PRESS RELEASE

2023 financial results and update on clinical activities under development

- Excellent one-year interim follow-up results with the Kalios™ mitral ring and strategic shift towards the US market
- Excellent performance of the Epygon valve after one year of follow-up and growing recognition of the biomimetic mitral valve concept
- First in human successful implantation for the Artus artificial sphincter, for the treatment of urinary incontinence
- Reiterated confidence of key shareholders through the granting of current account advances, extending its financial horizon until end of July 2024

Aix-en-Provence, 25 April 2024 – Affluent Medical (ISIN: FR0013333077 – Ticker: AFME), a French clinical-phase MedTech company specialising in the international development and industrialisation of innovative medical prostheses, is today publishing its 2023 annual results and providing an update on its clinical studies.

Several key milestones achieved in 2023

Several key milestones were achieved in 2023, especially regarding the progress of clinical studies, with the start of the Epygon pilot study and the excellent clinical results for Kalios™ in terms of efficacy and safety profile at one year. The period was also marked by the strengthening of the management team by adding valuable expertise to the important areas of product development through to marketing.

At the same time, the Company successfully completed a financing in the form of a capital increase with pre-emptive subscription rights maintained, carried out by issuing shares with redeemable share subscription warrants in the gross amount of €13.7 million and with the acquisition of 10% of the share capital by LCEA.

Kalios™: Strategic shift towards the US market following the positive one-year results of the Optimise II pivotal study

Kalios™ is the only mitral valve annuloplasty device that can be percutaneously adjusted to treat residual and recurrent mitral insufficiency at any time after implantation, repeatedly and with a beating heart, thereby avoiding another open-heart operation. Affluent Medical estimates that Kalios™ would avoid repeat surgery for 30-40% of patients within five years of their operation.

The market for mitral valve repair surgery was worth an estimated at $1.5 billion in 2023 in the US and Europe, up 3.5% per year.

The Optimise II pivotal study on Kalios™ was designed to assess the medical device's safety and efficacy in the surgical treatment of mitral regurgitation with catheter-based adjustment.

In September 2023, the Company presented interim data on 20 patients treated in five clinical centers in Europe after one year of implantation. After one year, none of the patients had mitral regurgitation > 2+, which met the study's primary objective.

The study's safety profile is excellent: no deaths, myocardial infarction, valvular thrombosis or endocarditis were reported. The study involved 13 patients with degenerative mitral regurgitation and 7 with functional mitral regurgitation. Five intraoperative adjustments were performed, and one patient was adjusted 11 months after

surgery. From the four patients adjusted perioperatively, with one year follow up, excellent results were observed and were maintained (grade 1+).

Following the analysis of these positive one-year data, Affluent Medical decided to refocus its resources on the US market and enter into discussions with the US Food and Drug Administration (FDA). In December 2023, the Company made a pre-submission to the FDA to assess the marketing authorisation process for its Kalios™ medical device as a Class 2 device that can rely on an equivalent (510(k)) or a risk analysis (De Novo). Class 2 pathway would allow simplified access to the market compared to the initial European strategy.

The US market offers several marketing advantages; the average selling price of a mitral ring is 25-30% higher than in Europe and obtaining approval in the US is perfectly aligned with the strategy to secure commercial partners primarily located in the US (Medtronic, Boston Scientific, Abbott, Edwards Life Science, etc.). As such, the European study was suspended during this strategic refocusing.

Epygon: First successful implantation of the valve and opening of new investigation centres

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. The TMVI (transcatheter mitral valve implantation) market for endovascular valves has greater market potential than TAVI (transcatheter aortic valve implantation – over $8 billion at maturity), according to Allied Market Research and Azoth Market Research.

In March 2023, Affluent Medical announced the successful first implantation of the Epygon biomimetic mitral heart valve in a patient presenting a profile of severe mitral insufficiency associated with several comorbidity factors.

This implantation was performed by the minimally invasive transcatheter route, by Prof. Stefano Salizzoni, MD, PhD – co-investigator in the Minerva pilot clinical study – and his team, at the Molinette Hospital of Health and Science in Turin, Italy. After one month of follow-up, the patient improved her functional condition, increasing her New York Heart Association (NYHA) functional status from III to II; this results in a resumption of the person's daily activities without becoming completely breathless. The echocardiogram showed excellent function of the Epygon valve.

Approval by the data monitoring and safety committee enabled the Company to treat other patients with the Epygon valve. Two additional investigation centres were approved to participate in the clinical trial (Seville and Budapest). Applications were submitted at five new centres (Linz in Austria, Modena and Milan in Italy, Bad Nauheim in Germany, and Madrid) with the target to open these new centres by the second half of the year.

Affluent Medical accelerated patient assessments to 92 patients in 2023, with the goal of implanting up to 10 patients to complete the pilot phase. A Simulands simulator was developed and validated in 2023 to strengthen the surgical training of clinical investigators and provide the Company with greater organisational flexibility. The Company has also expanded the valve-size portfolio with two new sizes (40 and 42) and has initiated activities to enable the treatment of patients with size 44. These additional developments will speed up patient screening as they are progressively approved at the investigation centres.

Artus: Start of the European pilot study

Affluent Medical points out that the Artus medical device is the first mechanical artificial sphincter that patients can activate via remote control, for the treatment of moderate to severe urinary incontinence in both men and women. The urinary sphincters currently on the market were not initially developed for women, even though women account for 80% of patients. According to Optima Insights, the global market for medical devices for treating urinary incontinence (including strips, neurostimulators and artificial sphincters) is expected to reach $4.3 billion by 2027, growing an annual 11% on average between 2019 and 2027.

In December 2023, the first clinical investigation centre in Prague, Czech Republic, began screening patients to initiate the Dry pilot study. Several other centres have opened in Europe, including in Poland, where the first phase of the assessment and approval of the protocol with the ethics committee has been completed. Affluent Medical is awaiting approval from the Polish authorities to begin patient recruitment. A total of 70 patients are to be recruited for the pilot and pivotal phases of this study.

The pilot phase, which is expected to be completed by the second half of 2024, will first focus on men, then another pilot study will initiate trials in women.

Urinary incontinence is a major public health problem for over 400 million people worldwide without any innovation for 40 years, with patients suffering from poor quality of life associated with the psychological disorders linked to this condition.

Success of the 2023 capital increase

On 6 March 2023, Affluent Medical announced the success of its capital increase with pre-emptive subscription rights maintained, carried out by issuing shares with redeemable share subscription warrants in the gross amount of €13.7 million (excluding any exercise of the redeemable share subscription warrants).

Changes in shareholder structure and governance

Following LCEA's subscription to the capital increase carried out by Affluent Medical on 6 March 2023, the fund management Company became the second largest shareholder in Affluent Medical, with 10.25% of the share capital and 7.10% of the voting rights alongside the long-standing shareholder Truffle Capital. Vincent Bourgeois was co-opted as director to represent LCEA, this new shareholder.

Strengthening of the executive committee with several appointments

In January 2023, Affluent Medical announced the recruitment of three members of the management team with the appointment of Céline Buard as Marketing Director, Olivier Belamy as Industrialization Director and Claire André as Quality Assurance Director.

In July 2023, Affluent Medical announced the appointments of Christophe de Vregille as Chief Financial Officer and Benjamin Renault as Development Director.

These five experienced individuals joined the existing management team to support the execution of the development plan and address the next steps leading to the marketing of Affluent Medical's three advanced medical devices.

POST-CLOSING EVENTS

Since the beginning of 2024, Affluent Medical has made substantial new advances for each of its three medical devices.

Kalios™: 510(k) premarket notification filed with the FDA

A 510(k) or De Novo is a premarket submission to the FDA to demonstrate that the device being assessed is as safe and effective as another comparable device already on the market.

Affluent Medical held a meeting with the FDA in Q1 2024 to discuss its comments. The encouraging observations at this meeting will be taken into account as part of the market access strategy for Kalios™ in accordance with US regulations. An additional pre-submission to the FDA is planned for Q3 2024 to finalise the validation of the regulatory strategy.

Epygon: Exceptional performance of the Epygon valve after one year

An article on the success of the first in human implantation of its transcatheter mitral valve Epygon entitled "*A Mono-Leaflet, Low-Profile Transcatheter Mitral Prosthesis: First-in-Human Implantation*" was published in the prestigious Journal of the American College of Cardiology: Cardiovascular Interventions.

In February 2024, 1-year follow-up of the first patient was performed and the transoesophageal echocardiographic examination revealed excellent valve performance, with no mitral regurgitation or para-valvular leakage.

Lastly, a survey of over 60 interventional cardiologists and heart surgeons found that 70% of interventional cardiologists refer their patients to heart surgeons, underlining the differentiation of the Epygon valve in preserving the natural vortex (blood circulation in the heart) allowing a better patient recovery.

Artus: Success of the first in human implantation of the Artus artificial sphincter for the treatment of stress urinary incontinence

A first in human implantation of the minimally invasive Artus medical device for the treatment of urinary incontinence as part of the European pilot study was announced in March 2024.

This first implantation of the Artus artificial 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, on a 68-year-old man with severe urinary incontinence. The device will be activated approximately six weeks after implantation as soon as wound healing after surgery is complete.

Affluent Medical intends to treat ten men as part of the pivotal study by the second half of 2024 before initiating trials in women at the end of the year.

Bridge financing of €3.5 million

At the end of January 2024, Affluent Medical announced the completion of €3.5 million in bridge financing from its main shareholders (Truffle Capital, LCEA, Ginko Invest, Denos and Hayk Holding), in the form of a capital increase with the cancellation of pre-emptive subscription rights of shareholders for a category of beneficiaries. The transaction enables the company to finance its operational needs, including covering costs related to regulatory support for interactions with the FDA concerning Kalios™, the initiation of the pilot study in men for Artus and the continuation of the pilot study for Epygon. With this bridge financing, the financial horizon was extended until May 2024 without impacting operational activities.

Reiterated confidence of key shareholders through the granting of current account advances, extending its financial horizon until July 2024

To enable its short-term operational needs, Affluent Medical secured a new bridge financing from its main shareholders in the amount of €3.5 million. This financing was carried out in the form of current account advances enabling the Company to extend its financial horizon until end of July 2024. The shareholders participating in this financing were as follows: Truffle Capital, Ginko Invest.

At the same time, the Company continues to actively explore various additional financing options that may include capital increases, as well as strategic partnerships, reflecting its commitment to securing the resources necessary for its future developments.

2023 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 24 April 2024. They are audited by the Statutory Auditors and the audit report relating to the 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 on 30 April 2024: www.affluentmedical.com.

In €k, at 31 December (audited financial statements – IFRS)	31/12/2023 12 months	31/12/2022 12 months
Other operating income	1,224	1,339
Consumed purchases	(2,132)	(2,443)
External expenses	(6,017)	(5,566)
Personnel expenses	(6,141)	(5,213)
Taxes	(97)	(85)
Allocations to provisions net of reversals	-	119
Other current operating income and expenses	178	9
Depreciation and amortisation	(2,413)	(2,450)
CURRENT OPERATING INCOME	**(15,398)**	**(14,290)**
OPERATING PROFIT (LOSS) after share in net income of associates	**(15,398)**	**(14,290)**
Net financial income	(405)	(1,110)
Income tax	150	173
NET INCOME	**(15,653)**	**(15,227)**
Cash flow from operating activities	(12,054)	(11,081)
Cash flow from investment activities	(184)	(146)
Cash flow from financing activities	11,316	2,401
Increase (decrease) in cash	**(922)**	**(8,826)**
Cash and cash equivalents	**1,657**	**2,579**

Other operating income mainly consists of the Research Tax Credit paid in respect of 2023, totalling €1.2 million.

The change in operating expenses at the end of 2023 reflects the increase in the Group's workforce, with the recruitment of new members of the executive committee and external expenses as part of the development of the various ongoing clinical programmes. At the end of the financial year, the Company had an average headcount of 59 employees, versus 54 at the end of 2022.

Depreciation and amortisation charges include, in particular, charges relating to technologies developed in-house.

Financial income at 31 December 2023 notably includes interest paid and the balance of the amortised cost of bonds in the amount of -€0.4 million.

Net income showed a loss of €15.6 million, relatively stable compared with net income in 2022.

About Affluent Medical

Affluent Medical is a French MedTech company, founded by Truffle Capital, with the ambition to become a global leader in the treatment of structural heart diseases, which are the world's leading cause of mortality, and urinary incontinence, which currently affects one in four adults.

Affluent Medical develops next-generation, mini-invasive, innovative, adjustable, and biomimetic implants to restore critical physiological functions. The product candidates developed by the Company are currently all in clinical studies.

Subject to raising the necessary funds to finance its strategy and to positive results from ongoing clinical studies, the Company's ambition is to gradually commercialize its products early 2026.

For more information, visit www.affluentmedical.com

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