

Press release March 27, 2018

Sedana Medical AB (publ), Year-End report 2017

Strong sales growth and increased interest in AnaConDa and inhalation sedation

Financial summary October–December

- Net sales during the fourth quarter amounted to 10,795 (8,872) KSEK, corresponding to an increase of 22 % compared with the same period in 2016.
- Earnings before interest, taxes, depreciation and amortization (EBITDA) amounted to -838 (937) KSEK. This corresponds to an EBITDA margin of -7.8 % (10.6 %).
- Earnings before interest and taxes (EBIT) amounted to -1,912 (832) KSEK, which corresponds to an EBIT margin of -17.7 % (9.4 %).
- Cash flow from operations before changes in working capital amounted to -960 (1,109) KSEK.
- Liquid funds at the end of the period amounted to 85,322 (8,296) KSEK.

Significant events during October–December

- Senior Consultant and Associate Professor Peter Sackey was recruited as Chief Medical Officer (CMO).
- All remaining outstanding warrants in the incentive programme 2017/2021, which was initiated in conjunction with the IPO, were acquired by incoming Chief Medical Officer Peter Sackey.
- The company appointed Erik Penser Bank as a new Certified Adviser.
- Sedana Medical's distributor in Japan applied for registration of the medical device AnaConDa on November 23.
- Sedana Medical's nomination committee was appointed.
- In December, our sales organization in France was strengthened by the addition of two Key Account Managers to meet demand and further develop the market.

Financial summary January–December

- Net sales during the year amounted to 40,428 (32,155) KSEK, which corresponds to an increase of 26 % compared with the same period in 2016.
- Earnings before interest, taxes, depreciation and amortization (EBITDA) amounted to -736 (994) KSEK. This corresponds to an EBITDA margin of -1.8 % (3.1 %).
- Earnings before interest and taxes (EBIT) amounted to -3,488 (618) KSEK, which corresponds to an EBIT margin of -8.6 % (1.9 %).
- Cash flow from operations before changes in working capital amounted to -4,232 (186) KSEK.

Significant events after the end of the financial year

- Peter Sackey took office as a medical director on January 8, 2018.
- Sedana Medical AB (publ) opened its own sales operations in Norway and Denmark.

CEO comments

The final quarter of the year and 2017 is now complete. We are pleased with our efforts. We have been working to develop our sales and marketing efforts in Europe while continuing our registration strategy, especially in Europe, but also in the USA and Asia. All of this is done to strengthen our leading role in inhalation sedation.

Our vision of developing inhalation sedation with IsoConDa and AnaConDa as a global standard method for sedation of mechanically ventilated patients in intensive care remains firm. We live up to our previously expressed financial ambition of achieving an average annual increase in sales of more than 20 %, and an EBITDA figure that is not significantly negative in the time prior to the registration of IsoConDa in Europe. At the same time, we are building up a larger sales and marketing organization. It is our ambition to reach annual sales in excess of 500 MSEK and have an EBITDA margin of around 40 % three years after the registration of IsoConDa in Europe.

The fourth quarter shows sale growth of 22 % and on a full-year basis we will reach a 26 % growth rate compared with 2016. This growth clearly shows that we offer a therapy that truly generates added medical value. In line with our plans, the operational costs increase as we develop the organization and increase our market presence. This generates an EBITDA for the fourth quarter of -838 KSEK and for the full-year 2017 of -736 KSEK.

SALES DEVELOPMENTS

Sales during the last quarter of the year continue to increase and is in line with our targets. The German market goes from strength to strength. New clinics are added every month and sales to existing clinics are increasing continuously. Almost 500 clinics in Germany now use AnaConDa regularly at approximately 400 hospitals and interest is increasing. Recently, a symposium on the theme of inhalation sedation was held at an intensive care congress in Bremen, Germany. There was a great interest in our symposium and the number of visitors was more than ever. Even in France, demand from more interested clinics grows. During the quarter, we have strengthened our French sales organization with another 2 key account managers.

REGULATORY AND MEDICAL DEVELOPMENTS

The most important task for the next two years is to register the inhalation sedation with our drug candidate IsoConDa (isoflurane) in Europe. We are working intensively with the clinical registration study currently in progress in Germany.

Performing clinical studies in intensive care is challenging and requires much energy from both sponsors and investigators. However, I believe we are able to cope with these challenges in a good and satisfactory way. Recruitment of patients and clinics is ongoing and we expect to do an interim analysis in the late summer of 2018 in order to determine how many patients need to participate in the study. In parallel with this registration study, preparations are in place to have the registration application complete and ready for the day that the analysis of the study is finished.

Work on preparing for a US registration of both pharmaceuticals and medical devices is ongoing, and we are confident that the plan for how we are to register the therapy in the US will be completed in 2018.

In Asia, our Japanese distributor applied for registration of AnaConDa in November. Our strategy, as in Europe, is to start by registering AnaConDa to establish ourselves in Japan and then evaluate the possibilities for taking the next step. We are also looking into opportunities in China.

In conclusion, I am pleased with our efforts in the fourth quarter and the whole of 2017. We are well on course to achieving our high ambitions, both in terms of our goals for registration and growth. 2017 has demonstrated that Sedana Medical is well placed to pioneer the process of offering the first commercial solution for inhalation sedation within intensive care, a market with a sales potential of SEK 10-20 billion annually.

Christer Ahlberg, President and CEO

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*Sedana Medical is listed on Nasdaq First North in Stockholm
and Erik Penser Bank (+46 8 463 83 00) is certified adviser to Sedana Medical.*

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 27 March 2018 at 07.00 AM (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 the Nordic countries, Germany, France and Spain as well as external distributors in the rest of Europe, Middle East, Canada, Australia and South Korea. The company headquarters are based in Stockholm, Sweden with R&D operations in Ireland.