

Press release April 27, 2023, 07.00 CET.

Sedana Medical AB's Interim report January-March 2023

Back to growth

First quarter 2023

- Net sales for the quarter totalled MSEK 37.8 (33.7), equivalent to an increase of 12% compared to 2022. At constant exchange rates, sales increased by 5%.
- Gross profit was MSEK 27.5 (23.0) equivalent to a margin of 73% (68%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -10.7 (-16.4), equivalent to an EBITDA margin of -28% (-49%).
- Operating income (EBIT) totalled MSEK -16.3 (-22.1), equivalent to an EBIT margin of -43% (-66%).
- Net income for the quarter was MSEK -16.1 (-19.0) and earnings per share before and after dilution was SEK -0.16 (-0.19).
- Cash and short-term investments at the end of the quarter totalled MSEK 560 compared to MSEK 608 at the beginning of the quarter, whereof short-term investments was MSEK 309 (0).
- Cash flow from operating activities totalled MSEK -7.0 (-27.5).
- In order to favor from better interest rates, investments in short-term deposits were made of MSEK -306.2 during the quarter. Cash flow from investing activities thus totalled MSEK -345.5 (-32.1).
- Total cash flow for the quarter was MSEK -353.8 (-60.9). Adjusted for the allocation of cash to deposits, total cash flow was MSEK -47.6 (-60.9).

CEO comments

Back to growth and off to a good start into 2023

Our three priorities for 2023 are to bring Sedana Medical back on a growth path, to get closer to break-even in our ex-US business and to make headway towards the NDA approval in the US. During the first quarter of 2023, we have made good progress against all these three priorities.

Organic growth in all direct markets

After a turbulent 2022, which was characterized by different market headwinds in the Covid-19 aftermath, I am happy to report positive year-over-year growth in every one of our direct markets. Our main market Germany grew by 13% (6% in local currencies). This is despite a lower number of ventilated ICU patients compared to last year, which was still impacted by the tail of the last Covid-19 wave hitting the ICUs. On average, the number of total ICU patients in high-care and ECMO settings (including both ventilated and non-ventilated patients) was 5% lower than last year, while the number of ventilated Covid-19 patients declined by 74%. On a positive note, we saw both gaps narrowing during the quarter, meaning that we are gradually reaching normalized comparators.

Our other direct markets Spain, France, UK, Nordics and Benelux grew by 61% (52% in local currencies), marking the strongest quarter these markets have delivered to date, including the Covid-19 period. In Spain, we received a positive decision by the Ministry of Health regarding pricing and reimbursement, which is an important milestone and a potential inflection point for further growth. A similar inflection point in the UK could be the MHRA approval, which is still outstanding.

Meanwhile, we saw another decline of -39% (-43% at fixed currencies) in our distributor markets. The gap is again explained by the lack of orders from our South American distributor who continues to work through high inventory levels, which were built during Covid-19. Excluding this one distributor, we saw higher distributor sales than last year, and quarter-over-quarter growth for the third time in a row. The last sizeable order from South America was received in the second quarter 2022, meaning that the negative impact from this effect will subside after the second quarter this year.

Working towards profitability in today's core business

We are eagerly looking forward to entering our largest-potential market, the United States, which may open a new growth horizon for Sedana Medical. We want to be able to take this exciting step with the security of a profitable business outside the US. Therefore, we are aiming to achieve break-even in today's geographical footprint before entering the US.

Hard work has been, and is, ongoing to optimize all elements of our cost structure, enhance organizational effectiveness and build a forceful commercial company. Among others, this work includes cost negotiations with key suppliers, more disciplined management of distribution cost, shifting of investments towards profitable growth opportunities and an overall streamlining of headquarter, administrative and overhead functions. The



overall number of employees and consultants has decreased from 107 at the end of 2021 to 92 at the end of this year's first quarter, while simultaneously strengthening the frontline teams in our key markets.

These measures are starting to show effect. The gross margin increased to 73% during the quarter, up from 68% last year. It should be noted however that our price adjustments in the market show effect in the profit and loss statement faster than cost increases in the supply chain, which is expected to decrease the gross margin slightly over time.

The EBITDA loss for the first quarter was reduced by 35% and the overall operating expense level came down by 4% in an inflationary environment, while at the same time the share of selling expenses in overall operating expenses increased by 2 percentage points.

USA: continued progress in our INSPiRE-ICU program

During the first quarter, I had the pleasure of meeting most of our clinical trial sites at an investigator meeting in Boston and also visited several hospitals. I am very proud to have so many of America's most prominent institutions involved in our trials and focused on the goal of bringing a potentially paradigm-changing therapy to US patients. It is great to see the motivation and excitement among the teams, which received an extra boost after FDA had granted our development program fast track designation.

The opening of new sites and enrolment of patients is progressing and we remain focused on our target to conclude enrolment this year and – assuming successful FDA review – start our launch early 2025.

Continued focus on commercial execution, cost effectiveness, and finishing the US trials

Together with my passionate colleagues, I remain fully focused on our priorities: We will continue to focus on commercial execution in our key markets to make inhaled sedation the standard of care in as many intensive care units as possible. We will continue to work on our organizational effectiveness and ensuring that our investments are targeted at profitable growth opportunities. And, we will work hard to finalize our INSPiRE-ICU trials in the US.

While 2022 was a turbulent year with numerous negative external effects, we have used the time to build a stronger and healthier Sedana Medical and are looking forward to seeing the impact.

I would like to take the opportunity to thank our shareholders for your continued support throughout a stormy year 2022 at the stock market. An exciting year lies ahead, and we are off to a good start.

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 April 27, 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 Q1 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 April 27, 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.