PRESS RELEASE

H1 2023 RESULTS

Major advances in clinical programs

Extension of cash horizon to February 2024

- **Progress in structural heart activities:**
  - First successful implantation of the Epygon valve and continuation of the pilot study
  - Excellent clinical results for Kalios in terms of efficacy and an excellent 1-year safety profile
- **Financing of clinical operations:**
  - Successful capital increase carried out in March 2023, totaling €13.7m
  - Extension of financial visibility until February 2024

Aix-en-Provence, September 28, 2023 – 5:45 pm CEST – Affluent Medical (ISIN code: FR0013333077 – ticker: AFME), a French clinical-stage MedTech company specializing in the international development and production engineering of innovative medical prostheses, today announces its financial results for H1 2023 and provides an update on the development of its various clinical programs.

NEW CLINICAL ADVANCES IN 2023

Since early 2023, Affluent Medical has been developing its medical devices and announced important clinical advances in each of its three programs.

EPYGON: First implantation of mitral heart valve successfully completed and additional investigation centers identified

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 can receive open heart surgery, which poses a high risk of death and hospitalization.

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 with a severe mitral valve insufficiency profile combined with several comorbidity factors. This implantation was carried out via a minimally invasive transcatheter route, by Prof. Stefano Salizzoni, MD, PhD – co-investigator of 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, changing her New York Heart Association (NYHA) functional status from III to II, which results in a resumption of day-to-day activities without complete exhaustion. The echocardiogram showed excellent function of the Epygon valve.

Approval from the DSMB (data safety and monitoring board) allowed the Company to treat additional patients with the Epygon valve.

More recently, one additional center was approved to participate in the clinical trial (Seville), bringing the total number of centers to ten. Affluent Medical has accelerated the number of screened patients to 80, with the aim of implanting up to 10 patients to complete the pilot phase.

The Company recently developed two new valve sizes (sizes 40 and 42). These two additional sizes will accelerate patient screening while gradually being authorized in additional countries (already approved in Spain and Austria).

KALIOS: Positive interim results confirmed at one year for the mitral ring and strategic shift towards the US market

Kalios is the only mitral annuloplasty device that can be adjusted percutaneously to treat both residual and recurrent mitral valve insufficiency, at any time after implantation, repeatedly and with a beating heart, thereby avoiding a repeat open-heart operation. Affluent Medical believes that Kalios would avoid further intervention for potentially 30-40% of patients over a five-year horizon. 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.

After the announcement of excellent interim results in July 2022, Affluent Medical presented in September 2023 an intermediate dataset on 20 patients treated in five centers in Europe after one year implementation.

At one year, none of the patients had MR >2+, thus meeting the pre-defined efficacy endpoint of the study.

The safety profile of the study was excellent: no death, no myocardial infarction, no valve thrombosis and no endocarditis were reported, up to one year.

The study covered 13 patients who presented with primary (degenerative) mitral regurgitation and seven with secondary (functional) mitral regurgitation. Five post-implant adjustments were performed, and one patient was adjusted at 11 months after surgery. Of the four patients adjusted peri-operatively, excellent results were observed, which have been maintained up to one year.

In line with the analysis of the positive data at one year from the Optimize II pivotal study, the Company has decided to refocus resources on the US market and rapidly enter into discussions with the US Food and Drug Administration (FDA).

The US market offers several advantages beyond being the world's largest unified medtech market: on the commercialization side, the average selling price of a mitral ring is 25-30% higher compared to Europe, offering more possibilities for a premium product such as Kalios. In addition, obtaining approval in the US is well aligned with the Company's strategy to secure commercial partners, which are mostly located in the US (Medtronic, Boston Scientific, Abbott, Edwards Lifesciences, etc.).

To optimize expenses, the European trial has been put on hold while this strategic shift takes place.

ARTUS: Start of the Dry pilot study by the end of the fiscal year

Artus is the first artificial sphincter that can be activated by the patient with 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 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.

According to Optima Insights, the global market for medical devices to treat urinary incontinence (slings, neurostimulators, artificial sphincters) is set to reach $4.3 billion by 2027, with an average annual growth rate of 11% between 2019 and 2027.

The European Dry pilot study on the Artus medical device in the treatment of urinary incontinence in humans is expected to begin by the end of 2023.

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

It is planned to recruit a total of 70 patients for the pilot and pivotal phases of this study.

Success of the March 2023 capital increase

On March 6, 2023, Affluent Medical announced the success of its capital increase with the continuation of the PSR through the issuance of shares with redeemable share subscription warrants (BSAR) for a gross amount of €13.7m (excluding any exercise of BSAR).

The last fundraising carried out on March 6, 2023, as well as the good control of its expenses, enabled Affluent Medical to extend its cash horizon to February 2024.

Financing the next stages of its development:

Affluent Medical is exploring the best financing options to support the next stages of its development. Affluent Medical plans to carry out a capital increase in the coming months. This transaction would be intended to finance ongoing clinical programs and could receive the support of its reference shareholders.

FINANCIAL STATEMENTS FOR H1 2023

The main financial items under IFRS are presented in the table below and were approved by the Board of Directors at its meeting of Monday, September 25, 2023. The Statutory Auditors conducted a limited review of the half-year financial statements.

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

Consolidated income statement (in thousands of euros)	06/30/2023 6 months	06/30/2022 6 months
Other operating income	590	705
Purchases	(1,037)	(1,505)
External costs	(2,828)	(2,478)
Personnel expenses	(2,996)	(2,888)
Taxes and duties	(49)	(37)
Provisions net of reversals	-	110
Other current operating income and expenses	101	(22)
Depreciation & amortization	(1,206)	(1,231)
CURRENT OPERATING INCOME	**(7,425)**	**(7,346)**
OPERATING INCOME after share of net income of equity affiliates	**(7,425)**	**(7,346)**
Net financial income	(633)	(931)
Income taxes	78	85
NET INCOME (LOSS)	**(7,980)**	**(8,192)**
Cash flow from operating activities	(8,531)	(6,451)
Cash flow from investing activities	(34)	(62)
Cash flow from financing activities	12,531	**(1,512)**
Increase (decrease) in cash	**3,966**	**(8,025)**
Cash and cash equivalents	**6,545**	**3,380**

The stability of operating expenses recorded in H1 2023 was linked to a decrease in purchases, offset by the increase in external expenses.

Purchases in H1 2023 decreased by €469,000 compared to H1 2022 and consist mainly of outsourcing purchases (external studies, subcontracting and scientific consultation). In 2022, several pre-clinical studies were conducted, which led to an increase in study purchases.

The change in external costs between the two periods is mainly due to consulting and engineering fees, up by €200,000.

The increase in personnel expenses reflects the gradual strengthening of the Group's workforce in R&D activities and management positions.

The Group had an average headcount of 52 employees at the end of H1 2023, compared with 49 one year previously.

The change in financial income in H1 2023 notably includes accrued interest of €610,000 on repayable advances (Mivana study and Piave Artus) and paid interest of €38,000 (€79,000 in H1 2022). ; the decrease resulting from the end of the Kreos contract in 2022 includes changes in the fair value of derivative liabilities in accordance with IFRS 9 "Financial Instruments" in the amount of +€53,000 (-€33,000 in H1 2022).

Over the past half-year, the Company has managed to streamline its expenses and refine its budget forecasts, enabling it to secure its financing until February 2024.

Lastly, the net result recorded in H1 2023 showed a loss of €8,000, compared with a loss of €8,200 a year earlier.

As a reminder, Affluent Medical announced the success of its capital increase with pre-emptive subscription rights ("PSR") by issuing Shares with Redeemable Share Subscription Warrants ("ABSAR") in March, the amount of which, including the issue premium, was approximately €13.7m, after partial exercise of the extension clause. The company issued 10,146,450 ABSAR at a unit subscription price of €1.35.

Availability of the 2023 half-year financial report

The financial report on the interim financial statements for 2023 is available to the public and was filed with the French Financial Markets Authority on September 28, 2023. It is also available on the company's website in the investor area section.

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 gradually commercialize its products from the end of 2025/early 2026.
For more information, visit www.affluentmedical.com

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