



Interim report

January–March 2023

sedana medical ab (publ)



"Back to growth"

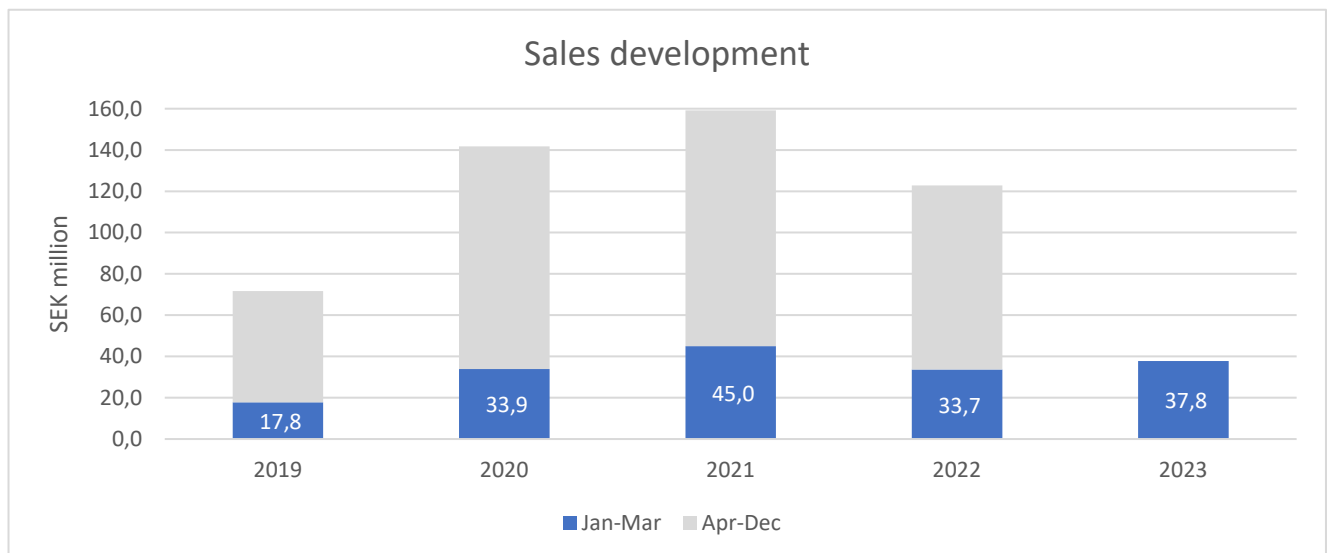
Johannes Doll, President & CEO

Q1 Q2 Q3 Q4

Financial summary

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).



Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve patients' 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 was founded in 2005 and is listed on Nasdaq Stockholm. The company's head office is in Stockholm, Sweden.

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

Significant events during the period

- In January, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation (FTD) for the evaluation of isoflurane delivered via Sedaconda ACD-S for sedation of mechanically ventilated patients in intensive care in the US.
- Patient recruitment for the company's pediatric phase III clinical study in Europe (IsoCOMFORT) was completed.
- In January, Nasdaq Stockholm's Listing Committee approved Sedana Medical's application for admission to trading of the company's shares on Nasdaq Stockholm and the company's shares thus changed marketplace from First North Growth Market to Nasdaq Stockholm's main market. First day of trading on Nasdaq Stockholm was 25 January.
- In February, market approval for Sedaconda (isoflurane) was received in Italy.

Significant events after the period

- In April we received a positive decision by the Ministry of Health in Spain regarding pricing and reimbursement.

Financial targets

The company aims at achieving revenue in excess of SEK 500 million in Europe in 2025 and an EBITDA margin of 40 percent when the company has reached a steady state following the launch phase in the United States.

Business update

Sales and commercial execution

Sedana Medical's vision is to make inhaled sedation the new standard of care in intensive care units (ICUs). Our therapy for inhaled sedation in the ICU consists of the medical device Sedaconda ACD, the pharmaceutical Sedaconda® (Isoflurane) and accessories, and it's being commercialized across Europe leveraging our own sales teams, and globally via distributors.

For the last 18 months, we have focused on building a stronger commercial company by funnelling our investments towards profitable growth opportunities and enhancing the effectiveness of our country sales organizations.

Our philosophy is to invest in countries that show good growth momentum and generate positive cash flows. For example, we have expanded the sales teams in Germany and Spain. Reversely, we have reduced or delayed further investments in lower-potential geographies until we see a clear trend towards break-even. With this approach, we will ensure that all countries contribute positively to the company over time.

At the same time, we are placing emphasis on enhancing our field force effectiveness. For example, we have implemented a better customer targeting process, more effective selling model and more rigorous performance management.

In the first quarter of 2023, all our direct markets report organic sales growth compared to the prior year, in contrast to the turbulent 2022 which had markedly fewer ICU patients and reduced ICU operations after the Covid-19 pandemic in 2020-2021. In our main market Germany, sales grew by 13% in the quarter (6% in local currency), despite sales in the first quarter last year being positively impacted by the tail of the last pandemic wave to hit ICUs. Our other direct markets (Spain, France, UK, Nordics and Benelux) grew by 61% in the quarter (52% in local currency). In our distributor markets, sales declined by 39% in the quarter compared to the prior year, driven by a decline in sales to our South American distributor, which is working through high stock levels since the pandemic. Our other distributor markets report growth in the period, especially in the Middle East.

As we have stated previously, we are beginning to see a gradual return to pre-pandemic market conditions during 2023. The remaining headwinds include primarily continued staff shortages, which are likely to take time to resolve, and more recently strikes of both nurses and doctors, for example in UK and France. While these issues sometimes prohibit or delay start-ups of new accounts, trainings or customer visits, we are overall facing a more favorable environment than in 2022.

Regulatory and pricing/reimbursement approvals

Sedaconda (isoflurane) has received regulatory approvals by the national competent authorities in 17 countries: Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden and Switzerland. Since the first shipment of Sedaconda (isoflurane) to customers in Germany in February 2022, the pharmaceutical has been made available in Sweden, Norway, the Netherlands and France. In addition, Sedaconda (isoflurane) has been launched in Slovenia via our distributor in the country.

In Spain, the Ministry of Health granted us pricing and reimbursement approval in April, marking an important milestone in one of our key markets. Also during the first quarter, 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.

In the UK, more than two years after the submission, we are still awaiting regulatory approval from the authorities (MHRA). We have received questions from MHRA, proving that the case is progressing, but still have not received a confirmed timeline. We are eagerly awaiting approval in the UK so we can leverage the positive guidance from UK's National Institute for Care and Health Excellence (NICE) we received in early 2022, where they recommend Sedaconda ACD as a cost-saving option compared to intravenous (IV) sedation.

US clinical program and launch preparations

Sedana Medical's US clinical program INSPIRE-ICU, aiming at obtaining NDA approval for inhaled sedation in the ICU, is progressing and we continue to work towards a US launch in early 2025. The US has the highest commercial potential of all markets for Sedana Medical, as it has over 100,000 ICU beds and higher sedation therapy price levels than Europe.

INSPIRE-ICU consists of two randomized double-blind clinical studies (INSPIRE-ICU 1 and 2) to confirm and ensure efficacy and safety, based on the same set-up and end-points as the European study (SED001). The total number of patients included in the two studies will be around 600 (of which 470 randomized and 130 run-in) and the company aims to include approximately 25 clinics. We remain highly encouraged by the enthusiasm expressed by the healthcare professionals participating in the trials when they see the benefits of inhaled sedation. 2023 will be the main year for patient recruitment and capex related to the US clinical program. Importantly, Sedana Medical is well funded to complete the study and achieve US approval, with 560 MSEK in cash and short-term deposits at the end of the quarter.

In early 2023, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation (FTD) for the evaluation of isoflurane via the Sedaconda ACD-S device for sedation of mechanically ventilated patients in the intensive care (ICU) setting. Fast Track is a process designed to facilitate the development and expedite the review of therapies that treat serious conditions and fill an unmet medical need. The purpose is to get important new therapies to the patient earlier.

Cost management and resource allocation

Turning our ex-US business profitable before we enter the US market is a strategic goal for the company. We need to invest in profitable growth opportunities, while at the same time making sure to manage our resources in a prudent way.

This means shifting spending from administrative functions to sales functions, and from headquarters to our main direct markets.

So far, we have been able to compensate for cost increases in our supply chain and shipping and grew our gross margin to 73% in the first quarter 2023 (68%) driven primarily by price adjustments and managing transportation towards sea freight. That said, we do see cost increases for materials and key components, and we maintain active dialogue with our suppliers on all potential price adjustments. As our own price increases show effect in our profit and loss statement faster than the increases in cost of goods, the gross margin may decrease slightly in the coming quarters. As communicated previously, our target margin remains above 70%.

Our efforts to increase efficiency in our operating cost base continue, and we have set plans for 2023 to further prioritize profitable growth initiatives and reduce spending on administration and other overhead costs. In this quarter, despite the inflationary environment, we report a reduction in operating expenses to 44 MSEK from 45 MSEK during the same quarter last year.

EBITDA for the quarter was -10.7 MSEK, compared with -16.4 MSEK last year.

Financial summary

(KSEK)	Jan-Mar		Jan-Dec
	2023	2022	2022
Net sales	37,781	33,654	122,865
Gross profit	27,489	22,990	86,074
Gross margin %	73%	68%	70%
EBITDA	-10,661	-16,444	-83,138
EBITDA margin %	-28%	-49%	-68%
Operating income (EBIT)	-16,297	-22,061	-105,887
Operating margin %	-43%	-66%	-86%
Income after net financial items	-16,010	-18,826	-72,933
Net income	-16,122	-18,973	-73,507
Net income margin %	-43%	-56%	-60%
Total assets	1,064,043	1,141,361	1,081,588
Equity	1,012,430	1,082,203	1,029,155
Equity ratio %	95%	95%	95%
Quick ratio %	1187%	1492%	1299%
Debt to equity ratio %	5%	5%	5%
Average number of full-time employees for the period	79	87	86
Number of employees at balance date	83	94	85
Number of employees and consultants at balance date	92	102	95
Average number of shares before dilution	99,336,960	99,336,960	99,336,960
Average number of shares after dilution	99,336,960	99,490,544	99,336,960
Number of shares at balance date before dilution	99,336,960	99,336,960	99,336,960
Number of shares at balance date after dilution	99,336,960	99,490,544	99,336,960
Earnings per share before dilution, SEK	-0.16	-0.19	-0.74
Earnings per share after dilution, SEK	-0.16	-0.19	-0.74

Group performance

Net sales

Net sales for the quarter amounted to KSEK 37,781 (33,654), corresponding to an increase of 12 percent. Adjusted for currency effects, the quarter showed an increase of 5 percent. The increase is mainly related to Other direct markets, where all regions contributed positively. The increased sales were partially offset by negative growth in our Distributor markets, which, also during this quarter, was affected by high inventory levels in South America both at the distributors and at the hospitals. Outside South America the Distributor markets showed positive growth during the first quarter of the year.

(KSEK)	Jan-Mar			Jan-Dec	
	2023	2022	%	%*	2022
Germany	25,267	22,384	13%	6%	86,099
Other direct sales	9,043	5,625	61%	52%	21,831
Distributor markets	3,470	5,645	-39%	-43%	14,935
Total net sales	37,781	33,654	12%	5%	122,865

*) at constant exchange rates

Gross profit and margin

The gross profit during the quarter amounted to KSEK 27,489 (22,990), corresponding to a gross margin of 73 (68) percent. The increase is primarily an effect of higher sales prices compared to the previous quarter and lower unallocated central costs.

Selling expenses

Selling expenses for the quarter amounted to KSEK -26,691 (26,597) which is in line with the previous year.

Administrative expenses

Administrative expenses for the quarter were KSEK -12,474 (-12,561), which corresponds to a decrease of 1 percent.

Research and development expenses

Research and development expenses for the quarter amounted KSEK -5,095 (-5,314), which corresponds to a decrease of 4 percent.

Other operating income/expenses

Other operating income mainly consists of positive unrealised exchange rate differences on operating items. These totalled KSEK 6,813 (6,233) for the quarter.

Other operating expenses mainly consist of negative unrealised exchange rate differences on operating items. These totalled KSEK -6,338 (-6,813) for the quarter.

Net financial items and earnings per share

Net financial items for the quarter totalled KSEK 287 (3,236). The amounts consist mainly of unrealised exchange rate differences on cash and cash invested in USD.

Group tax expense for the quarter was KSEK -112 (-147) and consists mainly of current tax in Germany. Consequently, earnings per share amounted to SEK -0.16 (-0.19) for the quarter.

Capitalised development expenditures

Capitalised development expenditures as of March 31 amounted to KSEK 426,074 compared to KSEK 390,530 at the beginning of the year. The amount mainly consists of expenses related to the clinical studies and registration work carried out in connection with the European market approval of Sedaconda (isoflurane) and thus also inhaled sedation. The amount also includes expenses related to the clinical studies and registration work in the United States preparing for a future market approval. The increase compared to the beginning of the year amounts to KSEK 35,544 and mainly relates to investments in clinical studies and registration work for Sedaconda ACD and Sedaconda (isoflurane) in the US as well as investments related to the company's pediatric study IsoCOMFORT (SED002).

Inventory

As of March 31, inventory amounted to KSEK 38,868 compared to KSEK 38,597 at the beginning of the year. The inventory mainly consists of finished goods and trade goods.

Equity and debt

Equity on March 31 was KSEK 1,012,430, compared to KSEK 1,029,155 at the beginning of the year. This corresponds to SEK 10.19 (10.89) per share. Equity/assets ratio was 95 percent, compared to 95 percent at the beginning of the year. Debt/equity ratio on March 31 was 5 percent, compared to 5 percent at the beginning of the year. The Group had no long-term debt on March 31.

Cash, cash position and short-term investments

Cash and cash equivalents decreased by KSEK 356,099 during the quarter and totalled KSEK 251,643 on March 31, compared to KSEK 607,742 at the beginning of the quarter. Cash flow from operating activities before changes in working capital for the quarter was KSEK -9,983 (-16,288). Cash flow from changes in working capital totalled KSEK 3,005 (-11,239) and was positively impacted during the quarter mainly due to payments from customers. Cash flow from operating activities thus totalled KSEK -6,979 (-27,527).

Cash flow from investing activities for the quarter totalled KSEK -345,539 (-32,145). During the quarter, KSEK 306,156 of the company's cash and cash equivalents were invested short-term in favor of better interest rates. Other investments mostly consist of intangible assets, mainly development expenses for clinical studies and work on registration of Sedaconda ACD and Sedaconda (isoflurane) in the United States, as well as investments related to the company's paediatric study IsoCOMFORT (SED002).

Cash flow from financing activities for the quarter totalled KSEK -1,243 (-1,204) and relates to amortisation of lease liabilities.

Translation differences in cash and cash equivalents amounted to KSEK -2,339 during the quarter and are mainly related to cash and cash equivalents held in USD. Cash flow per share for the quarter was SEK -3,56 (-0,61). Adjusted for the investment in short-term investments, the cash flow per share amounted to SEK -0.48 (-0.61).

Parent company

The Parent Company's net sales for the quarter totalled KSEK 37,736 (33,626), of which intra-group sales were KSEK 2,188 (1,653).

Operating income for the period totalled KSEK -13,810 (-17,388). Net financial items were KSEK 910 (3,544) and relate mainly to unrealised exchange gains on cash balances in foreign currencies, mainly USD.

Shareholders' equity in the Parent Company totalled KSEK 1,037,446 at March 31 2023, compared to KSEK 1,050,412 at the beginning of the year. This corresponds to a decrease of KSEK 12,965. Share capital totalled KSEK 2,483, compared to KSEK 2,483 at the beginning of the year.

Cash and cash equivalents stood at KSEK 235,115, compared to KSEK 587,909 at the beginning of the year. Available funds in the parent company, including short-term investments, amounted to KSEK 543,657 compared to KSEK 587,909 at the beginning of the year.

The Sedana Medical share

Sedana Medical share was listed on Nasdaq First North Growth Market Stockholm in 2017 and are since January 25, 2023 listed on Nasdaq Stockholm. Market capitalisation at the end of the first quarter was SEK 2,124 million.

The price paid for Sedana Medical shares was SEK 18.70 at the start of the year and SEK 21.38 at the end of the quarter. The lowest closing price during the quarter was recorded on March 21 and was SEK 18.60. The highest closing price was recorded on January 13 and was SEK 27.30.

Share information

	Jan-Mar		Jan-Dec
	2023	2022	2022
Net income, KSEK	-16,122	-18,973	-73,507
Cash flow, KSEK	-353,760	-60,877	-254,722
Number of shares at balance date	99,336,960	99,336,960	99,336,960
Average number of shares	99,336,960	99,336,960	99,336,960
Outstanding warrants at balance date	1,003,959	505,368	1,003,959
Average number of warrants	1,003,959	509,368	758,664
Share capital at balance date, KSEK	2,483	2,483	2,483
Equity at balance date, KSEK	1,012,430	1,082,203	1,029,156
Earnings per share before dilution, SEK	-0.16	-0.19	-0.74
Earnings per share after dilution, SEK	-0.16	-0.19	-0.74
Equity per share, SEK	10.19	10.89	10.36
Cash flow per share, SEK	-3.56	-0.61	-2.56

Largest shareholders at the end of the period

	No of shares	Share
Linc AB	10,111,030	10.2%
Swedbank Robur Funds	9,519,013	9.6%
Anders Walldov direct and indirect (Brohuvudet AB)	8,500,000	8.6%
Handelsbanken Funds	7,300,000	7.3%
Ola Magnusson direct and indirect (Magiola AB)	4,462,098	4.5%
Sten Gibeck	4,286,276	4.3%
Öhrman Funds	4,150,984	4.2%
Highclere International Investors LLP	2,382,254	2.4%
Bank of Norway	2,690,924	2.7%
AMF Pension	2,491,000	2.5%
Berenberg Funds	1,823,547	1.8%
Third Swedish National Pensen Fund	1,735,989	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Amundi	1,190,512	1.2%
Philip Earle	1,104,456	1.1%
Fifteen largest shareholders	63,414,547	63.8%
Others	35,922,413	36.2%
Total	99,336,960	100.0%

Facts about the share

Trading <i>Nasdaq Stockholm</i>
No of shares as per Mar 31, 2023 99 336 960
Market cap as per Mar 31, 2023 <i>SEK 2,124 million</i>
Ticker <i>SEDANA</i>
ISIN <i>SE0015988373</i>
LEI-code <i>549300FQ3NJRI56LCX32</i>

Certification from the Board of Directors and the CEO

The Board of Directors and the Chief Executive Officer certify that this interim report presents a true and fair view of the operations, financial position and earnings of the parent company and the Group and describes material risks and uncertainties faced by the parent company and the companies forming part of the Group.

Danderyd 27 April 2023

Thomas Eklund
Chairman of the Board

Claus Bjerre
Deputy chairman

Hilde Furberg
Board member

Ola Magnusson
Board member

Eva Walde
Board member

Christoffer Rosenblad
Board member

Johannes Doll
President and CEO

This interim report has not been subject to review by the company's auditors. This document has been prepared in Swedish and English versions. In the event of any discrepancies between the Swedish and English versions, the Swedish version will take precedence.

Contacts and invitation to presentation

Johannes Doll, President and CEO, +46 76 303 66 66
Johan Spetz, CFO, +46 73 036 37 89
ir@sedanamedical.com

Sedana Medical is listed on Nasdaq Stockholm.

Presentation of the interim report

Sedana Medical presents the interim report to investors, asset managers, analysts and media on April 27 2023 at 13.30. The presentation will be held in English and takes place via telephone conference and audio webcast. More information is available at: <https://financialhearings.com/event/45893>

After the presentation, a recorded version of the webcast will be available at: <https://sedanamedical.com/investors>

Financial calendar

Annual General Meeting 2023	16 May 2023
Interim Report Q2 2023	21 July 2023
Interim Report Q3 2023	26 October 2023

Consolidated income statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2023	2022	2022
Net sales	37,781	33,654	122,865
Cost of goods sold	-10,292	-10,663	-36,791
Gross profit	27,489	22,990	86,074
Selling expenses	-26,691	-26,597	-112,469
Administrative expenses	-12,474	-12,561	-57,473
Research and development expenses	-5,095	-5,314	-19,944
Other operating income	6,813	6,233	13,319
Other operating expenses	-6,338	-6,813	-15,394
Operating income	-16,297	-22,061	-105,887
Financial items			
Financial income	1,243	3,455	48,300
Financial expenses	-956	-219	-15,346
Net financial items	287	3,236	32,954
Income before taxes	-16,010	-18,826	-72,933
Tax	-112	-147	-574
Net income	-16,122	-18,973	-73,507
Earnings per share, based on earnings attributable to the parent company's ordinary shareholders:			
Before dilution	-0.16	-0.19	-0.74
After dilution	-0.16	-0.19	-0.74
Operating income (EBIT)	-16,297	-22,061	-105,887
Whereof amortisation of intangible assets	-3,859	-3,806	-15,538
Whereof depreciation of tangible assets	-1,778	-1,812	-7,211
EBITDA	-10,661	-16,444	-83,138

Consolidated statement of other comprehensive income, summary

(KSEK)	Jan-Mar		Jan-Dec
	2023	2022	2022
Net income	-16,122	-18,973	-73,507
Other comprehensive income			
Items that can later be reclassified to the income statement:			
Translation differences from foreign operations	-604	-183	-2,834
Other comprehensive income, net after tax	-604	-183	-2,834
Total comprehensive income	-16,726	-19,156	-76,341
Total comprehensive income as a whole attributable to the parent company's shareholders	-16,726	-19,156	-76,341

Consolidated balance sheet, summary

(KSEK)	Mar 31, 2023	Mar 31, 2022	Dec 31, 2022
ASSETS			
Intangible assets			
Capitalised development expenditure	426,074	295,391	390,530
Concessions, patents, licenses, etc.	3,119	2,595	2,849
Tangible assets			
Machinery and other technical facilities	901	1,195	955
Equipment, tools and installations	3,937	5,984	4,492
Rights of use	8,653	10,343	9,271
Financial assets			
Other long-term assets	46	42	46
Deferred tax assets			
	31	26	29
Total fixed assets	442,761	315,577	408,172
Inventory	38,868	18,498	38,597
Tax receivables	826	712	514
Accounts receivable	13,920	15,187	15,849
Prepayments and accrued income	5,628	7,771	6,017
Other receivables	1,855	4,999	4,697
Short-term investments	308,542	-	-
Cash and cash equivalents	251,643	778,617	607,742
Total current assets	621,282	825,784	673,416
TOTAL ASSETS	1,064,043	1,141,361	1,081,588
EQUITY AND LIABILITIES			
Equity			
Share capital	2,483	2,483	2,483
Other contributed capital	1,226,435	1,222,298	1,226,435
Translation difference	-3,254	1	-2,650
Retained earnings including net profit	-213,235	-142,579	-197,113
Equity attributable to the parent company's shareholders	1,012,430	1,082,203	1,029,155
Non-current liabilities			
Leasing liabilities	2,533	5,059	3,576
Total non-current liabilities	2,533	5,059	3,576
Current liabilities			
Leasing liabilities	5,536	4,805	5,167
Accounts payable	2,559	12,927	11,270
Tax debt	1,331	2,655	2,559
Other liabilities	5,751	11,676	6,929
Accrued expenses and deferred income	33,902	22,036	22,932
Total current liabilities	49,080	54,099	48,857
Total liabilities	51,613	59,158	52,433
TOTAL EQUITY AND LIABILITIES	1,064,043	1,141,361	1,081,588

Consolidated statement of changes in equity, summary

Equity attributable to parent company shareholders

(KSEK)	Share capital	Other contributed capital	Translation difference	Retained earnings incl net income	Total
Opening equity at Jan 1, 2022	2,483	1,222,395	184	-123,606	1,101,456
Net income	-	-	-	-18,973	-18,973
Other comprehensive income	-	-	-183	-	-183
Total comprehensive income	-	-	-183	-18,973	-19,156
Transactions with the Group's owners					
Repurchase of warrants	-	-97	-	-	-97
Total transactions with the Group's owners	-	-97	-	-	-97
Closing equity at Mar 31, 2022	2,483	1,222,298	1	-142,579	1,082,203

(KSEK)	Share capital	Other contributed capital	Translation difference	Retained earnings incl net income	Total
Opening equity at Jan 1, 2023	2,483	1,226,436	-2,650	-197,113	1,029,157
Net income	-	-	-	-16,122	-16,122
Other comprehensive income	-	-	-604	-	-604
Total comprehensive income	-	-	-604	-16,122	-16,726
Transactions with the Group's owners	-	-	-	-	-
Total transactions with the Group's owners	-	-	-	-	-
Closing equity at Mar 31, 2023	2,483	1,226,436	-3,254	-213,235	1,012,430

Consolidated cash flow statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2023	2022	2022
Operating activities			
Operating income	-16,297	-22,061	-105,887
<i>Adjustments for non-cash items</i>			
Depreciations and amortisations	5,637	5,618	22,749
Exchange rate differences	133	236	-863
Other non-cash items	711	114	1,152
Interest received	0	0	3,580
Interest paid	-55	-63	-255
Taxes paid	-112	-131	-583
Cash flow from operating activities before changes in working capital	-9,983	-16,288	-80,108
<i>Cash flow from changes in working capital</i>			
Cash flow from inventories	-871	-7,405	-27,504
Cash flow from operating receivables	4,690	4,194	7,494
Cash flow from operating liabilities	-814	-8,028	-15,315
Cash flow from operating activities	-6,979	-27,527	-115,433
Investing activities			
Investments in intangible assets	-39,289	-31,660	-137,048
Investments in tangible assets	-93	-486	-735
Investments in short-term deposits	-306,156	-	-
Cash flow from investing activities	-345,539	-32,145	-137,783
Financing activities			
New share issue	-	-	-
Issue expenses	-	-	-
Amortisation of leasing liabilities	-1,243	-1,107	-4,510
Received premium for warrant subscription	-	-	3,590
Costs related to warrant programme	-	-	-490
Repurchase of warrants	-	-97	-97
Cash flow from financing activities	-1,243	-1,204	-1,507
Cash flow for the period	-353,760	-60,877	-254,722
Cash and cash equivalents at the beginning of the period	607,742	836,181	836,181
Translation difference	-2,339	3,313	26,283
Cash and cash equivalents at the end of the period	251,643	778,617	607,742

Parent company income statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2023	2022	2022
Net sales	37,736	33,626	122,726
Cost of goods sold	-9,833	-9,735	-34,092
Gross profit	27,903	23,891	88,634
Selling expenses	-16,869	-15,382	-68,360
Administration costs	-24,697	-26,902	-112,498
Research and development costs	-4,346	-4,361	-16,927
Other operating income	10,237	11,961	30,757
Other operating expenses	-6,038	-6,596	-15,238
Operating income	-13,810	-17,388	-93,632
Financial items			
Financial income	1,806	3,698	48,965
Financial expenses	-896	-155	-15,074
Net financial items	910	3,544	33,891
Income after net financial items	-12,900	-13,844	-59,741
Group contribution	-	-	0
Income before tax	-12,900	-13,844	-59,741
Income tax	-	-	-
Net income	-12,900	-13,844	-59,741

Parent company statement of other comprehensive income, summary

(KSEK)	Jan-Mar		Jan-Dec
	2023	2022	2022
Net income	-12,900	-13,844	-59,741
Other comprehensive income			
Items that can later be reclassified to the income statement:			
Translation differences from foreign operations	-65	-63	-416
	-65	-63	-416
Other comprehensive income, net after tax			
Total comprehensive income	-12,965	-13,907	-60,158

Parent company balance sheet, summary

(KSEK)	Mar 31, 2023	Mar 31, 2022	Dec 31, 2022
ASSETS			
Intangible assets			
Capitalised development expenditure	398,971	279,575	365,470
Tangible assets			
Machinery and other technical facilities	790	815	795
Equipment, tools and installations	3,574	5,312	4,066
Financial assets			
Other long-term assets	404	404	404
Non-current receivables, group companies	35,271	30,531	34,518
Total fixed assets	439,010	316,636	405,253
Inventory	38,868	18,498	38,597
Tax receivables	4	19	4
Accounts receivable	11,916	13,172	14,102
Receivables, group companies	64,916	41,973	49,893
Prepayments and accrued income	5,595	7,105	5,823
Other receivables	1,066	4,422	4,072
Short-term investments	308,542	-	-
Cash and cash equivalents	235,115	765,449	587,909
Total current assets	666,022	850,637	700,401
TOTAL ASSETS	1,105,031	1,167,273	1,105,654
(KSEK)			
	Mar 31, 2023	Mar 31, 2022	Dec 31, 2022
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	2,483	2,483	2,483
Fund for capitalised development expenses	390,482	272,270	356,396
<i>Non-restricted equity</i>			
Share premium fund	1,226,435	1,222,298	1,226,435
Retained earnings	-569,055	-390,683	-475,162
Net income	-12,900	-13,844	-59,741
Equity attributable to the parent company's shareholders	1,037,446	1,092,525	1,050,412
Current liabilities			
Accounts payable	1,901	12,063	10,711
Liabilities to group companies	31,155	34,039	18,092
Tax debt	1,130	1,568	2,300
Other liabilities	3,972	7,927	5,287
Accrued expenses and deferred income	29,428	19,151	18,852
Total current liabilities	67,585	74,748	55,242
Total liabilities	67,585	74,748	55,242
TOTAL EQUITY AND LIABILITIES	1,105,031	1,167,273	1,105,654

Other information

General information

Sedana Medical (publ), with corporate identity number 556670-2519, is a limited company registered in Sweden with registered office in Danderyd. The address of the head office is Vendevägen 89, SE-182 32 Danderyd, Sweden. The object of the company's operations is to develop, manufacture and sell medical devices and pharmaceuticals. Sedana Medical AB is the Parent Company of the Sedana Medical Group. Unless otherwise indicated, all amounts are stated in thousands of Swedish kronor (KSEK). All amounts, unless otherwise indicated, are rounded to the nearest thousand. Figures in brackets relate to the comparative year.

For the Group's financial assets and liabilities, their carrying amount is considered to be a reasonable estimate of fair value as they essentially refer to current receivables and liabilities, so that the discounting effect is insignificant.

Accounting principles

This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting. The parent company Interim report has been prepared in accordance with the Annual Accounts Act and Swedish Financial Reporting Board recommendation RFR 2. Applied accounting policies agree with those described in the 2022 Annual Report of Sedana Medical. None of the other published standards and interpretations that are mandatory for the Group for the financial year 2023 are deemed to have any impact on the Group's financial reports.

Important estimates

Estimates and judgements are evaluated regularly and based on historical experience and other factors, including expectations of future events considered reasonable under prevailing circumstances. For further information, see the Group's 2022 Annual Report.

Alternative performance measures

Alternative performance measures relate to financial performance indicators used by the senior management and investors to assess the Group's earnings and financial position which cannot be read or derived directly from the financial statements. These financial performance indicators are intended to facilitate analysis of the Group's development. The alternative performance measures should accordingly be regarded as complementing the financial reporting prepared in accordance with IFRS. The financial performance indicators presented in this report may differ from similar indicators used by other companies.

These key ratios that are not defined according to IFRS are also presented in the report because they are considered to constitute important supplementary key ratios for the company's results. For information on these key ratios and how they have been calculated, please see definitions on page 21 and <https://sedanamedical.com/investors/financial-reports-presentations/key-ratios/>

Risk

Sedana Medical's operations, earnings and financial position are affected by a number of risk factors. These are principally related to demand for medical devices, fluctuating exchange rates and access to funding. More information about Sedana Medical's risks and management of these risks can be found in the 2022 Annual Report on pages 40-42.

Personnel

During the period, the Group had an average of 79 (87) full time employees and 7 (10) full time consultants, representing an decrease of 10 on the same period in 2022. At the end of the quarter, the total number of employees was 83 and the total number of consultants was 9 compared to 94 and 8 respectively at the corresponding balance date last year. The decrease in the number of employees and consultants is partly a result of efficiency measures in central administrative and support functions.

Transactions with related parties

Transactions with related parties take place on market terms. During 2021, Sedana Medical provided a loan amounting to KSEK 300 to Stefan Krisch and as of March 31, the claim amounts to KSEK 300. Stefan is part of Sedana Medical's management team. During 2021, a consulting agreement was also signed between Sedana Medical and board member Claus Bjerre. In total, since the agreement was signed, 50 KSEK regarding this agreement has been settled.

Sedana Medical reports compensation and benefits to senior executives in accordance with IAS 19 Employee benefits. Additional information can be found in Sedana Medical's annual report for 2022, page 54-55.

Warrant programme

At the end of the interim period Sedana Medical had 1,003,959 outstanding warrants where 1 warrant equals 1 share at conversion.

Programme	Position	Number of acquired warrants at the beginning of the period	Number of acquired warrants during the period	Number of expired warrants during the period	Number of repurchased warrants during the period	Number of warrants at the end of the period	Terms*	Strike price (SEK)
2020/2023	CEO	0	0	0	0	0	1:1	83.65
2020/2023	Senior management	4,000	0	0	0	4,000	1:1	83.65
2020/2023	Other employees	26,560	0	0	0	26,560	1:1	83.65
2020/2023	Total	30,560	0	0	0	30,560	1:1	83.65
<i>Exercise period 1 June 2023 - 30 September 2023</i>								
2020/2024	CEO	0	0	0	0	0	1:1	123.88
2020/2024	Senior management	25,200	0	0	0	25,200	1:1	123.88
2020/2024	Other employees	123,252	0	0	0	123,252	1:1	123.88
2020/2024	Total	148,452	0	0	0	148,452	1:1	123.88
<i>Exercise period 1 February 2024 - 31 May 2024</i>								
2022/2025:1	CEO	495,000	0	0	0	495,000	1:1	46.24
2022/2025:1	Senior management	0	0	0	0	0	1:1	46.24
2022/2025:1	Other employees	0	0	0	0	0	1:1	46.24
2022/2025:1	Total	495,000	0	0	0	495,000	1:1	46.24
<i>Exercise period 30 May 2025 - 30 September 2025</i>								
2022/2025:2	CEO	0	0	0	0	0	1:1	46.24
2022/2025:2	Senior management	231,606	0	0	0	231,606	1:1	46.24
2022/2025:2	Other employees	98,341	0	0	0	98,341	1:1	46.24
2022/2025:2	Total	329,947	0	0	0	329,947	1:1	46.24
<i>Exercise period 30 May 2025 - 30 September 2025</i>								
Total	CEO	495,000	0	0	0	495,000		
Total	Senior management	260,806	0	0	0	260,806		
Total	Other employees	248,153	0	0	0	248,153		
	Total	1,003,959	0	0	0	1,003,959		

* 1:1 = 1 warrant = 1 share at conversion

Definitions

Average number of full-time employees during the period

Number of full-time employees at the end of each period divided by number of periods

Balance sheet total

Total assets

Cash flow per share

Cash flow for the period divided by average number of shares before dilution

Debt to equity ratio

Total liabilities divided by total equity

EBIT

Operating income/Earnings before interest and taxes

EBITDA

Earnings before interest, taxes, depreciation and amortisation

EBITDA margin

EBITDA divided by net sales

Equity to assets ratio

Total equity divided by total assets

Equity per share

Equity divided by number of shares at the end of the period, before dilution

Gross margin

Gross profit divided by net sales

Net income margin

Net income divided by net sales

Number of employees at the end of the period

Number of employees excluding consultants regardless of employment rate per balance sheet date. Sick leave and parental leave are included. Holidays are not excluded

Number of employees and consultants at the end of the period

Number of employees including consultants regardless of employment rate per balance sheet date. Sick leave and parental leave are included. Holidays are not excluded

Operating margin

Operating income divided by net sales

Quick ratio

Current assets excluding inventories divided by current liabilities

Tax rates for the parent company

2023: 20,6%

2022: 20.6%