

SMAIO reports 2025 sales of €9.2m, representing an increase of +67%

- + U.S. sales rose by **+138% to €7m**, and by **+160% to \$7.9m** (excluding currency effects).
- + Strong **growth across North American centers that were already active** in 2024 (**+130%**).
- + **11 new North American surgeons using SMAIO solutions in 2025**, representing less than 10% of total sales, suggesting continued sustained growth in 2026.
- + **Two major initial industrial partnerships signed in 2025** for the KEOPS-4ME open platform, enabling the large-scale rollout of patient-specific K-Rods starting in Q2 2026.
- + **Strong cash position of €5.8m** as of December 31, 2025.

Webconference in French today at 6:30 pm CET:
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Dallas (United States) and Lyon (France), January 20, 2026 – 5:45 pm CET – SMAIO (Software, Machines and Adaptive Implants in Orthopaedics – Euronext Growth Paris, ISIN: FR0014005180 / Ticker: ALSMA, eligible for the PEA-PME scheme), a French-American player specialized in complex spine surgery, offering an integrated pre, intra, and post-operative solution based on a 3D planning software, adaptive implants and related services, today published its annual sales and cash position for the full year to December 31, 2025.

Philippe ROUSSOULY, Chairman and CEO of SMAIO, stated: *"In 2025, SMAIO significantly increased its sales in the United States, reaching €7.0 million in sales, representing a 2.4-fold increase compared with 2024 (+138%), despite an unfavorable evolution of the euro/dollar exchange rate over the year. Excluding currency effects, North American sales were multiplied by 2.6 to \$7.9 million. Adoption of the Kheiron system in the U.S. continues to progress rapidly, with 326 procedures performed in 2025 versus 180 in 2024, mainly for complex spine surgeries, enabling a premium pricing position.*

The seven main centers already registered in 2024 significantly increased their activity (+130%), while eight new centers, representing less than 10% of SMAIO's sales in the United States in 2025, have progressively adopted the Kheiron solution, pointing to further sustained growth as early as 2026.

The success of the Sagittal Alignment Think Tank held in December in New York, with 40 participating surgeons, testifies to the growing interest of North American surgeons in SMAIO's solutions and opens the possibility of registering the full Kheiron and K-Rods solution in 5 to 10 new major U.S. centers in 2026, further strengthening the Group's medium- and long-term growth base.

The first distribution partnerships signed for the KEOPS-4ME platform with Highridge Medical and Orthofix, together with the 510(k) clearances obtained for SMAIO's custom-made rods combined with these partners' pedicle screws, will enable the generation of a new revenue stream starting in mid-2026 across several dozen centers. Discussions with another partner could potentially be finalized during 2026, further strengthening SMAIO's distribution capacity for patient-specific K-Rods.

Finally, SMAIO's R&D projects, supported by non-dilutive funding from Bpifrance and the Auvergne-Rhône-Alpes Region and driven by our Scientific Advisory Board strengthened by two new members in 2025, aim to further reinforce SMAIO's technological differentiation and establish it as a reference in vertebral realignment in the United States within five years."

2025 annual sales

In millions of euros*	2025	2024	Change
Implant sales**	9.0	5.3	+70%
of which United States	7.0	2.9	+138%
of which rest of the world (outside France)	1.2	1.3	-10%
of which France	0.9	1.1	-20%
Other	0.1	0.2	-23%
TOTAL GROUP	9.2	5.5	+67%

* Unaudited data; ** Including patient-specific rods

The **SMAIO Group's annual sales** reached €9.2 million in 2025, compared with €5.5 million in 2024.

The Group's activity, mainly comprising sales of implants and instruments, grew by +67%, driven by dynamic sales of the Kheiron implant system in the US market, which now accounts for more than 75% of total Group sales.

In the United States, revenue rose by +138% to €7.0 million, despite an unfavorable exchange rate impact of €0.3 million. Sales in dollars, excluding currency effects, increased by +160% to \$7.9 million, attesting to the growing adoption of SMAIO solutions by surgeons in this strategic market, where the Company is already present in around fifteen centers, including eight activated during the past financial year.

Internationally, excluding France, revenue amounted to €1.2 million (-10%), while in France it reached €0.9 million (-20%), illustrating the Company's strategic focus on the United States, the market offering the greatest growth and value creation potential. Other revenue, mainly related to instruments and ancillary services, amounted to €0.1 million, compared with €0.2 million in 2024.

Financial position as of December 31, 2025

SMAIO's cash position amounted to €5.8 million as of December 31, 2025, compared with €3.2 million as of December 31, 2024.

This change is explained by:

- a controlled level of cash burn;
- the receipt of €2.0 million in non-dilutive financing, in the form of a 0% interest loan co-financed by the European Union, the Auvergne-Rhône-Alpes Region and Bpifrance (€1.0 million, with a 7.5-year maturity and a 2.5-year repayment deferral), as well as two loans from a banking pool comprising BNP Paribas and Société Générale (€1.0 million, with a 4-year maturity);
- a €2.5 million fund-raising subscribed by NextStage AM, consisting of a €1.5 million capital increase and a €1.0 million convertible bond issue.

Strategy and outlook

In 2026, SMAIO will continue to build on the foundations laid over the past financial years to continue the international deployment of its solutions, strengthen its technological leadership and pursue a sustainable growth trajectory, through:

- Gradual penetration of the high value-added complex spinal deformity market in the United States, based on a dual approach relying on:
 - direct collaborations with surgeons in leading centers, through training initiatives and regular exchanges with key opinion leaders (KOLs), notably via the *Sagittal Alignment Think Tank* events, whose growing success provides strong visibility for SMAIO's solutions.
 - the KEOPS-4ME platform, whose rollout through the first partnerships with *Highridge Medical* and *Orthofix* will enable, from Q2 2026, the introduction of solutions combining SMAIO's patient-specific K-Rods with the pedicle screws of partner companies within their

hospital networks. Additional partnerships could be finalized during the current financial year.

- Continued investment in Research and Development, aimed at further enriching and differentiating SMAIO's solution portfolio, in particular through the progressive integration of new functionalities to make spinal alignment planning more accurate, more realistic and faster. In this respect, SMAIO benefits from the expertise and sector vision of its U.S. Scientific Advisory Board, comprising four renowned surgeons.

Commercial execution in the United States and innovation will therefore remain two key levers to strengthen the clinical value of SMAIO's solutions and support its long-term growth.

Upcoming financial news

- Full-year 2025 results:** April 14, 2026 (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. The Company's open platform deployed in the United States, KEOPS-4ME, is designed to deliver a personalized and data-driven approach to complex spine surgery, enabling SMAIO to partner commercially with major U.S. surgical companies and provide their surgeon clients with patient-specific implants. Based in Dallas (United States) and 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

Contacts

SMAIO

Philippe Roussouly
Chief Executive Officer
Renaut Fritsch
Chief Financial Officer
investors@smaio.com

NewCap

Dusan Oresansky/Thomas Cozzolino
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

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