Press release May 6, 2021, 07.00 CET.

Sedana Medical AB (publ), First Quarter Report 2021

A quarter of launch preparations and continued increase in sales, lifted by the pandemic

Financial Summary

This interim report has been prepared in accordance with IFRS with function-based income statement compared with cost-based income statement as previously.

January-March 2021

- Net sales for the first quarter totalled MSEK 45 (34), equivalent to an increase of 33% on the same quarter in 2020. At fixed exchange rates, sales increased by 40%.
- Gross profit was MSEK 29 (23), equivalent to a margin of 64% (67%). The lower margin is principally an effect of the continued high transport costs resulting from the COVID-19 pandemic. Adjusted for the increased freight costs, the gross margin is slightly higher than for the first quarter last year.
- In connection with the transition to a function-based income statement, costs have been redistributed to the cost of goods sold, which has reduced the gross margin by approximately 3 percentage points. These costs consist of depreciation and supply costs. With increased sales and economies of scale, the effect of these costs on the gross margin will diminish.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -8 (2), equivalent to an EBITDA margin of -18% (5%).
- Earnings before interest and taxes (EBIT) totalled MSEK -10 (0), equivalent to an EBIT margin of -23% (0%).
- Net profit for the period was MSEK -9 (2), and earnings per share before/after dilution were SEK -0.39 (-0.07).
- Cash flow from operating activities before changes in working capital totalled MSEK -9 (1).
- Cash flow from investing activities totalled MSEK -21 (-14).
- Cash flow totalled MSEK -33 (-23).
- Cash and cash equivalents at the end of the period totalled MSEK 344, against MSEK 376 at the start of the year.

Significant events during the period

- An application for market approval for the drug candidate Sedaconda (isoflurane), previously known as IsoConDa, for inhaled sedation in intensive care was submitted in Switzerland and the United Kingdom.
- The first patient was included in the company's paediatric study IsoCOMFORT (SED002), which is conducted to investigate if inhaled sedation with Sedaconda (isoflurane) delivered via AnaConDa is a safe and more effective method of sedation than intravenously administered midazolam, for children below 18 years of age.
- Sedana Medical's CEO, Christer Ahlberg, announced that he is stepping down as CEO to become the CEO of Cinclus Pharma AB.
- No significant events have occurred after the end of the period.

CEO comments

Sedana Medical operates according to a clear strategy to develop inhaled sedation into a global standard therapy in intensive care. The first quarter of the year was notable for preparations ahead of our European launch of Sedaconda (isoflurane) during the second half of the year and ahead of our forthcoming expansion in the United States. Day-to-day operations and our sales continued to be dominated by the COVID-19 pandemic.

ICU sedation is precisely the treatment that severely ill COVID-19 patients very often need, and demand for AnaConDa and accessories was strong during the third wave of the pandemic that hit many countries during the first quarter. Sales in the quarter were SEK 45 million, up 40 percent on the previous year, at constant exchange rates. The trend in sales continued to be highly positive as a result of COVID-19. We are, however, seeing a further increase in freight costs compared with previously, as a result of the pandemic, which has a negative impact on our gross profit. Adjusted for the increased freight costs our underlying gross margin is now slightly higher than in previous quarters. In terms of sales, we now recognise Germany, our distribution markets and other direct sales markets, which show that demand rose sharply in our distribution countries, focused on Latin America. Germany was hit by a third wave during the quarter, contributing to an increase mainly at the end of the quarter. Since the end of the quarter, we have also succeeded in having our quality system approved under MDR 2017/745, which is a decisive milestone for the future.

Our strategic plan to achieve our vision of making inhaled sedation a new global standard therapy in intensive care is based on four steps: 1) Establish AnaConDa in as many markets as possible. 2) Apply for marketing authorisation for Sedaconda, initially in the EU and later in other markets. 3) Secure strong medical evidence. 4) Establish the therapy in guidelines as a first-line alternative. We made progress in all these steps during the quarter.

With regard to establishing AnaConDa in as many markets as possible, during the quarter we strengthened our presence in the Middle East and South America, where we are working closely with our distributors. In South America, demand additionally increased sharply as a result of the pandemic, and we launched the therapy at many new clinics via our distributor. By establishing AnaConDa in as many markets as possible, we are building experience at the clinics ahead of market approval for Sedaconda. In that way, we are building on a solid foundation for continued expansion.

With regard to the second step in our strategy, having the pharmaceutical product Sedaconda and inhaled sedation therapy approved, it was very pleasing to submit applications for marketing authorisation for Sedaconda in the United Kingdom and Switzerland during the quarter. As a result, the treatment will move from being off-label to fully approved, and we will be able to sell the whole therapy, that is to say both the medical device AnaConDa with accessories and the pharmaceutical product Sedaconda. We submitted an EU application at the end of last year, and if everything goes well we anticipate approval in 15 EU countries during the second half of 2021. We anticipate being able to launch during the first half of 2022 in the United Kingdom and during 2022 in Switzerland.

Now that we are approaching commercialisation in Europe, our work has been concentrated on launch activities. A key factor in successful commercialisation is acceptance by payers in healthcare systems, and during the quarter we worked intensively to establish good contacts and have devoted a large amount of time to preparing price, procurement and reimbursement processes in various countries.

The preparations ahead of our American registration were intensive during the quarter. We are working on several parallel processes ahead of the IND (Investigational New Drug) application which is required to enable us to initiate two pivotal phase 3 studies. Among other things, we have initiated processes to recruit our own staff in the United States, to take part in the study work there, and during the quarter we continued to work in particular on completing the tox studies and the human factors validations to enable us to submit the IND application.

Some processes have, however, been delayed by the pandemic, in particular the interaction with the FDA, which has significantly prolonged response times. As a consequence, we no longer anticipate being able to obtain IND approval after the summer but rather during the autumn, and we therefore anticipate including the first patient in the study concerned at the end of Q1 or the beginning of Q2 2022. We are doing what we can to speed up the processes while maintaining quality and to prepare the clinics to be involved in the studies in the best possible way, for efficient patient recruitment when it gets underway.

With regard to the third step in our strategy, securing medical evidence with the help of more studies showing that inhaled sedation is a better and more cost-effective treatment than the current standard therapy, it is very pleasing that during the quarter we were able to announce that the first patient had been included in our paediatric study IsoCOMFORT (SED002). This study is conducted to investigate if inhaled sedation with Sedaconda delivered via AnaConDa is a safe and more effective method of sedation than intravenously administered midazolam for children below 18 years of age. The study is expected to be completed during the second half of 2022 and is intended to lead to an approved paediatric indication for inhaled sedation.

IsoCOMFORT (SED002) is our first own 'superiority' study. This means a study performed to show that inhaled sedation with AnaConDa has characteristics superior to intravenous standard sedation. The investigator-initiated studies we support – INASED, SESAR and ISCA – are all superiority studies performed to demonstrate significant benefits, for example with regard to wake-up times, shorter time to extubation, fewer side effects such as delirium, higher proportion of spontaneous breathing in patients, better oxygen uptake, shorter ICU treatment times etc. As a result, the treatment will gain ground and be included in national and international recommendations, as well as gradually taking the position of a new standard therapy throughout the world.

Overall, we can look back on another intensive quarter. This is my twentieth quarter as CEO of Sedana Medical, and these are probably my last CEO Comments as the company's CEO. It has been highly enjoyable and exciting years, and it has been an honour to build up Sedana Medical along with all the incredibly professional employees. In view of how well Sedana Medical has developed, the time feels right to hand over the baton to a new CEO.

The company has developed superbly well over those years, with a multiple increase in sales, while we have marketing authorisation within reach later this year and establishment of a presence in the United States in years to come. Sedana Medical today has a very solid foundation on which to successfully develop inhaled sedation into a global standard.

Christer Ahlberg, President and CEO

Please find the full interim report at: www.sedanamedical.com under Investors/annual & interim reports. 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 May 6, 2021.
To participate, please dial: +46 8 505 566 426 93

For additional log in information:
https://financialhearings.com/event/13793
https://tv.streamfabriken.com/sedana-medical-q1-2021

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Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm.
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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 May 6, 2021 at 07:00 am (CET).

About Sedana Medical

Sedana Medical AB (publ) develops and sells the medical device AnaConDa for the administration of volatile anaesthetics. Through a combination of AnaConDa and the drug candidate Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated intensive care patients. The company has applied for market approval in Europe for Sedaconda and expects an approval in the second half of 2021.

Today, mechanically ventilated intensive care patients are sedated intravenously which leads to several challenges for both patients and care givers. Challenges that are solved by inhaled sedation. Globally, seven to eight million patients are estimated to be sedated in intensive care due to mechanical ventilation, evenly distributed between the US, Europe, and Asia.

These patients are on average sedated three to four days. Sedana Medical estimates the total market potential to SEK 20-30 billion. Three years after marketing approval in Europe, Sedana Medical expects sales of SEK 500 million in Europe and an EBITDA margin of about 40 percent. The company has initiated processes to obtain market approval in the US in 2024 and in markets outside the EU.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordics and Spain as well as external distributors in other parts of Europe, Australia, Canada, China, India, Israel, Japan, Mexico and South Korea. The company was founded in 2005 and is headquartered in Stockholm, Sweden, with medical device development in Ireland.