sedanamedical

ANNUAL REPORT 2022

Sale of the first bottles of Sedaconda® (isoflurane) in Europe

NICE recommends Sedaconda ACD as a cost-saving option

Inclusion of the first patient in the clinical programme in the United States

Fast Track Designation for inhaled sedation granted by the US FDA

Start of trading in the company's share on Nasdaq Stockholm in January 2023

2022

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In 2022, Sedana Medical took several important steps closer to our vision – to make inhaled sedation a global standard therapy for mechanically ventilated patients in intensive care.

The first patient was included in the clinical programme in the United States, NICE recommended Sedaconda ACD as a cost-saving option and the first bottles of Sedaconda (isoflurane) were sold in Europe.

In early 2023, the therapy was granted Fast Track Designation by the United States FDA and the company's share was listed on Nasdaq Stockholm.

Inhaled sedation is a simple, effective and predictable therapy

Through the unique medical device Sedaconda ACD (Anaesthetic Conserving Device), in combination with the pharmaceutical product Sedaconda (isoflurane), Sedana Medical provides a therapy for inhaled sedation that has potential to become a new global standard therapy for the sedation of mechanically ventilated patients in intensive care.

Sedana Medical's vision is for inhaled sedation to become a global standard therapy for patients in intensive care. With the positive results of the European pivotal study SED001, the foundation has been laid for establishing inhaled sedation as a simple, effective and predictable therapy for the sedation of mechanically ventilated intensive care patients.

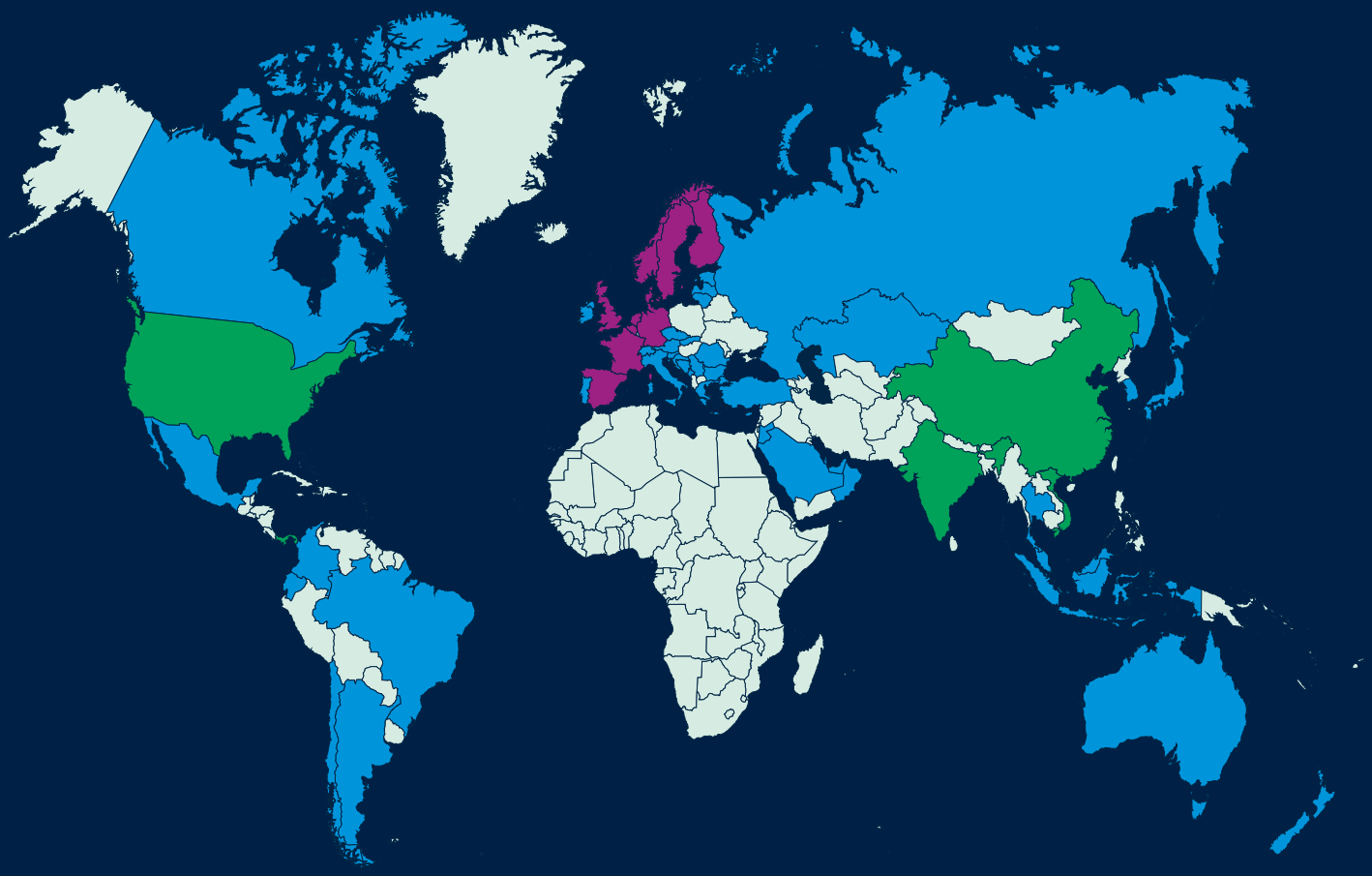
With the aim of obtaining US market approval for the therapy, Sedana Medical is conducting two pivotal studies, INSPiRE-ICU 1 and INSPiRE-ICU 2, in the United States. It is estimated that treatment of the last patient in the programme will be completed in the fourth quarter of 2023. Provided approval is granted by the US drug regulatory authority, the FDA, the goal is an American launch in early 2025.

Sedana Medical achieved sales of SEK 123 million in 2022, representing a decrease of 27 percent at constant exchange rates compared to 2021. With fewer patients in intensive care and hospital staff shortages after the Covid-19 pandemic, leading to reduced sales in 2022, the company's sales were 71 percent higher than in 2019 (the year prior to the pandemic). The company's largest market is Germany, which accounted for 70 percent of total sales in 2022. Sedana Medical also has direct sales in Benelux, France, the Nordic region, Spain and the United Kingdom. In other parts of Europe, as well as in Asia, Australia, Canada and South and Central America, the company has sales through distributors.

The company's financial goal is to attain revenue in 2025 in excess of MSEK 500 in Europe and an EBITDA margin of 40 percent when the company has attained a stable position in the United States.

Sedana Medical was established in 2005 in conjunction with the acquisition of the technology behind Sedaconda ACD. The company's head office is in Stockholm, Sweden. The company's share (ticker: SEDANA) was listed on Nasdaq First North Growth Market Stockholm in 2017, and trading in the share was switched to the Nasdaq main list in Stockholm in January 2023.

"The company's vision is for inhaled sedation to become a global standard therapy for patients in intensive care"



Sedana Medical in brief

Sedana Medical AB (publ) is a pioneer medtech 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.

8

million patients

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

Sedation of mechanically ventilated patients in intensive care

Almost half of all patients in an intensive care unit need help with breathing by means of a ventilator. Patients need to be sedated (lowering the level of consciousness) to cope with mechanical ventilation and other necessary therapies. Inhaled sedation meets several of the challenges posed by present-day standard therapy with intravenous drugs.

Sedaconda (isoflurane) was launched in Europe in 2022

Sedana Medical took several important steps in 2022. Among other things, sales of the company's pharmaceutical product Sedaconda (isoflurane) to clinics in Europe began, NICE in the United Kingdom recommended Sedaconda ACD as a cost-saving option and the pivotal studies in the United States were initiated.

Q1

- The National Institute for Health and Care Excellence (NICE) published positive guidelines for Sedaconda ACD as a cost-saving alternative to intravenous sedation.
- Sedaconda (isoflurane) was launched in Germany, and the very first bottles of Sedaconda (isoflurane) were delivered to clinics.
- A post-hoc-analysis of the Sedaconda study was presented as a poster at the world's largest congress for intensive care and emergency medicine, ISICEM.
- Sedaconda ACD received market approval in Brazil and Indonesia.
- Johan Spetz was appointed as the new CFO.

Q2

- The first patient was included in the company's clinical phase III programme, INSPiRE-ICU, in the United States.
- Sedaconda (isoflurane) was launched in the Netherlands, Sweden and Norway.

"NICE's positive guidelines on Sedaconda ACD was one of several favourable new developments in 2022"

Q3

- Sedaconda ACD was granted an MDR (Medical Device Regulation) certificate.
- Sedaconda (isoflurane) was granted market approval in Switzerland.
- Sedaconda (isoflurane) was launched in France and in Slovenia (via a distributor).

Q4

- Two posters on inhaled sedation were presented at the annual congress of the European Society of Intensive Care Medicine, ESICM Lives, in 2022.
- Sedaconda (isoflurane) received market approval in Poland, and market approval has therefore been received in all 15 countries covered by the DCP procedure.
- The Paediatric Committee of the EMA expressed a favourable opinion on the protocol for the paediatric study, enabling an accelerated conclusion.

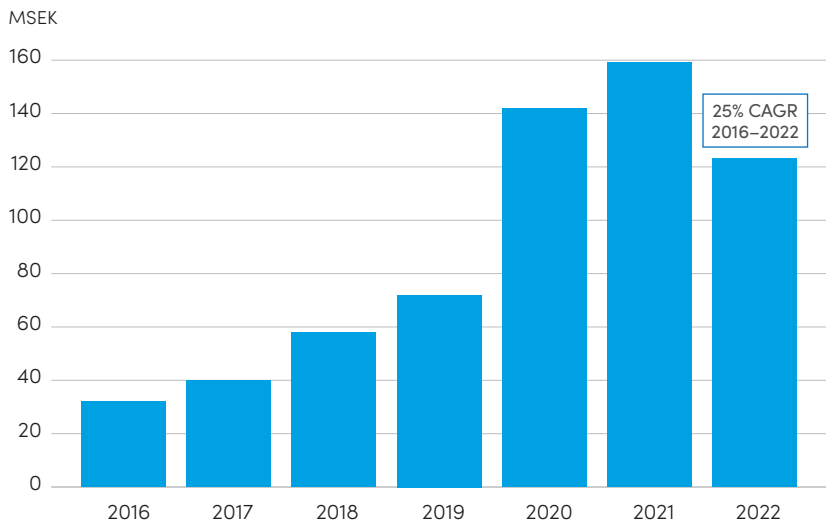
Events after the end of the financial year

- Trading in the company's share on Nasdaq Stockholm began
- The therapy was granted Fast Track Designation by the US FDA.

Key performance indicators for the Group

Amounts in KSEK (thousands of SEK), unless otherwise stated	2022	2021
Net sales	122,865	159,152
Gross profit	86,074	106,706
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-83,138	-50,093
Operating income (EBIT)	-105,887	-61,493
Net income for the period	-73,507	-57,966
Gross margin %	70%	67%
EBITDA %	-68%	-31%
Operating margin (EBIT) %	-86%	-39%
Profit margin %	-60%	-36%
Balance sheet total	1,081,588	1,167,580
Equity ratio %	95%	94%
Quick ratio %	1299%	1414%
Average number of employees	86	73

Sales development, full year



>40

countries

Sedaconda ACD is currently present in more than 40 countries

123

million SEK

Net sales in 2022 totalled SEK 123 million

71%

sales growth

Compared with 2019, which was the last year before Covid-19

Ukraine

The war in Ukraine has manageable consequences for Sedana Medical. The company does not have a presence in Ukraine, and has only insignificant distributor sales in Russia. The company's AMG-06 gas monitor is produced by a Russian company. The gas monitor makes only a minor contribution to Sedana Medical's revenue, but is important for the performance of therapy with Sedaconda products. The company has halted purchases of AMG-06 gas monitors since the invasion of Ukraine. In the short term, Sedana Medical has sufficient stocks to be able to meet customer demand, and therefore does not consider this to pose a major challenge to the business. In addition, the company offers gas monitors from another manufacturer. The company is also holding discussions with further manufacturers and therefore sees good prospects of continuing to supply gas monitors to its customers.

"In 2022 we made great progress with the launch of our pharmaceutical product Sedaconda (isoflurane) in Europe and started our clinical programme in the United States."

Significant progress on our two main priorities

In 2022 we made great progress in our two priority areas: We saw good progress in the commercialisation of our pharmaceutical product Sedaconda (isoflurane), which was launched in Europe, and we started our clinical programme in the United States, which is the market where we see the greatest potential. In addition, we were granted Fast Track Designation by the US FDA in January 2023.

2022 – a year characterised by a temporary decline in our market

After two exceptional years, 2020 and 2021, characterised by the global Covid-19 pandemic, during which Sedana Medical's sales reached new heights, 2022 was also affected by a number of external market factors. As well as the expected decrease in Covid-19 patients in intensive care units (ICUs) around the world, hospitals in our largest markets suffered from severe staff shortages, and there were also continued hygiene measures, which resulted in lower levels of community-acquired infections.

We consequently saw a marked decrease in the number of ventilated patients in intensive care units during the year. German intensive care units during the fourth quarter of 2022 can serve as an example. During that period, only 30 percent were reporting normal activity, the number of ventilated Covid-19 patients per day fell by 75 percent compared to 2021 and the total number of ICU patients per day fell by 18 percent.

In these market conditions, we achieved net sales of SEK 123 million for the full year 2022, down 23 percent (27 percent at constant exchange rates). Our sales were, however, 71 percent higher than for the same period in 2019, the last year not affected by Covid-19.

United States: Fast Track Designation and progress in our clinical studies

In early 2023 our development programme was granted Fast Track Designation in the United States by the US Food and Drug Administration (FDA). The purpose of the FDA's Fast Track Designation is to allow patients in the United States to quickly gain access to important therapies. Fast Track Designation provides many potential advantages, for example faster and more frequent communication with the FDA, as well as the possibility of ongoing review, priority review and accelerated approval.

During the year, our clinical studies INSPiRE ICU 1 and 2 moved forward, with the first patients being included in April 2022. We have 20 clinics that are actively recruiting for the study and are very pleased with the commitment and interest shown in the study by some of the most important opinion leaders in the United States in our area. Assuming positive study results and FDA approval according to schedule, we aim to launch in the United States in early 2025.

Positive news in the regulatory area and with regard to price/reimbursement in several countries

In the fourth quarter of 2022 Sedaconda (isoflurane) was approved in Poland, and we have consequently obtained national approval in all 15 countries that were included in our first European application. In February 2023, we obtained market approval in Italy, where our existing distributor will also sell the pharmaceutical product. Together with Switzerland, where we obtained approval during the third quarter, we now have approval in a total of 17 countries in Europe.

We are making progress with pricing and reimbursement processes in several countries in Europe and are greatly assisted by, for example, the Spanish intensive and critical care medicine organisation SEMICYUC issuing new therapy recommendations for sedation and delirium. In the new therapy algorithm, isoflurane is recommended as a first-line option, at the same level as propofol, for moderate and deep sedation. The positive guidelines from NICE (National Institute for Health and Care Excellence), which recommend our products for inhaled sedation and also confirm the significant health-economic benefits over intravenous sedation, are also of great assistance in these discussions.

Change of listing to the Nasdaq Stockholm Main Market

On 25 January 2023 we were given the opportunity to ring the opening bell at Nasdaq Stockholm, meaning that Sedana Medical has now been transferred from First North Growth Market to the Nasdaq Stockholm Main Market. With our growing global presence and the opportunities to enter the lucrative US market, the Sedana Medical share is attracting increasing interest from international investors. We believe that the Main Market offers greater opportunities to broaden our shareholder base internationally.

Focus for 2023: Growth in sales, continued cost-effectiveness and completion of our US studies

Now that we have come to the end of the transitional year of 2022 and are expecting a gradual transition to the 'new normal' after Covid-19, our focus is on implementing our main priorities. We are firmly resolved to lead Sedana Medical back to growth and closer to profitability, and will be working hard to complete patient recruitment for our studies in the United States this year.

I would like to take this opportunity to thank all our shareholders for their continued support during a turbulent year on the stock market. We have an exciting year ahead of us, and I look forward to continuing to update you on our progress.

Johannes Doll, *President and CEO*

HISTORY IN BRIEF

2023

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

The first patient is included in the pivotal studies in the United States.

2022

Launch of Sedaconda (isoflurane) in Europe.

NICE recommends Sedaconda ACD as a cost-saving option.

2021

Sedaconda (isoflurane) receives European market approval.

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.

2010

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

2005

Sedana Medical is established in Uppsala.

1999

Sedaconda ACD is tested clinically for the first time.

2003

Sedaconda ACD obtains CE mark.

The 1990s

The company Louis Gibeck AB develops a prototype of Sedaconda ACD that, 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 intensive care patients mechanically ventilated for longer than 24 hours, which is cost-effective for society.

Financial targets

Sedana Medical aims to achieve sales in excess of SEK 500 million in Europe by 2025 and an EBITDA margin of 40 percent when the company has attained a stable position in the United States.

Strategy

Over the next few years, Sedana Medical's strategy to attain its vision will focus on:

1. Successfully commercialising Sedaconda (isoflurane) in combination with Sedaconda ACD in the EU and in other selected markets.
2. Preparing for commercialisation in the important US market by registering Sedaconda ACD and Sedaconda (isoflurane) as a combination therapy.
3. Commercialising Sedaconda ACD through distributors in selected markets worldwide.

Sedation in ICU

The introduction of inhaled sedation into intensive care is a potential paradigm shift in the care of critically ill patients.

Formulation of problem

Intensive care units treat critically ill patients with serious, life-threatening diseases and injuries. Common conditions treated in intensive care include trauma (accidents), multiple organ failure, sepsis (blood poisoning) and acute pulmonary failure. These very critical conditions often mean that breathing support through a ventilator, known as mechanical ventilation, is necessary. Of the total number of patients admitted to intensive care units, between 30 and 50 percent need help with their breathing through mechanical ventilation[1].

Mechanical ventilation can be a traumatic and unpleasant experience. To help the patient better tolerate mechanical ventilation and relieve anxiety, agitation and pain, and to prevent the patient from self extubating by pulling the tube out of their airways, the patient usually needs to be sedated. Sedation is also necessary so that healthcare professionals are able to carry out the necessary therapies and examinations. The sedation of mechanically ventilated patients often continues for extended periods, usually two to five days.

Challenges with intravenous sedation

There are many challenges with intravenous sedation of intensive care patients. Many of the challenges are in essence attributable to the intravenous drugs accumulating in the body over time, resulting in adverse effects. Wake-up times are often long and unpredictable. It can take from 90 minutes up to 130 hours to wake up a patient[2], which means that therapy in ICU becomes longer than necessary and that extubation (removal of the breathing tube from the airways) is difficult to plan. Furthermore, the concentration of pharmaceutical product is difficult to monitor. Many cases of developed tolerance, withdrawal symptoms or agitation/delirium (20–35 percent of cases) occur[3].

The market for sedatives in intensive care

The current market for sedatives in intensive care consists mostly of intravenous drugs, with propofol, midazolam (based on benzodiazepine), dexmedetomidine and remifentanil dominating. These pharmaceutical products are usually generic, but still command relatively high prices, especially in the United States. Sedana Medical estimates that propofol has more than half the market and pharmaceutical products based on benzodiazepine have the next largest share of the market, but estimates that benzodiazepines are losing market share to propofol and dexmedetomidine.

All these side effects lead to prolonged therapy times in intensive care. In addition, delirium has been linked to increased mortality and impaired cognitive function several years after intensive care is completed. Intravenous sedatives are eliminated through the liver and/or kidneys, the function of which is often impaired in intensive care patients. This poses a risk of accumulation of pharmaceutical products, in turn leading to high mortality among long-term ventilated patients[4].

Propofol or benzodiazepines are most commonly used at present in the intravenous sedation of intensive care patients. Propofol is a well-established pharmaceutical product that should not, however, be used for more than a few days, to avoid the risk of extended time to wake-up and also of more severe side effects, including heart failure. In addition, there are clear recommendations that benzodiazepines should not be used for sedation in intensive care owing to adverse effects such as extended time to wake-up (like propofol) and risk of respiratory problems and delirium. These pharmaceutical products are nevertheless used, as the options are limited.

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.

Expectations for 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

Inhaled sedation offers several medical advantages over the well-established intravenous alternatives, including:

- **Wake-up times are short (10–20 minutes) and predictable**[5]. When therapy has been completed, it is important that the patient wakes up and can take part in rehabilitation as soon as possible. Early and predictable wake-up also means that planning of the clinical workflow can be improved and time to extubation can be shortened.
- **Depth of sedation is easy to control**, which reduces the risk of oversedation or undersedation and makes it easier to wake the patient to check neurological status. This reduces the need for computed tomography (CT) scans. When using intravenous sedation, relatively light sedation is beneficial to avoid accumulation and prolonged time to wake up. With inhaled sedation, the pharmaceutical is eliminated rapidly, and depth of sedation in itself therefore does not become problematic[6].
- **Side effects** such as hallucinations and delirium are less common[7].
- **Elimination via the lungs.** As pharmaceutical products for inhaled sedation are, in principle, eliminated only via the lungs, the requirement for metabolism in the liver or kidneys is minimal, meaning that inhaled sedation can also be used on patients with kidney or liver disease[8].
- **Reduced opioid use.** With the use of isoflurane, the dose of analgesics such as remifentanil and other opioids can be reduced by approximately 30 percent compared to intravenous sedation[9]. This means a reduced risk of dependency, withdrawal symptoms, delirium and impaired bowel function[10].
- **A higher proportion of spontaneous breathing** improves the prospects of maintained lung function during and after ventilator therapy[11].

Footnotes – see Bibliography on page 86.

Health-economic benefits

Based on data from the Sedaconda (SED001) study, Sedana Medical conducted a post-hoc analysis showing 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 to 4,000 per bed day and patient in Europe, intensive care patients are expensive for hospitals. The cost of a patient in intensive care is estimated to be three to five times higher than that of a patient in an ordinary hospital ward. By reducing the number of bed-days in intensive care, care costs can be lowered, while the patient's prognosis is better.

The daily cost of intravenous sedation is difficult to estimate and varies greatly from country to country. The cost calculation is made more difficult by the fact that different pharmaceutical products are often combined (for example propofol and midazolam) to achieve the desired effect and because dosages may vary depending on the patient's weight, condition and tolerance of the pharmaceutical product. The great number of factors means that the cost of intravenous sedation can vary sharply.

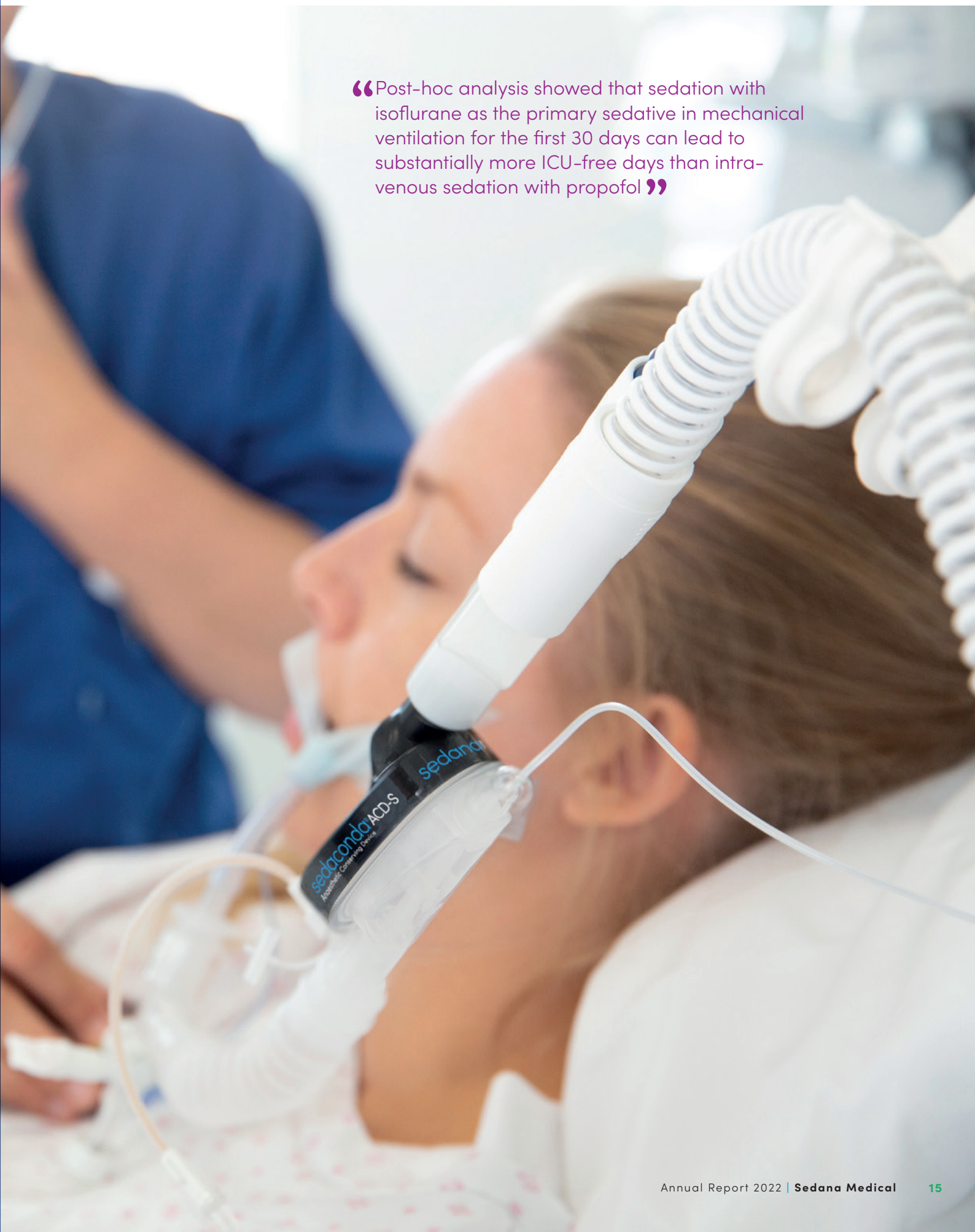
The health-economic benefits of inhaled sedation were further underlined in 2022 when the UK National institute for Health and Care Excellence (NICE) issued positive guidelines recommending Sedaconda ACD as a cost-effective alternative to intravenous sedation (in England and Wales) for delivery of inhaled sedation in intensive care. NICE's cost models show cost savings of around GBP 3,800 per adult patient compared to intravenous sedation (30 days timeframe for adult patients needing mechanical ventilation for 24 hours or longer in intensive care). The health-economic saving with inhaled sedation is a very important factor in the choice of sedation therapy.

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

The clinical phase III study Sedaconda (SED001) is the largest ever randomised study of inhaled sedation. The study shows 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, in comparison to propofol, Sedaconda, delivered via Sedaconda ACD 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.

The study was conducted during 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 of Sedaconda (isoflurane).

In August 2021, the results of the Sedaconda study were published in the highly respected scientific journal The Lancet Respiratory Medicine.



> “Post-hoc analysis showed that sedation with isoflurane as the primary sedative in mechanical ventilation for the first 30 days can lead to substantially more ICU-free days than intravenous sedation with propofol”

Unique patented technology in innovative therapy

Sedana Medical's therapy for inhaled sedation in intensive care consists of the medical device Sedaconda ACD (Anaesthetic Conserving Device), the pharmaceutical product Sedaconda (isoflurane), and accessories. The main device Sedaconda ACD is a unique and innovative device for simple and effective delivery of volatile anaesthetics.

Sedaconda ACD has been developed for simple delivery of volatile anaesthetic to mechanically ventilated patients. The device is intended for single use and has to be replaced every 24 hours.

The device works together with modern intensive care ventilators, syringe pumps and gas analysers. For most hospitals, this means they can avoid expensive new investments in equipment. Sedaconda ACD does not have any electrical components and is compatible with magnetic resonance imaging and computed tomography. Together with existing intensive care equipment, Sedaconda ACD represents an optimal solution for the sedation of severely ill patients.

Sedana Medical also sells the pharmaceutical product Sedaconda (isoflurane), which together with Sedaconda ACD represents the first and only approved therapy for inhaled sedation in intensive care in Europe.

In addition, Sedana Medical sells accessories that enable and simplify the use of Sedaconda ACD and Sedaconda (isoflurane).. These include, for example, syringes to supply Sedaconda ACD with the pharmaceutical product and the FlurAbsorb filter used to prevent the spread of volatile anaesthetics after use.

High reuse reduces consumption of pharmaceuticals

Sedaconda ACD enables around 90% of the pharmaceutical in the exhaled air to be retained in the filter and subsequently reused in the inhalation phase. The residual pharmaceutical product passes through the ventilator, through the exhaust line and is captured by the company's FlurAbsorb filter. The high reuse contributes to reducing the consumption of pharmaceutical product, and FlurAbsorb reduces spreading of gas after use. Studies confirm very low emissions, well below permitted limit values.

Sedaconda ACD –

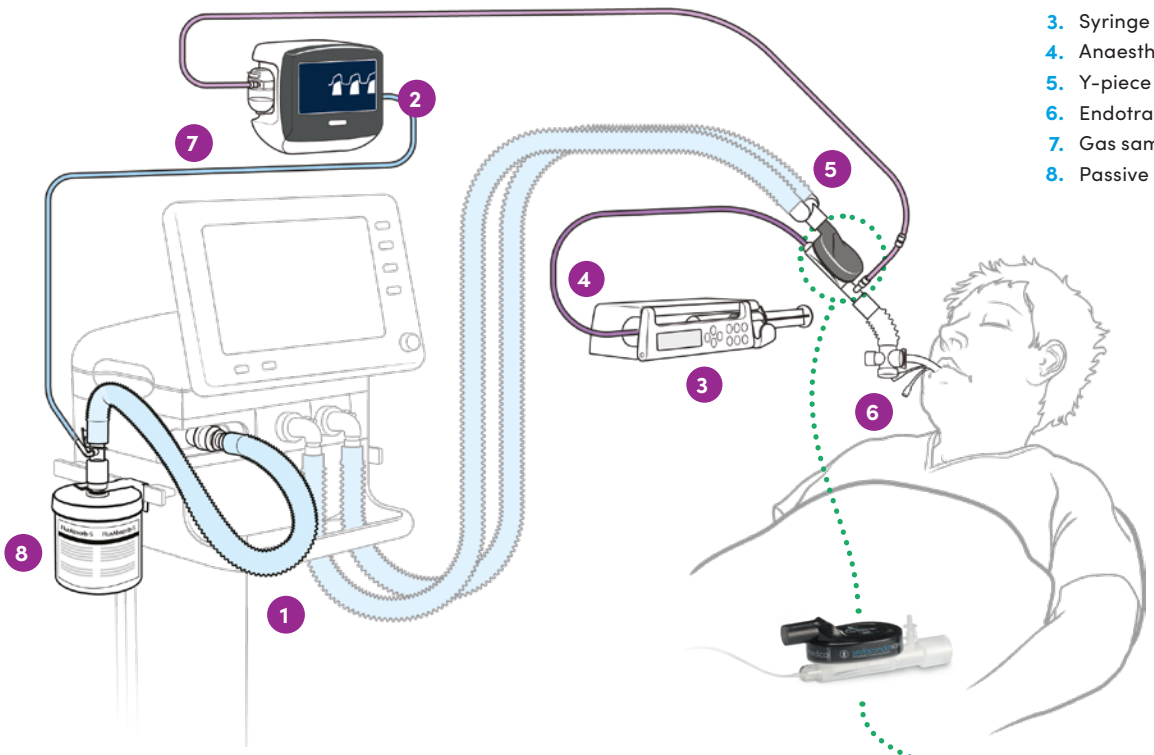
makes simple and effective delivery possible with a high level of re-use

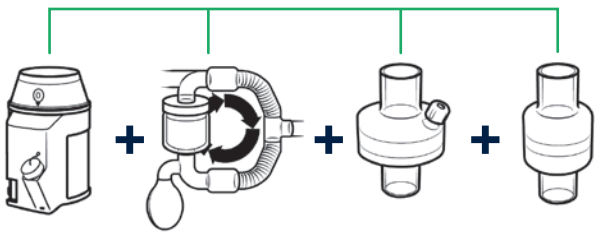
- Liquid anaesthetic is delivered to the Sedaconda ACD, where it is vaporised.
- During inhalation the vaporised pharmaceutical is transported to the patient.
- The pharmaceutical is rapidly distributed via the lungs and the blood circulation to the brain, where it exerts the desired effect.
- Pharmaceutical 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.

Footnotes – see Bibliography on page 86.

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 ET 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 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).

The Sedaconda ACD combines four functions for simple and effective delivery of volatile anaesthetics.

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.

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.

Every year, more than 30 million patients are admitted to intensive care units around the world. Many of them are in an extremely critical condition and need breathing support with the aid of a ventilator, known as mechanical ventilation. Around 40 percent of the total number of patients admitted to intensive care units need to be mechanically ventilated[12].

Sedation is usually necessary to enable mechanical ventilation and other necessary acute measures to be tolerated. Eight million patients a year need both mechanical ventilation and sedation and thus represent the target group for inhaled sedation. On average, these patients are sedated for two to five days.

Because the problems with intravenous sedation are less evident in sedation for shorter periods, intravenous sedation will continue to play a significant role. For extended periods of sedation, the shortcomings of intravenous sedation are greater, and there is a greater need for alternative methods of sedation.

> "By demonstrating significant benefits, the treatment is expected to gain ground and be included in national guidelines, and gradually become a new standard therapy throughout the world"

Towards a paradigm shift in intensive care

Sedana Medical's purpose is to improve patient life during and beyond sedation. In order to fulfil this purpose, the company is working to make inhaled sedation a standard therapy for mechanically ventilated patients in intensive care.

Sedana Medical will continue to secure 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, as well as gradually take the position of a new standard therapy throughout the world.

The competitive situation

Sedana Medical assesses the competition from other providers of inhaled sedation for intensive care to be very limited. As far as Sedana Medical is aware, there is only one other supplier at present providing inhaled solutions for volatile anaesthetics for intensive care. This is the German company TIM, which was acquired by the larger healthcare company Dahlhausen in 2022. This competitor has developed a medical device for delivery of volatile anaesthetics in intensive care called MIRUS™. To the company's knowledge, however, TIM/Dahlhausen does not have approval to market the benefits of inhaled sedation for intensive care as Sedana Medical holds the only marketing authorisation for pharmaceutical products with the indication of inhaled sedation in intensive care. Only pharmaceutical products that have obtained registration for marketing authorisation from EMA (European Medicines Agency) are allowed to be marketed in the EU.

Sedaconda ACD has higher efficacy than MIRUS™ as a greater proportion of the volatiles anaesthetic can be reflected (re-used), resulting in lower consumption of the anaesthetic. From a financial perspective, Sedana Medical's assessment is that MIRUS™ has somewhat lower everyday usage costs than Sedaconda ACD, but that MIRUS™ at the same time carries a higher investment cost as it requires its own device, while Sedaconda ACD can be used with existing intensive care equipment. With Sedaconda ACD, hospitals therefore do not need to invest in intensive care equipment to the same extent.

Isoflurane and other volatile anaesthetics such as sevoflurane are offered on the market by suppliers other than Sedana Medical. However, to Sedana Medical's knowledge, the company's Sedaconda (isoflurane) is the only volatile anaesthetic to have obtained approval for the indication of inhaled sedation in intensive care. Isoflurane is commonly available in hospitals, and among other things is used as a general aesthetic in surgery. Isoflurane or other inhaled anaesthetics from other suppliers may therefore be used for intensive care patients even if they are not approved for this indication.

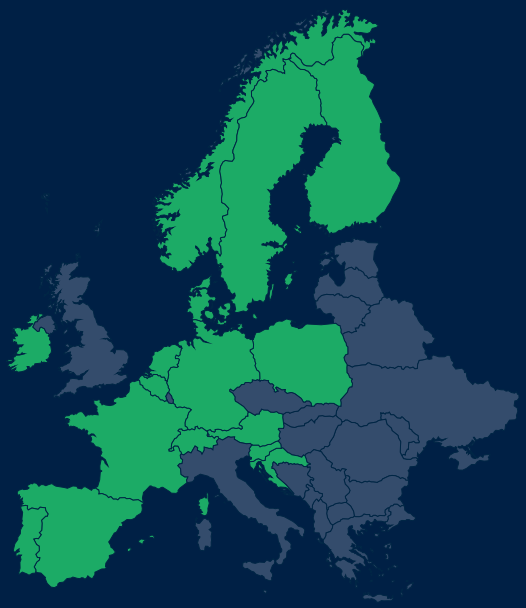
>30
million ICU patients globally per year

~12
million patients need ventilator support due to:
Trauma • Surgery •Sepsis
Multiple organ failure
Pneumonia • Covid-19

~8
million patients need to be ventilated and sedated

Market approval in Europe – a key milestone

At the end of July 2021, Sedana Medical obtained market approval in Europe for the pharmaceutical product Sedaconda (isoflurane), delivered via Sedaconda ACD for inhaled sedation in intensive care, in 15 of the EU Member States plus Norway. The application was granted through what is known as a decentralised procedure (DCP), which means that Sedana Medical has been able to apply for national approvals. At the end of 2022, Sedana Medical had obtained market approval in all 15 countries where the DCP approval applies, as well as in Switzerland.



United States – the market with the greatest potential

The United States has more than 100,000 ICU beds and significantly higher price levels for sedation therapies than Europe, making the United States the market with the greatest commercial potential for Sedana Medical.

Sedana Medical has evaluated alternative approaches to launching the Sedaconda therapy, and during autumn 2021 the company took the strategic decision to build up its own commercial organisation in the United States to attain the highest possible shareholder value. To ensure that Sedana Medical has the financial strength and stability required to prepare a commercial launch in the United States, the company took in around SEK 615 million before transaction-related expenses in a directed new share issue in December 2021.

The key activities in the United States are:

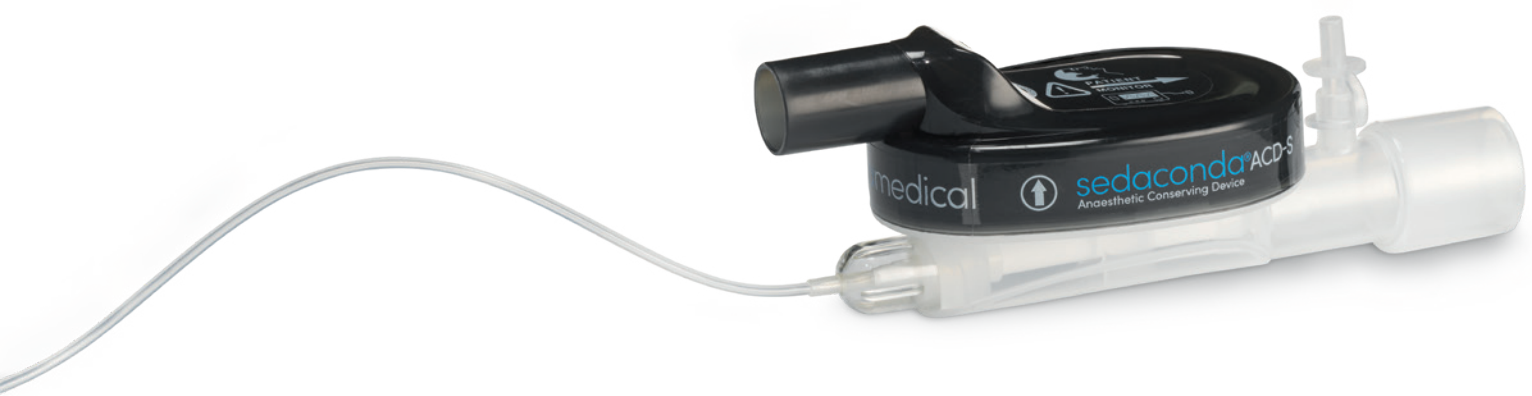
- optimising the clinical programme to further strengthen the evidence base, including patient follow-ups after three and six months;
- analysing the US market at the regional and hospital levels, including pricing and remuneration systems;
- expanding the US organisation and establishing a local sales team;
- preparing the market for a successful launch, and
- implementing the launch of Sedaconda ACD and Sedaconda (isoflurane) on the US market in 2025, after expected approval in 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 2022, Sedana Medical's US subsidiary had four employees working mainly as clinical training specialists at the sites where the clinical trials are being conducted.

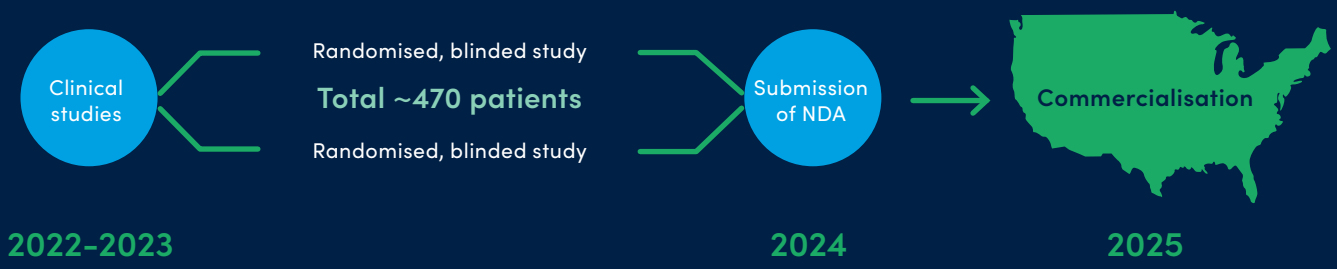
The goal is to obtain registration in the United States in 2024 for Sedaconda (isoflurane) and Sedaconda ACD as a combination product, which is regarded as providing better regulatory protection for the therapy than if Sedaconda and Sedaconda ACD had each been registered separately.

Comparison with Germany – the company's largest market today

Sedana Medical estimates that the company to date has succeeded in establishing the Sedaconda therapy in over half of all intensive care units in Germany, despite the fact that the therapy did not obtain market approval until 2021. An important reason for extensive use before 2021 was that new guidelines for sedation were published in Germany as long ago as 2010. The guidelines proposed inhaled sedation as an alternative to intravenous sedation in intensive care for certain patient groups. The new guidelines, together with positive statements from a number of German opinion leaders, has led to extensive use in Germany. Until 2021 the intensive care units were, however, obliged to use pharmaceutical products intended for anaesthesia in operating theatres, as approval for use in intensive care had not yet been granted. There are around 22,000 intensive care beds in Germany, compared to around 107,000 in the United States. In addition, the list prices for therapies in the United States are significantly higher than in Europe, making the United States the largest potential market for inhaled sedation.



FDA in favour of combined registration



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.

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 patients in intensive care in the United States. The FDA's Fast Track Designation is designed to facilitate the expedited development and review of new drugs or biologics that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The aim is to enable patients to have faster access to important new drugs.

A comparison between Germany and the United States

The United States offers the greatest market potential for inhaled sedation

	Germany	USA
Intensive care beds	~22,000	~107,000
List price of propofol	47–57 EUR/day	360–438 EUR/day*
Penetration	Current penetration approx.10%	Target for launch 2025

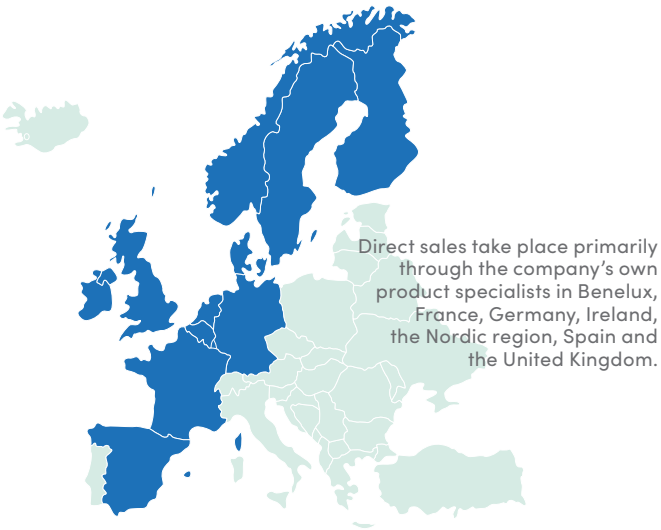
**Discounts on list prices are higher in the United States than in Europe*

Direct sale – Sedana Medical's preferred sales channel

Germany is Sedana Medical's largest market, accounting for 70 percent of the company's total sales in 2022. Other direct markets – Benelux, France, the Nordic region, Spain and the United Kingdom – accounted for 18 percent. Sedana Medical has sales through distributors in most of the rest of Europe.

Sedana Medical's salespeople are product specialists who train the clinics in how to use the devices and how to carry out the therapy. The salespeople in the main are basically nurses with a background in intensive care, which means that they possess the knowledge and experience necessary to train customers.

Direct sale is associated with higher costs than distribution sale, but the benefits associated with direct sale include Sedana Medical's ability to control the sales process to a greater degree and maintain valuable contact with clinics and purchasers, while also enjoying higher gross margins.



Distributor markets outside the EU

Sedana Medical cooperates with distributors as a low-risk means of initiating sales and quickly establishing Sedaconda ACD in intensive care in countries where the company does not have direct sales. Sedana Medical has distributor agreements in all parts of the world except Africa, and Sedaconda ACD is sold in over 40 countries.

There is also great interest in inhaled sedation outside the United States and Europe, and Sedana Medical has seen a clear increase in interest in Sedaconda ACD and inhaled sedation in other parts of the world. Sales increased sharply in the distributor markets of Mexico, Colombia and Ecuador during the Covid-19 pandemic, but as a consequence of a build-up of stocks at the end of 2021 pending a new wave of Covid-19 sales were lower in 2022. It is clear, however, that the positive reception in 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 Sedaconda (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.

In 2022, Sedaconda ACD received market approval in Brazil and Indonesia, two markets with considerable potential for the company. Brazil, for example, has 26,000 ICU beds and Indonesia 30,000, compared to Germany which has 22,000 ICU beds.

Customer base

The target groups for the company's products are intensive care physicians, intensive care nurses and decision-makers with responsibility for purchasing medical devices as well as pharmaceutical products for these departments. The customer base consists primarily of intensive care units in university hospitals and large and medium-sized hospitals. The devices are bought for the clinics through hospital procurement departments, and in many cases Sedana Medical receives requests to participate in tenders.

The company also reaches its customers by taking part in international congresses, by leading researchers presenting their results at scientific congresses and by assisting in therapy initiation in clinics. Sales differ between countries and regions, but a common feature in all markets is the ambition to create demand among physicians and nurses, who are the ones who most clearly see the benefits of inhaled sedation in day-to-day operation.

The repurchase rate is very high. It is worth mentioning, by way of example, that the company's 100 largest customers in Germany in 2021 all made repurchases in 2022, despite significantly lower total patient numbers following the Covid-19 pandemic. The rate of acquisition of new customers in 2022 was stable, with Sedana Medical on average acquiring three new hospital customers per week during the year.

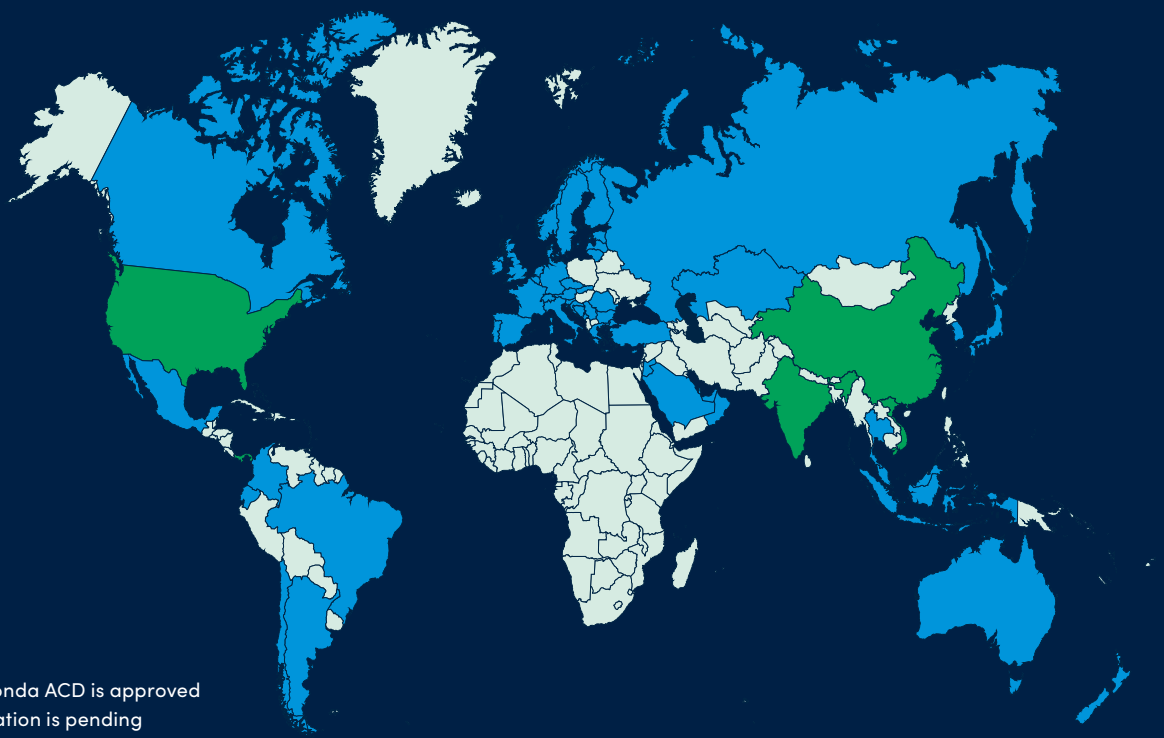
Sedaconda ACD is used throughout the world

In 2022, Sedaconda ACD received market approval in Brazil and Indonesia, two markets with considerable potential for the company. Brazil, for example, has 26,000 ICU beds and Indonesia 30,000, compared to Germany which has 22,000 ICU beds.

26,000
Brazil

30,000
Indonesia

22,000
Germany



- Markets where Sedaconda ACD is approved
- Markets where registration is pending

We're on the right track

Spain is one of Sedana Medical's fastest-growing markets outside Germany. The company's local team is led by Carlos Navarro.

Carlos Navarro is the Country Manager for Spain, where the team consists of four Key Account Managers and Medical Science Liaison.

Please tell us about Sedana Medical's Spanish operations.
We see a clearly positive trend for the introduction of our therapy in ICUs in Spain thanks to the efficacy of the therapy and, among other things, the confidence that customers have in us for the support we provide and our extensive knowledge of the therapy. The Covid-19 pandemic clearly showed that it was necessary for Spain to invest to increase the number of ICU beds in the country. Before the pandemic there were only around 4,000 ICU beds in Spain. The number increased to around 9,000 during the pandemic and currently there are about 7,500-8,000 ICU beds in Spain. Importantly, our strong growth has continued also after the pandemic.

Which is your most important selling point?
The effectiveness of the therapy is without a doubt the most important. Even in highly complex patients where other sedation methods fail, our therapy is successful, and this is of great value to healthcare professionals. Inhaled sedation provides several advantages compared to other sedation methods, for example that the patient needs less sedative and analgesic drugs; is able to wake up quickly and undergo neurological evaluations in a regular and timely manner; as well as reducing the overall ICU stay. All these benefits are valuable both for the patient and the hospital staff. In addition, having a sales team with clinical experience of using the therapy adds extra value to the customer and provides a high degree of confidence in Sedana Medical.

Which feedback do you get from users?
They appreciate the support and our fast response time to solve their problems. Many see us as a partner who wants to help them and their patients, which creates a fantastic work dynamic and great cooperation. It is highly satisfying to receive feedback from nurses and doctors explaining, for example, that they do not have to give so many drugs to a patient to keep them sedated. They also tell us that the patient is better sedated than with the previous therapy and that they can quickly wake up the patient and start the recovery process early.

Do you get any feedback from payers?
In Spain we depend on a hospital's Finance department accepting the introduction of our therapy in the ICU. To achieve this, we support the healthcare professionals by providing solid documentation on the therapy and its benefits; both clinical and health economic benefits. Something that is helping us a lot is, for example, the UK NICE guidelines that shows significant savings for the healthcare system when using our therapy due to the reduction of days patients spend in the ICU.

How has interest developed for inhaled sedation in Spain?
Interest in Spain originated from a group of doctors who understood that sedation is of strategic importance for a successful ICU outcomes. If a good sedation strategy is established with each patient, this will have a direct impact on the outcome for that patient's stay in the ICU, and the recovery process afterwards. The objective of these pioneering doctors has been to not only focus on how to sedate a patient here and now, but also to consider the patient's condition at the end of the ICU stay and during the subsequent recovery phase. In addition, there are very few sedative drugs available in the market and some of them are related to a higher incidence of delirium and other negative side effects. This situation made these doctors look for new alternatives to try to solve the current sedation problems, and Sedana Medical has been able to provide a great solution.

> “When we participate in scientific conferences there is great interest – many want to learn more about inhaled sedation. In addition, scientific councils are developing protocols for inhaled sedation, which shows the growing significance of our therapy in Spain”

What has happened now that Covid-19 pressure has eased?
Fortunately, the pandemic is now behind us. While it led to higher ICU patient numbers, it also limited us in terms of introducing our therapy. During 2020-2021, ICUs were operating under extreme workload and stress levels, which worked against us. As the pandemic has subsided since 2021, we see that our customers are increasingly eager to learn again and introduce new treatments such as inhaled sedation for the benefit of the patients. Something that Covid-19 made clear to everyone is that some patients are very difficult to sedate with intravenous sedation, creating a compelling argument to have inhaled sedation in the therapeutic arsenal, and learn to use it as your preferred option.

What do you anticipate for the future?
I’m optimistic, not only because of the feedback from our current customers but also because of the strong interest from other ICUs that are not yet customers. When we participate in scientific conferences, our activities are a resounding success, and we can see a strong desire to learn more about inhaled sedation. In addition, scientific councils in Spain are updating or developing inhaled sedation protocols, which demonstrates the importance that our therapy is acquiring in the country. We have much work ahead of us, but we are totally convinced that we are heading in the right direction to reach our goal of making inhaled sedation the first line choice for sedation in Spanish ICUs.

Clinical studies in the United States

Sedana Medical is conducting a clinical programme in the United States which is to form the basis for market approval and launch of Sedaconda therapy.

INSPiRE-ICU 1 & 2 • SED003 & SED004

With the aim of achieving US market approval in 2024, 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 the efficacy and safety of sedation with Sedaconda (isoflurane) delivered via Sedaconda ACD. To fulfil the FDA requirements, the studies will be observer-blinded, and the primary endpoint will be the proportion of time spent at adequate sedation depth. The studies will be carried out at around 30 highly reputed clinics in the United States and include a total of around 470 randomised patients. 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) performed in Europe in 2017–2019. The aim is to show that Sedaconda (isoflurane) delivered via Sedaconda ACD is effective and not inferior to propofol for sedation of mechanically ventilated patients in intensive care. The primary endpoint is time within the desired interval for depth of sedation, with use of further pharmaceutical products for sedation, assessed on the Richmond Agitation Sedation Scale (RASS). In addition, the studies will examine several secondary endpoints, including use of opioids, time to wake-up, cognitive recovery after sedation has been completed and rate of spontaneous breathing. The studies are blinded to fulfil FDA requirements.

As the Sedaconda study (SED001) was not blinded, it could not be used as one of the two clinical studies required by the FDA. The work on the European study gave Sedana Medical great experience that is of benefit in implementation of the US studies. In addition, the European study can provide support to the NDA application and be used in the safety database.

The first patient in INSPiRE-ICU was included in April 2022, and it is estimated that the treatment of the last patient will be completed in the fourth quarter of 2023. Provided approval is granted by the FDA in 2024, the goal is an American launch in early 2025.

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 patients in intensive care in the United States.

The FDA’s FTD is designed to facilitate the expedited development and review of new drugs or biologics that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The aim is to enable patients to have faster access to important new drugs.

A clinical programme with FTD can benefit from more frequent communication with the FDA during the development and review process and be entitled to accelerated approval and priority review if certain criteria are met. Another benefit may be what is known as rolling review, which means that completed sections of the registration application (new drug application, NDA) can be submitted for FDA review, instead of all sections of the application needing to be completed prior to submission.

INSPiRE-ICU 1 & 2 for US market approval

2022 | 2023 | 2024

INSPiRE-ICU 1

SED003

(USA adults) n=235 **FPI** Q2 2022 **LPO** Q4 2023

INSPiRE-ICU 2

SED004

(USA adults) n=235 **FPI** Q2 2022 **LPO** Q4 2023

FPI – First patient in **LPO** – Last patient out

~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.

There is great interest in the technique and the study

Dr Christopher G. Hughes is a 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.

Professor Christopher Hughes,
senior huvudprövare INSPiRE-ICU

What is your experience in inhaled sedation?

Up until the start of the INSPiRE-ICU trials, all of my experience with inhaled sedation was in the operating rooms. There would be discussion about using inhaled sedation in the ICU for special cases, such as severe bronchospasm or seizure, but there really wasn't a way to bring it to a larger number of patients who could potentially benefit.

How did you come in contact with inhaled sedation and Sedana Medical?

I became aware of Sedana Medical, and the potential for more widespread use of inhaled sedation, with the first small trials using the original AnaConDa device. It was great to see this product and technique advancing towards something that could be used in our ICU settings. Our Critical Illness, Brain Dysfunction, and Survivorship Center at Vanderbilt is a worldwide leader in studying sedation techniques in the ICU, including different strategies and medications. We were performing a trial of the two most commonly used IV sedatives, and when the potential to do a trial of inhaled sedation in the United States arose, we were very interested to say the least. Since that time, it has been a great collaboration and close working relationship between our investigators, Sedana Medical, and many others to bring inhaled sedation studies to the United States.

Do you see a need for alternatives to IV sedation? If so, why?

Absolutely! All of the currently available IV sedatives have significant limitations and side effects, and it often requires mixing and matching several agents. The COVID pandemic highlighted these limitations, in particular. We need a sedative that works for the majority of patients and allows tight control of sedation levels.

In your experience so far, which are the potential advantages with inhaled sedation?

First off, it will work in everyone with regard to causing sedation. We know this from the ORs and have seen it in the ICU already, allowing us to sedate difficult patients where other agents have not worked. The speed of achieving sedation and then waking up when ready gives us a much more responsive agent than our other options. I also think patients will wake up with clearer brain function with inhaled sedation than the longer acting IV sedatives that accumulate. Additionally, inhaled sedation has the potential to allow us to wean the ventilator faster and use less opioid medication for pain control, both of which can potentially translate to overall better recovery of our critically ill patients.

> "I think all intensive care specialists are looking for better ways of sedating their patients"

Do you see any patient groups for which inhaled sedation could be a good option?

From my experience so far and from its potential advantages, I think it could be a good option for just about every ICU patient on the ventilator. A few groups that it may particularly helpful for include patients that are traditionally hard to sedate (alcohol or drug use, psychiatric disorders, chronic pain medications for example), those that we want to go from deep sedation to fast wakeups such as after major surgery or cardiac arrest, and those with significant lung injury.

What can you tell us about the INSPiRE-ICU trial?

There is a lot of excitement about the technique and the trial from physicians, nurses, and respiratory therapists. We had to adapt some of the training to meet the workflow in the United States, but our providers have picked up the technique quickly and have been really impressed with how it has worked. We get a lot of comments about how shocked people are with how fast the patients wake up and how clear they wake up. We even get several requests to keep people on the drug off the trial, which of course we can't do, but I think emphasizes how people have embraced inhaled sedation.

Has patient recruitment gone well?

Yes, it overall has. With all complex trials, especially with new agents or techniques, it takes a bit to build momentum and get all the sites up and running. Plus enrolling critically ill patients adds an additional challenge. But the families and patients, along with the providers, have been really interested in the study when approached, which is important. So now it is primarily about getting the rest of the sites launched and keeping the momentum.

If successful, what impact will the trials have?

I think all ICU providers are looking for better ways to sedate our patients, as it is one of the hardest and most frustrating parts of caring for patients on the ventilator and leads to significant issues for patients, families, and providers. If the trials turn out like we think they will, the impact would be extensive as it will add a very useful tool that has the chance to shift the paradigm of how we sedate our patients.

Are there any additional studies you would like to see?

After the main general trials are complete, I think a lot of opportunities exist for concentrating on specific patient populations that inhaled sedation may benefit, such as ECMO patients or severe ARDS patients, that we did not include in the trials, while also identifying subgroups that did particularly better with inhaled sedation from the trial. I am also interested in seeing if deeper levels of sedation lead to less issues with inhaled sedation compared to IV sedation since it does not accumulate like IV agents and fast wakeups can still occur after deep sedation. This would allow potentially easier patient care in the ICU while not seeing the prolonged brain dysfunction, ventilator duration, length of stay, and other negative outcomes from deep vs. light sedation levels in the ICU. Finally, I think there is a lot of potential for the Sedaconda device and inhaled sedation to provide safe sedation in low resource settings.

Do you see any hurdles for a successful uptake of the therapy?

As with any new technique that shifts ways of thinking, I think the biggest hurdle will be dissemination and providers internalizing and understanding the potential benefits to apply to patient care. Thus, providers, especially those without anesthesia training, getting comfortable with inhaled sedation in the ICU so that lack of familiarity or knowledge doesn't prevent doing what is best for patients. I also think it will be important given the current economic climate to evaluate the overall cost of sedation and the episode of care to see how inhaled sedation may actually save costs while improving patient care.

Is there anything else you would like to add?

Only that we have done a lot of trials in ICU patients, and this is the most excited I have seen our bedside staff and providers about a new technique and trial in general. It just takes seeing one patient for them to believe in the technique! The bedside providers, in addition to the investigators of course, really want to see the trials be successful and for us to have the opportunity to use inhaled sedation regularly in the future.

Clinical studies confirm therapeutic benefits and pave the way for a new standard therapy

Sedana Medical's paediatric study

In addition to the US studies, Sedana Medical is conducting a paediatric clinical phase III study, IsoCOMFORT (SED002), as the basis for a paediatric indication in Europe.

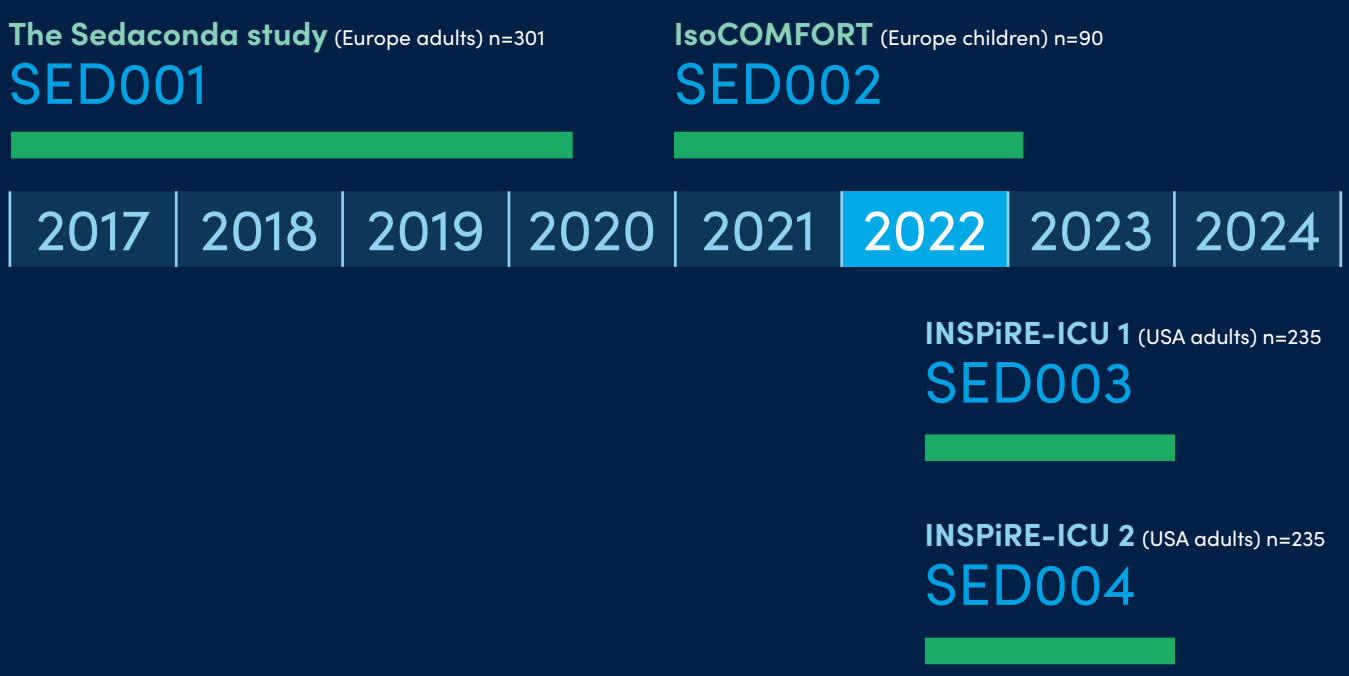
IsoCOMFORT – SED002

In Sedana Medical's paediatric study IsoCOMFORT, the efficacy and safety of Sedaconda (isoflurane), delivered via Sedaconda ACD, is compared with intravenous midazolam for the sedation of mechanically ventilated patients aged 3–17. The patients are sedated for 12–48 hours with either sedation therapy, and the primary endpoint is the proportion of time spent at adequate depth of sedation. The study covers patients from intensive care units in Germany, France, Spain and the United Kingdom, and recruited its first patients in the first quarter of 2021. Patient recruitment was completed in January 2023.

In December 2022, Sedana Medical received a positive statement from the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) on the company's proposal to amend the agreed paediatric investigation plan (PIP) for the study. The previous study design was intended to show statistically better results than midazolam based on 160 patients. The new design is intended to show statistically equivalent results (non-inferiority) to midazolam, meaning that Sedana Medical estimates that around 90 evaluable patients are sufficient to complete the study. This enables faster completion of the study, earlier approval of a paediatric indication and lower investments.

Given the change in the protocol and the assumption of a positive result from the study, Sedana Medical anticipates approval of the paediatric indication in Europe through a decentralised procedure in the fourth quarter of 2023 or the first quarter of 2024. Midazolam is currently the only sedation option for children in intensive care, as propofol is contraindicated due to the risk of severe side effects. Inhaled sedation would add an important sedation option for a vulnerable and challenging group of patients.

Sedana Medical's studies



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

SESAR
The SESAR study (led by Associate Professor Matthieu Jabaudon at the Centre Hospitalier Universitaire Clermont-Ferrand, France) is a randomised, controlled study covering 700 intensive care patients with ARDS (Acute Respiratory Distress Syndrome). Inhaled sedation with sevoflurane for up to seven days is compared to intravenously delivered propofol. The primary aim is to assess the efficacy of inhaled sedation measured as the number of ventilator-free days at day 28. The study is being conducted at 30 intensive care units across France and is expected to be completed in 2023.

INASED
The INASED study (led by Dr Pierre Bailly and Professor Erwan L'Her at the Centre Hospitalier Régionale Universitaire Brest, France) is a randomised, controlled study covering 250 patients who are expected to need mechanical ventilation in an intensive care unit for more than 24 hours. The primary objective is to assess the incidence of delirium after inhaled sedation with isoflurane compared to intravenously delivered propofol. The study is being conducted at ten intensive care units in France and is expected to be completed in 2023.

> "Two independent studies in inhaled sedation are expected to be completed in 2023"

Research grants increase knowledge of inhaled sedation

The Sedana Medical Research Grant is an annual research grant that was established in 2019. It offers a unique opportunity for the scientific community to improve its understanding of sedation in critically ill patients in intensive care. A grant of between EUR 10,000 and 30,000 will be awarded to one to three individual academic researchers, which furthers the prospects for research in Sedana Medical's field, with the aim of leading to medical advances for the benefit of patients and society.

Sustainability

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

Doing business in a global and regulated environment poses many challenges. Sedana Medical's Code of Conduct is a framework stating what the company considers to be responsible and appropriate conduct. Sedana Medical endeavours to act responsibly in everything we do by maintaining a high standard in research, business ethics and policies. aimed at creating a sustainable organisation. Our core values – Explore, Cooperate, and Trust – help shape our culture and guide us in our daily work.

Sedana Medical supports the Ten Principles of the UN Global Compact in the areas of human rights, labour, environment and anti-corruption. Linked to human rights, this means that the company has to promote human rights throughout the business, as well as among customers and suppliers, and ensure that the company does not directly or indirectly in any way enable deviations from the principle of human rights in connection with its operations. The company strives for openness and transparency in its business operations, and its work on sustainability 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 employees are success factors in the company's aspiration to be an attractive employer. We sell our devices and 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, in 2022 we drew up an anticorruption policy and updated our code of conduct, which applies to all employees, the Board of Directors, consultants and temporary staff. The Code of Conduct includes sustainability, the work environment, health and safety, the environment, gender equality and purchasing.

Sedana Medical continues to grow, which means that the need for more staff and new skills is increasing. During the year, the company welcomed many new colleagues, who in their respective roles will strengthen the organisation. At the end of 2022, the company had 85 employees and 9 interim consultants in 5 countries.

At Sedana Medical we believe our diversity is a strength. We are also very proud to have an even gender balance of 51: 49 in favour of men. We have a clear recruitment process based on competence and experience and are using a structured process with evidence-based questioning, to ensure that we do not discriminate. In 2022 a mentorship programme was introduced for people who are new to positions that involve managing staff. They 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.

In 2022, a legal function was established and a chief legal officer was appointed. New policies and procedures were developed during the year, such as an anticorruption policy, a corporate governance policy and an HR policy. In addition, a number of other policies were updated during the year.

Working environment

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 outcome of the major staff survey conducted in 2021 has formed the basis for changes and improvements. The survey was followed up in 2022 with four regular smaller surveys (Pulse Check). These brief pulse checks have guided us on whether our efforts to improve involvement are working. Regular minor checks remind staff that their opinions are important and a constantly prioritised issue in the company. In 2022 'I Suggest' was launched, a tool for the whole organisation to submit suggestions for improvements and/or changes.

During the year we also introduced 'Board Member for a Day', with the aim of everyone in the organisation being able to make their voice heard. The initiative is run by the HR Department and 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. A new team is assembled every month.

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. A whistleblower policy was designed during the year.

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 counteracting 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 whistleblower 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 during the year.

Responsible purchasing

Sedana Medical successively introduces clauses into our agreements with our suppliers in which they undertake to comply with our 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.

Our values and our Code of Conduct promote responsible action. 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 is to 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 must carry out their work with as little impact on health and the environment as possible. Sedana Medical must 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 aware technology.

Sedana Medical strives constantly to reduce the quantity of plastic used for packaging. In general terms, for the whole of our product portfolio we aim to use recycled plastic where possible, to use plastics that can be recycled, and label more clearly all material that can be recycled. Our goal is to offer our customers a sustainable solution for the use and handling of isoflurane.

During the year, 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
- Local purchasing
- Increased reflection efficiency of Sedaconda ACD
- Increased capture efficiency and potential recycling of anaesthetic gas

The device• Sedaconda ACD

Sedana Medical is mindful of the selection of materials incorporated into our devices 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 desflurane[13].

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 air[14].

3. Emissions after use are minimised by using the FlurAbsorb filter to capture unreflected gas. As a result, the working 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 values[15].

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 form[16].

Transport

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.

Own vehicles

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.

Travel on company business

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.

Responsible purchasing

A major part of our 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.

Exchange of knowledge

Sedana Medical works close to and in dialogue with healthcare services to understand their needs but also to be able to act in response to complaints and requests and supply products and services that create added value. We also regularly attend scientific conferences and congresses to share medical advances and take part in discussions on ways of improving medical practice. By doing so we can continue to develop our products, so they meet medical needs even better. We also arrange scientific meetings and training to support exchange of knowledge, both nationally and internationally.

Quality management

Sedana Medical's 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).

The product life cycle of inhaled sedation

Material and manufacturing

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

Transport

- Minimising air freight
- Reducing volumes of packaging to make transport more efficient

Recycling and disposal

- 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.

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

IP – Active strategy protects the device

Sedana Medical has an active strategy for intellectual property rights and endeavours to maximise the protection of its products and technical innovations. To protect these rights, the company uses a three-part strategy that includes patent protection, complicating measures and registrations.

Patent protection

Since developing Sedaconda ACD, Sedana Medical has protected its innovations through patents. Sedana Medical's patent portfolio at present comprises six patent families, all related to the company's products. New applications are made regularly as the company's devices are developed. Applications are made internationally to gain protection on the global market.

Sedana Medical currently has patent protection for a number of patients on the European and US markets, as well as other markets that have been judged important to protect. In November 2020, the company was granted patent protection for an enhancement of Sedaconda ACD that made it possible to reduce 'dead space' by 50 percent, the technology used in Sedaconda ACD-S. The company's latest application was submitted to the European Patent Office (EPO) in April 2022.

Complicating measures

Sedana Medical has developed and is continuing to enhance its existing product portfolio. The system is based on solutions where the whole process, from the liquid in the bottle to the gas delivered to the patient, can be protected by proprietary design. These protections, for example connectors and packaging solutions, make the Sedaconda ACD system easier to use together with Sedaconda (isoflurane) than with generic pharmaceutical products.

Registrations

As a result of Sedana Medical having applied for full registration, which consequently also covers a paediatric plan, obtained approval means information protection for eight years and market protection for two years in several markets in Europe for the use of isoflurane for sedation in intensive care. The registration is valid for Sedaconda (isoflurane) delivered via Sedaconda ACD. Other combinations of volatile anaesthetics and delivery methods for sedation in intensive care continue to be non-registered (off label).

With regard to the US market, the company intends to register Sedaconda ACD and Sedaconda (isoflurane) as a combination product, which means that the way of gaining access to Sedana Medical's inhaled sedation for intensive care use in the United States will be by using Sedana Medical's two products together.

Know-how

Sedana Medical has built up significant experience in the organisation regarding inhaled sedation and related product development. Sedana Medical's freedom-to-operate analyses, which check the risks of infringement of the intellectual property rights of others, has not brought to light anything that obstructs the company's development and commercialisation of inhaled sedation. The analysis has included a competition analysis of existing therapies and therapies under development in the largest markets.

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 2022 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 2022 was SEK 98.05, and the last price paid at the end of the year was SEK 18.70. During the year a total of 67 million Sedana Medical shares were traded at a value of SEK 2.4 billion, which is equivalent to a turnover rate of around 67 percent. On average, around 268,000 shares were traded per trading day.

Price trend

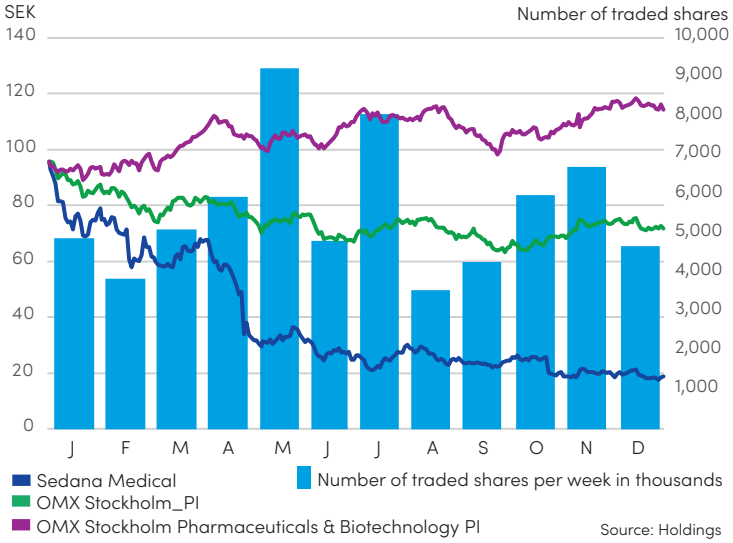
During the year, the Sedana Medical share price declined by 81 percent, while the First North All Share index over the same period fell by 44 percent. The highest price paid was SEK 95.60, recorded on 3 January 2022, and the lowest price paid was SEK 17.70, recorded on 28 December 2022. At year-end 2022, the Sedana Medical share price was SEK 18.70, equivalent to a market capitalisation of SEK 1,858 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	Overallotment 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



Source: Holdings

Facts about Sedana Medical shares

Trading venue	Nasdaq Stockholm
Number of shares at 31 Dec 2022	99,336,960
Market capitalisation	MSEK 1,858
Ticker	SEDANA
ISIN	SE0015988373
LEI code	549300FQ3NJRI56LCX32

The 15 largest shareholders at 31 December 2022

	Number of shares	Holding
Linc AB	10,111,030	10.2%
Swedbank Robur Fonder	9,519,013	9.6%
Handelsbanken Fonder	8,667,052	8.7%
Anders Walldov directly and indirectly (Brohuvudet AB)	8,500,000	8.6%
Ola Magnusson direct and indirectly (Magiola AB)	4,462,098	4.5%
Sten Gibeck	4,286,276	4.3%
Öhman Fonder	4,139,985	4.2%
Highclere International Investors LLP	2,823,538	2.8%
Berenberg Funds	2,714,675	2.7%
Norges Bank	2,637,258	2.7%
AMF Pension	2,491,000	2.5%
Tredje AP-fonden	1,735,989	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Coeli	1,235,368	1.2%
Philip Earle	1,099,491	1.1%
Fifteen largest shareholders	**66,089,237**	**66.5%**
Other	33,247,723	33.5%
Total	**99,336,960**	**100.0%**

Source: Modular Finance

Shareholder distribution by size

	Number of share-holders	Number of shares	% capital	% share-holders
1–100	3,297	118,623	0.1%	44.9%
101–200	958	147,002	0.2%	13.0%
201–500	1,094	380,142	0.4%	14.9%
501–1000	744	562,471	0.6%	10.1%
1001–2000	505	743,716	0.8%	6.9%
2001–5000	367	1,238,289	1.3%	5.0%
5001–10000	150	1,121,993	1.1%	2.0%
10001–20000	86	1,235,205	1.2%	1.2%
20001–50000	57	1,853,725	1.9%	0.8%
50001–100000	22	1,546,414	1.6%	0.3%
100001–200000	14	1,920,910	1.9%	0.2%
200001–500000	20	6,386,517	6.4%	0.3%
500001–1000000	13	9,468,617	9.5%	0.2%
1000001–2000000	6	8,469,967	8.5%	0.1%
2000001–	10	57,637,250	58.0%	0.1%
Anonymous ownership		6,506,119	6.5%	
Total	**7,343**	**99,336,960**	**100%**	**100%**

Source: Modular Finance

Warrant programme

Warrant programme 2020/2023

The Annual General Meeting of Sedana Medical AB (publ) held on 19 May 2020 resolved to implement a new warrant programme for staff (employees and consultants) of the Sedana Medical Group. The company therefore issued at the 325,000 warrants in the 2020/2023 series at the AGM, entitling holders to subscribe to a total of 325,000 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 July to 30 September 2023 at a subscription price of SEK 83.63 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, 42,480 series 2020/2023 warrants 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 2020/2023 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 2020/2023 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 4,248 through the issue of 42,480 shares in the company, equivalent to a dilution of approximately 0.04 percent based on the number of shares in the company at the balance sheet date.

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 to implement 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.
The subsidy is repaid in whole or part if the employee leaves their employment during the three-year period.
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 2022.

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 2022.

The business in brief

Sedana Medical is a Swedish medtech and pharmaceutical company. 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 properties 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 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.

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 National Institute for Health and Care Excellence (NICE) in the UK issued positive guidance and recommends Sedaconda ACD as a cost-saving option for delivering inhaled sedation in intensive care, as an alternative to intravenous sedation.
- In February, the first bottles of Sedaconda (isoflurane) were delivered to clinics in Germany, the company's largest market.
- In March, a post-hoc analysis of the Sedaconda study was presented as a poster at one of the world's largest congresses for intensive care and emergency medicine, ISICEM, in Brussels with the conclusion that sedation with isoflurane as primary sedative in mechanical ventilation during the first 30 days after randomisation was associated with significantly more ICU-free days than sedation with propofol, with a difference of four days.
- Sedaconda ACD was approved during the first quarter in Brazil and Indonesia. With 26,000 and 300,00 ICU beds respectively, the two countries represent significant potential markets.

2nd quarter

- During the second quarter, 'end of procedure' was reached in Italy, an important milestone in the application process for Sedaconda.
- In April the first patient was included in the clinical programme in the United States.
- The Annual General Meeting in May resolved to implement two new warrant programmes 2022/2025: 1 and 2022/2025: 2, for the CEO and certain employees.
- The Annual General Meeting in May resolved to newly elect Hilde Furberg as an ordinary member of the Board. Bengt Julander did not stand for re-election.
- During the second quarter, Sedaconda (isoflurane) was launched in the Netherlands, Sweden and Norway.

3rd quarter

- In August, an MDR (Medical Device Regulation) certificate was obtained, ensuring continued access to the European market for Sedaconda ACD under the new MDR, in good time before the previous certificate expires in 2024.

- During the third quarter Sedaconda (isoflurane) was launched in France, and market approval was obtained in Switzerland.

4th quarter

- At the beginning of December, Sedana Medical received market approval for inhaled sedation in Poland, meaning that the company has gained market approval in all 15 countries included in the DCP procedure (EU approval for decentralised procedure), which was obtained in July 2021.
- At the end of the quarter, a positive message was received from the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) on the company's proposal to amend the agreed paediatric investigation plan (PIP) for the ongoing paediatric clinical phase III study in Europe (IsoCOMFORT).

Significant events after the end of the period

- 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.
- 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 the 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.

Anticipated future developments

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 life during and beyond sedation.

Vision

To make inhaled sedation a standard therapy in intensive care.

Financial targets

The company aims to attain revenue in 2025 in excess of MSEK 500 in Europe and an EBITDA margin of 40 percent when the company has attained a stable position in the United States.

Strategy

The company's strategy to attain its vision will focus over the next few years on:

1. Successfully commercialising Sedaconda (isoflurane) in combination with Sedaconda ACD in the EU and in other selected markets.
2. Preparing for commercialisation in the important US market by registering Sedaconda (isoflurane) and the Sedaconda ACD as a combination therapy.
3. Commercialising Sedaconda ACD through distributors in selected markets worldwide.

Effects of the Covid-19 pandemic

Covid-19 affected Sedana Medical's operations during the pandemic. The effects have been both positive and negative, primarily the higher number of ventilated patients in intensive care in 2020–2021, but also negative effects such as limited access to hospital customers. In 2022, intensive care units in our markets experienced a sharp decrease in intubated patients compared to the pandemic years. There continues to be great uncertainty over what the 'new normal' will look like and how soon we will reach it, for example how long ICU activity will be limited by staff shortages and to what extent capacity in intensive care will remain reduced after the pandemic.

Effects of the war in Ukraine

We are naturally following developments regarding the war in Ukraine. However, in the short term the effects for Sedana Medical are manageable. During the year we bought some of our gas analysers from a Russian manufacturer, but since the outbreak of the war in Ukraine we have stopped buying gas analysers from Russia. Devices held in our inventory are still available for sale, but we also offer a gas analyser from another manufacturer. In addition, we are in discussion with further manufacturers, and we do not see any risk of not being able to supply gas analysers to our customers. The gas analyser makes only a minor contribution to sales, but is important to our therapy.

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 develop-

ment 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 can 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. Under the provisions of the Medical Devices Directive (MDD), the company's current medical devices certificate is valid until 26 May 2024. 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 sedatives 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 2022

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://sedanamedical.com/investors/financial-reports-presentations/

Summary consolidated figures

KSEK	2022	2021	2020	2019	2018*
Net sales	122,865	159,152	141,770	71,646	57,896
Gross profit	86,074	106,706	88,903	46,767	42,897
Gross margin %	70%	67%	63%	65%	74%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-83,138	-50,093	-14,294	-12,932	-4,232
EBITDA margin %	-68%	-31%	-10%	-18%	-7%
Operating income (EBIT)	-105,887	-61,493	-21,359	-17,120	-8,238
Operating margin %	-86%	-39%	-15%	-24%	-14%
Net income for the period	-73,507	-57,966	-27,139	-16,380	-6,869
Profit margin %	-60%	-36%	-19%	-23%	-12%
Balance sheet total	1,081,588	1,167,580	600,097	595,766	231,550
Equity ratio %	95%	94%	92%	96%	94%
Quick ratio %	1299%	1414%	929%	1872%	1220%
Average number of employees	86	73	55	39	26

Summary Parent Company figures

KSEK	2022	2021	2020	2019	2018*
Net sales	122,726	159,107	121,238	46,213	55,856
Gross profit	88,634	109,445	82,531	15,592	21,126
Gross margin %	72%	69%	68%	34%	38%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-77,459	-50,250	-26,608	-14,773	-4,888
EBITDA margin %	-63%	-32%	-22%	-32%	-9%
Operating income (EBIT)	-93,632	-55,161	-27,577	-16,051	-6,431
Operating margin %	-76%	-35%	-23%	-36%	-12%
Net income for the period	-59,741	-63,629	-28,767	-14,800	-3,755
Profit margin %	-49%	-40%	-24%	-33%	-7%
Balance sheet total	1,105,654	1,164,900	603,470	615,476	257,060
Equity ratio %	95%	95%	93%	95%	89%
Quick ratio %	1198%	1479%	941%	1444%	631%
Average number of employees	53	41	25	24	17

*Accounting according to previous K3 rules.

Net sales

Net sales for the year totalled KSEK 122,865 (159,152), equivalent to a decrease of 23 percent. Adjusted for currency effects, 2022 showed a decrease of 27 percent. In Germany, sales decreased by 24 percent, mainly due to a sharp decrease in the number of ventilated patients in intensive care units. In other direct markets in Europe, we have seen similar effects with fewer ventilated intensive care patients, shortages of hospital staff and limited access to hospitals. However, this was offset by good underlying growth, particularly in Spain and the United Kingdom, leading to an overall increase in sales of 9 percent in our other direct markets. With regard to distributor markets, the decrease relates mainly to South America, where we had strong sales in the previous year, and sales this year have been affected by continued high inventory levels among both distributors and hospitals.

Cost of goods sold

The cost of goods sold totalled KSEK 36,791 (52,446), representing a decrease of 30 percent. Gross profit was KSEK 86,074 (106,706), equivalent to a gross margin of 70 (67) percent. The increase is mainly an effect of higher selling prices and lower freight costs compared to the previous year.

Selling expenses

Selling expenses for the full year were KSEK 112,469 (96,573), representing an increase of 16 percent. The increase is primarily a result of an increased level of activity compared to the previous year, which was impacted by restrictions, costs in connection with preparations for the US market but also commenced amortisation for the EU registration project.

Administrative expenses

Administrative expenses in the Group totalled KSEK 57,473 (51,736), representing an increase of 11 percent. The higher costs are of a non-recurring nature and are largely related to the work on the change of trading venue from Nasdaq First North Growth Market to the Nasdaq Stockholm Main Market,

which has been partly offset by lower personnel expenses in 2022 than in the previous year as a result of efficiencies in administrative functions.

Research and development expenses

Research and development expenses for the full year 2022 totalled KSEK 19,944 (19,704), equivalent to an increase of 1 percent.

Operating income

Group operating income for the full year was KSEK -105,887 (-61,493). The decline in income is explained by reduced sales, which has led to reduced gross profit but also higher selling expenses mainly relating to an increased level of activity compared to the previous year, which was impacted by restrictions, costs in connection with preparations for the US market but also commenced amortisation for the EU registration project.

Net financial items

Net financial items totalled KSEK 32,954 (4,122) and are explained by unrealised exchange gains, primarily related to cash and cash equivalents invested in USD.

Tax

The Group reported a tax expense of KSEK -574 in 2022, compared to KSEK -595 in the previous year. The tax is attributed principally to Germany.

Net income for the year

The Group reported earnings after tax of KSEK -73,507 (-57,966) for the year. The decline in income is explained by reduced sales, which has led to reduced gross profit but also higher selling expenses mainly relating to an increased level of activity compared to the previous year, which was impacted by restrictions, costs in connection with preparations for the US market but also commenced amortisation for the EU registration project. These effects have been partially offset by positive, unrealised exchange effects on cash and cash equivalents denominated in USD.

Equity and liabilities

Equity at 31 December was KSEK 1,029,156, compared to KSEK 1,101,456 at the beginning of the year, equivalent to SEK 10.36 (11.09) per share. Equity/assets ratio was 95 percent, compared to 94 percent at the beginning of the year.

Debt/equity ratio at 31 December was 5 percent, compared to 6 percent at the beginning of the year. The Group had no long-term loans at 31 December.

Cash and cash equivalents and cash flow

For 2022, cash and cash equivalents decreased by KSEK 228,439. Cash flow from operating activities before change in working capital for the full year was KSEK -80,108 (-52,809). Cash flow from changes in working capital totalled KSEK -35,324 (11,588) and was negatively impacted during the year primarily by increased inventory levels but also by lower liabilities. Cash flow from operating activities thus totalled KSEK -115,433 (-41,221).

Cash flow from investing activities totalled KSEK -137,783 (-110,255). The investments mostly consist of intangible assets, mainly development expenses for clinical studies and work on registration of Sedaconda ACD and Sedaconda (isoflurane) in the United States, as well as investments related to the company's paediatric study IsoCOMFORT (SED002).

Cash flow from financing activities totalled KSEK -1,507 (605,071) and is mainly related to payments regarding the warrant programme launched in May at the time of the Annual General Meeting, as well as amortisation of lease liabilities.

The translation difference in cash and cash equivalents during the year totalled KSEK 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 -2.56 (4.89).

Investments

Investments during the 2022 financial year totalled KSEK 110,255 (84,619). Investments during 2022 primarily relate to:

- Capitalised expenses for development work, KSEK 135,589
- Internal expenses for the preparation of patents, KSEK 1,459
- Purchase of plant and machinery, KSEK 0
- Purchase of fixtures, fittings and tools, KSEK 735.

Parent Company

The Parent Company's net sales for the full year totalled KSEK 122,726 (159,107), of which intra-group sales totalled KSEK 6,306 (6,602).

Operating income for the full year totalled KSEK -93,632 (-55,161). Net financial items were KSEK 33,891 (-8,467) 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 1,050,412 at 31 December 2022, compared to KSEK 1,106,529 at the beginning of the year. Share capital totalled KSEK 2,483, which is unchanged compared to the beginning of the year.

Cash and cash equivalents totalled KSEK 587,909, compared to KSEK 816,279 at the beginning of the year.

Organisation and Personnel

Employees

At the end of 2022, Sedana Medical had 85 employees. Of these, 43 employees were men and 42 were women. The corresponding figures at the end of 2021 were 90 employees, of whom 43 were men and 47 were women.

Proposed appropriation of earnings

The Board of Directors proposes that no dividend be paid for the financial year 2022.
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	
Share premium reserve	1,226,435,473
Accumulated loss	-475,162,148
Net income for the year	-59,741,497
Total non-restricted reserves	**691,531,828**

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	
Share premium reserve	1,226,435,473
Accumulated loss	-534,903,645
Total non-restricted reserves	**691,531,828**

Financial information

Consolidated income statement

KSEK	Note	2022	2021
Net sales	4	122,865	159,152
Cost of goods sold	7	-36,791	-52,446
Gross profit		**86,074**	**106,706**
Selling expenses		-112,469	-96,573
Administrative expenses		-57,473	-51,736
Research and development expenses		-19,944	-19,704
Other operating income	8	13,319	4,013
Other operating expenses	9	-15,394	-4,199
Operating income	5,6,7	**-105,887**	**-61,493**
Financial items			
Financial income		48,300	11,285
Financial expenses		-15,346	-7,163
Net financial items	10	**32,954**	**4,122**
Profit/loss before tax		**-72,933**	**-57,371**
Income tax	11	-574	-595
Net income for the year		**-73,507**	**-57,966**
Earnings per share, calculated on earnings attributable to shareholders in the Parent Company:	12		
Before dilution		-0.74	-0.62
After dilution		-0.74	-0.62
Operating income		**-105,887**	**-61,493**
Amortisation of intangible assets		-15,538	-4,720
Depreciation of property, plant and equipment		-7,211	-6,680
EBITDA		**-83,138**	**-50,093**

Consolidated statement of comprehensive income

KSEK	Note	2022	2021
Net income for the year		**-73,507**	**-57,966**
Other comprehensive income			
Items that may be reclassified later to the income statement:			
Translation differences from operations abroad		-2,834	-322
Other comprehensive income, net after tax		**-2,834**	**-322**
Total comprehensive income		-76,341	-58,288
Total comprehensive income wholly attributable to shareholders in the Parent Company		**-76,341**	**-58,288**

Consolidated balance sheet

KSEK	Note	31 Dec 2022	31 Dec 2021
ASSETS			
Intangible assets			
Capitalised development expenditure	13	390,530	268,201
Concessions, patents, licences, etc.	14	2,849	1,786
Property, plant and equipment			
Plant and machinery	15	955	1,309
Equipment, tools, fixtures and fittings	16	4,492	6,154
Right-of-use assets	24	9,271	9,324
Financial assets			
Deferred tax assets	17	29	23
Other non-current assets		46	42
Total non-current assets		**408,172**	**286,839**
Inventories	18	38,597	11,093
Tax receivables		514	410
Accounts receivable	19	15,849	20,345
Prepaid expenses and accrued income	20	6,017	7,115
Other receivables		4,697	5,597
Cash and cash equivalents	21	607,742	836,181
Total current assets		**673,416**	**880,741**
TOTAL ASSETS		**1,081,588**	**1,167,580**

KSEK	Note	31 Dec 2022	31 Dec 2021
EQUITY AND LIABILITIES			
Equity	22,23		
Share capital		2,483	2,483
Other contributed capital		1,226,435	1,222,395
Translation reserve		-2,650	184
Retained earnings including net income for the year		-197,113	-123,606
Equity attributable to shareholders in the Parent Company		**1,029,155**	**1,101,456**
Non-current liabilities			
Non-current lease liabilities	24,27,28	3,576	4,642
Total non-current liabilities		**3,576**	**4,642**
Current liabilities			
Current lease liabilities	24,27,28	5,167	4,232
Accounts payable	28	11,270	15,036
Tax liabilities		2,559	3,997
Other liabilities	25	6,929	18,473
Accrued expenses and prepaid income	26	22,932	19,744
Total current liabilities		**48,857**	**61,482**
Total liabilities		**52,433**	**66,124**
TOTAL EQUITY AND LIABILITIES		**1,081,588**	**1,167,580**

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 2021	**2,305**	**613,923**	**506**	**-65,640**	**551,094**
Net income for the year	-	-	-	-57,966	-57,966
Other comprehensive income for the year	-	-	-322	-	-322
Comprehensive income for the year	-	-	-322	-57,966	-58,288
Transactions with shareholders in the Group					
New share issue	178	614,722	-	-	614,900
Issue expenses	-	-7,946	-	-	-7,946
Premium received on issue of warrants	-	1,760	-	-	1,760
Buyback of warrants	-	-64	-	-	-64
Total transactions with shareholders in the Group	178	608,472	-	-	608,650
Closing equity at 31 Dec 2021	**2,483**	**1,222,395**	**184**	**-123,606**	**1,101,456**
Opening equity at 1 Jan 2022	**2,483**	**1,222,395**	**184**	**-123,606**	**1,101,456**
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
Buyback 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**	**1,226,436**	**-2,650**	**-197,113**	**1,029,156**

Consolidated cash flow statement

KSEK	Note	2022	2021
Operating activities			
Operating income		-105,887	-61,493
Adjustments for non-cash items:			
Depreciation, amortisation and impairment		23,901	13,327
Exchange-rate differences		-863	-4,080
Interest received		3,580	0
Interest paid		-255	-243
Income tax paid		-583	-320
Cash flow from operating activities before changes in working capital		**-80,108**	**-52,809**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in inventories		-27,504	-2,296
Increase (-)/Decrease (+) in operating receivables		7,494	-2,169
Increase (+)/Decrease (-) in operating liabilities		-15,315	16,053
Cash flow from operating activities		**-115,433**	**-41,221**
Investing activities			
Investment in intangible assets	13,14	-137,048	-105,063
Investment in property, plant and equipment	15,16	-735	-5,192
Cash flow from investing activities		**-137,783**	**-110,255**
Financing activities			
New share issue	22	-	614,900
Issue expenses	22	-	-7,946
Amortisation of leasing liabilities	24,27	-4,510	-3,579
Premium received for warrant subscription	22	3,590	1,696
Expenses for warrant programme	22	-490	0
Buyback of warrants		-97	-
Cash flow from financing activities		**-1,507**	**605,071**
Cash flow for the year		**-254,722**	**453,595**
Cash and cash equivalents at the beginning of the period		836,181	376,171
Translation difference in cash and cash equivalents		26,283	6,415
Cash and cash equivalents at the end of the period	21	**607,742**	**836,181**

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 2022 have had any 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 (and consultants). 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 licenses. 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, 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 measured at accrued acquisition value if it fulfils both of the following conditions and has not been identified as being 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.

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.

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.

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 by the Group's marginal borrowing rate, which beyond the Group's credit risk reflects the lease period, currency and quality of an underlying asset as intended security of the contract concerned.

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 KSEK 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 value. The recoverable value is the higher of the asset's fair value less selling costs and its value in use. In estimating impairment loss, 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 Annual Accounts Act, principally regarding financial 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 financial 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. No such reserve is recognised at 31 December 2022. 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 2022. 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	2022	2021
Sweden (Group domicile)	348	610
Germany (major market)	86,099	108,699
Other direct markets	21,378	18,452
Distributor markets	15,040	31,391
Total	**122,865**	**159,152**

Revenue per sales channel

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

KSEK	2022	2021
Direct sale markets	107,825	127,761
Distributor markets	15,040	31,391
Total	**122,865**	**159,152**

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	2022	2021
Sweden (Group domicile)	375,390	266,845
Ireland	29,078	17,044
Rest of the world*	3,629	2,885
Total	**408,097**	**286,774**

*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

	2022			2021		
	Total	Women	Men	Total	Women	Men
Parent Company						
Sweden	48	25	22	38	22	16
Spain	5	1	4	3	1	2
Total Parent Company	**53**	**27**	**26**	**41**	**23**	**18**
Group						
Ireland	3	2	1	5	2	3
France	5	2	3	6	3	3
Netherlands	3	–	3	2	–	2
Norway	1	1	–	2	1	1
USA	3	2	1	3	3	–
United Kingdom	4	2	2	3	1	2
Germany	13	7	7	14	6	8
Group total	**86**	**43**	**43**	**76**	**39**	**37**
Senior executives, at year-end						
Board of Directors	6	2	4	6	1	5
CEO and senior executives	10	3	7	9	4	5

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 2022					
Chairman of the Board Thomas Eklund	553	–	–	–	553
Board member Claus Bjerre	308	–	–	–	308
Board member Hilde Furberg [1]	150	–	–	–	150
Board member Bengt Julander [2]	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 (9 persons)	8,660	951	394	2,159	12,164
Total	**13,538**	**2,061**	**398**	**2,876**	**18,874**
Salaries and other remuneration 2021					
Chairman of the Board Thomas Eklund	475	–	–	–	475
Board member Claus Bjerre [3]	183	–	–	–	183
Board member Sten Gibeck [4]	33	–	–	–	33
Board member Bengt Julander	121	–	–	–	121
Board member Ola Magnusson	100	–	–	–	100
Board member Eva Walde	167	–	–	–	167
Board member Christoffer Rosenblad	188	–	–	–	188
CEO Christer Ahlberg [5]	1,080	638	59	277	2,054
CEO Johannes Doll [6]	1,040	1,000	1	171	2,212
Other senior executives (7 persons)	10,042	1,487	314	1,789	13,631
Total	**13,429**	**3,124**	**375**	**2,237**	**19,165**

1) Member of the Board from May 2022
2) Member of the Board until May 2022
3) Member of the Board from May 2021
4) Member of the Board until May 2021
5) CEO until June 2021
6) CEO from October 2021

Salaries and other remuneration and social security expenses

KSEK	2022				2021			
	Salaries and other remuner-ation	(of which bonuses)	Social security expenses	(of which pension expenses)	Salaries and other remuner-ation	(of which bonuses)	Social security expenses	(of which pension expenses)
Board members, Chief Executive Officer and other senior executives	15,998	(2,061)	8,975	(2,876)	16,928	(3,124)	7,049	(2,237)
Other employees	69,472	(3,750)	26,679	(9,716)	57,842	(5,809)	20,319	(8,585)
Total	**85,470**	**(5,811)**	**35,655**	**(12,592)**	**74,770**	**(8,933)**	**27,368**	**(10,822)**

Reported variable compensation is to some extent based on judgments and may be subject to change upon board approval.

KSEK	2022	2021
Salaries and other remuneration	85,470	74,770
Social security contributions	23,062	16,546
Pension expenses – defined-contribution plans	12,592	10,822
Total employee benefits	**121,124**	**102,138**

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 income 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 77–80.

For further information about warrants, see Note 23.

NOTE 6 Fee and reimbursement of expenses to auditors

KSEK	2022	2021
PwC		
Audit engagement	703	638
Auditing services other than the audit engagement	96	10
Tax advice	70	147
Other services	927	91
Total	1,796	886
Other auditors		
Audit engagement	313	265
Auditing services other than the audit engagement	-	-
Tax advice	-	-
Other services	-	-
Total	**313**	**265**
Total	**2,109**	**1,151**

NOTE 7 Operating expenses broken down by type of expense

KSEK	2022	2021
Goods for resale	31,637	46,592
Other external expenses	74,981	73,791
Personnel expenses	97,310	88,676
Depreciation	22,749	11,400
Total	**226,677**	**220,459**

NOTE 8 Other operating income

KSEK	2022	2021
Exchange gains on operating receivables/ liabilities	13,314	3,813
Other	5	200
Total	**13,319**	**4,013**

NOTE 9 Other operating expenses

KSEK	2022	2021
Exchange losses on operating receivables/ liabilities	15,267	4,109
Other	127	90
Total	**15,394**	**4,199**

NOTE 10 Net financial items

KSEK	2022	2021
Interest income	3,578	-
Exchange gains	44,722	11,285
Total financial income	**48,300**	**11,285**
Interest expense, other	-255	-243
Exchange losses	-15,091	-6,920
Total financial expense	**-15,346**	**-7,163**
Net financial items	**32,954**	**4,122**

NOTE 11 Tax

Current tax expense (–)/tax income (+)

KSEK	2022	2021
Tax expense/tax income for the year	-515	-549
Adjustment of tax attributable to previous years	-65	-24
Total current tax	**-580**	**-573**
Deferred tax		
Change in deferred tax	6	-22
Total deferred tax	**6**	**-22**
Total recognised tax expense/tax income	**-574**	**-595**

Reconciliation of recognised tax

KSEK	2022	2021
Profit/loss before tax	-72,933	-57,371
Tax at current tax rate for Parent Company	15,024	11,818
Tax effect of:		
- non-deductible expenses	-193	-89
- non-taxable income	-	-
- other tax rates for foreign subsidiaries/ branches	-1,406	-1,014
- increase in loss carry-forwards without corresponding capitalisation of deferred tax	-14,501	-19,527
- utilisation of previously non-capitalised loss carry-forwards	78	294
- tax relating to previous years	-66	-24
- deductible expenses which are not included in the result	490	7,946
- other	-	1
Recognised effective tax	**-574**	**-595**
Average effective tax rate (%)	0.8%	1.0%

The Group has tax loss carry-forwards of KSEK 234,953 (156,824). No deferred tax receivable has been recognised as at 31 December 2022. 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 2021 or 2022 as conversion to ordinary shares means a lower loss per share.

Measure of income used in the calculation of earnings per share

	Before dilution		After dilution	
KSEK	2022	2021	2022	2021
Profit attributable to shareholders in the Parent Company:				
Earnings per share, before and after dilution	-0.74	-0.62	-0.74	-0.62
Total	**-0.74**	**-0.62**	**-0.74**	**-0.62**

Weighted average number of ordinary shares

	2022	2021
Weighted average number of ordinary shares in calculation of earnings per share before dilution	99,336,960	92,774,631
Adjustment for calculation of earnings per share after dilution:		
Warrants	-	190,080
Weighted average number of ordinary shares and potential ordinary shares used as denominator in calculation of earnings per share after dilution	**99,336,960**	**92,964,711**

NOTE 13 Capitalised expenditure on development work and similar work

KSEK	31 Dec 2022	31 Dec 2021
Accumulated acquisition values:		
- At the beginning of the year	272,959	167,734
- Acquisitions	135,589	104,973
- Translation differences for the year	1,884	252
- At the end of the year	**410,432**	**272,959**
Accumulated depreciation according to plan:		
- At the beginning of the year	-4,758	-1,356
- Depreciation for the year	-14,944	-3,373
- Translation differences for the year	-200	-29
- At the end of the year	**-19,902**	**-4,758**
Carrying amount at the end of the year	**390,530**	**268,201**
The carrying amount above relates to:		
Development work within the medical sector	381,457	260,724
Other capitalised development expenses	9,073	7,477
Depreciation for the year by function:		
Cost of goods sold	-807	-459
Selling expenses	-12,686	-2,840
Administrative expenses	-1,149	-
Research and development expenses	-302	-74

Total expenditure on research and development expensed during the period amounts to KSEK 19,944 (19,704).

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 23 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 28 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 recognised value of goodwill cannot be justified.

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

KSEK	31 Dec 2022	31 Dec 2021
Accumulated acquisition values:		
- At the beginning of the year	8,670	8,245
- Acquisitions	1,459	89
- Translation differences for the year	1,674	336
- At the end of the year	**11,803**	**8,670**
Accumulated depreciation according to plan:		
- At the beginning of the year	-6,884	-5,247
- Depreciation for the year	-594	-1,347
- Translation differences for the year	-1,476	-290
- At the end of the year	**-8,954**	**-6,884**
Carrying amount at the end of the year	**2,849**	**1,786**

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

NOTE 15 Plant and machinery

KSEK	31 Dec 2022	31 Dec 2021
Accumulated acquisition values:		
- At the beginning of the year	3,771	10,694
- Acquisitions	-	782
- Reclassifications	-	-7,746
- Disposals	-15	-32
- Translation differences for the year	241	73
- At the end of the year	**3,997**	**3,771**
Accumulated depreciation according to plan:		
- At the beginning of the year	-2,462	-4,983
- Reclassifications	-	3,583
- Depreciation for the year	-370	-1,021
- Disposals	5	10
- Translation differences for the year	-215	-51
- At the end of the year	**-3,042**	**-2,462**
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	**955**	**1,309**

NOTE 16 Equipment, tools, fixtures and fittings

KSEK	31 Dec 2022	31 Dec 2021
Accumulated acquisition values:		
- At the beginning of the year	12,089	1,908
- Acquisitions	735	4,410
- Disposals	-72	-1,609
- Reclassifications	-	7,344
- Translation differences for the year	284	36
- At the end of the year	**13,036**	**12,089**
Accumulated depreciation according to plan:		
- At the beginning of the year	-5,935	-695
- Reclassifications	-	-3,181
- Disposals	29	-6
- Depreciation for the year	-2,411	-2,030
- Translation differences for the year	-227	-23
- At the end of the year	**-8,544**	**-5,935**
Carrying amount at the end of the year	**4,492**	**6,154**

NOTE 17 Deferred tax

Deferred tax receivables and liabilities are broken down as follows:

KSEK	31 Dec 2022	31 Dec 2021
Deferred tax assets:		
Loss carry-forwards	-	-
Inventories	-	-
Lease liability	29	23
Deferred tax liabilities:		
Right-of-use asset	-	-
Deferred tax assets (net)	**29**	**23**

KSEK	Loss carry-forwards	Lease liability	Inventories	Total
Deferred tax assets:				
At 1 January 2021	-	11	34	45
Recognised in the comprehensive income statement, 2021	-	12	-34	-22
At 31 December 2021	-	23	-	23
Recognised in the comprehensive income statement, 2022	-	6	-	6
At 31 December 2022	**-**	**29**	**-**	**29**

NOTE 18 Inventories

KSEK	31 Dec 2022	31 Dec 2021
Raw materials and consumables	792	622
Finished goods and goods for resale	37,805	10,471
Total	**38,597**	**11,093**

During the year, costs of materials were recognised in the income statement of KSEK 31,637 (46,593) as cost of goods sold.

NOTE 19 Accounts receivable

KSEK	31 Dec 2022	31 Dec 2021
Accounts receivable	15,886	20,345
Less provision for expected credit losses	-37	-
Accounts receivable – net	**15,849**	**20,345**

Group reserve for expected credit losses at 31 December 2022 total KSEK 37 (0). 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 2022	31 Dec 2021
EUR	12,693	16,705
GBP	1,874	2,659
USD	1,003	442
SEK	170	234
NOK	103	184
DKK	6	121
Accounts receivable – net	**15,849**	**20,345**

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 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%	2,205	-37
Total		**15,886**	**-37**
31 December 2021			
Not overdue	0%	13,057	-
Overdue 1–30 days	0%	3,055	-
Overdue 31–60 days	0%	2,050	-
Overdue 61–90 days	0%	545	-
Overdue more than 90 days	0%	1,638	-
Total		**20,345**	**-**

NOTE 20 Prepaid expenses and accrued income

KSEK	31 Dec 2022	31 Dec 2021
Rent	772	712
Pension	15	1,003
Bonus	1,878	-
Insurance	814	580
Capitalised development expenditure	-	787
Software	1,377	1,177
Marketing, congresses	267	987
R&D material	36	414
Other	858	1,455
Total	**6,017**	**7,115**

NOTE 21 Cash and cash equivalents

KSEK	31 Dec 2022	31 Dec 2021
Bank deposits	607,742	836,181
Total	**607,742**	**836,181**

NOTE 22 Shareholders' equity

KSEK	Number of shares	Share capital	Other contributed capital
Share capital and other contributed capital			
At 1 January 2021	23,046,740	2,305	613,923
Split	69,140,220	0	0
New share issue	7,150,000	178	608,472
At 31 December 2021	99,336,960	2,483	1,222,395
Warrant programme	0	0	4,040
At 31 December 2022	**99,336,960**	**2,483**	**1,226,435**

The share capital at 31 December 2022 consists of 99,336,960 ordinary shares with a quotient value of SEK 0.025.

All the shares that have been issued by the Parent Company are fully paid up. Transaction expenses in connection with contributed capital totalled KSEK 490 (7,946).

NOTE 23 Warrants

Warrants 2021

Programme	Position	Number of acquired warrants at the beginning of the period	Number of acquired warrants during the period	Number of exercised warrants during the period	Number of warrants bought back during the period	Number of warrants at the end of the period	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	251,168	–	–	33,904	217,264	1: 1	35.56
2019/2022	**Total**	**356,340**	**–**	**–**	**33,904**	**322,436**	**1: 1**	**35.56**
Exercise period 1 July 2022–30 November 2022								
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	–	–	–	38,480	1: 1	83.65
2020/2023	**Total**	**42,480**	**–**	**–**	**–**	**42,480**	**1: 1**	**83.65**
Exercise period 1 June 2023–30 September 2023								
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**
Exercise period 1 February 2024–31 May 2024								
Total	CEO	–	–	–	–	–		
Total	Other senior executives	109,172	25,200	–	–	134,372		
Total	Other employees	289,648	123,252	–	33,904	378,996		
	Total	**398,820**	**148,452**	**–**	**33,904**	**513,368**		

Warrants 2022

Programme	Position	Number of acquired warrants at the beginning of the period	Number of acquired warrants during the period	Number of warrants lapsing during the period	Number of warrants bought back during the period	Number of warrants at the end of the period	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**
Exercise period 1 July 2022–30 November 2022								
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**
Exercise period 1 June 2023–30 September 2023								
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**
Exercise period 1 February 2024–31 May 2024								
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**
Exercise period 30 May 2025–30 September 2025								
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**
Exercise period 1 June 2023–30 September 2025								
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**		

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

For further information regarding the warrant programmes, see page 38.

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 2022	31 Dec 2021
Property, plant and equipment owned	5,447	7,463
Right-of-use assets	9,271	9,324
Total	**14,718**	**16,787**

Right-of-use asset

KSEK	Buildings	Vehicles	Equipment and tools	Total
At 1 January 2021	7,421	1,226	145	8,792
Depreciation during the year, 2021	-2,031	-1,865	-83	-3,979
New assets	-	4,511	-	4,511
At 31 December 2021	**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
Closing balance, 31 December 2022	**4,879**	**4,392**	**0**	**9,271**

Lease liability

KSEK	31 Dec 2022	31 Dec 2021
Lease liability included in statement of financial position		
Current lease liabilities	5,167	4,232
Non-current lease liabilities	3,576	4,642
Total	**8,743**	**8,874**

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	2022	2021
Interest on lease liabilities	227	219
Amortisation	4,265	3,979
Variable lease payments not included in lease liability	1,120	1,368
Costs of short-term leases	12	3
Costs of leases of low value, not short-term leases of low value	60	55
Total	**5,684**	**5,624**

Amounts recognised in the cash flow statement

KSEK	2022	2021
Total cash flows attributable to leases	**-6,982**	**-6,147**

NOTE 25 Other current liabilities

KSEK	31 Dec 2022	31 Dec 2021
VAT	2,705	5,203
Employee withholding tax	1,997	2,198
Social security contributions	2,011	1,500
Liabilities to employees	27	8,400
Other liabilities	189	1,172
Total	**6,929**	**18,473**

NOTE 26 Accrued expenses and prepaid income

KSEK	31 Dec 2022	31 Dec 2021
Salaries, holidays, social security expenses	12,862	7,854
Consultants' fees	3,940	4,905
Auditing	1,002	903
Transport	332	972
Capitalised development expenditure	2,909	3,610
Other	1,887	1,500
Total	**22,932**	**19,744**

NOTE 27 Changes in liabilities belonging to financing activities

			Non-cash items		
KSEK	1 Jan 2021	Cash flow	Exchange-rate-differences	Newly signed leases	31 Dec 2021
Lease liability	8,291	-3,579	-47	4,209	8,874
Total	**8,291**	**-3,579**	**-47**	**4,209**	**8,874**

			Non-cash items		
KSEK	1 Jan 2022	Cash flow	Exchange-rate differences	Newly signed leases	31 Dec 2022
Lease liability	8,874	-4,510	-261	4,640	8,743
Total	**8,874**	**-4,510**	**-261**	**4,640**	**8,743**

NOTE 28 Financial risk and risk management

Classification and fair value
All financial instruments are measured at accrued acquisition value. Carrying amount of accounts receivable, 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 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%	10,160	4,634
USD/SEK	+/- 10%	715	29,876

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. Financial credit risk exists mainly against the company's banks in different countries. Sedana Medical only uses large and well-established banks with a high credit rating in each country, and locates cash and short-term investments to 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 among 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.

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 2021							
Lease liabilities	4,232	3,229	1,413	-	-	-	**8,874**
Accounts payable	15,036	-	-	-	-	-	**15,036**
31 December 2022							
Lease liabilities	5,167	2,774	627	175	-	-	**8,743**
Accounts payable	11,270	-	-	-	-	-	**11,270**

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 2022 the receivable totalled KSEK 300. Stefan has been a member of the Sedana Medical management team since the previous year. In 2021, a consultancy agreement was signed between Sedana Medical and Board member Claus Bjerre. In 2022, KSEK 50 relating to this agreement was invoiced and settled.

NOTE 30 Significant events after the end of the financial year

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.

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 the 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.

Parent Company income statement

KSEK	Note	2022	2021
Net sales	1,2	122,726	159,107
Cost of goods sold	2,5	-34,092	-49,662
Gross profit		**88,634**	**109,445**
Operating expenses	3,4,5,8		
Selling expenses		-68,360	-58,487
Administrative expenses		-112,498	-102,312
Research and development expenses		-16,927	-15,592
Other operating income	2,6	30,757	15,766
Other operating expenses	7	-15,238	-3,981
Operating income		**-93,632**	**-55,161**
Financial items			
Financial income		48,965	12,621
Financial expenses		-15,074	-21,088
Net financial items	9	**33,891**	**-8,467**
Income after financial items		**-59,741**	**-63,628**
Group contributions	10	0	-1
Profit/loss before tax		**-59,741**	**-63,629**
Income tax	11	-	-
Net income for the year		**-59,741**	**-63,629**

Parent Company statement of other comprehensive income

KSEK	Note	2022	2021
Net income for the year		**-59,741**	**-63,629**
Other comprehensive income			
Items that may be reclassified later to the income statement:			
Translation differences from operations abroad		-417	-93
Other comprehensive income during the year, net after tax		**-417**	**-93**
Comprehensive income for the year		**-60,158**	**-63,722**

Parent Company balance sheet

KSEK	Note	31 Dec 2022	31 Dec 2021
ASSETS			
Intangible assets			
Capitalised development expenditure	12	365,470	253,928
Property, plant and equipment			
Plant and machinery	13	795	835
Equipment, tools, fixtures and fittings	14	4,066	5,389
Financial assets			
Participations in Group companies	15	404	404
Receivables in Group companies	16	34,518	29,819
Total non-current assets		**405,253**	**290,375**
Inventories	17	38,597	11,093
Tax receivables		4	4
Accounts receivable	18	14,102	17,934
Receivables in Group companies		49,893	19,158
Prepaid expenses and accrued income	19	5,824	5,721
Other receivables		4,072	4,336
Cash and bank balances	20	587,909	816,279
Total current assets		**700,401**	**874,525**
TOTAL ASSETS		**1,105,654**	**1,164,900**

KSEK	Note	31 Dec 2022	31 Dec 2021
EQUITY AND LIABILITIES			
Equity	21,22		
Restricted equity			
Share capital		2,483	2,483
Fund for development expenditure		356,396	246,451
Non-restricted equity			
Share premium reserve		1,226,435	1,222,395
Retained earnings		-475,162	-301,172
Net income for the year		-59,741	-63,629
Equity attributable to shareholders in the Parent Company		**1,050,412**	**1,106,528**
Current liabilities			
Accounts payable		10,711	13,662
Liabilities to Group companies		18,092	10,937
Tax liabilities		2,300	2,118
Other liabilities	23	5,287	16,027
Accrued expenses and prepaid income	24	18,852	15,628
Total current liabilities		**55,242**	**58,372**
Total liabilities		**55,242**	**58,372**
TOTAL EQUITY AND LIABILITIES		**1,105,654**	**1,164,900**

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 2021	**2,305**	**154,405**	**613,923**	**-209,033**	**561,600**
Net income for the year	-	-	-	-63,629	-63,629
Other comprehensive income for the year	-	-	-	-93	-93
Comprehensive income for the year	-	-	-	-63,722	-63,722
Changes in the carrying amounts recognised directly in equity					
New share issue	178	-	614,722	-	614,900
Issue expenses	-	-	-7,946	-	-7,946
Premium received on issue of warrants	-	-	1,760	-	1,760
Buyback of warrants	-	-	-64	-	-64
Total	178	-	608,472	-	608,650
Transfer between items in equity					
Capitalisation of development expenditure	-	92,046	-	-92,046	-
Total	-	92,046	-	-92,046	-
Closing equity at 31 Dec 2021	**2,483**	**246,451**	**1,222,395**	**-364,801**	**1,106,528**
Opening equity at 1 Jan 2022	**2,483**	**246,451**	**1,222,395**	**-364,800**	**1,106,529**
Net income for the year	-	-	-	-59,741	-59,741
Other comprehensive income for the year	-	-	-	-416	-416
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
Buyback of warrants	-	-	-97	-	-97
Expenses for warrant programme	-	-	-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**	**1,050,412**

Parent Company cash flow statement

KSEK	Note	2022	2021
Operating activities			
Operating income		-93,632	-55,161
Adjustments for non-cash items:			
Depreciation, amortisation and impairment		16,173	4,911
Exchange-rate differences		2,026	-2,671
Other non-cash items		1,112	936
Total		**-74,321**	**-51,985**
Interest received		3,578	0
Interest paid		-22	-23
Income tax paid		-	-
Cash flow from operating activities before changes in working capital		**-70,765**	**-52,008**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in inventories		-27,504	-1,848
Increase (-)/Decrease (+) in operating receivables		-26,764	-26,003
Increase (+)/Decrease (-) in operating liabilities		-3,129	24,296
Cash flow from operating activities		**-128,162**	**-55,563**
Investing activities			
Investment in intangible assets	12	-125,679	-100,581
Investment in property, plant and equipment	13,14	-718	-4,183
Acquisition of financial assets		0	-3,046
Cash flow from investing activities		**-126,397**	**-107,810**
Financing activities			
New share issue	21	-	614,900
Issue expenses	21	-	-7,946
Premium received for warrant subscription	21	3,589	1,696
Expenses for warrant programme	21	-489	0
Buyback of warrants	21	-97	0
Cash flow from financing activities		**3,003**	**608,650**
Cash flow for the period		**-251,556**	**445,277**
Cash and cash equivalents at the beginning of the period		**816,279**	**365,113**
Translation difference in cash and cash equivalents		23,186	5,889
Cash and cash equivalents at the end of the period	20	**587,909**	**816,279**

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	2022	2021
Sweden (Group domicile)	348	610
Germany (major market)	86,099	108,699
Other direct markets	21,239	18,407
Distributor markets	15,040	31,391
Total	**122,726**	**159,107**

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

NOTE 2 Intra-Group purchases and sales

KSEK	2022	2021
Sale of goods relating to Group companies	6,306	6,602
Operating income concerning services relating to Group companies	18,423	11,826
Purchase of goods relating to Group companies	9	945

NOTE 3 Employees, personnel expenses and remuneration of senior executives

Average number of employees

	2022			2021		
	Total	Women	Men	Total	Women	Men
Parent Company						
Sweden	48	25	22	38	22	16
Spain	5	1	4	3	1	2
Total Parent Company	**53**	**27**	**26**	**41**	**23**	**18**
Senior executives, at year-end						
Board of Directors	6	2	4	6	1	5
CEO and senior executives	10	3	7	9	4	5

Salaries and other remuneration and social security expenses

	2022				2021			
KSEK	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	15,998	(2,061)	8,975	(2,876)	12,525	(2,544)	5,743	(1,728)
Other employees	37,582	(1,602)	17,266	(6,361)	34,097	(2,470)	15,812	(6,097)
Total	**53,580**	**(3,664)**	**26,241**	**(9,237)**	**46,622**	**(5,013)**	**21,556**	**(7,824)**

KSEK	2022	2021
Salaries and other remuneration	53,580	46,622
Social security contributions	17,004	13,731
Pension expenses – defined-contribution plans	9,237	7,824
Total employee benefits	**79,821**	**68,177**

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 income 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 77–80.

For further information about warrants, see Note 22.

NOTE 4 Fee and reimbursement of expenses to auditors

KSEK	2022	2021
PwC		
Audit engagement	703	638
Auditing services other than the audit engagement	96	10
Tax advice	70	147
Other services	927	91
Total	1,796	886
Other auditors		
Audit engagement	-	47
Auditing services other than the audit engagement	-	-
Tax advice	-	-
Other services	-	-
Total	-	47
Total	**1,796**	**933**

NOTE 5 Operating expenses broken down by type of expense

KSEK	2022	2021
Goods for resale	31,663	47,229
Personnel expenses	61,675	56,099
Depreciation	16,173	4,911
Other operating expenses	122,366	117,814
Total	**231,877**	**226,053**

NOTE 6 Other operating income

KSEK	2022	2021
Exchange gains on operating receivables/ liabilities	12,329	3,799
Intra-group management fee	18,423	11,826
Other	5	141
Total	**30,757**	**15,766**

NOTE 7 Other operating expenses

KSEK	2022	2021
Exchange losses on operating receivables/ liabilities	15,238	3,981
Other	-	-
Total	**15,238**	**3,981**

NOTE 8 Operating leases – Lessee

KSEK	2022	2021
Contracted future minimum lease payments for non-cancellable contracts fall due:		
- Within one year	4,779	3,944
- Between one and five years	3,952	5,927
Total	**8,731**	**9,871**
Expensed lease payments for the year	4,083	3,460
Of which rent for premises	3,011	2,606

NOTE 9 Net financial items

KSEK	2022	2021
Interest income, Group companies	1,930	1,355
Interest income, other	3,578	0
Exchange gains	43,457	11,266
Total financial income	48,965	12,621
Interest expense, other	-22	-23
Impairment of internal receivables	0	-14,151
Exchange losses	-15,052	-6,914
Total financial expense	-15,074	-21,088
Total	**33,891**	**-8,467**

NOTE 10 Appropriations

KSEK	2022	2021
Group contributions paid	0	1
Total	**0**	**1**

NOTE 11 Tax

Current tax expense (-)/tax income (+)

KSEK	2022	2021
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	2022	2021
Profit/loss before tax	-59,471	-63,629
Tax at current tax rate for Parent Company	12,307	13,107
Tax effect of:		
- non-deductible expenses	-138	-2,981
- other tax rates for foreign subsidiaries/ branches	-11	-16
- increase in loss carry-forwards without corresponding capitalisation of deferred tax	-12,711	-18,149
- utilisation of previously non-capitalised loss carry-forwards	63	92
- deductible expenses which are not included in the result	490	7,946
- other	-	1
Recognised effective tax	**-**	**-**

Unutilised loss carry-forwards for which no deferred tax receivable has been recognised total KSEK 194,058 at 31 Dec 2022 (31 Dec 2021: KSEK 134,959). 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 2022	31 Dec 2021
Accumulated acquisition values:		
- At the beginning of the year	256,842	156,261
- Acquisitions	125,678	100,581
- Translation differences for the year	–	-
- At the end of the year	**382,520**	**256,842**
Accumulated depreciation according to plan:		
- At the beginning of the year	-2,914	-
- Depreciation for the year	-14,136	-2,914
- Translation differences for the year	–	-
- At the end of the year	**-17,050**	**-2,914**
Carrying amount at the end of the year	**365,470**	**253,928**
The carrying amount above relates to:		
Development work within the medical sector	356,397	246,451
Other capitalised development expenses	9,073	7,477
Depreciation for the year by function:		
Selling expenses	-12,686	-2,840
Administrative expenses	-1,148	-
Research and development expenses	-302	-74

NOTE 13 Plant and machinery

KSEK	31 Dec 2022	31 Dec 2021
Accumulated acquisition values:		
- At the beginning of the year	1,030	6,226
- Acquisitions	-	748
- Reclassifications	-	-5,932
- Disposals	-15	-15
- Translation differences for the year	-	3
- At the end of the year	**1,015**	**1,030**
Accumulated depreciation according to plan:		
- At the beginning of the year	-195	-1,892
- Reclassifications	-	2,097
- Depreciation for the year	-30	-409
- Disposals	5	10
- Translation differences for the year	-	-1
- At the end of the year	**-220**	**-195**
Carrying amount at the end of the year		
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	**795**	**835**

NOTE 14 Equipment, tools, fixtures and fittings

KSEK	31 Dec 2022	31 Dec 2021
Accumulated acquisition values:		
- At the beginning of the year	9,192	815
- Acquisitions	718	3,435
- Reclassifications	-	5,932
- Disposals	-72	-993
- Translation differences for the year	29	3
- At the end of the year	**9,867**	**9,192**
Accumulated depreciation according to plan:		
- At the beginning of the year	-3,803	-177
- Reclassifications	-	-2,097
- Depreciation for the year	-2,006	-1,588
- Disposals	29	61
- Translation differences for the year	-21	-2
- At the end of the year	**-5,801**	**-3,803**
Carrying amount at the end of the year	**4,066**	**5,389**

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 2022	Book value 31 Dec 2021
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 2022	31 Dec 2021
Accumulated acquisition values:		
Opening cost	404	395
Acquired participating interests	-	9
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 2022	31 Dec 2021
Accumulated acquisition values:		
- At the beginning of the year	43,970	38,539
- Added receivables	1,957	4,397
- Deducted receivables	3,989	1,034
- At the end of the year	**49,916**	**43,970**
Accumulated impairments:		
- At the beginning of the year	-14,151	-
- Additional impairments	-	-14,151
- Currency translation	-1,247	-
- At the end of the year	**-15,398**	**-14,151**
Carrying amount at the end of the year	**34,518**	**29,819**

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 2022	31 Dec 2021
Raw materials and consumables	792	622
Finished goods and goods for resale	37,805	10,471
Total	**38,597**	**11,093**

During the year, costs of materials of KSEK 31,663 (47,229) were recognised in the income statement as cost of goods sold.

NOTE 18 Accounts receivable

KSEK	31 Dec 2022	31 Dec 2021
Accounts receivable	14,124	17,934
Less provision for expected credit losses	-22	-
Accounts receivable – net	**14,102**	**17,934**

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 2022	31 Dec 2021
EUR	10,946	14,282
SEK	170	234
GBP	1,874	2,659
NOK	103	184
DKK	6	121
USD	1,003	454
Accounts receivable – net	**14,102**	**17,934**

NOTE 19 Prepaid expenses and accrued income

KSEK	31 Dec 2022	31 Dec 2021
Rent	757	698
Pension	15	1,003
Bonus	1,878	–
Insurance	710	530
Capitalised development expenditure	–	787
Software	1,377	1,028
Marketing, congresses	267	708
Other	820	967
Total	**5,824**	**5,721**

NOTE 20 Cash and cash equivalents

KSEK	31 Dec 2022	31 Dec 2021
Bank deposits	587,909	816,279
Total	**587,909**	**816,279**

NOTE 21 Shareholders' equity

KSEK	Number of shares	Share capital	Share premium reserve
Share capital and other contributed capital			
At 1 January 2021	23,046,740	2,305	613,923
Split 4: 1	69,140,220	0	0
New share issue	7,150,000	178	608,472
At 31 December 2021	**99,336,960**	**2,483**	**1,222,395**
Warrant programme	0	0	4,040
At 31 December 2022	**99,336,960**	**2,483**	**1,226,435**

The share capital at 31 December 2022 consists of 99,336,960 ordinary shares with a quotient value of SEK 0.025.

All the shares that have been issued by the Parent Company are fully paid up.
Transaction expenses in connection with contributed capital totalled KSEK 490 (7,946)

NOTE 22 Warrants

Warrants 2021

Programme	Position	Number of acquired warrants at the start of the period	Number of acquired warrants during the period	Number of exercised warrants during the period	Number of warrants bought back during the period	Number of warrants at the end of the period	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	251,168	–	–	33,904	217,264	1: 1	35.56
2019/2022	**Total**	**356,340**	**–**	**–**	**33,904**	**322,436**	**1: 1**	**35.56**
Exercise period 1 July 2022–30 November 2022								
2020/2023	CEO	–	–	–	–	–	1: 1	83.65
2020/2023	Other senior executives	16,000	–	–	–	16,000	1: 1	83.65
2020/2023	Other employees	26,480	–	–	–	26,480	1: 1	83.65
2020/2023	**Total**	**42,480**	**–**	**–**	**–**	**42,480**	**1: 1**	**83.65**
Exercise period 1 June 2023–30 September 2023								
2020/2024	CEO	–	–	–	–	–	1: 1	123.88
2020/2024	Other senior executives	–	–	–	–	–	1: 1	123.88
2020/2024	Other employees	–	148,452	–	–	148,452	1: 1	123.88
2020/2024	**Total**	**–**	**148,452**	**–**	**–**	**148,452**	**1: 1**	**123.88**
Exercise period 1 February 2024–31 May 2024								
Total	CEO	–	–	–	–	–		
Total	Other senior executives	121,172	–	–	–	121,172		
Total	Other employees	277,648	148,452	–	33,904	392,196		
Total		**398,820**	**148,452**	**–**	**33,904**	**513,368**		

NOTE 22 Warrants, cont.

Warrants 2022

Programme	Position	Number of acquired warrants at the start of the period	Number of acquired warrants during the period	Number of warrants lapsing during the period	Number of warrants bought back during the period	Number of warrants at the end of the period	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**
Exercise period 1 July 2022–30 November 2022								
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**
Exercise period 1 June 2023–30 September 2023								
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**
Exercise period 1 February 2024–31 May 2024								
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**
Exercise period 30 May 2025–30 September 2025								
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**
Exercise period 1 June 2023–30 September 2025								
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**		

* 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 2022	31 Dec 2021
VAT	2,582	5,049
Employee withholding tax	1,525	1,732
Social security contributions	1,162	1,149
Liabilities to employees	18	6,924
Other liabilities	-	1,173
Total	**5,287**	**16,027**

NOTE 24 Accrued expenses and prepaid income

KSEK	31 Dec 2022	31 Dec 2021
Salaries, holidays, social security expenses	9,669	4,330
Consultants' fees	3,404	4,814
Auditing	739	520
Transport	332	854
Capitalised development expenditure	2,909	3,610
Other	1,799	1,500
Total	**18,852**	**15,628**

NOTE 25 Appropriation of profit or loss

SEK	
Funds available to the Annual General Meeting:	
Accumulated loss	-475,162,148
Share premium reserve	1,226,435,473
Net income for the year	-59,741,497
Total	**691,531,828**
The Board proposes that the available funds be appropriated as follows:	
Share premium reserve	1,226,435,473
Accumulated loss in new account	-534,903,645
Total	**691,531,828**

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 2022 the receivable totalled KSEK 300. Stefan has been a member of the Sedana Medical management team since the previous year. In 2021, a consultancy agreement was signed between Sedana Medical and Board member Claus Bjerre. In 2022, KSEK 50 relating to this agreement was invoiced and settled.

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.

Certification by the Board of Directors and the Chief Executive Officer

The Board of directors and the Chief Executive Officer certify that the consolidated accounts have been prepared in accordance with international accounting standards IFRS as they have been adopted by the EU and give a true and fair view of the group's position and results.
The annual report has been prepared in accordance with good accounting practice and gives a true and fair view of the parent company's position and results. The administration report for the group and the parent company provides a true and fair overview of the development of the group's and parent company's operations, position and results and describes significant risks and uncertainty factors which the parent company and the companies that are part of the group face.

Danderyd, 3 April 2023

Thomas Eklund
Chairman of the Board

Claus Bjerre
Vice 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 3 April 2023

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 2022. The annual accounts and consolidated accounts of the company are included on pages 39-73 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 2022 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 2022 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 consolidated income satement and consolidated balance sheet for 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.

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 1-38 and 77-86. 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 audit 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) for the year 2022 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' 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], I (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 Sedana Medical AB (publ) for the financial year 2022.

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 the 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 audit firm applies ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and 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 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 has been marked with iXBRL in accordance with what follows from the Esef regulation.

Öhrlings PricewaterhouseCoopers AB, Torsgatan 21, 113 97 Stockholm, was appointed auditor of Sedana Medical AB (publ) by the general meeting of the shareholders on the 11 May 2022 and has been the company's auditor since the 19 May 2020.

Uppsala 3 April 2023

Öhrlings PricewaterhouseCoopers AB

Leonard Daun
Authorized Public Accountant

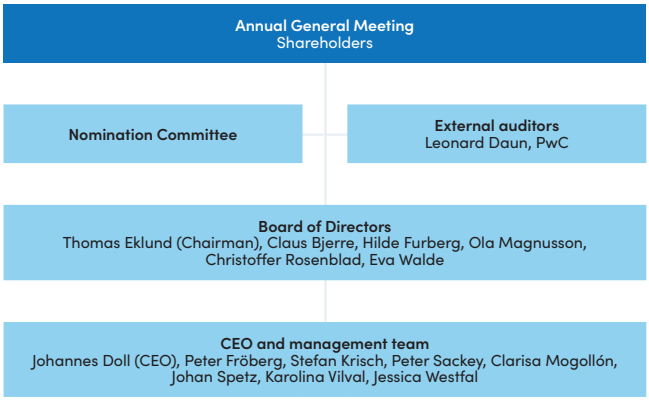
Corporate Governance

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. This description summarises how corporate governance is organised and how it was pursued in 2022.

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
- 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

External regulatory frameworks affecting the articles of association

- Swedish Companies Act
- Accounting regulations
- Rulebook for issuers of shares

Swedish Code of Corporate Governance

The Swedish Code of Corporate Governance ('the Code') specifies a higher standard of good corporate governance than the minimum requirements of the Swedish Companies Act. The Code has not been applicable to the 2022 financial year.

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 determine 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.

Nomination Committee

The AGM of the Company held on 11 May 2022 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.

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. As of the closing date of the financial year, the company's Board consists of six members. For information concerning each member of the Board, see pages 81–82.

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.

Board attendance and fee

	Year elected	Attendance number of meetings in 2022 (10)	Board fee resolved by 2022 AGM (ksek)	Attendance of audit committee meetings in 2022 (7)	Audit committee fee decided by the 2021 AGM (ksek)	Independent in relation to:	
						Company	Shareholders
Chairman of the Board							
Thomas Eklund	2014	10	550	6	30	Yes	Yes
Board member							
Claus Bjerre	2021	10	325			Yes	Yes
Hilde Furberg	2022	7	225			Yes	Yes
Ola Magnusson	2005	9	225	4	30	Yes	Yes
Christoffer Rosenblad	2020	10	225	7	75	Yes	Yes
Eva Walde	2018	10	225			Yes	Yes

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 collated results of the survey, including comments made, are presented by reproducing responses for each question with means and standard deviations. The work of the Board was evaluated in late 2022.

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 Board has decided not to establish any remuneration committee as the Board considers it more appropriate for the whole Board to fulfil the tasks which, under the Code, are incumbent on the remuneration committee. The Board discusses matters concerning remuneration and terms of employment for the senior management and draws up proposals for guidelines on remuneration of the Chief Executive Officer and senior executives, which the Board presents to the Annual General Meeting for resolution. The company has adopted Guidelines for Remuneration of Senior Executives.

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. In 2022, Johannes Doll was the Company's CEO. Sedana Medical's senior management otherwise consisted of Chief Financial Officer Johan Spetz (took up duties on 28 March 2022), Chief Medical Officer Peter Sackey, Vice President Regulatory Affairs and QA Jessica Westfal, Supply Chain and Manufacturing Director Stefan Krisch, General Counsel Karolina Vilval (took up duties 15 August 2022), Chief Technology Officer Peter Fröberg, and Head of Marketing Clarisa Mogollón (took up duties 15 September 2022).

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 and financial controller activities
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 40–42. 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. It is ultimately a matter of ensuring that

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 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 decided not to establish any remuneration committee as the Board considers it more appropriate for the whole Board to fulfil the tasks which, under the Code, are incumbent on the remuneration committee.

Remuneration for members of the Sedana Medical Board is resolved by the AGM. The Annual General Meeting held on 11 May 2022 passed a resolution concerning annual Board fees in the amount of SEK 550,000 to the Chairman, SEK 325,000 to the Board member and Vice Chairman Claus Bjerre, and SEK 225,000 each 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 six monthly salaries. 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 2022 was KSEK 914. Remuneration of the Company's accountant is paid on current account.

Board of Directors

Thomas Eklund

Born: 1967

Nationality: Swedish

Position: Member of the Board and Chairman of the Board of Sedana Medical since 2014.

Education and work experience: Thomas holds an MBA from the Stockholm School of Economics. Approximately 25 years of experience from senior positions in banking, life science and healthcare. CEO of Investor Growth Capital (renamed as Patricia Industries) over the period 2002–2012, a private equity company owned by Investor AB with a focus on long-term investments in technology, healthcare and industry. Former Board member in life science companies, such as Swedish Orphan International AB (Chairman) and Carmel Pharma AB.

Other current appointments: Member of the Board of Biotage AB, Boule Diagnostics AB, Immedica Pharma Holding AB, Mabtech Group Holding AB, Mabtech Holding AB, Surgical Science Sweden AB, Swedencare AB (publ) and Board member in affiliates to these companies and smaller family companies.

Shareholding in Sedana Medical: 1,666,464 shares via Tedsalus AB. Independent in relation to both the company and its management and the company's major shareholders.

Claus Bjerre

Born: 1971

Nationality: Danish

Position: Member of the Board and Vice Chairman 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 for 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: 4,500 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. Ola was the founder of Sedana Medical in 2005 and served as CEO until 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: 4,462,098 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 an M.Sc. from Chalmers University of Technology and a master's degree in economics from the School of Business and Economics 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 (since 2022) at 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 Chair of the Board of her own company Movits Consulting AB and deputy member of the Board of Finnson & Partners AB.

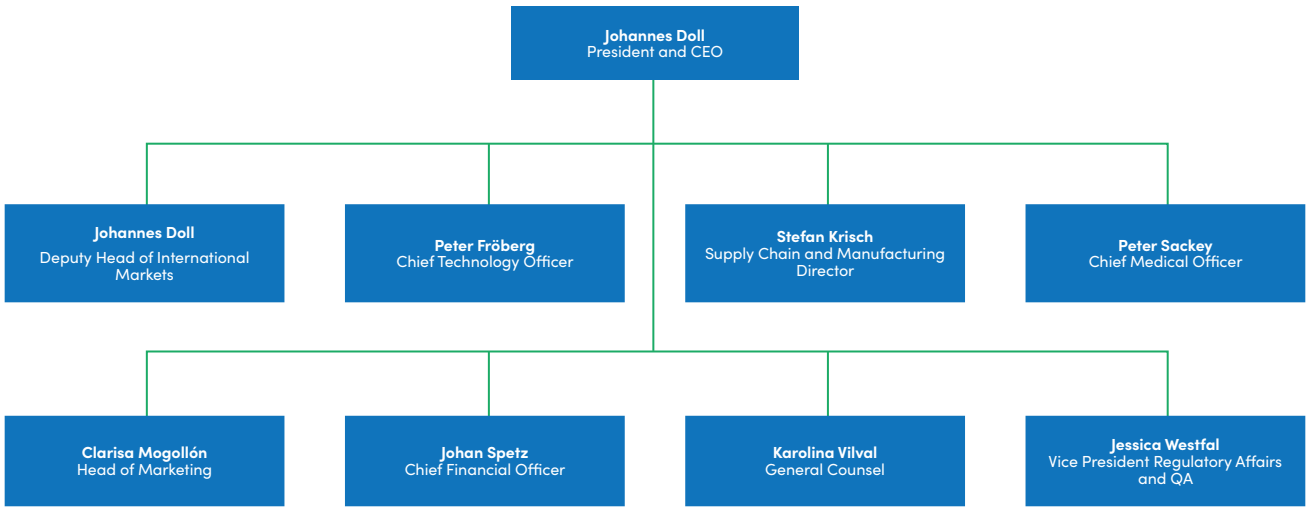
Shareholding in Sedana Medical: 12,800 shares. Independent in relation to both the company and its management and the company's major shareholders.

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 product specialists employed in Germany, France, the Nordics, the UK and Spain. During 2022, the average number of employees was 86. 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 increased the number of employees as the Group has grown and has consequently 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.

Company management

The Group Management Team consists of President and CEO Johannes Doll, Chief Technology Officer Peter Fröberg, Supply Chain and Manufacturing Director Stefan Krisch, Chief Medical Officer Peter Sackey, Head of Marketing Clarisa Mogollón, Chief Financial Officer Johan Spetz, General Counsel Karolina Vilval and Vice President Regulatory Affairs and QA Jessica Westfal.



Group management

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: 17,630 shares and 495,000 warrants.

Peter Fröberg

Born: 1971

Nationality: Swedish

Position: Chief Technology Officer since May 2021.

Education and work experience: Master's degree in engineering from the Royal Institute of Technology (KTH) in Stockholm. More than 20 years of experience of product development and business development, as product manager at Elekta Instrument AB and as consultant in Life Science.

Shareholding in Sedana Medical: No shares. 30,000 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: Head of Marketing since September 2022.

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 shareholding.

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: 187,468 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: 15,073 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 shareholding.

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 Unimedic AB (2006–2020), among other things as head of quality and product development, and at AstraZeneca AB (1998–2006).

Shareholding in Sedana Medical: No shares. 18,260 warrants. Related party 692 shares.

Literature references

Page	Footnote	Source:
12	1	Society of Critical Care of Medicine (20-30% in the US), International Comparison in Critical Care (53.7%) and Review for the NHS Executive of Adult Care Services: An International (42-60% for seven European countries)
12	2	Röhm KD, Wolf MW, Schöllhorn T, Schellhaass A, Boldt J, Piper SN. Short-term sevoflurane sedation using the anaesthetic conserving device after cardiothoracic surgery. Intensive Care Med. 2008;34(9): 1683-1689 Mesnil M, Capdevila X, Bringuier S, et al. Long-term sedation in intensive care unit: A randomized comparison between inhaled sevoflurane and intravenous Propofol or midazolam. Intensive Care Med. 2011;37(6): 933-941 Hanafy MA. Clinical evaluation of inhalational sedation following coronary artery bypass grafting. Egypt J Anaesth. 2005;21(3): 237-242 Sackey P V, Martling C-R, 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 Shelly MP, Sultan MA, Bodenham A, Park GR: Midazolam infusions in critically ill patients. Eur J Anaesthesiol 1991, 8: 21-27
12	3	Röhm KD, Wolf MW, Schöllhorn T, Schellhaass A, Boldt J, Piper SN. Short-term sevoflurane sedation using the anaesthetic conserving device after cardiothoracic surgery. Intensive Care Med. 2008;34(9): 1683-1689 Mesnil M, Capdevila X, Bringuier S, et al. Long-term sedation in intensive care unit: A randomized comparison between inhaled sevoflurane and intravenous Propofol or midazolam. Intensive Care Med. 2011;37(6): 933-941
12	4	Bellgardt, M., Bomberg, M., Dasch B. et al, Survivial after long-term isoflurane sedation as opposed to intravenous sedation in cirtically ill surgical patients, Eur J Anaesthesiol 2015; 32: 1-8
13	5	Sackey, PV, Martling C-R, 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	L'Her, E., Lenaig, D., Pili, R., "Feasibility and Potential Cost/Benefit of Routine isoflurane Sedation Using an AnestheticConserving Device: a Prospective Obervational Study", Respiratory Care, 2008.
13	7	Sackey, PV., et al. "Short-and long-term follow-up of intensive care unit patients after sedation with isoflurane and midazolam – A pilot study." Critical care medicine 36.3 (2008): 801-806
13	8	Sackey, PV, Martling C-R, 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	9	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	10	Stephan A. Schug, Detlev Zech and Stefan Grand. Adverse Effects of Systemic Opioid Analgesics Drug Safety 199;27 (3): 200-213
13	11	Bellgardt, M., Bomberg, M., Dasch B. et al, Survival after long-term isoflurane sedation as opposed to intravenous sedation in critically ill surgical patients, Eur J Anaesthesiol 2015; 32: 1-8
18	12	Wunsch H, Wagner J, Herlim M, Chong DH, Kramer AA, Halpern SD. ICU occupancy and mechanical ventilator use in the United States. Crit Care Med, december 2013.
33	13	Sherman et al. Anesthesia & Analgesia 2012
33	14	Farrel et al., J Clin Mon Comput 2018l
33	15	Sackey et al., Crit Care 2004, Gonzalez-Rodriguez et al., Rev Esp Anestesiol Reanim 2014, Pickworth et al., Can J Anaesth 2013, Herzog-Niescery et al., Minerva Anestesiol 2018.
33	16	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 randomised, either for the group receiving the therapy 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 2023

The Annual General Meeting of Sedana Medical AB (publ) will be held on Tuesday 16 May 2023 at 1.00 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 8 May 2023 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 8 May 2023. 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 10 May 2023 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. Registrations for the Annual General Meeting will begin at 12.30 pm.

For further information, please contact

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Corporate identity number: 556670–2519

Financial calendar

Interim report 1st quarter 2023:	27 April 2023
AGM 2023:	16 May 2023
Interim report 2nd quarter 2023:	21 July 2023
Interim report 3rd quarter 2023:	26 October 2023

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