

SpineGuard Reports its H1 2024 Financial Results

- Revenue growth by 10% at constant exchange rate
- Net loss reduced by 20% and EBITDA improved by 30%

PARIS (France) and BOULDER (CO, USA), September 11, 2024 – 6:00 pm CEST - **SpineGuard** (FR0011464452 - ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) local conductivity sensing technology to secure and streamline the placement of bone implants, today announces its financial results for the half year ending June 30, 2024, as approved by the Board of Directors on September 11, 2024.

Pierre Jérôme, Co-founder, Chairman and CEO of SpineGuard, stated: “First-half results for 2024 are in line with our business plan. We started the year with a return to growth in the first quarter of 2024, followed by an acceleration in the second quarter spurred by our strengthened American commercial structure and our partnership with Omnia Medical. As a result, we achieved double-digit growth at constant exchange rate in the first half of the year and maintained the gross margin level close to 80%. Net loss improved by almost 20% and EBITDA by over 30%. Regarding sales, the gradual launch of new devices embedding DSG® technology should significantly contribute to sustaining growth over the coming quarters. Concurrently, we are working to obtain approval for the entire PediGuard range products in China as well as forging new strategic partnerships to complete our financing and successfully roll out the dental and robotic applications of our technology. With the achievement of these objectives and outlook, we confirm our ability to reach financial breakeven in the course of 2026.”

€ thousands – IFRS	H1 2024	H1 2023
Revenue	2,445	2,234
Gross margin	1,943	1,768
Gross margin (%)	79.5%	79.1%
Sales, distribution, marketing	- 2,025	- 2,072
Administrative costs	- 776	- 996
Research & Development	- 752	- 580
Recurring operating profit / (loss)	- 1,612	- 1,880
Non-recurring operating costs	-	- 87
Operating profit / (loss)	- 1,612	- 1,967
Financial result	- 10	- 32
Income tax	-	- 9
Net profit / (loss)	- 1,602	- 2,009
EBITDA	- 1,230	- 1,805

Note: unaudited figures

H1 2024 Key Financial Highlights

3,291 DSG units were sold in H1 2024 (vs. 3,029 units in H1 2023), representing an overall growth of +9%. The 100,000 surgical procedures threshold was reached at the end of January 2024¹.

The revenue for the first half of 2024 amounted to €2,445 K (vs. €2,234 K for the same period in 2023), an increase of 9% as reported and 10% at constant exchange rate. This improvement was driven by the direct takeover of WishBone accounts, significant orders from Omnia Medical and the positive impact of the new American team put in place by SpineGuard last spring.

In Europe, 2024 first-half revenue from products was up 6%, mainly driven by Germany, the Netherlands, Greece, Spain and Slovakia. Sales in Latin America and the Middle East decreased by 19% due to lower orders in Mexico and Peru, and by 22% respectively due to the base effect of a major order in Saudi Arabia in the first half of 2023, which is expected in the second half this year. In Asia, revenue was up 34% thanks to Japan and Taiwan. In China, the pediatric orthopedic department of the Drum Tower Hospital in Nanjing, China's leading center for the treatment of scoliosis, run by a renowned surgeon, Professor Yong Qiu, now uses Classic PediGuard, for which SpineGuard obtained renewed registration from the NMPA (National Medical Products Administration, China's equivalent of the FDA), on a daily basis. At the same time, trials were conducted on the Curved and Miniaturized PediGuard products, for which regulatory approvals are expected in early 2025. As a reminder, the clearance process is being carried out in China in collaboration with the Franco-Chinese specialist consultant VVR² enabling SpineGuard to be the sole proprietary of its product registrations in China.

Gross margin came to 79.5% on June 30, 2024, compared with 79.1% on June 30, 2023. This change is mainly due to a higher contribution from US sales, a market with the highest selling prices.

Current operating expenses totaled €3,553 K in the first 6 months of 2024, compared with €3,648 K in the first half of 2023, an improvement by €93 K, mainly reflecting a €220 K reduction in administrative costs. Sales and marketing expenses were at roughly the same level as in the first half of 2023, while R&D expenditure rose by €202 K as a result of the development and approval of new products to extend the PediGuard product range, as detailed below.

Recurring operating loss was reduced to -€1,612 K on June 30, 2024, compared with -€1,880 K on June 30, 2023, a 14% improvement. Net loss improved by 20% to -€1,602 K on June 30, 2024, and EBITDA by 30%, to -€1,230 K.

Cash and liquid investments, recorded under current financial assets as of June 30, 2024, amounted to €1,119 K compared with €3,893 K as of December 31, 2023. In light of the consolidated cash and cash equivalents of €1,646 K as of August 31, 2024, as well as the forecasted cash flows and continued commercial growth, the Company estimates that it will be able to cover its financing needs and maintain its operations until March 2025. The Company decided not to include the equity line set up with Nice & Green mid-2023 in its cash flow forecast and to prioritize other sources of financing. To date, the Board of Directors maintains the going concern principle in light of the above-mentioned assumptions and initiatives taken by the Management to ensure the Company's financial continuation beyond March 2025. In this framework, the Company is exploring various financing solutions, including strategic partnerships.

¹ ["SpineGuard reaches the milestone of 100,000 surgeries and over 30 publications with DSG® technology"](#), on February 6, 2024

² Support for industrial and commercial development

Execution of the New Products Development Roadmap

Threaded PediGuard for anterior surgery

As announced on September 3, SpineGuard obtained the EC-MDR certification for its class IIa and IIr devices, enabling the Company to launch the Threaded PediGuard for anterior surgery approach in Europe.

PsiGuard, the Cannulated PediGuard for sacroiliac fusion co-developed with Omnia Medical

The industrial design was finalized in the first half of 2024 and the first series were manufactured. The US Food and Drug Administration (FDA) approval process is well advanced, with a validation test in the anatomy laboratory by four American surgeons and submission of the “510K” file at the end of June. Commercial launch is therefore expected in late 2024/early 2025, depending on the speed of the regulatory review process.

Drill Bits with DSG sensor for usage with power drills and navigation

During the first half of 2024, the Company finalized the design and industrialization of a range of drill bits embedded with the DSG technology that are suitable for orthopedic drills and are compatible with the dominant surgical navigation system in the market, as well as with the DSG Connect interface. SpineGuard received the FDA's feedback via a pre-submission and a “panel meeting” to prepare the necessary validation tests. The “510K” application will therefore be submitted at the end of 2024/ early 2025 for commercial roll out in 2025. At the same time, the Company has developed the prototype of a smart drilling guide, using its algorithms derived from robotics research to detect a bone breach situation and automatically stop the drilling progress.

DSG sensor embedded Smart screw with Omnia Medical

SpineGuard completed the components (electronic handle and sensing pin) required to integrate the DSG technology into Omnia Medical's pedicle screw system. The engineering teams at Omnia Medical and SpineGuard joined forces to develop the implant and instrument system, with the aim of launching the combined product during 2025. The product will primarily target the American market.

Application of DSG to Robotic-assisted bone resection

SpineGuard successfully completed work within the FAROS consortium in the first half of 2024 demonstrating the effectiveness of DSG technology to secure Robotic Assisted Pedicle Drilling. The results led SpineGuard's Scientific Advisory Board to use DSG detection to pre-cut a volume of bones from the vertebral body using robotic assistance. Such a delicate procedure corresponds to a strong clinical need and carries value not yet tapped by manufacturers of robotic-assisted surgery platforms. In collaboration with ISIR (Institute for Intelligent Systems and Robotics) laboratory at Sorbonne University, the Company conducted highly promising robotic tests of this application, which provided the basis for strategic discussions with robotics industry leaders.

H2 2024 outlook

In the second half of 2024, SpineGuard is continuing its sales drive, particularly in the United States, its product registration efforts in China and gradual market roll out of the previously mentioned new products to sustain its revenue growth. The Company is also working on building strategic partnerships and strengthening its financial position.

The Company's 2024 half-year financial report is available in the “Investors” > “Documentation” section of the www.spineguard.com website, in French only.

Next financial press release: Third-quarter 2024 revenue, on October 9, 2024, after market closing.

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 embedding its technology. Over 100,000 surgical procedures have been secured worldwide thanks to DSG® and 34 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 is expanding the scope of its DSG® technology to the treatment of scoliosis via anterior approach, sacroiliac joint fusion, dental implantology and innovations such as the « smart » pedicle screw and power drill or 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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