Press release



# SpineGuard reports full-year 2014 financial results and provides guidance for 1Q15 revenue

- 2H14 sales recovery continues into 1Q15
  - Well controlled operating cash flow
- Smart Screw development ahead of schedule

**PARIS and SAN FRANCISCO, March 25, 2015** – **SpineGuard** (FR0011464452 – ALSGD), an innovative company that designs, develops and markets disposable medical devices intended to make spine surgery safer, reported today its full-year 2014 financial results as approved by the Board of Directors on March 24, 2015.

Pierre Jérôme, CEO of SpineGuard, said: "2014 has been a challenging year revenue-wise but we ended 2014 on an encouraging trend and I can say with confidence that we will post over 20% cc growth for 1Q15. While improving our sales execution and marketing capabilities to address the healthcare reforms, we accelerated the deployment of our pipeline and partnership strategy. Our most recent news releases on the granting of EU patent for the "smart screw", the FDA clearance to market PediGuard in MIS and the 2 "smart screw" partnerships are demonstrating SpineGuard's commitment to establish the DSG<sup>m</sup> (Dynamic Surgical Guidance) technology as a standard of care in spine and beyond. These results were achieved without compromising SpineGuard's financial discipline evidenced by the well-controlled net operating cash flow."

€ thousands – IFRS Audited	Dec 31, 2014	Dec 31, 2013
Revenue	4,436	4,615
Gross margin	3,778	4,027
Gross margin (% of revenue)	85.2%	87.3%
Sales, distribution & marketing	5,416	4,761
Administrative costs	1,907	1,607
Research & Development	934	811
Other expenses	-	-
Operating profit / (loss)	-4,479	-3,152
Pre-tax profit / (loss)	-4,539	-3,515
Net profit / (loss)	-4,539	-3,515

Starting with first quarter 2015, SpineGuard will report revenue on a quarterly basis. First quarter 2015 revenue will be published on April 8, 2015.

## Financial performance highlights

In 2014, SpineGuard reported full-year revenue of €4,436k compared with €4,615k for the full-year 2013. Growth returned in the second half of 2014 at +10.4% compared with the first half of 2014. 6,063 PediGuard units were sold compared with 6,308 in 2013, including 3,212 in the United States, i.e. 53%.

The gross margin of 85.2% at Dec. 31, 2014 compared with the prior year of 87.3% remains solid. The 210 bps decrease reflected for 140 bps the temporary impact of additional production costs on the XS range products launched in 2014; the balance was associated to the country mix compared with 2013.

The Company reported a net loss of  $\notin$ 4,539k for the full-year 2014 compared with a loss of  $\notin$ 3,515k for the full-year 2013. Excluding the IFRS2 impact<sup>1</sup> ( $\notin$ -507k), operating expenses were  $\notin$ 7,506k, an increase of + $\notin$ 572k or +8.2% compared with 2013, mainly driven by an investment in sales and marketing ( $\notin$ -404k), which has started to positively impact the revenue in the second half.

At December 31, 2014, cash and cash equivalents were €2,507 compared with €6,395k at December 31, 2013. The main variances between 2014 and 2013 were as follows:

- The operating cash flow was €-3,317k compared with the previous year of €-2,994k, i.e. €-323k.
- Reimbursement of bonds, subscribed by Norgine, of €829k for tranche A and €220k for tranche B.
- The start of the reimbursement of the Oséo Innovation loan for €75k.
- The increase in shareholders' equity as a result of two Paceo<sup>®</sup> equity facility draws in February and June, totaling €688k (net of expenses).

The Company also has an available equity line (Paceo) of 325.000 shares representing an estimated €1.7M net of expenses at March 24, 2015 stock price.

The Company's workforce count was 25 at the end of 2014, flat compared with December 2013.

Working capital was €406k compared with €322k for the full-year 2013, illustrating consistently over the past 2 years the low and atypical level of cash required compared with industry standards. Inventory of finished products decreased to €236k compared with €272k as of December 2013.

## A fruitful year in line with company's strategic goals marked by tangible strides on the "smart screw"

#### Sales and Marketing:

- After a challenging first half due to the healthcare reform implementation, US recovered in the second half thanks to a more focused sales execution toward hospital systems and teaching institutions (25 at the end of 2014 vs. 19 at the end of 2013), as well as the continuous improvement of the agent network with 74 agencies in place as of December 31<sup>st</sup> (+3 vs. end of 2013).
- The performance in the rest of the world was altered by Brazil however the Company delivered strong growth in France (+21%), Germany (+73%), Switzerland (+43%) and other Latin American countries (+30%) as well as a promising start in Japan. The ANVISA certification obtained at the end of 2014 following a successful inspection will allow SpineGuard to register more products in Brazil in the future.
- Positioning of the DSG<sup>™</sup> platform and investment in marketing through two new hires (US and OUS) and a number of initiatives thriving on influential surgeons and robust clinical data.

#### Clinical:

• Seventh and eighth publications in peer-reviewed journals on the PediGuard clinical value by Dr Cheng in the *Journal of Neurosurgery* in August and Dr Williams in *Columa Columna* in November.

<sup>&</sup>lt;sup>1</sup> Fair value of equity-based payments

- Seven podium presentations by seven different surgeons at seven different international scientific congresses along the year.
- Three new clinical studies completed: osteoporotic patients, learning curve of residents, and radiation exposure reduction in thoraco-lumbar.

#### Research & Development:

- Significant momentum and acceleration of the DSG Screw & Tap projects with tangible strides on the technical and partnership fronts;
- Completion of the PediGuard product offering with the launch of the XS line and beveled Cannulated;
- Two new patents filed on the X-ray Free Navigation project.

### **Recent events:**

January 29:	Grant of patent by the European Patent Office under the number <i>1781198</i> for the integration of the DSG technology directly into a pedicle screw, by far the most frequently used implant in spine surgery.
February 3:	510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the PediGuard products for Minimally Invasive Surgery (MIS).

- February 11: Co-development partnership with Neuro France Implants (NFI) for the integration of the DSG technology into NFI's pedicle screw system.
- March 4: First US co-development partnership with Zavation for the integration of the DSG technology into Zavation's pedicle screw system.
- March 24: Headquarters relocation from Saint-Mandé to Vincennes.

#### Next financial press release: 2015 first quarter revenue: April 8, 2015

#### About SpineGuard®

Co-founded in 2009 by Pierre Jérôme and Stéphane Bette, former executives at Medtronic Sofamor-Danek and SpineVision, SpineGuard's mission is to make spine surgery safer and its primary objective to establish its Dynamic Surgical Guidance (DSG<sup>™</sup>) technology as the global standard of care for safer screw placement in spine surgery and beyond. Co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer, PediGuard is the world's first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Real-time feedback is provided via audio and visual signals. Over 37,000 procedures have been performed worldwide with FDA-cleared and CE-marked PediGuard. Seven studies published in peer-reviewed medical and scientific journals have demonstrated that PediGuard detects 98% of pedicle breaches, presents an average screw placement accuracy of 97% (vs. 93% for surgical navigation), provides threefold fewer pedicle perforations than with the free-hand technique and a threefold reduction in neuro-monitoring alarms. It also limits radiation exposure by 25-30% and decreases by 15% the time for pedicle screw placement. The company also focuses on developing and exploring other applications for its DSG platform. SpineGuard has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

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