

# SMAIO provides update on its partnership with NuVasive and confirms its strategic focus on the U.S. market

Dallas (United States) & Lyon (France), January 27, 2025 – 6:00 pm CET – SMAIO (Software, Machines and Adaptative Implants in Orthopaedics – Euronext Growth Paris, ISIN: FR0014005180 / Ticker: ALSMA), a French-American player specialized in complex spine surgery with a global offer comprising software, adaptative implants and related services, today provides an update regarding its historical partnership with NuVasive and confirms its strategic focus on the Company's development in the United States.

In the first quarter of 2022, SMAIO and NuVasive, a global leader in spine technology innovation, entered into a development and license agreement to further advance SMAIO's surgical planning solutions and commercialization efforts in the United States. As part of this collaboration, NuVasive invested \$5 million (€4.5 million<sup>1</sup>) at the time of the IPO of SMAIO in April 2022, and agreed to certain milestone payments as part of a development and license agreement (hereinafter the "Development Agreement").

In June 2023, SMAIO received the first milestone payment of \$3 million (€2.8 million) following FDA 510(k) clearance of the customized surgery planning software co-developed by both companies. On September 1<sup>st</sup>, 2023, NuVasive was acquired by Globus Medical, a U.S.-based company specialized in musculoskeletal devices and implants<sup>2</sup>.

In view of their different strategic orientations, SMAIO and NuVasive have mutually agreed to end their software co-development efforts. Accordingly, the Development Agreement has been terminated, effective immediately and with no compensation on either side. As part of the termination, any exclusivity and sales restrictions shall cease and no further payments will be made from NuVasive.

Independently of its agreement with NuVasive, SMAIO has been proactively structuring its operations and successfully implemented a targeted growth strategy in the United States. Since the commencement of the Development Agreement, the parties had not advanced a software product beyond internal development stages. Therefore, termination of the Development Agreement will have no impact on SMAIO sales.

SMAIO Group intends to accelerate its U.S. presence and commercial development, notably through Think Tanks, discussions with KOLs, training courses and other initiatives efficiently driven by its recently formed U.S. scientific advisory board<sup>3</sup>. SMAIO is also evaluating new partnering options with major players in the spine industry, mainly for its planning and patient specific implants technology embedded inside its Kheiron implant system. Given its multiple assets, the Company is confident of continuing its sustained growth momentum over the coming half-years.

**Philippe ROUSSOULY, Chairman and CEO of SMAIO**, stated: "While we have greatly appreciated the contribution of our partnership with NuVasive, we are now at a turning point in SMAIO's history. Over the past two years, we have structured the Company, expanded in the U.S. and developed the necessary expertise and technology to achieve our goals independently.

Our expansion in the U.S. is key, and we are progressing well in this endeavor, as shown by our commercial performance with U.S. sales reaching quickly more than half of our total commercial activity in 2024, one year after having established ourselves in the North American market. We intend to further expand in this high value-added market to drive sustainable growth, spurred by the rapid adoption of our solutions by reference surgical centers in the region. With a robust foundation in advanced surgical planning and customized

<sup>&</sup>lt;sup>1</sup> Based on an indicative exchange rate of 1 euro for 1.10 dollar

<sup>&</sup>lt;sup>2</sup> On February 9, 2023, Globus Medical signed an agreement to acquire NuVasive in an all-stock transaction valued at approximately \$3.1 billion. This acquisition was completed on September 1, 2023. Globus Medical continues to own 15.55% of the Company's share capital

<sup>&</sup>lt;sup>3</sup> See the press release published by the Company on October 15, 2024



implants, SMAIO is well-positioned to pursue its growth and create value. The recent foundation of our scientific advisory board will support the dissemination of our technology throughout the region and we intend to position SMAIO as an international leader in the spinal realignment market and generate sustained growth over time."

## Upcoming financial news:

• Full-year 2024 results: Tuesday, April 15, 2025 (after market)

### **About SMAIO**

A precursor in the use of clinical data and imaging of the spine, SMAIO designs global solutions for spine surgery specialists. The Company has recognized expertise thanks to KEOPS, its Big Data management software that has become a global reference with more than 100,000 patient cases documented.

SMAIO offers spine surgeons a comprehensive platform, I-Kontrol, incorporating planning, implants and related services, enabling them to treat spinal pathologies in a safe, effective and lasting way.

SMAIO is positioned at the forefront of innovation with the ambition of providing surgeons with the first active robotic solution enabling a high level of performance and repeatability to be achieved.

Based in Lyon, France, SMAIO benefits from the skill and expertise of more than 40 highly specialized staff.

For further information, please visit our website: <u>www.smaio.com</u>

#### Contacts

#### SMAIO

Philippe Roussouly Chairman & CEO Renaut Fritsch Chief Financial Officer investors@smaio.com NewCap

Dusan Öresansky/Aurélie Manavarere Investor Relations smaio@newcap.eu Tel.: +33 (0)1 44 71 94 92 NewCap Arthur Rouillé

Media Relations smaio@newcap.eu Tel.: +33 (0)1 44 71 00 15

Listing market: **Euronext Growth Paris** ISIN: **FR0014005I80** Ticker: **ALSMA** 



### Disclaimer

This press release contains non-factual elements, including, but not limited to, certain statements regarding future results and other future events. These statements are based on the current vision and assumptions of the management of the Company. They incorporate known and unknown risks and uncertainties that could result in significant differences in results, profitability and expected events. In addition, SMAIO, its shareholders and its affiliates, directors, officers, counsels and employees have not verified the accuracy of, and make no representations or warranties about, statistical information or forecast information contained within this news release and that originates or is derived from third party sources or industry publications; these statistical data and forecast information are only used in this press release for information purposes. Finally, this press release may be drafted in French and in English. In the event of differences between the two texts, the French version will prevail.