Press release August 22, 2019, 07:00 CET.

# Sedana Medical AB (publ), Interim report Q2, 2019

## Strategic partnership in Asia and continued strong growth

### Financial summary, April - June

- Net sales during the second quarter amounted to KSEK 17,359 (14,485) corresponding to an increase of 20% compared with the same period in 2018.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to KSEK -2,330 (-1,006) KSEK. This corresponds to an EBITDA margin of -13% (-7%).
- Earnings before interest and taxes (EBIT) amounted to KSEK -3,377 (-2,007), which corresponds to an EBIT margin of -19% (-14%).
- Cash flow from operations before changes in working capital amounted to KSEK -2,094 (-389).
- Cash flow from investment activities amounted to KSEK -13,415 (-8,812).
- Cash flow for the period amounted KSEK -12,576 (102,325).
- Liquid funds at the end of the period amounted to KSEK 137,317 (181,591).

### Financial Summary, January- June

- Net sales during the second quarter amounted to KSEK 35,173 (29,972) corresponding to an increase of 17% compared with the same period in 2018.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to KSEK -4,972 (-1,794) KSEK. This corresponds to an EBITDA margin of -14% (-6,0%).
- Earnings before interest and taxes (EBIT) amounted to KSEK -7,037 (-3,737), which corresponds to an EBIT margin of -20% (-13%).
- Cash flow from operations before changes in working capital amounted to KSEK -3,928 (-1,210).
- Cash flow from investment activities amounted to KSEK -24,096 (-13,194).
- Cash flow for the period amounted KSEK -22,136 (96,046).

### Significant events during the period

- During the pre-IND meeting the US Food and Drug Administration (FDA) was positive about the combination registration of IsoConDa and AnaConDa in the US. Sedana Medical now has a clear view of measures that must be taken in order to reach marketing authorization approval of both IsoConDa and AnaConDa in the US. The meeting also confirmed Sedana Medical's estimate of the time and cost of a US approval that is expected to occur in 2024.
- First patient in Japan was treated with AnaConDa and IsoConDa registration work in Japan was initiated.
- Sedana Medical AB (publ) entered into a 10-year exclusive distribution agreement with the Chinese distributor Kyuan Xinhai Medical, a subsidiary of partly state-owned Shanghai Pharma, the second largest life science company in China. Kyuan will immediately commence the fast-track registration of AnaConDa in China and estimates approval will be obtained in less than two years. The Chinese market potential for sedation in intensive care is estimated to be five to six million ventilation days annually.
- At the Annual General Meeting on May 28, 2019, it was resolved to introduce a new stock option program for employees in the Sedana Medical Group.

## Significant events after the period

- Sedana Medical AB (publ) entered into a distribution agreement with the Indian distributor Hansraj Nayyar Medical. Sales will commence in the fall and a registration process will start in parallel. Hansraj Nayyar has committed to a first framework order of 25,000 euros. The Indian market potential for sedation in intensive care is estimated to be around two million ventilation days annually.

## CEO comments

The second quarter was characterized by continued commercial growth and following up our successes from the first quarter, which, from a clinical perspective, was our strongest ever. This applies partly to the positive interim analysis for the IsoConDa study and the approval of our planned pediatric study and partly to our planned US registration. During the quarter we also made great progress in Asia. In terms of sales, the second quarter was a good quarter. We reached the company's second highest sales ever with growth by 20% in the quarter and our best half year ever.

As far as the IsoConDa study is concerned, the work is going according to plan. To ensure that we reach our goal of including the last patient in the study around the turn of the year 2019/2020, we have added three new sites in Slovenia where our therapy is already well used. The sites will be initiated in August. We expect to submit an application for a market approval for IsoConDa (isoflurane) in the summer of 2020 in 16 European countries in a first registration round. If all goes well, we can have a European market approval during the second half of 2021. During the quarter, we also worked hard to prepare the pediatric study that will begin in 2020. Our plan is for the study to include sites in 4 European countries.

Within the company, we are now increasing the pace and developing our sales and marketing department to prepare for the launch of IsoConDa. In the largest European countries, we develop our own sales organizations, while in the markets we do not work with direct sales we create a well-developed distributor organization.

At our pre-IND meeting in March, the FDA was positive about the registration of IsoConDa and AnaConDa as a combination product in the United States. We got a clear view and understanding on the way forward in the US and this quarter we have moved on with our work. We have already recruited a director of clinical development for the US who will be based in Stockholm. We also intend to set up a company in the US to be able to carry out the work on the management of studies, registration and market access. In close cooperation with relevant consultants and US key opinion leaders, we have begun the quarter to prepare the studies that the FDA requires. The plan is to reach US approval in 2024 and around 2022 we will decide whether to launch ourselves or together with a local partner.

During the spring, we updated our estimate of the total market potential for inhaled sedation in intensive care to SEK 20-30 billion annually. Europe and the US are two important markets for us. However, the patients sedated due to intensive care mechanical ventilation are globally evenly distributed between the US, Europe and Asia, and we are therefore very pleased with the progress we made in Asia during the quarter.

In Japan, the first patient was treated at the University Hospital in Shiga during the quarter, and in addition, AnaConDa treatment is evaluated by the ethics committees at further five university hospitals. AnaConDa has been market approved in Japan since November 2018 but IsoConDa is not yet approved for sedation and therefore the treatment must initially be approved by ethical committees at each hospital. Work on investigating how to register IsoConDa in Japan began during the quarter.

In China, we entered into a 10-years exclusive distribution agreement with Chinese distributor Kyuan Xinhai Medical, a subsidiary of China's second largest life-science company, the partially state-owned Shanghai Pharma, during the quarter. Kyuan is launching a so-called "fast-track", for registration work by AnaConDa in China and expects approval to be obtained within less than two years.

During the quarter, we also presented this year's Sedana Medical Research Foundation fellows. Due to the large medical possibilities with volatile anesthetics, the interest in research in inhalation sedation is generally very large and we received several good applications. This year's winners are three particularly interesting research projects in Italy, France and Switzerland, each of which will in its own way take the therapy forward both scientifically and geographically. We are continuously working close to the academy to find more interesting projects in order to highlight the benefits of therapy compared to intravenous treatment.

In summary, we summarize a good quarter that takes us closer to our goals; to register IsoConDa in Europe 2021, market approval in the US 2024 and to establish us in the major markets in Asia. The goals are a first step towards our vision of making inhalation sedation with AnaConDa and IsoConDa a standard treatment for mechanically ventilated patients in intensive care worldwide. I look forward to continuing 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 13:30 am (CET) Thursday August 22, 2019.
To participate, please dial: +46 8 566 42 705
Or join us at: https://tv.streamfabriken.com/sedana-medical-q2-2019

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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 August 22, 2019 at 7:00 a.m. (CET).*

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**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, Great Britain and Spain as well as external distributors in the rest of Europe, Canada, Australia, Japan and South Korea. The company headquarters are based in Stockholm, Sweden with R&D operations in Ireland.