SEDANAMEDICAL

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Sedana Medical AB (publ), Fourth Quarter and Year-end Report

Registration application submitted in the EU – strong sales increase as a result of COVID-19

Financial Summary

This year-end report has been prepared in accordance with IFRS, and comparative periods have been restated.

October-December 2020

- Net sales amounted to MSE 46 (20), equivalent to an increase of 129% on the same period of 2019.
- Earnings before interest, taxes, depreciation and amortization (EBITDA) amounted to SEK -5 (-4), equivalent to an EBITDA margin of -10% (-20%).
- Earnings before interest and taxes (EBIT) amounted to MSEK -7 (-5), equivalent to an EBIT margin of -15% (-25%).
- Net income for the period was MSEK -11 (-7), and basic and diluted earnings per share were SEK -0.48 (-0.30).
- Cash flow from operations activities before changes in working capital totalled MSEK -2(-3).
- Cash flow from investing activities amounted to MSEK -31(-17).
- Cash flow for the period was MSEK -29 (343).
- Cash and cash equivalents at the end of the period totalled MSEK 376 (465).

January-December 2020

- Net sales amounted to MSEK 142 (72), equivalent to an increase of 98% on same period of 2019.
- Earnings before interest, taxes, depreciation and amortization (EBITDA) amounted to MSEK -14 (-13), equivalent to an EBITDA margin of -10% (-18%).
- Earnings before interest and taxes (EBIT) amounted to MSEK -21 (-17), equivalent to an EBIT margin of -15% (-24%).
- Net income for the period was MSEK -27(-16), and basic and diluted earnings per share were SEK -1.19 (-0.78).
- Cash flow from operating activities before changes in working capital totalled MSEK -8 (-10).
- Cash flow from investing activities amounted to MSEK -85 (-54).
- Cash flow for the period was MSEK -87 (305).

Significant events during the period

- Susanne Andersson was appointed as the new CFO, to take up duties during the first quarter of 2021. She succeeds Maria Engström, who chose to leave the position of CFO on her own initiative.
- The National Institute for Health and Care Excellence (NICE) in the United Kingdom issued a Medtech Innovation Briefing (MIB) on the use of AnaConDa as an alternative to intravenous sedation in intensive care.
- The Chairman of the Board contacted the three largest shareholders or shareholder groups in terms of voting power to invite each of them to appoint a representative to make up a nominations committee along with the Chairman of the Board.
- Sedana Medical was granted a further patent for the medical device AnaConDa. The technology that the patent protects enables a reduction of the so-called dead space with the help of inserts.
- An application for market approval was submitted for the drug candidate Sedaconda (isoflurane), previously known as IsoConDa, for inhaled sedation in intensive care. Applications were submitted to the German regulatory authority BfArM (Federal Institute for Drugs and Medical Devices) and a number of other European regulatory authorities under what is known as a DCP procedure.

- The results for some of the secondary endpoints in the company's study as a basis for registration, Sedaconda (SED-001, previously known as the IsoConDa study), were presented at the congress ESICM LIVES 2020, 6–9 December 2020.

Significant events after the period

- In January, an application was submitted for market approval for the drug candidate Sedaconda (isoflurane), previously known as IsoConDa, for inhaled sedation within intensive care in Switzerland.
- As a consequence of the resolution by the Annual General Meeting held on 19 May 2020 to implement a new 2020/2024 warrant programme with a maximum of 360,000 warrants for new employees, 37,113 have been transferred to employees. Surplus warrants will be cancelled. If all the warrants are exercised, dilution of around 0.2 percent will occur, based on the number of shares in the company at 31 December 2020.
- In February, an application was submitted for market approval for the drug candidate Sedaconda (isoflurane) for inhalation sedation within intensive care in the UK.
- In February, it was announced that the first patient was included in the company's pediatric study IsoCOMFORT (SED002). The study is expected to be completed during the second half of 2022 and is aimed at leading to an approved pediatric indication for inhaled sedation.
- The Board of Directors has decided to propose to the Annual General Meeting that the company implement a 4:1 split of shares, which means that the number of shares will be four times the present amount and become 92,186,960 shares.
- On February 24, the company announced that Christer Ahlberg has informed the board of directors of Sedana Medical that he is resigning as CEO to become CEO of Cinclus Pharma AB. Christer Ahlberg will remain as CEO until the summer of 2021 and the board has started a process to find a replacement.

CEO comments

2020 was, to say the least, an exceptional year, as a result of the COVID-19 pandemic, which posed great challenges. As far as Sedana Medical is concerned, I am proud that we succeeded in helping medical care in many places around the world in 2020. In addition, our therapy really had an opportunity to show how much it can offer, both to individual patients and to medical care as a whole.

The fourth quarter was notable for intensive work, firstly with activities ahead of the launch of Sedaconda in Europe during the second half of 2021 and secondly with preparations ahead of our future phase III studies in the United States.

The COVID-19 pandemic has a great impact on our entire business operation, as ICU sedation is precisely the therapy that severely ill COVID-19 patients often need. As our therapy potentially leads to fewer side effects and better oxygen uptake in the lungs, demand for AnaConDa and its accessories was strong during the year. An additional factor contributing to strong demand is that the therapy contributes to increased patient capacity in ICU, which has been important during the pandemic.

Sales showed strong increase in the quarter by as much as 129 percent (137% excluding currency effects), to SEK 46 million, and sales for the full year doubled to SEK 142 million. We interpret this as indicating that the initial sales pressure due to the pandemic has increased again as a result of a second wave with a rise in the number of COVID-19 patients in intensive care units, but also that the ICUs, including new ones, are continuing to use our therapy for patients other than those being treated for COVID-19. We are also seeing an increase in demand in new regions such as Central and South America as a consequence of their severe COVID-19 situation.

The results for some of the secondary endpoints in the phase III study forming the basis for clinical registration Sedaconda (SED-001) were presented at the ESICM congress in December. The secondary endpoints show that Sedaconda (isoflurane) enables faster and controlled recovery, reduced need for opiates and a higher proportion of spontaneous breathing compared with propofol. A high proportion of spontaneous breathing is important as it improves the prospects of lung function being maintained during and other ventilator therapy.

The Sedaconda study was designed as a non-inferiority study, which means that its primary purpose is to show that our therapy is not inferior to propofol in maintaining an adequate sedation level. Based specifically on the study design, the good results for the study's secondary endpoints were not something we had anticipated. We have

seen in previous studies that inhaled sedation has a faster and predictable recovery time, but it is highly positive to have this confirmed in a large, randomised study. Being able to reduce the use of opiates for these patients and make spontaneous breathing possible using the therapy is of great clinical significance. The full results of the study will be presented in a scientific journal in 2021.

The top-line results reported in July 2020 show that Sedaconda, delivered via AnaConDa, is an effective and safe method of sedation for mechanically ventilated intensive care patients comparable to propofol. The results will form the basis for the application for market approval for the drug candidate Sedaconda for inhaled sedation in intensive care units that we submitted in November to the German regulatory authority BfArM and a number of other European regulatory authorities under what is known as a DCP procedure.

The application marks the starting point for the review process for Sedaconda in 15 EU Member States, including Norway. If all goes well, we anticipate authorisation during the second half of 2021. An application for a second group of EU Member States can then be submitted. It normally takes around six months to obtain authorisation for a second group of countries.

When we obtain marketing authorisation for Sedaconda, we will be able to exclusively launch the inhaled sedation therapy in Europe. The therapy consists of our pharmaceutical product Sedaconda , which will then be authorised to only be administrated via our medical device AnaConDa. We chose Sedaconda as the name to highlight the link to Sedana Medical and the pharmaceutical product's unique use in sedation. At the same time, we communicate that the pharmaceutical product is to be delivered via AnaConDa by retaining CONDA in the name.

The European authorisation will provide very good support in future registration processes in other markets where we are working to make inhaled sedation a standard method within intensive care. After the end of the quarter, we submitted applications to Switzerland and the United Kingdom, which following Brexit works solely with national applications. Our work on the European study has taught us a lot that we benefit from in the design and execution of the American studies, for example.

Now that we are approaching commercialisation in Europe, our work has been focused on launching activities in Europe, while our work in the United States has also intensified, albeit on preparations ahead of the phase III studies. We are working towards being able to submit an IND (Investigational New Drug) application during the summer of 2021 to obtain authorisation to begin the studies. IND authorisation is conditional on the commenced toxicity studies being completed. It is therefore gratifying to be able to note that these studies have progressed at a good pace and according to plan. Depending on how the pandemic develops, we anticipate being able to obtain IND authorisation during the summer in order to be able to include the first patient in each study during the second half of 2021.

A further patent for AnaConDa was granted during the quarter. The technique protected by the patent enables what is known as dead space to be reduced, using inserts and is key to the continued development of inhaled sedation. A decrease in dead space for mechanically ventilated patients is always desirable for intensive care, as it makes lung-protective ventilation possible in comparison with higher dead space. As well as seeing great clinical benefits, we are greatly strengthening our patent protection with this patent. Any competitors or ordinary, passive HME filters will not be able to reduce their dead spacing using inserts without infringing our new patent. The patent has been granted in Europe, and we have also filed a patent application in the United States and other countries.

I would like to take the opportunity to thank all the employees for their great contribution during an intensive and challenging 2020. The fourth quarter has really laid the foundation for a very exciting 2021, with the launch in Europe and the first patients being included in our clinical trials in the United States.

I look forward to coming back to you during the year.

Christer Ahlberg, President and CEO

Please find the full interim report at: www.sedanamedical.com under Investors/annual & interim reports.

Sedana Medical will hold a telephone conference at 13:30 pm (CET) Thursday February 25, 2021.
To participate, please dial: +46 8 505 583 66

For additional log in information:
https://financialhearings.com/event/13490
https://tv.streamfabriken.com/sedana-medical-q4-2020

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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 February 25, 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.