single-shot cryoablation platform for the treatment of atrial fibrillation (AF). The addition of this cryoballoon platform positions the company as the first to have both cryothermal and radiofrequency (RF) single-shot, balloon-based ablation therapies in its portfolio. Boston Scientific has been an investor in Cryterion since its inception in 2016 and the transaction price for the approximately 65 percent remaining stake not already owned by Boston Scientific consists of \$202 million in up-front cash.

The quickly expanding global electrophysiology (EP) market is estimated to reach \$5 billion in 2018. Additionally, single-shot ablation therapies are believed to be the fastest growing sub-segment within the EP market, with rates well into the double digits, and trending toward more than \$1 billion over the next few years.

Patients with AF – a common heart rhythm disorder – are often treated with anti-arrhythmic drugs as well as cardiac ablation. Ablation therapy is the process of delivering RF (heating) or cryothermal (cooling) energy to the areas of the heart muscle responsible for the abnormal heart rhythm. Both types of energy can be used to isolate pulmonary veins, which are often the source of AF.

The Cryterion Medical cryoablation platform uses cryothermal energy to interrupt the irregular electrical signals that can cause AF. Developed with a next-generation balloon catheter, advanced mapping catheter, steerable sheath and enhanced console, the system is designed to streamline overall procedural workflow, enhance maneuverability and improve positioning in challenging anatomy.

"Initial clinical study results demonstrate that our system has a promising safety profile as well as acute efficacy," said Keegan Harper, president and chief executive officer, Cryterion Medical, Inc. "We look forward to bringing this advanced cryoablation system to market with the support of Boston Scientific."

Performance of the cryoablation system from Cryterion Medical is being investigated in a clinical study in Europe. Clinical evidence from this study will be included in a regulatory submission for CE Mark, expected in early 2019. The company will also pursue regulatory approval in the U.S. and plans to submit an investigational device exemption (IDE) application to the U.S. Food and Drug Administration, with patient enrollment expected to begin in 2019.

"The acquisition of Cryterion Medical enhances our AF ablation procedure offerings, allowing physicians to select a therapeutic option based on clinical preference and specific patient needs," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management and Global Health Policy, Boston Scientific. "We are committed to providing physicians with a comprehensive suite of therapies that lead the way for clinical advancements and address the needs of the increasing population of patients with AF."

Boston Scientific offers an innovative portfolio of EP products and services for the diagnosis and management of cardiac rhythm disorders. The company continues to expand its EP offerings through internal investments and acquisitions.

Cryterion is headquartered in Carlsbad, California, with offices in Montreal, Canada and Wexford, Ireland.

Boston Scientific expects the transaction to be immaterial on an adjusted earnings per share basis through

2020, and accretive thereafter. On a GAAP basis for 2019 and subsequent years, the transaction is expected to be less accretive, or more dilutive as the case may be, due to amortization expense and acquisition-related net charges. For 2018 on a GAAP basis, the transaction is expected to be accretive due to a one-time gain on prior investment.

**The Cryterion cryoablation system is 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 more than 35 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 acquisition, 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.

Use of Non-GAAP Financial Measures

To supplement our consolidated financial statements presented on a GAAP basis, we disclose certain non-GAAP financial measures, including adjusted net income (earnings) per share that excludes certain charges and/or credits. These non-GAAP financial measures are not in accordance with generally accepted accounting principles in the United States and should not be considered in isolation from or as a replacement for the most directly comparable GAAP financial measures. Further, other companies may calculate these non-GAAP financial measures differently than we do, which may limit the usefulness of those measures for comparative purposes.

To calculate adjusted net income (earnings) per share we exclude certain charges (credits) from GAAP net

income, including amortization expense, acquisition-related net charges (credits) and restructuring and restructuring-related net charges (credits). Please refer to Part II, Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations in our most recent Annual Report filed on Form 10-K for an explanation of each of these adjustments and the reasons for excluding each item.

The GAAP financial measures most directly comparable to adjusted net income per share is GAAP net income and GAAP net income per share.

Management uses these supplemental non-GAAP financial measures to evaluate performance period over period, to analyze the underlying trends in our business, to assess our performance relative to our competitors, and to establish operational goals and forecasts that are used in allocating resources. In addition, management uses these non-GAAP financial measures to further its understanding of the performance of our operating segments. The adjustments excluded from our non-GAAP financial measures are consistent with those excluded from our operating segments' measures of net sales and profit or loss. These adjustments are excluded from the segment measures that are reported to our chief operating decision maker that are used to make operating decisions and assess performance.

We believe that presenting adjusted net income per share, in addition to the corresponding GAAP financial measures, provides investors greater transparency to the information used by management for its operational decision-making and allows investors to see our results "through the eyes" of management. We further believe that providing this information assists our investors in understanding our operating performance and the methodology used by management to evaluate and measure such performance.

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