

Boston Scientific Announces Agreement to Acquire Claret Medical, Inc. Addition of FDA-cleared Sentinel® Cerebral Embolic Protection System to Expand Company's Structural Heart Offerings

MARLBOROUGH, Mass., July 20, 2018 [/PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced it has signed an agreement to acquire Claret Medical, Inc., a privately-held company that has developed and commercialized the Sentinel® Cerebral Embolic Protection System. The device is used to protect the brain during certain interventional procedures, predominately in patients undergoing transcatheter aortic valve replacement (TAVR). The transaction price consists of \$220 million in up-front cash, as well as a potential reimbursement-based milestone payment of up to \$50 million.

The Sentinel System – which received CE Mark in 2014 and FDA clearance in 2017 – is the only device cleared to protect patients against the risk of stroke during TAVR, a minimally-invasive procedure to replace the aortic valve in patients with severe aortic stenosis. Embolic debris such as calcium or tissue can break loose during the procedure, travel through the bloodstream towards the brain and potentially cause neurological and neurocognitive damage. Recent studies have estimated approximately four percent of patients experience a clinically-apparent stroke within 30 days of a TAVR procedure.^{1,2,3,4,5,6}

"Through the development and commercialization of the Sentinel System, Claret Medical has successfully introduced a new layer of safety and peace of mind for physicians and their patients undergoing TAVR procedures," said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. "This acquisition will expand our commercial portfolio to include an important adjunctive offering aimed at improving TAVR patient outcomes. We also see potential for future use in other left heart and endovascular procedures such as mitral valve repair and replacement, left atrial appendage closure and pulmonary vein isolation ablation procedures for atrial fibrillation."

In the pivotal SENTINEL trial, the landmark study that led to FDA clearance and commercial introduction of this first-time therapy in the U.S., the Sentinel System reduced the incidence of strokes by 63 percent within the first 72 hours of the procedure.⁷ In clinical studies, the Sentinel System captured debris flowing towards the brain in 99 percent of TAVR cases, regardless of the type of replacement valve that was used.⁸

"We have been pleased by the consistent, high-quality clinical evidence generated by the committed thought leaders at leading academic centers, as well as the rapid physician adoption of the device – utilized on average in 60 percent of TAVR procedures performed across 100 centers – within just 12 months of carefully-controlled U.S. commercialization," said Azin Parhizgar, PhD, president and chief executive officer, Claret Medical. "Nearly 10,000 patients have been treated worldwide with the Sentinel System, and we are confident that the leadership of Boston Scientific will enable increased momentum and improved patient access to this valuable technology."

Claret Medical is based in Santa Rosa, CA, and has approximately 120 employees. The acquisition is projected to close during the third quarter of 2018, subject to customary closing conditions.

The transaction is expected to be immaterial to adjusted earnings per share in 2018, accretive in 2019 and increasingly accretive thereafter. On a GAAP basis, 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.

¹ Leon, et al., N Engl J Med. 2010;363:1597-1607.

² Webb, et al., J Am Coll Cardiol Intv. 2015;8:1797-1806.

³ Smith, et al., N Engl J Med. 2011;364:2187-98.

⁴ Leon, et al., N Engl J Med 2016;374:1609-20.

⁵ Popma, et al., J Am Coll Cardiol 2014;63:1972-81.

⁶ Adams, et al., N Engl J Med 2014;370:1790-98.

⁷ Kapadia S, et al. JACC. Jan 2017; 69(4): 367-377.

⁸ Schmidt T, et al. JACC: Cardiovascular Interventions. Jul 2018; 11(13): 1262-1273.

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 and adjusted net income (earnings) per share that excludes certain charges and/or credits, such as amortization expense and acquisition-related net charges (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. For further information regarding our non-GAAP measures, see Part II, Item 7 - *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our most recent Annual Report on Form 10-K, which we may update in Quarterly Reports on Form 10-Q we have filed or will file hereafter.

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