PRESS RELEASE
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2021 full-year results and update on clinical programs

Affluent Medical (ISIN code: FR0013333077 – Ticker: AFME), a French medtech specialising in the international development and industrialisation of innovative medical prostheses, at a clinical stage, to treat urinary incontinence and mitral valve pathology, publishes its annual results for 2021 today and provides an update on the development of its various clinical studies.

OVERVIEW OF FINANCIAL INFORMATION

The main consolidated financial statements prepared under IFRS are presented in the table below and approved by the Board of Directors at its meeting of 24 March 2022 and have been audited by the Statutory Auditors and the audit report on 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 at the end of April 2022: www.affluentmedical.com.

In thousands of euros, at 31 December *(Audited consolidated financial statements – IFRS standards)*	**2021**	**2020**
Other operating income	1,451	824
Purchases consumed	(2,518)	(3,108)
External expenses	(5,496)	(3,563)
Personnel expenses	(4,405)	(4,694)
Taxes and duties	(88)	(67)
Other current operating income and expenses	145	46
Provisions net of reversals	98	(125)
Depreciation and amortisation	(2,420)	(1,907)
CURRENT OPERATING INCOME	**(13,233)**	**(12,594)**
Share of net income of equity-accounted companies	(14)	(398)
OPERATING INCOME *After share of net income of equity-accounted companies*	**(13,247)**	**(12,992)**
Financial income (expense)	(2,010)	(1,536)
Income taxes	437	209
NET INCOME (LOSS)	**(14,820)**	**(14,319)**

In thousands of euros, at 31 December *(consolidated financial statements – IFRS standards)*	**2021**	**2020**
Cash flows from operating activities	(12,364)	(8,936)
Cash flows from investing activities	(160)	(304)
Cash flows from financing activities	18,281	12,762
Increase (decrease) in cash	**5,757**	**3,522**
Cash and cash equivalents	**11,410**	**5,650**

Other operating income includes research tax credits and subsidies incurred in connection with projects financed by BPI for an amount of €1,101k for the full year 2021.

Purchases consumed decreased by nearly €600k in line with the level of activity of the *Optimise II* study launched in 2019 for the Kalios device.

The increase in external expenses includes €1,181k in costs related to the IPO.

The increase in personnel expenses between 2020 and 2021 is due to the gradual increase in the Company's workforce involved in R&D activities, clinical operations and regulatory and quality functions. At 31 December 2021, the Group's average headcount was 48 employees compared to 42 employees in 2020. However, the increase in personnel expenses was offset by a reduction in expenses relating to share-based payments (IFRS 2) for equity instruments granted to employees or corporate officers.

In 2021, the operating income was € - 13,247k and mainly reflects the operational and human resources investments made in R&D for the clinical programs of the various medical devices as well as the expenses related to the Company's IPO.

Financial income (expense) includes in particular the amortised cost of bonds in the amount of €1,832k in 2021 (compared to €1,326k in 2020), accrued interest on repayable advances of €1,106k in 2021 (€730k in 2020) and the change in fair value of the derivative liabilities relating to the conversion option of +€1,041k in 2021 (compared to +€597k in 2020) in application of IFRS 9.

Cash consumption related to operating activities amounted to €12,364k, *i.e.* a monthly consumption of approximately €1 million.

In terms of financing activities, in 2021 the Company undertook the following:

- a capital increase concomitant with the Company's IPO for €25,000k (€21,425k net of fees and €2,000k subscribed with Kreos by offsetting receivables);
- the collection of repayable advances of €2,529k;
- the collection of loans guaranteed by the State for an amount of €795k;
- the repayment of €3,000k of the convertible bonds issued to Head Leader Limited;
- the repayment of maturities for the Kreos Capital loan in the amount of €2,164k;
- the payment of €500k on a liquidity contract for the Affluent Medical share (AFME) entrusted to Kepler Cheuvreux.

Cash at the end of December 2021 stood at €11,410k, covering financing needs up to September 2022.

In order to finance its future development and investments, the Company is currently studying various options to continue its activity and its development beyond this horizon. These solutions could, without being restrictive, involve capital increases, setting up bonds and obtaining public financing.

At the same time, the Company is actively pursuing its search for partnerships that would be a source of revenue for the Kardiozis technology and for the Artus and Epygon medical devices, particularly in the US market.

IMPLEMENTATION OF THE SHARE BUYBACK PROGRAM – BUYBACK OF A BLOCK OF 43,000 OFF-MARKET EQUITIES

On 24 March 2022, the Board of Directors decided to implement the share buyback program approved by the General Meeting of 6 April 2021 in its 19th resolution, with a view to the off-market buyback of a block of 43,000 of its own shares, representing 0.24% of its share capital. These shares, held by the Swiss company Myopowers Medical Technologies SA, the Company's minority shareholder, are intended to be partly cancelled and partly used to cover the Company's free share allocation plans. They will be acquired for a price corresponding to the average by the volumes of the last 10 trading sessions preceding the completion of the buyback with a discount of 5%. This buyback will be financed entirely by the Company's cash.

Taking into account the shares held under the liquidity contract, at the end of this block buyback, the Company will own 0.7% of treasury shares on that day.

This acquisition does not change the current control position of Affluent Medical.

UPDATE ON CLINICAL PROGRAMS

In 2021, ongoing clinical developments were affected by the Covid-19 pandemic, which extended the patient recruitment times provided for in the Company's initial plan. However, delays were controlled, and additional centres were opened in new countries so as not to jeopardise the development dynamic and marketing of medical devices.

In summary, the milestones to date are as follows:

	Marketing Europe	Marketing US
KALIOS	2024	-
ARTUS	2024	H2 2025
EPYGON	2026	2026/2027

Artus: marketing in Europe in 2024

Moderate to severe urinary incontinence is a major public health problem with more than 100 million adults[1] worldwide currently affected by this pathology[2], which has no effective treatment and has a massive impact on patients' quality of life and psychological state. In total, the market for medical devices to treat urinary incontinence is expected to reach $4.3 billion in 2027[3], with an average annual growth rate of 11% between 2019 and 2027.

Artus is the first artificial sphincter that can be activated by the patient *via* remote control to treat moderate to severe urinary incontinence in men and women.

As part of the clinical study (named *Dry*) for the Artus device to treat urinary incontinence, a pivotal phase with a view to obtaining the CE marking is planned in the 2nd half of 2022 with six centres initially and extending to at least ten centres in 2023. These centres will be located in the Czech Republic, Spain, Serbia, France and Italy, and will include a total of 70 patients.

This study should enable marketing in Europe in 2024.

The device has also been developed to treat incontinence in women and a pivotal study is planned for 2023, for marketing among this patient population in 2025.

In parallel with studies carried out in Europe, Affluent Medical will submit an application for Breakthrough Therapy Designation[4] with the FDA in anticipation of the launch of a pivotal study in the United States which could begin in 2023 for marketing in 2025.

Kalios: marketing in Europe in 2024

Mitral insufficiency is a serious and fatal heart disease that affects nearly 2% of the global population[5], with an incidence that increases as patients age.

[1] People over 20 years old.

[2] Company estimates based on the study "New Artificial Urinary Sphincter Devices in the Treatment of Male Iatrogenic Incontinence and Severity of Urinary Incontinence and Effect on Quality of Life in Women by Incontinence Type".

[3] Urinary Incontinence (UI) Devices (Optima Insights, September 2020).

[4] The FDA created the "Breakthrough Therapy Designation" in 2012 to "expedite development and review of new drugs to address unmet medical need in the treatment of a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies."

[5] Steve Douedi, Hani Douedi (August 2020).

According to Affluent Medical estimates, fewer than 4% of the 4 million patients with severe mitral insufficiency benefit from surgery. Without surgery, the risks of death and hospitalisation are high, with mortality of up to 50% after five years and hospitalisation for 90% of patients still alive.[6]

The global mitral insufficiency market is estimated at $4.7 billion in 2027[7], which corresponds to average annual growth of more than 14%.

Affluent Medical is currently developing two medical devices to address the treatment of mitral insufficiency: Kalios and Epygon.

Kalios is the only prosthesis for mitral heart valve repair, which allows multiple postoperative readjustments *via* the transcatheter route without general anaesthesia.

Following the positive results of the *Optimise* study, Affluent Medical initiated a clinical study, *Optimise II* pivotal for its Kalios device. This study, which provides for the recruitment of 62 patients, was launched in November 2019.

To date, 21 patients have benefited from the implantation of the Kalios device, including five for which the ring was adjusted. Affluent Medical had planned to finalise recruitments in the 2nd half of 2021. However, the Covid-19 pandemic led to two interrupted implant procedures due to the unavailability of hospitals during this period. This delay led to the study being extended by approximately one year with a delay in the recruitment of around fifty patients. However, patient monitoring was carried out normally. The clinical study is taking place in nine centres *ie*. one in Austria, two in Germany, one in Switzerland and five in Italy. New centres are being opened to accelerate recruitment in 2022.

On 16 September 2021, the Company announced successful first adjustment of the Kalios mitral ring on a patient suffering from postoperative recurrence of severe mitral insufficiency 11 months after implantation. The adjustment, carried out without surgical procedure in July 2021, involved inserting balloons into the subcutaneous line to reduce the size of the ring under echographic control, leading to a significant reduction in leakage to initial post-implementation level with immediate monitoring of the effectiveness of the adjustment. The patient, who is under scheduled medical monitoring, has no limitations on their ordinary activities.

Affluent Medical's objective is to be able to market Kalios in Europe from 2024.

Epygon: launch of the "First-In Human" clinical study in 2022 for marketing in Europe in 2026

Epygon is the only physiological cardiac bioprosthesis that mimics the native mitral valve and blood flows, implanted by transcatheter, without "open heart" surgery.

The "First-in Human" clinical study of the Epygon implant in three countries, named *Minerva* has obtained all the necessary approvals from the regulatory authorities and ethics committees. Launched in the first half of 2022, Minerva is a prospective, non-randomised, single-arm study. The aim of the study is to ensure the safety and technical feasibility of implanting the Epygon mitral valve with a transapical transcatheter system.

This study provides for the inclusion of around fifteen patients, with recruitment initially planned in four centres in Austria, Italy and Spain. Given the health situation in recent months, four additional centres were added in these countries as well as another in Serbia to ensure recruitment for this study.

This will be followed by a pivotal study starting in the 2nd half of 2023 with a view to marketing in Europe in 2026. The size of this study remains to be confirmed.

In addition to Europe, Affluent Medical will file a request for Breakthrough Therapy Designation to the FDA in anticipation of the launch of a feasibility study (EFS) in the United States, beginning at the end of 2023, which will be followed by a pivotal study for marketing in 2026/2027.

[6] Department of Cardiovascular Medicine Cleveland Clinic Foundation Journal of the American College of Cardiology.

[7] Transcatheter mitral valve implantation market size (Emergen research – September 2020).

"The Covid-19 pandemic has shifted our business plan, as it has many other players in our sector, and it has also slowed down our patient recruitment program over the period. However, our teams remained mobilised, opening additional centres in several countries in order to securing the continuation of our clinical programs. We are now on track to get our devices to market quickly and meet the expectations of the millions of patients with these pathologies whose medical needs are currently unmet," **says Michel Finance, Chairman and Chief Executive Officer of Affluent Medical.**

About Affluent Medical

Affluent Medical is a French player in MedTech, founded by Truffle Capital, with the aim of becoming a global leader in the treatment of heart and vascular diseases, which are the leading cause of death worldwide, and of urinary incontinence, which today affects one in four adults. Affluent Medical develops innovative, next-generation minimally invasive implants to restore essential physiological functions in these areas. The four major technologies developed by the Company are currently in the pre-clinical and clinical study phase. Kalios is set to be the first medical device to be marketed in Europe.

For more information, please visit: www.affluentmedical.com

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