

## SMAIO announces strong first-half 2025 results and robust growth in business activity in the third quarter of 2025

- + Strong sales growth in H1 2025: **+126% to €5.0 million**
- + Increase in **gross margin in H1 2025 to 85%** vs. 64% in H1 2024
- + **Significant improvement in EBITDA (+96%)** reaching break-even (vs. -€0.6 million in H1 2024)
- + **Solid cash position of €4.7 million** as of June 30, 2025
- + Strong sales growth in Q3 2025: **+87% to €2.0 million, o/w +153% in the United States**
- + Further commercial ramp-up in the **United States** expected in 2026 with a **first distribution agreement** signed with **Highridge Medical** for the **KEOPS-4ME open platform**

**Webconference in French today at 6 pm CEST:**

**[Register here](#)**

**Dallas (United States) & Lyon (France), October 14, 2025 – 5 :45 pm CEST – SMAIO (Software, Machines and Adaptive 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, adaptive implants and related services, today publishes its consolidated results for the first half of 2025<sup>1</sup> and its sales for the third quarter of 2025.

**Philippe ROUSSOULY, Chairman and CEO of SMAIO, stated:** *"The results for the first half of 2025 confirm the soundness of our strategy and the growing appeal of our offering, particularly in the United States, the world's largest market for spine surgery.*

*The Group's first-half 2025 sales increased by +126% compared to the first half of 2024, reaching €5.0 million, 75% of which came from sales of Kheiron system implants combined with custom-made K-Rods in the United States. This performance confirms the significant impact of our initiatives to attract a growing number of leading surgeons in the United States to our technology, and our ability to effectively deploy our offering in the centers where they operate.*

*This growth across the Atlantic—a highly lucrative market—is reflected in the improvement of all our financial indicators for the first half of 2025, with the gross margin reaching 85% (+21 points) and a significant improvement in EBITDA (+96%). This validates our cost-controlled commercial approach with a range of implants focused on complex surgery, initially targeting key centers that are likely to subsequently create broader emulation in the US market and beyond. In the coming months, we will nevertheless continue to invest. Firstly, in innovation, by continuing our developments that leverage our extensive database, combining AI with our KEOPS Balance Analyzer 3D planning system, with the aim of offering surgeons ever more powerful, accurate, and scalable solutions that reduce analysis time and thus increase the volume of patients that can be treated.*

<sup>1</sup> Data not audited. The half-yearly financial report on SMAIO's consolidated financial statements will be available, in French, on the Company's website ([www.smaio-finance.com](http://www.smaio-finance.com)) and on the Euronext website ([www.euronext.com](http://www.euronext.com)) within the legal timeframe.

Secondly, by expanding the scope of the North American centers in which we wish to deploy. In this regard, the success of our surgeon training program, Sagittal Alignment Think Tank, continues unabated, with our next session in December already fully booked with more than 40 registrants.

The Group's strong commercial momentum continued in the third quarter of 2025, despite a particularly quiet summer period this year, which is traditionally marked by lower hospital activity. Our sales grew by 87% to €2.0 million, including a 153% increase to €1.5 million in the United States.

The North American market will continue to drive our growth in 2026 and beyond. Recently opened centers will gain momentum, while three to five new centers could open by the start of fiscal year 2026. We will also benefit from the commercial rollout of our KEOPS-4ME open technology platform through partnerships, such as the one recently signed with Highridge Medical, which will lead to much wider distribution across our partners' hospital networks. The open platform is expected to contribute to sales and margins from the second quarter of 2026, given the time needed to deploy the solution in the targeted centers.

Bolstered by these advances and with a solid cash position of €4.7 million, we are more confident than ever in the execution of our strategy, which aims to position SMAIO as a leading player in the international spinal realignment market."

First-half 2025 consolidated results: improvement in all financial indicators

Simplified income statement (SMAIO consolidated financial statements, € millions)	H1 2025*	H1 2024*	Change
Sales	5.0	2.2	+126%
<b>Implant sales</b>	4.9	2.1	+136%
of wich United States	3.8	0.8	+360%
of wich rest of the world (outside France)	0.7	0.7	-7%
of wich France	0.5	0.6	-12%
<b>Others</b>	0.1	0.1	-
Gross margin	4.3	1.4	+201%
Gross margin rate	85%	64%	+21 pts
Operating expenses	(5.2)	(3.1)	+68%
Operating income	(0.9)	(1.7)	+44%
Net financial income	(0.1)	(0.1)	-
Research tax credit	0.2	0.2	-
Net income	(0.7)	(1.2)	+41%

EBITDA (after Research Tax Credit restatement)	0.0	(0.6)	+96%
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\* Unaudited figures.

The SMAIO Group's first-half 2025 **sales** amounted to €5.0 million, compared with €2.2 million in the first half of 2024, representing an increase of +126% driven by strong implant sales in the US market, which now accounts for more than 75% of the Group's business. **Implant sales** account for almost all of the Group's sales and grew by 136% to €4.9 million.

The **gross margin rate** was 85%, an improvement of +21 points compared to the previous financial year due to the very strong acceleration of activity in the United States, where margins are the highest in the sector.

**Operating expenses** for the first half of 2025 increased by 68% compared to the same period in 2024, reaching €5.2 million, mainly due to a mechanical increase in sales commissions on the US market linked to sales growth.

**Consolidated operating income** for the first half of 2025 showed a loss of €0.9 million, down from a loss of €1.7 million for the same period in 2024, thanks to effective sales development in the United States.

After taking into account **financial income** of €0.1 million and total **tax income** of €0.3 million (including €0.2 million in research tax credit), SMAIO's **net income** for the first half of 2025 showed a loss of €0.7 million, compared with a loss of €1.2 million a year earlier.

**EBITDA** for the first half of 2025 improved by +96%, reaching a level close to break-even (-€0.03 million).

**Solid financial structure**

During the first half of 2025, SMAIO raised €2.5 million in funding, comprising a €1.5 million capital increase and a €1 million convertible bond issue.

As of June 30, 2025, SMAIO thus has a solid cash position of €4.7 million, compared with €3.2 million at the end of 2024, enabling it to pursue its growth strategy focused on the North American market and its R&D.

**Signing of a first distribution agreement for the KEOPS-4ME open platform in the United States**

Marking the commercial launch of its KEOPS-4ME open platform in the United States, SMAIO signed its first major distribution agreement at the end of September 2025 with Highridge Medical, one of the world's largest privately held spine companies.

Under this partnership, surgeons who are Highridge Medical customers will have access to all of SMAIO's spinal realignment planning features and will be able to combine SMAIO technology with their existing implant systems in a modular and open configuration.

This alliance gives SMAIO greater access to a large network of specialized centers and spine surgeons in the United States, and the company plans to enter into new partnerships of this type in North America in the near future.

**Strong sales growth in the third quarter and the first nine months of 2025**

In millions of euros	Q3 2025*	Q3 2024	Change	9M 2025	9M 2024	Change
<b>Sales of implants and instruments **</b>	<b>2.0</b>	<b>1.1</b>	<b>+88%</b>	<b>6.9</b>	<b>3.1</b>	<b>+120%</b>
<i>of which United States</i>	<i>1.7</i>	<i>0.7</i>	<i>+153%</i>	<i>5.5</i>	<i>1.5</i>	<i>+268%</i>
<i>of which rest of the world (outside France)</i>	<i>0.2</i>	<i>0.2</i>	<i>-19%</i>	<i>0.8</i>	<i>0.9</i>	<i>-10%</i>
<i>of which France</i>	<i>0.1</i>	<i>0.2</i>	<i>-24%</i>	<i>0.6</i>	<i>0.8</i>	<i>-15%</i>
<b>Other</b>	-	-	-	<b>0,1</b>	<b>0,1</b>	-
<b>Total Group sales</b>	<b>2.0</b>	<b>1.1</b>	<b>+87%</b>	<b>7.0</b>	<b>3.3</b>	<b>+113%</b>

\* Data not audited; \*\* Including custom-made rods

In the **third quarter of 2025**, the SMAIO Group posted **sales** of €2 million, mainly consisting of implant sales, up 88% compared to the third quarter of 2024.

This significant increase reflects the continued expansion of the business in the United States, where the Group generated €1.7 million in sales (\$2.0 million), representing 83% of the business activity, up 153% compared to the same period in 2024.

Over the **first nine months** of fiscal year 2025, the SMAIO Group generated sales of €7 million, a sustained increase of 113% compared to the same period in 2024, fueled by strong performance in the North American market (+268% to €5.5 million or \$6.1 million).

Strategy and outlook

Over the coming semesters, SMAIO will continue to execute its strategic roadmap, benefiting from increased financial flexibility and leveraging two key drivers:

- **Commercial ramp-up in the United States:** intensification of initiatives with referral centers specializing in complex spinal surgery and organization of specialized training courses for surgeons, with the next session scheduled to take place in New York in December 2025. SMAIO aims to reach around 20 user centers by the end of 2026. The rollout of the KEOPS-4ME platform to surgeons in the Highridge Medical network and through new partnerships with other major players in the sector will be another significant growth driver.
- **Ongoing investment in innovation and development:** integration of artificial intelligence modules into surgical planning solutions to provide surgeons with increasingly powerful, precise, and scalable tools, such as automating the 3D reconstruction model of the spine, which until now has been obtained by identifying key anatomical elements on patient X-rays, and predicting realignment following surgery on areas of the spine that have not been operated on.

In the mid and long term, the SMAIO Group intends to strengthen its position as a leading player in the international spinal realignment market.

Upcoming financial events:

- **Full year 2025 sales:** Tuesday, January 20, 2026 (after market close)

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

Contacts SMAIO

SMAIO

Philippe Roussouly  
Chief Executive Officer  
Renaut Fritsch  
Chief Financial Officer  
[investors@smaio.com](mailto:investors@smaio.com)

NewCap

Dusan Oresansky/ Aurélie Manavarere  
Investor Relations  
[smaio@newcap.eu](mailto:smaio@newcap.eu)  
Tel.: +33 (0)1 44 71 94 92

NewCap

Arthur Rouillé  
Media Relations  
[smaio@newcap.eu](mailto:smaio@newcap.eu)  
Tel.: +33 (0)1 44 71 00 15

Listing market: Euronext Growth Paris  
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