

# Year-end report

January-December 2023

sedana medical ab (publ)



"Full year sales at upper end of financial guidance and an exciting year ahead!"

Johannes Doll, President & CEO

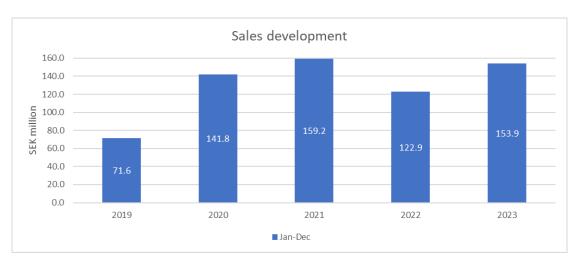
## Financial summary

## Fourth quarter 2023

- Net sales for the quarter totalled MSEK 44.5 (35.8), equivalent to an increase of 24% compared to the same quarter 2022. At constant exchange rates, sales increased by 18%.
- Gross profit was MSEK 31.0 (25.7) equivalent to a margin of 70% (72%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -9.1 (-17.6), equivalent to an EBITDA margin of -20% (-49%). EBITDA ex-US for the quarter was MSEK -8.1 (-17.4) corresponding to a margin of -19% (-49%).
- Operating income (EBIT) totalled MSEK -14.9 (-23.2), equivalent to an EBIT margin of -33% (-65%).
- Net income for the quarter was MSEK -38.1 (-35.9) and earnings per share before and after dilution was SEK -0.38 (-0.36). The decrease in net income is due to a lower financial net compared to the same quarter 2022.
- Cash and short-term investments at the end of the quarter totalled MSEK 382 compared to MSEK 453 at the beginning
  of the quarter.
- Cash flow from operating activities totalled MSEK 8.8 (-22.6). The positive operating cash flow derives from received interest on cash and cash equivalents of MSEK 8.9 (3.6).
- Cash flow from investments in intangible assets totalled MSEK -41.5 (-27.3). Total cash flow from investment activities totalled MSEK -41.8 (27.3).
- Total cash flow for the quarter was MSEK -34.3 (-51.1).

## January-December 2023

- Net sales totalled MSEK 153.9 (122.9), equivalent to an increase of 25% compared to 2022. At constant exchange rates, sales increased by 16%.
- Gross profit was MSEK 109.0 (86.1), equivalent to a margin of 71% (70%).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -43.0 (-83.1), equivalent to an EBITDA margin of -28% (-68%). EBITDA ex-US for the year was MSEK -40.1 (-80.2) corresponding to a margin of -26% (-65%).
- Operating income (EBIT) totalled MSEK -65.5 (-105.9), equivalent to an EBIT margin of -43% (-86%).
- Net income for the year was MSEK -59.6 (-73.5) and earnings per share before and after dilution was SEK -0.60 (-0.74).
- Cash and short-term investments amounted to MSEK 382 at the end of the period compared to MSEK 608 at the beginning of the year, of which short-term investments were MSEK 151 (0).
- Cash flow from operating activities totalled MSEK -38.1 (-115.4).
- Investments in intangible assets amounted to MSEK -168.4 (-137.0)
- In order to favor from better interest rates, investments in short-term deposits were made during the year. These amounted to a total of MSEK -465.4 whereof MSEK 312.4 has been repaid. Cash flow from investing activities thus totalled MSEK -322.0 (-137.8).
- Total cash flow for the year was MSEK -364.9 (-254.7). Adjusted for the allocation of cash to deposits, total cash flow was MSEK -211.8 (-254.7).
- The Board of Directors proposes that no dividend be paid for the 2023 financial year.



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

## Full year sales at upper end of financial guidance and an exciting year ahead

Reflecting on the progress we have made during the year 2023, I am pleased to see that Sedana Medical stands as a much stronger and healthier company today compared to a year ago: we have returned to consistent sales growth after the challenging post-Covid period, we have taken decisive steps towards reaching profitability in our ex-US business, and we are making progress towards our launch on the US market - our single largest growth opportunity and a pivotal milestone for the company.

#### **Continued sales growth**

We report net sales of 154 MSEK for the full year, which is at the upper end of our financial guidance of 145-155 MSEK. Excluding exchange rate effects, we have grown the business 18% in Q4 and 16% for the full year, translating to 24% and 25% in SEK, respectively.

In Q4, ICUs in our main market Germany saw approximately 9% less patients than the year before. Despite that market headwind, our German business grew by 9% in the quarter and 14% in the full year (15% and 23% in SEK respectively). Overall, we were able to increase the market penetration of our therapy from 10% in 2022 to approximately 12% in 2023. The growth is a result of our strategic focus to continuously enhance field force effectiveness, by maximizing the time we spend with our customers and to help them identify more patients likely to benefit from the compelling clinical benefits of inhaled sedation.



Our other direct markets achieved a growth rate of 54% in Q4 and 56% for the full year (62% and 67% in SEK). The robust growth has increased the share of these markets in our total sales from 18% in 2022 to 24% in 2023. Spain continued to be the main growth engine, and with the pricing and reimbursement approval and the subsequent launch of our pharmaceutical Sedaconda (isoflurane) in Q4, further growth is anticipated. Our other markets are also going into 2024 with a positive momentum. After the MHRA approval in Q4, we are finally able to actively promote inhaled sedation as a registered treatment in the UK. And with several important university hospitals as new customers and promising tenders underway, France is also poised for growth in 2024.

For the first time in 2023, our distributor markets showed positive growth in Q4. Sales were 18% higher than last year (25% in SEK). To counter previous sales declines, we have revamped our distributor model, established a new leadership team and intensified our focus on key partners with the highest growth prospects.

## Decisive steps towards ex-US profitability

2024 will be an important year for Sedana Medical as we aim to reach EBITDA break-even in our ex-US business during the year. This would mark a significant achievement, representing the first time in the company's history, with the exception of Q1 2020, when the extraordinary Covid-related sales resulted in a slightly positive EBITDA.

Continuing on the positive trajectory, our full-year EBITDA loss excluding US-related costs amounted to 40 MSEK, which is half of the 80 MSEK loss recorded in the preceding year. Notably, the remaining loss in Q4 was 8 MSEK, with 2 MSEK attributed to severance payments related to further organizational streamlining.

The consistent improvement in our bottom line quarter after quarter underscores our commitment to financial resilience and our clear aim to reach ex-US break-even during the year.

## **Progress in the USA**

We estimate the market potential for our inhaled sedation products in the United States 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 compared to Europe, and an overall attractive pricing environment.

Beyond the evident clinical benefits for patients, the key determinant of a medical product's success in the US market lies in its reimbursement status and impact on customers' economics. In the past quarter, we conducted an in-depth analysis of the US reimbursement landscape and how our therapy aligns within it. Based on these insights, we are now even more optimistic about the commercial success of inhaled sedation in the US.

Although a variety of inpatient hospital payment mechanisms exist, the DRG ("diagnoses-related groups") system is the dominant one for ventilated patients in the ICU. Under the DRGs, a hospital is paid a preset rate based on the patient's diagnoses and procedures. For mechanically ventilated patients, this will in most cases mean that hospitals will see a tangible positive financial effect if patients wake up faster, spend less time on the ventilator and leave the ICU faster – all of which are benefits of inhaled sedation, which we are hoping to prove in our US clinical trial.

Moreover, heightened awareness of opioid risks in the US, exacerbated by the opioid crisis with over 100,000 drug overdose deaths annually, positions our inhaled sedation therapy as a compelling future alternative. If our US study confirms the significant reduction of opioid use observed in our previous clinical studies, we stand to benefit from the widespread preference for opioid-sparing therapies.

The benefits of inhaled sedation are also well aligned with existing treatment recommendations, such as the CDC's "Wake up and Breathe" Collaborative, which is intended to get patients off the ventilator sooner and improve recovery time, opening up opportunities to get well positioned in treatment guidelines.

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. INSPIRE-ICU 1 has now recruited more than 200 of 235 randomized patients and INSPIRE-ICU 2 is following slightly behind. 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.

With 382 MSEK in cash and short-term investments and a plan to reach EBITDA break-even ex-US during 2024, we assess we have funding in place to achieve US approval and launch in the US market.

### An exciting year ahead

Coming out of a successful 2023, we have set ourselves ambitious targets for 2024: reaching an all-time-high in sales, delivering EBITDA break-even ex-US during the year, and receiving top-line data from our INSPIRE-ICU program in the US, which could open the doors to the single biggest growth opportunity of our future. I am excited about the prospects of this year and look forward to updating you on our progress.

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.
- 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.
- The Annual General Meeting in May decided on Claus Bjerre as the new chairman of the board.
- Topline results from the pediatric phase III IsoCOMFORT study were presented mid-May.
- At the end of June, a post-hoc analysis of the Sedaconda study SED001 was published in the Journal of Critical Care.
- In July the American FDA informed Sedana Medical that data regarding long-term outcomes needs to be included in the Clinical Study Report (CSR) of the INSPiRE-ICU trials before the New Drug Application (NDA) can be submitted.
- At the end of September, the US Patent and Trademark Office (USPTO) granted Sedana Medical a patent for the medical device Sedaconda ACD-S.
- In October in the United Kingdom, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Sedana Medical marketing authorization for the company's pharmaceutical product Sedaconda (isoflurane).
- In Spain, the Ministry of Health granted pricing and reimbursement approval to Sedaconda (isoflurane) in October.
- In October the enrollment of the planned 700 patients in the investigator-initiated trial SESAR was completed.
- In November, the European Medicines Agency's Paediatric Committee issued a positive opinion regarding the compliance with the company's Paediatric Investigation Plan, which confirms data exclusivity and market protection for Sedana Medical's Sedaconda (isoflurane) until 2031.
- In December, the company submitted a Type II variation with the aim of including the paediatric population (3-17 years) into the existing Sedaconda indication for inhaled sedation of mechanically ventilated patients in Europe.

## Significant events after the period

• No significant events after the period

## **Market potential**

With its innovative product portfolio for inhaled sedation, Sedana Medical is targeting mechanically ventilated patients in intensive care units. Geographically, Sedana Medical has a clear focus on today's direct markets in Europe (Germany, Spain, France, UK, Nordics and Benelux) and its largest potential market, the United States.

In today's direct markets in Europe, a bit less than 1 million intensive care patients annually require mechanical ventilation and sedation<sup>1</sup>. Based on this patient population, Sedana Medical sees a market potential for its current product portfolio of approximately 3-4 billion SEK.

In the United States, somewhat more than 2 million patients are mechanically ventilated and sedated each year<sup>2</sup>. Assuming a comparable approved label as in Europe, the market potential in the United States is estimated to be 10-12 billion SEK. This number assumes a relatively modest price difference compared to Europe. If Sedana Medical manages to obtain a price differential that is in line with other sedation therapies, the potential could increase accordingly.

The market potential is projected to grow at low-to-mid single digits per year in line with demographic trends.

In 2023, our sales level in Germany represented a penetration of approximately 12% of the market potential. The best performing sales territories in Germany had a penetration in excess of 20%. Meanwhile, the aggregate penetration in our other direct markets was still below 2%.

In addition to the primary focus on Europe and the United States, Sedana Medical has distributors in more than 30 countries on all continents.

## Strategic priorities

Sedana Medical has set 3 strategic priorities:

## 1. Achieve lasting and profitable sales growth in Europe

Our market authorizations in 18 European countries to date make Sedana Medical the only company offering an approved therapy for inhaled sedation in intensive care. With a strong focus on commercial execution and a prudent investment philosophy that prioritizes profitable growth, we aim at making inhaled sedation a standard therapy.

#### 2. Maximize the opportunity in the United States

With more than 100,000 intensive care beds and a generally higher price level for sedation therapies, the United States represent our largest potential market. After completion of our Phase III clinical program, which has received FDA fast track designation, and assuming FDA approval, we aspire to launch our products through our own commercial infrastructure.

#### 3. Build a long-term profitable company

Sedana Medical's model with high gross margins and a concentrated customer base (hospitals with intensive care) favours attractive profitability as continue to grow sales. It is a key priority to turn the Ex-US business profitable

<sup>&</sup>lt;sup>1</sup> Based on publicly available data per country and Sedana Medical's own research

<sup>&</sup>lt;sup>2</sup> Based on externally performed market opportunity study

during 2024, so the US launch can be executed based on a stable financial platform. As we will gradually reach scale and grow the share of US sales, our long-term target is an EBITDA margin around 40%.

## **Financial targets**

Sedana Medical provides short-term financial targets for net sales and EBITDA and updates these targets in the year-end report of each year or during the year, if needed.

Our financial targets:

- 2024 net sales growth between 14 and 18%, compared to 16% in 2023\*)
- EBITDA break-even of our Ex-US business during 2024

\*) at constant exchange rates

## **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 unique medical device Sedaconda ACD, the pharmaceutical Sedaconda® (isoflurane) and accessories, and is being commercialized across Europe leveraging our own sales teams, and globally via distributors. We are focused on building a stronger commercial company by directing our investments towards profitable growth opportunities and enhancing the effectiveness of our sales organization. Our philosophy is to invest in countries that show good growth momentum and generate positive cash flow. For example, we have expanded our 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 in the near term. With this approach, we 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 measures to maximize our customer-facing time, a better customer targeting process, more effective selling model and more rigorous performance management.

In 2023 we returned to a growth path after the Covid-19 pandemic aftermath during 2022. This trend continued in Q4, as we report net sales growth of 24% relative to 2022. Adjusted for currency effects, sales grew 18% in the quarter. For the full year 2023, we report net sales growth of 25% relative to 2022 (16% excl. currency effects). During all of 2023, the strong sales performance was driven by our main market Germany, as well as our other direct markets, where Spain is the main growth driver.

In Germany, sales grew by 15% in Q4 relative to last year (9% excl. currency effects), as access to customers has normalized, allowing our field teams to spend most of their time visiting customers.

In our other direct markets (Spain, France, UK, Nordics and Benelux) sales grew by 62% in the quarter (54% excl. currency effects). Among our other direct markets, Spain has been a top performer in recent quarters, and this was the case also in Q4. All direct markets report sales growth for the full year 2023.

We saw a healthy mix of growth from existing customers and sales from the more than 200 new and reactivated customers in our direct markets.

In our distributor markets, sales increased by 25% in Q4 compared to last year (18% excl. currency effects). As communicated in previous reports, the large negative year-over-year effect related to our main South American distributor left the quarterly comparisons in Q3 2023.

#### Regulatory and pricing/reimbursement approvals

Sedaconda (isoflurane) has now received regulatory approvals by the national authorities in all 18 countries where we have submitted an application: Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland and as announced during Q4, the United Kingdom. So far, the pharmaceutical has been made available in Germany, Sweden, Norway, the Netherlands, France and Spain. In addition, Sedaconda (isoflurane) has been launched in Slovenia via our distributor in the country.

In October, more than two years after submitting our application, we received regulatory approval for Sedaconda (Isoflurane) from the authorities in the UK (MHRA). 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. According to NICE, cost modelling had shown cost savings compared with intravenous (IV) sedation of approximately £3,800 per adult patient (30-day time horizon for adult patients needing mechanical ventilation for 24 hours or longer in intensive care). We expect the approval in combination with the positive NICE guidance will lead to more ICU patients in the UK benefitting from the clinically proven advantages of inhaled sedation. We will launch our pharmaceutical Sedaconda (isoflurane) in the UK, but the main growth driver will be our device business as we expect the approval to lead to increased use of the therapy overall.

Also during Q4, the Spanish Ministry of Health officially granted pricing and reimbursement approval for the pharmaceutical Sedaconda (isoflurane) in Spain and the pharmaceutical has been launched in December. Even before the pricing and reimbursement approval, Spain was our fastest-growing market in 2023. As several customers in Spain have awaited the pricing and reimbursement decision before implementing inhaled sedation in their respective hospitals we are anticipating further healthy growth in 2024.

Important milestones were reached in Q4 related to our plans to soon have our therapy approved in Europe also for children. In November, the main results from our paediatric IsoCOMFORT study were published in the Clinical Trials Registry EudraCT, and later in the same month we submitted a Type II variation with the aim of including the paediatric population (3-17 years) into the existing Sedaconda indication for inhaled sedation of mechanically ventilated patients in Europe. We expect End of Procedure in Q3 2024, after which the national approval processes will follow. For the adult indication, those lasted between 1 and 2 months for the majority of countries.

Separately, in November, the European Medicines Agency's Paediatric Committee issued a positive opinion regarding the compliance with the company's Paediatric Investigation Plan. This confirms data exclusivity and market protection for the adult indication of Sedaconda (isoflurane) until at least 2031.

## 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. 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 our 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). We remain highly encouraged by the enthusiasm expressed by the healthcare professionals participating in the trials when they see the benefits of inhaled sedation.

In early 2023, the U.S. Food and Drug Administration (FDA) granted our clinical program Fast Track Designation (FTD). 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 faster.

The overall timeline for the US program is unchanged. Patient recruitment for the clinical program is progressing, and based on the current trend recruitment is expected to be completed within months. Sedana Medical's prediction is that NDA submission can be expected in the early part of 2025. With a standard review time, approval can subsequently be expected by late 2025 or early 2026. Sedana Medical will have the opportunity to discuss with FDA if any of the potential benefits of the Fast Track Designation (accelerated approval, priority review, rolling review) will apply to Sedaconda, which might have a positive effect on overall communicated timelines. FDA will provide clarity about the expected review period after submission of the NDA.

Importantly, Sedana Medical is well funded to complete the study and achieve US approval, with MSEK 382 in cash and short-term deposits at the end of 2023, and a plan to reach EBITDA break-even in our ex-US business during 2024.

## Cost management and resource allocation

Before Sedana Medical enters the US market we want our ex-US business to be profitable, and we expect to achieve this in terms of EBITDA ex-US during 2024. This means we will continue to invest in profitable growth opportunities, while at the same time making sure to manage our resources in a prudent way. This includes shifting spending from administrative functions to customer-facing functions, and from headquarters to our main direct markets.

We report a gross margin in line with Q3 of 70% for Q4 2023, compared to 72% in Q4 2022. We have experienced cost increases for materials and key components and as most of our products are sourced outside Sweden, the weakened SEK has lead to an increase of our cost of goods. For the full year 2023, our gross margin is 71%, compared to 70% in 2022. We maintain close dialogue with our suppliers, and as communicated previously, our target gross margin remains at least 70%.

Our efforts to increase efficiency in our operating cost base continue, and we are implementing measures to further prioritize profitable growth initiatives and reduce spending on administration and other overhead costs. In Q4 2023, despite an inflationary environment and weak SEK, we report operating expenses of MSEK 44, down 10% compared to MSEK 49 in the same quarter last year. We have non-recurring costs in Q4 2023 related to re-organizations of MSEK 2. Adjusted for currency effects and non-recurring costs, our operating expenses were down 10% in Q4 compared to last year. EBITDA for the quarter was MSEK -9 (-20% EBITDA margin), compared to MSEK -18 in Q4 last year (-49% EBITDA margin).

For the full year 2023, we report operating expenses of MSEK 176, down 8% compared to MSEK 190 in 2022. Adjusted for currency effects, our operating expenses in 2023 are down 11% compared to 2022. EBITDA for the full year 2023 was MSEK -43 (-28% EBITDA margin), compared to MSEK -83 last year.

## Discontinuing sourcing of gas monitors from Russia

Sedana Medical has historically sold gas monitors produced by a Russian engineering company. Gas monitors are not an important source of revenue or profit for Sedana Medical but represent an important enabler of inhaled sedation in the ICU. Gas monitors are available from a range of medical device companies, but we see value in having the possibility to offer a gas monitor ourselves to be able to start up clinics quickly or expand the number of patients that can receive inhaled sedation in an ICU. When the war in Ukraine started, we decided to discontinue sourcing gas monitors from Russia. We have since sold monitors we have on stock, and in Q4 2023 we received the final shipment of monitors that had previously been produced for Sedana Medical and that were still on stock at the Russian supplier. In parallel, we have set up a new main supplier of gas monitors based in South Korea. Gas monitors from other manufacturers are also available in the market. As a result, we do not see a risk of not being able to supply gas monitors to our customers.

## Financial overview

	Oct-Dec		Jan-Dec	
(KSEK)	2023	2022	2023	2022
Net sales	44,544	35,805	153,867	122,865
Gross profit	30,960	25,744	108,981	86,074
Gross margin %	70%	72%	71%	70%
EBITDA	-9,051	-17,642	-42,974	-83,138
EBITDA margin %	-20%	-49%	-28%	-68%
EBITDA ex-US	-8,073	-17,372	-40,145	-80,190
Operating income (EBIT)	-14,850	-23,246	-65,547	-105,887
Operating margin %	-33%	-65%	-43%	-86%
Income after net financial items	-37,887	-35,774	-59,019	-72,933
Net income	-38,071	-35,941	-59,612	-73,507
Net income margin %	-85%	-100%	-39%	-60%
Total assets	1,014,056	1,081,588	1,014,056	1,081,588
Equity	969,995	1,029,156	969,995	1,029,156
Equity ratio %	96%	95%	96%	95%
Quick ratio %	968%	1299%	968%	1299%
Debt to equity ratio %	5%	5%	5%	5%
Average number of full-time employees for the period	77	81	79	86
Number of employees at balance date	79	85	79	85
Number of employees and consultants at balance date	86	95	86	95
Average number of shares before dilution	99,336,960	99,336,960	99,336,960	99,336,960
Average number of shares after dilution	99,336,960	99,336,960	99,336,960	99,336,960
Number of shares at balance date before dilution	99,336,960	99,336,960	99,336,960	99,336,960
Number of shares at balance date after dilution	99,336,960	99,336,960	99,336,960	99,336,960
Earnings per share before dilution, SEK	-0.38	-0.36	-0.60	-0.74
Earnings per share after dilution, SEK	-0.38	-0.36	-0.60	-0.74

## **Group performance**

#### Net sales

Net sales for the quarter amounted to KSEK 44,544 (35,805), corresponding to an increase of 24 percent. Adjusted for currency effects, the quarter showed an increase of 18 percent.

All sales channels show growth for the quarter, and the increase mainly refers to Other direct markets, where mainly Spain continued to show strong growth. Compared to the corresponding quarter last year, our other direct markets increased by 62 percent (54 percent at constant exchange rates). In Germany, the increase amounted to 15 percent (9 percent at constant exchange rates). Our distributor markets also contributed to the positive development during the quarter with a growth of 25 percent (18 percent at constant exchange rates). The increase in the Distributor markets mainly refers to Europe.

For the full year, net sales amounted to KSEK 153,867 (122,865), corresponding to an increase of 25 percent. Adjusted for currency effects, the increase was 16 percent.

	Oct-	-Dec			Jan-l	Dec		
(KSEK)	2023	2022	%	%*	2023	2022	%	%*
Germany	29,803	26,018	15%	9%	105,620	86,099	23%	14%
Other direct sales	11,002	6,786	62%	54%	36,548	21,831	67%	56%
Distributor markets	3,739	3,001	25%	18%	11,698	14,935	-22%	-27%
Total net sales	44,544	35,805	24%	18%	153,867	122,865	25%	16%

<sup>\*)</sup> at constant exchange rates

## Gross profit and margin

The gross profit for the quarter amounted to KSEK 30,960 (25,744), corresponding to a gross margin of 70 (72) percent. The decrease mainly relates to product mix effects and increasing material cost.

For the full year, the gross profit amounted to KSEK 108,981 (86,074), corresponding to a gross margin of 71 (70) percent. The increase is mainly due to higher sales prices compared to the previous year and lower allocated central costs.

#### Selling expenses

Selling expenses for the quarter amounted to KSEK -28,019 (-27,332), which is an increase of 3 percent compared to the previous year. The increase is partly due to a weaker Swedish krona compared to the corresponding quarter last year, but also to non-recurring personnel costs in the fourth quarter of this year. Excluding currency effects and these one-offs, selling expenses have decreased by 7 percent compared to the previous year.

For the full year, selling expenses amounted to KSEK -107,239 (-112,469).

#### Administrative expenses

Administrative expenses for the quarter amounted to KSEK -10,729 (-16,906), which corresponds to a decrease of 37 percent. The reduction is mainly due to costs related to the uplisting project in the fourth quarter of the previous year.

For the full year, the administrative expenses amounted to KSEK -47,504 (-57,473), corresponding to a decrease of 17 percent.

## Research and development expenses

Research and development expenses for the quarter amounted to KSEK -5,678 (-5,148), which corresponds to an increase of 10 percent. The increase is due to a slightly lower capitalisation rate compared to the previous year.

For the full year, research and development expenses amounted to KSEK -20,805 (-19,944), corresponding to an increase of 4 percent.

## Other operating income/expenses

Other operating income mainly consists of positive unrealised exchange rate differences on operating items. These totalled KSEK 7,889 (3,971) for the quarter. For the full year other operating income was KSEK 31,473 (13,319). Other operating expenses mainly consist of negative unrealised exchange rate differences on operating items. These totalled KSEK -9,274 (-3,574) for the quarter. For the full year other operating expenses were KSEK -30,453 (-15,394).

## Net financial items and earnings per share

Financial net for the quarter totalled KSEK -23,038 (-12,528). The amounts consist partly of unrealized exchange rate differences on cash invested in USD but also of received interest on cash and cash equivalents. For the full year the financial net amounted to KSEK 6,529 (32,954).

Group tax expense for the quarter was KSEK -184 (-167) and consists mainly of current tax in Germany. The group tax expense for the full year was KSEK -593 (-574).

Consequently, earnings per share amounted to SEK -0.38 (-0.36) for the quarter and SEK -0.60 (-0.74) for the full year.

## Capitalised development expenditures

Capitalised development expenditures as of December 31 amounted to KSEK 542,705 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 152,176 and relates mainly 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 December 31, inventory amounted to KSEK 42,975 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 December 31 was KSEK 969,995, compared to KSEK 1,029,155 at the beginning of the year. This corresponds to SEK 9,76 (10.36) per share. Equity/assets ratio was 96 percent, compared to 95 percent at the beginning of the year. Debt/equity ratio on December 31 was 4 percent, compared to 5 percent at the beginning of the year. The Group had no long-term debt on December 31.

## Cash, cash position and short-term investments

Cash and cash equivalents decreased by KSEK 59,631 during the quarter and totalled KSEK 231,180 on December 31, compared to KSEK 290,811 at the beginning of the quarter. Cash flow from operating activities before changes in working capital for the quarter was KSEK 14,053 (-8,905). Cash flow from changes in working capital totalled KSEK -5,275 (-13,655) and was mainly affected by higher accounts receivables at quarter end. Cash flow from operating activities thus totalled KSEK 8,777 (-22,560).

Cash flow from investing activities for the quarter totalled KSEK -41,843 (-27,313). The investments consist mostly 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 -1,223 (-1,184) and relates to amortization of lease liabilities.

Currency revaluation differences in cash and cash equivalents amounted to KSEK -25,343 (-16,777) during the quarter and are mainly related to cash and cash equivalents held in USD. Cash flow per share for the quarter was SEK -0.35 (-0.51).

During the full year cash and cash equivalents decreased by KSEK 376,562 and totalled KSEK 231,180 on December 31, compared to KSEK 607,742 at the beginning of the year. Cash flow from operating acivities before changes in working capital for the year was KSEK -17,132 (-80,108). Cash flow from changes in working capital amounted to KSEK -20,928 (-35,324), which was affected mainly by higher levels of accounts receivables due to the increased sales. Cash flow from operating activities thus totalled KSEK -38,061 (-115,433).

Cash flow from investing activities for the year amounted to KSEK -321,957 (-137,783). During the first quarter, KSEK 306,156 of the company's cash and cash equivalents were invested short-term to favor from better interest rates. These short-term investments were repaid with KSEK 312,348 during the third quarter, of which KSEK 159,261 were reinvested. 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 year totalled KSEK -4,857 (-1,507) and relates to amortization of lease liabilities. The decrease compared to the previous year refers to the premium received for warrants issued in the second quarter of 2022.

Currency revaluation differences in cash and cash equivalents for the period amounted to KSEK -11,687 (26,283) and are mainly related to cash and cash equivalents held in USD. Cash flow per share for the year was SEK -3.67 (-2.56). Adjusted for the investment in short-term investments, the cash flow per share amounted to SEK -2.13 (-2.56) equivalent to an improvement of SEK 0.43 per share.

## Parent company

The Parent Company's net sales for the full year totalled KSEK 153,767 (122,726), of which intra-group sales were KSEK 7,301 (6,306).

Operating income for the year totalled KSEK -57,283 (-93,632). Net financial items were KSEK 9,518 (33,891) and relate mainly to unrealised exchange gains on cash balances in foreign currencies, mainly USD, but also interest on the deposits that were repaid during the third quarter and received interest on cash and cash equivalents.

Shareholders' equity in the Parent Company totalled KSEK 1,002,640 at December 31 2023, compared to KSEK 1,050,412 at the beginning of the year. This corresponds to a decrease of KSEK 47,771. Share capital totalled KSEK 2,483, compared to KSEK 2,483 at the beginning of the year.

Cash and cash equivalents stood at KSEK 215,921, compared to KSEK 587,909 at the beginning of the year. Available funds in the parent company, including short-term deposits, amounted to KSEK 366,545 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 third quarter was MSEK 2,301.

The price paid for Sedana Medical shares was SEK 18.70 at the start of the year and SEK 23.16 at the end of the quarter. The lowest closing price during the year was recorded on October 23 and was SEK 16.46. The highest closing price was recorded on June 9 and was SEK 33.52.

## Share information

	Oct-[	Dec	Jan-D	)ec
	2023	2022	2023	2022
Net income, KSEK	-38,071	-35,941	-59,612	-73,507
Cash flow, KSEK	-34,288	-51,057	-364,875	-254,722
Number of shares at balance date	99,336,960	99,336,960	99,336,960	99,336,960
Average number of shares	99,336,960	99,336,960	99,336,960	99,336,960
Outstanding warrants at balance date	973,399	1,003,959	973,399	1,003,959
Average number of warrants	973,399	1,165,202	988,679	1,040,554
Share capital at balance date, KSEK	2,483	2,483	2,483	2,483
Equity at balance date, KSEK	969,995	1,029,156	969,995	1,029,156
Earnings per share before dilution, SEK	-0.38	-0.36	-0.60	-0.74
Earnings per share after dilution, SEK	-0.38	-0.36	-0.60	-0.74
Equity per share, SEK	9.76	10.36	9.76	10.36
Cash flow per share, SEK	-0.35	-0.51	-3.67	-2.56

## Largest shareholders at the end of the period

	No of shares	Share
Linc AB	10,111,030	10.2%
Anders Walldov direct and indirect (Brohuvudet AB)	10,000,000	10.1%
Swedbank Robur Funds	9,519,013	9.6%
Handelsbanken Funds	6,268,654	6.3%
Öhman Funds	4,382,095	4.4%
Ola Magnusson direct and indirect (Magiola AB)	4,312,098	4.3%
Sten Gibeck	4,196,597	4.2%
Highclere International Investors LLP	3,310,435	3.3%
Premier Miton Investors	2,671,820	2.7%
AMF Pension	2,491,000	2.5%
Berenberg Funds	1,983,744	2.0%
Third Swedish National Pensin Fund	1,735,989	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Amundi	1,344,738	1.4%
Avanza Pension	1,177,928	1.2%
Fifteen largest shareholders	65,171,605	65.6%
Others	34,165,355	34.4%
Total	99,336,960	100.0%

## Facts about the share

Trading Nasdaq Stockholm

No of shares as per Dec 31, 2023 99,336,960

Market cap as per Dec 31, 2023 SEK 2,301 million

Ticker SEDANA

ISIN SE0015988373

LEI-code 549300FQ3NJRI56LCX32

## 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 February 15, 2024

Claus Bjerre Hilde Furberg Ola Magnusson
Chairman of the Board Board member Board member

Eva Walde Christoffer Rosenblad Johannes Doll
Board member Board member President and CEO

This year-end 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

## Presentation of the year-end report

Sedana Medical presents the year-end report to investors, asset managers, analysts and media on February 15, 2024 at 13.30. The presentation will be held in English and takes place via telephone conference and audio webcast. More information is available at: <a href="https://www.finwire.tv/webcast/sedana-medical/year-end-report-2023/">https://www.finwire.tv/webcast/sedana-medical/year-end-report-2023/</a>

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

## Annual report and Annual general meeting

Sedana Medicals annual report will be available on the company's website, www.sedanamedical.com, from April 15, 2024. The annual general meeting will be held on Wednesday May 22, 2024.

## **Dividend**

The Board of directors proposes that no dividend is paid for the 2023 financial year.

## Financial calendar

Annual Report 2023 15 April 2024
Interim Report Q1 2024 25 April 2024
Annual General Meeting 2024 22 May 2024
Interim Report Q2 2024 23 July 2024
Interim Report Q3 2024 24 October 2024

## **Consolidated income statement, summary**

	Oct-De	<u> </u>	Jan-Dec	
(KSEK)	2023	2022	2023	2022
Net sales	44,544	35,805	153,867	122,865
Cost of goods sold	-13,584	-10,060	-44,886	-36,791
Gross profit	30,960	25,744	108,981	86,074
Selling expenses	-28,019	-27,332	-107,239	-112,469
Administrative expenses	-10,729	-16,906	-47,504	-57,473
Research and development expenses	-5,678	-5,148	-20,805	-19,944
Other operating income	7,889	3,971	31,473	13,319
Other operating expenses	-9,274	-3,574	-30,453	-15,394
Operating income	-14,850	-23,246	-65,547	-105,887
Net financial items	-23,038	-12,528	6,529	32,954
Income before taxes	-37,887	-35,774	-59,019	-72,933
Income tax	-184	-167	-593	-574
Net income	-38,071	-35,941	-59,612	-73,507
Earnings per share, based on earnings attributable to the parent company's ordinary shareholders:				
Before dilution	-0.38	-0.36	-0.60	-0.74
After dilution	-0.38	-0.36	-0.60	-0.74
Operating income (EBIT)	-14,850	-23,246	-65,547	-105,887
Whereof amortisation of intangible assets	-3,863	-3,792	-15,452	-15,538
Whereof depreciation of tangible assets	-1,935	-1,812	-7,122	-7,211
EBITDA	-9,051	-17,642	-42,974	-83,138

# Consolidated statement of other comprehensive income, summary

	Oct-D	Oct-Dec		Dec
(KSEK)	2023	2022	2023	2022
Net income	-38,071	-35,941	-59,612	-73,507
Other comprehensive income				
Items that can later be reclassified to the income statement:				
Translation differences from foreign operations	1,832	-881	451	-2,834
Other comprehensive income, net after tax	1,832	-881	451	-2,834
Total comprehensive income	-36,239	-36,822	-59,161	-76,341
Total comprehensive income as a whole attributable to the parent company's shareholders	-36,239	-36,822	-59,161	-76,341

# Consolidated balance sheet, summary

Machinery and other technical facilities         804         955           Rajument, tools and installations         2,551         4,492           Rights of use         4,912         9,271           Financial assets         45         46           Other long-term assets         31         29           Total fixed assets         31         29           Total fixed assets         554,435         406,171           Inventory         42,975         38,597           Tax receivables         739         514           Accounts receivable         24,180         15,849           Pereayments and accrued income         4,701         6,017           Other receivables         5,222         4,699           Short-term investments         150,624         -           Cash and cash equivalents         231,180         60,774           Total current assets         459,621         673,416           TOTAL ASSETS         1,04,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         Faulty         2,483         2,483           Cother contributed capital         2,243         2,499         2,26,355           Retai	(KSEK)	Dec 31, 2023	Dec 31, 2022
Internation   Seases   Seases   Sease   Seas			
Capitalised development expenditure         \$42,705         390,530           Concessions, patentis, licenses, etc.         3,326         2,849           Tangible assets         864         955           Medininery and other technical facilities         864         955           Equipment, tools and installations         2,551         4,492           Riphts of use         4,912         9,271           Financial assets         45         46           Other long-term assets         45         46           Deferred tax assets         31         29           Total fixed assets         554,435         408,171           Inventory         42,795         38,997           Tax receivable         239         514           Accounts receivable         24,180         15,849           Prepayments and accrued income         4,701         6,617           Other receivable         5,223         4,697           Short-term investments         150,624         -7           Cash and cosh quivalents         231,180         607,741           TOTAL ASSETS         1,014,056         1,081,588           CKSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         <			
Concessions, patents, licenses, etc.         3,326         2,849           Tangible assets         864         955           Equipment, tools and installations         2,551         4,492           Rights of use         4,912         9,271           Financial assets         31         29           Other long-term assets         45         46           Deferred tax assets         31         29           Total fixed assets         554,435         406,171           Inventory         42,975         38,597           Tax receivables         739         514           Accounts receivable         24,180         15,499           Prepayments and accrued income         4,701         6,017           Other receivables         5,223         4,697           Short-term investments         150,624         -           Cash and cash equivalents         231,8180         69,772           Total current assets         1,014,056         1,081,588           TOTAL ASSETS         1,014,056         1,081,588           CKSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         2,483         2,483           Retained earnings including net profit         2,199<		F42 70F	200 520
Tangible assets         Machinery and other technical facilities         864         955           Equipment, tools and installations         2,551         4,492         9,271           Kightins of use         4,912         9,271         9,271           Financial assets         31         45         46           Other long-term assets         31         29           Total fixed assets         554,435         406,171           Inventory         42,975         38,597           Tax receivables         739         514           Accounts receivable         739         514           Accounts receivable         4,701         6,617           Total crise investments         150,624         -           Cash and cosh equivalents         150,624         -           Cash and cosh equivalents         231,180         607,742           Total current assets         459,621         673,416           TOTAL ASSETS         1,04,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES Faulty         2         4,932         2,483           Cotter contributed capital         2,483         1,226,435           City Cotter contributed cap			
Machinery and other technical facilities         804         955           Rajument, tools and installations         2,551         4,492           Rights of use         4,912         9,271           Financial assets         45         46           Other long-term assets         31         29           Total fixed assets         31         29           Total fixed assets         554,435         406,171           Inventory         42,975         38,597           Tax receivables         739         514           Accounts receivable         24,180         15,849           Pereayments and accrued income         4,701         6,017           Other receivables         5,222         4,699           Short-term investments         150,624         -           Cash and cash equivalents         231,180         60,774           Total current assets         459,621         673,416           TOTAL ASSETS         1,04,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         Faulty         2,483         2,483           Cother contributed capital         2,243         2,499         2,26,355           Retai	Concessions, patents, licenses, etc.	3,326	2,849
Equipment, tools and installations         2,551         4,922           Rights of use         4,912         9,271           Pinancial assets         31         26           Deferred tax assets         31         29           Total fixed assets         554,435         406,171           Inventory         42,975         38,597           Tax receivables         739         514           Accounts receivable         4,701         6,017           Other receivables         4,701         6,017           Short-term investments         150,624         -           Cash and cash equivalents         231,180         607,742           Total current assets         459,621         673,416           TOTAL ASSETS         1,014,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         2         1,014,056         1,081,588           CKSEK)         Dec 31, 2023         Dec 31, 2022         2           EQUITY AND LIABILITIES         2,483         2,483         1,226,435         1,226,435         1,226,435         1,226,435         1,226,435         1,226,435         1,226,435         1,226,435         1,226,435         1,226,435	Tangible assets		
Rights of use	Machinery and other technical facilities	864	955
Parametal assets	Equipment, tools and installations	2,551	4,492
Other long-term assets         45         46           Deferred tax assets         31         29           Total fixed assets         554,435         408,171           Inventory         42,975         38,597           Tax receivables         739         514           Accounts receivable         24,180         15,849           Prepayments and accrued income         4,701         6,017           Other receivables         5,223         4,697           Short-term investments         150,624            Cash and cash equivalents         231,180         607,742           Cash and cash equivalents         231,180         607,742           Total current assets         459,621         673,416           TOTAL ASSETS         1,014,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         2         4           Equity         1,014,056         1,081,588           CKSEK)         Dec 31, 2023         Dec 31, 2022           REQUITY AND LIABILITIES         2         4           Equity         1,2026,435         1,226,435         1,226,435           Translation difference         2,493	Rights of use	4,912	9,271
Deferred tax assets   31   29     Total fixed assets   554,435   408,171     Inventory	Financial assets		
Total fixed assets         554,435         408,171           Inventory         42,975         38,597           Tax receivables         739         514           Accounts receivable         24,180         15,849           Prepayments and accrued income         4,701         6,017           Other receivables         5,223         4,697           Short-term investments         150,624	Other long-term assets	45	46
Inventory	Deferred tax assets	31	29
Tax receivables         739         514           Accounts receivable         24,180         15,849           Prepayments and accrued income         4,701         6,017           Other receivables         5,223         4,697           Short-term investments         150,624         -           Cash and cash equivalents         231,180         607,742           Cash and cash equivalents         31,014,056         1,081,588           TOTAL ASSETS         1,014,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         Fedity         5           EQUITY AND LIABILITIES         2         483         2,483           Other contributed capital         2,483         2,283         2,283           Other contributed capital         1,226,435         1	Total fixed assets	554,435	408,171
Tax receivables         739         514           Accounts receivable         24,180         15,849           Prepayments and accrued income         4,701         6,017           Other receivables         5,223         4,697           Short-term investments         150,624         -           Cash and cash equivalents         231,180         607,742           Cash and cash equivalents         31,014,056         1,081,588           TOTAL ASSETS         1,014,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         Fedity         5           EQUITY AND LIABILITIES         2         483         2,483           Other contributed capital         2,483         2,283         2,283           Other contributed capital         1,226,435         1	Inventory	42.075	29 507
Accounts receivable         24,180         15,849           Prepayments and accrued income         4,701         6,017           Other receivables         5,223         4,697           Short-term investments         150,624         -           Cash and cash equivalents         231,180         607,742           Total current assets         459,621         673,416           TOTAL ASSETS         1,014,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         2         483         2,483           Uher contributed capital         2,483         2,26435         1,226,435           Translation difference         -2,199         -2,650         2,650           Retained earnings including net profit         -2,199         -2,650         3,294         1,029,156           Non-current liabilities         1,012         3,576         3,576         3,576         3,576           Current liabilities         3,294         5,167         -         -         1,020         3,576           Current liabilities         3,294         5,167         -         -         -         -         -         -         -         -         -         -<			
Prepayments and accrued income         4,701         6,017           Other receivables         5,223         4,697           Short-term investments         150,624         -           Cash and cash equivalents         231,180         607,742           Total current assets         459,621         673,416           TOTAL ASSETS         1,014,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         2         483         2,483           Cother capital         2,483         2,483         2,483           Cother contributed capital         1,226,435         1,226,435         1,226,435           Translation difference         2,199         2,650         2,199         2,650           Retained earnings including net profit         2.55,724         -197,113         2,112         1,029,156           Non-current liabilities         1,012         3,576         0.00         3,576           Non-current liabilities         7         -         -         -         -         -         -         -         -         -         -         -         -         -         -         -         -         -         -         -			
Other receivables         5,223         4,697           Short-term investments         150,624         6.7,742           Cash and cash equivalents         231,180         607,742           Total current assets         459,621         673,416           TOTAL ASSETS         1,014,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES           Equity           Share capital         2,483         2,483           Other contributed capital         1,226,435         1,226,435           Translation difference         2,199         -2,650           Retained earnings including net profit         969,995         1,029,156           Non-current liabilities         1,012         3,576           Leasing liabilities         1,012         3,576           Current liabilities         1,020         3,576           Current liabilities         3,294         5,167           Tax debt         1,276         2,559           Accounts payable         5,292         11,270           Tax debt         1,276         2,559           Other liabilities         8,347         6,929<			
Short-term investments         150,624			
Cash and cash equivalents         231,180         607,742           Total current assets         459,621         673,416           TOTAL ASSETS         1,014,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         2         400,000         400,000           Equity         3         2,483         2,483         2,483         2,483         2,483         2,6435         1,226,435			4,037
Total current assets         459,621         673,416           TOTAL ASSETS         1,014,056         1,081,588           (KSEK)         Dec 31, 2023         Dec 31, 2022           EQUITY AND LIABILITIES         Equity         2           Share capital         2,483         2,483         2,483           Other contributed capital         1,226,435			607 742
TOTAL ASSETS   1,014,056   1,081,588			
Company   Comp			
EQUITY AND LIABILITIES  Equity  Share capital 2,483 2,483 2,483 20ther contributed capital 1,226,435 1,029,156 1,029,156 1,029,156 1,029,156 1,029,156 1,029,156 1,029,156 1,029,156 1,029,156 1,029,156 1,029,156 1,029,156 1,029,156			
Equity       2,483       2,483       2,483         Other contributed capital       1,226,435       1,226,435       1,226,435         Translation difference       -2,199       -2,650       -255,724       -197,113         Equity attributable to the parent company's shareholders       969,995       1,029,156         Non-current liabilities       1,012       3,576         Leasing liabilities       7          Deferred tax liabilities       1,020       3,576         Current liabilities       1,020       3,576         Current liabilities       3,294       5,167         Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	(KSEK)	Dec 31, 2023	Dec 31, 2022
Share capital       2,483       2,483         Other contributed capital       1,226,435       1,226,435         Translation difference       -2,199       -2,650         Retained earnings including net profit       -256,724       -197,113         Equity attributable to the parent company's shareholders       969,995       1,029,156         Non-current liabilities       1,012       3,576         Deferred tax liabilities       7          Total non-current liabilities       1,020       3,576         Current liabilities       3,294       5,167         Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	EQUITY AND LIABILITIES		
Other contributed capital       1,226,435       1,226,435         Translation difference       -2,199       -2,650         Retained earnings including net profit       -256,724       -197,113         Equity attributable to the parent company's shareholders       969,995       1,029,156         Non-current liabilities       1,012       3,576         Leasing liabilities       7       -         Deferred tax liabilities       1,020       3,576         Current liabilities       1,020       3,576         Current liabilities       3,294       5,167         Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Equity		
Translation difference         -2,199         -2,650           Retained earnings including net profit         -256,724         -197,113           Equity attributable to the parent company's shareholders         969,995         1,029,156           Non-current liabilities         1,012         3,576           Deferred tax liabilities         7         -           Total non-current liabilities         1,020         3,576           Current liabilities         3,294         5,167           Accounts payable         5,292         11,270           Accounts payable         1,276         2,559           Other liabilities         8,347         6,929           Accrued expenses and deferred income         24,832         22,932           Total current liabilities         43,041         48,856           Total liabilities         44,061         52,431	Share capital	2,483	2,483
Translation difference         -2,199         -2,650           Retained earnings including net profit         -256,724         -197,113           Equity attributable to the parent company's shareholders         969,995         1,029,156           Non-current liabilities         1,012         3,576           Leasing liabilities         7         -           Deferred tax liabilities         1,020         3,576           Current liabilities         1,020         3,576           Current liabilities         3,294         5,167           Accounts payable         5,292         11,270           Tax debt         1,276         2,559           Other liabilities         8,347         6,929           Accrued expenses and deferred income         24,832         22,932           Total current liabilities         43,041         48,856           Total liabilities         44,061         52,431	Other contributed capital	1,226,435	1,226,435
Equity attributable to the parent company's shareholders       969,995       1,029,156         Non-current liabilities       1,012       3,576         Leasing liabilities       7       -         Total non-current liabilities       1,020       3,576         Current liabilities       3,294       5,167         Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Translation difference		-2,650
Non-current liabilities         Leasing liabilities       1,012       3,576         Deferred tax liabilities       7       -         Total non-current liabilities       1,020       3,576         Current liabilities       3,294       5,167         Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Retained earnings including net profit	-256,724	-197,113
Leasing liabilities       1,012       3,576         Deferred tax liabilities       7       -         Total non-current liabilities       1,020       3,576         Current liabilities       3,294       5,167         Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Equity attributable to the parent company's shareholders	969,995	1,029,156
Deferred tax liabilities         7         -           Total non-current liabilities         1,020         3,576           Current liabilities         3,294         5,167           Accounts payable         5,292         11,270           Tax debt         1,276         2,559           Other liabilities         8,347         6,929           Accrued expenses and deferred income         24,832         22,932           Total current liabilities         43,041         48,856           Total liabilities         44,061         52,431	Non-current liabilities		
Total non-current liabilities       1,020       3,576         Current liabilities       3,294       5,167         Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Leasing liabilities	1,012	3,576
Current liabilities         Leasing liabilities       3,294       5,167         Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Deferred tax liabilities	7	-
Leasing liabilities       3,294       5,167         Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Total non-current liabilities	1,020	3,576
Accounts payable       5,292       11,270         Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Current liabilities		
Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Leasing liabilities	3,294	5,167
Tax debt       1,276       2,559         Other liabilities       8,347       6,929         Accrued expenses and deferred income       24,832       22,932         Total current liabilities       43,041       48,856         Total liabilities       44,061       52,431	Accounts payable	5,292	11,270
Accrued expenses and deferred income 24,832 22,932  Total current liabilities 43,041 48,856  Total liabilities 44,061 52,431	Tax debt	1,276	2,559
Total current liabilities 43,041 48,856  Total liabilities 44,061 52,431	Other liabilities	8,347	6,929
Total liabilities 44,061 52,431	Accrued expenses and deferred income	24,832	22,932
	Total current liabilities	43,041	48,856
TOTAL EQUITY AND LIABILITIES 1,014,056 1,081,588	Total liabilities	44,061	52,431
	TOTAL EQUITY AND LIABILITIES	1,014,056	1,081,588

# Consolidated statement of changes in equity, summary

<del>-</del>	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	-123,605	1,101,457
Net income	-	-	-	-73,507	-73,507
Other comprehensive income	-	-	-2,834	-	-2,834
Total comprehensive income	-	-	-2,834	-73,507	-76,341
Transactions with the Group's owners					
Received premium for warrant subscription	-	4,628	-	-	4,628
Costs related to warrant programme	-	-490	-	-	-490
Repurchase of warrants	-	-97	-	-	-97
Total transactions with the Group's owners	-	4,040	-	-	4,040
Closing equity at Dec 31, 2022	2,483	1,226,435	-2,650	-197,113	1,029,156

(KSEK)	Share capital	Other contributed capital	Translation difference	Retained earnings incl net income	Total
Opening equity at Jan 1, 2023	2,483	1,226,435	-2,650	-197,113	1,029,156
Net income	-	-	-	-59,612	-59,612
Other comprehensive income	-	-	451	-	451
Total comprehensive income	-	-	451	-59,612	-59,161
Transactions with the Group's owners	-	-	-	-	-
Total transactions with the Group's owners	-	-	-	-	-
Closing equity at Dec 31, 2023	2,483	1,226,435	-2,199	-256,724	969,995

# Consolidated cash flow statement, summary

	Oct-Dec		Jan-D	ec
(KSEK)	2023	2022	2023	2022
Operating activities				
Operating income	-14,850	-23,246	-65,547	-105,887
Adjustments for non-cash items	14,030	23,240	03,347	103,007
Depreciations and amortisations	5,798	5,603	22,573	22,749
Exchange rate differences	13,779	5,424	8,900	-863
Other non-cash items	618	-1	2,552	1,152
other new cash items	010	-	2,332	1,102
Interest received	8,943	3,578	15,168	3,580
Interest paid	-66	-74	-215	-255
Taxes paid	-170	-189	-564	-583
Cash flow from operating activities before changes in working capital	14,053	-8,905	-17,132	-80,108
Cash flow from changes in working capital				
Cash flow from inventories	5,023	-3,621	-6,738	-27,504
Cash flow from operating receivables	-6,132	-3,366	-6,253	7,494
Cash flow from operating liabilities	-4,166	-6,668	-7,937	-15,315
Cash flow from operating activities	8,777	-22,560	-38,061	-115,433
Investing activities				
Investments in intangible assets	-41,490	-27,285	-168,373	-137,048
Investments in tangible assets	-353	-28	-515	-735
Repaid short-term deposits	-	-	312,348	-
Investments in short-term deposits	-		-465,417	
Cash flow from investing activities	-41,843	-27,313	-321,957	-137,783
Financing activities				
New share issue	-	-	-	-
Issue expenses	-	-	-	-
Amortisation of leasing liabilities	-1,223	-1,183	-4,857	-4,510
Received premium for warrant subscription	-	-	-	3,590
Costs related to warrant programme	-	-	-	-490
Repurchase of warrants	-	<u> </u>	-	-97
Cash flow from financing activites	-1,223	-1,183	-4,857	-1,507
Cash flow for the period	-34,288	-51,057	-364,875	-254,722
Cash and cash equivalents at the beginning of the period	290,811	675,575	607,742	836,181
Currency revaluation difference	-25,343	-16,777	-11,687	26,283
Cash and cash equivalents at the end of the period	231,180	607,742	231,180	607,742

## Parent company income statement, summary

	Oct-	Dec	Jan-Dec	
(KSEK)	2023	2022	2023	2022
Net sales	44,514	35,768	153,767	122,726
Cost of goods sold	-13,068	-9,690	-43,115	-34,092
Gross profit	31,446	26,078	110,652	88,634
Selling expenses	-14,739	-17,922	-62,200	-68,360
Administration costs	-25,926	-28,608	-101,608	-112,498
Research and development costs	-5,058	-4,694	-18,137	-16,927
Other operating income	15,257	10,622	43,665	30,757
Other operating expenses	-8,900	-3,624	-29,656	-15,238
Operating income	-7,921	-18,148	-57,283	-93,632
Net financial items	-21,762	-12,203	9,518	33,891
Income after net financial items	-29,682	-30,351	-47,766	-59,741
Group contribution	11	0	11	0
Income before tax	-29,671	-30,351	-47,754	-59,741
Income tax	-	-	-	<u> </u>
Net income	-29,671	-30,351	-47,754	-59,741

# Parent company statement of other comprehensive income, summary

	Oct-	Oct-Dec		Jan-Dec	
(KSEK)	2023	2022	2023	2022	
Net income	-29,671	-30,351	-47,754	-59,741	
Other comprehensive income					
Items that can later be reclassified to the income statement:					
Translation differences from foreign operations	-181	-119	-17	-416	
	-181	-119	-17	-416	
Other comprehensive income, net after tax					
Total comprehensive income	-29,852	-30,471	-47,771	-60,158	

# Parent company balance sheet, summary

TOTAL EQUITY AND LIABILITIES

(KSEK)	Dec 31, 2023	Dec 31, 2022	
ASSETS			
Intangible assets			
Capitalised development expenditure	512,707	365,470	
Tangible assets			
Machinery and other technical facilities	819	795	
Equipment, tools and installations	2,345	4,066	
Financial assets			
Other long-term assets	404	404	
Non-current receivables, group companies	36,874	34,519	
Total fixed assets	553,148	405,253	
Inventory	42,975	38,597	
Tax receivables	125	4	
Accounts receivable	21,807	14,102	
Receivables, group companies	60,603	49,893	
Prepayments and accrued income	4,451	5,823	
Other receivables	4,235	4,072	
Short-term investments	150,624	0	
Cash and cash equivalents	215,921	587,909	
Total current assets	500,740	700,401	
TOTAL ASSETS	1,053,888	1,105,654	
(KSEK)	Dec 31, 2023	Dec 31, 2022	
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	2,483	2,483	
Fund for capitalised development expenses	505,854	356,396	
	303,834	330,330	
Non-restricted equity	303,634	333,630	
	1,226,435	1,226,435	
Non-restricted equity			
Non-restricted equity Share premium fund	1,226,435	1,226,435 -475,162	
Non-restricted equity Share premium fund Retained earnings	1,226,435 -684,378	1,226,435 -475,162	
Non-restricted equity Share premium fund Retained earnings Net income	1,226,435 -684,378 -47,754	1,226,435 -475,162 -59,741	
Non-restricted equity Share premium fund Retained earnings Net income Equity attributable to the parent company's shareholders	1,226,435 -684,378 -47,754	1,226,435 -475,162 -59,741	
Non-restricted equity Share premium fund Retained earnings Net income Equity attributable to the parent company's shareholders  Current liabilities	1,226,435 -684,378 -47,754 <b>1,002,640</b>	1,226,435 -475,162 -59,741 <b>1,050,412</b>	
Non-restricted equity Share premium fund Retained earnings Net income Equity attributable to the parent company's shareholders  Current liabilities Accounts payable	1,226,435 -684,378 -47,754 <b>1,002,640</b>	1,226,435 -475,162 -59,741 <b>1,050,412</b>	
Non-restricted equity Share premium fund Retained earnings Net income Equity attributable to the parent company's shareholders  Current liabilities Accounts payable Liabilities to group companies	1,226,435 -684,378 -47,754 <b>1,002,640</b> 4,577 18,170	1,226,435 -475,162 -59,741 <b>1,050,412</b> 10,711 18,092	
Non-restricted equity Share premium fund Retained earnings Net income Equity attributable to the parent company's shareholders  Current liabilities Accounts payable Liabilities to group companies Tax debt	1,226,435 -684,378 -47,754 <b>1,002,640</b> 4,577 18,170 1,066	1,226,435 -475,162 -59,741  1,050,412  10,711 18,092 2,300 5,287	
Non-restricted equity Share premium fund Retained earnings Net income Equity attributable to the parent company's shareholders  Current liabilities Accounts payable Liabilities to group companies Tax debt Other liabilities	1,226,435 -684,378 -47,754 <b>1,002,640</b> 4,577 18,170 1,066 6,869	1,226,435 -475,162 -59,741  1,050,412  10,711 18,092 2,300	

1,053,888

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 significant impact on the Group's financial reports.

During the year, investments have been made in short-term investments, so-called deposits in SEK and USD, with a term of 6 months. These are valued at amortized cost and converted to Swedish kronor according to the exchange rate on the balance sheet date.

## 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 22 and <a href="https://sedanamedical.com/sv/investerare/rapporter-presentationer/">https://sedanamedical.com/sv/investerare/rapporter-presentationer/</a>

## 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 year, the Group had an average of 79 (86) full time employees and 7 (7) full time consultants, representing a decrease of 7 on the same period in 2022. In terms of total headcount (i.e. regardless of full-time or part-time positions), the total number of employees was 79 and the total number of consultants was 7 at the end of the quarter, compared to 85 and 10 respectively at the corresponding balance date last year. The decrease in the number of people is mainly 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 December 31, the claim amounts to KSEK 274. 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, KSEK 200 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 year Sedana Medical had 973,399 outstanding warrants where 1 warrant equals 1 share at conversion.

		Number of acquired warrants at the beginning	Number of acquired warrants during the	Number of expired warrants during the	Number of repurchased warrants during the	Number of warrants at the end of		Strike price
Programme 2020/2023	Position CEO	of the period	period	period	period	the period	Terms* 1:1	(SEK) 83.65
•		4.000	-	4.000	-			
2020/2023	Senior management	4,000		-4,000			1:1	83.65
2020/2023	Other employees	26,560	-	-26,560	-	-	1:1	83.65
2020/2023	Total	30,560	-	-30,560	-	-	1:1	83.65
Exercise period :	1 June 2023 – 30 September 2023							
2020/2024	CEO	-	-	-	-	-	1:1	123.88
2020/2024	Senior management	25,200	-	-	-	25,200	1:1	123.88
2020/2024	Other employees	123,252	-	-	-	123,252	1:1	123.88
2020/2024	Total	148,452	-	-	-	148,452	1:1	123.88
Exercise period	1 February 2024 – 31 May 2024							
2022/2025:1	CEO	495,000	-	-	-	495,000	1:1	46.24
2022/2025:1	Senior management	-	-	-	-	-	1:1	46.24
2022/2025:1	Other employees	-	-	-	-	-	1:1	46.24
2022/2025:1	Total	495,000	-	-	-	495,000	1:1	46.24
Exercise period 3	30 May 2025 - 30 September 2025							
2022/2025:2	CEO		-	-	-	-	1:1	46.24
2022/2025:2	Senior management	231,606	-	-	-	231,606	1:1	46.24
2022/2025:2	Other employees	98,341	-	-	-	98,341	1:1	46.24
2022/2025:2	Total	329,947	-	-	-	329,947	1:1	46.24
Exercise period 3	30 May 2025 - 30 September 2025							
Totalt	CEO	495,000	-	-	-	495,000		
Totalt	Senior management	260,806	-	-4,000	-	256,806		
Totalt	Other employees	248,153	-	-26,560	-	221,593		
	Total	1,003,959	-	-30,560	-	973,399		

<sup>\*</sup> 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

#### **EBITDA ex-US**

Operating income (EBIT) less depreciation and write-downs as well as operating expenses attributable to the company's US business

#### 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%