



sedanamedical

Bringing inhaled sedation to intensive care

Interim report

January–March 2024

sedana medical ab (publ)



*"Off to a strong start
with record sales in Q1."*

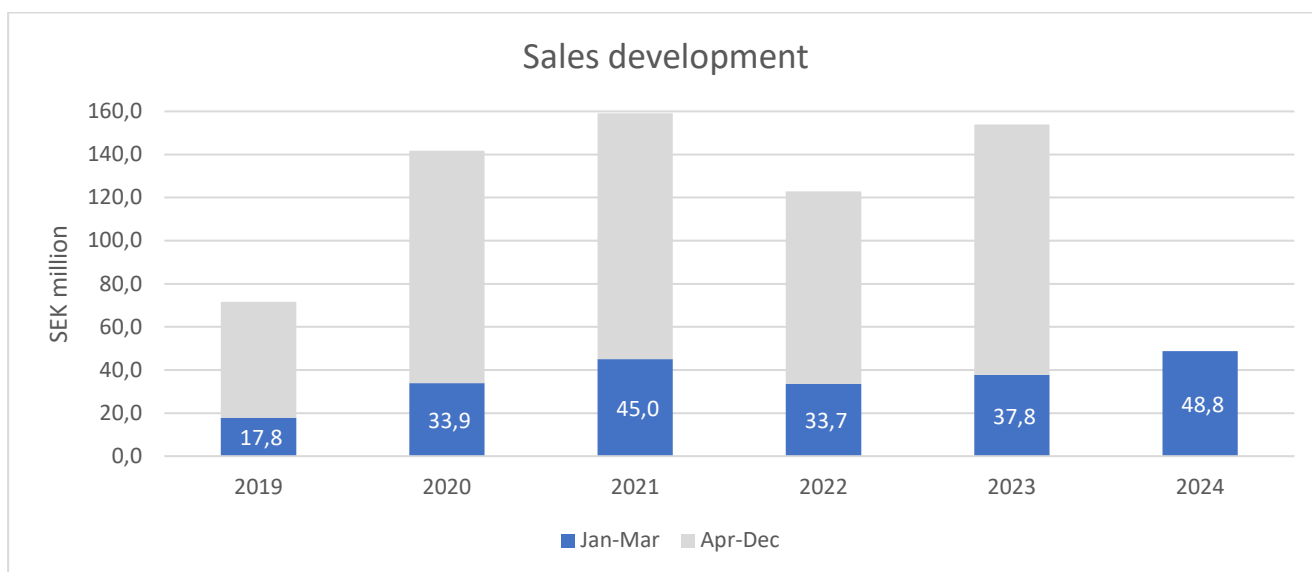
Johannes Doll, President & CEO

Q1 Q2 Q3 Q4

Financial summary

First quarter 2024

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



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

Off to a strong start with record sales in Q1.

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

Accelerated sales growth

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

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

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

Our distributor business grew 44% year over year excluding exchange rate effects, fueled by the first order from our main South American distributor since 2022, worth 1.4 MSEK. It is worth pointing out that this order includes sufficient stock for Mexico and Colombia for at least one year, which is in line with the typical ordering rhythm in the region. Besides the positive development in South America, we also saw growth of approximately 3% from our other distributor partners.

Further improved bottom line

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

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

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

Progress in the USA

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

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

Our timeline with regards to the US launch remains unchanged. We are working towards an NDA submission in the first quarter of 2025, positioning us for a potential launch in 2026, assuming the FDA adheres to their standard 10-month review time. We will apply for different benefits we may be entitled to, based on the Fast Track Designation that FDA has



granted us. If successful, this could mean an acceleration of several months. However, it's important to note that FDA will assess our eligibility for these benefits only after our NDA submission, following their standard protocol.

Exciting times ahead

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

Johannes Doll, President and CEO

Significant events during the period

- During the first quarter, Sedana Medical achieved the highest quarterly sales in the company's history, including the Covid-19 period, where sales were inflated by high patient numbers and unusual stocking effects.
- We achieved a positive EBITDA ex-US, which marks the first time in the company's history, with the exception of Q1 2020, when extraordinary Covid-related sales resulted in a slightly positive EBITDA.
- An ESG (Environmental, Social, Governance) Committee was established to underscore the commitment to build a long-term sustainable and responsible business.

Significant events after the period

- In April, the last patient was enrolled in the INSPIRE ICU-1 trial.

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 sedation¹. 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 year². 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%, leaving ample opportunities for growth.

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 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 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*

¹ Based on publicly available data per country and Sedana Medical's own research

² Based on externally performed market opportunity study

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, including effective incentive schemes that reward high performance.

Our growth trajectory that was re-established in 2023 accelerated during Q1 2024, as we report net sales growth of 29% relative to the same period in 2023. In local currency, sales grew 28%.

The strong sales performance was broad-based as our main market Germany, our other direct markets, and our distributor business all contributed well. In Germany, sales grew by 17% in local currency relative to last year, which is an acceleration relative to 2023, despite an 8% decrease in ICU patients.

In our other direct markets (Spain, France, UK, Nordics and Benelux) sales grew by 54% in local currency during the quarter. Among these markets, Spain has been a top performer in recent quarters, and this was the case also now. In addition, sales growth has markedly accelerated in the UK, after we obtained MHRA approval in late 2023.

In our distributor markets, sales increased by 44% in local currency compared to last year. The strong growth is driven by a large order from our main South American distributor, complemented by modest growth in other distributor markets as well.

During the quarter we have ended the partnership with our distributors in China and India. The registration process in China has already been delayed due to Covid-19 and other regulatory aspects. Our assessment is that time-consuming and potentially expensive efforts would have been required in these countries, and as a result we are focusing our efforts on key markets with near term profitable growth prospects.

Regulatory and pricing/reimbursement approvals in Europe

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 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 Q4 2023, 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 are now seeing that the MHRA approval in combination with the positive NICE guidance is leading to more ICU patients in the UK benefitting from the clinically proven advantages of inhaled sedation. Also during Q4 2023, the Spanish Ministry of Health granted pricing and reimbursement approval for the Sedaconda (isoflurane) in Spain. Subsequently, we launched Sedaconda (isoflurane) in Spain end of last year, which is now contributing to the strong sales growth in this market.

Regarding our paediatric IsoCOMFORT study we have filed the submission end of 2023, and BfArm has started the procedure in March, causing a delay of approximately 2 months. We expect End of Procedure in H2 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. The European Medicines Agency's Paediatric Committee issued a positive opinion regarding the compliance with the company's Paediatric Investigation Plan during Q4 of last year. This confirms data exclusivity and market protection for Sedaconda (isoflurane) until 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 around 130 run-in), recruited across 31 clinics. We have reported that patient recruitment for INSPIRE-ICU 1 has been completed, and recruitment for INSPIRE-ICU 2 is following closely behind. We remain highly encouraged by the

enthusiasm expressed by the healthcare professionals participating in the trials when they see the benefits of inhaled sedation.

Our prediction is that NDA submission can be expected in Q1 2025. With a standard review time, approval can subsequently be expected by early 2026. 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. Sedana Medical will have the opportunity to discuss with FDA at a pre-NDA meeting 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.

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. Several factors contribute to this significant opportunity, including the larger population size, a medical practice in favor of intubation compared to Europe, and an overall attractive pricing environment.

Beyond 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:

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, as we did in Europe.

Moreover, heightened awareness of opioid risks in the US, exacerbated by the opioid crisis with over 100,000 overdose deaths annually, positions our inhaled sedation therapy as a compelling future alternative. If our US study replicates the significant reduction of opioid use observed in our previous 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. Based on these insights, we are highly optimistic about the commercial potential of inhaled sedation in the US.

Importantly, Sedana Medical is financed to complete the study and achieve US approval, with MSEK 361 in cash at the end of Q1, and an ex-US business that achieved EBITDA break-even this quarter.

Cost management and resource allocation

We report positive EBITDA for our ex-US business in Q1 2024, helped by a positive currency effect, which constitutes a significant improvement since 2022 when the company reported an EBITDA loss of -83 MSEK. This has been achieved through a combination of shifting resources to customer-facing functions in our main markets, as well as outright cost reductions in administrative and headquarter functions.

We report a gross margin of 71% in Q1 2024, compared to 73% in Q1 2023 and 70% in Q4 2023. Proportionately higher share of Sedaconda (isoflurane) sales had a slight negative effect on the percentage gross margin. In addition, we are experiencing cost increases for materials and key components and maintain a close dialogue with our suppliers. As communicated previously, our target gross margin remains at least 70%, even though we may continue to see some volatility due to market and product mix effects. We report operating expenses of MSEK 44 in Q1 2024, which is in line with the same quarter of last year. EBITDA for the quarter was MSEK -1 corresponding to a margin of -2%, compared to MSEK -11 and -28% margin in the same quarter last year. EBITDA Ex-US for the quarter was positive of MSEK 2. We remain focused on profitable growth opportunities and manage our resources in a prudent way, in order to launch in the US backed by a solid foundation in Europe.

ESG sustainability

Sedana Medical aims to be a responsible partner to all customers, suppliers, employees, and other stakeholders, as well as an attractive long-term investment for our shareholders. Sedana Medical's Code of Conduct constitutes a framework for what the company considers to be responsible and appropriate conduct in order to build a long-term sustainable business. During the quarter we have established an ESG (Environmental, Social, Governance) Committee to further coordinate our efforts. Among other tasks, the Committee has initiated the work to map the Sedana Medical's carbon footprint and provide life-cycle analyses of our main products. We have also appointed a Sustainability Manager to further focus on these important matters.

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 received a final shipment of monitors that had previously been produced for Sedana Medical and that were still on stock at the supplier. In addition, we are continuing to provide service to our

customers for sold devices. In parallel, we have closed a partnership with a new main supplier of gas monitors. 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

(KSEK)	Jan-Mar		Jan-Dec
	2024	2023	2023
Net sales	48,821	37,781	153,867
Gross profit	34,769	27,489	108,981
Gross margin %	71%	73%	71%
EBITDA	-963	-10,661	-42,974
EBITDA margin %	-2%	-28%	-28%
EBITDA ex-US	1,588	-10,147	-40,145
Operating income (EBIT)	-6,566	-16,297	-65,547
Operating margin %	-13%	-43%	-43%
Income after net financial items	20,818	-16,010	-59,019
Net income	20,657	-16,122	-59,612
Net income margin %	42%	-43%	-39%
Total assets	1,044,179	1,064,043	1,014,056
Equity	988,542	1,012,430	969,995
Equity ratio %	95%	95%	96%
Quick ratio %	738%	1187%	968%
Debt to equity ratio %	6%	5%	5%
Average number of full-time employees for the period	77	79	79
Number of employees at balance date	83	83	79
Number of employees and consultants at balance date	90	92	86
Average number of shares before dilution	99,336,960	99,336,960	99,336,960
Average number of shares after dilution	99,336,960	99,336,960	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	99,336,960	99,336,960
Earnings per share before dilution, SEK	0.21	-0.16	-0.60
Earnings per share after dilution, SEK	0.21	-0.16	-0.60

Group performance

Net sales

Net sales for the quarter amounted to KSEK 48,821 (37,781), corresponding to an increase of 29 percent. Adjusted for currency effects, the quarter showed an increase of 28 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 55 percent (54 percent at constant exchange rates). In Germany, the increase amounted to 18 percent (17 percent at constant exchange rates). Our Distributor markets also contributed to the positive development during the quarter with a growth of 45 percent (44 percent at constant exchange rates). A large part of the increase in the Distributor markets is due to the fact that in the first quarter we received the first order since 2022 from our South American distributor, but a large part of the increase also stems from distributors in Europe.

(KSEK)	Jan-Mar		%	%*	Jan-Dec
	2024	2023			2023
Germany	29,760	25,267	18%	17%	105,620
Other direct sales	14,040	9,043	55%	54%	36,548
Distributor markets	5,021	3,470	45%	44%	11,698
Total net sales	48,821	37,781	29%	28%	153,867

*) at constant exchange rates

Gross profit and margin

The gross profit for the quarter amounted to KSEK 34,769 (27,489), corresponding to a gross margin of 71 (73) percent. The decrease mainly relates to product mix effects, such as a proportionately higher share of Sedaconda (isoflurane).

Selling expenses

Selling expenses for the quarter amounted to KSEK -26,349 (-26,691). The decrease compared to last year is due to efficiency measures within the distributor organization, which was partly offset by higher outbound logistics cost and sales bonuses compared to the previous year, as a result of the higher sales.

Administrative expenses

Administrative expenses for the quarter amounted to KSEK -11,978 (-12,474). The reduction compared to the previous year is mainly due to efficiencies within administrative functions.

Research and development expenses

Research and development expenses for the quarter amounted to KSEK -5,270 (-5,095), which corresponds to an increase of 3 percent. The increase is due to a slightly lower capitalisation rate compared to the previous year.

Other operating income/expenses

Other operating income mainly consists of positive unrealised exchange rate differences on operating items. These totalled KSEK 2,949 (6,813) for the quarter.

Other operating expenses mainly consist of negative unrealised exchange rate differences on operating items. These totalled KSEK -686 (-6,338) for the quarter.

Net financial items and earnings per share

Financial net for the quarter totalled KSEK 27,383 (287). The amounts consist partly of unrealized exchange rate differences on cash invested in USD but also of received interest on cash and cash equivalents.

Group tax expense for the quarter was KSEK -161 (-112) and consists mainly of current tax in Germany. Consequently, earnings per share amounted to SEK 0.21 (-0.16) for the quarter.

Capitalised development expenditures

Capitalised development expenditures as of March 31 amounted to KSEK 591,925 compared to KSEK 542,705 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 49,219 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 March 31, inventory amounted to KSEK 39,593 compared to KSEK 42,975 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 988,542, compared to KSEK 969,995 at the beginning of the year. This corresponds to SEK 9,95 (10.19) per share. Equity/assets ratio was 95 percent, compared to 96 percent at the beginning of the year. Debt/equity ratio on March 31 was 5 percent, compared to 4 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 short-term investments decreased by KSEK -20,893 to KSEK 360,911 at the end of the first quarter compared to MSEK 381,804 at the beginning of the quarter.

Cash flow from operating activities before changes in working capital for the quarter was KSEK -2,127 (-9,983). Cash flow from changes in working capital totalled KSEK 10,498 (3,005) and was mainly affected by increased short-term liabilities attributable to timing of payments regarding the clinical studies at the turn of the quarter. Cash flow from operating activities thus totalled KSEK 8,371 (-6,979).

Cash flow from investments in intangible assets amounted to KSEK -52,090 (-39,289) and consist mainly of 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). Repaid deposits during the quarter as well as the previous year's investment in deposits, amounted to KSEK 155,307 and KSEK -306,156 respectively. Total cash flow from investing activities for the quarter thus totalled KSEK 103,217 (-345,539).

Cash flow from financing activities for the quarter totalled KSEK -1,276 (-1,243) and relates to amortization of lease liabilities.

Currency revaluation differences in cash and cash equivalents amounted to KSEK 19,418 (-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 positive and amounted to SEK 1.11 (-3.56). Adjusted for repayments and investments in short-term investments, the cash flow per share amounted to SEK -0.45 (-0.48), corresponding to an improvement of SEK 0.03 per share.

Parent company

The Parent Company's net sales for the quarter totalled KSEK 48,761 (37,736), of which intra-group sales were KSEK 2,159 (2,188).

Operating income for the quarter totalled KSEK -3,158 (-13,810). Net financial items were KSEK 28,113 (910) and relate mainly to unrealised exchange gains on cash balances in foreign currencies, mainly USD, but also interest on the deposit that was repaid during the quarter and received interest on cash and cash equivalents.

Shareholders' equity in the Parent Company totalled KSEK 1,027,441 at March 31 2024, compared to KSEK 1,002,640 at the beginning of the year. This corresponds to an increase of KSEK 24,801. Share capital totalled KSEK 2,483, compared to KSEK 2,483 at the beginning of the year.

Cash and cash equivalents stood at KSEK 340,240, compared to KSEK 215,921 at the beginning of the year. Deposits of KSEK 155,307 were repaid during the quarter.

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 MSEK 1,590.

The price paid for Sedana Medical shares was SEK 23.16 at the start of the year and SEK 16.01 at the end of the quarter. The lowest closing price during the quarter was recorded on March 20 and was SEK 14.72. The highest closing price was recorded on January 2 and was SEK 24.36.

Share information

	Jan-Mar		Jan-Dec
	2024	2023	2023
Net income, KSEK	20,657	-16,122	-59,612
Cash flow, KSEK	110,313	-353,760	-364,875
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	973,399	1,003,959	973,399
Average number of warrants	973,399	1,003,959	988,679
Share capital at balance date, KSEK	2,483	2,483	2,483
Equity at balance date, KSEK	988,542	1,012,430	969,995
Earnings per share before dilution, SEK	0.21	-0.16	-0.60
Earnings per share after dilution, SEK	0.21	-0.16	-0.60
Equity per share, SEK	9.95	10.19	9.76
Cash flow per share, SEK	1.11	-3.56	-3.67

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	9,119,013	9.2%
Handelsbanken Funds	5,963,169	6.0%
Öhman Funds	4,520,825	4.6%
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	2,678,608	2.7%
AMF Pension	2,491,000	2.5%
Berenberg Funds	2,301,011	2.3%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Avanza Pension	1,593,700	1.6%
Amundi	1,453,679	1.5%
AXA Investment Managers	1,192,348	1.2%
Fifteen largest shareholders	64,909,977	65.3%
Others	34,426,983	34.7%
Total	99,336,960	100.0%

Facts about the share

Trading
Nasdaq Stockholm

No of shares as per Mar 31, 2024
99 336 960

Market cap as per Mar 31, 2024
SEK 1,590 million

Ticker
SEDANA

ISIN
SE0015988373

LEI-code
549300FQ3NJRI56LCX32

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 interim report

Sedana Medical presents the interim report to investors, asset managers, analysts and media on April 25, 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: <https://www.finwire.tv/webcast/sedana-medical/q1-2024/>

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

Financial calendar

Annual General Meeting 2024	22 May 2024 at 2:00 pm at Vendevägen 89, Danderyd. Registration begins at 1:30 pm.
Interim Report Q2 2024	23 July 2024
Interim Report Q3 2024	24 October 2024

The interim report for Sedana Medical AB (publ) has been issued by the company's CEO after authorization by the board.

Danderyd April 25, 2024

Johannes Doll
President and CEO

This interim report has not been subject to review by the company's auditors.

The report has been prepared in both Swedish and English versions. In the event of any discrepancies between the Swedish and English versions, the Swedish version will take precedence.

Consolidated income statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2024	2023	2023
Net sales	48,821	37,781	153,867
Cost of goods sold	-14,052	-10,292	-44,886
Gross profit	34,769	27,489	108,981
Selling expenses	-26,349	-26,691	-107,239
Administrative expenses	-11,978	-12,474	-47,504
Research and development expenses	-5,270	-5,095	-20,805
Other operating income	2,949	6,813	31,473
Other operating expenses	-686	-6,338	-30,453
Operating income	-6,566	-16,297	-65,547
Net financial items	27,383	287	6,529
Income before taxes	20,818	-16,010	-59,019
Income tax	-161	-112	-593
Net income	20,657	-16,122	-59,612
Earnings per share, based on earnings attributable to the parent company's ordinary shareholders:			
Before dilution	0.21	-0.16	-0.60
After dilution	0.21	-0.16	-0.60
Operating income (EBIT)	-6,566	-16,297	-65,547
Whereof amortisation of intangible assets	-3,960	-3,859	-15,452
Whereof depreciation of tangible assets	-1,642	-1,778	-7,122
EBITDA	-963	-10,661	-42,974

Consolidated statement of other comprehensive income, summary

(KSEK)	Jan-Mar		Jan-Dec
	2024	2023	2023
Net income	20,657	-16,122	-59,612
Other comprehensive income			
Items that can later be reclassified to the income statement:			
Translation differences from foreign operations	-2,110	-604	451
Other comprehensive income, net after tax	-2,110	-604	451
Total comprehensive income	18,547	-16,726	-59,161
Total comprehensive income as a whole attributable to the parent company's shareholders	18,547	-16,726	-59,161

Consolidated balance sheet, summary

(KSEK)	Mar 31, 2024	Mar 31, 2023	Dec 31, 2023
ASSETS			
Intangible assets			
Capitalised development expenditure	591,925	426,074	542,705
Concessions, patents, licenses, etc.	3,551	3,119	3,326
Tangible assets			
Machinery and other technical facilities	791	901	864
Equipment, tools and installations	2,176	3,937	2,551
Rights of use	4,946	8,653	4,912
Financial assets			
Other long-term assets	47	46	45
Deferred tax assets	26	31	31
Total fixed assets	603,461	442,761	554,435
Inventory	39,593	38,868	42,975
Tax receivables	2,528	826	739
Accounts receivable	26,810	13,920	24,180
Prepayments and accrued income	8,683	5,628	4,701
Other receivables	2,193	1,855	5,223
Short-term investments	0	308,542	150,624
Cash and cash equivalents	360,911	251,643	231,180
Total current assets	440,718	621,282	459,621
TOTAL ASSETS	1,044,179	1,064,043	1,014,056
(KSEK)	Mar 31, 2024	Mar 31, 2023	Dec 31, 2023
EQUITY AND LIABILITIES			
Equity			
Share capital	2,483	2,483	2,483
Other contributed capital	1,226,435	1,226,435	1,226,435
Translation difference	-4,309	-3,254	-2,199
Retained earnings including net profit	-236,067	-213,235	-256,724
Equity attributable to the parent company's shareholders	988,542	1,012,430	969,995
Non-current liabilities			
Leasing liabilities	1,288	2,533	1,012
Deferred tax liabilities	7	-	7
Total non-current liabilities	1,296	2,533	1,020
Current liabilities			
Leasing liabilities	2,990	5,536	3,294
Accounts payable	5,547	2,559	5,292
Tax debt	2,858	1,331	1,276
Other liabilities	9,955	5,751	8,347
Accrued expenses and deferred income	32,990	33,902	24,832
Total current liabilities	54,341	49,080	43,041
Total liabilities	55,637	51,613	44,061
TOTAL EQUITY AND LIABILITIES	1,044,179	1,064,043	1,014,056

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, 2023	2,483	1,226,435	-2,650	-197,113	1,029,156
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	1,226,435	-3,254	-213,235	1,012,430

(KSEK)	Share capital	Other contributed capital	Translation difference	Retained earnings incl net income	Total
Opening equity at Jan 1, 2024	2,483	1,226,435	-2,199	-256,724	969,995
Net income	-	-	-	20,657	20,657
Other comprehensive income	-	-	-2,110	-	-2,110
Total comprehensive income	-	-	-2,110	20,657	18,547
Transactions with the Group's owners					
Total transactions with the Group's owners	-	-	-	-	-
Closing equity at Mar 31, 2024	2,483	1,226,435	-4,309	-236,067	988,542

Consolidated cash flow statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2024	2023	2023
Operating activities			
Operating income	-6,566	-16,297	-65,547
<i>Adjustments for non-cash items</i>			
Depreciations and amortisations	5,602	5,637	22,573
Exchange rate differences	-6,273	133	8,900
Other non-cash items	658	711	2,552
Interest received	4,640	0	15,168
Interest paid	-32	-55	-215
Taxes paid	-157	-112	-564
Cash flow from operating activities before changes in working capital	-2,127	-9,983	-17,132
<i>Cash flow from changes in working capital</i>			
Cash flow from inventories	3,382	-871	-6,738
Cash flow from operating receivables	-3,741	4,690	-6,253
Cash flow from operating liabilities	10,857	-814	-7,937
Cash flow from operating activities	8,371	-6,979	-38,061
Investing activities			
Investments in intangible assets	-52,090	-39,289	-168,373
Investments in tangible assets	0	-93	-515
Repaid short-term deposits	155,307	0	312,348
Investments in short-term deposits	0	-306,156	-465,417
Cash flow from investing activities	103,217	-345,539	-321,957
Financing activities			
New share issue	-	-	-
Issue expenses	-	-	-
Amortisation of leasing liabilities	-1,276	-1,243	-4,857
Received premium for warrant subscription	-	-	-
Costs related to warrant programme	-	-	-
Cash flow from financing activities	-1,276	-1,243	-4,857
Cash flow for the period	110,313	-353,760	-364,875
Cash and cash equivalents at the beginning of the period	231,180	607,742	607,742
Currency revaluation difference	19,418	-2,339	-11,687
Cash and cash equivalents at the end of the period	360,911	251,643	231,180

Parent company income statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2024	2023	2023
Net sales	48,761	37,736	153,767
Cost of goods sold	-13,634	-9,833	-43,115
Gross profit	35,127	27,903	110,652
Selling expenses	-14,596	-16,869	-62,200
Administration costs	-26,399	-24,697	-101,608
Research and development costs	-4,706	-4,346	-18,137
Other operating income	8,128	10,237	43,665
Other operating expenses	-713	-6,038	-29,656
Operating income	-3,158	-13,810	-57,283
Net financial items	28,113	910	9,518
Income after net financial items	24,954	-12,900	-47,766
Group contribution	0	0	11
Income before tax	24,954	-12,900	-47,754
Income tax	0	0	0
Net income	24,954	-12,900	-47,754

Parent company statement of other comprehensive income, summary

(KSEK)	Jan-Mar		Jan-Dec
	2024	2023	2023
Net income	24,954	-12,900	-47,754
Other comprehensive income			
Items that can later be reclassified to the income statement:			
Translation differences from foreign operations	-154	-65	-17
	-154	-65	-17
Other comprehensive income, net after tax			
Total comprehensive income	24,800	-12,965	-47,771

Parent company balance sheet, summary

(KSEK)	Mar 31, 2024	Mar 31, 2023	Dec 31, 2023
ASSETS			
Intangible assets			
Capitalised development expenditure	559,597	398,971	512,707
Tangible assets			
Machinery and other technical facilities	759	790	819
Equipment, tools and installations	2,005	3,574	2,345
Financial assets			
Other long-term assets	404	404	404
Non-current receivables, group companies	38,769	35,271	36,874
Total fixed assets	601,533	439,010	553,148
Inventory	39,593	38,868	42,975
Tax receivables	2,489	4	125
Accounts receivable	25,017	11,916	21,807
Receivables, group companies	70,495	64,916	60,603
Prepayments and accrued income	8,485	5,595	4,451
Other receivables	889	1,066	4,235
Short-term investments	0	308,542	150,624
Cash and cash equivalents	340,240	235,115	215,921
Total current assets	487,208	666,022	500,740
TOTAL ASSETS	1,088,741	1,105,031	1,053,888

(KSEK)	Mar 31, 2024	Mar 31, 2023	Dec 31, 2023
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	2,483	2,483	2,483
Fund for capitalised development expenses	553,299	390,482	505,854
<i>Non-restricted equity</i>			
Share premium fund	1,226,435	1,226,435	1,226,435
Retained earnings	-779,731	-569,055	-684,378
Net income	24,954	-12,900	-47,754
Equity attributable to the parent company's shareholders	1,027,441	1,037,446	1,002,640
Current liabilities			
Accounts payable	5,261	1,901	4,577
Liabilities to group companies	15,080	31,155	18,170
Tax debt	2,433	1,130	1,066
Other liabilities	8,414	3,972	6,869
Accrued expenses and deferred income	30,112	29,428	20,566
Total current liabilities	61,300	67,585	51,248
Total liabilities	61,300	67,585	51,248
TOTAL EQUITY AND LIABILITIES	1,088,741	1,105,031	1,053,888

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 Svärdvägen 3A, SE-182 33 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 2023 Annual Report of Sedana Medical. None of the other published standards and interpretations that are mandatory for the Group for the financial year 2024 are deemed to have any significant 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 2023 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/>

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 2023 Annual Report on pages 32-34.

Personnel

During the quarter, the Group had an average of 77 (79) full time employees and 4 (7) full time consultants, representing a decrease of 5 on the same period in 2023. In terms of total headcount (i.e. regardless of full-time or part-time positions), the total number of employees was 83 and the total number of consultants was 7 at the end of the quarter, compared to 83 and 9 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 March 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 360 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 2023, page 50-51.

Warrant programme

At the end of the quarter Sedana Medical had 973,399 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)
2020/2024	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
<i>Exercise period 1 February 2024 – 31 May 2024</i>								
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
<i>Exercise period 30 May 2025 - 30 September 2025</i>								
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
<i>Exercise period 30 May 2025 - 30 September 2025</i>								
Total	CEO	495,000	-	-	-	495,000		
Total	Senior management	256,806	-	-	-	256,806		
Total	Other employees	221,593	-	-	-	221,593		
	Total	973,399	-	-	-	973,399		

* 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

2024: 20,6%

2023: 20.6%