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Sedana Medical AB's Interim report January-June 2024

Enrolment of both US clinical trials completed, on track for first results in 2H

Second quarter 2024

- Net sales for the quarter totaled MSEK 41.1 (37.3), equivalent to an increase of 10% compared to the same quarter 2023. At constant exchange rates, sales increased by 10%.
- Gross profit was MSEK 29.0 (26.6) equivalent to a margin of 71% (71%).
- Earnings before interest, taxes, depreciation and amortization (EBITDA) totaled MSEK -13.9 (-10.7), equivalent to an EBITDA margin of -34% (-29%). EBITDA ex-US for the quarter was MSEK -10.8 (-10.2) corresponding to a margin of -26% (-27%). EBITDA during the quarter was negatively impacted by exchange rate differences on operating balance sheet items of MSEK -2.2, while EBITDA in the second quarter last year included a positive such effect of MSEK 2.7.
- Operating income (EBIT) totaled MSEK -19.1 (-16.3), equivalent to an EBIT margin of -46% (-44%).
- Net income for the quarter was MSEK -17.2 (1.4) and earnings per share before and after dilution was SEK -0.18 (0.01). The decrease is mainly due to a lower financial net compared to the same quarter 2023. The financial net partly consists of unrealized currency effects on cash and cash equivalents held in USD, but also of interest revenue on cash and cash equivalents.
- Cash and cash equivalents at the end of the quarter totaled MSEK 304 compared to MSEK 361 at the beginning of the quarter.
- Cash flow from operating activities totaled MSEK 1.9 (-36.0). The positive operating cash flow derives mainly from payments from customers following high sales in the first quarter and also increased short-term liabilities due to phasing of payments regarding the US clinical program.
- Cash flow from investments in intangible assets, mostly driven by our US clinical program, totaled MSEK -55.6 (-45.8). Total cash flow from investment activities were MSEK -55.8 (-45.8).
- Total cash flow for the quarter was MSEK -54.4 (-83.0).

January-June 2024

- Net sales for the period totaled MSEK 89.9 (75.1), equivalent to an increase of 20% compared to 2023. At constant exchange rates, sales increased by 19%.
- Gross profit was MSEK 63.7 (54.1) equivalent to a margin of 71% (72%). The decrease is mainly due to product mix effects.
- Earnings before interest, taxes, depreciation and amortization (EBITDA) totaled MSEK -14.9 (-21.4), equivalent to an EBITDA margin of -17% (-28%). EBITDA ex-US was MSEK -9.2 (-20.3) corresponding to a margin of -10% (-27%).
- Operating income (EBIT) totaled MSEK -25.6 (-32.6), equivalent to an EBIT margin of -29% (-43%).
- Net income was MSEK 3.4 (-14.7) and earnings per share before and after dilution was SEK 0.03 (-0.15). The increase is due to a higher financial net compared to last year. The financial net partly consists of unrealized currency effects on cash and cash equivalents held in USD, but also of received interest on cash and cash equivalents.
- Cash and short-term investments at the end of the period totaled MSEK 304 compared to MSEK 382 at the beginning of the year, supported by a positive exchange rate effect of MSEK 17.1.
- Cash flow from operating activities totaled MSEK 10.3 (-43.0). The positive operating cash flow derives mainly from increased short-term liabilities due to phasing of payments regarding the US clinical program and also payments from customers following high sales in the first quarter together with received interest on cash and cash equivalents of MSEK 4.6 related to repaid deposits during the first quarter.
- Cash flow from investments in intangible assets, mostly driven by our US clinical program, totaled MSEK -107.7 (-85.0). Including repaid deposits and the previous year's investment in deposits, total cash flow from investment activities totaled MSEK 47.4 (-391.4).
- Total cash flow for the period was MSEK 55.9 (-436.7). Excluding the repaid deposits and the previous year's investment in deposits, the total cash flow amounted to MSEK -99.4 (-130.6).

CEO comments

We continue to focus on our ambitious goals for 2024: achieving an all-time-high in sales, reaching EBITDA break-even outside of the US during the year, and progressing towards our single biggest growth opportunity, launching in the United States. The highlights of the past months include the enrollment completion of both our Phase III clinical trials in the US and the acquisition of our main supplier Innovatif Cekal, an important milestone in building a long-term profitable company. Despite more modest sales growth compared to the first quarter, we have delivered H1 sales above our guidance.

H1 growth above our financial guidance

During last year's restructuring, we turned Sedana Medical into a much more commercially oriented company by vigorously shifting resources from the corporate headquarter to the frontline and implementing a disciplined investment approach, focusing on countries with strong momentum and profitability. This strategy has resulted in a return to a solid growth path after the post-Covid-19 period and we now operate almost all of our country organizations in a profitable way.

With net sales of 41 MSEK, we report the highest Q2 sales so far, and with a year-over-year growth rate of 19% excluding exchange rate effects in the first half year, we track above our full-year growth guidance corridor of 14-18%. While I am pleased with these results overall, we also have to clearly state that the Q2 growth rate of 10% is quite soft, especially in comparison to the excellent first quarter.

Part of the explanation for the difference in growth rates between Q1 and Q2 lies in the fact that Q1 and Q2 had almost the same sales level last year, which is atypical. Normally, we see a seasonal decline in Q2 compared to Q1 by on average 10%¹, as fewer patients require intensive care during the warmer months. With a 13% sales decline between Q1 and Q2 this year (correcting for the sizeable order from our South American distributor in Q1), the seasonal decline was more pronounced, especially in our main market Germany. In June, we measured the capacity utilization and the number of mechanically ventilated patients in a sample of 40 key German customers. We found that the share of mechanically ventilated patients relative to available ventilator beds was only 20%, compared to the normal range of 40-50%. This temporary absence of ventilated patients, likely due to the early onset of summer weather, led to very weak German sales in June, with a decline of over 20% compared to June 2023. Both April and May, as well as the first weeks of July, showed growth compared to the previous year, suggesting that the June decline was temporary.

Our other direct markets have continued their strong growth trajectory, achieving a growth rate for the second quarter of 46% excluding exchange rate effects. Spain remains our main growth engine, benefiting from an expanded customer base, pricing and reimbursement approval, and the launch of our pharmaceutical Sedaconda (isoflurane) in Q4 2023. Additionally, we have seen significantly accelerated sales growth in the UK following MHRA approval at the end of 2023. Our other direct markets now account for almost 30% of our total sales, underscoring the importance of our strategy to reduce dependence on our main market, Germany. This diversification is crucial as our direct markets outside Germany play an increasingly vital role in achieving our overall growth ambitions.

Our distributor business grew 29% year-over-year in Q2 excluding exchange rate effects, which is now the third consecutive quarter with solid year-over-year growth after a period of sales decline post-Covid. Our targeted approach, which focuses our support on select key partners with high potential and positive momentum, is bearing fruit.

Strategic acquisition for long-term profitability

We continue to take action to improve our bottom line, which underscores our commitment to financial resilience and our clear aim to reach ex-US break-even again during this year, as we did in Q1 (with some support from FX). In July, we have signed an agreement to acquire our main supplier Innovatif Cekal in Malaysia. After streamlining our non-customer-facing functions and shifting resources towards the frontline, this acquisition represents the next strategic move towards building a long-term profitable company. By taking control of the supply chain for our main product Sedaconda ACD and some accessories, we expect to add two percentage points to our EBITDA margin over time.

As anticipated, our Q2 EBITDA was lower than in Q1, when we achieved a positive ex-US EBITDA and nearly balanced group EBITDA. The primary driver of the decline is the seasonally lower sales level and an exchange rate effect of 4.5 MSEK. The remainder is explained by higher admin cost, which are mostly related to higher legal fees in connection with the acquisition of Innovatif Cekal and the long-term incentive program, which was approved by the AGM in May.

Enrollment completion in the USA

With a potential commercial launch upcoming already in 2026, we are becoming even more excited about the growth opportunity in the United States, where we estimate the market potential for our inhaled sedation products to 10-12 BSEK. This figure is approximately three times greater than the combined market potential of our current direct markets in Europe. Several factors contribute to this significant opportunity, including the larger population size, a medical practice more in favor of intubation, and an overall attractive pricing environment. With a good fit with the US healthcare and reimbursement system and a potentially significant positive impact on customers' economics, we feel well positioned for a successful US launch.

By recruiting the last patient in both INSPIRE ICU-1 and INSPIRE ICU-2 in April and May respectively, we have cleared a very important milestone on our road to the US market. Besides this great achievement, I am pleased that we remain on track with the activities that we can control, such as the ongoing long-term 3 and 6 month follow up assessment of the study patients, and the work on the different parts of the NDA dossier. We are hence still aiming for receiving top-line study data in the second half of this year and a submission in the first quarter of next year.

To meet this timeline, we will depend on the agency's acceptance of our analysis and submission plans and a positive data read-out. Also the FDA's decision regarding our eligibility for benefits based on the Fast Track

¹ Based on the years 2016-2022, excluding the exceptional Covid-19 year 2020

Designation may have an impact on the timeline. We continue to be in close exchange with the FDA, leveraging our Fast Track Designation including more frequent access to the agency.

Exciting times ahead

Reflecting on the progress we have made in the first half of the year, I continue to see Sedana Medical well on track to deliver on our goals. I would like to thank the entire Sedana Medical team for their efforts for the benefit of patients and ICU care teams, and of course our shareholders for your continued trust and support. With the ambition of ex-US break-even and hopefully positive topline data from the US, the second half of 2024 holds the potential to be an inflection point in Sedana Medical's journey. I am looking forward to updating you on our progress.

Johannes Doll, President and CEO

Please find the full report at: [Interim Reports | Sedana Medical](#)

This document has been prepared in both 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 (CET) Tuesday July 23, 2024.

If you wish to participate via webcast please use the link below. Via the webcast you are able to ask written questions. Link to webcast: [Sedana Medical – Q2 Presentation 2024 - Finwire](#)

If you wish to participate via teleconference: +46 850 539 728. Meeting ID: 893 1171 5665.

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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 July 23, 2024 at 07:00 am (CET).

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 Sedaconda ACD 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 Nordics, 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 Stockholm (SEDANA) and headquartered in Stockholm, Sweden.