



Letter to Shareholders – May 2019





Stéphane Bette, CEO

Pierre Jérôme, Chairman

Dear shareholders,

As our Shareholder Meeting is approaching, we thought it would be a good time to take a look back at our 2018 results, to underline our latest progress and to share with you our perspectives on SpineGuard your company that we founded with the ambition, still intact, to make spine surgery safer and to exploit the full potential of DSG® (Dynamic Surgical Guidance) technology, unique in its ability to differentiate bony tissues in real-time and without using X-Rays.

From a financial standpoint, the highlight of 2018 is that we reached operational profitability in the last quarter. This was a key objective on our roadmap to strengthen the company in an inhospitable stock market environment for our segment. The results were spectacular: our EBITDA improved from -2.8ME in 2017 to -0.59ME in 2018, net losses decreased by 43%, and our American subsidiary was profitable in the full year. In order to succeed, we had to significantly reduce our expenses through a drastic, but selective approach. The cuts had a negative impact on our commercial activities and resulted in 4% decrease of our sales (in constant currency).



Despite the environment and the strategic measures initiated that impacted our commercial activities, SpineGuard sold 9,001 units in 2018, (+ 3%), a record for the company. More than half of our sales were in the USA, by far the largest market for spine surgery devices. In China, second worldwide medical device market and quickly growing, we sold 1,000 units to our distribution partner XinRong in this first full year following our agreement in June 2017. As we announced in February, to-date our DSG technology has been used in more than 70,000 surgeries worldwide, while fourteen clinical studies have been published in prominent scientific peer-reviewed journals. The clinical and economic value of our DSG technology is established now beyond doubt and we have succeeded in creating a profitable business with our historical range of PediGuard® devices, single use surgical drilling tools for Spine Surgery.





« More than 9.000 DSG units sold in 2018, 1.000 in China »

In order to secure our cash runway, we closed two important financing operations in September:

- 1. We restructured our debt by issuing two non-convertible bond tranches totaling 6ME to Norgine Ventures and Harbert European Fund Advisors in substitution for IPF Partners.
- 2. We renewed an equity line with Nice & Green for 3ME over 15 months with no associated warrants.





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The control of our expenses allowed us not only to reach our goal of **operational profitability**, but most importantly, it also afforded us to **continue innovating**, which has been and remains a vital component of SpineGuard's DNA since its inception. 2018 was particularly fruitful in that front with the following notable achievements:

Our partnership with ISIR (Institut des Systèmes Intelligents et de Robotique) of Sorbonne Université, which is focused on surgical robotics. The objectives are to produce scientific evidence that DSG technology can detect bone breaches in a reliable and repeatable manner during robotic bone drilling and then to enable autonomous robotic placement of implants in bone. This program comes precisely at a time when surgical robots are becoming widespread in the orthopedic market and have caught the attention of all the market leaders. This collaboration started to bear fruit with the publication of a first patent application in late April 2019. This was followed up a few days ago with the acceptance of a first scientific article at the Hamlyn Symposium on Medical Robotics, a high profile conference that regroups all novelties in the world of surgical robotic research. To our knowledge DSG is the only proven technology capable of informing a robot about the tissue at the tip of its arm.



Robot featuring DSG sensing



300 surgeries with « smart » screws

The two most recent innovations brought to the market: the PediGuard Threaded and the « smart » DSG screw progressed well in 2018 and grew 85% in the first quarter of 2019. So far, more than 300 surgeries have been performed with spinal "smart" screws embedded with the DSG sensor. In addition, the clinical data we have collated are very encouraging, especially with regards to the gains made in shortening operative time and the reduction of exposure to radiation in the operating theatre.

At the same time, our partnership with the Adin group and its subsidiary ConfiDent specifically created to host the dental implantology application of DSG, is going very well. We obtained a series of successes with the publication of a preclinical study in June 2018, the CE mark grant and the manufacturing of the first batch of SafeGuard products for ConfiDent in December, and lastly, the considerable interest received at the IDS congress in Cologne last May.





Live dental surgeries at the IDS congress

These significant innovative advances are very promising, but in the short term, we have to face a powerful and rapid change of the spinal implant market in the USA. The robotic and new generation navigation platforms are now positioned in the heart of the battle for market share. Many large hospitals choose to acquire expensive, state of the art robotic assisted navigation equipment in order to secure their competitive positioning in their local markets. As a consequence they are terminating or reducing their usage of PediGuard. We have managed to offset the reduction from the large volume users by creating new accounts with a different profile, but our model and our limited commercial resources result in a return on investment which we deem insufficient.

This emerging market reality, combined with a volatile stock market for small capitalization companies such as ours, motivate us to persist with our expense control and to focus on the growth drivers that present the best midterm opportunities.



Our four key goals in 2019 are:

- 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. The best opportunity for SpineGuard to deploy its DSG technology and access high potential markets is via the strengths of the major industry players in Spine Surgery and Orthopedics. David Cassak, an American reporter recognized as a medtech expert, highlighted this tremendous potential in an article published last September in Medtech Strategist titled: "SpineGuard riding robotics' wave".
- 2. Beta-launch a new generation of PediGuard equipped with the DSG-Connect wireless module, a tablet that adds visual to auditory feedback. The value is in maximizing the usefulness of the PediGuard signal to the user and to enable data recording for medico-legal purposes. In addition, the device will assist in clinical studies of bone quality. This new generation of products showcases how digital information from "DSG measurement" can be exported to an external unit beyond its current use within PediGuard devices. It complements our robotic work and supports our efforts to create strategic partnerships in the field.







- 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. The demonstration of the value of SpineGuard's "smart" screw is also fundamental to accomplishing our ambition in surgical robotics: the automated insertion of bone implants embedded with the DSG sensor.
- 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.

The signature of strategic alliances has become a clear priority for SpineGuard to continue expanding the scope of DSG technology and create enterprise value by maximizing the new market opportunities. **We therefore gave a mandate to the American investment bank Healthios Capital Markets to assist us in this undertaking**.

In summary, SpineGuard's transformation is proceeding well. Building-up on the basis of an optimized PediGuard business and early revenues from "smart" screw and dental, we are now well on the way towards profitability and we continue innovating to generate future growth. In surgical robotics, our recent technological progress demonstrates the high potential of the DSG platform and its unique ability to differentiate bony tissues in real-time and without using X-Rays. To realize this potential, a strategic process has now commenced with the goal of creating strong industry deals. We are determined to make SpineGuard a success and to allow you to collect the fruit of our common investment.

We wish to sincerely thank you for your support since our listing.



Stéphane Bette, CEO and Pierre Jérôme, Chairman