

H1 2024 RESULTS

- Major advances in all three programs
- Several strategic agreements signed with the world medtech leader in cardiology
- Extension of financial runway to July 2025

- Several agreements signed in July 2024 with Edwards Lifesciences for an initial amount of €15m and an option to acquire the rights for Kalios™
- Positive feedback from the Food & Drug Administration (FDA) to accelerate access to the US market for Kalios™ through a simple De Novo or 510K pathway
- Progress in the ‘Dry’ pilot study with the Artus urinary sphincter, with 7 patients implanted by mid-September

Aix-en-Provence, September 26, 2024 – 5:45 p.m. CEST – Affluent Medical (ISIN: FR0013333077 – Ticker: AFME – "Affluent"), a French clinical-stage medical technology company specializing in the international development and industrialization of implantable innovative medical devices, is today publishing its financial results for H1 2024 and providing an update on its clinical and operational progress and the extension of its financial horizon until July 2025.

Strong progress with all three clinical programs

Since January 1, 2024, Affluent Medical has taken several major steps in the development of its three medical devices. At the same time, and to meet its operational needs, the Company has secured several financings and signed a strategic partnership with the leader in this space, Edwards Lifesciences.

MITRAL RING KALIOS™: Positive feedback from the FDA to quickly access the US market

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 a 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 \$1.5 billion in the US-Europe region in 2023, growing at 3.5% per year.

In line with the **US market access strategy announced in Q3 2023**, the Company made several pre-submissions to the FDA to assess the marketing authorization process for its medical device as a class 2 device, which is faster than the registration process in Europe.

In September 2024, Affluent Medical received positive feedback from the FDA on this approach and the Agency indicated that no additional patients would be required beyond the 26 patients already treated in the Optimise II study. The FDA also shared its recommendations for the long-term follow-up of patients in preparation for the future submission.

Affluent Medical's objective is to **submit a De Novo application with current clinical data at the end of 2025/early 2026, followed by commercial launch**, subject to Edwards' decisions.



MITRAL VALVE EPYGON: Acceleration of patient assessments and of activating clinical 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 to treat mitral valve 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 are able to have open heart surgery, which poses a high risk of death and hospitalization.

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 evaluations, achieving a fourfold increase in the number of patients included by the end of June 2024. The Company has increased the number of activated centers, with currently 11 centers in Europe. The selection criteria for this type of clinical study are highly stringent. As a result, Affluent Medical continues to work to increase the number of centers and has submitted applications for five new centers (in Austria, Italy, Germany and Spain), with the target of activating these sites in the coming months. **The goal is to implant up to 10 patients to complete the pilot phase.**

URINARY SPHINCTER ARTUS: seven patients already received implants; completion of pilot phase of study planned for Q4 2024

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

At the end of June, the safety criteria were met in the first two patients, who did not report any discomfort or inconvenience during the use of the device. A performance assessment will be conducted in the pivotal phase of the study, evaluating reduction in urinary leakage at three months post implantation.

As of mid-September 2024, seven patients had received an implant, representing over half of the planned patients for the pilot phase of the study. The Company plans to implant a total of 10 patients by Q4 2024 and then launch the pivotal phase of the study. An additional 60 patients are planned to be enrolled in the pivotal phase of the study, which will assess performance based on at least a 50% reduction in incontinence pads.

Ongoing support from major shareholders with two successive financings

€3.5 million capital increase subscribed by main shareholders

At the end of January 2024, Affluent Medical announced the completion of a €3.5 million bridge financing from its main shareholders (Truffle Capital, LCEA, Ginko Invest, Denos and Hayk Holding), in the form of a capital increase with cancellation of preferential subscription rights of shareholders in favor of a category of beneficiaries. The transaction enables the Company to finance operations, in particular the costs related to regulatory support for interactions with the FDA for Kalios™, the initiation of the pilot study for Artus and the continuation of the pilot study for Epygon.

Current account advances granted by reference shareholders

In April 2024, to finance its short-term operational needs, Affluent Medical carried out another bridge financing with its main shareholders in the amount of €3.5m. In the form of current account advances, the Company was able to extend its financial horizon until the end of July 2024 and explore various additional financing options. The shareholders that participated in this financing were Truffle Capital and Ginko Invest.



Signing in July 2024 of several strategic agreements with Edwards Lifesciences, a global leader in innovative solutions for cardiovascular diseases, which becomes a reference shareholder

On July 11, 2024, the Company entered into several agreements with Edwards Lifesciences relating to its interventional cardiology products (Kalios™ adjustable mitral ring) and technologies (mitral valve technology). Under these agreements, Affluent Medical received an initial cash payment of €15 million.

The three agreements break down as follows:

- **An initial payment of €5 million for an exclusive purchase option for KephaliOS**, the wholly owned subsidiary of Affluent Medical developing the innovative adjustable mitral ring Kalios™, 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'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 its right for the transcatheter pathway.** Affluent Medical is eligible to receive future royalties on all products that may be marketed using the licensed patents throughout the lifetime of these patents. Affluent Medical retains all rights to the transcatheter valve patents, including those for its Epygon mitral valve, which is currently in clinical development.
- **A €5 million payment as part of Edwards Lifesciences' acquisition of a stake in Affluent.** Edwards Lifesciences invested €5 million to acquire a stake in Affluent Medical, becoming a 9.21% shareholder. This investment was made as part of a capital increase with cancellation of preferential 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 July 11, 2024. **This strategic investment by Edwards Lifesciences marked an important step in the development of Affluent Medical, recognizing the innovation of its products.**

With the initial cash payment of €15 million received under these agreements, Affluent Medical's financial runway was extended by more than one year to July 2025.

In addition to this initial payment, in accordance with the agreements, **new payments could be made to Affluent, in particular, related to the exercise of the exclusive purchase option for KephaliOS, which would be triggered based on the results of the ongoing Optimise II pivotal clinical study with Kalios™, as well as royalty payments on the sales of surgical valves using Affluent's technology.**

**FINANCIAL STATEMENTS FOR H1 2024**

The main financial items under IFRS are presented in the table below and were approved by the Board of Directors at its meeting on Tuesday, September 24, 2024. The Statutory Auditors conducted a limited review of the half-year financial statements.

The full financial statements are available on the Company's website: www.affluentmedical.com.

Consolidated income statement (in thousands of euros)	6/30/2024	6/30/2023
	6 months	6 months
Other operating income	661	590
Purchases consumed	(918)	(1,037)
External costs	(3,721)	(2,828)
Personnel expenses	(3,691)	(2,996)
Taxes and duties	(36)	(49)
Provisions net of reversals	11	-
Other current operating income and expenses	89	101
Depreciation and amortization	(1,202)	(1,206)
CURRENT OPERATING INCOME	(8,807)	(7,425)
OPERATING INCOME after share of net income of equity affiliates	(8,807)	(7,425)
Net financial income	(638)	(633)
Income taxes	77	78
NET INCOME (LOSS)	(9,368)	(7,980)
Cash flow from operating activities	(3,702)	(8,531)
Cash flow from investing activities	(64)	(34)
Cash flow from financing activities	3,023	12,531
Increase (decrease) in cash	(743)	3,966
Cash and cash equivalents	914	6,545

During H1 2024, consumed purchases decreased by €119,000 compared with H1 2023, with a decrease of €141,000 in external study expenses.

The change in external costs between the two periods was mainly due to consulting, engineering and recruitment fees, up by €901,000.

The €405,000 increase in personnel expenses in the first half of 2024 was due to the increase in the Group's workforce in research and development, clinical activities and management functions.

The Group had an average headcount of 66 employees at the end of H1 2024, compared with 52 one year previously.

In the first half of 2024, financial income included: accrued interest of €618,000 on repayable advances (Mivana and PIAVE Artus); accrued interest of €38,000 on current account advances received in May 2024 from certain shareholders; interest paid of €63,000 (€27,000 in the first half of 2023) in connection with the pre-financing of research tax credit receivables; financial interest on leases of €21,000; the accretion of repayable advances in accordance with IAS 20 "Accounting for Government Grants and Disclosure of Government Assistance" of €7,000; and changes in the fair value of liabilities derivatives amounting to +€100,000 (+€53,000 in the first half of 2023).

The Company reported a net loss of €9.4 million in H1 2024, compared to a net loss of €8.0 million in the prior year period.



Availability of the 2024 half-year financial report

The interim financial report for 2024 is available to the public and was filed with the French Financial Markets Authority on September 26, 2024. It is also available on the company's website in the Investors section.



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

Contacts:

AFFLUENT MEDICAL

Sébastien LADET
Chief Executive Officer
investor@affluentmedical.com

PRIMATICE

Public Relations France
Thomas ROBOREL de CLIMENS
+33 (0)6 78 12 97 95
thomasdeclimens@primatice.com

SEITOSEI.ACTIFIN

Financial communications / Press relations

Ghislaine GASPARETTO / Jennifer JULLIA
+33 (0)6 21 10 49 24 / +33 (0)1 56 88 11 19
ghislaine.gasparetto@seitosei-actifin.com /
jennifer.jullia@seitosei-actifin.com

MC SERVICES AG

Media relations Europe

Caroline BERGMANN / Kirsten RÜHL
+49 (0)211 529252 20 / +49 (0)211 529252 16
affluent@mc-services.eu