

Press release July 21, 2022, 07.00 CET.

Sedana Medical AB Interim report January-June 2022

Committed to change the standard of care, with commercial progress and a strong balance sheet.

Second quarter 2022

- Net sales for the quarter totalled MSEK 27 (40), equivalent to a decrease of 32% compared to 2021. At constant exchange rates, sales decreased by 34%. The decrease is a consequence of a significant decline in ventilated patients in intensive care units.
- Gross profit was MSEK 19 (26), equivalent to a margin of 70% (66%). The improved margin is mainly an effect of a positive product mix, price adjustments and initiatives to reduce freight costs.
- Earnings before interest, taxes, depreciation, and amortisation (EBITDA) totalled MSEK -24 (-14), equivalent to an EBITDA margin of -89% (-36%).
- Operating income (EBIT) totalled MSEK -30 (-16), equivalent to an EBIT margin of -111% (-41%).
- Net profit for the quarter was MSEK -11 (-17), and earnings per share before and after dilution was SEK -0.11 (-0.18).
- Cash flow from operating activities totalled MSEK -39 (-12).
- Cash flow from investing activities totalled MSEK -39 (-23).
- Total cash flow was MSEK -75 (-36).
- Cash and cash equivalents at the end of the quarter totalled MSEK 722, compared to MSEK 779 at the beginning of the quarter.

January-June 2022

- Net sales totalled MSEK 61 (85), equivalent to a decrease of 28% compared to last year. At constant exchange rates, sales decreased by 31%. The decrease is a consequence of a significant decline in ventilated patients in intensive care units.
- Gross profit was MSEK 42 (55), equivalent to a margin of 69% (65%). The improved margin is mainly an effect of lower freight costs compared to the first half of the previous year.
- Earnings before interest, taxes, depreciation, and amortisation (EBITDA) totalled MSEK -40 (-23), equivalent to an EBITDA margin of -67% (-27%).
- Operating income (EBIT) totalled MSEK -52 (-27) equivalent to an EBIT margin of -86% (-32%).
- Net profit for the period was MSEK -30 (-26), and earnings per share before and after dilution were SEK -0.30 (-0.28).
- Cash flow from operating activities totalled MSEK -66 (-25).
- Cash flow from investing activities totalled MSEK -71 (-44).
- Total cash flow was MSEK -136 (-69).
- Cash and cash equivalents at the end of the period totalled MSEK 722, compared to MSEK 836 at the beginning of the year.

CEO comments

With a strong balance sheet, we are continuing on our mission towards standard of care

During the second quarter, we initiated our clinical program in the US and launched our pharmaceutical Sedaconda (isoflurane) in several additional European markets. Sales continued to be affected by a significant temporary contraction of the addressable market, but with cash of 722 MSEK we are well financed to execute on our strategy and the outlook remains very positive despite the near-term market headwinds.

Addressable market has temporarily contracted but outlook remains bright

We continued to see a significant contraction of our addressable market across our main geographies. In fact, the decline of intubated and ventilated patients in intensive care units was even more sizeable in Q2 than in Q1:

- As expected, the number of Covid-19 patients requiring ICU care has been at a much lower level than last year.
- As populations in our major markets still observe hygiene measures and work from home to a large extent, community-acquired infections such as flu and pneumonia have been at very low levels.
- Hospitals still suffer from personnel shortages, leading to less elective surgeries and an overall reduction of ICU capacity.

In light of these dynamics, we report net sales of 27 MSEK in the second quarter, a decline of 32% versus last year, to be compared with a decrease of the addressable market of 40-50% (see below). The decline is mainly driven by lower sales in Germany and in South America. In other markets, most notably Spain, France and UK, we have seen robust growth of 31% despite the challenging market environment.

While it is difficult to predict when exactly the situation in ICUs will find a "new normal", we know that most of the external effects are temporary and expect to see a normalized market from early 2023, subject of course to potential new waves of the pandemic. Importantly, Sedana Medical has the financial strength to endure even a longer-lasting uncertainty if needed. It goes without saying that we remain convinced that inhaled sedation will prevail due to both convincing clinical benefits over intravenous sedation and attractive health-economic advantages for our customers.

Positive underlying dynamic despite sales decline

Even despite the sales decline in the first half of this year, there are several positive underlying trends showing the positive momentum:

Taking a through-cycle-perspective, our sales in the first half of 2022 were 72% higher than for the same period of 2019. This shows that – despite the current reduction of ventilated patients – the use of inhaled sedation has made a significant step forward. With the European approval and the launch of Sedaconda (isoflurane) that positive trend will continue and accelerate.

The sales decline is likely less than the decline in ventilated patients. Based on publicly available data and a customer survey we have performed in our main market Germany mid-May, we estimate that the number of ventilated patients in ICUs has decreased by 40-50% vs. the previous year. Our sales in Germany have declined by approximately 30% in the same period. While this is only a snapshot, it implies that the underlying progress in terms of penetration is still intact.

We continue to see a number of positive leading indicators: we have on average added three new customers per week in the first half of the year, we have not lost any of our top-100 customers in Germany and we have sold to more customers in the first half of 2022 than a year ago.

Progress towards establishing inhaled sedation as standard of care

In Q2, we achieved a major milestone by initiating our clinical program in the US, with an intention to obtain NDA approval in 2024. We are seeing new clinical trial sites open on a regular basis and we are excited about the positive feedback and the enthusiasm of the investigators and their teams. We are progressing the patient recruiting according to plan and are looking forward to the coming months.

In Europe, we have launched Sedaconda (isoflurane) in more markets. Besides Germany, it is now available in the Netherlands, Sweden and Norway. In the remaining markets, we are making progress with the pricing and reimbursement processes and – assuming no delays on the authorities' side - continue to expect launches in all major markets by the end of the year.

The second quarter has also been filled with successful conferences and peer-to-peer events. We are seeing great interest, very good attendance to our events and more and more current and future customers considering inhaled sedation a possible new standard of care.

Focus on investing for growth and prudent cost management

Despite the turbulent macro-environment and the temporary contraction of our addressable market, we remain focused on what we can control, such as driving forward with our sales growth initiatives. At the same time, we have started an initiative to reduce costs and improve spend effectiveness in administrative and overhead functions, to ensure we channel our investments on driving sales growth and to counter-balance the temporary market factors.

Lastly, I would like to thank our shareholders for your continued support. We are very happy about the fact that many of our top-15 shareholders have increased their holdings during the quarter. It is encouraging to see that you share our belief in inhaled sedation and how it may transform ICU care for ventilated patients and are looking forward to an exciting future for Sedana Medical.

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) Thursday July 21, 2022.

To participate, please dial: +46 8 505 163 86, Pin code: 7926317#

For additional log in information:

<https://financialhearings.com/event/43301>

<https://tv.streamfabriken.com/sedana-medical-q2-2022>

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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 July 21, 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.