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Sedana Medical AB (publ), Second Quarter Report 2021

European approval of Sedaconda

Second quarter 2021

- Net sales totalled MSEK 40 (41), equivalent to a decrease of 2 percent compared to the second quarter of 2020. At constant exchange rates, sales increased by 3%. In May and June, we saw a slowdown in the third wave of the pandemic in Europe, while it is increasing in Latin America and other regions in our distributor markets.
- Gross profit was MSEK 26 (26), equivalent to a margin of 66% (64%). The improved margin is mainly an effect of lower transport costs during the quarter as a larger share of freight was carried by sea rather than by air.
- In connection with the transition to a function-based income statement, costs have been redistributed to cost of goods sold, which has reduced gross margin by approximately 3 percentage points. These costs consist of depreciation and costs related to logistics. With increased sales and economies of scale, the effect of these costs on gross margin will diminish.
- EBITDA totalled MSEK -14 (0), equivalent to an EBITDA margin of -36% (-1%). Also the second quarter was notable for preparations for our European launch of Sedaconda (isoflurane), which has impacted profit by approximately SEK -5 million in non-recurring launch costs.
- Earnings before interest and taxes (EBIT) totalled MSEK -16 (-2), equivalent to an EBIT margin of -41% (-5%).
- Net profit for the quarter was MSEK -17 (4), and earnings per share before/after dilution were SEK -0.19 (-0.04).
- Cash flow from operating activities totalled MSEK -12 (2).
- Cash flow from investing activities totalled MSEK -23 (-18).
- Total cash flow for the quarter amounted to MSEK -36 (-8).
- Cash and cash equivalents at the end of the quarter amounted to MSEK 308, compared to MSEK 344 at the start of the year.

January-June 2021

- Net sales for the interim period totalled MSEK 85 (74), equivalent to an increase of 14%. At constant exchange rates, net sales increased by 20%.
- Gross profit was MSEK 55 (49), equivalent to a margin of 65% (65%).
- In connection with the transition to a function-based income statement, costs have been redistributed to cost of goods sold, which has reduced gross margin by approximately 3 percentage points. These costs consist of depreciation and costs related to logistics. With increased sales and economies of scale, the effect of these costs on gross margin will diminish.
- EBITDA totalled MSEK -23 (1), equivalent to an EBITDA margin of -27% (2%).
- Earnings before interest and taxes (EBIT) totalled MSEK -27 (2), equivalent to an EBIT margin of -32% (-2%).
- Net profit for the interim period was MSEK -26 (-2), and earnings per share before/after dilution were SEK -0.28 (-0.02).
- Cash flow from operating activities totalled MSEK -25 (-6).
- Cash flow from investing activities totalled MSEK -44 (-32).
- Total cash flow for the interim period amounted to MSEK -69 (-31).
- Cash and cash equivalents at the end of the interim period amounted to MSEK 308, compared to MSEK 376 at the start of the year.

CEO Comments

At the end of July, an important milestone was reached with the gratifying news that we received - earlier than expected - DCP approval for the pharmaceutical product Sedaconda (isoflurane), as well as the treatment inhaled sedation. As a result, we are now seeking national approvals to launch the inhaled sedation therapy in 15 European countries. These national processes are expected to take about 1-3 months. Further encouraging news was announced on 13 August when Sedaconda[1] received its first national approval, from the French medicines agency ANSM.

Sales in the quarter totalled SEK 40 million, an increase of about 3 percent at fixed exchange rates compared to last year. The gross margin for the quarter was 66 percent, up 2 percentage points year-on-year as a result of lower transport costs in the quarter as a greater proportion of freight was carried by sea rather than by air.

[1] Sedaconda will be marketed in France under the brand name Cedaconda.

In Germany, our largest market, we saw continued strong momentum with sales up year-on-year and almost in line with Q1, despite a sharp downturn in the number of Covid-19 intensive care patients in May-June. This is a positive sign that clinics are continuing to broaden use beyond Covid-19 patients.

Other direct sales in Europe decreased compared to last year as a result of the slowing third wave of the pandemic. The previous year was notable for a massive increase in sales during April-May, at the start of the pandemic. These countries, which have a substantially smaller customer base than Germany, are even more affected in terms of sales by the decreasing number of Covid-19 patients in the ICU. However, we are seeing continued momentum here too, with existing and new hospital customers beginning to broaden use to other patient groups. These relationships will be very valuable for future marketing authorisations.

Sedana Medical operates according to a clear strategy based on several steps to develop inhaled sedation into a global standard therapy in intensive care.

The first step in the strategy is to establish AnaConDa (to be renamed Sedaconda ACD) in selected markets. During the quarter, we continued to strengthen our presence in our distributor markets, particularly in Latin America. Sales increased sharply compared to the previous year, and Mexico is our second largest market in the second quarter. Latin America is one of the regions in the world where the pandemic has put the greatest strain on health systems, with acute shortages of propofol in many countries. Our success can also be largely attributed to our local distributor, one of Latin America's leading distributors of healthcare products. There is strong interest in launching and selling AnaConDa/Sedaconda ACD in the markets we do not cover ourselves, which gives us the opportunity to work with the best distributors in each country.

With regard to the second step in our strategy, having the pharmaceutical product Sedaconda and inhaled sedation therapy approved, it was very pleasing to obtain DCP approval in July, as well as the first national marketing authorisation in France in August. Now that we are approaching commercialisation in Europe, our work has been concentrated on pre-launch activities. We are focusing on the pricing, procurement and reimbursement processes in each country, which is sometimes resource-intensive work, but acceptance by purchasers in healthcare systems is a key factor for successful commercialisation. In addition, despite continued shutdowns in many of our markets, we have managed to step up our level of activity at local congresses and meetings. We have also organised our own well-attended symposia in conjunction with these congresses. All in all, our level of activity has increased and will increase further as we come closer to the start of sales.

Part of the work ahead of the launch is the change of name for our medical device AnaConDa to Sedaconda ACD, which stands for Anaesthetic Conserving Device. The name strengthens the link to Sedana Medical and the unique area of use of sedation. The pharmaceutical product Sedaconda (isoflurane) is to be administered via AnaConDa/Sedaconda ACD, together making up the inhaled sedation therapy. The name change will be launched on 1 October.

Preparations ahead of our American registration were intense during the quarter. Shortly after the end of the quarter, we were able to announce that we had held an End of Phase II meeting with the US Food and Drug Administration (FDA). The purpose of this advisory meeting was to discuss the documentation ahead of phase 3 and to agree on the plan and design of the phase 3 studies. The meeting was successful - the FDA accepted our proposed phase 3 programme, including the study design and the primary endpoint for the studies - and means that we are able to enter phase 3 in line with the previously communicated timetable.

We are now working to submit an Investigational New Drug (IND) application in the autumn to allow us to start clinical studies and enrol the first patients in the studies at the turn of Q1/Q2 2022. There has been significant interest in participating in the studies from a large number of leading US centres. We aim to include around 30 centres and look forward to starting the inclusion of patients. We have established a subsidiary and recruited employees in the United States who will be involved in the studies. By successfully carrying out two randomised controlled trials, each including around 250 patients, we plan to obtain marketing authorisation before the end of 2024.

With regard to the third step in our strategy; With the aid of more studies, securing medical evidence showing that inhaled sedation is a better and more cost-effective treatment than today’s intravenous standard therapy, it was very pleasing to be able to report during the quarter that the Sedaconda study (SED001) was named one of the three best posters at the 52nd DGIIN & ÖGIAIN intensive care conference from 16 to 18 June 2021. DGIIN & ÖGIAIN is the joint annual congress of the German and Austrian acute and intensive care associations. It is highly positive that the study is receiving attention in Germany, which is our largest market.

All in all, we look back on yet another intensive quarter with success in all the steps in our strategy. On 1 October, I will be handing over the baton to our incoming President and CEO Johannes Doll and will continue in my role as Commercial Director. We look forward to coming back to you.

Jens Lindberg, acting CEO and President

Significant events during the period
First quarter

- An application for market approval for the candidate drug Sedaconda (isoflurane), previously known as IsoConDa, for inhaled sedation in intensive care was submitted in Switzerland and the United Kingdom.
- The first patient was included in the company's paediatric study IsoCOMFORT (SED002), which is being conducted to study whether inhaled sedation with Sedaconda (isoflurane) delivered via AnaConDa is a safe and more effective method of sedation than intravenously administered midazolam, for children below 18 years of age.
- Sedana Medical's CEO, Christer Ahlberg, announced that he is stepping down as CEO to become the CEO of Cinclus Pharma AB.

Second quarter

- In May, the Board appointed Johannes Doll as the new CEO. Johannes will take up duties on 1 October 2021. Sedana Medical's Commercial Director Jens Lindberg was appointed by the Board as acting CEO.
- The Annual General Meeting in May resolved, in line with the Board's proposal, to split the company's shares, with each existing share being divided into four new shares of the same class (4:1 split). The split was completed at the end of May.
- The pivotal phase 3 Sedaconda study (SED001) was selected as one of the top three posters at the 52nd DGIIN & ÖGIAIN Intensive Care Conference in June 2021.

Significant events after the period

- In early July, Sedana Medical's Quality Management System (QMS) received approval under the EU Medical Device Regulation (MDR) 2017/745. This approval means that Sedana Medical's Class I medical devices can continue to be sold with CE marking in the EU.
- A successful End of Phase II advisory meeting was completed with the US Food and Drug Administration (FDA). The FDA accepted Sedana Medical's proposed phase 3 programme, including the study design and the primary endpoint for the studies. The positive outcome allows the company to enter phase 3 in line with the communicated timeline.
- At the end of July, a positive outcome was received for the application for European marketing authorisation for the pharmaceutical product Sedaconda (isoflurane) for inhaled sedation in intensive care. Sedaconda is indicated for the sedation of mechanically ventilated adult intensive care patients and is to be administered only via the AnaConDa medical device.
- On 13 August, the first market approval for inhaled sedation was obtained in France. The application was approved by the French Medicines Agency, L'Agence nationale de sécurité du médicament et des produits de santé (ANSM) and is based on the DCP approval Sedana Medical received in July.

Please find the full interim report at: www.sedanamedical.com under Investors/annual & interim reports. This document has been prepared in a Swedish and English version. In the event of any deviations, the Swedish version shall prevail.

Sedana Medical will hold a telephone conference at 13:30 pm (CEST) Thursday August 19, 2021.
To participate, please dial: +46 8 505 583 52

For additional log in information:
https://tv.streamfabriken.com/sedana-medical-q2-2021
https://financialhearings.com/event/13794

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This information is such that Sedana Medical AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation and the Swedish Securities Markets Act. The information was released for public disclosure, through the agency of the contact persons above, on August 19, 2021 at 07:00 am (CEST).

Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm.
The company's Certified Adviser is Erik Penser Bank, +46 8 463 83 00, certifiedadviser@penser.se.

About Sedana Medical

Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve the patient's life during and beyond sedation. Through the combined strengths of the medical device

AnaConDa and the pharmaceutical Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated patients in intensive care.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordic, and Spain. In other parts of Europe as well as in Asia, Australia, Canada, and South- and Central America, the company works with external distributors.

Sedana Medical was founded in 2005, is listed on Nasdaq First North Growth Market (SEDANA) and headquartered in Stockholm, Sweden.