

Press release March 5, 2020, 07:00 CET.

Sedana Medical AB (publ), Year-end report, 2019

Another strong quarter with increased sales growth

Financial Summary October-December

- Net sales during the fourth quarter amounted to 20 056 (15 242) KSEK corresponding to an increase of 32% compared with the same period in 2018.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to -3 979 (-1 474) KSEK. This corresponds to an EBITDA margin of -20% (-10%).
- Earnings before interest and taxes (EBIT) amounted to -5 038 (-2 450) KSEK which corresponds to an EBIT margin of -25% (-16%).
- Cash flow from operations before changes in working capital amounted to -3 234 (-1 250) KSEK.
- Cash flow from investment activities amounted to -17 303 (-7 431) KSEK.
- Cash flow for the period amounted to 342 597 (-15 787) KSEK.
- Liquid funds at the end of the period amounted to 464 560 (159 351) KSEK.

Financial Summary January-December

- Net sales during the full year increased to 71 646 (57 896) KSEK corresponding to an increase of 24% compared with same period in 2018.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to -12 979 (-4 232) KSEK. This corresponds to an EBITDA margin of -18% (-7%).
- Earnings before interest and taxes (EBIT) amounted to -17 167 (-8 238) KSEK, which corresponds to an EBIT margin of -24% (-14%).
- Cash flow from operations before changes in working capital amounted to -11 074 (-2 761) KSEK.
- Cash flow from investment activities amounted to -54 132 (-29 127) KSEK.
- Cash flow for the period amounted to 305 212 (73 869) KSEK.

Significant events during the period

- Sedana Medical completed a private placement of 2 896 000 shares. The subscription price for the shares in the private placement was SEK 129.50 per share. Through the targeted new issue, which was several times oversubscribed, Sedana Medical received SEK 375 million before transaction costs. Investors in the new share issue consisted of a number of Swedish and international institutional investors, including AXA IM, Handelsbanken fonder, Joh. Berenberg Gossler & Co. KG (Berenberg), Swedbank Robur, Third AP fund and Öhman funds.
- Sedana Medical will sponsor two major investigator-initiated studies with AnaConDa in France during 2020-2023. One of the studies the company sponsors is the world's largest multicenter study with AnaConDa, SESAR. Sedana Medical will supply the investigators with AnaConDa and accessories. The primary purpose of the study is to demonstrate that inhalation sedation with AnaConDa has lung-protective functions, shortens ventilator time and has higher survival in severely pulmonary intensive care patients.

Sedana Medical also supports INASED, a large French multicenter study with isoflurane – the substance in the company's drug candidate IsoConDa – delivered with the company's medical device AnaConDa. The aim is mainly to show a reduced incidence of delirium in mechanically ventilated intensive care patients compared to intravenous sedation with propofol.

- Sedana Medical no longer communicates profit targets for the period leading up to the registration of IsoConDa in Europe and clarifies that the sales target of SEK 500 million three years after the European registration only applies to Europe. Sales outside Europe will be added in addition to this target.
- Sedana Medical AB (publ)'s Board Member Michael Ryan decided to resign on November 12, 2019. The Nomination Committee of Sedana Medical will begin work to find a successor.

Significant events after the period

- In January, the last patient was included in the pivotal IsoConDa-study. Thus, all 300 patients have been included in the European study which is expected to show "top-line" results during Q2 2020.
- Sedana Medical's CEO Christer Ahlberg sold 30 000 shares in the company and entered a 12 months lock-up agreement for his remaining 200 000 shares. He thereby remains as a committed long-term owner.

- Sedana Medical obtained market approval for AnaConDa in Mexico during January. The company's Mexican distributor Goba will begin sales work in the next few months and in parallel Sedana Medical will evaluate the possibility of registering the drug IsoConDa. Goba will also work for a registration of AnaConDa in Colombia.
- Sedana Medical established its own direct sales organization in Benelux.
- Sedana Medical donates AnaConDa and accessories to two hospitals in Wuhan and Zhejiang, China, for anti-epidemic use and evaluation of the effects of inhalation sedation with AnaConDa on severely ill Corona virus affected patients.

CEO comments

Based on our future scenario and our priorities, the fourth quarter is our strongest ever. We build quickly according to plan to meet our long-term goals. During the quarter we announced that we are sponsoring two large studies that, if successful, will be able to generate a paradigm shift in sedation in intensive care. In addition, during the quarter we succeeded in securing funding for the work to obtain market approval for our therapy in the US. Finally, after the end of the quarter, we have passed an important milestone by completing recruitment for our pivotal IsoConDa study. Overall, I am really proud that the entire organization delivers and continues to build a solid foundation for our continued journey.

When it comes to our commercial activities, it was gratifying to see our strong sales figures. Growth was 32 percent in the quarter. Germany remains the natural growth locomotive, but sales have also increased steadily in many other European direct sales markets, such as France and the UK. All in all, we meet the goals we have communicated and deliver well on our ambition to grow 20 percent per year before the registration of IsoConDa in Europe. After the end of the quarter, we announced that we are also opening up direct sales in Benelux by hiring sales personnel.

The co-financing of the two large multicenter studies SESAR and INASED is really gratifying. As a company, having the opportunity to contribute to medical development in this way is really a benefit. The studies are done partly to show that inhalation sedation with AnaConDa has lung protective properties (SESAR) with increased survival as a result and partly to show a reduced incidence of delirium (INASED) which is a major problem in intensive care. Positive results would significantly strengthen our clinical base and the studies have each separately the potential to dramatically change the perception of inhalation sedation in relation to intravenous sedation.

Through this type of study we gather evidence that, if positive, can be the basis for a paradigm shift in intensive care. These investigator-initiated studies are not only an important support in our continued regulatory and commercial expansion, but also provide a clue as to the great potential of our therapy. Our own studies will also provide greater evidence that is not only a prerequisite for regulatory approval, but which will also be of great commercial use.

The quarter was largely characterized by securing US registration. The money from the targeted new share issue that closed in the quarter - SEK 375 million before costs - will primarily be used to finance the way to a market approval of AnaConDa and IsoConDa in the USA. That we succeeded in raising so much money I see as a sign of strength and I want to take this opportunity to thank you for the trust given to us by both old and new owners.

After meeting with the US Medicines Agency, the FDA, we have a good picture of what we have to deliver to obtain market approval in the US. The combination registration of AnaConDa and IsoConDa includes activities such as two clinical studies involving a total of approximately 500 patients, human factors validation, toxicity studies, safety database, adaptation of the European pediatric study to the FDA's requirements and application for market approval (NDA). Work has intensified during the quarter and is proceeding according to plan. In 2022, we will decide how to commercialize the therapy; alone or together with a partner.

We achieved a major and important milestone shortly after the end of the quarter when we were able to announce that the last patient has been included in our pivotal IsoConDa study. The study with 300 patients has been conducted at more than twenty centers in Germany and Slovenia. To begin with, it is of course extremely gratifying that we keep the schedule in the world's largest study of inhalation sedation in intensive care. But above all, the study is crucial in order to move forward with our European application for market approval.

We are expecting to present "top-line" results in the second quarter 2020. This will enable the submission of an application for European market approval in 16 European countries in a first registration round in the third quarter of 2020. If everything goes according to plan, we expect an approval in the second half of 2021.

In order to carry out a complete application for marketing authorization, an approved pediatric study plan is also needed, which we received already in early 2019. The work to start the pediatric study, Iso-COMFORT, in 2020 began during the quarter. The outcome of the pediatric study is not a requirement for obtaining approval for use in adults, so the schedule for market approval of IsoConDa is not influenced by the Iso-COMFORT study.

To sum up, we are summarizing another strong quarter and I look forward to the continued journey together with you all.

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 09:00 am (CET) Thursday March 5, 2020.

To participate, please dial: +46 850 558 358

Or join us at: <https://tv.streamfabriken.com/sedana-medical-q4-2019>

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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 March 5, 2020 at 07:00 (CET).

Sedana Medical AB (publ) has developed and sells the medical device AnaConDa, for the administration of volatile anaesthetics to mechanically ventilated patients. A major clinical registration study is currently ongoing to obtain market approval in Europe for inhalation sedation in intensive care units with the pharmaceutical IsoConDa® (isoflurane).

Sedana Medical has direct sales in Benelux, France, Nordics, Germany, Spain and Great Britain as well as external distributors in the rest of Europe, Australia, Japan, Canada, Mexico and South Korea. The company headquarters are based in Stockholm, Sweden with R&D operations in Ireland.