

ANNUAL REPORT 2023

Sedana Medical was granted Fast Track Designation for inhaled sedation by the US FDA


The company applied for a paediatric indication after completing the IsoCOMFORT study

The company's share started trading on Nasdaq Stockholm Main Market

Sedaconda (isoflurane) was granted market approval in the United Kingdom, and has thus been approved in 18 European countries



2023



In 2023, Sedana Medical took several important steps closer to the company's vision – to make inhaled sedation a global standard therapy for sedation of mechanically ventilated patients in intensive care.

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2023 was a year of strong progress

Important milestones during the year included the company gaining Fast Track Designation from the United States FDA, submitting an application for a paediatric indication in Europe after results for the paediatric study IsoCOMFORT and gaining market approval for Sedaconda (isoflurane) in the United Kingdom, which means that Sedaconda (isoflurane) is now approved in all 18 countries where the company has submitted an application.

“Sedana Medical’s vision is to make inhaled sedation a standard therapy for the sedation of mechanically ventilated patients in intensive care.”

Q1

- Fast Track Designation for the company’s therapy was granted by the United States FDA.
- The last patient was recruited to the paediatric phase III study IsoCOMFORT.
- Trading in the company’s share began on the Nasdaq Stockholm Main Market.
- Sedaconda (isoflurane) was granted market approval in Italy.

Q2

- Top-line results were published for the IsoCOMFORT study.
- The Journal of Critical Care published a post-hoc analysis of the company’s Sedaconda study confirming several important benefits of inhaled sedation.

Q3

- The company announced an adjusted timetable for the US application after interaction with the FDA. The application is expected to be submitted in the first quarter of 2025.
- A patent was granted for Sedaconda ACD-S in the United States.

Q4

- Sedaconda (isoflurane) granted market approval in the United Kingdom and pricing and reimbursement approval in Spain.
- The investigator-initiated SESAR study reached full recruitment (700 patients).
- Results from IsoCOMFORT were published in the clinical trials database EudraCT.
- The company applied for a paediatric indication.
- The Paediatric Committee of EMA (European Medicines Agency) issued a positive opinion on compliance of the company’s paediatric investigation plan, which means data exclusivity and market protection for Sedaconda (isoflurane) until 2031.

Events after the end of the financial year

- No significant events after the end of the financial year.

Sedana Medical's unique medical device Sedaconda ACD in combination with the company's pharmaceutical product Sedaconda (isoflurane) enables an effective, simple and predictable method for inhaled sedation in intensive care. Sedana Medical's therapy has potential to become a new global standard therapy for the sedation of mechanically ventilated intensive care patients.



With the aim of gaining US market approval for the therapy, Sedana Medical is conducting two pivotal studies in the United States, INSPiRE-ICU 1 and INSPiRE-ICU 2. Provided approval is granted by the US drug regulatory authority, the FDA, the goal is a launch in the United States in 2026.

Sedana Medical achieved sales of SEK 154 million in 2023, representing an increase of 16 percent at constant exchange rates compared to 2022. The company's largest market is Germany, which accounted for 70 percent of total sales in 2023. Sedana Medical also has direct sales in Spain, France, the United Kingdom, Benelux and the Nordics. In other parts of Europe, as well as in Asia, Australia, Canada and South and Central America, the company works with external distributors.

The company's financial targets are to achieve growth in sales in 2024 of 14–18% adjusted for currency, as well as break-even at EBITDA level during the year for the business outside the United States.

Sedana Medical was established in 2005, is listed on Nasdaq Stockholm Main Market (SEDANA) and has its head office in Stockholm, Sweden.

Key performance indicators for the Group

Amounts in KSEK (thousands of SEK), unless otherwise stated	2023	2022
Net sales	153,867	122,865
Gross profit	108,981	86,074
Gross margin %	71%	70%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-42,974	-83,138
EBITDA margin %	-28%	-68%
Operating income (EBIT)	-65,547	-105,887
Operating margin (EBIT) %	-43%	-86%
Net income for the period	-59,612	-73,507
Profit margin %	-39%	-60%
Balance sheet total	1,014,056	1,081,588
Equity ratio %	96%	95%
Quick ratio %	968%	1,299%
Average number of employees	79	86

Sedana Medical in brief

Sedana Medical AB (publ) is a pioneer medical device and pharmaceutical company focused on inhaled sedation to improve the lives of intensive care patients during and beyond sedation. Through the combination of the medical device Sedaconda ACD and the pharmaceutical product Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated patients in intensive care.

Sedation of mechanically ventilated intensive care patients

Almost half of all patients in an intensive care unit need help with breathing from a ventilator. Patients need to be sedated (lowering the level of consciousness) to cope with mechanical ventilation and other necessary therapies. Every year, around eight million mechanically ventilated patients in intensive care globally are sedated. The patients are mostly sedated for two to five days. Inhaled sedation meets several of the challenges posed by present-day standard therapy with intravenous drugs.

8 million patients

Every year, around eight million mechanically ventilated patients in intensive care globally are sedated. The patients are mostly sedated for two to five days.



”We have ambitious targets for 2024: reaching an all-time-high in sales, delivering EBITDA break-even ex-US during the year, and receiving top-line data from our INSPIRE-ICU program in the US.”

Robust sales growth and an exciting year ahead

During the year 2023, Sedana Medical took several important steps towards becoming a stronger and healthier company. We have returned to consistent sales growth after the challenging post-Covid period, we have taken decisive steps towards reaching profitability in our ex-US business, and we are making progress towards our launch on the US market – our single largest growth opportunity and a pivotal milestone for the company.

Sales at upper end of financial guidance and decisive steps towards ex-US profitability

We report net sales of 154 MSEK for 2023, which is at the upper end of our financial guidance of 145-155 MSEK. Excluding exchange rate effects, the business grew 16% during the year, translating to 25% in SEK.

Sales in our main market Germany grew by 14% during the year (23% in SEK). Overall, we were able to increase the market penetration of our therapy from 10% in 2022 to approximately 12% in 2023. The growth is a result of our strategic focus to continuously enhance field force effectiveness, by maximizing the time we spend with our customers and by helping them identify more patients likely to benefit from the compelling clinical benefits of inhaled sedation.

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

For the first time in 2023, our distributor markets showed positive growth in Q4. To counter previous sales declines, we have revamped our distributor model, established a new leadership team and intensified our focus on key partners with the highest growth prospects.

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

The 2023 EBITDA loss excluding US-related costs amounted to 40 MSEK, which is half of the 80 MSEK loss recorded in the preceding year. Notably, the remaining loss in Q4 was 8 MSEK, with 2 MSEK attributed to severance payments related to further organizational streamlining.

Progress towards US launch

We estimate the market potential for our inhaled sedation products in the United States to 10-12 BSEK. This figure is approximately three times greater than the combined market potential of our current direct markets in Europe. Several factors contribute to this significant opportunity, including the large population size, a medical practice more in favor of intubation compared to Europe, and an overall attractive pricing environment.

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

Our timeline with regards to the US launch is 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. The recruitment of 235 randomized patients in INSPIRE-ICU 1 is expected to be completed shortly, and INSPIRE-ICU 2 is following closely behind. We will apply for different benefits we may be entitled to, based on the Fast Track Designation that FDA has granted us. If successful, this could mean an acceleration of several months.

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

An exciting year ahead

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

Johannes Doll
President and CEO

HISTORY IN BRIEF

2024

Trading in the company's share begins on Nasdaq Stockholm Main Market.

The company applied for a paediatric indication.

Data exclusivity and market protection for Sedaconda (isoflurane) until 2031.

Fast Track Designation for the company's therapy granted by the US FDA.

2023

Inclusion of the first patient in the pivotal studies in the United States.

NICE recommends Sedaconda ACD as a cost-saving alternative.

2021

Sedaconda (isoflurane) gains European market approval.

2022

Sedaconda (isoflurane) is launched in Europe.

2020

The Sedaconda study (SED001) reaches its primary endpoint.

2010–2020

Sedaconda ACD is granted market approval in markets outside the EU, including Japan, South Korea and Mexico.

2005

Sedana Medical is established in Uppsala.

2010

Inhaled sedation is described as an alternative to intravenous sedation in German healthcare guidelines.

2003

Sedaconda ACD gains CE mark.

1999

Sedaconda ACD is tested clinically for the first time.

The 1990s

The company Louis Gibeck AB develops a prototype of Sedaconda ACD which, through a special formulation of activated carbon, reflects 90 percent of exhaled pharmaceutical product, without reflecting carbon dioxide.

Inhaled sedation as a global standard therapy

Sedana Medical's vision is to make inhaled sedation a global standard therapy for the sedation of mechanically ventilated intensive care patients.

Purpose

To improve the patient's life during and beyond sedation in intensive care.

Vision

To make inhaled sedation a standard therapy for patients in intensive care.

Business concept

Sedana Medical's business concept is to provide a solution to the problems associated with current intravenous sedatives. This is to be achieved through the company's Sedaconda ACD technology which, together with the pharmaceutical product Sedaconda (isoflurane), offers an effective, user-friendly solution for the sedation of intensive care patients mechanically ventilated for longer than 24 hours which is cost-effective for society.

Strategy

Sedana Medical has established three strategic priorities:

1. Achieving lasting and profitable sales growth in Europe
2. Maximising the opportunities in the USA
3. Building a long-term profitable company

Financial targets

- Net sales growth of 14–18% adjusted for currency effects in 2024.
- Break-even at EBITDA level during the year for business outside the United States in 2024.

Sedana Medical has established three strategic priorities:

1. The company's market approvals, in 18 European countries to date, mean that Sedana Medical is the first and only company to offer an approved therapy for inhaled sedation in intensive care. With a strong focus on commercial execution and a restrained investment philosophy that prioritises profitable growth, the company aims to make inhaled sedation standard therapy.
2. With more than 100,000 intensive care beds and a generally higher price level for sedation therapies, the United States represents the company's largest potential market. After completion of the company's clinical phase III programme, which has been granted Fast Track Designation by the FDA, and provided approval is obtained, Sedana Medical aims to launch its products through a dedicated commercial organisation in the United States in 2026.
3. Sedana Medical's high gross margins and concentrated customer base (hospitals with intensive care) are important factors in achieving attractive profitability when sales increase. An important priority is to achieve profitability for the business outside the United States in 2024, so that the US launch can be based on a stable financial platform. Alongside financial sustainability, Sedana Medical is working to minimise the climate footprint of the company and the therapy in order to further promote long-term use of the company's products.

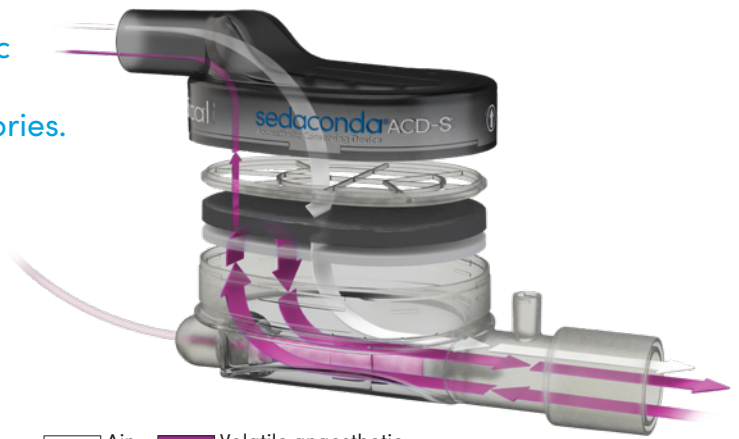
Unique patented technology in innovative therapy

Sedana Medical's offering consists of the medical device Sedaconda ACD (Anaesthetic Conserving Device), the pharmaceutical product Sedaconda (isoflurane) and accessories.

Sedaconda ACD, intended for single use and replacement every 24 hours, is a unique and innovative device for simple and effective delivery of volatile anaesthetics that works smoothly in combination with ventilators, syringe pumps and gas analysers already in place in ICU. For the customers, this means that they can manage without expensive new investments in equipment. Sedaconda ACD is protected by a number of different patents, and the therapy as a whole enjoys data exclusivity in Europe until 2031, making Sedana Medical the only company approved to market inhaled sedation in intensive care.

Sedaconda ACD – enables simple and effective delivery with a high level of re-use

- Liquid anaesthetic is delivered to the Sedaconda ACD, where it is vaporised.
- During inhalation the vaporised pharmaceutical is transported to the patient.

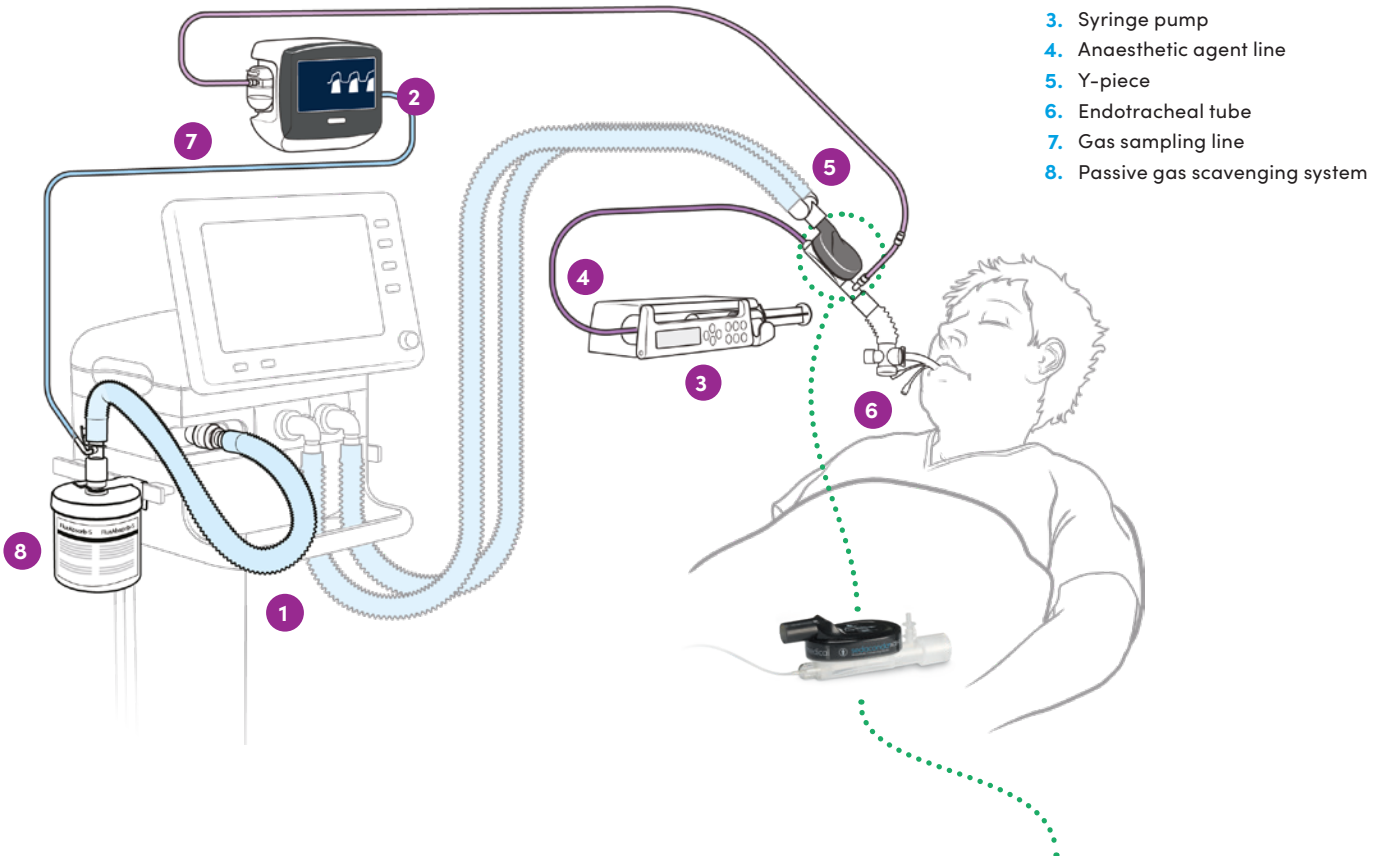


□ Air ■ Volatile anaesthetic

- The pharmaceutical is rapidly distributed via the lungs and the blood circulation to the brain, where it exerts its desired effect.
- Pharmaceutical in the exhaled air is absorbed in the filter in the Sedaconda ACD.
- On the next inhalation, the pharmaceutical is released from the filter, combined with new vaporised pharmaceutical and returned to the patient with the air flow.
- Approximately 90% of the pharmaceutical is recirculated in this way to the patient, reducing consumption.

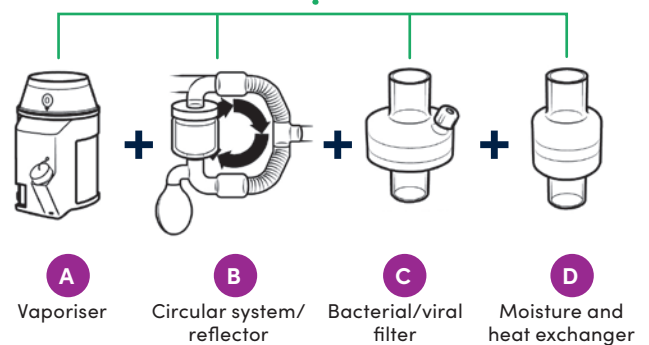


Sedaconda ACD is compatible with common ICU equipment



- 1. Ventilator
- 2. Gas analyser
- 3. Syringe pump
- 4. Anaesthetic agent line
- 5. Y-piece
- 6. Endotracheal tube
- 7. Gas sampling line
- 8. Passive gas scavenging system

The Sedaconda ACD is used in combination with a ventilator (1), a gas analyser (2) and a syringe pump (3). The specially designed syringe (with a unique connector) is placed in a standard syringe pump. The Sedaconda ACD is placed between the Y-piece (5) and the endotracheal tube (6). Sedaconda (isoflurane) is delivered from the syringe through the agent line (4) to the Sedaconda ACD, where the pharmaceutical is vaporised. The vaporised gas is delivered with the inspiratory flow from the ventilator to the patient. Approximately 90% of the anaesthetic agent in the expired air is absorbed by the carbon filter, released and returned to the patient during inhalation. The remaining anaesthetic agent passes through the ventilator, out through the exhaust line and is collected by the company's FlurAbsorb filter or by an active gas scavenging system (8).



Sedana Medical's unique and patented technology combines four functions – evaporation, reflection, humidification and filtration – in a single device: (A) a unique miniature vaporiser (required for controlled production of the anaesthetic gas), (B) a reflector with a unique activated carbon filter (for recirculation of the anaesthetic gas), (C) a bacterial and viral filter, and (D) a moisture and heat exchanger.

Sedation in intensive care

Increased use of inhaled sedation in intensive care units (ICUs) is a potential paradigm shift in the care of critically ill patients.



Expectations on a modern sedative for use in ICU are:

- + Fast-acting (the patient is sedated quickly)
- + Good controllability of depth of sedation
- + Few side effects
- + Rapid wake-up (which requires a low degree of accumulation and absence of active metabolites)

≡ All these expectations can be met by inhaled sedation

Sedation means putting a patient into a medically induced state of reduced consciousness to relieve anxiety, agitation and pain, traditionally through intravenously delivered pharmaceutical products.



Inhaled sedation has several medical benefits compared to traditional alternatives:

→ **Rapid and predictable wake-up:** Wake-up times are short (10–20 minutes) and predictable². It reduces time to extubation (disconnection from ventilator), improves clinical workflow and facilitates patient rehabilitation after therapy.

→ **Better control of depth of sedation:**

Inhaled sedation enables simpler control of depth of sedation³, which reduces the risk of over- or under-sedation and simplifies wake-up to check neurological status. This also reduces the need for computed tomography (CT) scans.

→ **Fewer side effects:** Hallucinations and delirium occur less frequently⁴.

→ **Effective elimination via the lungs:**

Pharmaceutical products for inhaled sedation are in principle eliminated only via the lungs, minimising the need for metabolism in the liver or kidneys. This makes inhaled sedation also suitable for patients with liver and kidney disease⁵.

→ **Reduced opioid use:** Through sedation with isoflurane, the dose of analgesics such as remifentanyl and other opioids can be reduced by approximately 30 percent compared to intravenous sedation⁶. This means a reduced risk of dependency, withdrawal symptoms, delirium and impaired bowel function⁷.

→ **Improved spontaneous breathing:**

A higher proportion of spontaneous breathing improves the prospects of maintained lung function during and after ventilator therapy⁸.

The problem facing ICUs

Intensive care units treat severely ill patients with life-threatening conditions such as trauma, organ failure, sepsis and acute lung failure. Many of these patients need mechanical ventilation to breathe. Sedation is used to manage this and reduce the patient's discomfort, also facilitating medical actions. It is usual for sedation to continue for several days. There are challenges with present-day intravenous sedation, often due to the intravenous drugs accumulating in the body over time. The challenges include long wake-up times, complicated monitoring of pharmaceutical product levels and side effects such as development of tolerance and delirium.

All these problems prolong the period of care in the intensive care unit and can affect the patients' survival and cognitive function. In addition, intravenous sedation can be problematic due to hepatic and renal impairment in intensive care patients, which can lead to an accumulation of pharmaceutical product and increased mortality among long-term ventilated patients¹. Owing to the risks of intravenous sedation, there are recommendations that limit the use of commonly occurring sedatives such as propofol and benzodiazepines, but these are nevertheless used as the alternatives are limited.

The Sedaconda study – a decisive breakthrough and the basis for market approval in Europe

The clinical phase III study Sedaconda (SED001), showed that Sedaconda (isoflurane), delivered via Sedaconda ACD, is an effective therapy for sedation of mechanically ventilated intensive care patients, comparable to propofol. In addition, the study shows that the therapy enables faster and more controlled wake-up, reduced need for opioids and a higher proportion of spontaneous breathing, which improves the prospects of maintained lung function during and after ventilator therapy compared to propofol.

The study took place over the period 2017–2019 at 21 clinics in Germany and three in Slovenia, and included 301 mechanically ventilated intensive care patients in need of sedation. The study results are the single greatest advance for inhaled sedation since Sedaconda ACD was developed, and form the basis for Sedana Medical's European market approval. In August 2021, the study results were published in the highly respected scientific journal *The Lancet Respiratory Medicine*.

Footnotes – see Literature references on page 78.

Health-economic benefits

A post-hoc analysis published in the *Journal of Critical Care* in June 2023 shows that sedation with isoflurane as the primary sedative in mechanical ventilation for the first 30 days leads to substantially more ICU-free days than intravenous sedation with propofol. The difference was four days.

At an average cost of around EUR 2,000–4,000 per bed day and patient in Europe, intensive care patients are expensive for hospitals. The cost of intensive care patients is estimated to be three to five times higher than that

“Inhaled sedation can lead to fewer ICU days, which can reduce care costs and improve patient prognoses”

of patients in ordinary hospital wards. By reducing the number of bed-days in intensive care, care costs can be lowered, while the patient’s prognosis is improved.

The daily cost of intravenous sedation varies sharply between countries, and the picture is complicated by different combinations of sedatives (for example propofol and midazolam) being used and dosage varying depending on the patient’s weight, condition and tolerance. It leads to significant variations in the cost of intravenous sedation.

The UK National Institute for Health and Care Excellence (NICE) back in 2022 recommended Sedaconda ACD as a cost-saving alternative for inhaled sedation in intensive care. According to NICE, cost modelling has identified savings of up to GBP 4,000 per adult patient compared to intravenous sedation (30 days timeframe for adult patients needing mechanical ventilation for 24 hours or longer in intensive care).

4,000 GBP

Modelling by NICE shows savings of up to GBP 4,000 per patient

4

fewer ICU days with inhaled sedation

2,000–4,000 EUR

cost of one ICU day



Towards a paradigm shift in intensive care

Sedana Medical is continuing to work on securing medical evidence demonstrating that inhaled sedation is a better and more cost-effective therapy than the current standard therapy.

By demonstrating significant benefits, the therapy is expected to gain ground and be included in national guidelines, and gradually become a new standard therapy throughout the world. The company's most important clinical programme now under way is INSPIRE-ICU – the clinical phase III programme in the United States (see pages 21-22).

In addition to its own clinical studies, Sedana Medical supports independent research in inhaled sedation. One of the prioritised studies supported by Sedana Medical is the SESAR study (SEvoflurane for Sedation in Acute Respiratory distress syndrome: A multicenter prospective randomized trial), which is being conducted with support from Sedana Medical and the French Ministry of Health.

IsoCOMFORT (SED002)

Sedana Medical's paediatric study

In 2021–2023, Sedana Medical conducted a paediatric clinical phase III study, IsoCOMFORT (SED002), which compared efficacy and safety for Sedaconda (isoflurane), delivered via Sedaconda ACD-S, with intravenous midazolam for the sedation of mechanically ventilated patients aged 3–17. The patients were sedated for 12–48 hours with one of the methods of sedation, and the primary endpoint was the proportion of time spent at adequate depth of sedation. The study covered around 90 evaluable patients from intensive care units in Germany, France, Spain and the United Kingdom.

The main results were published in the clinical trials database EudraCT in November 2023. Soon afterwards, Sedana Medical was able to announce that the Paediatric Committee of the EMA (European Medicines Agency) had issued a positive opinion regarding compliance of the company's paediatric investigation plan, which confirms data exclusivity and market protection for Sedaconda (isoflurane) until 2031. Sedana Medical applied for a paediatric indication in December 2023. The company expects the study to lead to market approval for children in Europe in 2024.

SESAR

Investigator-initiated study, the largest with Sedaconda ACD

SESAR is a randomised, controlled study covering 700 adult intensive care patients with moderate to severe respiratory failure (ARDS, Acute Respiratory Distress Syndrome). Inhaled sedation with sevoflurane for up to seven days is compared to intravenously delivered propofol. The primary endpoint is the efficacy of inhaled sedation assessed as the number of ventilator-free days at day 28. Secondary endpoints include changed function of the lungs and other organs.

The study, which is led by associate professor Matthieu Jabaudon at the Centre Hospitalier Universitaire Clermont-Ferrand, France, is being conducted at 30 intensive care units throughout France and recruited its last patient in November 2023. The same research team published results from a pilot study in 2017 which led to this larger study, designed to confirm the preliminary results from the pilot study.

The work on processing and analysing data is expected to continue at least until the second half of 2024. Sedation is challenging, particularly for patients with ARDS, and potential benefits beyond sedation effects would therefore make a new therapy method very attractive.

In addition to its own clinical studies, Sedana Medical supports independent research in inhaled sedation.

A market with great potential

Sedana Medical’s market consists of mechanically ventilated patients in need of sedation in intensive care units in all parts of the world.

Geographically, Sedana Medical has a clear focus on the company’s current direct markets in Europe (Germany, Spain, France, UK, Nordics, and Benelux) as well as the company’s largest potential market, the United States. The market potential is expected over time to increase in line with demographic trends.

”Demand is created among healthcare professionals by clarifying the benefits of inhaled sedation”

In Europe, where around a million intensive care patients need mechanical ventilation and sedation annually⁹, Sedana Medical estimates the market potential for its product portfolio at around SEK 3–4 billion. In the United States, where over two million intensive care patients need similar therapy¹⁰, Sedana Medical estimates the potential at SEK 10–12 billion, based on an assumption of a minor price difference of 10–20 percent compared with Europe. If the price difference is assumed to be similar to other sedation therapies, the potential can increase proportionally.

Beyond Europe and the United States, Sedana Medical has distributors in more than 30 countries around the world.

Sedana Medical covers most of Europe

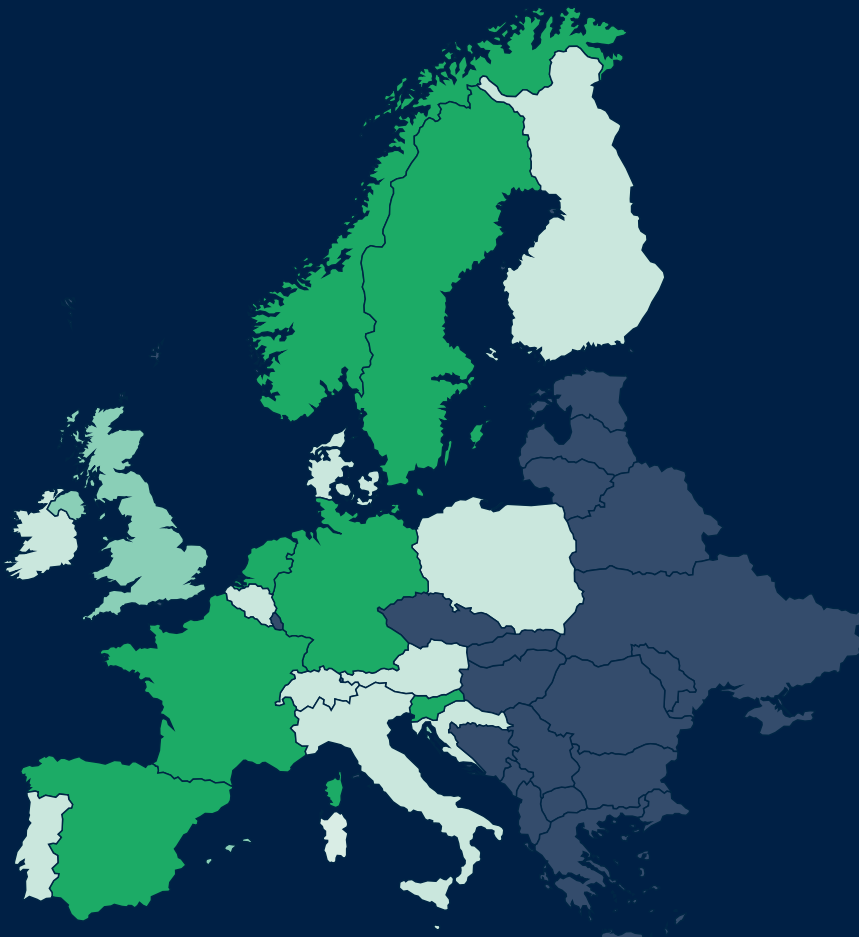
■ Countries where Sedaconda (isoflurane) has been launched

The pharmaceutical product to date has been launched in Germany, Sweden, Norway, the Netherlands, France and Spain as well as in Slovenia through a distributor.

■ Launch is expected to take place during spring 2024.

■ Countries where Sedaconda (isoflurane) is approved

Sedaconda (isoflurane) is approved by national authorities in all 18 countries where Sedana Medical has applied for approval: Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.





Spain – Sedana Medical’s fastest growing market

Spain is Sedana Medical’s fastest growing market. In 2023, the Spanish Ministry of Health granted price and reimbursement approval for the pharmaceutical product Sedaconda (isoflurane). Several customers in Spain have waited for the price and reimbursement decision before introducing inhaled sedation in their hospitals.

Carlos Navarro, Country Manager for Spain:

“We have a positive trend with regard to the introduction of Sedaconda ACD thanks to the trust our customers place in us due to the extensive knowledge we have of the therapy and the support we can provide in connection with therapy. Even in very complex patients, where other sedation strategies fail, our therapy is successful, and it is very valuable for care staff. I am optimistic about the future, not just because of the response from our present-day customers but also because of the great interest shown by other clinics. When we attend scientific conferences there is huge interest – many people want to learn more about inhaled sedation.”

Europe

Effective direct sales – the cornerstone of Sedana Medical’s success

Sedana Medical serve its most important markets

in Europe with its own sales force consisting of product specialists who are mostly former nurses with intensive care experience of their own. These experts train the clinics in correct use and implementation of the therapy. Germany is Sedana Medical’s largest market, accounting for 70 percent of the company’s sales in 2023, while other direct markets contributed 18 percent. In most of the rest of Europe and also other parts of the world, the company uses distributors.

The target groups include intensive care doctors, intensive care nurses and purchasing decision-makers for medical devices and pharmaceutical products. The customer base is dominated by university hospitals and large medium-sized hospitals, where the products are bought through the hospitals’ purchasing departments. Sedana Medical often attends international and national congresses to increase awareness of the therapy. The sales efforts are adapted to different countries and regions, but common to these efforts is an endeavour

to create demand among healthcare professionals by making clear the benefits of inhaled sedation for patients in day-to-day ICU activity, as well as clarifying the health-economic benefits for the hospital to the purchasing departments and other decision-makers.

Sedana Medical focuses on building a commercially strong company by directing investments towards profitable growth opportunities and improving the efficiency of the sales organisation. The company invests selectively in countries with good growth and positive cash flows, such as Germany and Spain, while investments in areas with lower potential are carefully adapted until the company is clearly trending towards break-even. This strategic approach ensures positive contributions over time from all markets. At the same time, steps are taken to increase efficiency in the sales force, for example through greater customer contact, a better customer-cultivating process, a more effective sales model and a more rigorous follow-up process.

Increased use and positive results

Uwe Veismann is the General Manager for Germany, the Nordics and Benelux. He started as a salesperson at Sedana Medical in 2009 and has gradually advanced within the organisation. In 2016 he became country manager for Germany. He took up his current role in November 2023.

Tell us about Sedana Medical's business in Germany

We have ten active salespeople, two regional managers, customer service and marketing staff. The pandemic meant that our sales rose, but at the same time forced an online launch of Sedaconda (isoflurane), due to limited in-person access to the hospitals, which was not optimal. All things considered, I am confident we would have had a good increase in sales in Germany in recent years even without the pandemic.

“We emphasise the pharmaceutical benefits over alternatives, and highlight in particular the clinical benefits of inhaled sedation”



How do you educate healthcare staff on the benefits and use of Sedaconda ACD?

As penetration is relatively high in Germany, we primarily focus on increasing use among existing customers where we build relationships with doctors, nurses and respiratory therapists. Transparent communication on the device's benefit/risk profile and addressing customers' questions are crucial. We emphasise the pharmaceutical benefits over alternatives, and highlight in particular the clinical benefits of inhaled sedation. We also try to include feedback from purchasers on the economic benefits for hospitals.

Are there ongoing clinical studies or research cooperations in Germany that involve Sedana Medical products?

We cooperate with universities and support investigator-initiated studies. To take an example, we are supporting a study examining the need for continuous gas analysis. If this study has a positive outcome, it can be meaningful for treatments and the future of the therapy.

How has interest in inhaled sedation developed?

We have noticed increased use and positive results, particularly during the pandemic. Sales have increased, and customers who started using Sedaconda ACD during the pandemic have continued to do so since, which suggests that the doctors regard the therapy as effective. There are several studies indicating drawbacks with traditional methods of sedation, while the benefits of inhaled sedation are highlighted. Despite intravenous drugs being competitors, the great interest shown and increasing use point to a positive path for inhaled sedation.

What do you think about the future for Sedana Medical in Germany?

I am optimistic about our continued growth. We expect updated guidelines for care within a few years, where we anticipate the Sedaconda therapy attaining higher levels of evidence and recommendation than today. The trend is also being driven by negative results for dexmedetomidine and propofol. In addition to this there is our paediatric study, which is further improving our future prospects.

Uwe Veismann is the General Manager for Germany, the Nordics and Benelux. He took up his present role in November 2023.

USA

The market with the greatest potential

The United States, with over 100 000 ICU beds and significantly higher price levels than Europe, represents the most significant potential market for inhaled sedation. By comparison, there are around 20,000 ICU beds in Germany, Sedana Medical's largest current market, where therapy prices are lower than in the United States.

Sedana Medical has successfully established Sedaconda therapy in more than half of Germany's intensive care units. This is partly due to guidelines from 2010 that recommend inhaled sedation as an option for certain patient groups, as well as strong support from German opinion leaders.

In 2023, sales in Germany reached a penetration of around 12 percent of market potential, with higher levels in the company's best-performing regions, where penetration exceeded 20 percent. Penetration on the direct markets outside Germany was below 2 percent.



Market potential in prioritized geographies

	Europe (direct markets)	United States
Ventilated adult ICU patients p.a.	~1 million	~2 million
Market potential inhaled sedation (low- to mid-single digit growth p.a.)	3–4 BSEK	10–12 BSEK
	Penetration rates 2023 <ul style="list-style-type: none"> • Germany: ~12% • Best territories in Germany: >20% • Other direct markets: <2% 	Key assumptions <ul style="list-style-type: none"> • Comparable approved label as in Europe • Assumed only modest price premium vs. Europe (10–20%) – upside if price difference in line with other sedation therapies (e.g., propofol) can be achieved

Sources: Europe: based on publicly available data by country and Sedana Medical analysis
USA: based on market assessment performed by external consultant company (Clarion Health)

Inhaled sedation can be a good alternative for almost all ventilated intensive care patients

Dr Hughes is one of the investigators in INSPIRE-ICU.

Dr Christopher G. Hughes, professor of anaesthesiology at the Department of Anesthesiology, Division of Anesthesia Critical Care Medicine at Vanderbilt University Medical Center (VUMC). Dr Hughes is responsible for the Critical Illness, Brain Dysfunction and Survivorship Center (CIBS) at VUMC.

“From my experience to date and from the potential benefits of inhaled sedation, I believe that inhaled sedation can be a good alternative for almost all ventilated intensive care patients.”



Clinical studies

Sedana Medical is conducting a clinical programme in the United States which aims to form the basis for market approval and launch of inhaled sedation for the ICU.

INSPIRE-ICU 1 & 2 (SED003 & SED004)

With the aim of achieving US market approval, Sedana Medical is conducting two parallel clinical studies, INSPIRE-ICU 1 & 2. These are two identical randomised phase III studies aiming to confirm and verify efficacy and safety for sedation with isoflurane delivered via Sedaconda ACD.

To fulfil the FDA requirements, the studies are observer-blinded, and the primary endpoint will be the proportion of time spent at adequate depth of sedation. The studies will be carried out at around 30 highly reputed clinics in the United States and include a total of around 600 patients (of which 470 randomised and 130 “run-in”). The name INSPIRE-ICU stands for Inhaled Sedation vs Propofol In Respiratory Failure.

The aim is to show that Sedaconda (isoflurane) delivered via Sedaconda ACD is effective and equivalent to propofol for sedation of mechanically ventilated patients in intensive care. In addition, several secondary endpoints are being studied, such as opioid use, time to wake-up, cognitive recovery and spontaneous breathing. The study design is similar to the Sedaconda study (SED001) successfully performed in Europe in 2017–2019.

The first patient was included in April 2022 and the last patient is expected to be included during the first half of 2024.

The work on the clinical studies is being implemented with the assistance of a US partner (clinical research organisation, CRO). At the end of 2023, Sedana Medical’s US subsidiary had four employees working mainly as clinical training specialists at the sites where the clinical trials are being conducted.

INSPIRE-ICU 1 & 2 for US market approval



~30

Sedana Medical intends to include around 30 clinics in the United States

Sedana Medical has engaged highly reputed clinics throughout the United States to take part in the company’s pivotal studies.



FPI – First patient in LPO – Last patient out

Towards a launch in the United States in 2026

Based on the INSPIRE-ICU study programme, Sedana Medical intends to submit an application for US market approval the first quarter of 2025.

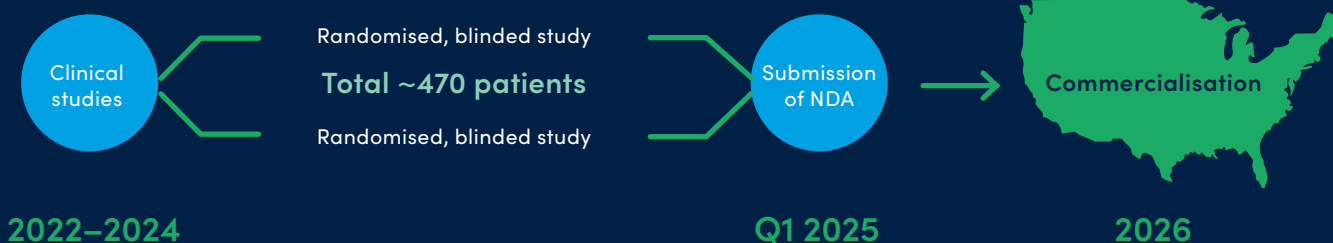
The goal is to obtain registration in the US for Sedaconda ACD and isoflurane, and based on FDA approval in late 2025 or early 2026, the goal is a potential US launch in early 2026.

To attain the highest possible shareholder value, Sedana Medical plans to launch its products commercially in the United States under its own auspices.

Ongoing and future key activities linked to this are:

- optimising the clinical programme to further strengthen the evidence base, including patient follow-ups after three and six months as per FDA instructions;
- analysing the US market at the regional and hospital levels, including pricing and remuneration systems;
- expanding the American organisation with the build-up of a dedicated sales force in the United States;
- preparing the market for a successful launch by increasing awareness.

Clinical studies are expected to lead to market approval



Fast Track Designation

In January 2023, the FDA granted Fast Track Designation (FTD) for the evaluation of isoflurane delivered via Sedaconda ACD-S for the sedation of mechanically ventilated intensive care patients in the United States.

Fast Track is a process designed to facilitate the development and expedite the review of therapies that treat serious conditions and fill an unmet medical need. The purpose is to get important new therapies to the patient earlier.

A clinical programme with FTD can benefit from more frequent communication with the FDA. In addition, the programme may be entitled to accelerated approval and priority review if certain criteria are met. A further benefit may be rolling review, which means that completed sections

of applications can be submitted one by one instead of all sections needing to have been completed prior to submission.

Sedana Medical will have an opportunity to discuss some of the potential FTD benefits with the FDA at what is known as a pre-NDA meeting, which might have a positive impact on the communicated timetable for launch in the United States.

Registration via 505(b)(2)

For the US market, the FDA has approved Sedana Medical taking the 505(b)(2) route to registration, which simplifies the company's options regarding using data collected previously. This registration is usually less demanding than 505(b)(1), which is used for completely new drug substances.

There is great interest in inhaled sedation across the world

Sedana Medical cooperates with distributors as a quick and low-risk way of establishing Sedaconda ACD in intensive care in countries where the company does not have its own sales force.

Sedana Medical has distributor agreements in all continents of the world except Africa, and Sedaconda ACD is sold in over 30 countries through distributors.

There is also great interest in inhaled sedation outside Europe and the United States, and Sedana Medical has seen increasing demand for Sedaconda ACD in other parts of the world. It is clear that the positive trend for inhaled sedation on the Spanish market is contributing to increasing awareness and customer interest in Latin and South America.

Markets are evaluated continuously, where market potential, availability and necessary investments justify registration of Sedaconda ACD and/or isoflurane. In the short term, Sedana Medical has no intention of establishing a presence with its own direct sales channels in markets outside Europe, except in the United States, but considers that these markets may be of potential interest for direct sales in the long term.





Sustainability

Sedana Medical aims to be a credible and reliable counterpart to its business partners, an attractive employer and a long-term investment for its shareholders.

Doing business in a global and regulated environment poses many potential challenges. Sedana Medical's Code of Conduct constitutes a framework for what the company considers to be responsible and appropriate conduct. We endeavour to act responsibly in everything we do in order to build a long-term sustainable business. Sedana Medical supports the Ten Principles of the UN Global Compact in the areas of human rights, labour, environment and anti-corruption. The company strives for openness and transparency in its business operations, and further development of its work on sustainability in all its forms is an ongoing process.

Responsible action

Sedana Medical endeavours always to act ethically, and we expect a high ethical standard from all our staff. Competent, responsible and committed staff are crucial to the company's ambition to act responsibly towards all counterparties and society at large. We sell our products directly to hospitals through dialogue with healthcare professionals and administrative staff, either on site at the hospital or at industry conferences. In some markets the company also takes part in public procurements. In interactions with our customers there is a risk of undesirable behaviour on the part of our employees, including corruption. To manage these risks, the company has a Code of Conduct, which applies to all employees, the Board of Directors, consultants and temporary staff, as well as an anti-corruption policy. The Code of Conduct includes sustainability, the work environment, health and safety, the environment, gender equality and purchasing. Both these documents are regularly updated to reflect our business and its risks.

An attractive employer

Sedana Medical is continuing to grow, which means that the need for staff and skills is increasing. In 2023, the company welcomed several new colleagues, people who in their respective roles will strengthen the organisation, while some colleagues also left Sedana Medical. At the end of 2023, the company had 79 (85) employees and 7 (10) interim consultants in (8) 8 countries.

At Sedana Medical we believe our diversity is a strength. We are also very proud to have an even gender balance of 48:52 in favour of men. We have a clear recruitment process based on skill and experience and use a structured process with evidence-based questioning, to ensure that we do not discriminate.

To make it easier for staff to be further developed, the company has a mentorship programme for people who are new to staff-managing positions. These are paired

with people in the organisation who have great experience of leadership and can act as a sounding board for the new employee during the initial period at the company.

Sedana Medical's work on being an attractive and inclusive employer is governed by the company's HR policy.

The work environment and employee commitment

Our ambition is to have a workplace free from work-related injuries or accidents. A working environment handbook is available for all employees with mandatory training during onboarding. The handbook contains a gender equality and diversity policy, a policy regarding harassment, discrimination and discriminatory treatment. The handbook also states that employees must report any occupational injuries. There is a union safety representative at head office for issues related to the working environment, as well as a process for systematic and regular review. Sedana Medical offers health insurance to all employees, and for employees in Sweden we also have a wellness allowance.

The company regularly conducts staff surveys as a basis for changes and improvements. In 2023, this was done on three occasions ('Pulse Check'). These surveys provide the company with guidance on how staff find the work environment and the company as an employer, as well as whether efforts to bring about continuous improvements are working. Regular surveys remind staff that their opinions are important and a constantly prioritised matter in the company. The company also uses a total called 'I Suggest', where the whole organisation can submit suggestions for improvements and/or changes.

Since 2022, the HR Department has also arranged a 'Board Member for a Day', with the aim of everyone in the organisation being able to make their voice heard. This concept means that around 8–10 people from different parts of the organisation are brought together to discuss ideas and issues that are then presented to the management team.

Sedana Medical staff are encouraged to report openly any phenomena or unethical behaviour to their line manager, the head of HR or the chief legal officer, or by using Sedana Medical's whistleblower system, Speak-Up, in accordance with the company's whistleblower policy. The whistleblower system, which is provided by an independent external party, makes anonymous dialogue possible between the employee and the company and is an important tool in drawing attention to and counter-acting behaviour that is not compatible with Sedana Medical's values at an early stage. All notifications made through Speak-Up are reviewed by the Legal Department and investigated according to Sedana Medical's whistle-

blower policy and followed up with suitable measures where necessary.

No forms of reprisal against anyone expressing concern or opinions, reporting irregularities in good faith or taking part in an investigation of a case are tolerated.

No reports of irregularities were received via the system in 2023.

Responsible purchasing

Sedana Medical successively introduces clauses into its agreements with its suppliers in which they undertake to comply with its Code of Conduct. This is a continuously ongoing dialogue with our suppliers and is reviewed on a regular basis. Compliance with our Code of Conduct plays a significant role in choice of supplier and continuation of the relationship. We have an ongoing dialogue and regularly review our suppliers. If any findings and non-conformances are found, we work together with the supplier concerned to correct the non-conformance.

There is zero tolerance of all forms of inappropriate payment, direct or indirect, regardless of whether it concerns a direct bribe or other type of payment, gift, benefit, remuneration or other representation that could constitute a breach of law, or which could influence or be thought to influence judgment.

Reduced environmental footprint

The business will be run in an environmentally sustainable manner based on the business circumstances and follow prevailing environmental laws and regulations. The work on the environment and sustainability must be based on the UN's Sustainable Development Goals. Sedana Medical will attain this goal by applying the principle of avoid, reduce and replace.

We endeavour to increase the competence and commitment of employees on environmental and sustainability issues, where everyone in the company should carry out their work with as little impact on health and the environment as possible. Sedana Medical will continuously strive to bring about improvements to reduce our adverse impact on the environment, take account of the environment and health in the development of products and processes and prioritise innovative, environmentally sound technology.

Sedana Medical's medical devices largely consist of plastic. In general terms, for the whole of our product portfolio we aim to use recycled plastic where possible, use plastics that can be recycled, and label clearly all material that can be recycled. We also make continuous efforts to reduce the amount of plastic used for packaging. Our goal is to offer our customers a sustainable solution for the use and handling of isoflurane.

In 2023, Sedana Medical continued to cooperate proactively with key stakeholders to identify opportunities to further minimise the environmental impact of our products. Initiatives currently under way include the following:

- Minimising consumption of plastics and volume of packaging
- Increased reflection efficiency of Sedaconda ACD
- Increased capture efficiency and potential recycling of anaesthetic gas

Sedana Medical recruited a Sustainability Manager in 2023 to direct the company's work towards a reduced climate footprint. In addition to the focal areas above, the company will also work on producing a life cycle assessment for the company's products for a more complete picture of its climate footprint, including scope 1, 2 and 3 CO₂ emissions.

The device Sedaconda ACD

Sedana Medical is mindful of the selection of materials and tries to include low environmental impact materials when possible, such as polypropylene, polyethylene, polycarbonate, high-density polyethylene, stainless steel, and, in some instances, rubber. Commonly used plastics such as polyvinyl chloride (PVC) biodegrade slowly and have the potential to affect aquatic ecosystems. Phthalates, which are used as plasticisers, have adverse effects on health when used. Sedana Medical endeavours to use phthalate-free plastics and materials with low environmental impact for Sedaconda ACD and its accessories.

The pharmaceutical product Sedaconda (isoflurane)

The environmental impact of a pharmaceutical depends on 1) its carbon footprint, 2) the quantities consumed, and 3) the quantities released into the atmosphere, and/or 4) into our waters after use.

1. The carbon footprint of a gas is most suitably measured in terms of global warming potential (GWP), which takes account of both effect and how long the gas stays in the atmosphere. The GWP of anaesthetic gases is generally high if these are released into the atmosphere. However, the GWP of isoflurane and sevoflurane is 15 and 20 times lower respectively than that of desflurane¹¹.
2. The consumption of pharmaceutical product can be reduced with the aid of high reflection (re-use). Sedaconda ACD reduces the quantity of consumed anaesthetic gases by reflecting (re-using) around 90 percent of the gas in the patient's exhaled air¹².
3. Emissions after use are minimised by using the company's FlurAbsorb product to capture unreflected gas. As a result, the work environment is protected locally for healthcare staff and emissions into the atmosphere are prevented. Studies confirm very low emissions in connection with use of Sedaconda ACD and Sedaconda (isoflurane), far below permitted limit values¹³.
4. The risk of potential discharges of Sedaconda (isoflurane) into aquatic systems is minimal as isoflurane undergoes minimal metabolism (less than 0.2 percent of the administered pharmaceutical product is eliminated via the kidneys), and elimination takes place almost exclusively via the respiratory tract in unchanged form¹⁴.

Transport and travel

Transport accounts for a large share of many companies' environmental footprint. Goods and services should be delivered with an awareness of, and concern for, the environment. We therefore make active efforts to minimise

air freight, which should be used in exceptional cases only. One aim is to use sea freight for at least 90 percent of our incoming volumes of freight. Sedana Medical also endeavours to improve the efficiency of transport by reducing the size of packaging for our products.

Some of our efforts to minimise the environmental impact of the business are focused on emissions from transport with our own vehicles. Our policy for company cars encourages a switch to alternatives with low CO₂ emissions, which has started to yield lower volumes of emissions.

Under our travel policy, a journey must always be booked using the most cost-effective option. Online meetings are always encouraged, to reduce environmental impact, cost and the impact travel has in terms of the balance between work and leisure. The company permits remote working whenever and wherever appropriate.

Environmental impact at suppliers

A major part of Sedana Medical's environmental impact arises in external operations through contract manufacturers and operators in logistics and distribution of our products. Sedana Medical strives for long-term and responsible relationships with suppliers and distributors and will aim for increased focus on environmental and sustainability issues through a continuous dialogue with them. A sustainable supply chain is crucial for resource-efficient products and processes. We work together with our suppliers, who manufacture, pack and distribute our products to reduce our environmental impact wherever we can.

Quality management

Sedana Medical's devices and products are developed and manufactured in accordance with quality-controlled processes. The company has a quality management system that fulfils the requirements of ISO 13485 (design and manufacturing of medical devices) and MDR 2017/745 and holds MDSAP (Medical Device Single Audit Program) certificates for Canada and Japan, among other countries, which certify compliance with standard and statutory requirements for medical devices. The company furthermore has wholesale licences and a certificate showing that the company complies with the rules for Good Distribution Practice for pharmaceutical products.

Sedana Medical's quality management system is evaluated by both internal and external reviewers, and regular inspections are made by both authorities and the company. Sedana Medical regularly reviews its suppliers, and if any findings and non-conformances are found, the company works with the supplier concerned on the basis of established procedures and standards to correct the non-conformance.

In its research and development work, Sedana Medical complies with the Declaration of Helsinki covering ethical principles governing how research and development involving humans must be conducted, as well as international standards such as Good Laboratory Practice (GLP) and Good Clinical Practice (GCP).

Sedana Medical works closely and in dialogue with the healthcare system as well as competent authorities in the market concerned to understand needs that change and to be able to act quickly and correctly in response to any complaints linked to the company's devices and production or action.

The product life cycle of inhaled sedation

Material and manufacturing

- Use of material with low environmental impact
- Use of recycled material and recyclable material
- Resource efficiency of manufacturing processes
- Reduction in the quantity of plastic for packaging

Recycling and disposal

- Plastic waste after therapy has been carried out is separated for recycling
- The FlurAbsorb filter and the enclosed gas are disposed of by incineration. Incineration residues (ash) and emissions to air are checked to make sure they are within the statutory limits set out in the relevant regulatory framework for incineration plants.



Transport

- Minimising air freight
- Reducing volumes of packaging to make transport more efficient
- Fuels with low environmental impact

Product use

- Sedaconda ACD reduces the quantity of consumed pharmaceutical product
- FlurAbsorb captures unreflected gas, minimising exposure for the environment and healthcare staff
- Negligible excretion via the kidneys means that minimal quantities of the pharmaceutical product are released into aquatic systems

Share information and shareholders

The Sedana Medical share was listed on Nasdaq First North Growth Market in June 2017, and has been listed on Nasdaq Stockholm since 25 January 2023. The share is included in the OMX Stockholm PI index.

Share capital

The total number of shares outstanding at 31 December 2023 was 99,336,960. At year-end, share capital totalled SEK 2,483,424. Each share entitles the holder to one vote at the general meeting of shareholders, and each shareholder has the right to vote for the full number of shares they hold. All outstanding shares are fully paid up. The company's share capital is expressed in Swedish kronor (SEK) and distributed across the company's outstanding shares at a quotient value of SEK 0.025 per share.

Share trading

The initial price when the shares were listed on First North Growth Market 2017 was SEK 4.88*. The opening price in 2023 was SEK 18.70, and the last price paid at the end of

the year was SEK 23.16. During the year a total of 47 million Sedana Medical shares were traded at a value of SEK 1.1 billion, which is equivalent to a turnover rate of around 47 percent. On average, around 188,000 shares were traded per trading day.

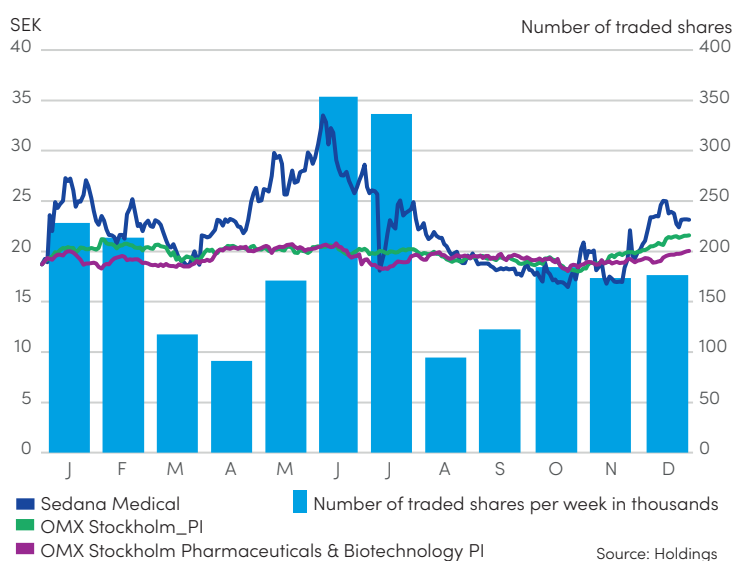
Price trend

Sedana Medical's share price rose by 24 percent during the year, while the OMX Stockholm Mid Cap Index rose by just over 9 percent over the same period. The highest price paid was SEK 33.52, recorded on 9 June 2023, and the lowest price paid was SEK 16.46, recorded on 23 October 2023. At year-end 2023, the Sedana Medical share price was SEK 23.16, equivalent to a market capitalisation of SEK 2,301 million.

*) Adjusted for the split carried out in May 2021.

Trend in share capital over time

Date of decision	Event	Change in shares	Total number of shares	Change in share capital (SEK)	Total share capital (SEK)	Quotient value (SEK)
20 Oct 2004	New formation	1,000	1,000	100,000	100,000	100
31 Oct 2009	New share issue	430	1,430	43,000	143,000	100
5 May 2011	New share issue	500	1,930	50,000	193,000	100
14 Sep 2015	New share issue	240	2,170	24,000	217,000	100
5 Apr 2017	Bonus issue	6,510	8,680	651,000	868,000	100
5 Apr 2017	Split	8,671,320	8,680,000	0	868,000	0.1
20 Jun 2017	Conversion of shareholder loans	613,594	9,293,594	61,359	929,359	0.1
20 Jun 2017	Exercised convertible bonds	1,881,509	11,175,103	188,151	1,117,510	0.1
20 Jun 2017	New share issue on IPO	5,128,205	16,303,308	512,821	1,630,331	0.1
10 Jul 2017	Overallocation option after IPO	769,230	17,072,538	76,923	1,707,254	0.1
5 Feb 2018	Conversion of warrants to shares, 2014/2019 programme	208,000	17,280,538	20,800	1,728,054	0.1
4 Jun 2018	New share issue	1,728,053	19,008,591	172,805	1,900,859	0.1
10 Oct 2018	Conversion of warrants to shares, 2014/2019 programme	148,000	19,156,591	14,800	1,915,659	0.1
27 Mar 2019	Conversion of warrants to shares, 2014/2019 programme	120,000	19,276,591	12,000	1,927,659	0.1
24 May 2019	Conversion of warrants to shares, 2014/2019 programme	140,000	19,416,591	14,000	1,941,659	0.1
14 Jun 2019	Conversion of warrants to shares, 2014/2019 programme	220,000	19,636,591	22,000	1,963,659	0.1
5 Aug 2019	Conversion of warrants to shares, 2014/2019 programme	100,000	19,736,591	10,000	1,973,659	0.1
28 Aug 2019	Conversion of warrants to shares, 2014/2019 programme	104,000	19,840,591	10,400	1,984,059	0.1
24 Oct 2019	New share issue	2,896,000	22,736,591	289,600	2,273,659	0.1
20 May 2020	Conversion of warrants to shares, 2017/2021 programme	310,149	23,046,740	31,015	2,304,674	0.1
10 May 2021	Split 4:1	69,140,220	92,186,960	0	2,304,674	0.025
2 Dec 2021	New share issue	7,150,000	99,336,960	178,750	2,483,424	0.025

Sedana Medical's share price trend and turnover

Facts about Sedana Medical shares

Trading venue	Nasdaq Stockholm
Number of shares at 31 Dec 2023	99,336,960
Market capitalisation	MSEK 2,301
Ticker	SEDANA
ISIN	SE0015988373
LEI code	549300FQ3NJR156LCX32

The 15 largest shareholders at 31 December 2023

	Number of shares	Holding
Linc AB	10,111,030	10.2%
"Anders Walldov directly and indirectly (Brohuvudet AB)"	10,000,000	10.1%
Swedbank Robur Fonder	9,519,013	9.6%
Handelsbanken Fonder	6,268,654	6.3%
Öhman Fonder	4,382,095	4.4%
"Ola Magnusson directly and indirectly (Magiola AB)"	4,312,098	4.3%
Sten Gibeck	4,196,597	4.2%
Highclere International Investors LLP	3,310,435	3.3%
Premier Miton Investors	2,671,820	2.7%
AMF Pension	2,491,000	2.5%
Berenberg Funds	1,983,744	2.0%
Tredje AP-fonden	1,735,989	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Amundi	1,344,738	1.4%
Avanza Pension	1,177,928	1.2%
Fifteen largest shareholders	65,171,605	65.6%
Other	34,165,355	34.4%
Total	99,336,960	100.0%

Source: Modular Finance

Shareholder distribution by size

	Number of shareholders	Number of shares	% capital	% share-holders
1 – 100	3,011	106,650	0.1%	44.0%
101 – 200	834	128,045	0.1%	12.2%
201 – 300	424	109,299	0.1%	6.2%
301 – 400	325	120,849	0.1%	4.7%
401 – 500	264	123,588	0.1%	3.9%
501 – 1,000	712	543,557	0.5%	10.4%
1,001 – 2,000	498	739,890	0.7%	7.3%
2,001 – 5,000	376	1,276,386	1.3%	5.5%
5,001 – 10,000	173	1,283,595	1.3%	2.5%
10,001 – 20,000	89	1,247,506	1.3%	1.3%
20,001 – 50,000	52	1,775,108	1.8%	0.8%
50,001 – 100,000	29	2,074,384	2.1%	0.4%
100,001 – 500,000	30	7,183,944	7.2%	0.4%
500,001 – 1,000,000	11	7,723,997	7.8%	0.2%
1,000,001 –	17	67,391,364	67.8%	0.2%
Anonymous ownership		7,508,798	7.6%	
Total	6,845	99,336,960	100%	100%

Source: Modular Finance

Warrant programmes

Warrant programme 2020/2024

The Annual General Meeting of Sedana Medical AB (publ) held on 19 May 2020 resolved to implement a new warrant programme for current and new staff (employees and consultants) of the Sedana Medical Group. The company therefore issued 360,000 series 2020/2024 warrants at the AGM, entitling holders to subscribe to a total of 360,000 shares, all of which were subscribed to by the company's subsidiary Sedana Medical Incentive AB for later transfer to employees in the Group. Each warrant entitles the holder to subscribe to one new share in Sedana Medical AB (publ) during the period 1 February to 31 May 2024 at a subscription price of SEK 123.88 per share. Full conditions apply to the warrants, including customary conversion terms, which mean that the subscription price, as well as the number of shares that the warrants qualify for subscription to, may in some cases be recalculated, for example in the event that the company makes changes in the share capital and/or the number of shares through, for example, issue of shares or other securities, aggregation or splitting of shares. At the balance sheet date, 148,452 warrants series 2020/2024 were held by staff in the Group. All transfers of warrants to staff in the Group have been made at market value, calculated according to the Black & Scholes valuation model by an external valuer. A condition for acquiring warrants under the 2020/2024 warrant programme was that employees have undertaken to sell back acquired warrants to Sedana Medical Incentive AB if their employment or appointment in the Group ends before three years have elapsed from the acquisition date. If all the 2020/2024 series warrants that have been transferred to staff in the Group at the balance sheet date are fully exercised, the company's share capital will increase by around SEK 14,845 through the issue of 148,452 shares in the company, equivalent to a dilution of approximately 0.15 percent based on the number of shares in the company at the balance sheet date.

Warrant programme 2022/2025

The Annual General Meeting of Sedana Medical AB (publ) held on 11 May 2022 resolved on the implementation of two new warrant programmes, 2022/2025:1 and 2022/2025:2, mainly for the CEO and certain selected employees. The company therefore issued 895,000 warrants at the AGM, all of which have been subscribed to by the company's subsidiary Sedana Medical Incentive AB. Each warrant entitles the holder to subscribe to one share in the period 30 May to 30 September 2025, at a subscription price of SEK 46.24, equivalent to 140 percent of the volume-weighted average price paid for Sedana Medical shares over the period 28 April to 11 May 2022. A total of 824,947 warrants were transferred to staff in May 2022. Transfers took place against payment of the estimated market value of the warrants calculated by an external valuer according to the Black & Scholes valuation model. The price per warrant was SEK 5.61, based on assumption of a risk-free interest rate during the term of the warrants of 0.4 percent, an estimated volatility for the company's share during the term of the warrants of 37 percent and no dividends or other transfers of value being implemented during the term of the warrants. Volatility has been estimated based on the historical volatility in the company's share. In connection with payment of the warrants, employees received premium subsidies in the form of extra salary amounting to SEK 2.93 before tax per warrant. If the employee leaves employment during the three-year period there is an option to claim repayment of the subsidy in full or in part. If all the warrants are exercised, 824,947 new shares will be issued, which is equivalent to a dilution of around 0.8 percent based on the number of shares in the company at 31 December 2023.

Administration report

The Board of Directors and Chief Executive Officer of Sedana Medical AB (publ), corporate identity number 556670–2519, hereby submit annual accounts and consolidated financial statements for the financial year 2023.

The business in brief

Sedana Medical is a Swedish medtech and pharmaceuticals group. The Group's operations comprise the development, manufacture and sales of medical devices and pharmaceutical products and the development of devices based on, or having synergies with, Sedaconda technology. The technology enables the simple, safe conversion of a liquid to a gas (evaporation) and the reuse (reflection) of volatile anaesthetics for use in anaesthesia and intensive care. The Group's product portfolio currently includes Sedaconda ACD with accessories and Sedaconda (isoflurane), the Group's pharmaceutical product based on the well-known substance isoflurane. Volatile anaesthetics have long been used to anaesthetise patients in connection with surgery. Complex, capital-intensive anaesthesia machines that require specially trained personnel are used for this purpose. Traditional anaesthesia machines lack several vital features which mean that they cannot be routinely used in an intensive care unit. Sedana Medical's device Sedaconda ACD, which in very simple terms can be regarded as an anaesthesia machine in miniature, is a solution that makes it practically and financially possible to use volatile anaesthetics to sedate mechanically ventilated intensive care patients. The market for the sedation of mechanically ventilated intensive care patients today consists of established drugs that are administered intravenously. Sedation through the inhalation of volatile anaesthetics has shown itself in many ways to be a safer, more effective solution for sedating intensive care patients than present-day intravenous sedation. Sedana Medical's vision is to develop inhaled sedation, using Sedaconda ACD and Sedaconda (isoflurane), into the global standard sedation method for mechanically ventilated patients in intensive care. To achieve this vision, the Group has been conducting a clinical phase III study in Europe aimed at gaining approval for the pharmaceutical product Sedaconda (isoflurane) and inhaled sedation therapy using Sedaconda ACD. Sedana Medical received European market approval in autumn 2021. A similar phase III study has also been in progress in the United States since 2022. Sedana Medical runs its own sales operations from a number of countries in Europe through subsidiaries and branches of the Parent Company Sedana Medical AB (publ), corporate identity number 556670–2519. The business in Germany consists of sales, storage and distribution. In Spain, sales operations are run by a branch office of the Parent Company. Germany is comfortably the Group's largest market, with around 70 percent of total sales. As well as in Germany and Spain, direct selling takes place in France, Norway, the UK and the Netherlands through wholly owned subsidiaries. In several other countries around the world, sales take place through partnerships with distributors. The company conducts R&D in Ireland through a wholly owned subsidiary. The manufacturing of Sedaconda ACD devices is carried out through contract manufacturers, but is controlled via the Irish subsidiary. The Parent Company's head office

and domicile are in Danderyd, Sweden. In June 2017, Sedana Medical was listed on Nasdaq First North Growth Market Stockholm, and in January 2023 the trading venue for the company's shares changed to Nasdaq Stockholm Main Market (ticker: SEDANA).

Significant events during the year

1st quarter

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

2nd quarter

- Topline results from the paediatric phase III study IsoCOMFORT were presented in mid-May. A post-hoc-analysis of the Sedaconda study SED001 was published in the Journal of Critical Care at the end of June.

3rd quarter

- In July, the US FDA announced that data on long-term effects needed to be included in the clinical study report (CSR) for the company's clinical programme INSPIRE-ICU before the company submits a new drug application (NDA).
- At the end of September, the US Patent and Trademark Office granted Sedana Medical a patent for the medical device Sedaconda ACD-S.

4th quarter

- The UK Medicines and Healthcare products Regulatory Agency (MHRA) granted Sedana Medical market approval for the company's pharmaceutical product Sedaconda (isoflurane).
- The Spanish Ministry of Health in October granted price and reimbursement approval for the pharmaceutical product Sedaconda (isoflurane).
- Recruitment of the planned 700 patients in the investigator-initiated SESAR study was reached in October.

- In November, the European Medicines Agency's Paediatric Committee issued a positive statement on the compliance of the company's paediatric investigation plan, which confirms data exclusivity and market protection for Sedana Medical's Sedaconda (isoflurane) until 2031.
- In December, the company submitted a type II variation with the aim of including the paediatric population (age 3–17) in the existing Sedaconda indication for inhaled sedation of mechanically ventilated patients in Europe.

Significant events after the end of the period

- No significant events after the end of the financial year.

Anticipated future development

In the coming years, the Group will apply its strategy to accomplish its mission and vision and achieve its established financial targets.

Purpose

To improve patient life during and beyond sedation.

Vision

To make inhaled sedation a global standard therapy for patients in intensive care.

Financial targets

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

Our financial targets:

- Growth in net sales in 2024 between 14 and 18%, compared with 16% for 2023 (*at constant exchange rates*)
- Break-even for EBITDA for business outside the United States in 2024

Strategic priorities

Sedana Medical has three strategic priorities:

1. Achieving lasting and profitable sales growth in Europe

Our market approvals, in 18 European countries to date, mean that Sedana Medical is the first company to offer an approved therapy for inhaled sedation in intensive care. With a strong focus on commercial execution and a restrained investment philosophy that prioritises profitable growth, we aim to make inhaled sedation standard therapy.

2. Maximising the opportunities in the United States

With more than 100,000 intensive care beds and a generally higher price level for sedation therapies, the United States represents our largest potential market. After completion of our clinical phase III programme, which has been granted Fast Track Designation by the FDA, provided approval is obtained, we aim to launch our products through a dedicated commercial organisation.

3. Building a long-term profitable company

Sedana Medical's model with high gross margins and a concentrated customer base (hospitals with intensive care) is advantageous in achieving attractive profitability when sales increase. An important priority is to achieve profitability for

the business outside the United States in 2024, so that the US launch can be based on a stable financial platform. Our long-term aim is to reach an EBITDA margin of around 40% when we have scaled up the business and increased the share of sales in the United States.

Risks

Sedana Medical's activities are affected by many factors that the company is partially able to control in some respects but not at all in others. These aspects can also be expressed as various risks. The risks can have a more or less significant impact on the company's earnings and financial position depending on whether and how they arise. Some of the risk factors considered to be of greatest significance for the company's future development are described below.

Risks related to the industry and the business

Risks related to the regulatory environment for medical devices and pharmaceutical products

Sedana Medical's device Sedaconda ACD with accessories and the pharmaceutical product Sedaconda (isoflurane) are subject to extensive regulation worldwide and are monitored by various industry-specific supervisory authorities. In addition to such industry-specific regulation, Sedana Medical is also subject to a number of other requirements and restrictions under the provisions of environmental, health and industrial safety legislation. There may be more such requirements in the future. The costs of compliance with applicable legislation, requirements and guidelines can be high. In addition the regulatory environment in general has become more stringent and extensive over time. If these regulations are not followed, it can lead to sanctions that could significantly increase Sedana Medical's costs, lead to delays in development and the commercialisation of the company's candidate devices, and substantially impair ability to generate planned revenue and achieve profitability. If these risks become reality, they could have a significant adverse effect on the company's business and financial position.

Risks related to the product classification system or market access process for medical devices and medicinal products

Before Sedana Medical's device Sedaconda ACD and accessories, either in combination with Sedaconda (isoflurane) or not, may be marketed in the area of inhaled sedation treatment in intensive care in any new national or regional market, the company must obtain market approval or similar authorisations from the relevant authorities in the countries where the company intends to market and sell its products. Changes in the process and requirements for market access may adversely affect Sedana Medical's ability to generate desired revenue. In order for class II and III medical devices to be marketed in the EU, a 'notified body' must first issue a certificate confirming that specified regulatory requirements have been met. The company's present-day certificate includes both the Medical Devices Directive (MDD) and the Medical Devices Regulation (MDR) for the medical devices, and is valid until 26 May 2025 and 25 August 2027 respectively. Because decisions taken by notified bodies are valid for a limited time, certificates must be renewed. All the risks described above could have a significant adverse effect on the company's operations, financial position and earnings.

Risks related to the implementation and outcomes of clinical studies

Sedana Medical conducts clinical studies with Sedaconda (isoflurane) for inhaled sedation in intensive care. Conducting studies is crucial in order for the company to market its medical device Sedaconda ACD together with Sedaconda (isoflurane) as therapy for inhaled sedation in intensive care in the markets the company intends to focus on. The company is thus dependent on obtaining positive outcomes in its clinical studies in order to achieve its long-term business objectives. The conduct of clinical trials is associated with a number of risks. Among them there is always a risk of delays and of the costs of studies being higher than expected.

Delays can occur due to problems in finding locations for studies, in gaining the necessary authority approvals for the performance of studies, in recruiting patients, in concluding satisfactory agreements for example with contract research organisations, suppliers, and study sites, etc. Delays can lead to increased costs, but also to late product launches, which may result in the company being unable to generate revenue as planned. Increased costs can also arise due to costs per patient being higher than estimated or a lack of quality in conduct of the study in the hospitals where it is performed, etc. Clinical trials may present negative or inadequate results in the area of therapy that Sedana Medical's devices focus on. If the desired results are not achieved, it may mean that the necessary market approvals fail to be issued, which in turn may jeopardise the company's ability to market and sell its devices and candidate devices. If the above risks become reality, they can have significant adverse effects on the company's ability to generate revenue and on its business, financial position and earnings.

Risks related to competition

Sedana Medical's products for inhaled sedation for intensive care patients are primarily exposed to competition from pharmaceuticals for intravenous sedation. Intravenous sedation is a well-established therapy and the standard therapy for the sedation of intensive care patients today. Even though Sedana Medical believes in its the ability of its devices to take market share from companies that sell medicinal products for intravenous sedation, there is always a risk that the company will not achieve the desired market acceptance. And even if Sedana Medical were to succeed in taking market share from conventional methods with sedatives for intravenous sedation, there is a risk of exposure to competition in the indication of inhaled sedation. The risks related to competition could have a significant adverse effect on the company's operations, financial position and earnings.

Risks related to third-party agreements regarding the performance of clinical studies and manufacturing

Sedana Medical engages external companies such as contract, research and manufacturing companies to conduct clinical trials and manufacture its devices. The operations of such companies are subject to extensive requirements regarding reporting, safety and the environment. There is a risk of these companies not complying with applicable legislation, regulations and the relevant ethical standards such as good manufacturing practice (GMP) and good clinical practice (GCP). There is also a risk of deficient or missed deliveries of products or services from external companies engaged today and in the future. This may affect the development and sales of Sedana Medical's devices negatively by causing delays and increasing costs. The company is not dependent on any individual contract research organisation or manufacturing company, but changing suppliers can be both expensive and time-consuming. The occurrence of the risks described above could have a significantly adverse effect on Sedana Medical's operations, financial position and earnings.

Risks related to unsuccessful market acceptance from healthcare providers, patients and healthcare purchasers including the possibility of being covered by remuneration systems

Even if a device meets the requirements for market access, such as by obtaining marketing authorisation, there is a risk that the desired level of market acceptance will not be achieved from physicians, hospitals, patients, healthcare purchasers and the industry in general, which could prevent Sedana Medical from generating desired revenue and could have a significant adverse effect on the company's operations, financial position and earnings.

Risks related to macroeconomic factors including pricing and demand for medical devices

Because Sedana Medical intends to market and sell its devices in several parts of the world, the company may be affected by general demand and the pricing of devices for sedating intensive care patients in relevant markets. Sedana Medical cannot predict how financial markets and the economic and political climate will develop or predict macroeconomic events. An economic downturn or weak economic development may lead to strains in the market for medical devices and medicinal products, leading to increasing pressure on hospitals, authorities and other healthcare purchasers to cut back on costs, potentially reducing the willingness to pay for such products in general, including those of Sedana Medical. If the risks described above become reality, they could have a significant adverse effect on the company's operations, financial position and earnings.

Dependence on sales and the development of a small number of devices

In the current situation, Sedana Medical is focusing principally on sales of Sedaconda ACD and the pharmaceutical product Sedaconda (isoflurane). The company's growth target is based entirely on technology and one specific field of therapy, inhaled sedation in intensive care. Sedana Medical's operations, financial position and earnings would suffer significant adverse effects from any setbacks for example in the clinical studies.

Risks related to key individuals and qualified personnel

Sedana Medical is dependent on its employees, in particular senior executives and other key staff. The company is dependent on its ability to recruit highly qualified personnel for the continued development of the business. If Sedana Medical were to lose any of its key personnel or fail to recruit qualified personnel, this could have a negative impact on the company's operations, financial position and earnings.

Risks related to the company's protection of its intellectual property rights

Patents and other intellectual property rights are a key asset in Sedana Medical's business, and thus any future successes are thus largely dependent on the opportunities of the company to maintain existing intellectual property rights such as trademarks and patents and to obtain protection for filed and future patent applications. Some of the company's patents for the Sedaconda ACD device with 100 ml dead space have expired or will expire shortly. Sedana Medical has submitted a number of patent applications related to the Sedaconda ACD with halved dead space, which ensures that a competitor or other company cannot develop Sedaconda ACD with 100 ml dead space into a version with smaller dead space. If the company's patents and other intellectual property rights were to be lost, not be approved or be limited, or if the company otherwise cannot maintain the necessary patent protection, this could have a negative effect on the company's operations, financial position and earnings.

Risks related to fluctuating foreign-exchange rates

The company reports its financial position and earnings in Swedish kronor (SEK). On the other hand, a major part of the company's operating costs and almost all revenue is in euros, and in the future the company's operating revenue and costs are expected to comprise other currencies, primarily the dollar. As a result, Sedana Medical is exposed to currency risks in relation to payment flows in and outside Sweden and the eurozone, such as fluctuations where the exchange rate changes from the time when an agreement is concluded until payment takes place under the agreement which can lead to exchange losses or gains ("transaction exposure") that the company cannot predict. Currency transaction losses could lead to significant adverse effects on the company's future operations, financial position and profits.

Risks related to current and additional financing

The volume of resources required to implement Sedana Medical's business plan including the development and commercialisation of medical devices and pharmaceutical products depends on a number of factors that are unknown at present. There is a risk of Sedana Medical not achieving sufficient revenue in time to be able to finance its operations and development. If the company cannot obtain acceptable financing, it may limit the company's ability to maintain its position in the market or competitiveness for its offerings. Sedana Medical may also be forced to seek additional financing in order to continue with its operations. Such financing can be sought through external investors or existing shareholders and take place through public or private financing initiatives. There is a risk that new capital cannot be obtained when needed or on acceptable terms or that the capital obtained is not sufficient to finance operations according to established business planning and established objectives. If the risks associated with problems in obtaining sufficient revenue or sufficient financing to maintain the company's operations become reality, it could have a significant adverse effect on operations, financial position and earnings.

Risks related to exposure to tax demands and changes in tax regulations

Sedana Medical's assessment is that the company complies with applicable tax legislation. However, from time to time various legislative options may be proposed that will have a negative impact on the company's tax situation. In addition, tax regulations are complex and subject to different interpretations. There are no guarantees that Sedana Medical's tax situation will not be challenged by tax authorities or that the company will be successful should such an event occur. A decision by the tax authority could change Sedana Medical's previous tax situation, which could have a negative impact on the company's operations, financial position and earnings.

Risks related to accumulated tax losses

Because the operation has generated significant deficits, Sedana Medical has major accumulated tax losses. Changes in ownership that lead to an individual's gaining controlling influence over the company could lead to limitations in the ability to make use of such losses in the future. The ability to make use of losses in the future may also be negatively affected by changes in applicable legislation. Such limitations and changes could have a negative effect on Sedana Medical's operations, financial position and earnings.

Financial review of 2023

Alternative performance indicators

Alternative performance indicators relate to financial indicators used by the senior management and investors to assess the Group's results and financial position which cannot be read or derived directly from the financial statements. These financial indicators are intended to facilitate analysis of the Group's development. The alternative performance indicators should accordingly be regarded as complementing the financial reporting prepared in accordance with IFRS. The financial indicators presented in this report may differ from similar indicators used by other companies. These performance indicators, which are not defined according to IFRS, are also presented in the report as they are considered to represent complementary performance indicators for the company's results. For information on these performance indicators and how they have been calculated, please see <https://sedana-medical.com/investors/financial-reports-presentations/>

Net sales

Net sales for the year totalled KSEK 153,867 (122,865), equivalent to an increase of 25 percent. Adjusted for currency effects, 2023 showed an increase of 16 percent. In Germany, sales increased by 23 percent, principally due to a mix of new and returning

customers. Our other direct markets in Europe showed growth of 67 percent, with Spain continuing to be the prime driver. With regard to distributor markets, sales there declined by 22 percent, principally due to high inventory levels up to autumn 2023 at both distributors and hospitals.

Cost of goods sold and gross profit

The cost of goods sold totalled KSEK 44,886 (36,791), representing an increase of 22 percent.

Gross profit was KSEK 108,981 (86,074), representing a gross margin of 71 (70) percent. The increase is mainly an effect of higher selling prices compared to the previous year.

Selling expenses

Selling expenses for the full year were KSEK 107,239 (112,469), representing a decrease of 5 percent. The decrease is principally a result of efficiency improvements in central functions.

Administrative expenses

Administrative expenses in the Group totalled KSEK 47,504 (57,473), representing a decrease of 17 percent. The decreased expenses are principally due to costs of a non-recurring nature in 2022 relating to work on the change of listing from Nasdaq First North Growth Market to Nasdaq Main Market Stockholm.

Summary consolidated figures

KSEK	2023	2022	2021	2020	2019
Net sales	153,867	122,865	159,152	141,770	71,646
Gross profit	108,981	86,074	106,706	88,903	46,767
Gross margin %	71%	70%	67%	63%	65%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-42,974	-83,138	-50,093	-14,294	-12,932
EBITDA margin %	-28%	-68%	-31%	-10%	-18%
Earnings before interest and taxes (EBIT)	-65,547	-105,887	-61,493	-21,359	-17,120
Operating margin %	-43%	-86%	-39%	-15%	-24%
Net income for the year	-59,612	-73,507	-57,966	-27,139	-16,380
Profit margin %	-39%	-60%	-36%	-19%	-23%
Balance sheet total	1,014,056	1,081,588	1,167,580	600,097	595,766
Equity ratio %	96%	95%	94%	92%	96%
Quick ratio %	968%	1,299%	1,414%	929%	1,872%
Average number of employees	79	86	73	55	39

Summary Parent Company figures

KSEK	2023	2022	2021	2020	2019
Net sales	153,767	122,726	159,107	121,238	46,213
Gross profit	110,652	88,634	109,445	82,531	15,592
Gross margin %	72%	72%	69%	68%	34%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-40,520	-77,459	-50,250	-26,608	-14,773
EBITDA margin %	-26%	-63%	-32%	-22%	-32%
Earnings before interest and taxes (EBIT)	-57,283	-93,632	-55,161	-27,577	-16,051
Operating margin %	-37%	-76%	-35%	-23%	-36%
Net income for the year	-47,754	-59,741	-63,629	-28,767	-14,800
Profit margin %	-31%	-49%	-40%	-24%	-33%
Balance sheet total	1,053,888	1,105,654	1,164,900	603,470	615,476
Equity ratio %	95%	95%	95%	93%	95%
Quick ratio %	893%	1198%	1,479%	941%	1,444%
Average number of employees	46	53	41	25	24

Research and development expenses

Research and development expenses for the full year 2023 totalled KSEK 20,805 (19,944), equivalent to an increase of 4 percent.

Operating income

Group operating income for the full year was KSEK -65,547 (-105,887). The improvement in earnings is explained by increased sales at a slightly higher margin and lower expenses principally in central functions.

Net financial items

Net financial items totalled KSEK 6,528 (32,954), and the decrease is principally due to larger unrealised exchange losses compared to the previous year, mainly relating to cash and cash equivalents invested in USD.

Tax

The Group reported a tax expense of KSEK -593 in 2023, compared to KSEK -574 in the previous year. The tax is attributed principally to Germany.

Net income for the year

The Group reported earnings after tax of KSEK -59,612 (-73,507) for the year. The improvement in earnings is explained by increased sales at a slightly higher margin and lower expenses principally in central functions. These effects have been partly offset by negative, unrealised currency effects in comparison with the previous year, principally regarding cash and cash equivalents invested in USD.

Equity and liabilities

Equity at 31 December was KSEK 969,995, compared to KSEK 1,029,155 at the beginning of the year, equivalent to SEK 9.76 (10.36) per share. Equity/assets ratio was 96 percent, compared to 95 percent at the beginning of the year.

Debt/equity ratio at 31 December was 4 percent, compared to 5 percent at the beginning of the year. The Group had no long-term loans at 31 December.

Cash and cash equivalents and cash flow

Group cash and cash equivalents for 2023 rose by KSEK 376,562 at 31 December to KSEK 231,180, compared to KSEK 607,742 at the beginning of the year. Cash flow from operating activities before change in working capital for the year was KSEK -17,132 (-80,108). Cash flow from change in working capital was KSEK -20,928 (-35,324), mainly impacted by higher accounts receivable due to the increased sales. Cash flow from operating activities consequently totalled KSEK -38,061 (-115,433).

Cash flow from investing activities for the quarter totalled KSEK -321,957 (-137,783). During the first quarter, KSEK 306,156 of the company's cash and cash equivalents was invested in the short term in favour of better interest terms. These investments were repaid at KSEK 312,348 during the third quarter, of which KSEK 159,261 was reinvested. Other investments for 2023 mostly consist of intangible assets, mainly development expenses for clinical studies and work on registration of Sedaconda ACD and Sedaconda (isoflurane) in the United States, as well as investments related to the company's paediatric study IsoCOMFORT (SED002).

Cash flow from financing activities totalled KSEK -4,857 (-1 507) and relates to amortisation of lease liabilities. The

decrease in comparison with the previous year relates to premium received for issued warrants in the second quarter of 2022.

The translation difference in cash and cash equivalents during the year totalled KSEK 11,687 (26,283) and is principally due to the Group having cash and cash equivalents denominated in USD. Cash flow per share for the year was SEK -3.67 (-2.56). Adjusted for short-term investments, cash flow per share was SEK -2.13 (-2.56), representing an improvement of SEK 0.43 per share.

Investments

Investments during the 2023 financial year totalled KSEK 168,889 (137,783). Investments during 2023 primarily relate to:

- Capitalised expenses for development work, KSEK 167,863
- Internal expenses for the preparation of patents, KSEK 511
- Purchase of plant and machinery, KSEK 353
- Purchase of fixtures, fittings and tools, KSEK 162.

Parent Company

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

Operating income for the full year totalled KSEK -57,284 (-93,632). Net financial items were KSEK 9,518 (-33,891) and relate mainly to unrealised exchanges gains on cash and cash equivalents denominated in USD and revaluations of internal loans.

Shareholders' equity in the Parent Company totalled KSEK 1,002,640 at 31 December 2023, compared to KSEK 1,050,411 at the beginning of the year. Share capital totalled KSEK 2,483, compared to KSEK 2,483 at the beginning of the year.

Cash and cash equivalents totalled KSEK 366,545, compared to KSEK 587,909 at the beginning of the year.

Organisation and Personnel

In 2023, Sedana Medical had 79 employees. Of these, 41 employees were men and 38 were women. The corresponding figures for 2022 were 86 employees, of whom 43 were men and 43 were women.

Proposed appropriation of earnings

The Board of Directors proposes that no dividend be paid for the financial year 2023.

The amount available for appropriation at the Annual General Meeting comprises unrestricted reserves, accumulated loss and net income for the year in the Parent Company:

SEK	
Retained earnings	542,057,183
Net income for the year	-47,754,127
Total non-restricted reserves	494,303,056

The Board of Directors proposes that retained earnings available to the Annual General Meeting and the share premium reserve be carried forward. Following appropriation, unrestricted equity totals:

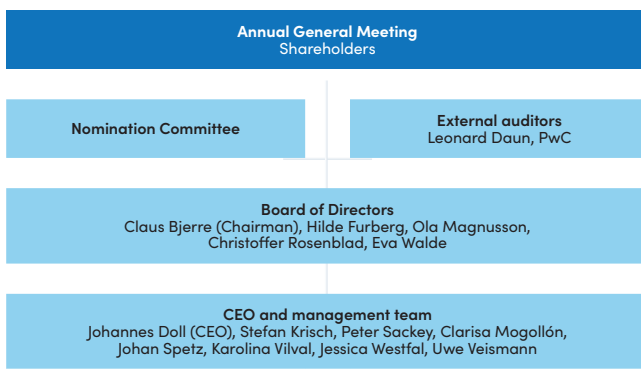
SEK	
Retained earnings	494,303,056
Total non-restricted reserves	494,303,056

Corporate Governance

Legislation and articles of association

Sedana Medical AB (publ) ('Sedana Medical' or 'the Company') is a Swedish public company with domicile in Danderyd. The Company's shares were listed on Nasdaq First North Growth Market on 21 June 2017, and changed trading venue to the Nasdaq Stockholm Main Market on 25 January 2023. In connection with the change of listing, the Company went over from applying the rules applicable to Nasdaq First North Growth Market to following the Nasdaq Stockholm Nordic Main Market Rulebook for Issuers of Shares. The Company has applied the Swedish Code of Corporate Governance ('the Code') since the day the shares were listed on the Nasdaq Stockholm Main Market. As well as legislation, the Rulebook for Issuers of Shares and the Code, corporate governance is primarily based upon the Company's articles of association and internal guidelines.

The illustration below shows Sedana Medical's corporate governance model and how the various bodies function.



Internal instructions and policies of significance among other things to corporate governance

- Articles of association
- Board's rules of procedure and CEO instructions
- Instructions for the audit committee
- Guidelines for Remuneration of Senior Executives
- Code of Conduct
- Corporate governance policy
- Financial policy
- Financial reporting policy
- Financial manual
- Authorisation instructions
- Information policy
- Insider policy
- IT policy
- Whistleblower policy
- Anticorruption policy
- Guidelines for related party transactions
- Corporate Governance Policy
- Information Security Policy
- Risk Management Policy

External regulatory frameworks affecting the articles of association

- Swedish Code of Corporate Governance
- Swedish Companies Act
- Accounting regulations
- Rulebook for issuers of shares

Deviations from the Code of Corporate Governance

The Board of Sedana Medical did not hold any meeting during the year with the company's auditor without senior management participation, which the Code specifies (Rule 7.6). The Company has not otherwise deviated from the Issuer Rules or good practice on the stockmarket. The Swedish Code for Corporate Governance is available on www.bolagsstyrning.se and the Issuer Rules is available on [på www.nasdaqomxnordic.com](http://pa.www.nasdaqomxnordic.com).

Annual General Meeting

Shareholder influence in the company is exercised at the Annual General Meeting which, in accordance with the Swedish Companies Act, is the company's highest decision-making body. As the Company's highest decision-making body, the Annual General Meeting can take decisions about all matters in the Company that do not constitute another company body's exclusive area of competence. The Annual General Meeting thus plays a superior role in relation to the Company's Board of Directors and the Chief Executive Officer. Notices to attend, minutes and communiqués from shareholders' meetings will be kept available on the company's website. At an Annual General Meeting, which under the Swedish Companies Act must be held within six months from the end of each financial year, resolutions must be made concerning the approval of the income statement and balance sheet, allocations concerning the company's profit or loss, discharging the Board of Directors and Chief Executive Officer from liability, election of Board members and auditors, and remuneration of the Board and auditor. At the general meeting of shareholders, the shareholders also make decisions on other key issues for the Company, such as amendment of the Company's articles of association, any new issue of shares, etc. If the Board judges there to be reason to hold an AGM before the next AGM, or if an auditor in the Company or holder of at least one-tenth of all the shares in the Company so requests in writing, the Board must call an extraordinary general meeting. Notice to attend an AGM and extraordinary general meeting where changes to the articles of association will be addressed must be given at the earliest six weeks and at the latest four weeks before the meeting. Notice to attend another extraordinary general meeting must be given at the earliest six weeks and at the latest three weeks before the meeting. Notice to attend is given through the Official Swedish Gazette (Post- och Inrikes Tidningar) and the company's website. At the same time, an announcement that notice has been given must be placed in the Swedish daily business newspaper Dagens Industri. To be allowed to attend the Annual General Meeting, a shareholder must notify their intention to attend the meeting no later than the date stated on the notice calling the meeting. This day may not be a Saturday, Sunday, public holiday, Midsummer's Eve, Christmas Eve or New Year's Eve and may not fall earlier than five working days before the meeting. Shareholders may attend the annual general meeting in person or be represented by proxy, and may also be assisted by not more than two persons. There are usually opportunities for shareholders to register their attendance of the Annual General Meeting in a number of ways in accordance with instructions in the notice to attend. Shareholders wishing to have a matter addressed at the meeting must submit a request in writing to the company's Board. Such a request must usually reach the Board not later than seven weeks before the Annual General Meeting. In order to deter-

mine who has the right to attend and vote at an Annual General Meeting, Euroclear Sweden AB, at the Company's request, must provide the company with a list of all shareholders as of the record date in connection with each Annual General Meeting. Shareholders whose shares are registered in the name of a nominee or trustee must instruct the nominee to temporarily register the shares in the shareholder's own name (voting right registration) in order to be eligible to participate and vote their shares at an Annual General Meeting. Such registration must be completed not later than the applicable record date and ceases to be valid after the record date. Shareholders whose shares are directly registered in an account in the Euroclear system will be included automatically in the list of shareholders. There are no restrictions regarding how many votes each shareholder may cast at a general meeting of shareholders. The 2023 annual general meeting resolved, in accordance with the Board's proposal, to authorise the Board, on one or more occasions before the next AGM, with or without deviation from the shareholders' right of pre-emption, to decide on a new share issue. As a result of a new share issue supported by the authorisation, with deviation from the shareholders' right of pre-emption, the company's share capital may not be increased by an amount exceeding ten (10) percent of the share capital in the company at the time when the authorisation is utilised for the first time.

Annual General Meeting 2024

The AGM 2024 will be held on Wednesday May 22. For right to participate and more information see page 79 or www.sedanamedical.com. Notes from the AGM will be published on www.sedanamedical.com.

Major shareholders

Two shareholders in Sedana Medical have direct or indirect shareholdings in the company representing at least one tenth of the number of votes for all shares in the company. Linc AB holds shares representing 10.2% of the number of votes and Anders Walldov (Brohuvudet AB) holds shares representing 10.1% of the number of votes.

Nomination Committee

The AGM of the Company held on 16 May 2023 resolved to adopt the following principles for appointment and instructions in respect of nominations prior to future AGMs. The following principles and instructions apply until any resolution changing them is adopted by the AGM. The Nomination Committee must comprise the Chairman of the Board and three members appointed by the three biggest shareholders in terms of votes at the end of the third quarter of the year concerned. Every year, the Chairman of the Board must contact the shareholders who are eligible to appoint members. If any of the shareholders chooses to waive their right to appoint a member to the Nomination Committee, the right is transferred to the next largest shareholder in terms of votes, and so forth. However, no more than five additional shareholders need not be contacted, unless the Chairman of the Board finds there to be special reasons for this to be done. When shareholders are contacted requesting them to appoint members to the Nomination Committee, the Chairman of the Board must establish the necessary rules such as the last day by which to respond, etc. The names of the Nomination Committee members and the names of the shareholders appointing the members must be published no later than six months before the AGM. The Nomination Committee appoints its own chair internally. The Chairman of the Board may not be the chair of the nomination committee. If a member leaves the Nomination Committee before its work is completed, and the committee considers a replacement necessary, the

replacement must be appointed by the same shareholder who appointed the retired member or, if the latter shareholder is no longer among the three largest shareholders in terms of votes, by the shareholder who belongs to this group. If a shareholder, having appointed a certain member, has significantly reduced his holding in the company, and the nomination committee finds it appropriate in view of the possible need for continuity for the forthcoming AGM, the member must leave the nomination committee and the committee must offer the biggest shareholder who has not appointed a member to the committee the opportunity to appoint a new member. Nomination committee members do not receive remuneration from the company. Any expenses arising in connection with the nomination committee's work must be paid by the company on the condition that they are approved by the Chairman of the Board. The Nomination Committee ahead of the 2024 AGM was presented on 24 October 2023 and comprises:

- Claus Bjerre, Chairman of the Board
- Karl Tobieson, appointed by Linc AB
- Patrik Walldov, appointed by Anders Walldov (including direct ownership through Brohuvudet AB)
- Monica Åsmyr, appointed by Swedbank Robur Fonder

Board of Directors

Duties of the Board of Directors

After the Annual General Meeting, the Board of Directors is the company's highest decision-making body. The Board is also the company's highest executive body and representative of the Company. In addition, under the Swedish Companies Act, the Board is responsible for the Company's organisation, the administration of its affairs, the ongoing assessment of the Company's and Group's financial situation, and ensuring that the Company's organisation is designed such that the Company's accounting, asset management and the financial circumstances in other respects are satisfactorily controlled. The Chairman of the Board bears special responsibility for directing the work of the Board and making sure that the Board fulfils its statutory duties. The Board's assignments include setting forth the Company's overall goals and strategies, supervising major investments, ensuring satisfactory control of the Company's compliance with legislation and other regulations that apply to the Company's operations, and the Company's compliance with internal policy documents. The Board's assignments also include ensuring that the company's disclosures to the market and investors are characterised by openness and that they are accurate, relevant and reliable, as well as appointing, evaluating and if necessary dismissing the company's Chief Executive Officer. In accordance with the Swedish Companies Act, the Board has adopted written rules of procedure for its work that are evaluated, updated and re-adopted annually. The Board meets regularly according to a schedule set forth in the rules of procedure that includes certain fixed agenda items and other agenda items as necessary. The Chief Executive Officer has acted as rapporteur at all Board meetings, and other senior executives have acted as rapporteur depending on the issues discussed.

Composition of the Board of Directors

According to the company's articles of association, the Board must comprise at least three (3) and not more than six (6) members. A member is elected annually by the Annual General Meeting for the period until the next Annual General Meeting has been held. There is no limit for how long a member may sit on the Board. According to the Code, a majority of the Board members elected by the AGM should be independent in relation to the Company and Management. All Board members of Sedana Medical are deemed independent in relation to the Company and Management. All Board members including

Board attendance and fee

	Year elected	Attendance number of meetings in 2023 (11)	Board fee resolved by 2023 AGM (KSEK)	Attendance of audit committee meetings in 2023 (6)	Audit committee fee decided by the 2023 AGM (KSEK)	Independent in relation to:	
						Company	Shareholders
Chairman of the Board							
Claus Bjerre	2021	10	625	4	30	Yes	Yes
Board member							
Hilde Furberg	2022	11	250			Yes	Yes
Ola Magnusson	2005	11	250	6	30	Yes	Yes
Christoffer Rosenblad	2020	11	250	6	75	Yes	Yes
Eva Walde	2018	10	250			Yes	Yes
Tomas Eklund*	2014	4		2		Yes	Yes

*Resigned as chair in 2023.

the Chairman are also deemed independent in relation to the Company's largest shareholders. Sedana Medical thereby fulfills the Code's requirements for independence. As of the closing date of the financial year, the Company's Board consists of five members: Claus Bjerre (Chairman), Ola Magnusson, Ewa Walde, Christoffer Rosenblad and Hilde Furberg. For information concerning each member of the Board, see page 74.

Chairman of the Board

The Chairman of the Board is tasked with directing the work of the Board and ensuring that it is carried out effectively and that the Board fulfils its obligations. Through contacts with the CEO, the Chairman must observe the Company's development and make sure that the Board members are continuously provided with the information they need to monitor the Company's position, financial planning and development. Furthermore, the Chairman must consult the CEO on strategic matters and check that the Board's decisions are effectively executed. The Chairman of the Board is responsible for contacts with shareholders on ownership matters and for conveying the views of the shareholders to the Board. The Chairman does not take part in the operational work of the Board, nor is the Chairman part of company management.

The work of the Board

The Board follows written rules of procedure that must be reviewed annually and adopted at the Board meeting following election. Among other things, the rules of procedure govern the Board's working methods, assignments, decision-making within the Company, the Board's meeting procedures, the Chairman's tasks and the allocation of work between the Board and the CEO. Instructions regarding financial reporting and the CEO instructions are also set forth in connection with the meeting of the Board following election. In parallel with Board meetings, the Chairman of the Board and the CEO maintain a dialog concerning the administration of the company. The Board meets according to an annual timetable, and must hold at least five scheduled Board meetings between each AGM. The Chairman of the Board is responsible for evaluating the work of the Board including the efforts of individual members. This takes place through an annual, structured evaluation with subsequent discussions in the Board and Nomination Committee, where the evaluation is used as a tool to develop the work of the Board, and provide information for the Nomination Committee. The work of the Board was evaluated during the end of 2023, and the outcome has been discussed in the Nomination Committee.

Committees

The Board appoints an audit committee at its first meeting following election. The tasks of the Audit Committee are described in instructions for the Audit Committee. Within the

framework of the Board's work, the Audit Committee is to monitor the company's financial reporting and prepare matters relating to the company's financial reporting and auditing under Chapter 8, Section 49 b of the Swedish Companies Act and to fulfil the tasks that follow from EU Regulation No 537/2014. The company's audit committee at the balance sheet date for the financial year consists of Christoffer Rosenblad (chair), Claus Bjerre and Ola Magnusson. In 2023 the Board appointed a remuneration committee to discuss the tasks which, under the Code, are incumbent upon the remuneration committee, such as decisions concerning the remuneration and terms of employment of the senior management and proposals for guidelines for the remuneration of the Chief Executive Officer and senior executives, which the Board submits for resolution by the Annual General Meeting. The Company's remuneration committee at the balance sheet date for the financial year consists of Claus Bjerre (chair), Christoffer Rosenblad and Hilde Furberg. The remuneration committee held its first meeting in February 2024.

The CEO and other senior executives

The company's CEO is subordinate to the Board and, under the provisions of the Swedish Companies Act, takes care of day-to-day company administration in compliance with the Board's guidelines and instructions. Measures that, with regard to the scope and nature of the Company's operations, are of an unusual nature or of great significance do not fall within day-to-day administration and must as a rule be prepared and presented to the Board for a decision. The company's CEO must also take necessary measures to ensure that the company's accounting records are completed in compliance with the law and that administration of funds is performed in a satisfactory manner. The allocation of work between the Board and the CEO is described in the Board's rules of procedure and the written CEO instructions. The Board continually evaluates the Chief Executive Officer's work and the Chairman also initiated during the year a structured, annual CEO evaluation. In 2023, Johannes Doll was the Company's CEO. Sedana Medical's senior management otherwise consisted of Chief Financial Officer Johan Spetz, Chief Medical Officer Peter Sackey, Vice President Regulatory Affairs and QA Jessica Westfal, Supply Chain and Manufacturing Director Stefan Krisch, General Counsel Karolina Vilval, Chief Technology Officer Peter Fröberg (resigned from his position on 31 December 2023), Chief Commercial Officer Clarisa Mogollón and Uwe Veismann, General Manager Germany, Nordics and Benelux (took up duties on 1 July 2023).

Internal control and audit

Under the Swedish Companies Act, the Board is responsible for the company's organisation, the administration of its affairs, ongoing assessment of the company's and Group's financial situation, and ensuring that the company's organisation is

designed such that company's accounting, asset management and financial circumstances in other respects are satisfactorily controlled. The Board presents here the most important elements of the Company's system of internal control and risk management in connection with financial reporting. Internal control in Sedana Medical follows the established COSO framework, which consists of five components: control environment, risk assessment, control activities, information and communication, and follow-up.

Control environment

The control environment represents the basis of the Company's internal control, and contains the culture the Board and senior management work from, and that they communicate and convey to the business through internal regulations. Clear distribution of roles and responsibilities enables effective management of the risks to the business, among other things through the Board's rules of procedure and through instructions for the Chief Executive Officer. In operating activities the Chief Executive Officer is responsible for the system of internal controls required to create a control environment for material risks. The Chief Executive Officer reports regularly to the Board. Sedana Medical also has guidelines and policies regarding financial reporting, information management, etc. The Company's Board and management regularly review this system and update it where necessary.

Risk assessment

Effective risk management supports the business by enabling profitable business initiatives combined with good control of risk-taking. Sedana Medical's risk management process includes the entire business. Material risks that have been identified by the Company are described on pages 32–34. The risk management process contributes structure and a systematic approach to proactively identify and manage risks that may have an adverse impact on the ability of the business to achieve established targets and consequently affect the Company's financial position.

Control activities

Control activities are aimed at managing identified risks and contributing to good internal control and effectiveness. Control activities relating to financial reporting include approvals of decisions and transactions, account reconciliations and follow-up and analysis of outcomes. Control activities may be built into the Company's systems such as Netsuite and Aaro, or be manual.

Information and communication

Sedana Medical has information and communication paths internally and externally aimed at ensuring effective and correct provision of information, including regarding the Company's financial development. The guidelines for internal and external communication are described in Sedana Medical's information policy. Ultimately this entails making sure that the statutory and regulatory information duty is fulfilled and that investors receive correct information on time. The Board and its audit committee regularly receive financial reports pertaining to the Group's position and profit trend. The procedures for external provision of information are aimed at supplying the market with relevant, reliable and correct information about the Company's development and financial position. The Company's guidelines include how such information should take place, who is authorised to provide a particular type of information and when a logbook is to be kept.

Follow-up

The Board and the audit committee decide on monitoring of internal control, and the Company's CFO is responsible for internal control being maintained in accordance with what the Board has decided. The Board continuously assesses the information provided by the senior management, regarding both financial information and the effectiveness of internal control, including any proposals for improvement measures from the external auditor linked to the latter's examination of internal control. The Company's external auditor reports his or her findings and assessment of internal control to the audit committee.

Auditor

In its capacity as a public company, the Company is required to have at least one auditor for auditing of the Company's and consolidated annual accounts and accounting records and the administration of the Board and the Chief Executive Officer. The audit must be as detailed and comprehensive as generally accepted auditing standards require. The company's auditors are elected by the Annual General Meeting in compliance with the Swedish Companies Act. Accordingly, an auditor in a Swedish limited company is engaged by, and reports to, the Annual General Meeting and may not be guided in her work by the Board or any other senior executive. According to the company's articles of association, the Annual General Meeting must appoint at least one (1) and not more than two (2) auditors with not more than two (2) deputy auditors. The Company's current authorised public accountant is Leonard Daun from Öhrlings PricewaterhouseCoopers AB (PWC).

Internal audit

Sedana Medical to date has not found cause to set up a separate internal audit function within the financial area, as the company is relatively small in size and the constantly ongoing work on internal control has meant that awareness of internal control in the Group is considered high. The question of a separate internal audit function will be examined as the Company grows.

Remuneration of Board members, senior executives and auditor

The Board has appointed a remuneration committee to discuss the tasks incumbent on the remuneration committee under the Code. Remuneration for members of the Sedana Medical Board is resolved by the AGM. The Annual General Meeting held on 16 May 2023 passed a resolution concerning annual Board fees in the amount of SEK 625,000 to the Chairman, and SEK 250,000 to the other Board members. The Annual General Meeting also resolved on a fee to the members of the Audit Committee of SEK 75,000 to the Chairman and SEK 30,000 to each of the members. Remuneration to senior executives who are employees follows the Company's Guidelines for Remuneration of Senior Executives and may consist of basic salary, variable remuneration, pension and other benefits. In addition to his monthly salary, the CEO Johannes Doll has the right to an annual bonus amounting to not more than 70% of the basic salary. The bonus is linked to the Company's sales, its operating income before interest, taxes, depreciation and amortisation (EBITDA) and performance in relation to pre-determined targets. In addition to statutory pension, the Company sets aside an amount equivalent to 22 percent of the CEO's fixed monthly salary to an occupational pension scheme determined by the CEO. The mutual period of notice is 12 months. After the end of the notice period, severance pay is paid corresponding to 6 monthly salaries. In other respects, the CEO is subject to the usual terms of employment containing provisions on secrecy, non-competition and recruitment bans. The total remuneration of the auditor for the financial year 2023 was KSEK 914. Remuneration of the Company's accountant is paid on current account.

Financial information

Consolidated income statement

KSEK	Note	2023	2022
Net sales	4	153,867	122,865
Cost of goods sold	7	-44,886	-36,791
Gross profit		108,981	86,074
Selling expenses		-107,239	-112,469
Administrative expenses		-47,504	-57,473
Research and development expenses		-20,805	-19,944
Other operating income	8	31,473	13,319
Other operating expenses	9	-30,453	-15,394
Operating income	5, 6, 7	-65,547	-105,887
Profit/loss from financial items			
Financial income		15,873	48,300
Financial expenses		-9,345	-15,346
Net financial items	10	6,528	32,954
Profit/loss before tax		-59,019	-72,933
Income tax	11	-593	-574
Net income for the year		-59,612	-73,507
Earnings per share, calculated on earnings attributable to shareholders in the Parent Company:			
Before dilution	12	-0.60	-0.74
After dilution		-0.60	-0.74
Operating income		-65,547	-105,887
Amortisation of intangible assets		-15,452	-15,538
Depreciation of property, plant and equipment		-7,121	-7,211
EBITDA		-42,974	-83,138

Consolidated statement of comprehensive income

KSEK	Note	2023	2022
Net income for the year		-59,612	-73,507
Other comprehensive income			
Items that may be reclassified later to the income statement:			
Translation differences from operations abroad		451	-2,834
Other comprehensive income, net after tax		451	-2,834
Total comprehensive income		-59,161	-76,341
Total comprehensive income wholly attributable to shareholders in the Parent Company		-59,161	-76,341

Consolidated balance sheet

KSEK	Note	31 Dec 2023	31 Dec 2022
ASSETS			
Intangible assets			
Capitalised development expenditure	13	542,705	390,530
Concessions, patents, licences, etc.	14	3,326	2,849
Property, plant and equipment			
Plant and machinery	15	864	955
Equipment, tools, fixtures and fittings	16	2,551	4,492
Right-of-use assets	24	4,912	9,271
Financial assets			
Deferred tax assets	17	31	29
Other non-current assets		46	46
Total non-current assets		554,435	408,172
Inventories	18	42,975	38,597
Tax receivables		739	514
Accounts receivable	19	24,180	15,849
Prepaid expenses and accrued income	20	4,701	6,017
Other receivables		5,223	4,697
Short-term investments	28	150,624	-
Cash and cash equivalents	21	231,180	607,742
Total current assets		459,622	673,416
TOTAL ASSETS		1,014,057	1,081,588

KSEK	Note	31 Dec 2023	31 Dec 2022
EQUITY AND LIABILITIES			
Equity			
	22, 23		
Share capital		2,483	2,483
Other contributed capital		1,226,435	1,226,435
Translation reserve		-2,199	-2,650
Retained earnings including profit or loss for the year		-256,724	-197,113
Equity attributable to shareholders in the Parent Company		969,995	1,029,155
Provisions			
Deferred tax liabilities	17	7	0
Total provisions		7	0
Non-current liabilities			
Non-current lease liabilities	24, 27, 28	1,012	3,576
Total non-current liabilities		1,012	3,576
Current liabilities			
Current lease liabilities	24, 27, 28	3,294	5,167
Accounts payable	28	5,169	11,270
Tax liabilities	11	1,276	2,559
Other liabilities	25	8,471	6,929
Accrued expenses and prepaid income	26	24,833	22,932
Total current liabilities		43,043	48,857
Total liabilities		44,062	52,433
TOTAL EQUITY AND LIABILITIES		1,014,057	1,081,588

Consolidated statement of changes in equity

Equity attributable to shareholders in the Parent Company

KSEK	Share capital	Other contributed capital	Translation reserve	Retained earnings incl. net income for the year	Total
Opening equity at 1 Jan 2022	2,483	1,222,394	184	-123,606	1,101,455
Net income for the year	-	-	-	-73,507	-73,507
Other comprehensive income for the year	-	-	-2,834	-	-2,834
Comprehensive income for the year	-	-	-2,834	-73,507	-76,341
Transactions with shareholders in the Group					
Premium received on issue of warrants	-	4,628	-	-	4,628
Repurchase of warrants	-	-97	-	-	-97
Expenses for warrant programme	-	-490	-	-	-490
Total transactions with shareholders in the Group	-	4,041	-	-	4,041
Closing equity at 31 Dec 2022	2,483	1,226,435	-2,650	-197,113	1,029,155
Opening equity at 1 Jan 2023	2,483	1,226,435	-2,650	-197,113	1,029,155
Net income for the year	-	-	-	-59,612	-59,612
Other comprehensive income for the year	-	-	451	-	451
Comprehensive income for the year	-	-	451	-59,612	-59,161
Transactions with shareholders in the Group					
Total transactions with shareholders in the Group	-	-	-	-	-
Closing equity at 31 Dec 2023	2,483	1,226,435	-2,199	-256,724	969,995

Consolidated cash flow statement

KSEK	Note	2023	2022
Operating activities			
Operating income		-65,547	-105,887
Adjustments for non-cash items:			
Depreciation, amortisation and impairment		25,126	23,901
Exchange-rate differences		8,900	-863
Interest received		15,168	3,580
Interest paid		-215	-255
Income tax paid		-564	-583
Cash flow from operating activities before changes in working capital		-17,132	-80,108
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in inventories		-6,738	-27,504
Increase (-)/Decrease (+) in operating receivables		-6,254	7,494
Increase (+)/Decrease (-) in operating liabilities		-7,937	-15,315
Cash flow from operating activities		-38,061	-115,433
Investing activities			
Investments in intangible assets	13, 14	-168,373	-137,048
Investments in property, plant and equipment	15, 16	-515	-735
Investments in short-term investments		-465,417	-
Sale of short-term investments		312,348	-
Cash flow from investing activities		-321,957	-137,783
Financing activities			
Amortisation of leasing liabilities	24, 27	-4,857	-4,510
Premium received for warrant subscription	22	-	3,590
Expenses for warrant programme	22	-	-490
Repurchase of warrants		-	-97
Cash flow from financing activities		-4,857	-1,507
Cash flow for the year		-364,875	-254,722
Cash and cash equivalents at the beginning of the year		607,742	836,181
Exchange rate difference in cash and cash equivalents		-11,687	26,283
Cash and cash equivalents at the end of the year	21	231,180	607,742

Notes

NOTE 1 General information

Sedana Medical (publ), with corporate identity number 556670-2519, is a limited company registered in Sweden with domicile in Danderyd. The address of the head office is Vendevägen 89, SE-182 32 Danderyd, Sweden. The object of the company's operations is to develop, manufacture and sell medical devices and pharmaceutical products. 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 the fair value as they essentially refer to current receivables and liabilities, with which the discounting effect is insignificant.

NOTE 2 Significant accounting and measurement policies

The key accounting policies applied in the preparation of these consolidated financial statements are stated below. These policies have been applied consistently for all the periods presented, unless otherwise stated. The consolidated financial statements of Sedana Medical (publ) have been prepared in accordance with the Annual Accounts Act, RFR 1 Supplementary Accounting Rules for Groups, International Financial Reporting Standards (IFRS) and interpretations from the IFRS Interpretations Committee (IFRIC), as adopted by the EU.

Preparing reports in accordance with IFRS necessitates making a number of important estimates for accounting purposes. The management is also required to make certain assessments in applying the Group's accounting policies. The areas containing a high degree of assessment, which are complex or where assumptions and estimates are of material significance to the consolidated financial statements are stated in Note 3.

New and revised standards not yet adopted by the Group

None of the new or amended standards that have entered into force after 1 January 2023 have had a material impact on Sedana Medical's financial reporting.

Group accounting policies

Subsidiaries

Subsidiaries are companies over which Sedana Medical AB (publ) has a controlling influence. Controlling influence exists if Sedana Medical AB (publ) has influence over the object of investment, is exposed to or has the right to variable return from its commitment and can use its influence over the investment to affect return. In determining whether a controlling influence exists, account is taken of potential shares carrying voting rights and whether de facto control exists. Subsidiaries are included in the consolidated financial statements as of the date when the controlling influence is transferred to the Group. They are deconsolidated from the date on which the controlling influence ceases.

Transactions eliminated on consolidation

Intra-Group receivables and payables, income or expenses and unrealised gains or losses arising from intra-group transactions among Group companies are eliminated in their entirety in preparing the consolidated financial statements. Accounting policies for subsidiaries have been changed where appropriate to guarantee consistent application of the Group's policies.

Segment reporting

The most senior executive decision-maker in Sedana Medical (publ) is the Chief Executive Officer (CEO), as is it primarily the CEO who is responsible allocating resources and evaluating results. The assessment of the Group's segments is based on the financial information reported to the CEO. This information, as the basis for allocating resources and assessing the Group's results, concerns the Group as a whole. As the CEO follows up the business as a unit (a concept), the whole of the business is comprised of a single segment.

Translation of foreign currency

Functional currency and presentation currency

The Parent Company's functional currency is Swedish kronor (SEK), which is also the presentation currency for the Group. The financial statements for the Group are therefore presented in SEK.

Transactions and balance-sheet items in foreign currencies

Transactions in foreign currencies are translated to the functional currency at the exchange rate prevailing on the date of the transaction. Functional currency is the currency of the primary economic environments in which the companies operate. Monetary assets and liabilities in foreign currency are translated to the functional currency at the rate prevailing on the balance sheet date. Exchange-rate differences arising on translation are recognised in net income for the year. Non-monetary assets and liabilities recognised at historical cost are translated at the exchange rate prevailing on the transaction date.

Translation of foreign operations

Assets and liabilities in foreign operations are translated from the functional currency of the foreign operation to the Group's presentation currency, SEK, at the exchange rate prevailing on the balance-sheet date. Income and expense in a foreign operation are translated to SEK at an annual average exchange rate representing an approximation of the exchange rates prevailing at the time of the transaction concerned. Translation differences arising on translation of foreign operations are recognised in other comprehensive income and are accumulated in a separate component of equity, known as translation reserve.

Revenue

Sale of goods

The Group's revenue consists of medical devices and is principally made up of the sale of Sedaconda ACD and accessories. The Group also sells the pharmaceutical product Sedaconda (isoflurane) and gas analysers. The Group's performance obligation in its contracts is to provide the items specified in the contract. Whether any transport services represent a separate performance obligation depends on the terms of delivery, i.e. whether control of the product has passed to the customer before transport takes place. Revenue is recognised when control of the asset has been transferred to the customer. A receivable is recognised when control of the goods has been transferred to the customer as the remuneration at this time is certain and it is only the passage of time that is required before payment has to be made. No material financing component is deemed to exist at the time of sale, as the credit period is normally 30 days net. The transaction price principally consists of fixed price per sold quantity. There are also cash discounts and, to a limited extent, volume discounts based on accumulated sales over a 12-month period. Sales revenue is recognised based on the price in the contract, less calculated discounts. Volume discounts are calculated and recognised based on experience, using either expected value after an estimation of the most likely amount, and are recognised only to the extent that it is highly likely that no material reversal will arise.

Financial income and expense

The Group's financial income and expense include interest income and interest expense. Interest income or interest expense is recognised according to the effective interest method. The effective interest rate is the interest rate which exactly discounts the estimated future incoming and outgoing payments during the expected term of the financial instrument to the recognised gross value of the financial asset or the accrued acquisition value of the financial liability.

Employee benefits

Short-term employee benefits

Short-term employee benefits which are expected to be settled within 12 months after the accounting year-end are recognised as current liabilities at the undiscounted amount expected to be paid when the liabilities are settled. The expense is recognised in the statement of comprehensive income when the related services are received. A provision is recognised for the expected cost involved in profit-sharing and bonus payments where the Group has a legally binding or informal obligation to make such payments as a result of the performance of services obtained from employees, and the obligation can be measured reliably.

Defined-contribution pension plans

The Group has only defined-contribution pension plans. Defined-contribution pension plans are pension plans where the company's obligation is limited to the contributions the company has undertaken to pay. In such a case, the size of the employee's pension depends on the contributions the company has paid into the plan or to an insurance company, and the capital return yielded by the contributions. In consequence, actuarial risk (that benefits will be lower than expected) and investment risk (that assets invested will be insufficient to meet expected benefits) fall on the employee. The company's obligations relating to contributions to defined-contribution plans are recognised as an expense in net income for the year at the rate at which they are vested by employees providing services to the company during a period.

Share-related remuneration – Incentive programmes in the form of warrants

In some jurisdictions, Sedana Medical offers warrant programmes to employees. Participants pay a premium per warrant calculated using the Black-Scholes method by an independent institution. As the employees have paid market value for the warrants, there is no remuneration to expense. For some programmes, employees have received premium subsidy in the form of extra salary, and the cost of these premium subsidies is recognised over the vesting period of the warrants. The subsidy is repaid in whole or part if the employee leaves their employment during the three-year period.

Taxes

Income tax comprises current and deferred tax. Income tax is recognised in net income for the year, except when underlying transactions have been recognised under other comprehensive income or under equity, in which case the associated tax effect is recognised under other comprehensive income or under equity. Current tax is tax that is to be paid or received during the current year, based on the tax rates that were adopted or were adopted in practice on the balance sheet date. Current tax also includes adjustment of current tax attributable to previous periods.

Deferred tax is calculated according to the balance sheet method based on temporary differences between carrying amounts and the value of assets and liabilities for tax purposes. Temporary differences are not taken into account for the difference arising on initial recognition of assets and liabilities which are not business combinations which, at the time of the transaction, do not affect either net profit or loss or profit or loss for tax purposes. In addition, temporary differences attributable to shares in subsidiaries which are not expected to be reversed in the foreseeable future are not recognised. The valuation of deferred tax is based on how the underlying assets or liabilities are expected to be realised or settled.

Deferred tax is calculated using the tax rates and tax rules adopted or adopted in practice on the balance sheet date. Deferred tax receivables in respect of deductible temporary differences and loss carry-forwards are reported only insofar as it is likely that it will be possible for these to be utilised. The value of deferred tax assets is reduced when it is no longer deemed likely that they can be utilised. Any additional income tax arising in payment of dividend is recognised at the same time as the dividend is recognised as a liability. Deferred tax assets and tax liabilities are offset when there is a legal right to offset current tax assets and tax liabilities and when the deferred tax assets and the tax liabilities relate to taxes charged by one and the same tax authority and pertain to either the same taxpayer or a different taxpayer, where there is an intention to settle the balances through net payments.

Classification, etc.

Non-current assets essentially consist of amounts expected to be recovered or paid after more than twelve months, counting from the balance-sheet date, while current assets essentially consist of amounts expected to be recovered within twelve months counting from the balance-sheet date. Non-current liabilities essentially comprise amounts which Sedana Medical (publ) at the end of the reporting period has an unconditional right to decide to pay more than twelve months after the end of the reporting period. If Sedana Medical (publ) does not have such a right at the end of the reporting period, the amount of liability is recognised as a current liability.

Intangible assets

Research and development

All expenditure arising during the research phase is expensed as it arises. Expenditure on development (attributable principally to clinical projects, patents, medical device units), where research results or other knowledge are applied to bring about new or improved products or processes, are recognised as an intangible asset in the statement of financial position, when all the criteria below are met.

- It is technically feasible to complete the intangible asset so that it will be available for use;
- the intention is to complete the intangible asset and use or sell it;
- the company is able to use or sell the intangible asset;
- it is likely that the intangible asset will generate future financial benefits;
- necessary and adequate technical, financial and other resources are available to complete the development and to use or sell the asset;
- the expenditure attributable to the intangible asset can be calculated in a reliable manner.

The carrying amount includes all directly attributable costs, for example for materials and services, employee benefits and amortisation of patents and licences. Other expenditure on development which does not fulfil the criteria above is recognised in net income for the year as an expense when it arises.

Other intangible assets

Other intangible assets which have been acquired by the Group comprise concessions, patents and licences and are recognised at cost less accumulated amortisation and any impairment losses.

Amortisation methods

Amortisation is recognised in the statement of comprehensive income on a straight-line basis over the estimated useful lives of the assets. The useful life lives are reviewed at least annually. Intangible assets with definite useful lives are amortised from the time when they become available for use.

The estimated useful lives of the assets are:

- | | |
|---|------------|
| • Concessions, patents, licences and similar | 5–10 years |
| • Capitalised development expenses/
Clinical projects, medical devices | 5–10 years |

Property, plant and equipment

Property, plant and equipment is recognised in the Group at cost less accumulated depreciation and any impairment losses. Cost includes the purchase price and expenditure directly attributable to the asset in order to bring it into the position and condition necessary for it to be utilised in accordance with the purpose of the acquisition. The carrying amount of an item of property, plant and equipment is derecognised in the statement of financial position on its sale or disposal, and when no future financial benefit can be expected from the use or sale/disposal of the asset. Gains or losses arising from the sale or disposal of an asset consist of the difference between the sale price and the asset's carrying value, less direct selling expenses. Gains and losses are recognised as other operating income/expense.

Additional expenditure

Additional expenditure is added to cost only if it is likely that the future financial benefits associated with the asset will accrue to the company and the cost can be calculated reliably. All other additional expenses are reported as a cost in the period in which they arise.

Amortisation methods

Depreciation takes place on a straight-line basis over the estimated useful life of the asset.

Estimated useful lives:

- | | |
|---|-----------|
| • Plant and machinery | 3–5 years |
| • Equipment, tools, fixtures and fittings | 3–5 years |

The depreciation methods applied, residual values and useful lives are reviewed at the end of each year.

Financial instruments

The Group's financial assets and liabilities consist of the items cash and cash equivalents, short-term investments, accounts receivable and accounts payable.

Recognition and initial measurement

Accounts receivable are recognised when they are issued. Other financial assets and financial liabilities are recognised when the Group becomes a party to the contractual terms of the instrument. A financial asset or financial liability is measured on initial recognition at fair value plus transaction expenses directly attributable to the acquisition or issue. An account receivable without a significant financing component is measured at the transaction price.

Classification and subsequent measurement

Financial assets

On initial recognition, a financial asset is classified as measured at: accrued acquisition value; fair value through other comprehensive income; or fair value through profit or loss. The Group recognises all financial assets at accrued acquisition value.

Financial assets measured at accrued acquisition value

A financial asset is valued at accrued acquisition value if it fulfils both of the following conditions and has not been identified as measured at fair value through profit or loss:

- it is held under a business model, the objective of which is to hold financial assets for the purpose of obtaining contractual cash flows;
- the agreed terms for the financial asset give rise at particular times to cash flows which are only payments of principal and interest on the outstanding principal.

The subsequent measurement of financial assets measured at accrued acquisition value takes place at accrued acquisition value using the effective interest method. The accrued acquisition value is reduced by any impairment losses. Interest income, exchange gains and losses and impairment losses are recognised in profit or loss. Gains or losses arising on derecognition are recognised in profit or loss.

Accounts receivable

Accounts receivable are amounts attributable to customers regarding goods sold or services carried out in the ordinary course of business. Accounts receivable are classified as current assets. Accounts receivable are initially recognised at fair value. The Group holds accounts receivable for the purpose of collecting contractual cash flows.

Short-term investments

Short-term investments relate to cash and cash equivalents invested in what are known as deposits, with a term of 6 months. These are measured at accrued acquisition value and are converted to Swedish kronor at the rate prevailing on the closing date.

Cash and cash equivalents

Cash and cash equivalents for the most part consist of cash at financial institutions. Cash and cash equivalents are recognised at their nominal amount, which corresponds to fair value.

Financial liabilities

Financial liabilities are classified as measured at accrued acquisition value or fair value through profit or loss. The Group recognises all financial liabilities after initial recognition at accrued acquisition value with application of the effective interest method. Interest expenses and exchange gains and losses are recognised in profit or loss. Gains and losses on derecognition are also recognised in profit or loss.

Accounts payable

Accounts payable are financial instruments and pertain to obligations to pay for goods or services which have been acquired in the ordinary course of business from suppliers. Accounts payable are classified as current liabilities if they fall due within one year. If not, they are treated as non-current liabilities.

Derecognition in the statement of financial position

Financial assets

The Group derecognises a financial asset in the statement of financial position when the contractual rights to the cash flows from the financial asset cease, or if it transfers the right to receive the contractual cash flows through a transaction in which all risks and benefits of ownership have been materially transferred, or in which the Group does not transfer or materially retains all the risks and benefits of ownership and it does not retain control of the financial asset.

Financial liabilities

The Group derecognises a financial liability in the statement of financial position when the commitments stated in the contract are fulfilled, are cancelled or cease. The Group also derecognises a financial liability when the contractual terms are modified and the cash flows from the modified liability are materially different. In that case a new financial liability is recognised at fair value based on the modified terms. When a financial liability is derecognised, the difference between the carrying amount which has been derecognised and the payment which has been made (including transferred non-monetary assets and assumed liabilities) is recognised in profit or loss.

Leases

When a contract is entered into, the Group assesses whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract transfers the right during a particular period to determine the use of an identified asset in exchange for payment. Contracts may contain both lease and non-lease components. The Group distributes the payment under the contract to each component based on the stand-alone price.

Leases where the Group is lessee

The Group leases properties, vehicles and plant and equipment. The Group recognises a right-of-use asset and a lease liability at the commencement date of the lease. The right-of-use asset is measured initially at cost, which consists of the initial value of the lease liability plus lease payments made on or before the commencement date. The right-of-use asset is amortised on a straight-line basis from the commencement date to the earlier of the end of the period of use of the asset and the end of the lease period, which for the Group is normally the end of the lease period. The lease liability – which is divided into current and non-current portions – is measured initially at the present value of remaining lease payments during the estimated lease period. The lease period consists of the non-terminable period plus further periods in the contract if it is assessed as reasonably certain at the commencement date that these will be utilised. The lease payments are normally discounted.

The lease liability comprises the present value of the following payments during the estimated lease period:

- fixed payments, including in-substance fixed payments;
- variable lease payments linked to an index or a rate, initially measured using the index or rate prevailing at the commencement date.

The value of the liability is increased by the interest expense for the period concerned and is reduced by the lease payments. The interest expense is calculated as the value of the liability times the discount rate. The lease liability for the Group's premises with rent which is index-linked is calculated on the rent applicable at the end of the reporting period concerned. At this time the liability is adjusted, with corresponding adjustment of the carrying amount of the right-of-use asset. In a corresponding manner, the value of the liability and the asset is adjusted at the time when re-assessment is made of the lease term. This takes place at the time when the last termination date within the previously estimated lease term for rental contracts has passed, or when significant events occur or the circumstances have significantly changed in a way which is within the control of the Group and affects the current assessment of the lease term. No right-of-use asset or lease liability is recognised for leases which have a lease term of 12 months or less or with an underlying asset of low value, below SEK 50. Lease payments for these leases are recognised as an expense on a straight-line basis over the lease term.

Inventories

Inventories are measured at the lower of cost and net realisable value. The cost of inventories is calculated by application of the first-in first-out method (FIFO) and includes expenditure which has arisen in the acquisition of the inventories and transport of these to their current location and condition. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and to make the sale.

Impairments

Impairment of property, plant and equipment and intangible assets

Intangible assets which are not ready for use are not amortised but are tested annually for any impairment loss. Assets subject to amortisation are reviewed for decrease in value whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment is made in the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less selling costs and its value in use. In estimating impairment need, assets are grouped at the lowest levels at which there are materially independent cash flows (cash-generating units). For assets which have previously been impaired, a test of whether reversal should be carried out is performed on each balance sheet date.

Impairment of financial assets

The Group estimates future expected credit losses linked to assets recognised at accrued acquisition value. The Group recognises a credit reserve for such expected credit losses at each reporting date. For accounts receivable, the Group applies the simplified approach for credit reservation, that is to say the reserve will correspond to the expected loss over the whole life of the account receivable. In order to measure the expected credit losses, accounts receivable have been grouped based on shared credit risk characteristics and days past due. The Group makes use of forward-looking variables for expected credit losses.

Equity**Share capital**

Ordinary shares are classified as equity. Transaction expenses which can be directly attributed to issue of new ordinary shares are recognised, net after tax, in equity as a deduction from the issue proceeds.

Dividends

Dividends are recognised as a liability following approval by the Annual General Meeting.

Earnings per share

The calculation of basic earnings per share is based on the Group's net income for the year attributable to the Parent Company's owners and on the weighted average number of shares outstanding during the year. In calculating diluted earnings per share, the profit and the average number of shares are adjusted to take account of the effects of diluting potential ordinary shares, which during reported periods originate from warrants issued to employees. The dilution from the warrants is based on a calculation of how many shares hypothetically could have been purchased during the period at the redemption price. The shares which would not have been able to be purchased lead to dilution. Potential ordinary shares are treated as dilutive only during periods when it leads to a lower profit or greater loss per share.

Contingent liabilities

A contingent liability is disclosed when there is a possible commitment that arises from past events and whose existence is confirmed only by the occurrence or non-occurrence of one or more uncertain future events beyond the Group's control, or when there is a commitment that is not recognised as a liability or provision because it is not likely that an outflow of resources will be required or cannot be calculated with sufficient reliability.

Cash flow statement

The cash flow statement is prepared in accordance with IAS 7, Statement of Cash Flows, using the indirect method. The recognised cash flow includes only transactions involving inflows and outflows of cash. Cash and bank balances are classified as cash and cash equivalents.

Parent Company accounting policies**Basis of preparation of the reports**

Sedana Medical AB (publ), corporate identity number 556670-2519, is the Parent Company of the Group. RFR 2 requires the Parent Company to apply in its annual financial statements International Financial Reporting Standards (IFRS) as adopted by the EU, as far as this is possible under the Swedish Annual Accounts Act and the Swedish Pension Obligations Vesting Act, and with regard to the relationship between accounting and taxation. The recommendation sets out certain exceptions and supplements which are required with regard to IFRS.

The Parent Company applies the same policies as are presented in the consolidated financial statements, with the exception of the following. The policies have been consistently applied for all years presented, unless otherwise stated. Preparing reports in accordance with RFR 2 necessitates making a number of key accounting estimates. It is also required that the management make certain assessments in applying the Parent Company's accounting policies. The areas containing a high degree of assessment, which are complex or where assumptions and estimates are of material significance to the annual financial statements, are stated in Note 3 to the consolidated financial statements.

The Parent Company is exposed through its operations to a number of different financial risks: market risk (currency risk and interest-rate risk), credit risk and liquidity risk. The Parent Company's overall risk management is to endeavour to minimise potential unfavourable effects on the Group's financial results. For more information about financial risks, refer to the Group's Note 28.

Layout

The income statement and balance sheet follow the layout in the Annual Accounts Act. This means differences compared with the consolidated financial statements, principally regarding finance income and expenses, statement of comprehensive income, provisions and statement of changes in equity.

Group contributions

The alternative rule is applied in recognising Group contributions, which means that both Group contributions received and paid are recognised as appropriations. The tax effect is recognised in profit and loss.

Shares and participations in subsidiaries

Shares and participations in subsidiaries are recognised at cost less any impairments. Cost includes acquisition-related costs and any additional purchase considerations. Dividends received are recognised as finance income. If an amount is distributed exceeding the subsidiary's comprehensive income for the period or meaning that the book value of the net assets of the holding in the consolidated financial statements is less than the book value of the participations, it is an indication of an impairment loss.

When there is an indication that shares and participations in subsidiaries have decreased in value, a calculation of recoverable amount is made. If this is lower than the carrying amount, an impairment is made. Impairments are recognised on the line Profit/loss from participations in Group companies.

Financial instruments

Financial assets are classified in a different way in the Parent Company's balance sheet than in the consolidated balance sheet. The principles set out in IFRS 9 regarding when financial instruments are to be recognised in and derecognised from a statement of financial position are applied. Financial instruments are measured based on cost. The principles of impairment testing and expected credit loss provision in IFRS 9 are applied in calculating the net realisable value of receivables recognised as current assets. For a receivable which is recognised at accrued acquisition value at Group level, this means that the loss reserve recognised in the Group is also taken up in a legal entity. The principles of impairment testing and expected credit loss provision in IFRS 9 are applied as far as possible in assessing and calculating impairment loss for financial assets recognised as non-current assets. The simplified method is applied only to intra-group accounts receivable. The complete model is applied to other intra-group receivables. Interest income and interest expense are recognised according to the effective interest method. Dividend income is recognised when the company's right to receive payment of the dividend has been established, it is probable that the financial benefits associated with the dividend will accrue to the company and the dividend can be reliably measured.

Equity

When own development works are capitalised, a corresponding amount is transferred from non-restricted equity to a fund for development expenses which constitutes restricted equity. When capitalised amounts are amortised or impaired or disposed of, a corresponding amount is transferred from the fund for development expenses to non-restricted equity.

Deferred income tax

Amounts allocated as untaxed reserves constitute taxable temporary differences. However, because of the association between recognition and taxation, the deferred tax liability on untaxed reserves in a legal entity is recognised as a part of untaxed reserves. The appropriations in the income statement are also recognised including deferred tax.

Leases

All leases, whether finance or operational, are recognised as operational leases (rental contracts).

NOTE 3 Critical accounting estimates and judgements**Assessments and estimates in the financial statements**

The preparation of financial statements in accordance with IFRS requires the senior management to make assessments and estimates and to make assumptions that influence the application of the accounting policies and carrying amounts for assets, liabilities, income and expenses. The actual outcome may differ from these estimates and assessments. The estimates and assumptions are reviewed regularly. Changes to these estimates are reported in the period when the change is made if the change has only affected this period, or in the period when the change is made and future periods if the change affects both the current period and future periods. Assessments made by the senior management in application of IFRS which have a significant impact on the financial statements and estimates made which may result in material adjustments in the financial statements of the subsequent year are described in more detail below:

Capitalisation of development expenses

Capitalised development expenses are tested for impairment annually, and an assessment is made of whether there is a need for impairment of assets. The test, which is a calculation of the current value of future cash flows generated from the asset, is assessed and approved by the Board. The assets are reviewed monthly. When an asset is completed, a basis needs to be prepared with a confirmed final value of the asset and a proposed depreciation period for approval by the Board. If an assessment is made during the year that the asset has fallen in value, an impairment test is prepared and presented for a decision by the Board. The medical devices which at present are depreciated have been estimated to have a depreciation period of 5 years. The depreciation periods applied by the Group for capitalised development expenses may differ from the technical lifetime. If the asset is found not to fulfil the requirements for the impairment test, the asset carried on the balance sheet is carried wholly or partially as income.

Deferred tax

The valuation of loss carry-forwards and the ability of the company to utilise unused loss carry-forwards is based on the company's estimates of future taxable income in different tax jurisdictions and includes assumptions on whether costs which have not yet been the object of taxation are deductible. The Group for the time being recognises tax deficits, and no value for loss carry-forwards is recorded in the balance sheet. See also Group Note 11 regarding loss carry-forwards.

Inventories

Inventories are recognised at the lower of cost according to the first-in first-out principle and net realisable value. The value of inventories is adjusted by estimated decrease in value of expired articles and handling expenses. If net realisable value is lower than cost, a reserve is established for inventory obsolescence. The reserve at 31 December 2023 is KSEK 2,360 (KSEK 0). See also the Group's Note 18 regarding inventories.

Accounts receivable

The group has accounts receivable, primarily in the Swedish parent company, but also to some extent in foreign subsidiaries. The valuation of accounts receivable is based on assessment made by management. There is nothing to indicate that further write-downs of accounts receivable need to be made as at 31 December 2023. For further information on amounts and currencies for accounts receivable, credit loss reserve and maturity structure see Group Note 19.

NOTE 4 Net sales**Revenue by geographical region**

The table below shows revenue from external customers broken down by country, based on where customers are located:

KSEK	2023	2022
Sweden (Group domicile)	713	348
Germany (major market)	105,620	86,099
Other direct markets	35,836	21,378
Distributor markets	11,698	15,040
Total	153,867	122,865

Revenue per sales channel

The table below shows revenue from external customers broken down by sales channel:

KSEK	2023	2022
Direct sale markets	142,169	107,825
Distributor markets	11,698	15,040
Total	153,867	122,865

Non-current assets broken down by country

Non-current assets, other than financial instruments, and deferred tax receivables (there are no assets in connection with benefits after termination of employment or rights under insurance contracts), are broken down by country as follows:

KSEK	2023	2022
Sweden (Group domicile)	517,971	375,390
Ireland	34,053	29,078
Rest of the world*	2,334	3,629
Total	554,358	408,097

*Make up the rest of the world, in which no country is considered major.

The breakdown of non-current assets above has been based on ownership of the non-current asset.

NOTE 5 Employees, personnel expenses and remuneration of senior executives**Average number of employees**

	2023			2022		
	Total	Women	Men	Total	Women	Men
Parent Company						
Sweden	40	20	20	48	25	22
Spain	6	2	4	5	1	4
Total Parent Company	46	22	24	53	27	26
Group						
Ireland	3	2	1	3	2	1
France	6	3	3	5	2	3
Netherlands	3	–	3	3	–	3
Norway	–	–	–	1	1	–
USA	4	3	1	3	2	1
United Kingdom	4	2	2	4	2	2
Germany	14	8	7	13	7	7
Group total	79	38	41	86	43	43
Senior executives, at year-end						
Board of Directors	6	2	4	6	2	4
CEO and senior executives	8	3	5	9	3	6

Salary and other remuneration and social security expenses, including pension expenses

KSEK	Basic salary/ Board fee	Variable remuneration	Other benefits	Pension expense	Total
Salaries and other remuneration 2023					
Chairman of the Board Claus Bjerre ¹⁾	545	–	–	–	545
Chairman of the Board Thomas Eklund ²⁾	193	–	–	–	193
Board member Hilde Furberg	242	–	–	–	242
Board member Ola Magnusson	272	–	–	–	272
Board member Eva Walde	242	–	–	–	242
Board member Christoffer Rosenblad	317	–	–	–	317
CEO Johannes Doll	3,260	1,238	4	742	5,244
Other senior executives (8 persons)	10,755	1,460	406	2,810	15,431
Total	15,826	2,698	410	3,552	22,486
Salaries and other remuneration 2022					
Chairman of the Board Thomas Eklund	553	–	–	–	553
Board member Claus Bjerre	308	–	–	–	308
Board member Hilde Furberg ³⁾	150	–	–	–	150
Board member Bengt Julander ⁴⁾	42	–	–	–	42
Board member Ola Magnusson	203	–	–	–	203
Board member Eva Walde	208	–	–	–	208
Board member Christoffer Rosenblad	267	–	–	–	267
CEO Johannes Doll	3,147	1,111	4	717	4,979
Other senior executives (8 persons)	8,660	951	394	2,159	12,164
Total	13,538	2,061	398	2,876	18,874

1) Chairman of the Board from May 2023

2) Chairman of the Board until May 2023

3) Member of the Board from May 2022

4) Member of the Board until May 2022

Salaries and other remuneration and social security expenses

KSEK	2023				2022			
	Salaries and other remuneration	(of which bonuses)	Social security expenses	(of which pension expenses)	Salaries and other remuneration	(of which bonuses)	Social security expenses	(of which pension expenses)
Board members, Chief Executive Officer and other senior executives	18,934	(2,698)	9,038	(3,552)	15,998	(2,061)	8,975	(2,876)
Other employees	68,259	(4,509)	22,813	(9,716)	69,472	(3,750)	26,679	(9,716)
Total	87,193	(7,207)	31,851	(13,268)	85,470	(5,811)	35,655	(12,592)

KSEK	2023	2022
Salaries and other remuneration	87,193	85,470
Social security contributions	18,583	23,063
Pension expenses – defined-contribution plans	13,268	12,592
Total employee benefits	119,044	121,125

Remuneration of senior executives

Remuneration of senior executives who are employees may consist of basic salary, variable remuneration, pension and other benefits. In addition to his monthly salary, the CEO Johannes Doll has the right to an annual bonus amounting to not more than 70% of the base salary. The bonus is linked to the Company's sales, its operating income before interest, taxes, depreciation and amortisation (EBITDA) and performance in relation to pre-determined targets. In addition to statutory pension, the Company sets aside an amount equivalent to 22 percent of the CEO's fixed monthly salary to an occupational pension scheme determined by the CEO. The mutual period of notice is 12 months. After the end of the notice period, severance pay is paid corresponding to 6 monthly salaries. In other respects, the CEO is subject to the usual terms of employment containing provisions on secrecy, non-competition and recruitment bans.

For information on guidelines for remuneration of senior executives, see the section on corporate governance, pages 37–40.

For further information about warrants, see Note 23.

NOTE 6 Fee and reimbursement of expenses to auditors

KSEK	2023	2022
PwC		
Audit engagement	809	703
Auditing services other than the audit engagement	95	96
Tax advice	-	70
Other services	10	927
Total	914	1,796
Other auditors		
Audit engagement	297	313
Auditing services other than the audit engagement	-	-
Tax advice	-	-
Other services	-	-
Total	297	313
Total	1,211	2,109

NOTE 7 Operating expenses broken down by type of expense

KSEK	2023	2022
Goods for resale	39,892	31,637
Other external expenses	60,133	74,981
Personnel expenses	97,836	97,310
Depreciation	22,573	22,749
Total	220,434	226,677

NOTE 8 Other operating income

KSEK	2023	2022
Exchange gains on operating receivables/liabilities	31,048	13,314
Other	425	5
Total	31,473	13,319

NOTE 9 Other operating expenses

KSEK	2023	2022
Exchange losses on operating receivables/liabilities	30,043	15,267
Other	410	127
Total	30,453	15,394

NOTE 10 Net financial items

KSEK	2023	2022
Interest income	15,168	3,578
Exchange gains	705	44,722
Total financial income	15,873	48,300
Interest expense, other	-215	-255
Exchange losses	-9,130	-15,091
Total financial expense	-9,345	-15,346
Net financial items	6,528	32,954

NOTE 11 Tax**Current tax expense (-)/tax income (+)**

KSEK	2023	2022
Tax expense/tax income for the year	-564	-515
Adjustment of tax attributable to previous years	-22	-65
Total current tax	-586	-580
Deferred tax		
Change in deferred tax	-7	6
Total deferred tax	-7	6
Total recognised tax expense/tax income	-593	-574

Reconciliation of recognised tax

KSEK	2023	2022
Profit/loss before tax	-59,019	-72,933
Tax at current tax rate for Parent Company	12,158	15,024
Tax effect of:		
- non-deductible expenses	-172	-193
- non-taxable income	-	-
- other tax rates for foreign subsidiaries/branches	-1,229	-1,406
- increase in loss carry-forwards without corresponding capitalisation of deferred tax	-11,584	-14,501
- utilisation of previously non-capitalised loss carry-forwards	256	78
- tax relating to previous years	-22	-66
- deductible expenses which are not included in the result	-	490
- other	-	-
Recognised effective tax	-593	-574
Average effective tax rate (%)	1.0%	0.8%

The Group has tax loss carry-forwards of KSEK 294,500 (234,934). The loss carry-forwards are not time-limited.

NOTE 12 Earnings per share

Earnings per share is calculated by dividing net income for the year by a weighted average number of outstanding ordinary shares during the period. Sedana Medical has potential ordinary shares in the form of warrants. However, these have not yet given rise to any dilution effect for 2022 or 2023 as conversion to ordinary shares means a lower loss per share.

Measure of income used in the calculation of earnings per share

KSEK	Before dilution		After dilution	
	2023	2022	2023	2022
Profit attributable to shareholders in the Parent Company:				
Earnings per share, before and after dilution	-0.60	-0.74	-0.60	-0.74
Total	-0.60	-0.74	-0.60	-0.74

Weighted average number of ordinary shares

	2023	2022
Weighted average number of ordinary shares in calculation of earnings per share before dilution	99,336,960	99,336,960
Adjustment for calculation of earnings per share after dilution:		
Warrants	-	-
Weighted average number of ordinary shares and potential ordinary shares used as denominator in calculation of earnings per share after dilution	99,336,960	99,336,960

NOTE 13 Capitalised expenditure on development work and similar work

KSEK	31 Dec 2023	31 Dec 2022
Accumulated acquisition values:		
- At the beginning of the year	410,432	272,959
- Acquisitions	167,863	135,589
- Translation differences for the year	-276	1,884
- At the end of the year	578,019	410,432
Accumulated depreciation according to plan:		
- At the beginning of the year	-19,902	-4,758
- Depreciation for the year	-15,443	-14,944
- Translation differences for the year	31	-200
- At the end of the year	-35,314	-19,902
Carrying amount at the end of the year	542,705	390,530
The carrying amount above relates to:		
Development work within the medical sector	535,852	381,457
Other capitalised development expenses	6,853	9,073
Depreciation for the year by function:		
Cost of goods sold	-685	-807
Selling expenses	-13,188	-12,686
Administrative expenses	-1,265	-1,149
Research and development expenses	-305	-302

Total expenditure on research and development expensed during the period amounts to KSEK 20,805 (19,944).

Expenditure on development work is capitalised as it arises. Impairment testing of capitalised expenditure takes place annually and when there are indications of an impairment loss. Capitalised expenditure for development work has been impairment tested on the basis of budget and forecasts, where the first year in the forecast is based on the company's budget and the subsequent years have been restated with estimated rate of growth. The rate of growth has been produced internally, based on historical data, the management's combined experience and the management's best estimate of the company's development potential and market growth. The forecast cash flows have been computed at present value with a discount rate of 21 percent before tax. The most important variables in the forecast are market share and market growth, gross margins, selling expenses and investments. Recoverable amount, which in the Group is calculated as value in use, exceeds the carrying amount for all impairment-tested assets. The senior management's assessment is that no reasonable changes to the important variables and assumptions lead to the recoverable amount of the entity becoming lower than the carrying amounts.

To support the impairment tests, an overall analysis has been made of the sensitivity of the variables used in the model. An assumption of a rise in discount rate to 26 percent demonstrates that the recoverable amounts still exceed the carrying amounts. Other assumptions such as gross margin, investment needs and rate of growth have been assumed to be constant. Reasonable changes in these assumptions over time are assumed not to lead to any indication that the carrying amount cannot be justified.

NOTE 14 Concessions, patents, licences, trademarks and similar rights

KSEK	31 Dec 2023	31 Dec 2022
Accumulated acquisition values:		
- At the beginning of the year	11,803	8,670
- Acquisitions	511	1,459
- Translation differences for the year	-79	1,674
- At the end of the year	12,235	11,803
Accumulated depreciation according to plan:		
- At the beginning of the year	-8,954	-6,884
- Depreciation for the year	-9	-594
- Translation differences for the year	54	-1,476
- At the end of the year	-8,909	-8,954
Carrying amount at the end of the year	3,326	2,849

The income statement includes amortisation for the year as above wholly under Cost of goods sold.

NOTE 15 Plant and machinery

KSEK	31 Dec 2023	31 Dec 2022
Accumulated acquisition values:		
- At the beginning of the year	3,997	3,771
- Acquisitions	353	-
- Reclassifications	-	-
- Disposals	-	-15
- Translation differences for the year	-9	241
- At the end of the year	4,341	3,997
Accumulated depreciation according to plan:		
- At the beginning of the year	-3,042	-2,462
- Reclassifications	-	-
- Depreciation for the year	-447	-370
- Disposals	-	5
- Translation differences for the year	12	-215
- At the end of the year	-3,477	-3,042
Accumulated impairments:		
- At the beginning of the year	-	-
- Reclassifications	-	-
- Disposals	-	-
- Translation differences for the year	-	-
- At the end of the year	-	-
Carrying amount at the end of the year	864	955

NOTE 16 Equipment, tools, fixtures and fittings

KSEK	31 Dec 2023	31 Dec 2022
Accumulated acquisition values:		
- At the beginning of the year	13,036	12,089
- Acquisitions	162	735
- Disposals	-578	-72
- Reclassifications	-	-
- Translation differences for the year	-10	284
- At the end of the year	12,610	13,036
Accumulated depreciation according to plan:		
- At the beginning of the year	-8,544	-5,935
- Reclassifications	-	-
- Disposals	370	29
- Depreciation for the year	-1,903	-2,411
- Translation differences for the year	18	-227
- At the end of the year	-10,059	-8,544
Carrying amount at the end of the year	2,551	4,492

NOTE 17 Deferred tax

Deferred tax receivables and liabilities are broken down as follows:

KSEK	31 Dec 2023	31 Dec 2022
Deferred tax assets:		
Loss carry-forwards	-	-
Inventories	-	-
Lease liability	31	29
Deferred tax liabilities:		
Right-of-use asset	-7	-
Deferred tax assets (net)	24	29

KSEK	Loss carry-forwards	Lease liability	Inventories	Total
Deferred tax assets:				
At 1 January 2022	-	23	0	23
Recognised in the comprehensive income statement, 2022	-	6	-	6
At 31 December 2022	-	29	0	29
Recognised in the comprehensive income statement, 2023	-	2	-	2
At 31 December 2023	-	31	0	31

KSEK	Loss carry-forwards	Lease liability	Inventories	Total
Deferred tax liabilities:				
Recognised in the comprehensive income statement, 2023	-	-7	-	-7
At 31 December 2023	-	-7	0	-7

NOTE 18 Inventories

KSEK	31 Dec 2023	31 Dec 2022
Raw materials and consumables	5,544	792
Finished goods and goods for resale	37,431	37,805
Total	42,975	38,597

During the financial year, costs of materials were recognised in the income statement of KSEK 44,886 (KSEK 36,791) as cost of goods sold.

NOTE 19 Accounts receivable

KSEK	31 Dec 2023	31 Dec 2022
Accounts receivable	24,202	15,886
Less provision for expected credit losses	-22	-37
Accounts receivable – net	24,180	15,849

Group reserve for expected credit losses at 31 December 2023 totals KSEK 22 (37). Credit losses are generally low, one of the reasons for this being that the majority of the receivables are issued to public hospitals, where ability to pay is good and risk is low. The fair value of accounts receivable corresponds to their carrying amount, as the discounting effect is not significant. No accounts receivable have been pledged as security for any liability.

Recognised amounts, per currency, for Group accounts receivable are as follows:

KSEK	31 Dec 2023	31 Dec 2022
EUR	21,856	12,693
GBP	2,040	1,874
USD	0	1,003
SEK	207	170
NOK	64	103
DKK	13	6
Accounts receivable – net	24,180	15,849

The age analysis of the Group's accounts receivable is as follows:

	Expected level of loss in %	Recognised amount gross	Credit loss reserve
31 December 2023			
Not overdue	0%	2,603	–
Overdue 1–30 days	0%	13,456	–
Overdue 31–60 days	0%	2,780	–
Overdue 61–90 days	0%	1,484	–
Overdue more than 90 days	1%	3,878	-22
Total		24,201	-22

31 December 2022

Not overdue	0%	741	–
Overdue 1–30 days	0%	7,226	–
Overdue 31–60 days	0%	4,490	–
Overdue 61–90 days	0%	1,225	–
Overdue more than 90 days	2%	2,204	-37
Total		15,886	-37

NOTE 20 Prepaid expenses and accrued income

KSEK	31 Dec 2023	31 Dec 2022
Rent	505	772
Pension		15
Bonus	1,073	1,878
Insurance	687	814
Development expenditure	584	–
Software	1,439	1,377
Marketing, congresses	233	267
R&D material		36
Other	180	858
Total	4,701	6,017

NOTE 21 Cash and cash equivalents

KSEK	31 Dec 2023	31 Dec 2022
Bank deposits	231,180	607,742
Total	231,180	607,742

NOTE 22 Shareholders' equity

KSEK	Number of shares	Share capital	Other contributed capital
Share capital and other contributed capital			
At 1 January 2022	99,336,960	2,483	1,226,435
At 31 December 2022	99,336,960	2,483	1,226,435
At 31 December 2023	99,336,960	2,483	1,226,435

The share capital at 31 December 2023 consists of 99,336,960 ordinary shares with a quotient value of SEK 0.025.

NOTE 23 Warrants**Warrants 2022**

Programme	Position	Number of acquired warrants at the beginning of the year	Number of acquired warrants during the year	Number of lapsed warrants during the year	Number of bought-back warrants during the year	Number of warrants at the end of the year	Terms*	Exercise price (SEK)
2019/2022	CEO	-	-	-	-	-	1:1	35.56
2019/2022	Other senior executives	105,172	-	-105,172	-	-	1:1	35.56
2019/2022	Other employees	217,264	-	-217,264	-	-	1:1	35.56
2019/2022	Total	322,436	-	-322,436	-	-	1:1	35.56
<i>Exercise period 1 July 2022–30 November 2022</i>								
2020/2023	CEO	-	-	-	-	-	1:1	83.65
2020/2023	Other senior executives	4,000	-	-	-	4,000	1:1	83.65
2020/2023	Other employees	38,480	-	-	-11,920	26,560	1:1	83.65
2020/2023	Total	42,480	-	-	-11,920	30,560	1:1	83.65
<i>Exercise period 1 June 2023–30 September 2023</i>								
2020/2024	CEO	-	-	-	-	-	1:1	123.88
2020/2024	Other senior executives	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	Other senior executives	-	-	-	-	-	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	Other senior executives	-	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 1 June 2023–30 September 2023</i>								
Total	CEO	-	495,000	-	-	495,000		
Total	Other senior executives	134,372	231,606	-105,172	-	260,806		
Total	Other employees	378,996	98,341	-217,264	-11,920	248,153		
	Total	513,368	824,947	-322,436	-11,920	1,003,959		

Warrants 2023

Programme	Position	Number of acquired warrants at the beginning of the year	Number of acquired warrants during the year	Number of lapsed warrants during the year	Number of bought-back warrants during the year	Number of warrants at the end of the year	Terms*	Exercise price (SEK)
2020/2023	CEO	-	-	-	-	-	1:1	83.65
2020/2023	Other senior executives	4,000	-	-4,000	-	-	1:1	83.65
2020/2023	Other employees	26,560	-	-26,560	-	-	1:1	83.65
2020/2023	Total	30,560	-	-30,560	-	-	1:1	83.65
<i>Exercise period 1 June 2023–30 September 2023</i>								
2020/2024	CEO	-	-	-	-	-	1:1	123.88
2020/2024	Other senior executives	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	Other senior executives	-	-	-	-	-	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	Other senior executives	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	Other senior executives	260,806	-	-4,000	-	256,806		
Total	Other employees	248,153	-	-26,560	-	221,593		
	Total	1,003,959	-	-30,560	-	973,399		

* 1: 1 = 1 warrant = 1 share on conversion. All amounts are restated according to a 4:1 split, 27 May 2021

NOTE 24 Leases

Leases where the company is lessee

Group property, plant and equipment consists of both owned and leased assets.

Sedana Medical leases several types of assets: properties, vehicles and equipment and tools. No leases contain covenants or other restrictions beyond the security in the leased asset.

KSEK	31 Dec 2023	31 Dec 2022
Property, plant and equipment owned	3,415	5,447
Right-of-use assets	4,912	9,271
Total	8,327	14,718

Right-of-use asset

KSEK	Buildings	Vehicles	Equipment and tools	Total
At 1 January 2022	5,390	3,872	62	9,324
Depreciation during the year, 2022	-1,660	-2,541	-62	-4,263
New assets	1,149	3,061	-	4,210
At 31 December 2022	4,879	4,392	0	9,271
Depreciation during the year, 2023	-2,537	-2,594	-	-5,131
New assets	-	772	-	772
Closing balance, 31 December 2023	2,342	2,570	0	4,912

Lease liability

KSEK	31 Dec 2023	31 Dec 2022
Lease liability included in statement of financial position		
Current lease liabilities	3,294	5,167
Non-current lease liabilities	1,012	3,576
Total	4,306	8,743

For a maturity analysis of the lease liabilities, see Note 28 Financial risks and risk management in the section on liquidity risk.

Amount recognised in profit or loss

KSEK	2023	2022
Interest on lease liabilities	174	227
Depreciation	5,131	4,265
Variable lease payments not included in lease liability	976	1,120
Costs of short-term leases	27	12
Costs of leases of low value, not short-term leases of low value	34	60
Total	6,342	5,684

Amounts recognised in the cash flow statement

KSEK	2023	2022
Total cash flows attributable to leases	-7,201	-6,982

NOTE 25 Other current liabilities

KSEK	31 Dec 2023	31 Dec 2022
VAT	4,654	2,705
Employee withholding tax	1,967	1,997
Social security contributions	1,296	2,011
Liabilities to employees	535	27
Other liabilities	19	189
Total	8,471	6,929

NOTE 26 Accrued expenses and prepaid income

KSEK	31 Dec 2023	31 Dec 2022
Salaries, holidays, social security expenses	15,308	12,862
Lawyers' fees	404	-
Consultants' fees	1,605	3,940
Auditing	1,093	1,002
Transport	232	332
Development expenditure	4,890	2,909
Other	1,301	1,887
Total	24,833	22,932

NOTE 27 Changes in liabilities belonging to financing activities

KSEK	31 Dec 2021	Cash flow	Non-cash items		31 Dec 2022
			Exchange-rate differences	Newly signed leases	
Lease liability	8,874	-4,510	-261	4,640	8,743
Total	8,874	-4,510	-261	4,640	8,743

KSEK	31 Dec 2022	Cash flow	Non-cash items		31 Dec 2023
			Exchange-rate differences	Newly signed leases	
Lease liability	8,743	-4,857	-36	456	4,306
Total	8,743	-4,857	-36	456	4,306

NOTE 28 Financial risk and risk management

Financial instruments

	Financial assets measured at			Financial liabilities measured at accrued acquisition value	Total
	fair value through profit or loss	fair value through other comprehensive income	accrued acquisition value		
31 Dec 2023					
Accounts receivable			24,180		24,180
Short-term investments			150,624		150,624
Cash and cash equivalents			231,180		231,180
Total financial assets	-	-	405,984		405,984
Borrowing from credit institutions				-	-
Accounts payable				5,169	5,169
Accrued expenses				24,833	24,833
Total financial liabilities				30,002	30,002
31 Dec 2022					
Accounts receivable			15,849		15,849
Short-term investments			-		-
Cash and cash equivalents			607,742		607,742
Total financial assets	-	-	623,591		623,591
Borrowing from credit institutions				-	-
Accounts payable				11,270	11,270
Accrued expenses				22,932	22,932
Total financial liabilities				34,202	34,202

Classification and fair value

All financial instruments are measured at accrued acquisition value. Carrying amount of accounts receivable, short-term investments, cash and cash equivalents and accounts payable represents a reasonable approximation of fair value.

Financial risks and risk management

The Group is exposed to various types of financial risks through its operations.

Framework for financial risk management

The Group's treasury policy for management of financial risks has been approved by the Board and forms a framework of guidelines and rules in the form of risk mandates and limits on financing activities. Responsibility for the Group's financial transactions and risks is managed centrally by Group's financial function, which is within the Parent Company. The overarching objective for the financial function is to provide cost-effective financing and to minimise negative effects on Group earnings originating from market risks, contract risks, tax risks, currency risks, etc. The CFO, who is ultimately responsible for ensuring that the treasury policy is followed and that the risks are minimised, reports regularly to the Group audit committee, which is chaired by a member of the Board.

Currency risk

The company reports its financial position and earnings in Swedish kronor (SEK). On the other hand, a large proportion of the company's operating expenses and almost all revenue consist of euros. As a result, Sedana Medical is exposed to currency risks in relation to payment flows in and outside Sweden and the eurozone, such as fluctuations where the exchange rate changes from the time when an agreement is concluded until payment takes place under the agreement. This can lead to currency transaction losses or gains (transaction exposure), which the company cannot predict. Currency transaction losses could lead to significant adverse effects on the company's future operations, financial position and profits. In addition, comparability between periods is affected by changes in exchange rates.

Sensitivity analysis of currency risk

Risk	Change, %	Effect on income, KSEK	Effect on net assets, KSEK
Currency			
EUR/SEK	+/- 10%	2,951	5,841
USD/SEK	+/- 10%	295	30,368

Maturity analysis – Maturity structure of financial liabilities

KSEK	Within 1 year	1–2 years	2–3 years	3–4 years	4–5 years	More than 5 years	Total
31 December 2023							
Lease liabilities	3,294	823	189	-	-	-	4,306
Accounts payable	5,169	-	-	-	-	-	5,169
31 December 2022							
Lease liabilities	5,167	2,774	627	175	-	-	8,743
Accounts payable	11,270	-	-	-	-	-	11,270

Liquidity risk

The liquidity risk is the risk of the Group facing problems in fulfilling its obligations which are associated with financial liabilities. The Group monitors liquidity monthly in comparison to the tactical and strategic financial plan and prepares a liquidity plan weekly. The Group's strategic forecasts covering 5 years contain long-term liquidity planning. Liquidity planning is used to manage liquidity risk and the costs of financing of the Group. The objective is for the Group to be able to meet its financial commitments in both upturns and downturns without significant unpredictable costs and without risking the Group's reputation. The liquidity risks are managed centrally for the whole Group by the central financial department. Sedana Medical ensures short-term payment readiness by having good liquidity readiness in the form of cash resources. The Group's financial liabilities consist mostly of liabilities attributable to day-to-day operations with short maturities of between 30 and 60 days.

Credit risk

The Group's financial transactions give risk to credit risks towards financial counterparties. Credit risk or counterparty risk means the risk of loss if the counterparty does not fulfil its obligations. Sedana Medical's credit risk policy states that credit risk must be limited by only counterparties with good creditworthiness being accepted and through regulated agreements. There is a financial credit risk principally through the company's banks in different countries. Sedana Medical only uses large and well-established banks with a high credit rating in the country concerned, and locates cash and short-term investments in banks in stable jurisdictions, primarily Sweden. Commercial credit risk is limited by a homogeneous customer stock with good creditworthiness as 90% of the company's accounts receivable are issued to the public sector (direct sale). Credit risk is also assessed as low in relation to Sedana Medical's customers in the private sector (distributors). However, a more extensive credit risk assessment is made for these receivables. For maturity analysis of accounts receivable, see also Group Note 19.

Market risk

The largest single market risk for Sedana Medical is political. Changes in healthcare remuneration systems may have great effects on individual markets by grants being reduced or deferred to the future. This risk is limited by Sedana Medical operating in a large number of geographical markets.

NOTE 29 Related party transactions

Transactions with related parties take place on market terms. In 2021, Sedana Medical issued a loan amounting to KSEK 300 to Stefan Krisch, and at 31 December 2023 the receivable totalled KSEK 274. Stefan is member of the Sedana Medical management team. In 2021, a consultancy agreement was signed between Sedana Medical and Board member Claus Bjerre. In total, KSEK 200 relating to this agreement has been invoiced and settled since the agreement was signed.

Sedana Medical recognises remuneration and benefits to senior executives in accordance with IAS 19 Employee benefits. Further information can be found in Note 5 to the consolidated financial statements.

NOTE 30 Significant events after the end of the financial year

No significant events after the end of the financial year.

Parent Company income statement

KSEK	Note	2023	2022
Net sales	1, 2	153,767	122,726
Cost of goods sold	2, 5	-43,115	-34,092
Gross profit		110,652	88,634
Operating expenses	3, 4, 5, 8		
Selling expenses		-62,200	-68,360
Administrative expenses		-101,608	-112,498
Research and development expenses		-18,137	-16,927
Other operating income	6	43,665	30,757
Other operating expenses	7	-29,656	-15,238
Operating income		-57,284	-93,632
Profit/loss from financial items			
Financial income		18,701	48,965
Financial expenses		-9,183	-15,074
Net financial items	9	9,518	33,891
Income after financial items		-47,766	-59,741
Group contributions	10	11	0
Profit/loss before tax		-47,754	-59,741
Income tax	11	-	-
Net income for the year		-47,754	-59,741

Parent Company statement of other comprehensive income

KSEK	Note	2023	2022
Net income for the year		-47,754	-59,741
Other comprehensive income			
Items that may be reclassified later to the income statement:			
Translation differences from operations abroad		-17	-417
Other comprehensive income during the year, net after tax		-17	-417
Comprehensive income for the year		-47,771	-60,158

Parent Company balance sheet

KSEK	Note	31 Dec 2023	31 Dec 2022
ASSETS			
Intangible assets			
Capitalised development expenditure	12	512,707	365,470
Property, plant and equipment			
Plant and machinery	13	819	795
Equipment, tools, fixtures and fittings	14	2,345	4,066
Financial assets			
Participations in Group companies	15	404	404
Receivables in Group companies	16	36,874	34,518
Total non-current assets		553,149	405,253
Inventories	17	42,975	38,597
Tax receivables		124	4
Accounts receivable	18	21,807	14,102
Receivables in Group companies		60,603	49,893
Prepaid expenses and accrued income	19	4,451	5,824
Other receivables		4,234	4,072
Short-term investments		150,624	-
Cash and cash equivalents	20	215,921	587,909
Total current assets		500,739	700,401
TOTAL ASSETS		1,053,888	1,105,654

KSEK	Note	31 Dec 2023	31 Dec 2022
EQUITY AND LIABILITIES			
Equity			
21, 22			
Restricted equity			
Share capital		2,483	2,483
Fund for development expenditure		505,854	356,396
Non-restricted equity			
Share premium reserve		1,226,435	1,226,435
Retained earnings		-684,378	-475,162
Net income for the year		-47,754	-59,741
Equity attributable to shareholders in the Parent Company		1,002,640	1,050,411
Current liabilities			
Accounts payable		4,428	10,711
Liabilities to Group companies		18,170	18,092
Tax liabilities		1,066	2,301
Other liabilities	23	7,018	5,287
Accrued expenses and prepaid income	24	20,566	18,852
Total current liabilities		51,248	55,243
Total liabilities		51,248	55,243
TOTAL EQUITY AND LIABILITIES		1,053,888	1,105,654

Change in equity, Parent Company

Equity attributable to shareholders in the Parent Company

KSEK	Restricted equity		Non-restricted equity		Total
	Share capital	Fund for development expenditure	Share premium reserve	Retained earnings incl. net income for the year	Total equity
Opening equity at 1 Jan 2022	2,483	246,451	1,222,394	-364,800	1,106,529
Net income for the year	-	-	-	-59,741	-59,741
Other comprehensive income for the year	-	-	-	-417	-417
Comprehensive income for the year	-	-	-	-60,158	-60,158
Changes in the carrying amounts recognised directly in equity					
Premium received on issue of warrants	-	-	4,628	-	4,628
Repurchase of warrants	-	-	-97	-	-97
Expenses for warrant programmes	-	-	-490	-	-490
Total	-	-	4,041	-	4,041
Transfer between items in equity					
Capitalisation of development expenditure	-	109,945	-	-109,945	-
Total	-	109,945	-	-109,945	-
Closing equity at 31 Dec 2022	2,483	356,396	1,226,435	-534,903	1,050,411
Opening equity at 1 Jan 2023	2,483	356,396	1,226,435	-534,903	1,050,411
Net income for the year	-	-	-	-47,754	-47,754
Other comprehensive income for the year	-	-	-	-17	-17
Comprehensive income for the year	-	-	-	-47,771	-47,771
Changes in the carrying amounts recognised directly in equity					
Premium received on issue of warrants	-	-	-	-	-
Repurchase of warrants	-	-	-	-	-
Expenses for warrant programme	-	-	-	-	-
Total	-	-	-	-	-
Transfer between items in equity					
Capitalisation of development expenditure	-	149,458	-	-149,458	-
Total	-	149,458	-	-149,458	-
Closing equity at 31 Dec 2023	2,483	505,854	1,226,435	-732,132	1,002,640

Parent Company cash flow statement

KSEK	Note	2023	2022
Operating activities			
Operating income		-57,283	-93,632
Adjustments for non-cash items:			
Depreciation, amortisation and impairment		16,763	16,173
Exchange-rate differences		5,838	2,026
Other non-cash items		219	1,112
Total		-34,463	-74,321
Interest received		15,155	3,578
Interest paid		-40	-22
Income tax paid		-	-
Cash flow from operating activities before changes in working capital		-19,348	-70,765
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in inventories		-4,378	-27,504
Increase (-)/Decrease (+) in operating receivables		-17,325	-26,764
Increase (+)/Decrease (-) in operating liabilities		-3,994	-3,129
Cash flow from operating activities		-45,045	-128,162
Investing activities			
Investments in intangible assets	12	-161,995	-125,679
Investments in property, plant and equipment	13.14	-515	-718
Investments in short-term investments		-465,417	-
Sale of short-term investments		312,348	-
Cash flow from investing activities		-315,579	-126,397
Financing activities			
Premium received for warrant subscription	21	-	3,589
Expenses for warrant programme	21	-	-489
Repurchase of warrants	21	-	-97
Cash flow from financing activities		-	3,003
Cash flow for the year		-360,624	-251,556
Cash and cash equivalents at the beginning of the year		587,909	816,279
Exchange rate difference in cash and cash equivalents		-11,364	23,186
Cash and cash equivalents at the end of the year	20	215,921	587,909

Parent Company notes

NOTE 1 Net sales**Revenue by geographical region**

The table below shows revenue from external customers broken down by country, based on where customers are located:

KSEK	2023	2022
Sweden (Group domicile)	713	348
Germany (major market)	105,620	86,099
Other direct markets	35,736	21,239
Distributor markets	11,698	15,040
Total	153,767	122,726

For information concerning intra-group sales, see Note 2.

NOTE 2 Intra-Group purchases and sales

KSEK	2023	2022
Sale of goods relating to Group companies	7,301	6,306
Operating income concerning services relating to Group companies	12,066	18,423
Purchase of goods relating to Group companies	-8	9

NOTE 3 Employees, personnel expenses and remuneration of senior executives**Average number of employees**

	2023			2022		
	Total	Women	Men	Total	Women	Men
Parent Company						
Sweden	40	20	20	48	25	22
Spain	6	2	4	5	1	4
Total Parent Company	46	22	24	53	27	26
Senior executives, at year-end						
Board of Directors	5	2	3	6	2	4
CEO and senior executives	8	3	5	10	3	7

Salaries and other remuneration and social security expenses

KSEK	2023				2022			
	Salaries and other remuneration	(of which bonuses)	Social security expenses	(of which pension expenses)	Salaries and other remuneration	(of which bonuses)	Social security expenses	(of which pension expenses)
Board members, Chief Executive Officer and other senior executives	18,125	(2,527)	8,927	(3,528)	15,998	(2,061)	8,975	(2,876)
Other employees	35,642	(2,934)	13,384	(4,826)	37,582	(1,602)	17,266	(6,361)
Total	53,767	(5,461)	22,311	(8,355)	53,580	(3,664)	26,241	(9,237)

KSEK	2023	2022
Salaries and other remuneration	53,767	53,580
Social security contributions	13,957	17,004
Pension expenses – defined-contribution plans	8,355	9,237
Total employee benefits	76,079	79,821

Remuneration of senior executives

Remuneration of senior executives who are employees may consist of basic salary, variable remuneration, pension and other benefits. In addition to his monthly salary, the CEO Johannes Doll has the right to an annual bonus amounting to not more than six monthly salaries. The bonus is linked to the Company's sales, its operating earnings before interest, taxes, depreciation and amortisation (EBITDA), the Company's cash and cash equivalents at year-end and performance in relation to pre-determined targets. In addition to statutory pension, the Company sets aside an amount equivalent to 22 percent of the CEO's fixed monthly salary to an occupational pension scheme determined by the CEO. The

mutual period of notice is 12 months. After the end of the notice period, severance pay is paid corresponding to 6 monthly salaries. In other respects, the CEO is subject to the usual terms of employment containing provisions on secrecy, non-competition and recruitment bans.

For information on guidelines for remuneration of senior executives, see the section on corporate governance, pages 37–40.

For further information about warrants, see Note 22.

NOTE 4 Fee and reimbursement of expenses to auditors

KSEK	2023	2022
PwC		
Audit engagement	809	703
Auditing services other than the audit engagement	95	96
Tax advice	0	70
Other services	10	927
Total	914	1,796
Other auditors		
Audit engagement	-	-
Auditing services other than the audit engagement	-	-
Tax advice	-	-
Other services	-	-
Total	0	0
Total	914	1,796

NOTE 5 Operating expenses broken down by type of expense

KSEK	2023	2022
Goods for resale	39,932	31,663
Personnel expenses	63,117	61,675
Depreciation	16,763	16,173
Other operating expenses	105,248	122,366
Total	225,060	231,877

NOTE 6 Other operating income

KSEK	2023	2022
Exchange gains on operating receivables/liabilities	31,189	12,329
Intra-group management fee	12,066	18,423
Other	410	5
Total	43,665	30,757

NOTE 7 Other operating expenses

KSEK	2023	2022
Exchange losses on operating receivables/liabilities	29,257	15,238
Other	399	-
Total	29,656	15,238

NOTE 8 Operating leases – Lessee

KSEK	2023	2022
Contracted future minimum lease payments for non-cancellable contracts fall due:		
- Within one year	3,215	4,779
- Between one and five years	467	3,952
Total	3,682	8,731
Expensed lease payments for the year	4,588	4,083
Of which rent for premises	3,436	3,011

NOTE 9 Net financial items

KSEK	2023	2022
Interest income, Group companies	2,836	1,930
Interest income, other	15,155	3,578
Exchange gains	710	43,457
Total financial income	18,701	48,965
Interest expense, other	-40	-22
Exchange losses	-9,143	-15,052
Total financial expense	-9,183	-15,074
Total	9,518	33,891

NOTE 10 Appropriations

KSEK	2023	2022
Group contributions paid	0	0
Group contributions received	11	0
Total	11	0

NOTE 11 Tax**Current tax expense (-)/tax income (+)**

KSEK	2023	2022
Tax expense/tax income for the year	-	-
Adjustment of tax attributable to previous years	-	-
Total current tax	-	-
Deferred tax		
Deferred tax on temporary differences	-	-
Total deferred tax	-	-
Total recognised tax expense/tax income	-	-

Reconciliation of recognised tax

KSEK	2023	2022
Profit/loss before tax	-47,754	-59,471
Tax at current tax rate for Parent Company	9,837	12,307
Tax effect of:		
- non-deductible expenses	-125	-138
- other tax rates for foreign subsidiaries/branches	-45	-11
- increase in loss carry-forwards without corresponding capitalisation of deferred tax	-9,923	-12,711
- utilisation of previously non-capitalised loss carry-forwards	256	63
- deductible expenses which are not included in the result	-	490
- other	-	-
Recognised effective tax	-	-

Unutilised loss carry-forwards for which no deferred tax receivable has been recognised total KSEK 241,205 at 31 Dec 2023 (31 Dec 2022: KSEK 194,038). The loss carry-forwards are not time-limited. Deferred tax receivable is not recognised as the Group has judged the criteria for recognising a deferred tax receivable in accordance with IAS 12 not to be met.

NOTE 12 Capitalised expenditure on development work

KSEK	31 Dec 2023	31 Dec 2022
Accumulated acquisition values:		
- At the beginning of the year	382,520	256,842
- Acquisitions	161,995	125,678
- Translation differences for the year	-	-
- At the end of the year	544,515	382,520
Accumulated depreciation according to plan:		
- At the beginning of the year	-17,050	-2,914
- Depreciation for the year	-14,757	-14,136
- Translation differences for the year	-	-
- At the end of the year	-31,807	-17,050
Carrying amount at the end of the year	512,707	365,470
The carrying amount above relates to:		
Development work within the medical sector	505,854	356,397
Other capitalised development expenses	6,853	9,073
Depreciation for the year by function:		
Selling expenses	-13,188	-12,686
Administrative expenses	-1,265	-1,148
Research and development expenses	-305	-302

NOTE 13 Plant and machinery

KSEK	31 Dec 2023	31 Dec 2022
Accumulated acquisition values:		
- At the beginning of the year	1,015	1,030
- Acquisitions	354	-
- Reclassifications	-	-
- Disposals	-	-15
- Translation differences for the year	-	-
- At the end of the year	1,369	1,015
Accumulated depreciation according to plan:		
- At the beginning of the year	-220	-195
- Reclassifications	-	-
- Depreciation for the year	-330	-30
- Disposals	-	5
- Translation differences for the year	-	-
- At the end of the year	-550	-220
Carrying amount at the end of the year	819	795

NOTE 14 Equipment, tools, fixtures and fittings

KSEK	31 Dec 2023	31 Dec 2022
Accumulated acquisition values:		
- At the beginning of the year	9,867	9,192
- Acquisitions	161	718
- Reclassifications	-	-
- Disposals	-578	-72
- Translation differences for the year	-1	29
- At the end of the year	9,449	9,867
Accumulated depreciation according to plan:		
- At the beginning of the year	-5,801	-3,803
- Reclassifications	-	-
- Depreciation for the year	-1,676	-2,006
- Disposals	370	29
- Translation differences for the year	3	-21
- At the end of the year	-7,104	-5,801
Carrying amount at the end of the year	2,345	4,066

NOTE 15 Shares and participations in Group companies

	Corporate identity number	Domicile and country of registration and operation	Share of equity directly owned by the Parent Company (%)	Share of equity directly owned by the Group (%)	Number of shares	Book value 31 Dec 2023	Book value 31 Dec 2022
Sedana Medical Ltd	IE551634	Naas, Ireland	100%		1	0	0
Sedana Medical Incentive AB	559109-8826	Danderyd, Sweden	100%		50,000	50	50
Sedana Medical Sàrl	809 876 865	Paris, France		100%	2,000	-	-
Sedana Medical Norway AS	822 363 202	Oslo, Norway	100%		30,000	33	33
Sedana Medical UK Ltd	NI659985	Belfast, United Kingdom	100%		1	0	0
Sedana Medical Germany GmbH	HRB250971	Geretsried-Gelting, Germany	100%		26,000	313	313
Sedana Medical Netherlands B.V.	76 605 434	Amsterdam, Netherlands	100%		1	0	0
Sedana Medical Inc.	86-3543115	Wilmington, USA	100%		100	8	8

KSEK	31 Dec 2023	31 Dec 2022
Accumulated acquisition values:		
Opening cost	404	404
Acquired participating interests	-	-
Reclassifications	-	-
Closing accumulated cost	404	404
Accumulated impairments:		
Opening accumulated impairments	-	-
Impairments for the year	-	-
Closing accumulated impairments	-	-
Closing carrying amount	404	404

NOTE 16 Receivables in Group companies

KSEK	31 Dec 2023	31 Dec 2022
Accumulated acquisition values:		
- At the beginning of the year	49,916	43,970
- Added receivables	2,803	1,957
- Deducted receivables	-492	3,989
- At the end of the year	52,227	49,916
Accumulated impairments:		
- At the beginning of the year	-15,398	-14,151
- Additional impairments	-	-
- Currency translation	45	-1,247
- At the end of the year	-15,353	-15,398
Carrying amount at the end of the year	36,874	34,518

Accumulated impairments relate to impairment of intra-group receivables as a result of the restructuring of the Group implemented at the end of 2020.

NOTE 17 Inventories

KSEK	31 Dec 2023	31 Dec 2022
Raw materials and consumables	5,544	792
Finished goods and goods for resale	37,431	37,805
Total	42,975	38,597

During the financial year, costs of materials were recognised in the income statement of KSEK 39,932 (KSEK 31,663) as cost of goods sold.

NOTE 18 Accounts receivable

KSEK	31 Dec 2023	31 Dec 2022
Accounts receivable	21,829	14,124
Less provision for expected credit losses	-22	-22
Accounts receivable – net	21,807	14,102

The fair value of accounts receivable corresponds to their carrying amount, as the discounting effect is not significant.

No accounts receivable have been pledged as security for any liability.

Recognised amounts, by currency, for Parent Company accounts receivable are as follows:

KSEK	31 Dec 2023	31 Dec 2022
EUR	19,482	10,946
SEK	207	170
GBP	2,040	1,874
NOK	65	103
DKK	13	6
USD	-	1,003
Accounts receivable – net	21,807	14,102

NOTE 19 Prepaid expenses and accrued income

KSEK	31 Dec 2023	31 Dec 2022
Rent	805	757
Pension	-	15
Bonus	1,073	1,878
Insurance	649	710
Capitalised development expenditure	-	-
Software	1,408	1,377
Marketing, congresses	20	267
Other	496	820
Total	4,451	5,824

NOTE 20 Cash and cash equivalents

KSEK	31 Dec 2023	31 Dec 2022
Bank deposits	215,921	587,909
Total	215,921	587,909

NOTE 21 Shareholders' equity

KSEK	Number of shares	Share capital	Other contributed capital
At 1 January 2022	99,336,960	2,483	1,222,395
Warrant programmes	0	0	4,040
At 31 December 2022	99,336,960	2,483	1,226,435
At 31 December 2023	99,336,960	2,483	1,226,435

The share capital at 31 December 2023 consists of 99,336,960 ordinary shares with a quotient value of SEK 0.025.

NOTE 22 Warrants
Warrants 2022

Programme	Position	Number of acquired warrants at the beginning of the year	Number of acquired warrants during the year	Number of lapsed warrants during the year	Number of bought-back warrants during the year	Number of warrants at the end of the year	Terms*	Exercise price (SEK)
2019/2022	CEO	-	-	-	-	-	1:1	35.56
2019/2022	Other senior executives	105,172	-	-105,172	-	-	1:1	35.56
2019/2022	Other employees	217,264	-	-217,264	-	-	1:1	35.56
2019/2022	Total	322,436	-	-322,436	-	-	1:1	35.56
<i>Exercise period 1 July 2022–30 November 2022</i>								
2020/2023	CEO	-	-	-	-	-	1:1	83.65
2020/2023	Other senior executives	4,000	-	-	-	4,000	1:1	83.65
2020/2023	Other employees	38,480	-	-	-11,920	26,560	1:1	83.65
2020/2023	Total	42,480	-	-	-11,920	30,560	1:1	83.65
<i>Exercise period 1 June 2023–30 September 2023</i>								
2020/2024	CEO	-	-	-	-	-	1:1	123.88
2020/2024	Other senior executives	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	Other senior executives	-	-	-	-	-	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	Other senior executives	-	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 1 June 2023–30 September 2023</i>								
Total	CEO	-	495,000	-	-	495,000		
Total	Other senior executives	134,372	231,606	-105,172	-	260,806		
Total	Other employees	378,996	98,341	-217,264	-11,920	248,153		
Total	Total	513,368	824,947	-322,436	-11,920	1,003,959		

Warrants 2023

Programme	Position	Number of acquired warrants at the beginning of the year	Number of acquired warrants during the year	Number of lapsed warrants during the year	Number of bought-back warrants during the year	Number of warrants at the end of the year	Terms*	Exercise price (SEK)
2020/2023	CEO	-	-	-	-	-	1:1	83.65
2020/2023	Other senior executives	4,000	-	-4,000	-	-	1:1	83.65
2020/2023	Other employees	26,560	-	-26,560	-	-	1:1	83.65
2020/2023	Total	30,560	-	-30,560	-	-	1:1	83.65
<i>Exercise period 1 June 2023–30 September 2023</i>								
2020/2024	CEO	-	-	-	-	-	1:1	123.88
2020/2024	Other senior executives	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	Other senior executives	-	-	-	-	-	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	Other senior executives	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	Other senior executives	260,806	-	-4,000	-	256,806		
Total	Other employees	248,153	-	-26,560	-	221,593		
Total	Total	1,003,959	-	-30,560	-	973,399		

* 1:1 = 1 warrant = 1 share on conversion. All amounts are restated according to a 4:1 split, 27 May 2021

NOTE 23 Other current liabilities

KSEK	31 Dec 2023	31 Dec 2022
VAT	4,572	2,582
Employee withholding tax	1,490	1,525
Social security contributions	956	1,162
Liabilities to employees	-	18
Other liabilities	0	-
Total	7,018	5,287

NOTE 24 Accrued expenses and prepaid income

KSEK	31 Dec 2023	31 Dec 2022
Salaries, holidays, social security expenses	12,204	9,669
Consultants' fees	933	3,404
Auditing	829	739
Transport	232	332
Capitalised development expenditure	4,818	2,909
Other	1,550	1,799
Total	20,566	18,852

NOTE 25 Appropriation of profit or loss

SEK	
Funds available to the Annual General Meeting:	
Accumulated loss	-684,378,290
Share premium reserve	1,226,435,473
Net income for the year	-47,754,127
Total	494,303,056
The Board proposes that the available funds be appropriated as follows:	
Share premium reserve	1,226,435,473
Accumulated loss in new account	-732,132,417
Total	494,303,056

NOTE 26 Related party transactions

Transactions with related parties take place on market terms. In 2021, Sedana Medical issued a loan amounting to KSEK 300 to Stefan Krisch, and at 31 December 2023 the receivable totalled KSEK 274. Stefan is member of the Sedana Medical management team. In 2021, a consultancy agreement was signed between Sedana Medical and Board member Claus Bjerre. In total, KSEK 200 relating to this agreement has been invoiced and settled since the agreement was signed. For information concerning remuneration of senior executives and warrants, see Notes 5 and 23 to the consolidated financial statements.

NOTE 27 Significant events after the end of the financial year

For information concerning significant events after the end of the financial year, see Note 30 to the consolidated accounts, page 58.

Certification by the Board of Directors and the Chief Executive Officer

The Board of Directors certifies that this annual report provides a true and fair view of the Group's operations, financial position and results.

Danderyd, 15 April 2024

Claus Bjerre
Chairman of the Board

Hilde Furberg
Board member

Ola Magnusson
Board member

Christoffer Rosenblad
Board member

Eva Walde
Board member

Johannes Doll
President and CEO

Our auditor's report was submitted on 15 April 2024

Öhrlings PricewaterhouseCoopers AB

Leonard Daun
Authorised Public Accountant

Auditor's report

To the general meeting of the shareholders of Sedana Medical AB (publ),
corporate identity number 556670-2519

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of Sedana Medical AB (publ) for the year 2023 with exception of the Corporate Governance report on pages 37-40. The annual accounts and consolidated accounts of the company are included on pages 31-69 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 december 2023 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 december 2023 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Our audit approach

Audit scope

We designed our audit by determining materiality and assessing the risks of material misstatement in the consolidated financial statements. In particular, we considered where management made subjective judgements; for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits, we also addressed the risk of management override of internal controls, including among other matters consideration of whether there was evidence of bias that represented a risk of material misstatement due to fraud.

We tailored the scope of our audit in order to perform sufficient work to enable us to provide an opinion on the consolidated financial statements as a whole, taking into account the structure of the Group, the accounting processes and controls, and the industry in which the group operates.

Materiality

The scope of our audit was influenced by our application of materiality. An audit is designed to obtain reasonable assurance whether the financial statements are free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the consolidated financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall group materiality for the consolidated financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Key audit matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

Key audit matter**Capitalized Development Expenses**

The group's recognized capitalized development costs amounted to SEK 542 million. The item is material from a financial reporting perspective.

The group continuously conducts development work. The purpose of the projects is to develop new products and improve existing ones.

Significant accounting estimates include an assessment of whether the requirements for capitalization are met. As part of its impairment testing, the group needed to assess a number of factors, such as future cash flows. Due to the degree of estimation involved, it was our assessment that capitalized development expenditure is a key audit area. The group's annual report note 2 "Significant accounting and valuation principles", section Intangible assets, shows how the group has reported and valued the balance sheet item. Note 3 "Important estimates and judgments for accounting purposes" shows which judgments the group has made. The company's management has determined that there was no write-down need for the capitalized development expenses.

How our audit addressed the Key audit matter

Our audit procedures include among other things the following:

- We have obtained an understanding of Sedana Medicals processes for capitalizing development costs and subsequent valuation.
- We have examined a sample of the year's capitalized costs to obtain assurance that they qualify for capitalization.
- We have examined the company's impairment testing.
- We have examined information provided in the financial statements.

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-30 and 74-79. The report "Sedana Medical AB remuneration report 2023" for the Sedana Medical Group, published on the company's website on April 15, 2024 also constitutes other information. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Director's and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the

Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts. A further description of our responsibility for the audit of the annual accounts and consolidated accounts is available on Revisorsinspektionen's website: www.revisorsinspektionen.se/revisornsansvar. This description is part of the auditor's report.

Report on other legal and regulatory requirements

The auditor's examination of the administration of the company and the proposed appropriations of the company's profit or loss

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Director's and the Managing Director of Sedana Medical AB (publ) AB for the year 2023 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Director's and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Director's and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial

situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

A further description of our responsibility for the audit of the administration is available on Revisorsinspektionen's website: www.revisorsinspektionen.se/revisornsansvar. This description is part of the auditor's report.

The auditor's examination of the ESEF report

Opinion

In addition to our audit of the annual accounts and consolidated accounts, We have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for ABC AB (publ) for the financial year 2023.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report has been prepared in a format that, in all material respects, enables uniform electronic reporting.

Basis for Opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the Esef report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of Sedana Medical AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibilities of the Board of Director's (and the Managing Director)

The Board of Directors and the Managing Director are responsible for the preparation of Esef report in accordance with the Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the ESEF report.

The firm applies International Standard on Quality Management 1, which requires the firm to design, imple-

ment and operate a system of quality management including policies or procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design audit procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors (and the Managing Director), but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of assumptions made by the Board of Directors and the Managing Director.

The procedures mainly include a validation that the Esef report has been prepared in a valid XHTML format and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the consolidated statement of financial performance, financial position, changes in equity, cash flow and disclosures in the Esef report have been marked with iXBRL in accordance with what follows from the Esef regulation

The auditor's examination of the corporate governance statement

The Board of Directors is responsible for that the corporate governance statement on pages 37-40 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's auditing standard RevR 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act/ the Annual Accounts Act for Credit Institutions and Securities Companies/ the Annual Accounts Act for Insurance Companies.

Öhrlings PricewaterhouseCoopers AB, Torsgatan 21, 113 97 Stockholm, was appointed auditor of Sedana Medical AB by the general meeting of the shareholders on the 11 may 2023 and has been the company's auditor since the 19 may 2020.

Stockholm, April 15 2024

Öhrlings PricewaterhouseCoopers AB

Leonard Daun
Authorized Public Accountant

Board of Directors



Claus Bjerre

Born: 1971 **Nationality:** Danish

Position: Chairman of the Board and Member of the Board of Sedana Medical since 2021.

Education and work experience: Claus holds an M.Sc. from Copenhagen Business School and an MBA in strategy and economics from UCLA Anderson School of Management. He was CEO of Atos Medical 2014–2018. Atos Medical was sold by EQT to PAI Partners in 2016. From 2006 to 2014, Claus held many senior positions in Coloplast A/S, a Danish global medtech company that provides consumer products, most recently with responsibility for North America, Japan and Australia. Prior to Coloplast, he spent 10 years in corporate strategy, mergers and acquisitions and private equity in various sectors for McKinsey & Company, Nordic Capital and Mattel.

Other current appointments: Chairman of the Board of Clinisupplies Ltd., senior advisor to KKR & Co, Inc. and CEO at Eden Invest LLC.

Shareholding in Sedana Medical: No shareholding. Independent in relation to both the company and its management and the company's major shareholders.



Hilde Furberg

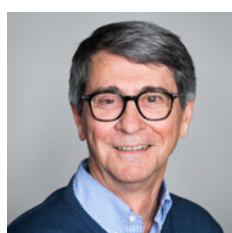
Born: 1958 **Nationality:** Norwegian

Position: Member of the Board of Sedana Medical since 2022.

Education and work experience: Hilde Furberg holds a master's degree in chemistry from Oslo University and is an independent consultant and professional Board member. She has broad experience of leadership from her 35 years in sales, marketing, strategy and management in Pharma/Biotech, from both small and large global businesses. Hilde has worked operationally in businesses such as Genzyme and Baxter, most recently as Senior President EMEA Rare Diseases for Sanofi Genzyme. In addition to this, Hilde has experience as a member of the boards of BerGenBio, Probi, Pronova, Clavis, Algeta, Tappin and CombiGene and as Chair of the Board of Blueprint Genetics.

Other current appointments: Industrial advisor to Investinor and member of the boards of PCI Biotech, Calliditas Therapeutics, OncoZenge, Bio-Me and Herantis.

Shareholding in Sedana Medical: 1,500 shares. Independent in relation to both the company and its management and the company's major shareholders.



Ola Magnusson

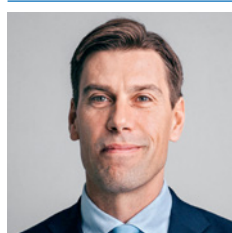
Born: 1948 **Nationality:** Swedish

Position: Member of the Board of Sedana Medical since 2005. Previously CEO of Sedana Medical (2005–2011).

Education and work experience: Ola holds an upper secondary school qualification in engineering specialising in chemistry from Gothenburg Technical Upper Secondary School. Ola has more than 25 years of experience in the pharmaceutical industry mainly in marketing, sales and different management positions, including 4 years in the US for Pharmacia in the 1980s and 1990s. Ola also has more than 20 years of experience in the medtech industry as CEO of Louis Gibeck AB where he was responsible for the company's listing on the OTC exchange in Stockholm and as Managing Director EMEA at Hudson RCI AB after its acquisition of Louis Gibeck AB. Started at Sedana Medical in 2005 and served as CEO up to 2011.

Other current appointments: Chairman of the Board of Eataway AB. Member of the Board of TransCutan AB and member of the boards of small family companies.

Shareholding in Sedana Medical: 4,312,098 shares privately and through Magiola Consulting AB. Independent in relation to both the company and its management and the company's major shareholders.



Christoffer Rosenblad

Born: 1975 **Nationality:** Swedish

Position: Member of the Board of Sedana Medical since 2020.

Education and work experience: Christoffer holds a master's degree in engineering from Chalmers University of Technology and an MSc in business and economics from the School of Business, Economics and Law at the University of Gothenburg. During the period 2012–2020 he was CFO of XVIVO Perfusion AB. During the period 2015–2017, he led XVIVO's North American operations and was resident in the United States. During the period from 2001 to 2012, he held senior positions in finance and strategic management at Novartis and LG Electronics.

Other current appointments: CEO of XVIVO Perfusion AB.

Shareholding in Sedana Medical: 10,000 shares. Independent in relation to both the company and its management and the company's major shareholders.



Eva Walde

Born: 1963 **Nationality:** Swedish

Position: Member of the Board of Sedana Medical since 2018.

Education and work experience: Eva holds a master's degree from the School of Economics in Gothenburg, Sweden. Over 20 years of experience in the pharmaceutical and medtech industries, mainly in marketing and sales as well as corporate management. Formerly VP Commercial Operations, International Region at Phadia / ThermoFisher Scientific, as well Strategic Affairs Director at Johnson & Johnson Nordic AB, Medical Device and Strategic Development Manager at Pfizer AB.

Other current appointments: Vice President Marketing at Olink Proteomics AB, member of the Board of Senzime AB since 2020, CEO and Chairman of the Board of her own company Movits Consulting AB and deputy member of the Board of Finnson & Partners AB.

Shareholding in Sedana Medical: 12,800 shares. Independent in relation to both the company and its management and the company's major shareholders.

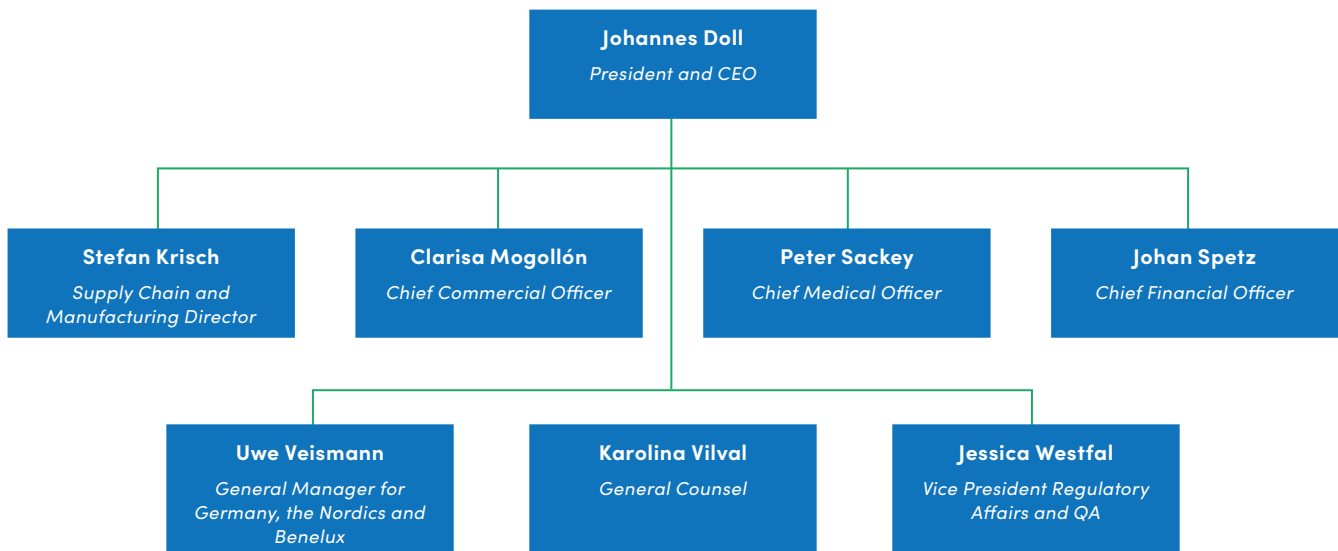
Organisation

Sedana Medical has staff with a broad background and experience in company management, marketing, sales, production and R&D from both the pharmaceutical and medical technology industries. Sedana Medical's head office is in Danderyd, Stockholm. The Group also has a number of employed product specialists in the Netherlands, Germany, France, the Nordics, the United Kingdom and Spain. During 2023, the average number of employees was 79. Through its long-term, determined efforts, the Group has created a strong organisation that attracts experienced personnel to the company. In recent years, Sedana Medical has made the organisation well prepared for the market launch of inhaled sedation therapy. To achieve its operational and financial objectives, Sedana

Medical has paid close attention to strengthening its product specialist organisation on current and future markets and boosting pharmaceutical expertise throughout the organisation.

Group management

The Group's management team consists of: President and CEO Johannes Doll, Supply Chain and Manufacturing Director Stefan Krisch, Chief Commercial Officer Clarisa Mogollón, Chief Medical Officer Peter Sackey, Chief Financial Officer Johan Spetz, General Manager Germany, Nordics and Benelux Uwe Veismann, General Counsel Karolina Vilval and Vice President Regulatory Affairs and QA Jessica Westfal.



Management team



Johannes Doll

Born: 1981

Nationality: German

Position: President and CEO since October 2021

Education and work experience: MBA, University of Texas, and Dipl. Kaufmann, WHU Otto Beisheim School of Management, Germany. During the period 2013–2021, Johannes was part of the management team at Orexo AB, most recently as Executive Vice President & Chief Commercial Officer. Before that, 2004–2013, Johannes worked at McKinsey & Company as an adviser to companies in the global pharmaceutical and medtech industries and also to venture capital companies.

Shareholding in Sedana Medical: 117,630 shares and 495,000 warrants.



Stefan Krisch

Born: 1974

Nationality: Swedish

Position: Supply Chain and Manufacturing Director since March 2021.

Education and work experience: Master's degree in mechanical engineering from the Royal Institute of Technology (KTH) in Stockholm, Sweden and Technische Universität Darmstadt, Germany. Studies in economics at Stockholm University. Stefan has around 20 years of experience of working in senior positions in various industries, principally in manufacturing, logistics and business development. Former CEO of Svensk Dos AB, CEO of Dipylon Medical AB and production manager at AB Gustavsberg. Founder of Eker Bicycles AB and Eker Production Ltd, Uganda.

Other current appointments: Chairman of the Board of Eker Bicycles AB and Eker Production Ltd, Uganda. Owner of K-Consulting (sole proprietorship).

Shareholding in Sedana Medical: 5,600 shares and 74,400 warrants.



Clarisa Mogollón

Born: 1977

Nationality: Swedish

Position: Chief Commercial Officer since 2023. In the management team since 2022, previously Head of Marketing.

Education and work experience: Clarisa holds an MBA from Heriot-Watt University, Scotland. Before starting at Sedana Medical, Clarisa worked as Sr VP Sales and Marketing at 3C Carbon Group AG, where she was also a member of the management team. Over the period 2012–2021, Clarisa was part of the management team at Stille AB, where she worked as VP Sales & Marketing and General Manager with global responsibility for customers such as Philips, Siemens, Getinge and GE Healthcare. Clarisa previously worked at Philips Healthcare 2009–2011, in various positions.

Shareholding in Sedana Medical: No holdings.



Peter Sackey

Born: 1971

Nationality: Swedish

Position: Medical Director of Sedana Medical since January 2018, employed since 2018.

Education and work experience: Peter obtained his degree in medicine at Karolinska Institutet, Stockholm in 1997. Before he started at Sedana Medical, he worked for more than 20 years in the Department of Perioperative Medicine and Intensive Care, Karolinska University Hospital and holds European qualifications in anaesthesia (DESA) and intensive care (EDIC). He defended his PhD thesis entitled "Isoflurane sedation in Intensive Care Unit patients" at Karolinska Institutet in 2006. Peter is an associate professor at Karolinska Institutet and has supervised several doctoral students in sedation in intensive care and pain monitoring, and continues to be active in research in intensive care.

Previous positions: Senior Consultant, Head of Neurocritical Care, Department of Perioperative Medicine and Intensive Care, Karolinska University Hospital.

Other current appointments: Associate professor, Department of Physiology and Pharmacology, Karolinska Institutet.

Shareholding in Sedana Medical: 237,468 shares and 69,073 warrants.



Johan Spetz

Born: 1984

Nationality: Swedish

Position: Chief Financial Officer since April 2022.

Education and work experience: Johan holds an M.Sc. from the Stockholm School of Economics. Over the period 2013–2021 Johan worked at the investment bank Pareto Securities, of which in 2015–2021 as partner and head of equities analysis in Stockholm. Before Pareto, Johan worked as a financial analyst at Goldman Sachs in London and New York, 2009–2013.

Shareholding in Sedana Medical: 115,073 shares and 69,073 warrants.



Karolina Vilval

Born: 1979

Nationality: Swedish

Position: General Counsel since August 2022.

Education and work experience: Law degree from Stockholm University. Karolina has worked as a lawyer in the pharmaceutical industry for more than 15 years. Before joining Sedana Medical, she worked at Oncopeptides as General Counsel. Karolina has previously worked at Gilead Sciences, Biovitrum and Swedish Orphan Biovitrum (Sobi) in various positions in Legal Affairs.

Shareholding in Sedana Medical: No holdings.



Jessica Westfal

Born: 1974

Nationality: Swedish

Position: Vice President Regulatory Affairs and QA since May 2020.

Education and work experience: Jessica holds an M.Sc. in analytical chemistry from Umeå University. She has previously worked at Unimedica AB (2006–2020), among other things as head of quality and product development, and at Astra-Zeneca AB (1998–2006).

Shareholding in Sedana Medical: No shares. 14,260 warrants. Related party 692 shares.



Uwe Veismann

Born: 1981

Nationality: German

Position: General Manager for Germany, the Nordics, Benelux

Education and work experience: Uwe has nurse training from Münster University since 2003 with qualifications in intensive care and anaesthesia from 2008 and with six years of experience from various medical departments. In addition, Uwe holds a Bachelor Professional of Pharmaceutical Consultancy (CCI) from October 2021. He began his career at Sedana Medical as Area Sales Manager in October 2009 and was appointed country manager for Germany in 2016, fulfilling the role of General Manager Germany since July 2023.

Shareholding in Sedana Medical: No holdings.

Literature references

Page	Footnote	Source:
13	1	Bellgardt, M., Bomberg, M., Dasch B. et al, Survival after longterm isoflurane sedation as opposed to intravenous sedation in critically ill surgical patients, Eur J Anaesthesiol 2015; 32: 18
13	2	Sackey, PV, Martling CR, Granath F, Radell PJ. Prolonged isoflurane sedation of intensive care unit patients with the Anesthetic Conserving Device. Crit Care Med., 2004;32(11): 2241 2246
13	3	L'Her, E., Lenaig, D., Pili, R., "Feasibility and Potential Cost/Benefit of Routine isoflurane Sedation Using an Anesthetic Conserving Device: a Prospective Observational Study", Respiratory Care, 2008.
13	4	Sackey, PV., et al. "Short and longterm followup of intensive care unit patients after sedation with isoflurane and midazolam – A pilot study." Critical care medicine 36.3 (2008): 801806
13	5	Sackey, PV, Martling CR, Granath F, Radell PJ. Prolonged isoflurane sedation of intensive care unit patients with the Anesthetic Conserving Device. Crit Care Med., 2004;32(11): 2241 2246
13	6	Heider et al. Does volatile sedation with sevoflurane allow spontaneous breathing during prolonged prone positioning in intubated ARDS patients? A retrospective observational feasibility trial. Ann. Intensive Care (2019) 9:41
13	7	Stephan A. Schug, Detlev Zech and Stefan Grand. Adverse Effects of Systemic Opioid Analgesics Drug Safety 199;27 (3):200213
13	8	Bellgardt, M., Bomberg, M., Dasch B. et al, Survival after longterm isoflurane sedation as opposed to intravenous sedation in critically ill surgical patients, Eur J Anaesthesiol 2015; 32:18
16	9	Based on publicly available data per country and Sedana Medical's own analyses
16	10	Based on an externally conducted survey of market opportunities
26	11	Sherman et al. Anesthesia & Analgesia 2012
26	12	Farrel et al., J Clin Mon Comput 2018l
26	13	5 Sackey et al., Crit Care 2004, GonzalezRodriguez et al., Rev Esp Anesthesiol Reanim 2014, Pickworth et al., Can J Anaesth 2013, HerzogNiescery et al., Minerva Anesthesiol 2018.
26	14	Holaday et al., Anesthesiology 1975

Glossary

ARDS Acute Respiratory Distress Syndrome, acute lung failure.

CRO, contract research organisation, a company that provides research services on a contractual basis. A CRO may provide services such as biopharmaceutical development, biological assay development, commercialisation, preclinical and clinical research.

DCP procedure, decentralised procedure, a parallel, decentralised procedure for marketing authorisation of a pharmaceutical product in more than one EU member state. It can be used for pharmaceutical products that do not need to be approved through the centralised procedure and that have not already been approved in any member state.

Dead space A reduction in dead space for ventilated patients is always desirable as excess dead space in relation to the patient's lung volume poses a risk of carbon dioxide being re-breathed.

EMA European Medicines Agency.

Phase III study performed on a very large group of patients to finally define how useful a pharmaceutical product is in treating the disease concerned. In phase I studies the drug candidate is used for the first time in humans to test safety, and in phase II studies the efficacy of the therapy and what dose is optimal are studied.

FDA US Food and Drug Administration.

General anaesthesia otherwise known as narcosis. An umbrella term for putting the patient to sleep far beyond consciousness.

INASED a randomised, controlled trial with 250 patients aimed at showing reduced incidence of delirium in inhaled sedation.

IND approval Investigational New Drug, authorisation to start clinical testing and transport a pharmaceutical product within the United States before it has market approval. A similar procedure exists in the EU.

Propofol infusion syndrome Propofol infusion syndrome (PRIS), a syndrome that can affect patients undergoing long-term therapy with high doses of propofol. It can lead to heart failure, rhabdomyolysis (disintegration of skeletal muscle cells), metabolic acidosis and kidney failure.

Volatile anaesthetic agents, for example isoflurane, sevoflurane and desflurane, can be used for both sedation and general anaesthesia.

Inhaled sedation sedation by delivery of a volatile anaesthetic agent via the respiratory tract.

Isoflurane a pharmaceutical substance that has been used for decades in general anaesthesia.

Mechanical ventilation assisted breathing in respiratory failure.

NDA, New Drug Application, application to the FDA for approval of a new pharmaceutical product for sale and marketing in the United States.

Paediatric Investigation Plan (PIP) a paediatric investigation plan is a development plan aimed at ensuring that necessary data are obtained through studies on children to support the approval of a pharmaceutical product for children.

PDCO the Paediatric Committee of the European Medicines Agency

Randomised controlled trial (RCT) a study design in which the participants are selected by chance, that it is to say by randomisation, either for the group receiving the treatment to be studied or for a control group.

Sedation is putting a person medically into a condition of reduced consciousness in order to alleviate anxiety, agitation and pain.

SESAR a randomised, controlled study covering 700 patients with acute lung failure, also known as Acute Respiratory Distress Syndrome (ARDS), aimed at showing that inhaled sedation has lung-protective properties.

SMRG, Sedana Medical Research Grant, a research grant established in 2019 and awarded annually for research in Sedana Medical's area.

Shareholder information, future events

Annual General Meeting 2024

The Annual General Meeting of Sedana Medical AB (publ) will be held on Wednesday 22 May 2024 at 2.00 pm at Vendevägen 89, Danderyd. Shareholders who wish to participate in the Annual General Meeting must be listed as a shareholder in the presentation of the share register prepared by Euroclear Sweden AB concerning the circumstances on 14 May 2024 and must give notice of participation in accordance with what is stated in the Notice convening the Annual General Meeting. Shareholders whose shares are registered in the name of a nominee through the trust department of a bank or similar institution must, to be entitled to participate in the Meeting, register their shares in their own name, so that the shareholder is listed in the presentation of the share register as per 16 May 2024. Such registration may be temporary (so-called voting rights registration), and request for such voting rights registration shall be made to the nominee, in accordance with the nominee's routines, at such time in advance as decided by the nominee. Voting rights registrations that have been made by the nominee no later than 16 May 2024 will be taken into account in the presentation of the share register. Additional instructions will be stated in the Notice convening the Annual General Meeting, which will be published in April. Registration of arrival at the meeting will begin at 1.30 pm.

Address details and corporate identity number

Sedana Medical AB (publ)
Svärdvägen 3A
SE-182 33 Danderyd, Sweden
Corporate identity number: 556670-2519

Financial calendar

Interim report 1st quarter 2024: 25 April 2024
Annual General Meeting 2024: 22 May 2024
Interim report 2nd quarter 2024: 23 July 2024
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