**PRESS RELEASE** Aix-en-Provence, 27 May 2021- 8.00 a.m.



# AFFLUENT MEDICAL launches its IPO on the regulated Euronext Paris market

- Capital increase of approximately €33.0 million, which may be increased to approximately €43.6 million in the event of the full exercise of the extension and over-allotment clause
- Subscription commitments received in the amount of €20 million
- Indicative price range applicable to the Offering: between €7.40 and €9.80 per share
- Subscription period: from 27 May 2021 to 8 June 2021, inclusive, for the French Public Offer (5:00 p.m. for subscriptions over the counter and 8:00 p.m. for internet subscriptions) and until noon on 9 June 2021 for the international offering
- Eligible for the PEA and PEA-PME schemes <sup>1</sup>

Affluent Medical, a French medtech specialising in the international development and industrialisation of medical prostheses at the clinical stage to treat urinary incontinence and mitral insufficiency, (the "Company") announces the launch of its IPO for the admission of its shares to trading on the Euronext Paris regulated market (ISIN code: FR0013333077-mnemonic code: AFME). On 26 May 2021, the French Financial Markets Authority (AMF) approved the Prospectus under number 21-177, consisting of the Registration Document, approved on 12 April 2021 under number I.21-0007, a Supplement to the Registration Document approved on 26 May 2021 under the number I.21-025, a Securities Note and a summary of the Prospectus (included in the Securities Note).

### Michel Finance, Chief Executive Officer of Affluent Medical commented on the IPO:

"Affluent Medical develops innovative prostheses to meet medical needs in urology and interventional cardiology that are currently unmet. Today millions of patients worldwide suffer from urinary incontinence or mitral insufficiency. Our medical devices aim to meet these expectations by improving the quality of life and life expectancy of patients. Our proposed IPO is part of a pivotal period in our history when the initial development stages have been completed, major 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 expected as of 2023<sup>2</sup>, from sales of Kalios in Europe, after obtaining regulatory authorisations, and thus save and improve the lives of millions of patients across the world. I hope that we can count on the commitment of many institutional and private investors to support us in this project, which should make us a world leader in urology and interventional cardiology".

<sup>&</sup>lt;sup>1</sup> This scheme is conditional and within the limits of the available ceilings. Those interested are asked to contact their financial advisor.

<sup>&</sup>lt;sup>2</sup> Subject to completion of additional clinical development stages (see table on page 2 of the press release) and obtaining the financing necessary for the Company's development (see Liquidity risk factor, Section 3, Article 3.4. of the Registration Document).



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

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

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

The 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 billion<sup>3</sup>.

Product / Technology		Description	Clinical development <sup>4</sup>	CE marking	FDA approval
KALIOS		Mitral valve repair	<u>In Europe:</u> Clinical Stage - Study Optimised II - Pilot study successfully completed in 2018 - Pivotal study underway in Austria, Germany, Switzerland and Italy and to be completed in the 2 <sup>nd</sup> half of 2022: 15 patients have been recruited out of the planned 62	4 <sup>th</sup> quarter of 2022	-
ARTUS		Moderate to severe urinary incontinence	In Europe:       Clinical stage - Study Dry         -       Feasibility study successfully completed in 2018         -       Pilot/pivotal study launched between the 2 <sup>nd</sup> and 3 <sup>rd</sup> quarters of 2021 in Spain, Italy, Czech Republic and France: expected recruitment of 70 patients         In the United States:       Pivotal study launched in the 1 <sup>st</sup> half of 2022 for recruitment starting in the second half of 2022	4 <sup>th</sup> quarter of 2023	4 <sup>th</sup> quarter of 2024

<sup>&</sup>lt;sup>3</sup> Infoholic Research – 2017: Global Aortic Aneurysm Market – Drivers, Opportunities, Trends and Forecasts 2017-2023.

<sup>&</sup>lt;sup>4</sup> Subject to the impact of the Covid-19 pandemic and regulatory developments (see sections 3 and 9 of the Registration Document) and the obtaining of the necessary financing for the development of the Company, which must be provided in the context of a share capital increase on the occasion of the listing of the Company's shares on the regulated Euronext Paris market and, if applicable, any additional capital increases (see also section 3.4.1 of the Registration Document).



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Product / Technology		Description	Clinical development <sup>4</sup>	CE marking	FDA approval
EPYGON		Mitral valve replacement	<ul> <li><u>In Europe:</u> Clinical stage - Study Minerva</li> <li>Pilot study launched in the 2<sup>nd</sup> quarter of 2021 in Austria, Spain and Italy with the planned recruitment of 15 patients</li> <li>Pivotal study in the 2<sup>nd</sup> half of 2022</li> <li><u>In the United States:</u> Necessary work launched in the 1<sup>st</sup> half of 2022 to conduct a feasibility study followed by a pivotal study</li> </ul>	2 <sup>nd</sup> half of 2025	4 <sup>th</sup> quarter of 2025
KARDIOZIS		Abdominal aortic aneurysm	Technology validated by clinical trials and in vivo studies. Partnership research	-	-

## 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 adults<sup>5</sup> worldwide are affected by this disease<sup>6</sup>, which has no effective treatment and devastates 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<sup>7</sup>, with an average annual growth rate of 11% between 2019 and 2027.

**Mitral insufficiency** is a serious and fatal heart disease that affects nearly 2% of the global population<sup>8</sup>, with an incidence rate that increases with the age of patients.

Less than 4% of the 4 million patients who suffer from severe mitral 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 patients<sup>9</sup>.

The global mitral insufficiency market is estimated to be worth \$4.7 billion in 2027<sup>10</sup>, which corresponds to an average annual growth of more than 14%.

# A clear and fast-paced development strategy with initial revenue expected from 2023 as a result of sales of Kalios in Europe.

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 currently unmet;
- 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;

<sup>&</sup>lt;sup>5</sup> People over the age of 20

<sup>&</sup>lt;sup>6</sup> Company estimates based on the study "New Artificial Urinary Sphincter Devices in the Treatment of Male latrogenic Incontinence, and Severity of Urinary Incontinence and Effect on Quality of Life in Women, by Incontinence Type"

<sup>&</sup>lt;sup>7</sup> Urinary Incontinence (UI) Devices (Optima Insights, September 2020)

<sup>&</sup>lt;sup>8</sup> Steven Douedi, Hani Douedi (August 2020)

<sup>&</sup>lt;sup>9</sup> Department of Cardiovascular Medicine Cleveland Clinic Foundation - Journal of the American College of Cardiology

<sup>&</sup>lt;sup>10</sup> Transcatheter Mitral Valve Implantation Market Size (Emergen Research, September 2020)



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- 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 addressing rapidly growing markets of several billion dollars each (total targeted market of \$11 billion in 2027<sup>11</sup>); and
- 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;
- a reference founding shareholder, Truffle Capital, with many medtech and biotech successes, particularly in prostheses (Symetis, Carmat, Vexim, Abivax).

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 should – after obtaining regulatory authorisations and CE markings – quickly enter their respective target markets with initial revenue from Kalios sales expected as soon as 2023<sup>12</sup>.

# An IPO on the regulated Euronext Paris market for financing growth and the developments

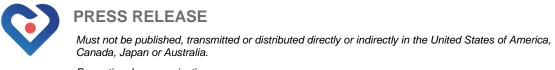
Affluent Medical's IPO is intended to provide the Company with the necessary financial resources to implement its development strategy and accelerate its growth. Estimated net proceeds in the context of this transaction (amounting to €29.7m which, in the event of full exercise of the Extension Clause of the Over-Allotment Option), it may be increased to €39.7mbased on the mid-point of the indicative price range) will enable Affluent Medical to pursue the following objectives:

- 40% expenses for clinical studies and regulatory approvals:
  - o clinical development in Europe to obtain the CE marking for Kalios ;
  - pivotal trials for Artus in Europe and the United States;
  - initiation of major pivotal trials in Europe and the United States for Epygon.
- 25% of research and development costs to continue to improve the Affluent Medical product portfolio (optimisation and new versions of existing medical devices);
- 20% of sales and marketing expenditure to set up an in-house sales force and expenses to produce medical devices on a large scale;
- 15% to redeem part of the financial debt composed by convertible bonds (amounting to €4.1m), ordinary bonds (amounting to €4.9m, of which €2.0 million will be reimbursed through the offset of part of the ordinary bonds in the context of the IPO in the context of the IPO), partners' current accounts (amounting to €1.0m), as well as part of the repayable advances of Bpifrance (for a maximum amount of €9.5m) as well as the State guaranteed loan (PGE) for a maximum amount of €2.9m).

Should the Offering be subscribed at no more than 75%, on the basis of the Offering Price equal to the low end of the indicative price range, the funds raised would essentially be allocated to the first of the abovementioned objectives, with the balance being used to partially repay the Group's financial debt related to the convertible bonds, ordinary bonds and shareholders' current accounts referred to above.

<sup>&</sup>lt;sup>11</sup> Targeted markets calculated as the sum of markets targeted by ARTUS (in 2027), EPYGON 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).

<sup>&</sup>lt;sup>12</sup> Subject to completion of additional clinical development stages (see table on page 2 of the press release) and obtaining the 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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## Eligibility of the offering for the PEA and PEA-PME

Affluent Medical announces that it fulfils the eligibility criteria for the PEA-PME scheme provided under Articles L.221-32-2 and D.221-113-5 et seq. of the French Monetary and Financial Code. Therefore, the Affluent Medical shares can be fully integrated into equity savings plans (*plans d'épargne en actions*, PEA) and PEA-PME accounts, which benefit from the same tax benefits as the classic PEA.

### **Availability of the Prospectus**

Copies of the Prospectus approved by the French Financial Markets Authority (AMF) are available free of charge and on simple request from Affluent Medical and on the following websites: <u>www.amf-france.org</u> and <u>https://investir.affluentmedical.com</u>. The approval of the Prospectus should not be considered as an endorsement on the securities offered or admitted to trading on the regulated market of Euronext Paris.

### **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 linked to delays or failures in the development of the Group's medical devices as well as Section 2 "Risk factors related to the Offering" in the Securities Note. 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 Affluent Medical, as well as on the market price of Affluent Medical shares. Potential investors are invited to read the Prospectus before making an investment decision in order to fully understand the potential risks and rewards associated with the decision to invest in the Company's securities.

## **Financial intermediaries and advisers**

Swiss Life Bangue Privée	Joint Global Coordinators – Joint Bookrunners
INVEST SECURITIES	Joint Global Coordinators – Joint Bookrunners
Dechert Legal Advisor	
pwc	Auditor
Expertea Audit	Auditor
Agili <sup>3F</sup>	IFRS Support
actifin	Financial Communication Advisor
dgm	Corporate Communication Advisor

# Find all the information on Affluent Medical's IPO project on:

https://investir.affluentmedical.com

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### MAIN TERMS AND CONDITIONS OF THE TRANSACTION

#### SHARE CAPITAL BEFORE THE TRANSACTION

*Société anonyme* (French corporation), with share capital of €15,256,824 divided into 15,256,824 shares of €1 each.

#### ■ CHARACTERISTICS OF THE SHARE

- Label: AFFLUENT MEDICAL
- Mnemonic code: AFME
- ISIN code: FR0013333077
- Listing market: Euronext Paris
- ICB Classification: 4535 Medical Equipment 20102010 Medical Equipment
- LEI: 969500N30CO4B5N2GN67
- Eligibility for PEA "PME-ETI" scheme <sup>13</sup>

#### ■ INDICATIVE PRICE RANGE

Between €7.40 and €9.80 per new share. This information is given purely for information purposes and should not, in any circumstances, be considered an indication of the offering price, which may be set outside this indicative range.

#### ■ INITIAL SIZE OF THE OFFERING

The offering shall be carried out through the issuance of 3,837,210 new shares to be issued, which may be increased to 4,412,791 new shares in the event that the Extension Clause is exercised in full and 661,918 additional new shares in the event that the Over-Allotment Option is exercised in full, i.e. a maximum of 5,074,709 offered shares in the event that the Extension Clause and the Over-Allotment Option are exercised in full.

#### ■ GROSS AMOUNT OF THE TRANSACTION

An amount of approximately  $\leq$ 33.0 million which may be increased to approximately  $\leq$ 38.0 million in the event of full exercise of the Extension Clause and to an amount of approximately  $\leq$ 43.6 million in the event that the Extension Clause and the Over-Allotment Option (based on the mid-point of the indicative price range of the offer, i.e.  $\leq$ 8.60) are fully exercised.

#### ■ NET PROCEEDS OF THE ISSUE

An net amount of approximately  $\leq 29.7$  million which may be increased to approximately  $\leq 34.4$  million in the event of full exercise of the Extension Clause and to an amount of approximately  $\leq 39.7$  million in the event that the Extension Clause and the Over-Allotment Option (based on the mid-point of the indicative price range of the offer, i.e.  $\leq 8.60$ ) are exercised in full.

#### ■ STRUCTURE OF THE OFFERING

The offered shares will be distributed as part of a global offering (the "Offering"), which shall include:

- a public offering in France in the form of an open price offering, mainly intended towards individuals (the "Open Price Offer" or "OPO"), it being specified that:
  - the orders will be broken down according to the number of shares requested: A1 Order fraction (from 1share up to and including 450 shares) and A2 Order fraction (over 450 shares);
  - the A1 Order fractions will benefit from preferential treatment compared to the A2 Order fractions in the event that all orders cannot be fully satisfied;
- an International Offering mainly intended for institutional investors (the "International Offering") comprising:

<sup>&</sup>lt;sup>13</sup> This scheme is conditional and within the limits of the available ceilings. Those interested are asked to contact their financial advisor.



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- a private placement in France; and
- an international private placement in certain countries (with the exception, in particular, of the United States of America, Japan, Canada, and Australia ).

Consequently, if demand for the OPO so permits, the number of shares allocated in response to orders issued as part of the FPO will be at least equal to 10% of the number of Offered Shares as part of the Offering (before any exercise of the Extension Clause and the Over-Allotment Option).

#### ■ LOCK-UP COMMITMENTS

- Lock-up commitment by the Company: 180 days;
- Lock-up commitment for Company shareholders: 180 days;
- Lock-up commitment for management and employees: 360 days.

#### SUBSCRIPTION UNDERTAKINGS

The Company has received subscription undertakings in the amount of €20 million (i.e. approximately 60.6% of the amount of the initial Offering based on the midpoint of the indicative price range of the Offering and 93.9% of the amount of the initial Offering subscribed at 75% based on the low end of the indicative price range of the Offering) from:

- 2 investment funds managed by Truffle Capital for an amount of €14,000K (including €4,000K as an underwriting undertaking in order to reach, if necessary, 75% of the amount of the Offering initially planned);

- Ginko Invest for an amount of 250 K€;

- Kreos Capital for an amount of 2,000 K€ through the offsetting of receivables;

- 7 individual investors for an amount of €2,900 K (including €750 K as an underwriting undertaking in order to reach, if necessary, 75% of the amount of the Offering initially planned);

- Friedland Gestion, Aurore Invest and Marsac Advisors for an amount of €850K as an underwriting undertaking in order to reach, if necessary, 75% of the amount of the Offering initially planned.

26 May 2021	<ul> <li>Approval of the Prospectus by the French Financial Markets Authority (AMF)</li> <li>Approval of the Supplement to the Registration Document by the AMF</li> </ul>		
27 May 2021	<ul> <li>Opening of the OPO and international offering</li> </ul>		
8 June 2021	<ul> <li>Closing of the OPO at 5:00 p.m. (Paris time) for subscriptions over the counter and at 8:00 p.m. (Paris time) for internet subscriptions</li> </ul>		
9 June 2021	<ul> <li>Closing of the International Offering at 12:00 p.m. (Paris time)</li> <li>Issuance of the press release announcing the result of the offering</li> </ul>		
11 June 2021	<ul> <li>Settlement-delivery of the OPO and the International Offering</li> </ul>		
14 June 2021	<ul> <li>Start of trading on the regulated Euronext Paris market</li> <li>Start of any stabilisation period</li> </ul>		
8 July 2021	<ul> <li>Deadline for exercising the Over-Allotment option</li> <li>End of any stabilisation period</li> </ul>		

#### ■ INDICATIVE CALENDAR



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#### Forward-looking data

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.

#### Disclaimer

This press release does not constitute and should not be considered as constituting a public offer or a solicitation of the public for any offer.

No communication or information relating to this operation or to Affluent Medical may be disseminated to the public in a country in which any registration or approval requirement must be met. No action has been taken (and will not be undertaken) in any country (other than France) in which such action would be required.

This communication is a promotional communication and does not constitute an offering or solicitation of an offer for the sale or subscription of securities requiring a prospectus within the meaning of Prospectus Regulation 2017/1129 of the European Parliament and Council of 14 June 2017, as amended (the "Prospectus Regulation"), which also applies in the United Kingdom in accordance with the European Union (Withdrawal) Act 2018 (the "EUWA").

In France, a public offering of securities may only be made pursuant to a prospectus approved by the AMF. With regard to the Member States of the European Economic Area other than France (the "Member States"), in whose territory the provisions of the Prospectus Regulation are applicable, and in the United Kingdom, no action has been taken or will be taken to allow a public offering of the securities making it necessary to publish a prospectus in one of those Member States or in the United Kingdom. Consequently, the securities of Affluent Medical may not and will not be offered in the United Kingdom or in any of the Member States other than France, except in accordance with the exceptions provided for in Article 3(2) of the Prospectus Regulation or in other cases that do not require the publication by Affluent Medical of a prospectus under Article 3 of the Prospectus Regulation and/or the regulations applicable in that Member State or the regulations applicable in the United Kingdom.

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This press release does not constitute or form part of any offer of financial securities or any solicitation to buy, subscribe or sell financial securities in the United States of America. Financial securities may only be offered, subscribed for or sold in the United States of America following registration under the U.S. Securities Act of 1933, as amended (the "U.S. Securities Act") and laws specific to each State applicable to financial securities, or as part of an exemption from this



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registration requirement. Affluent Medical shares have not been and will not be registered under the U.S. Securities Act and Affluent Medical does not intend to make any public offering of its securities in the United States of America.

This press release does not constitute an invitation to engage in, and is not intended to encourage, an investment activity, within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended (the "FSMA"). This document is intended solely for (i) persons outside the United Kingdom, or (ii) investment professionals within the meaning of Article 2 of the Prospectus Regulation, which also applies to the United Kingdom in accordance with the EUWA (x) to investment professionals within the meaning of Article 19(5) of the FSMA (Financial Promotion) Order 2005 (the "Regulation"), (y) to persons referred to in Article 49(2) (a) to (d) of the Regulation (companies with high equity capital, unregistered associations, etc.), and (z) to any other person to whom this press release may be sent in accordance with the law (all the persons mentioned in paragraphs (i), (ii), (ii)(x), (ii)(y) and (iv(ii)(z) being together referred to as the "Authorised Persons"). The financial securities of Affluent Medical referred to in this press release are intended solely for Authorised Persons and any invitation, offer or contract relating to the subscription, purchase or acquisition of financial securities may only be addressed to or entered into with Authorised Persons. Any person other than an Authorised Person must refrain from using or relying on this press release and the information it contains.

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