

SMAIO reports first-half 2026 results and sales for the third quarter of 2026

- + **Half-year sales rose by 3% to €5.1m**, driven by implant sales in the **United States, which increased by 3% to €3.9m** (up 10% to \$4.5m, excluding currency effects)
- + **Solid gross margin of 81%**
- + **EBITDA of -€0.8m**, reflecting increased R&D investments and marketing efforts to expand the network of surgeons
- + **Cash position of €7.0m** at June 30, 2026, providing support for the R&D and sales strategy
- + **Revenue for the first 9 months of 2026 rose by 2% to €7.2m**, driven by significant diversification of the customer base, reducing reliance on certain long-standing accounts
- + **Expansion of the North American network to support sustained long-term growth** driven by the rise of the open platform and the signing of new accounts

Webconference in French today at 6 p.m. (CEST):

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Dallas (United States) & Lyon (France), October 13, 2026 – 5:45 p.m. CEST – SMAIO (Software, Machines and Adaptive Implants in Orthopaedics – Euronext Growth Paris, ISIN Code: 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 announces its consolidated results for the first half of 2026 and its sales for the third quarter of 2026.

Philippe ROUSSOULY, Chairman and CEO of SMAIO, stated: *"In the third quarter of 2026, our sales totaled €2.0 million, remaining stable compared to last year. For the first nine months of the year, sales reached €7.2 million up 2%, with nearly 80% generated in the United States. In dollars, our North American sales rose 4% to \$6.4 million; converted to euros, they remained stable at €5.5 million, as unfavorable exchange rate movements had a negative impact of €0.2 million over the period.*

This moderate growth masks a profound transformation in our U.S. customer base. Four long-standing partner surgeons, who represented more than half of our U.S. sales in the first nine months of 2025 (\$3.5 million), reduced their activity in 2026 (\$2.2 million): three of them due to their move to new centers at the beginning of the year, and the fourth for personal reasons that affected his surgical practice beyond SMAIO.

To date, we are seeing a gradual resumption of surgeries following the registrations completed at two of the three new centers where the aforementioned surgeons have recently set up practice, and we hope to obtain registration for the third center in early 2027. We anticipate that the fourth surgeon mentioned will be unable to perform surgeries in the coming months, leading to a corresponding increase in the workload for the other SMAIO-affiliated surgeons working at the same center.

At the same time, our U.S. customer base has expanded significantly over the past nine months:

- About thirty surgeons have used our custom-made rods, either through our open platform in collaboration with our industrial partners or in combination with other compatible systems, for more than 80 procedures (more than \$260,000, compared to approximately \$100,000 in 2025).
- About ten new surgeons have signed up for our comprehensive package (over \$0.9 million).
- Our existing customers' activity across our entire product portfolio increased by nearly 27% (\$3.0 million compared with \$2.4 million).

This momentum is expected to gain further traction thanks to our industry partnerships. Following Orthofix, with the first billings for patient-specific rods K-ROD on the KEOPS-4ME open platform, and Highridge, the signing in early October of a distribution agreement with DePuy Synthes, one of the world's leading orthopedic companies, marks a major milestone. This third partnership with a leading player confirms the appeal of our open platform, which has the potential to become a powerful driver of adoption for our technologies in the United States. Sales volumes with Orthofix and Highridge are also expected to grow as the listings initiated since the beginning of the year in targeted centers take effect.

At the same time, we are increasing our R&D investments, both in our software, particularly our artificial intelligence applications designed for automated image processing and predictive analysis of patient data, and in our implants. We have made significant progress on our cobalt-chrome rod, which is highly anticipated by North American open-platform surgeons, as well as on the multi-axial version of our pedicle screw, which will offer our customers greater versatility in treating a growing number of patients.

Finally, we continue to raise awareness among the international surgical community about the concept of spinal alignment, following the recent success of our Sagittal Alignment Contest in Sydney, which drew about 40 participants, and the 5th edition of our Sagittal Alignment Think Tank, scheduled to take place in New York in December.

With cash and cash equivalents of €7.0 million at June 30, 2026, a range of innovative solutions, and a growing presence in U.S. centers of excellence, we are approaching the coming months with an unwavering commitment to making SMAIO the international leader in spinal alignment."

First-half 2026 consolidated results

Simplified income statement (SMAIO consolidated financial statements, € millions)	June 30, 2026*	June 30, 2025*	Change
Sales	5.1	5.0	+3%
Implant sales	5.1	4.9	+3%
of which United States	3.9	3.8	+4%
of which rest of the world (outside France)	0.7	0.7	n.s.
of which France	0.5	0.5	n.s.
Others	0.0	0.1	-
Gross margin	4.2	4.3	(2)%
Gross margin rate	81%	85%	(4) pts
Operating expenses	(5.9)	(5.2)	+15%
Operating income	(1.7)	(0.9)	(80)%
Financial results	0.1	(0.1)	+179%
Research tax credit	0.2	0.2	+18%
Net income – Group share	(1.2)	(0.7)	(72)%
EBITDA (after research tax credit restatement)	(0.8)	0.0	n.s.

* Unaudited figures

The SMAIO Group's first-half 2026 **sales**, which consists almost exclusively of implant sales, rose by 3% (+8% excluding currency effects), driven by the expansion of sales of the Kheiron implant system to new users in the U.S. market, which now accounts for more than 80% of the Group's total sales.

The **gross margin** stood at 81% at the end of the first half of 2026, compared with 85% for the same period in fiscal year 2025, reflecting an expansion of the production unit for patient-specific rods K-ROD during the second half of fiscal year 2025, which formed the basis of the strategy to penetrate the U.S. market, where margins are the highest in the industry.

Operating expenses for the first half of 2026 rose by 15% to €5.9 million, reflecting SMAIO's investments in its two strategic pillars:

- **R&D:** The Company has accelerated its investments in innovation, hardware, and software. On the one hand, SMAIO is in the process of finalizing the last steps required to bring its cobalt-chrome rods to market. On the other hand, the Group is enhancing its software and hardware, and developing applications to assist surgeons, with a view to continuously improving the planning and monitoring of spinal alignment.
- **Training and coordinating a network of expert surgeons:** With the support of its scientific advisory board and marketing teams, SMAIO has continued to roll out its surgeon training program and prepare new sessions of the Sagittal Alignment Think Tank, with the first one held in October 2026 in Sydney, Australia. These initiatives are a key driver of the adoption of SMAIO's solutions by spinal surgeons.

Consolidated operating income for the first half of 2026 showed a loss of €1.7 million as of June 30, 2026, compared with a loss of €0.9 million for the same period in fiscal year 2025.

After taking into account **financial income** of €0.1 million and total **tax income** of €0.4 million (including €0.2 million in research tax credit), SMAIO's **net income** for the first half of 2026 showed a loss of €1.2 million, compared with a loss of €0.7 million a year earlier.

EBITDA for the first half of 2026 was -€0.8 million, compared with -€0.03 million in the first half of 2025.

Sales for the third quarter and the first nine months of 2026

In millions of euros	9M 2026	9M 2025	Change
Sales of implants and instruments **	7.1	7.0	+2%
<i>of which United States</i>	<i>5.5</i>	<i>5.5</i>	<i>+1%</i>
<i>of which rest of the world (outside France)</i>	<i>0.9</i>	<i>0.8</i>	<i>+4%</i>
<i>of which France</i>	<i>0.7</i>	<i>0.6</i>	<i>+10%</i>
Others	0.1	0.1	-
Total Group sales	7.2	7.0	+2%

* Unaudited data; ** Including patient-specific rods K-ROD

In **the third quarter of 2026**, the Group's sales totaled €2.0 million, remaining stable compared to the third quarter of 2025. In the United States, implant sales totaled \$1.8 million (or €1.6 million), compared with \$2.0 million a year earlier. This slight decline in the United States reflects a shift in the surgeon base, with a decrease in activity from three long-standing clients and the still-gradual resumption of activity by one of the main users of the Kheiron system following its integration into a new university hospital. The relative stability of sales over the quarter thus illustrates the contribution of new centers and surgeons added to the network, as well as the gradual diversification of the Group's surgeon-client base.

For **the first nine months** of fiscal year 2026, sales totaled €7.2 million, including €5.5 million in the United States, which continued to be affected by the negative impact of euro/dollar exchange rate, resulting in a €0.2 million impact over the period.

In line with its strategy, the Group continued to expand its North American network: two new centers began operations, and SMAIO now relies on around 40 surgeons, in addition to users of the open platform. These developments, combined with the surgeons who began using the SMAIO solutions during the third quarter

of 2025, generated additional sales of \$0.9 million for the period. Sales from existing customers across the entire product portfolio grew by nearly 27% to \$3.0 million.

Solid financial structure

In March 2026, SMAIO completed a €3.6 million capital increase through the issuance of shares with stock warrants at a price of €7 per share to Eiffel Investment Group. If Eiffel Investment Group exercises all the stock warrants at a price of €7.30 per share, the maximum total amount of the offering could reach €4.5 million.

As of June 30, 2026, SMAIO had cash and cash equivalents of €7.0 million (compared with €5.9 million as of December 31, 2025), enabling it to continue its growth strategy focused on the North American market and R&D.

Highlights of the first half of 2026 and recent events

Strengthening the U.S. Scientific Advisory Board

In May 2026, SMAIO announced the appointment of Dr. Jeffrey M. Hills, an orthopedic surgeon specializing in complex spinal conditions in adults and children, and an Assistant Professor / Clinical at UT Health San Antonio (Texas), to its U.S. Scientific Advisory Board. His appointment is part of the company's strategy to build a network of leading experts in the United States, the world's largest market for spinal surgery.

Initiation of coverage by Portzamparc (BNP Paribas Group)

During the second quarter of 2026, the brokerage firm Portzamparc initiated coverage of SMAIO stock with a Buy recommendation and a price target of €8.80 per share. SMAIO stock is now covered by three research firms: Portzamparc, EuroLand Corporate, and TP ICAP.

Organization of Sagittal Alignment Contest in Sydney

On October 5, 2026, SMAIO, in collaboration with its Australian distribution partner Evolution Surgical, organized the Sagittal Alignment Contest in Sydney. The event, led by eight international experts in spinal surgery, including three members of SMAIO's North American Scientific Advisory Board (Dr. Brian Neuman, Dr. Jeffrey Hills, and Dr. Tenner Guillaume), provided an opportunity to present the main approaches to sagittal alignment to around 40 surgeons. At the heart of the event, two interactive workshops allowed participants to compare different correction strategies on real clinical cases, both pediatric and adult, with direct access to the planning software. This initiative illustrates SMAIO's commitment to bringing together a community of international surgeons around its approach to spinal alignment.



Agreement with DePuy Synthes for the KEOPS-4ME open platform

Under this agreement, signed on October 6, 2026, SMAIO intends to leverage expanded access to DePuy Synthes' hospital network to accelerate the adoption of its technology in the United States. This partnership confirms the appeal of the KEOPS-4ME open platform and is expected to serve as a major driver for its deployment.

Strategy and outlook

Over the next few quarters, SMAIO plans to focus on two growth drivers:

- **Growing penetration into U.S. centers of excellence:** SMAIO is continuing its direct collaborations with surgeons at leading centers, with the goal of establishing a denser commercial network and generating more recurring surgical business. At the same time, the rollout of the KEOPS-4ME platform through partnerships is expected to gain momentum and serve as a new growth driver;
- **Software innovation:** the gradual integration of new features into planning software and surgeon-assistance applications to make spinal alignment planning more accurate, more realistic, and faster.

With a growing user base and an expanded product line, the SMAIO Group intends to continue its growth trajectory in the United States, the world's leading market for spinal care.

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 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 50 highly specialized employees.

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

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