

Press release October 26, 2023, 07.00 CET.

Sedana Medical AB's Interim report January-September 2023

All-time-high Q3 sales and further steps towards ex-US profitability

Third quarter 2023

- Net sales for the quarter totalled MSEK 34.3 (26.5), equivalent to an increase of 29% compared to the same quarter 2022. At constant exchange rates, sales increased by 16%.
- Gross profit was MSEK 23.9 (18.4) equivalent to a margin of 70% (70%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -12.6 (-25.1), equivalent to an EBITDA margin of -37% (-95%). EBITDA ex-US for the quarter was MSEK -11.5 (-22.8).
- Operating income (EBIT) totalled MSEK -18.1 (-30.8), equivalent to an EBIT margin of -53% (-116%).
- Net income for the quarter was MSEK -6.8 (-7.4) and earnings per share before and after dilution was SEK -0.07 (-0.08).
- Cash and short-term investments at the end of the quarter totalled MSEK 453 compared to MSEK 504 at the beginning of the quarter.
- Cash flow from operating activities totalled MSEK -3.9 (-26.7).
- Cash flow from investments in intangible assets totalled MSEK -41.8 (-39.4). Including repayment of short-term deposits, total cash flow from investing activities totalled MSEK 111.2 (-39.5). The positive cash flow derives mainly from deposits invested in the first quarter which have been repaid during this quarter and were only partly reinvested.
- Total cash flow for the quarter was MSEK 106.2 (-67.4). Adjusted for the allocation of cash to deposits, total cash flow was MSEK -46.9 (-67.4).

January-September 2023

- Net sales totalled MSEK 109.3 (87.1), equivalent to an increase of 26% compared to 2022. At constant exchange rates, sales increased by 15%.
- Gross profit was MSEK 78.0 (60.3), equivalent to a margin of 71% (69%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -33.9 (-65.5), equivalent to an EBITDA margin of -31% (-75%). EBITDA ex-US for the interim period was MSEK -31.8 (-62.8).
- Operating income (EBIT) totalled MSEK -50.7 (-82.6), equivalent to an EBIT margin of -46% (-95%).
- Net income for the interim period was MSEK -21.5 (-37.6) and earnings per share before and after dilution was SEK -0.22 (-0.38).
- Cash and short-term investments amounted to MSEK 453 at the end of the period compared to MSEK 608 at the beginning of the year, of which short-term investments were MSEK 163 (0).
- Cash flow from operating activities totalled MSEK -46.8 (-92.9).
- In order to favor from better interest rates, investments in short-term deposits were made during the period. These amounted to a total of MSEK -465.4 whereof MSEK 312.4 has been repaid. Cash flow from investing activities thus totalled MSEK -280.1 (-110.5).
- Total cash flow for the period was MSEK -330.6 (-203.7). Adjusted for the allocation of cash to deposits, total cash flow was MSEK -177.5 (-203.7).

CEO comments

All-time-high Q3 sales and further steps towards ex-US profitability

We are looking back on another eventful quarter, in which we remained fully focused on our three strategic priorities: to grow sales in our core markets, to get closer to profitability in our ex-US business, and to make headway towards the NDA approval in the United States. Once again, I am pleased to report solid progress on each of these priorities.

Continued growth in our direct markets

After the turbulent post-Covid period in 2022, we have now shown robust year-over-year growth for the third quarter in a row. The business grew by 29% in the quarter (16% excluding the strong currency tailwinds), with our key markets in Europe fueling the growth.

Our main market Germany grew by 21% (9% excluding currency effects) and contributed approximately 70% of Sedana Medical's sales this quarter. The main growth driver in Germany continues to be an increased use of our therapy in existing customer accounts. This is in line with our strategy to continuously enhance field force effectiveness, by maximizing the time we spend with our customers and to help them identify more patients that are likely to benefit from the compelling clinical benefits of inhaled sedation.

Our other direct markets have continued on their strong growth path, with 87% higher sales than last year (69% excluding currency effects). While we see positive development across geographies, Spain continues to stand out as the leading growth engine. Our team's targeted approach, focusing on high-potential regions with high-frequency visits and outstanding customers service, is showing results.

After the end of the quarter, we reached two important milestones that could turn out to be inflection points in our continued growth journey. The Spanish Ministry of Health has now officially granted pricing and reimbursement approval in Spain. This is an important achievement as several potential customers in Spain have awaited the approval before implementing inhaled sedation at their hospitals. In the UK, the MHRA has finally approved Sedaconda (isoflurane), completing the list of 18 countries where inhaled sedation has received marketing authorization. Already in 2022, the UK National Institute for Health and Care Excellence (NICE) recommended the Sedaconda ACD as a cost-saving option for delivering inhaled sedation in intensive care. Together with the positive NICE guidance, we hope that the approval will lead to many ICU patients in the UK benefitting from the clinically proven advantages of inhaled sedation.

We are planning to launch our pharmaceutical Sedaconda (isoflurane) in both Spain and UK in the coming months. We anticipate, however, that the main sales and margin driver will be accelerated device sales, as we expect the approvals to lead to increased use of the therapy overall.

In our distributor markets, where we do not have our own commercial teams on the ground, we saw a sales decline of 11% (20% excluding currency effects). We are implementing a focused distributor strategy, which leads us to focus resources and support on our top distributors and apply an efficient support model for our smaller partners.

Further steps towards profitability ex-US

We continue to pursue our strategic priority of reaching break-even in our ex-US business during 2024. As a result of our efforts to streamline all elements of our cost structure, we have been able to reduce our EBITDA loss in the quarter to 12.6 MSEK. This compares to an EBITDA loss of 25.1 MSEK for the same period last year. While our gross margin remained stable at 70%, we have been able to reduce our operating expenses by 17% compared to last year (21% excluding currency effects).

Looking at our ex-US business in isolation, we see an EBITDA loss of 11.5 MSEK for the quarter. With continued sales growth and further disciplined actions on the cost side, we are committed to reach break-even ex-US during next year.

Entering the final phase in our US trials

Both our US clinical trials INSPIRE-ICU 1&2 are in full swing, with 27 clinical trial sites actively recruiting. Both studies have enrolled the majority of randomized patients and we are looking forward to the last part of the study.

The anticipated acceleration of enrolment rates after the summer months, which are seasonally slower in intensive care, has materialized a bit later than planned, so we currently expect both studies to run into 2024. The overall US time plan is unchanged and we continue to work towards the NDA submission in Q1 2025.

Apart from completing the recruitment of patients to the study, a key upcoming milestone will be the report of top-line data, which we expect next year.

It is worth repeating that our communicated timeline assumes no positive effects from the Fast Track Designation granted by FDA earlier this year. We will have the opportunity to discuss possible measures to accelerate the timeline, such as accelerated approval, priority review, and rolling review, in a pre-NDA meeting closer to submission.

While our emphasis is on completing the clinical trial as quickly as possible, we have also intensified our launch preparation activities. With an estimated market potential of 10-12 BSEK, the US clearly represents our largest long-term commercial opportunity.

Continued focus on our strategic priorities

It feels good to have left the Covid-19 aftermath behind and to be able to report consistent sales growth since the beginning of 2023. Our passionate team and I, continue to be fully focused on generating growth and reaching profitability in our ex-US business while simultaneously preparing for our exciting US opportunity.

I see the company well on track to meet our short-term financial guidance and deliver on our promise to make inhaled sedation a standard therapy in intensive care – for the benefit of critically ill patients worldwide.

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) Thursday October 26, 2023.

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 Q3 Report 2023 \(financialhearings.com\)](#)

If you wish to participate via teleconference please register on the link below. After registration you will be provided phone numbers and a conference ID to access the conference. You can ask questions verbally via the teleconference. Link to teleconference: [Call Access \(financialhearings.com\)](#)

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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 26, 2023 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.