Medtronic News

Medtronic to Acquire Affera

Acquisition to expand company's cardiac ablation portfolio, including first-time entry into mapping and navigation, within one of the fastest growing medtech markets

DUBLIN, Jan. 10, 2022 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced that it has entered into a definitive agreement to acquire Affera, Inc., a Boston area-based, privately held medical technology company. Affera designs and manufactures cardiac mapping and navigation systems and catheter-based cardiac ablation technologies, including a differentiated, focal pulsed field ablation solution, for the treatment of patients with cardiac arrhythmias (irregular heartbeats) such as atrial fibrillation (AF). Medtronic, through its minority investment portfolio, has been a strategic investor in Affera and currently holds a 3% ownership stake in the company.

The acquisition expands the Medtronic portfolio of advanced cardiac ablation products and accessories to meet physician needs within a growing patient population. Affera's technologies include the Affera Prism-1™ cardiac mapping and navigation platform and Sphere-9™ cardiac ablation catheter, investigational technologies designed to enable the rapid creation of detailed maps used by electrophysiologists (EP) to diagnose arrhythmias and deliver cardiac ablation therapy, respectively. The Affera full-suite of solutions and technologies will complement the existing Medtronic atrial and ventricular arrhythmia disease management portfolio and support the company's efforts to offer simple, safe, and effective cardiac ablation solutions to improve patient outcomes.

"The EP ablation market is an exciting and fast-moving segment of cardiology," saidRebecca Seidel, president of the Cardiac Ablation Solutions (CAS) business, which is part of the Cardiovascular Portfolio at Medtronic. "Bringing Affera into our organization, with our established footprint in the cardiac ablation space, will strengthen our ability to provide innovative therapies and enable Medtronic entry into additional EP technology segments, such as mapping and navigation, for the first time."

"Affera offers technologies that support physician customers as they work to improve clinical workflows, procedural efficiencies, and ultimately optimize patient care," said Stacy Beske, Ph.D., vice president of strategy, CAS.

Within the $8 billion worldwide EP ablation market, the prevalence of cardiac arrhythmias is growing rapidly, and the need to provide treatment to the increasing patient population, which encompasses AF, supraventricular tachycardia (SVT), and ventricular tachycardia (VT), is increasing. AF represents the largest disease segment, with nearly 60 million people affected worldwide[1]. AF is a progressive disease, meaning over time patients can experience more frequent, and longer episodes, and medication as well as catheter ablation can become less effective. Additionally, AF is associated with serious complications including heart failure, stroke, and increased risk of death.[2-345]

"This is an exciting day for patients who suffer from the burden of AF and other arrhythmias. This acquisition directly aligns with our vision of delivering novel solutions to address the rapidly growing demands for cardiac arrhythmia treatment," said Doron Harlev, founder and chief executive officer of Affera. "We are excited to focus on the integration of our technology with Medtronic and are confident that together we can increase patient access to ablation therapies."

In December 2021, Affera announced the commencement of the recently approved SPHERE PerAF Trial, a U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) pivotal randomized trial, to evaluate the safety and effectiveness of the Affera system for the treatment of persistent AF. Affera's product portfolio is not currently approved or available for sale or commercial use.

Financial Highlights

The acquisition is expected to close the first half of Medtronic fiscal year 2023, subject to the satisfaction to certain customary closing conditions. Following close, the transaction is expected to be less than 1% dilutive to Medtronic's adjusted earnings per share in each of the first three years, and neutral to accretive thereafter. The company expects dilution of approximately 5 cents in both year 1 and year 2 and approximately3 cents in year 3.

In collaboration with leading clinicians, researchers, and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Affera

Affera is a medical technology company dedicated to delivering unrivaled innovative solutions to address the rapidly growing demands for cardiac arrhythmia treatment. Affera is developing a comprehensive integrated platform to efficiently deliver durable therapy for a broad set of cardiac arrhythmia patients. For more information, visit www.affera.com.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

Any forward-looking statements, including, but not limited to, statements regarding the proposed transaction between Medtronic and Affera, the expected timetable for completing the transaction, strategic and other potential benefits of the transaction, including meeting Medtronic's long-term financial metrics for acquisitions, Affera products and product candidates, and other statements about Medtronic managements' future expectations, beliefs, goals, plans or prospects, are subject to risks and uncertainties including, but not limited to, the ability and timing to satisfy conditions to closing including regulatory approvals, the impact of the announcement of the transaction on the business, and other risks and uncertainties such as those described in Medtronic's reports and other filings with the Securities and Exchange Commission. Actual results may differ materially from anticipated results. Medtronic cautions investors not to place considerable reliance on the forward-looking statements contained in this press release. These forward-looking statements speak only as of the date of this document, and Medtronic undertakes no obligation to update or revise any of these statements except to the extent required by law.

---

[1] Roth GA, Mensah GA, Johnson CO et al. Global Burden of Cardiovascular Diseases and Risk Factors, 1990-2019: Update From the GBD 2019 Study. J Am Coll Cardiol 2020;76:2982-3021.

[2] Miyasaka Y, Barnes ME, Bailey KR, et al. Mortality trends in patients diagnosed with first atrial fibrillation: a 21-year community-based study. J Am Coll Cardiol 2007;49:986-92.

[3] Hindricks G, Potpara T, Dagres N, et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation

developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS). Eur Heart J 2020.

[4] Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. Stroke 1991;22:983-8.

[5] Lubitz SA, Moser C, Sullivan L, et al. Atrial fibrillation patterns and risks of subsequent stroke, heart failure, or death in the community. J Am Heart Assoc 2013;2:e000126

Contacts:

Allison Kyriagis	Ryan Weispfenning
Public Relations	Investor Relations
+1-612-750-6061	+1-763-505-4626

SOURCE Medtronic plc
