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SpineGuard names Pierre Guyot to Board of Directors

PARIS and SAN FRANCISCO (Jan. 2, 2014) – SpineGuard (FR0011464452 – ALSGD), an innovative medical device company focused on improving spine surgery safety, announced today that Pierre Guyot has been appointed to its Board of Directors.

Mr. Guyot has served as Chief Executive Officer and Board Director of Mölnlycke Healthcare since 2007, leading the very successful development of this Swedish corporation both in terms of growth and profitability. Throughout the last seven years, Mölnlycke has steadily grown into an over €1 billion revenue company and undisputed leader in many of its markets.

“I am delighted that Pierre has accepted to join SpineGuard. Having worked with him at Boston Scientific for a number of years, I know he will bring us invaluable strategic guidance as we expand commercially and develop new clinical applications for our PediGuard technology platform,” said Pierre Jérôme, co-founder and Chief Executive Officer of SpineGuard.

“I am very excited by the opportunity to join SpineGuard, a truly innovative company with a disruptive technology value proposition. I strongly believe that the PediGuard technology platform offers compelling multi-faceted benefits to both patients and health care practitioners. I look forward to adding value to the Board of Directors and contributing to the further successful development of the PediGuard platform,” said Mr. Guyot.

“We are very pleased to welcome a leader of Pierre Guyot’s caliber to the Board of SpineGuard. Pierre’s track record on successfully developing medical technology divisions and companies into dynamic growth businesses makes him an excellent addition to the Spineguard Board. Pierre’s expertise and leadership will be incredibly beneficial to SpineGuard, our employees and our shareholders,” added Alan Olsen, Chairman of SpineGuard.

Earlier in his career, Mr. Guyot held executive management positions at Becton Dickinson, Johnson & Johnson, and Boston Scientific.

About the PediGuard® Platform

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 29,000 procedures have been performed with PediGuard on all continents. 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 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.

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 has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

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SpineGuard’s 2013 revenue grows 20% to €4.6 million

In line with expectations

PARIS and SAN FRANCISCO, Jan. 23, 2014 – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops and markets disposable medical devices intended to make spine surgery safer, announced today its consolidated full-year 2013 revenue.

€ thousands - IFRS	2013	2012	Change constant currency
H1	2,318	1,827	+27%
H2	2,297	2,050	+12%
FY 2013	4,615	3,877	+20%

Unaudited

2013 annual revenue in line with the Company’s expectations

In 2013, SpineGuard recorded revenue of €4,615 thousand, a +20% CC growth vs. full-year 2012, in line with the Company’s expectations. Revenue totaled €3,369 thousand (+19% CC) in the United States and €1,247 thousand (+22% CC) in the rest of the world representing 3,142 and 3,166 units sold, respectively, and a total of 6,308 PediGuard. 30,000 surgical procedures have been performed with PediGuard since its introduction.

An intense year in terms of breakthroughs and achievements

Since its IPO in April last year, SpineGuard has continued to successfully execute according to its roadmap, making significant breakthroughs on the way:

United States: The Company’s geographical coverage was expanded with an additional 20 agencies, the sales management team was strengthened and multiple training and marketing actions were deployed. PediGuard is now used in over 20% of back-surgery teaching institutions that have adopted it in their curriculum. Furthermore, the FDA (Food & Drug Administration) has granted 510k clearance for the PediGuard’s new Classic XS and Curved XS PediGuard versions and has also cleared all the modifications applied to existing versions.

Rest of the World: The Company appointed another seasoned experienced sales manager to intensify the running of the numerous distributors across the world and their development. The Company received regulatory approval for the PediGuard in Russia (for the entire family of products), Mexico (Cannulated, Curved & Curved XS) and Japan (Classic; Curved & the new XS versions) with the notable adoption of its technology by leading spine surgeons of the Kobe University Graduate School of Medicine.

Pierre Jérôme, CEO and co-founder of SpineGuard, said: “We are pleased with the revenue recorded in 2013; it is in line with our expectations. The growing recognition of PediGuard’s clinical-economic value amongst spine specialists around the world further increases our confidence in our ability to achieve our vision of establishing our technology as a standard of care for making spine surgery safer. 2013 not only saw the success of our IPO, but also the realization of significant breakthroughs, notably in R&D, clinical studies, regulatory approvals and marketing. We envision with confidence the continuous deployment of our roadmap in 2014 and the creation of value expected by our shareholders, clients, staff and partners.”

Next financial press release: 2013 annual results, on March 25, 2014

About SpineGuard

Founded in 2009 and based in Paris and San Francisco, SpineGuard is an innovative Company that designs, develops and markets disposable medical devices intended to make spine surgery safer. Its PediGuard® core technology allows orthopedic spine surgeons and neurosurgeons to insert pedicle screws with unparalleled accuracy. Equipped with a sensor at its tip and electronics in its handle, PedGuard® measures changes in the electrical conductivity of surrounding tissue in real time and alerts the surgeon using audio feedback and a flashing light. Several key clinical studies have established the reliability and accuracy

of PediGuard® for pedicle screw placement, demonstrating significantly less radiation exposure of medical teams and shorter surgery time when it is used. The Pediguard® platform is protected by eight international patent families, approved and sold in 45 countries, CE Marked in Europe, and has received 510(k) clearance from the FDA in the United States. Over 30,000 surgical procedures have been performed worldwide using PediGuard®. The Company was awarded “innovative business” status by Oséo in 2009.

For further information, please go to www.spineguard.fr

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SpineGuard establishes three-year, no-minimum-draw Standby Equity Facility (PACEO®) with Société Générale

PARIS, SAN FRANCISCO, January 27, 2014 - SpineGuard (FR0011464452 - ALSGD), an innovative company that designs, develops and markets disposable medical devices intended to make spine surgery safer, announced today that it has entered into a Standby Equity Facility (PACEO®) with Société Générale as authorized by the Shareholders' Meeting of March 21, 2013. It remains at the sole discretion of SpineGuard to determine the timing of the funding.

"The Board of SpineGuard approved the set-up of a Standby Equity Facility. With this flexible and guaranteed solution, we are strengthening the capacity of our development, while limiting dilution of our shareholders," said Pierre Jérôme, CEO and co-founder of SpineGuard. *" This solution secures our financial resources over time and does not reflect an immediate need of cash considering SpineGuard's available cash & treasury of € 6.5M as of December 31, 2013."*

Under the terms of the agreement Société Générale has committed to purchase newly created shares at any time during the 36-month commitment period, within the global limit of 400,000 shares, being 9.3% of the 4,311,112 shares currently outstanding.

Should the entire standby equity facility be drawn down and resulting in the issuance of 400,000 new shares, a shareholder who currently owns 1% of the company's share capital would experience a reduction of his / her ownership to 0.92%.

For each tranche, the price to be paid equals the volume weighted average share price of the three trading days preceding the effective date of purchase with a discount capped at 8% dependent on the size of the drawing. This discount allows Société Générale, who is not positioned as a long-term shareholder in the Company, to purchase the shares independently of market volatility.

SpineGuard has no minimum drawdown obligation, and will use the facility at its sole discretion if market conditions are favorable and in the best interests of both the Company and its shareholders.

Next financial press release: 2013 annual results, March, 25 2014, before equity markets opening.

About SpineGuard®

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About pedicle screw-based stabilization

Pedicle screw-based stabilization has become the gold standard for treating spine instabilities and deformities. This market is growing due to the increasing number of patients requiring surgical treatment and a larger number of surgeons being trained in pedicle screw-based technologies. Technological advancements such as minimally invasive surgery, bone substitutes, dynamic stabilization and thoracic screws further reiterate the importance of pedicle screw placement. However, accuracy of pedicle screw placement remains a critical issue in spine surgery. In recently published papers studying screw placement accuracy, the average rate of misplaced screws is approximately 20% (Tian 2011, Gelalis 2011, Verma 2010) with 2-7% of patients presenting neurologic complications (Amato 2010, Amiot 2000, Waschke 2012) and 4-5% of patients having vascular complications (Sarлак 2009, Samdani 2009, Belmont 2002) due to misplaced screws.

About PACEO®

The PACEO® is an equity financing solution that was designed by Société Générale. The PACEO® helps issuers to diversify their

funding sources through an additional financing option, while preserving the financial balances. The PACEO® may be drawn at the issuer's sole discretion via the issue of new shares at a low discount to the then market price; this solution provides the same benefits as a capital increase while providing the same guarantee as a confirmed credit line. With this transaction, Société Générale, the leading institution for equity lines in France, has set up its 36th PACEO®.

Disclaimer / Forward-looking statements

This communication does not constitute an offer or invitation to subscribe for or purchase any securities of SpineGuard SA. This publication may contain certain forward-looking statements concerning the Company and its business. Such statements involve certain risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of the Company to be materially different from those expressed or implied by such statements. Readers should therefore not place undue reliance on these statements, particularly not in connection with any contract or investment decision. The Company disclaims any obligation to update these forward-looking statements.

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SpineGuard Reports Full-Year 2013 Financial Results

- Revenue growth: up 19% to €4.6 million (+20% CC)
 - Gross margin: up 20% to 87%
- Operating expenses: well-controlled
 - Cash position: €6.4 million

PARIS and SAN FRANCISCO, March 25, 2014 – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops and markets disposable bone-monitoring devices intended to make spine surgery safer, reported today its full-year 2013 financial results as approved by the Board of Directors on March 20, 2014.

€ thousands – IFRS Audited	Dec 31, 2013	Dec 31, 2012	Δ
Revenue	4,615	3,877	+19%
Gross margin	4,027	3,346	+20%
<i>Gross margin (% of revenue)</i>	87.3%	86.3%	
<i>Sales, distribution & marketing</i>	<i>4,761</i>	<i>4,201</i>	
<i>Administrative costs</i>	<i>1,607</i>	<i>1,746</i>	
<i>Research & Development</i>	<i>811</i>	<i>588</i>	
<i>Other expenses</i>	-	-	
Operating profit / (loss)	-3,152	-3,189	
Pre-tax profit / (loss)	-3,515	-3,266	
Net profit / (loss)	-3,515	-3,266	

2013: revenue growth and better-than-expected operating result

In 2013, SpineGuard reported full-year revenue of €4,615 thousand compared to €3,877 thousand for the full-year 2012, a 20% CC increase. 6,308 PediGuard units were sold compared to 5,225 for the full year 2012, including 3,142 in the United States; 1,341 in Europe; 973 in Latin America; 616 in the Middle East; and 236 in Asia-Pacific.

The gross margin remained very solid over the year at 87.3%. It was stable compared to the previous six-month results and continues to reflect PediGuard’s relatively low manufacturing costs, including for the recently-launched new versions (Cannulated PediGuard and the XS Range) whose manufacturing costs could be reduced as volumes grow.

SpineGuard’s business model, driven by continuous improvement in its supply chain and distribution, enables the optimization of operating expenses, which totaled €7,179 thousand in 2013 compared to €6,535 thousand for the full-year 2012.

The above elements allowed the Company to record a stable and well-controlled operating loss of €3,152 thousand compared to a loss of €3,189 thousand a year ago.

The Company reported a net loss of €3,515 thousand for the full-year 2013 compared to a loss of €3,266 thousand for the full-year 2012, after an interest charge of €278 thousand and a foreign currency charge of €84 thousand.

Working capital was €322 thousand compared to €139 thousand for the full-year 2012, illustrating the low and atypical level of cash required compared to industry standards, notably with inventory levels being reduced to €436 thousand compared to €498 thousand for the full-year 2012.

At December 31, 2013, cash and cash equivalents were €6,395 thousand compared to €2,314 thousand at December 31, 2012.

Key events: positive news flow aligned with objectives

Regulatory approvals

- FDA 510(k) clearance in the USA for the new XS Classic and XS Curved PediGuard versions;
- Regulatory “Ninsho” approval in Japan for the Classic and Curved versions, including XS;
- Registration in Mexico for the Cannulated, Curved and XS Curved ranges;
- Approval in Russia for the entire PediGuard bone-monitoring platform.

Commercial expansion

- An additional 20 agencies in the United States (giving a current total of 71);
- Sales commenced in Russia, Japan, Chile, Ecuador, Turkey and Kuwait;
- Change of distributor in Spain, Colombia and Australia;
- United States - recruitment of an Area Sales Manager covering the West of the country and three product Specialists (West, South and Northeast); promotion of the Area Sales Manager and Product Specialist covering the South of the country to Vice-President of US Sales and Area Sales Manager for the South, respectively. The US Sales & Marketing team now consists of 11 staff;
- Recruitment of a Sales Manager for German-speaking countries, Northern Europe and India. Surgeons education and clinical trials:
- 19 teaching institutions in the United States have adopted the PediGuard in their curriculum (20% of spine surgery teaching institutions in the USA);
- Undertaking of 4 prospective randomized studies aimed at proving the PediGuard’s clinical superiority with a better placement of the screws, reduction in radiation and shorter operating time. These studies cover the following areas: thoracic (France), thoraco-lumbar (Germany), osteoporosis (United States, Brazil) and learning curve (United States).

Research and development

- Patents granted for the SmartScrew and for Directional Improvement in the United States;
- Granting in China of the second part of the SmartScrew patent, following the granting of the first part in 2010;
- Limited-series prelaunch of the Classic PediGuard XS and Curved PediGuard XS miniaturized versions;
- Development of the Directional version of the Cannulated PediGuard;
- New applications of the PediGuard® platform: development of drawings and prototypes of the Spine SmartScrew and drilling instruments for traumatology.

Recent events

January 2: The Board of Directors resolved to ask the appointment of Pierre Guyot (CEO and Director of Mölnlycke Healthcare since 2007) as a Director at the next shareholders meeting.

January 24: Set-up of a Standby Equity Facility (Paceo®) with Societe Generale.

February 20: First drawdown on the Paceo for a total of €262 thousand, representing an increase of 25,000 issued shares and a total number of shares issued to date of 4,336,112.

Pierre Jérôme, CEO of SpineGuard, said «*We are really pleased with our financial and strategic performance in 2013. Our enhanced resources and visibility since the IPO are enabling us to exploit the amazing potential of our technology platform at a faster pace. The development of the PediGuard SmartScrew is well underway. We are convinced it represents a major breakthrough for patients undergoing back surgery. This project also offers particularly promising perspectives in traumatology, the fastest-growing orthopedic segment. These new applications are based on a solid clinical foundation and represent a true medium-term opportunity of growth for SpineGuard and its partners.*»

Next financial press release: 2014 half-year revenue: July 17, 2014

About SpineGuard

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designs, develops and markets disposable bone-monitoring devices intended to make spine surgery safer. Its PediGuard® core technology allows orthopedic spine surgeons and neurosurgeons to insert pedicle screws with unparalleled accuracy. Equipped with a sensor at its tip and electronics in its handle, PediGuard® measures changes in the electrical conductivity of surrounding tissue in real time and alerts the surgeon using audio feedback and a flashing light. Several key clinical studies have established the reliability and accuracy of PediGuard® for pedicle screw placement, demonstrating significantly less radiation exposure of medical teams and shorter surgery time when it is used. The PediGuard® platform is protected by eight international patent families, approved and sold in 45 countries, CE Marked in Europe, and has received 510(k) clearance from the FDA in the United States. Over 30,000 surgical procedures have been performed worldwide using PediGuard®. The company was company awarded «innovative business» status by Oséo in 2009.

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PediGuard® Bone-Monitoring Device from SpineGuard demonstrates high accuracy for C2-screw fixation in treating 50 patients with cervical spine disease

Clinical data presented from the podium at 5th Annual Meeting of the Cervical Spine Research Society–Asia Pacific (CSRS-AP)

PARIS and SAN FRANCISCO (April 29, 2014) – SpineGuard (FR0011464452 – ALSGD), an innovative medical device company focused on improving spine surgery safety, announced today that the anticipation of pedicle breaches using its FDA-cleared and CE-marked PediGuard® device in a prospective clinical analysis of 50 patients with “rather rare and severe cervical spine disease” was 100% accurate in identifying an impassable cortical pedicle isthmus in 34 pedicles. The data was presented by principal investigator Heiko Koller, MD, PhD, at the 5th Annual Meeting of CSRS-AP in Ho Chi Minh City, Vietnam. In 34 pedicles a decision to stop pedicle screw tract preparation based on a signal from the PediGuard device that suggested an impassable cortical stimulus isthmus was later confirmed appropriate based on analysis of postoperative CT scans.

« We surgeons are constantly faced with difficult treatment planning for complex cervical deformities. By integrating the PediGuard device into surgery, we are able to provide our patients with greater construct stability, less neurological risk, and a better overall surgical outcome, » said Dr. Koller, Werner Wicker Klinik, Bad Wildungen - Germany.

By far, pedicle screws are the most common implant used in spinal surgery. Unfortunately, high rates of pedicle screw misplacements in the vertebra persist, which can lead to dramatic neurologic and vascular impairment. The scientific literature reveals that about 20% of pedicle screws are misplaced using conventional techniques, causing a 2% to 9% overall complication rate. Several published clinical studies in peer-reviewed medical journals have demonstrated the excellent pedicle screw placement accuracy of PediGuard®.

About the PediGuard® Bone-Monitoring Platform

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 30,000 procedures have been performed with PediGuard on all continents. 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 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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SpineGuard's PediGuard® bone-monitoring device is adopted by 20th U.S. spine-surgery teaching institution

PARIS and SAN FRANCISCO, May 13, 2014 – SpineGuard (FR0011464452 – ALSGD) announced today that its PediGuard platform has been adopted by the 20th major spine-surgery teaching institution in the United States: Children's Hospital of New Orleans.

"We are very pleased that twenty of the U.S.'s finest teaching hospitals have now adopted our PediGuard bone-monitoring devices to ensure optimal training of their residents and fellows for safe pedicle screw placement," said Stephane Bette, Co-founder and US General Manager of SpineGuard.

"An obvious advantage of the PediGuard technology is that there is no radiation required during pedicle screw placement. There is increasing concern about the long term consequences of medical treatment based radiation exposure. The dosage is cumulative, and has been shown to significantly affect the lifetime risk for cancer," said Andrew G. King, M.D., Orthopedic Surgeon, Children's Hospital New Orleans; and, Professor and Chair, Department of Orthopedic Surgery, LSU Health Sciences Center. *"For this reason alone, pedicle screw placement navigated by sensors in the pedicle probe is gaining popularity, and with technological advances, should become standard."*

«PediGuard has helped me guide residents in placing safe and accurate pedicle screws. This was corroborated by a recent cadaver study we conducted comparing the accuracy of screw placement among residents with varied experience implanting pedicle screws,» said Faheem Sandhu, M.D., PhD, Professor of Neurosurgery, Director of Spine Surgery, Georgetown University Hospital.

Dean Chou, M.D., Associate Professor of Neurosurgery, The UCSF Spine Center, University of California San Francisco says that *"To consistently ensure safe and accurate pedicle screw placement while training the future generation of surgeons, we provide our residents and fellows with the best technologies available. The PediGuard device certainly ranks as a critical instrument to ensure safe spine surgery."*

"I have found the PediGuard probe to be an invaluable tool to assist me in the safe placement of pedicle screws in my pediatric patients with often challenging spinal deformities," says Brian G. Smith, M.D., Professor, Program Director, Director of Pediatric Orthopaedics, Yale University School of Medicine. *"The PediGuard probe enables me to identify very accurately the path for pedicle screw insertion in a manner that both enhances patient safety and minimizes radiation exposure to the patient and surgical staff. In addition this device has been a wonderful teaching aid for fellows and residents. I use the PediGuard probe on all my spinal deformity cases."*

"The PediGuard provides me with auditory and tactile feedback to help accurately position pedicle screws, particularly in severe deformities." said Jacques D'Astous, M.D., Clinical Professor, Orthopaedic Surgery, University of Utah, Shriners Hospital in Salt Lake City. *"Most importantly, the auditory feedback is helpful in warning me of potential breaches when the resident or fellow across the table is probing the pedicles on the contralateral side. It is a valuable teaching tool which improves the safety of pedicle screw insertion particularly in a teaching hospital."*

"PediGuard is a great training tool for spine fellows like myself," said Ali M. Maziad, M.D., the Pediatric Orthopaedics and Spine Deformity Fellow at Connecticut Children's Medical Center in Hartford, Conn.

"There's a very narrow margin for error. Misplaced pedicle screws can result in catastrophic complications. Also, multiple attempts at screw placement can result in less-than-optimal fixation. You only have one shot to get the best possible screw for any given level. I strive to have safe and accurate screw placement the first time, every time, and I make sure to use every possible technological advantage available to ensure the safety of my patients, which is where PediGuard is advantageous," concluded Dr. Maziad, who was trained to use PediGuard during his previous spine deformity fellowship at the Hospital for Special Surgery (HSS) in New York.

"Through our collaboration with a number of international scientific societies and the presence of our technology in many teaching institutions across the globe, we are committed to enabling young spine surgeons such as Dr. Ali Maziad to be trained on our PediGuard® bone-monitoring devices. It is definitely part of SpineGuard's

mission i.e. making spine surgery safer." concluded Pierre Jérôme, Cofounder and CEO of SpineGuard.

See other testimonials from eminent spine surgeons regarding the challenges of pedicle screw placement and the dangers of radiation exposure [on this page](#).

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About pedicle screw-based stabilization

Pedicle screw-based stabilization has become the gold standard for treating spine instabilities and deformities. This market is growing due to the increasing number of patients requiring surgical treatment and a larger number of surgeons being trained in pedicle screw-based technologies. Technological advancements such as minimally invasive surgery, bone substitutes, dynamic stabilization and thoracic screws further reiterate the importance of pedicle screw placement. However, accuracy of pedicle screw placement remains a critical issue in spine surgery. In recently published papers studying screw placement accuracy, the average rate of misplaced screws is approximately 20% (Tian 2011, Gelalis 2011, Verma 2010) with 2-9% of patients presenting neurologic complications (Amato 2010, Amiot 2000, Waschke 2012) and 4-5% of patients having vascular complications (Sarлак 2009, Samdani 2009, Belmont 2002) due to misplaced screws.

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SpineGuard appoints Kris Kumar as U.S. Marketing Director

PARIS and SAN FRANCISCO (May 27, 2014) – SpineGuard (FR0011464452 – ALSGD), an innovative medical device company focused on improving spine surgery safety with its family of bone-monitoring devices, announced today that Kris Kumar has joined SpineGuard Inc. as U.S. Marketing Director.

Mr. Kumar brings a 20-year successful career with Zimmer, Synthes, J&J Depuy and Kyphon (Medtronic), with increasing responsibilities: from product development engineering to product management, sales management and marketing leadership.

“With the appointment of Kris, we are strengthening our U.S. team and marketing capabilities to further drive the adoption of PediGuard in pedicle screw placement and expand our bone-monitoring platform toward new applications. Kris’ hands-on experience in developing and marketing new technologies in spine and general orthopedics will help us leverage our unique product offering, our burgeoning clinical evidence, and our network of key opinion leaders & teaching institutions,” said Pierre Jérôme, co-founder and Chief Executive Officer of SpineGuard.

“I am very happy to join SpineGuard because its technology is unique in that it is not just an incremental improvement over existing technologies, but rather a radically new stand-alone technology. The PediGuard devices improve implant placement accuracy, while significantly decreasing radiation exposure for the surgeon, hospital staff and patient. Also, with the plethora of clinical evidence already generated, SpineGuard is well-positioned for significant growth,” said Kris Kumar.

About the PediGuard® Bone-Monitoring Platform

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 30,000 procedures have been performed with PediGuard on all continents. 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 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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SpineGuard® introduces Bevel-Cannulated PediGuard®, the newest addition of its Dynamic Surgical Guidance platform

PARIS and SAN FRANCISCO, June 11, 2014 - SpineGuard announced today that it is expanding its Dynamic Surgical Guidance platform for enhanced pedicle screw placement by introducing the Bevel-Tip Cannulated PediGuard at the occasion of the WCMISST (World Congress of Minimally Invasive Spine Surgery and Techniques) on June 11-14 in Paris.

«The bevel-tip is a much needed addition to the Cannulated PediGuard product offering. In my experience, using needles with such a tip minimizes «skiving» of the needle at the pedicle entry point and helps me steer the needle as I am advancing down a pedicle. This tip and the PediGuard technology are a perfect complement to each other: the technology tells me accurately in real-time what's ahead and the tips help me effortlessly steer accordingly,» said John Williams, M.D., a spine surgeon from Ft. Wayne, Indiana, USA.

«The unique and substantial benefits to patient, surgeons & OR staff directly related to the use of the PediGuard Dynamic Surgical Guidance technology have been validated by growing clinical evidence published in peer-reviewed medical journals,» says Pierre Jérôme, CEO & Co-founder of SpineGuard. *«We believe that the Cannulated PediGuard will play a significant role in accelerating the shift of more spine surgeries toward minimally invasive procedure».*

About Minimally Invasive Pedicle Screw Placement*

Minimally Invasive Spine Surgery (MIS) has been developed to treat disorders of the spine with less disruption to the muscles. This can result in decreased operative blood loss and reduced soft tissue destruction, allowing quicker recovery and faster patient return to normal function. However the pedicle screw placement challenge is even greater in these less invasive procedures because surgeons must compensate for the lack of visual landmarks and tactile feel with massive use of fluoroscopy, exposing themselves and the rest of the OR team to considerable amounts of radiations. So in addition to unacceptably high rates of misplacements that can lead to a number of serious complications for patients - such as spinal cord damage resulting in various degrees of neurological impairment, pedicle screws placed with conventional techniques show high exposure of surgeons, staff and patients to radiation. Indeed, spine surgeons more than double their life time radiation exposure limits in less than 10 years when using fluoroscopy and/or x-ray to guide pedicle screw placement.

Cannulated PediGuard expands the applicability of pedicle screw placement with real-time feedback by allowing spine surgeons to benefit from the PediGuard Dynamic Surgical Guidance technology in the small, confined spaces of MIS. Nearly one million spine procedures using pedicle screws are performed annually worldwide**. We estimate that 15% of these procedures are now done via a minimally invasive approach; this percentage is rapidly growing driven by innovation and surgeon training.

* Source: www.spineuniverse.com

** : I-Data research

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PediGuard® Dynamic Surgical Guidance device from SpineGuard is recognized as “the cutting-edge and the new gold standard in spine care” by Becker’s Healthcare



Stéphane Bette, SpineGuard’s Co-founder & US General Manager (left), receiving Becker’s award during the 12th Annual Spine, Orthopedic and Pain Management-Driven ASC Conference in Chicago – June 12th.

PARIS and SAN FRANCISCO (June 19, 2014) – SpineGuard (FR0011464452 – ALSGD), an innovative medical device company focused on improving spine surgery safety, announced today that its PediGuard device has been recognized by Becker’s Healthcare with the 2014 Spine Device Award for advancing spine technology and patient care and representing both the cutting-edge and gold standard in spine care.

Becker’s Healthcare publicly solicited recommendations for this list. The list was developed based on editorial research and expert surgeon reviews. Device manufacturers do not and cannot influence Becker’s Healthcare to be included in this elite list.

PediGuard’s ability to significantly improve accuracy of pedicle screw placement has been demonstrated in several clinical studies and published in specialty-leading peer-reviewed medical journals. *“This award is a gratifying reward for SpineGuard’s team, its shareholders and its partners. It is also a great encouragement to further advance our Dynamic Surgical Guidance platform for continuously improving patients’ and healthcare professionals’ safety, which is our company mission,”* said Pierre Jérôme, CEO & Co-founder of SpineGuard.

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SpineGuard reports 1H 2014 revenues €2.1 million Company accelerates the development of its Smart Screw

PARIS and SAN FRANCISCO, July 17, 2014 - SpineGuard (FR0011464452 - ALSGD), an innovative company that designs, develops and markets disposable medical devices intended to make spine surgery safer, today announced its revenues for its first half through June 30, 2014.

€ Thousands - IFRS	H1 2014	H1 2013	Variance % Constant Currency	Variance % As Reported
Revenue (June 30)	2,108	2,318	-6%	-9%

Unaudited data

The Company generated revenue of €2.1 million for the first half of 2014, down 6% CC over the same period last year, a negative impact of 300 bps due to the euro/dollar parity. This first half-year underperformance was essentially due to a short-term unfavorable context in the United States, which account for 50% of units sold and 71% of revenue.

The implementation of the Affordable Care Act («ACA») has resulted in American hospitals increasing the control of their spending and tightening the conditions for adopting innovative medical technologies such as PediGuard. However, the main aim of the ACA is to improve the quality of care, prevent complications and avoid revision surgeries. Consequently, financial incentives are gradually being put into place to encourage American hospitals to implement the most efficient and reliable available technologies. The PediGuard is perfectly aligned with these dynamics and trend.

To quickly adapt to the market context, SpineGuard recruited a marketing director in the United States in order to best capitalize on its clinical data and reference centers as well as to intensify the medico-economic messages aimed at surgeons and hospitals. Simultaneously, the Company continued to focus its R&D effort on the potentially disruptive Smart Screw and is running ahead of its initial development plan.

Elsewhere in the world, the Asia-Pacific and Middle East regions recorded satisfactory progress, particularly in Japan and Saudi Arabia with new positive prospects expected during the second half of the year. Latin American revenue was penalized by Brazilian’s distributor reorganization in response to changing market conditions. In Europe, growth continued in several countries such as France, Germany and Switzerland. The growth of the whole region was tempered by lower sales in Russia related to the first stocking order invoiced in February 2013.

Pierre Jérôme, CEO of SpineGuard, said: *«The disappointing revenue figure recorded over the first half of 2014 does not reflect yet the major progress accomplished by the Company in recent months and in no way alters our ambitions. We have continued to execute our roadmap through the strengthening of our marketing team, the initiation of new clinical trials, PediGuard’s adoption by more than 20 US-Spine Surgery teaching institutions, an increased presence on the podiums of international scientific congresses, the launch of the Bevel-Cannulated PediGuard and the acceleration of the Smart Screw project.»*

Stéphane Bette, SpineGuard’s Chief Technical Officer and US General Manager, added: *«The Smart Screw’s development is progressing much faster than expected thanks to the support of our Scientific Advisory Board and the work of our R&D team. By achieving to miniaturize the sensor, we reached a decisive milestone in terms of our technology’s compatibility with the numerous screw systems available in the Spine Fixation market. With the Smart Screw concept, our technology will be accessible to hospitals through the implant itself while allowing surgeons to become even more efficient when inserting pedicle screws.»*

Pierre Jérôme concluded: *«Our Dynamic Surgical Guidance platform is intended to become a standard of care for making spine surgery safer. Within a difficult context, the sales trajectory of a company dedicated to a disruptive medical technology such as ours cannot be totally linear. Following a delicate start to the year, June’s growth was back at around 20% over June 2013 and, with the help of our partners, we are relentlessly pursuing our technological, clinical and commercial deployment.»*

Next financial press release: the financial statements for the 1st half of 2014, on September 24, 2014
SpineGuard to participate in the Healthcare & Biotechnologies Conference organized by Société Générale on September 24, 2014 in Paris.

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. Real-time 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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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 €42K and represented 200 bps.

Excluding the impact of IFRS2¹, operating expenses were €3,751k compared with €3,478k for H1 2013, an increase of €273k or +7.8% compared with June 30, 2013. The Company reported a net loss of €2,467k for the first half of 2014 compared with a loss of €1,650 for the first half of 2013, i.e. a difference €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 Pacey equity facility draws in February and June, €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.

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SpineGuard successfully passes ANVISA’s inspection, paving the way for registration of its new products in Brazil

PARIS and SAN FRANCISCO, Dec. 1s, 2014 – SpineGuard (FR0011464452 – ALSGD) announced today that it has received certification from the Brazilian governmental regulatory authority ANVISA (Agência Nacional de Vigilância Sanitária) following a three-day inspection in Paris. Such certification by ANVISA has recently become the mandatory precursor to register new medical devices for marketing in Brazil.

“This ANVISA certification consolidates our regulatory position in Brazil, an important market for SpineGuard,” said Pierre Jérôme, Co-founder and Chief Executive Officer of SpineGuard. *“It will allow us to initiate the registration process for the Curved, Cannulated and XS versions of PediGuard in this large market.”*

Recently, SpineGuard’s Dynamic Surgical Guidance technology was recognized by Becker’s Healthcare, a leading spine industry authority, with the “2014 Spine Device Award” for “advancing spine technology and patient care and representing both the cutting-edge and gold standard in spine care.”

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