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Sedana Medical AB Interim report January-September 2022

Sales growth in our direct markets despite temporary market headwinds

Third quarter 2022

- Net sales for the quarter totalled MSEK 26,5 (28,3), equivalent to a decrease of 6% compared to 2021. At constant exchange rates, sales decreased by 10%.
- Gross profit was MSEK 18,4 (19,1), equivalent to a margin of 70% (68%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -25,1 (-14,0), equivalent to an EBITDA margin of -95% (-50%).
- Operating income (EBIT) totalled MSEK -30,8 (-16,1), equivalent to an EBIT margin of -116% (-57%).
- Net profit for the quarter was MSEK -7,4 (-14,9), and earnings per share before and after dilution was SEK -0.08 (-0.17).
- Cash flow from operating activities totalled MSEK -26,7 (-14,5).
- Cash flow from investing activities totalled MSEK -39,5 (-32,7).
- Total cash flow was MSEK -67,4 (-48,1).
- Cash and cash equivalents at the end of the quarter totalled MSEK 676, compared to MSEK 722 at the beginning of the quarter.

January-September 2022

- Net sales totalled MSEK 87,1 (112,8), equivalent to a decrease of 23% compared to the previous year. At constant exchange rates, sales decreased by 26%.
- Gross profit was MSEK 60,3 (73,9), equivalent to a margin of 69% (66%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -65,5 (-36,6), equivalent to an EBITDA margin of -75% (-32%).
- Operating income (EBIT) totalled MSEK -82,6 (-42,8) equivalent to an EBIT margin of -95% (-38%).
- Net profit for the period was MSEK -37,6 (-41,2), and earnings per share before and after dilution was SEK -0.38 (-0.45).
- Cash flow from operating activities totalled MSEK -92,9 (-39,7).
- Cash flow from investing activities totalled MSEK -110,5 (-76,9).
- Total cash flow was MSEK -203,7 (-117,3).
- Cash and cash equivalents at the end of the period totalled MSEK 676, compared to MSEK 836 at the beginning of the year.

CEO comments

Sales growth in our direct markets despite temporary market headwinds

For the third quarter, we report sales growth both in Germany and in our other direct markets, despite a lower number of ventilated patients and continued restricted operations in ICUs.

Temporary market headwinds...

As we anticipated, we have still seen a lower number of mechanically ventilated patients in ICUs compared to last year, albeit to a lesser extent than in previous quarters as the Covid-19 effect on last year's Q3 sales was comparatively modest.

In our main market Germany for instance, we saw the number of patients treated in ICUs during the quarter (including both ventilated and non-ventilated patients) drop by 10%, while the number of mechanically ventilated Covid-19 patients dropped by 20%¹.

¹ Statistics exclude low-care beds (which don't tend to be equipped with ventilators)

In addition, hospitals across our markets continue to suffer from staff shortages. In Germany, 64% of ICUs reported to operate under restricted or partly restricted conditions during the quarter.

...but sales growth in direct markets

For the third quarter, we report net sales of 26.5 MSEK, a decline of 6% (10% in local currencies) compared to last year. Sales in the quarter were 59% higher than 2019, the last year prior to the Covid-19 pandemic.

I am pleased to see positive growth in the markets where we have our own commercial teams on the ground. In Germany, we have grown sales by 11% (6% in local currencies) while our other direct markets Spain, France, UK, Benelux and the Nordics delivered 20% year-over-year growth (15% in local currencies).

For our distributor markets, we have seen a significant sales decline of 65% (67% in local currencies) compared to a strong Q3 in 2021. Apart from the high sales in Q3 2021, which were still impacted by Covid-19, the decline is explained by continued high stock levels at our main distributor in South America and the resulting temporary lack of new orders. Our other distributors in aggregate showed positive growth during the quarter.

Sedaconda® (isoflurane) launch continues in more countries

I am pleased to report that Sedaconda (isoflurane) has been launched in France, adding another important country to the growing list of markets where we can promote the full inhaled sedation therapy, consisting of both the medical device Sedaconda ACD and our proprietary pharmaceutical Sedaconda (isoflurane). As of today, Sedaconda (isoflurane) is available in Germany, France, Netherlands, Sweden, Norway, and Slovenia.

In Spain, the pricing and reimbursement process is progressing according to plan, and – assuming the authorities stick to the anticipated timeline – we expect to launch Sedaconda (isoflurane) in late Q4 or early Q1, which should lead to a further acceleration of the good momentum we see in Spain.

We received market authorization in Switzerland during the quarter, and continue to await approvals in the UK, Italy and Poland. We continue to expect approval in Italy and Poland before the end of the year, but the UK authorities have now informed us that approval will be further delayed into next year due to high workload at MHRA and we will receive a timeline for approval in Q1 2023.

During the quarter, we have received Medical Device Regulation (MDR) certification for Sedaconda ACD. The new EU MDR regulation was implemented to ensure an even higher level of quality and safety for medical devices in Europe. While this positive outcome was expected, I am proud of our team's efforts to achieve this important milestone to secure future market access for our products, well ahead of the deadline in 2024.

Progress in the United States

We are making good progress with our INSPIRE-ICU clinical trials in the United States. The majority of our clinical trial sites are up and running and actively recruiting patients, and we are happy about the excitement and motivation we see in the study teams. If we can keep the anticipated pace of patient recruitment, we should see the last patient leave the clinic in Q4, 2023 and hence – assuming FDA approval – expect to deliver according to our plan to launch in the United States early 2025.

In parallel, we are ramping up our preparations from a commercial perspective to further deepen our understanding of the market potential, its market access requirements and purchasing processes of our future customers.

Outlook: back to normal from 2023?

The last significant Covid-19 wave reaching the ICUs started in August 2021, therefore impacting part of Q3 and all of Q4 last year, with significantly elevated numbers of ventilated patients. Afterwards, during the first three quarters of 2022, Sedana Medical's sales have been impacted by a number of external factors, such as a temporary contraction of the addressable market and restricted hospital operations coming out of the pandemic. While we have always been confident about the underlying dynamic and progress, the obvious question is when we will enter a "new normal".

Of course, there is still significant uncertainty, but the consensus among our customers, who are working on the frontlines, appears to be that we can expect more normalized ICU patient numbers from early 2023, while some of the effects, most notably staff shortages, may take longer to resolve.

As always, we remain fully focused on what we have under our control: First and foremost, we are putting great emphasis on commercial execution by implementing our sales growth initiatives in order to make inhaled sedation the standard of care in more and more hospitals.

I would like to thank you for your trust and support and look forward to updating you on our progress.

Johannes Doll, President and CEO



Please find the full report at: sedanamedical.com

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 (CET) Tuesday October 25, 2022.

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Link to audiocast: <https://ir.financialhearings.com/sedana-medical-q3-2022>

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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 October 25, 2022, at 07:00 am (CET).

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 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 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.