

PRESS RELEASE

Aix-en-Provence, September 28, 2022 at 5:45 p.m.



Financial results for H1 2022 and significant progresses in 2022

- Excellent interim results from the Optimise II pivotal study for the Kalios™ mitral ring
- Appointment of Sébastien Ladet, who leaves Medtronic to Affluent Medical, as Chief Executive Officer
- Successful completion of the capital increase with preferential subscription rights
- Appointment of Michel Therin as new Board Member
- Appointment of Christophe Giot as Vice President of Clinical Affairs

Affluent Medical (ISIN code: FR0013333077 - ticker: AFME), a French MedTech specializing in the international development and industrialization of innovative medical devices, at a clinical stage, to treat urinary incontinence and cardiac mitral valve pathologies, publishes today its financial results for the first half of 2022 and provides an update on the significant progresses made in 2022.

2022 SIGNIFICANT PROGRESSES

- **New clinical advances for the three next-generation minimally invasive medical devices in urology and functional heart**

Since the beginning of the year, Affluent Medical has successfully managed new patient recruitment timelines to be able to continue its clinical studies for its three medical devices.

The Company thus announced excellent interim results for the Optimize II pivotal study for the Kalios™ mitral ring, which allows the patient to avoid additional invasive surgery.

Optimize II is a prospective five-year study across 10 European centers and has been designed to assess the safety and effectiveness of the Kalios™ device for the surgical treatment of mitral regurgitation with optional intra-operative and/or post-operative non-surgical adjustments.

The interim data announced last July are for the first 16 patients. Recruited in three centers; nine patients had primary mitral regurgitation and seven patients had secondary mitral regurgitation. Mean age was 66 years old and 75% of patients had a functional deficiency NYHA¹ III or IV. Mitral regurgitation grade² was ≥ 3 in 14 patients.

In 50% of the cases, the patients benefited from a concomitant cardiac surgery intervention on top of the Kalios™ surgical ring. In **four cases (25%), a post implantation adjustment** was performed due to remaining or relapse regurgitation of grade 3 to 4. Three adjustments were performed perioperatively and **one adjustment at 11 months post implantation with no need for the patient to undergo another long-lasting and significant open-heart surgical procedure.**

Mitral regurgitation grade was reduced at 30 days by at least two grades as compared to baseline and no patients had mitral regurgitation grade > 2 . These results were maintained at six months.

Functional status also improved as no patients had NYHA $> II$ at discharge and these results were maintained up to six months.

Progress has also been made on the Minerva study for the Epygon medical device, the only physiological cardiac valve that mimics the native mitral valve and blood flows, which foresees the

¹ NYHA: The NYHA classification is a scale of diagnostic, prognostic and therapeutic interest that expresses the clinical severity of heart failure.

² Mitral regurgitation grade: Graduation allowing to define the importance of the mitral leak following an ultrasound examination.



recruitment of about 15 patients. In the coming weeks, Affluent Medical plans to increase the number of clinical investigation centers from 4 to 9 with a goal of 11 centers during 2023. A pivotal study in Europe and the United States should begin at the earliest at the end of 2023 with a view to filing a CE mark application in 2026/2027. The first patient is expected to be implanted by the end of the year. A breakthrough therapy designation request is expected to be filed with the FDA within the next six months.

Lastly, the Dry study for the Artus medical device to treat urinary incontinence expects to recruit its first patients in 2023 as part of a pilot/pivotal study in men followed by the launch of a pivotal study in women. The application for CE marking should be filed at the end of 2024, followed by commercial launch in Europe. In the United States, a breakthrough therapy designation request is expected to be filed with the FDA within the next six months.

- **Sébastien Ladet appointed Chief Executive Officer and Michel Finance confirmed as Chairman of the Board of Directors**

In August, the Board of Directors decided to adapt its mode of governance by separating the roles of Chairman of the Board of Directors and Chief Executive Officer.

Consequently, Sébastien Ladet joined the company as Chief Executive Officer and Michel Finance will remain in his role as Chairman of the Board of Directors.

Sébastien Ladet has extensive and solid experience acquired at Medtronic in the development of new implantable medical devices through to their international commercialization. His experience in the United States as a member of the Hernia and Hemostats business management team as Director of Strategy and Investment Portfolio Management will allow Affluent Medical to strengthen its strategy and its operational excellence for these clinical and pre-sales phases.

Michel Finance will continue his mandate as Chairman of the Board of Directors and will simultaneously keep executive functions until the end of the year to support the transition and to bring to the management team his long and successful experience in the deployment of growth strategies in several listed companies in the healthcare field.

- **Successful capital increase with maintenance of PSRs (preferential subscription rights)**

On September 20, Affluent Medical announced a successful capital increase through the issue of New Shares with Preferential Subscription Rights maintained. The Company raised a gross amount of €6.0 million.

The proceeds of the issue will allow the Company to strengthen its financial structure and secure the financing of its clinical development programs for its Artus (launch of the pilot/pivotal study), Kalios™ (finalization of the inclusion of patients) and Epygon medical devices (pilot study).

- **Michel Therin named new Board Member, replacing Daniel Hayoz who has become an Observer**

Michel Therin, DVM and Ph.D., joined the Board of Directors of the Company in August, replacing Daniel Hayoz who has become an Observer. Michel Therin has extensive experience in the definition and implementation of international MedTech deployment strategies.

President of Siemens Healthineers - Innovative Therapies, Michel Thérin steered the development strategy of the interventional imaging business focused on oncology, neurology and cardiovascular care.

Before that, he spent more than 10 years at Medtronic as Vice President US and France, in charge of the development and marketing of innovative surgical devices, and after he served as Vice President of Research and Development and General Manager at the Floreane Medical Implants start-up, where he was in charge of the development and launch of breakthrough innovations in the field of abdominal and pelvic reconstruction worldwide.

Michel Therin holds a double doctorate in veterinary medicine (Ecole Nationale Vétérinaire de Maison Alfort) and in biomedical engineering (Paris XIII).

- **Christophe Giot named Vice President Clinical Affairs**

Dr. Giot, who joined Affluent Medical last July, has medical practice experience in hospitals, particularly in the field of vascular diseases. He has held positions of clinical responsibility in many international pharmaceutical groups (Sanofi, Astra Zeneca, UCB, Bristol Myers Squibb and Actelion).

Since 2014, he has been Director of Clinical Affairs Europe for Edwards Lifesciences and more recently Chief Medical Officer at Terumo for EMEA.



Christophe Giot is a cardiologist and studied at the Université libre of Brussels.

OVERVIEW OF FINANCIAL INFORMATION

The main financial items under IFRS are presented in the table below and were approved by the Board of Directors at its meeting of September 26, 2022. 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)	6/30/2022 6 months	6/30/2021 6 months
Other operating income	705	596
Purchases consumed	(1,505)	(1,351)
External expenses	(2,478)	(3,111)
Personnel expenses	(2,888)	(2,573)
Taxes and duties	(37)	(31)
Provisions net of reversals	110	153
Other current operating income and expenses	(22)	134
Depreciation and amortization	(1,231)	(1,176)
CURRENT OPERATING INCOME	(7,346)	(7,359)
OPERATING INCOME after share of net income of equity affiliates	(7,346)	(7,373)
Financial income (expense)	(931)	(339)
Income taxes	85	103
NET INCOME (LOSS)	(8,192)	(7,610)
Cash flow from operating activities	(6,451)	(5,203)
Cash flow from investing activities	(62)	(218)
Cash flow from financing activities	(1,512)	19,918
Increase (decrease) in cash	(8,025)	14,498
Cash and cash equivalents	3,380	20,145

The change in the amount of operating expenses as of June 30, 2022 reflects the strengthening of the Group's workforce, particularly in Research and Development, offset by the decrease in external expenses, related to the costs of the IPO in June 2021, recorded in the amount of €1,181 thousand.

Purchases consumed increased by €154 thousand in the first half of 2022 compared with the first half of 2021. This rise was mainly due to the €125 thousand increase in external research expenses and the €32 thousand increase in laboratory supplies.

The change in external expenses between the two periods was mainly due to the costs incurred as part of the June 2021 IPO process, the fees directly attributable to the capital increase concomitant with the IPO were recorded as a deduction from shareholders' equity for a total amount of €1,663 thousand.

The €306 thousand increase in personnel expenses between the two periods was due to the gradual strengthening of the research and development and management teams that occurred over the course of fiscal year 2021, which had impacts in 2022, as well as to the new hires made in 2022.

The Group had an average headcount of 49 employees in the first half of 2022.

Financial income (expense) in the first half of 2022 included, in particular, -€152 thousand in amortized cost and accrued interest on bonds, €613 thousand in accrued interest on repayable advances and €106 thousand in interest paid in 2022.

The decline in cash consumption related to financing activities was mainly due to the collection of the research tax credit prefinanced receivable for an amount of €673 thousand, the repayment of maturities for the Kreos



PRESS RELEASE

Capital loan for an amount of €602 thousand, and the redemption of the Head Leader bond for an amount of €1,000 thousand.

The Board of Directors applied the going-concern principle based on the data and the measures implemented by Management, although current cash flow forecasts do not ensure positive cash flow until March 2023. The capital increase carried out in September 2022 serves as a financing bridge to give the Company the time it needs to consider other financing options.

That is why various solutions remain under consideration by the Company to enable it to continue to finance its activity and development. These could take the form of carrying out capital increases, issuing bonds or obtaining public financing.

The financial report on the interim financial statements for the year ended December 31, 2022, is available to the public and was filed with the Autorité des Marchés Financiers on September 28, 2022. It is also available on the company's website in the investor relations section.

Upcoming events: October 6 & 7, 2022 – Investor Access Forum, Paris



About Affluent Medical

Affluent Medical is a French player in MedTech, founded by Truffle Capital, with the ambition of becoming a global leader in the treatment of heart and vascular 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 implants to restore critical physiological functions in these areas. The four major technologies developed by the company are currently in preclinical and clinical studies. Kalios™ is set to be the first medical device to be marketed in Europe.

For more information: www.affluentmedical.com

Contacts:

AFFLUENT MEDICAL

Jérôme Geoffroy
Chief Financial Officer
investor@affluentmedical.com

ACTIFIN, financial communications

Ghislaine Gasparetto
+33 (0) 6 21 10 49 24
affluentmedical@actifin.fr

ACTIFIN, financial press relations

Jennifer Jullia
+33 (0) 6 47 97 54 87
jjullia@actifin.fr

PRIMATICE, public relations France

Thomas Roborel de Climens
+33 (0)6 78 12 97 95
thomasdeclimens@primatice.com