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# Sedana Medical AB's Year-end report 2022

## Fast track designation in the US and our strongest quarter in 2022

## Fourth quarter 2022

- Net sales for the quarter totalled MSEK 35.8 (46.4), equivalent to a decrease of 23% compared to 2021. At constant exchange rates, sales decreased by 28%.
- Gross profit was MSEK 25.7 (32.8) equivalent to a margin of 72% (71%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -17.6 (-13.5), equivalent to an EBITDA margin of -49% (-29%).
- Operating income (EBIT) totalled MSEK -23.2 (-18.7), equivalent to an EBIT margin of -65% (-40%).
- Net income for the quarter was MSEK -35.9 (-16.8) and earnings per share before and after dilution was SEK -0.36 (-0.18).
- Cash flow from operating activities totalled MSEK -22.6 (-1.6).
- Cash flow from investing activities totalled MSEK -27.3 (-33.4).
- Total cash flow was MSEK -51.1 (570.9).
- Cash and cash equivalents at the end of the quarter totalled MSEK 608 MSEK compared to MSEK 676 at the beginning of the quarter.

## January-December 2022

- Net sales totalled MSEK 122.9 (159.2), equivalent to a decrease of 23% compared to the previous year. At constant exchange rates, sales decreased by 27%.
- Gross profit was MSEK 86.1 (106.7), equivalent to a margin of 70% (67%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -83.1 (-50.1), equivalent to an EBITDA margin of -68% (-31%).
- Operating income (EBIT) totalled MSEK -105.9 (-61.5) equivalent to an EBIT margin of -86% (-39%).
- Net income for the year was MSEK -73.5 (-58.0), and earnings per share before and after dilution was SEK -0.74 (-0.62).
- Cash flow from operating activities totalled MSEK -115.4 (-41.2).
- Cash flow from investing activities totalled MSEK -137.8 (-110.3).
- Total cash flow was MSEK -254.7 (453.6).
- Cash and cash equivalents at the end of the year totalled MSEK 608, compared to MSEK 836 at the beginning of the year.
- The Board of Directors proposes that no dividend be paid for the 2022 financial year.

## CEO comments

### *Fast track designation in the US and our strongest quarter in 2022*

**In the fourth quarter of 2022, we made important steps forward with both of our main priorities: We see progress in the commercial execution in Europe and have been granted fast track designation by the FDA for our highest potential market, the United States.**

### *2022 – a year characterized by a temporary contraction of our addressable market*

After two exceptional years during the global Covid-19 pandemic, 2020 and 2021, when Sedana Medical's sales reached new heights, we have now concluded 2022, which was impacted by a number of external market influences. In addition to the expected decline of Covid-19 patients in ICUs around the globe, hospitals in all our major markets were plagued with severe staff shortages, and continued hygiene measures resulted in lower level of community-acquired infections.

As a result, we saw significantly lower numbers of ventilated intensive care patients throughout the year. This trend continued in the fourth quarter. On average, only 30% of German intensive care units reported regular operations during the quarter. The number of ventilated Covid-19 patients per day in German ICUs dropped by 75% versus 2021 while the number of ICU patients per day overall declined by 18%.

Against these market conditions, we report net sales of 35.8 MSEK for the quarter. This represents a decline of 23% versus last year (28% in local currencies), but also marks the strongest quarter in 2022. For the year, we achieved net sales of 122.9 MSEK, a decline of 23% (27% in local currencies). Taking a through-cycle

perspective however, we have seen a 71% sales increase compared to 2019, the last full year that was not impacted by Covid-19.

### *USA: fast track designation and progress in our clinical trials*

I am delighted to report that FDA has granted our development program fast track designation in the United States. FDA's fast track program exists in order to bring important therapies to US patients in an expedited way. A fast track designation has several potential benefits, such as closer and more frequent interactions with FDA, as well as possible granting of rolling review, priority review or accelerated approval.

Meanwhile our clinical trials INSPiRE-ICU 1&2 are progressing. We now have close to 20 clinical trial sites actively recruiting and we are very pleased with the level of commitment and excitement among some of the US leading key opinion leaders in our space. Assuming positive trial results and timely approval by the FDA, we are aiming at a US launch early 2025.

### *Positive regulatory and pricing/reimbursement news in several countries*

With the approval of Sedaconda (isoflurane) in Poland in Q4, 2022, we have now received national approvals in all 15 countries that were included in our first European submission. In February 2023, we received market approval in Italy, where our existing distributor for the device will also sell the pharmaceutical. Together with Switzerland, where approval was received in Q3, this brings the number of approvals to 17 countries in Europe.

We have finalized our price negotiation and signed a contract with the German payor association (GKV-SV). We have thereby completed the pricing and reimbursement process in Germany and secured a satisfactory list price for Sedaconda (isoflurane), which allows us to keep our current net prices in the market.

In Spain, the timeline for pricing and reimbursement approval has lagged behind our expectations after the Spanish authorities did not grant an approval of our pricing and reimbursement submission in December. We are in active discussions with the Spanish authorities and hope to make swift progress towards an approval. On a very positive note, the Spanish intensive medicine society SEMICYUC has issued new treatment recommendations for sedation and delirium. In the new treatment algorithm, isoflurane is recommended as first line option, on the same level as propofol, for moderate and deep sedation.

We are still eagerly awaiting MHRA approval in the UK as we believe we are well positioned to accelerate our growth in the UK upon approval. We could then benefit even more from the positive NICE guidance, which recommends our products for inhaled sedation and also confirms a significant health economic benefit versus intravenous sedation. In recent communication, MHRA has informed us that we can expect an update from them by the end of February/beginning of March.

### *Uplisting to Nasdaq Stockholm main market*

On January 25th, we were able to ring the opening bell at Nasdaq Stockholm, and Sedana Medical has thus successfully transitioned from First North Growth Market to the Nasdaq Stockholm main market. With our growing global presence and the prospects of entering the attractive US market, Sedana Medical's equity story is becoming more appealing to international investors, and we believe that the main market offers us better conditions for broadening our shareholder base internationally.

### *Focus for 2023 is on sales growth, further cost efficiency measures and finishing the US trials*

Now that we have completed the transition year 2022 and are expecting to gradually enter into a "new normal" after Covid-19, we are fully focused on executing on our key priorities. We are committed to leading Sedana Medical back on a growth path and closer towards profitability and will work hard to complete patient recruitment in our US trials this year.

I would like to take the opportunity to thank our shareholders for your continued support throughout a turbulent year at the stock market. An exciting year lies ahead for Sedana Medical, and 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) Thursday February 16, 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 Q4 Report 2022 (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 February 16, 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.