

PRESS RELEASE

Aix-en-Provence, 13 April 2021 – 7:30 a.m.



AFFLUENT MEDICAL announces the approval of its Registration Document by the French Financial Markets Authority (*Autorité des marchés financiers* – AMF) as part of its proposed IPO on the Euronext Paris regulated market

Affluent Medical, a French medtech specialising in the international development and industrial scale-up of innovative medical prostheses, at a clinical stage, to treat urinary incontinence and mitral cardiac insufficiency, announces today the approval of its Registration Document by the AMF under number I.21-007 on 12 April 2021.

The approval of this Registration Document is the first step in Affluent Medical's proposed IPO on the Euronext Paris regulated market, subject to market conditions and the approval by the AMF of the Prospectus relating to the operation.

Michel Finance, Chairman and Chief Executive Officer of Affluent Medical said:

"Affluent Medical aims to become a global player in medtech by developing innovative prostheses that address unmet major medical needs in urology and interventional cardiology. Today millions of patients worldwide suffer from urinary incontinence or mitral cardiac insufficiency. Our medical devices currently in clinical development aim to meet these needs by improving the quality of life and life expectancy of patients. Our proposed IPO is part of a pivotal period in our history with initial key development stages completed, necessary investments made and positive pre-clinical and clinical results already achieved. Thanks to our teams' solid expertise, we are now determined to pursue our business plan with initial revenue from Kalios sales in Europe expected as soon as 2023¹, after obtaining regulatory authorisations, and thus to save and improve the lives of millions of patients across the world."

A portfolio of 3 innovative and minimally invasive medical prostheses for the treatment of urinary incontinence and mitral cardiac insufficiency

Affluent Medical is developing a portfolio of medical prostheses offering innovative solutions that mimic human physiology to treat urinary incontinence and mitral cardiac insufficiency.

These minimally invasive medical devices have the advantage of restoring critical functions and simplifying surgical procedures while reducing the total cost of care for patients and public healthcare systems in the short and long term.

Affluent Medical's product portfolio currently includes three prostheses and one innovative technology protected by 31 patent families in all of its target markets:

¹ Subject to the completion of additional clinical development stages and obtaining financing necessary for the Company's development.



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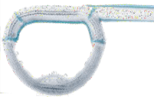



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- **Artus**: the first artificial sphincter that patients can activate *via* a remote control, for the treatment of moderate to severe urinary incontinence in men and women;
- **Kalios**: the only prosthesis for mitral heart valve repair that allows for multiple post-operative readjustments *via* a transcatheter procedure without general anaesthesia;
- **Epygon**: the only physiological cardiac bioprosthesis that mimics the native mitral valve and blood flow and can be implanted *via* minimally invasive procedures without an “open heart” surgery.

Initial development stages have been completed for these three products with major investments made and positive pre-clinical and clinical results already obtained.

In addition, Affluent Medical is developing an innovative technology, **Kardiozis**, which uses the properties of thrombogenic fibres to treat abdominal aortic aneurysm, providing embolisation to reduce the risk of aneurysm rupture. Affluent Medical is currently in discussions with several major players in the sector to sign a partnership agreement to develop endoprostheses incorporating this technology in an estimated market of \$1.7 billion².

Product/Technology	Description	Clinical development ³	CE marking	FDA approval
Kalios	 Mitral valve repair	<u>In Europe</u> : Clinical Stage - Study Optimise II - Pilot study successfully completed in 2018 - Pivotal study underway in Austria, Germany, Switzerland and Italy and to be completed in the 2 nd half of 2022: 15 patients were recruited out of the planned 62	4 th quarter of 2022	-
Artus	 Moderate to severe urinary incontinence	<u>In Europe</u> : Clinical stage - Study Dry - Feasibility study successfully completed in 2018 - Pilot/pivotal study initiated between the 2 nd and 3 rd quarters of 2021 in Spain, Italy, the Czech Republic and France: planned recruitment of 70 patients <u>In the United States</u> : Pivotal study initiated in the 1 st half of 2022 with recruitment starting in the 2 nd half of 2022	4 th quarter of 2023	4 th quarter of 2024
Epygon	 Mitral valve replacement	<u>In Europe</u> : Clinical stage - Study Minerva - Pilot study initiated in the 2 nd quarter of 2021 in Austria, Spain and Italy with the planned recruitment of 15 patients - Pivotal study in the 2 nd half of 2022 <u>In the United States</u> : Necessary work initiated in the 1 st half of 2022 to conduct a feasibility study followed by a pivotal study	2 nd half of 2025	4 th quarter of 2025
Kardiozis	 Abdominal aortic aneurysm	Technology validated by clinical trials and in vivo studies. Partnership research	-	-

² Infoholic Research – 2017: Global Aortic Aneurysm Market – Drivers, Opportunities, Trends and Forecasts 2017-2023

³ Subject to the impact of the Covid-19 pandemic and regulatory developments (refer to sections 3 and 9 of the Registration Document) and the obtaining of the funding necessary for the development of the Company which must in particular be provided in within the framework of a capital increase on the occasion of the admission of the Company's shares to trading on the regulated market of Euronext Paris and, where applicable, additional capital increases (see also section 3.4. 1 of the Registration Document).



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Strategic positioning in high-potential global markets

Affluent Medical targets global markets with strong growth potential, driven in particular by longer life expectancies.

Moderate to severe urinary incontinence is a major public health problem: currently more than 100 million adults⁴ worldwide are affected by this disease⁵, which has no effective treatment and devastates patients' quality of life and psychological well-being.

In total, the market for medical devices to treat urinary incontinence is expected to reach \$4.3 billion in 2027⁶, with an average annual growth rate of 11% between 2019 and 2027.

Mitral cardiac insufficiency is a serious and fatal heart disease that affects nearly 2% of the global population⁷, with an incidence rate that increases with the age of patients.

Less than 4% of the 4 million patients who suffer from severe mitral cardiac insufficiency undergo surgery, according to Affluent Medical's estimates. In the absence of surgery, the risks of death and hospitalisation are high, with up to a 50% risk of death at five years and a 90% risk of hospitalisation for surviving patients⁸.

The global mitral cardiac insufficiency market is estimated to reach \$4.7 billion in 2027⁹, which corresponds to an average annual growth of more than 14%.

A clear and rapid development strategy with initial revenue from Kalios sales in Europe expected as soon as 2023

Affluent Medical's ambition is to become a world leader in the field of urology and interventional cardiology. In a competitive environment in which larger companies operate and benefit from more significant clinical, industrial and business experience, Affluent Medical has decisive competitive advantages that will help it achieve its ambition:

- addressed pathologies characterised by medical needs that are unmet today;
- prostheses with unique, minimally invasive characteristics that mimic human physiology and facilitate surgical procedures to promote the rapid adoption of devices by practitioners;
- the support of opinion leaders and a world-renowned scientific committee;
- a team of recognised professionals with extensive experience in the development, industrial scale-up and marketing of medical devices;
- a portfolio of three innovative medical devices under development addressing rapidly growing markets of several billion dollars each (total addressable market of \$11 billion in 2027¹⁰);
- thirty-one patent families comprising around 300 patents and patent applications in Europe, the United States and other major markets covering Artus and Kalios products until 2037, Epygon until 2038 and Kardiozis until 2041;

⁴ People over the age of 20.

⁵ 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".

⁶Urinary Incontinence (UI) Devices (Optima Insights, September 2020).

⁷ Steven Douedi, Hani Douedi (August 2020).

⁸ Department of Cardiovascular Medicine Cleveland Clinic Foundation - Journal of the American College of Cardiology.

⁹ Transcatheter Mitral Valve Implantation Market Size (Emergen Research, September 2020).

¹⁰ Addressable markets calculated as the sum of markets addressed by ARTUS (in 2027), EPYGN and KALIOS (in 2027) and KARDIOZIS (in 2023): Urinary Incontinence (UI) Devices (Optima Insights, September 2020)/Transcatheter Mitral Valve Implantation MarketSize (Emergen Research, September 2020)/Global Aortic Aneurysm Market (Infoholic Research 2017).



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- a reference founding shareholder, Truffle Capital, with many medtech successes, particularly in prostheses (Symetis, Carmat, Vexim).

Affluent Medical will capitalise on these strong assets to deploy a clear business and industrial strategy, relying on its own sales forces in key European countries (Germany, France, Italy and the United Kingdom) and on commercial agreements with strategic partners and local distributors in the United States, China (joint venture agreements with Shanghai Zuquan Investment Management Company) and the rest of Europe.

The three products developed by Affluent Medical in urology and interventional cardiology are all in the clinical phase and are expected – after obtaining regulatory authorisations and CE markings – to quickly enter their respective target markets with initial revenue from Kalios sales in Europe expected as soon as 2023¹¹.

Availability of the Registration Document

Copies of Affluent Medical's Registration Document, approved by the AMF on 12 April 2021 under number I.21-007, are available free of charge and on request from the Company, at Affluent Medical's registered office, 320 avenue Archimède – Les Pléiades III-Bâtiment B, 13100 Aix-en-Provence, France, as well as on the websites of the AMF (<https://www.amf-france.org>) and Affluent Medical (<https://investir.affluentmedical.com>). The Registration Document contains a detailed description of Affluent Medical, in particular its business, strategy, financial position and the corresponding risk factors.

Risk factors

Affluent Medical draws the public's attention to the risk factors described in Chapter 3 of the Registration Document, particularly on the liquidity risk, and the risks associated with delays or failures in the development of the group's medical devices. The occurrence of one or more of these risks may have a material adverse effect on the business, assets, financial position, results or outlook of the Affluent Medical Group, as well as on the market price of Affluent Medical shares.

**Find all information related
to Affluent Medical's proposed IPO on:
<https://investir.affluentmedical.com>**

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¹¹ Subject to the completion of additional clinical development stages (see table on page 2 of the press release) and obtaining financing necessary for the Company's development (see liquidity risk factor, section 3, article 3.4.1 of the Registration Document)



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Forward-looking Statements

This press release contains information on Affluent Medical's outlook and areas for development.

Such information is sometimes identified by the use of the future tense, the conditional mood or forward-looking terms such as "estimate", "consider", "envisage", "think", "aim", "expect", "intend", "should", "have the ambition of", "believe", "wish", "could", or the negative forms of the same terms as the case may be, or any other variant or similar expression.

This information does not constitute historical facts and must not be construed as warranting that the anticipated events and results will actually materialise. This information is based on data, assumptions and estimates considered reasonable by Affluent Medical. It is liable to change or be altered due to uncertainties concerning the economic, financial, competitive and regulatory environment. The forward-looking information mentioned in this press release is given only as of this date. Affluent Medical operates in a competitive and constantly changing environment. It may therefore be unable to anticipate all risks, uncertainties or other factors that may affect its business activity, their potential impact on its business activity or the extent to which the materialisation of a risk or combination of risks could produce results significantly different from those mentioned in any forward-looking information, it being understood that none of that forward-looking information is a guarantee of actual results.

Affluent Medical makes no commitment to publish updates to this information or the assumptions on which it is based, except for any legal or regulatory obligation that may be applicable to it.

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