

Affluent Medical announces several key appointments for Medical and Clinical affairs.

- Appointment of Dr. Howard C. Herrmann as strategic Chief Medical Officer for structural heart platform.
- Appointment of Pr. Nicolas Barry Delongchamps as strategic Chief Medical Officer for Urology platform.
- Federica Azzimonti joins as Director of Clinical Operations, bringing extensive expertise to optimize clinical trial readiness for market launch.

Aix-en-Provence, March 11, 2025 – 5:45 p.m. CET – Affluent Medical (ISIN: FR0013333077 – Ticker: AFME – "Affluent"), a French clinical-stage medical technology company specializing in the development and industrialization of implantable innovative medical devices, today announced three key leadership appointments. These strategic additions aim to accelerate the company's progress towards market access for its advanced product pipeline.

New Chief Medical Officers to Drive Specialized Platforms

Affluent Medical has appointed Dr. Howard C. Herrmann as strategic Chief Medical Officer (CMO) for its Structural Heart Platform and Pr. Nicolas Barry Delongchamps as strategic CMO for its Urology Platform. These key appointments underscore Affluent Medical commitment to enhancing its clinical expertise and driving innovation as it advances its groundbreaking devices, including mitral ring KALIOS™, mitral valve EPYGON and artificial urinary sphincter ARTUS.

Dr. Howard C. Herrmann, a renowned interventional cardiologist, is Professor of Medicine at the Perelman School of Medicine at the University of Pennsylvania and Director of Interventional Cardiology at the Hospital of the University of Pennsylvania, Philadelphia. With over three decades of experience in transcatheter device therapies for valvular and structural heart diseases, he has authored over 500 publications and served as President of the Pennsylvania Chapter of the American College of Cardiology. His profound expertise in structural heart care will guide the development of Affluent's next-generation structural heart devices.

Pr. Nicolas Barry Delongchamps, a distinguished urologist and professor at Paris-Cité University, brings extensive expertise in minimally invasive surgery for benign prostatic hyperplasia and urinary incontinence. His knowledge and experience with urinary incontinence will support Affluent Medical's strategy in urology, driving innovation in this critical area.

Expanding Operational Expertise with New Director of Clinical Operations

Further bolstering its operational capabilities, Affluent Medical has named **Federica Azzimonti** as Director of Clinical Operations. With close to 25 years of experience in managing international clinical studies across cardiovascular and other medical specialties, Federica brings a wealth of expertise in trial optimization and execution. In collaboration with both strategic CMOs, she will lead the operational aspects of Affluent Medical clinical trials, ensuring streamlined execution as the company prepares for pivotal stages.

"These appointments come at a crucial time as we enter our next phase of growth, transitioning into pivotal phases and continuing to progress towards commercialization of our devices." said **Sébastien Ladet, CEO of Affluent Medical**. *"The addition of strong medical experts has been a deliberate move that demonstrates Affluent Medical commitment to execute and to offer the best available therapies worldwide."*



About Affluent Medical's Specialized Platforms

MITRAL RING KALIOS™:

Kalios™ is the only mitral annuloplasty device that can be simply adjusted percutaneously by a cardiologist to treat both residual or recurrent mitral valve insufficiency, at any time after implantation, repeatedly and with a beating heart, thereby avoiding repeat open-heart surgery. Affluent Medical believes that Kalios™ would avoid further intervention for potentially 30% to 40% of patients over a five-year horizon.

Following positive feedback from the FDA in September 2024, Affluent Medical's objective is to submit a De Novo application with current clinical data at the end of 2025/early 2026 to be followed by commercial launch, subject to Edwards' decisions, with whom Affluent Medical has signed several agreements related to its structural heart products (adjustable mitral annulus Kalios™) and technologies (mitral valve technology).

MITRAL VALVE EPYGMON:

Epygon is the only biomimetic mitral heart valve that mimics the anatomy of the native mitral valve and physiological blood flow, able to be implanted via a transcatheter route. This transcatheter approach avoids an invasive open-heart procedure and associated complications to treat mitral valve insufficiency.

In 2024, the company began a collaboration with Prof. Mohammad Sarraf, MD, interventional cardiologist at the Mayo Clinic in the US, to evaluate the benefits of the biomimetic design of the Epygon valve. This innovative design aims to replicate the anatomy and natural physiology of the native mitral valve to enable patients to recover good cardiac function more quickly.

During the first half of 2024, Affluent Medical accelerated patient screening, achieving a fourfold increase in the number of patients screened by the end of June 2024 with the goal to implant up to ten patients to complete the pilot phase.

URINARY SPHINCTER ARTUS:

Artus is the first artificial urinary sphincter that can be activated by the patient with a simple remote control for the treatment of moderate to severe urinary incontinence. Urinary incontinence is a major public health problem for over 400 million people worldwide without any innovation in the last 40 years, causing patients to suffer a reduced quality of life associated with the psychological disorders related to the disease.

In January 2025, the Company announced the completion of the enrollment for the pilot phase of the European multicenter clinical study in humans with the successful 10th minimally invasive implantation of the Artus urinary sphincter with, to date, 100% of devices having been successfully activated and the safety profile remains positive. The pivotal phase, aiming to validate the device's performance in reducing incontinence in several dozen patients, is scheduled to begin in Q2 2025.

With women representing about 80% of patients suffering from urinary incontinence, the Company will submit the dossier in order to begin a pilot study in women in the first half of 2025, aiming to extend indications for its Artus urinary sphincter.



About Affluent Medical

Affluent Medical is a French medical technologies company, founded by Truffle Capital, that aims to become a global leader in the treatment of structural heart diseases, one of the world's leading causes of mortality, and urinary incontinence, which currently affects one in four adults.

Affluent Medical develops next-generation implants that are minimally invasive, innovative, adjustable and biomimetic, designed to restore essential physiological functions. The candidate products developed by the Company are all undergoing clinical studies in humans.

Subject to raising the funds necessary to finance its strategy and the positive results of ongoing clinical studies, the Company aims to gradually market its products from 2026, directly or indirectly.

For more information, please visit www.affluentmedical.com



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