

Medtronic completes acquisition of Affera

Acquisition adds mapping and navigation platform to company's cardiac ablation portfolio and brings an integrated system of diagnostic and therapeutic tools to address a broad spectrum of arrhythmias

DUBLIN, Aug. 30, 2022 [/PRNewswire/](#) -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced that it has completed the acquisition of Affera, Inc. This acquisition expands the company's cardiac ablation portfolio to include its first-ever cardiac mapping and navigation platform that encompasses a differentiated, fully integrated diagnostic, focal pulsed field and radiofrequency ablation solution.

The investigational Affera technology is designed to provide solutions for patients with cardiac arrhythmias (irregular heartbeats) such as atrial fibrillation (AF). Through this acquisition Medtronic gains the Affera Prism-1™ cardiac mapping and navigation platform, which will be compatible with Medtronic and multiple, competitive therapeutic catheters and technologies. The company also adds the Sphere-9™ cardiac diagnostic and ablation catheter that enables the rapid creation of detailed electro-anatomical maps and delivers radio frequency (RF) and pulsed field (PF) cardiac ablation therapies. Additional Affera pipeline products such as the Arc-10 coronary sinus (CS) diagnostic catheter and Sphere PVI ablation catheter, which is a single shot device which delivers pulsed field ablation (PFA) energy, are also included.

"This acquisition marks an important growth milestone for our cardiac ablation portfolio," said Rebecca Seidel, president of the Cardiac Ablation Solutions (CAS) business, which is part of the Cardiovascular Portfolio at Medtronic. "We're incredibly proud to have led the industry with the introduction of the proven safe and effective cryoablation technology; and now these new additions to our portfolio help support a leap forward in our commitment to build a comprehensive portfolio and help physicians achieve the best outcomes for patients."

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 differentiated, safe, and effective cardiac ablation solutions. Currently, the prevalence of cardiac arrhythmias including AF, supraventricular tachycardia (SVT), and ventricular tachycardia (VT), is increasing rapidly. AF represents the largest disease segment, with nearly 60 million people affected worldwide¹.

"The Affera team is very excited to be joining Medtronic Cardiac Ablation Solutions. The acquisition enhances and accelerates our ability to treat millions of patients around the world suffering from cardiac arrhythmia with our innovative technology," said Doron Harlev, founder and chief executive officer of Affera. "Our team designed the Affera platform with physicians and patients in mind, to advance the field of electrophysiology while supporting safe and efficient cardiac ablation procedures."

In December 2021, Affera announced the commencement of the recently approved SPHERE Per-AF Trial, a U.S. Food and Drug Administration Investigational Device Exemption pivotal randomized trial, to evaluate the safety and effectiveness of the Affera system for the treatment of persistent AF. As part of the closure, Medtronic will continue to support the SPHERE Per-AF Pivotal Trial. Affera's product portfolio is not currently approved or available for sale or commercial use.

Financial Highlights

Consistent with the financial impact disclosed in January 2022 when the Affera transaction was announced, Medtronic expects the transaction 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 continues to expect dilution of approximately 5 cents in both year 1 and year 2 and approximately 3 cents in year 3. Given the timing of today's closing announcement, this translates into approximately 3 to 4 cents in fiscal year 2023, approximately 5 cents in fiscal year 2024, and approximately 4 cents in fiscal year 2025. The dilution was contemplated in the company's fiscal year 2023 adjusted earnings per share guidance that the company reiterated on August 23, 2022.

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 in Dublin, 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 95,000+ 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](https://twitter.com/Medtronic) on Twitter and [LinkedIn](https://www.linkedin.com/company/medtronic).

Any forward-looking statements, including, but not limited to, statements regarding 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 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.

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