PRESS RELEASE

H1 2025 RESULTS:
Affluent Medical took major new and transformative steps during the first half of 2025

- Success of the pilot phase of the clinical trial on Artus and start of the pivotal phase;
- US regulatory trajectory on Kalios confirmed with the FDA;
- Continuation of the pilot phase of the clinical trial on Epygon and promising results on hemodynamic properties;
- Medical expertise enhanced with the recruitment of two strategic medical directors – cardiologist Prof. Howard Herrmann and urologist Prof. Nicolas Barry Delongchamp;
- Extension of the horizon of the cash position to end-2025 thanks to the support of historical shareholders.

Aix-en-Provence, 30 September 2025 - 5.45 p.m. CEST - Affluent Medical (ISIN: FR0013333077 – ticker: AFME – "Affluent"), a French clinical-stage medical technology company specialised in the international development and industrialisation of innovative implantable medical devices, is today publishing its 2025 first-half results and providing an update on recent clinical, regulatory and financial milestones.

Sébastien Ladet, Chief Executive Officer of Affluent Medical, said:

"This first half of 2025 marks several important milestones for Affluent Medical. With the completion of the pilot phase of the clinical trial and launch of the pivotal phase for Artus, ongoing interaction with the FDA on the regulatory trajectory for Kalios™ in the US and the first hemodynamic results of Epygon, we have reached major milestones that bring our three medical devices closer to market launch.

Our mission is clear: to transform disruptive innovations into concrete solutions to meet two major health challenges, mitral valve insufficiency and urinary incontinence, two pathologies that affect several million patients worldwide and for which no satisfactory therapeutic solution has been found to date. Backed by a strengthened Board of Directors and the renewed commitment of our shareholders, we are moving decisively towards the marketing phase, confident in our ability to create sustainable value for patients, physicians and our partners."

NEW MAJOR AND TRANSFORMATIVE STEPS TAKEN IN THE FIRST HALF OF 2025

The first half of 2025 saw Affluent Medical reach a turning point in the execution of its roadmap. The robustness of its clinical portfolio was confirmed with critical milestones reached on its three leading medical devices, while its governance was strengthened and financial visibility secured.

ARTUS URINARY SPHINCTER: completion of the pilot phase and launch of the pivotal phase in Europe

Artus is the first artificial urinary sphincter for the treatment of moderate to severe urinary incontinence that can be activated by the patient using a simple remote control. Urinary incontinence is a major public health problem for over 400 million people worldwide for which there has been no breakthrough in the last 40 years. Patients suffer a reduced quality of life associated with the psychological disorders related to the disease.

The first half of 2025 marked a turning point for Artus.

In January 2025, Affluent Medical announced the completion of the pilot phase of the European multicentre clinical trial in humans with the success of the tenth minimally invasive implantation of the urinary sphincter.

In April 2025, Affluent Medical announced that it had made progress towards launch of SPHINX, the clinical trial on implantation in women. This study, which is expected to be launched across Europe during the second half of 2025, will assess the safety profile and performance of the Artus artificial urinary sphincter in female patients at major medical centres in France and Europe. This is an important step in expanding the range of treatment options available to women with stress urinary incontinence (SUI).

A first implantation of the Artus device in a female anatomical model was successfully performed by Professor Véronique Phé, a leading European urologist at the Tenon Hospital in Paris, to assess the implantation process in women. Using the Da Vinci robotic laparoscopy system, it has been confirmed that the device can be implanted with precision and ease, demonstrating that it is perfectly suited for minimally invasive surgery.

In May 2025, the external Data Monitoring and Safety Board (DSMB) authorised the initiation of the pivotal phase of the DRY multicentre study following the positive review of the safety profile of the pilot clinical phase. The pivotal phase aims to validate the efficacy of Artus in reducing urinary leakage by at least 50% and will enrol dozens of patients in leading urology centres in Italy, Spain, France and Belgium, in addition to countries already approved for the pilot study.

KALIOS™ MITRAL RING: acceleration of the regulatory trajectory for marketing in the US

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 at 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 overall 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™: the Food and Drug Administration (FDA) validated a strategy of accelerated access to the US market via 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 Company's submission and marketing process.

Combined with the exclusive purchase option granted to Edwards Lifesciences, the global leader in structural cardiology, this advance reinforces the potential of Kalios™ and strengthens its strategic positioning in the strategically important North American market.

During the first half of the year, the Company finalised work on adapting the supply chain to the requirements of the FDA, notably with the selection and commissioning of suppliers.

The objective remains to be able to file for market access based on the current clinical data, followed by marketing, based on the decisions of its partner Edwards Lifesciences.

EPYGON MITRAL VALVE: acceleration of the clinical programme

Epygon is the only biomimetic cardiac mitral valve, mimicking the anatomy of the native mitral valve and physiological blood flows, implantable via transcatheter delivery. This transcatheter approach avoids an invasive open-heart procedure and associated complications in treating mitral failure.

This serious and potentially fatal disease affects 2% of the world's population, around 160 million people. However, less than 4% of patients with a severe form can have open-heart surgery, which poses a high risk of death and hospitalisation.

In 2024, the clinical programme was accelerated, with a four-fold increase in patient recruitment in the first half of the year and the gradual opening of new European centres. Eleven centres are now active, and five more – in Austria, Italy, Germany and Spain – are being evaluated to further expand the ability to include new patients in the study. The objective is to finalise the pilot phase with implantation in ten patients.

This clinical programme is also being supported by a high-level scientific collaboration with the Mayo Clinic (USA), which aims to document the unique hemodynamic benefits of Epygon's asymmetric design. These

advances confirm the positioning of this device in the growing market for transcatheter mitral valve replacement (TMVI), in which Epygon is expected to emerge as a standard solution.

Strengthened governance and medical expertise

Affluent Medical has strengthened its organisation to prepare for the transition to the marketing phase. In February 2025, Liane Teplitsky, CEO of Artedrone and a recognised expert in the MedTech sector, joined the Board of Directors.

Then, in March 2025, three key appointments were made in medical and clinical expertise:

- Dr. Howard C. Herrmann (University of Pennsylvania), Strategic Medical Director in Structural Cardiology,
- Prof. Nicolas Barry Delongchamps (Cochin Hospital, Paris), Strategic Medical Director in Urology, and
- Federica Azzimonti, Director of Clinical Operations, an expert in international trials.

These appointments give the Company leading governance and expertise to bring its medical devices to the market.

Extended financial visibility thanks to the support of historical shareholders

In June, Affluent Medical raised €5.4 million via a convertible bond issue that was fully subscribed by its historical shareholders: Truffle Capital, Financière Memnon, Hayk Holding Sàrl, Mrs Simone Merkle, and Ginko Invest.

This transaction extends the horizon of the cash position until the end of the 2025 financial year, making it possible to finance the next stages of value creation on its three programmes: 41% of the funds are allocated to Artus, 38% to Kalios™ and 21% to Epygon.

The renewal of this support illustrates the shareholders' confidence in the Company's strategy and in its ability to transform its clinical advances into market opportunities.

H1 2025 FINANCIAL RESULTS

The main financial items under IFRS are presented in the table below and were approved by the Board of Directors at its meeting of 29 September 2025. The Statutory Auditors conducted a limited review of the interim financial statements.

The full financial statements are available on our website: www.affluentmedical.com.

Consolidated income statement (in €k)	30/06/2025 6 months	30/06/2024 6 months
Other operating income	577	661
Consumed purchases	(1,719)	(918)
External expenses	(2,706)	(3,721)
Personnel expenses	(4,090)	(3,691)
Taxes	(39)	(36)
Allocations to provisions net of reversals	-	11
Other current operating income and expenses	59	89
Depreciation and amortisation	(1,173)	(1,202)
CURRENT OPERATING INCOME (LOSS)	**(9,091)**	**(8,807)**
OPERATING INCOME (LOSS) after share in net income of associates	**(9,091)**	**(8,807)**
Net financial income	(311)	(638)
Income tax	30	77
NET INCOME (LOSS)	**(9,372)**	**(9,368)**
Cash flow from operating activities	(6,791)	(3,702)
Cash flow from investment activities	5,213	(64)
Cash flow from financing activities	5,689	3,023
Increase (decrease) in cash	**4,113**	**(743)**
Cash and cash equivalents	**5,336**	**914**

During the first half of 2025, consumed purchases increased by €801k compared with the first half of 2024, with the €1,048k increase in external research expenses related to the accelerated development of Kalios, and the finalisation of the pilot phase and start of the pivotal phase for Artus.

The change in external expenses between the two periods is mainly due to a decrease in consulting, engineering and recruitment fees of €854k.

The €556k increase in personnel expenses between the first half of 2024 and the first half of 2025 (excluding the effect of IFRS 2 – share-based payments) can be explained by the gradual increase in the Group's workforce in research and development, clinical activities and management functions.

The Group had an average headcount of 76 employees in the first half of 2025 compared with 66 in the first half of 2024.

Net financial income breaks down mainly as follows in the first half of 2025:

- accrued interest of €641k (€618k in the first half of 2024) on repayable advances (Mivana and PIAVE);
- changes in the fair value of derivative liabilities in accordance with IFRS 9 "Financial Instruments" for +€53k (+€100k in the first half of 2024);
- the change in the fair value of derivative net assets linked to convertible bonds issued in June 2025 in the amount of +€320k.

Lastly, there was a net loss in the first half of 2025 of €9.4m, after a loss of €9.4m in the first half of 2024.

Availability of the 2025 interim financial report

The H1 2025 financial report is available to the public from the AMF with which it was filed on 30 September 2025. It is also available on the "Investors" page of the Company's website.

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

Contacts:

AFFLUENT MEDICAL

Sébastien Ladet
CEO
investor@affluentmedical.com

SEITOSEI.ACTIFIN
Financial communication
Ghislaine Gasparetto
+33 (0)6 85 36 76 81
ghislaine.gasparetto@seitosei-actifin.com
Press Relations
Jennifer Jullia
presse@seitosei-actifin.com