

SpineGuard announces its full-year 2022 financial results and its first quarter 2023 sales

- Sales of €5.6 million, up 27% and EBITDA improved by 17% in 2022
 - Increased investments in innovation & for the US business
 - Cash runway over 24 months
 - 1Q23 sales growing 12%

PARIS and BOULDER (CO), April 13, 2023, at 06:00pm CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG (Dynamic Surgical Guidance) sensing technology to secure and streamline the placement of bone implants, announced today its full-year 2022 financial results, as approved by the Board of Directors on April 13, 2023, and its first quarter 2023 sales.

€ thousands – IFRS audited	2022	2021
Revenue	5,600	4,405
Gross Margin	4,715	3,606
<i>Gross margin (% of revenue)</i>	<i>84.2 %</i>	<i>81.9 %</i>
<i>Sales, distribution & marketing</i>	<i>3,700</i>	<i>2,660</i>
<i>Administrative costs</i>	<i>1,640</i>	<i>1,394</i>
<i>Research & Development</i>	<i>901</i>	<i>791</i>
Operating profit / (loss)	-1,526	-1,239
Non-recurring operating costs	-135	-110
Financial Result	-427	-299
Income Tax	-305	-76
Net profit / (loss)	-2,393	-1,725
EBITDA	-888	-1,063

Pierre Jérôme, co-founder, Chairman and CEO of SpineGuard, said: “2022 has been particularly fruitful for SpineGuard with strong sales uptake, EBITDA improvement, the signature of new strategic partnerships and significant strides on the innovation front. In a context where the surgical assistance systems to secure bone implant placement (navigation, robotics, augmented reality, etc.) are becoming a must-have, our DSG technology stands out and affirms its unique capacity to differentiate tissues in an extremely accurate manner, in real time, in-situ and without X-rays. It is now protected by 79 patents and its clinical relevance evidenced by 24 scientific publications and over 95,000 surgeries including 500 performed with our new DSG Connect platform. The added value of the latter is undeniable as it facilitates surgeon adoption thanks to signal visualization and because it enables data collection which is very precious to continue to expand the scope of our sensing technology. Although in the process of re-organizing and strengthening our US operations, we have started 2023 with double digit growth in the first quarter and with great prospects ahead of us. The IMAST (International Meeting on Advanced Spine Techniques) congress that took place at the end of March in Dublin, Ireland, confirmed DSG’s very strong benefits for the insertion of screws in the vertebral body, an emerging fast growing surgical technique to treat scoliosis without fusion and for which we obtained FDA clearance in 2022.”

Improved EBITDA and increased investments in innovation and for the US business development

2022 sales increased at € 5,600 K (+27.1%) compared to 2021 (+17,4% cc) thanks to a solid contribution of Europe, Latin America and the US back to double digit growth.

Gross margin improved by 230 bps at 84.2% vs. 81.9% mainly due to the higher average selling prices and a yet limited impact of the increase of manufacturing costs. Losses due to inventory obsolescence were also reduced in 2022 and impacted positively compared to 2021.

Operating expenses increased by 29.2% or € 1,413 K reflecting the impact of the investments in sales, marketing and innovation in R&D, while maintaining a rigorous control of operational expenses over the year.

The Operating Loss is € 1,526 K vs € 1,239 K in 2021.

Working capital requirements were € 452 K vs. € -133 K in 2021 related to inventory and account receivable increases.

Financial expenses were € -427 K mainly corresponding to the interest charges of the venture loan with Norgine Venture, Harbert European Growth Capital and Bpifrance. There are € 12 K of forex rate losses and € 115 K of non-cash financial expenses, which have no impact on the cash and are related to the compliance with IFRS accounting principles on financing instruments.

EBITDA improved 17% at € -888 K vs. € -1,063 K in 2021.

Cash runway extended over 24 months

At December 31, 2022, cash and cash equivalents were € 4.1 M. The balance of € 3.0 M of the convertible warrants (BSAR) with Nice & Green was drawn during Q1-2023. As of March 31, 2023, cash and cash equivalents were € 5.8 M and SpineGuard's cash runway stands at over 24 months.

Significant R&D advances

Robotic application:

Following previous years solid progress, SpineGuard decided to pursue a new collaboration with the ISIR and LIB (Laboratoire d'Imagerie Biomédicales) labs of Sorbonne University. The new collaboration aims at continuing the research for the automated detection and prevention of bone breaches and adding an ultrasound component. In parallel, the Company continues to take steps for its IP protection.

The European collaboration project FAROS (Functional Accurate RObotic Surgery) continued, with tangible results in 2022. Those results were validated by the payment by the European Union of the mid-term grants.

Robotic DSG application to a smart drill:

In 2022, the Company progressed in the design of a universal solution aiming at enhancing orthopedic power drills currently used in hospitals. The objective is to alert the surgeon of the imminence of a bone breach and to automatically stop the drilling thus preventing the neurologic or vascular complications. The advances made can be summarized as:

- availability of the second generation of a functional prototype;
- the addition of depth measurement to feed the DSG breach detection algorithm;
- the addition of angle measurement;
- the filing of patents;
- the various tests and presentation to the scientific committee and;
- the preliminary identification of the regulatory path in the US and Europe.

Connectivity and signal visualization:

The new generation of PediGuard “DSG Connect” products includes a Bluetooth-like transmitter as well as data visualization and processing software on a dedicated tablet. This new platform aims to facilitate the visual interpretation of the DSG signal by surgeons and to allow them to record data for follow-up and research purposes in measure bone quality.

DSG Connect is FDA cleared in the United States and ANVISA cleared in Brazil. The commercial launch continued in 2022 with:

- the completion of over 500 surgeries under the limited release marketing phase by 50 surgeons in the cleared areas and validation of the commercial potential together with an impressive technical data collection for the full release of the product;
- the refinement of the new electronic card;
- the improvement of the ergonomics of the tablet application;
- the full commercial release at the Eurospine and NASS congresses, the two largest world congresses in the field of spine surgery in Europe and the USA.

Bone Quality Measurement (BQM):

Following the first data collected by Hôpital Trousseau in Paris in 2021, 2022 allowed surgeons using DSG Connect to collect record preliminary bone quality data that they can analyze retrospectively and enable them to prepare a broader protocol for 2023.

Collaboration with the US company Omnia Medical:

The collaboration between the two companies initiated in September 2022 resulted in regular project reviews that allowed the Research and Development teams to progress in design of the “smart screw” and “sacro-iliac instrumentation” and planning for the coming FDA approval steps.

Dental implantology – worldwide license and collaboration with ConfiDent, a subsidiary of Adin:

The partnership with ConfiDent ABC (Adin Group) for dental implantology continues. We are experiencing some delays in the execution of the development plan necessitating to reschedule and to consider different alternatives.

Strengthening of intellectual property:

In 2022, the Company consolidated and extended its international patent portfolio. To date, SpineGuard holds a total of 79 patents and applications, in 19 families.

2023 First quarter revenue

Global revenue in the first quarter of 2023 was € 1,271 K vs. € 1,131 K in Q1 2022 a 12% increase as reported and 10% cc.

SpineGuard sold 1,621 DSG units in the first quarter of 2023 vs. 1,361 units in Q1 2022 of which 565 units in the USA vs. 569 in 2022.

US revenue increased by 4% as reported (flat cc) at € 766 K vs. € 739 K.

Outside the USA, the positive dynamics initiated since the second half of 2020 continued, and revenue grew by 29% at € 504 K vs. € 392 K in the first quarter of 2023. This is the tenth consecutive quarter with double digit growth OUS.

SpineGuard Priorities

SpineGuard is focusing on the following priorities while investing selectively and with rigor:

1. Boost commercial activities with DSG-Connect and WishBone Medical
2. Develop a DSG drill bit and a universal drill guide embedding the DSG robotic intelligence
3. Implement the agreement recently signed with Omnia Medical
4. Deploy the DSG digital technology in the surgical robotic and dental fields
5. Sign new strategic partnerships

Next events

General Shareholders Meeting on June 8, 2023 (and June 29, 2023, if second summoning)
2023 half-year revenue on July 12, 2023

About SpineGuard®

Founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard is an innovative company deploying its proprietary radiation-free real time sensing technology DSG® (Dynamic Surgical Guidance) to secure and streamline the placement of implants in the skeleton. SpineGuard designs, develops and markets medical devices that have been used in over 95,000 surgical procedures worldwide. Twenty-four studies published in peer-reviewed scientific journals have demonstrated the multiple benefits DSG® offers to patients, surgeons, surgical staff and hospitals. Building on these strong fundamentals and several strategic partnerships, SpineGuard has expanded the scope of its DSG® technology in innovative applications such as the « smart » pedicle screw, the DSG Connect visualization and registration interface, dental implantology and surgical robotics. DSG® was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. SpineGuard has engaged in multiple ESG initiatives.

For further information, visit www.spineguard.com

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