

# A NEW PARADIGM IN SPINE SURGERY

Investors' Presentation

**SMARD**

# Disclaimer

This presentation has been prepared by SMAIO (the « Company »), solely for use in connection with investor presentations (the « Presentation »). By receiving this Presentation and attending this meeting, you acknowledge that you have read and understood the restrictions set forth below. This Presentation does not constitute or form part of any offer or invitation to sell, buy or subscribe for any securities. Neither this document, nor any portion of this document, forms the basis of, nor should it be relied upon in support of, any contract or commitment. Any decision to acquire or subscribe for securities in any future offering could only be made on the basis of the information contained in any offering document that may be prepared and/or issued by the Company in connection with such offering.

This Presentation is provided to you personally for your information only and is to be used solely for the purpose of presenting the Company. The information contained in this document is confidential and may not be disclosed, reproduced or distributed, directly or indirectly, to any other person or published, in whole or in part, for any purpose whatsoever, without the consent of the Company.

Some of this information is forward-looking and may include profitability forecasts or targets. Such forward-looking information does not reflect the current earnings or financial performance of the Company or the industry in which it currently operates and is subject to risks and uncertainties that could cause actual results to differ materially. These objectives and development paths are not historical data and should not be interpreted as guarantees that the facts and data stated will occur, that the assumptions will be verified or that the objectives will be achieved. By their nature, these objectives may not be achieved and the statements or information contained in the Presentation may prove to be erroneous, without the Company, its advisors and their representatives being under any obligation to update them, subject to applicable regulations.

A detailed description of the Company's business, strategy, financial condition and risk factors is included in the Registration Document (« Document d'enregistrement ») which was registered by the French Financial Markets Regulator (« Autorité des marchés financiers ») on 1<sup>st</sup> February, 2022 under number 1<sup>st</sup>.

The Company shall not be liable for the information provided in the Presentation or for the use of such information by the reader, it being specified that none of this information has been independently verified. No representation, warranty or undertaking, express or implied, is made by the Company to the reader in connection with the Presentation. In particular, no representation or warranty, express or implied, is made as to the accuracy, completeness, truthfulness, or reasonableness of the information, opinions and projections contained herein.

The Presentation (including any copy that may be made) is not to be brought into, transmitted to, or introduced into the United States of America, Canada, Australia or Japan, or distributed or redistributed to a resident of any of those countries. The distribution of the Presentation in other countries may be subject to legal or regulatory restrictions, and persons in possession of this document should familiarize themselves with and observe such restrictions. Failure to comply with these restrictions may constitute a violation of applicable securities laws.



# AGENDA

01

A new paradigm in spine surgery

02

A global and innovative solution for sustainable and powerful spine realignment

03

A fast-growing market driven by needs for effective and reliable solutions

04

The IPO project to leverage the immense potential of data and automate spine surgery



# 01 A new paradigm in spinal surgery

# Speakers



**Philippe  
ROUSSOULY**

Chief Executive Officer

## **STRATEGY, INNOVATION AND LEADERSHIP**

- Founded SMAIO in 2009
- Strategy consultant with Accenture and Corporate Value Associates.
- Graduated from ESSEC Business School



**Fabrice  
KILFIGER**

Chief Financial Officer

## **FINANCE AND ADMINISTRATION**

- 30 years of experience in Corporate finance (audit firm, US corporations, International listed groups, Medical Device companies)
- Graduated from GEM (Grenoble Management School), specialized in Finance and Management

# Spinal Pathologies

The disease of the century with surgical treatments being too often a source of complications

Thoraco-lumbar fusion recognized as the gold standard to address spinal pathologies, faces two significant limitations

## UNSUTABLE IMPLANTS

**1980'** : Start of the spinal fusion market and sales of first implants

**2010'** : First patient specific rods

**Today** : 90% of available devices prevent precises execution of surgical planning

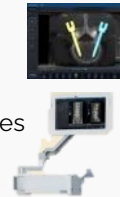


## POORLY ORGANIZED SURGERY

**2010'** : appearance of new concepts around planning and robotics

- Imaging
- Vertebral alignment / screw positioning
- Passive surgical robots

**Today** : lack of patient data management leading to inaccurate surgeries as well as risky and costly revision surgeries



Need for a comprehensive spinal strategy to achieve sustainable outcomes

# Our vision :

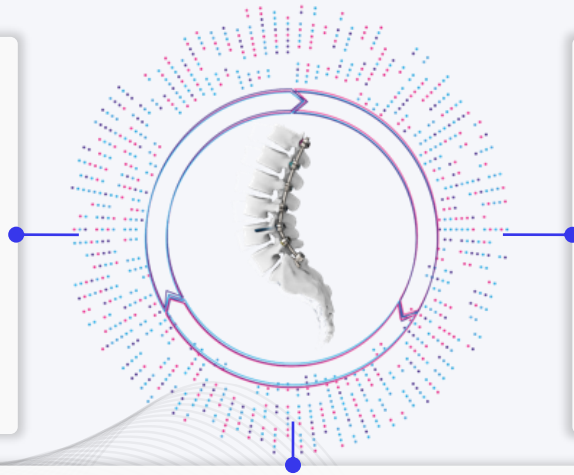
Sustainable physiological sagittal balance restoration



# 01

## Planning

- **Big data and predictive algorithms**
- Improve surgery for **better patient quality of life**



# 02

## Execution

- **Patients' specific rods**
- **Translation screws** for a perfect and progressive alignment of the spine to the rods
- **3D printed morpho adapted pedicle drilling guides for ultra-precise execution of surgery**

# 03

## Follow-up

- **Patients' quality of life follow up**
- **Patients' biomechanical balance monitoring**



**SMAIO: A unique player in spine surgery offering integrated / repeatable / predictable solutions to accurately restore sagittal balance**

# Management team

composed of specialists from the spinal industry



## Philippe ROUSSOULY

Chief Executive Officer

### STRATEGY, INNOVATION AND MANAGEMENT

- Founded SMAIO in 2009
- Strategy consultant with Accenture and Corporate Value Associates.
- Graduated from ESSEC Business School



## Jean-Charles ROUSSOULY

Chief Operating Officer

### R&D, QUALITY, REGULATORY AFFAIRS, INDUSTRIALIZATION AND LOGISTICS

- 16 years of experience in the development of implants spinal, hips and extremities implants
- Mechanical engineer, graduated from ECAM (Lyon)



## Fabrice KILFIGER

Chief Financial Officer

### FINANCE AND ADMINISTRATION

- 30 years of experience in Corporate finance (audit firm, US corporations, International listed groups, Medical Device companies)
- Graduated from GEM (Grenoble Management School), specialized in Finance and Management



## Romain SCHNEEWEIS

VP Sales and Marketing

### BUSINESS DEVELOPMENT

- 10 years of experience in international sales for medical device companies – Recently acted as VP Europe sales for Mediceara
- Graduated from Montpellier Business School in 2012



## Yasura NAKATA

VP Legal

### LEGAL EXPERTISE IN MEDICAL DEVICE AND PHARMACEUTICAL CORPORATIONS

- Joined SMAIO in 2018
- 12 years of experience within the Otsuka Group
- Lawyer from the Tokyo court
- PhD in law from CHUO University (Japan)



# A unique company

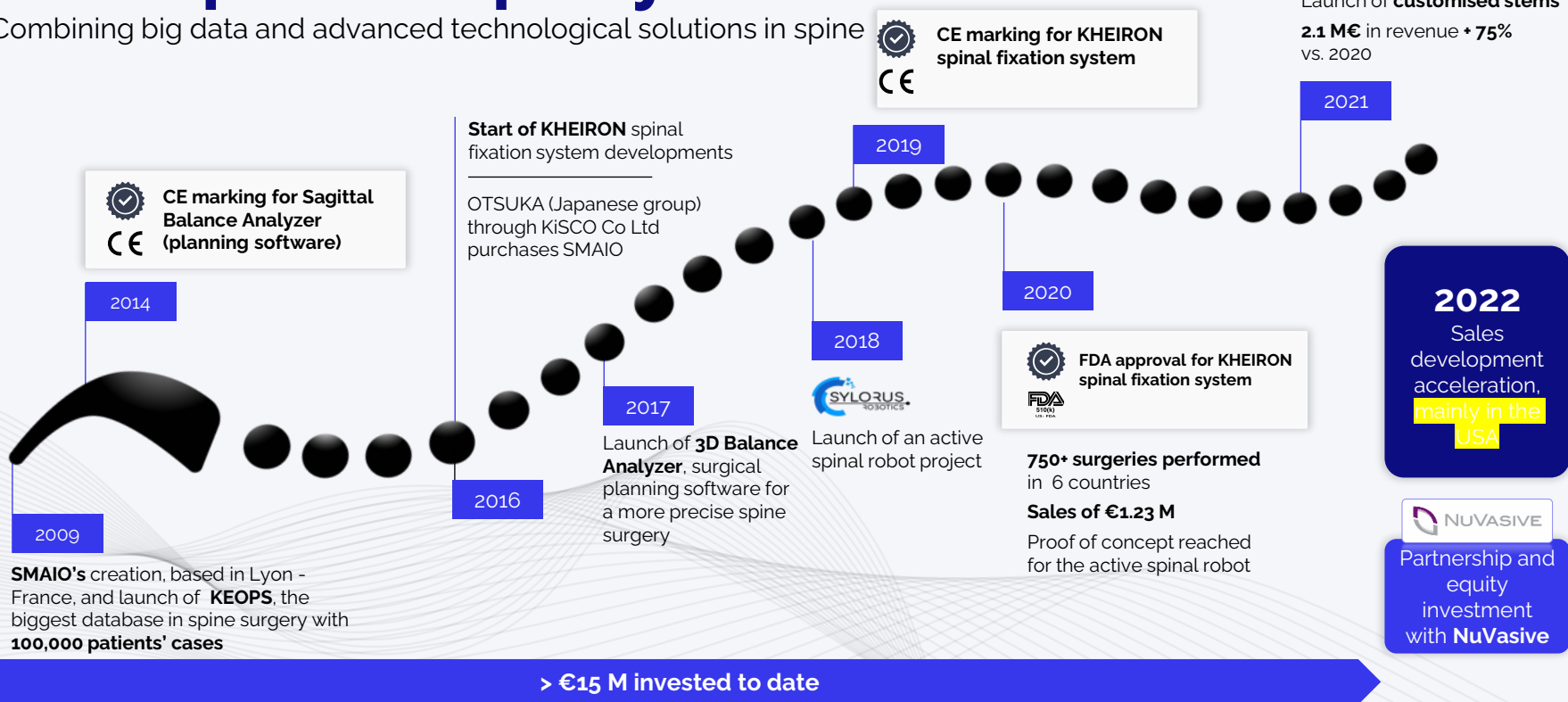
Combining big data and advanced technological solutions in spine

Sylorus Robotics contributes to SMAIO

1,400+ surgeries performed to date

Launch of **customised stems**

2.1 M€ in revenue + 75% vs. 2020



A unique spinal robot project coupled to sustainable and dynamic growth

\* KISCO Co. Ltd. is a subsidiary of Otsuka Medical Device, a Japanese health company listed on the Tokyo stock of Exchange  
\*\* SYLORUS Scientific SA is held by Philippe Roussouly (80 %), SMAIO's CEO and by Pierre Roussouly (20 %).

# A disruptive positioning

to leverage the immense potential of data and eventually automate spinal surgery



## Holistic approach

of spine surgery combining, planning, execution, post-op follow up and scientific education



3

Patents' families (implants, robot, vertebral realignment)



## The World's leading

Spinal surgery database with over 100,000 patient cases



6

countries commercially active

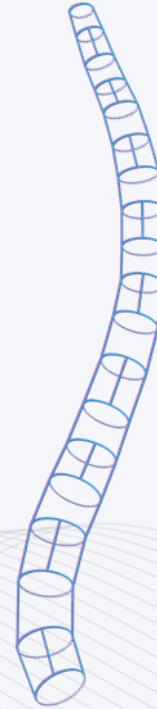


30

Highly qualified employees (40% of whom are engineers)



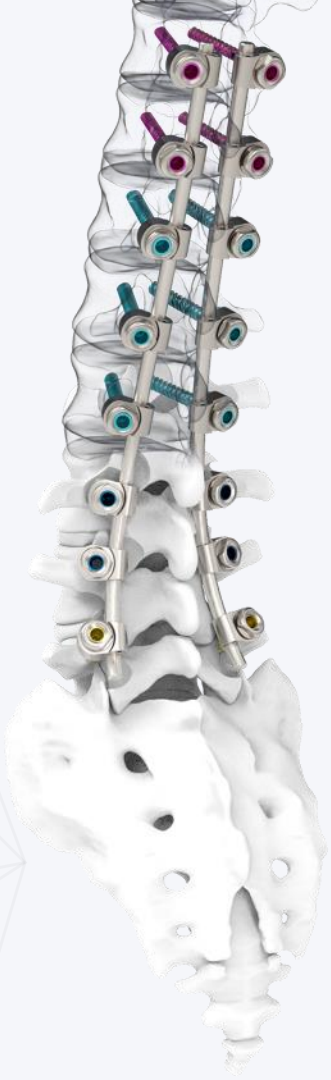
1<sup>st</sup> active robot project for spinal surgery



## SMAiD

- SOFTWARE
- MACHINES and
- ADAPTATIVE
- IMPLANTS in
- ORTHOPAEDICS





# 02

**A global and innovative  
solution for sustainable  
and powerful spine  
realignment**

# i-Kontrol:

Holistic solutions platform to restore long term spino-pelvic alignment



**I-Plan**

## Plan the surgery

From implants selection to the step-by-step description of the procedure thanks to big data (3D Balance Analyzer and Keops)



**I-Perform**

## Optimal execution of the surgery

with patient specific implants (Kheiron system)



**I-Check**

## Monitor outcome

over time and increase the number of cases in the Keops database



**I-Learn**

## Train surgeons

To permanently improve the process and the number of KOL users

Pushing the continuous improvement process in spine surgery to its climax

# i-Plan:

Ultra-precise surgical planning thanks to big data



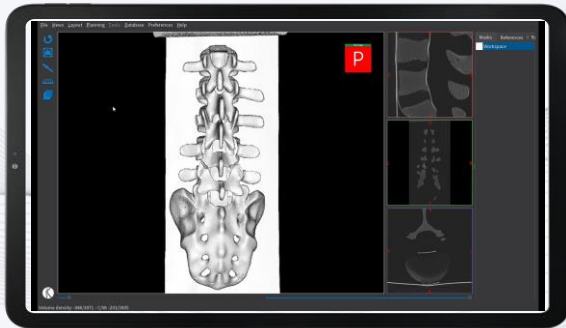
## Global realignment planning :

- 3D Modelization
- Simulation of the ideal correction

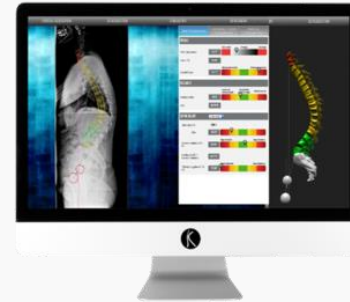


## Implants selection and perfect vertebra alignment on the rods

- Vertebral screw positioning thanks to k-guides



## 3D Balance Analyzer

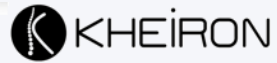


- Numerous clinical and imaging parameters
- Benchmark with ten of thousands of treated patients
- Precise description of the planned surgery


Take advantage of big data to provide surgeons with the best pre-operative strategy

# i-Perform:


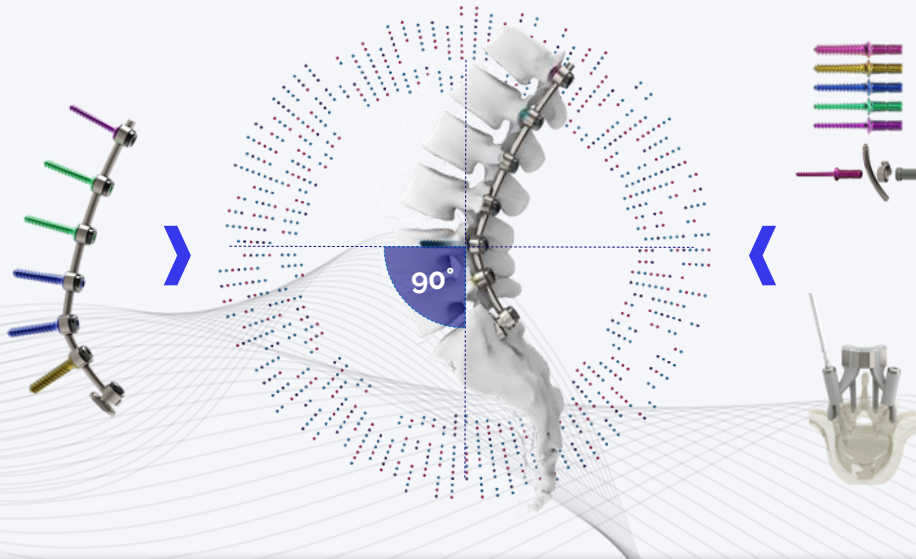
A patient specific surgery for optimal patient spine realignment




Spinal fixation system with strong progressive deformity reduction



**Customized rods**  
Bending from 3D Balance Analyzer modeling



**Translation screws**  
Perpendicular insertion to the rods



**K-guides**  
Drilling guides for precise positioning of screws

## Clinical advantages

- Pedicle screws inserted at 90° for a perfect spinal correction
- Vertebral bodies perfectly aligned on the rod

# Strong clinical outcome (1/2)

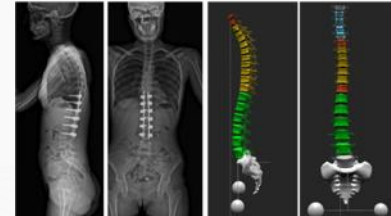
## CASE 1



Pre-op

Post-op

## CASE 2

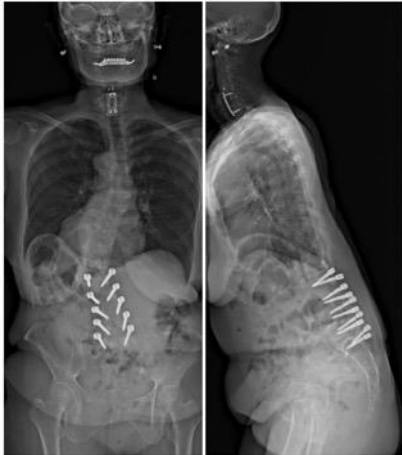


Over 1,400 surgeries performed since June 2019 in 6 countries :  
very high clinical outcomes and surgeons / patients satisfaction

# Strong clinical outcome (2/2)

Revision surgery of a former dynamic stabilization

Pre-op



Man  
69 years old

T4-iliac

Post-op

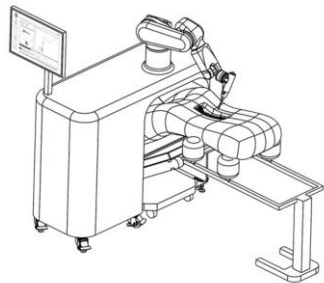


Successful restoration of sagittal balance in revision surgery



# SPIDER

The i-perform solution at the forefront of active spinal robot innovations



SPIDER PROJECT  
Octobre 2021



**Passive version  
by 2025**

Vertebrae detection  
through palpation



**Active version  
by 2026**

**The most advanced and comprehensive active robotic solution on the market whose integration into the surgical strategy has been embedded from start**



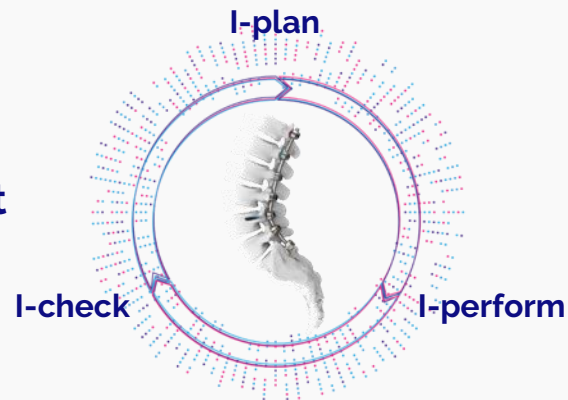
## Data Management



- Pathologies' segmentation
- Monitoring of patients' quality of life
- Identification of potential complication
- Follow-up of patient biomechanical improvements



**Continuous improvement  
process of spine surgery**



## I-Check :

Ability to measure and track surgeries with Keeps

The most advanced monitoring tool to predict spinal surgery outcomes

# I-Learn:

Teach surgeons the best practices for restoring patient's sagittal balance



## Sagittal Balance Academy

- **Around 20 surgeons** gathered together for one day and coached by KOL users
- **Practical cases** of increasing difficulties from the Keops' data base are analyzed
- **i-perform** techniques are taught during cadaver labs workshop



## Konnect program

- Meetings organized between **KOL and other specialists**
- Opportunity to attend **specific surgical procedures**
- **Clinical cases review** in order to train i-kontrol technologies to new surgeons
- Already 10 sessions organized

Two comprehensive training programs to raise awareness among surgeons and key opinion leaders

# Strong intellectual property

As a barrier to competitive entry



## 4 patents on robotics technologies:

- Vertebrae detection through robotic palpation
- Unique configuration of the robotic station to integrate into the operating room
- Unique drilling and screwing technology in the vertebrae
- Software module to determine the entry point of a pedicle and plan implant positioning



## 1 patent on realignment algorithm

- Back shape restoration algorithm to make custom rods



## 5 patents on implants design

SMAIO technologies' competitive edge is protected to ensure the exploitation of the potential of data and develop the automation of spine surgery

# Expected benefits

For all stakeholders



**Patient**



- Sustainable sagittal alignment after the surgery
- Significant improvement in quality of life



**Surgeon**



- SMAIO teams support throughout the surgical planning process
- Personalized medicine approach and patient satisfaction enhancement



**Hospital**



- Inventory optimization through better planned surgeries
- Cost savings linked to the decrease in the number of revision surgeries



**Health system**



- Sustainability of clinical outcome
- Marge savings due to early return to work

**Strong adoption drivers to create a unique competitive position**



03

**A fast-growing market  
driven by the need for  
efficient and reliable  
solutions**

# A \$10 billion market

Where posterior spinal fusion has become the standard of treatment



Worldwide spinal market (2019)

**\$10 Billion**



Worldwide market for spinal fusion (2019)

**\$3 Billion**



**6 US companies** share  
**84% of the market**



**+400 manufacturers** offering  
very similar poly-axial tulip  
pedicle screws



**+ 1,000,000** instrumented  
surgeries performed per year



**\$ 3,500** average worldwide  
revenue per surgery with an  
average gross margin of **70%**

Average revenue / surgery in the USA <sup>1,2,3</sup> :

**\$ 7,370** (degenerative surgery)

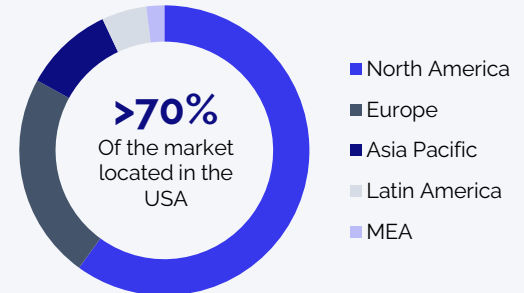


**\$ 26,000** (complex surgery)

## Spinal fusion has become the standard of treatment for :

- Degenerative pathologies (stenosis)
- Deformities (scoliosis)
- Vertebral fractures

**Screws and rods revenues account for 1/3 of the spine market**



Sources : Company

1. 2015 Instrumented Thoracolumbar Procedures annually (409,100). 2013 Millennium Research Group, Inc., Table 87 "Thoracolumbar Fusions, by Indication".
2. \$26,000 per case. Medicea estimated implant and BGE revenues per complex spine procedure.
3. \$7,370 per case. Medicea estimated implant and BGE revenues per 1-2 level degen procedure.

# A fast-growing market

driven by the need for a more global solution



\*Source : SPINE Market Group (March 2021)



# Major players in the sector

Constantly looking for innovative technologies

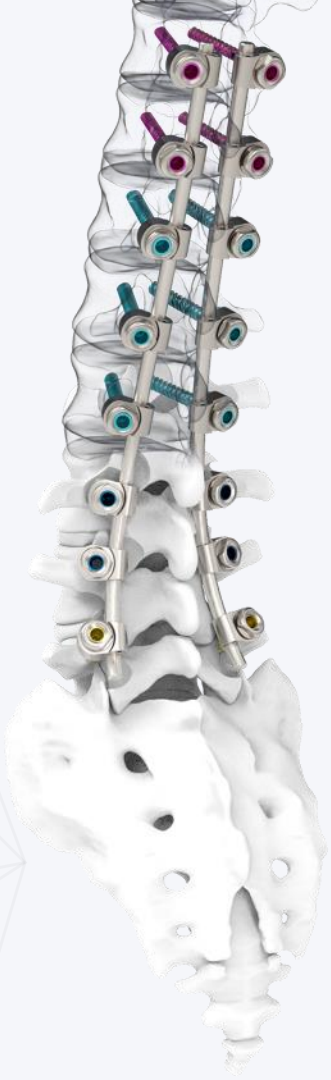
## Most recent financial M&A deals :



# A unique competitive positioning

Thanks to SMAIO's holistic approach

	Vertebral alignment planning	Planning of screws and IBD insertion	Patient specific rods	Intra- Operative Imaging	Navigation	Surgery reduction monitoring	Robotics	Patients data management
<b>SMAIO</b>	✓	✓	✓	✓ 2025	✓ 2023	✓ 2022	✓ ✗ Long term project	✓ 2010
<b>Medtronic</b>	✓	✓	✓	✓	✓	✗	✓ <b>Mazor Robotics</b>	✗
<b>DePuySynthes</b>	✗	✗	✗	✓	✓	✗	✓ <b>ORTHOTAXY</b> <small>Introduces Patient Specific Customization</small>	✗
<b>NUVASIVE</b>	✓	✓	✓	✗	✓	✓	✓ <b>PULSE ROBOTICS</b>	✗
<b>stryker K2M</b>	✓	✓	✗	✓	✓	✗	✓ <b>Mako</b>	✓
<b>zimmer</b>	✗	✓	✗	✗	✗	✗	✓ <b>medtech</b> <small>INNOVATIVE MEDICAL TECHNOLOGY</small>	✗
<b>GLOBUS MEDICAL</b>	✓	✓	✗	✗	✓	✗	✓ <b>EXCELSIUS MEDICAL</b>	✗



04

**The IPO project to  
leverage the immense  
potential of data and  
automate spine surgery**

# Key Financial figures

Income Statement (€'000)	30.06.2021 (6 months)	31.12.2020 (12 months)	31.12.2019 (12 months)
<b>Sales</b>	<b>1 031</b>	<b>1 232</b>	<b>390</b>
Internal production	439	704	329
Other income	64	165	42
<b>Revenue</b>	<b>1 534</b>	<b>2 101</b>	<b>761</b>
Purchases of goods	(535)	(599)	(141)
Other purchases and external charges	(703)	(1 050)	(649)
Salaries & wages	(1 529)	(2 230)	(1 523)
Other charges	(53)	(80)	(14)
<b>EBITDA</b>	<b>(1 286)</b>	<b>(1 858)</b>	<b>(1 566)</b>
Amortizations & depreciations	(475)	(628)	(299)
<b>Operating income / (loss)</b>	<b>(1 761)</b>	<b>(2 486)</b>	<b>(1 865)</b>
Financial income / (loss)	(15)	(16)	(9)
Income / (loss) before tax	(1 776)	(2 502)	(1 874)
Exceptional income / (loss)	(2)	-	(5)
Corporate tax	178	278	190
<b>Net income / (loss)</b>	<b>(1 600)</b>	<b>(2 224)</b>	<b>(1 689)</b>

## Main financial indicators as of 30.06.2021

Gross margin :  
**50%**

EBITDA :  
**(1.3 M€)**

## 2021 Sales

**2.1 M€**  
+73% vs. 2020

# A strategy of conquest

combining ultra-precise planning, tailor-made execution of surgery and analytical monitoring of data and results



**PARTNERSHIP WITH NUVASIVE**  
FOR US PRESENCE



**SALES INCREASE**



R&D INNOVATIONS TO AUTOMATE SURGERY AND  
**OPEN THE FIELD OF ACTIVE ROBOTICS**

# Strategic Partnership with NuVasive

To expand SMAIO's presence in the USA



One of the worldwide  
leaders in spine

- Sales > **\$1.1 Bn** in 2021
- Available cash : **\$246 M** at 12.31.2021
- Capitalization : **\$ 2,7 Bn** at 02.24.2022
- **2,700** employees

## 01

Equity Investment  
**\$10m**

- **\$5m** at IPO

## 02

Milestones  
**\$5m**

- **\$3m** after FDA approval of the customised version of the 3D Balance Analyzer software integrating NuVasive implants
- **\$2m** once the 3D Balance Analyzer software is integrated within NuVasive platform

## 03

License agreement


- **Co-exclusivity of 3 years** for using the **3D Balance Analyzer** software in the USA from the time of integration on the NuVasive platform
- **Surgical planning performed** by SMAIO on NuVasive's behalf and invoiced to NuVasive


Significant expected increase in sales thanks to surgical planning placed to SMAIO by NuVasive

# Sales strategy


An efficient mix of direct sales and distribution

## Optimized strategy based on targeted geographical areas

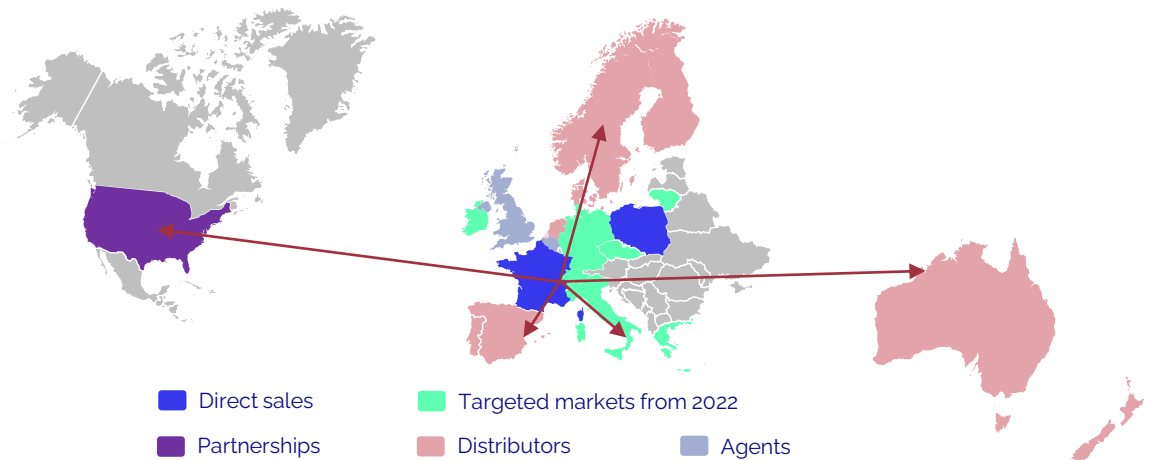
North America 

Partnership 

Europe



Asia Pacific - Australia 



**01 Direct sales**

- 3 sales representatives in France
- Launch of a dedicated sales network in strategic countries

**02 Distributors**

- Northern of Europe
- Spain + Portugal
- Australia

**03 Agents**

- Agents network for the Benelux, the UK and the USA

**Strong sales acceleration expected from new countries from 2022 onwards**

# Securing supplies

And ramping up manufacturing

## TODAY

### SUBCONTRACTING

- Instruments are manufactured in France and in the USA
- Implants are manufactured in France by 2 subcontractors

### CAPACITY

- 5 to 10 surgeries / day



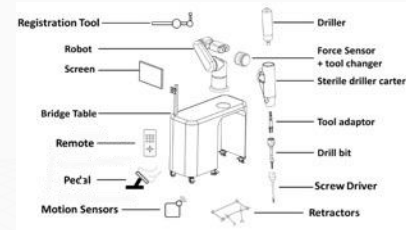
## MEDIUM TERM

### IN-HOUSE MANUFACTURING

- Start of factory construction in 2024
- Factory go-live beginning of 2026

### CAPACITY

- Around 20 surgeries / day
- In-house design and assembly of the robot

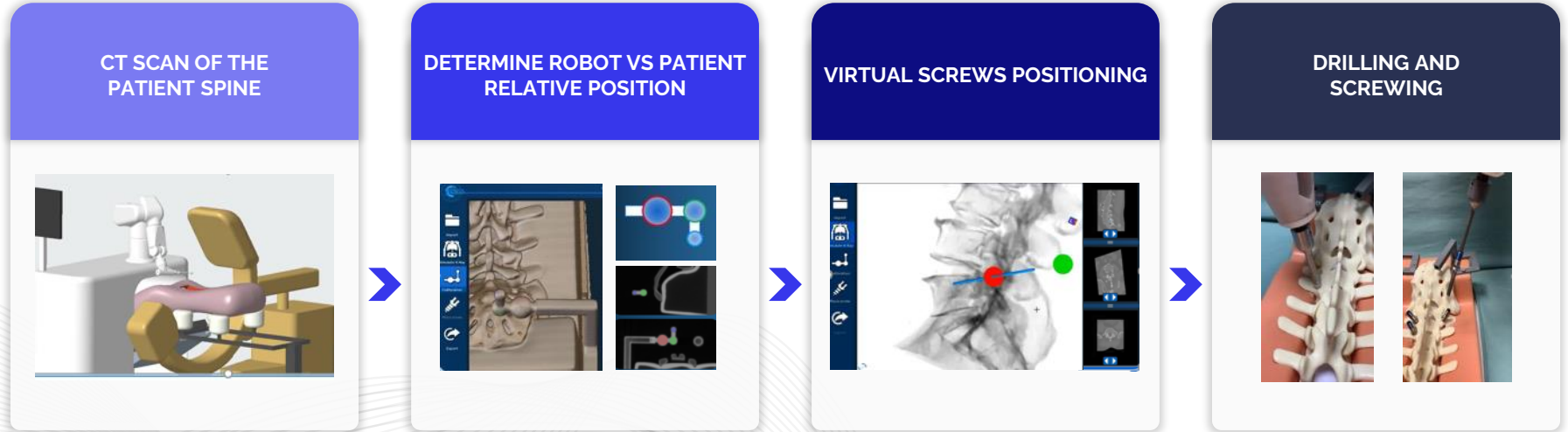


Decrease of manufacturing costs from 50% to 20% of sales



# SPIDER Project

Active robotics project for spinal surgery



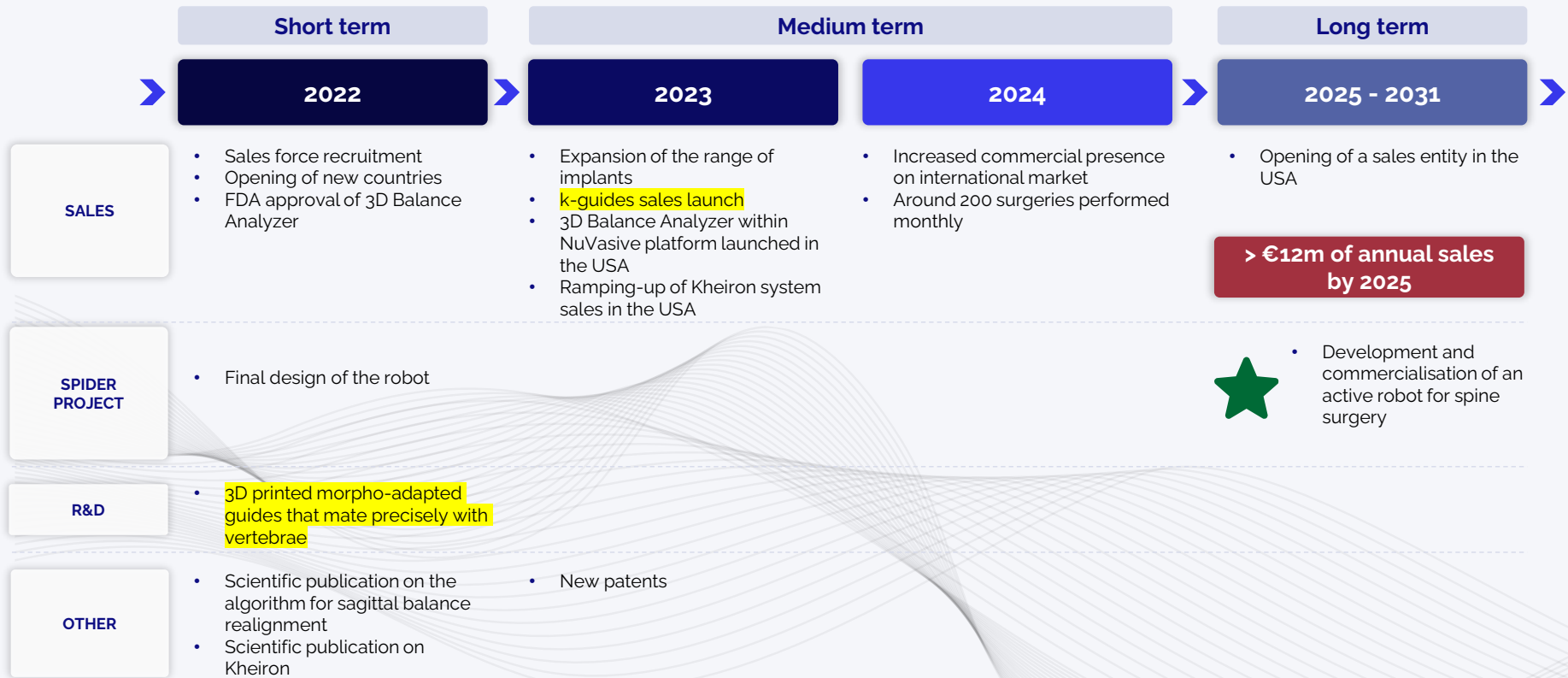
## Clinical benefits

- Control accuracy and repeatability of the surgery
- Surgery time optimization
- Securing the procedure
- Obtaining satisfactory clinical outcome

Unique tool allowing surgeons to focus on the patient treatment strategy

# Dense and regular and newsflow

Until the active robot is brought to the market in 2026



# An IPO to finance SMAIO's ramp-up

and open up the field of active robotics in the long term

38%

## Industrial partnership with NuVasive

- Co-development of a software platform for planning and monitoring surgeries
- Obtaining FDA approvals
- Ramp-up of the Image and Data Analysis Service



## Funds raised

€8 to €10m



45%

## Working capital and sales development

- Expanding the sales network (U.S., Europe and Australia)

17%

## R&D innovation

- Development of 3D printed morpho-adapted guides and trackers
- Availability of ultra-precise pedicle targeting kits

# Invest in the development

Of the pioneer of active robotic spine surgery

01

**Unique company in spine surgery with holistic vision designed from start** and combining planning, execution and outcome analysis integrated technologies

02

**The largest database** to provide a solution adapted to each patient thanks to predictive algorithms

03

**Optimal surgery execution thanks to patient specific implants** to restore sustainable sagittal balance

04

**Driving the use of active robotics** in spinal surgery

05

**Visionary management and strong partnership with NuVasive** to position SMAIO as the new success story of French medtech