

2024 FULL YEAR RESULTS

Affluent Medical reached major new milestones in executing its clinical roadmap

- Signing of transformative agreements with Edwards Lifesciences, generating an initial payment of €15 million and marking significant industry recognition in the field of structural cardiology
- Positive feedback from the Food & Drug Administration (FDA) on Kalios™, validating the accelerated regulatory strategy for the US market
- Acceleration of the clinical development of Epygon relying on centers with multidisciplinary heart teams to demonstrate the valve's physiological properties
- Finalization of the pilot phase for Artus in humans, paving the way for launch of the pivotal phase in Q2 2025

Aix-en-Provence, April 24, 2025 – 5:45 p.m. CEST – Affluent Medical (ISIN: FR0013333077 – Ticker: AFME – “Affluent”), a French clinical-stage medical technology company specialized in the international development and industrialization of innovative implantable medical devices, is today releasing its full-year results for 2024.

Marked by key clinical, regulatory, strategic and financial milestones, 2024 was a year in which Affluent Medical advanced to a decisive new stage in its trajectory, bringing it even closer to the go-to-market phase of its innovative devices.

On this occasion, Sébastien Ladet, Chief Executive Officer of Affluent Medical, said:

“2024 was a transformational year in Affluent Medical’s roadmap. The clinical and regulatory approvals obtained, industry recognition of our technologies from a global MedTech player and strengthening of our organization allow us to embark with confidence on a new phase of our development. We are now ready to move our devices from the clinical stage to the reality of the market, with the goal of bringing concrete and innovative solutions to millions of patients worldwide.”

SIGNIFICANT NEW AND TRANSFORMATIVE MILESTONES REACHED IN 2024

2024 was marked by strong momentum, illustrated in particular by the signing of transformational agreements with Edwards Lifesciences, positive feedback from the FDA on Kalios™ for rapid strategic access to the US market, the ramp-up of the Epygon clinical program, and the latest promising clinical results of the Artus artificial urinary sphincter.

Major strategic validation with a global MedTech player

On July 11, 2024, Affluent Medical reached a major milestone with the signature of several agreements with Edwards Lifesciences, a global MedTech player, recognizing the relevance and potential of the technologies developed by it in the field of structural cardiology.

Under these agreements, Affluent Medical received an initial cash payment of €15 million, split as follows:

- **An initial payment of €5 million for an exclusive purchase option on Kephaios**, the wholly-owned subsidiary of Affluent Medical which is developing Kalios™, an innovative adjustable mitral ring, based



on the results of its clinical study. Operational activities for the development of Kalios™ will continue to be managed exclusively by Affluent Medical during the life of the option.

- **An initial payment of €5 million for Affluent Medical's global, non-exclusive intellectual property license on the biomimetic heart valve replacement technology. The agreement is limited to open-heart surgery, enabling Affluent Medical to retain all rights related to the transcatheter pathway.** Affluent Medical is eligible to receive future royalties on all products that may be marketed under the licensed patents throughout the lifetime of these patents. Affluent Medical retains all rights to the transcatheter valve patents, including those on its Epygon mitral valve currently in clinical development.
- **A payment of €5 million as part of Edwards Lifesciences' acquisition of a stake in Affluent.** Edwards Lifesciences invested €5 million to acquire a 9.21% stake in Affluent Medical. This investment was made as part of a capital increase with the waiver of the pre-emptive subscription rights of shareholders, through an offer reserved for certain categories of beneficiaries. The unit subscription price, set at €1.38 per share (including a par value of €0.10 and an issue premium of €1.28), reflected a 15% discount on the weighted average price over the last 20 trading sessions before 11 July 2024. **This strategic investment by Edwards Lifesciences marked an important step in the development of Affluent Medical, recognizing the innovation of its products.**

In addition to this initial payment, and in accordance with the agreements, **new payments could be made to Affluent Medical, notably linked to the exercise of the exclusive purchase option on KephaliOS, which would be triggered based on the results of the ongoing Optimise II pivotal clinical study on Kalios™ as well as royalty payments on the sales of surgical valves that use Affluent technology.**

This strategic alliance strengthens Affluent Medical's industry and financial visibility, while opening new prospects for collaboration in anticipation of the future launch of its medical devices on the market.

KALIOS™ MITRAL RING: Positive feedback from the Food & Drug Administration (FDA) on rapid strategic access to the US market

Kalios™ is the only mitral annuloplasty device that can be adjusted percutaneously by a cardiologist to treat both residual and recurrent mitral valve insufficiency, at any time after implantation, repeatedly and with a beating heart, thus 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. The global market for mitral valve repair surgery was estimated to be worth \$1.5 billion in the US-Europe region in 2023, growing at 3.5% per year.

In 2024, a key regulatory milestone was reached for Kalios™. Following a series of interactions initiated in 2023, the Food and Drug Administration (FDA) validated the market access strategy proposed by Affluent Medical, which provides for a De Novo procedure based on existing data from the European pivotal study, Optimise II. No additional patients will be required, which significantly shortens the submission and market access process.

This decision, combined with the exclusive purchase option granted to Edwards, gives Kalios™ a stronger positioning in the North American market, considered the most strategic market for valve repair devices.

Affluent Medical's objective is to be able to file for market access based on the current clinical data in 2026, followed by marketing, based on the decisions of its partner Edwards Lifesciences.

EPYGON MITRAL VALVE: Acceleration of patient assessments and the opening of centers

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 in treating mitral insufficiency.

This serious and potentially fatal disease affects 2% of the world's population, or approximately 160 million people. However, fewer than 4% of patients with a severe form can benefit from open heart surgery due to the high risk of death and hospitalization.



In 2024, the clinical program accelerated rapidly with a four-fold increase in enrollment in the first half of the year, driven by the opening of new centers in Europe. Currently, 11 centers are in operation and five additional centers are under evaluation (Austria, Italy, Germany and Spain) with plans to open in the coming months. **The goal is to implant up to ten patients to complete the pilot phase.**

Scientifically, 2024 also saw Affluent Medical collaboration with Dr. Mohammad Sarraf, interventional cardiologist at the Mayo Clinic (USA), to assess the unique hemodynamic advantage of Epygon's asymmetric design. These advances help to further differentiate the device in a rapidly emerging TMVI market.

ARTUS URINARY SPHINCTER: clinical validation of the first generation of remote-controlled urinary sphincter in humans

Artus is the first artificial urinary sphincter that can be activated by the patient using a 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, with no innovation in this area over the last 40 years. Patients suffer a reduced quality of life due to the psychological disorders associated with the disease.

In March 2024, the first implant of the Artus next-generation urinary sphincter was successfully performed by Prof. Roman Zachoval, MD, PhD, Head of the Department of Urology at Thomayer University Hospital in Prague, Czech Republic.

In January 2025, Affluent Medical announced that it had completed the pilot phase of the clinical study, with the success of the tenth minimally invasive implantation of the Artus urinary sphincter. The results of this first clinical phase will guide the execution of the pivotal phase, which is expected to begin in the second quarter of 2025. The pivotal phase aims to validate the performance of the device in reducing incontinence in several dozen patients.

In April 2025, Affluent Medical announced progress towards its next clinical study, SPHINX, in women. These trials are expected to be launched across Europe in the second half of 2025 and will evaluate the safety and performance of the Artus artificial urinary sphincter in female patients; it will begin at major medical centers in France with a possible expansion to other European countries, including Spain and Belgium.

In preparation for this launch, Affluent Medical succeeded in carrying out the first implant of the Artus device in a female anatomical model. The intervention, led by Professor Véronique Phé, a leading European urologist at Tenon Hospital in Paris, evaluated the implantation process in women. Using the Da Vinci robotic-assisted laparoscopy system, it confirmed that the device can be implanted with precision and ease, demonstrating that it is perfectly suited for minimally invasive surgery.

A stronger financial structure and greater visibility

During 2024, Affluent Medical implemented two bridge financing arrangements (January and April) for a total of €7 million, through its main shareholders.

These transactions, combined with the initial payment of €15 million in July under the agreements entered into with Edwards Lifesciences, have extended the company's financial horizon until summer 2025, preserving its ability to execute its clinical and strategic roadmap.

At the same time, with the help of its reference shareholder, the Company continues with confidence to explore financing options and strategic partnerships.

POST-CLOSING ANNOUNCEMENTS

Finalization of the pilot phase for Artus

In January 2025, Affluent Medical announced that it had completed the pilot phase of its clinical study on the Artus artificial urinary sphincter. The tenth implant procedure marked the end of patient recruitment in this first phase. All devices were successfully activated six weeks after surgery, with no reported complications,



confirming a good safety profile and ease of use of the device. The preliminary performance results, particularly in terms of reducing urinary leakage, are considered very encouraging. Building on these results, Affluent Medical plans to launch the pivotal phase in the second quarter of 2025, in parallel with the submission of a clinical study protocol for women, who are particularly affected by this under-researched disease.

Appointment of Liane Teplitsky, a recognized expert in the MedTech sector, to the Board of Directors

In February 2025, Affluent Medical co-opted Liane Teplitsky, CEO of Artdrone and a recognized expert in the MedTech sector, to its Board of Directors. Having gained international experience at Zimmer Biomet, Abbott and St Jude Medical, she brings valuable expertise in industrialization, marketing strategy and innovation management.

Liane Teplitsky's in-depth knowledge of advanced medical technologies and their global deployment will be a key asset for Affluent Medical as it structures its future stages of growth.

Better structuring of medical and clinical affairs

In March 2025, Affluent Medical announced additions to its medical management team with the appointment of three leading experts:

- **Dr. Howard C. Herrmann**, a world-renowned interventional cardiologist (University of Pennsylvania), was appointed Strategic Medical Director of Structural Cardiology.
- **Prof. Nicolas Barry Delongchamps**, urologist (Cochin Hospital), was appointed to oversee medical affairs in urology.
- **Federica Azzimonti**, with 25 years of experience in international clinical trials, was appointed Director of Clinical Operations.

These appointments boost Affluent Medical's clinical and operational expertise at a strategic stage in its development as it prepares to initiate several pivotal studies and file its first applications for market approval.

FINANCIAL RESULTS FOR THE 2024 FINANCIAL YEAR

The main financial items under IFRS, presented in the table below, were approved by the Board of Directors at its meeting of April 23, 2025. They have been audited by the Statutory Auditors and the audit report relating to certification is currently being issued.

The full financial statements will be included in the Universal Registration Document, which will be posted on the Company's website no later than April 30, 2025: www.affluentmedical.com.



In €k at December 31 (Audited consolidated financial statements - IFRS)	12/31/2024 12 months	12/31/2023 12 months
Other income	4,118	-
Other operating income	1,232	1,224
Purchases consumed	(3,262)	(2,132)
External expenses	(6,887)	(6,017)
Personnel expenses	(7,240)	(6,141)
Taxes and duties	(65)	(97)
Provisions net of reversals	11	-
Other current operating income and expenses	(150)	178
Depreciation and amortization	(2,396)	(2,413)
CURRENT OPERATING INCOME	(14,639)	(15,398)
OPERATING INCOME after share of net income of equity affiliates	(14,639)	(15,398)
Net financial income	(242)	(405)
Income taxes	142	150
NET INCOME (LOSS)	(14,739)	(15,653)
Cash flow from operating activities	(11,324)	(12,054)
Cash flow from investing activities	(480)	(184)
Cash flow from financing activities	11,370	11,316
Increase (decrease) in cash	(434)	(922)
Cash and cash equivalents	1,223	1,657
Money market SICAVs presented in other current financial assets	5,393	-

Other income at December 31, 2024 includes the portion allocated under IFRS as part of the global deal with Edwards Lifesciences granting the non-exclusive global license on the Epygon valve.

Other operating income mainly consists of the Research Tax Credit for the periods presented in the amount of €1.2 million in 2023 and 2024.

The change in operating expenses between 2023 and 2024 reflects the increase in the Group's workforce and external expenses related to the development of the various clinical programs underway, in particular the launch of the DRY study.

At December 31, 2024, the Company had an average headcount of 69 employees compared with 59 at December 31, 2023.

Depreciation and amortization charges in 2023 and 2024 include in particular charges relating to technologies developed in-house.

Net financial income at December 31, 2024 includes in particular accrued interest on repayable advances offset by the change in the fair value of the liability on the Kreos stock warrants and financial income on investments made.

A consolidated net loss of €14.7 million was recorded at December 31, 2024, which is relatively comparable to the consolidated loss at December 31, 2023 (€15.6 million).

Cash and cash equivalents and investments in money market SICAVs (presented in other current financial assets under IFRS) totaled €6,616 thousand at December 31, 2024 compared with €1,657 thousand at December 31, 2023.



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.

For more information, please visit www.affluentmedical.com

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