PRESS RELEASE

2022 full year results and update on clinical activities under development.

- **Excellent interim results from the Optimise II pivotal study for the Kalios™ mitral ring and increase in the number of clinical centers.**
- **First successful clinical implantation of the Epygon mitral heart valve by minimally invasive transcatheter approach.**
- **Appointment of a new management team and strengthening of the leadership team to accelerate clinical studies and prepare for commercialization.**
- **New sources of financing to support the advancement of the three clinical studies and the next development steps.**

Aix-en-Provence, March 30, 2023 - 17:45 pm CET- Affluent Medical (ISIN code: FR0013333077 – ticker: AFME), a French MedTech specializing in the international development and industrialization of innovative medical prostheses, at a clinical stage, to treat mitral heart valve pathology and urinary incontinence, today released its annual results for 2022 and provided an update on the development of its various clinical studies.

SIGNIFICANT PROGRESS ACHIEVED IN 2022 AND EARLY 2023

The year 2022 was a pivotal year for the progress of the various clinical studies underway, with the structuring of teams around a strengthened leadership team to prepare and accelerate the recruitment of patients in clinical studies, industrialization and marketing. The recruitment and implementation of field clinical specialists has been carried out for Germany, Austria, Italy and Spain to ensure the proper recruitment of patients in clinical trials. At the same time, an initial financing in the form of a capital increase with preferential subscription rights (DPS) was successfully completed last September for a gross amount of €6 million.

Epygon: Initial success of the first transcatheter clinical implantation in Italy

Epygon is the only biomimetic cardiac mitral valve that mimics the anatomy of the native mitral valve, the physiological blood flow and can be implanted through transcatheter approach. This approach avoids an invasive "open heart" procedure and associated complications to treat cardiac mitral insufficiency.

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

The TMVI (transcatheter mitral valve implantation) market for endovascular valves has a larger market potential than TAVI (more than $8 billion at maturity) according to Allied Market Research and Azoth Market Research.

Minerva's pilot clinical study of the minimally invasive Epygon medical device to treat mitral valve regurgitation is currently being conducted in several investigative centers in Italy, Austria and Spain.

During the last quarter of 2022, 3 additional centers were approved to participate in the clinical trial in Turin, Innsbruck and Belgrade bringing the total number of centers to 9.

At the end of 2022, the Company finalized the development of valve sizes 40 and 42 and submitted the clinical amendments, already accepted in Spain and Austria. This important step will accelerate patient recruitment, as the company estimates that 35% of patients evaluated will require sizes 40 and 42.

On March 9, 2023, Affluent Medical announced the first successful clinical implantation of its Epygon transcatheter mitral heart valve in a patient in Italy. The procedure was performed in a beating heart by Prof. Salizzoni in Turin with a valve placement time of fifteen minutes and very positive feedback on the ease of use of the product. The patient quickly presented a satisfactory state of health and was discharged from the hospital at D+5. The discharge visit showed a very good echographic result regarding the mitral valve: no left ventricular outflow tract obstruction, no regurgitation, no gradient, and no para-valvular leak. This first implantation represents encouraging initial results regarding the benefit of the biomimetic design of the Epygon valve.

Seven additional centers are being evaluated in Spain, Italy, Hungary, and Germany to secure our pilot study objective and prepare for the pivotal study. The number of patients evaluated has increased significantly, +80%, since July 2022.

The study will evaluate several dozen patients to implant the Epygon valve in 10 to 15 adult patients with severe mitral regurgitation, with a NYHA[1] functional class III to IV, and an LVEF (ejection fraction) greater than or equal to 30%. These patients are all at high risk for open mitral valve surgery and are therefore eligible for transcatheter repair.

The objectives of the study are to evaluate the safety and efficacy of Epygon valve implantation at 30 days. Patients will be followed for 5 years.

Kalios™: Excellent interim results from the Optimise II pivotal study and opening of additional clinical centers

Kalios™ is the only mitral annuloplasty device that can be adjusted percutaneously to treat both residual and recurrent mitral insufficiency at any time after implantation, repeatedly and with a beating heart, thereby avoiding a repeat open-heart operation. Affluent Medical estimates that Kalios™ would prevent repeat surgery for potentially 30-40% of patients within 5 years. The market for mitral valve repair surgery is estimated to be worth $1.5 billion in the US-Europe region in 2023, growing at 3.5% per year.

The European Optimise II pivotal study of Kalios™ underway in 8 European centers with 26 patients was designed to evaluate the safety and efficacy of the device for the surgical treatment of mitral regurgitation with non-surgical adjustments.

An additional 1 center has received approval in Germany and dossiers have been submitted in 5 other clinical centers in Italy, Germany and Serbia. 3 additional centers in Germany are under evaluation. The total number of clinical centers will be between 15 and 20 in order to accelerate patient recruitment in the Optimise II study.

MRI compatibility has also been conditionally validated in 2022 and amendments submitted in clinical centers with retroactive effect on patients already implanted have been adopted.

In this study, excellent interim results were announced in July 2022, confirmed by additional results presented at the EACTS - European Association of Cardio-Thoracic Surgery Congress - in early October 2022, following the follow-up of 8 additional patients.

The 26 patients included in this study are distributed in 5 centers (Vienna, Cotignola, Florence, Leipzig and Passau), with half of the patients having primary (degenerative) mitral regurgitation and the other half having functional secondary mitral regurgitation. More than 80% of patients had NYHA[2] <2 at discharge, and these results were maintained up to 6 months. The safety profile of the study was excellent, no deaths were reported, 4 major cardiac events in 3 patients were observed at 30 days.

In 6 cases (24%), a post-implantation adjustment was performed because of residual or recurrent grade 3 to 4 regurgitation. Five adjustments were performed during implantation to avoid prolonged surgery and extracorporeal circulation reconnection. Finally, an adjustment at 11 months after implantation was performed without the patient having to undergo another lengthy and extensive open-heart surgery.

[1] *Ejection fraction: The ejection fraction (EF) is the percentage of blood in the main pumping chamber that is ejected with each beat. It can be easily estimated by echocardiography.*

[2] *NYHA: The NYHA classification is a clinical severity scale for heart failure with diagnostic, prognostic and therapeutic value.*

The study plans to recruit a total of 62 patients and is expected to be completed in the second half of 2023.

Artus: Pilot study to start in the first half of 2023

Artus is the first patient-activated artificial sphincter for the treatment of moderate to severe urinary incontinence.

Urinary incontinence is a major public health problem for more than 400 million people worldwide with no innovation in the last 40 years and patients suffering from a degraded quality of life associated with psychological disorders related to the pathology.

According to Optima Insights, the global market for medical devices to treat urinary incontinence (slings, neurostimulators, artificial sphincters) is expected to be $4.3 billion by 2027, growing at a CAGR of 11% between 2019 and 2027.

The European Dry pilot study on the Artus medical device for the treatment of urinary incontinence in men will be initiated in the first half of 2023 and is to be followed immediately by a pivotal study ending in the second half of 2024.

1 clinical center is open in Prague and several centers are being opened in Spain, Poland and Belgium for the pilot phase.

A total of 70 patients are expected to be enrolled in the pilot and pivotal phases of this study. In 2024, the Company should start a clinical study in Europe in women and a study in the United States to access this market.

Strengthening of the governance and the Management Committee to address the next stages of development

Following the appointment of Sébastien Ladet as Chief Executive Officer in July 2022 and Michel Therin as Chairman of the Board of Directors in December 2022, several key recruitments were made at the beginning of 2023 within the management team to prepare for the next stages of industrialization and marketing of the three innovative medical devices, Kalios™, Artus and Epygon.

Thus, following the strengthening of the clinical team with the arrival of Christophe Giot as Vice President of Clinical Affairs in July 2022, the Company has recruited three new members of the Management Committee with the arrival of Céline Buard as Marketing Director, Olivier Belamy as Director of Industrialization and Claire André as Director of Quality Assurance.

Successful capital increases with preferential subscription rights in September 2022 and March 2023

On September 20, Affluent Medical announced the success of its capital increase through the issuance of new shares with preferential subscription rights, raising a gross amount of €6.0 million.
On March 2, 2023, Affluent Medical carried out a new capital increase by issuing shares with redeemable warrants for a gross amount raised of €13.7 million (excluding the possible exercise of the BSARs).

SUMMARY FINANCIAL RESULTS 2022

The main IFRS financial information is presented in the table below and was approved by the Board of Directors at its meeting of March 28, 2023. They have been audited by the Statutory Auditors and the audit report relating to the certification is being issued.

The complete financial statements will be included in the Universal Registration Document which will be posted on the Company's website on April 28, 2023: www.affluentmedical.com.

€k, At 31 December Audited consolidated income statement (IFRS)	31/12/2022 12 months	31/12/2021 12 months
Other operating income	1,339	1,451
Purchases consumed	(2,443)	(2,518)
External expenses	(5,566)	(5,496)
Personnel expenses	(5,213)	(4,405)
Taxes and duties	(85)	(88)
Provisions net of reversals	119	98
Other current operating income and expenses	9	145
Depreciation and amortization	(2,450)	(2,420)
CURRENT OPERATING INCOME	**(14,290)**	**(13,233)**
OPERATING INCOME after share of net income of equity affiliates	**(14,290)**	**(13,247)**
Financial income (expense)	(1,110)	(2,010)
Income taxes	173	437
NET INCOME (LOSS)	**(15,227)**	**(14,820)**
Cash flow from operating activities	(11,081)	(12,364)
Cash flow from investing activities	(146)	(160)
Cash flow from financing activities	2,401	18,281
Increase (decrease) in cash	**(8,826)**	**5,757**
Cash and cash equivalents	**2,579**	**11,405**

Other operating income consists mainly of the Research Tax Credit paid for 2022 for €1.3 million.

The change in operating expenses at the end of 2022 reflects the strengthening of the Group's workforce with the recruitment of new members of the Management Committee and external expenses in the context of the development of the various clinical programs in progress (external expenses for 2021 included €1,181k of expenses related to the IPO). The Company had an average of 54 employees at the end of the year, compared with 48 at the end of 2021.

Depreciation and amortization expenses include in particular expenses relating to internally developed technologies.

Financial result at December 31, 2022 includes interest paid and amortized cost of bonds for -0.3 M€, accrued interest on repayable advances for €-0.7 million and the change in fair value of derivative liabilities for € -0.1 million.

The net result is a loss of €15.2 million, relatively stable compared to the net result of 2021.

The increase in net debt in 2022 of €6.8 million is mainly explained by the repayments made in 2022 on the bond issued to Kreos Capital for €1.1 million and by the repayment of the balance of the second tranche of the 2019 CBs to Head Leader in January 2022 for €1 million. These debt reductions are more than offset by a reduction in cash of €8.8 million.

The latest fundraising completed on March 6, 2023, allows Affluent Medical to extend its cash horizon until November 2023. To ensure the financing of its future developments and the pursuit of its strategy beyond November 2023, Affluent Medical intends to look for new financing solutions, notably through the implementation of a venture loan for an amount of €6 million for which discussions have been initiated, through a capital increase depending on market conditions, or through non-dilutive financing within the framework of an innovation aid scheme in the form of subsidies and reimbursable advances aimed at financing clinical programs.

The Group could also enter into partnerships for its Kardiozis technology and for its Artus, Epygon or Kalios™ medical devices on the American market, which would be a source of revenue.

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 in preclinical and clinical studies.
Kalios™, the first mitral adjustable annuloplasty ring, should be the first Affluent Medical device to be marketed. Subject to raising the necessary funds to finance its strategy and to positive results from ongoing clinical studies, the Company's ambition is to progressively commercialize its products starting in 2025.

For more information: www.affluentmedical.com

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