

PRESS RELEASE

Aix-en-Provence, 22 September 2021 – 5:45 PM



Financial results for the first half of 2021 and main clinical update

Affluent Medical (ISIN code: FR0013333077 – mnemonic: AFME), a French medtech specialised in the international development and industrialisation of innovative medical prostheses – at a clinical stage – to treat urinary incontinence and the pathology of the heart mitral valve, is publishing its financial results today for the first half of 2021 and providing an update on the development of its various clinical studies.

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 20 September 2021. The audit work and the limited review of the half-year financial statements were carried out by the Statutory Auditors.

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

Consolidated income statement (in thousands of euros)	30/06/2021	30/06/2020
	6 months	6 months
Other operating income	596	357
Purchases consumed	(1,351)	(1,509)
External expenses	(3,111)	(1,687)
Personnel expenses	(2,573)	(2,233)
Taxes and duties	(31)	(26)
Provisions net of reversals	153	(50)
Other current operating income and expenses	134	(49)
Depreciation and amortisation	(1,176)	(742)
CURRENT OPERATING INCOME	(7,359)	(5,939)
OPERATING INCOME after share of net income of equity affiliates	(7,373)	(6,214)
Financial income (loss)	(339)	(1,278)
Income taxes	103	115
Net income (loss) for the period	(7,610)	(7,052)
Cash flow from operating activities	(5,203)	(5,542)
Cash flow from investing activities	(218)	(214)
Cash flow from financing activities	19,918	6,105
Increase (Decrease) in cash	14,497	349
Cash and cash equivalents	20,145	2,475



Operating expenses amounted to €7,955 thousand at 30 June 2021 compared to €6,296 thousand at 30 June 2020, an increase of €1,660 thousand. This change is mainly due to the costs related to the Company's IPO in the first half of 2021, which amounted to €1,181 thousand in expenses, as well as the strengthening of the Group's research and development and regulatory affairs teams.

During the first half of 2021, purchases consumed fell by €158 thousand compared to the first half of 2020. This decrease is mainly due to the decrease in external research expenses offset by the increase in laboratory supplies.

The €538 thousand increase in personnel expenses (excluding IFRS 2 – Share-based payments) was due to the gradual strengthening of the Group's research and development and regulatory affairs teams.

The financial result was improved by the early redemption of convertible bonds following the IPO.

The increase in cash consumption related to financing activities is mainly related to the capital increase carried out on 14 June 2021, at the time of the Company's IPO for a gross value of €25,000 thousand, including the conversion of Kreos Capital debt.

MAIN HIGHLIGHTS SINCE 1 JANUARY 2021

- **Successful IPO on Euronext Paris**

On 9 June 2021, Affluent Medical announced the success of its IPO on the regulated market of Euronext Paris. In this context, the Company carried out a capital increase of €25 million, with the issue of 2,906,978 new ordinary shares.

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

New patients were included in the pivotal study on the **Kalios** mitral valve ring, the only ring that can be readjusted several times after being implanted without surgery. In order to include all of the study's patients, and despite the health crisis in Europe, new centres will be added to the current nine clinical centres.

An adjustment to the Kalios mitral ring was made on 12 July 2021 by Professor A. Albertini at the Cotignola hospital centre in Italy 11 months after it was implanted. The mitral regurgitation was a 4+ grade leak. Mitral regurgitations occur in 40% of cases after the ring is implanted. The post-surgery results are in line with expectations and reduced the mitral leak to a grade 1+ leak. The surgeon noted that the adjustment via the transcatheter route was easy and quick.

The patient, who is under scheduled medical monitoring, is currently classified as NYHA I¹ and therefore has no limitations on his day-to-day activities.

The Czech and Spanish Ethics Committees issued a favourable opinion on the launch of a pivotal study on the **Artus** medical device for the treatment of moderate to severe urinary incontinence. Applications to receive regulatory authorisation were also submitted to the health authorities in the two countries. The Company is currently answering the Spanish and Czech competent authorities within the framework of the application process to receive regulatory authorisation for our pivotal study. In Spain, following delays due to the Covid-19 crisis, this review was extended by three months on the request of the Spanish health authorities.

The recruitment of patients within the framework of the pilot study to carry out the implantation of the

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



Epygon valve bioprosthesis, capable of imitating the native mitral valve and restoring physiological blood flow in the heart, is underway in Austria, Italy and Spain. Within the framework of our agreement with a distributor in Spain, new investigation centres are currently in the process of opening. All the surgeons at the four clinical centres participating in this clinical study received training on the Epygon device and feedback is currently very positive.

- **Appointment of two internationally renowned professors to the Scientific Advisory Board and strengthening of the organisation**

Appointment of Véronique Phé and Roxana Mehran to Affluent Medical's Scientific Committee

Professor Véronique Phé is a Doctor of Medicine specialising in urological surgery. She is the first woman to have been appointed University Professor of Urology and teaches at La Sorbonne. Her clinical practice focuses on functional urology and neuro-urology, and in particular on urinary incontinence for women and men. She has developed skills in reconstructive surgery and minimally invasive surgery with laparoscopic robot-assisted procedures applied to neuro-urological and incontinent patients. She holds various positions within learned societies in urology (French Association of Urology, French College of Urologists, etc.). In addition, she has published more than 140 articles in renowned scientific journals (European Urology, Nature Reviews Urology, BJU International, Journal of Urology, etc.) and has received various national and international awards for her work in urology, including the prestigious "EAU Crystal Matula Award" in 2021.

Professor Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI is an internationally renowned interventional cardiologist specialising in clinical research and health policy at the Icahn School of Medicine, Mount Sinai Hospital, New York, United States. Professor Mehran has created a world-renowned university research centre and has conducted numerous studies worldwide as principal investigator.

She is currently a member of the Board of Directors of the American College of Cardiology (ACC) and is one of the founders and Scientific Directors of the Cardiovascular Research Foundation (CRF). She was appointed for three consecutive years in *Clarivate Analytics* as "Most Cited Researchers – Top 1%" and in "The World's Most Influential Scientific Minds" (*Thomson Reuters*).

Professor Mehran currently heads the Lancet Commission on Cardiovascular Disease in Women, which brings together leading researchers from around the world with clinical expertise in cardiovascular medicine.

Professor Mehran has received several awards, including the 2016 Bernadine Healy Leadership in Cardiovascular Disease Award from the American College of Cardiology, the Women's Heart Nanette Wenger Award for Excellence in Research and Education, the 2019 Ellis Island Medal of Honor, the 2019 ESC Silver Medal and the Andreas Grüntzig Lecture plaque.

Appointment of Jean-Dominique Béhéty as Director of the Kalios programme

Jean-Dominique Béhéty has devoted his entire career to the medical devices industry. He started as a qualification technician at Ela Medical in the early 1990s. After that he joined SAIME, which became ResMed Paris, a leading player in the field of in-home and hospital respiratory support, where he successively held several positions and ultimately managed the Group's last industrial site in Europe. His tasks included spearheading strategic changes, particularly overhauling processes and developing a service-based business. Starting in 2018 he broadened his field of expertise by engaging in various entrepreneurial projects before joining Affluent Medical.



PRESS RELEASE

Upcoming events

27 and 28 September 2021: Investor Access Forum, Paris, France

4 and 5 October 2021: HealthTech Innovation Days, Paris, France

21 and 22 October 2021: Midcap Event Forum, Paris, France

23 November 2021 : Investir Day, Paris



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 preclinical and clinical study phase. The first medical device should be marketed and sold by 2023 with Kalios in Europe.

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

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