

## SMAIO publishes its first-half 2024 results and announces the creation of a high-profile scientific advisory board to support its development in the United States

- + Sales of implants and instruments up +81% to €2.2 million
- + Margin on implant sales up sharply to 79% from 71% at end 2023, driven by the ramp-up of surgeries in the United States
- + Good management of operating expenses (+16%), reflecting targeted, controlled sales deployment in the US market
- + Solid cash position of €5.1m at June 30, 2024
- + Creation of a scientific advisory board with the appointment of first two North American surgeons, experts in spinal alignment

**Lyon, October 15, 2024 – 6:00 pm CEST – SMAIO (Software, Machines and Adaptive Implants in Orthopaedics – Euronext Growth Paris, ISIN: FR0014005180 / Ticker: ALSMA), a French player specialized in complex spine surgery with a global offer comprising software, adaptive implants and related services, today published its first-half 2024 results<sup>1</sup> approved by the Board of Directors on October 14, 2024 and announced the creation of a scientific advisory board to support its development in the United States.**

**Philippe ROUSSOULY, Chairman and CEO of SMAIO**, said: *"The first half of 2024 was marked by strong sales growth momentum in the US market, which now accounts for more than a third of our commercial activity. This performance reflects the successful launch of SMAIO's targeted growth strategy, based on the rapid adoption of our solutions by a dozen prescribing surgical centers in the United States.*

*This is the result of the educational work carried out by the company over the past two years on its vertebral realignment concept, through training courses, practical sessions and "think tanks" organized in key centers. This work will continue to develop over the coming months, and we are confident of sustained sales growth in the United States, where margins in the spinal surgery segment are the highest in the world. In this respect, we are delighted to initiate the creation of a North American scientific advisory board, comprising leading surgeons, which will enable us to accelerate the dissemination of our technology in this key market.*

*The company is also continuing to manage its sales and marketing costs very carefully, using a number of local distributors who are paid according to sales, while benefiting from the support of our customer support team, and my direct presence in the United States to develop new accounts.*

*The sales growth that will be driven by the North American market, combined with strict control of fixed costs incurred by the company mainly for innovation, maintenance and development of new industrial certifications for its products, as well as a targeted promotional strategy, supported by recognized KOLs, should enable SMAIO to position itself as an international leader in the spinal realignment market and generate profitable growth over time."*

<sup>1</sup> Data not audited. The half-yearly financial report on SMAIO's consolidated financial statements is 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)).

## First-half 2024 consolidated results

Simplified income statement (SMAIO consolidated financial statements*, € millions)	H1 2024	H1 2023 pro forma**	H1 2023
<b>Sales</b>	<b>2.2</b>	<b>1.2</b>	<b>4.0</b>
<i>of which France</i>	0.6	0.6	0.6
<i>of which the United States</i>	0.8	-	-
<i>of which rest of the world</i>	0.8	0.6	0.6
<i>of which milestone payment</i>	-	-	2.8
Capitalized production	0.4	0.4	0.4
<b>Operating income</b>	<b>2.6</b>	<b>1.6</b>	<b>4.4</b>
Operating expenses	(4.3)	(3.7)	(3.7)
<b>Operating profit/(loss)</b>	<b>(1.7)</b>	<b>(1.9)</b>	<b>0.9</b>
<b>Financial profit/(loss)</b>	<b>0.1</b>	<b>(0.1)</b>	<b>(0.1)</b>
<b>Net profit/(loss) - Group share</b>	<b>(1.2)</b>	<b>(1.7)</b>	<b>1.1</b>

\* Data not audited

\*\* To provide comparable information, the company is presenting a simplified income statement including pro forma H1 2023 figures, excluding the milestone payment.

**Sales** for the first half of 2024 amounted to €2.2 million, compared with €4.0 million for the same period in 2023, which included a €2.8 million milestone payment from NuVasive.

SMAIO's implant and instrument sales generated €2.1 million in the first half of 2024, up 80% on the first half of 2023, driven by the opening of its US subsidiary (€0.8 million in the first half of 2024) and increased business activity in Scandinavia.

The **margin** on implant sales, which account for 95% of SMAIO's total business, stands at 79%, up 8 points on December 31, 2023 (71%) and 12 points on June 30, 2023 (67%) due to the start of billing in the United States, where margins are the highest in the sector.

**Operating expenses** rose by €0.6 million compared to the first half of 2023, mainly as a result of a mechanical increase in commissions on sales in the US market, which are keeping pace with sales growth, a rise in payroll as the Group finalizes the structuring of its operational teams, notably for customer support in the United States, and, lastly, depreciation and amortization charges directly correlated with R&D efforts, mainly to develop the artificial intelligence modules deployed in the surgical planning offering.

Taking these factors into account, consolidated **operating income** showed a loss of €1.7 million for the first half of 2024, compared with a profit of €0.9 million for the same period in 2023, which included a non-recurring milestone payment of €2.8 million.

After recognition of **financial income** of €0.1 million, mainly from returns on capital-guaranteed cash investments, total **tax income** of €0.4 million including a €0.2 million research tax credit, and deferred taxes, SMAIO's **net income** for the first half of 2024 was a loss of €1.2 million.

### Solid financial structure

The cash position of SMAIO at June 30, 2024 was €5.1 million, compared with €6.9 million at December 31, 2023. This trend demonstrates the ability of SMAIO to develop its business in new, high-potential markets, and to invest in R&D and business development - growth drivers for the Group - while keeping its costs under control.

Shareholders' equity of SMAIO stood at €8 million at June 30, 2024, compared with €9.3 million at December 31, 2023.

## Significant post-closing event

### Creation of a leading scientific advisory board to support development in the United States

After around 100 surgeries performed by SMAIO in the United States since the beginning of 2024, the Company is initiating the creation of a North American scientific advisory board. As such, **Dr. Brian J. Neuman** (orthopedic surgeon) and **Dr. Camilo Molina** (neurosurgeon), both practicing at the prestigious Washington University School of Medicine in St. Louis, have agreed to join this new scientific board, with the following main missions:

- collaborate with SMAIO in the development of implant technologies and software, adapting them to the specific needs of North American patients and surgeons;
- contribute to the analysis and publication of scientific results obtained through the use of SMAIO technologies, in particular those using artificial intelligence;
- communicate with their peers about the benefits of using SMAIO technologies for both patient and surgeon;
- train peers in the use of SMAIO technologies for the planning and execution of spine realignment surgery.

This new scientific advisory board is a major strategic resource for SMAIO and will provide the Company with expertise and support for its development in the United States, as well as facilitating the organization of "Sagittal Alignment Think Thanks" across North America.

**Philippe ROUSSOULY, Chairman and CEO of SMAIO**, comments: *"We are pleased and honored to formalize this collaboration with Brian J. Neuman and Camilo Molina, who share SMAIO's values and philosophy, and are among the most renowned experts in complex spine surgery in the United States. This agreement demonstrates both the attention paid by the Company to the management of its financial resources, and the long-term confidence that surgeons have in the project undertaken. We are confident that we will soon be able to announce similar agreements with other leading U.S. surgeons. Their expertise will considerably strengthen our position in the North American market, which is not highly demanding but also lucrative, and will help to spread our innovative technology to a growing number of surgeons in this geographic area of strategic importance to our growth. We are convinced that our close cooperation will ultimately enable us to establish a new paradigm in the treatment of U.S. patients, based on the consideration of individual morphological specificities, and thus improve surgical outcomes".*

**Brian J. Neuman, Chief of the Spine Division at Washington University in St. Louis**, states: *"We are delighted to be joining SMAIO's scientific project, which aims to significantly improve care of patients requiring surgical spine realignment. Our aim is to play an active role in the development of SMAIO's technologies before introducing their benefits to other surgeons facing the same challenges as those who receive daily treatment at Washington University".*

**Camilo Molina, Head of Complex Neurosurgery Department at Washington University in St. Louis**, adds: *"As an innovative European company with expertise in spine realignment thanks to a comprehensive database, SMAIO has tremendous development potential and will have to constantly take into account the specific requirements of the North American market to perform on a large scale. Our aim is to bring our expertise to the exciting scientific and technological research projects launched by the Company in the spine realignment field supported by artificial intelligence, while gearing future developments towards user experience as optimized as possible given the constraints that we face in the United States."*

The profiles of the two founding members of the scientific advisory board and their remuneration, mainly in the form of warrants issued to their benefit, are detailed in the appendix to this press release.

## Strategy and outlook

Over the coming months, SMAIO will continue to implement its strategic plan and build growth based on the following key drivers:

- **Pursue commercial deployment in the United States**, a high value-added market where the Group intends to accelerate its development, notably through Think Tanks, discussions with KOLs and training courses for surgeons at reference centers. Within this framework, the two surgeons from the newly formed scientific advisory board, Brian J. Neuman and Camilo Molina, will have actively

participated in the preparation of an upcoming Think Tank to be held in New York in early December 2024.

- **Continuously invest in the development of new functionalities** and progressively integrate artificial intelligence into SMAIO's planning solutions. In this respect, the presentation this summer at the Las Vegas congress, organized by the international Spine Study Group, of the new preoperative planning platform connected to the future KEOPS-4ME artificial intelligence modules was very well received. Demonstrations were given by Dr. Mike Kelly (Rady Children's Hospital-San Diego), one of the US's leading specialists in the treatment of spinal deformities, on scoliosis realignment simulators. Thanks to these developments, SMAIO intends to make spinal alignment planning both more realistic and faster.

On the strength of these ambitions, SMAIO should experience sustained growth momentum over the coming six months.

#### Upcoming financial news:

- **Full-year 2024 sales:** Tuesday, January 21, 2025 (after market close)
- **Full-year 2024 results:** Tuesday, April 15, 2025 (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](http://www.smaio.com)

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## APPENDIX

### Profile of the founding members of the scientific advisory board

**Dr. Brian J. Neuman** is an orthopedic surgeon at Washington University in St. Louis, specializing in the surgical treatment of complex spinal deformity conditions for adult and pediatric patients. He is professor in the Orthopedics Department at Washington University in St. Louis and is involved in many international spine societies where he collaborates with international experts to develop and validate new surgical techniques, as well as methods to better assess the impact of patient and surgical factors on overall outcomes following ASD surgery. His studies, published in leading scientific journals, focus on improving spine surgery outcomes by integrating robotics and minimally invasive surgery techniques.

**Dr. Camilo Molina** is neurosurgeon and associated professor of neurosurgery and orthopedic surgery at Washington University in St. Louis. He is director of the Spine Deformities and Oncology Department, and co-director of the Department of Patient Safety and Quality Improvement. As Deputy Director of Spine Innovation at the Center for Innovation in Neuroscience and Technology, he is involved in several research projects and specializes in the treatment of spine disorders, including tumors, deformities and trauma. He also contributed to the first FDA-approved augmented reality-assisted spine surgery procedure in the United States.

As member of the American Association of Neurological Surgeons (FAANS), North American Spine Society (NASS) and Congress of Neurological Surgeons (CNS), he has received numerous awards for his contributions to neurosurgery and spine research, including the Johns Hopkins Dept. of Neurosurgery Harvey Cushing Research Award, the Howard Hughes Medical Institute Medical Student Fellows Grant, and the AO Spine Hansjorg Wyss Foundation Award.

### Scientific advisory board remuneration

The commitment of the members of the scientific advisory board will involve several dozen hours of scientific work each year for the benefit of the Company, valued at hourly rates fully in line with current market practices in the United States.

In this context, and to preserve its financial resources, SMAIO has implemented an original method of remunerating the surgeons, to the extent that they will be remunerated mainly by the allocation of a total number of 150,000 share subscription warrants (the "**Warrants**") to their benefit.

### Summary of the terms and conditions of Warrants issue to the first members of the scientific advisory board

This issue follows the delegation of authority granted to the Board of Directors by the Combined General Meeting of June 18, 2024, under the terms of the 12<sup>th</sup> resolution, of an extraordinary character (issue of ordinary shares and/or any other securities giving immediate and/or deferred access by any means to the Company's capital, with cancellation of shareholders' preferential subscription rights in favor of a category of persons) and the decisions of the Board of Directors on October 14, 2024.

The Warrants will be issued for cash, to be paid up in full by cash payment or by offsetting against certain, liquid and payable debts held by the beneficiary surgeons against SMAIO on the date of their subscription, it being specified that the Board of Directors meeting of October 14, 2024 set the unit subscription price of the Warrants at an amount of two euros and twenty-seven cents (€2.27) per Warrant.

In addition, the warrants will not be listed, will be issued in registered form and will be registered in the name of their holder in a pure registered account in the Company's share accounts.

Each warrant will entitle its holder to subscribe for one (1) ordinary share in the Company, subject to compliance by the members of the scientific advisory board with all the legal and regulatory conditions and those set out in the plan regulations relating to the warrants, issued at a total unit price, including issue premium, of three euros and six hundred and eighty-three ten-thousandths of a euro (€3.0683), i.e. a par value of nineteen euro cents (€0.19) and two euros and eight thousand seven hundred and eighty-three ten-thousandths of a euro (€2.8783) issue premium per SMAIO share.



In accordance with the delegation of authority granted by the Combined Shareholders' Meeting of June 18, 2024, the subscription price of the shares allotted on exercise of the warrants shall be at least equal to the volume-weighted average of the share prices for the last three (3) trading days prior to the Board of Directors' meeting of October 14, 2024, less a maximum discount of twenty percent (20.00%) compared with the stated average.

The maximum number of shares that may be issued on exercise of the Warrants is therefore 150,000 ordinary shares, representing around 2.87% of the Company's current capital. These shares will be registered and subject to all legal and statutory provisions and will carry dividend rights as from the date of their creation, it being specified that the new shares will be assimilated to the existing ordinary shares. Details of the dilutive effects of this operation are presented below.

By the end of 2024, several more US surgeons are expected to join SMAIO's scientific advisory board and should benefit from a remuneration scheme like that described above.

**Impact of the issue on equity per share:**

	<b>Equity per share (in €)</b>
<b>Prior to the Warrants issue</b>	€1.53
<b>After exercise of the 150,000 Warrants and issue of 150,000 corresponding new shares</b>	€1.61

**Impact of the issue on the situation of a shareholder:**

	<b>Shareholder interest (in %)</b>
<b>Prior to the issue of the warrants</b>	1.00%
<b>After exercise of the 150,000 Warrants and issue of 150,000 corresponding new shares</b>	0.97%