

Press release

Stockholm 8 February 2024

Bactiguard Holding AB's year-end report 2023

Stable fourth quarter marking the end of a challenging year

Fourth quarter 2023 (October – December)

- Total revenues amounted to SEK 61.3 (72.2) million, a decrease of 15.0 %. Net sales amounted to SEK 56.3 (61.3) million. Adjusted for the currency effect, net sales decreased by 9 %.
- Operating loss amounted to SEK 23.8 (13.3) million, a decrease of SEK 10.5 million.
- EBITDA amounted to SEK -4.2 (-1.1) million.
- Net loss for the period amounted to SEK 27.2 (14.2) million.
- Loss per share, before and after dilution, amounted to SEK 0.78 (0.40).
- Cash flow from operating activities amounted to SEK 10.1 (7.0) million, corresponding to SEK 0.29 (0.20) per share.
- New financial targets for 2028: Net sales SEK 1.000 million, EBITDA SEK 500 million.

The period January – December 2023

- Total revenues amounted to SEK 223.2 (253.5) million, a decrease of 12.0 %. Net sales amounted to SEK 201.5 (223.6) million. Adjusted for the currency effect, net sales decreased by 13 %.
- Operating loss amounted to SEK 131.9 (55.7) million, a decrease of SEK 76.3 million, SEK 42 million of the operating loss are due to the Q2 provision.
- EBITDA amounted to SEK -76.1 (-6.4) million, SEK 42 million of which are due to the Q2 provision.
- Net loss for the period amounted to SEK 138.4 (52.9) million.
- Loss per share, before and after dilution, amounted to SEK 3.95 (1.51).
- Cash flow from operating activities amounted to SEK -52.3 (3.1) million, corresponding to SEK -1.49 (0.09) per share.

Key events during the quarter

- Announced a sharpened strategy with full focus on license business and phasing out the BIP portfolio.
- Stefan Grass, CMO announced that he is leaving Bactiguard.
- A study on the antithrombotic effect of Bactiguard's coating (by Bactiguard, KTH and Karolinska Institutet) was published in Scientific Reports.
- New financial targets for 2028: Net sales SEK 1.000 million, EBITDA SEK 500 million.
- Patrick Bach appointed CFO.
- Announced strengthened relationship with Beckton Dickinson (BD), with an interim agreement granting BD exclusive global license (excluding China) for Foleys with Bactiguard's coating.

Key events after the end of the quarter

- Christine Lind appointed new CEO and joins Bactiguard at the beginning of May 2024.
- Agreement with Dentsply Sirona not to pursue the application development project further due to changed priorities at Dentsply Sirona.
- Hydrocyn aqua received approval from the Central Drugs Standard Control Organization (CDSCO) to start commercialization in India.

CEO statement

Year-end report 2023: Stable fourth quarter marking the end of a challenging year

Revenues for Q4 2023 amounted to SEK 61 million, a decrease of 15 percent compared to Q4 2022. Total revenues for 2023 came in at SEK 223 million, a decrease of 12 percent (2022: SEK 253 million). EBITDA for Q4 2023 amounted to SEK -4 million (Q4 2022: SEK -1 million) which was in line with expectations given the new strategy and phasing out of the BIP portfolio. For the full-year 2023, EBITDA was SEK -76 million (2022: SEK -6 million). Costs for Q4 amounted to SEK 85 million (Q4 2022: SEK 85 million) and for the full-year 2023, SEK 355 million (2022: SEK 309 million) which includes the SEK 42 million provision from the July 2023 profit warning.

A year of fundamental change

2023 was a year of fundamental change; change in terms of a sharpened strategy with focus on the licensing business and phasing out of the non-profitable BIP portfolio (i. e. the Bactiguard coated urinary catheter Foleys, central venous catheters, and endotracheal tubes). And change also in terms of culture and ways of working – Bactiguard, in its entirety, is now geared to evolve into a knowledge and specialist organization. This marks a profound change and is a prerequisite to achieving profitability and reaching our financial targets.

And speaking about change, yesterday evening we announced some really exciting news. Bactiguard has appointed Christine Lind as its new CEO. With her international background, firm experience from our industry combined with her modern, collaborative and executional leadership style, Christine perfectly fits the bill for Bactiguard and our strategy ahead.

For 2023, the BPP (i. e. the Bactiguard Product Portfolio) revenues were SEK 84 million, an increase of 36 percent compared to 2022 which is partly attributable to the “end-of-life” BIP products sales in Q4. As previously stated, with the BIP portfolio fully phased out, the license focused strategy will negatively affect BIP revenues by SEK 25 million on a full-year basis while the yearly savings are anticipated to be over SEK 25 million. Wound Management, now a stand-alone business oriented for growth and profitability, stands for SEK 54 million of the BPP full-year 2023 revenues. This represents an increase of 24 percent compared to 2022, in line with our expectations.

An important first step in the phasing out of BIP products was the strengthened relationship with our license partner Beckton Dickinson (BD), one of the largest global medical technology companies. In Q4, we signed an interim agreement granting BD an exclusive global license (excluding China) for Bactiguard coated Foleys catheters. The handover process is ongoing and has been well-received among distributors and end-users. We expect the extended BD agreement to have a small but positive effect on the 2024 income statement and contribute more substantially over time. In addition, we are in dialogue with both current and potential partners to license out Bactiguard’s technology for the central venous catheters and endotracheal tubes, underpinned by the solid clinical data we have across the BIP portfolio. This will, however, have limited impact on the income statement for 2024.

Our infection prevention technology is our most important asset

The unique infection prevention technology is Bactiguard’s most important asset. During the year, we have increased focus on R&D and strengthened the coating development organization. As a result of the strategic review, all coating and development activities will be performed in Sweden and in Q4, we started building a new lab facility in Markaryd. In addition to host training and technology certification activities, it will be a complementary site for R&D activities and will also be used to set up demo production lines for license partners.

Intellectual property and patents are an integral part of our strategy, and we are continuously monitoring and finetuning our intellectual property portfolio to keep the highest protection standards. Our technology is robustly protected across eight different relevant patent families and notably in 2023, a US patent was granted which can be maintained until 2040.

And to put our technology into an even longer-term perspective, it takes time to get acceptance for change and innovation in our industry. Bactiguard has invested hundreds of millions of SEK in our own coated medical devices over the past decade. Even though the return has not yet been materialized, the solid clinical evidence gathered is the bedrock of Bactiguard’s sharpened strategy and for future license partnerships.

Licensing business the greatest future potential

During Q4, we started to primarily focus our efforts fully on the license business which is where the greatest future potential for Bactiguard lies, both from a profitability and impact perspective. License revenues amounted to SEK 32 million for Q4 which was 31 percent below Q4 2022.

Full-year 2023, license revenues came in at SEK 117 million, a decrease of 27 percent compared to 2022. Q4 2022 in particular was a record quarter in our partnership with BD, who at the time was building up stock levels which were then adjusted during 2023. These adjustments are the main reason for the license revenue decrease in 2023. In Q4 2023, BD were back at pre-covid-19 levels.

Zooming in on Zimmer Biomet, we see continued roll-out across Europe with increasing sales in both existing and new European markets. In addition, a launch in Japan is expected in July 2024 and after that, Zimmer Biomet will offer Bactiguard coated products in markets representing around 50 percent of their trauma sales. As reported in Q3, it is our best guess that Zimmer Biomet obtains FDA approval early 2026. Worth noting, though, is that around 50 percent of Zimmer Biomet's trauma offering is outside the US.

On Dentsply Sirona, we have agreed not to pursue the application development project further due to changed priorities at Dentsply Sirona. We are already in dialogue with other leading dental organizations and there is a continued strong interest thanks to clinical evidence supporting the efficacy of the coating technology in the oral cavity space.

From 2024, our revenues will be reported in three stages of partnerships: application development partners, exclusivity partners and license partners. We will communicate signed partnerships in the two latter stages, as this is where the revenue generation kicks in. With the new strategy, Bactiguard's revenues and margins are expected to increase significantly, and we are committed to reach the financial targets set in October 2023.

Outlook – global healthcare issues as pressing as ever

As we gaze ahead, I am confident with our ability to grasp the vast opportunities in meeting unmet medical needs – the global societal challenges, including healthcare-associated infections and antimicrobial resistance, are as pressing as ever. With the political unrest and natural disasters across the globe, the need for safe medical devices in crisis situations becomes painfully obvious. We see early indications of a significant change with increased interest and demand from state defense related organizations as well as NGOs. To reiterate what I have said many times before, to mitigate the risks associated with biofilm formation, medical devices intended to stay in the body for more than two days should be coated. And Bactiguard has the solution, a safe and biocompatible coating technology making it simple to avoid medical device related infections. By joining forces with leading MedTech partners, I am convinced that our infection prevention technology will become the global standard of care, as stated in our vision.

In June 2024, Bactiguard has been listed on Nasdaq Stockholm for ten years – looking back, ten years with an array of opportunities and challenges as well as cheers and setbacks. One thing has been constant – a strong determination to make a positive impact on healthcare and for the wellbeing of patients around the world. In the anniversary spirit, we are opening a new office centrally located in Stockholm, for easier partner interaction and talent attraction.

I would like to conclude 2023 by extending my deepest appreciation to investors, partners, and employees for your trust and dedication. I would also like to take the opportunity to welcome Christine onboard – looking forward to unleashing the true potential of our unique technology together!

Thomas von Koch, CEO

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Presentation of Bactiguard Holding AB's year-end report 2023

An audiocast for investors, analysts and media will be held at 11:00 CET today 8 February 2024. CEO Thomas von Koch will present the year-end report 2023 together with CFO Patrick Bach, and answer questions. The report and a presentation is available on bactiguard.com

To participate in the audiocast, please use this link: [Year-end Report 2023](#)

Bactiguard®

About Bactiguard

Bactiguard is a global MedTech company developing safe and biocompatible technology to prevent medical device related infections. The company's unique technology is based on an ultra-thin noble metal coating that prevents bacterial adhesion and biofilm formation on medical devices. Bactiguard's infection prevention technology and solutions decrease patient suffering, save lives, and unburden healthcare resources while also fighting 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 that apply the technology to their medical devices and sell them under their own brand or co-branded with Bactiguard. The company also has a portfolio of wound management products.

Bactiguard is headquartered in Stockholm and listed on Nasdaq Stockholm.

Read more about Bactiguard: www.bactiguard.com

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