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Bringing inhaled sedation to intensive care

Interim Report

January-September 2024

sedana medical ab (publ)

"Raising our 2024 sales guidance and integrating our European trial into the US submission - strengthening our file, but extending timelines."

Johannes Doll, President & CEO

Q1 Q2 **Q3** Q4

Financial summary

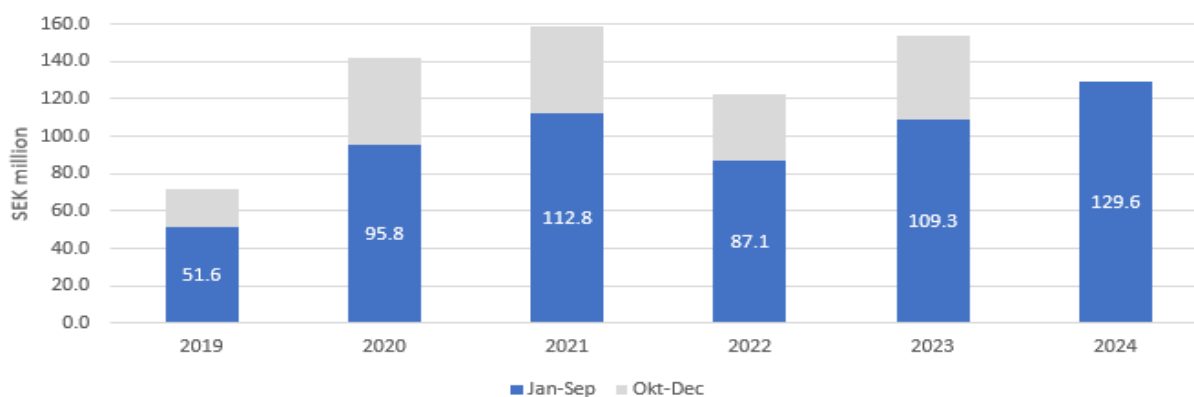
Third quarter 2024

- Net sales for the quarter totaled MSEK 39.7 (34.3), equivalent to an increase of 16% compared to the same quarter 2023. At constant exchange rates, sales increased by 20%.
- Gross profit was MSEK 28.3 (23.9) equivalent to a margin of 71% (70%).
- Earnings before interest, taxes, depreciation and amortization (EBITDA) totaled MSEK -9.0 (-12.6), equivalent to an EBITDA margin of -23% (-37%). EBITDA ex-US for the quarter was MSEK -5.3 (-11.9) corresponding to a margin of -13% (-35%).
- Operating income (EBIT) totaled MSEK -14.3 (-18.1), equivalent to an EBIT margin of -36% (-53%).
- Net income for the quarter was MSEK -22.6 (-6.8) and earnings per share before and after dilution was SEK -0.22 (-0.07). The decrease is mainly due to a lower 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 interest revenue on cash and cash equivalents.
- Cash and cash equivalents at the end of the quarter totaled MSEK 226.4 compared to MSEK 304.3 at the beginning of the quarter.
- Cash flow from operating activities totaled MSEK -29.3 (-3.9). The cash flow has primarily been affected by payments of short-term liabilities related to investments in our US clinical program, which is why accounts payable and accrued expenses also have decreased.
- Cash flow from investments in intangible assets, mostly driven by our US clinical program, totaled MSEK -36.3 (-41.8). Total cash flow from investment activities were MSEK -37.1 (111.2). The positive cash flow in Q3 2023 derives mainly from deposits invested in the first quarter 2023, which were repaid during the third quarter 2023.
- Total cash flow for the quarter was MSEK -67.3 (106.2). Considering the allocations of liquid assets to short-term investments during 2023, the total cash flow amounted to -67.3 (-46.9) MSEK. Negative currency effects on cash and cash equivalents amounted to -10.5 (-2.4) MSEK for the quarter.

January-September 2024

- Net sales for the period totaled MSEK 129.6 (109.3), equivalent to an increase of 19% compared to 2023. At constant exchange rates, sales increased by 19%.
- Gross profit was MSEK 92.0 (78.0) equivalent to a margin of 71% (71%).
- Earnings before interest, taxes, depreciation and amortization (EBITDA) totaled MSEK -23.9 (-33.9), equivalent to an EBITDA margin of -18% (-31%). EBITDA ex-US was MSEK -14.4 (-32.5) corresponding to a margin of -11% (-30%).
- Operating income (EBIT) totaled MSEK -39.9 (-50.7), equivalent to an EBIT margin of -31% (-46%).
- Net income was MSEK -19.2 (-21.5) and earnings per share before and after dilution was SEK -0.19 (-0.22). The increase in operating profit is due to higher sales and lower operational costs, which are offset by a lower financial net compared to the previous year. The financial net partly consists of unrealized currency effects on cash and cash equivalents held in USD, but also of interest received on cash and cash equivalents.
- Cash and short-term investments at the end of the period totaled MSEK 226.4 compared to MSEK 381.8 at the beginning of the year, supported by a positive exchange rate effect of MSEK 6.6.
- Cash flow from operating activities totaled MSEK -19.1 (-46.8). The improved cash flow from operating activities is primarily due to an increase in operating profit. The cash flow from changes in working capital is higher than the previous period due to lower inventory and higher receivables.
- Cash flow from investments in intangible assets, mostly driven by our US clinical program, totaled MSEK -144.0 (-126.9). Including repaid deposits and the previous year's investment in deposits, total cash flow from investment activities totaled MSEK 10.4 (-280.1).
- Total cash flow for the period was MSEK -11.4 (-330.6). Excluding the repaid deposits and the previous year's investment in deposits, the total cash flow amounted to MSEK -166.7 (-177.5).

Sales development



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

With a strong focus on our top three priorities - driving robust sales growth, advancing our journey towards US market entry, and achieving ex-US EBITDA break-even – I am pleased to report another quarter of solid progress:

- ***Building on 20% growth in Q3 and 19% year-to-date, we are raising our full-year financial guidance to 17-20% net sales growth.***
- ***On the US front, we will follow the FDA's recommendation to integrate our European trial into our US submission. While this step will affect the timeline and associated costs, it is expected to strengthen our filing.***
- ***The agreement to acquire our primary supplier, along with our continued commitment to cost discipline, puts us on track to build a long-term profitable company.***

Raising our financial guidance

We report net sales of 39.7 MSEK in the quarter, representing a year-over-year growth of 20%, excluding exchange rate effects. Year-to-date, we have delivered sales growth of 19% and hence continue to track ahead of our sales growth guidance range of 14-18% for the full year. We are therefore raising our full year guidance to 17-20% net sales growth, excluding exchange rate effects.

Our main market Germany grew by 9% in the third quarter and reached approximately the same sales level as in Q2, while the average German intensive care unit reported 9% less patients in Q3 versus the previous quarter. The decline in the number of patients is in line with the typical seasonal pattern.

Our other direct markets once more demonstrated their strong momentum, with sales growth of 49% in local currencies. The growth was again fuelled by an excellent performance in Spain, benefiting from strong commercial execution, an expanded customer base, favorable treatment guidelines, and the launch of our pharmaceutical Sedaconda (isoflurane) with pricing and reimbursement approval.

The UK also continued their accelerated growth path, following MHRA approval at the end of 2023. With the continued high growth, our other direct markets now account for almost 30% of our total sales, underscoring the importance of our strategy to reduce dependence on our main market, Germany. This diversification is crucial as our direct markets outside Germany play an increasingly vital role in achieving our overall growth ambitions.

Our distributor business grew 30% year over year excluding exchange rate effects, which is now the fourth consecutive quarter with solid growth after a period of sales decline. Our targeted approach, which focuses our support on select key partners with high potential and positive momentum, is continuing to bear fruit.

Integrating our European trial into the US submission, shifting submission timeline

Earlier this year, we cleared the important milestone of completing enrolment of our two pivotal trials in the United States. Since then, the long-term follow up of both studies has been progressing according to plan and is nearing completion. We are now awaiting high-level results for both studies.

In our journey towards US market entry, we are pursuing a clear strategy of de-risking our submission by seeking frequent interactions with the FDA and creating alignment on important aspects of the file before we submit. Contrary to our expectations based on earlier feedback, the FDA has recommended that an additional pooled efficacy analysis of all three Phase 3 clinical trials (i.e. the European clinical study and both US clinical trials) be included in the submission. In addition, the FDA has indicated that stand-alone ISE and ISS (Integrated Summary of Effectiveness and Safety) documentation will be required.

We have decided to follow the FDA's recommendation to integrate the data from our European trial into our US submission, as we expect this to strengthen our NDA submission. The first step is a feasibility study to determine the technical and clinical feasibility to pool all relevant endpoint data from the European and US studies that differ slightly in several aspects, such as methods and timing of endpoint measurements, intercurrent events, and data formats.

If the feasibility phase is successful, we will perform the pooling analyses and include them in the submission. These efforts would extend the submission timeline by approximately one year and add approximately 20-30 MSEK in additional cost. Besides the feasibility phase, the extra work includes an extension of the statistical analysis plan, development of programs to pool data across the studies, a conversion of the dataset to comply with the FDA's requirements for data standards and extended documents for the Integrated Summary of Effectiveness (ISE) and the Integrated Summary of Safety (ISS), for which the FDA has requested separate stand-alone documents in Module 5 of the dossier.



In their review and approval decision, the FDA would then consider each of the US trials individually and they would also review the pooled analyses across all three trials, to which we now have the opportunity to add 300 patients at comparably limited cost. We are confident that this approach will ensure the most robust submission and hence support our long-term goals.

Like all FDA processes, both the period leading up to submission and the review itself are subject to uncertainties with regards to the timeline. We will therefore maintain close communication with the FDA and keep you updated on our progress through the CEO's comments in upcoming reports.

Progressing towards building a long-term profitable company

We continue to be focused on building a long-term profitable company and have since 2022 taken decisive measures to streamline our non-customer facing functions and implementing a vigorous shift of resources towards the frontline. Our efforts have had clear results and we have significantly improved our profitability since 2022. For Q3, we report a negative ex-US EBITDA of -5 MSEK, which is an improvement vs. -12 MSEK last year and also vs. -11 MSEK in the previous quarter. As a further move to improve our financial resilience, we have signed an agreement to acquire our main supplier Innovatif Cekal in Malaysia during the quarter and continue to expect closing of the deal before year end. The transaction is expected to add two percentage points to our bottom line once we have sold our existing stock and is therefore another building block of future profitability.

Our cash level at the end of the quarter amounted to 226 MSEK, which we deem sufficient to execute on our plan. Importantly, also with the additional scope of the US submission, we are estimating 2025 capitalized expenses will be significantly lower than in 2024.

Exciting times ahead

When entering this year, we knew that 2024 had the potential to be a defining year for Sedana Medical's future. With only one quarter to go, I see the company well on track to deliver on the goal of reaching an all-time high in sales, in line with our raised sales guidance. At the same time, we are making good progress towards ex-US break even and building a long-term profitable company.

On the US side, the upcoming high-level results will mark another key milestone, I welcome the opportunity to integrate our European trial into the US file and therefore strengthen the submission for our highest-potential market.

I am looking forward to updating you on our progress.

Johannes Doll, President and CEO

Significant events during the period

First quarter

- 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, in the first quarter which marked 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.

Second quarter

- Enrollment of both our US clinical studies was completed in April and May respectively.
- Two new Board members were elected by the AGM in May: Donna Haire and Jens Viebke.

Third quarter

- In July, Sedana Medical announced the acquisition of Innovatif Cekal, the supplier of the company's main product Sedaconda ACD. Acquiring Innovatif Cekal enables better control of the supply chain and improved profitability by reducing the cost of goods sold. Closing of the acquisition is expected in the second half of the year.

Significant events after the period

- In October, Sedana Medical took the decision to integrate our European trial into the US submission, strengthening the file, and shifting submission timeline by approximately one year.

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.

The company's main device Sedaconda ACD is approved and sold in more than 40 countries. In 18 of these countries, Sedana Medical has approval for both its main device Sedaconda ACD and its proprietary pharmaceutical Sedaconda (isoflurane).

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) favors attractive profitability as continue to grow sales. It is a key priority to turn the Ex-US business profitable

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

² 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 guidance

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

Our financial guidance:

- 2024 net sales growth between 17 and 20% (increased from previously 14-18%), 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. We have recruited another Key Account Manager to the Spanish team in the third quarter and are planning to extend the UK team now that the sales growth has gained momentum. Conversely, we have reduced or delayed further investments in lower-potential geographies until we see a clear trend towards local profitability 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 has continued during 2024. We report net sales growth of 20% in Q3, and 19% for the first 9 months of 2024, excluding currency effects. In reported currency, sales grew 16% in Q3 and 19% YTD, respectively.

The sales growth momentum picked up in Q3 relative to Q2. In our main market Germany, sales increased by 9% in local currency, compared with a decrease of 4% in Q2. The weaker growth rate in Q2 was due to two factors: a strong comparator period in 2023 due to an unusual seasonal pattern, and an exceptionally weak June in 2024, with fewer-than-normal ventilated patients. In Q3, the average ICU in Germany saw 9% less ICU patients compared to Q2, which is in line with the typical seasonality. But against that trend, the German business reached approximately the same sales level as in the previous quarter.

In our other direct markets (Spain, France, UK, Nordics and Benelux) sales grew by 49% during the quarter in local currency (44% in reported currency). Among these markets, Spain and UK continue to be the top performers in terms of growth rate – albeit from a lower base in the UK relative to Spain.

In our distributor markets, sales increased by 30% in Q3 compared to last year in local currencies (24% in reported currency). The growth in Q3 was driven mainly by our prioritized distributor partners in Europe.

Regulatory and pricing/reimbursement approvals in Europe

Sedaconda (isoflurane) has 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, France, Spain, Sweden, Norway, Belgium and the Netherlands. 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). The MHRA approval in combination with the positive NICE guidance is leading to more ICU patients in the UK benefitting from inhaled sedation, which we can clearly see reflected in our sales YTD. Also late 2023, the Spanish Ministry of Health granted pricing and reimbursement approval for Sedaconda (isoflurane) and we launched the pharmaceutical in the country, which is now contributing to the strong sales growth in this market.

At the end of 2023 we filed the regulatory submission to the EU competent authority to obtain an approval for sedation of mechanically ventilated children in intensive care. We expect that the regulatory review process of the Reference Member State and Concerned Member States in Europe will be completed in Q4 2024, after which the national approval processes will follow. The European Medicines Agency's Pediatric Committee issued a positive opinion regarding the compliance with the company's Pediatric Investigation Plan during Q4 2023. This confirms data exclusivity and market protection for Sedaconda (isoflurane) until 2031.

US clinical program and launch preparations

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. 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.

Sedana Medical's US clinical program INSPIRE-ICU, aiming at obtaining NDA approval for inhaled sedation in the ICU, reached a significant milestone in Q2 when patient recruitment for both the INSPIRE-ICU 1 and 2 clinical trials was completed (as announced on April 25 and May 29, respectively). The two randomized double-blind clinical studies aim to confirm and ensure efficacy and safety, based on similar set-up and end-points as our European study (SED001). The total number of patients included in the two studies is 557 (of which 470 randomized and the remainder run-in patients), recruited across 30 clinics. We remain highly encouraged by the enthusiasm expressed by the healthcare professionals participating in the trials when they see the benefits of inhaled sedation. We are now awaiting topline results for the two clinical trials.

We are pursuing a strategy of derisking our submission by seeking frequent interactions with the FDA and creating alignment on important aspects of the file before we submit. Recent FDA interaction has resulted in a recommendation from the agency to include our European study SED-001 in the US submission. This constitutes an opportunity for us to further enhance our US file and is thus considered long-term value-accretive for the company, but it also affects both the US timeline and costs. The next step is a feasibility study to determine whether it is technically feasible to pool data from the US and European studies. If successful, the pooling and complete ISE and ISS (Integrated Summaries of Effectiveness and Safety) documentation would extend the submission timeline by approximately one year and add 20-30 MSEK in additional cost, but we are confident that this approach will ensure the most robust submission and ultimately support our long-term goals.

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 will apply to Sedaconda, which might have a positive effect on overall communicated timelines.

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 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 opportunities to get well positioned in treatment guidelines. Based on these insights, we are highly optimistic about the commercial success of inhaled sedation in the US.

As our US clinical program now has completed the patient recruitment phase and work intensifies on preparing our dossier for NDA submission, our US activities are simultaneously becoming more commercial. During the summer we strengthened our Medical Affairs and Marketing presence in the US, to engage with key opinion leaders and healthcare professionals, and further enhance our understanding of the US market ahead of launch.

Importantly, Sedana Medical is financed to achieve US approval, with MSEK 226 in cash at the end of Q3.

Acquisition of Innovatif Cikal

In July we announced the acquisition of Innovatif Cikal, the supplier of our main product (Sedaconda ACD), which represents the next logical step in building a long-term profitable company, after the restructuring and cost saving program that was implemented last year.

Innovatif Cikal (IC) is a manufacturer of medical devices based in Klang near Kuala Lumpur, Malaysia. IC has two customers: Sedana Medical and another Nordic medical technology company. IC produces Sedana Medical's main product Sedaconda ACD and certain accessories such as adapters, and Sedana Medical has accounted for the majority of IC's sales in recent years.

By vertically integrating IC, we assume direct control over a larger share of our cost of goods sold, which reduces the risks related to future cost fluctuations and supply disruptions. The acquisition enables improved control of the future scale-up of production capacity to meet our growth plans. In addition, it allows for potential cost reduction initiatives to be implemented over time.

The acquisition will also improve our margin on our main device and drive value creation, in particular over time as sales are expected to grow further. Over time, when the existing stock at the time of closing has been depleted, the deal is

expected to add two percentage points to Sedana Medical's EBITDA, which means that we expect value creation from the acquisition well in excess of the purchase price.

Sedana Medical will purchase all shares in IC for 34 MSEK on a cash and debt free basis. 75% of the purchase price is paid upon closing of the transaction, and the remaining 25% is to be paid 2 years after closing. Based on IC's financial result for the year 2023, the purchase price corresponds to an EBITDA multiple of 4.3x and a P/E multiple of 5.7x. There is no long-term debt in IC.

We will finance the transaction with existing cash. The acquisition is expected to have a net positive impact on our cash flow from operations from 2025 and a net positive impact on our cash balance from 2028. Importantly, we remain financed to deliver on the company's strategic plan also after the acquisition, including obtaining market approval in the USA.

Closing of the transaction is subject to certain deliverables on the part of the seller and is expected to take place during Q4 2024.

Cost management and resource allocation

We report a gross margin of 71% in Q3 2024, which is up from 70% in Q3 2023 and in line with Q2 2024. We are experiencing cost increases for materials and key components and maintain a close dialogue with our suppliers.

We report operating expenses of MSEK 43 in Q3 2024, which is up from MSEK 41 in Q3 2023, mainly driven by organizational changes and administrative costs related to the acquisition of Innovatif Cekal. However, operating expenses are down sequentially from MSEK 46 in Q2 2024, mainly due to seasonally lower market activity levels.

We report Group EBITDA for the quarter of MSEK -9 compared to MSEK -13 in the same quarter last year and MSEK -14 in Q2 2024. Ex-US EBITDA for the quarter was MSEK -5, compared with MSEK -12 in the same quarter last year and MSEK -11 in Q2 2024.

We remain focused on profitable growth opportunities and making sure to manage our resources in a prudent way, 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 to build a long-term sustainable business. During Q3, our ESG (Environmental, Social, Governance) Committee has continued the work to map Sedana Medical's carbon footprint and provide life-cycle analyses of our main products.

Financial overview

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2024	2023	2024	2023	2023
Net sales	39,720	34,255	129,597	109,323	153,867
Gross profit	28,266	23,938	91,986	78,021	108,981
Gross margin %	71%	70%	71%	71%	71%
EBITDA	-9,007	-12,550	-23,879	-33,922	-42,974
EBITDA margin %	-23%	-37%	-18%	-31%	-28%
EBITDA ex-US	-5,277	-11,942	-14,447	-32,498	-40,145
Operating income (EBIT)	-14,306	-18,090	-39,931	-50,697	-65,547
Operating margin %	-36%	-53%	-31%	-46%	-43%
Income after net financial items	-22,479	-6,739	-18,640	-21,131	-59,019
Net income	-22,616	-6,843	-19,172	-21,541	-59,612
Net income margin %	-57%	-20%	-15%	-20%	-39%
Total assets	998,238	1,053,686	998,238	1,053,686	1,014,056
Equity	949,994	1,006,234	949,994	1,006,234	969,995
Equity ratio %	95%	95%	95%	95%	96%
Quick ratio %	602%	1048%	602%	1048%	968%
Debt to equity ratio %	5%	5%	5%	5%	5%
Average number of full-time employees for the period	72	80	75	80	79
Number of employees at balance date	78	83	78	83	79
Number of employees and consultants at balance date	86	92	86	92	86
Average number of shares before dilution	99,336,960	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	99,336,960
Number of shares at balance date before dilution	99,336,960	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	99,336,960
Earnings per share before dilution, SEK	-0.22	-0.07	-0.19	-0.22	-0.60
Earnings per share after dilution, SEK	-0.22	-0.07	-0.19	-0.22	-0.60

Group performance

Net sales

Net sales for the quarter amounted to KSEK 39,720 (34,255), corresponding to an increase of 16 %. Adjusted for currency effects, the quarter showed an increase of 20 %.

Other direct markets in Europe contributed the most to the increase in absolute terms, with a growth of 44% (49% at constant exchange rates) compared to the same quarter last year. For our main market, Germany, sales increased by 6% (9% at constant exchange rates), and sales in distributor markets increased by 24% (30% at constant exchange rates). In our other direct markets, the growth is driven by Spain and UK.

For the interim period, net sales amounted to KSEK 129,597 (109,323, which corresponded to an increase of 19 %. Adjusted for currency effects, the increase was 19 %.

(KSEK)	Jul-Sep				Jan-Sep				Jan-Dec
	2024	2023	%	%*	2024	2023	%	%*	2023
Germany	25,600	24,197	6%	9%	80,797	75,818	7%	7%	105,620
Other direct sales	11,631	8,053	44%	49%	38,062	25,547	49%	49%	36,548
Distributor markets	2,490	2,004	24%	30%	10,739	7,959	35%	36%	11,698
Total net sales	39,720	34,255	16%	20%	129,597	109,323	19%	19%	153,867

*) at constant exchange rates

Gross profit and margin

The gross profit for the quarter amounted to KSEK 28,266 (23,938), corresponding to a gross margin of 71 (70) %.

For the interim period, the gross profit amounted to KSEK 91,986 (78,021), corresponding to a gross margin of 71 (71) %. The increase for the quarter is primarily due to product mix effects.

Selling expenses

Selling expenses for the quarter amounted to KSEK -23,558 (-24,768). The decrease compared to the previous year is mainly due to efficiencies within the sales, marketing, and distribution organization.

For the interim period selling expenses amounted to KSEK -76,633 (-79,221).

Administrative expenses

Administrative expenses for the quarter amounted to KSEK -13,719 (-11,446). The increase compared to the previous year is mainly due to higher personnel costs and costs related to the acquisition of Innovatif Cekal, amounting to approximately KSEK 600, which are non-recurring.

For the interim period, administrative expenses amounted to KSEK -40,047 (-36,776).

Research and development expenses

Research and development expenses for the quarter amounted to KSEK -5,476 (-5,065). The increase is due to higher personnel costs and market registration fees.

For the interim period, research and development expenses amounted to KSEK -15,494 (-15,127) KSEK.

Other operating income/expenses

Other operating income and expenses mainly consists of unrealized exchange rate differences on operating items. These totaled KSEK 181 (-749) for the quarter.

For the interim period other operating income and expenses were KSEK -257 (2,405).

Net financial items and earnings per share

Financial net for the quarter totaled KSEK -8,173 (11,350). For the interim period the financial net was KSEK 21,292 (29,566). 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 -137 (-103). For the interim period group tax expense was KSEK -532 (-410) and consists mainly of current tax in Germany.

Consequently, earnings per share amounted to SEK -0.22 (-0.07) for the quarter and SEK -0.19 (-0.22) for the interim period.

Capitalized development expenditures

Capitalized development expenditures as of September 30 amounted to KSEK 675,179 compared to KSEK 542,705 at the beginning of the year. The amount mainly consists of investments 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 132,474 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 30 September, inventory amounted to KSEK 39,464 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 30 September was KSEK 949,994, compared to KSEK 969,995 at the beginning of the year. This corresponds to SEK 9.56 (10.13) per share. Equity/assets ratio was 95%, compared to 96% at the beginning of the year. Debt/equity ratio on September 30 was 5 %, compared to 4 % at the beginning of the year. The Group had no long-term debt on September 30.

Cash, cash position and short-term investments

Cash and cash equivalents decreased during the quarter by KSEK -77,830 to KSEK 226,394 at the end of the quarter compared to KSEK 304,224 at the beginning of the quarter.

Cash flow from operating activities before changes in working capital for the quarter was KSEK -8,986 (-1,784). Cash flow from changes in working capital totaled KSEK -20,347 (-2,099) which during the quarter was mainly affected by decrease in short-term liabilities for investments in the US clinical program by payments of accounts payable and accrued expenses. Consequently, the cash flow from operating activities amounted to -29,333 (-3,883) KSEK.

Cash flow from investments in intangible assets amounted to KSEK -36,331 (-41,841) and consist mainly of development expenses for clinical studies and work on registration of Sedaconda ACD and Sedaconda (isoflurane) in the United States. The positive cash flow for the quarter previous year derives from short-term deposits invested in the first quarter 2023 which have been repaid in third quarter 2023 and only partly reinvested which led to an overall positive cash flow from short-term deposits of KSEK 153,087. Total cash flow from investing activities for the quarter totaled KSEK -37,017 (111,246).

Cash flow from financing activities for the quarter totaled KSEK -964 (-1,204) and relates to amortization of lease liabilities.

Currency revaluation differences in cash and cash equivalents amounted to KSEK -10,515 (-2,361) during the quarter and are mainly related to cash and cash equivalents held in USD. Cash flow per share for the quarter amounted to SEK -0.68 (1.07).

During the interim period cash and cash equivalents decreased by KSEK -155,410 and totaled KSEK 226,394 on September 30, compared to KSEK 381,804 at the beginning of the year.

Cash flow from operating activities before changes in working capital for the period was KSEK -23,104 (-31,185). Cash flow from changes in working capital amounted to KSEK 4,053 (-15,653), which during the period was mainly affected by increased short-term receivables and interest received of 4.6 MSEK in connection with refunded deposits during the first quarter. Consequently, the cash flow from operating activities amounted to -19,051 (-46,838) KSEK.

Cash flow from investments in intangible assets amounted to KSEK -144,038 (-126,884) for the interim period and consist mainly of development expenses for clinical studies and work on registration of Sedaconda ACD and Sedaconda (isoflurane) in the United States. Repaid deposits during the first quarter 2024 as well as the previous year's repayment and investment in deposits, amounted to KSEK 155,307 (-153,069). Total cash flow from investment activities thus amounted to KSEK 10,402 (-280,115).

Cash flow from financing activities for the period totaled KSEK -2,759 (-3,634) and relates to amortization of lease liabilities.

Currency revaluation differences in cash and cash equivalents for the period amounted to KSEK 6,623 (13,656) and are mainly related to cash and cash equivalents held in USD. Cash flow per share for the period was SEK -0.11 (-3.33). Adjusted for repayments and investments in short-term investments, the cash flow per share amounted to SEK -0.11 (-1.79).

Parent company

The Parent Company's net sales for the period totaled KSEK 129,468 (109,254), of which intra-group sales were KSEK 5,572 (5,722).

Operating income for the period totaled KSEK -38,458 (-49,362). Net financial items were KSEK 23,308 (31,279) and relates 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 totaled KSEK 987,478 at 30 September 2024, compared to KSEK 1,002,640 at the beginning of the year. This corresponds to a decrease of KSEK 15,163. Share capital totaled KSEK 2,483, compared to KSEK 2,483 at the beginning of the year.

Cash and cash equivalents stood at KSEK 215,000, compared to KSEK 215,921 at the beginning of the year. Deposits of KSEK 155,307 were repaid during the first quarter.

The Sedana Medical share

Sedana Medical share was listed on Nasdaq First North Growth Market Stockholm in 2017 and is since January 25, 2023 listed on Nasdaq Stockholm. Market capitalisation at the end of the third quarter was MSEK 2,384.

The price paid for Sedana Medical shares was SEK 23.16 at the start of the year and SEK 24.00 at the end of the quarter. The lowest closing price during the interim period was recorded on April 14 and was SEK 14.04. The highest closing price was recorded on July 12 and was SEK 28.05.

Share information

	Jul-Sep		Jan-Jun		Jan-Dec
	2024	2023	2024	2023	2023
Net income, KSEK	-22,616	-6,843	-19,172	-21,541	-59,612
Cash flow, KSEK	-67,315	106,159	-11,409	-330,587	-364,875
Number of shares at balance date	99,336,960	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	99,336,960
Outstanding warrants at balance date	824,947	973,399	824,947	973,399	973,399
Average number of warrants	824,947	988,679	874,431	993,772	988,679
Share capital at balance date, KSEK	2,483	2,483	2,483	2,483	2,483
Equity at balance date, KSEK	949,994	1,006,234	949,994	1,006,234	969,995
Earnings per share before dilution, SEK	-0.22	-0.07	-0.19	-0.22	-0.60
Earnings per share after dilution, SEK	-0.22	-0.07	-0.19	-0.22	-0.60
Equity per share, SEK	9.56	10.13	9.56	10.13	9.76
Cash flow per share, SEK	-0.68	1.07	-0.11	-3.33	-3.67

Largest shareholders at the end of the period

	No of shares	Share
Linc AB	10,796,076	10.9%
Anders Walldov direct and indirect (Brohuvudet AB)	10,000,000	10.1%
Swedbank Robur Funds	7,969,013	8.0%
Lannebo Funds	6,982,144	7.0%
Handelsbanken Funds	5,548,598	5.6%
Ola Magnusson direct and indirect (Magiola AB)	4,312,098	4.3%
Sten Gibeck	4,196,597	4.2%
Premier Miton Investors	3,707,581	3.7%
Highclere International Investors LLP	2,798,220	2.8%
AMF Pension	2,491,000	2.5%
Amundi	1,910,763	1.9%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Avanza Pension	1,479,016	1.5%
AXA Investment Managers	1,188,069	1.2%
Berenberg Funds	1,150,411	1.2%
Fifteen largest shareholders	66,196,030	66.6%
Others	33,140,930	33.4%
Total	99,336,960	100.0%

Facts about the share

Trading

Nasdaq Stockholm

No of shares as per Sep 30, 2024
99 336 960

Market cap as per Sep 30, 2024
SEK 2,384 million

Ticker

SEDANA

ISIN

SE0015988373

LEI-code

549300FQ3NJRI56LCX32

Contacts and invitation to presentation

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Presentation of the interim report

Sedana Medical presents the interim report to investors, asset managers, analysts and media on October 24 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/q3-2024/>

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

Nomination committee for the 2025 Annual General Meeting

Medical's Nomination Committee for the 2025 Annual General Meeting has been appointed and consists of Karl Tobieson, appointed by Linc AB, Patrik Walldov, appointed by Anders Walldov (including indirect holding via Brohuvudet AB), Monica Åsmyr, appointed by Swedbank Robur Fonder and Claus Bjerre, Chairman of the Board. The Nomination Committee together represents 28,96 percent of the voting rights for all voting shares in the company as of September 30, 2024. The Nomination Committee shall submit proposals for resolution by the 2025 General Meeting pertaining to the election of Chairman of the Meeting, fees and composition of the Board, auditors' fees and the election of auditors and, if necessary, proposal for changes in the instruction to the Nomination Committee. Shareholders wishing to submit proposals to Sedana Medical's Nomination Committee can do so by sending an e-mail to info@sedanamedical.com (subject "Nomination Committee") or by letter posted to Sedana Medical AB (publ), Attn: Sedana Medical Nomination Committee, Svärdvägen 3A, SE-182 33, Danderyd, Sweden. A proposal must reach the Nomination Committee no later than by 28 mars, 2025, to be included in the notice to attend and the agenda for the annual general meeting.

Financial calendar

Year-End Report 2024	February 13 2025
Annual Report 2024	April 11 2025
Interim Report Q1 2025	May 6 2025
Annual General Meeting 2025	May 15, 2025
Interim Report Q2 2025	July 18, 2025
Interim Report Q3 2025	October 24 2025

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

Danderyd 24 October 2024

Johannes Doll
President and CEO

This interim report has 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.

Auditor's report

Sedana Medical AB (publ) reg. no. 556670-2519

Introduction

We have reviewed the condensed interim financial information (interim report) of Sedana Medical AB (publ) as of September 30 2024 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Stockholm 24 October 2024

Öhrlings PricewaterhouseCoopers AB

Lars Kylberg
Authorized Public Accountant

Consolidated income statement, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2024	2023	2024	2023	2023
Net sales	39,720	34,255	129,597	109,323	153,867
Cost of goods sold	-11,455	-10,317	-37,612	-31,302	-44,886
Gross profit	28,266	23,938	91,986	78,021	108,981
Selling expenses	-23,558	-24,768	-76,633	-79,221	-107,239
Administrative expenses	-13,719	-11,446	-40,047	-36,776	-47,504
Research and development expenses	-5,476	-5,065	-15,494	-15,127	-20,805
Other operating income/expenses	181	-749	257	2,405	1,020
Operating income	-14,306	-18,090	-39,931	-50,697	-65,547
Net financial items	-8,173	11,350	21,292	29,566	6,529
Income before taxes	-22,479	-6,739	-18,640	-21,131	-59,019
Income tax	-137	-103	-532	-410	-593
Net income	-22,616	-6,843	-19,172	-21,541	-59,612
Earnings per share, based on earnings attributable to the parent company's ordinary shareholders:					
Before dilution	-0.22	-0.07	-0.19	-0.22	-0.60
After dilution	-0.22	-0.07	-0.19	-0.22	-0.60
Operating income (EBIT)	-14,306	-18,090	-39,931	-50,697	-65,547
Whereof amortisation of intangible assets	-3,963	-3,868	-11,887	-11,589	-15,452
Whereof depreciation of tangible assets	-1,336	-1,672	-4,166	-5,186	-7,122
EBITDA	-9,007	-12,550	-23,879	-33,922	-42,974

Consolidated statement of other comprehensive income, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2024	2023	2024	2023	2023
Net income	-22,616	-6,843	-19,172	-21,541	-59,612
Other comprehensive income					
Items that can later be reclassified to the income statement:					
Translation differences from foreign operations	318	1,205	-901	-1,381	451
Other comprehensive income, net after tax	318	1,205	-901	-1,381	451
Total comprehensive income	-22,298	-5,637	-20,073	-22,922	-59,161
Total comprehensive income as a whole attributable to the parent company's shareholders	-22,298	-5,637	-20,073	-22,922	-59,161

Consolidated balance sheet, summary

(KSEK)	Sep 30, 2024	Sep 30, 2023	Dec 31, 2023
ASSETS			
Intangible assets			
Capitalised development expenditure	675,179	506,207	542,705
Concessions, patents, licenses, etc.	3,588	3,387	3,326
Tangible assets			
Machinery and other technical facilities	652	842	864
Equipment, tools and installations	2,188	3,015	2,551
Rights of use	7,751	5,928	4,912
Financial assets			
Other long-term assets	46	47	45
Deferred tax assets			
	22	28	31
Total fixed assets	689,427	519,454	554,435
Inventory	39,464	48,558	42,975
Tax receivables	3,757	1,370	739
Accounts receivable	18,743	15,591	24,180
Prepayments and accrued income	16,749	13,499	4,701
Other receivables	3,704	1,784	5,223
Short-term investments	0	162,620	150,624
Cash and cash equivalents	226,394	290,811	231,180
Total current assets	308,811	534,233	459,621
TOTAL ASSETS	998,238	1,053,686	1,014,056
(KSEK)			
	Sep 30, 2024	Sep 30, 2023	Dec 31, 2023
EQUITY AND LIABILITIES			
Equity			
Share capital	2,483	2,483	2,483
Other contributed capital	1,226,507	1,226,435	1,226,436
Translation difference	-3,100	-4,031	-2,199
Retained earnings including net profit	-275,896	-218,654	-256,724
Equity attributable to the parent company's shareholders	949,994	1,006,234	969,995
Non-current liabilities			
Leasing liabilities	3,507	1,130	1,012
Provision for social security contributions	22	-	-
Deferred tax liabilities	7	-	7
Total non-current liabilities	3,536	1,130	1,020
Current liabilities			
Leasing liabilities	3,735	4,209	3,294
Accounts payable	4,020	9,212	5,292
Tax debt	3,900	1,261	1,276
Other liabilities	6,392	5,123	8,347
Accrued expenses and deferred income	26,661	26,517	24,832
Total current liabilities	44,708	46,322	43,041
Total liabilities	48,244	47,452	44,061
TOTAL EQUITY AND LIABILITIES	998,238	1,053,686	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	1,226,436	-2,650	-197,113	1,029,156
Net income	-	-	-	-21,541	-21,541
Other comprehensive income	-	-	-1,381	-	-1,381
Total comprehensive income	-	-	-1,381	-21,541	-22,922
Transactions with the Group's owners					
Total transactions with the Group's owners	-	-	-	-	-
Closing equity at Sep 30, 2023	2,483	1,226,436	-4,031	-218,654	1,006,234

(KSEK)	Share capital	Other contributed capital	Translation difference	Retained earnings incl net income	Total
Opening equity at Jan 1, 2024	2,483	1,226,436	-2,199	-256,724	969,996
Net income	-	-	-	-19,172	-19,172
Other comprehensive income	-	-	-901	-	-901
Total comprehensive income	-	-	-901	-19,172	-20,073
Transactions with the Group's owners					
Share-based remuneration	-	71	-	-	71
Total transactions with the Group's owners	-	71	-	-	71
Closing equity at Sep 30, 2024	2,483	1,226,507	-3,100	-275,896	949,994

Consolidated cash flow statement, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2024	2023	2024	2023	2023
Operating activities					
Operating income	-14,306	-18,090	-39,931	-50,697	-65,547
<i>Adjustments for non-cash items</i>					
Depreciations and amortisations	5,299	5,539	16,053	16,775	22,573
Exchange rate differences	48	4,084	-5,032	-4,879	8,900
Other non-cash items	133	601	1,792	1,935	2,552
Interest received	2	6,210	4,659	6,225	15,168
Interest paid	-45	-39	-137	-149	-215
Taxes paid	-118	-88	-507	-394	-564
Cash flow from operating activities before changes in working capital	-8,986	-1,784	-23,104	-31,185	-17,132
<i>Cash flow from changes in working capital</i>					
Cash flow from inventories	-997	-3,512	3,510	-11,761	-6,738
Cash flow from operating receivables	-2,522	1,536	1,060	-121	-6,253
Cash flow from operating liabilities	-16,828	-123	-518	-3,771	-7,937
Cash flow from operating activities	-29,333	-3,883	-19,051	-46,838	-38,061
Investing activities					
Investments in intangible assets	-36,331	-41,841	-144,038	-126,884	-168,373
Investments in tangible assets	-686	0	-868	-162	-515
Repaid short-term deposits	0	312,348	155,307	312,348	312,348
Investments in short-term deposits	0	-159,261	0	-465,417	-465,417
Cash flow from investing activities	-37,017	111,246	10,402	-280,115	-321,957
Financing activities					
New share issue	0	0	0	0	-
Issue expenses	0	0	0	0	-
Amortisation of leasing liabilities	-964	-1,204	-2,759	-3,634	-4,857
Received premium for warrant subscription	0	0	0	0	-
Costs related to warrant programme	0	0	0	0	-
Repurchase of warrants	0	0	0	0	-
Cash flow from financing activities	-964	-1,205	-2,759	-3,634	-4,857
Cash flow for the period	-67,315	106,159	-11,409	-330,587	-364,875
Cash and cash equivalents at the beginning of the period	304,224	187,013	231,180	607,742	607,742
Currency revaluation difference	-10,515	-2,361	6,623	13,656	-11,687
Cash and cash equivalents at the end of the period	226,394	290,811	226,394	290,811	231,180

Parent company income statement, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2024	2023	2024	2023	2023
Net sales	39,686	34,265	129,468	109,254	153,767
Cost of goods sold	-11,049	-10,010	-36,358	-30,048	-43,115
Gross profit	28,636	24,254	93,110	79,206	110,652
Selling expenses	-13,105	-14,249	-41,457	-47,461	-62,200
Administration costs	-23,607	-23,905	-83,729	-75,682	-101,608
Research and development costs	-4,987	-4,355	-13,820	-13,079	-18,137
Other operating income/expenses	3,015	495	7,438	7,653	14,009
Operating income	-10,049	-17,759	-38,458	-49,362	-57,283
Net financial items	-7,313	12,549	23,308	31,279	9,518
Income after net financial items	-17,361	-5,210	-15,151	-18,083	-47,766
Group contribution	-	-	-	-	11
Income before tax	-17,361	-5,210	-15,151	-18,083	-47,754
Income tax	-	-	-	-	-
Net income	-17,361	-5,210	-15,151	-18,083	-47,754

Parent company statement of other comprehensive income, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2024	2023	2024	2023	2023
Net income	-17,361	-5,210	-15,151	-18,083	-47,754
Other comprehensive income					
Items that can later be reclassified to the income statement:					
Translation differences from foreign operations	16	446	-83	164	-17
	16	446	-83	164	-17
Other comprehensive income, net after tax					
Total comprehensive income	-17,345	-4,764	-15,234	-17,919	-47,771

Parent company balance sheet, summary

(KSEK)	Sep 30, 2024	Sep 30, 2023	Dec 31, 2023
ASSETS			
Intangible assets			
Capitalised development expenditure	642,121	475,584	512,707
Tangible assets			
Machinery and other technical facilities	640	779	819
Equipment, tools and installations	2,086	2,757	2,345
Financial assets			
Other long-term assets	404	404	404
Non-current receivables, group companies	38,830	36,885	36,874
Total fixed assets	684,080	516,409	553,148
Inventory	39,464	48,558	42,975
Tax receivables	3,719	559	125
Accounts receivable	16,752	12,988	21,807
Receivables, group companies	64,523	54,453	60,603
Prepayments and accrued income	16,344	12,980	4,451
Other receivables	2,614	637	4,235
Short-term investments	0	162,620	150,624
Cash and cash equivalents	215,000	279,162	215,921
Total current assets	358,415	571,956	500,740
TOTAL ASSETS	1,042,495	1,088,365	1,053,888
(KSEK)			
	Sep 30, 2024	Sep 30, 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	636,317	468,176	505,854
<i>Non-restricted equity</i>			
Share premium fund	1,226,507	1,226,435	1,226,435
Retained earnings	-862,678	-646,848	-684,378
Net income	-15,151	-18,083	-47,754
Equity attributable to the parent company's shareholders	987,478	1,032,163	1,002,640
Provisions			
Other provisions	22	-	-
Total provisions	22	-	-
Current liabilities			
Accounts payable	4,124	8,780	4,577
Liabilities to group companies	19,505	20,672	18,170
Tax debt	3,368	1,079	1,066
Other liabilities	5,133	3,487	6,869
Accrued expenses and deferred income	22,866	22,183	20,566
Total current liabilities	54,995	56,201	51,248
Total liabilities	54,995	56,201	51,248
TOTAL EQUITY AND LIABILITIES	1,042,495	1,088,365	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 22 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 interim period, the Group had an average of 75 (80) full time employees and 5 (7) full time consultants, representing a decrease of 7 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 78 and the total number of consultants was 8 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, a consulting agreement was signed between Sedana Medical and board member Claus Bjerre. In total, since the agreement was signed, KSEK 360 regarding this agreement has been settled. The agreement ended during the second quarter of 2024.

In 2024, a consultancy agreement was signed between Sedana Medical and The Eriah Group Inc. The board member Donna Haire is the CEO of The Eriah Group Inc., and the company has invoiced services amounting to 62 KSEK during the quarter.

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.

Performance based incentive program (LTI 2024)

The Annual General Meeting 2024 decided on a performance-based incentive program LTI 2024 for employees of Sedana Medical, comprising 1,133,810 performance rights in the form of warrants. To ensure the delivery of the warrants and future estimated social security contributions in connection with the exercise of the options, Sedana Medical's subsidiary Sedana Medical Incentive AB has subscribed for 1,490,053 warrants, of which 1,062,803 were allocated to employees as of September 30, 2024. The performance rights have been issued to participants in the program free of charge. Each warrant entitles the holder to acquire one new share in the company at an exercise price of SEK 26.33. The outcome of LTI 2024 is

conditional on the company achieving a performance target regarding the average annual growth rate of net sales for the financial years 2024, 2025, and 2026 ("Performance Target"), excluding currency effects. The Performance Target has been determined by the company's board of directors, taking into account the company's business plan and is deemed to be in line with market practice and appropriate. Detailed information on the Performance Target and the outcome of LTI 2024 will be provided during the first half of 2027. If the Performance Target is not fully met, a participant's right to exercise Performance Rights will gradually be reduced to zero, depending on the extent the Performance Target is reached.

At the end of the period, the full utilization of the performance-based incentive program would increase the share capital by KSEK 37 through the issuance of 1,449,053 shares, corresponding to a dilution of 1.5 percent

Warrant programme

At the end of the period Sedana Medical had 824,947 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	-	-25,200	-	231,606		
Total	Other employees	221,593	-	-123,252	-	98,341		
	Total	973,399	-	-148,452	-	824,947		

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