

Bactiguard Holding AB's Interim Report Q3 2023

Transformation of Bactiguard into a license focused business with the vision to become the global standard of care

Third quarter 2023 (July – September)

- Total revenues amounted to SEK 49.5 (66.2) million, a decrease of 25 %. Net sales amounted to SEK 45.5 (58.7) million. Adjusted for the currency effect, net sales decreased by 23 %.
- Operating loss amounted to SEK 21.6 (11.0) million, an increase of SEK 10.6 million.
- EBITDA amounted to SEK -9.5 (2.5) million.
- Net loss for the period amounted to SEK 24.6 (8.5) million.
- Loss per share, before and after dilution, amounted to SEK 0.70 (0.24).
- Cash flow from operating activities amounted to SEK -35.0 (9.9) million, corresponding to SEK -1.00 (0.28) per share.

The period January – September 2023

- Total revenues amounted to SEK 161.8 (181.3) million, a decrease of 11 %. Net sales amounted to SEK 145.3 (162.3) million. Adjusted for the currency effect, net sales decreased by 10 %.
- Operating loss amounted to SEK 108.1 (42.4) million, an increase of SEK 65.8 million, SEK 42 million of the operating loss are due to the Q2 provision.
- EBITDA amounted to SEK -71.8 (-5.3) million, SEK 42 million of which are due to the Q2 provision.
- Net loss for the period amounted to SEK 111.2 (38.7) million.
- Loss per share, before and after dilution, amounted to SEK 3.17 (1.10).
- Cash flow from operating activities amounted to SEK -62.4 (-3.9) million, corresponding to SEK -1.78 (-0.11) per share.

Key events during the quarter

- Anders Göransson, Global Head of licensing, left Bactiguard.

Key events after the end of the quarter

- In October, Bactiguard announced a sharpened strategy focused on the licensing business and phasing out of the BIP portfolio.
- Stefan Grass, Chief Medical Officer, announced that he is leaving Bactiguard.
- A study by Bactiguard, KTH and Karolinska Institutet, was published in Scientific Reports.
- New financial targets, to be delivered by year-end 2028, were published; Net sales SEK 1000 million, EBITDA SEK 500 million and 10 application areas in license partnerships.



CEO statement

Transformation of Bactiguard into a license focused business with the vision to become the global standard of care

Revenues for the third quarter 2023 came in at SEK 49,5 million, a decrease of 25 percent compared to Q3 2022. EBITDA for the quarter amounted to SEK -9.5 million (Q3 2022: SEK 2.5 million). Total costs were lower than Q3 last year and amounted to SEK 71.1 million (Q3 2022 SEK 77.1 million).

Biggest strategic shift in Bactiguard's history

As reported on October 5, Bactiguard has sharpened its strategy to fully focus on the licensing business and put all efforts and our core strengths to enable leading global medtech companies bring medical devices with Bactiguard's unique coating technology to the market. This is the biggest strategic shift in our history and will fundamentally reshape the company, from production to a knowledge specialist organization. I feel confident that this will unleash the potential for our infection prevention technology and simultaneously increase global patient reach. And importantly, lead Bactiguard to profitability.

The transformation process is making good progress. The licensing organization is being strengthened, and we have intense and promising discussions with potential outsourcing partners, both with current and new license partners, while simultaneously terminating the production of the BIP portfolio of coated medical devices. Our main priority is to ensure a smooth transition and minimize supply disruptions for our distributors. We are also investing in the R&D and coating development organizational structure by strengthening these crucial competencies. To further institutionalize our processes, we have launched the Bactiguard Billy Södervall Academy in Markaryd to formalize knowledge sharing and initiate a technology certification, effective both within Bactiguard and with license partners.

We anticipate that once the BIP production and the BIP sales organization are phased out and the products are outsourced to a partner, a loss will quickly turn into a profit. As communicated, the financial impact of the new license focused strategy will, over time, negatively affect the BIP revenues by SEK 25 million while the yearly savings for Bactiguard are anticipated to be more than SEK 25 million.

Slow revenue generation, as anticipated

As communicated in the Q2 report, the licensing revenues for Q3 are severely impacted by the adjusted levels of our license partner Beckton Dickinson (BD), one of the largest global medical technology companies. As stated in Q2, we expect the BD levels to soon be back on pre-covid volumes and we foresee more normalized licensing revenues already in Q4 2023. The licensing revenues amounted to SEK 20.8 million (51 percent below Q3 2022).

The roll-out of ZNN Bactiguard continues across clinics in Europe, and in Japan it is ready for commercial launch during the first half of 2024. The FDA process on Zimmer Biomet's broader orthopedics portfolio is making progress, albeit at a slower pace than we had hoped for. Even though it is frustrating that the process takes time, thorough preparation will facilitate future registrations of the entire product portfolio. It is our best guess that Zimmer Biomet will obtain approval from the FDA in early 2026.

Our collaboration with Zimmer Biomet is excellent and as part of their global strategy "Let's talk about infections", they showcased Bactiguard's coating technology at the European Bone and Joint Infection Society conference in Switzerland mid-October where the theme was the challenges with infections within orthopedic implantology, and more specifically the dangers of biofilm. Adding to that the growing global concerns over antibiotic resistance, our technology is an unprecedented non-antibiotic-releasing alternative to avoid implant related infections. The orthopedics therapeutic area has an underlying market size of roughly USD 40 billion of which Zimmer Biomet has a market share between 10 and 30 percent, hence the potential in our collaboration is great – from a mission, impact, and profitability perspective.

As with any development project, there is uncertainty whether the development project with Dentsply Sirona will turn into a full-blown license agreement, but we will have more clarity before the year end. We have robust clinical evidence supporting the efficacy of our coating technology, and we are confident about our ability to prevent infections also in the dental area.

BPP reported total revenues of SEK 24.6 million for Q3, an increase by 51 percent compared to Q3 2022. Even though the BIP portfolio of coated medical devices had strong Q3 sales of SEK 7.0 million (Q3 2022 SEK 3.8 million), the long-term profitability issues remain. When it comes to sales within Wound Management, revenues amounted to SEK 17.6 million, which was in line with expectations with a growth of 40 percent compared to Q3 2022.



New Executive Management team

As of today, the Executive Management team will include, in addition to the CEO, Bactiguard's CFO, COO (with an overall responsibility for the licensing business), CTO and Head of Communications & Investor Relations. The compilation reflects the competencies Bactiguard needs to drive a successful execution of the new strategy in collaboration with the rest of the team of experts at Bactiguard.

In addition, Stefan Grass, Chief Medical Officer, and deputy CEO, has decided to leave Bactiguard. Stefan has made valuable contributions strengthening our clinical evidence base during his tenure, and we would like to thank him for his time with us and wish him all the best for the future. Simultaneously, we are pleased to inform you that Pankaj Malhotra has been appointed Chief Medical Officer. Pankaj is an MD and will be part of the licensing team and report to the COO.

Outlook – new vision to become the global standard of care

The updated financial targets, as announced yesterday evening, reflect what the Board of Directors and Executive Management team consider to be reasonable mid-term expectations of Bactiguard given our new strategic direction. But they also reflect what we believe in terms of the potential for Bactiguard's coating technology. We are launching a new vision, to become the global standard of care for medical device related infections. This will be achieved by us joining forces with license partners with a common mission to redefine healthcare and improve health worldwide. Our new strategy in a nutshell.

Q3 was another disappointing quarter but our aspirations for the future are bold. We are now putting a fundamental transformation in motion and foreseeing positive dynamic effects following the focused efforts. Bactiguard's coating technology has a great potential to capture one of the most unmet needs of global health care – it is a safe and simple way to avoid biofilm formation resulting in infections on medical devices. We have a clear strategy to fulfill our commitment to championing a healthier world by preventing infections and turning losses into profits during 2024.

Thomas von Koch, CEO

Bactiguard Holding AB's (publ) Interim Report Q3 2023 is available at www.bactiguard.com

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Presentation of Bactiguard Holding AB's Interim Report Q3 2023

An audiocast for investors, analysts and media will be held at **11:00 CEST today, October 27, 2023**. CEO Thomas von Koch will present the report, comment on the updated financial targets, and, together with CFO Carin Jakobson, answer questions.

To participate in the audiocast, please use this link:

www.bactiguard.com/report/q3-2023/

About Bactiguard

Bactiguard is a global medtech company that develops antibacterial, biocompatible and safe technology and solutions to prevent medical device related infections across five therapeutic areas – orthopedics, urology, intravascular/critical care, dental, and wound care.

Bactiguard's unique technology is based on a thin noble metal coating that prevents bacterial adhesion and biofilm formation on medical devices. Bactiguard's infection prevention solutions make a positive impact by decreasing patient suffering, saving lives and unburden healthcare resources. They also fight against antimicrobial resistance, one of the most serious threats to global health and modern medicine.

Bactiguard operates through license partnerships with leading global medtech companies, such as BD and Zimmer Biomet, enabling them to bring medical devices with the company's unique infection prevention technology to the market. Bactiguard also has a portfolio of wound management products and sutures.

Bactiguard is headquartered in Stockholm and listed on Nasdaq Stockholm.

Read more about Bactiguard: www.bactiguard.com

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