SEDANAMEDICAL

Pioneering volatile anaesthetic delivery

Interest in inhaled sedation increased significantly during the year

Submitted **application for marketing authorisation in Europe**

The pivotal **Sedaconda study reached its primary endpoint**

Well on the way to the vision of making inhaled sedation **a global standard therapy**

2020

ANNUAL REPORT

CONTENTS

Through the strong results obtained in the pivotal study with Sedaconda (isoflurane), administered via AnaConDa, Sedana Medical has laid the foundation for inhaled sedation, a simple, effective and safe therapy for sedation of intensive care patients.

In this way the company has taken a major step closer to its vision – for inhaled sedation to be a global standard therapy for patients in intensive care.

> Inhaled sedation offers clear benefits compared with current standard therapy.

INHALED SEDATION AS A STANDARD THERAPY

Using its unique technology for the administration of volatile anaesthetics, Sedana Medical has developed inhaled sedation, a new therapy for sedation of intensive care patients that is simple and effective and has potential to become the new standard for sedation of mechanically ventilated intensive care patients.

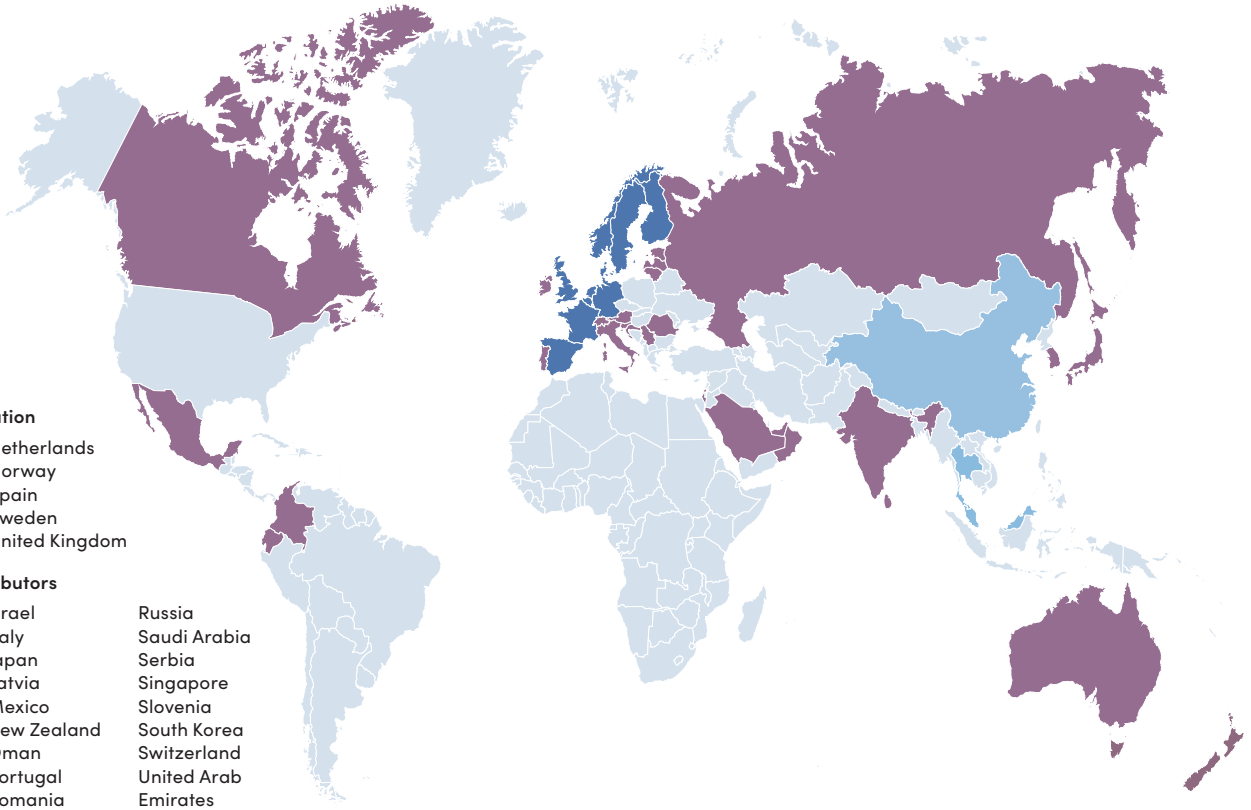
ANACONDA IS APPROVED
in Europe for the administration of volatile anaesthetics.

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 treatments.

Every year, around eight million patients evenly distributed between the United States, Europe and Asia, are sedated with mechanical ventilation in intensive care. The patients are usually sedated for two to five days. Sedana Medical estimates the total market potential to be between SEK 20–30 billion. Furthermore, the market is growing as populations age. Today, the standard intravenous treatment presents a number of challenges for both patients and healthcare that inhaled sedation solves.

Sedana Medical has developed and sells the medical device AnaConDa for inhaled sedation of mechanically ventilated patients. The product makes it possible to administer volatile anaesthetics via the airways, known as inhaled sedation, which gives intensive care access to a new method of sedation that is simple to control, effective, safe and cost-effective.

No volatile anaesthetic is currently approved for sedation in intensive care. Sedana Medical in 2020 completed a pivotal clinical study to obtain market approval in Europe for inhaled sedation in inten-



- **Own sales organisation**
  - Belgium
  - Denmark
  - Finland
  - France
  - Germany
  - Netherlands
  - Norway
  - Spain
  - Sweden
  - United Kingdom
- **Sales through distributors**
  - Australia
  - Austria
  - Canada
  - Colombia
  - Croatia
  - Ecuador
  - Estonia
  - India
  - Ireland
  - Israel
  - Italy
  - Japan
  - Latvia
  - Mexico
  - New Zealand
  - Oman
  - Portugal
  - Romania
  - Russia
  - Saudi Arabia
  - Serbia
  - Singapore
  - Slovenia
  - South Korea
  - Switzerland
  - United Arab Emirates
- **Distributor (AnaConDa registration pending)**
  - China
  - Malaysia
  - Thailand

8

MILLION PATIENTS

sedated and ventilated in intensive care.

142

SALES

In 2020, Sedana Medical achieved sales of SEK 142 million.

sive care with the pharmaceutical product Sedaconda (isoflurane).

Sedana Medical anticipates obtaining European market approval for the pharmaceutical product Sedaconda, and consequently for inhaled sedation therapy, in the second half of 2021. In the company's assessment, it will be the first clinically validated treatment for inhaled sedation in intensive care in the world. The plan is to be represented in a large number of European markets with established networks and reference clinics when the company receives approval, in order to be able to penetrate the market quickly. Sedana Medical expects sales in Europe three years later to reach SEK 500 million with an EBITDA margin of around 40 percent.

The company has also initiated activities to obtain market approval in other markets outside the EU. In the United States, Sedana Medical has initiated a process aimed at obtaining market approval in 2024.

In 2020, Sedana Medical achieved sales of SEK 142 million. Sales have grown significantly since 2010 despite the therapy being off-label, as isoflurane is not approved for sedation in intensive care. The company has its own sales organisations in the Benelux, France, Germany, the Nordics, Spain and the United Kingdom, as well as distributors in parts of the rest of Europe, Australia, Canada, China, India, China, Japan, New Zealand, Saudi Arabia and South Korea. The company's largest market is Germany.

Sedana Medical was established in 2005 in connection with the acquisition of AnaConDa technology. The company has its head office in Danderyd, Sweden, and conducts R&D in Ireland through its wholly owned subsidiary, Sedana Medical Ltd. Production takes place through contract manufacturers. In June 2017 the company's shares (ticker: SEDANA) were listed on Nasdaq First North Growth Market Stockholm.

Sedana Medical's market consists primarily of sedation of mechanically ventilated intensive care patients.

AN INTENSIVE YEAR WITH PROGRESS ON MANY LEVELS

The strong results in the pivotal clinical Sedaconda study (SED001) is the single largest advance towards acceptance of inhaled sedation since the technique was developed. During the year, Sedana Medical was greatly impacted by the pandemic, which resulted in a significant rise in sales but also increased awareness of the company and interest in inhaled sedation.

NET REVENUE 2020

142 MSEK

SALES GROWTH IN 2020

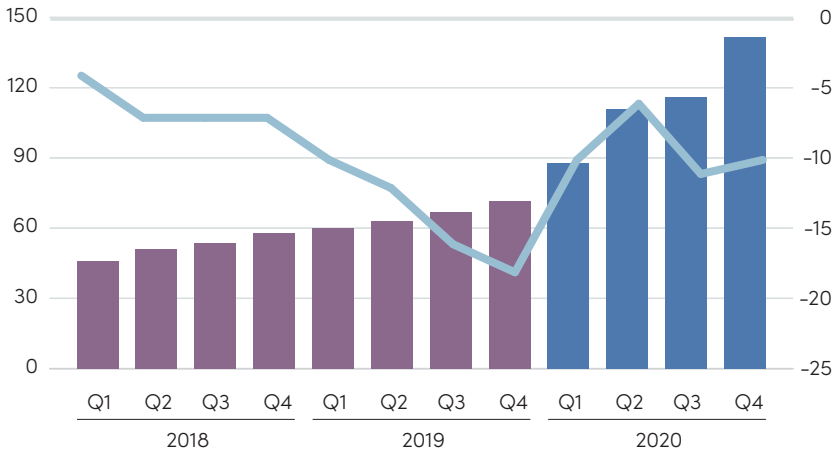
98 %

Key ratios for the Group

Amounts in thousands of SEK (KSEK)	2020	2019	2018*
Net revenue	141,770	71,646	57,896
Gross profit	88,903	48,539	42,897
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-14,294	-12,932	-4,232
Earnings before interest and taxes (EBIT)	-21,359	-17,120	-8,238
Profit or loss for the period	-27,139	-16,380	-6,869
Gross margin %	63%	68%	74%
EBITDA %	-10%	-18%	-7%
Operating margin (EBIT) %	-15%	-24%	-14%
Profit/loss for the period as % of net sales	-19%	-23%	-12%
Balance sheet total	600,097	595,766	231,550
Equity ratio %	92%	96%	94%
Quick ratio %	929%	1872%	1220%
Average number of employees	64	39	26

*Accounting according to previous K3 rules.

Sales revenue and EBITDA margin, 12 months rolling



Q1

In January, the last patient, out of a total of 301 patients, was included in the European pivotal study SED001 (previously called the IsoConDa study).

Sedana Medical received market approval for AnaConDa in Mexico, and established its own sales organisation in Benelux.

Sedana Medical donated AnaConDa with accessories to two hospitals in Wuhan and Zhejiang, China, for anti-epidemic use and evaluation of the effects of inhaled sedation via AnaConDa on severely ill COVID-19 patients.

The growth rate for the first quarter of 2020 was significantly higher than expected. Revenue for the first quarter of 2020 was SEK 34 million, equivalent to growth of around 90 percent compared with the same period of the previous year.

Q2

The first patient was included in the French SESAR study, which compares inhaled sedation and intravenous sedation for patients with acute respiratory distress syndrome (ARDS). Sedana Medical is contributing financial support and study materials.

A multinational, investigator-initiated study of inhaled sedation in COVID-19-related ARDS, ISCA, received financial support from Sedana Medical. The study is being carried out in intensive care units in several European countries.

The CEO, CFO and medical director of Sedana Medical increased their holdings by exercising all the warrants they were entitled to in the 2017/21 incentive programme.

Sedana Medical signed agreements with distributors in Bulgaria, Cyprus, the Czech Republic, Greece and Slovakia.

Q3

Sedana Medical obtained market approval in Saudi Arabia and signed distribution agreements in Saudi Arabia, the United Arab Emirates and Oman.

Sedana Medical's pivotal study SED001 reached its primary endpoint, to show that Sedaconda (isoflurane), administered via AnaConDa, is an effective method of sedation for ventilated intensive care patients, comparable to propofol.

Sedana Medical signed a distribution agreement in Australia and New Zealand.

Q4

Susanne Andersson was appointed as the new CFO to take up duties during the first quarter of 2021. Susanne succeeds Maria Engström, who has chosen on her own initiative to leave the position of CFO for an advisory role for Sedana Medical's management.

The National Institute for Health and Care Excellence (NICE) in the United Kingdom issued a Medtech Innovation Briefing (MIB) on the use of AnaConDa as an alternative to intravenous sedation in intensive care.

Sedana Medical was granted a further European patent that enables what is known as dead space to be reduced, providing great clinical benefits.

An application for market approval for Sedaconda was submitted in 15 countries in the EU.

COVID-19

Sedana Medical saw a strongly positive trend in sales during parts of 2020, partly as a consequence of the COVID-19 pandemic, as the treatment potentially leads to fewer side effects and better oxygen uptake.

There continues to be great uncertainty over how the COVID-19 pandemic in general will develop around the world. Its impacts range from the inclination and ability of clinics to use new sedation methods during a time of crisis to a possible shortage of, or reduced access to, intravenous sedatives.

DELIVERY ACCORDING TO A CLEAR STRATEGY

I am proud that we succeeded in helping medical care in many places around the world in 2020. In addition, our therapy really had an opportunity to show how much it can offer, both to individual patients and to medical care as a whole. Expressed in concise terms, it can be said that COVID-19 was a catalyst that made Sedana Medical move from words to action.

To achieve our vision that inhaled sedation should be a global standard therapy in intensive care, we have devised a strategic plan based on four steps. In 2020 we delivered simultaneously on several levels of this strategy, and we also intend to do so in 2021.

With regard to the **first step**, having AnaConDa approved in as many markets as possible, we now have market approval for AnaConDa in several important markets outside the EU, such as Australia, Canada, Japan, South Korea and Mexico. In 2020, we additionally signed distribution agreements for AnaConDa for Colombia, Ecuador, Oman, Saudi Arabia, Singapore, Thailand and the United Arab Emirates.

It is important to us that AnaConDa is approved even before Sedaconda (isoflurane) has been approved, as using AnaConDa gives the healthcare system experience before the pharmaceutical product is approved, which will speed up and facilitate uptake of the therapy.

Use of AnaConDa was accelerated in 2020 as a result of the COVID-19 pandemic, because ICU sedation is precisely the treatment that severely ill COVID-19 patients very often need. Clinicians are continuing to use inhaled sedation for patients other than COVID-19 patients. When we obtain market approval, we will obtain it from a higher level than would have been the case without COVID-19.

The **second step** is to have the pharmaceutical product Sedaconda and, at the same time, inhaled sedation therapy approved. I would venture to say that in 2020 we took huge strides in these processes. In Europe, as well as in other markets.

The strong top-line results in our pivotal phase 3 study Sedaconda reported in July 2020 constitute the single largest advance for inhaled sedation since AnaConDa was developed.

The study results confirm the clinical experience from physicians across the world and form the basis for the application for European market approval we submitted in the fourth quarter to the German medicines agency BfArM and 14 other European regulatory authorities through what is known as a DCP procedure. The full results of the study will be published in a scientific journal in 2021.

If all goes well, we anticipate market approval during the second half of 2021. This may additionally open the door to a number of other markets that can quickly start up based on an European registration. Market approval means that the therapy moves from off-label to fully approved, which means we can freely and exclusively market our pharmaceutical product and our medical devices that form part of our unique therapy.

> "**We have delivered simultaneously on several levels of our strategy,** and we also intend to do so in 2021."

We also made great progress during the year in our work ahead of a US registration. To confirm and ensure efficacy and safety, two randomised blinded clinical studies with a total of around 500 patients will be conducted. Part of the preparations ahead of the clinical studies are full-scale toxicity studies and a human factors validation. We are working towards being able to submit an IND application during the summer of 2021 and including the first patient in the clinical studies during the second half of 2021. The plan is to have around 30 American centres in the studies. The goal is to achieve US registration in 2024, and in 2022 we will decide on our commercialisation strategy for the United States.

The European Sedaconda study is designed as a non-inferiority study, which means that its primary purpose is to demonstrate that our therapy is not worse than propofol in maintaining an adequate sedation level. We therefore did not have particularly high hopes with regard to the secondary endpoints. In December we

were, however, able to report that several of the secondary endpoints show significant improvements, that the therapy enables faster and more controlled wake-up, a reduced need for opioids and a higher proportion of spontaneous breathing, which increases the prospects of maintained lung function during and after ventilator therapy. The results may be of great clinical significance and make a strong contribution to the third step in our strategy, to demonstrate significant superiority to intravenous sedation.

Our **third step** is to expand use of the therapy through studies that are being done to demonstrate superiority to intravenous sedation. We do so by supporting investigator-initiated studies such as INASED, SESAR and ISCA. Several advances were made in these studies during the year. The studies are being done to demonstrate that inhaled sedation via AnaConDa has lung-protective properties resulting in increased survival (SESAR), reduced incidence of delirium and improved cognitive recovery following sedation (INASED), and that inhaled sedation is a therapy superior to intravenous sedation for patients with COVID-19-related ARDS (ISCA).

Through this type of investigator-initiated studies and our own studies which we are planning, for example in the United States, we are gathering evidence that will form the basis for a paradigm shift in intensive care. We will continue to support this type of studies as they provide important backing in our continued regulatory and commercial expansion. As an element in this support, in 2019 we established the Sedana Medical Research Grant (SMRG), to encourage and support international academic research and raise awareness and knowledge of sedation of mechanically ventilated intensive care patients. Three research projects were selected for funding in 2020.

To achieve our goal of making inhaled sedation a global standard therapy in intensive care, we must pass through the **fourth step** in our strategy, to show superiority to other options to such an extent that our therapy is included in national guidelines. Inhaled sedation will gain ground and be included in national recommendations, as well as gradually become a new standard therapy throughout the world. This will be done with the help of more studies that secure medical evidence and demonstrate that inhaled sedation is a better and more cost-effective therapy than current standard therapy.

AnaConDa has been included in German guidelines since 2010, which is an important reason why Sedana Medical has been able to gain such a large share of the German market without market approval.

> **Clinicians are continuing to use inhaled sedation** for patients other than COVID-19 patients.

In light of this, it was highly encouraging that the National Institute for Excellence (NICE) in the United Kingdom issued a Medtech Innovation Briefing (MIB) on the use of AnaConDa as an alternative to intravenous sedation in intensive care. Obtaining this positive MIB from NICE, without the therapy yet being fully approved, is powerful acknowledgement and bodes well for future recommendations from other advisory bodies and future dialogues with purchasers. In 2020, the therapy was also included in the Pan-American guidelines as an alternative, and inhaled sedation was additionally mentioned in French and American guidelines for therapy of COVID-19 patients.

We are archiving a highly intensive 2020, and intend to deliver an at least equally exciting 2021. Our most important milestones in 2021 will be the launch of Sedaconda in Europe and inclusion of the first patients in the clinical studies in the United States. I look forward to returning to tell you about our continued progress.

Danderyd, April 2021

Christer Ahlberg
CEO and Group President

INHALED SEDATION AS A GLOBAL STANDARD THERAPY

40%

THE COMPANY'S TARGET
The target is to achieve revenue in excess of SEK 500 million in Europe and an EBITDA margin of 40 percent three years after registration in Europe.

Purpose

To improve life during and beyond sedation.

Vision

To make inhaled sedation a standard therapy in critical care.

Financial targets

The company's target, until market approval of the pharmaceutical product Sedaconda (isoflurane) has been obtained, is to increase sales by an average of more than 20 percent per year while building up a larger medical, sales and marketing organisation.

The target is to achieve revenue in excess of SEK 500 million and an EBITDA margin of 40 percent three years after registration in Europe.

Strategy

The company has formulated and follows a strategy that can be summarised in three points:

1. Establish AnaConDa in as many markets as possible.
2. Apply for marketing authorisation for Sedaconda and inhaled sedation, initially in the EU and later in other markets. In the United States we intend to register Sedaconda and AnaConDa as a combination therapy.
3. Secure medical evidence leading to inhaled sedation gradually becoming a new standard therapy throughout the world.

"Sedana Medical's vision is to make inhaled sedation a global standard therapy for mechanically ventilated patients in intensive care. A first step is to register Sedaconda and therefore also inhaled sedation in Europe.

1999 – AnaConDa is tested clinically for the first time

2005 – Sedana Medical is established in Uppsala

Office opens in Germany

2008 – Studies show that short-term sedation with sevoflurane and AnaConDa following heart and chest surgery results in significantly shorter ventilation time and hospitalisation

2010 – The German society of intensive care specialists writes in its recommendations that inhaled sedation is an alternative to intravenous sedation

SEDANA MEDICAL'S HISTORY IN BRIEF

The text is based on extracts from an interview with Sten Gibeck, a member of the Board of Sedana Medical since 2005 and former Chairman of the Board, and Ola Magnusson, founder and CEO of Sedana Medical during the period 2005–2011. The full interview can be found in the Sedana Medical annual report for 2018.

"Sedana Medical originated from a product that was developed at Louis Gibeck AB, which among other things developed moisture-heat exchangers. In the 1990s, a prototype was developed that was able, through a special formulation of activated carbon, to reflect 90 percent of exhaled anaesthetic gas without reflecting carbon dioxide. The initial idea was to develop a new and cheap general anaesthetic system; following input from intensive care specialists, development was focused on sedation in intensive care. AnaConDa received a CE mark in 2003 and attracted considerable attention at intensive care congresses in Amsterdam and Paris in 2003 and 2004. Several clinicians in Germany conducted clinical studies that were presented at various seminars and showed good results for patients. The breakthrough came in 2010, when the German Society of Anaesthesiology and Intensive Care Medicine in its recommendations for sedation of intensive care patients described inhaled sedation as an alternative to intravenous sedation. We believe passionately in inhaled sedation and are pleased that thousands of patients have already been sedated and benefited from the therapy."

2012

2013

R&D laboratory opens in Kildare, Ireland

2014

AnaConDa is now used in Canada, Australia and large parts of Europe

2015

Studies show one-year mortality to be significantly lower in patients given isoflurane compared to intravenously sedated patients

2016

Over 200,000 AnaConDa units have been used since launch

2017

AnaConDa receives market approval in South Korea

AnaConDa-S is launched in Europe

The company is listed on Nasdaq First North

2018

Own sales offices opened in the United Kingdom and the Nordics

AnaConDa receives market approval in Japan

2019

Distribution agreements concluded in India and China

AnaConDa is approved for use on children in the EU

2020

AnaConDa receives market approval in Mexico and Saudi Arabia

Own sales company opened in the Benelux

The phase 3 study SED001 reaches its primary endpoint

European application submitted for market approval for Sedaconda

→

SEDATION IS ONE OF THE MOST COMMON ACTIONS IN ICU

Sedation means putting a patient into a medically induced state of reduced consciousness to relieve anxiety, agitation and pain, traditionally by the intravenous route.

High unsatisfied need in sedation in ICUs

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.

Between 30 and 50 percent of patients need help with breathing from a ventilator[1]. Sedation is usually necessary to ensure patient well-being and safety, and for mechanical ventilation and other necessary acute measures to be tolerated.

However, there are many problems with intravenous sedation of intensive care patients. 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 the intensive care unit becomes longer than necessary and that extubation (removal of the breathing tube from the throat) is difficult to plan. Furthermore, the concentration of pharmaceuticals 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 intensive care therapy. Also, delirium has been linked to increased mortality and impaired cognitive function several years after intensive care is completed. Because intravenous sedatives are eliminated via the liver or kidneys, and these functions are often impaired in

Potential problems, challenges and side effects from intravenous sedation in intensive care

1 Accumulation
- The intravenous pharmaceuticals accumulate over time, contributing to a long half life.

2 Metabolism and metabolites
- Dependent on liver metabolism and renal excretion for elimination. Intensive care patients often have impaired liver and kidney function, which extends the half life of intravenous sedatives and substantially increases the risk of over-sedation and delayed wake-up.

3 Wake-up times
- Prolonged, extremely unpredictable wake-up times.
- Extubation (removal of breathing tube) difficult to plan.
- Neurological evaluation takes time and is difficult to interpret due to the residual effects of sedation.
- Increased time on mechanical ventilation and extended stays in the intensive care unit, in particular for elderly patients, are associated with health risks and high costs. Also extends hospitalisation after intensive care.

4 Side effects
- Withdrawal symptoms and withdrawal problems such as autonomic stress, delirium, hallucinogenic effects. Delirium is clearly linked to increased mortality and cognitive problems in the year following intensive care.
- Interaction with other pharmaceuticals.
- Dependency/tolerance development (tachyphylaxis).
- Propofol infusion syndrome with potentially fatal outcome.

5 Depth of sedation
- The level of sedation is difficult to control and monitor, which increases the risk of over or under-sedation.
- Time is wasted checking, pausing and restarting sedation instead of treating the patient.
- Often leads to the need for additional pharmaceuticals to maintain depth of sedation.

intensive care patients, there is a risk of an accumulation of medicines. Taken together, the above leads to high mortality in long-term ventilated patients [4].

Inhaled sedation offers many benefits

Inhaled sedation has been shown to provide several benefits. Wake-up times are significantly shorter (10–20 minutes [5]) and more predictable, which means that clinical workflow planning can be improved and the time to extubation can be reduced. The depth of sedation is easy to control and the risks of over or under-sedation decrease. Furthermore, the risk of side effects such as hallucinations and delirium is lower, [6] and because the inhaled sedative is eliminated almost entirely through the lungs, the need for metabolism in the liver or kidneys is minimal. Overall, mortality has been shown to decrease with inhaled sedation [4].

A broad, growing body of literature shows that lighter sedation is beneficial for patients under intravenous sedation. This method avoids accumulation problems and extended wake-up times. In inhaled sedation, the pharmaceutical is eliminated rapidly, and therefore depth of sedation in itself does not become problematic. The patient can be woken quickly, regardless of depth of sedation.

In other words, the advantages of inhaled sedation are well known, but until AnaConDa was established on the market there was no good tool or method of administering volatile anaesthetics in intensive care.

Expectations for a modern sedative for use in ICU are that it is fast-acting, allows easy controllability of depth of sedation, causes few effects and allows rapid wake-up (it requires a low degree of accumulation and no active metabolites). All these expectations can be met by inhaled sedation.

> **"The benefits of inhaled sedation are well known**, but there has not been any good tool or method for administering volatile anaesthetics.

Until AnaConDa was established on the market there was no good tool or method for administering volatile anaesthetics in intensive care.

Facts about sedation

Sedatives is a collective term for tranquillising and sometimes analgesic pharmaceuticals used in many areas of healthcare. Sedation means putting a patient into a medically induced state of reduced consciousness to relieve anxiety, agitation and pain, traditionally by the intravenous route. The sedation of patients who are ventilated mechanically on a ventilator often continues for extended periods, usually between two and five days. The concept of sedation encompasses a range of levels of consciousness, and a number of different scales are used to measure them.

For the sake of simplicity, a three-level scale defined by the American Society of Anesthesiologists is used here:

Minimal sedation – mitigates anxiety and induces a relaxed state. The patient is fully conscious without any impact on the body's functions.

Moderate sedation– induces a lower level of consciousness, but the patient still responds when touched or addressed. Airway reflexes, breathing and cardiac function are kept intact.

Deep sedation – the patient is beyond consciousness but responds to repeated pain stimuli. Cardiac function is maintained, but airway reflexes and breathing may be impaired.

General anaesthesia, also known as narcosis, is a further level deeper than sedation and a collective term for putting the patient to sleep with pain relief and far beyond consciousness, so that the surgery can be performed. The patient is so deeply anaesthetised that assistance with breathing is needed. During general anaesthesia, an anaesthesia machine is used where a preparation is delivered by inhalation according to current practice, or in some cases intravenously.

Therapeutic benefits of inhaled sedation

Benzodiazepines are mostly used in intravenous sedation of intensive care patients today despite there being clear recommendations that benzodiazepines should not be used for sedation in intensive care. It is done because the options are limited. Sedana Medical firmly believe that inhaled sedation can take its place.

Sedana Medical's pivotal study Sedaconda (SED001, previously called the IsoConDa study) studies, among other things, on-off effects and reliable wake-up with inhaled sedation. The study compared time to extubation, time on ventilator and time in intensive care unit compared to intravenous sedation. In July 2020, Sedana Medical announced that the study reached its primary endpoint; to show that Sedaconda (isoflurane), delivered via AnaConDa, is an effective therapy for sedation of mechanically ventilated intensive care patients, and non-inferior to propofol.

The result of some of the secondary endpoints of the study were presented at the congress European Society of Intensive Care Medicine (ESCIM) in December 2020. They show that Sedaconda, delivered via AnaConDa, compared with propofol, enables possible faster and more controlled wake-up, reduced need for opioids and a higher proportion of spontaneous breathing, which increases the prospects of maintained lung function during and after ventilator therapy. The full results of the study will be published in a scientific journal in 2021.

Inhaled sedation provides clear benefits compared to current standard treatment

Inhaled sedation, compared to the current intravenous standard, provides the treated patient with a number of medical benefits, some of which are listed below:

- **Has been associated with lower mortality**[1].
- **Potential for shorter time in the intensive care unit:** small risk of dependence, withdrawal symptoms and/or delirium and fewer hospital infections are expected to lead to shorter hospitalisation. The daily cost for an intensive care unit patient in Europe is estimated to be EUR 1,000–3,000[2].
- **Organ-protective properties.** Inhaled sedation has potentially protective properties for the heart, brain and lungs [3].
- **Can be used on patients with kidney and liver disease.** Isoflurane is administered and eliminated via the lungs with minimal breakdown in the body. (Intravenous sedation is metabolised in the liver and eliminated through the kidneys.)
- **Higher proportion of spontaneous breathing.** Increases the prospects of maintained lung function during and after ventilator therapy[4].
- **Bronchodilatory effect.** Improves lung function in patients with COPD and asthma[4].
- **Reduced opioid use.** When isoflurane is used, the dose of analgesic pharmaceuticals such as remifentanil and other opioids can be reduced by more than 35 percent [5] compared to the use of intravenous sedation, which reduces the risk of opioid dependence and lowers the cost of sedation. As well as the risk of opioid dependence, high opioid doses leads to impaired gastrointestinal function, which is common in intensive care.
- **Shorter wake-up times.** When treatment has been completed and the patient must be woken up, it is important that the patient is awake and collaborate in rehabilitation as soon as possible. Early and predictable wake-up also makes it easier for staff to plan their work.
- **Easier control of depth of sedation.** It is simpler to wake up patients to check their neurological status, thus reducing the need for additional CT scans.

Benefits	Inhaled sedation	Intravenous sedation*
On-off effect and predictable wake-up		
Significantly shorter wake-up times	10–20 min	90 min–130 hours
Shorter stay in ICU for patients who have been under deep sedation	4–16 days	6–27 days
Significantly shorter time from completed sedation to completed ventilator therapy	10–35 minutes	150–600 minutes
Reliable efficacy and safety		
Reduced incidence of hallucinations, delirium	2 out of 10 patients	5 out of 7 patients
Reduced use of opiates	2.7 mg/hour	4.2 mg/hour
Potential organ-protective properties		
Lower hospital mortality in long-term ventilated patients (> 96 hours)	40%	63%
Price per day	**SEK 1,000**	**SEK 200–3,000**

* The price of intravenous sedation depends on the dosage, the number of drugs used together, the patient's condition and the country the patient is in. The costs of extended stays in the intensive care unit and the additional treatment required due to complications from sedation are not included. The costs of extended stays in intensive care units due to intravenous sedation are not included.

Trends in sedation

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

1. Increased awareness of the risks of delirium

The number of scientific studies examining the incidence of delirium in intensive care patients has increased considerably over the past decade, and delirium has been recognised as a growing public health problem in the United States. Delirium affects up to 80 percent of all mechanically ventilated intensive care patients, and the annual cost of managing intensive care patients with delirium is between USD 4 and 16 billion in the United States alone[6]. The objective of the INASED study initiated in 2020 is to demonstrate a reduced incidence of delirium with inhaled sedation in mechanically ventilated intensive care patients compared to intravenous sedation with propofol.

2. Lung-protective properties of volatile anaesthetics

It has long been known that volatile anaesthetics have anti-inflammatory properties. Many lung diseases that acutely impair lung capacity have inflammatory components. Studies on both large and small animals have found that it is possible to reduce inflammation in the lung and thus increase oxygen uptake. The same pattern has now been demonstrated in humans in a smaller study. The SESAR study initiated in 2020 is aimed at further strengthening the evidence on this important question.

3. Reduced use of benzodiazepines

Several studies show that benzodiazepines used for extended periods can lead to a number of undesirable clinical effects. Extended periods of ventilation, increased time in the intensive care unit and the incidence of delirium are some of the undesirable effects linked to the use of these drugs.

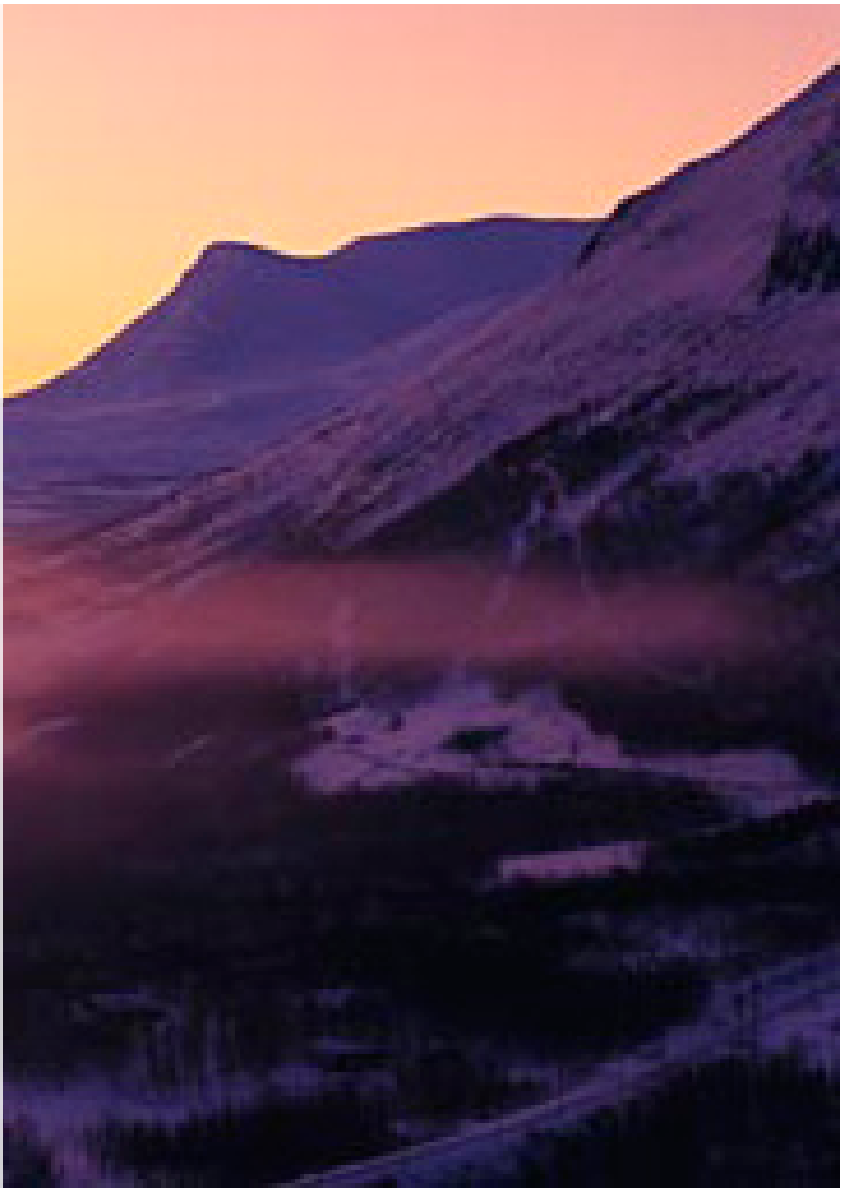
4. An ageing population

There is an underlying global trend, especially in Europe and the United States, toward an ageing population. The proportion of people in Europe above the age of 65 is expected to rise from 16 percent in 2010 to 27 percent in 2050. Elderly people are generally in weaker health and have a poorer ability to recover after an operation or serious injury, which means that elderly people who end up in intensive care tend to stay longer than young people.

5. The need to reduce healthcare costs

The costliest beds in a hospital are those occupied by intensive care patients, and there are therefore compelling incentives to shorten time in intensive care instead of increasing the number of expensive intensive care beds. As a result of an ageing population and an average life expectancy that is expected to go on rising, costs of healthcare in general and intensive care in particular are also expected to continue to rise.

> **"Inhaled sedation is a potential paradigm shift** in intensive care.



Marketing authorisation is the key

Isoflurane is a volatile anaesthetic that has been used for decades in operating theatres around the world for short-term treatments under general anaesthesia. Isoflurane is not currently approved for sedation in intensive care. It may not be marketed for the indication of sedation in intensive care until marketing authorisation has been obtained.

Sedana Medical's sales have been hampered by the fact that a volatile anaesthetic has not been approved for sedation in intensive care. An important element in the company's growth strategy is therefore obtaining marketing authorisation in Europe, and later in other countries such as the United States. It will then be possible for the treatment to be actively marketed, which is expected to have a significant impact on sales, as general acceptance of the treatment will increase sharply.

Despite the treatment currently being off-label, Sedana Medical succeeded in gaining just under five percent of the German market for the sedation of mechanically ventilated intensive care patients in 2020. An important explanation 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. Some 700 intensive care unit around Germany sedate mechanically ventilated intensive care patients with Sedana Medical's devices.

The National Institute for Excellence (NICE) in the United Kingdom issued a Medtech Innovation Briefing (MIB) on the use of AnaConDa as an alternative to intravenous sedation in intensive care in October 2020. NICE is responsible for providing national guidance on treatments for the National Health Service in the United Kingdom. The MIB document refers to five publications on a total of 1,098 patients which show that intensive care sedation using AnaConDa is as effective as intravenous sedation and can result in reduced ventilator time. The fact that the clinical experts in the MIB document express a positive opinion on inhaled sedation is powerful acknowledgement and bodes well for future recommendations from other advisory bodies and future dialogues with purchasers.

Up to and including 2020, total use of inhaled sedation using AnaConDa is estimated at 600,000 care days and over 500,000 AnaConDa units have been sold.

~700

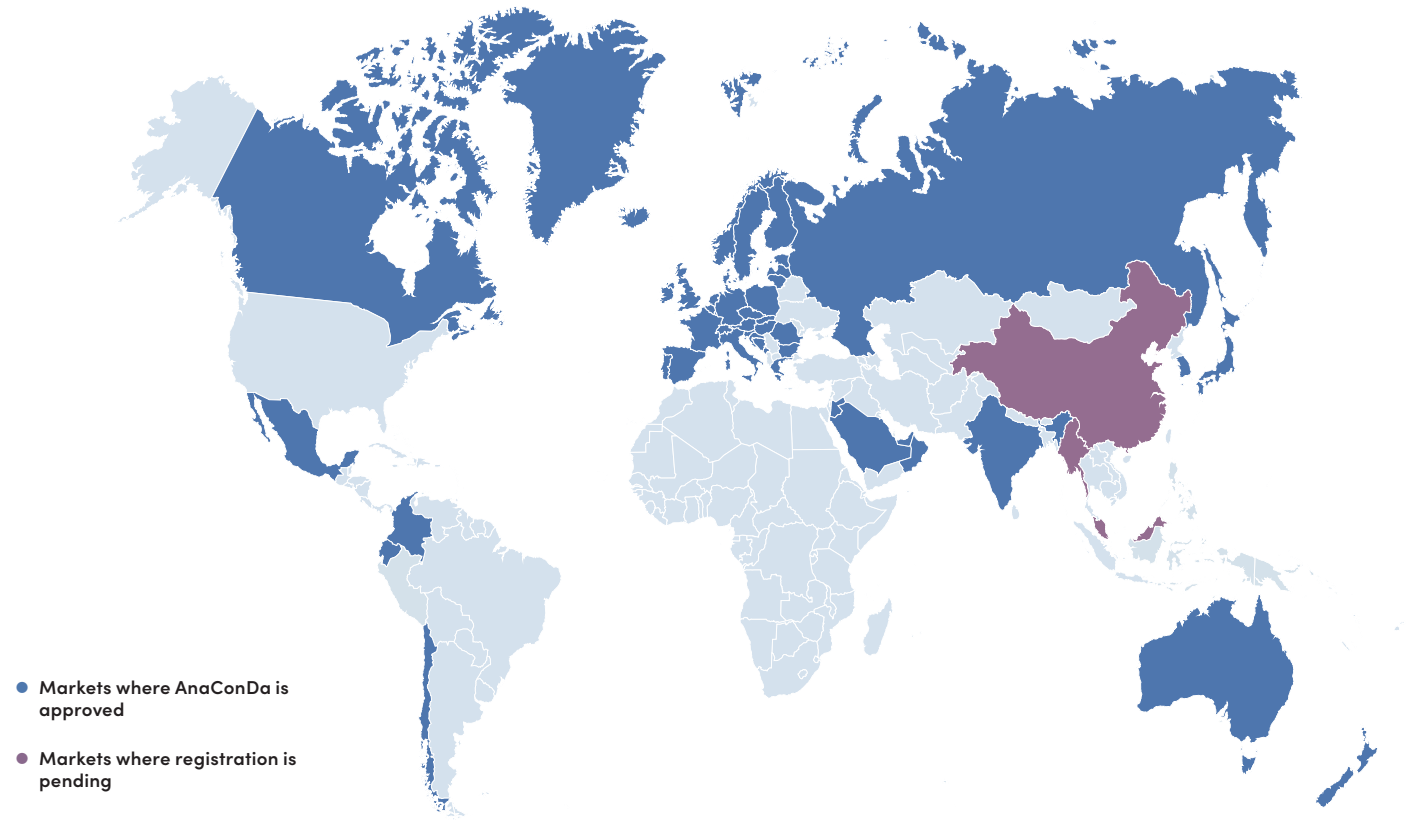
INTENSIVE CARE UNITS ACROSS GERMANY

sedate mechanically ventilated intensive care patients with Sedana Medical's devices.

~5%

OF THE TOTAL MARKET POTENTIAL IN GERMANY

Markets where AnaConDa is approved or where registration is pending



IN THE EYE OF THE STORM

Today Magnus Falkenhav works at Sedana Medical, but in the spring of 2020 he had managerial responsibility for a COVID-19 intensive care unit at Karolinska University Hospital in Solna, Sweden.

Magnus Falkenhav believes that ICU patients throughout the world can be greatly helped by AnaConDa.

Tell us what tempted you to start at Sedana Medical.

The crucial factor was that my friend and former colleague in ICU at Karolinska University Hospital, Sedana's Chief Medical Officer Peter Sackey, asked me. We have worked together for many years, and I was involved in treating the patients included in the world's first AnaConDa study in the early 2000s. Peter conducted the study in our ICU, and it then became a standard therapy for some categories of patient, for example after cardiac arrest. It gave us the opportunity to quickly assess the degree of consciousness so that we could predict any brain damage due to lack of oxygen.

> **We must therefore show that AnaConDa and isoflurane sedate** at least as well, and with a better profile and fewer side effects, through well-conducted, representative studies.

I also helped Peter to start up and run our ICU outpatient clinic, where we followed up psychological and physical symptoms remaining after ICU care. This work created an interest in ethics and follow-up, as many of the patients continued to be very unwell. I do believe that isoflurane with AnaConDa can make a difference for many ICU patients around the world with regard to being correctly sedated, waking up quickly and with less acute confusion, delirium. I believe in the product. I have now been given the opportunity, with Peter and his capable team, to do research on this.

You had managerial responsibility for a COVID-19 ICU at Karolinska University Hospital in Solna last spring. Can you tell us a little about your experiences from that time?

It was an exceptional experience, and I am proud of our effort. There were almost surreal days when, after some horrific scenarios, we quickly succeeded in scaling up and opening three new COVID-19 ICUs in addition to the five ordinary ones we had already filled. Everyone was focused and solution-oriented, not least our managers, who worked constantly. We converted large recovery wards with an open-plan solution so that we could have a better overview. ICU nurses and ICU nursing assistants had to take responsibility for far more patients than usual, together with colleagues who not usually or never had worked in an ICU before. They undertook an enormous job with very ill patients in full personal protective equipment for 12–13 hour shifts and with a few breaks. This went on for several months. I also had many specialists and doctors in training, residents and colleagues from other specialties helping us. They all had to be managed and looked after in this difficult, new and uncertain environment. We mostly had 27 patients in the COVID ICU I helped to staff.

One of several challenges we faced was to find sedation that worked. This coronavirus with the inflammation it causes affects almost all the body's organs, including the brain. We had to use several different medicines which, in addition, sometimes ran out. When, after a long period of ventilator care, we finally had to wake up the patients, very many of them were highly confused, delirious.

ICU at Karolinska University Hospital in Solna Photograph: Oscar Segerström

"ICU nurses and ICU nursing assistants had to take responsibility for far more patients than usual, together with colleagues who not usually or never had worked in an ICU before. They undertook an enormous job with very ill patients in full personal protective equipment for 12–13 hour shifts and with few breaks for several months."

What role do you think AnaConDa can play in ICU care in the future?

I have started playing with the words 'wide, fast and clear'. AnaConDa with isoflurane can put even very complicated patients to sleep who otherwise need several different medicines, while the gas leaves the body quickly through the lungs, without break-down, metabolism, in the body. In addition, we find that, despite long sedation on a ventilator, the patients are not confused and are responsive for continued care. I think that ICU patients around the world who need to be sedated for several days can be greatly helped by this change in sedation strategy. If we can also show that reduced inflammation in the lungs can influence the course of events, it is no longer just a matter of sedation.

Good study results and the support of key opinion leaders are important. Given your history as a clinician, are there other ways of convincing the medical community of the benefits of the therapy?

Those who have responsibility for purchasing obviously play a great role in general cost assessment, but ICU managers decide on the care together with experienced clinicians and researchers. We must not forget the nurses who have to connect and control the sedation. They need a simple and quick system that works.

What, in your view, is the greatest benefit of the treatment compared to intravenous sedation?

As I said earlier, you can put almost any patient at all to sleep on a ventilator and yet wake them up quickly to make contact with them. This is also a great benefit for family present, who are relieved to be recognised by the patient.

What, in your view, are the greatest obstacles to Sedana Medical in convincing healthcare to use AnaConDa?

Propofol and dexmedetomodine are dominant drugs today that work well and are easy to administer. However, they are not without side effects linked to their profile and metabolism. We must therefore show that AnaConDa and isoflurane sedate at least as well, and with a better profile and fewer side effects, through well-conducted, representative studies. This in order for them to be recommended by the large international ICU societies as a first-line treatment for sedation of ICU patients on ventilators.

A SIMPLE AND SOUGHT-AFTER ALTERNATIVE

AnaConDa is a unique, innovative device that enables safe and simple administration of volatile anaesthetics, which was not previously possible without an anaesthesia machine.

AnaConDa is designed to be simple to use and to work together with modern intensive care ventilators, syringe pumps and gas analysers. For most hospitals, this means that they can avoid expensive new investments.

AnaConDa is a medical device developed for administration of volatile anaesthetics to mechanically ventilated patients. It is intended for single use and has to be replaced every 24 hours.

Why is an ordinary anaesthesia machine not used?

Anaesthesia machines are used for the administration of general anaesthetics in operating theatres, but are neither intended nor approved for use in intensive care, where they perform poorly. They are not used owing to their size and high capital costs and costs in use. The great requirement for administration and monitoring by a specialist makes the use of anaesthesia machines labour-intensive and impractical for inhaled sedation in intensive care.

In addition to AnaConDa, various accessories are also marketed to facilitate and simplify the use of AnaConDa. For example, these include syringes to supply AnaConDa with isoflurane and the FlurAbsorb filter used to prevent the spread of volatile anaesthetics into the intensive care room when sedating via AnaConDa.

The technology

Sedana Medical's unique and patented technology combines four functions that exist in anaesthesia machines in a single unit: 1) a unique miniature vaporiser (required for controlled production of the anaesthetic gas), 2) a reflector with a unique

activated carbon filter (for recirculation of the anaesthetic gas, 3) a bacterial and virus filter, and 4) a moisture and heat exchanger.

The technology enables very efficient reflection of anaesthetic gas from expiration air; more than 90 percent of the gas remains in the active carbon filter and is re-used during the inspiration phase. This high level of reuse not only helps reduce the consumption of volatile anaesthetics, but also the spread of gas to the surroundings, and studies confirm very low, non-clinically relevant emissions far below permitted limits.

AnaConDa is used in combination with a ventilator, a gas analyser and a syringe pump. The specially designed syringe (with a unique connector) is placed in a standard syringe pump. The device is placed in the breathing circuit between the Y-piece and the endotracheal tube. Liquid anaesthetic is delivered from the syringe through the anaesthetic agent line to the device, where it is vaporised inside. The vaporised gas is delivered with the inspiratory flow from the ventilator to the patient. The gas analyser samples the gas from the port and displays the concentration of anaesthetic in the exhaled air in Fet% or MAC values (which indicate pharmaceutical product concentration). The device does not have any electrical components and is compatible with magnetic resonance imaging and computed tomography.

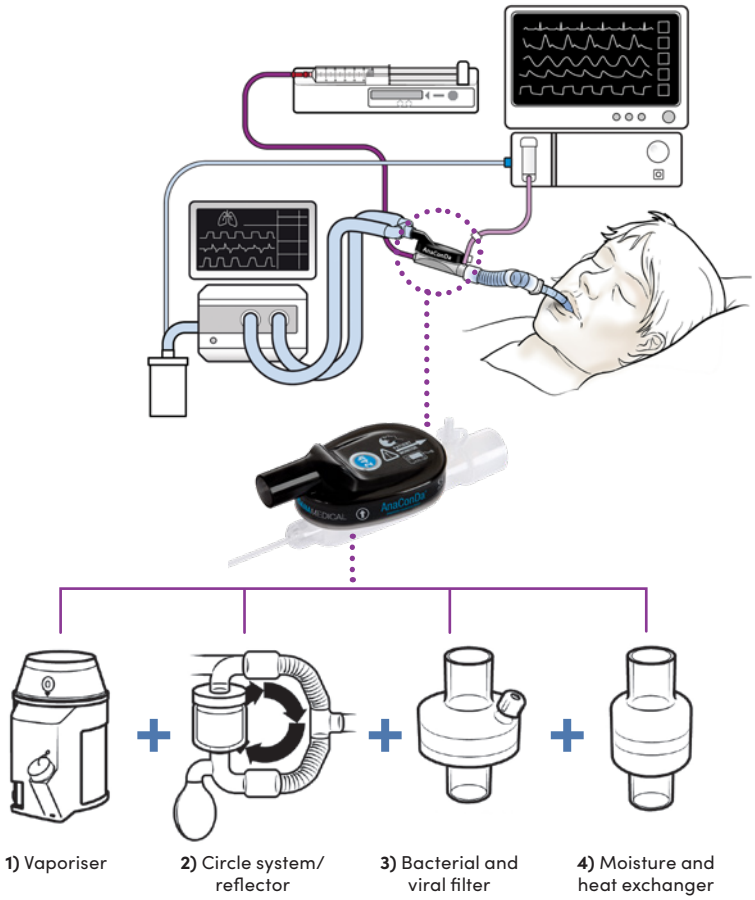
Thanks to the unique design, most of the exhaled anaesthetic is adsorbed by the carbon filter, released and returned to the patient on inspiration.
The residual anaesthetic passes through the ventilator, out through the exhaust and is captured by the company's FlurAbsorb filter or by the active gas scavenging system.

The competitive situation

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

> "The design makes it possible to administer a volatile anaesthetic agent**in a simple, safe and effective way.**

AnaConDa combines four functions that, together with existing intensive care equipment, provide an optimal solution for the sedation of severely ill patients.



Combines four functions for safe and effective administration of volatile anaesthetics

- Evaporation, reflection, humidification and filtration

In addition

- Clinically proven efficacy and safety
- Simple to operate
- Simple to monitor dosage
- Contributes to reducing consumption of volatile anaesthetics
- Single-use system with no need for electricity or maintenance
- CE-marked

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.

Reduced dead space provides major clinical benefits

The first version of AnaConDa had 100 ml of dead space and was aimed at adult intensive care patients. In continued development of the technology, Sedana Medical launched a new, improved version in March 2017 in which dead space was halved from 100 ml to 50 ml. 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.

The reduction in dead space also facilitates use on patients who, for various reasons, have a lower lung volume than is typical of an adult, for example children or patients who have reduced lung capacity due to lung disease. Sedana Medical estimates this improvement to have led to an increase in the target group of around 25 percent. As the healthcare system generally aims to reduce dead space for all patients who are mechanically ventilated, Sedana Medical's sales are dominated by the 50 ml version AnaConDa-S.

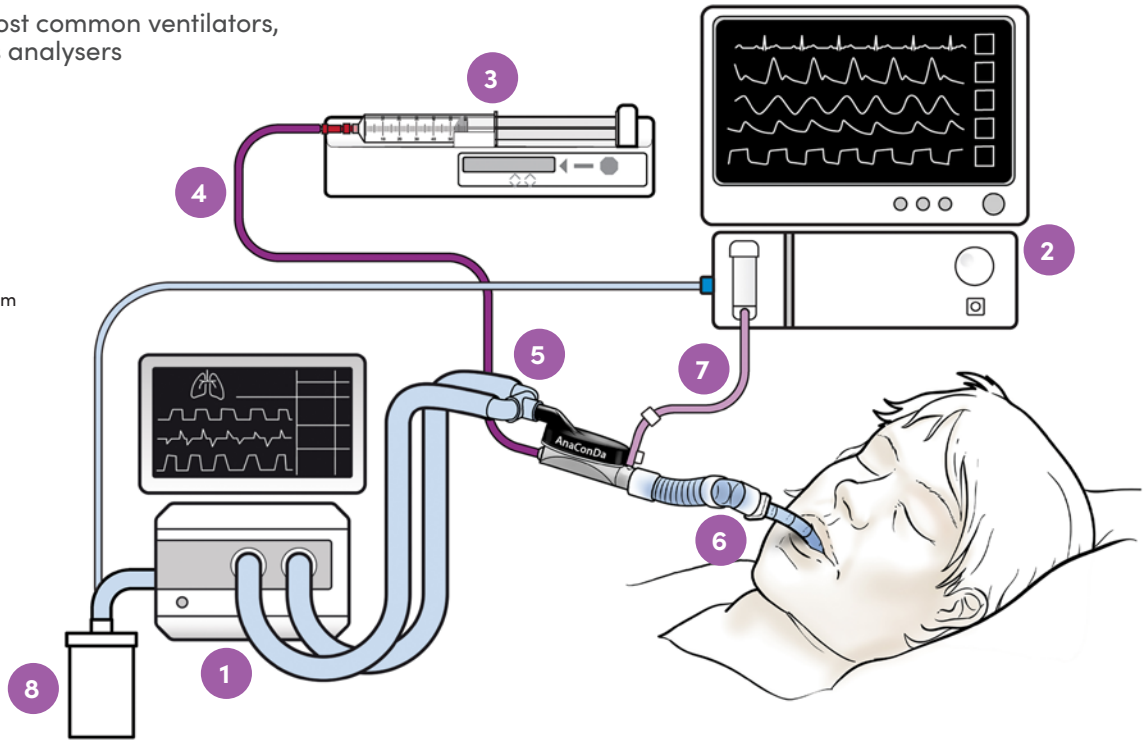
In November 2020, Sedana Medical was granted another European patent that protects a reduction in dead space with the aid of inlay material. This patent is key to continued development, and the target is to reduce dead space by 20 percent to 40 ml. As well as reduced dead space providing great clinical benefits, Sedana Medical is greatly strengthening its patent protection with the new patent. Any competitors or ordinary passive HME filters will not be able to reduce their dead spacing using inlay material without infringing Sedana Medical's patent.

Intellectual property rights

Sedana Medical has an active strategy for intellectual property rights and endeavours to maximise the protection of its devices and

Compatible with the most common ventilators, syringe pumps and gas analysers

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



AnaConDa is used in combination with a ventilator, a gas analyser and a syringe pump. The specially designed syringe is placed in a standard syringe pump. The device is placed in the breathing circuit between the Y-piece and the endotracheal tube .

Liquid anaesthetic is delivered from the syringe through the anaesthetic agent line to AnaConDa where it is evaporated. The vaporised gas is delivered with the inspiratory flow from the ventilator to the patient. Most of the anaesthetic in the exhaled air is adsorbed by the carbon filter, released and returned to the patient on inspiration. The remaining anaesthetic passes through the ventilator, out through the exhaust and is captured by the company's FlurAbsorb filter or by the active gas scavenging system.

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 AnaConDa, Sedana Medical has protected its innovations through patents. Sedana Medical's patent portfolio currently comprises five patent families. Two new patent applications were submitted in 2016 for the newly developed AnaConDa-S (50 ml). One relates to protection of the unit's design, and the other, which was granted in Europe in 2020, is intended to create a product with 50 ml of dead space. 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 patient as a gas, can be protected. These protections, for example unique couplings and packaging solutions, make AnaConDa simple and safe to connect, while the connection of generic products is made more difficult.

Registrations

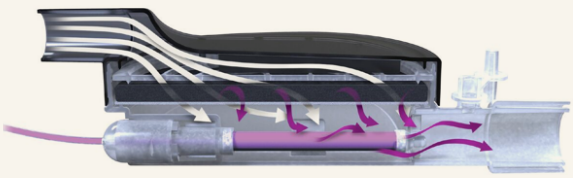
By applying for full registration, including a paediatric plan, approval will mean that Sedana Medical will enjoy ten years of market exclusivity in Europe for the use of isoflurane for sedation in intensive care. The registration applies to the company's candidate drug Sedaconda (isoflurane) administered via AnaConDa. Other combinations of volatile anaesthetics and delivery methods for sedation in intensive care will 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.

Inspiration



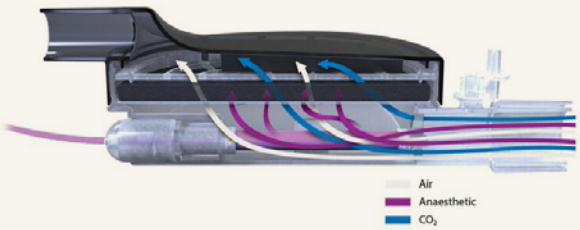
START

When inspiration begins, air/oxygen is carried from the ventilator and passes through the AnaConDa device.

END

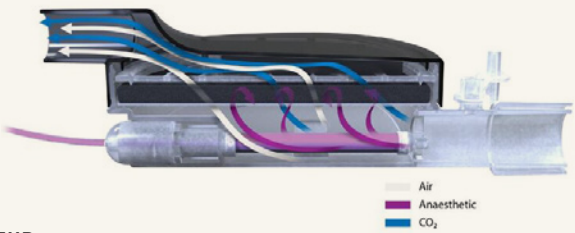
During inspiration, anaesthetic is released from the activated carbon filter, where it previously was adsorbed during expiration, and is transported together with air/oxygen to the patient. New anaesthetic is constantly evaporated in the mini-evaporator.

Expiration



START

At the start of expiration, exhaled air from the patient contains air, carbon dioxide and volatile anaesthetic.



END

Air/oxygen and carbon dioxide pass through the active carbon filter while the majority of the volatile anaesthetic is adsorbed by the activated carbon filter. Expired air (almost exclusively air/oxygen and carbon dioxide), then passes out through the ventilator tubing and then through the ventilator outlet.

THE PIVOTAL CLINICAL STUDY SEDACONDA, SED001

The Sedaconda study shows that Sedaconda (isoflurane), delivered via AnaConDa, is an effective therapy for sedation of mechanically ventilated intensive care patients that is comparable to propofol. The results are the basis for Sedana Medical's application for European registration.

In 2017, Sedana Medical initiated the pivotal clinical phase 3 study Sedaconda (SED001, previously called the IsoConDa study), which is aimed at having the drug candidate Sedaconda (previously called IsoConDa) approved for inhaled sedation in intensive care in Europe. The study was the world's largest study of inhaled sedation in intensive care.

In July 2020, Sedana Medical was able to announce that the study reached its primary endpoint; to show that Sedaconda, delivered via AnaConDa, is an effective therapy for sedation of mechanically ventilated intensive care patients, that is 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 AnaConDa was developed.

"By applying for full registration, approval will mean ten years of market exclusivity in Europe for the use of isoflurane in sedation for intensive care.

The result of some of the secondary endpoints of the study were presented at the congress European Society of Intensive Care Medicine (ESCIM) in December 2020. They show that Sedaconda, delivered via AnaConDa, compared to propofol, enables possible faster and more controlled wake-up, a reduced need for opioids and a higher proportion of spontaneous breathing (which increases the prospects of maintained lung function during and after ventilator therapy). The full results of the study will be published in a scientific journal in 2021.

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, administered via AnaConDa, 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 intensive care patients in need of sedation and is a randomised, controlled and open-label study to confirm efficacy and safety. The patients were randomly allocated to one of two groups, in one of which patients are sedated with intravenous propofol while the other group is sedated with Sedaconda delivered via AnaConDa.

Alongside the study, other documentation was collated for the marketing authorisation application (MAA) for pharmaceutical product in the EU, which was submitted

The IsoCOMFORT study

The IsoCOMFORT study (SE002) is conducted to investigate if inhaled sedation using the AnaConDa is a safe and more effective method of sedation than intravenously administered midazolam for children below 18 years of age.

The study is intended to lead to an approved paediatric indication for inhaled sedation. As propofol is contraindicated for ICU sedation in children due to the risks of serious adverse events, midazolam is the only sedation option for children in ICU, and there is therefore a great medical need.

The patients will be sedated for 12–48 hours with either midazolam delivered intravenously or by inhaled sedation with isoflurane. Patient recruitment is anticipated to continue for 18 months. The primary endpoint of the study is the proportion of time with adequate sedation. It is estimated that the study will be completed in the second half of 2022.

'A supportive, prospective multicentre-study can form the basis for broad acceptance in paediatric intensive care. There is a great deal of frustration concerning ICU sedation in general, so I feel people are open to new therapies that can provide more treatment options.'

Doctor **Peter Radell**, senior physician and assistant professor in anaesthesiology and intensive care, a member of the steering group that has planned the paediatric study IsoCOMFORT.

301

THE STUDY INCLUDED
301 mechanically ventilated intensive care patients in need of sedation.

in November 2020. This collation includes a preclinical evaluation, a pharmaceutical technical summary and what is known as a paediatric investigational plan (PIP). Sedana Medical initiated a paediatric study in 2021 with the name IsoCOMFORT. An approved paediatric study plan is sufficient to apply for marketing authorisation. The results of the IsoCOMFORT study are thus not a requirement for approval for use on adults, and the timetable for authorisation of Sedaconda is consequently not affected by the IsoCOMFORT study.

By applying for full registration including a paediatric plan, 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. 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. In addition, there will also be an approved paediatric indication for inhaled sedation in the foreseeable future.

Sedana Medical's own studies

SED001 – Sedaconda (formerly IsoConDa)

A randomised, controlled, open-label study to confirm the efficacy and safety of sedation with isoflurane administered via AnaConDa in mechanically ventilated ICU patients.

Primary endpoint: To demonstrate that sedation with Sedaconda administered via AnaConDa is non-inferior to propofol in maintaining an adequate level of sedation.

Comparator: Propofol

Participating countries: Germany, Slovenia

FPI 2 July 2017

LPO January 2020

Topline results were presented in July 2020

SED002 – IsoCOMFORT

This study compares the efficacy and safety of inhaled isoflurane administered via AnaConDa-S, with intravenous midazolam in sedation of mechanically ventilated patients below 18 years of age (3–17).

Primary endpoint: To compare the percentage of time with adequate sedation depth (according to the COMFORT B scale) for patients treated with isoflurane compared with midazolam.

Participating countries: Spain, Germany, Sweden, France

FPI September 2020

LPO February 2022

Study report Q2–2022

SED003

A phase 3 study to confirm efficacy and safety of sedation with isoflurane administered via AnaConDa

Participating country: USA

Comparator: Propofol

Indication: Sedation in mechanical ventilation for up to 48 hours

FPI Dec 2021

LPO Q2 2023

Study report Q4 2023

SED004

A phase 3 study to confirm efficacy and safety of sedation with isoflurane administered via AnaConDa

Participating country: USA

Comparator: Propofol

Indication: Sedation in mechanical ventilation for up to 48 hours

FPI Dec 2021

LPO Q2 2023

Study report Q4 2023

"WE ALWAYS TAKE ANACONDA WITH US IN THE HELICOPTER OR AMBULANCE"

Rihard Knafelj, physician, PhD, University Medical Center Ljubljana, Slovenia, national investigator for the Sedaconda study in Slovenia, talks about the study and how he first started using AnaConDa.

I sometimes work in the helicopter collection team, and we always take AnaConDa with us in the helicopter or ambulance, and we do not change sedation when we are in a transport ventilator.

When did you first come in contact with inhaled sedation?

I saw the AnaConDa for the first time many years ago at the ESICM conference (European Society of Intensive Care Medicine) and soon after, Sedana Medical's former CEO Ola Magnusson came to our clinic and showed us how to use it. Some 12 years ago we were one of the first clinics in the world to start using the technology.

Did you start using it right away?

We had such a fantastic experience with our first AnaConDa patient that we were hooked from the start. She was 18 years old had leukemia and ARDS and had a bone marrow transplant but caught the flu. She had been ventilated for two weeks and had propofol, midazolam, morphine and ketamine, all at the same time, but she metabolized all drugs too quickly. We decided to use the

AnaConDa and the effect was amazing. We were able to take out all other drugs and she was able to breathe by herself. She stayed on the AnaConDa for 42 days and today, she is a happy young woman with two kids, and has not had a relapse in twelve years.

Did you experience any drawback with the technology, since it was so new?

We were early adopters, so in the beginning, there were still some issues with dead space as we were using the old 100 ml version, but nothing challenging or complicated. My own background is from the medical ICU and no one in our team is an anaesthesiologist, so we are not trained in inhaled therapies, but it is not complicated, and we adopted fast. I am passionate about this, volatile sedation is patient friendly, even lifesaving, easy and safe.

Some ICU anaesthesiologists seem initially hesitant about inhaled anaesthetics, why do you think that is the case?

Both sevoflurane and isoflurane are old drugs, developed in the 70s and introduced more broadly in the 90s. Anaesthesiologist think the drugs can be toxic and are afraid of the unusual hereditary condition malignant hyperthermia. It is a risk that we are aware of and we keep dantrolene (skeletal muscle relaxant) at hand, but we have never seen it in our ICU. On the other hand, we have seen numerous patients with propofol infusion syndrome. It's lethal. I even wonder how many cases in the world of unexplainable "septic chock" that could have been related to propofol and propofol infusion syndrome there are.

Rihard Knafelj, physician, PhD, University Medical Centre Ljubljana, Slovenia. National investigator for the Sedaconda study in Slovenia.

So far, you have used AnaConDa with sevoflurane, but Sedaconda is isoflurane. Is that an issue?

There are class effects from inhaled sedation that make it a better choice for most patients than intravenous sedation, no matter if you use sevoflurane or isoflurane. Personally, I would have preferred sevoflurane, but I can see why Sedana Medical has chosen isoflurane. It probably works better as a "one size fits all" drug.

What can you tell us about the Sedaconda trial?

Most of the findings from the study are things that we have seen for many years. As an example, reduced opioid consumption when using AnaConDa. That is not only because you sedate deeply, it is a fact that inhaled anaesthetics reduces the need for opioids. In our experience, inhaled sedation works very well, we have never seen a patient that we cannot sedate with AnaConDa.

Which are the hurdles for a successful uptake of the therapy?

When people see the advantages of the therapy, I think they are easily convinced. But, of course, the staff need to be educated in the therapy. They might think it is complicated, but it is not. We introduced the therapy at some clinics in Croatia last year and saw that we really needed to be hands on in our teaching. By nature, mankind is lazy and scared of new things. Now, the clinic where we were the most hands on, are exclusively using AnaConDa on their patients.

On which patients do you use the therapy?

At first, we only used it on ARDS patients, but in a few months, we started using it on other patients as well. Today, it is our preferred mode of sedation for all patients. I am proud to say that we have been benzodiazepine free for five years in our medical ICU. For example, for COPD patients (chronic obstructive pulmonary disease), inhaled anesthetics work amazingly.

What do you mean with all patients?

All in all, I'd say that we use inhaled sedation as a first line therapy on 70 percent of our patients and 30 percent are on propofol. We only use propofol for the patients we expect to be sedated for a short period of time (maybe just overnight). Occasionally, I work in the helicopter retrieval team and we always take AnaConDa with us in the helicopter or the ambulance and we do not change sedation when on a transport ventilator.

STUDIES PAVING THE WAY FOR A NEW TREATMENT STANDARD

Sedana Medical is supporting several investigator-initiated studies in addition to its own registration studies that help create a strong, long-term scientific platform for inhaled sedation.

'I firmly believe that these studies (SED001, INASED and SESAR) will contribute invaluable data to continue to improve the management and outcomes of critically ill patients, and to possibly propose inhaled sedation as a serious first-line alternative to intravenous sedation of ICU patients.'

Assistant professor **Matthieu Jabaudon** at the Centre Hospitalier Universitaire (CHU) Clermont-Ferrand, principal investigator for the French multicentre study SESAR

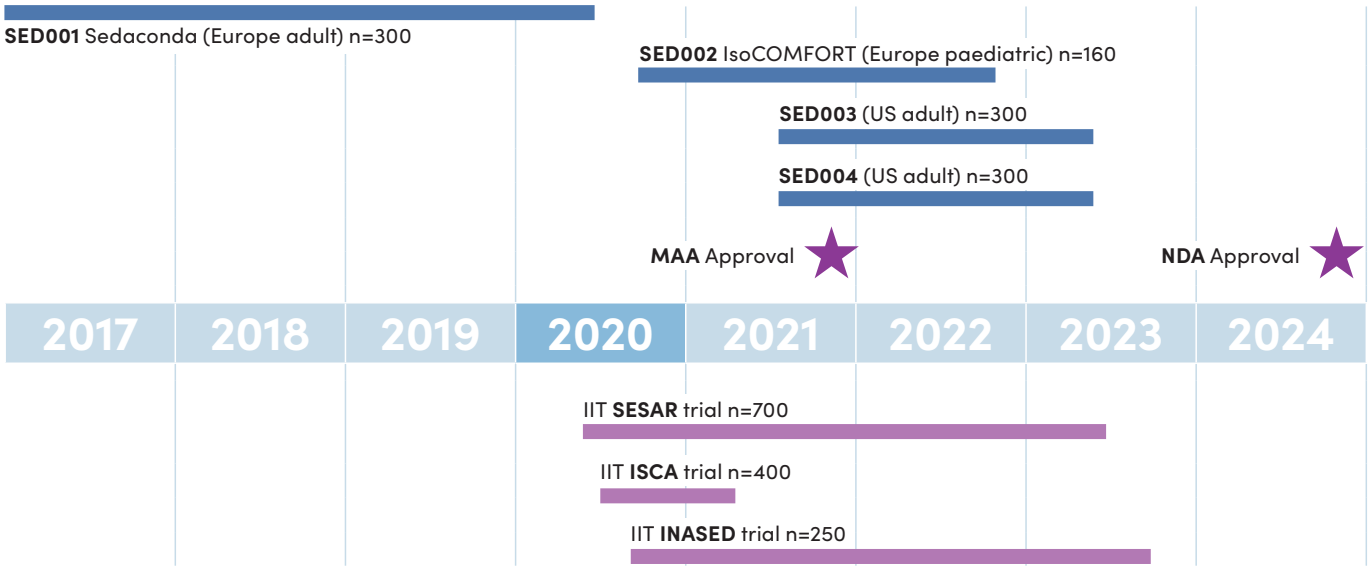
In 2020, two major French multicentre studies were initiated, **INASED** and **SESAR**, which are financially supported by Sedana Medical.

The studies are further studying a number of therapeutic benefits of inhaled sedation that were not studied in the Sedaconda study, but which in several cases have also been demonstrated in smaller studies[1].

Sedana Medical is partially funding the French investigator-initiated multicentre study SESAR. Therapeutic effects for patients with impaired lung function are investigated in the study. Among other things, the study is exploring whether inhaled sedation can result in improved oxygenation, reduced number of cases of pneumonia and bronchodilator effect. Sedana Medical is also funding INASED, another major French multicentre study. This study aims to demonstrate a reduced incidence of delirium in mechanically ventilated intensive care patients receiving inhaled sedation compared to intravenous sedation with propofol.

If positive outcomes are obtained, the studies could significantly promote commercial adoption of inhaled sedation as standard therapy in intensive care, and the studies each have potential to dramatically change views on inhaled sedation. One of the studies could also be used for regulatory purposes.

Pipeline: four own studies and three investigator-initiated studies confirm therapeutic benefits and pave the way for a new standard



Investigator-initiated studies with potential to dramatically changes views on inhaled sedation

SESAR is a randomised, controlled study of 700 patients with acute lung failure, also known as Acute Respiratory Distress Syndrome (ARDS). Up to 30 percent of mechanically ventilated patients in intensive care units suffer from ARDS, a serious condition with a 35–45 percent hospital mortality rate. The primary endpoint of the study is to show that inhaled sedation has lung-protective properties, shortens ventilator time, and leads to higher survival in intensive care patients with severe lung disease. The study, which is being conducted at 30 different intensive care units in France, began in May 2020 and is expected to take three years to complete.

> "The primary endpoint of the SESAR study is to show that inhaled sedation has lung-protective properties for ARDS patients, **shorten ventilator time and higher survival in intensive care patients with severe lung disease.**

The principal investigator for the study is Dr Matthieu Jabaudon at the Centre Hospitalier Universitaire (CHU), Clermont-Ferrand. The study will compare current standard propofol treatment with inhaled sedation of sevoflurane. The study's primary endpoint is to demonstrate shorter ventilator treatment time in inhaled sedation. An earlier, smaller study by the same research team showed inhaled sedation to be associated with improved lung function in patients with ARDS[1]. The same effects have also been demonstrated in several animal studies. If this large study has a positive outcome, it will dramatically change the perception of inhaled sedation compared to intravenous sedation.

INASED is a randomised, controlled study of 250 patients who are expected to need mechanical ventilation in an intensive care unit for more than 24 hours. The study is being conducted at ten different intensive care units and is led by the principal investigators Dr Pierre Bailly and Professor Erwan L'Her, at the Centre Hospitalier Regionale Universitaire Brest, France. The study began in August 2020 and is scheduled for completion in August 2023 following a 24-month inclusion period and a 12-month cognitive follow-up.

The study's primary endpoint is to demonstrate reduced incidence of delirium following inhaled sedation compared to current intravenous standard propofol therapy. Efficacy and safety of inhaled sedation for critically ill patients is being investigated in the study. The study is investigating whether inhaled sedation works in all patients, whether the patients need several medicinal products (polypharmacy), have fewer problems after wake-up, are more alert and calm with fewer hallucinations and delirium, have a low or no risk of developing tolerance, ceiling effects and withdrawal symptoms, and whether the patient's use of opioids decreases.

The ISCAstudy, Inhaled Sedation in COVID-19-related Acute Respiratory Distress Syndrome, was initiated in the second quarter of 2020 and will include at least 400 patients in 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. Inhaled sedation appears promising for this group of patients as the treatment has anti-inflammatory effects and advantageous pharmacokinetics in patients with ARDS and multiple organ failure.

700

SESAR
is a randomised, controlled study of 700 patients with acute respiratory distress syndrome (ARDS).

250

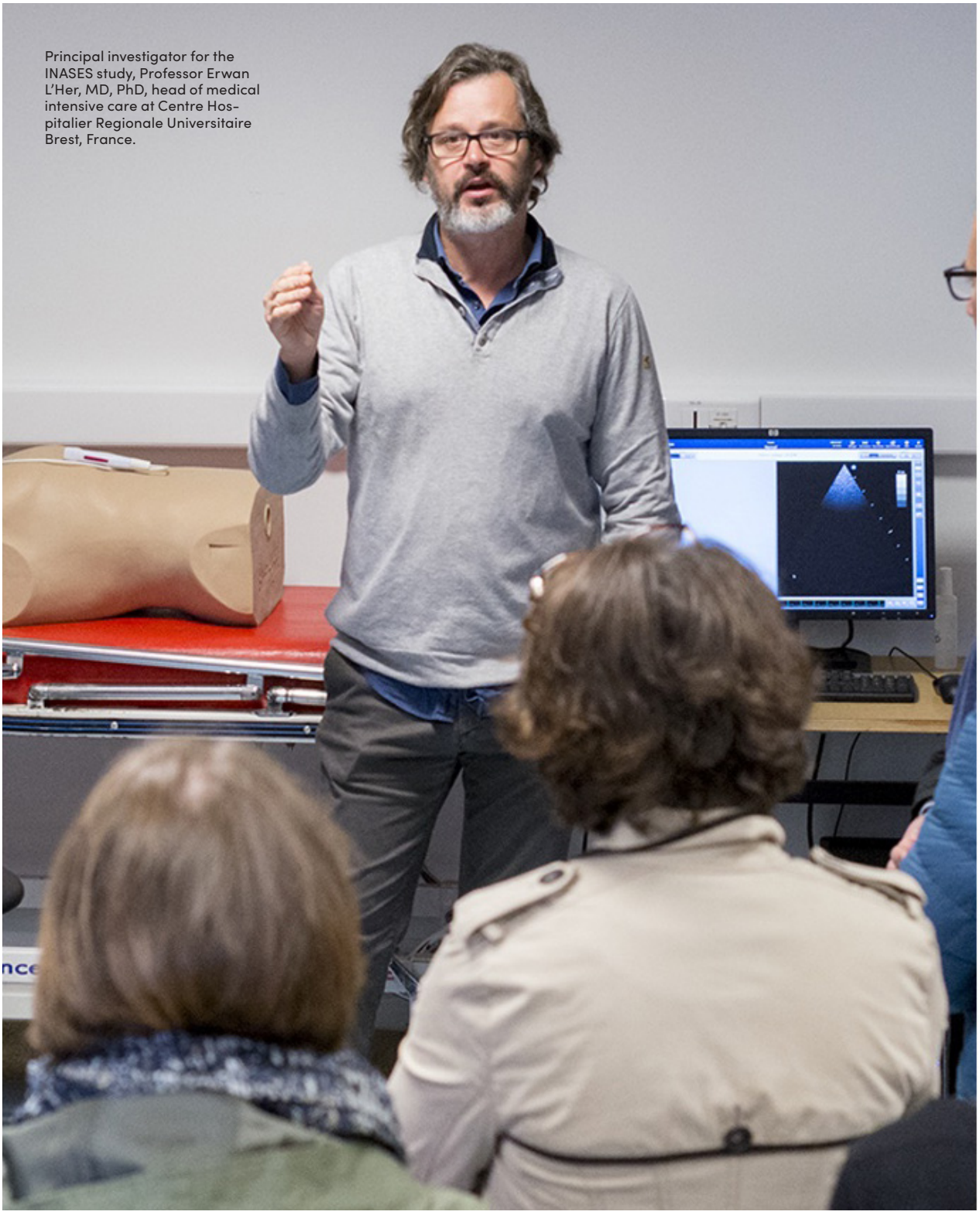
INASED
is a randomised, controlled study of 250 patients who are anticipated to need mechanical ventilation in an intensive care unit for more than 24 hours.

400

ISCA
was initiated in the second half of 2020 and will include at least 400 patients in around 30 intensive care units.

A FIRST-LINE THERAPY IN ICU

The principal investigator of the INASED study, Professor Erwan L'Her, wants to move all patients to inhaled sedation.



Principal investigator for the INASES study, Professor Erwan L'Her, MD, PhD, head of medical intensive care at Centre Hospitalier Regionale Universitaire Brest, France.

When did you first come in contact with Sedana Medical?

I am responsible for the evaluation and development of new biomedical devices and have been using AnaConDa since it was initially launched almost 15 years ago. Initially, we only used it some 20 times a year, only for our most difficult patients, for example drug addicts who can be very hard to sedate.

But now you use it more frequently thanks to COVID-19?

Yes, indeed. We saw at an early stage that COVID-19 patients required huge amounts of sedatives, not only because they were sedated for very long periods of time, but also as COVID-19 patients have proven very hard to sedate, sometimes we would need to more than double the drug dose. So, initially we started to use inhaled sedation to avoid drug shortage.

But we also started to use inhaled sedation more frequently as we had some very scary, almost catastrophic experiences when we used propofol. Several patients experienced delirium and other dreadful side effects due the prolonged use of propofol. So, to avoid problems that arise from such high doses of intravenous sedation, we now use inhaled sedation on all our COVID-19 patients. With inhaled sedation we avoid delirium, get shorter wake up times and also a lowered cost. These advantages are immense.

You even performed a small study on these patients?

Yes, we performed an open cohort study on 60 COVID-19 patients. The study showed that inhaled sedation achieved the goal of sedation and at the same time the use of opioids was reduced. As sedation efficacy is so high, opioids are not needed in the usual amount. We were glad to see the same results in the large Sedaconda study. It confirms all things that were already knew, but on a very large basis.

Tell us about the large INASED study that you are planning.

We are comparing intravenous propofol with inhaled sedation and hope to achieve results that can promote inhaled sedation as a first line therapy. The primary endpoint is decreased delirium, but we are also looking at cognitive functions three months after therapy. We plan to include patients that will be sedated a long period of time; seven to ten days, which is considerably longer than the 48 hours (+/-6 hours) that patients were sedated in the Sedaconda study. So, we are looking at the long-term effects of long-term use of isoflurane.

The study is sponsored by Sedana Medical.

Yes, we have been planning this study for three years, but it was very difficult to find financial support. In France, there are few ICU units that use inhaled sedatives in clinical routine as many anaesthesiologists see isoflurane as an old-fashioned drug and are much more used to sevoflurane that has several benefits such as a more rapid recovery time. They are used to the operating room and like sevoflurane better than isoflurane. However, the ICU is totally different from the operating room and I am totally convinced that isoflurane is better.

Is there even a resistance towards isoflurane?

It comes down to habit. Isoflurane is not delivered on routine. It is less difficult to give an intravenous injection of propofol or the newer drug dexmedetomidine, a quite new drug that costs a lot, than getting used to filters, fine tuning and monitoring. So, there are some technical tricks with inhaled sedation that one needs to manage, but they are not that difficult and the benefits to patients and us as healthcare providers definitely make it worth the effort.

You seem to be a believer in inhaled sedation even though the INASED study is not yet completed.

Yes, COVID-19 proved to us that inhaled sedation should be a first line treatment, before propofol and dexmedetomidine. We are totally converting all our patients and will use inhaled sedation as a first line therapy for all.

RESEARCH GRANTS PROMOTE MEDICAL PROGRESS

Sedana Medical research grants are a unique opportunity for the scientific community to increase knowledge of sedation in critically ill patients.

Sedana Medical Research Grant is a research grant that was established in 2019 and is awarded annually. A grant of between EUR 10,000 and 30,000 per year for up to two years will be awarded to one to three individual academic researchers, which promotes 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 volatile anaesthetics offer, interest in research into inhaled sedation is very high in general, and in 2020 we received several good applications. Those selected in 2020 are three particularly interesting research projects in France and Germany.

One of the studies is being done to increase understanding of the lung-protective effects of inhaled sedation in ARDS. Another is investigating whether patients undergoing heart valve surgery benefit from postoperative inhaled sedation. And the third is examining the possibility of inhaled sedation during heart surgery (bypass surgery), as volatile anaesthetics have well-known heart-protective properties. The selected studies were each assessed in their own way as being capable of taking inhaled sedation forward.

Title: **Effects of sevoflurane on extravascular lung water and pulmonary vascular permeability in patients with acute respiratory distress syndrome**

Investigators: Dr Christopher Lai, MD, Professor Xavier Monnet, MD, Tài Pham, MD, PhD, Medical Intensive Care Unit, Hôpital Bicêtre, University Paris-Saclay, Le Kremlin-Bicêtre, France

Title: **AnaConDa Device in cardiac surgery: an easy solution to achieve total inhalation anaesthesia with sevoflurane**

Investigators: Francois Labaste, MD, Professor Vincent Miniville, MD, Professor Bertrand Marcheix, MD, Service d'Anesthésie et Réanimation, Cardiaque Surgery, Centre Hospitalier Universitaire de Toulouse, France

Title: **Volatile short-term sedation in patients undergoing cardiac valve surgery: a prospective randomized controlled trial**

Investigators: Armin Flinspach, MD and Elisabeth Adam, MD, Department of Anaesthesiology, Intensive Care Medicine and Pain Therapy University Hospital, Frankfurt and Goethe University, Frankfurt, Germany

Research grants promotes the prospects for research in Sedana Medical's field, with the aim of leading to medical advances for the benefit of patients and society.

THE MARKET IS ESTIMATED AT SEK 20–30 BILLION

Sedana Medical's market consists of sedated and mechanically ventilated patients in intensive care units around the world.

Sedana Medical's market consists of sedated and mechanically ventilated patients in intensive care units in all parts of the world. Every year, around 30 million patients are admitted to intensive care units around the world. Many of them are in extremely critical condition, making breathing support using a ventilator necessary. This type of support is usually referred to as mechanical ventilation, and of the total number of patients admitted to intensive care units, between 30 and 50 percent are ventilated mechanically.

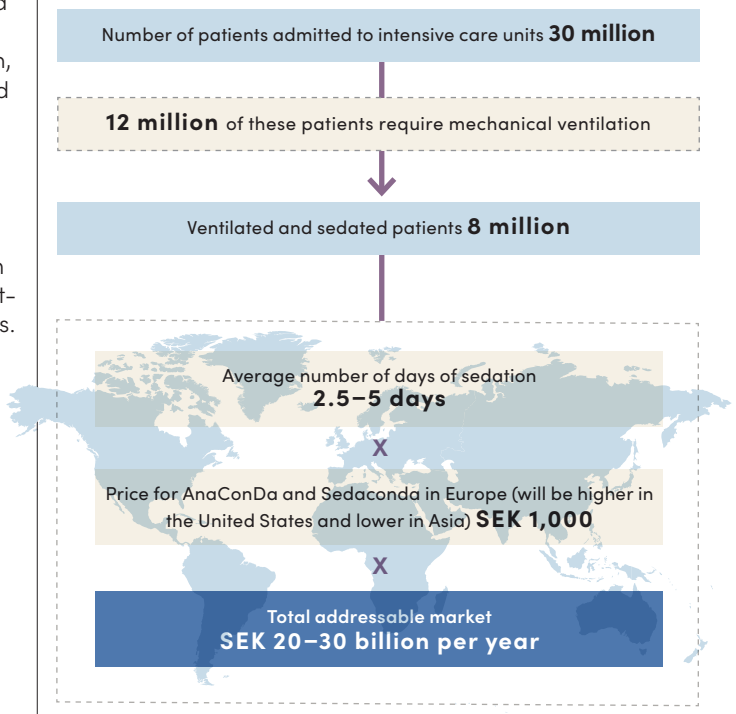
Mechanical ventilation can be a very traumatic and unpleasant experience. Sedation is used to provide comfort and safety, to relieve anxiety, agitation and pain and to prevent the patient from self extubating by wresting the tube out of their airways. Sedation is also necessary so nursing staff are to be able to carry out the treatments required.

> **Sedana Medical is well positioned to offer** the first commercial solution for inhaled sedation in intensive care.

Propofol and narcotic products such as benzodiazepines are currently used for the sedation of mechanically ventilated patients. They are given intravenously, and while they have well-known advantages, there are also a number of drawbacks, both for the healthcare system and for the patients.

Of the 30 million patients around the world who are treated in intensive care every year, eight million a year need both ventilation and sedation and thus represent the direct target group for AnaConDa. On average, these patients are sedated for two to five days. The global average cost of inhaled sedation is estimated at around SEK 1,000 per day, and Sedana Medical estimates the size of the market to be between SEK 20 and 30 billion. The market in SEK is relatively evenly distributed between the regions USA, Europe and Asia, but price levels in the USA are estimated to be higher.

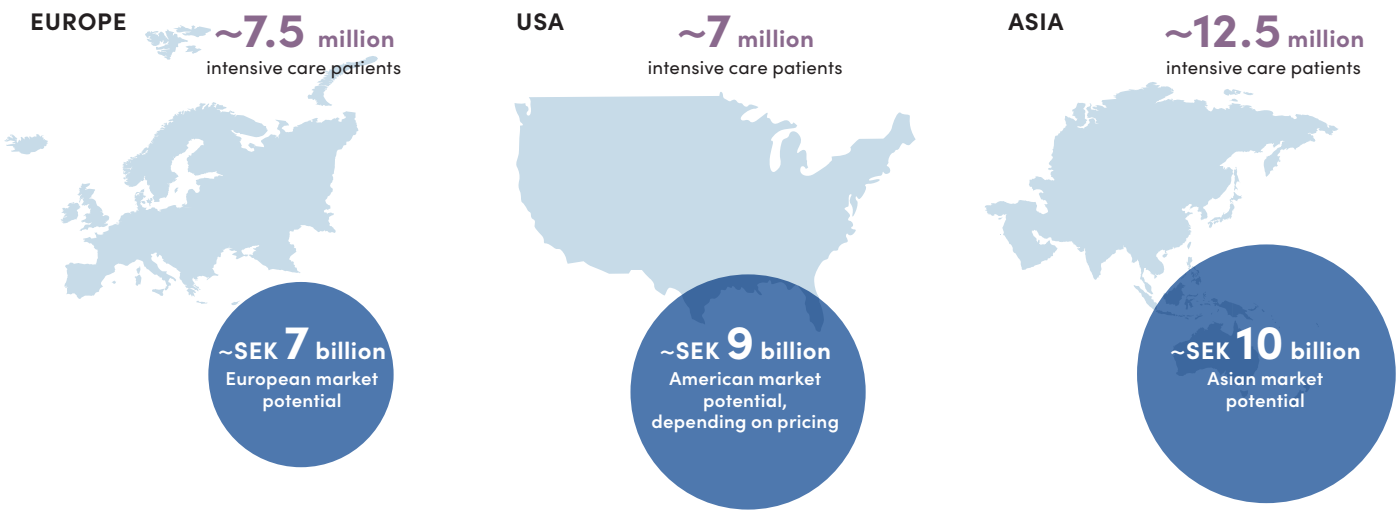
Sedana Medical's market potential for inhaled sedation



*Market size based on the company's estimates.

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, the shortcomings of intravenous sedation are greater, and there is a major need for alternative methods of sedation.

Sedana Medical's principal target group consists of patients with impaired lung function and mechanically ventilated, sedated intensive care patients in need of reliable wake-up times and efficacy with a low risk of withdrawal problems such as delirium.



The competitive situation

The current market for sedatives in intensive care consists only of intravenous drugs. The company estimates the total annual size of this market to be around SEK 20 billion, 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 market share, but estimates benzodiazepines to be 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.

Costs

At an average cost of around SEK 30,000 per bed day and patient, intensive care patients are expensive. The cost of an intensive care unit is three to five times higher than an ordinary hospital ward, and despite the fact that these patients only make up around 10 percent of all hospital admissions, they can account for almost 20 percent of a hospital's total budget. Thus there are compelling financial reasons for hospitals to reduce the number of bed days. In addition Sedana Medical considers intensive care clinics to be relatively price-insensitive with regard to sedatives as they account for a relatively small part of the total cost of healthcare.

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 tolerance of the product. The great number of factors means that the cost of intravenous sedation can range between SEK 200 and 3,000 per day. Costs in the United States are significantly higher, and Sedana Medical estimates average costs to be around three times higher than in Europe. Sedana Medical estimates the average cost of intravenous sedation in Europe to be around SEK 500 per day, which is lower than the daily cost of inhaled sedation, which is estimated at around SEK 1,000 per day.

It takes a long while to establish a new form of treatment in healthcare, and it requires key opinion leaders in the field to back the therapy. If it is not endorsed by these people and expert healthcare bodies, it will be very difficult to succeed.

Accordingly, Sedana Medical has long focused on establishing contacts with precisely 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 new guidelines. Because such activities must be managed by Sedana Medical, there is a clear advantage in pursuing its own sales.

Sedana Medical's sales have thus far taken place through traditional direct sales and distributors. The company works with product specialists who train clinicians in how the devices work and how treatment should be carried out. 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, and accounts for around 90 percent of the company's total sales. Direct sale takes place primary through the company's own product specialists in ten European countries: Belgium, Denmark, Finland, France, Germany, Netherlands, Norway, Spain, Sweden and the United Kingdom.

Direct sale markets in 2020

8

MILLION PATIENTS MAKE UP THE DIRECT TARGET GROUP

Of the 30 million patients around the world who are treated in intensive care every year, eight million a year need both ventilation and sedation and thus represent the direct target group for AnaConDa.

20–30

BILLION SEK

The global average cost of sedation using isoflurane and AnaConDa is estimated at around SEK 1,000 per day, giving a total market valuation of between SEK 20 and 30 billion.

They also train customers in initiating the treatment in a safe way. Direct sale is associated with higher cost 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 margins. The plan is for the company's own sales organisation to cover the most important European markets in connection with the registration of the pharmaceutical product in Europe, which is expected to take place in the second half of 2021.

> Direct sale **offers many benefits.**

Sedana Medical also has some sales through distributors in Europe. In 2020, Sedana Medical signed agreements with distributors in Bulgaria, Cyprus, the Czech Republic, Greece and Slovakia. Other European markets with distributor sales are the Austria, Baltic states, Croatia, Ireland, Italy, Portugal, Romania, Serbia, Slovenia and Switzerland.

Distributor markets outside the EU

Sedana Medical has engaged distributors as a low-risk means of initiating sales and quickly establishing inhaled sedation for intensive care in countries where it does not have direct sales. Sedana Medical has dis-

tribution agreements in Australia, Canada, China, India, Israel, Japan, Mexico, New Zealand, Russia and South Korea. Distribution agreements were additionally signed in 2020 for Colombia, Ecuador, Malaysia, Oman, Saudi Arabia, Singapore, Thailand and the United Arab Emirates. In the short term, the company has no intention of establishing a presence in markets outside Europe, and possibly the United States, but considers that they may be of potential interest in the long term.

Customer base

The target group for the company's products is intensive care physicians, intensive care nurses and decision-makers with responsibility for purchasing medical devices and pharmaceutical products for these departments. The customer base consists primarily of intensive care units in medium-sized and large hospitals and university hospitals. The product is bought for the clinics through hospital procurement departments, and in many cases Sedana Medical receives requests to participate in procurements. Sedana Medical's largest market is Germany which, together with other markets where it has direct sales, has acted as a test market to explore demand for the treatment.

> **"There are compelling financial reasons** for hospitals to reduce the number of bed days.

The company also reaches its customers by taking part in international congresses and through leading researchers and clinicians presenting their findings at scientific congresses and by providing assistance in therapy initiations at clinics. Sales differ between countries and regions but common to all markets is the ambition to create demand among doctors and nurses who, together with intensive care patients, are end-customers for the treatment.

"DISTRIBUTORS HAVE A NOSE FOR WHEN SOMETHING IS AFOOT"

Sedana Medical's newly appointed Vice President Commercial Operations, Jens Lindberg, talks about what is required to launch a therapy, as opposed to selling a medical device.

Jens Lindberg, Vice President Commercial Operations at Sedana Medical since 1 April 2020.

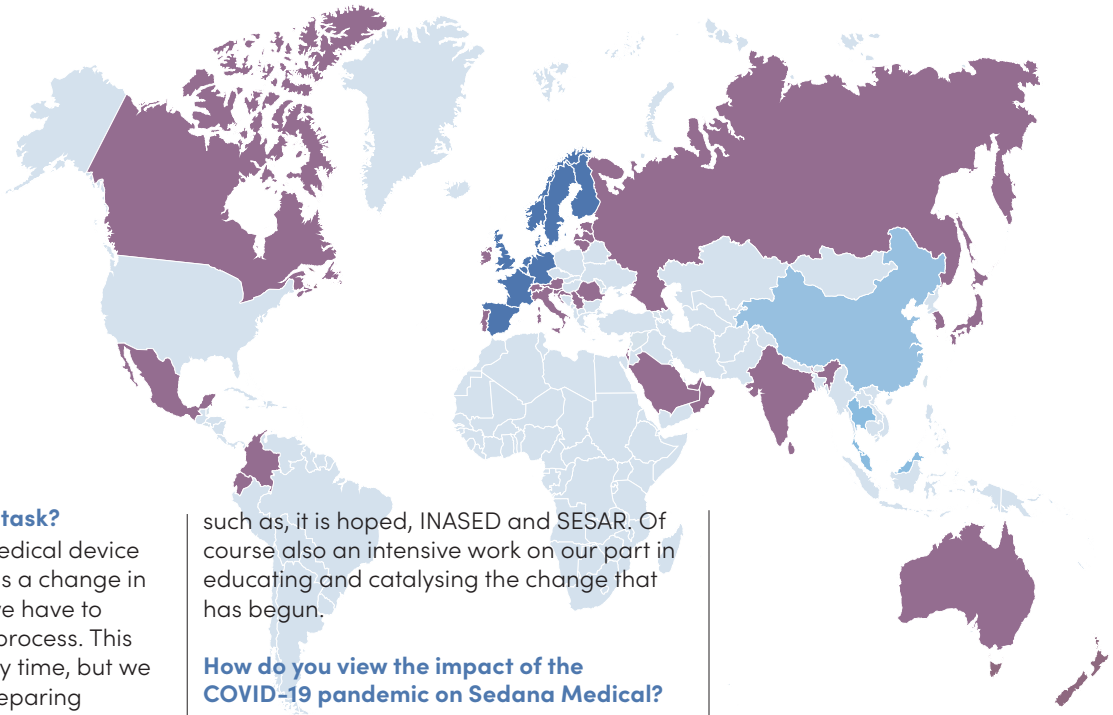
What made you start at Sedana Medical?
It was above all three things, Sedana Medical is a Swedish company, with Swedish innovation and expanding strongly with very positive development. What attracted me is the challenge that Sedana Medical faces with regard to changing how patients in intensive care are sedated. We do not out-compete another product, but the challenge is more extensive, as we are changing a whole way of working for both doctors and nurses.

You had a similar journey at AstraZeneca?
We changed whole work processes when we introduced new forms of treatment in oncology, which required a completely different way of managing patients. New processes, forms of cooperation and procedures were required for both diagnostics and treatment, in several different types of cancer. It was very much like the challenge Sedana Medical is facing now. It is a case of getting multidisciplinary teams in intensive care to work together: the nurses, those who are responsible for the medical devices, and treating physicians. We must get them to set up new procedures and processes to sedate patients.

How do you tackle that challenge?
I think the change we are creating in healthcare is exciting, and it appears that healthcare thinks so, too. We notice strong commitment from the healthcare system, as they see clear benefits for many of their patients with a good product and good treatment, but we must help them along the way. Our greatest 'competitor' is perhaps the inertia in the system. Even if there is great enthusiasm in a hospital, they have to change their way of working, and there is always inertia. Not resistance, but inertia. But once the change has been implemented, there is power and strong ownership. Those who are involved want it to work.

What do you bring with you from your previous job?
I have been commercial manager for global pharmaceutical products in phase 3 at AstraZeneca, so I have experience in what is required to prepare and execute a launch. Among other things, the question of price and reimbursement is a great challenge in the introduction and launch of pharmaceutical products with extensive application processes and negotiations at both national and local levels.

Can you tell us a little about your thoughts on the new trademark Sedaconda?
We are launching a therapy – inhaled sedation – which means a pharmaceutical product, a medical device for delivery of the pharmaceutical, and number of additional products that, together, create a complete system. Sedaconda is our new trademark for inhaled sedation which, through, SEDA has a clear link to both Sedana Medical and sedation. At the same time, we are retaining the trademark strength in AnaConDa by retaining CONDA, which stands for Conserving Device.



'During the year we have gained many new distributors around the world, for example in Mexico, South America, Saudi Arabia and South-East Asia, which I regard as an incredibly positive signal', says Jens Lindberg.

What is your most important task?
When we go from selling a medical device to selling a therapy that entails a change in work method, it means that we have to reorganise most of our sales process. This obviously takes up much of my time, but we also spend a lot of time on preparing pricing, procurement and reimbursement processes in various countries. In addition, we are growing quite a lot as an organisation, both in the countries where we have a presence and in new countries, and a lot of time is spent building up an organisation that can deal with both medtech and pharmaceuticals.

What are your principal sales arguments?
The most important sales argument of all is positive outcome in the Sedaconda study and regulatory market approval. For many hospitals it confirms the expectation and positive picture that exist regarding inhaled sedation and its potential clinical benefits. Then the issue of health-economic impact will be a very important issue in many countries in determining whether inhaled sedation will become established as a standard therapy. We consider ourselves to have a strong argument in a comparison with todays standard therapy propofol as studies have shown that inhaled sedation reduces time on a ventilator and the time a patient remains in ICU, which can provide great health-economic gains.

What more support do you need in commercialisation?
We are already seeing great interest in the therapy today, but for it become the standard therapy there is obviously a need for market approval in the regions where the therapy is being launched. It is then a matter of what magnitude of change one wants to bring about. From the side of the healthcare system, there is already a positive response and a wish to implement inhaled sedation, but for it to become a standard therapy, as well as market approval there is also a need for further supportive phase 3/4 studies such as, it is hoped, INASED and SESAR. Of course also an intensive work on our part in educating and catalysing the change that has begun.

How do you view the impact of the COVID-19 pandemic on Sedana Medical?
Sales were substantially higher than expected in 2020. Part of this is a one-off increase because COVID-19 has meant more patients in intensive care in need of sedation, but it has also led to a number of new hospitals being added as customers.

> **"We are growing quite a lot as an organisation, both in the countries where we have a presence and in new countries,** and a lot of time is spent building up an organisation that can deal with both medtech and pharmaceuticals.

All in all, beyond one-off effects we have reached a long-term higher level with more hospitals as customers and existing customers who have expanded their use. We can see something of a snowball effect when new hospitals are added. It creates interest in other hospitals and a wish also to be able to offer inhaled sedation.

Can you tell us something about the progress that was made outside Europe during the year?
During the year we have gained many new distributors around the world, for example in Mexico, South America, Saudi Arabia and South-East Asia, which I regard as an incredibly positive signal. The fact that we have expanded the number of distributors shows that there is confidence in our product and, above all, in inhaled sedation. My experience is that distributors do not take on new products unless they believe that change is coming. Distributors have a nose for when something is afoot. New distributors and new hospitals are a sign that the change is happening now, and it has been accelerated by COVID-19.

STRATEGIC PRIORITIES CHECKED OFF

Sedana Medical has a clear picture of the strategic priorities that must be made in order for it to achieve its vision of making inhaled sedation the standard therapy for mechanically ventilated patients in intensive care.
Many important steps were taken in 2020.

The strong top-line results in the pivotal clinical Sedaconda study (SED001) is the single largest advance for inhaled sedation since AnaConDa was developed.

Sedana Medical's strategic planning for how the company is to achieve its vision of making inhaled sedation a new global standard therapy in intensive care is based on three steps:

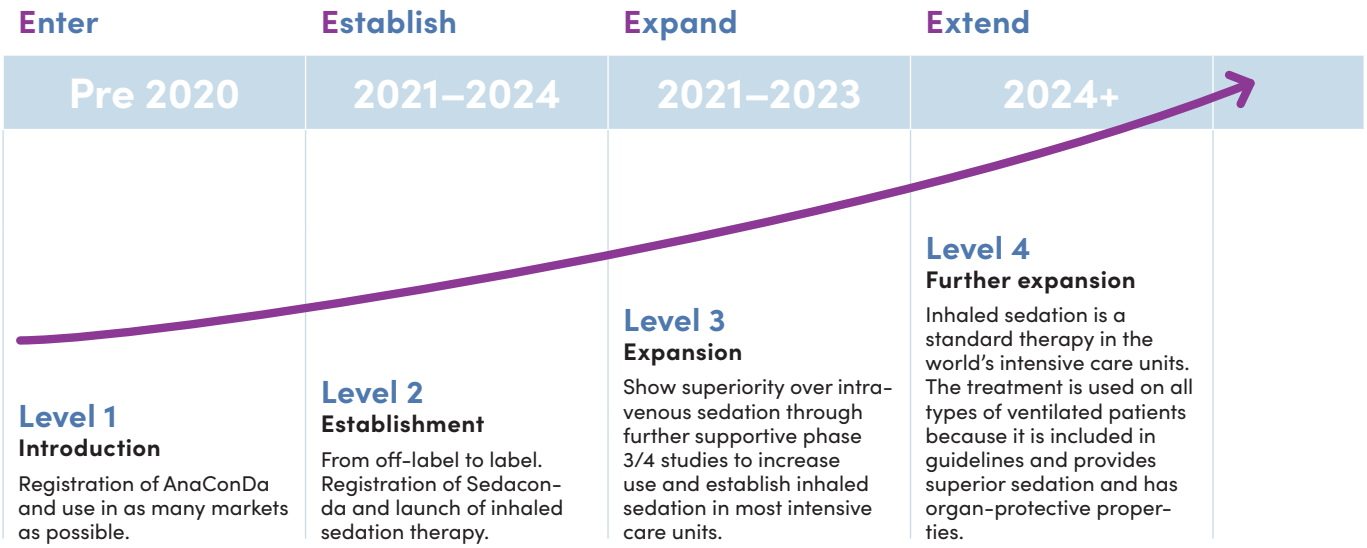
1. Establish AnaConDa in as many markets as possible to enable use, build experience, support investigator-initiated studies and be able to run pivotal clinical non-inferiority studies, showing that inhaled sedation is as good a method of sedation as the current standard therapy.

2. Apply for marketing authorisation for Sedaconda (isoflurane) and inhaled sedation, initially in the EU and later in other markets. In that way, the treatment will move from being off-label to fully approved. We therefore sell the whole treatment including both a pharmaceutical product and the medical devices (in the EU this is estimated to be from the second half of 2021).

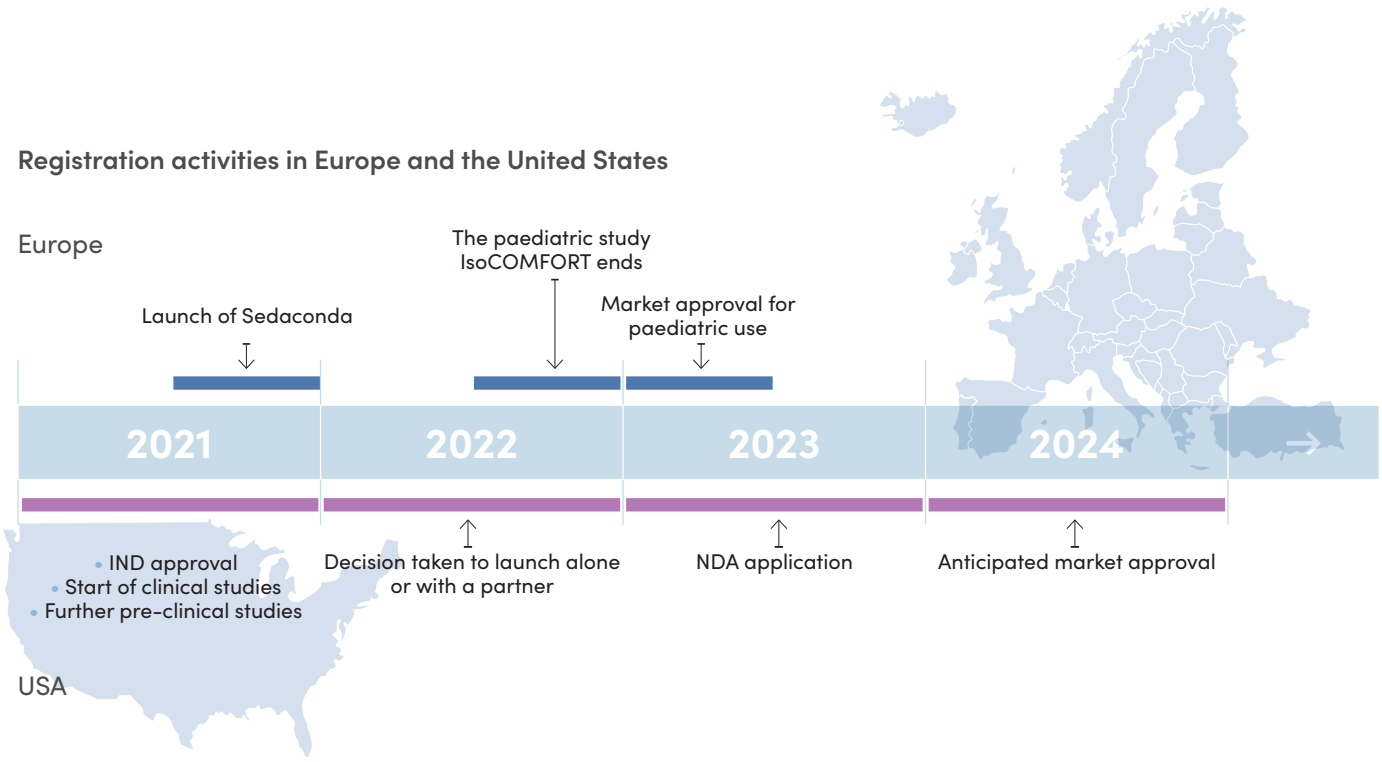
3. With the assistance of more studies that secure medical evidence demonstrating that inhaled sedation is a better and more cost-effective therapy than current standard therapy. This can be done, among other ways, by demonstrating significant benefits with regard to wake-up times, shorter time to extubation, fewer side effects such as delirium, larger proportion of spontaneous breathing in the patients, better oxygen uptake, shorter ICU treatment times etc. In that way, the treatment will gain ground and be included in national guidelines, as well as gradually taking the place of a new standard therapy throughout the world.

Sedana Medical's vision and strategic plan – EEEE

The vision is to make inhaled sedation a global standard therapy in intensive care



Registration activities in Europe and the United States



THE OBJECTIVE IS APPROVAL IN THE UNITED STATES IN 2024

Preparations for the American phase 3 studies were intensive during the year. In March 2019, Sedana Medical held a meeting with the U.S. Food and Drug Administration (FDA), what is known as a pre-IND meeting, where the FDA proved to be in favour of registration of Sedaconda (isoflurane) and AnaConDa as a combination product in the United States.

Two randomised clinical studies with around 250 patients each will be carried out to confirm and ensure efficacy and safety.

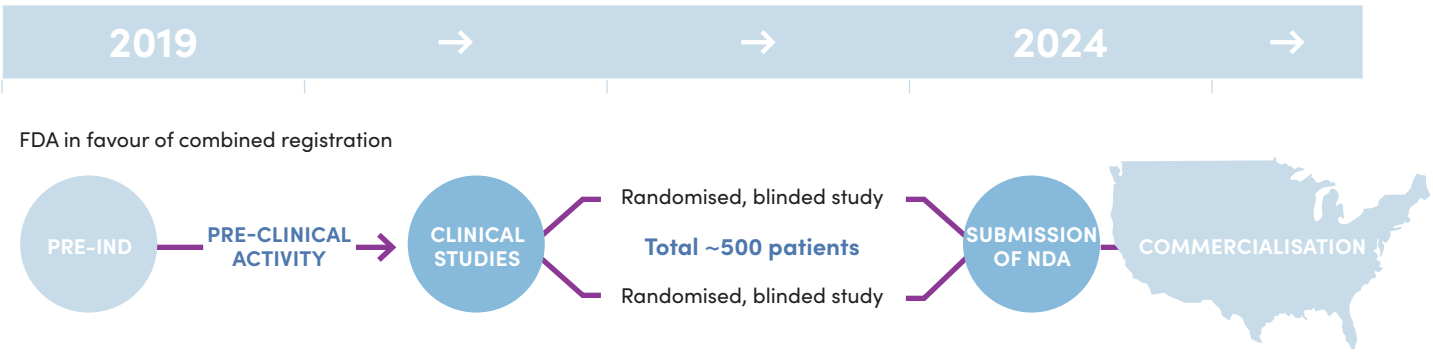
In 2020, Sedana Medical worked towards being able to submit an IND (Investigational New Drug) application during the first half of 2021 to obtain authorisation to begin the studies. IND approval is conditional on the commenced toxicity studies being completed. Depending on how the pandemic develops, Sedana Medical anticipates being able to obtain IND approval before the summer of 2021 in order to be able to include the first patient in each study during the second half of 2021.

Sedana Medical has chosen a CRO and has interest from many renowned clinicians and investigators to take part in the studies. The plan is to include around 30 American clinics.

As the European registration 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, however, taught Sedana Medical much 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 a requirement from the FDA.

Sedana Medical intends to be able to carry out the work involved in studies, registration and market access itself. The objective is to obtain registration in the United States in 2024, and in 2022 the company will decide on commercialisation strategy, i.e. whether the launch is to be done alone or with a partner.

In the autumn of 2019, Sedana Medical secured funding for registration in the United States through a directed new share issue.



Non-clinical data

Relevant documentation that must be supplemented with additional data and approved by the FDA:

- Toxicity studies – PPND*
- Validation of human factors

Clinical studies

Two randomised blinded clinical studies to be conducted to confirm and ensure efficacy and safety.

Safety database

Patients from these clinical studies, as well as patients from the European study, will be included in the safety database covering 500 isoflurane patients.

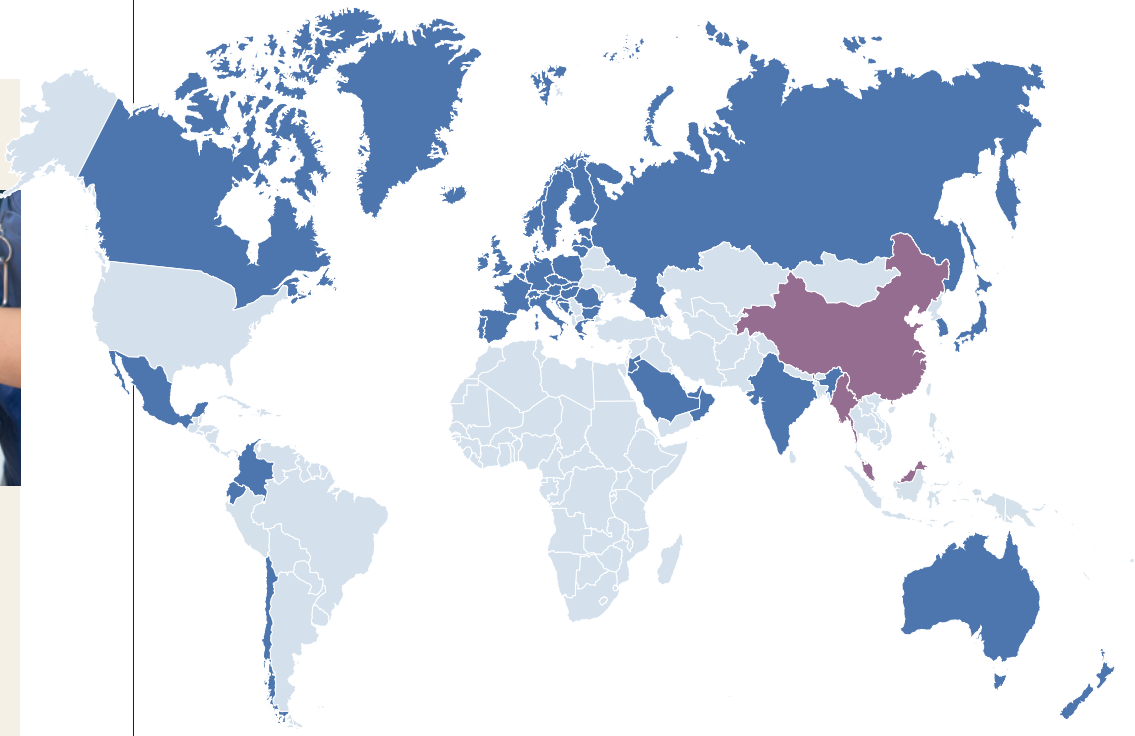
Commercialisation

The commercialisation strategy decision for the United States – whether the company will launch alone or together with a local partner – will be decided in 2022.

*PPND: development before and after birth.

AnaConDa IS USED TODAY THROUGHOUT THE WORLD

A number of advances were also made outside Europe during 2020, especially in South America and the Middle East.



Sedana Medical obtained market approval for AnaConDa in Mexico and Saudi Arabia and signed distribution agreements for Colombia, Ecuador, Malaysia, Oman, Saudi Arabia, Singapore, Thailand and the United Arab Emirates, among other countries. In addition, Sedana Medical signed an agreement with a new distributor for Australia and New Zealand.

Sedana Medical has previously already had distributors in the following countries outside Europe: Canada, China, India, Israel, Japan, Mexico, Russia and South Korea.

In China, Malaysia, Oman and Thailand, Sedana Medical has distributors who in 2020 did not yet have any sales.

In the short term, Sedana Medical has no intention of establishing a presence with its own direct sales channels in markets outside Europe, and possibly the United States, but considers that they may be of potential interest in the long term.

Registration via 505 (b) (2)

Because the drug substance isoflurane has been available for decades, 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. Because registration requirements have become more stringent in the many years since isoflurane was first registered, Sedana Medical will fill certain gaps in the existing documentation and supplement it with data for approval by the FDA, including animal toxicology studies.

Because AnaConDa is not yet registered in the United States, a human factors validation must be performed. This validation is carried out on all advanced pharmaceutical products submitted for registration and is done to exclude the effect of the human factor on efficacy and safety in use. Work on human factors validation began in 2019 together with Beth Israel Deaconess Medical Center and Harvard Medical School in the United States.

STUDIES PROVIDE GUIDANCE

Dr Brian O'Gara is Assistant Professor of Anaesthesia at Harvard Medical School, Beth Israel Deaconess Medical Center (BIDMC), USA.

Dr Brian O'Gara is Assistant Professor of Anaesthesia at Harvard Medical School, Beth Israel Deaconess Medical Center (BIDMC), USA.

Could you tell us a bit about your experience from inhaled sedation?

I became interested in inhaled sedation 3-4 years ago, when I was looking into preliminary research that suggested that volatile anaesthetics could provide anti-inflammatory protection for various types of lung injury.

When did you first come in contact with Sedana Medical?

One of the special areas of research here at the BIDMC department of anaesthesia, especially in critical care, revolves around taking care of patients with acute respiratory distress syndrome (ARDS). We were collaborating with the PETAL Network (Prevention and Early Treatment of Acute Lung Injury) which conducts large trials mainly on critical care patients, including those with ARDS. Through that, we learned more about inhaled sedation and we are interested in exploring it as a potential option for these types of patients.

Have you had any experience in inhaled sedation?

Since I first came across inhaled sedation, I have led a small clinical trial in patients undergoing cardiac surgery, testing if inhaled sevoflurane can prevent lung inflammation and reduce pulmonary complications as compared to anaesthesia with propofol. As many others across the globe have experienced, COVID-19 has delayed the publication of scientific results - the results for this trial are still pending publication.

You have also experienced inhaled sedation in other countries.

Yes, as I have a research interest in inhaled sedation in the ICU, I joined a trip to Germany where I could see the use of the technique in real life use firsthand. I was very impressed both by how comfortably sedated the patients were and how comfortable the nursing staff and the doctors seemed to be in using the technique.

There are a couple of intravenous anaesthetics, is there a need for inhaled sedation?

Despite recent advances in the last couple of decades with short acting intravenous anaesthetics I still think there is room for an alternative sedative that can safely provide sedation without significant accumulation or causing organ toxicity. Inhaled sedation has the potential to make a big impact as it does not accumulate in the body to the degree that for example midazolam does. Of course, we have to look into the long term use in the FDA studies, but at least in the preliminary experience in Europe and Canada inhaled sedation does not cause any serious untoward side effects such as seen with propofol infusion syndrome. So, although sedation as it stands is already pretty good, there are still cases for which we would like alternatives, where the use of current agents is either not practical or safe.

What is so special about inhaled sedation?

From what I have seen in preliminary work, inhaled sedation enables caregivers to wake the patient up very quickly, even after being sedated for a longer period of time. Inhaled sedation seems to be very good at keeping patients deeply sedated but at the same time being able to wake patients up quickly. This is not easily done with other therapies and has the potential to be very valuable in ICU care where it is not always possible to lightly sedate patients. It is highly interesting, and I hope we can investigate it thoroughly in the upcoming trials.

> **Inhaled sedation appears to be very good** at keeping patients deeply sedated, while patients can be woken up quickly.

Which are the hurdles when it comes to uptake of the therapy?

One is teaching colleagues who are not anaesthesia providers about inhaled anaesthetics and the nuances that go into their administration and the monitoring that is required. Another issue that will require further study would be the introduction of both a new substance and new equipment, including gas monitoring. All in all, a new work-flow paradigm would require input from multiple levels of providers; nurses, doctors and respiratory therapists. There are some medical hurdles and some logistical hurdles, so it makes for an interesting planning process, and further study will illuminate a path forward.

Dr. O'Gara is receiving consultancy fees from Sedana Medical

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. In the Code of Conduct, the Board of Sedana Medical has set out the principles of business ethics that the company must abide by. They are an important framework for responsible enterprise and a tool for preventing and detecting any violations of the Code of Conduct. Local and global legislation must be respected in all operations, and good professional practice and regulations must be followed.

The Code of Conduct covers all employees, the Board, consultants, suppliers and any temporary staff. Sedana Medical's Code of Conduct also includes sustainability efforts, the work environment, health and safety, the environment, gender equality and purchasing. To complement the Code of Conduct, there are also a number of policies that all employees, consultants and temporary staff are expected to follow.

Sedana Medical is affiliated to the UN Global Compact and endorses its ten principles of human rights, labour law, the environment and anticorruption. Sedana Medical strives for openness and transparency in its business operations, and its work on sustainability is an ongoing process. As a consequence of the company's business model, a large part of its environmental impact comes from contract manufacturers. In 2021, Sedana Medical is initiating cooperation with an external party aimed at analysing areas of development and identifying and setting short and long-term goals for the company's continued sustainability efforts.

Environment

The business is to be run in an environmentally sustainable manner based on the circumstances of the business and follow prevailing environmental laws and regulations. The work on the environment and sustainability must be based on the UN's Sustainable Development Goals. Sedana Medical will work to increase the competence and commitment of its 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 its negative impact on the environment, take account of the environment and health in the development of products and processes and prioritise innovative, environmentally aware technology. Goods and services must be delivered with an awareness of, and concern for, the environment. The modes of transport used must always be as economical and environmentally friendly as possible. The company therefore makes active efforts to minimise air freight, and this mode of transport must be used in exceptional cases only.

A large project was conducted during the year for the purpose of optimising and streamlining warehousing, logistics and transport. Sedana Medical lays the foundation for more efficient use of resources by replacing partners for warehousing and logistics, which is an important element of the business. To further reduce negative environmental impact from transport, the company works towards dual sourcing

through a complementary production site within the EU, in addition to the one that already exists in Malaysia. This will reduce the complexity of the transport process and enable optimised choice of mode of transport.

Sedana Medical strives for long-term and responsible relationships with suppliers and distributors and will aim for increased focus on environmental and sustainability issues through a constant dialogue with them. The company endeavours to follow international conventions and laws together with its partners. A sustainable supply chain is crucial for resource-efficient products and processes.

Sedana Medical aspires to contribute to a sustainable care environment. AnaConDa technology enables very efficient reflection of anaesthetic gas from expiratory air; around 90 percent of the gas remains in the active carbon filter and is re-used during the inspiratory phase. Residual gas passes through the ventilator and is collected in the company's filter FlurAbsorb. High re-use contributes to reducing both consumption of volatile anaesthetics and dispersal of gas in the surroundings, which contributes to reducing the negative environmental footprint.

Responsible enterprise

Sedana Medical is continuing to grow, which means that the need for more staff and new skills is increasing. At the end of 2020, the company had 69 employees in eight countries. Of these employees, 48 percent are women and 52 percent are men. During the year, the company primarily recruited people who will strengthen the organisation in their particular roles ahead of future product launches and the company's geographical expansion.

Competent, responsible and committed employees are success factors in the company's aspiration to be an attractive employer. Employees are encouraged in this important work among other things to share ideas and opinions. The year saw the introduction of 'I Suggest', a direct channel to parts of the management team where employees can make suggestions for improvements, irrespective of whether the company's products and services or the environment and health are concerned. Some of the company's efforts to minimise the environmental impact of the business is focused on emissions from transport with the company's own vehicles. During the year, Sedana Medical updated its policy for company cars, to encourage and facilitate a transition to greener alternatives with low carbon dioxide emissions, such as electric cars and plug-in hybrids.

Whistleblower function

All employees are encouraged to report suspected irregularities, improper behaviour or violations of the company's Code of Conduct. During the year a whistleblower system was procured, which is provided by an independent external third party. The system 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 Sedan 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.

Diversity and inclusion

Diversity can be looked at from many angles, such as gender, ethnicity, age, education and professional background. For Sedana Medical, an inclusive culture is characterised by openness, justice, trust and respect. Initiatives that support diversity and inclusion were prepared during the year and will be introduced by the company's management team in 2021. The focus will be on projects concerned with inclusive leadership and overarching training on diversity.

Counteracting corruption

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.

Sedana Medical will work to increase the competence and commitment of its 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.

Creating value

In February 2020, during the initial phase of the pandemic, Sedana Medical donated the company's product AnaConDa with accessories to two hospitals in Wuhan and Zhejiang in China. Sedana Medical wanted to contribute through this initiative to the treatment of severely ill patients who have been affected by COVID-19 and, at the same time, contribute to an exchange of knowledge and experience.

Healthcare faces a paradigm shift, where inhaled sedation in intensive care is used to an ever greater extent. From a global perspective, knowledge and experience of inhaled sedation varies greatly. Sedana Medical has an important role to play, by promoting and enabling increased exchange of knowledge and experience between intensive care units both locally and globally.

As well as providing innovative products and solutions, Sedana Medical tailors training for personnel concerned in intensive care units and offers consultancy, installation and technical support on site. The in-depth knowledge that the company's employees possess is part of Sedana Medical's offering as a trustworthy and reliable supplier.

Sedana Medical works close to and in dialogue with customers to understand their needs, but can also act in response to complaints and requests and supply products and services that create added value.

The needs of the healthcare system for staff trained in intensive care have been very great during the ongoing pandemic. There are several intensive care nurses and doctors among the company's employees. Sedana Medical has given those employees wishing to do so an opportunity to work in intensive care units and consequently support the healthcare system in this exceptional situation.

Sedana Medical is working to have AnaConDa registered in as many countries as possible, including developing countries. The aspiration is to make AnaConDa available globally so that even healthcare organisations with limited financial resources and lacking advanced technology can sedate patients in a simple, safe and effective way.

Sedana Medical Research Grant

Sedana Medical believes in working in partnerships – through various initiatives and research projects – that can lead to continued development and meaningful improvement for patients in intensive care. The

company supports the research world for example through Sedana Medical Research Grant (SMRG), which was introduced in 2019. The purpose of SMRG is to support research initiated and run by the researchers themselves, with the focus on projects that make a major contribution to greater understanding and knowledge of the sedation of severely ill patients in intensive care.

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 holds MDSAP certificates for Canada and Japan, certifying standard and statutory requirements for medical devices.

Sedana Medical's quality management system is evaluated by both internal and external reviewers, and regular inspections are held 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.

Other important work during the year was preparing and implementing the future EU Medical Devices Regulation (MDR 2017/745).

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, and international standards such as Good Laboratory Practice (GLP) and Good Clinical Practice (GCP).

SHARE INFORMATION

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

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.

Share capital

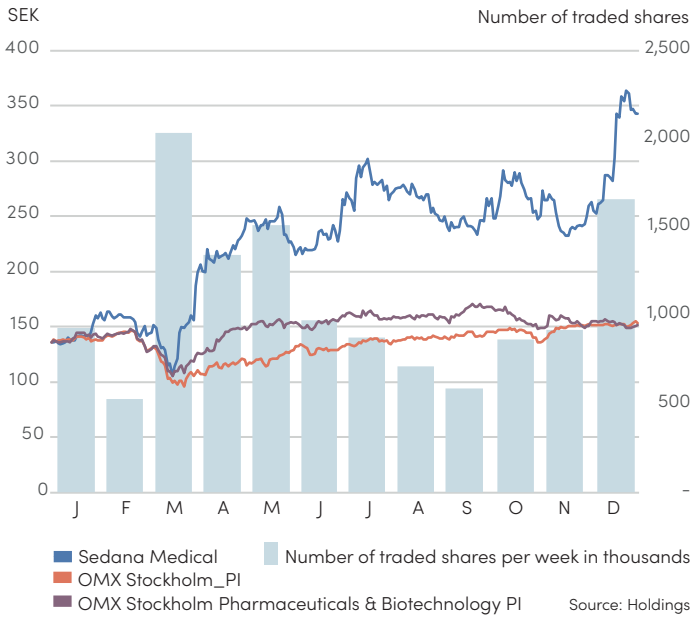
The total number of shares outstanding at 31 December 2020 was 23,046,740. At year-end, share capital totalled SEK 2,304,674. Each share entitles the holder to one vote, and each shareholder has the right to vote for the full number of shares that he or she holds. All outstanding shares are fully paid. 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 0.10 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 Oct. 2004	New formation	1,000	1,000	100,000	100,000	100
31 Oct 2009	New share issue	430	1,430	43,000	143,000	100
5 May 2011	New share issue	500	1,930	50,000	193,000	100
14 Sep 2015	New share issue	240	2,170	24,000	240,000	100
5 Apr 2017	Bonus issue	6,510	8,680	651,000	868,000	100
5 Apr 2017	Split [1)]	8,671,320	8,680,000	0	868,000	0.1
20 Jun 2017	Conversion of shareholder loans	613,594	9,293,594	61,359	929,359	0.1
20 Jun 2017	Exercised convertible bonds	1,881,509	11,175,103	188,151	1,117,510	0.1
20 Jun 2017	New share issue on IPO	5,128,205	16,303,308	512,821	1,630,331	0.1
10 Jul 2017	Overallotment option after IPO	769,230	17,072,538	76,923	1,707,254	0.1
5 Feb 2018	Exercise of warrants, 2014/2019 programme	208,000	17,280,538	20,800	1,728,054	0.1
4 Jun 2018	New share issue	1,728,053	19,008,591	172,805	1,900,859	0.1
10 Oct 2018	Exercise of warrants, 2014/2019 programme	148,000	19,156,591	14,800	1,915,659	0.1
27 Mar 2019	Exercise of warrants, 2014/2019 programme	120,000	19,276,591	12,000	1,927,659	0.1
24 May 2019	Exercise of warrants, 2014/2019 programme	140,000	19,416,591	14,000	1,941,659	0.1
14 Jun 2019	Exercise of warrants, 2014/2019 programme	220,000	19,636,591	22,000	1,963,659	0.1
5 Aug 2019	Exercise of warrants, 2014/2019 programme	100,000	19,736,591	10,000	1,973,659	0.1
26 Aug 2019	Exercise of warrants, 2014/2019 programme	104,000	19,840,591	10,400	1,984,059	0.1
24 Oct 2019	New share issue	2,896,000	22,736,591	289,600	2,273,659	0.1
20 May 2020	Exercise of warrants, 2017/2021 programme	310,149	23,046,740	31,015	2,304,674	0.1

[1)] Share split 1:1000.

Sedana Medical's share price trend and turnover



Share trading

The initial price when the shares were listed on First North Growth Market 2017 was SEK 19.50. The opening price in 2020 was SEK 136, and at the end of the year the last price paid was SEK 343. During the year a total of 12 million Sedana Medical shares were traded at a value of SEK 2,8 billion, which is equivalent to a turnover rate of around 52 percent. On average, around 48,000 shares were traded per trading day.

Price trend

During the year, the Sedana Medical share price rose by 152 percent, while the First North All Share index over the same period rose by 66 percent.

The highest price paid was SEK 372.50 recorded on 22 December 2020, and the lowest price paid was SEK 99.00, recorded on 16 March 2020.

At year-end 2020, the Sedana Medical share price was SEK 343.00, equivalent to a market capitalisation of SEK 7,905 billion.

The 15 largest shareholders at 31 December 2020

	Number of shares	Holding
Handelsbanken Fonder	2,173,763	9.4%
Swedbank Robur Fonder	2,110,895	9.2%
Linc AB	1,899,701	8.2%
Anders Walldov	1,690,000	7.3%
Sten Gibeck	1,219,944	5.3%
Ola Magnusson	1,153,432	5.0%
Öhman Fonder	743,416	3.2%
Berenberg Funds	609,440	2.6%
Nordnet Pensionsförsäkring	501,422	2.2%
Third AP Fund	475,000	2.1%
Avanza Pension	471,331	2.0%
Thomas Eklund	416,616	1.8%
Highclere International Investors LLP	364,798	1.6%
Christer Ahlberg	259,000	1.1%
Philip Earle	257,500	1.1%
Total top 15	**14,346,258**	**62.2%**
Other	8,700,482	37.8%
Total	**23,046,740**	**100.0%**

Source: Modular Finance

Shareholder distribution by size

	Number of shareholders	Number of shares	% capital	% share-holders
1–100	3,580	111,687	0.5%	66.5%
101–200	573	89,800	0.4%	10.6%
201–500	584	201,184	0.9%	10.9%
501–1000	265	204,589	0.9%	4.9%
1001–2000	142	215,001	0.9%	2.6%
2001–5000	100	335,501	1.5%	1.9%
5001–10000	39	280,007	1.2%	0.7%
10001–20000	31	453,233	2.0%	0.6%
20001–50000	15	467,048	2.0%	0.3%
50001–100000	22	1,696,526	7.4%	0.4%
100001–200000	10	1,575,326	6.8%	0.2%
200001–500000	11	3,412,984	14.8%	0.2%
500001–1000000	3	1,854,278	8.0%	0.1%
1000001–2000000	4	5,963,077	25.9%	0.1%
2000001 -	2	4,284,658	18.6%	0.0%
Anonymous ownership	N/A	1,901,841	8.3%	N/A
Total	**5,381**	**23,046,740**	**100%**	**100%**

Source: Modular Finance

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 142.23 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, e.g. 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, 89,085 warrants in the 2019/2022 series had been transferred to employees in the Group, the remaining 307,208 warrants having been cancelled at 30 September 2019. 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. The total purchase sum for the warrants transferred at the balance sheet date is SEK 1,746,138. A precondition for acquiring warrants under the Deborah framework for the 2019/2022 warrants 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 time of acquisition. If all the 2019/2022 series warrants that have been transferred to staff in the Group at the balance-sheet date are fully utilised, the company's share capital will increase by around SEK 8 909 through the issue of 89,085 shares in the company, equivalent to a dilution of approximately 0.4 percent based on the number of shares in the company at the balance sheet date.

Warrant programme 2017/2021

The annual general meeting held on 19 May 2017 resolved to establish a warrant-based incentive programme aimed at key individuals in Sedana Medical. A resolution was passed to issue a total of 310,149 warrants in the 2017/2021 series, all of which were subscribed to and allocated to the company's subsidiary Sedana Medical Incentive AB for onward transfer to participants in the incentive programme. A total of 310,149 warrants have been transferred to participants in the programme. All participants are senior executives of Sedana Medical. The warrants have been transferred on market terms. The transfer price has been calculated by an independent institute using the Black & Scholes model. Each warrant entitles the holder to subscribe to one share in Sedana Medical AB (publ) at a subscription price equivalent to 130 percent of the issue price in the IPO, which was SEK 19.50. The warrants may be exercised during the period from 15 May 2020 to 31 January 2021. The warrants are also subject to customary conditions for conversion in connection with share issues, etc. If all warrants transferred to participants in the incentive programme are exercised, the share capital of Sedana Medical AB (publ) will increase by around SEK 31,015 through the issue of 310 149 shares, equivalent to dilution of around 1.4 percent based on the number of shares in the company on the balance sheet date.

All warrants in the company's incentive programme 2017/21 were exercised by the warrant holders in May 2020, leading to an increase in the number of shares and votes in the company of 310,149. The share capital increased as a consequence of this by around SEK 31,015. The incentive programme was equivalent to a dilution effect of approximately 1.35 percent. Sedana Medical was supplied with issue proceeds of around SEK 7.86 million. The CEO, CFO and CMO of Sedana Medical increased their shareholding in the company through the exercise of warrants.

Facts about Sedana Medical shares

Listing	Nasdaq First North Growth Market Stockholm
Number of shares *	23,046,740
Market capitalisation, MSEK *	7,905
Ticker	SEDANA
ISIN	SE0009947534
LEI-code	549300FQ3NJRI56LCX32

* At 31 Dec. 2020

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 2020.

The business in brief

Sedana Medical is a Swedish medical devices group on the way to also becoming a medicinal products company. The Group's operations comprise the development, manufacture and sales of medical devices and the development of devices and pharmaceutical products based on, or which have synergies with, AnaConDa technology. The technology enables the simple, safe conversion of a liquid to a gas (evaporation) and the reuse (reflection) of volatile anaesthetics for use in anaesthesia and intensive care. The Group's product portfolio currently includes AnaConDa with accessories and in the near future Sedaconda, the Group's candidate drug based on the well-known substance isoflurane.

Volatile anaesthetics have long been used to anaesthetise patients in connection with surgery. Complex, capital-intensive anaesthesia machines that require specially trained personnel are used for this purpose. Traditional anaesthesia machines lack several vital properties which mean that they cannot be routinely used in an intensive care unit. Sedana Medical's device AnaConDa, which in very simple terms can be regarded as an anaesthesia machine in miniature, is a solution that makes it practically and financially possible to use volatile anaesthetics to sedate mechanically ventilated intensive care patients. The market for the sedation of mechanically ventilated intensive care patients today consists of established drugs that are administered intravenously. Sedation through the inhalation of volatile anaesthetics has shown itself in many ways to be a safer, more effective solution for sedating intensive care patients than present-day intravenous sedation. Despite the fact that Sedana Medical does not yet have market authorisation for Sedaconda, the Group has shown rising net sales for several years through sale of its CE-marked device AnaConDa.

Sedana Medical's vision is to develop inhaled sedation, using Sedaconda and AnaConDa, into the global standard sedation method for mechanically ventilated patients in intensive care. To achieve this vision, the Group has been conducting a clinical phase 3 registration study since autumn 2016 aimed at gaining approval for the medicinal product Sedaconda and inhaled sedation therapy using AnaConDa. If all goes well, Sedana Medical anticipates obtaining European market approval in the second half of 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. Until 31 August 2019, the German business was run by a branch office of the Parent Company. With effect from 1 September 2019, the branch office became a wholly owned subsidiary. In Spain, sales operations are run by a branch office of the Parent Company. Germany is by far the Group's largest market, with over 80 percent of total sales. As well as in Germany and Spain, direct selling takes place in France, Norway, the UK and the Netherlands through whollyowned 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 AnaConDa devices 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: (ticker: SEDANA) were listed on Nasdaq First North Growth Market , Stockholm, Sweden.

Significant events during the year

1st Quarter

- AnaConDa and accessories were donated to two hospitals in China (Wuhan and Zhejiang) at the time of the outbreak of the COVID-19 pandemic.

2nd Quarter

- At the beginning of April, the company announced a significantly higher rate of growth for the first quarter of 2020 than expected. Revenue for the first quarter of 2020 was SEK 34 million, equivalent to growth of around 90 percent compared with the same period of the previous year.
- Sedana Medical announced at the beginning of May that the company would provide financial support to a multinational study of inhaled sedation in COVID-19-related ARDS. The study (ISCA) is being carried out in intensive care units in several European countries.
- In May, the first patient was included in SESAR, a study comparing inhaled sedation and intravenous sedation for patients with acute respiratory distress syndrome (ARDS). The study is being run in France, and Sedana Medical is contributing financial support and study materials.
- At the 2020 Annual General Meeting of Sedana Medical, all the proposals from the Board and the Nomination Committee were approved. For the period until the next Annual General Meeting, the current Board members were re-elected and Christoffer Rosenblad was newly elected. The Annual General Meeting resolved to elect Öhrlings PricewaterhouseCoopers AB as auditors for the period until the end of the next Annual General Meeting, with the authorised public accountant Leonard Daun as auditor in charge.
- All warrants in the company's incentive programme 2017/2021 were exercised by the warrant holders, leading to an increase in the number of shares and votes in the company of 310,149.
- Sedana Medical announced in June that the company had signed agreements with distributors in Bulgaria, Cyprus, the Czech Republic, Greece and Slovakia. By expanding into Eastern Europe, the company aims to bolster its position ahead of the forthcoming market launch of its therapy.

3rd Quarter

- Market approval was obtained in Saudi Arabia for the medical device AnaConDa, and distribution agreements were concluded with distributors in Saudi Arabia, the United Arab Emirates and Oman. Sales are expected to begin shortly in Saudi Arabia and within a few months in the other countries.
- On 10 July, Sedana Medical announced top-line results for the company's pivotal phase 3 study for the medicinal product Sedaconda. The study reached its primary endpoint; to show that Sedaconda (isoflurane), delivered by AnaConDa, is an effective method of sedation therapy for mechanically ventilated intensive care patients, and non-inferior to propofol.
- Distribution agreements for sale in Australia and New Zealand were signed with the distributor Device Technologies. As AnaConDa already has marketing authorisation in both markets, sales can start immediately.

4th Quarter

- Susanne Andersson was appointed as the new CFO to take up duties during the first quarter of 2021. She succeeds Maria Engström, who chose to leave the position of CFO on her own initiative.
- The National Institute for Health and Care Excellence (NICE) in the United Kingdom issued a Medtech Innovation Briefing (MIB) on the use of AnaConDa as an alternative to intravenous sedation in intensive care.
- The Chairman of the Board contacted the three largest shareholders or shareholder groups in terms of voting power to invite each of them to appoint a representative to make up a nominations committee along with the Chairman of the Board.
- Sedana Medical was granted a further patent for the medical device AnaConDa. The technique protected by the patent enables what is known as dead space to be reduced, using inlay material.
- An application for marketing authorisation was submitted for the candidate drug Sedaconda (isoflurane), previously known as IsoConDa, for inhaled sedation in intensive care. Applications were submitted to the German regulatory authority BfArM (Federal Institute for Drugs and Medical Devices) and a number of other European regulatory authorities under the DCP procedure.
- The results for some of the secondary endpoints in the company's pivotal study, Sedaconda (SED-001, previously known as the IsoConDa study), were presented at the ongoing congress ESICM LIVES 2020, 6–9 December 2020.

Significant events after the end of the period

- In January, an application was submitted for market approval for the candidate drug Sedaconda (isoflurane), previously known as IsoConDa, for inhaled sedation in intensive care in Switzerland.
- As a consequence of the resolution by the Annual General Meeting held on 19 May 2020 to implement a new 2020/2024 warrant programme with a maximum of 360,000 warrants for new employees, 37,113 have been transferred to employees. Surplus warrants will be cancelled. If all the warrants are exercised, dilution of around 0.2 percent will occur, based on the number of shares in the company at 31 December 2020.
- In February, an application was submitted for market approval for the candidate drug Sedaconda (isoflurane) for inhaled sedation in intensive care in the United Kingdom.
- In February, it was announced that the first patient had been included in the company's paediatric study IsoCOMFORT (SED002). The study is expected to be completed during the second half of 2022 and is intended to lead to an approved paediatric indication for inhaled sedation.
- The Board has decided to propose to the Annual General Meeting that the company carry out a 4:1 share split, which means that the number of shares increases fourfold to 92,186,960.
- On 24 February, it was announced that Christer Ahlberg had informed the Board of Sedana Medical of his decision to step down as CEO to become CEO of Cinclus Pharma AB. Christer Ahlberg will remain as CEO until the summer of 2021, and the Board has initiated a process to find a successor.

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 patient lives during and after sedation.

Vision

That inhaled sedation should be standard therapy for patients in intensive care.

Financial targets

The company's target, until market approval of the medicinal product Sedaconda (isoflurane) has been obtained, is to increase sales by an average of more than 20 percent per year while building up a larger medical, sales and marketing organisation. The target is to achieve revenue in excess of SEK 500 million and an EBITDA margin of 40 percent three years after registration in Europe.

Strategy

The company has created, and abides by, a strategy that can be summarised by the following three points:

1. Have AnaConDa approved in as many markets as possible.
2. Have the medicinal product Sedaconda and inhaled sedation therapy approved, in a first stage in the EU and later in more markets. In the United States we intend to register Sedaconda and AnaConDa as a combination therapy.
3. Secure medical evidence leading to inhaled sedation gradually becoming a new standard therapy throughout the world.

Effects of the COVID19 pandemic

The outbreak of COVID-19 was declared a pandemic by WHO on 11 March 2020. In the situation that has arisen, Sedana Medical is prioritising the health and safety of its staff and taking measures to limit spread of the virus in accordance with instructions from authorities. The pandemic has led to

increased demand for the company's devices from intensive care units around the world. The reason is that drugs that are delivered by AnaConDa, isoflurane or sevoflurane, have lung protective effects which become especially important and useful for patients with breathing problems caused by severe viral infection in COVID-19. Sedana Medical is taking active steps to mitigate any effects of disruptions in the production and logistics chain by working closely with subcontractors and logistics partners. Sedana Medical saw a very positive trend in sales in 2020, partly as a consequence of the COVID-19 pandemic, as our therapy potentially leads to fewer side effects and better oxygen uptake in the lungs. 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 inclination and ability of clinical facilities to use new sedation therapies during a time of crisis to a possible shortage of, or reduced access to, intravenous sedatives in a possible third wave of the COVID-19 pandemic and mutated viruses and future availability of vaccines.

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 medicinal products

Sedana Medical's device AnaConDa with accessories and the forthcoming medicinal product Sedaconda is subject to extensive regulation worldwide and is 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 AnaConDa and accessories, either in combination with Sedaconda 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. In February 2021, Sedana Medical conducted an audit of the British Standards Institution, which is the company's certification body. This is in order to be certified under the new Medical Device Regulation (MDR). However, this renewal process can be time-consuming, especially when the original application is extended to include new therapeutic areas or otherwise undergoes significant changes. 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

During the fourth quarter of 2016, Sedana Medical initiated clinical studies as the basis for registration in respect of its candidate drug Sedaconda (isoflurane) for use in the area of inhaled sedation therapy in intensive care. Completion of the study is crucial in order for the company to market its medical device AnaConDa together with Sedaconda 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 from the clinical studies in progress 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 third-party agreements regarding the performance of clinical studies and manufacturing

Sedana Medical engages external companies such as contract research organisations 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 doctors, 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 competition

Sedana Medical's inhaled sedation devices for intensive care patients are primarily exposed to competition from sedatives for intravenous therapy. Intravenous sedation is a well-established therapy method and the standard treatment 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 treatment, 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 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

Today, Sedana Medical focuses mainly on sales of AnaConDa, and conducting a clinical phase 3 study of the candidate drug Sedaconda with the aim of obtaining marketing authorisation for the product for use together with AnaConDa and its accessories. 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 phase 3 study.

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 old version of the AnaConDa device with 100 ml dead space have expired or will expire shortly. Sedana Medical has submitted a number of patent applications related to the new AnaConDa technology with halved dead space, which ensures that a competitor or other company cannot develop the old version of AnaConDa 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. 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 medicinal 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 2020

Net sales

Group net revenue for the full year 2020 totalled KSEK 141,770 (71,646), an increase of KSEK 70,124 or 98 percent. The equivalent increase excluding currency effects was 100 percent. The increase is due to the large increase in sales that has taken place in connection with the COVID-19 pandemic.

Cost of goods sold

The cost of goods for resale totalled KSEK 52,867 (24,879), representing an increase of 112 percent. The increase is due to sales growth, product mix and the fact that the company has had higher transport costs due to the COVID-19 situation.

Selling expenses

Selling expenses for the whole year were KSEK 65,124 (37,326), representing an increase of 74 percent. The reason for the increase compared with the previous year is the continued build-up of the commercial organisation and medical affairs ahead of the launch of Sedaconda.

Administrative expenses

Administrative expenses in the Group totalled KSEK 37,296 (18,989), representing an increase of 96 percent. The increase is a result of the general growth in the company and expansion of office premises and associated equipment, as well as purchased services.

Financial summary 2020

Summary consolidated figures

KSEK unless otherwise stated	2020	2019	2018*	2017*	2016*
Net sales	141,770	71,646	57,896	40,428	32,155
Gross profit	88,903	46,767	42,897	29,662	21,346
Gross margin %	63%	65%	74%	73%	66%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-14,294	-12,932	-4,232	-736	994
EBITDA %	-10%	-18%	-7%	-2%	3%
Earnings before interest and taxes (EBIT)	-21,359	-17,120	-8,238	-3,488	618
Operating margin (EBIT) %	-15%	-24%	-14%	-9%	2%
Net profit	-27,139	-16,380	-6,869	-3,876	1,286
Profit margin %	-19%	-23%	-12%	-10%	4%
Balance sheet total	600,097	595,766	231,550	131,376	23,624
Equity ratio %	92%	96%	94%	89%	5%
Quick ratio %	929%	1872%	1220%	640%	80%
Average number of employees	64	39	26	17	16

Summary parent company figures

KSEK unless otherwise stated	2020	2019	2018*	2017*	2016*
Net sales	121,238	46,213	55,856	31,495	27,940
Gross profit	82,531	15,591	21,126	13,339	12,105
Gross margin %	68%	34%	38%	42%	43%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	-26,608	-14,773	-4,888	1,346	6,088
EBITDA %	-22%	-32%	-9%	4%	22%
Earnings before interest and taxes (EBIT)	-27,577	-16,051	-6,431	1,277	5,958
Operating margin (EBIT) %	-23%	-36%	-12%	4%	21%
Net profit	-28,767	-14,800	-3,755	1,659	6,179
Profit margin %	-24%	-33%	-7%	5%	22%
Balance sheet total	603,470	615,476	257,060	38,329	31,231
Equity ratio %	93%	95%	89%	24%	58%
Quick ratio %	941%	1444%	631%	60%	252%
Average number of employees	22.9	23.6	17.0	8.7	7.4

*Accounting according to previous K3 rules.

Research and development expenses
For the whole year of 2020, research and development expenses were KSEK 7,859 (7,347), an increase of 7 percent. Sedana Medical capitalises all development expenses in the balance sheet under intangible assets and has few expenses recognised as research.

Operating income
Group operating income for the full year was KSEK -21,359 (-17,120, a decline in income of 25 percent. The decline is explained by build-up of the organisation and preparations for the launch of Sedaconda.

Net financial items
Net financial items totalled KSEK -2,745 (149), which is explained by unrealised exchange losses.

Taxes
The Group reported a tax expense of KSEK -3,035 for 2020. Tax income of KSEK 591 was reported for the corresponding period of the previous year. The tax income for 2019 is explained by changes in deferred tax.

Net profit/loss for the year
The Group reported net income of KSEK -27,139 (-16,380) for the year. The decline in earnings compared to the previous year is due mainly to lower operating income.

Equity and liabilities
Group equity at 31 December 2020 totalled KSEK 551,094, compared with KSEK 569,358 at the start of the year, a decrease of KSEK 18,264. During 2020, all warrants in the 2017/2021 warrant programme were converted into shares. A new warrant programme, 2020/2023, was resolved upon at the Annual General Meeting in May and was launched the same month. After deduction of expenses, the company received new capital totalling KSEK 8,251 during the period as a result of these activities. Issuing expenses totalled KSEK 125 and have been recognised in equity.

Cash and cash equivalents and cash flow
Cash and cash equivalents at the end of the period totalled KSEK 376,171 (464,560), a decrease of KSEK 88,389 compared with the start of the year. Cash flow from operating activities before change in working capital was KSEK -8,279 (-9,592). Cash flow from operating activities including change in working capital was KSEK -7,846 (-7,174). The change in working capital compared with the same period for the previous year is primarily due to an improvement in cash flow from operating receivables. Cash flow from investments was SEK -84,619 thousand (-54,132) comprising mainly intangible assets of which the major part concerns capitalised development expenses, mostly made up of expenses for the clinical study Sedaconda EU (SED001). Cash flow from financing activities showed a net sum of KSEK 5,787 (366,518) and is principally due to the new share issue which took place in May 2020 when all the warrants in the 2017/2021 programme were converted to shares (KSEK 7,737 including costs). Cash flow for the period additionally relates to premiums paid for warrants in a new 2020/2023 programme (KSEK 515) and repayment of lease liabilities.

Investments
Investments during the 2020 financial year totalled KSEK 84,619 (54,132). Investments during 2020 primarily relate to:
- Capitalised expenses for development work, KSEK 71,676
- Internal expenses for the preparation of patents, KSEK 336
- Purchase of plant and machinery, KSEK 11,122
- Purchase of fixtures, fittings and tools, KSEK 1,000.

Parent Company
Sedana Medical AB (publ), corporate identity number 556670–2519, is the Parent Company of the Group. Its operations consist of clinical development, sales and administrative and management functions. The Parent Company includes a branch office in Spain where operations consist of sale of devices. Until 31 August 2019, the Parent Company had a branch office in Germany. With effect from 1 September 2019, the German branch office's operations were transferred to a wholly-owned German subsidiary, and no longer constitute part of the Parent Company. The Parent Company's net sales for the full year totalled KSEK 121,238 (46,213). The increase in net sales is principally due to the increase in sales resulting from the COVID-19 pandemic, but is also due to intra-Group restructuring which has taken place. Operating income was KSEK -27,577 (-16,051), representing a decrease of KSEK 11,526. Net financial income/expense in 2020 was KSEK 1,181 (1,263). Net income for the year was KSEK -28,767 (-14,800). At 31 December 2020, equity in the Parent Company, Sedana Medical AB (publ), totalled KSEK 561,600 (581,915).

Share capital totalled KSEK 2,305 thousand (2,274), equivalent to an increase of KSEK 31. The increase is due to conversion of all warrants in the 2017/2021 programme to shares. The company now has a total 23,046,740 issued shares as of 31 December 2020. At year-end 2020, there are also 99,705 outstanding warrants in two different warrant programmes, 2019/2022 and 2020/2023. Cash and cash equivalents totalled KSEK 365,113 (455,206).

Organisation and Personnel

Employees
At the end of 2020, Sedana Medical had 65 employees. Of these, 34 employees were men and 21 were women. The corresponding figures at the end of 2019 were 41 employees, of whom 22 were men, and 19 women.

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 2020/2024, mainly for new staff. The company therefore issued at the AGM 360,000 warrants, all of which have been subscribed to by the company's subsidiary Sedana Medical Incentive AB. Each warrant entitles the holder to subscribe to one share in the period 1 February to 31 May 2024, at a subscription price of SEK 495.52, equivalent to 140 percent of the volume-weighted average price paid for Sedana Medical shares over the period 1–30 January 2021. A total of 37,113 warrants were transferred to staff in February 2021. Transfers took place against payment of the estimated market value of the warrants calculated according to the Black & Sholes valuation model by an external valuer. The surplus 322,887 warrants will be cancelled. If all the warrants are exercised, 37,113 new shares will be issued, which is equivalent to a dilution of around 0.2 percent based on the number of shares in the company at 31 December 2020.

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 AGM 325,000 warrants in the 2020/2023 series, 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 November 2023 at a subscription price of SEK 334.60 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, 10 620 warrants in the 2020/2023 series had been submitted to staff in the Group, the remaining 314 380 warrants being in the process of being cancelled. 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. The total purchase sum for the warrants transferred at the balance sheet date is SEK 514,539. A precondition 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 1,062 through the issue of 10,620 shares in the company, equivalent to a dilution of approximately 0.05 percent based on the number of shares in the company at the balance sheet date.

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) of 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 142.23 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, e.g. 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, 89,085 warrants in the 2019/2022 series had been transferred to employees in the Group, the remaining 307,208 warrants having been cancelled at 30 September 2019. 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.

The total purchase sum for the warrants transferred at the balance sheet date is SEK 1,746,138. A precondition for acquiring warrants under the Deborah framework for 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 8 909 through the issue of 89,085 shares in the company, equivalent to a dilution of approximately 0.4 percent based on the number of shares in the company at the balance sheet date.

Warrant programme 2017/2021

The annual general meeting held on 19 May 2017 resolved to establish a warrant-based incentive programme aimed at key individuals in Sedana Medical. A resolution was passed to issue a total of 310,149 warrants in the 2017/2021 series, all of which were subscribed to and allocated to the company's subsidiary Sedana Medical Incentive AB for onward transfer to participants in the incentive programme. A total of 310,149 warrants have been transferred to participants in the programme. All participants are senior executives of Sedana Medical. The warrants have been transferred on market terms. The transfer price has been calculated by an independent institute using the Black & Scholes model. Each warrant entitles the holder to subscribe to one share in Sedana Medical AB (publ) at a subscription price equivalent to 130 percent of the issue price in the IPO, which was SEK 19.50. The warrants may be exercised during the period from 15 May 2020 to 31 January 2021. The warrants are also subject to customary conditions for conversion in connection with share issues, etc. If all warrants transferred to participants in the incentive programme are fully exercised, the share capital of Sedana Medical AB (publ) will increase by around SEK 31,015 through the issue of 310,149 shares. At the end of the period, all the warrants had been converted to shares. No warrants in the 2017/2021 programme thus remain, and the programme has been closed.

Proposed appropriation of earnings

The Board of Directors proposes that no dividend is to be paid for the financial year 2020. 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	613 922 552
Accumulated loss	-180 265 514
Net profit/loss for the year	-28 766 942
Total non-restricted reserves	**404 890 096**

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

SEK	
Share premium reserve	613,922,552
Accumulated loss	-209,032,456
Total non-restricted reserves	**404,890,096**

FINANCIAL INFORMATION

Consolidated income statement

		Full year	
KSEK	Note	2020	2019
Net sales	4	141,770	71,646
Cost of goods sold	7	-52,867	-24,879
Gross profit		**88,903**	**46,767**
Selling expenses		-65,123	-37,326
Administrative expenses		-37,296	-18,989
Research and development expenses		-7,859	-7,347
Other operating income	8	2,805	2,092
Other operating expense	9	-2,789	-2,317
Operating profit (EBIT)	5.6.7	**-21,359**	**-17,120**
Financial items			
Financial income		529	2,456
Financial expense		-3,274	-2,307
Net financial items	10	**-2,745**	**149**
Earnings before tax		**-24,104**	**-16,971**
Taxes	11	-3,035	591
Profit or loss for the period		**-27,139**	**-16,380**
Earnings per share, calculated on earnings attributable to shareholders in the Parent Company:	12		
Basic		-1.19	-0.78
Diluted		-1.19	-0.78
EBITDA		-14,294	-12,932
Amortisation of intangible assets		-1,756	-1,772
Depreciation of property, plant and equipment		-5,309	-2,417
Operating profit (EBIT)		-21,359	-17,120

Consolidated statement of comprehensive income

		Full year	
KSEK	Note	2020	2019
Profit or loss for the period		**-27,139**	**-16,380**
Other comprehensive income			
Items that may be reclassified later to the income statement:			
Translation differences from operations abroad		624	-117
Other comprehensive income, net after tax		624	-117
Total comprehensive income		-26,515	-16,497
Total comprehensive wholly attributable to shareholders in the Parent Company		**-26,515**	**-16,497**

Consolidated balance sheet

(KSEK)	Note	31 Dec 2020	31 Dec 2019	1 Jan 2019
ASSETS				
Intangible assets				
Capitalised development expenditure	13	166,378	95,487	46,161
Concessions, patents, licenses, etc.	14	2,998	4,160	5,243
Property, plant and equipment				
Plant and machinery	15	5,711	4,385	4,129
Equipment, tools, fixtures and fittings	16	1,213	489	580
Right-of-use assets	24	8,792	2,773	2,439
Financial assets				
Deferred tax assets	17	45	2,211	1,591
Other non-current receivables		41	0	0
Total non-current assets		**185,178**	**109,505**	**60,143**
Inventories	18	9,087	7,378	6,295
Tax receivables		453	6	349
Accounts receivable	19	19,484	6,467	4,985
Prepaid expenses and accrued income	20	5,609	4,347	1,406
Other receivables		4,115	3,503	1,294
Cash and cash equivalents	21	376,171	464,560	159,351
Total current assets		**414,919**	**486,261**	**173,680**
TOTAL ASSETS		**600,097**	**595,766**	**233,823**

(KSEK)	Note	31 Dec 2020	31 Dec 2019	1 Jan 2019
EQUITY AND LIABILITIES				
Equity	22.23			
Share capital		2,305	2,274	1,916
Other capital provided		613,923	605,702	238,016
Translation reserve		506	-117	0
Retained earnings including profit or loss for the period		-65,640	-38,501	-22,121
Equity attributable to shareholders in the Parent Company		**551,094**	**569,358**	**217,811**
Non-current liabilities				
Non-current leasing liabilities	24.27	5,324	828	1,102
Total non-current liabilities		**5,324**	**828**	**1,102**
Current liabilities				
Current leasing liabilities	24.27	2,967	1,709	1,171
Accounts payable		16,371	11,004	4,430
Tax liabilities		2,718	1,254	487
Other liabilities	25	7,668	3,346	1,864
Accrued expenses and prepaid income	26	13,955	8,267	6,958
Total current liabilities		**43,679**	**25,580**	**14,910**
Total liabilities		49,003	26,408	16,012
TOTAL EQUITY AND LIABILITIES		**600,097**	**595,766**	**233,823**

Consolidated statement of changes in equity

Equity attributable to shareholders in the Parent Company

KSEK	Share capital	Other capital provided	Translation reserve	Retained earnings including profit or loss for the year	Total
Opening equity at 1 Jan 2019	**1,916**	**238,016**	**-**	**-22,121**	**217,811**
Net profit/loss for the year	-	-	-	-16,380	-16,380
Other comprehensive income for the year	-	-	-117	-	-117
Comprehensive income for the year	-	-	-117	-16,380	-16,497
Transactions with shareholders in the Group					
New share issue	358	376,384	-	-	376,742
Issue expenses	-	-10,115	-	-	-10,115
Premium received on issue of warrants	-	1,746	-	-	1,746
Expenses for warrant programme	-	-329	-	-	-329
Total transactions with shareholders in the Group	358	367,686	-	-	368,044
Closing equity at 31 Dec 2019	**2,274**	**605,702**	**-117**	**-38,501**	**569,358**
Opening equity at 1 Jan 2020	**2,274**	**605,702**	**-117**	**-38,501**	**569,358**
Net profit/loss for the year	-	-	-	-27,139	-27,139
Other comprehensive income for the year	-	-	623	-	623
Comprehensive income for the year	-	-	623	-27,139	-26,516
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	-	-58	-	-	-58
Total transactions with shareholders in the Group	31	8,220	-	-	8,251
Closing equity at 31 Dec 2020	**2,305**	**613,923**	**506**	**-65,640**	**551,094**

Consolidated cash flow statement

		Full year	
(KSEK)	Note	2020	2019
Operating activities			
Operating profit		-21 360	-17 120
Adjustment of non-cash items:			
Depreciation and write-downs		14,476	7,068
Exchange-rate differences		-362	282
Total		**-7,246**	**-9,770**
Interest received		25	3
Interest paid		-189	-82
Income tax paid		-869	257
Cash flow from operating activities before changes in working capital		**-8,279**	**-9,592**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in inventories		-1,158	-1,077
Increase (-)/Decrease (+) in operating receivables		-15,292	-6,663
Increase (+)/Decrease (-) in operating liabilities		16,883	10,157
Cash flow from operating activities		**-7,846**	**-7,174**
Investing activities			
Investment in intangible assets	13,14	-72,175	-49,839
Investment in property, plant and equipment	15,16	-12,444	-4,293
Cash flow from investing activities		**-84,619**	**-54,132**
Financing activities			
New share issue	23	7,862	376,742
Issue expenses	23	-68	-10,115
Repayment of lease liabilities	24,27	-2,464	-1,525
Premium received for warrant subscription	23	515	1,746
Expenses for warrant programme	23	-58	-330
Cash flow from financing activities		**5,787**	**366,518**
Cash flow for the period		**-86,678**	**305,212**
Cash and cash equivalents at the beginning of the period		464,560	159,351
Translation difference in cash and cash equivalents		-1,711	-3
Cash and cash equivalents at the end of the period	**21**	**376,171**	**464,560**

NOTES

Accounting policies

Sedana Medical AB (publ) and the Group apply IFRS with a transition date of 1 January 2019. The first external reporting in accordance with IFRS is the Year-End Report and Annual Report for 2020

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. 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.

This annual report is the first report of Sedana Medical (publ) to be prepared in accordance with IFRS. The consolidated financial statements have been prepared in accordance with the cost method. Historical financial information has been restated from 1 January 2019, which is the date of transition to accounting in accordance with IFRS. Explanations for the transition from previously applied accounting policies to IFRS and what effects the restatement has had on statements of comprehensive income and equity are presented in Note 32.

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
A number of new standards and interpretations enter into force for financial years commencing after 1 January 2020 and later and have not been applied in this preparation of these financial statements. 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 follows up the business as a unit (a concept), the whole of the business is comprised of a single segment.

Translation of foreign currency

Functional currency and presentation currency
The Parent Company's functional currency is Swedish kronor (SEK), which is also the reporting 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 reporting 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 AnaConDa 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 grants
Government grants are 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 amounts. 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 amortised cost 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 units	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 amortised cost 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. As the Group publishes its consolidated financial statements and the chosen accounting policy for this is IFRS, the Parent Company is changing its accounting policy from applying K3 to RFR 2 'Financial Reporting for Legal Entities' as of 1 January 2019, which is the date of transition to IFRS. For detailed information regarding the transition of the Parent Company to RFR 2, see Note 29. 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, 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. See also Group Note 11 regarding loss carry-forwards.

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	2020	2019
Sweden (Group domicile)	1,477	97
Germany (major market)	103,063	61,599
Other markets	37,230	9,950
Total	**141,770**	**71,646**

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

KSEK	2020	2019
Direct sale markets	125,272	66,133
Distribution markets	16,498	5,513
Total	**141,770**	**71,646**

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

KSEK	2020	2019
Sweden (Group domicile)	168,474	90,518
Ireland	15,174	13,453
Rest of the world*	1,443	3,323
Total	**185,091**	**107,294**

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

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

NOTE 5 Employees, personnel expenses and remuneration of senior executives

Average number of employees

	2020			2019		
	Total	Women	Men	Total	Women	Men
Parent Company						
Sweden	20.9	12.6	8.3	15.3	8.2	7.1
Germany	–	–	–	6.9	2.2	4.7
Spain	2.0	–	2.0	1.4	0.5	0.9
Total Parent Company	**22.9**	**12.6**	**10.3**	**23.6**	**10.9**	**12.7**
Group						
Ireland	6.9	2.0	4.9	7.3	1.8	5.6
France	4.2	1.2	3.0	2.9	0.1	2.8
Netherlands	2.0	–	2.0	–	–	–
Norway	2.0	1.0	1.0	1.7	1.0	0.7
United Kingdom	2.7	0.7	2.0	–	–	–
Germany	14.0	6.0	8.0	3.1	1.3	1.8
Group total	**54.6**	**23.4**	**31.2**	**38.6**	**15.1**	**23.6**
Senior executives, at year-end						
Board of Directors	6	1	5	5	1	4
CEO and senior executives	5	2	3	5	1	4

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 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	117	–	–	–	117
CEO Christer Ahlberg	1,890	190	108	448	2,636
Other senior executives (5 individuals)	7,122	402	203	1,285	9,012
Total	**9,904**	**592**	**311**	**1,732**	**12,540**
Salaries and other remuneration 2019					
Chairman of the Board Thomas Eklund	292	–	–	–	292
Board member Sten Gibeck	50	–	–	–	50
Board member Bengt Julander	50	–	–	–	50
Board member Ola Magnusson	50	–	–	–	50
Board member Michael Ryan	530	–	–	–	530
Board member Eva Walde	100	–	–	–	100
CEO Christer Ahlberg	1,535	167	112	373	2,187
Other senior executives (4 individuals)	5,843	–	161	724	6,728
Total	**8,449**	**167**	**272**	**1,097**	**9,986**

Salaries and other remuneration and social security expenses

	2020				2019			
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	10,807	(592)	4,829	(1,732)	8,889	(167)	3,184	(1,097)
Other employees	43,702	(2,259)	12,427	(5,207)	27,512	–	7,581	(3,331)
Total	**54,509**	**(2,851)**	**17,255**	**(6,939)**	**36,400**	**(167)**	**10,764**	**(4,428)**

KSEK	2020	2019
Salaries and other remuneration	54,509	36,400
Social security contributions	10,317	6,336
Pension expenses – defined-contribution plans	6,939	4,428
Total employee benefits	**71,764**	**47,165**

For further information about warrants, see Note 23.

For information on guidelines for remuneration of senior executives, see the section on corporate governance, pages 90–92.

NOTE 6 Fee and reimbursement of expenses paid to auditors

KSEK	2020	2019
PwC*		
Audit engagement	478	0
Tax advice	0	0
Other services	436	0
Total	**914**	**0**
R3 Revisionsbyrå KB*		
Audit engagement	126	220
Tax advice	0	0
Other services	0	24
Total	**126**	**244**
Other auditors		
Audit engagement	455	334
Tax advice	0	159
Other services	0	0
Total	**455**	**493**
Total	**1,495**	**737**

*PwC became the new auditors at the 2020 AGM.

NOTE 7 Operating expenses broken down by type of cost

KSEK	2020	2019
Goods for resale	45,914	19,232
Other external expenses	49,991	27,076
Personnel expenses	60,176	38,045
Depreciation	7,065	4,188
Total	**163,145**	**88,541**

NOTE 8 Other operating income

KSEK	2020	2019
Exchange gains on operating receivables/liabilities	2,805	1,788
Other	0	304
Total	**2,805**	**2,092**

NOTE 9 Other operating expenses

KSEK	2020	2019
Exchange losses on operating receivables/liabilities	2,623	2,229
Other	166	88
Total	**2,789**	**2,317**

NOTE 10 Net financial items

KSEK	2020	2019
Exchange gains	529	2,456
Total financial income	**529**	**2,456**
Interest expense, other	-189	-82
Exchange losses	-3,084	-2,225
Total financial expense	-3,274	-2,307
Net financial income/expense	**-2,745**	**149**

NOTE 11 Taxes

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

KSEK	2020	2019
Tax expense/tax income for the year	-1,019	-20
Adjustment of tax attributable to previous years	150	-8
Total current tax	**-869**	**-28**
Deferred tax		
Change in deferred tax	-2,166	620
Total deferred tax	**-2,166**	**620**
Total recognised tax expense/tax income	**-3,035**	**592**

Reconciliation of recognised tax

KSEK	2020	2019
Earnings before tax	-24,104	-16,971
Tax at current tax rate for Parent Company	5,158	3,632
Tax effect of:		
- non-deductible expenses	-99	-114
- non-taxable income	0	34
- other tax rates for foreign subsidiaries/ branches	-1,495	323
- increase in loss carry-forwards without corresponding capitalisation of deferred tax	-7,023	-3,770
- utilisation of previously non-capitalised loss carry-forwards	234	0
tax relating to previous years	150	-8
- other	40	494
Recognised effective tax	**-3,035**	**591**
Average effective tax rate (%)	12.6%	-3.5%

The Group has tax loss carry-forwards of KSEK 91,090 (KSEK 58,274). There is no maturity for any of the loss carry-forwards.

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 2019 or 2020 as conversion to ordinary shares means a lower loss per share.]

Income measure used in the calculation of earnings per share

	Basic		Diluted	
KSEK	2020	2019	2020	2019
Profit attributable to shareholders in the Parent Company:				
Earnings per share, basic and diluted	-1.19	-0.78	-1.19	-0.78
Total	**-1.20**	**-0.78**	**-1.20**	**-0.78**

Weighted average number of ordinary shares

Number	2020	2019
Weighted average number of ordinary shares in calculation of basic earnings per share	22,891,666	20,946,591
Adjustment for calculation of diluted earnings per share:		
Warrants	249,470	994,149
Weighted average number of ordinary shares and potential ordinary shares used as denominator in calculation of diluted earnings per share	**23,141,135**	**21,940,740**

NOTE 13 Capitalised expenditure on development work and similar work

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accrued acquisition values:			
- At start of year	96,528	46,825	21,010
- Acquisitions	71,676	49,591	24,455
- Translation differences for the year	-470	113	1,360
- At the end of the year	**167,734**	**96,528**	**46,825**
Accumulated depreciation according to plan:			
- At start of year	-1,042	-663	-288
- Depreciation for the year	-370	-374	-362
- Translation differences for the year	56	-5	-13
- At the end of the year	**-1,356**	**-1,042**	**-663**
Carrying amount at the end of the year	**166,378**	**95,487**	**46,162**
Carrying amount above relates to:			
Development work within the medical sector	164,522	95,487	46,162
Other capitalised development expenses	1,856	-	-

The income statement includes depreciation as above wholly under research and development expenses. Total expenditure on research and development expensed during the period amounts to KSEK 7,859 (7,347).

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

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accrued acquisition values:			
- At start of year	7,719	7,387	6,502
- Acquisitions	336	176	647
- Translation differences for the year	-307	156	238
- At the end of the year	**7,748**	**7,719**	**7,387**
Accumulated depreciation according to plan:			
- At start of year	-3,559	-2,144	-759
- Depreciation for the year	-1,386	-1,398	-1,350
- Translation differences for the year	195	-16	-35
- At the end of the year	**-4,750**	**-3,559**	**-2,144**
Carrying amount at the end of the year	**2,998**	**4,161**	**5,243**

The income statement includes amortisation as above wholly under Administrative expenses.

NOTE 15 Plant and machinery

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accrued acquisition values:			
- At start of year	11,815	10,349	5,068
- Acquisitions	11,122	3,729	3,675
- Reclassifications	-2,357	74	1,351
- Disposals	-9,712	-2,392	-
- Translation differences for the year	-174	56	255
- At the end of the year	**10,694**	**11,815**	**10,349**
Accumulated depreciation according to plan:			
- At start of year	-6,080	-3,744	-1,524
- Reclassifications	1,006	-1,048	-
- Depreciation for the year	-2,806	-2,290	-2,185
- Disposals	2,774	1,022	-
- Translation differences for the year	123	-20	-35
- At the end of the year	**-4,983**	**-6,080**	**-3,744**
Carrying amount at the end of the year			
Accumulated impairments:			
- At start of year	-1,350	-2,476	-719
- Reclassifications	1,350	1,106	29
- Disposals	-	-	-1,752
- Translation differences for the year	-	20	-34
- At the end of the year	**-**	**-1,350**	**-2,476**
Carrying amount at the end of the year	**5,711**	**4,385**	**4,129**

NOTE 16 Equipment, tools, fixtures and fittings

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accrued acquisition values:			
- At start of year	968	1,839	2,701
- Acquisitions	1,000	163	350
- Reclassifications	-14	-1,042	-1,381
- Translation differences for the year	-46	8	169
- At the end of the year	**1,908**	**968**	**1,839**
Accumulated depreciation according to plan:			
- At start of year	-478	-1,259	-1,174
- Reclassifications	14	911	34
- Depreciation for the year	-252	-127	-109
- Translation differences for the year	21	-4	-10
- At the end of the year	**-695**	**-479**	**-1,259**
Carrying amount at the end of the year	**1,213**	**489**	**580**

NOT 17 Deferred tax

Deferred tax receivables and liabilities are broken down as follows:

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Deferred tax assets:			
Loss carry-forwards	-	-	-
Inventories	34	2,205	1,591
Lease liability	11	6	0
Deferred tax liabilities:			
Right-of-use asset	-	-	-
Deferred tax assets (net)	**45**	**2,211**	**1,591**

KSEK	Loss carry-forwards	Lease liability	Invent-ories	Total
Deferred tax assets:				
At 1 January 2019	-	-	1,591	1,591
Recognised in the compre-hensive income statement	-	6	614	620
At 31 December 2019	-	6	2,205	2,211
Recognised in the compre-hensive income statement	-	5	-2,171	-2,166
At 31 December 2020	**-**	**11**	**34**	**45**

NOTE 18 Inventories

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Finished goods and goods for resale	9,087	7,378	6,295
Total	**9,087**	**7,378**	**6,295**

During the financial year, costs of materials were recognised in the income statement of KSEK 52,867 (KSEK 24,879) as cost of goods sold.

NOTE 19 Accounts receivable

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accounts receivable	19,484	6,467	4,985
Less provision for expected credit losses	-	-	-
Accounts receivable - net	**19,484**	**6,467**	**4,985**

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 2020	31 Dec 2019	1 Jan 2019
EUR	18,746	6,285	4,821
SEK	230	8	1
GBP	378	84	19
NOK	119	84	144
DKK	11	6	-
Total	**19,484**	**6,467**	**4,985**

NOTE 20 Prepaid expenses and accrued income

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Rent	448	53	166
Pension	493	266	-
Insurance	385	315	112
Capitalised development expenditure	1,525	2,429	49
Software	665	125	14
Marketing, congresses	954	609	492
R&D material	440	233	132
Other	699	317	441
Total	**5,609**	**4,347**	**1,406**

NOTE 21 Cash and cash equivalents

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Bank deposits	376,171	464,560	159,351
Total	**376,171**	**464,560**	**159,351**

Bank overdraft facilities of SEK 500,000 are unutilised at 31 Dec 2020.

NOTE 22 Shareholders' equity

Group

KSEK	Number of shares	Share capital	Other capital provided
Share capital and other provided capital			
At 1 January 2019	19,156,591	1,916	238,016
Exercise of warrants	3,580,000	358	367,686
At 31 December 2019	**22,736,591**	**2,274**	**605,702**
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**

The share capital at 31 December 2020 consists of 23,046,740 ordinary shares with a quotient value of SEK 0.1.

All the shares that have been issued by the Parent Company are fully paid up. Transaction expenses for new share issue in connection with conversion of warrants totalled KSEK 68 (10,115) for the full year 2020.

NOTE 23 Warrants

Warrants 2019

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 at the end of the period	Terms*	Redemption price (SEK)
2014/2019	CEO	–	–	–	–	1:4000	2.50
2014/2019	Other senior executives	116	–	116	–	1:4000	2.50
2014/2019	Other employees and former employees	55	–	55	–	1:4000	2.50
2014/2019	**Total**	**171**	**–**	**171**	**–**	**1:4000**	**2.50**
2017/2021	CEO	184,200	–	–	184,200	1:1	25.35
2017/2021	Other senior executives	125,949	–	–	125,949	1:1	25.35
2017/2021	Other employees	–	–	–	–	1:1	25.35
2017/2021	**Total**	**310,149**	**–**	**–**	**310,149**	**1:1**	**25.35**
2019/2022	CEO	–	–	–	–	1:1	142.23
2019/2022	Other senior executives	26,293	–	–	26,293	1:1	142.23
2019/2022	Other employees	62,792	–	–	62,792	1:1	142.23
2019/2022	**Total**	**89,085**	**–**	**–**	**89,085**	**1:1**	**142.23**
Total	CEO	184,200	–	–	184,200		
Total	Other senior executives	152,358	–	116	152,242		
Total	Other employees	62,847	–	55	62,792		
Total		**399,405**	**–**	**171**	**399,234**		

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 at the end of the period	Terms*	Redemption price (SEK)
2017/2021	CEO	184,200	–	184,200	–	1:1	25.35
2017/2021	Other senior executives	125,949	–	125,949	–	1:1	25.35
2017/2021	Other employees	–	–	–	–	1:1	25.35
2017/2021	**Total**	**310,149**	**–**	**310,149**	**–**	**1:1**	**25.35**
2019/2022	CEO	–	–	–	–	1:1	142.23
2019/2022	Other senior executives	26,293	–	–	26,293	1:1	142.23
2019/2022	Other employees	62,792	–	–	62,792	1:1	142.23
2019/2022	**Total**	**89,085**	**–**	**–**	**89,085**	**1:1**	**142.23**
2020/2023	CEO	–	–	–	–	1:1	334.60
2020/2023	Other senior executives	–	4,000	–	4,000	1:1	334.60
2020/2023	Other employees	–	6,620	–	6,620	1:1	334.60
2020/2023	**Total**	**–**	**10,620**	**–**	**10,620**	**1:1**	**334.60**
Total	CEO	184,200	–	184,200	–		
Total	Other senior executives	152,242	4,000	125,949	30,293		
Total	Other employees	62,792	6,620	–	69,412		
Total		**399,234**	**10,620**	**310,149**	**99,705**		

*1:1 = 1 warrant = 1 share on conversion. 1:4000 = 1 warrant = 4000 shares on conversion.

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 2020	31 Dec 2019	1 Jan 2019
Property, plant and equipment owned	5,711	4,874	4,129
Right-of-use assets	8,792	2,773	2,439
Total	**14,503**	**7,647**	**6,568**

Right-of-use asset

	Buildings	Vehicles	Equipment and tools	Total
Depreciation during the year, 2019	519	996	21	1,536
Closing balance, 31 December 2019	**1,117**	**1,428**	**228**	**2,773**
Depreciation during the year, 2020	996	1,165	83	2,244
Closing balance, 31 December 2020	**7,421**	**1,226**	**145**	**8,792**

Lease liability

	31 Dec 2020	31 Dec 2019	1 Jan 2019
Lease liability included in statements of financial position			
Current lease liabilities	2,967	1,709	1,171
Non-current lease liabilities	5,324	828	1,102
Total	**8,291**	**2,537**	**2,273**

For a maturity analysis of the lease liabilities, see Note 25 Financial risks and risk management in the section on liquidity risk.

Amount recognised in profit or loss

	31 Dec 2020	31 Dec 2019	1 Jan 2019
Interest on lease liabilities	106	75	-
Depreciation	2,244	1,536	-
Variable lease payments not included in lease liability	627	234	-
Costs of short-term leases	4	268	-
Costs of leases of low value, not short-term leasing of low value	34	18	-
Total	**2,350**	**1,611**	**-**

Amounts recognised in the cash flow statement

	31 Dec 2020	31 Dec 2019	1 Jan 2019
Total cash flows attributable to leases	**-4,142**	**-2,439**	**-**

NOTE 25 Other current liabilities

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
VAT	323	54	164
Employee withholding tax	1,628	773	599
Social security contributions	1,381	758	385
Liabilities to employees	3,107	1,203	67
Other liabilities	1,228	558	649
Total	**7,668**	**3,346**	**1,864**

NOTE 26 Accrued expenses and prepaid income

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Salaries, holidays, social security expenses	7,729	4,418	3,664
Lawyers' fees	1,775	1,025	225
Consultants' fees	1,192	180	-
Auditing	716	468	245
Delivery	609	-	57
Supplied goods not invoiced	545	-	1,266
Other	1,388	2,176	1,502
Total	**13,955**	**8,267**	**6,958**

NOTE 27 Changes in liabilities belonging to financing activities

			Non cash items		
KSEK	1 Jan 2019	Cash flow	Exchange-rate differences	Other	31 Dec 2019
Lease liability	2,273	-1,525	93	1,696	2,537
Total	**2,273**	**-1,525**	**93**	**1,696**	**2,537**

			Non cash items		
KSEK	1 Jan 2020	Cash flow	Exchange-rate differences	Other	31 Dec 2020
Lease liability	2,537	-2,464	38	8,180	8,291
Total	**2,537**	**-2,464**	**38**	**8,180**	**8,291**

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. In the future, the company's operating income and expenses are expected also to consist of other currencies. 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 have a significant adverse effect 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	Impact on net assets, KSEK
Currency			
EUR/SEK	+/- 10%	+/- 371	+/- 1,565
USD/SEK*			

**The company's exposure to USD at present is limited but may increase in connection with forthcoming phase 3 studies in the United States.*

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.

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 Transactions with related parties

KSEK	2020 Purchases of services	2020 Purchases of goods	2019 Purchases of services	2019 Purchases of goods
Group				
Tecscan Ltd	-	-	202	-
Lismed Ltd	101	10,259	101	4,985
Group total	**101**	**10,259**	**303**	**4,985**

Tecscan Ltd is a company related to the former Board member Michael Ryan. Purchases of services from Tecscan Ltd relate to services for business development. Lismed Ltd is a company related to Ron Farrell, R&D director of the Group during the first quarter of 2020 and a member of the Board of the Group's Irish subsidiary.

Purchases of goods from Lismed Ltd concern the device Flurasorb and accessories which in turn are accessories to AnaConDa.

Purchases of services from Lismed Ltd concern technical support.
At the end of the year, there was an outstanding liability to Lismed Ltd of KSEK 732.

NOTE 30 Important events after the end of the financial year

In January, an application was submitted for marketing authorisation for the candidate drug Sedaconda (isoflurane), previously known as IsoConDa, for inhaled sedation in intensive care in Switzerland.

As a consequence of the resolution by the Annual General Meeting held on 19 May 2020 to implement a new 2020/2024 warrant programme with a maximum of 360,000 warrants for new employees, 37,113 have been transferred to employees. Surplus warrants will be cancelled. If all the warrants are exercised, dilution of around 0.2 percent will occur, based on the number of shares in the company at 31 December 2020.

In February, an application was submitted for marketing authorisation for the candidate drug Sedaconda (isoflurane) for inhaled sedation in intensive care in the United Kingdom.

In February, it was announced that the first patient had been included in the company's paediatric study IsoCOMFORT (SED002). The study is expected to be completed during the second half of 2022 and is intended to lead to approved paediatric indication for inhaled sedation.

The Board has decided to propose to the Annual General Meeting that the company carry out a 4:1 share split, which means that the number of shares increases fourfold to 92,186,960.

On 24 February, it was announced that Christer Ahlberg had informed the Board of Sedana Medical of his resignation as CEO to become CEO of Cinclus Pharma AB. Christer Ahlberg will remain as CEO until the summer of 2021, and the Board has initiated a process to find a successor.

The Annual General Meeting of Sedana Medical AB (publ) held on 19 May 2020 resolved to implement a new warrant programme 2020/2024, mainly for new staff. The company therefore issued at the AGM 360,000 warrants, all of which have been subscribed to by the company's subsidiary Sedana Medical Incentive AB. Each warrant entitles the holder to subscribe to one share in the period 1 February to 31 May 2024, at a subscription price of SEK 495.52, equivalent to 140 percent of the volume-weighted average price paid for Sedana Medical shares over the period 1–30 January 2021. In February 2021, 37,113 warrants were transferred at a subscription price of SEK 495.52, equivalent to 140 percent of the volume-weighted average price paid for Sedana Medical shares over the period 1–30January 2021. A total of 37,113 warrants were transferred to staff in February 2021. Transfers took place against payment of the estimated market value of the warrants calculated according to the Black & Sholes valuation model by an external valuer. The surplus 322,887 warrants will be cancelled. If all the warrants are exercised, 37,113 new shares will be issued, which is equivalent to a dilution of around 0.2 percent based on the number of shares in the company at 31 December 2020.

NOTE 31 Explanations regarding the transition from cost-based to function-based income statement

KSEK	Classified by nature of expense	Other operating income	Goods for resale	Other external expenses	Personnel expenses	Depreciation, amortisation and impairment	Classified by function
Net sales	71,646	-	-	-	-	-	71,646
Other operating income	2,092	-2,092	-	-	-	-	-
Cost of goods sold	-	-	-19,233	-342	-2,930	-2,377	-24,882
Gross profit or loss	**73,738**						**46,764**
Goods for resale	-19,233	-	19,233	-	-	-	-
Other external expenses	-27,122	-	-	27,122		-	-
Personnel expenses	-38,045	-	-	-	38,045	-	-
Depreciation, amortisation and impairment of property, plant and equipment and intangible assets	-4,188	-	-	-	-	4,188	-
Selling expenses	-	-	-	-13,041	-22,775	-1,533	-37,349
Administrative expenses	-	-	-	-9,057	-9,819	-134	-19,010
Research and development expenses	-	-	-	-4,682	-2,521	-144	-7,347
Other operating income	-	2,092	-	-	-	-	2,092
Other operating expense	-2,317	-	-	-	-	-	-2,317
Operating income	**-17,167**	**-**	**-**	**-**	**-**	**-**	**-17,167**
Financial income	2,456	-	-	-	-	-	2,456
Financial expense	-2,232	-	-	-	-	-	-2,232
Profit/loss after financial items	**-16,943**	**-**	**-**	**-**	**-**	**-**	**-16,943**
Earnings before tax	**-16,943**	**-**	**-**	**-**	**-**	**-**	**-16,943**
Income tax	585	-	-	-	-	-	585
Profit or loss for the period	**-16,358**	**-**	**-**	**-**	**-**	**-**	**-16,358**

NOTE 32 Explanations regarding transition to IFRS – Bridges to IFRS

This financial report for the Group is the first to have been prepared with application of IFRS, as stated in Note 1.

The accounting policies set out in Note 1 have been applied in the preparation of the consolidated financial reports for the financial year 2020 and for the comparative year 2019, as well as for the Group's opening IFRS balance sheet at 1 January 2019. In the preparation of the Group's opening IFRS balance sheet, amounts that have been recognised in accordance with previously applied accounting policies have been adjusted in accordance with IFRS. Explanations of how the transition from previous accounting policies to IFRS has affected the Group's financial position, financial results and cash flows can be found in the following tables and explanations of these tables.

Choices made in the transition to accounting under IFRS
The transition to IFRS is presented in accordance with IFRS 1 First-time Adoption of IFRS. The general rule is that all applicable IFRS and IAS standards which have entered into force and been approved by the EU at 31 December 2020 are to be applied with retroactive effect. However, IFRS 1 contains transitional provisions which give entities some freedom of choice.

The exceptions permitted by IFRS to full retroactive application which the Company has chosen to apply in the transition from previously applied accounting policies to IFRS are stated below. Exception for cumulative translation differences.

IFRS 1 permits cumulative translation differences recognised in equity to be reset to zero at the time of transition to IFRS. This signifies a relaxation compared with establishing cumulative translation differences in accordance with IAS 21, The Effects of Changes in Foreign Exchange Rates, from the time when the Company's subsidiaries were formed. The Company has chosen to reset to zero all cumulative translation differences in the translation reserve and to reclassify these to retained earnings at the time of transition to IFRS at 1 January 2019.

IFRS 16 Leases
The Group applies IFRS 16 with effect from 1 January 2019. The Group applies the simplified transition method, which means that rights-of use are measured at an amount equivalent to the lease liability at 1 January 2019 (adjusted for prepaid and accrued lease payments).

In addition, the Group has made the following choices at the time of transition
- To exclude lease contracts whose lease term ends within twelve months from the time of transition to IFRS (1 Jan 2019) and lease contracts for which the underlying asset is of low value.
- To use estimates made subsequently in establishment of the lease term in cases where the contract contain options to extend or terminate the lease contract.

Reconciliation between previously applied accounting policies and IFRS
Under IFRS 1, the Group is required to present a reconciliation between equity and total comprehensive income recognised in accordance with previously applied accounting policies and equity and total comprehensive income in accordance with IFRS. The tables below show the reconciliation between previously applied accounting policies and IFRS for the period concerned for equity and total comprehensive income.

Effects on income statement, balance sheet and equity
The tables below show the above effects on the income statement, balance sheet and equity as though IFRS had been applied in 2019 and 2020.

Statement of financial position, Group, 1 January 2019 (Table 1)

KSEK	K3 31 Dec 2018	Effect of IFRS 1 - Translation reserve	Effect of IFRS 16 - Leases	IFRS 1 Jan 2019
Assets				
Intangible assets				
Capitalised development expenditure	46,161	-	-	46,161
Concessions, patents, licenses, etc.	5,243	-	-	5,243
Property, plant and equipment	-	-	-	
Plant and machinery	4,129	-	-	4,129
Equipment, tools, fixtures and fittings	580	-	-	580
Right-of-use assets	-	-	2,439	2,439
Deferred tax assets	1,591	-	-	1,591
Total non-current assets	**57,704**	**-**	**2,439**	**60,143**
Inventories	6,295	-	-	6,295
Contract assets	-	-	-	-
Tax receivables	349	-	-	349
Accounts receivable	4,985	-	-	4,985
Prepaid expenses and accrued income	1,572	-	-166	1,406
Other receivables	1,294	-	-	1,294
Cash and cash equivalents	159,351	-	-	159,351
Total current assets	**173,846**	**-**	**-166**	**173,680**
Total assets	**231,550**	**-**	**2,273**	**233,823**
Equity and liabilities				
Equity				
Share capital	1,916	-	-	1,916
Other capital provided	238,016	-	-	238,016
Translation reserves	-	-	-	-
Retained earnings including profit or loss for the period	-22,121	-	-	-22,121
Equity attributable to shareholders in the Parent Company	217,811	-	-	-
Non-current liabilities				
Non-current lease liabilities	-	-	1,102	1,102
Other non-current liabilities	-	-	-	-
Total non-current liabilities	**-**	**-**	**1,102**	**1,102**
Current liabilities				
Liabilities to credit institutions				
Current interest-bearing liabilities				
Current lease liabilities	-	-	1,171	1,171
Accounts payable	4,430	-	-	4,430
Contract liabilities	0	-	-	-
Tax liabilities	487	-	-	487
Other liabilities	1,864	-	-	1,864
Accrued expenses and prepaid income	6,958	-	-	6,958
Total current liabilities	**13,739**	**-**	**1,171**	**14,910**
Total liabilities	**13,739**	**-**	**2,273**	**16,012**
Total equity and liabilities	**231,550**	**-**	**2,273**	**233,823**

Income statement for the Group, 1 January to 31 December 2019 (Table 2)

KSEK	According to IFRS	Effect of IFRS 1 – Translation reserve	Effect of IFRS 16 – Leases	According to IFRS
Net sales	71,646	–	–	71,646
Cost of goods sold	-24,882	–	3	-24,879
Gross profit or loss	**46,764**	**–**	**3**	**46,767**
Selling expenses	-37,349	–	23	-37,326
Administrative expenses	-19,010	–	21	-18,989
Research and development expenses	-7,347	–	–	-7,347
Impairment of accounts receivable and contract assets	–	–	–	–
Other operating income	2,092	–	–	2,092
Other operating expense	-2,317	–	–	-2,317
Operating profit (EBIT)	**-17,167**	**–**	**47**	**-17 120**
Financial items				
Financial income	2,456	–	–	2,456
Financial expense	-2,232	–	-75	-2,307
Net financial items	**224**	**–**	**-75**	**149**
Earnings before tax	**-16,943**	**–**	**-28**	**-16,971**
Taxes	585	–	6	591
Profit or loss for the period	**-16,358**	**–**	**-22**	**-16,380**

Statement of financial position, Group, 31 December 2019 (Table 3)

KSEK	K3 31 Dec 2019	Effect of IFRS 1 – Translation reserve	Effect of IFRS 16 – Leases	IFRS 31 Dec 2019
Assets				
Intangible assets				
Capitalised development expenditure	95,487	–	–	95,487
Concessions, patents, licenses, etc.	4,160	–	–	4,160
Property, plant and equipment				
Plant and machinery	4,385	–	–	4,385
Equipment, tools, fixtures and fittings	489	–	–	489
Right-of-use assets	–	–	2,773	2,773
Deferred tax assets	2,205	–	6	2,211
Total non-current assets	**106,726**	**–**	**2,779**	**109,505**
Inventories	7,378	–	–	7,378
Tax receivables	6	–	–	6
Accounts receivable	6,467	–	–	6,467
Prepaid expenses and accrued income	4,611	–	-264	4,347
Other receivables	3,503	–	–	3,503
Cash and cash equivalents	464,560	–	–	464,560
Total current assets	**486,525**	**–**	**-264**	**486,261**
Total assets	**593,251**	**–**	**2,515**	**595,766**
Equity and liabilities				
Equity				
Share capital	2,274	–	–	2,274
Other capital provided	605,702	–	–	605,702
Translation reserves	–	-117	–	-117
Retained earnings including profit or loss for the period	-38,596	117	-22	-38,501
Equity attributable to shareholders in the Parent Company	**569,380**	**–**	**-22**	**569,358**
Non-current liabilities				
Non-current leasing liabilities	–	–	828	828
Other non-current liabilities	–	–	–	–
Total non-current liabilities	**–**	**–**	**828**	**828**
Current liabilities				
Liabilities to credit institutions	–	–	–	–
Current interest-bearing liabilities	–	–	–	–
Current leasing liabilities	–	–	1,709	1,709
Accounts payable	11,004	–	–	11,004
Tax liabilities	1,254	–	–	1,254
Other liabilities	3,346	–	–	3,346
Accrued expenses and prepaid income	8,267	–	–	8,267
Total current liabilities	**23,871**	**–**	**1,709**	**25,580**
Total liabilities	**23,871**	**–**	**2,537**	**26,408**
Total equity and liabilities	**593,251**	**–**	**2,515**	**595,766**

Cash flow statement - Group (Table 4)

(KSEK)	31 Dec 2019 K3	Effect of transition to IFRS	31 Dec 2019 IFRS
Operating activities			
Operating profit	-17,167	47	-17 120
Adjustment for non-cash items			
Depreciation and write-downs	5,558	1,510	7,068
Exchange-rate differences	282	-	282
Provisions	-	-	-
Total	**-11,327**	**1,557**	**-9,770**
Interest received	3	-	3
Interest paid	-7	-75	-82
Income tax paid	257	-	257
Cash flow from operating activities before changes in working capital	**-11,074**	**1,482**	**-9,592**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in inventories	-1,077	-	-1,077
Increase (-)/Decrease (+) in operating receivables	-6,706	43	-6,663
Increase (+)/Decrease (-) in operating liabilities	10,157	-	10,157
Cash flow from operating activities	**-8,700**	**1,525**	**-7,175**
Investing activities			
Investment in intangible assets	-49,839	-	-49,839
Investment in property, plant and equipment	-4,293	-	-4,293
Cash flow from investing activities	**-54,132**	**-**	**-54,132**
Financing activities			
New share issue	376,742	-	376,742
Issue expenses	-10,115	-	-10,115
Premium received for warrant subscription	1,746	-	1,746
Expenses for warrant programme	-330	-	-330
Repayment of lease liabilities		-1,525	-1,525
Cash flow from financing activities	**368,043**	**-1,525**	**366,518**
Cash flow for the period	**305,212**	**-**	**305,212**
Cash and cash equivalents at the beginning of the period	**159,351**	**-**	**159,351**
Translation difference in cash and cash equivalents	-2	-	-2
Cash and cash equivalents at the end of the period	**464,560**	**-**	**464,560**

Supplementary disclosures

Transfer of translation differences to reserves
Translation differences are presented in accordance with IFRS in other comprehensive income and recognised in the item 'reserves' in equity. The Company has chosen to reset cumulative translation differences to zero on transition to IFRS, and no amount is therefore allocated to reserves at 1 January 2019 (Table 1). In subsequent periods, translation differences relating to translation of foreign subsidiaries are presented in 'other comprehensive income' (Tables 2 and 3) and recognised in 'reserves' in equity (Table 3). Amounts transferred to the statements of comprehensive income and balance sheets above relate to amounts which under previously applied accounting policies have been recognised directly against retained earnings in equity.

Leases
At the time of transition to IFRS, the Group recognises a right-of-use asset and a lease liability in the balance sheet (Table 1) for leases which in accordance with previously applied policies have been classified as operating leases, and which do not relate to assets of low value or short-term contacts.

The lease liability is measured at the present value of the remaining lease payments, totalling KSEK 2,273 at 1 January 2019 (Table 1) and KSEK 2,537 at 31 December 2019 (Table 3). Right-of-use assets are measured at the time of transition at an amount which is equivalent to the value of the lease liability adjusted for prepaid lease payments. Right-of-use assets at the time of transition totalled KSEK 2,439 (Table 1) and KSEK 2,773 at 31 December 2019 (Table 4). In the statement of comprehensive income, right-of-use assets are amortised on a straight-line basis over the length of the lease and interest is calculated on the lease liability at a fixed interest rate for the liability recognised during the period concerned. In the statement of comprehensive income (Table 3), amortisation of right-of-use assets is recognised distributed between the functions Selling expenses and Administrative expenses, and the interest exchange is recognised in financial expenses, instead of lease payments which were previously recognised in Other external expenses. Amortisation of right-of-use assets totalled KSEK 1,536 for the financial year 2019 and interest expenses totalled KSEK 75. The weighted average marginal borrowing date used on the day of first-time application (1 January 2019) was 3.0%.

Reclassification and classification

Income statement (Tables 2 and 3)
Reclassifications have taken place of the following items in the income statement: 'Other interest income and similar profit/loss items' is designated 'financial income', 'interest expenses and similar profit/loss items' are designated 'financial expenses' and 'tax on net profit for the year' is designated 'income tax'.
In comparison with previous accounting policies, other comprehensive income is added in connection with the income statement.

Comprehensive income statement (Table 2)
In comparison with previous accounting policies, other comprehensive income is added in connection with the income statement.

Statement of financial position (Tables 1 and 4)
The following reclassifications have taken place in the statement of financial position:
- 'Cash at bank' is named 'cash and cash equivalents'.
- Translation differences are recognised in the item 'Reserves'. Translation differences were reset to zero at the time of transition to IFRS at 1 January 2019, and the item 'Reserves' is therefore KSEK 0 in the opening IFRS balance sheet.

Other
Under IFRS, only transactions with shareholders are recognised directly in equity; other items are presented in other comprehensive income and recognised in equity. For the Company, this means that exchange-rate differences on translation of foreign subsidiaries are presented in 'other comprehensive income' in the statement of comprehensive income and recognised in the item 'reserves' in equity.

Parent Company income statement

KSEK	Note	Full year 2020	2019
Net sales	1,2	121,238	46,213
Cost of goods sold	2,5	-38,707	-30,622
Gross profit or loss		**82,531**	**15,591**
Operating expenses	3,4,5,8		
Selling expenses		-72,666	-30,193
Administrative expenses		-38,668	-19,277
Research and development expenses		-3,953	-931
Other operating income	2,6	7,790	20,817
Other operating expense	7	-2,611	-2,058
Operating profit (EBIT)		**-27,577**	**-16,051**
Financial items			
Interest income and similar income		1,778	3,409
Interest expense and similar expenses		-2,959	-2,146
Net financial items	9	**-1,181**	**1,263**
Profit/loss after financial items		**-28,758**	**-14,788**
Group contributions	10	-9	-12
Earnings before tax		**-28,767**	**-14,800**
Income tax	11	0	0
Net profit/loss for the year		**-28,767**	**-14,800**

Parent Company statement of other comprehensive income

KSEK	Note	Full year 2020	2019
Net profit/loss for the year		**-28,767**	**-14,800**
Other comprehensive income			
Items that may be reclassified later to the income statement:			
Translation differences from operations abroad		200	-39
Other comprehensive income during the year, net after tax		**200**	**-39**
Comprehensive income for the year		**-28,567**	**-14,839**

Parent Company balance sheet

(KSEK)	Note	31 Dec 2020	31 Dec 2019	1 Jan 2019
ASSETS				
Intangible assets				
Capitalised development expenditure	12	156,261	88,047	42,297
Property, plant and equipment				
Plant and machinery	13	4,334	840	2,414
Equipment, tools, fixtures and fittings	14	638	221	279
Financial assets				
Participations in Group companies	15	395	395	50
Receivables in Group companies	16	38,539	40,418	24,019
Total non-current assets		200,167	129,921	69,059
Inventories	17	9,245	984	9,227
Tax receivables		4	4	349
Accounts receivable	18	17,925	359	4,381
Receivables in Group companies		2,239	21,828	12,648
Prepaid expenses and accrued income	19	5,575	4,090	1,351
Other receivables		3,202	3,084	1,239
Cash and bank balances	20	365,113	455,206	158,806
Total current assets		403,303	485,555	188,001
TOTAL ASSETS		**603,470**	**615,476**	**257,060**

(KSEK)	Note	31 Dec 2020	31 Dec 2019	1 Jan 2019
EQUITY AND LIABILITIES				
Equity	21,22			
Restricted equity				
Share capital		2,305	2,274	1,916
Fund for development expenditure		154,405	88,047	42,297
Non restricted equity				
Share premium reserve		613,923	605,702	237,691
Retained earnings		-180,266	-99,308	-49,439
Net profit/loss for the year		-28,767	-14,800	-3,755
Equity attributable to shareholders in the Parent Company		561,600	581,915	228,710
Current liabilities				
Accounts payable		15,469	6,845	2,281
Liabilities to Group companies		10,095	19,596	20,131
Tax liabilities		1,387	826	0
Other liabilities	23	4,707	2,001	1,341
Accrued expenses and prepaid income	24	10,212	4,293	4,597
Total current liabilities		41,870	33,561	28,350
Total liabilities		41,870	33,561	28,350
TOTAL EQUITY AND LIABILITIES		**603,470**	**615,476**	**257,060**

Change in equity, Parent Company

Equity attributable to shareholders in the Parent Company

	Restricted equity		Non restricted equity		Total
KSEK	Share capital	Fund for development expenditure	Share premium reserve	Retained earnings including profit or loss for the year	Total equity
Opening equity 1 January 2019	**1,916**	**42,297**	**238,017**	**-53,520**	**228,710**
Net profit/loss for the year	-	-	-	-14,800	-14,800
Other comprehensive income	-	-	-	-39	-39
Comprehensive income for the year	**-**	**-**	**-**	**-14,838**	**-14,838**
Changes in the carrying amounts recognised directly in equity					**-**
New share issue	358	-	376,384	-	376,742
Issue expenses	-	-	-10,115	-	-10,115
Premium received for warrant subscription	-	-	1,746	-	1,746
Expenses for warrant programme	-	-	-330	-	-330
Total	**358**	**-**	**367,685**	**-**	**368,043**
Transfer between items in equity					
Capitalisation of development expenditure	-	45,750	-	-45,750	-
Total	**-**	**45,750**	**-**	**-45,750**	**-**
Closing equity 31 December 2019	**2,274**	**88,047**	**605,702**	**-114,108**	**581,915**
Opening equity 1 January 2020	**2,274**	**88,047**	**605,702**	**-114,108**	**581,915**
Net profit/loss for the year	-	-	-	-28,767	-28,767
Other comprehensive income	-	-	-	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 for warrant subscription	-	-	515	-	515
Expenses for warrant programme	-	-	-58	-	-58
Total	**31**	**-**	**8,220**	**-**	**8,251**
Transfer between items in equity					
Capitalisation of development expenditure	-	66,358	-	-66,358	-
Total	**-**	**66,358**	**-**	**-66,358**	**-**
Closing equity 31 December 2020	**2,305**	**154,405**	**613,923**	**-209,033**	**561,600**

Parent Company cash flow statement

(KSEK)	Note	Full year 2020	2019
Operating activities			
Operating profit		-27,577	-16,050
Adjustment of non-cash items:			
Depreciation and write-downs		1,442	2,253
Exchange-rate differences		629	547
Total		**-25,506**	**-13,251**
Interest received		1,336	964
Interest paid		-8	-4
Income tax paid		0	343
Cash flow from operating activities before changes in working capital		**-24,178**	**-11,948**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in inventories		-8,262	8,218
Increase (-)/Decrease (+) in operating receivables		396	-8,459
Increase (+)/Decrease (-) in operating liabilities		8,380	5,168
Cash flow from operating activities		**-23,664**	**-7,022**
Investing activities			
Investment in intangible assets	12	-68,213	-45,750
Investment in property, plant and equipment	13, 14	-4,893	-1,832
Acquisition of financial assets		-283	-15,529
Cash flow from investing activities		**-73,389**	**-63,111**
Financing activities			
New share issue	22	7,862	376,742
Issue expenses	22	-68	-10,115
Premium received for warrant subscription	22	515	0
Expenses for warrant programme	22	-58	0
Cash flow from financing activities		**8,251**	**366,627**
Cash flow for the period		**-88,802**	**296,494**
Cash and bank balances at the beginning of the period		**455,206**	**158,806**
Translation difference in cash and cash equivalents		-1,291	-94
Cash and bank balances at the end of the period	**20**	**365,113**	**455,206**

Accounting policies

For information concerning the Parent Company's accounting policies, see page 65.

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	2020	2019
Sweden	1,477	97
Germany	68,564	37,579
Other markets	51,197	8,537
Total	**121,238**	**46,213**

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

NOTE 2 Intra-Group purchases and sales

KSEK	2020	2019
Sale of goods relating to group companies	31,602	1,088
Operating income concerning services relating to group companies	33,566	18,636
Purchase of goods relating to Group companies	20,286	28,602

NOTE 3 Employees, personnel expenses and remuneration of senior executives

Average number of employees

	2020			2019		
	Total	Women	Men	Total	Women	Men
Parent Company						
Sweden	20.9	12.6	8.3	15.3	8.2	7.1
Germany	-	-	-	6.9	2.2	4.7
Spain	2.0	-	2.0	1.4	0.5	0.9
Total Parent Company	**22.9**	**12.6**	**10.3**	**23.6**	**10.9**	**12.7**
Senior executives, at year-end						
Board of Directors	6	1	5	5	1	4
CEO and senior executives	5	2	3	5	1	4

Salaries and other remuneration and social security expenses

	2020				2019			
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	8,770	(440)	4,741	(1,644)	5,756	(167)	3,134	(1,086)
Other employees	19,268	(383)	7,230	(3,159)	18,182	-	5,641	(2,669)
Total	**28,038**	**(824)**	**11,971**	**(4,803)**	**23,938**	**(167)**	**8,774**	**(3,756)**

KSEK	2020	2019
Salaries and other remuneration	28,038	23,938
Social security contributions	7,167	5,019
Pension expenses – defined-contribution plans	4,803	3,756
Total employee benefits	**40,009**	**32,712**

For further information about warrants, see Note 22.

For information on guidelines for remuneration of senior executives, see the section on corporate governance, pages 90–92.

NOTE 4 Fee and reimbursement of expenses to auditors

KSEK	2020	2019
PwC*		
Audit engagement	478	0
Tax advice	0	0
Other services	436	0
Total	914	0
R3 Revisionsbyrå KB*		
Audit engagement	117	220
Tax advice	0	0
Other services	0	0
Total	117	220
Other auditors		
Audit engagement	53	158
Tax advice	0	104
Other services	0	0
Total	53	261
Total	**1,084**	**482**

*PwC became the new auditors at the 2020 AGM.

NOTE 5 Operating expenses classified by nature of expense

KSEK	2020	2019
Goods for resale	35,618	30,362
Personnel expenses	87,443	24,232
Depreciation	29,964	25,151
Other operating expense	969	1,278
Total	**153,994**	**81,023**

NOTE 6 Other operating income

KSEK	2020	2019
Exchange gains on operating receivables/ liabilities	1,678	1,777
Intra-Group management fee	6,112	18,439
Other	-	601
Total	**7,790**	**20,817**

NOTE 7 Other operating expenses

KSEK	2020	2019
Exchange losses on operating receivables/ liabilities	2,611	2,005
Other	0	53
Total	**2,611**	**2,058**

NOTE 8 Operating leases - Lessee

KSEK	2020	2019
Contracted future minimum lease payments for non-cancellable contracts are due:		
- Within one year	2,922	1,524
- Between one and five years	7,031	870
Total	**9,953**	**2,394**
Expensed lease payments for the year	1,981	1,720
Of which rent for premises	1,387	955

NOTE 9 Net financial items

KSEK	2020	2019
Interest income, Group companies	1,312	964
Interest income, other	25	3
Exchange gains	442	2,442
Total financial expense	**1,778**	**3,409**
Interest expense, other	-9	-4
Exchange losses	-2,950	-2,142
Total financial expense	-2,959	-2,146
Net financial income/expense	**-1,181**	**1,263**

NOTE 10 Appropriations

KSEK	2020	2019
Group contributions paid	9	12
Total	**9**	**12**

NOTE 11 Income tax

KSEK	2020	2019
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	2020	2019
Earnings before tax	-28,767	-14,800
Tax at current tax rate for Parent Company	6,156	3,167
Tax effect of:		
- non-deductible expenses	-75	-76
- other tax rates for foreign subsidiaries/ branches	-10	66
- increase in loss carry-forwards without corresponding capitalisation of deferred tax	-6,137	-3,157
- utilisation of previously non-capitalised loss carry-forwards	67	0
- other	-1	0
Recognised effective tax	**0**	**0**

Unutilised loss carry-forwards for which no deferred tax receivable has been recognised total KSEK 78,102 at 31 Dec 2020 (31 Dec 2019: 50,379, 1 Jan 2019: KSEK 35,281). 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 deferred tax in accordance with IAS 12 not to be met.

NOTE 12 Capitalised expenditure on development work

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accrued acquisition values:			
- At start of year	88,047	42,297	6,403
- Acquisitions	68,214	45,750	35,895
- Translation differences for the year	-	-	-
- At the end of the year	**156,261**	**88,047**	**42,297**
Accumulated depreciation according to plan:			
- At start of year	-	-	-
- Depreciation for the year	-	-	-
- Translation differences for the year	-	-	-
- At the end of the year	-	-	-
Carrying amount at the end of the year	**156,261**	**88,047**	**42,297**
Carrying amount above relates to:			
Development work within the medical sector	154,405	88,047	42,297
Other capitalised develop-ment expenses	1,856	0	0

The income statement includes depreciation as above wholly under research and development expenses.

NOTE 13 Plant and machinery

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accrued acquisition values:			
- At start of year	1,872	7,963	5,068
- Acquisitions	4,367	530	2,819
- Reclassifications	-	-6,621	-83
- Translation differences for the year	-13	-	160
- At the end of the year	**6,226**	**1,872**	**7,963**
Accumulated depreciation according to plan:			
- At start of year	-1,032	-3,045	-1,524
- Reclassifications	-	2,406	-
- Depreciation for the year	-865	-394	-1,515
- Translation differences for the year	5	-	-5
- At the end of the year	**-1,892**	**-1,032**	**-3,045**
Accumulated impairments:			
- At start of year	-	-2,505	-719
- Reclassifications	-	2,505	-
- Impairment for the year	-	-	-1,752
- ranslation differences for the year	-	-	-34
- At the end of the year	**-**	**-**	**-2,505**
Carrying amount at the end of the year	**4,334**	**839**	**2,414**

NOTE 14 Equipment, tools, fixtures and fittings

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accrued acquisition values:			
- At start of year	300	525	273
- Acquisitions	515	82	189
- Disposals	-	-	-30
- Reclassifications	-	-307	83
- Translation differences for the year	-	-	9
- At the end of the year	**815**	**300**	**525**
Accumulated depreciation according to plan:			
- At start of year	-79	-246	-209
- Reclassifications	-	221	-
- Depreciation for the year	-98	-55	-33
- Disposals	-	-	6
- Translation differences for the year	-	-	-9
- At the end of the year	**-177**	**-79**	**-246**
Carrying amount at the end of the year	**638**	**221**	**279**

NOTE 15 Shares and participations in Group companies

	Corporate identity number	Domicile and country of registration and operation	Share of equity directly owned by the Parent Company (%)	Share of equity directly owned by the Group (%)	Number of shares	Book value 31 Dec 2020	Book value 31 Dec 2019	Book value 1 Jan 2019
Sedana Medical Ltd	IE551634	Naas, Ireland	100%		1	-	-	-
Sedana Medical Incentive AB	559109-8826	Danderyd, Sweden	100%		50,000	50	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	-	-	-
Sedana Medical Germany GmbH	HRB250971	Geretsried-Gelting, Germany	100%		26,000	313	312	-
Sedana Medical Netherlands B.V.	76605434	Amsterdam, Netherlands	100%		1	-	-	-

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accrued acquisition values:			
Opening acquisition value	394	50	50
Acquired participating interests	-	344	-
Reclassifications	1	-	-
Closing accumulated acquisition value	395	394	50
Accumulated impairments:			
Opening accumulated impairments	-	-	-
Impairments for the year	-	-	-
Closing accumulated impairments	-	-	-
Closing carrying amount	**395**	**394**	**50**

NOTE 16 Receivables in Group companies

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accrued acquisition values:			
- At start of year	40,418	24,019	24,019
- Added receivables	6,022	41,286	-
- Deducted receivables	-7,901	-24,887	-
Total	**38,539**	**40,418**	**24,019**

NOTE 17 Inventories

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Finished goods and goods for resale	9,245	984	9,227
Total	**9,245**	**984**	**9,227**

During the financial year, costs of materials were recognised in the income statement of KSEK 38,707 (KSEK 30,622) as cost of goods sold.

NOT 18 Accounts receivable

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Accounts receivable	17,925	359	4,381
Less provision for expected credit losses	-	-	-
Accounts receivable - net	**17,925**	**359**	**4,381**

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 2020	31 Dec 2019	1 Jan 2019
EUR	17,187	177	4,222
SEK	230	8	2
GBP	378	84	14
NOK	119	84	143
DKK	11	6	-
Total	**17,925**	**359**	**4,381**

NOTE 19 Prepaid expenses and accrued income

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Rent	644	201	188
Pension	490	266	-
Insurance	351	280	112
Capitalised development expenditure	1,525	2,429	49
Software	665	125	14
Marketing, congresses	954	533	399
R&D material	174	-	-
Other	772	256	589
Total	**5,575**	**4,090**	**1,351**

NOTE 20 Cash and bank balances

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Bank deposits	365,113	455,206	158,806
Total	**365,113**	**455,206**	**158,806**

Bank overdraft facilities of SEK 500,000 are unutilised at 31 Dec 2020.

NOTE 21 Shareholders' equity

KSEK	Number of shares	Share capital	Share premium reservel
Share capital and share premium reserve			
At 1 January 2019	19,156,591	1,916	238,016
Exercise of warrants	3,580,000	358	367,686
At 31 December 2019	**22,736,591**	**2,274**	**605,702**
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**

The share capital at 31 December 2020 consists of 23,046,740 ordinary shares with a quotient value of SEK 0.1.

All the shares that have been issued by the Parent Company are fully paid up. Transaction expenses for new share issue in connection with conversion of warrants totalled KSEK 68 (10,115) for the full year 2020.

NOTE 22 Warrants

Warrants 2019

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 at the end of the period	Terms*	Redemption price (SEK)
2014/2019	CEO	–	–	–	–	1:4000	2.50
2014/2019	Other senior executives	116	–	116	–	1:4000	2.50
2014/2019	Other employees and former employees	55	–	55	–	1:4000	2.50
2014/2019	**Total**	**171**	**–**	**171**	**–**	**1:4000**	**2.50**
2017/2021	CEO	184,200	–	–	184,200	1:1	25.35
2017/2021	Other senior executives	125,949	–	–	125,949	1:1	25.35
2017/2021	Other employees	–	–	–	–	1:1	25.35
2017/2021	**Total**	**310,149**	**–**	**–**	**310,149**	**1:1**	**25.35**
2019/2022	CEO	–	–	–	–	1:1	142.23
2019/2022	Other senior executives	26,293	–	–	26,293	1:1	142.23
2019/2022	Other employees	62,792	–	–	62,792	1:1	142.23
2019/2022	**Total**	**89,085**	**–**	**–**	**89,085**	**1:1**	**142.23**
Total	CEO	184,200	–	–	184,200		
Total	Other senior executives	152,358	–	116	152,242		
Total	Other employees	62,847	–	55	62,792		
Total		**399,405**	**–**	**171**	**399,234**		

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 at the end of the period	Terms*	Redemption price (SEK)
2017/2021	CEO	184,200	–	184,200	–	1:1	25.35
2017/2021	Other senior executives	125,949	–	125,949	–	1:1	25.35
2017/2021	Other employees	–	–	–	–	1:1	25.35
2017/2021	**Total**	**310,149**	**–**	**310,149**	**–**	**1:1**	**25.35**
2019/2022	CEO	–	–	–	–	1:1	142.23
2019/2022	Other senior executives	26,293	–	–	26,293	1:1	142.23
2019/2022	Other employees	62,792	–	–	62,792	1:1	142.23
2019/2022	**Total**	**89,085**	**–**	**–**	**89,085**	**1:1**	**142.23**
2020/2023	CEO	–	–	–	–	1:1	334.60
2020/2023	Other senior executives	–	4,000	–	4,000	1:1	334.60
2020/2023	Other employees	–	6,620	–	6,620	1:1	334.60
2020/2023	**Total**	**–**	**10,620**	**–**	**10,620**	**1:1**	**334.60**
Total	CEO	184,200	–	184,200	–		
Total	Other senior executives	152,242	4,000	125,949	30,293		
Total	Other employees	62,792	6,620	–	69,412		
Total		**399,234**	**10,620**	**310,149**	**99,705**		

*1:1 = 1 warrant = 1 share on conversion. 1:4000 = 1 warrant = 4000 shares on conversion.

NOTE 23 Other current liabilities

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
VAT	278	24	164
Employee withholding tax	1,270	558	599
Social security contributions	643	457	326
Liabilities to employees	1,621	964	67
Other liabilities	895	-	185
Total	**4,707**	**2,001**	**1,341**

NOT 24 Accrued expenses and prepaid income

KSEK	31 Dec 2020	31 Dec 2019	1 Jan 2019
Salaries, holidays, social security expenses	4,241	1,918	3,663
Lawyers' fees	1,775	1,025	225
Consultants' fees	1,192	180	-
Auditing	535	351	169
Delivery	356	-	-
Supplied goods not invoiced	545	-	-
Other	1,568	819	539
Total	**10,212**	**4,293**	**4,597**

NOTE 25 Appropriation of profit or loss

SEK	
Funds available to the Annual General Meeting:	
Accumulated loss	-180,265,514
Share premium reserve	613,922,552
Net profit/loss for the year	-28,766,942
Total	**404,890,096**

The Board proposes that the available funds be appropriated as follows:	
Share premium reserve	613,922,552
Accumulated loss in new account	-209,032,456
Total	**404,890,096**

NOTE 26 Transactions with related parties

KSEK	2020		2019	
	Purchases of services	Purchases of goods	Purchases of services	Purchases of goods
Parent Company				
Lismed Ltd	101	2,262	101	0
Parent Company total	**101**	**2,262**	**101**	**0**

Lismed Ltd is a company related to Ron Farrell, R&D director of the Group during the first quarter of 2020 and a member of the Board of the Group's Irish subsidiary.

Purchases of goods from Lismed Ltd concern the device Flurasorb and accessories which in turn are accessories to AnaConDa.

Purchases of services from Lismed Ltd concern technical support. At the end of the year, there was an outstanding liability to Lismed Ltd of KSEK 732. For information concerning remuneration of senior executives and warrants, see Notes 5 and 23 to the consolidated accounts.

NOTE 27 Important events after the end of the financial year

For information concerning important events after the end of the financial year, see Note 30 to the consolidated accounts, page 76.

NOTE 28 Explanations regarding the transition from cost-based to function-based income statement

KSEK	Classified by nature of expense	Other operating income	Goods for resale	Other external expenses	Personnel expenses	Depreciation, amortisation and impairment	Classified by function
Net sales	44,929	–	–	–	–	–	44,929
Other operating income	22,101	-22,101	–	–	–	–	–
Cost of goods sold	–	–	-30,362	-130	–	-130	-30,622
Gross profit or loss	**67,030**	**–**	**–**	**–**	**–**	**–**	**14,307**
Operating expenses	–	–	–	–	–	–	–
Goods for resale	-30,362	–	30,362	–	–	–	–
Other external expenses	-24,232	–	–	24,232	–	–	–
Personnel expenses	-25,151	–	–	–	25,151	–	–
Depreciation, amortisation and impairment of property, plant and equipment and intangible assets	-1,278	–	–	–	–	1,278	–
Selling expenses	–	–	–	-14,304	-14,957	-931	-30,192
Administrative expenses	–	–	–	-9,857	-9,286	-134	-19,277
Research and development expenses	–	–	–	59	-908	-83	-932
Other operating income	–	22,101	–	–	–	–	22,101
Other operating expense	-2,058	–	–	–	–	–	-2,058
Operating income	**-16,051**	**–**	**–**	**–**	**–**	**–**	**-16,051**
Financial income	3,409	–	–	–	–	–	3,409
Financial expense	-2,146	–	–	–	–	–	-2,146
Profit/loss after financial items	**-14,788**	**–**	**–**	**–**	**–**	**–**	**-14,788**
Group contributions	**-12**	**–**	**–**	**–**	**–**	**–**	**-12**
Earnings before tax	**-14,800**	**–**	**–**	**–**	**–**	**–**	**-14,800**
Income tax	–	–	–	–	–	–	
Net profit/loss for the year	**-14,800**	**–**	**–**	**–**	**–**	**–**	**-14,800**

NOTE 29 Bridging transition to RFR2

As the Group is publishing its first consolidated financial statements and the chosen accounting policy for this is IFRS, the Parent Company is changing its accounting policy from applying K3 to RFR 2 'Financial Reporting for Legal Entities'. Transition to RFR 2 has not had any effect on the Parent Company, either in opening IFRS balance sheets or in the accounting period. RFR 2 requires the Parent Company to apply in its annual financial statements International Financial Reporting Standards (IFRS) as adopted by the EU, to the extent that this is possible under the Swedish Annual Accounts Act and the Swedish Pension Obligations Vesting Act, and taking account of the relationship betwee accounting and taxation. The recommendation sets out certain exceptions and supplements which are required with regard to IFRS.

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. For a more detailed description of Sedana Medical's risks, refer to the Group's prospectus bmitted in connection with listing on Nasdaq First North Growth Market Stockholm, Sweden.

Danderyd, 14 April 2021

Thomas Eklund
Chairman of the Board

Sten Gibeck
Board member

Bengt Julander
Board member

Ola Magnusson
Board member

Christoffer Rosenblad
Board member

Eva Walde
Board member

Christer Ahlberg
President and CEO

Our auditor's report was submitted on 14 April 2021

Öhrlings PricewaterhouseCoopers AB

Leonard Daun
Authorized 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 2020. The annual accounts and consolidated accounts of the company are included on pages 54-95 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 2020 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 2020 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 matter
The audit of the annual accounts and consolidated accounts for year 2019 was performed by another auditor who submitted an auditor´s report dated 22 April 2020, with unmodified opinions in the Report on the annual accounts and consolidated accounts.

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 1-53 and 98-107. The Board of Directors and the Managing Director are responsible for this other information.

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

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

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

Responsibilities of the Board of Director's and the Managing Director
The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

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

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

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

Report on other legal and regulatory requirements

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 2020 and the proposed appropriations of the company's profit or loss.

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

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

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

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

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

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

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

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

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

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

Stockholm 14 april 2021

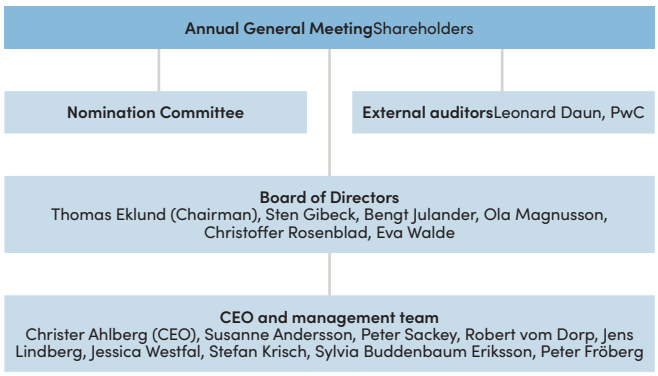
Öhrlings PricewaterhouseCoopers AB

Leonard Daun
Authorized 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 19 May 2020.

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



Internal instructions and policies of importance for 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 regulations

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 attendance and fee

	Year elected	Attendance number of meetings in 2020 (16)	Board fee decided by 2020 AGM, KSEK	Attendance of audit committee meetings in 2020 (3)	Audit committee fee decided by the 2020 AGM, KSEK	Independent in relation to:	
						Company	Shareholders
Chairman of the Board							
Thomas Eklund	2014	16	400	3	25	Yes	Yes
Board member							
Sten Gibeck	2005	16	100			Yes	Yes
Bengt Julander	2011	16	100	2	12.5	Yes	Yes
Ola Magnusson	2005	16	100			Yes	Yes
Christoffer Rosenblad	2020	7	150	3	12.5	Yes	Yes
Eva Walde	2018	16	150			Yes	Yes

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 financial reporting and prepare matters relating to the company' financial reporting and auditing under Chapter 8 section 49b of the Swedish Companies Act and fulfil the tasks which follow from EU Regulation No 537/2014. 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. Christer Ahlberg was the company's CEO on the closing date. Sedana Medical's senior management otherwise consisted of CFO Susanne Andersson (took up duties on 11 January 2021), CMO Peter Sackey, VP Business Development Robert vom Dorp, VP Commercial Operations Jens Lindberg, VP Regulatory Affairs and QA Jessica Westfal, Supply Chain and Manufacturing Director Stefan Krisch (took up duties on 8 March 2021), HR Director Sylvia Buddenbaum Eriksson and Chief Technology Officer Peter Fröberg.

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 Pricewaterhouse-Coopers 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 19 May 2020 passed a resolution concerning annual Board fees in the amount of SEK 400,000 to the Chairman, SEK 150 000 to the Board members Christoffer Rosenblad and Eva Walde and SEK 100,000 each to the other Board members. The Annual General Meeting resolved that an audit committee be established in 2020, to be chaired by Christoffer Rosenblad with a fee of SEK 25,000 and with a fee of SEK 12,500 for the members Thomas Eklund and Bengt Julander. Remuneration of senior executives who are employees may consist of basic salary, variable remuneration, pension and other benefits. In addition to his monthly salary, CEO Christer Ahlberg has the right to an annual bonus amounting to not more than five 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 25 percent of the CEO's fixed monthly salary to an occupational pension scheme determined by the CEO. The period of notice for termination is six months on the part of the CEO and 12 months on the part of the Company. 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 2020 was KSEK 914. Remuneration of the Company's accountant is paid on current account.

BOARD OF DIRECTORS

Thomas Eklund

Chairman of the Board

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 leading positions in banking, life science and healthcare. CEO, Investor Growth Capital (renamed as Patricia Industries) during 2002–2012, a private equity company owned by Investor AB with a focus on long-term investments in technology, industrial and healthcare. Former board member in life science companies, e.g. Swedish Orphan International AB (chairman) and Carmel Pharma AB.

Other current appointments: Member of the Board of Biotage AB, Bio-Works Technologies AB, Bio-Works Sweden AB, Boule Diagnostics AB, Excillum Aktiebolag, 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: 416,616 shares via Tedsalus AB.

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

Sten Gibeck

Board member

Born: 1943

Nationality: Swedish

Position: Member of the Board at Sedana Medical since 2005. Former Chairman of the Board.

Education and work experience: Sten holds a higher business economics qualification from the National Swedish Union of Clerical Employees. Sten is a former owner and CEO of Louis Gibeck AB during its journey from being a small distribution company to achieving a leading position in its field in e.g. Germany, France, Japan and the USA.

Other current appointments: –

Shareholding in Sedana Medical: 1,219,944 shares.

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

Bengt Julander

Board member

Born: 1953

Nationality: Swedish

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

Education and work experience: Bengt is a qualified pharmacist, M.Sc. from Uppsala University. Bengt has more than 30 years of experience in the life science industry. Owner and Chairman in Linc AB, with investments in the pharmaceutical and medtech industry.

Other current appointments: Chairman in Linc AB and Knil AB. Member of the Board of Animal Probiotics Sweden AB, Cronhamn Invest AB, Livland Skog AB, Medivir Aktiebolag, nWise AB, Part Production Sweden AB, Reison Medical AB, Stille 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: 1,899,701 shares via Linc AB.

Independent in relation to the company, its management but not in relation to major shareholders.

Ola Magnusson
Board member

Born: 1948

Nationality: Swedish

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

E**ducation and work experience:** Ola holds an upper secondary school qualification in engineering specializing in chemistry from Gothenburg Technical Upper Secondary School. Ola has more than 25 years of experience in the pharmaceutical industry mainly within marketing, sales and different management positions including four years in the US for Pharmacia in the 80ies and 90ies. Ola also has more than 20 years' experience in the medical device industry as CEO for Louis Gibeck AB where he was responsible for the listing on the OTC exchange in Stockholm and as Managing Director EMEA, Hudson RCI AB after its acquisition of Louis Gibeck AB.
Ola was the founder of Sedana Medical 2005 and acted as CEO up to 2011.

Other current appointments: Chairman in Eataway AB. Board member in TransCutan AB and board member in smaller family companies.

Shareholding in Sedana Medical: 1,157,432 shares privately and via Magiola Consulting AB.

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

Eva Walde
Board member

Born: 1963

Nationality: Swedish

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

Education and work experience: Eva has a BSc from the School of Economics in Gothenburg, Sweden. Over 20 years of experience in the pharmaceutical and medical technology industry, mainly in marketing and sales as well as management. Formerly VP Commercial Operations, International Region at Phadia / ThermoFisher Scientific as well Strategic Affairs Director at Johnson & Johnson Nordic AB, Medical Device and Strategic Development Manager at Pfizer AB.

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

Shareholding in Sedana Medical: 3,200 shares.

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

Christoffer Rosenblad
Board member

Born: 1975

Nationality: Swedish

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

Education and work experience: Christoffer has a Master of Science degree from Chalmers University of Technology and a degree in economics from the School of Business and Economics at the University of Gothenburg. During 2012-2020 he was CFO for XVIVO Perfusion AB. During the years 2015–2017, he led XVIVO's North American operations and resided in the United States. From 2001 to 2012, he has had leading 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: 0 shares.

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

ORGANISATION

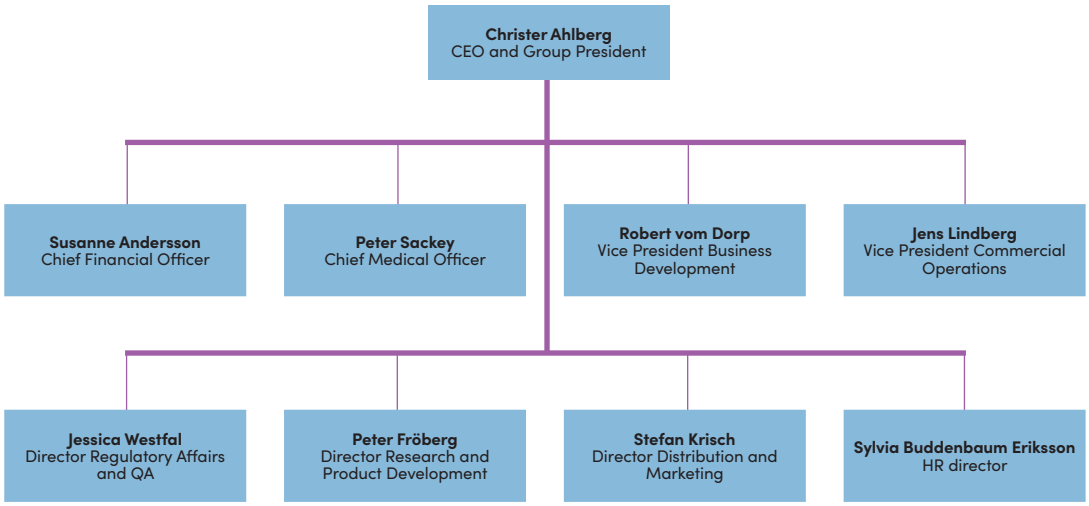
Sedana Medical has staff with a broad background and experience in company management, marketing, sales, production and R&D from both the pharmaceutical and medical device industries.

Sedana Medical's head office is in Danderyd, Stockholm, while research and development is located in Ireland. The Group also has a number of product specialists employed in Germany, France, the Nordics, the UK and Spain. During 2020, the average number of employees was 55. Through its long-term, determined efforts, the Group has created a strong organisation that attracts experienced personnel to the company.

Over the next few years, Sedana Medical will increase the number of employees as the Group grows and consequently make the organisation well prepared for the market launch of inhaled sedation therapy. To achieve its operational and financial objectives, Sedana Medical will pay close attention to strengthening its product specialist organisation on current and future markets and boosting pharmaceutical expertise throughout the organisation.

Company management

The Group's management team consists of President and CEO Christer Ahlberg, CFO Susanne Andersson, VP Commercial Operations Jens Lindberg, VP Regulatory Affairs and QA Jessica Westfal, VP Business Development Robert vom Dorp, CMO Peter Sackey, Chief Technology Officer Peter Fröberg, Supply Chain and Manufacturing Director Stefan Krisch and HR director Sylvia Buddenbaum Eriksson.



GROUP MANAGEMENT

Christer Ahlberg

President and CEO

Born: 1971

Nationality: Swedish

Position: Chief Executive Officer and Group President of Sedana Medical since February 2017. Employed since 2017.

Education and work experience: Christer holds a BSc in business administration and economics from Örebro University. Previous experience in the pharmaceutical industry, most recently as CEO at Unimedic Group (2010–2016), CEO at Eisai AB (2005–2010), and more than 10 years of experience in senior positions in sales, marketing and market access in the pharmaceutical industry, at AstraZeneca, Meda and Wyeth, among others.

Other current appointments: Member of the Board of FrostPharma AB, Prooxpharma AB and Glycorex Transplantation AB. CEO and deputy member of the Board of Waxholm by the sea aktiebolag.

Shareholding in Sedana Medical: 259,000 shares.

Susanne Andersson

Born: 1971

Nationality: Swedish

Position: Chief Financial Officer (CFO) since January 2021.

Education and work experience: Bachelor of Business Administration from College of Charleston, S.C., USA. Former CFO at Pricer, CFO & Head of Communications at ChromoGenics, VP Head of Investor Relations at PostNord, CFO at Nordic Mines and 15+ years of experience in various financial and management positions in Ericsson and the telecoms industry.

Other current appointments: –

Shareholding in Sedana Medical: no 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 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 118 shares.

Robert vom Dorp

Born: 1970

Nationality: German

Position: Vice President Business Development at Sedana Medical since April 2020, employed since 2005.

Education and work experience: Robert holds an MBA in economics from the University of Applied Sciences at Hochschule Koblenz. Has also studied industrial organisation. Experience in sales in medical devices since 2001, previously as account manager for devices in anaesthesia, ventilation and intensive care at Hudson RCI and Teleflex Medical. Responsible for marketing, strategy, sales and HR at Sedana Medical's sales office (branch) in Germany. Also responsible for dealers in Austria and Switzerland. Previously consultant at company which issued ISO certification to hospitals.

Other current appointments: –

Shareholding in Sedana Medical: 100,000 shares.

Peter Fröberg

Born: 1971

Nationality: Swedish

Position: Chief Technology Officer (CTO), consultant since November 2020.

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 product manager at AB Gustavsberg. Founder of Eker Bicycles AB and Eker Production Ltd, Uganda.

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

Shareholding in Sedana Medical: 1,400 shares and 6,300 warrants.

Jens Lindberg

Born: 1971

Nationality: Swedish

Position: Vice President Commercial Operations since April 2020, employed since 2020.

Education and work experience: B.S. Business Administration and 25 years in local and global commercial roles in AstraZeneca.

Other current appointments: –

Shareholding in Sedana Medical: no shares. 3,000 warrants in the 2020/2023 warrant programme, corresponding to 3,000 shares.

Peter Sackey

Born: 1971

Nationality: Swedish

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

Education and work experience: Peter obtained his degree in medicine at Karolinska Institutet in 1997. He has worked for more than 20 years in the Department of Perioperative Medicine and Intensive Care, Karolinska University Hospital and holds European qualifications in anaesthesia (DESA) and intensive care (EDIC). He completed his PhD thesis entitled "Isoflurane sedation in Intensive Care Unit patients" at Karolinska Institutet in 2006. Peter is an associate professor at Karolinska Institutet, has supervised several PhD students and is active in ICU-related research.

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

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

Shareholding in Sedana Medical: 63,142 shares and 26,293 warrants in the 2019/2022 warrant programme, corresponding to 26,293 shares.

Jessica Westfal

Born: 1974

Nationality: Swedish

Position: Vice President Regulatory Affairs and QA since 2020, employed since 2020.

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

Other current appointments: –

Shareholding in Sedana Medical: no shares, related party 173 shares. 1,000 warrants in the 2020/2023 warrant programme, corresponding to 1,000 shares.

Literature references

Page	Source:
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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.

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.

Inhaled sedation sedation by administration 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.

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

Phase 4 study is performed after a medicinal product has started to be marketed to monitor long-term effects and detect any unusual side effects.

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

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

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

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

SMRG, Sedana Medical Research Grant, a research grant that was instituted in 2019 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.

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

Shareholder information, future events

Annual General Meeting

The Annual General Meeting of Sedana Medical will be held on 10 May 2021, at 3.00 pm on the company's premises at Vendevägen 89, Danderyd.

To be eligible to attend the meeting, shareholders must be registered in the shareholders' register maintained by Euroclear Sweden AB by 4 May 2021. In good time before this date, shareholders who have registered their shares in the name of a nominee or trustee should, through the offices of the nominee or trustee, temporarily register the shares in their own name to be eligible to attend. Registration for the meeting begins at 2.45 pm.

Certified adviser

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Financial calendar

Interim report 1st Quarter 2021:	6 May 2021
AGM:	10 May 2021
Interim report 2nd Quarter 2021:	12 August 2021
Interim report 3rd Quarter 2021:	4 November 2021

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