

# 2023 sales up +120% to €5.4 million

# + Strong growth in sales driven by the \$3m (~€2.8m) milestone payment from NuVasive during H1 2023

+ Acceleration in sales of the Kheiron system (+40% vs. Q4 2022) thanks to the ramp-up of surgeries in the United States

Lyon, January 23, 2024 – 6:00 pm CET – SMAIO (Software, Machines and Adaptative Implants in Orthopaedics – Euronext Growth Paris ISIN: FR0014005180 / Ticker: ALSMA), a French player specialized in complex spine surgery with a global offer comprising software, adaptative implants and related services, today published its annual sales for the year to December 31, 2023.

**Philippe ROUSSOULY, Chairman and CEO of SMAIO**, said: "In 2023, we achieved several key milestones that enabled us to deliver operational performance and initiate our commercial expansion in the United States. Obtaining FDA 510(k) clearance for the customized version of our surgical planning software was an important first milestone, leading to a \$3 million payment from our U.S. partner, NuVasive. Besides, we continued our efforts to train surgeons in the United States on our technologies and philosophy, in order to spread our offering in the world's leading spine market. Through our U.S. subsidiary SMAIO USA, we performed 27 surgeries in 2023, of which 24 in the fourth quarter alone with our Kheiron and K-rods implants and customized planning solutions. We intend to build on this momentum, by increasing the number of U.S. hospitals in which our solutions will be registered in 2024, and by intensifying our training initiatives on our technologies for surgeons practicing in these hospitals or expressing significant interest in our offerings."

#### 2023 annual sales

In € thousands	December 31, 2023	December 31, 2022	Change
SMAIO SA (parent Company)	7,623	2,442	+212%
- intra-group sales	(2,574)	-	N⁄A
SMAIO SA (excluding intra-group sales)	5,049	2,442	+107%
SMAIO USA	334	-	N/A
SMAIO Group	5,383	2,442	+120%
of which France	1,110	1,101	+1%
of which milestone payment	2,765	-	N/A
of which international	1,508	1,341	+12%
* Unaudited data			

In **2023**, **SMAIO SA's sales** amounted to €7.6 million, up +212% compared to 2022. When excluding intragroup sales of implants between SMAIO SA and its U.S. subsidiary SMAIO USA, and considering only the hospital implant sales conducted by the latter, **SMAIO Group's sales** came to  $\in$ 5.4 million<sup>1</sup>, reflecting a +120% growth compared with 2022.

Excluding the NuVasive milestone payment, SMAIO Group's sales primarily consisted of sales of the Kheiron system, comprising customized implants and rods, amounting to €2.5 million over 2023. The latter were particularly strong in the last quarter of the year (+40% vs. Q4 2022), due to implants in the U.S. market following the gradual registration of 4 new centers initiated during H2 2023. As a result, 27 surgeries were performed in the United States in the 2<sup>nd</sup> half of 2023, including 24 in the last quarter, demonstrating the strong momentum of Kheiron system adoption by North American surgeons.

In addition to sustaining the performance achieved in the fourth quarter of 2023 over a full year in 2024, SMAIO expects to complete several registrations, currently underway, in other hospitals where surgeons who participated in the training programs organized in Dallas (November 2022) or San Diego (November 2023) are practicing, which should accelerate the Company's sales growth in the United States in 2024.

# Upcoming financial publication

• FY 2023 results: April 16, 2024, 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 Chief Executive Officer Renaut Fritsch Chief Financial Officer investors@smaio.com NewCap Dusan Oresansky/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** 

<sup>&</sup>lt;sup>1</sup> The financial statements published relate to the SMAIO SA corporate entity, as the company does not yet publish consolidated financial statements. However, in order to provide accurate financial information, the Company is reporting its sales on the basis of SMAIO SA's sales after elimination of intra-group sales to SMAIO USA, and increased by sales generated by SMAIO USA directly to its hospital customers,

## 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.