Spine Guard®

Six Months 2014 Financial Results

- Solid gross margin of 85.6%
- Stable working capital requirements
- Cash position: €4.7 million
- Development of the Smart Screw ahead of schedule

PARIS & SAN FRANCISCO, September 24, 2014 – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops, and markets disposable medical devices intended to make spine surgery safer, announced today financial results for the half year ending June 30, 2014, as approved by the Board of Directors on September 22, 2014.

€ thousands - IFRS	H1 2014	H1 2013
Revenue	2,110	2,318
Gross margin	1,807	2,028
Gross margin (% of revenue)	85.6%	87.5%
Sales, distribution, marketing	-2,624	-2,315
Administrative costs	-1,010	-772
Research & Development	-501	-484
Operating profit / (loss)	-2,328	-1,544
Pre-tax profit / (loss)	-2,467	-1,650
Net profit / (loss)	-2,467	-1,650

NB: unaudited

Operating expenses under control

For H1 2014, the Company reported revenue of €2,110k, down 6% cc compared with H1 2013 and down 9% as reported. The shortfall of H1 2014 was essentially due to short-term unfavorable conditions in the United States (which accounted for 50% of units sold and 71% of revenue). Tight control of operating expenses limited the impact of lower-than-expected H1 2014 revenue on the operating figure over the period.

The gross margin of 85.6% at June 30, 2014, compared with the prior year of 87.5% remains solid. The slight decrease reflects the temporary impact of additional production costs on the XS range products pre-launched at the end of 2013. These incremental costs are associated with the manufacturing process and pre-production adjustment phases. They came to \leq 42k and represented 200 bps.

Excluding the impact of IFRS2ⁱ, operating expenses were $\leq 3,751k$ compared with $\leq 3,478k$ for H1 2013, an increase of $\leq 273k$ or +7.8% compared with June 30, 2013. The Company reported a net loss of $\leq 2,467k$ for the first half of 2014 compared with a loss of $\leq 1,650$ for the first half of 2013, i.e. a difference of $\leq 817k$.



Working capital requirements were €320k, flat compared with €322k at December 31, 2013, which illustrates the Company's ability to control its cash requirements to finance operations.

At June 30, 2014, cash and cash equivalents were €4,728k compared with €6,395k at December 31, 2013. This decrease was notably due to:

- The operating cash flow of € (1,759)k compared with the previous year of €(1,517)k.
- The repayment of bonds, subscribed by Norgine, of €414k for tranche A and €81k for tranche B.
- The start of the repayment of the Oseo Innovation loan, for €38k.
- The increase in shareholders' equity, as a result of two Paceo equity facility draws in February and June, totaling €688k (net of expenses).

The Company's workforce count is 26 at H1 2014, compared with 22 at H1 2013 and 25 at the end of December 2013.

Outlook and recent events:

The revenue shortfall recorded over the first half of 2014 does not reflect the significant achievements of the Company in recent months, and in no way alters its ambitions. SpineGuard continues to roll out and implement the roadmap which was presented at the time of its IPO.

The sales and marketing team has been strengthened. PediGuard has already been adopted by over 20% of the US spine-surgery teaching institutions. The data presented by Dr. Koller in April (at the CSRS-Asian annual meeting) confirms PediGuard's potential in cervical surgery. Eight additional scientific papers concerning PediGuard are scheduled to be presented at different congresses between now and the end of 2014. The commercialization of the miniaturized versions (XS) of PediGuard is accelerating, with products fully available since June 2014. Additionally, the recent launch of the active bevel-tip completes the Cannulated line of PediGuard in meeting the needs of minimally invasive surgery.

As previously mentioned, improving the safety of surgical operations is steadily becoming a major issue within the health care systems. This is clearly reflected in the performance reporting metrics mandated by health care authorities, most notably in the United States, under the Affordable Care Act. This important trend is a major indicator for the broad adoption of PediGuard and the success of SpineGuard, whose Dynamic Surgical Guidance platform currently stands alone in its ability to differentiate between tissues, in real-time, with limited radiation exposure to surgical teams and patients.

The Company is now well positioned to capitalize on these market conditions for its commercial, clinical, and technological deployment, particularly as the Smart Screw's development is progressing faster than expected thanks to the support of its Scientific Advisory Board and the work of its R&D team. SpineGuard has reached a decisive milestone by miniaturizing its sensor technology. The Company has created a platform that is compatible with the multiple pedicle screw systems on the market. This Smart Screw represents a potentially major technological breakthrough by making the insertion of the most-used spinal implant easier and more reliable. The Company now has prototypes to show the players in this field, who are interested in a co-development partnership, offering them an opportunity to take a lead in the intensely competitive pedicle screw system market, thereby accelerating SpineGuard's plan for mid-term growth.

Pierre Jérôme, CEO of SpineGuard, said: "Paradoxically, we feel stronger after this first half despite revenue being below what one should expect from SpineGuard. Indeed, while the current transformations taking place within our sector – on the health economic and industrial front – are penalizing us in the short term: they first and foremost validate our ambition and our strategy. More than ever, our Dynamic Surgical Guidance platform is intended to become a standard of care for making spine surgery safer, and we are continuing to work on it relentlessly."



Next financial press release: 2014 annual revenue, January 20, 2015 (subject to change)

SpineGuard is participating in the Healthcare & Biotechnologies Conference organized by Société Générale on September 24, 2014 in Paris.

About SpineGuard®

Co-founded in 2009 by Pierre Jérôme and Stéphane Bette, former executives at Medtronic Sofamor-Danek and SpineVision, SpineGuard's primary objective is to establish its FDA-cleared and CE-marked PediGuard[®] device as the global standard of care for safer screw placement in spine surgery. SpineGuard's mission is to make spine surgery safer. The company is also exploring other applications for its Dynamic Surgical Guidance technology platform. SpineGuard has offices in San Francisco and Paris. SpineGuard was awarded with the 2014 Spine Device Award for advancing spine technology and patient care by Becker's Healthcare. For further information, visit www.spineguard.com.

About PediGuard®

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. Realtime feedback is provided via audio and visual signals. Over 30,000 procedures have been performed with PediGuard worldwide. Several 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. 92% on average for surgical navigation), provides 3-fold less pedicle perforations than with free-hand technique and a 3-fold reduction in neuro-monitoring alarms. It also limits radiation exposure by 25-30% and decreases by 15% the time for pedicle screw placement.

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^{*i*} Fair value of equity-based payments

