

SMAIO reports strong FY 2025 results, amid robust growth in activity

- + **Annual Group sales: +67% to €9.2m**
- + Implant sales in the **United States: +138% to €7.0m**
- + **Gross margin rate: +14 points to 83%**
- + **EBITDA improved by +36% to -€0.8m** vs. -€1.3m in 2024
- + **Solid cash position of €5.9m** as of December 31, 2025, further strengthened by a successful €3.6m fundraising completed in March 2026

Dallas & Lyon, April 14, 2026 – 6:00 pm CEST – SMAIO (Software, Machines and Adaptive Implants in Orthopaedics – Euronext Growth Paris, ISIN Code: FR0014005180 / Ticker: ALSMA), a French-American company specialized in complex spine surgery and offering an integrated pre-, intra- and postoperative solution based on 3D planning software, adaptive implants and related services, today announces its consolidated results for the 2025 financial year¹.

Philippe ROUSSOULY, Chairman and CEO of SMAIO, said: "SMAIO delivered a particularly strong performance in 2025, with sales up +67% to €9.2 million. This performance was driven by the excellent momentum of our implant sales in the United States, which rose by +138% to €7.0 million and now account for more than 75% of our activity.

The strong ramp-up in the US market, the most profitable spine market in the world, enabled us to achieve a gross margin rate of 83%, up 14 points year-on-year.

At the same time, we were able to support this growth with a controlled cost structure, allowing us to continue improving our profitability indicators, including a 36% reduction in our EBITDA loss to €0.8 million, despite an unfavorable exchange rate environment, the introduction of tariffs, increased investment in training new users, and several strategic hires made during the fiscal year, the positive effects of which on the company's margin will become apparent in the medium term.

These achievements demonstrate the relevance of our strategic decisions, which are centered, on the one hand, on the U.S. market—where margins are highest—and, on the other hand, on a strong specialization in complex surgeries performed by a limited number of centers of excellence.

In the near future, the strategic partnerships concluded with Highridge Medical and Orthofix for the commercialization of our KEOPS-4ME platform will complement this strategy through a broader deployment of our solutions across several dozen US centers and are expected to become one of SMAIO's growth drivers in the United States from the second half of 2026 onward.

Thanks to the financing transactions completed in 2025, we strengthened our financial structure under very favorable conditions. Our cash position reached €5.9 million as of December 31, 2025, and was further strengthened at the beginning of this year with a €3.6 million fundraising, providing us with the flexibility required to pursue our ambitious growth strategy focused on the North American market and our R&D projects.

Building on these structuring milestones and a solid financial position, we now have all the assets needed to continue our growth trajectory and strengthen SMAIO's position as a leading player in vertebral realignment."

¹ The financial statements were approved by the Board of Directors on April 13, 2026. The audit procedures for the 2025 consolidated and parent company financial statements have been completed. The management and group report, the corporate governance report, the financial statements, and the auditor's reports relating to these financial statements will be posted online within the legal deadlines on the Company's website (www.smaio-finance.com) and on the Euronext website (www.euronext.com).

2025 consolidated results

Simplified income statement (SMAIO consolidated accounts, €m)	2025	2024	Change
Sales	9.2	5.5	+67%
Implants sales	9.1	5.3	+70%
of which United States	7.0	2.9	+138%
of which Rest of the world (excluding France)	1.2	1.3	(10)%
of which France	0.9	1.1	(20)%
Other	0.1	0.2	(23)%
Gross margin	7.6	3.8	+101%
Gross margin rate	83%	69%	+14 pts
Operating expenses	(10.3)	(7)	+47%
Operating income	(2.6)	(3.2)	+17%
Financial income/(loss)	(0.1)	0.1	(200)%
Research tax credit	0.4	0.4	-
Net income – Group share	(2.2)	(2.3)	+5%
EBITDA (after recognition of the research tax credit)	(0.8)	(1.3)	+36%

SMAIO Group sales amounted to €9.2 million in 2025, compared with €5.5 million in 2024, representing growth of +67%, driven by the momentum of implant sales in the US market (+138%), which now account for more than 75% of the Group's activity. **Implant sales** represent almost all of the Group's sales and increased by 70% to €9.1 million.

The gross margin rate came to 83%, an improvement of 14 points compared with the previous financial year (69%), due to the very strong acceleration of activity in the United States, where margins are the highest in the sector.

Operating expenses for 2025 amounted to €10.3 million, up +47% compared with 2024, reflecting:

- a mechanical increase in sales commissions in the US market, linked to sales growth;
- the Company's investment in strategic areas that will generate mid-term growth, such as R&D, surgeon training and clinical data generation.

Consolidated operating income for 2025 showed a loss of €2.6 million, reduced by 17% compared with a loss of €3.2 million in the same period of 2024, thanks to the efficient development of sales in the United States.

After considering a negative **financial result** of -€0.1 million and total **tax income** of €0.5 million (including €0.4 million in research tax credit), SMAIO posted a **net loss** of €2.2 million for 2025, compared with a net loss of €2.3 million a year earlier.

EBITDA improved by +36% in 2025 to -€0.8 million.

Solid financial structure

As of December 31, 2025, SMAIO had a cash position of €5.9 million, up from €3.2 million at end-2024, notably as a result of:

- a €2.5 million fundraising, comprising a €1.5 million capital increase and a €1.0 million issuance of convertible bonds;
- the issuance of loans for a total amount of €2.0 million.

In March 2026, SMAIO completed a €3.6 million capital increase through the issuance of shares with warrants attached (ABSA), at a price of €7 per share, subscribed by Eiffel Investment Group. Should all the warrants be exercised by Eiffel Investment Group, at a price of €7.3 per share, the maximum total amount of the transaction could reach €4.5 million.

SMAIO therefore benefits from a strengthened and flexible financial structure, enabling it to pursue its growth strategy focused on the North American market and its R&D efforts.

2025 highlights

Strengthening of the Scientific Advisory Board in the United States

During the financial year, SMAIO welcomed two new members to its North American Scientific Advisory Board. Dr. Donald J. Blaskiewicz, neurosurgeon (St. Luke's Clinic, Boise, Idaho), and Dr. Tenner Guillaume, orthopaedic surgeon (Gillette Children's Hospital, St. Paul, Minnesota), will contribute their expertise alongside the two founding members to support the dissemination of SMAIO's technology within the North American surgical community.

First distribution agreements for the KEOPS-4ME open platform in the United States

During the second half of 2025, SMAIO launched its KEOPS-4ME open platform by signing its first two distribution agreements with major players in the US spine surgery market, Highridge Medical and Orthofix. Under these agreements, surgeons who are customers of Highridge Medical and Orthofix will gain access to all SMAIO vertebral realignment planning functionalities and will be able to combine SMAIO patient-specific rod technology with their existing implant systems in an open, modular configuration. SMAIO intends to capitalize on its position as an innovative and reliable commercial partner for these major surgical companies and to develop future collaborations around its open platform.

Appointment of Matthieu Ville as Chief Commercial Officer

In the second half of 2025, SMAIO appointed Matthieu Ville as Chief Commercial Officer. With more than fifteen years of international experience in the innovation and commercialization of medical technologies (Medicrea/Medtronic, NuVasive, eCential Robotics), he will lead SMAIO's global sales and marketing strategy, notably to accelerate the adoption of iKontrol and the KEOPS-4ME open platform in the United States.

Record attendance at the 4th Sagittal Alignment Think Tank held in New York

In mid-December 2025, SMAIO successfully held its 4th US Think Tank in New York, bringing together a record number of nearly 60 spine experts, including more than 40 surgeons. Participants were able to test the key solutions of the iKontrol ecosystem, notably the KEOPS Balance Analyzer 3D software and the Kheiron system. This event further strengthens the adoption of SMAIO technologies in the United States and reinforces its pioneering role in training surgeons in its holistic sagittal balance approach.

Strategy and outlook

In 2026, SMAIO intends to continue the optimized deployment of its innovative solutions in order to strengthen its technological leadership and pursue a sustainable growth trajectory, through two key levers:

- **Accelerated penetration of the complex spinal deformity market in the United States**, based on a dual approach relying on:
 - direct collaborations with surgeons, through training initiatives and regular interactions with key opinion leaders (KOLs), notably during the Sagittal Alignment Think Tanks, which are attracting growing interest from both the medical and industrial communities;
 - the KEOPS-4ME platform, whose effective rollout from the second half of 2026 onward will represent a new growth driver and a foundation for future collaborations with other North American spine players.

- **Continuous investment in Research & Development**, to enrich and further differentiate SMAIO's solution portfolio, particularly through the progressive integration of new functionalities to make vertebral alignment planning more accurate, more realistic and faster.

Upcoming financial event :

- **First-quarter 2026 sales:** May 12, 2026 (after market)

À propos de 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 its big data database, which has become a global reference with more than 100,000 patient cases documented. SMAIO offers spine surgeons a comprehensive platform, i-Kontrol, incorporating planning, implantable devices and related services, enabling them to treat spinal pathologies in a safe, effective and lasting way. The open platform deployed by the Company in the United States, KEOPS-4ME, is designed to offer a personalized and data-driven approach for complex spine surgeries, enabling SMAIO to enter into commercial partnerships with major US surgical companies and to provide their surgeon customers 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 employees.

For further information, please visit: www.smaio.com

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Listing market: **Euronext Growth Paris**

ISIN : **FR0014005180**

Ticker: **ALSMA**



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