

SpineGuard announces its full-year 2021 financial results and its first quarter 2022 sales

- Improved net result and US operations profitable
 - Strengthened investments for innovation
 - Cash runway over 24 months
 - Back to growth in 1Q22

PARIS and BOULDER (CO), April 28, 2022, 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 2021 financial results, as approved by the Board of Directors on April 28, 2022 and its first quarter 2022 sales.

€ thousands – IFRS audited	2021	2020
Revenue	4 405	4 852
Gross Margin	3 606	4 036
Gross margin (% of revenue)	81,9 %	83,2%
Sales, distribution & marketing	2 660	2 578
Administrative costs	1 394	1 740
Research & Development	791	680
Operating profit / (loss)	-1 239	-961
Non-recurring operating costs	-110	-875
Financial Result	-299	-844
Income Tax	-76	-37
Net profit / (loss)	-1 725	-2 716
EBITDA	-1 063	-1 284

Pierre Jérôme, co-founder, Chairman and CEO of SpineGuard, said: "In 2021, we considerably strengthened the company financially while significantly advancing our innovation pipeline and putting in place the necessary means to boost the commercial dynamic in the United States. We are now back to growth in this first quarter of 2022 despite the impact of the Omicron variant on elective surgery's activity in January and February. This first quarter is already proving particularly fruitful for SpineGuard with consecutively the signing of a very promising partnership with WishBone Medical in pediatric orthopedics, the 19th clinical publication on our DSG technology, our first patent in robotics and the clearance by the FDA for the commercial release of the Threaded PediGuard in anterior approach spine surgery. Three of these four great achievements directly concern the US market, the largest and most strategic for SpineGuard."

Net operating result under control and increased investments for innovation

The Company increased its investments for innovation and strengthened its commercial activity in the United States while maintaining strict discipline on expenses.

The Net Loss was reduced to € -1,725K vs. € -2,716K in 2020.

Gross margin decreased by 130 bps at 81.9% vs. 83.2% mainly due to the lower percentage of sales made in the United States where sales prices are higher than in the rest of the world. Sales prices remained stable in the United States while they increased in the rest of the world due to a significantly different country mix compared to 2020.

Operating expenses decreased by 3.1% or € 153K reflecting a rigorous control of operational expenses over the year in the still impacting context of the Covid-19 pandemic. Non-recurring operating costs are mainly related to the French "sauvegarde" and US Chapter 11 proceedings at € 110K vs. € 875K in 2020.

Working capital requirements were € -133K vs. € -176K in 2020.

Financial expenses were € -299K mainly corresponding to the interest charges of the venture loan with Norgine Venture, Harbert European Growth Capital and Bpifrance. There are € 44K of forex rate gains and € 179K 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.

Cash runway extended over 24 months

At December 31, 2021, cash and cash equivalents were € 5.2M, plus the secured € 5.0M of convertible warrants (BSAR) secured with Nice & Green. As of March 31, 2022, cash and cash equivalents were € 4.3M. With the balance of the equity line of € 5.0M, SpineGuard's cash runway stands at over 24 months.

In addition, should 100% of the Warrants be exercised, the free allocation of Redeemable Warrants set up in June 2021 may generate gross proceeds of € 5,370K and would extend by 24 month the cash runway.

Significant R&D advances

Robotic application:

In 2021, the collaborative work with the ISIR of Sorbonne University made solid progress with the implementation of a new platform of experimental equipment including a medical grade robotic arm, a programmable drilling set, as well as various equipment. This enabled specific 3rd generation programming for the automated detection of bone breaches and the performance of a large-scale invitro study which produced outstanding results: 100% success in 104 drillings with a submillimeter precision. In parallel, the Company took steps for its IP protection.

The European collaboration project Faros (Functional Accurate RObotic Surgery) continued, with tangible results expected in 2022, which will reinforce the value proposition of the DSG technology and bring differentiation to orthopedic robots.

Robotic DSG application to a smart drill:

The company started in 2021 the development of a universal solution called "SUD" (Smart Universal Drill), aiming at enhancing orthopedic power drills currently used in hospitals. This device integrating the fruits of the robotic DSG program will allow for the detection of an impending bone breach to automatically stop the drilling thus preventing neurologic or vascular complications. It will be universal in the field of orthopedic surgery, in spine and beyond, because it will adapt to any drill in the market and to any surgical technique used by the surgeon: manual, navigated, or guided by a robotic arm.

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 interpretation of the DSG signal by surgeons and to allow them to record data for follow-up and research purposes for the measurement of bone quality. Over a hundred surgeries were performed as part of the pre-launch in Europe, the United States and Brazil despite the constraints of the pandemic. The extremely encouraging feedback from the first users should allow a full commercial launch during the NASS (North American Spine Society) and the Eurospine in October of this year.

Bone Quality Measurement (BQM):

In 2021, Sorbonne University finalized the collection of DSG data from the surgeries performed at the Trousseau Hospital of Paris to feed the algorithms of our robotics program and measure bone quality.

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

The partnership with ConfiDent ABC (Adin Group) within the framework of the exclusive worldwide license agreement for DSG technology for dental implantology continues with the objective to launch a disruptive product in this field.

Strengthening of intellectual property:

In 2021, the Company consolidated and extended its international patent portfolio with the following highlights:

- Obtention of the "Real Time" patent in Japan and the United States after the 2020 granting in China. These patents extend the protection of DSG technology until 2035 in geographies representing major markets in the sector,
- Multiple applications were filed in the field of robotics and dental,
- A total of 80 patents and applications, in 17 families as of today.

End of the French 'sauvegarde' and US Chapter 11 proceedings

On March 24, 2021, the Commercial Court of Creteil ended the voluntary French 'sauvegarde' proceeding engaged by the Company. The U.S. court of Delaware did the same on August 24, 2021. The company is now executing the agreed plans.

2022 First quarter revenue

Global revenue in the first quarter of 2022 was € 1,131K vs. € 1,049K in Q1 2021 a 7.9% increase as reported in a context significantly impacted by the Omicron variant peaks of infection in January and February which forced many hospitals to defer elective surgeries particularly in the US and in Europe due to staff shortages and in order to face the new influx of Covid-19 patients.

SpineGuard sold 1,361 DSG units in the first quarter of 2022 vs. 1,360 units in Q1 2021 of which 569 units in the USA vs. 558 in 2021.

US revenue increased by 6% as reported (-2% cc) at € 739K vs. € 700K. Outside the USA, the positive dynamics initiated in the second half of 2020 continued, and revenue grew by 13% at € 392K vs. € 348K in the first quarter of 2021. This is the sixth consecutive quarter with double digit growth OUS.

2022 Perspectives

SpineGuard is focusing on the following priorities while investing selectively to remain close to breakeven:

- 1. Boost commercial activities with the launch of the DSG-Connect visual interface and the partnership with WishBone Medical
- 2. Deploy the DSG digital technology in the surgical robotic field
- 3. Develop a Smart Universal Drill (SUD) embedding the DSG AI
- 4. Support ConfiDent with the design and scale-up of the DSG dental applications
- 5. Sign new strategic partnerships

Next events:

General Meeting on June 8, 2022 2022 half-year revenue on July 12, 2022

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 85,000 surgical procedures worldwide. Nineteen 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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