

Press release April 25, 2024, 07.00 CET.

## Sedana Medical AB's Interim report January-March 2024

### Off to a strong start with record sales in Q1

#### First quarter 2024

- Net sales for the quarter totalled MSEK 48.8 (37.8), equivalent to an increase of 29% compared to the same quarter 2023. At constant exchange rates, sales increased by 28%.
- Gross profit was MSEK 34.8 (27.5) equivalent to a margin of 71% (73%). The decrease is mainly due to product mix effects.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -1.0 (-10.7), equivalent to an EBITDA margin of -2% (-28%). EBITDA ex-US for the quarter was MSEK 1.6 (-10.1) corresponding to a margin of 3% (-27%).
- Operating income (EBIT) totalled MSEK -6.6 (-16.3), equivalent to an EBIT margin of -13% (-43%).
- Net income for the quarter was MSEK 20.7 (-16.1) and earnings per share before and after dilution was SEK 0.21 (-0.16). The increase is due to a higher financial net compared to the same quarter 2023. The financial net partly consists of unrealized currency effects on cash and cash equivalents held in USD, but also of received interest on cash and cash equivalents.
- Cash and short-term investments at the end of the quarter totalled MSEK 361 compared to MSEK 382 at the beginning of the quarter, supported by a positive exchange rate effect of MSEK 17.8.
- Cash flow from operating activities totalled MSEK 8.4 (-7.0). The positive operating cash flow derives partly from received interest on cash and cash equivalents of MSEK 4.6 related to repaid deposits but also to increased short-term liabilities as payments for investments in the US studies were made at the beginning of April.
- Cash flow from investments in intangible assets, mostly driven by our US clinical program, totalled MSEK -52.1 (-39.3). Including the quarter's repaid deposits and the previous year's investment in deposits, total cash flow from investment activities totalled MSEK 103.2 (-345.5).
- Total cash flow for the quarter was MSEK 110.3 (-353.8). Excluding the repaid deposits and the previous year's investment in deposits, the total cash flow amounted to MSEK -45.0 (-47.6).

### CEO comments

#### *Off to a strong start with record sales in Q1*

**Coming out of a successful 2023, we have established ambitious goals for 2024: achieving an all-time-high in sales, attaining EBITDA break-even outside of the US within the year, and obtaining top-line data from our U.S. clinical program, which could pave the way to our single biggest growth opportunity. With record sales in Q1, our ex-US EBITDA in balance, and the last patient enrolled in INSPIRE ICU-1, I am delighted to report strong progress across all of these areas.**

#### **Accelerated sales growth**

We report net sales of 49 MSEK for Q1, which marks the highest quarterly sales in Sedana Medical's history, including the Covid-19 period. Compared to last year, we have grown the business by 28%, translating to 29% in SEK.

Our main market Germany delivered a year-over-year growth of 17% in the quarter. This is despite an 8% decrease of ICU patients. Following our investment philosophy to focus on profitable markets with healthy momentum, we extended the German field team during 2023. Furthermore, we remain focused on continuously enhancing field force effectiveness, by maximizing the time we spend with our customers and helping them identify more patients likely to benefit from the compelling clinical benefits of inhaled sedation. I am very pleased that this strategy is bearing fruit.

Our other direct markets remain on their strong trajectory and achieved a growth rate of 54% excluding exchange rate effects. Once again, Spain was our main growth engine, building on an expanding customer base, the pricing and reimbursement approval and the launch of our pharmaceutical Sedaconda (isoflurane) in Q4. Furthermore, I am pleased to report that we have seen significantly accelerated sales growth in the UK, after obtaining MHRA approval end of 2023. With now 29% of our total sales, our direct markets outside Germany play an increasingly vital role to live up to our overall growth ambitions.

Our distributor business grew 44% year over year excluding exchange rate effects, fueled by the first order from our main South American distributor since 2022, worth 1.4 MSEK. It is worth pointing out that this order

includes sufficient stock for Mexico and Colombia for at least one year, which is in line with the typical ordering rhythm in the region. Besides the positive development in South America, we also saw growth of approximately 3% from our other distributor partners.

### ***Further improved bottom line***

We continue on the path of consistent improvement in our bottom line quarter after quarter, which underscores our commitment to financial resilience and our clear aim to reach ex-US break-even during this year. In Q1, we report an EBITDA loss of -1.0 MSEK for the company, which compares to a loss of -10.6 MSEK last year. For our ex-US business in isolation, we have even seen a slightly positive EBITDA of 1.6 MSEK, helped by a positive exchange rate effect of 2.3 MSEK.

The substantial improvement of the bottom line over the last year is a result of our two-pronged strategy to drive profitable sales growth, while simultaneously reducing our operating expenses. The decisive steps we have taken to streamline our headquarter and reduce the cost for non-customer-facing activities, has allowed us to implement a vigorous shift of resources and investments towards the frontline teams and hence profitable growth opportunities in our key markets.

While we may see seasonally lower sales in Q2 and Q3 as a function of less busy intensive care units, I am proud that we have improved our EBITDA so remarkably, after reporting the biggest full-year EBITDA loss in the company's history only 14 months ago.

### ***Progress in the USA***

With the gratifying development in Europe, we become even more excited about the growth opportunity in the United States, where we estimate the market potential for our inhaled sedation products to 10-12 BSEK. This figure is approximately three times greater than the combined market potential of our current direct markets in Europe. Several factors contribute to this significant opportunity, including the larger population size, a medical practice more in favor of intubation, and an overall attractive pricing environment. With a good fit with the US healthcare and reimbursement system and a potentially significant positive impact on hospitals' economics, we feel well positioned for a successful US launch.

We have celebrated the enrolment of the last patient for INSPIRE ICU-1 and INSPIRE ICU-2 has 23 patients remaining. While we are finishing off the enrolment period, intense work on the dossier is already underway.

Our timeline with regards to the US launch remains unchanged. We are working towards an NDA submission in the first quarter of 2025, positioning us for a potential launch in 2026, assuming the FDA adheres to their standard 10-month review time. We will apply for different benefits we may be entitled to, based on the Fast Track Designation that FDA has granted us. If successful, this could mean an acceleration of several months. However, it's important to note that FDA will assess our eligibility for these benefits only after our NDA submission, following their standard protocol.

### ***Exciting times ahead***

I am very pleased with the progress we have made during the quarter. While it would be premature to change our financial targets for the full year, the strong start into 2024 puts us on a good trajectory to deliver on our goals. I would like to thank the entire Sedana Medical team for once again going above and beyond and delivering a strong quarter, and of course our shareholders for your continued trust and support. With the ambition of ex-US break-even during the year and hopefully positive topline data from the US, 2024 holds the potential to be a true inflection point in Sedana Medical's journey. 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 April 25, 2024.

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 Presentation 2024 - Finwire](#)



If you wish to participate via teleconference: +46 850 520 017. Meeting ID: 893 6725 2998.

**For additional information, please contact:**

Johannes Doll, CEO, +46 (0)76 303 66 66  
Johan Spetz, CFO, +46 (0)730 36 37 89  
ir@sedanamedical.com

*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 25, 2024 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.