

SMAIO announces its first-half 2022 results

- + **First-half 2022 sales up +28% to €1.3 million**
- + **Improvement in the sales margin thanks to better implant procurement conditions**
- + **Exceptional income of +€7.4 million resulting from the dropping of the current account held by the Otsuka Group in SMAIO's favor**
- + **Success of April's IPO: cash position of €7.3 million at June 30, 2022**

Lyon (France), September 27, 2022 – 6 pm CEST – SMAIO (Software, Machines and Adaptative Implants in Orthopaedics – Euronext Growth Paris ISIN: FR0014005180 / Ticker: ALSMA, eligible for PEA-PME equity savings plans), a French player specialized in complex spine surgery with a global offer comprising software, adaptative implants and related services, today published its results for the first half of 2022¹, approved by the Board of Directors on September 26, 2022.

Philippe ROUSSOULY, Chairman and CEO of SMAIO, commented: *"This first half of 2022 was marked by the strengthening of our financial capabilities and the strategic contract signed with our American partner NuVasive within the framework of our Initial Public Offering on the Euronext Growth market in Paris. At the same time, we have continued our commercial development, notably abroad where our revenue has recorded substantial growth, whilst improving our sales margin thanks to better implant procurement conditions. In the United States, our priority market, we have met key milestones with the first surgical procedures performed and the granting of two FDA 510(k) clearances for our surgery planning software and our patient-specific rods. Building on our strengthened financial situation and this positive momentum, in the coming months we will focus on organizing training programs in order to promote SMAIO's technologies and services internationally, with a particular emphasis on the United States. Furthermore, in early 2023, our partnership agreement with NuVasive should allow us to obtain a first milestone payment of \$3 million followed by recurrent revenue thanks to imaging analysis services undertaken by SMAIO's operators for NuVasive's clients".*

First-half 2022 results

Simplified income statement (€ millions)	H1 2022	H1 2021
Sales	1.32	1.03
Operating income	1.70	1.53
Operating expenses	(3.45)	(3.29)
Operating profit/(loss)	(1.75)	(1.76)
Exceptional income/(expenses)	7.40	(0.3)
Net profit/(loss)	5.37	(1.60)

Sales totaled €1.3 million in the first half of 2022, an increase of +28% compared with the first half of 2021 (€1.0 million). This improvement was the result of buoyant growth in international activity (+119%), and notably of the ramping up of our historical distributors in Spain and Scandinavia, new distribution agreements signed in the Baltic states and Greece and the first surgical procedures performed in the United States.

¹ The half-year financial report relating to these first-half financial statements will be posted within the statutory time limits on the Company's website (www.smaio-finance.com) and the Euronext website (www.euronext.com).

As in 2021, sales of implants and rods accounted for almost all of the Company's sales (96%). The software segment, with the Keops platform, accounted for the balance (4%) and will see substantial growth over the coming semesters, notably following the granting of 510(k) clearance by the FDA and thanks to the partnership and licensing agreement signed with NuVasive, a global leader in spine technology innovation.

SMAIO's **gross margin** reached a new high of 60%, versus 52% at end-June 2021 and 55% at end-December 2021, thanks to an increased presence on international markets, historically more lucrative, and the more advantageous implant procurement conditions obtained in 2021. The margin on implant sales alone also saw a significant improvement, increasing from 50% in H1 2021 to 63% in the same period of 2022.

Other operating expenses increased in the first half of 2022, primarily as a result of the amortization of the new sets of instruments loaned out or given to hospitals on consignment, the amortization of R&D costs reflecting the intensification of the Company's innovation efforts, as well as inventory depreciations. Amortization, impairment and provision charges came to €0.6 million in the first half of 2022, vs. €0.5 million a year earlier.

The **operating loss** was €1.75 million in the first half of 2022, stable compared with the first half of 2021.

Exceptional items totaled +€7.40 million and consisted entirely of the dropping of the current account held by Japanese group Otsuka – longstanding SMAIO shareholder – to the Company's benefit.

Once a tax expense of €0.27 million is taken into account, there was a **net profit** of €5.4 million in the first half of 2022 compared with a net loss of €1.6 million in the same period of 2021.

Strengthened financial structure

SMAIO had cash and cash equivalents of €7.33 million at June 30, 2022, compared with €0.57 million at December 31, 2021. This figure notably includes the €7.5 million net proceeds of the Company's IPO on the Euronext Growth market in Paris in April 2022. This cash position will allow the Company to finance its development in accordance with the strategy presented to the financial community at that time.

Shareholders' equity stood at €12.32 million at end-June 2022, vs. -€0.62 million at end-December 2021.

On February 1, 2022, Otsuka announced that it was discontinuing its activities in orthopedics and took the decision to transfer its interests to SMAIO's Vice-President of Operations, as well as its current account to SMAIO's only other shareholder, Sylorus Scientific². Furthermore, it also decided to entirely cancel SMAIO's current account debt, thus making the Company debt-free.

H1 2022 highlights

- **Value-creating partnership with NuVasive, a global leader in spine technology innovation**

Sharing a similar vision of the importance of spinal realignment planning and implant placement to achieve favorable, repeatable and long-lasting results, in the first quarter of 2022 NuVasive and SMAIO signed a partnership and licensing agreement to further develop SMAIO's surgical planning solutions and to support the innovation pipeline and commercialization efforts.

As part of this collaboration, NuVasive has pledged to invest a total of \$10 million (~€9 million³) in the Company, of which \$5 million (~€4.5 million³) has already been invested within the framework of SMAIO's IPO, the balance consisting of milestone payments that will be made when the Company receives FDA 510(k) clearance for two software solutions interfacing with the U.S. group's technological platforms. NuVasive has exclusivity regarding the planning tool development partnerships implemented by SMAIO for a three-year period from the date on which the second software solution is approved.

Moreover, within the framework of this partnership, SMAIO will put in place an image analysis and planning assistance service for NuVasive's clients, which will be billed and will thus generate recurring payments

² Sylorus Scientific SA is 80% owned by Mr. Philippe Roussouly, Chairman and CEO of SMAIO, and 20% owned by Mr. Pierre Roussouly (Philippe's father).

³ based on an exchange rate of 1.10 dollars per euro at the time the contract was implemented in March 2022

proportional to the number of analyses performed. This partnership leaves SMAIO free to distribute its own customized bending solutions and the remainder of its KHEIRON implant range either directly or via its network of distributors.

- **Two 510(k) clearances to accelerate development in the United States**

In June, SMAIO announced that it had been granted two 510(k) clearances by the FDA for the key components of its i-Kontrol platform: the Balance Analyzer 3D surgery planning software and the K-rod patient-specific union rod. Thanks to these approvals, SMAIO can now offer its i-Kontrol solution to North American medical centers. These clearances represent a major step in the American market penetration strategy that will be based on the distribution of the comprehensive i-Kontrol solution to key centers invited to participate in training programs called the "*sagittal alignment academy*", as well as on imaging analysis services distributed via NuVasive's network as soon as the first version of the SMAIO surgery planning software jointly developed with its California partner is approved.

Strategy and outlook

Over the coming months, and in accordance with the strategy announced at the time of its IPO, the Company will pursue three key objectives:

1. The ramping up of the partnership with NuVasive, focusing on the development of a customized version of the i-plan platform for NuVasive and, at the same time, an image analysis service offer.
2. The marketing of the i-Kontrol solution in Europe, the United States and Australia. To achieve this, the Company will build on its own sales force, its partner NuVasive in the United States and a network of distributors and agents.
3. The development of innovative R&D projects aimed at improving the accuracy, speed and reliability of spine surgery, with morphologically adapted guides 3D-printed from scans of the vertebrae to be operated upon enabling implants to be accurately positioned in the pedicles, or morphologically adapted trackers allowing vertebrae to be detected in space in order to steer them or guide a robotic arm.

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 30 highly specialized staff.

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

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