

## SMAIO announces 2024 sales of €5.5m, more than half of which generated in the United States

- + Implant sales growth in excess of 100%, thanks to a strategic focus on the US market, driving strong revenue growth which is now mainly generated in the United States
- + Establishment of the Group's sales and general management in the United States (Dallas, Texas), enabling 2024 sales to reach €2.9m in this strategic market, with a record fourth quarter at €1.5m.
- + 8 user centers in the United States at end-2024 and advanced registration process in 5 additional centers, pointing to further sustained growth in 2025

**Dallas (United States) & Lyon (France), January 21, 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 published its annual sales for the full year to December 31, 2024.

**Philippe ROUSSOULY, Chairman and CEO of SMAIO**, said: "The year 2024 marked a decisive turning point for SMAIO, with the establishment of the company's general and sales management in the United States, in order to be at the heart of the world's leading market for spinal implants (70% of global value), and accelerate the Group's growth.

*The average quarterly increase in North American sales of over 60% for the year testifies to the relevance of this strategy, which is based on collaboration with a targeted number of centers of excellence, alongside the Group's historical centers in Europe.*

*The establishment of SMAIO's North American Scientific Advisory Board, which will be expanded over the course of 2025, is further evidence of the company's determination to align its offering with the most ambitious US scientific and technological standards. With this in mind, SMAIO's strengths in data, artificial intelligence and spinal realignment give it a unique position among industry leaders and are attracting the interest of spinal deformity experts in the United States, as evidenced by the exponential growth in participation in its "Sagittal Alignment Think Tank" training programs.*

*As a result, the United States now accounts for more than half of our business, and we are focusing most of our efforts on realizing this vision of a company combining the excellence and creativity of French engineering in the field of medical devices, with deep commercial and scientific roots in the United States, serving a group of leading American surgeons who share our philosophy.*

*The Group's annual sales are up +110% on FY 2023 (excluding milestone), at €5.5 million. The majority (55%) of sales came from Kheiron System implants combined with custom-made K-Rods stems in the United States. This performance, achieved in just 12 months, confirms the significant impact of our initiatives to win over the leading American surgeons to our technology, and our ability to deploy our offering widely in the centers where they operate.*

*The year 2025 will be marked by our continued expansion in the United States. Our solutions will continue to be distributed directly, in proximity to American surgeons, and nationwide by our distribution partners, who are commissioned on sales.*

*Given the very positive feedback from surgeons using our products, the enthusiastic reception of our offer by prospective customers, and our ongoing innovation, we believe we can rapidly position SMAIO on a profitable and sustainable growth trajectory, to make it a key international leader in the spinal realignment market."*

## 2024 annual sales

In € thousands*	2024	2023	Change
<b>Implant sales**</b>	<b>5,347</b>	<b>2,443</b>	<b>+119%</b>
<i>of which the United States</i>	2,936	334	+779%
<i>of which rest of the world (outside France)</i>	1,325	1,040	+27%
<i>of which France</i>	1,086	1,069	+2%
<b>Instruments sales</b>	<b>55</b>	<b>76</b>	<b>-28%</b>
<b>Licenses Keops</b>	<b>96</b>	<b>99</b>	<b>-3%</b>
<b>Subtotal Group sales</b>	<b>5,498</b>	<b>2,618</b>	<b>+110%</b>
<b>Exceptional milestone payment</b>	<b>-</b>	<b>2,765</b>	<b>n/a</b>
<b>TOTAL GROUP</b>	<b>5,498</b>	<b>5,383</b>	<b>+2%</b>

\* Unaudited data; \*\* Including custom-made rods

The **SMAIO Group's annual sales** reached €5.5 million in 2024, compared with €5.4 million in 2023, which included an exceptional €2.8 million milestone payment received by SMAIO under the partnership agreement with NuVasive.

Excluding milestone payments, the SMAIO Group's activity, mainly comprising sales of implants and instruments, grew by +110%, driven by dynamic sales of the Kheiron implant system in the US market, which now accounts for 53% of total Group sales.

In the United States, the Group generated sales of €2.9 million in full-year 2024, including €2.1 million in the second half. The US sales rose by an average of 62% between each quarter of the year, reaching €1.5 million in the fourth quarter alone, attesting to the growing adoption of SMAIO solutions by surgeons in this region.

### Growing success of "Sagittal Alignment Think Tank" training program in the United States

Training surgeons and raising their awareness of the vertebral realignment concepts developed by SMAIO and its partner-surgeons is an integral part of the Company's growth strategy in the United States.

In the wake of the first sessions (Dallas in 2022, San Diego in 2023), SMAIO held the 3<sup>rd</sup> "Sagittal Alignment Think Tank" in New York in December 2024. The event was a huge success, with a record attendance of more than 35 North American surgeons and experts, a 3-fold increase on the first session in Dallas. Participants were able to use the KEOPS Balance Analyzer 3D software to analyze real-life cases and take part in several workshops on realistic simulators using *Kheiron Spinal Fixation System* osteosynthesis equipment, two flagship products in the SMAIO portfolio.

These events also leave plenty of room for expert discussion and enable SMAIO to gather valuable feedback from some of the best spinal deformity surgeons in the US to stay at the forefront of innovation.

### Strategy and outlook

In 2025, SMAIO will continue to implement its strategic plan, the main levers of which will be:

- **Intensification of sales deployment in the United States**, a high value-added market where the Group will pursue its initiatives through the "Sagittal Alignment Think Tank", exchanges with KOLs and training courses for surgeons at reference centers, with the support of its North American scientific advisory board established in the second half of 2024, which will be joined by new experts in the course of 2025. SMAIO is also in the process of registering its solutions in 5 new US centers, which will extend commercial coverage to 13 user centers in the short term.

- **Continuous investment** in the development of new functionalities, based on the progressive integration of Artificial Intelligence into SMAIO's planning solutions. At the International Spine Study Group's Las Vegas conference last summer, the Group presented its new preoperative planning platform, connected to the future KEOPS-4ME artificial intelligence modules, which was very well received. Thanks to these advances, SMAIO intends to make spinal alignment planning both faster and more realistic.

Driven by these ambitions, SMAIO should maintain a sustained growth momentum in 2025 and beyond.

### Upcoming financial news:

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

### About SMAIO ([www.smaio.com](http://www.smaio.com))

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: [www.smaio.com](http://www.smaio.com)

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