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Sedana Medical AB (publ), interim report Q2, 2020

All time high sales and positive study result

Financial Summary April-June

- Net sales during the quarter amounted to KSEK 40 509 (17 359) corresponding to an increase of 133% compared with the same period in 2019.
- Earnings before interest, taxes, depreciation and amortization (EBITDA) amounted to KSEK -777 (-2 330). This corresponds to an EBITDA margin of -1,9% (-13,4%).
- Earnings before interest and taxes (EBIT) amounted to KSEK -1 917 (-3 377) which corresponds to an EBIT margin of -4,7% (-19,5%).
- Net income for the period was KSEK -3 595 (-1 723) and earnings per share before and after dilution was SEK -0,16.
- Cash flow from operations before changes in working capital amounted to KSEK 730 (-2 094).
- Cash flow from investment activities amounted to KSEK -17 710 (-13 415).
- Cash flow for the period amounted to KSEK -7 988 (-12 576).
- Liquid funds at the end of the period amounted to KSEK 433 537 (137 317).

Financial Summary January-June

- Net sales for the period amounted to KSEK 74 341 (35 173) corresponding to an increase of 111% compared with the same period in 2019.
- Earnings before interest, taxes, depreciation and amortization (EBITDA) amounted to KSEK 427 (-4 972). This corresponds to an EBITDA margin of 0,6% (-14,1%).
- Earnings before interest and taxes (EBIT) amounted to KSEK -1 835 (-7 037) corresponding to an EBIT margin of -2,5% (-20,0%).
- Net income for the period was KSEK -1 894 (-4 694) and earnings per share before and after dilution was SEK -0,08.
- Cash flow from operations before changes in working capital amounted to KSEK 891 (-3 928).
- Cash flow from investment activities amounted to KSEK -31 953 (-24 096).
- Cash flow for the period amounted to KSEK -30 688 (-22 136).

Significant events during the period

- In the beginning of April, the company announced a sales increase for the first quarter of 2020 that was significantly higher than expected. Sales for the first quarter of 2020 was SEK 34 million, which corresponds to a growth of around 90 percent compared to the same period last year.

- Sedana Medical announced in the beginning of May that the company will support a multinational study of inhaled sedation in covid-19-related ARDS. The study is conducted in intensive care units in several European countries. The study will be led by associate professor Matthieu Jabaudon from Clermont-Ferrand, France who also leads the SESAR study. The national coordinators are professor Jean-Michel Constantin, Paris (France), associate professor Tobias Becher, Kiel (Germany), professor Rafael Badenes, Valencia (Spain), associate professor Martin Schläpfer and professor Beatrice Beck-Schimmer, Zürich (Switzerland).

- In May, the first patient was enrolled in SESAR, a study comparing inhaled sedation and intravenous sedation for patients with Acute Respiratory Distress Syndrome, ARDS. The study is conducted in France and Sedana Medical contributes with financial support and study material.

- At the annual general meeting of Sedana Medical, all proposals from the Board and the Nomination Committee were approved. Until the next annual general meeting, all current board members were re-elected and Christoffer Rosenblad was newly elected. The general meeting resolved to elect Öhrlings PricewaterhouseCoopers AB as new auditor for the period until the end of the next annual general meeting, with the chartered accountant Leonard Daun as principal auditor.

- All warrants in the company's incentive program 2017/21 have been exercised by the warrant holders, leading to an increase in the number of shares and votes in the company by 310 149. Accordingly, the share capital was increased by

SEK 31 015. Through the exercise of the warrants, Sedana Medical's CEO, CFO and CMO have increased their ownership in the company.

- Sedana Medical announced in June that the company has signed agreements with distributors in Bulgaria, Cyprus, Greece, Slovakia and the Czech Republic. By expanding in Eastern Europe, the company wants to strengthen its position ahead of the upcoming market launch of its therapy.

Significant events after the period

- On July 1, the company announced that it had received market approval in Saudi Arabia for its medical device AnaConDa, and that distribution agreements had been concluded with distributors in Saudi Arabia, the United Arab Emirates and Oman. Sales are expected to begin shortly in Saudi Arabia and within a few months in the other countries.

- On July 10, Sedana Medical announced top line result for the company's registration-based phase 3 study for the drug IsoConDa. The study reached its primary endpoint; to show that IsoConDa (isoflurane), administered with AnaConDa, is an effective sedation method, for ventilator-intensive care patients, which is non-inferior to propofol. Secondary endpoints are under analysis and will be published together with the primary endpoint in a scientific journal after peer-review. The results indicate that IsoConDa is an effective and safe sedation method and will form the basis for the company's application for European market approval later during 2020.

- On August 19, the company announced that it has signed a distribution agreement for sales in Australia and New Zealand with the distributor Device Technologies. As the AnaConDa already has market approval in both markets, sales can start immediately.

Outlook 2020 – covid-19

Sedana Medical has after the end of the second quarter, compared with the period March-May, seen a normalized but continued positive sales development as a result of the covid-19 pandemic.

In comparison with the situation before the covid-19 pandemic, the company sees a higher growth. Several intensive care clinics have prepared for the pandemic through material procurement and training, mainly for the treatment of covid-19-related ARDS. Of the increase in growth, about 40% comes from new intensive care clinics having started using inhaled sedation and 60% from existing customers increasing their use. The rate of sales growth decreased at the end of the quarter compared with the beginning. This coincides with a slowdown in the spread of covid-19 in Europe in particular, where Sedana Medical has its main sales.

For the full year 2020, Sedana Medical cannot make an assessment of the sales development due to the uncertainties that follow from the covid-19 pandemic. These uncertainties range from hospitals' and clinics' propensity and ability to use new sedation methods during a crisis to a possible shortage or reduced availability of intravenous sedation drugs in the event of a second wave of covid-19 pandemic.

CEO comments

Positive top line results
– a milestone on the road to our vision

Operations during the second quarter continued to be characterized by the covid-19 pandemic but also by intensive work ahead of our upcoming US expansion. First, however, I would like to address the most important milestone in many years that occurred shortly after the end of the quarter when we announced positive top line results in our pivotal phase 3 study SED-001. The study is the single largest progress in the area of inhaled sedation since AnaConDa was developed and we are extremely proud to have conducted the world's largest study of inhalation sedation in intensive care.

The goal when we initiated the work with the study several years ago was to be able to register inhaled sedation with IsoConDa (isoflurane), administered with AnaConDa, in Europe in order to approach our vision to make inhaled sedation a new global standard method in intensive care. Through the positive top line results, we have come a long way towards our vision. The study reached its primary end point; to show that IsoConDa administered with AnaConDa is an effective sedation method for ventilator-intensive care patients that is not inferior to today's intravenous standard sedation with propofol.

The strong top line results confirm the clinical experience of physicians worldwide and the strong study results will form the basis for the application for European market approval that we will submit as soon as possible during the fourth quarter of this year. In a first registration round, the application will cover 16 European countries and if all goes well, we expect approval in the second half of 2021. A market approval in Europe can also open the door to several other markets and we are currently investigating exactly which markets that quickly can open up based on a European registration.

The secondary objectives in the SED-001 study are currently being analyzed and will be presented together with the primary objectives in a scientific journal at the beginning of next year. Of course, we have high hopes also regarding the secondary results, but the strong top line results are sufficient as a basis for our application for market approval.

The SED-001 study is designed as a non-inferiority study, which means that its primary purpose is to show that our therapy is not worse than propofol in maintaining an adequate sedation level. The secondary goals of the study include time to wake up, proportion of time with spontaneous breathing, need for painkillers, ICU- and ventilator-free days and organ function over time. If these goals succeed in showing good results, it is of course a bonus, but nothing that we count on due to the study design. In that respect, we have higher hopes for the large investigator-initiated studies that we support; SESAR, INASED and ISCA.

These studies are done partly to show that inhaled sedation with AnaConDa has lung protective properties (SESAR) with increased survival as a result and partly to show a reduced incidence of delirium (INASED) and improved cognitive recovery after sedation which is a major problem in intensive care. Positive results would significantly strengthen our clinical base and each of the studies have the potential to dramatically change the view of inhaled sedation in relation to intravenous sedation. Through this type of study, we gather evidence which, if it is positive, together with already published evidence, can form the basis for a paradigm shift in intensive care. The studies are an important support in our continued regulatory and commercial expansion and provide an indication of the great potential of our therapy.

The same applies to the ISCA study, Inhaled Sedation in Covid-19-related Acute Respiratory Distress Syndrome, which was initiated in the quarter and is performed on at least 400 patients in about 30 intensive care units in France, Germany, Spain and Switzerland. The outcome for covid-19-ARDS patients receiving inhaled sedation is compared with the outcome for the same type of patients receiving intravenous sedation. Inhaled sedation is promising for this patient group as the treatment has anti-inflammatory effects and beneficial pharmacokinetics in patients with ARDS and multiple organ failure.

The covid-19 pandemic has not only affected the type of studies we choose to support but has also continued to strongly influence our entire business since ICU sedation is exactly the treatment that severe covid-19 ill patients need. In addition, our treatment can increase patient flow at ICU, which is important when access to ICU beds is limited.

Sales in the quarter were SEK 41 million, an increase of 133 percent compared with the same period last year. It is both completely new clinics that have been added as customers and current customers that have increased their use. The increase for the first half of the year consists of approximately 40% concerning new customers and 60% concerning existing customers. The EBITDA result was SEK -0,8 million and the gross margin was 67 percent, compared with 77 percent in the same period last year. The slightly lower gross margin is largely an effect of the fact that we sold a lot of gas monitors in the second quarter and that we have had higher costs for transportation due to the covid-19 situation. The gas monitors have lower gross margin. However, it is very promising for the future that more and more clinics will invest in more gas monitors used in connection with inhaled sedation.

Our commercial expansion has undeniably received an extra boost from the pandemic. In these times of crisis, it is obvious that a not yet achieved market approval has not played as big a role as usual and once we get a market approval, we will get it from a higher base than would have been the case without covid-19.

The pandemic has led to us receiving of a large number of inquiries about clinical studies, retrospective data collection and other studies to further clarify the benefits of inhaled sedation. It is, of course, extremely gratifying at the same time as it takes up some administrative resources. The ISCA study is one of the studies we, during the quarter, have decided to support, and we try to prioritize wisely between all the proposals that come to us.

There is great interest in our treatment even in the markets that we ourselves do not cover. During the quarter, we signed sales agreements with distributors in the Middle East and Eastern Europe. Through the expansion of our distributor network, we are strengthening our position ahead of the upcoming market launch of our therapy. On July 1, we also received market approval for AnaConDa in Saudi Arabia.

For Europe, our focus now is on submitting the registration documentation to the authorities during the fourth quarter, preparations for the commercialization and launch of our therapy and continued product development. Our clinical development focus will move from Europe to the USA in the coming years. Preparations for next year's American phase 3 studies have been intensive during the quarter and we are rapidly approaching the start of our studies. To confirm and ensure efficacy and safety, two clinical, randomized and blinded studies of a total of 300 - 550 patients will be performed. The number of patients needed for both studies together is the same as we initially had as a requirement in the European study. Because the FDA imposed different requirements on the phase 3 studies than the SED-001 study, the SED-001 study could not constitute one of the two clinical studies required by the FDA. The SED-001 study, on the other hand, is of course supportive of our application and is also used in the safety database of in total 500 isoflurane patients, which is one of the FDA's requirements.

Part of the preparations for the clinical studies are the toxicity studies that are currently underway and where we are breaking new ground week by week. The studies are progressing at a good pace and according to plan, but it has been a

challenge to be the first company ever to carry out this type of long-term sedation. A large part of the work has been put on pure methodological issues in this full-scale tox program.

During the winter and spring of 2021, the plan is to start hiring staff in the United States. We are working to be able to submit an IND application during the first quarter of 2021 and to include the first patient in the clinical studies during next year. Right now, we are in the final stages of choosing CRO companies and the development of protocols and the plan is to have about 40 American centers in the studies. In the US, we are working for a combination registration, which means enhanced competition protection. We are pleased that the financing for our US work was secured through the directed new issue that was carried out in the autumn of 2019. The goal is to reach a US registration in 2024 and in 2022 we will decide on our commercialization strategy for the US.

All in all, we are adding another extremely intensive but successful quarter behind us. The pandemic has undeniably accelerated interest in our treatment, despite the fact that the pandemic itself thankfully seems to be slowing down in many countries, which means a return to normal conditions in the intensive care units around the world. I look forward to coming back to you.

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) Tuesday August 25, 2020.
To participate, please dial: +46 8 566 42 693
Or join us at: https://tv.streamfabriken.com/sedana-medical-q2-2020

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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 25, 2020 at 07:00 am (CET).

About Sedana Medical

Sedana Medical AB (publ) has developed and sells the medical device AnaConDa for the administration of volatile anaesthetics. Through a combination of AnaConDa and the candidate drug IsoConDa (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated intensive care patients. The company is working to obtain market approval in Europe for inhaled sedation in intensive care with the pharmaceutical IsoConDa® (isoflurane) during 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. Based on an estimate of seven to eight million patients being sedated in intensive care due to mechanical ventilation globally, on average three to four days, Sedana Medical estimates the total market potential to SEK 20-30 billion, evenly distributed between the US, Europe and Asia. Three years after market 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 a process to obtain market approval in the US in 2024. Registration activities have also been initiated in other markets outside the EU.

Sedana Medical has direct sales in the Nordic countries, Germany, Benelux, France, Great Britain and Spain as well as external distributors in parts of the rest 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.