

SMAIO publishes its 2023 annual results

- + Net profit of €1.1m in the parent Company financial statements (loss of €0.8m in consolidated statements*), reflecting effective cost control in a context of growth and investment in surgical planning technologies using artificial intelligence
- + Significant improvement in margin on implant sales to 67% in the parent Company financial statements (in 71% consolidated statements*), vs. 63% in 2022
- + Solid cash position of €6.8m (€6.9m in consolidated statements*) at December 31, 2023

Lyon, April 16, 2024 – 6:00 pm CEST – SMAIO (Software, Machines and Adaptative Implants in Orthopaedics – Euronext Growth Paris, ISIN: FR0014005180 / Ticker: ALSMA), a French player specialized in complex spine surgery with a global offer comprising software, adaptative implants and related services, today published its 2023 annual results¹ approved by the Board of Directors on April 15, 2024.

Philippe ROUSSOULY, Chairman and CEO of SMAIO, said: *"The year 2023 marked a major turning point in SMAIO's history with the achievement of our 3 main objectives. First of all, the FDA's 510(k) certification of the customized version of our surgical planning software enabled us to receive a \$3 million payment from our American partner, NuVasive. This demonstrates our expertise and paves the way for the upcoming release of a brand-new surgical planning platform incorporating artificial intelligence to model the spine and provide practitioners with an optimized simulation of the surgical outcomes to be achieved. In the second part of the year, we activated several major user centers of SMAIO solutions in the US, demonstrating the increasing adoption of our technology by surgeons and validating the relevance of the various training programs we have conducted in the US over the past months. Finally, we have strengthened our financial structure through non-dilutive funding of €2.5 million, providing us with the necessary resources to continue deploying our growth strategy focused on the North American market."*

Full-year 2023 results

SMAIO SA

Simplified income statement (SMAIO SA – parent Company - in €m)	2023	2022
Sales	7.6	2.4
Capitalized production	1.1	0.7
Operating income	8.9	3.2
Operating expenses	(8.2)	(7.2)
Operating profit/(loss)	0.7	(4.0)
Exceptional income/(expenses)	-	6.6
Net profit/(loss)	1.1	2.8

¹ The audit procedures on the annual accounts have been completed. The management report, the corporate governance report, the annual financial statements and the auditor's report relating to these annual financial statements will be available within the legal deadlines on the Company's website (www.smaio-finance.com) and on the Euronext website (www.euronext.com).

Taking into account intra-group sales of implants, which are strongly linked to the growth of SMAIO's U.S. subsidiary, **SMAIO SA's sales 2023** amounted to €7.6 million, up +212% compared to 2022. After neutralizing intra-group sales of implants between SMAIO SA and its U.S. subsidiary SMAIO USA and considering only the hospital implant sales conducted by the latter, **SMAIO Group's sales** came to €5.4 million*, representing a +120% growth compared to 2022. Sales of the Kheiron system, consisting of customized implants and rods, were particularly strong in the last quarter of the year (+40% vs. Q4 2022) due to surgeries performed in the U.S., initiated during the second half of 2023.

Capitalized production reached €1.1 million compared with €0.7 million in 2022, reflecting SMAIO's R&D efforts and enabling to position the Company as a key differentiator in the spinal surgery sector.

The **margin on the purchase cost** of implant sales has continued its upward trend, up from 63% in 2022 to 67% in 2023 (71% on a consolidated basis*). This trend is the direct result of the optimization of the Company's purchasing prices, coupled with the growth in international sales in high value-added markets. This margin should continue to increase significantly for SMAIO from 2024 with the ramp-up of the U.S. subsidiary, a market where margins have historically been higher.

The increase in **other operating expenses** is the result of the efforts made by SMAIO in R&D, since its IPO in April 2022, with the strengthening of its software development teams integrating artificial intelligence (AI) and the promotion of its solutions through the "Sagittal Alignment Academy" training courses held in Europe and the United States.

In view of the above, **operating profit** for 2023 stands at €0.7 million, compared with a loss of -€4.0 million in 2022.

After considering a research tax credit of €0.4 million, **net profit** for 2023 stood at €1.1 million, compared with a profit of €2.8 million for the same period in 2022, which was the result of exceptional income following the cancellation of SMAIO's debts to its main shareholder, Sylorus Scientific, prior to the company's IPO.

SMAIO Group (for information only)

SMAIO does not exceed any of the 3 thresholds set by art. R233-17 of the French Commercial Code and did not produce consolidated financial statements for the year ended December 31, 2023. However, to provide accurate and comparable financial information, the Company is informing the public of the SMAIO Group's consolidated results after elimination of internal transactions and non-tax consolidation restatements.

Simplified income statement (Consolidated statements - in €m)	2023	2022
Sales	5.4	2.4
<i>of which France</i>	<i>1.1</i>	<i>1.1</i>
<i>of which US</i>	<i>0.3</i>	<i>-</i>
<i>of which Rest of the World</i>	<i>1.2</i>	<i>1.3</i>
<i>of which milestone payment</i>	<i>2.8</i>	<i>-</i>
Operating profit/(loss)	(1.1)	(4.0)
Exceptional income/(expenses)	-	6.6
Net profit/(loss)	(0.8)	2.8

* Unaudited figures

The SMAIO Group's operating result amounted to -€1.1 million, after restatement of sales of implants, instruments and services between the parent company SMAIO SA and its U.S. subsidiary SMAIO USA in order to give it the necessary resources to implement its strategy of entering the U.S. market, and after incorporating the margin on the purchase cost of implant sales to U.S. hospitals, at 91%.

Solid financial structure

The cash position of SMAIO SA was €6.8 million at December 31, 2023 (€6.9 million in consolidated statements* and €6.5 million after deduction of the portion of bank loans still to be repaid in 2024), compared with €5.7 million at December 31, 2022. This increase is due to a good control over cash burn levels, the milestone payment from NuVasive, and the receipt of a non-dilutive financing of €2.5 million in the form of a R&D loan from Bpifrance Innovation (€1 million, that includes a 3-year grace period) and two loans from a banking pool, including BNP Paribas and Société Générale (€1.5 million, 4-year maturity).

The equity of SMAIO SA stood at €10.8 million (€8.9 million in consolidated statements*) at December 31, 2023, compared with €9.8 million at December 31, 2022.

2023 highlights

- **FDA 510(k) clearance for customized version of surgical planning software co-developed with NuVasive**

In June 2023, SMAIO announced that it had obtained FDA 510(k) clearance for the customized version of its "Balance Analyzer 3D" surgical planning software, co-developed with NuVasive. The achievement of this first milestone, in line with the roadmap presented by SMAIO at the time of its IPO in April 2022, triggered the payment of \$3 million by NuVasive to SMAIO. Following the acquisition of NuVasive by Globus Medical, a U.S. company specializing in spinal instruments and implants, SMAIO is continuing discussions with the latter on the next steps in the partnership, which includes an additional payment linked to the development of a future version of the Balance Analyzer 3D, the core technologies of which can be used by both companies. SMAIO will keep the market informed of the outcome of discussions with Globus Medical.

- **Success of a new "Sagittal Alignment Think Thank" educational program in the United States**

As a follow-up to the first four Sagittal Alignment Academy training programs for its European (Copenhagen, Madrid and Brussels in October 2022 and April 2023) and North American (Dallas in November 2022) customers, SMAIO has accelerated the dissemination of its holistic approach to spine surgery in the United States with the first Sagittal Alignment Think Tank in November 2023.

SMAIO's goal is to develop a consensus with North American surgeons on a patient-specific method of spinal realignment, based on the extensive data in SMAIO's KEOPS database, from which it is developing several technologies using artificial intelligence². These training courses provide an opportunity to understand how the i-kontrol platform can be used to accurately plan and perform spinal realignment surgery in daily practice.

Strategy and outlook

SMAIO is continuing to implement its strategic plan presented at the time of the IPO, and will continue to build its growth by investing its resources in 2 main areas:

- The development of highly innovative solutions based on the Kheiron system and the KEOPS Balance Analyzer 3D planning software, for its own use or through customized versions incorporating artificial intelligence.
- The development of its commercial activity in the United States via its complete i-kontrol package or its customized planning solutions using SMAIO's new AI platform, which is currently being rolled out, with the aim of reaching around ten i-kontrol surgeons and around forty users of the AI planning platform on a recurring basis by the end of 2025.

² The artificial intelligence embedded in SMAIO's software can, for example, automatically identify key anatomical landmarks on X-rays, enabling the patient's spine to be modelled in 3D while measuring the corresponding shape and position angles, or simulate the most appropriate spinal shape to be restored for each patient by surgery, as well as the effects of surgery on the spinal alignment of non-operated levels, and the subsequent positioning of the pelvis.

Upcoming financial events:

- **Annual General Meeting:** June 18, 2024
- **Sales for the first half of 2024:** July 16, 2024 (after market close)
- **Half-year 2024 results:** October 15, 2024 (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 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

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