

# SpineGuard Announces Full-Year 2024 Financial Results and First Quarter 2025 Sales

 Significant reduction in losses of €1.1 million, with consolidated net income improving by 26% in 2024

PARIS, BOULDER (Colorado), April 15, 2025 - 6:00 pm 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, today announces its full-year 2024 financial results for the year ended December 31, 2024, as approved by the Board of Directors on April 15, 2025, and its first guarter 2025 sales.

# **2024 Financial Results**

In € thousands – IFRS audited	2024	2023
Revenue	4,648	4,313
Gross margin	3,628	3,379
Gross margin (%)	78.1 %	78.3 %
Sales, distribution, marketing	3,871	4,065
Administrative costs	1,522	1,800
Research & Development	1,295	1,434
Recurring operating profit / (loss)	-3,061	-3,919
Non-recurring operating costs	-	-57
Financial result	-21	-225
Taxes	-	18
Net income / (loss)	-3,082	-4,183

**Pierre Jérôme, Chairman, CEO and Co-founder of SpineGuard**, states: "Achieving operational breakeven by the end of 2026 remains SpineGuard's top financial priority. With a 26% improvement in our net income for 2024 full financial year, we have gone part of the way, and the ongoing transfer of our US subsidiary to our partner Omnia Medical should enable us to further reduce our structural costs and increase our operating profitability. The strengthening of this strategic alliance with Omnia Medical also opens up significant growth opportunities for us in the US, particularly with our new PsiFGuard device for interventional sacroiliac fusion, and more broadly with our entire PediGuard range integrated into their spine implant offering. Finally, the latest advances made by our R&D team on the design, functionalities and integrability of our DSG technology confirm its unique positioning — as a real-time guidance without X-ray in direct contact with bone - and its high potential added value for skeletal surgery assistance platforms."

## 2024 Net Income Improved by 26%

As announced in January 2025, 2024 revenue amounted to €4,648 K, representing an increase by 8% at actual and constant exchange rates compared to 2023.

6,142 DSG units were sold in 2024 vs. 6,138 units in 2023, of which 2,489 units were sold in the United States, representing 41% of total units sold.

In the United States, 2024 revenue was up 20% compared to 2023. This favorable trend was driven by significant orders from Omnia Medical, the direct takeover of pediatric accounts previously covered by Wishbone Medical, and the impact of SpineGuard's newly established team in the US put in place in spring 2023.

In Europe, revenue generated grew by 4%, driven mainly by Greece, Slovakia, Germany and the Netherlands. The Middle East posted 19% growth, supported by a strong order level from distributors in Israel and Turkey.

Latin America was down by 12% and Asia by 64%, due to the temporary absence of orders from XinRong Medical, SpineGuard's distributor in China. The Chinese medical device market underwent several upheavals in 2024 which slowed down XinRong's business plan. However, the situation has been gradually improving in recent months. Approval by the NMPA (National Medical Products Administration, China's regulatory authority) of the Curved PediGuard and XS models, expected in 2025, is an important milestone ahead for the commercial deployment of DSG technology in China, the world's second-largest spinal implant market.

The gross margin rate remains stable at around 78% as of December 31, 2024.

Current operating expenses fell by 8% (i.e. €609 K), mainly due to:

- reduced administrative costs; and
- no impairment of trade receivables in 2024, compared with 2023 when it amounted to €378 K, following the unilateral decision by Adin Dental Implant Systems, parent company of ConfiDent ABC, to terminate their DSG dental application project for financial reasons.

Recurring operating loss stood at -€3,061 K as of December 31, 2024, compared with -€3,919 K as of December 31, 2023.

Net financial expense improved significantly to -€21 K, corresponding mainly to interest expense on debt with Norgine, Harbert European Growth and Bpifrance, net foreign exchange gains of €183 K, and income from investments (term accounts) of €97 K.

Net income therefore totaled -€3,082 K in 2024, compared with -€4,183 K in 2023, an improvement of +€1,101 K compared to the previous year.

Operating working capital as of December 31, 2024 was €599 K, compared to €540 K as of December 31, 2023.

Cash and cash equivalents (shown under current financial assets) as of December 31, 2024 came to €719 K, compared to €3,893 K as of December 31, 2023. This change in cash and cash equivalents is mainly due to:

- Cash flow from operations improvement from -€3,545 K in 2023 to -€2,245 K in 2024, with cash used to finance operations down from -€3,649 K in 2023 to -€2,360 K in 2024, an improvement of €1,289 K;
- Increase in the change in working capital requirements of €115 K over 2024, mainly due to the reduction in short-term debts;
- Repayment of bonds subscribed with Norgine Venture and Harbert European Growth in the amount of €840 K in principal and €146 K in interest;
- Repayment of the Bpifrance loan in the amount of €49 K; and
- Net proceeds from the capital increase carried out in July 2024 for €701 K.

# Q1 2025 Revenue and Cash Position

In € thousands - IFRS (unaudited)	2025	2024	Change
First Quarter	1,206	1,351	-10.7%

SpineGuard's consolidated revenue came to €1,206 K in the first quarter of 2025, down 11% compared to the first quarter of 2024, but up 17% on the fourth quarter of 2024 (€1,028 K).

In the United States, first-quarter 2025 sales came to \$893 K, down 12% on first-quarter 2024, but up 28% on fourth-quarter 2024 (\$696 K). In France, sales were up 23% on the first quarter 2024 and 20% on the fourth quarter 2024.

1,679 DSG units were sold in Q1 2025 vs. 1,780 units in Q1 2024. 753 units were sold in the United States, representing 45% of all units sold.

The cash position as of March 31, 2025 was €650 K.

In light of the bond financing of up to €1 million put in place and announced on January 7, 2025¹, the completion of the capital increase, settled and delivered on April 2, 2025, which generated net proceeds of €721 K, and its commercial and financial outlook, SpineGuard estimates that it will be able to fund its financing needs until October 2025.

In addition, SpineGuard is in the process of forging strategic partnerships and studying various options and measures to strengthen the Company's financing.

### **Continued Significant Technological and Regulatory Progress**

# Threaded PediGuard for anterior surgery

In September 2024, SpineGuard obtained CE approval under the new European MDR regulations for its Threaded PediGuard for anterior surgery approach, enabling its launch at the Eurospine congress in Vienna in October.

### Clearance of the PediGuard range in China

In September 2024, SpineGuard obtained the renewal of its certificate for the marketing of its PediGuard products in straight form (2.5; 3.2 and 4.0mm) in China. SpineGuard has also prepared the clearance file for the Curved and XS models and submitted it to the Chinese authorities (NMPA), which is currently under review.

# "PsiFGuard" project co-developed with US company Omnia Medical

During 2024, SpineGuard finalized the design and industrialization of its new "PsiFGuard" product intended for posterior sacroiliac joint fusion ("PSIF"). In July, the Company filed the clearance with the FDA and obtained the FDA clearance for the marketing of this new product in the US in September. Finally, SpineGuard delivered to Omnia Medical the first batches of products manufactured in 2024.

<sup>&</sup>lt;sup>1</sup> "SpineGuard completes a bond financing to support the deployment of its new products"

#### DSG universal drill bit

In 2024, SpineGuard completed the design and industrialization of the drill equipped with its DSG technology, designed to adapt to the market's orthopedic drills and navigation systems. The Company has also precisely determined the regulatory approval pathway in the United States with the FDA, via a presubmission process. Finally, SpineGuard presented the new device in numerous meetings with industry players, surgeons, distributors and sales agents to refine its design and determine its market positioning. Concurrently, the Company has developed a functional prototype of a smart drilling guide capable of automatically detecting a bone breach situation using algorithms from its robotics program and stopping drilling progress using an automatic-stop system. This smart guide will be developed in 2025 and, along with the DSG drill, will support strategic discussions with medical robot manufacturers for integration within their orthopedic surgery platforms.

## DSG technology applications for robotic platforms

The aim is to develop know-how and intellectual property that can be licensed to one or more industrial players in the field of robotic orthopedic surgery, enabling them to differentiate themselves on the market by enhancing the performance and safety of their robotic surgical assistance platform. To this end, SpineGuard is making steady progress by demonstrating the benefits of DSG technology in robotic spine surgery and filing new patent families. In particular, the Company has developed algorithms to automatically detect and prevent bone breaches during pilot hole drilling for pedicle screw placement.

- Bone resection: in 2024, the team in charge of the robotic application demonstrated, through a new series of experiments, that DSG could also be used to secure robot-assisted bone cutting, a high potential market not currently commercially addressed by players in the sector. SpineGuard could present its advances at the end-of-year congresses of SRS (Scoliosis Research Society), NASS (North American Spine Society) and Eurospine, generating considerable interest.
- Collaboration within the "FAROS" (Functional Accurate Robotic Surgery) consortium: in September 2024, the project successfully demonstrated the effectiveness of safe robotic pedicle drilling using DSG technology on anatomical subjects, in the presence of the European Community representatives. The team then contributed to the final report in collaboration with the Universities of KU Louvain, Sorbonne, Kings College and Balgrist Surgery School.

### Combining DSG with innovative ultrasound technology

Since 2014, SpineGuard has patented ultrasound technology that enables the entry point and drilling trajectory to be determined from the bone surface, without X-rays, before drilling insertion. This technology perfectly complements DSG, as, once the drill has begun to penetrate the bone, DSG takes over to prevent any breach with extreme precision. In 2024, work on the CIFRE thesis, conducted under the joint supervision of the ISIR (Institut des Systèmes Intelligents et de Robotique) and LIB (Laboratoire d'Imagerie Biomédicale) laboratories, continued with the design and manufacture of a dedicated transducer and the execution of robotic ultrasound scanning experiments on vertebral pedicle.

### Bone quality measurement

DSG measurement of bone electrical conductivity could be used to measure the local bone density of patients during surgery. This measurement is of clinical value, for example, in supporting intra-operative decisions such as the choice of bone anchors, their number, or the use of bone-reinforcing cement. It could also be useful for prescribing bone-strengthening treatments post-operatively. In dental implantology, this measurement could also be used to optimize the calibration of the bone drilling in which the implant will be housed, in order to achieve maximum stability and osseointegration.

To demonstrate that DSG can be used to measure bone density, in 2024 surgeons from France, the US and Brazil recorded DSG bone measurement data from patients during surgeries using PediGuard

devices. This will enable to assess their correlation with standard radiological bone density examinations. To date, nearly 1,500 data points have been collected during 39 surgeries, with preliminary analysis underway and data collection ongoing.

# **Upcoming events:**

Combined General Meeting, on June 10, 2025 (first notice) Combined General Meeting on June 25, 2025 (second call, if applicable) Sales for the 2<sup>nd</sup> quarter 2025, on July 09, 2025

#### 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 <a href="https://www.spineguard.com">www.spineguard.com</a>

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