

SMAIO, pioneer of a spinal surgery holistic approach, launches its initial public offering on the Euronext Growth[®] market in Paris

- + SMAIO develops one of the world's largest spine patient databases, whose analysis enables to continuously improve patient care
- + Pioneer of a spinal surgery holistic approach combining
 - o spinal realignment and precise implants positioning planning,
 - o assisted surgery execution by 3D printed custom-made guides and patient specific union rods respecting patient anatomy,
 - o multi criteria patient outcomes analysis platform combining imaging and clinical data
- + A €9m investment from NuVasive, a global leader in spine innovation, including approximately €4.5m in subscription commitments for the IPO, and €4.5m in milestone payments (potentially within 36 months) contingent subject to regulatory approvals from the FDA
- + Fixed Price Offer at €5.54 per share
- + Initial size of the offering: capital increase of €9m, which may be increased to approximately €11.9m if the Extension Clause and the Over-Allotment Option are exercised in full
- + Subscription Commitments of up to €6.8m, of which approximately €4.5m from NuVasive and €2m from NextStage AM
- + Subscription period from March 24 to March 31, 2022 (5:00 p.m. CET for over-the-counter subscriptions and purchases, 8:00 p.m. by Internet) for the Public Offering and until March 31, 2022 (5:30 p.m. CET) for the Global Offering
- + Settlement-delivery scheduled for April 5, 2022 and start of trading of the shares scheduled for April 6, 2022
- + Eligibility for: PEA, PEA-PME, Income tax reduction, Innovative Company by Bpifrance, Economic reinvestment within the framework of a capital contribution and subsequent share transfer (article 150-0 B ter of the French General Tax Code)



Lyon (France), March 23, 2022 – 9:00 p.m. CET – SMAIO (Software, Machines and Adaptative Implants in Orthopaedics), a French player specialized in complex spine surgery with a global offer comprising software, adaptative implants and related services, announces the launch of its initial public offering with a view to listing its shares for trading on the multilateral trading facility of Euronext Growth® market in Paris (ISIN Code: FR0014005180 / Ticker: ALSMA).

The French Financial Markets Authority (*Autorité des marchés financiers*, the "**AMF**") approved the Prospectus relating to the Company's initial public offering on March 23, 2022 under number 22-067. The document is available free of charge at SMAIO, as well as on the websites of SMAIO (www.smaio-finance.com) and the AMF (www.amf-france.org).

Philippe ROUSSOULY, CEO of SMAIO, stated: *"Our IPO project is a major step for SMAIO which aims to establish a new paradigm in spine surgery. Nowadays, the main players are first and foremost implant manufacturers who subsequently introduced software tools to help the surgeon improve surgery outcomes, SMAIO's distinctive approach relies on more than ten years' experience in spine data collection and processing, monitoring spine surgeries performance and risk, deploying a global strategy combining precise planning, tailor-made execution served by several integrated technologies assistance to the surgeon and an analytical long term patient data follow-up. Pioneering in the use of data to treat spinal pathologies, SMAIO relies on KEOPS, the largest database containing more than 100,000 patient cases, in order to perform tailor-made surgeries providing sustainable patient balance. A leading innovator in surgical planning, the Company has also secured an investment with NuVasive, a global leader in spine technology innovation, which further enables SMAIO's innovation roadmap and commercialization efforts. Benefiting from solid clinical results thanks to more than 1,400 surgeries performed to date with its implants, SMAIO brings real added value to the healthcare system by monitoring patient quality of life. These post-operative data continue to feed the SMAIO database and constantly increase the quality of future interventions. Our holistic approach thus makes it possible to push the process of continuous improvement of spine surgery as much as possible. Positioned in a fast-growing market, driven by the need for efficient and reliable solutions, SMAIO aims, thanks to this IPO project, to accelerate its commercial development, particularly in the United States, the world's leading spine market. while exploiting the immense potential of its database and its tailor-made surgical technologies, ultimately opening the way to active robotics and the progressive automation of surgical procedures".*

SMAIO's ambition

“ Optimize the surgical procedure with a holistic range of solutions to restore the sagittal balance of patients in a sustainable way ”

Today, the standard treatment for spinal pathologies, the posterior fusion, faces two major limitations: spinal surgery often proves to be insufficiently planned, while most implants prevent precise execution of the surgical plan, which can lead to surgeries that are unsuited to the specificities of each patient, risky and generating expensive revisions. On the posterior fusion market accounting for 3 billion euros¹, SMAIO is positioned as one of the few players able to overcome these two limits thanks to an approach designed since the beginning as global and integrated. It provides the surgeon with a range of holistic solutions called i-kontrol, optimizing his operating capabilities to achieve favorable long term lasting results as systematically as possible. This innovative approach is based on three pillars: precise tailor-made planning configured according to the surgeon preferences, integrated technology to assist in the execution of surgery and analytical performance and risk monitoring for each surgical procedure.

01 Precise surgical planning thanks to big data² and predictive algorithms

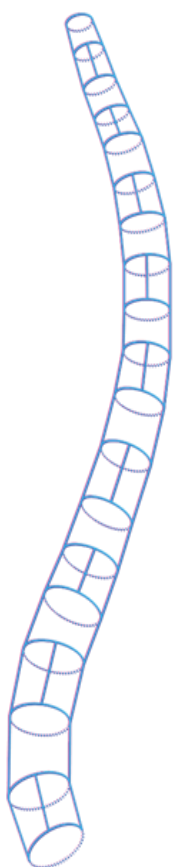
Based on its data management platform, KEOPS (Knowledge base for Orthopedic PhysicianS), which lists more than 100,000 patient cases operated on for more than ten years, SMAIO provides the surgeon with a precise roadmap to enable him to choose the best surgical strategy for positioning the implants and restoring the best suited shape of the back for each patient.

02 Optimal surgery execution thanks to patient-specific implants and tailor-made guides

SMAIO offers an assisted realization of the surgical procedure-based point by point on the roadmap drawn during the planning phase with the aim of optimally restoring the patient's balance. By using morpho adapted pedicle drilling guides adapted to each vertebra anatomy, the specifically designed pedicle screws, precisely implanted in each pedicle, generate a progressive realignment of the spine on patient specific rods and harmoniously drive the segments that were not operated and the pelvis towards an economical position respecting each patient morphology.

03 Monitoring of patients' quality of life and training of surgeons

SMAIO's platform enables patients' quality of life to be monitored by appraising them at various post-operative stages. The continuous analysis of the data collected and cross-analysis of clinical data and imaging contribute to a continuous improvement process. Furthermore, SMAIO offers training programs whose goal is to educate surgeons in best practices allowing the patient's sagittal balance to be restored in a safe and sustainable way.



¹ The Millennium Research Group

² SMAIO is developing an algorithm to restore the physiological shape of the back using a database of over 100,000 patient files

Strong clinical outcomes with more than 1,400 surgeries performed in 6 countries

Since 2010, and the release of the KEOPS database, SMAIO has enabled hundreds of spinal surgery specialists to precisely analyze the performance and risk of the surgeries they perform. As early as 2014, the **KEOPS sagittal balance analyzer** spinal realignment planning software has been used to plan several thousand cases of balance restoration, the execution having been carried out with manual bending by the surgeon with most implant ranges available in the market. Following the CE marking obtained for its own range of KHEIRON implants in June 2019, more than 1,400 surgeries have been performed by surgeons with SMAIO solutions. Patient specific K-rods have been marketed in Europe since June 2021.

Backed by solid clinical performance, the KHEIRON range received 510(k) approval from the Food and Drug Administration (FDA – North American health authority) in 2020, allowing it to be registered in the United States where the first surgeries were performed at the end of 2021.

Announces investment with NuVasive, a global leader in spine technology innovation

Sharing a similar vision regarding the importance of spinal realignment planning and implant placement to achieve favorable, repeatable and long-lasting results, NuVasive and SMAIO have entered into a development and license agreement to further advance SMAIO's surgical planning solutions, support the innovation pipeline and commercialization efforts.

As part of this collaboration, NuVasive will invest a total of \$10 million (9 M€³) in SMAIO, which includes a commitment to the capital increase at the time of the IPO along with several milestone payments as part of a development and license agreement.

In addition, SMAIO will provide image processing and planning services for NuVasive customers, generating an additional revenue stream for SMAIO.

A winning strategy combining commercial development, particularly in the United States, and breakthrough R&D developments

1. An optimized business development strategy combining direct sales and distribution with a sales target of €12m and a positive net result by 2025

Already having a commercial presence in 6 European countries and with an upward trajectory of its revenues since KHEIRON implant release in 2019 (€390k revenues in 2019 vs €2.1m in 2021⁴), SMAIO intends to continue to accelerate the sales of its solution in new areas of interest in Europe, the United States and Australia. The Company plans to strengthen its sales team in France and its network of agents and distributors for international development.

SMAIO primarily targets the United States, the leading market for spinal surgery, which represents more than 70% of the world market in value and is characterized by higher selling prices compared to other geographical areas. The investment from NuVasive will help to quickly strengthen SMAIO's commercial visibility and reputation in this area.

By 2025, the Company intends to exceed an annual sales volume of €12m and generate a positive net result.

2. An R&D project to rapidly strengthen SMAIO's position on the spine market and opening opportunities for industrial collaborations to market the first active surgical robots

In the 2nd half of 2022, the Company plans the release of innovative pedicle targeting guides that will make the positioning of the KHEIRON screw extremely simple and will further improve the precise execution of the surgical roadmap in conjunction with the custom-made K-rods and KHEIRON realigning screws.

At the same time, the Company intends to launch the production of 3D-printed supports capable of coupling precisely with each vertebra of the patient to produce specific trackers associated to each vertebra. Located by a camera, these trackers will be able to guide a robotic arm that takes into account the patient's micromovements such as breathing.

³ based on an indicative exchange rate of 1 euro for 1.10 dollar

⁴ non-audited revenue

This technology, which has been patented, will open up the field of active robotics and will generate numerous partnership opportunities for SMAIO in order to eventually develop a robot capable of performing part of the surgical procedure autonomously, alongside the surgeon.

Use of proceeds

The net proceeds of the issuance of the New Shares in the framework of the Offer will be used to provide SMAIO with the necessary means to finance its ambitious development strategy and open up the field of active robotics in the long term, according to the following breakdown

- approximately 38% to the development of a customized version of the i-plan platform for NuVasive (including KEOPS, Balance Analyzer 3D, and SPIDER Plan software and related services) called "NuVasive Planning Solution", designed to interface with the Pulse® integrated technology platform, and the parallel ramp-up of image analysis services;
- approximately 45% to the Company's commercial development in various markets (Europe, Australia, United States), in order to promote sales of the KHEIRON system and the Company's customized implants to targeted surgeons through a network of agents and/or distributors that will be progressively expanded, to the accompanying working capital requirement, and to the addition of a poly-axiality function to the screws of the KHEIRON system in order to make it more adapted to the needs of the U.S. market;
- approximately 17% to the development of the patented technology of morpho-adapted guides and trackers, demonstrating its decisive contribution to active robotics by making available a precise pedicle aiming kit, which can be interfaced with any passive robot on the market to make it active.

In the event that the Offer is subscribed for only up to 75%, on the basis of an Offer Price (i.e., estimated net proceeds of €5,95m), the funds raised would be allocated to the above objectives in the same proportions.

Structure of the Offer

It is planned that the distribution of the offered shares will be carried out within the framework of a global offer (the "Offer"), comprising:

- a public offering in France in the form of a fixed price offer, mainly intended for individuals (the "Fixed Price Offer" or "FPO"); it being specified that: orders will be broken down according to the number of shares requested: order fraction A1: from 1 share up to and including 200 shares, and order fraction A2: above 200 shares;
- a global placement mainly intended for institutional investors (the "Global Placement") comprising a private placement in France and an international private placement in certain countries (with the exception, in particular, of the United States, Canada, Australia and Japan).

Initial size of the Offer

The Company will issue a maximum number of 1,624,548 new ordinary shares (the "Initial New Shares") within the framework of a capital increase in cash with cancellation of the shareholders' preferential subscription rights by way of a public offering (corresponding, for information purposes, to a total amount, including the issue premium, of approximately €9.00m).

Extension Clause

In order to satisfy the subscription requests received within the framework of the Offer, the Company may, depending on the size of the demand and after consultation with the Lead Manager and Bookrunner, decide to increase the number of New Shares by a maximum of 15%, corresponding to a maximum number of 243,682 Additional New Shares (the "Extension Clause"), i.e. a number of ordinary shares to be issued which may be increased to 1,868,230 in case of exercise in full of the Extension Clause.

Over-Allotment Option

In order to cover possible over-allotments, the Company will grant to the Lead Manager - Bookrunner an over-allotment option (the "Over-allotment Option") allowing the subscription of supplementary new shares within the limit of 15% of the number of New Shares, i.e. a maximum of 280,234 Supplementary New Shares, at the Offer Price. This Over-Allotment Option may be exercised in one go at any time, in whole or in part, during a period of thirty calendar days as from the date of the commencement of trading of the shares on the Euronext Growth® Paris market, i.e., for information purposes, at the latest on April 6, 2022 (inclusive). In case of exercise in full of the over-allotment option, the number of Offered Shares (Initial New Shares, Additional New Shares and Supplementary New Shares) would represent 2,148,464 new ordinary shares.

Price of the Offer

The price of the Offered Shares in the OPF will be equal to the price of the Offered Shares in the Global Offering (the "Offer Price").

The Offer Price has been determined by the Board of Directors of the Company on March 22, 2022 at €5.54 per share.

Amount of the Offer

For information purposes, the gross and net proceeds of the issue would be as follows

In €m	Issuance of 75.55%	Issuance of 100%	After full exercise of the Extension Clause and before the Over-Allotment Option	After full exercise of the Extension Clause and the Over-Allotment Option
Gross proceeds	€6.75m	€9.00m	€10.35m	€11.90m
Estimated expenses	€0.80m	€0.95m	€1.05m	€1.16m
Net proceeds	€5.95m	€8.05m	€9.30m	€10.74m
Theoretical market cap	€26.82m	€29.02m	€30.37m	€31.93m

Subscription commitments received

SMAIO has received subscription commitments from new investors for a total amount of €6.50m (i.e. 72% of the amount of the Offer), including approximately €4.5m from NuVasive and €2.00m from NextStage AM. In addition, Sylorus Scientific, the Company's historical shareholder, has made a subscription commitment of €0.30m, bringing the total subscription commitments received by the Company to €6.80m, i.e. 75.55% of the amount of the Offer.

Lock-up commitments

The Company has undertaken to the Lead Manager and Bookrunner not to issue, offer or transfer, or grant any promise to transfer, either directly or indirectly (in particular in the form of derivative transactions involving shares), shares or securities giving the right, by conversion, exchange, redemption presentation of a warrant or in any other way to the allocation of securities issued or to be issued in representation of a portion of the Company's capital, nor to publicly formulate the intention to carry out one or more of the transactions listed above in this paragraph, as from the date of signature of the Placing Agreement and until the expiration of a period of 180 calendar days following the date of settlement-delivery of the Offer, subject to certain exceptions.

All the shareholders of the Company as of the date of the Offering Memorandum have undertaken towards the Lead Manager and Bookrunner to keep all the shares they will hold on the date of the settlement-delivery of the Offer, for a period of 365 calendar days following the date of settlement-delivery of the Offer and subject to certain customary exceptions.

It should be noted that NuVasive and NextStage, which have undertaken to subscribe to the Offer, have not made any lock-up commitment.

Sylorus Scientific has not made any lock-up commitment for the subscribed shares.

Indicative schedule of the Offer

March 23, 2022	Approval of the Prospectus by the AMF. Availability of the Prospectus. Publication of the press release announcing the Offer and the availability of the Prospectus.
March 24, 2022	Publication by Euronext of the notice of opening of the OPF. Opening of the OPF and the Global Placement.
March 31, 2022	Closing of the OPF at 5 p.m. (Paris time) for subscriptions at the counters and at 8 p.m. (Paris time) for subscriptions by Internet. Closing of the Global Offering at 5.30 p.m. (Paris time)
April 1 st , 2022	Allocations / Possible exercise of the Extension Clause Publication by Euronext of the notice of result of the Offer. Publication of the press release indicating the result of the Offer First listing of the Company's shares on Euronext Growth®
April 5, 2022	Settlement-delivery of the OPF and the Global Placement.
April 6, 2022	Start of the trading of the Company's shares on Euronext Growth® on a quotation line entitled "SMAIO". Start of the stabilization period, if any.
May 6, 2022	Deadline for the exercise of the Over-Allotment Option. End of the stabilization period, if any.

Terms of subscription and purchase

Persons wishing to participate in the OPF will have to deposit their orders with an authorized financial intermediary in France, at the latest on March 31, 2022 at 5 p.m. (Paris time) for subscriptions at the counter and at 8 p.m. (Paris time) for subscriptions by Internet, if this possibility is given to them by their financial intermediary

In order to be taken into account, the orders issued in the framework of the Global Offering must be received by Midcap, a division of TP ICAP (Europe) SA (the "Lead Manager and Bookrunner") at the latest on March 31, 2022 at 5.30 p.m. (Paris time), except in the event of early closing.

Revocation of purchase and subscription orders

Subscription orders received from private individuals by Internet within the framework of the OPF will be revocable, by Internet, until the closing of the OPF, on March 31, 2022 at 8 p.m. (Paris time). It is up to the investors to contact their financial intermediary in order to verify if orders transmitted by other channels are revocable and under which conditions or if orders transmitted by Internet can be revoked otherwise than by Internet.

Any order issued within the framework of the Global Offering may be revoked with the Lead Manager and Bookrunner until March 31, 2022 at 5:30 p.m. (Paris time), unless the offering is closed early or extended.

Eligibility of the Offer to the PEA, PEA-PME schemes, to the reduction of the income tax, and to the economic reinvestment within the framework of a capital contribution and subsequent share transfer (article 150-0 B ter of the French General Tax Code)

SMAIO considers that it complies with the eligibility criteria for the PEA PME-ETI scheme specified by the provisions of articles L. 221-32-2 and D.221-113-5 et seq. of the French monetary and financial code. Consequently, SMAIO shares may be included in stock savings plans (PEA) and PEA PME-ETI accounts, which benefit from the same tax advantages as the classic PEA.

Payments for direct subscription to SMAIO's capital may entitle investors to a 25% income tax reduction, pursuant to Article 199 terdecies-0 A of the French General Tax Code and under the 2019 Finance Act. Investors likely to benefit from this income tax reduction are invited to consult their usual tax advisor in order to assess their personal situation with regard to the specific applicable regulations.

The Company is also eligible for the measures defined in article 150-0 B ter of the French General Tax Code, which allows people who have divested securities contributed within three years of their contribution to benefit from the maintaining of tax deferral in the case of cash subscriptions.

SMAIO is also labelled as an "Innovative Company" by Bpifrance.

Identification codes of the SMAIO shares

Name: SMAIO
 ISIN code: FR0014005180
 Ticker: ALSMA
 Industry sector - ICB Classification: Medical Equipment - 20102010

Financial intermediaries and advisors



Lead Manager and Bookrunner



Listing sponsor



Deal counsel

Availability of the Prospectus

The Prospectus, approved by the AMF on March 23, 2022 under number 22-067, is available on SMAIO's website dedicated to this IPO operation (<https://www.smaio-finance.com>) and on the AMF's website (<https://www.amf-france.org>), as well as free of charge upon request from the Company's head offices: SMAIO, 2, Place Berthe Morisot 69800 Saint-Priest, France.

The approval of the Prospectus by the AMF should not be considered as a favorable opinion on the securities offered.

SMAIO draws the public's attention to section 3 "Risk Factors" of the Prospectus. The occurrence of one or more of these risks could have a material adverse effect on the Company's business, reputation, financial condition, results of operations or prospects, as well as the market price of SMAIO's shares.

SMAIO draws particular attention to the following significant risks:

- **Risk related to current and future financing needs: the Company's ability to raise additional funds will depend on financial, economic and market conditions. Given its development model, several rounds of financing would probably be necessary, and the risk of dilution for shareholders could be high;**
- **Liquidity risk: the Company's available cash and the pre-financing of the research tax credit do not allow it to cover its financial needs beyond 30 April 2022.**

Forward-looking statements

Certain information contained in this press release consists of forward-looking statements rather than historical data. These forward-looking statements are based on opinions, forecasts and current assumptions, including and not limited to assumptions relating to SMAIO's current and future strategy and the environment in which SMAIO operates. They involve known and unknown risks, uncertainties and other factors that could cause actual results, performances or achievements, or sectoral performances or other events, to differ significantly from those described or suggested by these forward-looking statements. These risks and uncertainties include those indicated and detailed in section 3, "Risk Factors", of the Registration Document approved by the AMF on March 23, 2022 under number 22-067.

These forward-looking statements are given only as of the date of this press release, and SMAIO expressly disclaims any obligation or undertaking to publish updates or corrections to the forward-looking statements contained in this press release to reflect changes affecting the forecasts or events, conditions or circumstances on which these forward-looking statements are based. The information and forward-looking statements provided are no guarantee of future performance and are subject to various risks and uncertainties, many of which are difficult to predict and are generally beyond SMAIO's control. Actual results could differ significantly from those described, suggested or forecast by the information and forward-looking statements contained in this document.

Risk factors

SMAIO would like to draw the public's attention to section 3, "Risk Factors", of the Registration Document approved by the AMF on March 23, 2022 under number 22-067.

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 systematically 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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Disclaimer

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No communication or information concerning this press release or concerning SMAIO may be published in a country or region requiring registration or approval. No action has been taken (or will be taken) in any country (other than France) in which such action would be required. A public offering of securities in France would only be made after approval by the Autorité des marchés financiers of the relevant prospectus.

This press release is promotional communication and does not constitute a prospectus within the meaning of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 (the "Prospectus Regulation").

With respect to member states of the European Economic Area other than France (the "Member States"), no action has been taken nor will be taken to permit an offer of the securities to the public that would require the publication of a prospectus in any of the Member States. Accordingly, the Shares may only be offered and will only be offered in the Member States (i) to qualified investors within the meaning of the Prospectus Regulation or (ii) in accordance with the other exemptions set out in Article 1(4) of the Prospectus Regulation.

For the purpose of this paragraph, the notion of "offer to the public" in each of the Member States is defined as any communication in any form and by any means to persons providing sufficient information on the terms of the offer and on the securities to be offered so as to enable an investor to decide to purchase or subscribe for such securities.

This offering restriction is in addition to other offering restrictions applicable in the Member States.

The distribution of this press release has not been made and has not been approved by an authorised person within the meaning of section 21(1) of the Financial Services and Markets Act 2000. Accordingly, this press release is directed at and intended solely for (i) persons located outside the United Kingdom, (ii) investment professionals within the meaning of section 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, (iii) persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated association, etc.) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or (iv) any other person to whom this press release may otherwise be communicated in accordance with the Act (the persons mentioned in paragraphs (i), (ii), (iii) and (iv) together being referred to as the "Relevant Authorised Persons"). This press release does not constitute a prospectus approved by the Financial Conduct Authority or any other regulatory authority of the United Kingdom within the meaning of Section 85 of the Financial Services and Markets Act 2000.

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