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2021 Annual Report

Sedaconda (isoflurane) receives European market approval

The Lancet Respiratory Medicine publishes the Sedaconda study

IND approval from FDA for Phase III studies in the US

Record year with sales of SEK 159 million

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Sedana Medical reached an important milestone in 2021 when the pharmaceutical product Sedaconda (isoflurane), and consequently inhaled sedation therapy, received European market approval.

The approval is based on the strong results from the Sedaconda study (SED001). Through the approval, the company has taken a major step towards its vision to make inhaled sedation a standard therapy in critcal care.

Inhaled sedation is a simple, effective and predictable therapy

Through the unique medical device Sedaconda ACD (Anaesthetic Conserving Device), previously known as AnaConDa, 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 has developed and sells the medical device Sedaconda ACD for inhaled sedation of mechanically ventilated patients in intensive care. With the positive results of the clinical study SED001 with Sedaconda (isoflurane) delivered via Sedaconda ACD, the foundation has been laid for establishing inhaled sedation, a simple, effective and predictable therapy for the sedation of intensive care patients. The company's vision is for inhaled sedation to become a global standard therapy for patients in intensive care. The results of the study were published in The Lancet Respiratory Medicine in August 2021.

Sedana Medical reached an important milestone in 2021 when the pharmaceutical product Sedaconda (isoflurane), and consequently inhaled sedation, received European market approval. Another important milestone was reached when the application to start clinical studies in the United States was approved. Sedana Medical plans to obtain market approval in the United States in 2024.

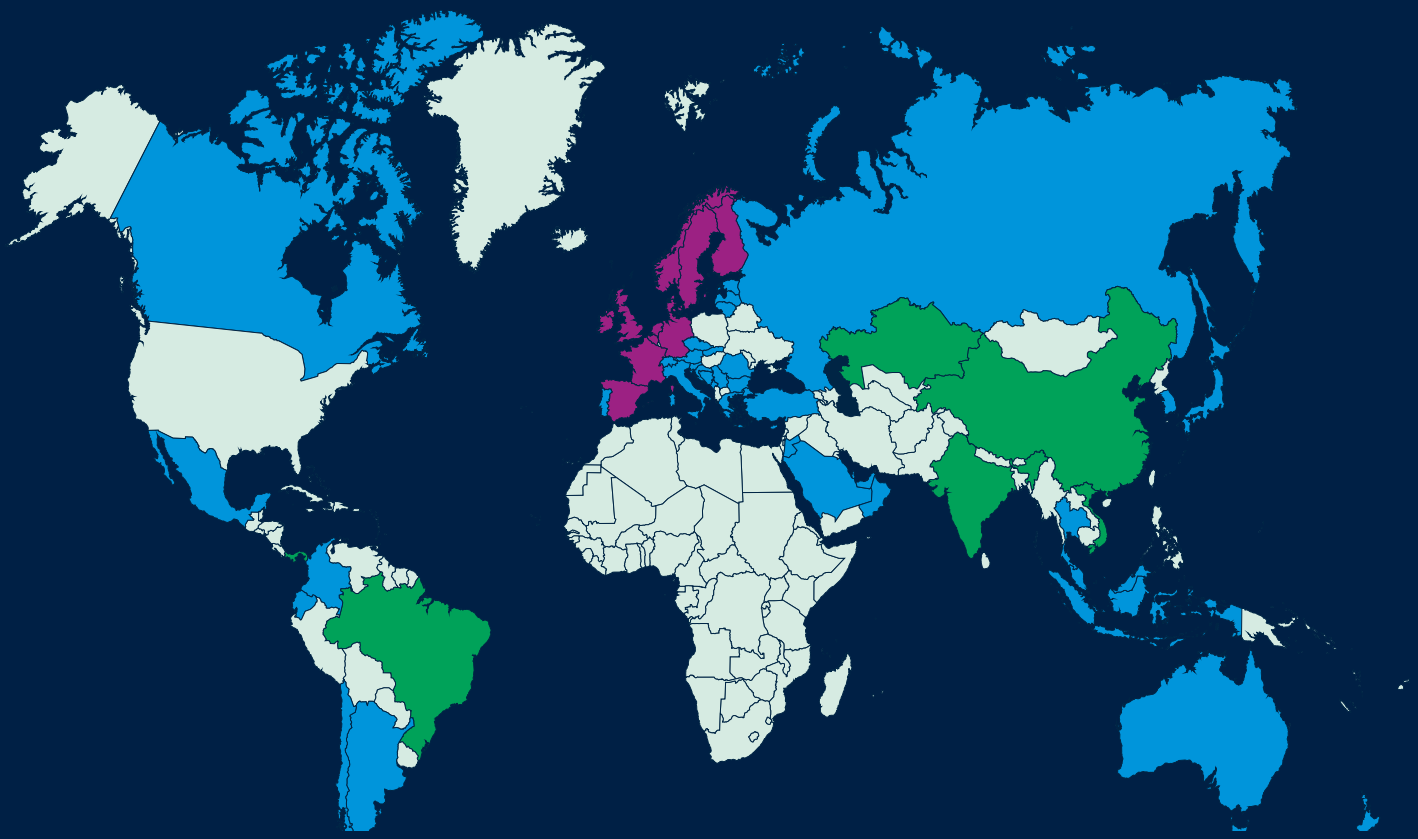
Sedana Medical achieved sales of SEK 159 million in 2021, representing an increase of 16 percent, at constant exchange rates, despite the therapy having been 'off-label'. The company's largest market is Germany, which accounted for 68 percent of total sales in 2021. Sedana Medical also has direct sales in Benelux, France, Ireland, 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 works with distributors.

> "The foundation has been laid for establishing inhaled sedation, a simple, effective and predictable therapy for the sedation of patients in intensive care"

At the end of 2021 the company made a directed share issue totalling SEK 615 million before issue expenses. The net proceeds will be used to fund the preparations for commercialisation of the Sedaconda products in the United States by building up a separate dedicated operation.

The company's financial target is to achieve revenue in excess of SEK 500 million in Europe three years after registration of Sedaconda in Europe (2024). When the company has reached a stable market position in the United States, the target is to achieve an EBITDA margin of approximately 40 percent.

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. Production takes place through contract manufacturers. In June 2017, the company's shares (ticker: SEDANA) were listed on Nasdaq First North Growth Market Stockholm.



- Own sales organisation
- Sales through distributors
- Ongoing registration process for Sedaconda ACD

Sedana Medical in brief

Sedana Medical strives to improve patients' lives during and beyond sedation in intensive care by providing the medical device Sedaconda ACD and the pharmaceutical product Sedaconda (isoflurane), and in doing so enables inhaled sedation for mechanically ventilated patients in intensive care.

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.

2–3

billion euro

Sedana Medical estimates the total market potential to be EUR 2–3 billion. Furthermore, the market is growing as populations age.

159

million SEK

In 2021, Sedana Medical achieved sales of SEK 159 million.

8

million patients

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

Highlight of the year – market approval for inhaled sedation

In 2021, Sedana Medical obtained market approval for the pharmaceutical product Sedaconda (isoflurane) through what is known as a decentralised procedure (DCP). The application was based on the positive results in the Phase III study Sedaconda (SED001), the single largest advance towards acceptance of inhaled sedation since the technique was developed. The results of the study were published in The Lancet Respiratory Medicine.

Q1

- Applications for market approval for Sedaconda (isoflurane) were submitted in Switzerland and the United Kingdom.
- The first patient was included in the company's paediatric study IsoCOMFORT (SED002).
- Sedana Medical's CEO, Christer Ahlberg, announced his resignation to become CEO of an unlisted company.

Q2

- A share split (4:1) was completed at the end of May.

"The publication in The Lancet Respiratory Medicine was one of several highlights 2021"

Q3

- Sedana Medical's quality system received MDR approval, meaning that the company's Class I medical devices can continue to be sold with CE marking in the EU.
- At an advisory meeting, the US authority FDA accepted Sedana Medical's proposal for a Phase III programme.
- DCP approval of the application for registration of the pharmaceutical product Sedaconda (isoflurane) for inhaled sedation in intensive care in Europe.
- The results of the Sedaconda study (SED001) were published in The Lancet Respiratory Medicine.
- Market approval for Sedaconda (isoflurane) in Germany.

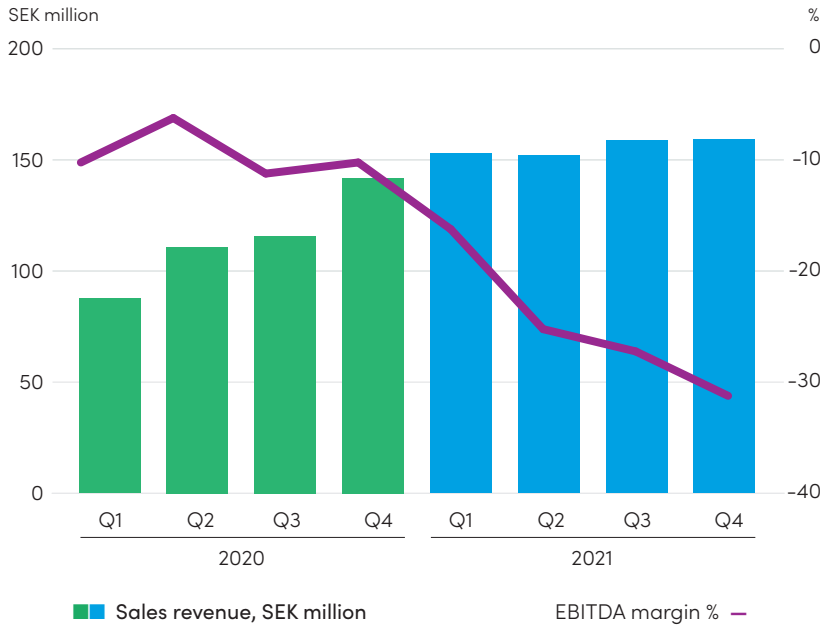
Q4

- After being appointed by the Board in May, Johannes Doll took up duties as the new President and CEO of Sedana Medical.
- A directed share issue contributed SEK 615 million before issue expenses.
- The company received IND approval from the FDA to enable pivotal clinical Phase III studies with the Sedaconda products to begin in the United States.
- An application for market approval for Sedaconda (isoflurane) in Italy was submitted.
- Application for market approval for Sedaconda ACD in China was submitted.

Key performance indicators for the Group

Amounts in thousands of SEK	2021	2020	2019
Net sales	159,152	141,770	71,646
Gross profit	106,706	88,903	48,539
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-50,093	-14,294	-12,932
Operating income (EBIT)	-61,493	-21,359	-17,120
Net income	-57,966	-27,139	-16,380
Gross margin %	67%	63%	68%
EBITDA margin %	-31%	-10%	-18%
Operating margin (EBIT) %	-39%	-15%	-24%
Profit margin %	-36%	-19%	-23%
Balance sheet total	1,167,580	600,097	595,766
Equity ratio %	94%	92%	96%
Quick ratio %	1,414%	929%	1,872%
Average number of employees	76	57	39

Sales revenue and EBITDA margin, 12 months rolling



Covid-19

Sedana Medical recorded a significant increase in demand in 2020 as a result of the pandemic.

In 2021 the company saw a similar trend, particularly in distributor markets, primarily in Latin America.

There continues to be great uncertainty over the future development of the Covid-19 pandemic in general around the world. Its impacts range from the propensity and ability of clinics to use new sedation therapies in a time of crisis to a possible shortage of, or reduced access to, intravenous sedatives, as well as mutant variants and future availability of vaccines. Short-term effects may therefore arise in sales in individual quarters, but the long-term potential for Sedana Medical's products does not depend on Covid-19.

In operational terms, Covid-19 has meant that more clinics are now trained and equipped to use inhaled sedation.

683,000

units sold

Up to and including 2021, 683,000 Sedaconda ACD units have been sold.

159

million SEK

Net sales in 2021 totalled SEK 159 million.

16%

sales growth in 2021 (at constant exchange rates)

A strong platform for EU launch and important steps towards US approval

In 2021, we delivered the highest turnover in our history and made strong progress on both of our main priorities: to execute an excellent launch of Sedaconda (isoflurane) in Europe and to prepare for the important US market.

Sedana Medical's purpose is to improve life during and beyond sedation. In order to live up to that purpose we are aiming to make inhaled sedation a standard therapy in intensive care units around the world. We are looking back onto an eventful year, in which we reached several important milestones and made good progress towards our goals.

In the first weeks after joining Sedana Medical on October 1, I made it a priority to visit intensive care units in several countries and gather first-hand feedback from our customers. I had the opportunity to speak with many physicians, nurses, and hospital administrators about their views on inhaled sedation and their experience with the medical device Sedaconda ACD. I am inspired by the fact that the clear benefits of inhaled sedation versus current standard of care, which we showed in the pivotal trial SED001, are seen, and confirmed by hospital staff for their patients every day. I find this strong feedback very encouraging as we continue our journey to make inhaled sedation a standard therapy in intensive care.

> "In July, we reached a key milestone when we obtained European DCP approval and by year end, we had national approval in 14 of the 15 countries included in the DCP approval"

We have reached an excellent starting position for the launch of our pharmaceutical product Sedaconda (isoflurane). In July, we reached a key milestone when we obtained European DCP approval and by year end, we had national approval in 14 of the 15 countries included in the DCP approval. During 2022, we expect four more countries to approve Sedaconda (isoflurane): the United Kingdom, Switzerland, Poland, and Italy.

In the latter part of the year, we took an important strategic decision regarding our largest potential market, the United States, where we will build our own commercial organization to launch the Sedaconda products. Following this decision, we carried out a successful directed share issue that raised SEK 615 million, which gives us the financial strength we need to implement our ambitious US strategy. I would like to take this opportunity to thank both our new and existing shareholders for their support and trust in Sedana Medical. In December, the FDA approved our IND (Investigational New Drug) application, which allows us to initiate pivotal clinical Phase III trials in the United States. We look forward to bringing our Sedaconda products to patients in the US.

In January 2022, Sedaconda ACD received positive guidance from the National Institute for Health and Care Excellence (NICE) recommending Sedaconda ACD as a cost-saving option for delivering inhaled sedation in intensive care as an alternative to intravenous sedation. After showing meaningful clinical benefits of Sedaconda (isoflurane) versus intravenous sedation in our pivotal trial SED001, NICE has now confirmed that the use of Sedaconda ACD leads to considerable cost savings compared to intravenous sedation of approximately GPB 3.800 per adult patient.

We ended an eventful and successful year in a strong position, which lays a good foundation for future success. Our most important milestones in 2022 will be the launch of Sedaconda in Europe and inclusion of the first patients in the clinical trials in the United States. I look forward to coming back to you regarding our continued progress.

Johannes Doll
President and CEO

Inhaled sedation as a global standard therapy

Sedana Medical's vision is to develop inhaled sedation into a global standard therapy for sedation of mechanically ventilated patients in intensive care. A first milestone was reached in 2021 when the pharmaceutical product Sedaconda (isoflurane), and consequently also inhaled sedation therapy, received European market approval.

Purpose

To improve life during and beyond sedation.

Vision

To make inhaled sedation a standard therapy in critical care.

Financial targets

The target is to achieve revenue in excess of SEK 500 million in Europe three years after registration of Sedaconda in Europe (2024). When the company has attained a stable market position in the United States, the target is to achieve an EBITDA margin of approximately 40 percent.

Strategy

The company's strategy to reach its vision will over the next few years 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 (isoflurane) and Sedaconda ACD as a combination therapy.
3. Commercialising Sedaconda ACD through distributors in selected markets worldwide.

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.

1999

Sedaconda ACD is tested clinically for the first time.

2003

Sedaconda ACD obtains CE mark.

2005

Sedana Medical is established in Uppsala.

2010

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

2010–2020

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

2020

The Sedaconda study (SED001) reaches its primary endpoint.

2021

The paediatric study IsoCOMFORT (SED002) includes its first patient.

Sedaconda (isoflurane) receives European market approval.

The US studies (SED003 & SED004) receive IND approval from the FDA.

Sedation in ICU – problem and solution

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

Intensive care units treat critically ill patients with serious, life-threatening diseases and injuries. Common conditions treated in intensive care include trauma, multiple organ failure, sepsis 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 very traumatic and unpleasant experience. To help the patient better tolerate mechanical ventilation and to provide comfort and safety, the patient is sedated to relieve anxiety, agitation and pain and to prevent the patient from self extubating by pulling the tube out of their airways. 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 between two and five days.

Challenges with intravenous sedation

There are many challenges with intravenous sedation of intensive care patients. To begin with, 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 treatment 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]. All these side effects lead to a significant increase in the length of ICU stay. 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 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].

Sedation in ICU

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

Inhaled sedation provides clear benefits compared to current standard therapy

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 risk of a severe side effect, including heart failure. In addition, there are clear recommendations that benzodiazepines should not be used for sedation in intensive care owing to adverse events. These pharmaceutical products are nevertheless used, as the options are limited. Sedana Medical firmly believes that inhaled sedation can fulfil this role.

Expectations of a modern sedative for use in ICU are that it is fast-acting, allows good controllability of sedation depth, causes few side effects and allows 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 has been shown to provide several benefits:

Wake-up times are short (10–20 minutes[5]) and predictable. When treatment has been completed, it is important that the patient wake up and 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 over- or undersedation and makes it easy to wake the patient to check neurological status. This reduces the need for computed tomography (CT) scans. When using intravenous sedation, a broad and growing literature has shown that 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.

Time in the intensive care unit can probably be shortened as the reduced risk of dependence, withdrawal symptoms and/or delirium are expected to lead to shorter hospitalisation.

Side effects such as hallucinations and delirium are less common[6].

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.

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[7] compared to intravenous sedation. This reduces the risk of opioid dependence and lowers the cost of sedation.

A higher proportion of spontaneous breathing improves the prospects of maintained lung function during and after ventilator therapy[4]. With lowered doses of opioids, it is likely that spontaneous breathing can be maintained to a greater extent.

Trends in sedation

Sedana Medical sees five principal trends that affect underlying market growth:

1.

Increased awareness of the risks associated with no or very light sedation

New publications illustrate the risks and the foregone benefits with no or very light sedation.

2.

Increased interest in pharmaceutical products whose elimination is independent of hepatic or renal function

Many ICU patients have impaired hepatic or renal function, leading to reduced ability to break down pharmaceutical products that are eliminated via the liver and kidneys.

3.

Increased trend towards abandoning the use of benzodiazepines

Benzodiazepines used for extended periods can lead to a number of undesirable clinical effects.

4.

Ageing population

Elderly persons generally have a more complex clinical picture and poorer ability to recover, which means they tend to stay in intensive care longer than younger patients.

5.

Need to reduce healthcare costs

The most costly beds in a hospital are those occupied by intensive care patients, and there are therefore compelling incentives to shorten patients' time in intensive care. The daily cost for an intensive care unit patient in Europe is estimated to be EUR 2,000–4,000[8]. As a result of an ageing population and an average life expectancy that is expected to increase, costs of healthcare in general and intensive care in particular are expected to continue to rise.

Footnotes – see Bibliography on page 86.

Unique patented technology in an innovative product

Sedaconda ACD (Anaesthetic Conserving Device) is a unique and innovative product for simple and effective delivery of inhaled anaesthetics.

Sedaconda ACD has been developed for simple delivery of inhaled anaesthetics 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. Together with existing intensive care equipment, Sedaconda ACD represents an optimal solution for the sedation of severely ill patients.

In addition, Sedana Medical sells accessories that enable and simplify the use of Sedaconda ACD. These include, for example, syringes to supply Sedaconda ACD with isoflurane and the FlurAbsorb filter used to prevent the spread of inhaled anaesthetics when sedating via Sedaconda ACD.

High reuse reduces consumption of pharmaceuticals

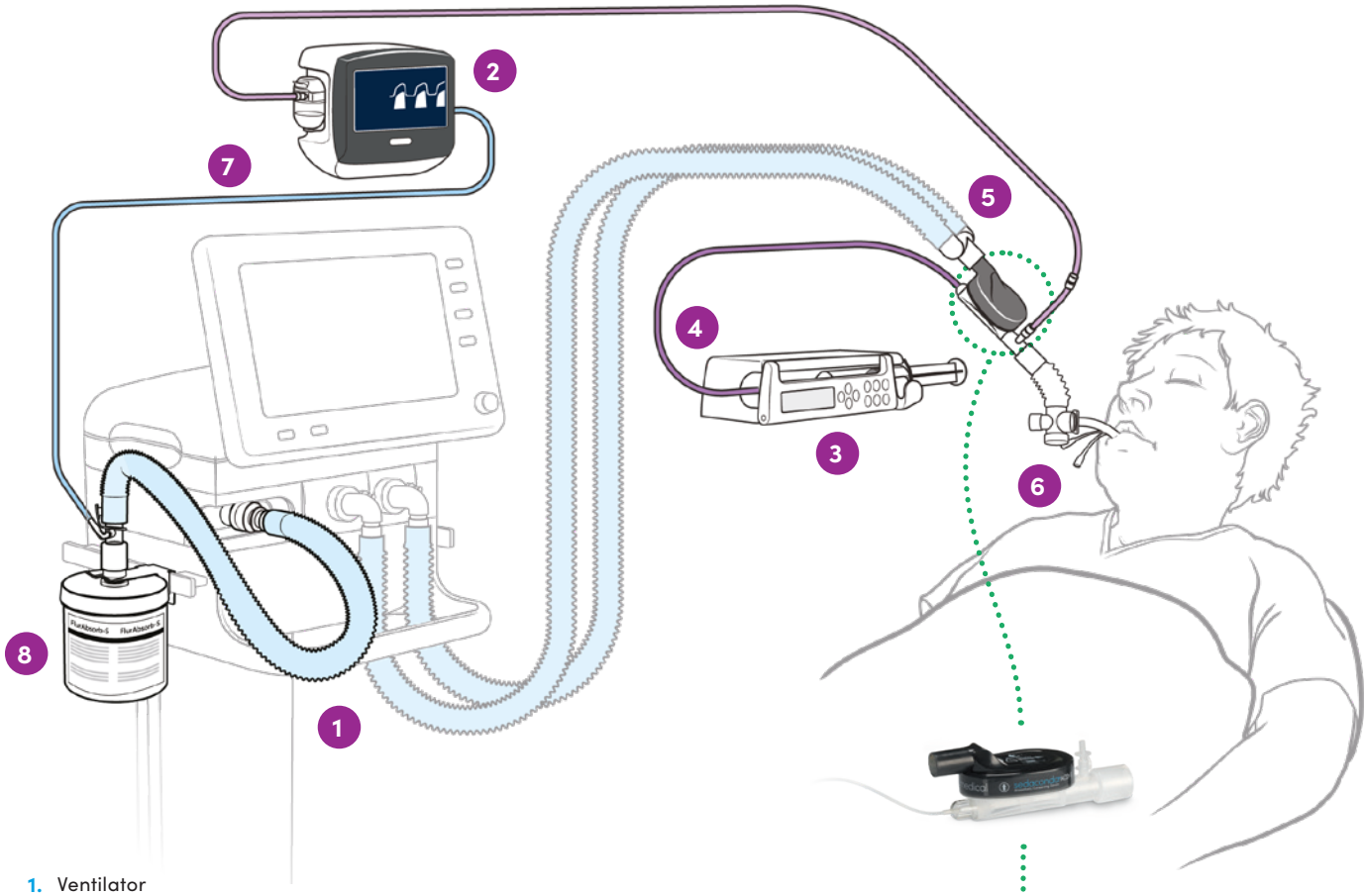
The technology of the Sedaconda ACD enables around 90% of the pharmaceutical in the exhaled air to be reflected and subsequently reused in the inhalation phase. The residual pharmaceutical product passes through the ventilator, through the exhaust line and is captured by the FlurAbsorb filter or by the active gas scavenging system. High reuse contributes to reducing both consumption of the pharmaceutical product and dispersal of gas in the surroundings. Studies confirm very low emissions well below permitted limit values.

Sedaconda ACD

Makes simple and effective delivery possible with a high level of reuse

- 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 adsorbed in the filter in the Sedaconda ACD.
- On the next inhalation, the pharmaceutical is released from the filter, combined with new vaporised pharmaceutical and returned to the patient with the air flow.
- Approximately 90 % of the pharmaceutical is recirculated in this way to the patient, reducing consumption.

Sedaconda ACD is compatible with common ICU equipment

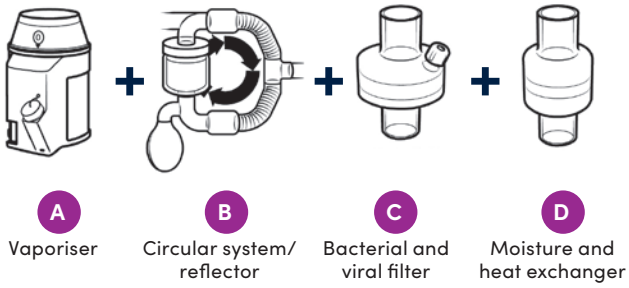


1. Ventilator
2. Gas analyser
3. Syringe pump
4. Anaesthetic agent line
5. Y-piece
6. Endotracheal tube
7. Gas sampling line
8. Passive gas scavenging system

The Sedaconda ACD is used in combination with a ventilator (1), a gas analyser (2) and a syringe pump (3). The specially designed syringe (with a unique connector) is placed in a standard syringe pump. The Sedaconda ACD is placed between the Y-piece (5) and the 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 adsorbed by the carbon filter, released and returned to the patient on inhalation. The remaining anaesthetic passes through the ventilator, out through the exhaust line and is captured by the FlurAbsorb filter or by an active gas scavenging system (8).

The Sedaconda ACD does not have any electrical components and is compatible with magnetic resonance imaging and computed tomography.



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

The Sedaconda study – a decisive breakthrough

The Sedaconda study (SED001) shows that Sedaconda (isoflurane) delivered via Sedaconda ACD is an effective therapy for sedation of mechanically ventilated intensive care patients, comparable to propofol. The results form the basis for Sedana Medical's European market approval.

In 2017 Sedana Medical initiated the clinical Phase III study Sedaconda (SED001), which was aimed at having the drug candidate Sedaconda (isoflurane) approved for inhaled sedation in intensive care in Europe. The Sedaconda study is the largest ever randomised study of inhaled sedation.

> "The results of the Sedaconda study (SED001) are the single largest advance towards acceptance of inhaled sedation since the technique was developed"

In July 2020, Sedana Medical was able to announce that the study had reached its primary endpoint: to show that Sedaconda, delivered via Sedaconda ACD, is an effective therapy for sedation of mechanically ventilated patients in intensive care, comparable to propofol. The study results confirm the clinical experience of inhaled sedation as an effective and safe method of sedation and represent the single greatest advance for inhaled sedation since the Sedaconda ACD was developed.

The secondary endpoints additionally show that Sedaconda, delivered via Sedaconda ACD, compared with propofol, 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.

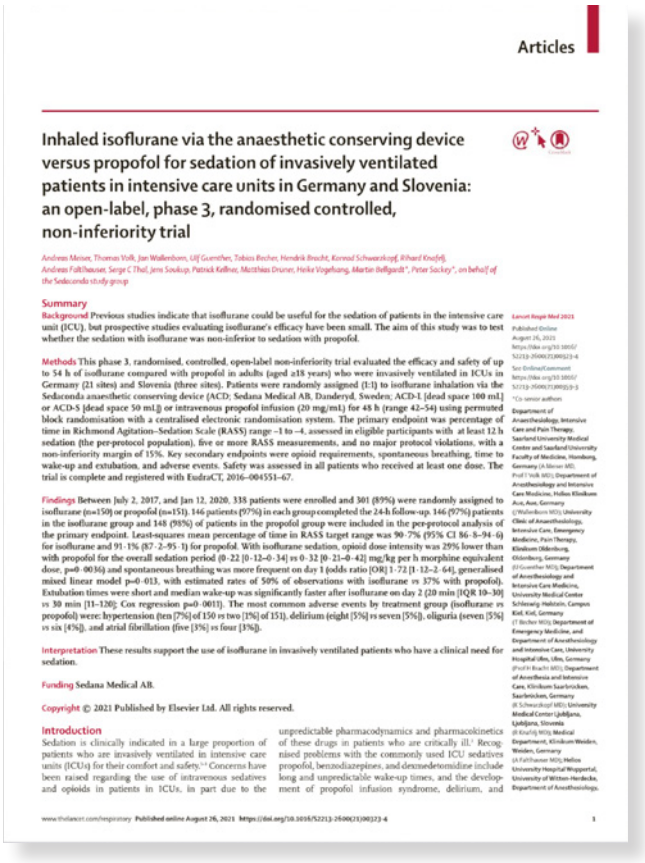
The study, which was conducted over the period 2017–2019 at 21 centres in Germany and three in Slovenia, is a non-inferiority study, meaning that its primary objective is to demonstrate that Sedaconda, delivered via Sedaconda ACD, is not worse than propofol in maintaining an adequate level of sedation. This is established by comparing the proportion of time that adequate depth of sedation is maintained with isoflurane compared to propofol.

The study covered 301 mechanically ventilated patients in intensive care in need of sedation. The patients were randomly allocated to one of two groups, in one of which patients were sedated with intravenously delivered propofol while the other group was sedated with Sedaconda delivered via Sedaconda ACD.

The Sedaconda study
shows that Sedaconda (isoflurane), delivered via Sedaconda ACD, is an effective therapy for sedation of mechanically ventilated intensive care patients, comparable to propofol.

Publication in The Lancet Respiratory Medicine – A major recognition

In August 2021, the results of the Sedaconda study (SED001) were published in the highly respected scientific journal The Lancet Respiratory Medicine. As this is the leading journal in the area of intensive care and pulmonary medicine, the publication is not just great recognition of inhaled sedation therapy but also an important element in efforts to establish inhaled sedation as a global standard therapy.



Articles

Inhaled isoflurane via the anaesthetic conserving device versus propofol for sedation of invasively ventilated patients in intensive care units in Germany and Slovenia: an open-label, phase 3, randomised controlled, non-inferiority trial

Summary

Introduction

➜ Access the full-length publication

"The results of the study, which is the largest in inhaled sedation, point to the efficacy and safety of isoflurane delivered via Sedaconda ACD and the benefits of the therapy, namely reduced opioid need, increased degree of spontaneous breathing and faster wake-up. Overall, there are now strong reasons for using inhaled sedation as first-line therapy."

The study's principal investigator in Germany, Associate Professor **Andreas Meiser**, Saarland University Medical Center, Homburg, Germany.

Sedana Medical also presented the study results both at the annual congress of ESICM Live (European Society of Intensive Care Medicine) and at ISICEM, the world's largest conference in intensive care and emergency medicine.

At the 52nd intensive care conference DHGIIN & ÖGIAIN in June 2021, the Sedaconda study was additionally chosen as one of the three best posters at the conference. This conference is the joint annual congress of the German and Austrian emergency medicine and intensive care societies, and it was highly positive that the Sedaconda study received this attention in Germany, the company's largest market.

Dr Jan Wallenborn is one of the investigators in the clinical Sedaconda study. He uses inhaled sedation as first-line therapy for several categories of patients.

"Inhaled sedation offers benefits for our patients"

Privatdozent, Dr. Jan Wallenborn is the medical director and senior consultant at the clinic for anesthesia and intensive care medicine at Helios Clinic in Aue, Germany, one of the clinics in Sedaconda study.

When and how did you first encounter inhaled sedation?
My first contact with inhaled sedation goes six years back. I was looking for an alternative to intravenous sedation and introduced inhaled sedation at my ICU five years ago. Initially, my ICU staff was not pleased by another new technique introduced by the chief medical director, but they fast learned to appreciate the advantages and easy use of inhaled sedation.

How come you were looking for an alternative to intravenous sedation?
Normally, analgosedation with sufentanil and propofol is the first choice at most ICUs worldwide. However, the recommended use of propofol is limited by time and dose. After that, substances with less favorable pharmacokinetics, such as benzodiazepines or neuroleptics, are used. As short awakening times and no influence on liver or kidney function are crucial in severely ill patients, we were looking for alternatives.

You were involved in the Sedaconda study, please tell us about your experience from the trial.
We all have had the problem of an approved device but lacked an approval for the use of isoflurane in the ICU. Taking the advantages of inhaled sedation into account, my staff was highly motivated to take part in the Sedaconda study. Now, we all are very proud to have contributed to this important study.

How has Covid-19 affected your clinic and the usage of inhaled sedation?
We already used inhaled sedation regularly at our ICU before Covid-19 occurred. The need for long term sedation in severe Covid-19 cases increased the use of inhaled sedation.

Which are the advantages you appreciate the most with inhaled sedation?
Firstly, our ICU nurses appreciate the easy use and reliable effect of inhaled sedation. Also, doctors appreciate the short awakening times in daily wake-up attempts, which is also a benefit to our patients. In general, we see advantages in patients with severe chronic obstructive pulmonary disease (COPD) or liver disease.

How do you use inhaled sedation today?
Our ICU nurses love this kind of sedation, but according to guidelines we initially start with propofol sedation, except for patients with severe liver disease, severe COPD/asthma or known propofol infusion syndrome. During the ICU stay we switch to inhaled sedation after seven days or earlier if intravenous sedation doesn't work well for the patient. Inhaled sedation is our favorite sedation in ARDS patients, who need deep sedation.

Do you expect to increase usage to other groups of patients?
We believe there could be an advantage in obese patients. As already mentioned, we use inhaled sedation as first line treatment in patients with severe COPD or liver disease.

Have you experienced propofol infusion syndrome (PRIS)?
Yes, of course, basically all staff in an ICU have seen PRIS. It's just a question of quantity of ICU patients over time. Because of the life-threatening character of PRIS, it is mandatory to keep the ICU staff aware of this. The same applies to malignant hyperthermia (MH) and inhaled sedation. Even though MH is less frequent than PRIS, clinicians must be aware of this syndrome as they need to react fast and in an appropriate manner.

Which hurdles do you see for the therapy to become widely adopted?
The biggest hurdle until now has been the missing approval of isoflurane use in the ICU, but now, thanks to the Sedaconda study this problem has been solved. Some intensivists have suspected technical issues like indoor air pollution or enlargement of dead space in ventilation, but all these problems are also already solved. Apart from "best sedation is no sedation", it is always an advantage to enlarge our opportunities so we can choose the best treatment for our patients.

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

Sedana Medical's studies

In addition to the Sedaconda study (SED001), Sedana Medical is conducting a paediatric study as the basis for a paediatric market approval and planning pivotal studies in the United States.

IsoCOMFORT • SED002

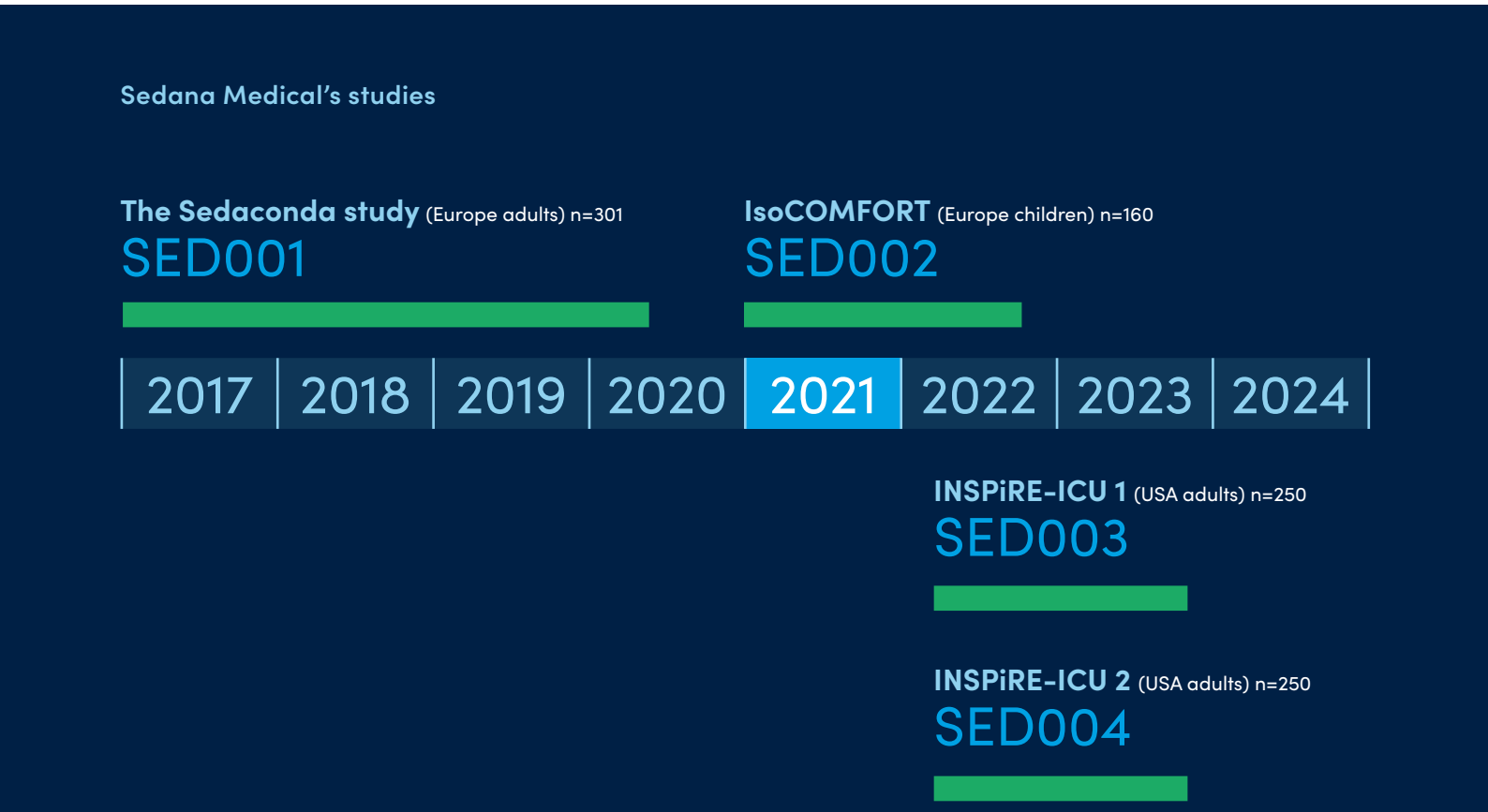
Sedana Medical's paediatric study, IsoCOMFORT, compares the efficacy and safety of Sedaconda (isoflurane), delivered via Sedaconda ACD, with intravenous midazolam in the sedation of mechanically ventilated patients below the age of 18 (ages 3–17). The patients will be sedated for 12–48 hours with either sedation therapy, and the primary endpoint is the proportion of time spent at adequate depth of sedation (according to the COMFORT B scale).

The study will cover 160 patients from intensive care units in Sweden, Germany, France and Spain, and it recruited its first patients in the first quarter of 2021. The study is expected to lead to an approved paediatric indication for inhaled sedation. Midazolam is currently the only sedation option for children in intensive care units, as propofol is contraindicated due to the risk of severe side effects.

In 2019, Sedana Medical received approval for a Paediatric Investigation Plan (PIP) by the European Medicines Agency's Paediatric Committee (PDCO). This approval is important, as conducting studies in children is one of the conditions to be met to obtain ten years of market exclusivity in Europe for Sedaconda delivered via Sedaconda ACD.

INSPiRE-ICU 1 & 2 • SED003 & SED004

Sedana Medical will conduct the studies INSPiRE-ICU 1 & 2 in the United States, starting in 2022. These are two identical Phase III studies aiming to confirming the efficacy and safety of sedation with Sedaconda (isoflurane) delivered via Sedaconda ACD. Studies are of strategic significance, as they will form the basis for Sedana Medical's US market application. To fulfil the FDA requirements, the studies will be 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 500 patients. The name INSPiRE-ICU stands for Inhaled Sedation vs Propofol In Respiratory Failure.



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 Regionale 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 10 intensive care units in France and is expected to be completed in 2023.

ISCA
The ISCA study (led by Associate Professor Matthieu Jabaudon, France; Associate Professor Martin Schläpfer, Switzerland; Professor Rafael Badenes, Spain and Associate Professor Tobias Becher, Germany) is a retrospective observational study of 400 Covid-19-related ARDS patients comparing inhaled sedation (isoflurane or sevoflurane) with intravenous sedation. The primary objective 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 in France, Germany, Spain and Switzerland. Study results are expected in 2022.

> "The research grant furthers the prospects for research in Sedana Medical's area, with the aim of leading to medical advances in the field to the benefit of patients and healthcare"

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.

Because of the great medical opportunities inhaled anaesthetics offer, interest in research on inhaled sedation is very high in general, and in 2021 we received several good applications. The awarded project in 2021 is a particularly interesting research project in the United Kingdom.

Control, rapid effect and predictable wake-up

Goba's CEO Miguel Gonzalez in an interview about the market in Mexico, Colombia and Brazil.

Goba is Sedana Medical's partner and distributor in Mexico, Colombia and Brazil. In January 2020, Sedana Medical received market approval for Sedaconda ACD in Mexico, and in 2021 Mexico was one of Sedana Medical's largest markets. Miguel Gonzalez is Goba's CEO.

Please tell us about Goba.
In 1996, Goba Mexico was founded to provide health care products and equipment to doctors and hospitals. We now have 35 employees of which the majority are sales people, divided by business line and market segment (public and private). Our main lines of business are Radiology, ICUs, Hospital Equipment and Wound Care.

So, you sell other equipment to ICUs than only Sedaconda ACD?
Yes, in Mexico we sell equipment such as ventilators, monitors and specialized ICU beds. But in 2019, we started Goba Colombia focusing exclusively on promoting inhaled sedation through Sedana Medical's products. We currently have four sales people in Colombia and in the first half 2022 we will hire another three. In Q4 2021, we started Goba Brazil with the same objective and focus as in Colombia and in November 2021, we received the first Sedaconda ACD shipment to our warehouse in Brazil.

How did you first encounter Sedana Medical?
We found out about Sedana Medical at an ICU congress and through a doctor friend who told us about the benefits of the products. After that we began to investigate to learn more about Sedaconda ACD. The more we learned about the device and its advantages, the more we fell in love with the system. Another thing that surprised us, is that there is nothing similar in the market and possible competitors have a more complicated technology.

How has your co-operation developed?
In the beginning, it was a bit slow, but now we have overcome most obstacles, both in the registration processes and in producing promotional and educational materials in Spanish. Sedana Medical has given us medical support in training and support for medical users and webinars. We now have all promotional material, information and scientific documentation supported by Key Opinion Leaders in Spanish. We are working closely together with Sedana Medical, and our co-operation is working very well.

Which are in your view the unique selling points of the therapy?
There are many advantages, but from my point of view, one of the main benefits is the control of sedation, achieving a rapid onset and a predictable awakening, even in complicated patients. Another great advantage is that almost all elimination is pulmonary, which reduces the renal and hepatic load. Last but not least, awakening is improved by reducing delirium and hallucinations.

Which feedback do you get from users?
All anesthesiologists are enthusiastic about Sedaconda ACD as they know the advantages of inhaled sedation, since they use it continuously in operating rooms. Before Sedaconda ACD, they could not use inhaled sedation in the ICU in a simple, efficient, and non-polluting way. For intensive care physicians, the process is a little more complicated as they are not used to inhaled anesthetics, which causes some fear. With the help and enthusiasm of anesthesiologists, they are using the equipment and are telling us about advantages such as sedation control and better awakenings, even helping to eliminate lung spasm in some cases of Covid-19.

Do you get any feedback from payers?
We often get involved with the hospital purchasing departments who take all costs and savings into account in their calculations. It is difficult for them to evaluate the cost of intravenous versus inhaled sedation, but we are assisting them so they can calculate the total cost and potential cost savings.

How has interest developed for the therapy?
At the beginning of the Covid-19 pandemic, doctors had their hands full treating patients. They did not know what they were facing or how to treat it, so they were not easy to contact. As their knowledge evolved, we found more openness and interest in learning about inhaled sedation. When some intravenous sedatives became unavailable, many doctors wanted to use inhaled sedation as a substitute, and once they tried it, they found many benefits.

What has happened now that Covid-19 pressure has eased a bit?
In the post-Covid-19 phase, we have seen an interest in continuing with the use of inhaled sedation, in the hospitals that used it during Covid-19, but of course in less quantity as ICU occupation rates have decreased. There is still a lot of interest in inhaled sedation, but ICU personnel have a bit more time, so now we can make a more organized push, with more medical education and training.

What do you anticipate for the future?
We believe that inhaled sedation in the ICUs is beginning to be known, and in the future, it should be the first choice, but we have a lot of work to do as we must increase the awareness. We must convince, train, and educate all ICU personnel, and for them to get used to using inhaled sedation, we must make them keep us in mind. We have a great challenge ahead, but a bright future also awaits us.

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 are mechanically ventilated.

Sedation is usually necessary to ensure patient well-being and safety, and for 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.

Sedana Medical estimates the size of the global market to be between EUR 2 and 3 billion. The market is growing by around five percent annually as populations age. 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.

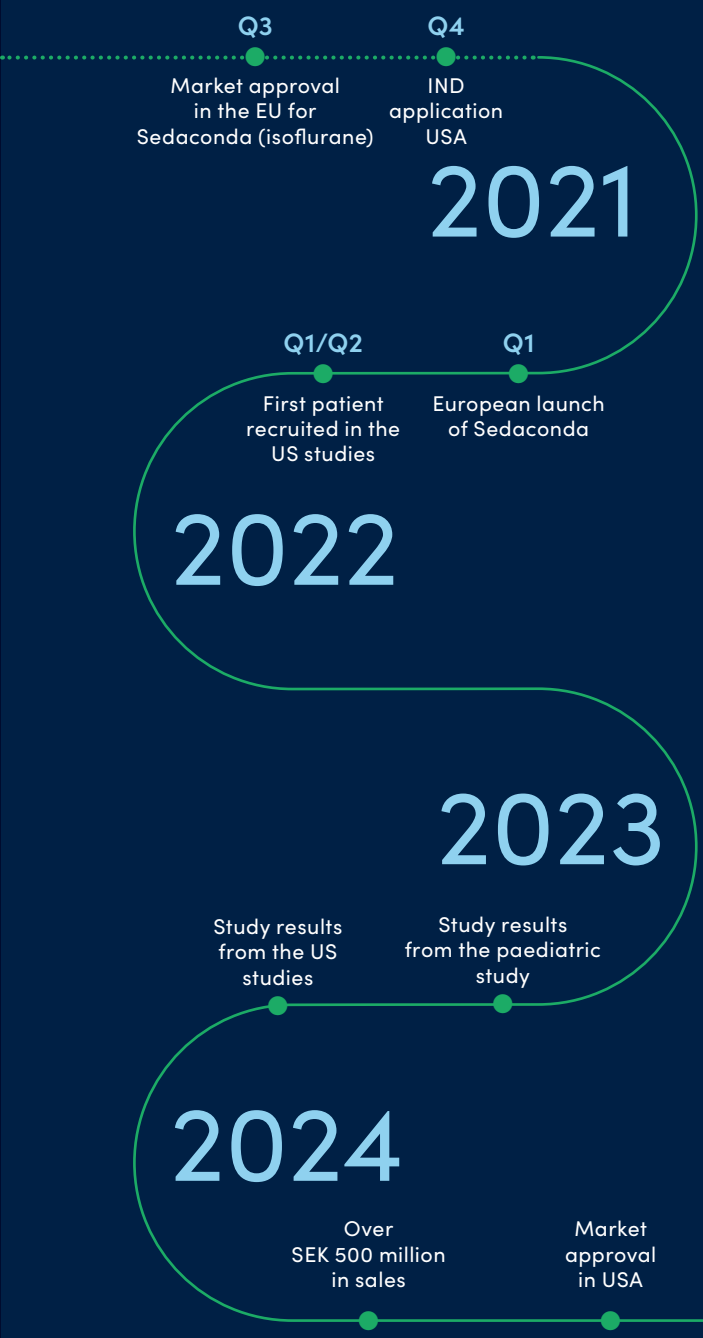
>30 million
ICU patients globally per year

~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

2–3 billion
EUR 2–3 billion global addressable market
(the market is growing ~5% annually)

Future milestones in line with the company's strategic plan



Towards a paradigm shift in intensive care

Sedana Medical's purpose is to improve life during and beyond sedation. In order to fulfil this purpose, we are pursuing our vision of making inhaled sedation a standard therapy for mechanically ventilated patients in intensive care.

Strategically, Sedana Medical focuses on three priorities:

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.

In addition, Sedana Medical will continue to secure medical evidence demonstrating that inhaled sedation is a better and more cost-effective therapy than current standard therapy. By demonstrating significant benefits, the treatment 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.

Market approval – a key milestone

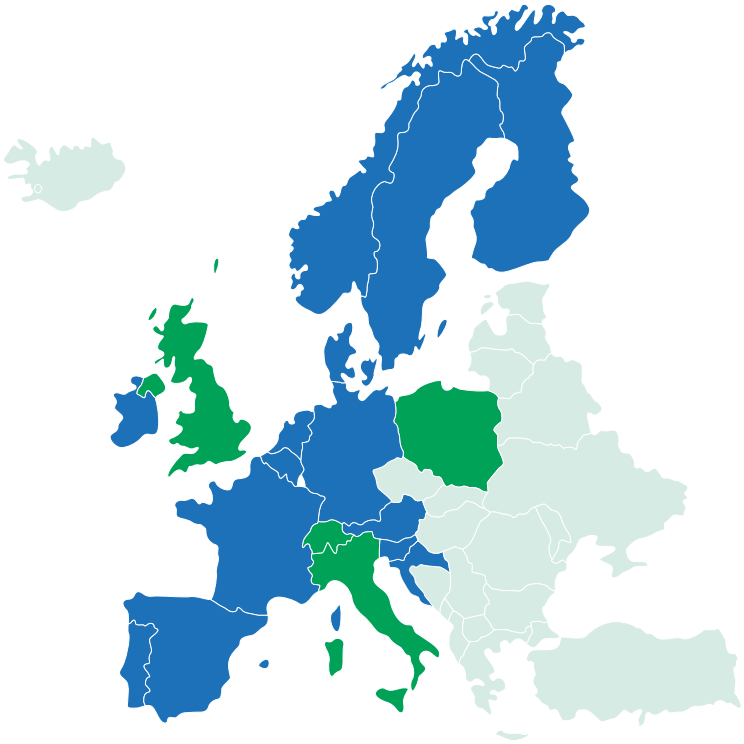
At the end of July 2021, Sedana Medical received European market approval for the pharmaceutical product Sedaconda (isoflurane), delivered via Sedaconda ACD for inhaled sedation in intensive care, in 15 of the EU Member States, as well as Norway. Approval was granted by the German regulatory authority BfArM (Federal Institute for Drugs and Medical Devices) and a number of other European regulatory authorities under a decentralised procedure, DCP.

The DCP approval is Sedana Medical's first market approval for Sedaconda (isoflurane) and a crucial milestone in making inhaled sedation a standard therapy in intensive care throughout the world. The approval meant that Sedana Medical was able to apply for national approvals. During the third quarter of 2021 BfArM granted market approval in Germany, and at the end of the year Sedana Medical had received market approval in 14 of the 15 countries where the DCP approval is valid.

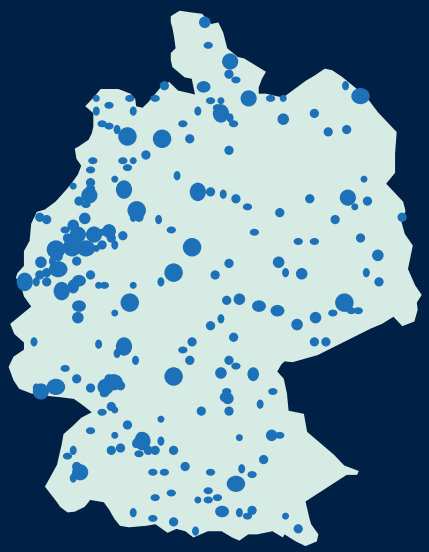
Sedana Medical additionally submitted applications for market approval in Italy, the United Kingdom and Switzerland in 2021. These processes are expected to lead to market approval in 2022.

As Sedana Medical's application contained a paediatric plan, the company is considered to have applied for 'full registration', which means that Sedana Medical's European market approval covers ten years of market exclusivity in Europe for the use of isoflurane for sedation in intensive care. During this period, no competitor will be able to market isoflurane for this purpose without having put together their own clinical documentation and undergone the same procedure as Sedana Medical.

European market approval for the pharmaceutical product Sedaconda (isoflurane)



- Markets where Sedaconda (isoflurane) is approved
- Market approval is expected in 2022



Germany – Sedana Medical's largest market

Sedana Medical estimates that the company has so far reached 8–10 percent of the German market potential for sedation of mechanically ventilated patients in intensive care, despite the therapy having been off-label. An important reason is that new guidelines for sedation were published in Germany in 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.

~900 | 55%

intensive care units

Approximately 900 intensive care units in Germany sedate mechanically ventilated patients in intensive care with Sedana Medical's devices today, equivalent to more than 55 percent of all German intensive care units.

Direct sale is Sedana Medical's preferred sales channel

It takes a long time to establish a new form of therapy in healthcare, which requires key opinion leaders in the area to back the therapy. If it is not endorsed by key opinion leaders and expert groups, it will be very difficult to succeed. Accordingly, Sedana Medical has since long focused on establishing contacts with these groups in order to build and develop the therapy together. This has been done using clinical studies, education, scientific congresses, exchange of information and experience and development of new guidelines. Because such activities must be managed by Sedana Medical, there is a clear advantage in the company pursuing its own local operations.

Sedana Medical's sales have so far taken place through traditional direct sale and distributors. The company works with product specialists who train the clinics in how to use the devices and how to carry out the treatment. The product specialists recruited by Sedana Medical mainly comprise nurses with a background in intensive care, which means that they possess the knowledge and experience necessary to train customers.

Direct sale

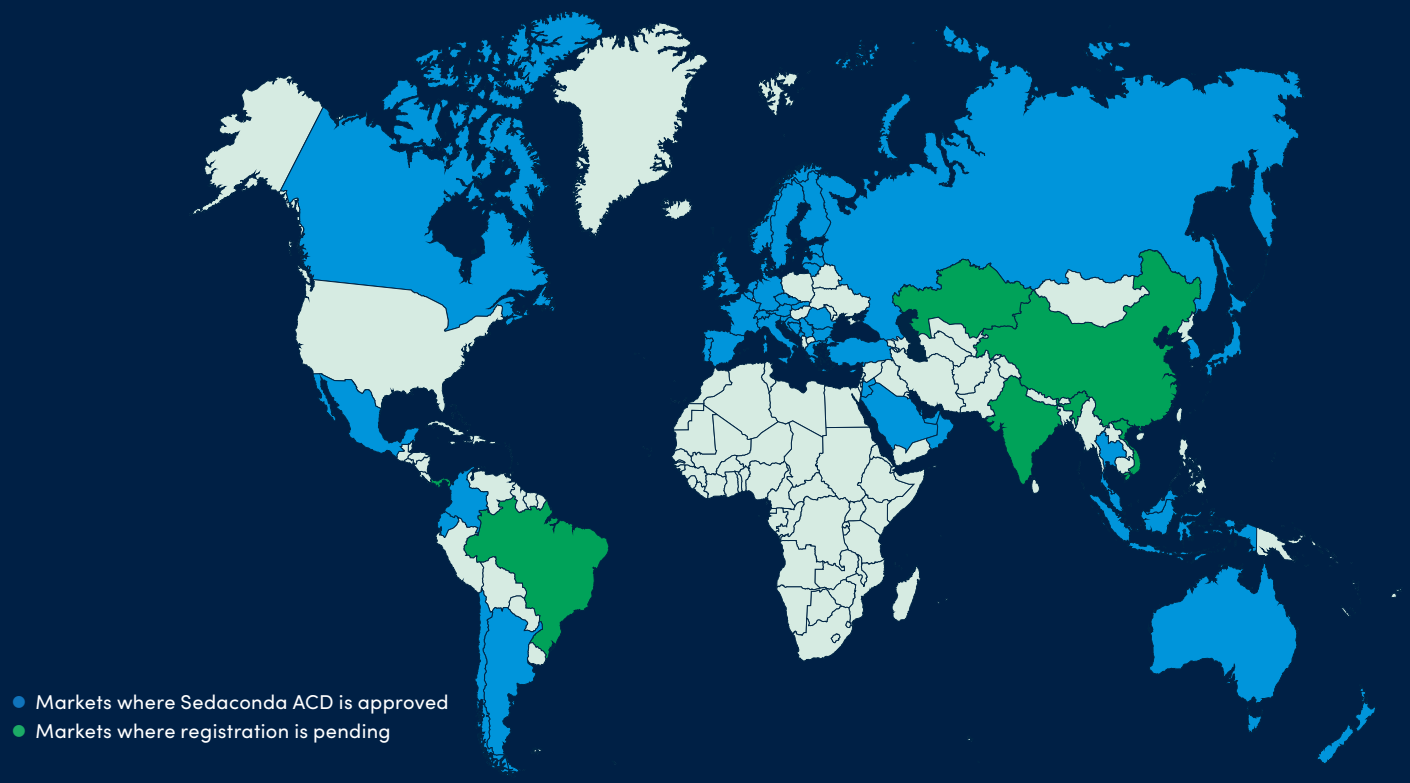
Direct sale is Sedana Medical's preferred sales channel. Germany is the company's largest market, accounting for around 68 percent of the company's total sales in 2021. Other direct markets accounted for around 12 percent. Direct sale takes place primarily through the company's own product specialists in Benelux, France, Germany, Ireland, the Nordics, Spain and the United Kingdom. Sedana Medical has sales through distributors in most of the rest of Europe.

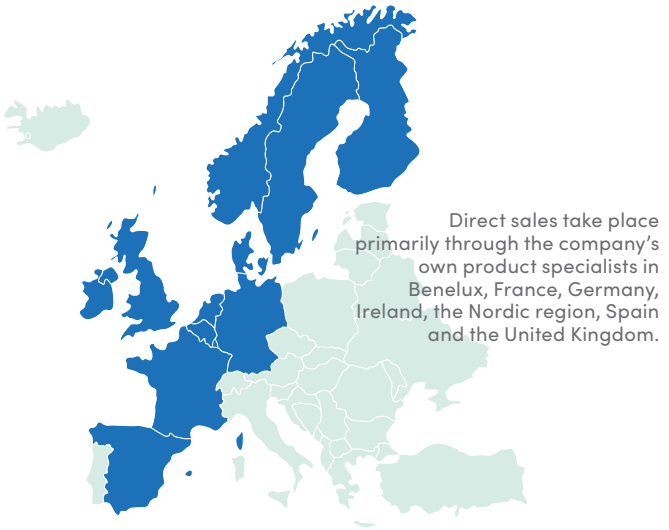
Sedaconda ACD is used throughout the world

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 the Sedaconda ACD and inhaled sedation in the rest of the world. This is partly a consequence of the Covid-19 pandemic, as there is often a great need for sedation in these patients in the ICUs. During 2021 Sedaconda ACD was sold in over 40 countries.

>40

countries where Sedaconda ACD is sold





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 while also enjoying higher profit margins.

Distributor markets outside the EU

Sedana Medical cooperates with distributors as a low-risk means of initiating sales and quickly establishing Sedaconda ACD for intensive care in countries where it does not have direct sales. Sedana Medical has distribution agreements in all parts of the world except Africa, and Sedaconda ACD is sold in over 40 countries. In 2021, Mexico was the company's second-largest market, followed by Colombia.

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 the United States, but considers these markets to be of potential interest in the long term.

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 medium-sized and large hospitals, as well as university hospitals. The products 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 providing assistance in therapy initiations in ICUs, taking part in international congresses and through leading researchers presenting their findings at scientific congresses. Sales differ between countries and regions, but common to all markets is the ambition to create demand among physicians and nurses.

The competitive situation

The current market for sedatives in intensive care consists mostly of intravenous drugs, with propofol, midazolam (based on benzodiazepine), dexmedetomidine and remifentanil dominating. These products are usually generic, but still command relatively high prices, especially in the United States.

The company estimates propofol to hold more than half the market and products based on benzodiazepine to have the next largest share of the market, but estimates benzodiazepines are losing market share to propofol and dexmedetomidine. Problems with tolerance development and delirium, such as hallucinations and delusions, have caused many physicians to advise against benzodiazepines for long-term sedation.

Sedaconda (isoflurane) delivered via Sedaconda ACD is the first therapy approved for inhaled sedation in intensive care. Sedana Medical considers it to be highly unlikely that any other inhaled anaesthetic with the same indication is in the process of registration. There is currently one alternative delivery system for inhaled pharmaceutical products, known as Mirus from the German company Technologie Institut Medizin GmbH (TIM). Sedana Medical considers it unlikely that TIM can register a pharmaceutical product to be combined with its device.

Costs

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.

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 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 product. The great number of factors means that the cost of intravenous sedation can vary sharply.

In January 2022, Sedana Medical announced that the National Institute for Health and Care Excellence (NICE) in the UK recommend Sedaconda ACD as a cost-saving option for delivering inhaled sedation in intensive care, as an alternative to intravenous sedation. The higher health-economic value of inhaled sedation is a very important argument in the choice of sedation therapy.

The target is US market approval in 2024

The market potential for inhaled sedation in ICU in the United States is estimated at over SEK 10 billion per year, which makes the market Sedana Medical's potentially largest.

Sedana Medical has evaluated alternative go-to-market models and has come to the conclusion that the best strategy for the company is to build up its own commercial operation in the US. To this end, in December 2021 the company made a directed share issue which contributed SEK 615 million to the company before transaction expenses. The issue ensured financial strength and flexibility to build up the company's own commercial organisation and launch on the US market.

Registration via 505(b)(2)

Because the drug substance isoflurane has been used for decades in operating rooms, the FDA accepts Sedana Medical taking a route to registration which, in simplified terms, allows the use of previously collected data (505(b)(2)).

Registration via 505(b)(2) is usually less demanding than 505(b)(1), which is used for completely new drug substances. The FDA approved Sedana Medical's Investigational New Drug Application (IND) in December 2021, which means that the clinical programme can begin in 2022.

The key activities in the United States are:

- optimising the clinical trials programme to further strengthen the evidence base, including patient follow-ups after three and six months in the two pivotal US studies;
- expanding the US organisation and establishing a local sales team;
- preparing the market for a successful launch, and
- carrying out the launch of Sedaconda ACD and Sedaconda (isoflurane) on the US market after expected approval in 2024.

The work on the clinical studies, registration and market access is being carried out with the assistance of an American CRO. In the second quarter of 2021 a subsidiary was also started in the United States, with the first staff recruited during the third quarter of 2021. They will act as clinical training specialists at the sites where the clinical studies are to be conducted.

The goal is to gain US registration in 2024 for Sedaconda (isoflurane) and Sedaconda ACD as a combined product, on which the FDA already expressed a favourable opinion in March 2019 at what is known as a pre-IND meeting. Registration of a combined product is regarded as providing better intellectual property rights protection for the therapy than if Sedaconda and Sedaconda ACD had each been registered separately.

A comparison between Germany and the United States

The United States offers the greatest market potential for inhaled sedation

	Germany	United States
Intensive care beds	~22.000	~107.000
List price of propofol	47–57 EUR/day	360–438 EUR/day*
Current penetration	8–10%	Target for approval 2024

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

Attracted by the potential in the therapy

Kaylee Gordon is a trained ventilation specialist (specialist in operating breathing aids, for example ventilators). As a clinical training specialist, she is one of the first employees of Sedana Medical in the United States.

You are one of the first employees in Sedana Medical US, what attracted you to the company?
I was approached by a recruiting company and was very impressed by the training materials and information that was available for the European market. I was attracted by the potential impact that inhaled sedation could have. It feels very exciting and, in the end, rewarding to work with a therapy that has this large potential to really make a difference for patient outcomes.

What have you done so far in the company?
When I started in September 2021, I almost immediately took a trip to Stockholm to meet the team and familiarize with the therapy. After a short trip back to Salt Lake City I was back in Europe for a lot of bed side training in London. So, the first time a Sedana Medical was very intense, but extremely productive. Since then, I have been meeting and establishing plans for education rollouts for doctors, nurses, and respiratory therapists at the clinical sites ahead of the start of the clinical trials SED003 and SED004.

You are a respiratory therapist yourself, what exactly is that?
Yes, I have a bachelor's degree which is very similar to a nursing degree, but with focus on the cardiopulmonary system. In Europe, it is common that nurses run airway management, but here in the US, that is done by respiratory therapists. We are experts in pulmonary health. In fact, all clinical educators that Sedana Medical has employed so far are respiratory therapists.

What will you, as clinical educators, do going forward?
During the studies, we will be educating and assisting the clinical sites in the trials. Once the therapy is approved, we will go boots on the ground and educate at clinics that have not participated in the studies. Thus, there will be a transition into more of a sales role, but even after the therapy is approved, we will sell by teaching how to use the therapy, and also how to use it well. I guess you could say that we will be educators forever.

In your view, which are the strongest selling points?
Everyone who has worked in an ICU has seen the problems with intravenous sedation. We've all seen the negative side effects, propofol infusion syndrome, delirium, long and unpredicable awakenings, but we never thought there was an alternative. It never crossed anyone's mind that you could introduce something new, that you could potentially prevent or reduce the negative side effects. Now that there is an alternative that can have such a positive effect on patient outcomes, interest is very high. Also, the rapid on-off, not having to wait for days to wake a patient up, that also seems to be an important selling point.

As the therapy requires a change of method or habit, is it a hard sell?
Not really. The problems with intravenous sedation are very persuasive. But of course, there is always some resistance when it comes to implementing new habits. However, it is very dependent on region and ultimately on individual physicians. Older are more set in their ways, so we educators need to be prepared with every tool and angle.

What is you most important task going forward?
We need to establish good relationships with the clinical sites. Both to be able to complete the studies on time and ultimately to be able to sell the therapy and impact patient outcomes all over the US.

> “It’s very exciting and ultimately rewarding to work with a therapy that has such great potential to make a real difference for patients”

Clinical studies in the United States

In July 2021, Sedana Medical had a successful advisory meeting with the FDA, what is known as an End of Phase II meeting, at which the FDA accepted the company´s Phase III programme proposals. In December 2021 the company gained an Investigational New Drug (IND) approval, which means that the company has been granted permission to begin the clinical Phase III studies with the Sedaconda products in the United States. The IND approval also means that the studies can start in line with the previously announced timetable.

Preparations for the Phase III studies were intensive during the year. Among other things, Sedana Medical worked on a human factors validation together with the Beth Israel Deaconess Medical Center (BIDMC) at Harvard Medical School in the United States. Animal toxicology studies are conducted as part of the preparations for the IND application.

Two randomised and observer-blinded multicentre clinical studies with around 250 patients each will be carried out to confirm and ensure efficacy and safety. The company aims to include approximately 30 highly reputed US centers in the two clinical studies.

The study design is similar to the Sedaconda study (SED001) performed in Europe. The primary endpoint in each study will be to show that Sedaconda (isoflurane) delivered via Sedaconda ACD is effective and non-inferior to propofol for sedation of mechanically ventilated patients in intensive care . The secondary endpoints relate to opioid need, spontaneous breathing, time to wake-up and cognitive recovery.

As the Sedaconda study (SED001) was not blinded, it could not be one of the two clinical studies required by the FDA. The work on the European study has given Sedana Medical great experience that is of benefit in the design and execution of the US studies. In addition, the European study can support the NDA application and be used in the safety database of 500 isoflurane patients, which is an FDA requirement.

IND – First step towards pivotal clinical studies

FPI – First patient in
LPO – Last patient out

FDA in favour of combined registration

30

Sedana Medical aims for 30 clinics in the United States

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

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. Our Code of Conduct is a framework for what Sedana Medical considers to be responsible and appropriate conduct. We aim 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.

The Code of Conduct covers all employees, the Board, consultants and temporary staff. Sedana Medical's Code of Conduct also includes sustainability, the work environment, health and safety, the environment, gender equality and purchasing.

WE SUPPORT

UN GLOBAL COMPACT

Sedana Medical support the Ten Principles of the UN Global Compact in the areas of human rights, labour, environment and anti-corruption. The company strives for openness and transparency in its business operations, and its work on sustainability is an ongoing process.

Responsible action

We endeavour always to act ethically and 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 are continuing to grow, which means that the need for more staff and new skills is increasing. During the year, we welcomed many new colleagues, people who will strengthen the organisation in their particular roles ahead of future product launches and the company's geographical expansion. At the end of 2021, the company had 90 employees and 17 interim consultants in 11 countries. At Sedana Medical we believe our diversity is a strength. Our team is made up of 17 nationalities. We are also very proud to have a gender balance of 52:48 in favour of women.

We have a clear recruitment process based on competence and experience and are using a structured process with evidence-based question technology, to ensure that we do not discriminate. By 2022, all line managers in our organization will be trained in non-discrimination recruitment. Our ambition is also 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 shall report any occupational injuries. We have at the head office, instituted an employee representation function for matters concerning the working environment and have established a process for systematic and regular review. We offer health insurance to all employees, and for employees in Sweden, we also have a wellness allowance.

In 2021, we conducted an employee survey. The outcome of this has been the basis for changes and improvements during the year. In 2022 we will also introduce pulse check surveys. These short engagement surveys will guide us if our efforts to improve engagement are working and enable us to identify emerging problems more quickly. These regular pulse surveys will, in addition to the annual employee survey, remind the workforce that employee opinions matter, and is an ongoing priority in our company.

Whistleblower function

All employees are expected to report suspicion of possible negligence, inappropriate behaviour, or violations of the company's Code of Conduct to their immediate supervisor or the HR department or to use Sedana Medical's whistleblower system, Speak-Up.

The system, which is provided by an independent external third party, makes anonymous dialogue possible between the employee and the company and is an important tool in drawing attention at an early stage and counteracting behaviour that is not compatible with Sedana Medical's values. 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.

Environment

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. We 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.

Reducing our environmental footprint

Goods and services must 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. A target for 2022 is for at least 90 percent of our freight volumes will be transported by sea freight.

We are mindful of the selection of materials incorporated into our devices and try to include low environmental impact materials when possible, such as Polypropylene, Polyethylene, Polycarbonate, High-density polyethylene, Stainless steel, and in some instances rubber.

During the year, we initiated a project aimed at improving and optimising the packaging of one of our largest products in terms of volume, Sedaconda ACD. The target is to reduce packaging volume by a third and in so doing to substantially reduce the quantity of plastic used. In addition, we will be able to ship more units per package and consequently make transport more efficient.

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.

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 CO_2 emissions, which has started to yield lower volumes of emissions.

Travel on company business

During the year we limited our travel in order to protect our staff against Covid-19, except for highly business-critical travel. Those staff who have been able to work remotely from home have been encouraged to do so. Ahead of reduced restrictions on travel, we are reviewing our travel policy: the travel must be made for the right reason and booked in the most cost-effective way. Online meetings are always encouraged, to reduce environmental impact, costs and the impact travel has in terms of the balance between work and leisure.

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. We strive 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.

We will gradually introduce clauses in agreements with our suppliers and manufacturer, where they undertake to uphold the Ten Principles of the United Nations Global Compact, or comparable standards, by complying with applicable laws and regulations. This will be a continually ongoing dialogue with our suppliers and reviewed on a regular basis. When choosing a supplier and the continuance of the relationship, compliance with the Ten Principles of the United Nations Global Compact, or comparable standards, will play a crucial role for Sedana Medical.

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 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.

Exchange of knowledge

We work close to and in dialogue with the health service to understand its 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 certificates for Canada and Japan, certifying 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).

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, Sedana Medical uses a four-part strategy that includes patent protection, complicating measures, registrations and know-how.

Patent protection

Since developing Sedaconda ACD, Sedana Medical has protected its innovations through patents. Sedana Medical's patent portfolio currently comprises five patent families. New patent registrations are continuously being added to protect new innovations that may be implemented in future products.

Complicating measures come from safety first

Sedana Medical has developed and is continuing to enhance a simple and safe system for inhaled sedation. The system is based on unique solutions where the whole process, from the liquid in the bottle to the gas delivered to the patient, can be protected. These protections, for example unique couplings and packaging solutions, make the Sedaconda ACD system simple and safe to connect, while the connection of generic products is made more difficult.

Registrations

By applying for full registration, i.e. also including a paediatric plan, DCP approval will mean that Sedana Medical will enjoy ten years of market exclusivity 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 inhaled anaesthetics and delivery methods for sedation in intensive care continue to be off label.

Know-how

Sedana Medical has extensive knowledge of inhaled sedation generated over the past ten years and active, successful product development. Sedana Medical's strategies, together with the company's knowhow and product development, provide Sedana Medical with strong protection and a stable basis for planned marketing initiatives.

Sedana Medical's freedom-to-operate analysis, which checks 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.

Share information and shareholders

Sedana Medical's share was listed on Nasdaq First North Growth Market Stockholm on 21 June 2017 and is included in both First North All share SEK and First North Health Care PI index.

Nasdaq First North and Certified Adviser

Nasdaq First North is an alternative market for Nordic growth companies designed primarily for small and medium-sized companies. It does not have the same legal status as a regulated market, and its regulatory framework is somewhat less extensive than those applicable in the exchange's larger marketplaces. Every company whose stock is traded on First North has a Certified Adviser who monitors the company's compliance with First North's regulations for the provision of information to the market and investors. Sedana Medical's appointed Certified Adviser is Erik Penser Bank, phone: +46 8 463 83 00, e-mail: certifiedadviser@penser.se.

Facts about Sedana Medical shares

Listing	Nasdaq First North Growth Market Sweden
Number of shares at 31 Dec 2021	99,336,960
Market capitalisation	SEK 9,740 million
Ticker	SEDANA
ISIN	SE0015988373
LEI code	549300FQ3NJRI56LCX32

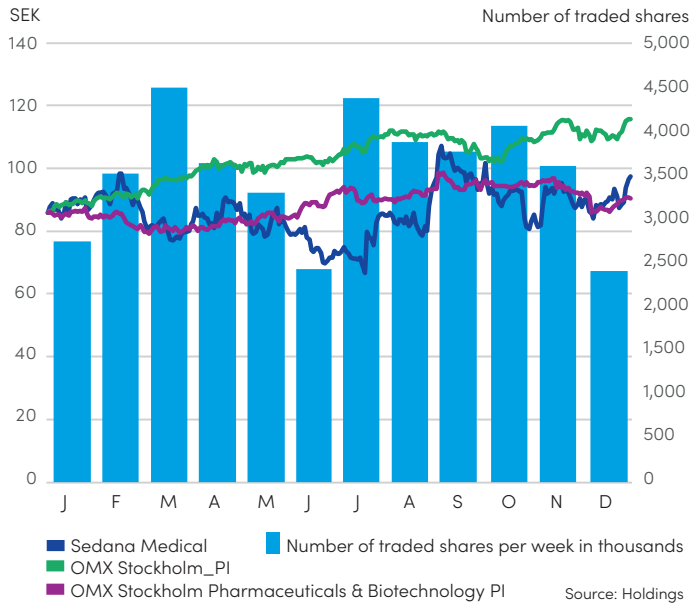
Share capital

The total number of shares outstanding at 31 December 2021 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.

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)
20.10.2004	New formation	1,000	1,000	100,000	100,000	100
31.10.2009	New share issue	430	1,430	43,000	143,000	100
05.05.2011	New share issue	500	1,930	50,000	193,000	100
14.09.2015	New share issue	240	2,170	24,000	217,000	100
05.04.2017	Bonus issue	6,510	8,680	651,000	868,000	100
05.04.2017	Split	8,671,320	8,680,000	0	868,000	0.1
20.06.2017	Conversion of shareholder loans	613,594	9,293,594	61,359	929,359	0.1
20.06.2017	Exercised convertible bonds	1,881,509	11,175,103	188,151	1,117,510	0.1
20.06.2017	New share issue on IPO	5,128,205	16,303,308	512,821	1,630,331	0.1
10.07.2017	Overallotment option after IPO	769,230	17,072,538	76,923	1,707,254	0.1
05.02.2018	Conversion of warrants to shares, 2014/2019 programme	208,000	17,280,538	20,800	1,728,054	0.1
04.06.2018	New share issue	1,728,053	19,008,591	172,805	1,900,859	0.1
10.10.2018	Conversion of warrants to shares, 2014/2019 programme	148,000	19,156,591	14,800	1,915,659	0.1
27.03.2019	Conversion of warrants to shares, 2014/2019 programme	120,000	19,276,591	12,000	1,927,659	0.1
24.05.2019	Conversion of warrants to shares, 2014/2019 programme	140,000	19,416,591	14,000	1,941,659	0.1
14.06.2019	Conversion of warrants to shares, 2014/2019 programme	220,000	19,636,591	22,000	1,963,659	0.1
05.08.2019	Conversion of warrants to shares, 2014/2019 programme	100,000	19,736,591	10,000	1,973,659	0.1
28.08.2019	Conversion of warrants to shares, 2014/2019 programme	104,000	19,840,591	10,400	1,984,059	0.1
24.10.2019	New share issue	2,896,000	22,736,591	289,600	2,273,659	0.1
20.05.2020	Exercise of warrants, 2017/2021 programme	310,149	23,046,740	31,015	2,304,674	0.1
10.05.2021	Split 4:1	69,140,220	92,186,960	0	2,304,674	0.025
02.12.2021	New share issue	7,150,000	99,336,960	178,750	2,483,424	0.025

Sedana Medical's share price trend and turnover



The 15 largest shareholders at 31 December 2021

	Number of shares	Holding
Swedbank Robur Fonder	9,329,589	9.4%
Handelsbanken Fonder	9,087,712	9.1%
Linc AB	8,064,804	8.1%
Anders Walldov directly and indirectly (Brohuvudet AB)	7,662,018	7.7%
Ola Magnusson direct and indirectly (Magiola AB)	4,572,098	4.6%
Sten Gibeck	4,279,776	4.3%
Öhman Fonder	4,087,019	4.1%
AMF Pension	3,870,000	3.9%
Berenberg Funds	1,905,101	1.9%
Avanza Pension	1,867,828	1.9%
Nordnet Pensionsförsäkring	1,803,870	1.8%
Tredje AP-fonden	1,735,989	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Highclere International Investors LLP	1,492,630	1.5%
DNCA Finance S.A	1,379,980	1.4%
Fifteen largest shareholders	**62,804,878**	**63.2%**
Other	36,532,082	36.8%
Total	**99,336,960**	**100.0%**

Source: Modular Finance

Share trading

The initial price when the shares were listed on First North Growth Market 2017 was SEK 4.88*. The opening price in 2021 was SEK 85.75, and the last price paid at the end of the year was SEK 98.05. During the year a total of 42 million Sedana Medical shares were traded at a value of SEK 3.6 billion, which is equivalent to a turnover rate of around 42 percent. On average, around 169,000 shares were traded per trading day.

Price trend

During the year, the Sedana Medical share price rose by 14 percent, while the First North All Share index over the same period fell by 2 percent. The highest price paid was SEK 107.10, recorded on 3 September 2021, and the lowest price paid was SEK 66.70, recorded on 20 July 2021. At year-end 2021, the Sedana Medical share price was SEK 98.05, equivalent to a market capitalisation of SEK 9,740 million.

Shareholder distribution by size

	Number of shareholders	Number of shares	% capital	% share-holders
1–100	3,584	129,424	0.1%	46.7%
101–200	1,081	166,247	0.2%	14.1%
201–500	1,144	398,614	0.4%	14.9%
501–1000	713	541,605	0.5%	9.3%
1001–2000	496	730,190	0.7%	6.5%
2001–5000	304	1,018,108	1.0%	4.0%
5001–10000	132	952,235	1.0%	1.7%
10001–20000	82	1,145,944	1.2%	1.1%
20001–50000	57	1,819,947	1.8%	0.7%
50001–100000	22	1,454,639	1.5%	0.3%
100001–200000	18	2,674,340	2.7%	0.2%
200001–500000	19	6,154,932	6.2%	0.2%
500001–1000000	12	8,791,151	8.9%	0.2%
1000001–2000000	8	12,936,353	13.0%	0.1%
2000001–	8	50,953,016	51.3%	0.1%
Anonymous ownership		9,470,215	9.4%	
Total	**7,680**	**99,336,960**	**100%**	**100%**

Source: Modular Finance

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

Warrant programme

Warrant programme 2019/2022

The Annual General Meeting of Sedana Medical AB (publ) held on 28 May 2019 resolved to implement a new warrant programme for staff (employees and consultants) in the Sedana Medical Group. The company therefore issued 370,000 warrants in the 2019/2022 series at the annual general meeting, entitling holders to subscribe to a total of 370,000 shares, all of which were subscribed to by the company's subsidiary Sedana Medical Incentive AB for later transfer to staff 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 November 2022 at a subscription price of SEK 35.56 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, 322,436 warrants series 2019/2022 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 2019/2022 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 2019/2022 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 32,244 through the issue of 322,436 shares in the company, equivalent to a dilution of approximately 0.3 percent based on the number of shares in the company at the balance sheet date.

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.

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 2021.

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 simple and safe conversion of liquid anaesthetics to gas by evaporation and the reuse (reflection) of inhaled anaesthetics for use in intensive care. The Group's product portfolio currently includes Sedaconda ACD with accessories and Sedaconda (isoflurane).

Inhaled anaesthetics have long been used to sedate patients during surgery. Complex, capital-intensive anaesthesia machines that require specially trained personnel are used for this purpose. Sedana Medical's device Sedaconda ACD is a solution that makes it practically and financially possible to use inhaled anaesthetics to sedate mechanically ventilated patients in intensive care .

Sedana Medical's vision is to make inhaled sedation a global standard therapy. To achieve this vision, the Group has been conducting a clinical phase III study aimed at gaining approval for the pharmaceutical product Sedaconda (isoflurane) delivered via Sedaconda ACD. Sedana Medical received European market approval in July 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 68 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 is carried out through contract manufacturers, but is controlled by the Irish subsidiary. The Parent Company's head office and domicile are in Danderyd, Sweden. In June 2017 the company's shares (ticker: SEDANA) were listed on Nasdaq First North Growth Market, Stockholm, Sweden.

Significant events during the year

1st quarter

- In January and February, applications for market approval for Sedaconda (isoflurane) for inhaled sedation in intensive care were submitted in Switzerland and the United Kingdom.
- In February, the first patient was included in the company's paediatric study IsoCOMFORT (SED002), which is being conducted to study whether inhaled sedation with Sedaconda (isoflurane) delivered via Sedaconda ACD is a safe and more effective method of sedation than intravenously administered midazolam, for children below 18 years of age.

2nd quarter

- A share split (4:1) was completed at the end of May.

3rd quarter

- In early July, Sedana Medical's Quality Management System (QMS) received approval under the EU Medical Device Regulation (MDR) 2017/745. This approval means that Sedana Medical's Class I medical devices can continue to be sold with CE marking in the EU.
- In July, a successful End of Phase 2 advisory meeting was completed with the US Food and Drug Administration (FDA). The FDA accepted Sedana Medical's proposed phase III programme, including the study design and the primary endpoint for the studies. The positive outcome allows the company to enter phase III in line with the communicated timeline.
- In July, a positive outcome was obtained for the application for European registration for the pharmaceutical product Sedaconda (isoflurane) for inhaled sedation in intensive care, known as DCP approval. Sedaconda is indicated for the sedation of mechanically ventilated adult intensive care patients and is to be delivered only via the Sedaconda ACD medical device.
- In August, the results of the company's pivotal study Sedaconda (SED001) were published in the highly respected scientific journal The Lancet Respiratory Medicine.
- At the end of September, market approval was obtained for Sedaconda (isoflurane) in Germany. The application was approved by the German regulatory authority BfArM and is based on the DCP approval obtained by Sedana Medical in July.

4th quarter

- After being appointed by the Board in May, Johannes Doll took up duties as the new President and CEO of Sedana Medical on 1 October 2021.
- In December, a directed new share issue was made which contributed SEK 615 million to the company.
- In December, an application was submitted for market approval for Sedaconda (isoflurane) for inhaled sedation in intensive care in Italy.
- In December, Investigational New Drug (IND) approval was received from the US Food and Drug Administration (FDA) to

enable pivotal phase III studies with the Sedaconda devices to begin in the United States.

- In December, Sedana Medical's Chinese partner, Kyuan Xinhai Medical, submitted an application for approval of Sedaconda ACD in China to the Chinese FDA.

Significant events after the end of the period

- In January, Johan Spetz was appointed as the new CFO. Johan Spetz succeeds Susanne Andersson, who leaves the position to take up other duties.
- 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.

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.

Objective

To improve live during and beyond sedation.

Vision

To make inhaled sedation a standard therapy in critical care.

Financial targets

The company's target is to achieve sales in excess of SEK 500 million in Europe three years after approval of Sedaconda (isoflurane). With regard to the decision to build up the company's own commercial organisation in the United States, the EBITDA target of 40 percent remains, but is expected to be achieved 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 Sedaconda ACD as a combination therapy.
3. Commercialising Sedaconda ACD through distributors in selected markets worldwide.

Effects of the Covid-19 pandemic

As a consequence of Covid-19, Sedana Medical recorded a sharp rise in demand in 2020. Similar effects were also noted in other geographical areas in 2021, particularly in the distributor markets and in particular in Latin America. The effect of Covid-19 was generally smaller in 2021 than in 2020, as a result of higher vaccination levels, milder virus variants and healthcare professionals having become accustomed to non-invasive inhalation.

There is continued uncertainty about the future development of the Covid-19 pandemic around the world. The impact of Covid-19 on Sedana Medical has included a potentially greater number of ventilated patients in ICU, but also more limited access to (particularly new) hospital customers. There may consequently be short-term impacts on sales during certain individual quarters, but the long-term potential of Sedana Medical's products does not depend on Covid-19.

Risks

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

Risks related to the industry and the business

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

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

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

Before Sedana Medical's device Sedaconda ACD and accessories, either in combination with Sedaconda (isoflurane) or not, may be marketed in the area of inhaled sedation treatment in intensive care in any new national or regional market, the company must obtain market approval or similar authorisations from the relevant authorities in the countries where the company intends to market and sell its products. Changes in the process and requirements for

market access 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 2021

Net sales
Group net revenue for the full year 2021 totalled KSEK 159,152 (141,770), an increase of KSEK 12 percent. The equivalent increase net of currency effects was 16 percent. Sales in Germany contributed 5 percent growth. Other direct markets showed a 13 percent decrease from the previous year, which is due to the first half of 2021 being negatively affected by significant build-up of stocks, driven by Covid-19 in 2020 and consequently fewer and lower orders in the first half of 2021.

Cost of goods sold
The cost of goods for resale totalled KSEK 52,446 (52,867), representing a decrease of 1 percent. The decrease is principally due to lower transport costs, which has been partly counteracted by a negative market mix effect for the full year

with increased sales in some distributor markets with slightly lower margins.

Selling expenses

Selling expenses for the whole year were KSEK 96,573 (65,123), representing an increase of 48 percent. The increase is principally due to higher costs as a result of a larger commercial and market organisation and a higher level of activity.

Administrative expenses

Administrative expenses in the Group totalled KSEK 51,736 (37,296), representing an increase of 39 percent. The increase is due to the general growth in the company as well as expansion of office premises and associated equipment.

Research and development expenses

Research and development expenses for the full year 2021 totalled KSEK 19,704 (7,859), equivalent to an increase of 151 percent. The increase is due to higher activity in clinical studies, an expanded R&D organisation compared to the previous year and an upscaling of QA.

Operating income

Group operating income for the full year was KSEK -61,493 (-21,359). The decline is explained by build-up of the organisation and preparations for the launch of Sedaconda (isoflurane).

Net financial items

Net financial items totalled KSEK 4,122 (-2,745), which is explained by unrealised exchange-rate effects.

Tax

The Group reported a tax expense of KSEK -595 in 2021, compared to KSEK -3,035 in the previous year. Tax for 2021 is attributed principally to Germany.

Financial review of 2021

Summary consolidated figures

KSEK	2021	2020	2019	2018*	2017*
Net sales	159,152	141,770	71,646	57,896	40,428
Gross profit	106,706	88,903	46,767	42,897	29,662
Gross margin %	67%	63%	65%	74%	73%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-50,093	-14,294	-12,932	-4,232	-736
EBITDA margin %	-31%	-10%	-18%	-7%	-2%
Operating income (EBIT)	-61,493	-21,359	-17,120	-8,238	-3,488
Operating margin %	-39%	-15%	-24%	-14%	-9%
Net income	-57,966	-27,139	-16,380	-6,869	-3,876
Profit margin %	-36%	-19%	-23%	-12%	-10%
Balance sheet total	1,167,580	600,097	595,766	231,550	131,376
Equity ratio %	94%	92%	96%	94%	89%
Quick ratio %	1414%	929%	1872%	1220%	640%
Average number of employees	76	57	39	26	17

Summary Parent Company figures

KSEK	2021	2020	2019	2018*	2017*
Net sales	159,107	121,238	46,213	55,856	31,495
Gross profit	109,445	82,531	15,592	21,126	13,339
Gross margin %	69%	68%	34%	38%	42%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-50,250	-26,608	-14,773	-4,888	1,346
EBITDA margin %	-32%	-22%	-32%	-9%	4%
Operating income (EBIT)	-55,161	-27,577	-16,051	-6,431	1,277
Operating margin %	-35%	-23%	-36%	-12%	4%
Net income	-63,629	-28,767	-14,800	-3,755	1,659
Profit margin %	-40%	-24%	-33%	-7%	5%
Balance sheet total	1,164,900	603,470	615,476	257,060	38,329
Equity ratio %	95%	93%	95%	89%	24%
Quick ratio %	1479%	941%	1444%	631%	60%
Average number of employees	41	25	24	17	9

*Accounting according to previous K3 rules.

Net income

The Group reported a net loss of KSEK -57,966 (-27,139) for the year. The decline in income compared to the previous year is explained by lower operating income as a result of the build-up of the organisation and preparations for the launch of Sedaconda (isoflurane).

Equity and liabilities

Group equity at 31 December 2021 totalled KSEK 1,101,456, compared with KSEK 551,094 at the start of the year, an increase of KSEK 550,362. A directed share issue was made in 2021 which contributed KSEK 614,900 to the company before deduction of issuing expenses, which totalled KSEK 7,946.

Cash and cash equivalents and cash flow

Cash and cash equivalents rose during the year by KSEK 460,010, and at 31 December totalled KSEK 836,181, compared to KSEK 376,171 at the start of the year. Cash flow from operating activities before change in working capital for the year was KSEK -52,809 (-8,278). Cash flow from change in working capital totalled KSEK 11,588 (433), which was positively impacted during the period by increased current liabilities. Cash flow from operating activities thus totalled KSEK -41,221 (-7,846).

Cash flow from investing activities totalled KSEK -110,255 (-84,619). The investments mostly consist of intangible assets, principally 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 paediatric study in the EU (SED002).

Cash flow from financing activities totalled KSEK 605,071 (5,787) and primarily relates to receipts from the new share issue made in December 2021, premiums paid for warrants in a new 2020/2024 programme and repayment of lease liabilities.

Investments

Investments during the 2021 financial year totalled KSEK 110,255 (84,619). Investments during 2021 primarily relate to:

- Capitalised expenses for development work, KSEK 104,973
- Internal expenses for the preparation of patents, KSEK 89
- Purchase of plant and machinery, KSEK 782
- Purchase of fixtures, fittings and tools, KSEK 4,410.

Parent Company

The Parent Company's net sales for the full year totalled KSEK 159,107 (121,238), of which intra-group sales totalled KSEK 6,602 (31,602). The increase compared to the same period of the previous year is due to the Parent Company having taken over the greater part of sales in the Group with effect from the third quarter of 2020.

Operating income for the full year totalled KSEK -55,161 (-27,577). Net financial items were KSEK -8,467 (-1,181) and relate primarily to an impairment of an intra-group receivable as a result of the restructuring of the Group implemented at the end of 2020, but also consist of unrealised exchange gains on internal loans.

Shareholders' equity in the Parent Company totalled KSEK 1,106,528 at 31 December 2021, compared to KSEK 561,600 at the start of the year, equivalent to an increase of KSEK 544,928. Share capital totalled KSEK 2,483, compared to KSEK 2,305 at the start of the year. The increase in shareholders' equity is mainly attributable to the new share issue carried out in December 2021.

Cash and cash equivalents totalled KSEK 816,279, compared to KSEK 365,113 at the start of the year.

Organisation and Personnel

Employees

At the end of 2021, Sedana Medical had 90 employees. Of these, 43 employees were men and 47 were women. The corresponding figures at the end of 2020 were 69 employees, of whom 35 were men and 34 were women.

Proposed appropriation of earnings

The Board of Directors proposes that no dividend be paid for the financial year 2021. The amount available for appropriation at the Annual General Meeting comprises unrestricted reserves, accumulated loss and the profit/loss for the year in the Parent Company:

SEK	
Share premium reserve	1,222,394,181
Accumulated loss	-301,171,865
Net profit/loss for the year	-63,628,498
Total non-restricted reserves	**857,593,818**

The Board proposes that available funds be appropriated such that SEK 857,593,818 is carried forward to the new account.

Financial information

Consolidated income statement

KSEK	Note	2021	2020
Net sales	4	159,152	141,770
Cost of goods sold	7	-52,446	-52,867
Gross profit		**106,706**	**88,903**
Selling expenses		-96,573	-65,123
Administrative expenses		-51,736	-37,296
Research and development expenses		-19,704	-7,859
Other operating income	8	4,013	2,805
Other operating expenses	9	-4,199	-2,789
Operating income	5,6,7	**-61,493**	**-21,359**
Financial items			
Financial income		11,285	529
Financial expenses		-7,163	-3,274
Net financial items	10	**4,122**	**-2,745**
Income before tax		**-57,371**	**-24,104**
Tax	11	-595	-3,035
Net income		**-57,966**	**-27,139**
Earnings per share, calculated on earnings attributable to shareholders in the Parent Company:	12		
Before dilution		-0.60	-0.30
After dilution		-0.60	-0.30
EBITDA		-50,093	-14,294
Amortisation of intangible assets		-4,720	-1,756
Depreciation of property, plant and equipment		-6,680	-5,309
Operating income		**-61,493**	**-21,359**

Consolidated statement of comprehensive income

KSEK	Note	2021	2020
Net income		**-57,966**	**-27,139**
Other comprehensive income			
Items that may be reclassified later to the income statement:			
Translation differences from operations abroad		-322	624
Other comprehensive income, net after tax		**-322**	**624**
Total comprehensive income		-58,288	-26,515
Total comprehensive income wholly attributable to shareholders in the Parent Company		**-58,288**	**-26,515**

Consolidated balance sheet

KSEK	Note	31 Dec 2021	31 Dec 2020
ASSETS			
Intangible assets			
Capitalised development expenditure	13	268,201	166,378
Concessions, patents, licenses, etc.	14	1,786	2,998
Property, plant and equipment			
Plant and machinery	15	1,309	5,711
Equipment, tools, fixtures and fittings	16	6,154	1,213
Right-of-use assets	24	9,324	8,792
Financial assets			
Deferred tax assets	17	23	45
Other long-term assets		42	41
Total long-term assets		**286,839**	**185,178**
Inventories	18	11,093	9,087
Tax receivables		410	453
Accounts receivable	19	20,345	19,484
Prepaid expenses and accrued income	20	7,115	5,609
Other receivables		5,597	4,115
Cash and cash equivalents	21	836,181	376,171
Total current assets		**880,741**	**414,919**
TOTAL ASSETS		**1,167,580**	**600,097**

KSEK	Note	31 Dec 2021	31 Dec 2020
EQUITY AND LIABILITIES			
Equity	22,23		
Share capital		2,483	2,305
Other contributed capital		1,222,395	613,923
Translation difference		184	506
Retained earnings including net income for the period		-123,606	-65,640
Equity attributable to shareholders in the Parent Company		**1,101,456**	**551,094**
Non-current liabilities			
Non-current lease liabilities	24,27	4,642	5,324
Total non-current liabilities		**4,642**	**5,324**
Current liabilities			
Current lease liabilities	24,27	4,232	2,967
Accounts payable		15,036	16,371
Tax liabilities		3,997	2,718
Other liabilities	25	18,473	7,668
Accrued expenses and prepaid income	26	19,744	13,955
Total current liabilities		**61,482**	**43,679**
Total liabilities		**66,124**	**49,003**
TOTAL EQUITY AND LIABILITIES		**1,167,580**	**600,097**

Consolidated statement of changes in equity

Equity attributable to shareholders in the Parent Company

KSEK	Share capital	Other contributed capital	Translation difference	Retained earnings incl. net income for the year	Total
Opening equity at 1 Jan 2020	**2,274**	**605,702**	**-117**	**-38,502**	**569,357**
Net income for the year	-	-	-	-27,138	-27,138
Other comprehensive income for the year	-	-	623	-	623
Comprehensive income for the year	–	–	623	-27,138	-26,515
Transactions with shareholders in the Group					
New share issue	31	7,831	-	-	7,862
Issue expenses	-	-68	-	-	-68
Premium received on issue of warrants	-	515	-	-	515
Expenses for warrant programme	-	-57	-	-	-57
Total transactions with shareholders in the Group	31	8,221	-	-	8,252
Closing equity at 31 Dec 2020	**2,305**	**613,923**	**506**	**-65,640**	**551,094**
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**

Consolidated cash flow statement

KSEK	Note	2021	2020
Operating activities			
Operating income		-61,493	-21,359
Adjustments for non-cash items:			
Depreciation, amortisation and impairment		13,327	14,476
Exchange-rate differences		-4,080	-362
Total		**-52,246**	**-7,245**
Interest received		0	25
Interest paid		-243	-189
Income tax paid		-320	-869
Cash flow from operating activities before changes in working capital		**-52,809**	**-8,278**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in inventories		-2,296	-1,158
Increase (-)/Decrease (+) in operating receivables		-2,169	-15,292
Increase (+)/Decrease (-) in operating liabilities		16,053	16,882
Cash flow from operating activities		**-41,221**	**-7,846**
Investing activities			
Investment in intangible assets	13,14	-105,063	-72,175
Investment in property, plant and equipment	15,16	-5,192	-12,444
Cash flow from investing activities		**-110,255**	**-84,619**
Financing activities			
New share issue	22	614,900	7,862
Issue expenses	22	-7,946	-68
Amortisation of leasing liabilities	24,27	-3,579	-2,464
Premium received for warrant subscription	22	1,696	515
Expenses for warrant programme	22	0	-58
Cash flow from financing activities		**605,071**	**5,787**
Cash flow for the period		**453,595**	**-86,678**
Cash and cash equivalents at the beginning of the period		376,171	464,560
Translation difference in cash and cash equivalents		6,415	-1,711
Cash and cash equivalents at the end of the period	21	**836,181**	**376,171**

Notes

NOTE 1 General information

Sedana Medical (publ), with corporate identity number 556670-2519, is a limited company registered in Sweden with registered office in Danderyd. The address of the headquarters 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 valuation policies

The key accounting policies applied in the preparation of these consolidated financial statements are presented 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 (IFRS IC), 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
No new or amended standards entering into effect after 1 January 2021 have been applied in the preparation of this financial report. No published standards which have not yet entered into force are assessed as having any impact on the Group.

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 monitors the business as a unit (a concept), the whole of the business is comprised of a single operating 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 profit or loss 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 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.

Government assistance
Government assistance is recognised at fair value when there is reasonable assurance that the amounts will be received and the Group will comply with the conditions attached to the grants. Grants which have been received before the conditions to recognise them as revenue have been fulfilled are recognised as a liability. Government grants are recognised systematically in income statements as a reduced cost over the same periods as the costs the grants are intended to offset.

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 profit or loss 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.

Taxes

Income tax comprises current and deferred tax. Income tax is recognised in net profit 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 profit or loss 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 valued at accrued acquisition value if it fulfils both of the following conditions and has not been identified as measured at fair value through profit or loss:

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

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

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

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 profit or loss 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 the Group's 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 2021. 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 per 31 December 2021. For further information on amounts and currencies for accounts receivable, credit loss reserve and maturity structure see the Group's 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	2021	2020
Sweden (Group domicile)	610	1,432
Germany (major market)	108,699	103,058
Other markets	49,843	37,280
Total	**159,152**	**141,770**

Revenue per sales channel

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

KSEK	2021	2020
Direct sale markets	127,761	125,062
Distribution markets	31,391	16,708
Total	**159,152**	**141,770**

Long-term assets broken down by country

Long-term 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	2021	2020
Sweden (Group domicile)	266,845	168,474
Ireland	17,044	15,174
Rest of the world*	2,885	1,443
Total	**286,774**	**185,091**

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

The breakdown of long-term assets above has been based on ownership of the long-term asset.

NOTE 5 Employees, personnel expenses and remuneration of senior executives

Average number of employees

	2021			2020		
	Total	Women	Men	Total	Women	Men
Parent Company						
Sweden	38	22	16	23	15	8
Spain	3	1	2	2	–	2
Total Parent Company	**41**	**23**	**18**	**25**	**15**	**10**
Group						
Ireland	5	2	3	7	2	5
France	6	3	3	5	2	3
Netherlands	2	–	2	2	–	2
Norway	2	1	1	2	1	1
United States	3	3	–	–		
United Kingdom	3	1	2	3	1	2
Germany	14	6	8	13	6	7
Group total	**76**	**39**	**37**	**57**	**27**	**30**
Senior executives, at year-end						
Board of Directors	6	1	5	6	1	5
CEO and senior executives	9	4	5	9	3	6

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

KSEK	Basic salary/ Board fee	Variable remuneration	Other benefits	Pension expense	Total
Salaries and other remuneration 2021					
Chairman of the Board Thomas Eklund	475	–	–	–	475
Board member Claus Bjerre [1]	183	–	–	–	183
Board member Sten Gibeck [2]	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 [3]	1,080	638	59	277	2,054
CEO Johannes Doll [4]	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**

NOTE 5 Employees, personnel expenses and remuneration of senior executives, cont.

KSEK	Basic salary/ Board fee	Variable remu-neration	Other benefits	Pension expense	Total
Salaries and other remuneration 2020					
Chairman of the Board Thomas Eklund	383	–	–	–	383
Board member Sten Gibeck	83	–	–	–	83
Board member Bengt Julander	92	–	–	–	92
Board member Ola Magnusson	83	–	–	–	83
Board member Eva Walde	133	–	–	–	133
Board member Christoffer Rosenblad [5)]	117	–	–	–	117
CEO Christer Ahlberg	1,890	190	108	448	2,636
Other senior executives (5 persons)	7,122	402	203	1,285	9,012
Total	**9,903**	**592**	**311**	**1,733**	**12,539**

1) Member of the Board from May 2021
2) Member of the Board until May 2021
3) CEO until June 2021
4) CEO from October 2021
5) Member of the Board from May 2020

Salaries and other remuneration and social security expenses

	2021				2020			
KSEK	Salaries and other remuner-ation	(of which bonuses)	Social security expenses	(of which pension expenses)	Salaries and other remu-neration	(of which bonuses)	Social security expenses	(of which pension expenses)
Board members, Chief Executive Officer and other senior executives	16,928	(3,124)	7,049	(2,237)	10,807	(592)	4,829	(1,732)
Other employees	57,842	(5,809)	20,319	(8,585)	43,702	(2,259)	12,427	(5,207)
Total	**74,770**	**(8,933)**	**27,368**	**(10,822)**	**54,509**	**(2,851)**	**17,256**	**(6,939)**

KSEK	2021	2020
Salaries and other remuneration	74,770	54,509
Social security contributions	16,546	10,317
Pension expenses – defined-contribution plans	10,822	6,939
Total employee benefits	**102,138**	**71,765**

Remuneration to senior executives
Remuneration to senior executives who are employees may consist of basic salary, variable remuneration, pension and other benefits. In addition to his monthly salary, CEO Johannes Doll is entitled to an annual bonus amounting to a maximum of six monthly salaries. The bonus is linked to the Company's sales, the Company's operating profit before interest, tax, write-downs, depreciation and goodwill amortization (EBITDA) and performance in relation to predetermined goals. In addition to the statutory pension, the Company puts aside one amount corresponding to 22 percent of the CEO's fixed monthly salary to a specific occupational pension solution decided by the CEO. The notice period is 12 months mutually. 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 78–80.

For further information about warrants, see Note 23.

NOTE 6 Fee and reimbursement of expenses paid to auditors

KSEK	2021	2020
PwC		
Audit engagement	638	478
Auditing services other than the audit engagement	10	-
Tax advice	147	-
Other services	91	436
Total	886	914
R3 Revisionsbyrå KB		
Audit engagement	-	126
Auditing services other than the audit engagement	-	-
Tax advice	-	-
Other services	-	-
Total	–	126
Other auditors		
Audit engagement	265	455
Auditing services other than the audit engagement	-	-
Tax advice	-	-
Other services	-	-
Total	**265**	**455**
Total	**1,151**	**1,495**

NOTE 7 Operating expenses broken down by type of expense

KSEK	2021	2020
Goods for resale	46,592	45,914
Other external expenses	73,791	49,991
Personnel expenses	88,676	60,176
Depreciation	11,400	7,065
Total	**220,459**	**163,146**

NOTE 8 Other operating income

KSEK	2021	2020
Exchange gains on operating receivables/ liabilities	3,813	3,653
Other	200	1
Total	**4,013**	**3,654**

NOTE 9 Other operating expenses

KSEK	2021	2020
Exchange losses on operating receivables/ liabilities	4,109	3,471
Other	90	166
Total	**4,199**	**3,637**

NOTE 10 Net financial items

KSEK	2021	2020
Exchange gains	11,285	529
Total financial income	**11,285**	**529**
Interest expense, other	-243	-189
Exchange losses	-6,920	-3,084
Total financial expense	**-7,163**	**-3,274**
Net financial items	**4,122**	**-2,745**

NOTE 11 Tax

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

KSEK	2021	2020
Tax expense/tax income for the year	-549	-1,019
Adjustment of tax attributable to previous years	-24	150
Total current tax	**-573**	**-869**
Deferred tax		
Change in deferred tax	-22	-2,166
Total deferred tax	**-22**	**-2,166**
Total recognised tax expense/tax income	**-595**	**-3,035**

Reconciliation of recognised tax

KSEK	2021	2020
Profit/loss before tax	-57,371	-24,104
Tax at current tax rate for Parent Company	11,818	5,158
Tax effect of:		
- non-deductible expenses	-89	-99
- non-taxable income	-	-
- other tax rates for foreign subsidiaries/ branches	-1,014	-1,495
- increase in loss carry-forwards without corresponding capitalisation of deferred tax	-19,527	-7,023
- utilisation of previously non-capitalised loss carry-forwards	294	234
- tax relating to previous years	-24	150
- deductible expenses which are not included in the result	7,946	-
- other	1	40
Recognised effective tax	**-595**	**-3,035**
Average effective tax rate (%)	1.0%	12,6%

The Group has tax loss carryforwards of KSEK 156,824 (91,090). Deficit deductions are not time-limited.

NOTE 12 Earnings per share

Earnings per share is calculated by dividing net profit 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 2020 or 2021 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	2021	2020	2021	2020
Profit attributable to shareholders in the Parent Company:				
Earnings per share, before and after dilution	-0.62	-0.30	-0.62	-0.30
Total	**-0.62**	**-0.30**	**-0.62**	**-0.30**

Weighted average number of ordinary shares

	2021	2020
Weighted average number of ordinary shares in calculation of basic earnings per share	92,774,631	91,556,662
Adjustment for calculation of diluted earnings per share:		
Warrants	190,079	997,878
Weighted average number of ordinary shares and potential ordinary shares used as denominator in calculation of diluted earnings per share	**92,964,711**	**92,554,540**

NOTE 13 Capitalised expenditure on development work and similar work

KSEK	31 Dec 2021	31 Dec 2020
Accumulated acquisition values:		
- At the start of the year	167,734	96,528
- Acquisitions	104,973	71,676
- Translation differences for the year	252	-470
- At the end of the year	**272,959**	**167,734**
Accumulated depreciation according to plan:		
- At the start of the year	-1,356	-1,042
- Depreciation for the year	-3,373	-370
- Translation differences for the year	-29	56
- At the end of the year	**-4,758**	**-1,356**
Carrying amount at the end of the year	**268,201**	**166,378**
The carrying amount above relates to:		
Development work within the medical sector	260,724	164,522
Other capitalised development expenses	7,477	1,856
Depreciation for the year by function:		
Cost of goods sold	-459	-
Selling expenses	-2,840	-
Research and development expenses	-74	-370

Total expenditure on research and development expensed during the period amounts to KSEK 19,704 (7,859).

Expenditure on development work is capitalised as it arises. A possible need for impairment relating to capitalised expenditure on development work is tested at least once per year or more often if there is an indication that a decrease in value may have occurred. The impairment test is based on estimated future cash flows.

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

KSEK	31 Dec 2021	31 Dec 2020
Accumulated acquisition values:		
- At the start of the year	8,245	8,612
- Acquisitions	89	336
- Translation differences for the year	336	-703
- At the end of the year	**8,670**	**8,245**
Accumulated depreciation according to plan:		
- At the start of the year	-5,247	-4,452
- Depreciation for the year	-1,347	-1,386
- Translation differences for the year	-290	591
- At the end of the year	**-6,884**	**-5,247**
Carrying amount at the end of the year	**1,786**	**2,998**

The income statement includes amortisation for the year as above wholly under Cost of goods sold. In 2020 the expense was included wholly under Administrative expenses.

NOTE 15 Plant and machinery

KSEK	31 Dec 2021	31 Dec 2020
Accumulated acquisition values:		
- At the start of the year	10,694	11,815
- Acquisitions	782	11,122
- Reclassifications	-7,746	-2,357
- Disposals	-32	-9,712
- Translation differences for the year	73	-174
- At the end of the year	**3,771**	**10,694**
Accumulated depreciation according to plan:		
- At the start of the year	-4,983	-6,080
- Reclassifications	3,583	1,006
- Depreciation for the year	-1,021	-2,806
- Disposals	10	2,774
- Translation differences for the year	-51	123
- At the end of the year	**-2,462**	**-4,983**
Carrying amount at the end of the year		
Accumulated impairments:		
- At the start of the year	–	-1,350
- Reclassifications	–	1,350
- Disposals	–	–
- Translation differences for the year	–	–
- At the end of the year	**–**	**–**
Carrying amount at the end of the year	**1,309**	**5,711**

NOTE 16 Equipment, tools, fixtures and fittings

KSEK	31 Dec 2021	31 Dec 2020
Accumulated acquisition values:		
- At the start of the year	1,908	968
- Acquisitions	4,410	1,000
- Disposals	-1,609	–
- Reclassifications	7,344	-14
- Translation differences for the year	36	-46
- At the end of the year	**12,089**	**1,908**
Accumulated depreciation according to plan:		
- At the start of the year	-695	-478
- Reclassifications	-3,181	14
- Disposals	-6	–
- Depreciation for the year	-2,030	-252
- Translation differences for the year	-23	21
- At the end of the year	**-5,935**	**-695**
Carrying amount at the end of the year	**6,154**	**1,213**

NOT 17 Deferred tax

Deferred tax receivables and liabilities are broken down as follows:

KSEK	31 Dec 2021	31 Dec 2020
Deferred tax assets:		
Loss carry-forwards	–	–
Inventories	–	34
Lease liability	23	11
Deferred tax liabilities:		
Right-of-use asset	–	–
Deferred tax assets (net)	**23**	**45**

KSEK	Loss carry-forwards	Lease liability	Inventories	Total
Deferred tax assets:				
At 31 December 2020	-	11	34	45
Recognised in the comprehensive income statement	-	12	-34	-22
At 31 December 2021	**–**	**23**	**0**	**23**

NOTE 18 Inventories

KSEK	31 Dec 2021	31 Dec 2020
Raw materials and consumables	622	-
Finished goods and goods for resale	10,471	9,087
Total	**11,093**	**9,087**

During the year, costs of materials were recognised in the income statement of KSEK 52,446 (KSEK 52,867) as cost of goods sold.

NOTE 19 Accounts receivable

KSEK	31 Dec 2021	31 Dec 2020
Accounts receivable	20,345	19,484
Less provision for expected credit losses	–	–
Accounts receivable – net	**20,345**	**19,484**

The Group has not had any reserve for expected credit losses for any of the periods as ability to pay has been good. One of the reasons for the above is 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 2021	31 Dec 2020
EUR	16,705	18,746
GBP	2,659	378
USD	442	-
SEK	234	230
NOK	184	119
DKK	121	11
Accounts receivable – net	**20,345**	**19,484**

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 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**	**-**
31 December 2020			
Not overdue	0%	18,114	-
Overdue 1–30 days	0%	514	-
Overdue 31–60 days	0%	290	-
Overdue 61–90 days	0%	185	-
Overdue more than 90 days	0%	381	-
Total		**19,484**	**-**

NOTE 20 Prepaid expenses and accrued income

KSEK	31 Dec 2021	31 Dec 2020
Rent	712	448
Pension	1,003	493
Insurance	580	385
Capitalised development expenditure	787	1,525
Software	1,177	665
Marketing, congresses	987	954
R&D material	414	440
Other	1,455	699
Total	**7,115**	**5,609**

NOTE 21 Cash and cash equivalents

KSEK	31 Dec 2021	31 Dec 2020
Bank deposits	836,181	376,171
Total	**836,181**	**376,171**

NOTE 22 Shareholders' equity

KSEK	Number of shares	Share capital	Other contributed capital
Share capital and other contributed capital			
At 1 January 2020	22,736,591	2,274	605,702
Exercise of warrants	310,149	31	8,221
At 31 December 2020	**23,046,740**	**2,305**	**613,923**
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**

The share capital at 31 December 2021 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 for a new share issue in December 2021 totalled KSEK 7,946 for the full year. Transaction expenses for 2020 totalled KSEK 68 and consisted of expenses in connection with conversion of warrants.

NOTE 23 Warrants

Warrants 2020

Programme	Position	Number of acquired warrants at the end 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*	Redemption price (SEK)
2017/2021	CEO	736,800	–	736,800	–	–	1:1	6.34
2017/2021	Other senior executives	503,796	–	503,796	–	–	1:1	6.34
2017/2021	Other employees	–	–	–	–	–	1:1	6.34
2017/2021	**Total**	**1,240,596**	**–**	**1,240,596**	**–**	**–**	**1:1**	**6.34**
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	–	–	–	251,168	1:1	35.56
2019/2022	**Total**	**356,340**	**–**	**–**	**–**	**356,340**	**1:1**	**35.56**
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**
Total	CEO	736,800	–	736,800	–	–		
Total	Other senior executives	608,968	16,000	503,796	–	121,172		
Total	Other employees	251,168	26,480	0	–	277,648		
	Total	**1,596,936**	**42,480**	**1,240,596**	**–**	**398,820**		

Warrants 2021

Programme	Position	Number of acquired warrants at the end 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*	Redemption 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**
Redemption 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**
Redemption 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**
Redemption 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**		

*1:1 = 1 warrant = 1 share on conversion. All amounts are restated according to a 4:1 split, 27.05.2021

NOTE 24 Leases

Leases where the company is lessee
Group property, plant and equipment consists of both owned and leased assets.

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

KSEK	31 Dec 2021	31 Dec 2020
Property, plant and equipment owned	1,309	5,711
Right-of-use assets	9,324	8,792
Total	**10,633**	**14,503**

Right-of-use asset

KSEK	Buildings	Vehicles	Equipment and tools	Total
Balance at 31 December 2020	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
Closing balance, 31 December 2021	**5,390**	**3,872**	**62**	**9,324**

Lease liability

KSEK	31 Dec 2021	31 Dec 2020
Lease liability included in statement of financial position		
Current lease liabilities	4,232	2,967
Non-current lease liabilities	4,642	5,324
Total	**8,874**	**8,291**

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	2021	2020
Interest on lease liabilities	219	106
Depreciation	3,979	2,244
Variable lease payments not included in lease liability	1,368	627
Costs of short-term leases	3	4
Costs of leases of low value, not short-term leases of low value	55	34
Total	**5,624**	**3,015**

Amounts recognised in the cash flow statement

KSEK	2021	2020
Total cash flows attributable to leases	**-6,147**	**-4,142**

NOTE 25 Other current liabilities

KSEK	31 Dec 2021	31 Dec 2020
VAT	5,203	323
Employee withholding tax	2,198	1,628
Social security contributions	1,500	1,381
Liabilities to employees	8,400	3,107
Other liabilities	1,172	1,228
Total	**18,473**	**7,667**

NOTE 26 Accrued expenses and prepaid income

KSEK	31 Dec 2021	31 Dec 2020
Salaries, holidays, social security expenses	7,854	7,729
Lawyers' fees	-	1,775
Consultants' fees	4,905	1,192
Auditing	903	716
Transport	972	609
Supplied goods not invoiced	-	545
Capitalised development expenditure	3,610	638
Other	1,500	750
Total	**19,744**	**13,954**

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**

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%	4,259	821
USD/SEK	+/- 10%	257	10,334

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. 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 a maturity analysis, see the Group's Note 19.

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

NOTE 29 Related party transactions

KSEK	2021 Purchases of services	2021 Purchases of goods	2020 Purchases of services	2020 Purchases of goods
Group				
Lismed Ltd	37	4,860	101	10,259
Group total	**37**	**4,860**	**101**	**10,259**

Lismed Ltd is a company related to Ron Farrell, who during the first quarter was a member of the Board of the Group's Irish subsidiary. Ron Farrell left his Board appointment at the beginning of the second quarter.

Purchases of goods from Lismed Ltd concern the device Flurasorb and accessories which in turn are accessories to Sedaconda ACD. Purchases of services from Lismed Ltd relate to technical support.

During the first quarter, Sedana Medical issued a loan in the amount of KSEK 300 to Stefan Krisch. Stefan has been a member of the Sedana Medical management team since the beginning of March 2021. During the second quarter, a consultancy agreement was signed between Sedana Medical and Board member Claus Bjerre. No amounts have yet been invoiced or settled in relation to this agreement.

Remuneration and benefits for Board members and senior executives are described in Note 5.

NOTE 30 Significant events after the end of the financial year

In January, Johan Spetz was appointed as the new CFO. Johan Spetz succeeds Susanne Andersson, who leaves the position to take up other duties.

In January, the National Institute for Health and Care Excellence (NICE) 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.

Parent Company income statement

KSEK	Note	2021	2020
Net sales	1,2	159,107	121,238
Cost of goods sold	2,5	-49,662	-38,707
Gross profit		**109,445**	**82,531**
Operating expenses	3,4,5,8		
Selling expenses		-58,487	-72,666
Administrative expenses		-102,312	-38,668
Research and development expenses		-15,592	-3,953
Other operating income	2,6	15,766	7,790
Other operating expenses	7	-3,981	-2,611
Operating income		**-55,161**	**-27,577**
Financial items			
Financial income		12,621	1,778
Financial expenses		-21,088	-2,959
Net financial items	9	**-8,467**	**-1,181**
Income after financial items		**-63,628**	**-28,758**
Group contributions	10	-1	-9
Income before tax		**-63,629**	**-28,767**
Income tax	11	-	-
Net income		**-63,629**	**-28,767**

Parent Company statement of other comprehensive income

KSEK	Note	2021	2020
Net income		**-63,629**	**-28,767**
Other comprehensive income			
Items that may be reclassified later to the income statement:			
Translation differences from operations abroad		-93	200
Other comprehensive income during the year, net after tax		**-93**	**200**
Comprehensive income for the year		**-63,722**	**-28,567**

Parent Company balance sheet

KSEK	Note	31 Dec 2021	31 Dec 2020
ASSETS			
Intangible assets			
Capitalised development expenditure	12	253,928	156,261
Property, plant and equipment			
Plant and machinery	13	835	4,334
Equipment, tools, fixtures and fittings	14	5,389	638
Financial assets			
Participations in Group companies	15	404	395
Receivables in Group companies	16	29,819	38,539
Total long-term assets		**290,375**	**200,167**
Inventories	17	11,093	9,245
Tax receivables		4	4
Accounts receivable	18	17,934	17,925
Receivables in Group companies		19,158	2,239
Prepaid expenses and accrued income	19	5,721	5,575
Other receivables		4,336	3,202
Cash and bank balances	20	816,279	365,113
Total current assets		**874,525**	**403,303**
TOTAL ASSETS		**1,164,900**	**603,470**

KSEK	Note	31 Dec 2021	31 Dec 2020
EQUITY AND LIABILITIES			
Equity	21,22		
Restricted equity			
Share capital		2,483	2,305
Fund for development expenditure		246,451	154,405
Non-restricted equity			
Share premium reserve		1,222,395	613,923
Retained earnings		-301,172	-180,266
Net income		-63,629	-28,767
Equity attributable to shareholders in the Parent Company		**1,106,528**	**561,600**
Current liabilities			
Accounts payable		13,662	15,469
Liabilities to Group companies		10,937	10,095
Tax liabilities		2,118	1,387
Other liabilities	23	16,027	4,707
Accrued expenses and prepaid income	24	15,628	10,212
Total current liabilities		**58,372**	**41,870**
Total liabilities		**58,372**	**41,870**
TOTAL EQUITY AND LIABILITIES		**1,164,900**	**603,470**

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 including net income for the year	Total equity
Opening equity at 1 Jan 2020	**2,274**	**88,047**	**605,702**	**-114,108**	**581,915**
Net income for the year	-	-	-	-28,767	-28,767
Other comprehensive income for the year	-	-	-	200	200
Comprehensive income for the year	–	–	–	-28,567	-28,567
Changes in the carrying amounts recognised directly in equity					
New share issue	31	-	7,831	-	7,862
Issue expenses	-	-	-68	-	-68
Premium received on issue of warrants	-	-	515	-	515
Expenses for warrant programme	-	-	-57	-	-57
Total	31	-	8,221	-	8,252
Transfer between items in equity					
Capitalisation of development expenditure	-	66,358	-	-66,358	-
Total	-	66,358	-	-66,358	-
Closing equity at 31 Dec 2020	**2,305**	**154,405**	**613,923**	**-209,033**	**561,600**
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
Repurchase 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**

Parent Company cash flow statement

KSEK	Note	2021	2020
Operating activities			
Operating income		-55,161	-27,577
Adjustments for non-cash items:			
Depreciation, amortisation and impairment		4,911	969
Exchange-rate differences		-2,671	629
Other non-cash items		936	473
Total		**-51,985**	**-25,506**
Interest received		0	1,336
Interest paid		-23	-8
Income tax paid		0	0
Cash flow from operating activities before changes in working capital		**-52,008**	**-24,178**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in inventories		-1,848	-8,262
Increase (-)/Decrease (+) in operating receivables		-26,003	396
Increase (+)/Decrease (-) in operating liabilities		24,296	8,380
Cash flow from operating activities		**-55,563**	**-23,664**
Investing activities			
Investment in intangible assets	12	-100,581	-68,213
Investment in property, plant and equipment	13,14	-4,183	-4,893
Acquisition of financial assets		-3,046	-283
Cash flow from investing activities		**-107,810**	**-73,389**
Financing activities			
New share issue	21	614,900	7,862
Issue expenses	21	-7,946	-68
Premium received for warrant subscription	21	1,696	515
Expenses for warrant programme	21	0	-58
Cash flow from financing activities		**608,650**	**8,251**
Cash flow for the period		**445,277**	**-88,802**
Cash and cash equivalents at the beginning of the period		**365,113**	**455,206**
Translation difference in cash and cash equivalents		5,889	-1,291
Cash and cash equivalents at the end of the period	20	**816,279**	**365,113**

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	2021	2020
Sweden (Group domicile)	610	1,432
Germany (major market)	108,699	68,564
Other markets	49,798	51,197
Total	**159,107**	**121,238**

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

NOTE 2 Intra-Group purchases and sales

KSEK	2021	2020
Sale of goods relating to Group companies	6,602	31,602
Operating income concerning services relating to Group companies	11,826	33,566
Purchase of goods relating to Group companies	945	20,286

NOTE 3 Employees, personnel expenses and remuneration of senior executives

Average number of employees

	2021			2020		
	Total	Women	Men	Total	Women	Men
Parent Company						
Sweden	38	22	16	23	15	8
Spain	3	1	2	2	–	2
Total Parent Company	**41**	**23**	**18**	**25**	**15**	**10**
Senior executives, at year-end						
Board of Directors	6	1	5	6	1	5
CEO and senior executives	9	4	5	9	3	6

Salaries and other remuneration and social security expenses

	2021				2020			
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	12,525	(2,544)	5,743	(1,728)	8,770	(440)	4,741	(1,644)
Other employees	34,097	(2,470)	15,812	(6,097)	19,268	(383)	7,230	(3,159)
Total	**46,622**	**(5,013)**	**21,556**	**(7,824)**	**28,038**	**(823)**	**11,971**	**(4,803)**

KSEK	2021	2020
Salaries and other remuneration	46,622	28,038
Social security contributions	13,731	7,168
Pension expenses – defined-contribution plans	7,824	4,803
Total employee benefits	**68,177**	**40,009**

Remuneration to senior executives
Remuneration to senior executives who are employees may consist of basic salary, variable remuneration, pension and other benefits. In addition to his monthly salary, CEO Johannes Doll is entitled to an annual bonus amounting to a maximum of six monthly salaries. The bonus is linked to the Company's sales, the Company's operating profit before interest, tax, write-downs, depreciation and goodwill amortization (EBITDA) and performance in relation to predetermined goals. In addition to the statutory pension, the Company puts aside one amount corresponding to 22 percent of the CEO's fixed monthly salary to a specific occupational pension solution decided by the CEO. The notice period is 12 months mutually. 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 78–80.

For further information about warrants, see Note 22.

NOTE 4 Fee and reimbursement of expenses to auditors

KSEK	2021	2020
PwC		
Audit engagement	638	478
Auditing services other than the audit engagement	10	-
Tax advice	147	-
Other services	91	436
Total	886	914
R3 Revisionsbyrå KB		
Audit engagement	-	117
Auditing services other than the audit engagement	-	-
Tax advice	-	-
Other services	-	-
Total	–	117
Other auditors		
Audit engagement	47	53
Auditing services other than the audit engagement	-	-
Tax advice	-	-
Other services	-	-
Total	47	53
Total	**933**	**1,084**

NOTE 5 Operating expenses classified by nature of expense

KSEK	2021	2020
Goods for resale	47,229	35,618
Personnel expenses	56,099	29,964
Depreciation	4,911	969
Other operating expenses	117,814	87,443
Total	**226,053**	**153,994**

NOTE 6 Other operating income

KSEK	2021	2020
Exchange gains on operating receivables/liabilities	3,799	1,678
Intra-group management fee	11,826	6,112
Other	141	–
Total	**15,766**	**7,790**

NOTE 7 Other operating expenses

KSEK	2021	2020
Exchange losses on operating receivables/liabilities	3,981	2,611
Other	–	–
Total	**3,981**	**2,611**

Note 8 Operating leases – Lessee

KSEK	2021	2020
Contracted future minimum lease payments for non-cancellable contracts fall due:		
- Within one year	3,944	2,922
- Between one and five years	5,927	7,031
Total	**9,871**	**9,953**
Expensed lease payments for the year	3,460	1,981
Of which rent for premises	2,606	1,387

NOTE 9 Net financial items

KSEK	2021	2020
Interest income, Group companies	1,355	1,312
Interest income, other	0	25
Exchange gains	11,266	442
Total financial income	12,621	1,779
Interest expense, other	-23	-9
Impairment of internal receivables	-14,151	0
Exchange losses	-6,914	-2,950
Total financial expense	-21,088	-2,959
Total	**-8,467**	**-1,180**

NOTE 10 Appropriations

KSEK	2021	2020
Group contributions paid	1	9
Total	**1**	**9**

NOTE 11 Income tax

KSEK	2021	2020
Current tax expense (-)/tax income (+)		
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	2021	2020
Profit/loss before tax	-63,629	-28,767
Tax at current tax rate for Parent Company	13,107	6,156
Tax effect of:		
- non-deductible expenses	-2,981	-75
- other tax rates for foreign subsidiaries/ branches	-16	-10
- increase in loss carry-forwards without corresponding capitalisation of deferred tax	-18,149	-6,137
- utilisation of previously non-capitalised loss carry-forwards	92	67
- deductible expenses which are not included in the result	7,946	-
- other	1	-1
Recognised effective tax	**0**	**0**

Unutilised loss carry-forwards for which no deferred tax receivable has been recognised total KSEK 134,959 at 31 Dec 2021 (31 Dec 2020: KSEK 78,102). The loss carry-forwards do not fall due at any time.

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 2021	31 Dec 2020
Accumulated acquisition values:		
- At the start of the year	156,261	88,047
- Acquisitions	100,581	68,214
- Translation differences for the year	-	-
- At the end of the year	**256,842**	**156,261**
Accumulated depreciation according to plan:		
- At the start of the year	-	-
- Depreciation for the year	-2,914	-
- Translation differences for the year	-	-
- At the end of the year	**-2,914**	**-**
Carrying amount at the end of the year	**253,928**	**156,261**
The carrying amount above relates to:		
Development work within the medical sector	246,451	154,405
Other capitalised development expenses	7,477	1,856
Depreciation for the year by function:		
Selling expenses	-2,840	-
Research and development expenses	-74	-

NOTE 13 Plant and machinery

KSEK	31 Dec 2021	31 Dec 2020
Accumulated acquisition values:		
- At the start of the year	6,226	1,872
- Acquisitions	748	4,367
- Reclassifications	-5,932	–
- Disposals	-15	–
- Translation differences for the year	3	-13
- At the end of the year	**1,030**	**6,226**
Accumulated depreciation according to plan:		
- At the start of the year	-1,892	-1,032
- Reclassifications	2,097	–
- Depreciation for the year	-409	-865
- Disposals	10	–
- Translation differences for the year	-1	5
- At the end of the year	**-195**	**-1,892**
Carrying amount at the end of the year		
Accumulated impairments:		
- At the start of the year	–	–
- Reclassifications	–	–
- Disposals	–	–
- Translation differences for the year	–	–
- At the end of the year	**–**	**–**
Carrying amount at the end of the year	**835**	**4,334**

NOTE 14 Equipment, tools, fixtures and fittings

KSEK	31 Dec 2021	31 Dec 2020
Accumulated acquisition values:		
- At the start of the year	815	300
- Acquisitions	3,435	515
- Reclassifications	5,932	–
- Disposals	-993	–
- Translation differences for the year	3	–
- At the end of the year	**9,192**	**815**
Accumulated depreciation according to plan:		
- At the start of the year	-177	-79
- Reclassifications	-2,097	–
- Depreciation for the year	-1,588	-98
- Disposals	61	–
- Translation differences for the year	-2	–
- At the end of the year	**-3,803**	**-177**
Carrying amount at the end of the year	**5,389**	**638**

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 value31 Dec 2021	Book value31 Dec 2020
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	-

KSEK	31 Dec 2021	31 Dec 2020
Accumulated acquisition values:		
Opening acquisition value	395	394
Acquired participating interests	9	-
Reclassifications	-	1
Closing accumulated acquisition value	404	395
Accumulated impairments:		
Opening accumulated impairments	-	-
Impairments for the year	-	-
Closing accumulated impairments	-	-
Closing carrying amount	**404**	**395**

NOTE 16 Receivables in Group companies

KSEK	31 Dec 2021	31 Dec 2020
Accumulated acquisition values:		
- At the start of the year	38,539	40,418
- Added receivables	5,845	6,022
- Deducted receivables	-414	-7,901
- At the end of the year	43,970	38,539
Accumulated impairments:		
- At the start of the year	-	-
- Additional impairments	-14,151	-
- At the end of the year	-14,151	-
Carrying amount at the end of the year	**29,819**	**38,539**

Impairments for the year relate to impairment of intra-group receivables as a result of the internal restructuring of the Group carried out at the end of 2020.

NOTE 17 Inventories

KSEK	31 Dec 2021	31 Dec 2020
Raw materials and consumables	622	-
Finished goods and goods for resale	10,471	9,245
Total	**11,093**	**9,245**

During the year, costs of materials were recognised in the income statement of KSEK 52,446 (KSEK 52,867) as cost of goods sold.

NOTE 18 Accounts receivable

KSEK	31 Dec 2021	31 Dec 2020
Accounts receivable	17,934	17,925
Less provision for expected credit losses	–	–
Accounts receivable – net	**17,934**	**17,925**

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 2021	31 Dec 2020
EUR	14,282	17,187
SEK	234	230
GBP	2,659	378
NOK	184	119
DKK	121	11
USD	454	–
Total	**17,934**	**17,925**

NOTE 19 Prepaid expenses and accrued income

KSEK	31 Dec 2021	31 Dec 2020
Rent	698	644
Pension	1,003	490
Insurance	530	351
Capitalised development expenditure	787	1,525
Software	1,028	665
Marketing, congresses	708	954
R&D material	-	174
Other	967	772
Total	**5,721**	**5,575**

NOTE 20 Cash and cash equivalents

KSEK	31 Dec 2021	31 Dec 2020
Bank deposits	816,279	365,113
Total	**816,279**	**365,113**

NOTE 21 Shareholders' equity

KSEK	Number of shares	Share capital	Other contributed capital
Share capital and other contributed capital			
At 1 January 2020	22,736,591	2,274	605,702
Exercise of warrants	310,149	31	8,221
At 31 December 2020	**23,046,740**	**2,305**	**613,923**
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**

The share capital at 31 December 2021 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 for new share issue in connection with the new share issue in 2021 totalled KSEK 7,946. Transaction expenses for 2020 in connection with conversion of warrants totalled KSEK 68.

NOTE 22 Warrants

Warrants 2020

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*	Redemption price (SEK)
2017/2021	CEO	736,800	-	736,800	-	-	1:1	6.34
2017/2021	Other senior executives	503,796	-	503,796	-	-	1:1	6.34
2017/2021	Other employees	-	-	-	-	-	1:1	6.34
2017/2021	**Total**	**1,240,596**	**-**	**1,240,596**	**-**	**-**	**1:1**	**6.34**
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	-	-	-	251,168	1:1	35.56
2019/2022	**Total**	**356,340**	**-**	**-**	**-**	**356,340**	**1:1**	**35.56**
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**
Total	CEO	736,800	-	736,800	-	-		
Total	Other senior executives	608,968	16,000	503,796	-	121,172		
Total	Other employees	251,168	26,480	0	-	277,648		
	Total	**1,596,936**	**42,480**	**1,240,596**	**-**	**398,820**		

NOTE 22 Warrants, cont.

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*	Redemption 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**
Redemption 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**
Redemption 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**
Redemption 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**		

*1:1 = 1 warrant = 1 share on conversion. All amounts are restated according to a 4:1 split, 27.05.2021

NOTE 23 Other current liabilities

KSEK	31 Dec 2021	31 Dec 2020
VAT	5,049	278
Employee withholding tax	1,732	1,270
Social security contributions	1,149	643
Liabilities to employees	6,924	1,621
Other liabilities	1,173	895
Total	**16,027**	**4,707**

NOTE 24 Accrued expenses and prepaid income

KSEK	31 Dec 2021	31 Dec 2020
Salaries, holidays, social security expenses	4,330	4,241
Lawyers' fees	-	1,775
Consultants' fees	4,814	1,192
Auditing	520	535
Transport	854	356
Supplied goods not invoiced	-	545
Capitalised development expenditure	3,610	638
Other	1,500	930
Total	**15,628**	**10,212**

NOTE 25 Appropriation of profit or loss

SEK	
Funds available to the Annual General Meeting:	
Accumulated loss	-301,171,865
Share premium reserve	1,222,394,181
Net profit/loss for the year	-63,628,498
Total	**857,593,818**

The Board proposes that available funds be appropriated such that SEK 857,593,818 is carried forward to the new account.

NOTE 26 Related party transactions

KSEK	2021 Purchases of services	2021 Purchases of goods	2020 Purchases of services	2020 Purchases of goods
Parent Company				
Lismed Ltd	37	4,339	101	2,262
Parent Company total	**37**	**4,339**	**101**	**2,262**

Lismed Ltd is a company related to Ron Farrell, who during the first quarter was a member of the Board of the Group's Irish subsidiary. Ron Farrell left his Board appointment at the beginning of the second quarter.

Purchases of goods from Lismed Ltd concern the device Flurasorb and accessories which in turn are accessories to Sedaconda ACD. Purchases of services from Lismed Ltd relate to technical support.

During the first quarter, Sedana Medical issued a loan in the amount of KSEK 300 to Stefan Krisch. Stefan has been a member of the Sedana Medical management team since the beginning of March 2021. During the second quarter, a consultancy agreement was signed between Sedana Medical and Board member Claus Bjerre. No amounts have yet been invoiced or settled in relation to this agreement.

For information concerning remuneration of senior executives and warrants, see Notes 5 and 23 to the consolidated financial statements.

NOTE 27 Significant events after the end of the financial year

For information concerning significant events after the end of the financial year, see Note 30 to the consolidated accounts, page 63.

Certification by the Board of Directors and the Chief Executive Officer

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

Danderyd, 7 April 2022

Thomas Eklund
Chairman of the Board

Claus Bjerre
Board member

Bengt Julander
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 7 April 2022

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 2021. The annual accounts and consolidated accounts of the company are included on pages 42-74 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 2021 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 2021 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

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

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.

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 1-41 and 78-81. 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.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit.

We also:

- identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Director's and the Managing Director.
- Conclude on the appropriateness of the Board of Director's and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

Report on other legal and regulatory requirements

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 2021 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.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Stockholm, 7 April 2022

Öhrlings PricewaterhouseCoopers AB

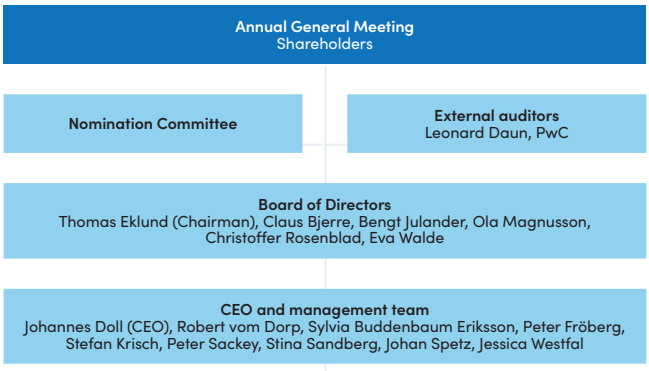
Leonard Daun
Authorised Public Accountant

Corporate Governance

Legislation and articles of association

Sedana Medical is a Swedish public limited liability company governed by Swedish law, primarily the Swedish Companies Act (2005:551) and the Swedish Annual Accounts Act (1995:1554). The company's shares were listed on the Nasdaq First North Growth Market on 21 June 2017. The company has since applied Nasdaq First North Growth Market's regulations. In addition to legislation and Nasdaq First North Growth Market's regulations, the company's articles of incorporation and its internal guidelines for corporate governance form the basis for the corporate governance. The articles of association set forth such things as the company's registered office, the focus of operations, limitations to share capital and the number of shares, and conditions to be met in order to attend the Annual General Meeting. The most recently adopted and registered articles of association were adopted at the Annual General Meeting held on 10 May 2021.

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
- Policy for financial reporting
- Authorisation instructions
- Information policy
- Insider policy
- IT policy
- Policy on conduct

External regulatory frameworks affecting the articles of association

- Swedish Companies Act
- Accounting regulations
- Nasdaq First North Growth Market rules

Swedish Code of Corporate Governance

The Swedish Code of Corporate Governance (the Code) sets forth a higher standard of good corporate governance than the minimum requirements of the Swedish Companies Act and must be applied by companies whose shares are admitted for trading on a regulated market in Sweden. The Code is not currently binding for companies whose shares are listed on Nasdaq First North Growth Market, and is thus not binding on the company. The company does not follow the Code, nor does it fulfil its requirements.

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 attend an annual general meeting, shareholders must be registered in the shareholders' register maintained by Euroclear Sweden AB on the record date, which falls not later than five working days before the meeting, and give notice of their intention to attend the meeting by not later than the day indicated in the notice to attend. 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 19 May 2017 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.

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.

Chairman of the Board

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

The work of the Board

The Board follows written rules of procedure that must be reviewed annually and adopted at the Board meeting following election. Among other things, the rules of procedure govern the Board's working methods, assignments, decision-making within the Company, the Board's meeting procedures, the Chairman's tasks and the allocation of work between the Board and the CEO. Instructions regarding financial reporting and the CEO instructions are also set forth in connection with the meeting of the Board following election. In parallel with Board meetings, the Chairman of the Board and the CEO maintain a dialog concerning the administration of the company. The Board meets according to an annual timetable, and must hold at least five scheduled Board meetings between each AGM.

Committees

At the Annual General Meeting held on 19 May 2020, it was decided that an audit committee would be introduced by the Board during the year. Within the framework of the Board's work, the Audit Committee is to monitor the company's finan-

Board attendance and fee

	Year elected	Attendance number of meetings in 2021 (16)	Board fee decided by 2021 AGM, KSEK	Attendance of audit committee meetings in 2021 (5)	Audit committee fee decided by the 2021 AGM, KSEK	Independent in relation to: Company	Independent in relation to: Shareholders
Chairman of the Board							
Thomas Eklund	2014	16	450	5	25	Yes	Yes
Board member							
Claus Bjerre	2021	10	275			Yes	Yes
Bengt Julander	2011	16	100	5	25	Yes	Yes
Ola Magnusson	2005	16	100			Yes	Yes
Christoffer Rosenblad	2020	16	175	5	50	Yes	Yes
Eva Walde	2018	15	175			Yes	Yes

cial reporting and prepare matters relating to the company' financial reporting and auditing under Chapter 8 section 49b of the Swedish Companies Act The Audit Committee has also continuously supported the Chief Executive Officer on major financing and structural issues and in the preparation of these matters for the Board. 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 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 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. At the time of signing of the annual accounts, Johannes Doll was the CEO of the company. Sedana Medical's senior management otherwise comprised General Manager DACH Robert vom Dorp, HR Director Sylvia Buddenbaum Eriksson, Chief Technology Officer Peter Fröberg, Supply Chain and Manufacturing Director Stefan Krisch, Chief Medical Officer Peter Sackey, Head of Global Marketing Stina Sandberg, CFO Johan Spetz (took up duties on 4 April 2022) and Vice President Regulatory Affairs and QA Jessica Westfal.

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 rules of procedure established by the Board include instructions for internal financial reporting. All interim reports and press releases are published on the company's web site (www.sedanamedical.com) as soon as they are released. 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).

Remuneration of Board members, senior executives and auditor

Remuneration for members of the Sedana Medical Board is resolved by the AGM. The Annual General Meeting held on 10 May 2021 resolved on Board fees on an annual basis of SEK 450,000 for the Chairman, SEK 100,000 each for Bengt Julander and Ola Magnusson, who are also major shareholders in the company, SEK 275,000 for Claus Bjerre and SEK 175,000 for each of the other members elected by the meeting. The Annual General Meeting further resolved on a fee for work on the Board's audit committee of SEK 50,000 to its chair and SEK 25,000 to each other member. Remuneration of senior executives who are employees may consist of basic salary, variable remuneration, pension and other benefits. In addition to his monthly salary, the CEO Johannes Doll has the right to an annual bonus amounting to not more than six monthly salaries. The bonus is linked to the company's sales, its operating earnings before interest, taxes, depreciation and amortisation (EBITDA) 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. The CEO is otherwise subject to customary terms of employment containing rules on confidentiality, non-competition and non-solicitation. The total remuneration of the auditor for the financial year 2021 was KSEK 886. 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 the company, its management and the company's major shareholders.

Claus Bjerre

Born: 1971

Nationality: Danish

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

Education and work experience: Claus has 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 from the start of 2014 through to the end of 2018. Atos Medical was sold by EQT to PAI Partners during his term 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 as President, 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: Senior adviser at KKR & Co, Inc. and CEO of Eden Invest LLC.

S**hareholding in Sedana Medical:**
No shareholding.

Independent in relation to the company, its management and the company's major shareholders.

Bengt Julander

Born: 1953

Nationality: Swedish

Position: Member of the Board of Sedana Medical since 2011.

Education and work experience: Bengt is a qualified pharmacist, with an M.Sc. from Uppsala University. Member of the Board of Linc AB, which invests in companies in the pharmaceutical and medical device industries.

Other current appointments: Chairman of Linc AB and Knil AB. Member of the Board of Cronhamn Invest AB, Livland Skog AB, Part Production Sweden AB, Reison Medical AB and Swevet Holding AB. Board member and deputy Board member in small affiliates to these companies and smaller family companies.

Shareholding in Sedana Medical:
7,598,804 shares via Linc AB.

Independent in relation to the company, 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 20+ years' 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: 4,629,728 shares privately and through Magiola Consulting AB.

Independent in relation to the company, 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 has an MSc 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: COO (since 2020) and Deputy CEO (since 2017) at XVIVO Perfusion AB.

Shareholding in Sedana Medical: No shareholding.

Independent in relation to the company, 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 has 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 / Thermo-Fisher Scientific, as well Strategic Affairs Director at Johnson & Johnson Nordic AB, Medical Device and Strategic Development Manager at Pfizer AB.

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

Shareholding in Sedana Medical: 12,800 shares.

Independent in relation to the company, its management and the company's major shareholders.

Organisation

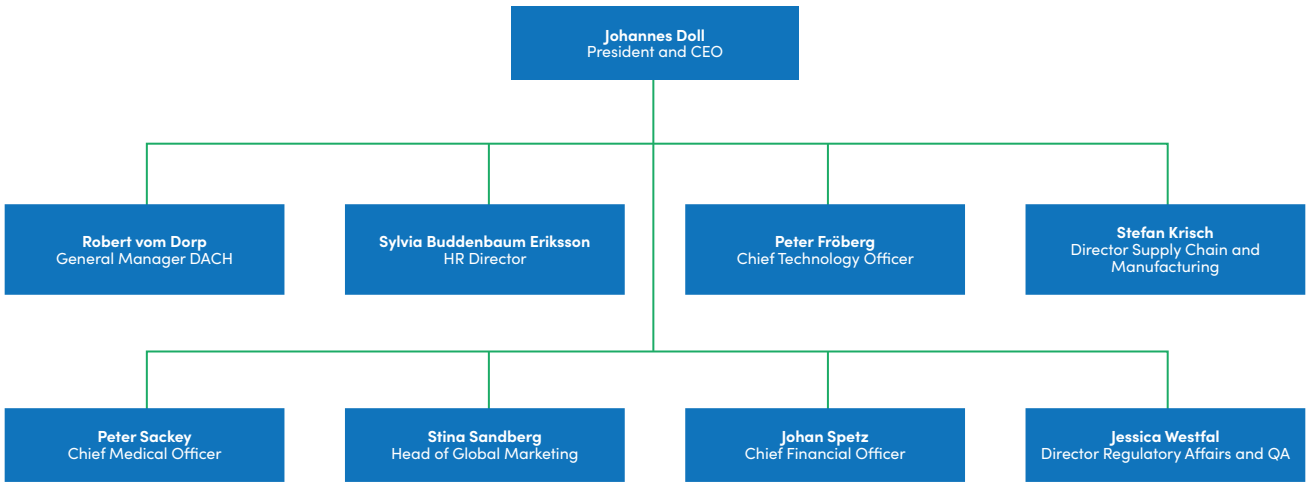
Sedana Medical has staff with a broad background and experience in company management, marketing, sales, production and R&D from both the pharmaceutical and medical technology industries.

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 2021, the average number of employees was 73. 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, General Manager DACH Robert vom Dorp, HR Director Sylvia Buddenbaum Eriksson, Chief Technology Officer Peter Fröberg, Supply Chain and Manufacturing Director Stefan Krisch, Chief Medical Officer Peter Sackey, Head of Global Marketing Stina Sandberg, CFO Johan Spetz 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: Johannes hold an MBA, from the University of Texas, and Dipl. Kaufmann, WHU Otto Beisheim School of Management, Germany. From 2013-2021, Johannes was part of the Executive Management team at Orexo AB, most recently as Executive Vice President and Chief Commercial Officer. Prior to joining Orexo, Johannes worked at McKinsey & Company from 2004 to 2013, advising international clients in the pharmaceutical and medical devices industry and the private equity sector.

Other current appointments: –

Shareholding in Sedana Medical: 11,360 shares.

Robert vom Dorp

Born: 1970

Nationality: German

Position: General Manager DACH since January 2022, employed since 2005.

Education and work experience: Robert holds an MBA in economics from the University of Applied Sciences at Hochschule Koblenz, Germany. Has also studied industrial organisation. Experience of working with sales in medical technology since 2001, previously as account manager for devices in anaesthesia, ventilation and intensive care at Hudson RCI and Teleflex Medical. Since 2005 he has had various roles in sales, marketing and business development at Sedana Medical.

Other current appointments: –

Shareholding in Sedana Medical: 305,000 shares.

Sylvia Buddenbaum Eriksson

Born: 1968

Nationality: Swedish

Position: HR Director, consultant since August 2020.

Education and work experience: Bachelor's degree in Economics, specialising in business economics, Stockholm University. Consultant in her own company since February 2019. Previously, among other things, VP HR at GroupM, VP HR at Lidl Sweden, HR & Public Relations Manager at Apoteksgruppen i Sverige AB/Apoteket omstrukturering AB, VP HR at Unilever Nordic and roles in finance.

Other current appointments: –

Shareholding in Sedana Medical: no shares, related party 72 shares.

Peter Fröberg

Born: 1971

Nationality: Swedish

Position: Chief Technology Officer (CTO) 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.

Other current appointments: –

Shareholding in Sedana Medical: no shares.

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 Eker Bicycles AB and Eker Production Ltd., Uganda. Owner K-Consulting (sole proprietor).

Shareholding in Sedana Medical: 5,600 shares and 25,200 warrants in the warrant program 2020/2024, corresponding to 25,200 shares.

Peter Sackey

Born: 1971

Nationality: Swedish

Position: Chief Medical Officer of Sedana Medical since January 2018.

Education and work experience: Peter received his doctor´s degree from Karolinska Institutet, Stockholm, in 1997. Before joining Sedana Medical, he worked for twenty years at the Department of Perioperative Medicine and Intensive Care, Karolinska University Hospital, and is Board-certified in Anesthesiology (DESA) and Intensive Care (EDIC).

He completed his Ph.D. thesis entitled "Isoflurane sedation in Intensive Care Unit patients" at Karolinska Institutet in 2006. He is an Associate professor at Karolinska Institutet, has supervised several Ph.D. students in ICU sedation, pain monitoring, and long-term outcomes research, and remains active in ICU-related research. 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 105,172 warrants in the 2019/2022 warrant programme, corresponding to 105,172 shares.

Stina Sandberg

Born: 1974

Nationality: Swedish

Position: Head of Global Marketing since June 2020, employed since 2019.

Education and work experience: Bachelor of Science in Nursing with over 20 years of experience from local and global commercial roles in various Life Science companies and as a consultant in own business.

Other current appointments: Owner of Stinsa Consulting AB.

Shareholding in Sedana Medical: no shares. 5,000 warrants in the 2019/2022 warrant programme, corresponding to 5,000 shares.

Johan Spetz

Born: 1984

Nationality: Swedish

Position: CFO since April 2022.

Education and work experience: Johan holds an MSc from the Stockholm School of Economics. Over the period 2013–2021 Johan worked at the investment bank Pareto Securities, of which 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.

Other current appointments: –

Shareholding in Sedana Medical: 8,612 shares.

Jessica Westfal

Born: 1974

Nationality: Swedish

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

Education and work experience: Jessica holds a MSc in Analytical Chemistry at Umeå University. She is a former employee at Unimedic AB (2006-2020) as Head of Quality and Product Development, and before that at AstraZeneca (1998-2006).

Other current appointments: –

Shareholding in Sedana Medical: no shares. 4,000 warrants in the 2020/2023 warrant programme, corresponding to 4,000 shares. Related party 692 shares.

Literature references

Page	Source:
Pages 12–13 Sedation	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)
	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
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	Shelly MP, Sultan MA, Bodenham A, Park GR: Midazolam infusions in critically ill patients. Eur J Anaesthesiol 1991, 8: 21-27
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	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
	5 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
	6 Sackey, Peter V., 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
	7 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
	8 Bittner M-I, Donnelly M, van Zanten AR, et al. How is intensive care reimbursed? A review of eight European countries. An Intensive Care. 2013;3:37

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 medicinal product in more than one EU member state. It can be used for medicinal 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.

Phase 3 study is performed on a very large group of patients to finally define how useful a pharmaceutical product is in treating the disease concerned. In phase 1 studies the drug candidate is used for the first time in humans to test safety, and in phase 2 studies the efficacy of the therapy and what dose is optimal are studied.

FDA US Food and Drug Administration, the American medicines agency.

General anaesthesia otherwise known as narcosis. A collective 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 medicinal product within the United States before it has market approval. A similar procedure exists in the EU.

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 anaesthetics for example isoflurane, sevoflurane and desflurane, can be used for both sedation and general anaesthesia.

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

ISCA Inhaled Sedation in Covid-19-related ARDS. A study that is sponsored by Sedana Medical and is being conducted on at least 400 patients at around 30 intensive care units in France, Germany, Spain and Switzerland, among other countries. The outcome for Covid-19 ARDS patients receiving inhaled sedation is compared to the outcome for the same type of patients receiving intravenous sedation.

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

Mechanical ventilation assisted breathing in respiratory failure.

Randomiserad 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) and is aimed at showing that inhaled sedation has lung-protective properties.

SMRG, Sedana Medical Research Grant, a research grant that was instituted in 2020 and is awarded annually for research in Sedana Medical's area with the aim of leading to medical progress in the field to the benefit of patients and society.

Shareholder information, future events

Annual General Meeting

The Annual General Meeting of Sedana Medical will be held on 11 May 2022.

In order to counteract the spreading of the corona virus, the board of directors of the company has, in accordance with the Act (2022:121) on Temporary Exceptions to Facilitate the Execution of General Meetings in Companies and Other Associations (Sw. lagen (2022:121) om tillfälliga undantag för att underlätta genomförandet av bolags- och föreningsstämmor), resolved that the general meeting shall be held without the physical presence of shareholders, proxies or third parties and that the shareholders shall instead be provided with the possibility to exercise their voting rights by post.

A shareholder who wishes to exercise its voting right at the general meeting shall: (a) be entered as a shareholder in the share register kept by Euroclear Sweden AB as of the record date Tuesday, 3 May 2022; and (b) have given notice of attendance at the general meeting by having cast a postal vote so that the postal vote is received by Euroclear Sweden AB no later than Tuesday, 10 May 2022.

For further information, see the notice of the Annual General Meeting on the company's web page.

Certified adviser

Erik Penser Bank is the certified adviser for Sedana Medical AB (publ).

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Financial calendar

Interim report 1st quarter 2022:	28 April 2022
AGM:	11 May 2022
Interim report 2nd quarter 2022:	21 July 2022
Interim report 3rd quarter 2022:	25 October 2022

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Bringing inhaled sedation to intensive care

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