Boston Scientific

Boston Scientific announces agreement to acquire Cortex, Inc.

Acquisition to complement electrophysiology portfolio with solution to advance the treatment of complex atrial fibrillation

MARLBOROUGH, Mass., Nov. 4, 2024 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has entered into a definitive agreement to acquire Cortex, Inc., an Ajax Health company. Cortex is a privately held medical technology company focused on the development of a diagnostic mapping solution which may identify triggers and drivers outside of the pulmonary veins that are foundational to atrial fibrillation (AF), a heart rhythm disorder affecting nearly 38 million people globally.[1]

Cardiac ablation – the process of delivering energy to areas of the heart responsible for creating abnormal heart rhythms – is a common treatment for AF. During these procedures, physicians often use a mapping system to examine and analyze a heart's electrical patterns to guide therapeutic applications. The OptiMap™ System developed by Cortex uses a basket catheter and proprietary algorithm to identify potential active AF sources, providing physicians with precise insights to efficiently deliver an individualized ablation strategy for their patients.

"We believe the addition of the Cortex technology complements our electrophysiology portfolio with a differentiated cardiac mapping offering to assist with complex AF cases," said Nick Spadea-Anello, global president, Electrophysiology, Boston Scientific. "The OptiMap System has demonstrated it can help physicians devise a targeted ablation strategy for complex cases, which can lead to improved procedural efficiency and outcomes in patients with challenging atrial arrhythmias.[2] We look forward to advancing this technology and driving future clinical evidence generation with the goal of making it accessible to physicians and patients globally in the years ahead."

Cortex received U.S. Food and Drug Administration 510(k) clearance for the OptiMap System in 2023 and recently completed the randomized, controlled FLOW-AF clinical trial with data demonstrating that OptiMap-guided treatment of AF sources in patients with persistent AF improved freedom from AF one year after an ablation by 51% compared with patients who received conventional pulmonary vein isolation therapy alone. Earlier this year, the company initiated a 300 patient, global clinical trial, RESOLVE-AF, evaluating the effectiveness of the OptiMap System in identifying extra-pulmonary vein sources.

"Cortex was established to provide physicians with a more intelligent and precise solution for patients with AF," said Duke Rohlen, chief executive officer, Cortex. "Joining Boston Scientific will allow us to further develop this technology, which we believe has the ability to transform the treatment of AF for patients around the world."

Boston Scientific expects to complete the transaction in the first half of 2025, subject to customary closing conditions. The transaction is expected to have an immaterial impact on adjusted earnings per share in 2025 and is expected to be slightly dilutive on a GAAP basis due to amortization expense and acquisition-related net charges. Specific terms of the transaction have not been disclosed.

About Boston Scientific
Boston Scientific transforms lives through innovative medical technologies that improve the health of patients around the world. As a global medical technology leader for more than 45 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 health care. Our portfolio of devices and therapies helps physicians diagnose and treat complex cardiovascular, respiratory, digestive, oncological, neurological and urological diseases and conditions. Learn more at www.bostonscientific.com and connect on LinkedIn and X, formerly Twitter.

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 our business plans, the financial and business impact of the transaction and the anticipated benefits of the transaction, the closing of the transaction and the timing thereof, clinical trials, 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, political, competitive, reimbursement and regulatory conditions; geopolitical events; manufacturing, distribution and supply chain disruptions and cost increases; disruptions caused by cybersecurity events; disruptions caused by public health emergencies or extreme weather or other climate change-related events; labor shortages and increases in labor costs; variations in outcomes of ongoing and future clinical trials and market studies; market competition for our products; expected procedural volumes; new product introductions; demographic trends; the closing and integration of acquisitions, including our ability to achieve the anticipated benefits of the proposed transaction and successfully integrate Cortex's operations; business disruptions (including disruptions in relationships with employees, customers and suppliers) following the announcement and/or closing of the proposed transaction; intellectual property; litigation; financial market conditions; future business decisions made by us and our competitors; the conditions to the completion of the proposed transaction, including the receipt of any required regulatory approvals and clearances, may not be satisfied at all or in a timely manner; and the closing of the proposed transaction may not occur or may be delayed.. 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, except as required by law. This cautionary statement is applicable to all forward-looking statements contained in this document.

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[1]Lippi G, Sanchis-Gomar F., et al. Global epidemiology of atrial fibrillation: An increasing epidemic and public health challenge. Int J Stroke. 2021; Feb 16:217-221.

[2]Reddy VY, Langbein A, Petru J, Szili-Torok T, Funasako M, Dinshaw L, Wijchers S, Rillig A, Spitzer SG, Bhagwandien R, Metzner A, Kong MH, Neuzil P. A Randomized Trial of Electrographic Flow-Guided Redo Ablation for Nonparoxysmal Atrial Fibrillation (FLOW-AF). JACC Clin Electrophysiol. 2024 Aug;10(8):1856-1869. doi: 10.1016/j.jacep.2024.03.040. Epub 2024 Jun 5. PMID: 38842972.

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