

SpineGuard reports 2025 half-year results and announces the implementation of a bond financing

- 54% improvement in operating result
- Implementation of a bond financing for up to €1,000,000

PARIS and BOULDER (CO), September 10, 2025 – 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 first half of the fiscal year ended June 30, 2025, as approved by the Board of Directors held on September 10, 2025, as well as the completion of a bond financing of up to €1 million.

Pierre Jérôme, Co-founder, Chairman and CEO of SpineGuard, stated: *"With a 54% improvement in operating result in the first half of 2025, we are on track to reach operational break-even by the end of 2026, SpineGuard's top financial priority. The ongoing transformation of our commercial model in the United States is part of this trajectory, with a targeted reduction in overhead and gradual improvements in operating profitability. Strengthening our strategic alliance with Omnia Medical is another key driver, enabling the integration of our DSG technologies (PediGuard, PsiFGuard, etc.) into Omnia Medical's spinal implant offering, thereby enhancing their competitiveness in the U.S. market. Furthermore, the latest progress achieved by our R&D team in the design, functionalities and integration of DSG technology reinforces its unique positioning - real-time, X-ray-free guidance at the bone interface - and its strong potential added value for surgical assistance platforms. We are also advancing discussions with several new potential partners interested in powered, robotic, and dental applications of DSG."*

€ thousands – IFRS	H1 2025	H1 2024
Revenue	2,120	2,445
Gross margin	1,664	1,943
Gross margin rate (%)	78.5%	79.5%
Sales, distribution, marketing	-1,117	-2,025
Administrative costs	-718	-776
Research & Development	-572	-752
Recurring operating profit / (loss)	-742	-1,612
Non-recurring operating costs	-	-
Operating profit / (loss)	-742	-1,612
Financial result	-340	-10
Income tax	-	-
Net profit / (loss)	-1,083	-1,602
EBITDA	-439	-1,230

Note: unaudited figures

Key financial highlights for the first half of 2025

As indicated in the press release issued on July 9, SpineGuard's consolidated revenue for the first half of 2025 amounted to €2,120 K, down 13.3% at current exchange rates (-12.7% at constant exchange rates) compared with the first half of 2024.

In the United States, first-half 2025 revenue was down 17.1% to \$1,476 K, compared to \$1,781 K in the first half of 2024. This decrease can be explained by the gradual transformation of SpineGuard's business model from direct sales in the United States towards a distribution model as part of its strategic partnership with Omnia Medical. This shift is reflected in an apparent drop in short-term revenue but should result in an improvement in the operating margin for the full year 2025. In the first half of 2025, the Company generated 64% of its revenue in the United States.

In the rest of the world, across SpineGuard's other main markets, revenue for the first half of 2025 grew strongly by: +22% in France, +16% in Latin America, and +49% in Asia, mainly driven by an order from XinRong in China. Business in Europe was down 9%, mainly due to the change of control of SpineGuard's distributor in the Benelux, and in the Middle East the activity decreased by 25% due to an unfavorable base effect following a major order booked in Saudi Arabia in H1 2024, which is expected this year in the second half.

3,068 DSG units were sold in the first half of 2025, compared with 3,291 units in the first half of 2024, representing an overall decrease of -6.8%. 1,142 units were sold in the United States in the first half, representing 37% of total units sold.

The gross margin rate stood at 78.5% as of June 30, 2025, compared with 79.5% as of June 30, 2024. This change is mainly due to a lower share of U.S. revenue, where selling prices are the highest.

The Company's current operating expenses amounted to €2,407 K for the first six months of 2025, compared with €3,556 K in the first half of 2024, an improvement of €1,149 K, mainly due to a reduction in selling, distribution, and marketing expenses of €908 K and in research and development expenses of €185 K. Administrative costs remained broadly stable year-on-year, with a decrease of €57 K compared with the first half of 2024.

The EBITDA thus amounted to €-439 K in the first half of 2025, compared with €-1,230 K in the first half of 2024.

The targeted reduction in structural costs and investments, undertaken to achieve operating breakeven by the end of 2026, SpineGuard's top financial priority, is yielding results with current operating income at €-742 K as of June 30, 2025, compared with €-1,612 K as of June 30, 2024, an improvement of 54%. Other operating expenses were nil as of June 30, 2025 and June 30, 2024.

The Company's net loss amounted to €-1,083 K in H1 2025, compared with €-1,602 K in H1 2024, an improvement of €519 K.

Headcount stood at 15 people as of June 30, 2025, compared with 22 at the end of December 2024 and 24 people as of June 30, 2024.

Working capital requirements as of June 30, 2025, amounted to €845 K, versus €599 K as of December 31, 2024, mainly due to an increase in account receivables, while inventories and tax and social liabilities decreased.

The cash position as of June 30, 2025, amounted to €745 K, compared with €719 K as of December 31, 2024.

This change mainly reflects:

- the sharp decrease in operating cash burn, which amounted to €-651 K in the first half of 2025, compared to €-1,837 K in the first half of 2024;
- the repayment of the Bpifrance loan (€48 K) and of bond loans subscribed from Norgine Venture and Harbert European Growth for €493 K (including interest);
- the capital increase with preferential subscription rights for €706 K net of fees;
- the subscription of 600 bonds by Hexagon Capital Fund for €600 K.

The Company's cash position as of August 31, 2025, amounts to €591 K.

Amortizing bond financing of up to €1 million

SpineGuard has arranged a new bond financing with the Luxembourg-based Hexagon Capital Fund, for a maximum amount of €1,000,000.

Each bond, with a nominal value of €1,000, will mature 24 months after issuance and will be amortized on a quarterly basis.

The bonds carry an annual interest rate of 10%, payable quarterly.

SpineGuard will repay principal and interest in cash, but retains the option to repay in shares at its sole discretion, under the authority granted by the twelfth (12th) resolution of the Ordinary and Extraordinary General Meeting held on June 25, 2025.

Taking into account the bond financing of up to €1 million that has been secured, its commercial and financial projections, the reduction in its expenses, and the progress made in ongoing discussions with potential partners with a view to concluding new strategic industrial agreements, the Board of Directors has adopted the going-concern assumption. SpineGuard believes it has sufficient funding to cover its financing needs until the second quarter of 2026.

Execution of the new product development roadmap

PsiFGuard, the cannulated PediGuard for sacroiliac fusion co-developed with Omnia Medical

In September 2024, SpineGuard obtained FDA clearance (U.S. regulatory authority for medical devices) for PsiFGuard. Shortly thereafter, Omnia Medical launched the commercialization of this product in combination with its sacroiliac fusion implant system, "PsiF 90". At the same time, Omnia Medical is preparing the introduction of its new "DNA" device, with an innovative design, which will be offered synergistically with PsiFGuard. This integrated solution will provide interventional physicians and surgeons a unique approach, optimizing the quality and precision of posterior sacroiliac fusion procedures.

Drill bits with DSG sensor and smart guide for orthopedic power drills and navigated and robot-assisted surgery

To further enhance the added value of the drill bit equipped with DSG technology, SpineGuard continued the design of a smart drilling guide prototype during the first half of 2025, which enables automatic safety stop in the event of bone breach, representing a major breakthrough in orthopedic surgery safety. This feature is based on algorithms developed by SpineGuard as part of the robotic application of DSG technology. The combination of the DSG sensor drill bit and the smart drilling guide has sparked renewed interest from industrial players in the sector, with whom discussions have been re-engaged around technical integration and commercialization potential.

Smart pedicle screw embedding DSG sensor with Omnia Medical

SpineGuard has finalized the components required to embed DSG technology into Omnia Medical's pedicle screw system, including the electronic handle and the sensor-equipped pin. At the same time, Omnia Medical has pursued the development of its implant and instrument system in 2025, which is still in the design phase. The current timeline anticipates finalizing of the implant system design and related regulatory submissions by the end of 2025, followed by regulatory filings for the DSG components in early 2026, with a combined commercial launch targeted for 2026.

Application of DSG to robot-assisted bone resection

As a reminder, following the design of its automatic detection of bone breach algorithm during robot-assisted pedicle drilling, in partnership with ISIR (Institute for Intelligent Systems and Robotics) at Sorbonne University, SpineGuard completed the European FAROS project in 2024. Building on this progress, SpineGuard began exploring the application of its DSG technology to bone resection in late 2024, a high-potential market for robotic surgery that remains untapped. In the first half of 2025, SpineGuard initiated the design of new instruments, such as bone drill bits, using computer-based electromagnetic simulation.

Regulatory clearance of the whole PediGuard range in China with XinRong Medical Group

After obtaining renewal of the certification for the "classic" PediGuard devices in September 2024, SpineGuard filed with the NMPA (China's regulatory authority for medical devices) for clearance of its curved and XS models. During the first half of 2025, SpineGuard responded to two successive rounds of questions from the Chinese examiner. A final series of questions is expected in the third quarter and could lead to marketing authorization before year-end.

Outlook

SpineGuard is continuing to work toward achieving operational break-even by the end of 2026. The gradual transformation of its U.S. business model will be a significant contributor to this goal. The ongoing sale of SpineGuard Inc. to Omnia Medical remains subject to customary conditions precedent, primarily the repayment of bonds issued by Norgine Venture and Harbert European Growth, with the final monthly payment due in January 2026. The Company is also focused on establishing strategic partnerships, strengthening its financing, and securing approval for the curved and XS PediGuard models in China.

The Company's 2025 half-year financial report is available on its website www.spineguard.com under the Investors > Documentation section.

Next financial press release: third quarter 2025 revenue, on October 9, 2025, after market close.

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 39 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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