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Sedana Medical AB fourth quarter and year-end report 2021

Sales at an all-time-high provide a strong platform for launch

Fourth quarter 2021

- Net sales totalled MSEK 46 (46), equivalent to an increase of 1% compared to the fourth quarter of 2020. At constant exchange rates, sales increased by 2%.
- Gross profit was MSEK 33 (30), equivalent to a margin of 71% (64%). The improved margin is primarily an effect of lower transportation costs, a favourable country mix and timing effects.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -13 (-6), equivalent to an EBITDA margin of -29% (-13%).
- Operating income (EBIT) totalled MSEK -19 (-8), equivalent to an EBIT margin of -40% (-17%).
- Net profit for the quarter was MSEK -17 (-12), and earnings per share before and after dilution was SEK -0.18 (-0.13).
- Cash flow from operating activities totalled MSEK -2 (3).
- Cash flow from investing activities totalled MSEK -33 (-31).
- Total cash flow was MSEK 571 (-29).
- Cash and cash equivalents at the end of the quarter totalled MSEK 836, compared to MSEK 262 at the start of the quarter.

January-December 2021

- Net sales for the full year totalled MSEK 159 (142), equivalent to an increase of 12%. At constant exchange rates, sales increased by 16%.
- Gross profit was MSEK 107 (89), equivalent to a margin of 67% (63%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -50 (-14), equivalent to an EBITDA margin of -31% (-10%).
- Operating income (EBIT) totalled MSEK -61 (-21), equivalent to an EBIT margin of -39% (-15%).
- Net profit for the year was MSEK -58 (-27), and earnings per share before and after dilution was SEK -0.62 (-0.30).
- Cash flow from operating activities totalled MSEK -41 (-8).
- Cash flow from investing activities totalled MSEK -110 (-85).
- Total cash flow was MSEK 454 (-87).
- Cash and cash equivalents at the end of the year totalled MSEK 836, compared to MSEK 376 at the start of the year.
- The Board of Directors proposes that no dividend be paid for the 2021 financial year.

CEO comments

Sales at an all-time-high provide a strong platform for launch

I am pleased to report another successful quarter for Sedana Medical. We have seen the highest sales in our history for both the quarter and the full year and made strong progress on both of our main priorities: to execute an excellent launch of Sedaconda (isoflurane) in Europe and to prepare for the important US market.

Sales in the quarter totalled SEK 46 million, slightly above the fourth quarter 2020 when Covid-19 had led to very high demand. For the full year, we saw sales of SEK 159 million, which makes 2021 our best year to date. At the same time, we grew our gross margin in the quarter to 71 per cent

which was driven by a shift of the sales mix towards higher-margin markets and the fact that we were able to ship almost all products by sea.

The strong sales performance puts us in an excellent starting position for the launch of Sedaconda (isoflurane). To date, we have received national approvals in 14 of the 15 EU countries that were included in the DCP approval in July 2021. Also during the quarter, we applied for market authorization in Italy, which means that we are expecting four more countries to approve Sedaconda (isoflurane) during 2022: the UK, Switzerland, Poland and Italy.

I am excited to report that the first bottles of Sedaconda (isoflurane) have been shipped to customers. Our main market Germany was the first country to launch. Depending on the speed of national pricing and reimbursement processes, we are looking forward to introducing the drug in more markets over the coming months. Assuming national approval in the UK, our aim is to launch Sedaconda (isoflurane) in all our major direct markets during this year. We are aiming at converting a significant share of today's off-label sales. The level and speed of this conversion will differ by country, and we are expecting a gradual sales ramp-up as hospitals will switch from generic volatile anaesthetics to Sedaconda (isoflurane) over time.

In the beginning of 2022, the National Institute for Health and Care Excellence (NICE) has issued positive guidance recommending Sedaconda ACD as a cost-saving option for delivering inhaled sedation in intensive care as an alternative to intravenous sedation. In their assessment, cost modelling shows cost savings compared with intravenous sedation of almost £4,000 per adult patient. This represents a major milestone for Sedana Medical as we have now received confirmation for significant health-economic benefits on top of the convincing clinical benefits we have seen in our clinical trial SED-001.

With regards to our largest potential market, the United States, we took the important strategic decision to build up our own commercial operations to launch the Sedaconda products. On the back of this decision, we successfully completed a directed share issue and raised SEK 615 million, which gives us the financial strength to implement our ambitious US strategy. We were able to close the share issue at no discount and are pleased with the quality and long-term orientation of the participating investors. I would like to take this opportunity to thank our new and existing shareholders for their support and trust in Sedana Medical.

In December, the FDA approved our Investigational New Drug (IND) application, which allows us to initiate phase III pivotal clinical trials in the United States. We are planning for the first patients to enter the clinic in early Q2 this year.

Outside our main markets, we obtained market approval for our medical device Sedaconda ACD in Argentina and Turkey. With 8.000 and 10.000 ICU beds respectively, both represent attractive commercial opportunities. With the Argentinean approval and the ongoing approval process in Brazil, we are further strengthening our presence in Latin America, where interest in our therapy has been very high and we have seen good traction.

In December, our partner Kyuan Xinhai Medical has submitted Sedaconda ACD for approval in China and continues to be in close dialogue with the Chinese FDA. Kyuan is a subsidiary of partly state-owned Shanghai Pharma, one of the largest life science companies in China.

On the supply side, we have made progress with our dual sourcing project as we started producing our Sedaconda syringes at a contract manufacturer in the European Union. We are aiming to add a second source for more products including our main device Sedaconda ACD during the year.

We have ended an eventful and successful year 2021 in a position of strength, laying a solid foundation for future success. I look forward to getting back to you on our progress.

Johannes Doll, President and CEO

Significant events during the period

- In January and February, applications for market approval for the drug candidate Sedaconda (isoflurane) for inhaled sedation in intensive care were submitted in Switzerland and the United Kingdom.
- In February, the first patient was included in the company's paediatric study IsoCOMFORT (SED002), which is being conducted to study whether inhaled sedation with Sedaconda (isoflurane) delivered via Sedaconda ACD is a safe and more effective method of sedation than intravenously administered midazolam, for children below 18 years of age.
- In June, the pivotal phase III Sedaconda study (SED001) was selected as one of the top three posters at the 52nd DGIIN & ÖGIAIN Intensive Care Conference.
- In early July, Sedana Medical's Quality Management System (QMS) received approval under the EU Medical Device Regulation (MDR) 2017/745. This approval means that Sedana Medical's Class I medical devices can continue to be sold with CE marking in the EU.
- In July, a successful End of Phase II advisory meeting was completed with the US Food and Drug Administration (FDA). The FDA accepted Sedana Medical's proposed phase III programme, including the study design and the primary endpoint for the studies. The positive outcome allows the company to enter phase III in line with the communicated timeline.
- In July, a positive outcome was obtained for the application for European marketing authorisation for the pharmaceutical product Sedaconda (isoflurane) for inhaled sedation in intensive care, known as DCP approval. Sedaconda is indicated for sedation of mechanically ventilated adult intensive care patients and is to be delivered only via the Sedaconda ACD medical device.
- In August, the results of the company's pivotal study Sedaconda (SED001) were published in the highly respected scientific journal The Lancet Respiratory Medicine.
- At the end of September, market approval was obtained for Sedaconda (isoflurane) in Germany. The application was approved by the German regulatory authority BfArM and is based on the DCP approval obtained by Sedana Medical in July.
- After being appointed by the Board in May, Johannes Doll took office as the new President and CEO of Sedana Medical on 1 October 2021.
- In December, a directed new share issue was made which contributed MSEK 615 to the company.
- In December, an application was submitted for market approval for Sedaconda (isoflurane) for inhaled sedation in intensive care in Italy.
- In December, Investigational New Drug (IND) approval was received from the US Food and Drug Administration (FDA) to enable pivotal phase III studies with the Sedaconda devices to begin in the United States.
- In December, Sedana Medical's Chinese partner Kyuan Xinhai Medical has submitted Sedaconda ACD for approval in China to the Chinese FDA.

Significant events after the period

- In January, Johan Spetz was appointed as the new CFO. Johan Spetz succeeds Susanne Andersson, who leaves the position to take up other duties.
- In January, the National Institute for Health and Care Excellence (NICE) issued positive guidance recommending Sedaconda ACD as a cost-saving option for delivering inhaled sedation in intensive care as an alternative to intravenous sedation.
- In February the first bottles of Sedaconda (isoflurane) were delivered to customers in Germany, the company's largest market.

Please find the full year-end report at: sedanamedical.com

This document has been prepared in a Swedish and English version. In the event of any deviations, the Swedish version shall prevail.

Sedana Medical will hold a telephone conference at 13:30 pm (CET) Thursday February 17, 2022.

To participate, please dial: +46 8 505 583 65

For additional log in information:

<https://financialhearings.com/event/43299>

<https://tv.streamfabriken.com/sedana-medical-q4-2021>

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This information is such that Sedana Medical AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact persons above, on February 17, 2022, at 07:00 am (CET).

Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm. The company's Certified Adviser is Erik Penser Bank, +46 8 463 83 00, certifiedadviser@penser.se.

About Sedana Medical

Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve the patient's life during and beyond sedation. Through the combined strengths of the medical device Sedaconda ACD and the pharmaceutical Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated patients in intensive care.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordic, and Spain. In other parts of Europe as well as in Asia, Australia, Canada, and South- and Central America, the company works with external distributors.

Sedana Medical was founded in 2005, is listed on Nasdaq First North Growth Market (SEDANA) and headquartered in Stockholm, Sweden.