

SpineGuard reports full-year 2015 financial results

- Sales increase 43% to €6.3M
- Net loss reduced by €0.7M to -€3.9M
- Secured Financing of €10.5M
- CE Mark and 1st surgeries performed with DSG™ smart screw and PediGuard® Threaded
 - PediGuard Classic range approved in China

PARIS and SAN FRANCISCO, March 23, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that develops and markets disposable medical devices designed to make spine surgery safer, reported today its full-year 2015 financial results as approved by the Board of Directors on March 22, 2016.

<i>€ thousands – IFRS Audited</i>	Dec 31, 2015	Dec 31, 2014
Revenue	6 346	4 436
Gross margin	5 365	3 778
<i>Gross margin (% of revenue)</i>	84,5 %	85,2 %
<i>Sales, distribution & marketing</i>	6 514	5 416
<i>Administrative costs</i>	1 968	1 907
<i>Research & Development</i>	857	934
Operating profit / (loss)	-3 974	-4 479
Pre-tax profit / (loss)	-3 878	-4 539
Net profit / (loss)	-3 878	-4 539

Pierre Jérôme, CEO and co-founder of SpineGuard, said: *“Whether you look at sales, financing or strategic achievements, 2015 was an excellent year for SpineGuard. The strong growth in the USA, Europe and Japan, as well as the regulatory approval in China, continue to validate the outstanding clinical value of the PediGuard range. Our Dynamic Surgical Guidance technology is now successfully integrated into the spinal implant itself thanks to the fruitful collaborations with our partners, Neuro France and Zavation. The CE-marking and successful first surgeries with DSG screws are already opening opportunities with great prospects for us.”*

Manuel Lanfossi, CFO of SpineGuard, added: *“By securing €7.7M financing with Bpifrance and IPF Partners, the company has reinforced its financial resources in a flexible way, providing the necessary means to properly deploy our new products worldwide. The solid growth achieved in 2015 combined with the control of the operating expenses and the working capital make us confident for the future.”*

Financial performance highlights 2015

In 2015, SpineGuard reported full-year revenue of €6,346k compared with €4,436k for 2014, a 43% increase on reported basis and 24% cc. 7,449 PediGuard units were sold compared with 6,063 in 2014, including 4,306 in the United States.

The gross margin of 84.5% at Dec. 31, 2015 compared with the prior year of 85.2% remains strong. The 70 bps decrease year on year was mainly caused by a different country – product mix compared with 2014.

The Company reported a net loss of €3,878k for the full-year 2014 compared with a loss of €4,539k for the full-year 2014, an improvement of €661k. Operating expenses were €9,337k, an increase of 13% compared with 2014, mainly driven by investments in sales and marketing (+20%).

At December 31, 2015, cash and cash equivalents were €3,229k compared with €2,507k at December 31, 2014. The main variances between 2015 and 2014 were as follows:

- Operating cash flow was €-2,596k compared with the previous year of €-3,317k, i.e. a decrease of €721k.
- Full reimbursement of the bonds, subscribed by Norgine, of €1,235k including capital, interest and fees for tranche A and tranche B.
- Continued repayment of the Oséo Innovation loan for €100k.
- The increase in shareholders' equity as a result of two Paceo® equity facility draws in April and May, totaling €345k (net of expenses) and of 2 equity financings for €2,359k.
- The first draw of the IPF Partners bonds for a net amount of €2,761k.
- The company also secured 3 export loans (COFACE) for a total of €61k.

Working capital was €-65k compared with €406k for the full-year 2014, continuing to illustrate the low and atypical level of cash required compared with industry standards.

SpineGuard secured an innovation loan with Bpifrance of €1.5M and also has the option to exercise the 3 remaining tranches with IPF Partners for a total of €3.2M for the bonds until the end of 2016.

The Company has an available equity line (Paceo) of 265.000 shares representing an estimated €1.3M net of expenses at March 22, 2016 stock price.

The Company's workforce count was 26 at the end of 2015, compared with 25 in December 2014.

2015: Excellent sales momentum and strategic objectives achieved

Sales and marketing:

The sales and marketing team now counts 10 people in the United States and 4 in Paris managing a network of:

- 77 agencies in the United States,
- 40 distributors in the rest of the world,
- 1 agent in France and Luxemburg.

Since the implementation of the Affordable Care Act (ACA) in 2014, US healthcare institutions have increasingly been made financially accountable for clinical outcomes improvements as well as reductions in complication and re-operation rates. This trend is favorable to medical devices which make health economic differences such as PediGuard. It explains the excellent commercial performance of 2015, in particular within hospital systems, which have referenced PediGuard in their product offering.

The Company continues to expand its distribution network throughout the United States and to enhance PediGuard's adoption in teaching institutions. 35 centers (compared to 25 end of 2014) are now using DSG enabled devices in their curriculum.

In the rest of the world, the Company continued to focus on training and marketing activities to support its distributors across geographies:

- In Europe, SpineGuard delivered significant revenue growth in France (+20%), the UK (+53%) and Germany (+23%). In Russia, numerous surgeons were trained in coordination with the distributor. However, the market there remains challenging due macro-economic factors and the weakening of the Ruble vs. the Euro.
- In Asia, the revenue growth in Japan remained strong with +60% after +54% in 2014 and SpineGuard continues to invest in this large market through its congress and field presence. Singapore also grew by +47% in Euro. In China, following the regulatory clearance by the Chinese Food & Drug Administration (CFDA) for the Classic PediGuard, the Company is selecting local distributors. Like in Japan, SpineGuard is taking a long term view to anchor its presence and success in what is now the world's second biggest market for pedicle screw surgeries.
- In Latin America, Chile and Peru grew +15% and +121% in value, respectively, while 2015 was a consolidation year in Mexico (-6%). Brazil did not recover both for macro-economic reasons but also due to distributor specific causes and the Company has begun discussions with other possible distributors.
- In the Middle-East, the global performance (+12% in value) was underwritten by winning a tender in Saudi Arabia which resulted in the sale of over 400 units.

In a major milestone, PediGuard Threaded (with DSG technology) received CE mark and first surgeries took place during the fourth quarter of 2015. The Company also deployed new marketing tools for surgeons and the sales teams, such as technical and sales brochures and videos that are also accessible on the Company's website.

Clinical:

2015 was a productive year. Eight surgeons presented their experience with PediGuard in international scientific conventions and six new clinical studies were completed:

- Prospective study regarding osteoporotic patients including a US and a Brazilian center.
- Retrospective study on scoliosis (France).
- Prospective study on scoliosis (Chile).
- *In vitro* study about the placement and use of PediGuard in cervical surgery.
- *In vitro* study about the placement and use of PediGuard in minimally invasive surgeries (MIS).
- Meta-analysis about screw misplacements covering more than 100 publications.

These studies will be published and / or presented at future congresses.

R&D:

Smart DSG Screw & PediGuard Threaded	The Company completed the design, launched the first batches of industrialized products and successfully performed first surgeries for both the PediGuard Threaded and the DSG screw developed with Neuro France Implants. In the United States, the design of the smart screw developed with Zavation was validated in 2015. Production started so we can perform surgeries in the US as soon as we receive clearance from the FDA.
Robotics	A detailed roadmap and schedule was defined laying out key steps and resources needed for this promising DSG application.
New IP and brands	Patents granted in Europe for the DSG screw, in China and Japan for bone quality measurement and in France for bony fusion monitoring. International extension of two patents regarding with the aim to determine the pedicle entry point without x-ray. Filing in France and international plus registration in France of the « DSG » brand standing for « Dynamic Surgical Guidance ».

Recent events:

- 5 Jan. 2016: World's first spinal fusion surgery performed with the one-step-insertion of pedicle "smart screws" guided by the DSG technology. This surgery was performed successfully by Dr. Court and his team in Paris. Additional surgeries have been performed since, in particular, by Dr. Bolger in Ireland.
- 11 Jan. 2016 : A total €7.7M debt financing was secured through an Innovation Loan of €1.5M with Bpifrance and the issuance of four tranches of bonds totaling €6.2M with IPF Partners. The first tranche of €3M was drawn on December 28, 2015.
- 25 Jan. 2016 : Steve McAdoo reinforces the company's senior management team as Vice President of Business Development.
- 16 Mar. 2016 Bpifrance loan of €1.5M received.
- 17 Mar. 2016 National stocking distribution agreement with OrthoPediatics for the exclusive commercialization of its PediGuard probes in pediatric institutions in the US.

Next financial press release: First Quarter 2016 revenue, on April 6, 2016.

About SpineGuard®

Co-founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard's mission is to make spine surgery safer. Its primary objective is to establish its proprietary DSG™ (Dynamic Surgical Guidance) technology as the global standard of surgical care, initially for safer screw placement in spine surgery and then in other surgeries. PediGuard®, the first device designed using DSG was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. It is the world's first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Over 40,000 surgical procedures have been performed worldwide with PediGuard. Numerous studies published in peer-reviewed medical and scientific journals have demonstrated the multiple benefits that PediGuard delivers to patients, surgical staff and hospitals. In 2015, SpineGuard started to expand the applications of DSG into pedicle screws through partnerships with innovative surgical companies in France and the US. SpineGuard has offices in San Francisco and Paris.

For further information, visit www.spineguard.com.

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