

SpineGuard Reports Six-Month 2019 Financial Results

- Net consolidated operating result improved by +51%
 - EBITDA improves by 27%
 - Gross Margin remains solid at 84.6%
- Cash available: 1M€ plus secured convertible bond facility of 1.8M€

Paris (France) and Boulder (CO, USA), September 18, 2019 – 18:00 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, announced today financial results for the half year ending June 30, 2019, as approved by the Board of Directors on September 17, 2019.

Stéphane Bette, CEO of SpineGuard, said: ‘Our financial performance reflects the company’s strategic turn and is in line with our expectations. The operating result improved by 51% while continuing to invest in the company’s future. We funded our R&D programs for the DSG robotic platform and the preparation of the launch of DSG-Connect. We supported the growth of the DSG smart screw and the dental application integrating DSG. Moving forward, we are continuing our efforts to control our cash by leveraging the PediGuard legacy business. Lastly, we are actively working with Healthios Capital Market toward signing significant partnerships to extend the use of DSG technology. We believe this will foster the return to growth and the creation of value for our shareholders.’

€ thousands – IFRS	H1 2019	H1 2018	H1 2017
Revenue	3,445	3,626	4,199
Gross margin	2,914	3,131	3,613
<i>Gross margin (% of revenue)</i>	84,6%	86,3%	86,0%
<i>Sales, distribution, marketing</i>	-1,868	-2,436	-3,400
<i>Administrative costs</i>	- 986	- 980	-1,055
<i>Research & Development</i>	-470	-554	-684
Non-recurring operating profit / (loss)	- 409	- 839	-1,526
Non-recurring operating costs	-92	0	-152
Operating profit / (loss)	-501	-839	-1,678
Financial result	-326	-229	-566
Income tax	21	0	0
Net profit / (loss)	-805	-1,086	-2,244
EBITDA	-351	-483	- 1,612

NB: unaudited

Non-recurring Operating loss improves by 51% at -0.4M€

Non-recurring operating loss improves by 51% at - €409K- vs. - €839K and EBITDA improves by 27% at € -351K at June 30, 2019 compared to - €483K at June 30, 2018.

Operating expenses were €3,332K compared with €3,970K for H1 2018, a decrease of €648K (16%) compared with June 30, 2018.

Gross margin of 84.6% at June 30, 2019 remains consistent compared with prior year result of 86.3%. The change mainly reflects a lower 2% ASP in the USA within the PediGuard Classic range that was partially offset by improved manufacturing costs.

For H1 2019, the Company reported revenues of €3,445K, down 5% (10% cc) compared with H1 2018. Revenue in the United States decreased 5% cc (-11% reported) to €2,867K in the first half of 2019, compared with €3,022K in the first half of 2018. In the rest of the world, revenue decreased by 4% during the first half of 2019 to €578K compared with €604K in the first half of 2018.

3,875 DSG units were sold in the first half of 2019 compared with 4,352 in the first half of 2018, including 2,256 in the United States, representing 58% of total units sold.

Working capital requirements were €919K compared with €806K at December 31, 2018.

At June 30, 2019, cash and cash equivalents were €988K compared with €1,062K at December 31, 2018, and is explained as follows:

- Operating cash flow of €(491)K compared with the same period last year of €(566)K.
- Equity funding using the equity line (OCAPI) for a gross amount of €1,000K throughout the period.
- The payment of interests to Norgine Ventures and Harbert European Growth of €223K and to Bpifrance of €31K.
- The repayment of capital to Bpifrance of €150K.

The Company's workforce count is 16 at H1 2019, compared to 19 at the end of December 2018.

Recent events and outlook:

In line with 2018, the Company maintained strong financial discipline and improved EBITDA by 27% at €-351K as of June 30, 2019 compared to €-483K in the same period of 2018.

Implementing strategic alliances to extend the use of the DSG technology is the priority for the Company. The market opportunities creating the highest value are well identified. As announced in the May Letter to Shareholders, SpineGuard hired the US based bank Healthios Capital Markets to support its initiatives.

These new partnerships will cover Spine and the broader musculoskeletal sector with a focus on navigation applications and robotics. Notably, we can remind of:

- The 3-year partnership for robotics with Tremplin Carnot (University of Paris) at the end of 2018 with a first patent filing published in April 2019.
- The relevance of the DSG technology beyond Spine applications materialized by the worldwide exclusive licensing for dental implantology to ConfiDent ABC (Adin Group) and the CE marking of the first generation of products.

SpineGuard is currently developing its DSG-Connect module adding visual to auditory feedback and taking a key step toward an easy integration of DSG technology into robots through automatic breach detection algorithms. DSG-Connect will also enable the launch of a new generation of PediGuard devices by adding a wireless module for the transmission of the measured signal and its visualization via an app on a tablet. The DSG platform remains is the only technology with the ability to differentiate tissues in real time without X-ray exposure to the patient, OR team and surgeon.

SpineGuard Inc. transferred its US operations from San Francisco to Boulder (Colorado) as of July 1 2019.

Outlook

The Company focuses on its four key objectives as listed in the May 2019 Letter to Shareholders:

1. Continue to publicize the scientific evidence for the value of DSG in surgical robotics and create one or several strategic alliances in this field.
2. Beta-launch a new generation of PediGuard equipped with the DSG-Connect wireless module, a tablet that adds visual to auditory feedback to optimize the usefulness of the DSG signal, enable data recording for medical-legal purposes and assist in clinical studies of bone quality.
3. Double the number of surgeries performed with DSG “smart” screws in the USA; publish the first clinical data and seek the right partnership to sell “smart” screws plus DSG-connect to non-robot equipped hospitals.
4. Execute a successful market test with the first generation SafeGuard products for dental implantology with our partner ConfiDent ABC, and prepare the future DSG products to be fully integrated into dental equipment.

Ongoing concern

As of 30 June 2019, cash and cash equivalents amount to €988K. Considering the cash position as of June 30, 2019, the availability of the equity line facility (OCAPI) and the recurring expected business, the Company estimates that it has cash available until April 2020. In order to cover future cash needs, the Board of Directors decided to:

- Optimize the usage of the available equity line (no warrants attached) implemented in November 2019 with Nice & Green totaling €3M€ over a 15 months period. The available balance as of 30 June 2019 is €1.8M.
- Consider a new equity line.
- Negotiate the restructuring and re-scheduling of the existing venture debt with the company’s lenders.
- As indicated in its May Letter to Shareholders, the Company hired the US based bank Healthios Capital Markets to assist in reaching partnership agreements such as the one for dental implantology.
- Pursue equity funding opportunities through those partnership agreements or a private placement.

The company’s half-year financial report is available in the Investors > Exchange filings section of the www.spineguard.com website.

Next financial press release: Third quarter 2019 revenue on October 15, 2019.

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 that have been used in over 70,000 surgical procedures worldwide. Fourteen studies published in peer-reviewed scientific journals have demonstrated the multiple benefits DSG® offers to patients, surgeons, surgical staff and hospitals. Building on these solid fundamentals and several strategic partnerships, SpineGuard has expanded its technology platform in a disruptive innovation: the « smart » pedicle screw launched late 2017 and is broadening the scope of applications in dental implantology and surgical robotics. DSG® was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer.

For further information, visit www.spineguard.com

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Contacts

SpineGuard

Stéphane Bette
Chief Executive Officer
Tel: +33 (0)1 45 18 45 19
s.bette@spineguard.com

Manuel Lanfossi
Chief Financial Officer
m.lanfossi@spineguard.com

Europe / NewCap

Investor Relations & Financial Communication
Mathilde Bohin / Pierre Laurent
Tel: +33 (0)1 44 71 94 94
spineguard@newcap.eu

