SEDANAMEDICAL

Pioneering volatile anaesthetic delivery

ANNUAL REPORT 19

Well on our way of becoming a pharmaceutical company

Aiming to establish a new standard treatment in intensive care

Clinical progress and international expansion

Inhaled sedation is a potential paradigm shift in intensive care

CONTENTS

AnaConDa provides access to simple controllable sedation that is efficient safe and cost-effective for the intensive care.

INHALED SEDATION CAN BECOME THE STANDARD METHOD

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

8

MILLION PATIENTS
sedated and ventilated in the ICUs.

Almost half of all patients in an intensive care unit need help with breathing by means of a ventilator. Patients need to be sedated to cope with mechanical ventilation and other necessary treatments.

Sedana Medical has developed and sells the AnaConDa product family of medical devices for the inhaled sedation of mechanically ventilated patients. AnaConDa allows the administration of volatile anesthetics such as the company's drug candidate IsoConDa® (isoflurane) via the respiratory tract, by means of so-called inhaled sedation. This means intensive care can gain access to simple, controllable sedation that is efficient, safe and cost-effective.

Sedana Medical's market for combination treatment with AnaConDa and IsoConDa consists primarily of sedated, mechanically ventilated intensive care patients. Today, the standard intravenous treatment presents a number of challenges for both patients and healthcare that inhaled sedation solves.

Every year, around 8 million patients evenly distributed between the USA, Europe and Asia, are sedated due to mechanical ventilation in intensive care. These patients are usually sedated for two to five days. Sedana Medical estimates the total market potential to be between SEK 20 to 30 billion. Furthermore, the market is growing as populations age.

AnaConDa is approved in the EU and Japan. However, because no volatile anesthetic drug is as yet approved for sedation in intensive care units, Sedana Medical has begun a drug registration study to gain market approval in Europe for inhaled sedation in intensive care using the drug IsoConDa.

Sedana Medical expects registration of IsoConDa in Europe to take place during 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 order to quickly penetrate the market, the plan is to establish representation, networks

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

30%

SALES

have grown by about 30 percent per year since 2010.

and reference clinics in multiple European countries once authorization for IsoConDa is granted. 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 begun activities to achieve market approval in other markets outside the EU. AnaConDa and IsoConDa are not yet approved in the USA, but Sedana Medical has begun the process to achieve market approval in 2024.

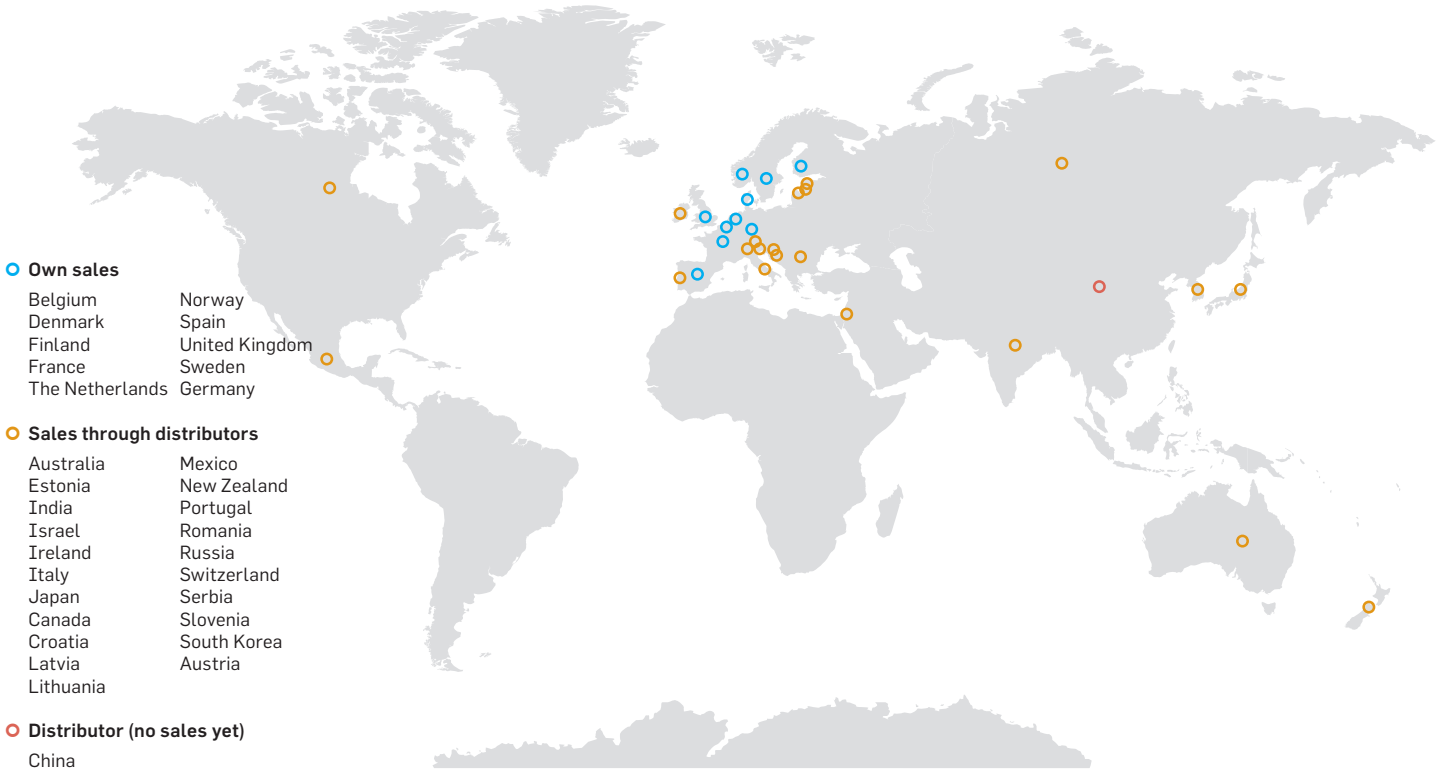
AnaConDa in brief

Anaconda provides the relevant functionality suitable for use in intensive care clinics, but in a very compact format and without the need for major investments or expensive operating staff. Thanks to its unique technology, AnaConDa provides a simple, effective way to make inhaled sedation the new standard for the sedation of intensive care patients.

In 2019, Sedana Medical achieved sales of SEK 72 million. Sales have grown by about 30 percent per year since 2010, even though the therapy is off-label. The company has its own sales organizations in the Nordics, Germany, France, the United Kingdom, Benelux (opened 2020) and Spain and distributors in other parts of Europe, Australia, Canada, China, India, Japan, South Korea and Mexico (opened 2020). The company's biggest market is Germany.

Sedana Medical was founded 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 via contract manufacturers. In June 2017, the company's stock was listed (ticker: SEDANA) on the Nasdaq First North Growth Market Stockholm.

Sedana Medical's vision is to make inhaled sedation using AnaConDa and IsoConDa the global standard within intensive care.



Own sales

Belgium, Denmark, Finland, France, The Netherlands, Norway, Spain, United Kingdom, Sweden, Germany

Sales through distributors

Australia, Estonia, India, Israel, Ireland, Italy, Japan, Canada, Croatia, Latvia, Lithuania, Mexico, New Zealand, Portugal, Romania, Russia, Switzerland, Serbia, Slovenia, South Korea, Austria

Distributor (no sales yet)

China

STRONG DEVELOPMENT IN LINE WITH OUR STRATEGY

Q1

The scheduled pediatric study plan received approval from the Pediatric Committee of EMA, European Medicines Agency, (PDCO).

Because the interim analysis of the IsoConDa registration study showed fewer variations in effect than anticipated, the study will only have to include a total of 300 patients instead of the 550 initially estimated.

Q2

The U.S. Food and Drug Administration (FDA) appeared positive to the registration of IsoConDa and AnaConDa as a combination product in the USA, and Sedana Medical's understanding of the regulatory requirements was confirmed. USA approval is expected to take place in 2024.

The first patient in Japan was treated with AnaConDa, and work on registration of IsoConDa in Japan began.

A ten year, exclusive distribution agreement was concluded with the Chinese distributor Kyuan Xinhai Medical. Kyuan is a subsidiary of China's second biggest life-science company, partially state-owned Shanghai Pharma. Kyuan expects market approval to be obtained for AnaConDa within less than two years.

Key ratios for the Group

Amounts in SEK thousands (000)	2019	2018	2017
Net Sales	71,645.6	57,896.2	40,427.7
Gross Profit	52,413.1	42,896.5	29,661.7
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-12,978.9	-4,232.3	-736.2
Earnings Before Interest and Taxes (EBIT)	-17,167.3	-8,238.2	-3,487.8
Net income	-16,357.8	-6,869.1	-3,875.7
Gross Margin (%)	73.2%	74.1%	73.4%
EBITDA %	-18.1%	-7.3%	-1.8%
EBIT %	-24.0%	-14.2%	-8.6%
Net income % of net sales	-22.8%	-11.9%	-9.6%
Total assets	593,251.4	231,549.8	131,376.3
Equity ratio	96.0%	94.1%	88.6%
Quick ratio	2007.2%	1219.6%	640.4%
Average number of employees	38.6	26.1	16.5

NET SALES 2019, SEK THOUSAND

71,646

SALES GROWTH IN 2019

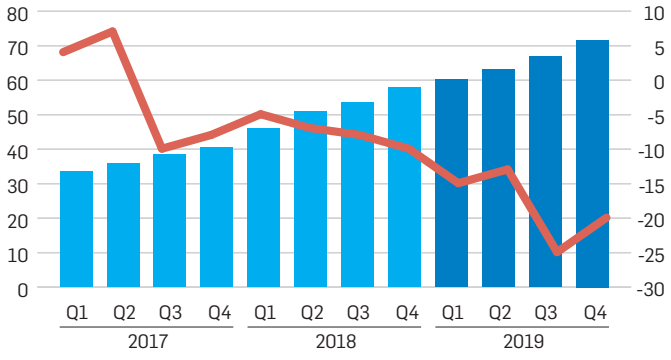
24%

Q3

A distribution agreement was concluded with Indian distributor Hansraj Nayyar Medical. Sales began during the fall in parallel with a registration process. Hansraj Nayyar committed to an initial framework order of EUR 25,000.

The European notifying body BSI Group approved the use of AnaConDa on children. The approval also means AnaConDa can be used on patients with severely impaired lung function.

Sales revenue and EBITDA margin, 12 month rolling



Q4

A targeted new share issue provided the company with SEK 375 million before transaction expenses. Investors in the new share issue consisted of a number of Swedish and international institutional investors including AXA IM, Handelsbanken Fonder, Joh. Berenberg Gossler & Co., KG (Berenberg), Swedbank Robur, Tredje AP-fonden and Öhman Fonder.

The world's biggest multicenter study with AnaConDa, SESAR, was announced in France. The study was investigator-initiated and Sedana Medical will provide them with AnaConDa and accessories. The study's primary objective is to demonstrate that inhaled sedation with AnaConDa has lung-protective characteristics, results in shorter ventilator time and higher survival among intensive care patients with severe pulmonary conditions.

The financial performance target was adjusted and the sales target clarified. Sedana Medical only provides the financial performance target for the period three years after IsoConDa registration in Europe at 40% of the EBITDA margin. The sales target for the corresponding period is SEK 500 million for Europe.

A further investigator-initiated major French multicenter study, INASED, was announced. The objective is to demonstrate a lower occurrence of delirium in mechanically ventilated intensive care patients compared to intravenous sedation with propofol. A positive outcome would significantly boost the company's clinical basis for regulatory and commercial expansion.

WE'RE PASSING MILESTONES AT A GOOD PACE

Based on our future scenario and priorities, 2019 was our strongest year ever. We've been quick to build on our foundations in order to achieve our long-term goals.

First of all, during the year we announced our sponsorship of two major studies which, if their outcomes are positive, will help engender a paradigm shift within intensive care. Secondly, we were able to secure financing for the work involved in obtaining market approval for our therapy in the USA. And finally, we passed an important milestone when we closed recruitment to our drug registration study for IsoConDa. In all, I'm proud that our entire organization has truly delivered and continues to build for the future on stable foundations.

When it comes to our commercial activities, I was pleased to note our robust sales figures. Growth was 24 percent for the full year. Germany continues to be the natural growth engine, but sales continued to grow steadily in many other European direct selling markets such as France and the United Kingdom. All in all, we're achieving the goals we announced and delivering well above our ambition of 20 percent growth per year before registration of IsoConDa in Europe. In the new year, we announced the start of direct sales in Benelux by engaging sales staff.

> **Sedana Medical sums up** yet another strong year that takes us closer to our goals.

The partial financing of SESAR and INASED, the two major multicenter studies, was most gratifying. As a company, being able to contribute to the development of medical science in this way is truly a privilege. The studies are being conducted partly to show that inhaled sedation with AnaConDa has lung-protective characteristics (SESAR) in ARDS patients resulting in higher survival rates, and also to demonstrate a reduced incidence of delirium (INASED), which is a major problem in intensive care. Positive outcomes would significantly boost our clinical base and each of the studies have the potential to dramatically change the perception of inhaled sedation compared to intravenous sedation.

Studies of this type allow us to gather evidence which, if positive, can form the basis of a paradigm shift within intensive care. Not only are these investigator-initiated studies important support for our continued regulatory and commercial expansion, they also give an indication of the enormous potential our therapy enjoys. Our own studies will also provide more evidence that is not only essential for regulatory approval, but will also be of great commercial benefit.

In this context, I'd like to take the opportunity to highlight the importance of our Sedana Medical Research Grant, which was established at the beginning of the year. The Grant will promote conditions for investigator-initiated studies within our field. The winners in 2019 were three particularly interesting research projects in Italy, France and Switzerland, and each in its own way will advance therapy both scientifically and geographically.

The year was largely characterized by efforts to ensure registration in the US. Money from the targeted new share issue which ended in the last quarter – SEK 375 million before expenses – will be used primarily to finance the journey to market approval for AnaConDa and IsoConDa in the USA. I view our success in bringing in this amount of money as a sign of strength, and I would like to use this moment to thank shareholders, old and new, for the trust they put in us.

Following our meeting with the U.S. Food and Drug Administration (FDA) we have a good understanding of what we must provide to obtain market approval. The combined registration of AnaConDa and IsoConDa also includes activities such as two clinical studies totaling around 500 patients, human factors

validation, toxicity studies, a safety database, adaptation of the European pediatrics study to meet FDA requirements and an application for market approval (NDA). Work intensified toward year-end and is proceeding according to plan. In 2022, we will decide how we should commercialize the therapy, i.e. by ourselves or together with a partner.

Our announcement immediately after year-end that the final patient had been included in our IsoConDa registration study was an undeniably important milestone. The 300-patient study was conducted at more than 20 centers in Germany and Slovenia. First of all, it's naturally extremely gratifying to have been right on schedule in the world's biggest study of inhaled sedation in intensive care. But above all, the study is crucial for our ability to proceed with our European market approval application.

Because we were able to close recruitment to the IsoConDa study at year-end, we expect to stay on schedule and if all goes well, we expect approval during the second half of 2021.

In order to carry out a full application for marketing authorization, we also need an approved pediatric study plan. We obtained approval in early 2019 and were able during the last quarter to begin work on starting the pediatric study, Iso-COMFORT, in 2020. Because the outcome from the pediatric study is not a requirement for approval for use on adults, the market approval schedule for IsoConDa is not affected by the Iso-COMFORT study.

As for our activities in the rest of the world, our work is moving forward at a fast, encouraging pace. We are present at a number of test clinics in Japan, but we cannot begin material discussions with the Japanese authorities about what is required for market approval before the European dossier is complete. In other words, we hope to know more sometime during the second half of 2020.

We concluded an agreement during the year with Chinese distributor Kyuan Xinhai Medical. They have now submitted an application for market approval of AnaConDa in China in line with their ambition of gaining approval for the therapy before the summer of 2021 (within two years of signing the agreement). In India, the first patients were treated with AnaConDa during the fourth quarter, and our Indian distributor Hansraj Nayyar Medical is responsible for the registration process for the therapy.

To summarize, we've had yet another strong year which takes us closer to our goal of registering IsoConDa in Europe during the second half of 2021, market approval in the USA in 2024 and establishing us in the major Asian markets We continue to expect annual sales of SEK 500 million in Europe and the EBITDA margin to be around 40 percent three years after the registration of IsoConDa in Europe. The goals are a first step toward our vision of making inhaled sedation with AnaConDa and IsoConDa a standard treatment for mechanically ventilated intensive care patients throughout the world. I look forward to continuing this journey with you all.

Christer Ahlberg
CEO and Group President

INHALED SEDATION IS DEVELOPING INTO THE GLOBAL STANDARD METHOD

Business concept

To provide a solution for many of the problems that today's intravenous sedation gives rise to. AnaConDa is a system for administering the volatile drug IsoConDa via the respiratory tract and enables inhaled sedation, which is an effective, safe, easily controllable, cost-effective means of sedation for mechanically ventilated patients in intensive care.

Vision

Inhaled sedation with AnaConDa and IsoConDa – a global standard method for the sedation of mechanically ventilated patients in intensive care.

Financial targets

The company's goal up until market approval is obtained for IsoConDa is to increase average sales by more than 20 percent per year while building up larger medical, sales and marketing organizations.

The goal is to achieve sales in excess of SEK 500 million in Europe and an EBITDA margin of 40 percent three years after the registration of IsoConDa.

Strategy

The company has created, and abides by, a strategy that can be summarized in three points:

1.

The registration of IsoConDa together with inhalation sedation in Europe

2.

Register AnaConDa and IsoConDa in the USA

3.

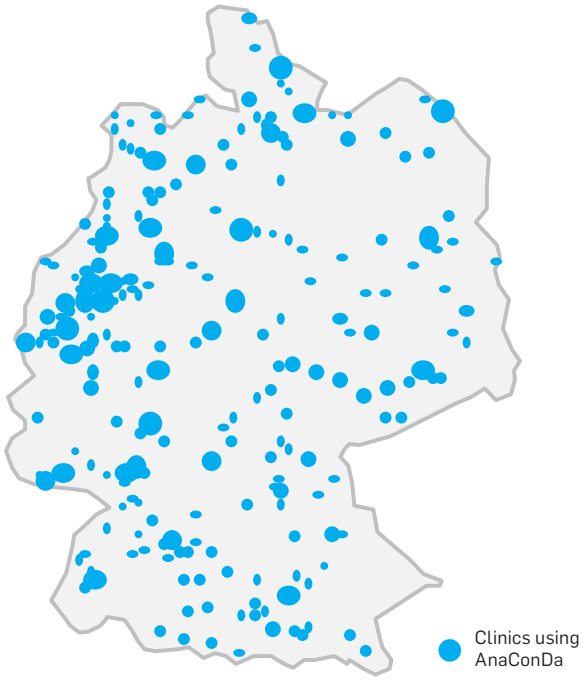
In close collaboration with the market, prepare for an effective, successful launch of the products and the therapy following their registration first in the EU and later in the USA.

20%

THE COMPANY'S GOAL

up until market approval is obtained for IsoConDa is to increase average sales by more than 20 percent per year.

SEDANA MEDICAL'S HISTORY IN BRIEF



~600

INTENSIVE CARE UNITS USE ANACONDA

5%

OF THE GERMAN MARKET POTENTIAL

Germany – Sedana Medical's test market

In 2010, new guidelines for the use of sedation were published in Germany. The guidelines put forward inhaled sedation and the use of isoflurane 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 have led to extensive use of AnaConDa in Germany. The company calculates that around 600 intensive care clinics across Germany use AnaConDa to sedate mechanically ventilated intensive care patients. Up until 2019, AnaConDa had been used for around 500,000 days. In 2019, German sales corresponded to around five percent of the German market potential. Between 2006 and 2019, Sedana Medical sold more than 350,000 AnaConDa units in Germany alone, and shows continued good growth.

1999
- AnaConDa tested clinically for the first time.

2005
- Sedana Medical founded in Uppsala
- Office opens in Germany

2008
- Studies show that short-term sedation with sevoflurane and AnaConDa following heart and thoracic surgery, result in significantly shorter ventilation times and hospital stays

2012
- Sales office opens in Madrid, Spain

2013
- R&D laboratory opens in Kildare, Ireland

2014
- AnaConDa now used in Canada, Australia and most 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 launched in Europe
- The company is listed on Nasdaq First North
- IsoConDa study begins

2018
- Opens own sales offices in the United Kingdom and the Nordics
- AnaConDa receives market approval in Japan
- Health-economics study shows the benefits of AnaConDa

2019
- Distribution agreements concluded in India and China
- Registration process in the USA begins
- AnaConDa approved for use on children in the EU
- Iso-COMFORT pediatrics study begins

INHALED SEDATION SOLVES THE PROBLEMS

The advantages of inhaled sedation are well-known, but before AnaConDa there was no good alternative for intensive care.

Sedation in the ICU – Major unsatisfied need

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 the patients need help with breathing by means of a ventilator[1]. Sedation is usually necessary to ensure comfort and safety and for the patient to tolerate mechanical ventilation and other necessary acute measures.

However, there are many problems with today's intravenous sedation of intensive care patients. Awakening times are often long and unpredictable. It can take between 90 minutes to 130 hours to wake a patient[2] which means that treatment in the intensive care unit is often longer than necessary and that extubation (removal of the breathing tube from the throat) is difficult to plan. Furthermore, drug concentration is difficult to monitor. Many cases occur of developed tolerance, withdrawal symptoms or agitation / delirium (20-35 percent of cases[3]). All of these side effects lead to a significant increase in the length of intensive care treatment. Also, delirium has been linked to increased mortality and impaired cognitive function years after intensive care. Because intravenous sedation drugs are eliminated via the liver or kidneys, and these functions are often impaired, there is a risk for an accumulation of drugs in the intensive care patient. Taken together, the above leads to high mortality in long-term ventilated patients[4].

On the other hand, inhaled sedation has been shown to provides several benefits. Awakening times are significantly shorter (10-20 minutes [5]) and more predictable, which means clinical workflow planning can be improved and the time till extubation 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 sedation drug is eliminated almost entirely through the lungs, the need for metabolism in the liver or

> **AnaConDa enables inhaled sedation of mechanically ventilated patients** in intensive care. AnaConDa administers the volatile anesthetic drug IsoConDa via the respiratory tract in an efficient, safe, simple, controlled and cost-effective manner.

Facts about sedation

Sedation drugs is a collective term for tranquilizing and sometimes analgesic drugs used in many healthcare areas. Sedation means putting a patient into a medically induced state of reduced consciousness to relieve anxiety, tension and pain, usually by intravenous means. The sedation of patients who are ventilated mechanically with the aid of a ventilator often continues for extended periods, usually between two and five days.

The concept of sedation encompasses a range of consciousness levels 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 bodily 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.

A concept known as general anesthesia is one level deeper than deep sedation and is used in conjunction with surgery.

General anesthesia is a collective term for a number of methods that use drugs to render a patient deeply unconscious and so oblivious to pain that surgery can be performed. The patient does not respond to any form of stimulation but is so deeply sedated that respiratory assistance is necessary. During general anesthesia, an anesthesia machine is used where a preparation is administered according to current practice through inhalation, or in some cases intravenously.

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

1. **Accumulation**
   - The intravenous preparation accumulates 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 manifestly increases the risk of over-sedation and delayed awakening.
3. **Awakening times**
   - Prolonged, extremely unpredictable awakening 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 under mechanical ventilation and extended stays in the intensive care unit, in particular for elderly patients, are associated with health risks and greater costs. Also extends the hospital stay after intensive care.
4. **Side effects**
   - Withdrawal symptoms and withdrawal problems such as autonomous stress, delirium, hallucinogenic effects. Delirium is clearly linked to increased mortality and cognitive problems in the year following intensive care.
   - Interaction with other drugs.
   - 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.
   - Energy is wasted controlling, pausing and restarting sedation instead of treating the patient.
   - Often leads to the need for additional drugs to maintain depth of sedation.

kidneys is minimal. Overall, mortality has been shown to decrease with inhaled sedation [4].

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

Intravenous sedation and medical problems

Sedation trends

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

- Increased awareness of the risks of delirium
- Lung-protective characteristics of volatile anesthetics
- Reduced use of benzodiazepines
- An aging population
- The need to reduce the cost of healthcare
- The benefits of lighter sedation

Increased awareness of the risks of delirium

The number of scientific studies examining the occurrence of delirium in intensive care patients has increased considerably over the past decade, and delirium has been recognized as a growing public health problem in the USA. 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 USA alone[7].

Lung protective characteristics in volatile anesthetics

It has long been known that volatile anesthetics have anti-inflammatory characteristics. Many lung diseases that acutely impair lung capacity have inflammatory causes. Studies on animals large and small 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. A major clinical study will be initiated in 2020 to further strengthen the evidence in this

“Inhaled sedation is a potential paradigm shift in intensive care.”

Professor Daniel Talmor, anesthesiologist and physician at Beth Israel Deaconess Medical Center.

important issue.

Reduced use of benzodiazepines

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

An aging population

There is an underlying global trend, especially in Europe and the USA, toward an aging 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 in general are in poorer health and have a lower ability to recover after an operation or serious injury, which means senior citizens who end up in intensive care tend to remain longer than young people.

The need to reduce the cost of healthcare

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

The benefits of lighter sedation

A broad, growing body of literature shows that lighter sedation is beneficial for patients under intravenous sedation This method avoids the accumulation problem and extended awakening times. Inhaled sedation is an eminently suitable method as the patient can quickly be woken, regardless of the depth of sedation, thanks to the rapid elimination of the drug.

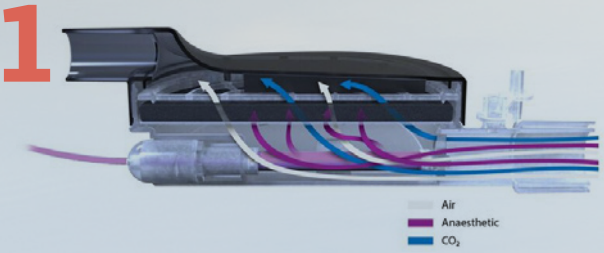
Expectations of a modern, calming ICU drug

- Fast-acting
- Easily controlled depth of sedation
- Fast awakening, which requires
  - A low level of accumulation
  - No active metabolites
- Few side effects

AnaConDa – ANESTHETIC CONSERVING DEVICE

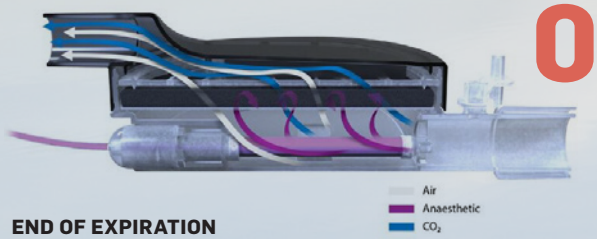
AnaConDa is a unique, innovative product that enables the safe, simple administration of volatile anesthetics, which was not previously possible without an anesthesia machine.

01



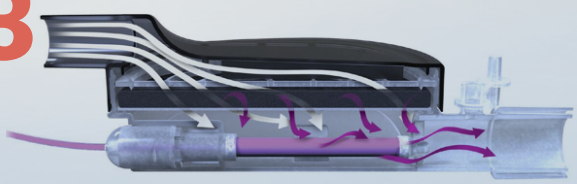
START OF EXPIRATION
At the start of expiration, expiration air contains CO_2 and the volatile anesthetic.

02



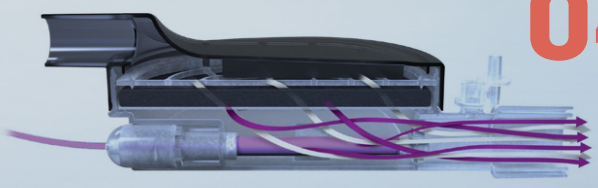
END OF EXPIRATION
Air/oxygen and CO_2 pass through the active charcoal filter while the majority of the volatile anesthetic is adsorbed by the activated charcoal filter.
Next, expiration air (almost exclusively air/oxygen and CO_2), passes out through the ventilator tubing and then through the ventilator outlet.

03



START OF INSPIRATION
When inspiration begins, air is carried from the ventilator and passes through the AnaConDa unit.

04



END OF INSPIRATION
During inspiration, anesthetic retained in the reflector is released from the activated charcoal filter into which it was previously adsorbed during expiration, and transported together with air/oxygen to the patient. New anesthetic is constantly evaporated in the mini-evaporator.

AnaConDa (Anesthetic Conserving Device) is an anesthetic delivery system developed for the administration of volatile anesthetics such as isoflurane or sevoflurane to mechanically ventilated patients.

AnaConDa is a less complicated alternative to an anesthesia machine. It is intended for single use and must be replaced every 24 hours. AnaConDa is a small device that is inserted between the endotracheal tube and the Y-piece AnaConDa's design incorporates a unique miniature vaporizer and a reflector that enable the simple, safe and efficient delivery of anesthetics. AnaConDa works with all types of ventilators and syringe pumps and delivers volatile anesthetics as effectively as an anesthesia machine.

Why not use an anesthesia machine?

Anesthesia machines are used for the administration of general anesthetics in operating theaters, 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 acquisition and operating costs. The major requirement for administration and monitoring by a specialist makes the use of anesthesia machines labor-intensive and impractical for inhaled sedation in intensive care.

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

AnaConDa-S

The original AnaConDa version (100 ml) is aimed at adult intensive care patients. In a continued development of the technology, Sedana Medical launched a new improved version of AnaConDa – AnaConDa-S – in March 2017 in which the so-called dead space was halved from 100 ml to 50 ml. The reduction in dead space means that AnaConDa can now be used on patients who for various reasons have lower lung volumes than a typical adult, e.g. children or patients who have reduced lung capacity due to illness. The company estimates that this improvement has led to an increase in the AnaConDa target group by around 25 percent. In general, healthcare seeks to reduce dead space in all patients, and the company is already able to note the domination of the market by the new 50 ml version. In 2019, AnaConDa was approved for use on children and patients with severely impaired lung function.

The technology

Sedana Medical's unique, patented AnaConDa technology combines the four functions incorporated in anesthesia machines in one single unit: a gas evaporator (required for the controlled production of the anesthesia gas), the reflector with a unique activated charcoal filter (for recirculating and conserving the anesthesia gas), a bacteria filter and a heat & moisture exchanger. The technology enables very efficient reflection of anesthesia gas from expiration air; more than 90 percent of the gas remains in the active charcoal filter and is re-used during the inspiration phase. This high level of reuse not only helps reduce the consumption of volatile anesthetics, but also the spread of gas to the surroundings,

AnaConDa – A compact unit with the most important anesthesia machine functions for intensive care

- Simple and easy to administer – can be administered by a nurse
- Low cost, single-use system for administering inhaled sedatives
- Accurate patient dosages that minimize over and under-sedation
- Compact size and comfortable design – seamless integration in the clinical workflow
- Low sedative consumption – more than 90 percent recirculated back to the patient
- Proven safety without emissions at the workplace
- Combines four functions (evaporation, reflection, humidification and filtration)
- A single-use delivery system that requires no electricity or maintenance
- CE-marked with strong European sales growth, patent possible up until 2036

AnaConDa is designed to be simple to use and to work together with all modern intensive care ventilators, syringe pumps and gas monitors. Ventilators, syringe pumps and gas monitors.

and studies confirm that AnaConDa has very low (clinically insignificant) emissions and is safe to use in intensive care clinics.

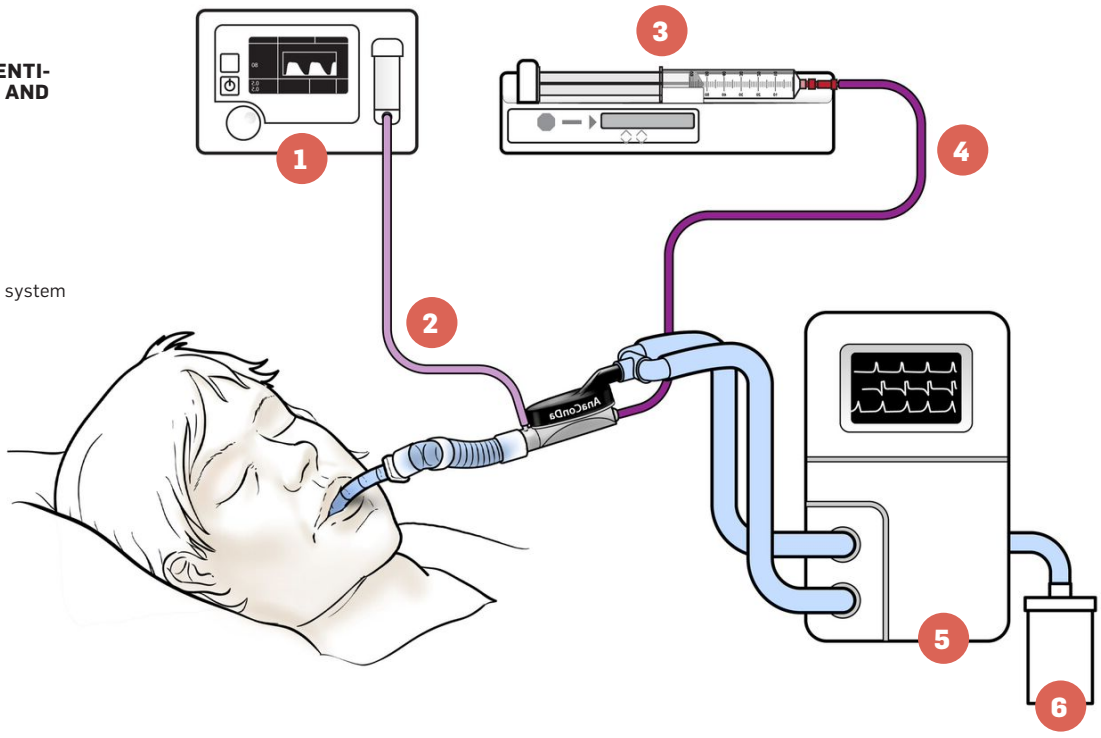
How does AnaConDa work?

AnaConDa is used in combination with a ventilator, a gas monitor and a syringe pump. The specially designed AnaConDa syringe (unique connector) is placed in a standard syringe pump. AnaConDa is placed in the breathing circuit between the Y-piece and the ET-tube. Liquid anesthetic is delivered from the syringe through the agent line to AnaConDa where it is vaporized inside the device. The evaporated gas is transported with the inspiration flow from the ventilator and delivered to the patient. The gas monitor samples the gas from the AnaConDa port and displays the exhaled concentration of anesthetic in Fet% or MAC values (which indicate drug concentration).

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

COMPATIBLE WITH ALL VENTILATORS, SYRINGE PUMPS AND GAS MONITORS.

1. Gas monitor or module
2. Measuring line
3. Syringe pump
4. Agent line
5. Ventilator
6. Passive or active scavenging system



IsoConDa AND ITS THERAPEUTICAL BENEFITS

IsoConDa is Sedana Medical's brand name for the drug isoflurane.

Isoflurane is a volatile anesthetic that has been used for decades in operating theaters around the world for short-term treatments under general anesthetic. Isoflurane is not currently approved for use for sedation in intensive care, but is only approved for use as a general anesthetic. When used together with AnaConDa for sedation, its use is off-label. IsoConDa may not be sold for the indication sedation in intensive care until marketing authorization is obtained.

Because Sedana Medical's sales of AnaConDa have been seriously hampered by the fact that IsoConDa is as yet not approved, an important part of the company's growth strategy is to conclude the registration study currently in progress and which is expected to result in marketing authorization in Europe during 2021. Once authorization is obtained, it will be possible to actively market IsoConDa and AnaConDa for their proper fields of application, which is expected to have a significant effect on sales. Moreover, Sedana Medical expects general acceptance of the treatment to increase markedly following authorization.

Today, there are clear recommendations advising against the use of benzodiazepines for sedation within intensive care, but the alternatives are limited. Sedana Medical is convinced that IsoConDa is able to fulfill this role.

Compared to the current intravenous standard, sedation with IsoConDa administered by AnaConDa provides the treated patient with a number of medical advantages, of which some are listed below:

- **Significant reduction in mortality** [1]
- **Potential for reduced time in the intensive care unit:** minor risk of tolerance development, dependency, withdrawal symptoms and / or delirium, while fewer infections in the hospital are expected to result in shorter hospital stays. The daily cost for an intensive care unit patient in Europe is estimated at EUR 1,000-3,000 [2].
- **Organ-protective characteristics.** Inhaled sedation has potential protective cardiovascular, respiratory and nervous system characteristics [3].
- **Can be used on patients with kidney and liver disease.** Isoflurane is administered and excreted via the lungs with minimal breakdown in the body. (Intravenous sedatives are metabolized in the liver and secreted by the kidneys).
- **Bronchodilatory effect** Improves lung function in patients with KOL, ARDS, asthma and other respiratory diseases [4].
- **Reduced opiate use.** When isoflurane is used, the dose of analgesic drugs 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 opiate dependence and lowers the cost of sedation. In addition to the risk of opiate dependency, elderly patients often have problems moving their bowels following treatment with opiates.
- **Shorter wake-up times.** When treatment is over and the patient must be awakened, it's important that the patient is awake and

Sedation with AnaConDa and IsoConDa provides a range of medical benefits.

cooperative as soon as possible. It also makes it easier for staff to plan their work.

- **Easier to control sedation levels.** It's simpler to wake patients every 24 hours to check their neurological status, thus reducing the need for additional CT examinations.

Product accessories

In addition to AnaConDa and IsoConDa, various accessories are also marketed to facilitate and simplify the use of AnaConDa. These include syringes to supply AnaConDa with isoflurane, special adapters to connect syringes to AnaConDa and the FlurAbsorb filter used to clean and remove any volatile anesthetic emitted into the intensive care room when sedating with AnaConDa.

Therapeutic benefits of inhaled sedation

There are currently three major studies in progress to confirm a number of therapeutic benefits of inhaled sedation. Most of these benefits have been shown earlier in smaller studies.

- The on/off effects and reliable awakening with inhaled sedation [6] – IsoConDa study
  - Shorter time to extubation ...
  - Shorter time to cooperation ...
  - Shorter time on the ventilator and in the intensive care unit... ... compared to intravenous sedation
- Therapeutic effects for patients with impaired lung function [7] – SESAR-study
  - Improved oxygenation
  - Reduction in the number of pneumonia cases
  - Bronchodilatory effect
- Reliable effect and safety of inhaled sedation for critically ill patients [8] – INASED study
  - Works on all patients
  - No need for multiple drugs (polypharmacy)
  - Fewer problems post awakening
  - Patients are more awake, calmer, have fewer hallucinations and less delirium
  - No or little risk of tolerance development, ceiling effects and abstinence symptoms.
  - Reduced use of opioids

IsoConDa provides clear benefits compared to the current standard treatment

Benefits	IsoConDa®	IV sedation
ON-OFF EFFECTS AND RELIABLE AWAKENING		
Significantly shorter awakening times	10-20 min	90 min-130 hours
Shorter stays in the intensive care unit for patients with deep sedation	4-16 days	6-27 days
Significantly shorter ventilator time	10-35 min	150-600 min
RELIABLE EFFECT AND SAFETY		
Reduced occurrence 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 QUALITIES		
Reduced hospital mortality in long-term ventilated patients (> 96 hours)	40%	63%
Reduced mortality after one year in long-term ventilated patients (> 96 hours)	50%	70%
Price per day	**EUR 100***	**EUR 20-300****

* Price for AnaConDa and IsoConDa together.
** 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 cost of extended stays in intensive care units due to intravenous sedation is not included.

THE IsoConDa STUDY IS THE BASIS FOR EUROPEAN REGISTRATION

Sedana Medical's vision is to develop inhaled sedation into the standard global sedation method for mechanically ventilated patients in intensive care. The first step will be to register the drug candidate IsoConDa (isoflurane) and thus also inhaled sedation in Europe.

In 2017, Sedana Medical initiated a clinical phase III study as the basis for registration aimed at getting IsoConDa (isoflurane) approved for inhaled sedation in intensive care in Europe.

The study is a clinical non-inferiority trial, meaning that its primary objective is to demonstrate that IsoConDa administered using AnaConDa is not inferior to propofol in maintaining an adequate level of sedation.

The study covers 300 mechanically ventilated intensive care patients in need of sedation and is a so-called randomized, controlled and open study to confirm efficacy and safety. The patients are randomly allocated to one of two groups, in one of which patients are sedated with intravenous propofol while the other group is sedated with IsoConDa administered by AnaConDa.

By registering the IsoConDa drug candidate administered with AnaConDa we are also registering inhaled sedation treatment in Europe.

The study was conducted in 21 centers in Germany and three in Slovenia. At the same time as the study, other documentation necessary for the application for market authorization is compiled. This includes e.g. a preclinical evaluation, a pharmaceutical technical summary and a plan for evaluating the use of IsoConDa on children in a so-called Pediatric Investigational Plan (PIP).

300

THE STUDY COMPRISES
a total of up to 300 mechanically ventilated intensive care patients in need of sedation.

Because it is applying for full registration including a pediatric plan, approval will mean that Sedana Medical will enjoy 10 years' marketing exclusivity in Europe for the use of isoflurane for sedation within intensive care. During this period, no competitor will be able to sell or market isoflurane for this purpose without having put together their own clinical documentation and undergoing the same procedure as Sedana Medical.

The study

Objectives

Primary objective:

To demonstrate that isoflurane administered by AnaConDa is as good as propofol in maintaining an adequate level of sedation.

Secondary objectives:

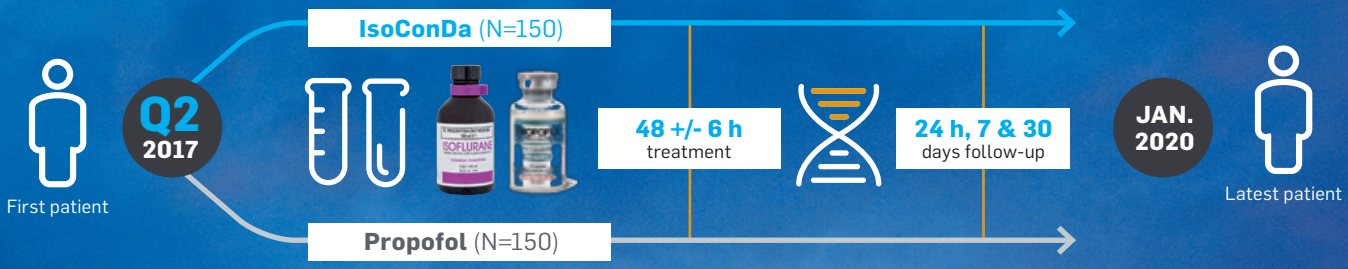
These include time to awakening; the proportion of time with spontaneous breathing, the need for analgesics, the number of ICU and ventilator-free days, and organ function over time.

Research objectives:

The isoflurane dosage under sedation; the need for supplementary sedation during the study; 30-day survival rate and practical aspects with AnaConDa.

European registration study

Phase 3 non-inferiority trial: IsoConDa compared with propofol



STUDY SUMMARY

A randomized, controlled, open study of mechanically ventilated intensive care patients to demonstrate the safety and effect of sedation using isoflurane with AnaConDa.

24 STUDY CENTERS

2020 TOP-LINE RESULTS

Q2 2020

AFTER 12-16 MONTHS

Marketing authorization in the EU is expected during the second half of 2021

WE REALIZED THAT THE THERAPY WAS BENEFICIAL

Associate Professor and Med. Dr. Andreas Meiser, at the University of Bochum is an anesthesiologist and one of the most experienced physicians in the world when it comes to using the AnaConDa and inhaled sedation.

When did you first come in contact with the therapy?
A long time ago I was at a congress in Germany when I first saw this funny thing, the AnaConDa, that I immediately wanted to try. This was something completely new for critically ill patients and I was aware I was doing something off label, so therefore, I was cautious, but very soon I saw that inhaled sedation gives us doctors better control than intravenous sedation.

Did you also immediately see positive effects for patients?
It was obvious that inhaled sedation gave us doctors better control, but we were not sure how inhaled sedation influenced patient outcome. So, we decided we had to do an outcome study. Together with Dr. Martin Bellgardt, I looked in our hospital database at all patients in the ICU that had been sedated for more than four days. Many patients that have been sedated for such a long time in the ICU die as they suffer from very severe illnesses, so if there was an effect it should be seen in this group. And indeed, we did see a significant reduction in mortality. Even when adjusting for age and severity of illness there was a significant effect. Of course, it was a retrospective study, but nevertheless, the results were robust. Actually, we were even surprised ourselves about how solid the results were. We had just wanted to show that the therapy was not harmful to patients; but realized that the therapy was even beneficial.

Eventually you published these results.
Actually, it took a long time to publish as the results were so provocative. To begin with, reviewers even said our results couldn't be true. But our results were solid and eventually our study was published in the European Journal of Anesthesiology in 2014. By now I have probably treated some 800 patients with the AnaConDa.

Which groups of patients benefit most from the AnaConDa?
Most of the patients I have treated probably benefitted in one way or the other from the therapy, but I would mention two groups of patients that benefitted the most. To begin with, some patients, often younger patients with abuse of alcohol or other substances, can hardly be sedated using intravenous drugs. Even if they get a heavy mixture of several drugs they are still agitated and need physical restraints. Some even pull out their catheters or the endotracheal tube despite a heavy drug mixture. When they are sedated with isoflurane, normal infusion rates suffice and the intravenous drugs can be paused. After some days, receptors recover and intravenous drugs can regain effectiveness. We call this a drug holiday.

Patients in need of deep sedation have also benefitted a lot?
Yes, this group is also special. Deep sedation is for example needed to enable kinetic therapy, therapeutic hypothermia or other procedures. These patients profit as they, despite deep sedation, almost invariably breathe spontaneously with the help of inhaled isoflurane sedation. Of course, they are ventilated and breathe with support of the ventilator, but they are also breathing with the help of their own diaphragm. This is very positive as it avoids wasting of the diaphragmatic muscle, and it also opens up the lower parts of the lungs that otherwise collapse and form atelectasis. Spontaneous breathing is

Dr. Andreas Meiser is leading the IsoConDa study together with Professor Thomas Volk.

> **The IsoConDa study is designed to show that isoflurane** is effective in sedation and of course it is effective; the substance has been around for many, many years.

made possible through inhaled sedation and the positive effects of that are important. Another advantage is that despite deep sedation, these patients awake fully within astonishingly short times, when the isoflurane is stopped.

Together with Professor Thomas Volk you are leading the IsoConDa study. Why is it so important?

It is a large study and I expect it to lead to the approval of a new therapy for the critically ill. This would be a very large event as it's been a very long time since a completely new therapy was approved in the ICU. There have been large promising studies showing positive effects for example of tight glucose control, hydrocortisone or drotrecogin alfa (activated protein C) as drug therapies for sepsis and hydroxyethyl starch for blood volume expansion, but in the end all these therapies failed.

Are you worried the IsoConDa study might fail as well?

There is a only a very low risk that The IsoConDa study fails. Even in that respect the study is quite unique. It is designed to show that isoflurane is effective in sedation and of course it is effective; the substance has been around for many, many years. We also have to show that the drug is safe, but all we have to show is that it is as safe as propofol, and it is, so this study cannot fail.

Do you think uptake for the therapy will be fast once the study is completed?

The fact that the therapy has to be used off-label is unfortunately holding back many doctors from using a therapy that would be beneficial for patients. They do not want to carry the legal risk, so once the therapy has marketing approval, I would expect a much faster uptake than is possible today.

ISO-COMFORT

At the same time as the IsoConDa study, other documentation necessary for the market authorization application (MAA) for sales of the drug in the EU is compiled.

A complete application includes a preclinical evaluation, a pharmaceutical technical summary and a so-called pediatric investigational plan (PIP). In February 2019, Sedana Medical's pediatric investigational plan was approved by the pediatric committee (PDCO) of the European medicine agency (EMA).

The study covers 160 children aged between 3 and 17 years. Sedation will last between 12 and 48 hours using either midazolam or isoflurane administered by AnaConDa. Recruitment of the first patient is planned for the fall of 2020. Patient recruitment is anticipated to continue for 18 months.

An approved pediatric study plan is sufficient for applying for marketing authorization. Thus because the outcome from the Iso-COMFORT study is not a requirement for approval for use on adults, the approval schedule for IsoConDa is not affected by the Iso-COMFORT study.

Because the registration documentation also covers children, an approval will not only mean that Sedana Medical will receive 10 years' market exclusivity in Europe for the use of isoflurane for sedation within intensive care, but for the foreseeable future there will also be an approved child indication for IsoConDa.

Iso-COMFORT

- 160 children between the ages of 3 and 17
- Isoflurane via AnaConDa compared to midazolam intravenously
- Sedation for 12-48 hours
- Primary endpoint: proportion with adequate sedation
- Patient recruiting period: approx 18 months
- Commences third quarter 2020
- Approx 18 pediatric intensive care units in Spain, Germany, France and Sweden

160

THE STUDY COMPRISES
160 children aged between 3 and 17 years.

A STUDY TO GAIN BROAD ACCEPTANCE

Dr Peter Radell, a veteran in inhaled sedation, is planning the pediatric study.

Doctor Peter Radell, chief physician and associate professor in anesthesiology and intensive care has extensive experience of AnaConDa technology. Today, Peter Radell is a member of the project group planning the pediatric study of Iso-COMFORT.

How did you first come into contact with Sedana Medical?

It was just before the company was formed. I was working as an anesthesiologist at Karolinska University Hospital when we were contacted by the company that had developed the first AnaConDa prototype. They wondered if there was an area of application for the technology within intensive care, which we naturally thought there was. It all resulted in Peter Sackey's 2006 dissertation entitled isoflurane sedation in ICU patients, which I supervised.

Why is the Iso-COMFORT study important?

It's extremely important in order to strengthen the scientific basis for the therapy. There are a number of supporting pediatric studies, but none of them are prospective or at multicenter level. Market approval for IsoConDa cannot be obtained without a study of this size, so it's crucial that the study be carried out. It feels highly professional that Sedana Medical is supporting the evaluation of the therapy, and to my knowledge there are no other, similar initiatives.

Isn't it especially important to find an alternative to intravenous sedation for children since propofol is not used on children?

Absolutely. Our arsenal is somewhat limited when it comes to sedating children. For example, we can see this in the surveys carried out in North America and Europe. There we see major variations in the drugs used and in the way they are used. This is a strong indication that there is no gold standard, but that each pediatric sedation alternative has its own pros and cons.

What do you hope the study will show?

We and many others have published studies showing good efficacy and safety, but a broader prospective study is required to seriously chart efficacy and safety. The study will provide answers to a number of questions and some of the evidence of efficacy and safety that only a major study can determine. Many of us with our own experience of using AnaConDa in practice are convinced of its advantages, but if the treatment is to achieve wide acceptance among clinics who as yet lack this experience, then we need a major study. A supportive, prospective multicenter-study could form the basis for broad acceptance in pediatric intensive care.

Can you tell us how preparations for the study are proceeding?

According to plan. This covers everything from various approvals from e.g. the PDCO and the Medical Products Agency to the recruitment of centers. I would like to emphasize that the collaboration between Sedana Medical and the clinics feels highly professional, and the company's willingness to take this on is greatly appreciated.

Is there anything in particular that you worry about?

Not really; but one concern could be the recruitment of centers that have no previous experience of using AnaConDa. We're used to using AnaConDa in Stockholm and look forward to conducting a prospective study, but this may not be the case for everyone, and so thorough preparation is essential, e.g. through training. The centers taking part must be fully prepared and motivated. As we know, the medical profession is relatively conservative when it comes to evaluating new treatments on patients.

Much of what is done in intensive care units takes place intravenously, and switching to inhaled sedation is a pretty big change. Do you think the profession is so conservative that it will inhibit adoption of the therapy?

Yes and no. People are naturally conservative and stick to what they know, but maybe to a lesser extent in the pediatric ICU world. There are several drugs we administer via the lungs, e.g. nitric oxide. So maybe we are more willing to test inhalation in pediatric intensive care. Also, there's a great deal of frustration concerning ICU sedation in general, so I feel people are open for new methods that can provide more treatment alternatives.

THE MARKET IS EVENLY DISTRIBUTED GEOGRAPHICALLY

Sedana Medical's market consists of sedated and mechanically ventilated patients in intensive care units all over 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 by means of 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.

Because mechanical ventilation can be extremely traumatic and unpleasant, sedation is used to provide comfort and safety, to relieve anxiety, unrest and pain and to prevent the patient from self extubating by wresting the tube out of the airway. Sedation is also necessary if staff are to be able to carry out the treatments required.

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

Narcotics such as benzodiazepines and propofol are used for the sedation of mechanically ventilated patients today. They are given intravenously and while they have well-known advantages there are also a number of disadvantages, both for healthcare and for the patients.

Of the 30 million patients around the world who are treated in intensive care every year, 8 million per year need both ventilation and sedation and thus constitute the direct target group for AnaConDa. On average, these patients are sedated for two to five days. The global average cost of sedation using IsoConDa and AnaConDa is estimated at around SEK 1,000 per day, and Sedana Medical estimates market size to be between SEK 20 and 30 billion. The market in SEK is relatively evenly distributed between the regions USA, Europe and Asia, but the price levels in the USA are expected to be higher.

Because the problems with intravenous sedation are less evident for sedation during 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.

The target group for the company's products are intensive care physicians, intensive care nurses and decision-makers with the responsibility for purchasing medical equipment and pharmaceuticals for these departments.

The competitive situation

The current market for sedation drugs in intensive care consists only of intravenous drugs. The company assesses the total annual size of this market to be around SEK 20 billion where propofol, midazolam (based on benzodiazepine), dexmedetomidine and remifentanil predominate. These drugs are usually generic, but still command relatively high prices, especially in the USA.

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

Costs

At an average cost of up to SEK 30,000 per patient day, intensive care patients are expensive. The cost of an intensive care unit is 3 to 5 times higher than an ordinary hospital ward, and despite the fact that these patients only constitute around 10 percent of all hospital admissions, they can consume closer to 20 percent of a hospital's total budget.

Thus there are compelling financial reasons for hospitals to reduce the number of ICU treatment days. What's more, Sedana Medical considers intensive care clinics to be relatively price insensitive in respect of sedation drugs as they constitute a relatively small part of the total cost of healthcare.

The daily cost for intravenous sedation is difficult to estimate and varies greatly from country to country. The cost calculation is made more difficult since different preparations are often combined (e.g. propofol and midazolam) to achieve the desired effect and because dosages

8

MILLIONS OF PATIENTS MAKE UP OUR DIRECT TARGET GROUP

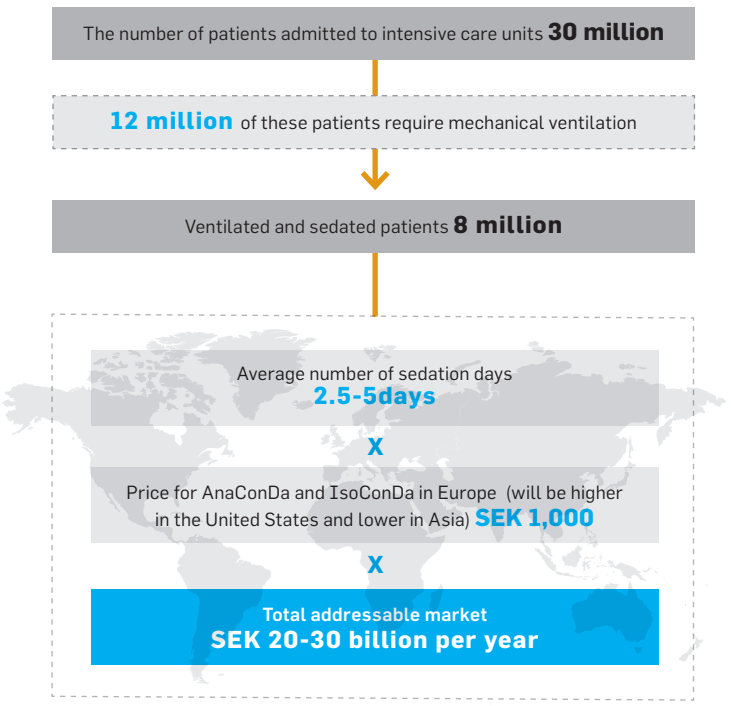
Of the 30 million patients around the world who are treated in intensive care every year, 8 million per year need both ventilation and sedation and thus constitute the direct target group for AnaConDa.

20–30

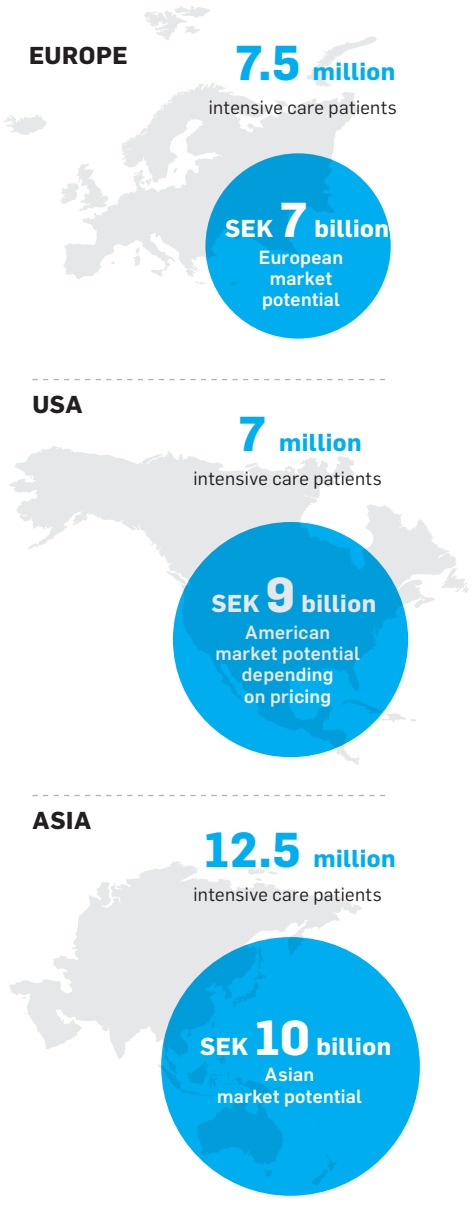
BILLION

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

Sedana Medical's market potential for AnaConDa and IsoConDa*



*Market size based on the company's estimates.



may vary depending on the patient's tolerance of the preparation.

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 USA are significantly higher and Sedana Medical estimates average costs to be around three times higher than in Europe. Sedana Medical estimates the average cost for intravenous sedation in Europe to be around SEK 500 per day, which is somewhat lower than the daily cost of AnaConDa and isoflurane. The cost of sedation using IsoConDa and AnaConDa is calculated at around SEK 1,000 per day.

It takes a long while to establish a new treatment therapy in healthcare, and it requires public opinion influencers in the field to back the therapy. If a treatment does not gain the support of such 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 with the aid of clinical studies, education, scientific congresses, the exchange of information and experience, and new guidelines. Because such activities must be managed by Sedana Medical, there is a clear advantage in conducting sales under its own auspices.

Sedana Medical's AnaConDa sales have hitherto taken place through conventional direct sales and dealers. The company works with product specialists that train clinicians in how the products work and how treatment should be carried out. The product specialists recruited by Sedana Medical consists mainly of nurses with a background in intensive care, which means they possess the knowledge and experience necessary for training customers.

Sedana Medical is well positioned to offer the first commercial solution for inhaled sedation within intensive care, a market with an annual sales potential of SEK 20-30 billion.

Sedana Medical markets with direct selling

Direct selling

Direct selling is Sedana Medical's preferred sales channel, and accounts for more than 90 percent of the company's total sales. In Benelux (open 2020) Germany, France, the Nordics, Spain and the United Kingdom, direct selling takes place primarily through in-house product specialists who also train customers in how to begin treatment safely. Direct sales are associated with higher cost than distributor sales. The benefits associated with direct selling include Sedana Medical's ability to control the sales process to a greater degree while also enjoying higher margins. The plan is for the in-house sales organization to cover the most important European markets in connection with the registration of IsoConDa in Europe.

Distributor markets outside the EU

AUSTRALIA CANADA CHINA INDIA

ISRAEL JAPAN MEXICO (2020) SOUTH KOREA

Sales through dealers

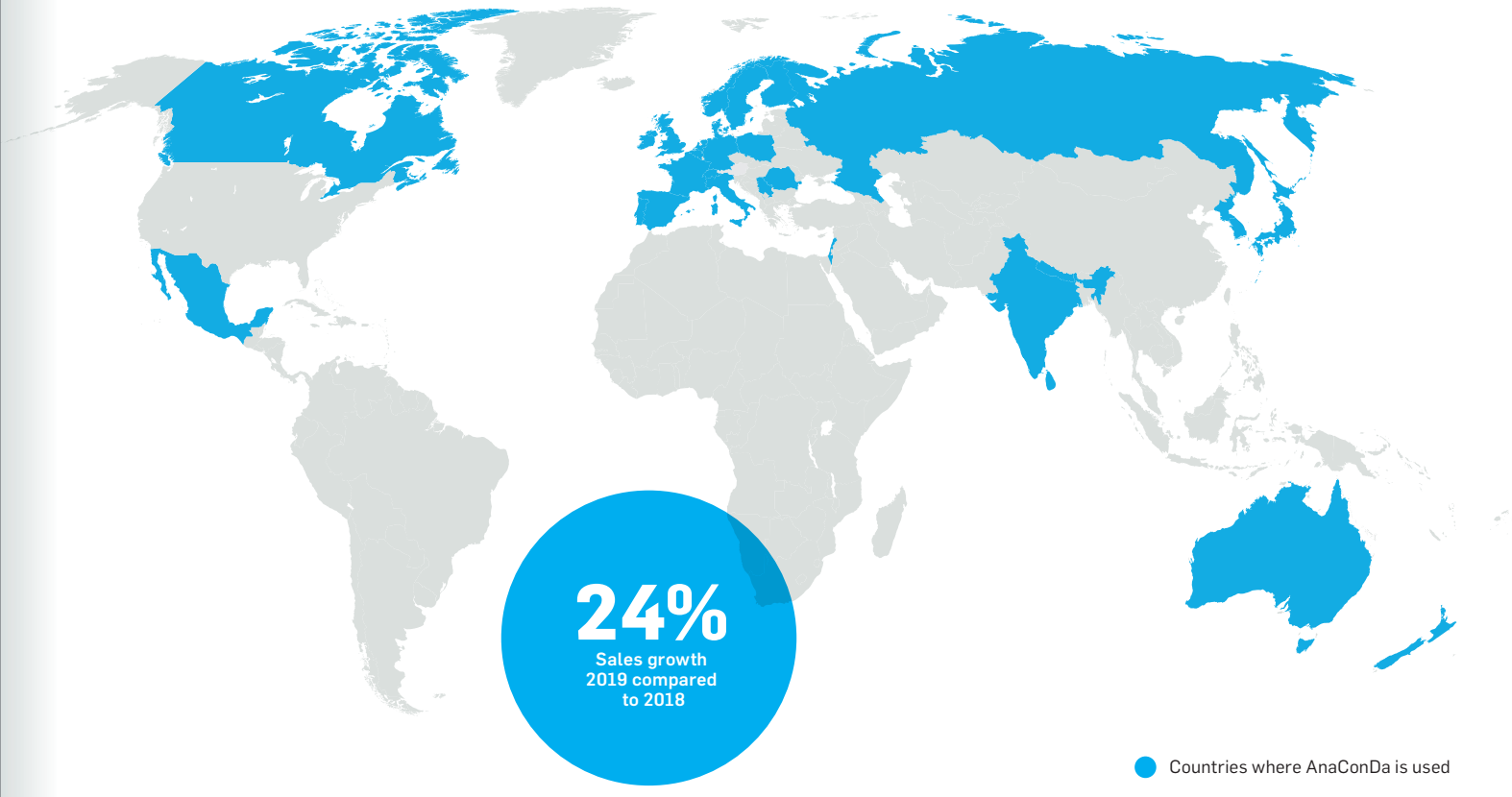
Sedana Medical has engaged dealers as a low risk means of initiating sales of AnaConDa and quickly establishing inhaled sedation for intensive care in countries where it does not conduct direct sales. Currently, Sedana Medical has distributor agreements in e.g. Australia, India, Japan, Canada, China, Mexico 2020, South Korea and Eastern Europe. In the short term, the company has no intention of setting up sales offices in these markets, but still feels the long-term potential to be of interest.

Customer base

Sedana Medical's customer base consists primarily of intensive care units in medium, large and university hospitals. The product is bought for the clinics via hospital procurement departments and in many cases Sedana Medical receives requests to participate in procurements. Sedana Medical's biggest market is Germany which, together with other markets where it conducts direct selling, has functioned as a test market to study demand for the therapy. Despite the fact that Sedana Medical has only assisted customers in the test markets, it has noted an increase in demand for the therapy.

The company also reaches out to its customers by taking part in exhibitions such as ESICM, ISICEM, DIVI, DAC, SFAR, and SRLF, and through the presentation by leading researchers and clinicians of their findings at scientific congresses and by providing assistance for therapy initialization at clinics. Sales differ between countries and regions but common for all markets is the ambition to create demand among doctors and nurses who, together with intensive care patients, are AnaConDa's end customers.

The use of AnaConDa is increasing



The SESAR study's primary objective is to demonstrate that inhaled sedation with AnaConDa has lung-protective characteristics for ARDS patients, results in shorter ventilator time and higher survival among intensive care patients with severe pulmonary conditions.

CONTRIBUTES TO STRONG, LONG-TERM SCIENTIFIC PLATFORM

Sedana Medical supports investigator-initiated studies that help create a strong, long-term scientific platform for inhaled sedation using AnaConDa and IsoConDa. The SESAR and INASED studies each has the potential to dramatically change the perception of inhaled sedation.

700

SESAR
is a randomized, controlled study covering 700 patients with acute respiratory distress syndrome (ARDS)

250

INASED
is a randomized, controlled study covering 250 patients that seeks to demonstrate a reduced occurrence of delirium.

Sedana Medical has previously supported several investigator-initiated studies in addition to its own registration studies that help create a strong, long-term scientific platform for inhaled sedation using AnaConDa and IsoConDa. Two major studies began in 2020 which, given positive outcomes, could significantly promote the commercial adoption of the treatment. One of the studies could also be used for regulatory purposes.

The company is providing partial finance for SESAR, the world's biggest multicenter study with AnaConDa in France. The study covers 700 patients and its primary objective is to demonstrate that inhaled sedation with AnaConDa has lung-protective characteristics, results in shorter ventilator times and higher survival rates among intensive care patients with severe pulmonary conditions. If this major study has a positive outcome, it will dramatically change the perception of inhaled sedation compared to intravenous sedation. Sedana Medical is also financing INASED, another major French multicenter study. This study seeks to demonstrate a reduced occurrence of delirium in mechanically ventilated intensive care patients sedated with isoflurane via AnaConDa compared to intravenous sedation with propofol.

SESAR is a randomized, controlled study covering 700 patients with acute respiratory distress syndrome (ARDS). Almost 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 study, which will be conducted at 30 different intensive care units in France, will begin in 2020 and is expected to take three years to complete. The principal investigator for the study is Dr Matthieu Jabaudon at the Centre Hospitalier Universitaire (CHU), Clermont-Ferrand. The study will compare today's standard propofol treatment with inhaled sedation (sevoflurane) using AnaConDa. The study's primary objective is to demonstrate shorter ventilator treatment times with sevoflurane sedation. An earlier, smaller study from the same research group showed inhaled sedation to be linked to improved lung function in patients with ARDS[1]. The same effects have also been demonstrated in several animal studies.

INASED is a randomized, controlled study covering 250 patients who are anticipated to need mechanical ventilation in an intensive care unit for more than 24 hours. The study will be conducted at 10 different intensive care units and led by the principal investigators Dr Pierre Bailly and professor Erwan L'Her, at the Centre Hospitalier Regionale Universitaire Brest, France. The study will start in the beginning of 2020 and is scheduled for completion in the beginning of 2023 following a 24-month inclusion period, and a 12-month cognitive follow-up. The study's primary objective is to demonstrate a reduced occurrence of delirium following sedation with isoflurane via AnaConDa compared to today's intravenous standard propofol therapy.

SESAR: A VERY AMBITIOUS STUDY

Associate professor Matthieu Jabaudon at Centre Hospitalier Universitaire (CHU) Clermont-Ferrand is the principal investigator of the French multicenter SESAR study on 700 lung-injured patients with ARDS.

Could you tell us about your history of inhaled sedation?

I've used inhaled sedation for ICU patients for about 15 years now, since my residency at CHU Clermont-Ferrand. As many others, our first use was in patients with severe asthma or bronchospasm, in whom bronchodilatory effects of halogenated agents sevoflurane and isoflurane are very effective. Meanwhile, multiple research studies were performed at our center in Clermont-Ferrand that fostered our enthusiasm for inhaled sedation. I now realize that these studies, most being monocenter studies, along with others from Sweden and Germany published at that time have indeed fostered global interest in inhaled ICU sedation.

What type of equipment did you use?

At the very beginning, we used equipment from the operating room, but of course this is very complicated in the ICU setting. I would say we have overall used the AnaConDa all along. There were other systems that we tried, mainly for tests and protocols, but the only equipment we kept onto so far was the AnaConDa system.

How did the SESAR study come about?

A few years ago, I was the principal investigator of a pilot monocentric sevoflurane study with improved oxygenation, and decreased inflammation and lung epithelial injury, in lung-injured patients with acute respiratory distress syndrome (ARDS). On the basis of these promising results, our team aimed at designing a larger clinical trial to confirm these potential lung-protective effects of inhaled sedation with halogenated agents in ICU patients with ARDS. While preparing the study, we reached out to Sedana Medical and after discussing potential support from the company, we are now happy and honored they are supporting the SESAR study.

What can you tell us the study?

It is a multicenter randomized controlled trial of inhaled sevoflurane versus intravenous propofol in patients with ARDS. The trial is funded by a 2018 "PHRC-National" grant from the French Ministry of Health and a 2019 Research Grant from the European Society of Anaesthesiology. As mentioned earlier, it also has strong support from Sedana Medical, not only through the provision of the equipment needed for the trial to deliver inhaled sedation and financial support aimed at training and evaluating inhaled sedation practice in participating centers, but also through their professionalism and expertise, which is of paramount importance for our team.

In my opinion, the training and evaluation of the practice of inhaled sedation that will be performed in all centers prior to patient recruitment will be a major contribution to ensure both patient safety and the best homogeneous practice of inhaled sedation within the study. Notably, nurses from participating centers will be trained by a nurse from our center in Clermont-Ferrand, thanks to great support from Sedana Medical.

Even though the SESAR study is sponsored by Sedana Medical, I would like to emphasize that the company of course has no influence on the study design, conduct or analysis in the study.

In the trial you are using sevoflurane, but IsoConDa is based on isoflurane. Do you think that's a drawback for Sedana Medical?

Most preclinical studies that support potential beneficial effects of inhaled sedation on the lung have been performed either with sevoflurane or isoflurane. Only a small fraction of them, along with the results from our pilot trial, have supported our choice of sevoflurane over isoflurane for the SESAR trial.

However, we are also currently conducting translational research at CHU Clermont-Ferrand and GreD, Université Clermont Auvergne to better understand the effects of both sevoflurane and isoflurane on the lung, using a combination of clinical observations with data from animal models and cell experiments. Of course, one cannot exclude that a class effect might be true for lung-protective effects of halogenated agents such as isoflurane and sevoflurane.

Why is the study so important?

First, because the primary objective is to asses potential lung-protective effects in critically ill patients with ARDS. Unfortunately, these patients have a very bad prognosis so far, so any intervention that could benefit them would be very welcome. Sedation, among many interventions in the ICU, is a very good candidate intervention to improve if possible.

Secondly, the study is a tremendous opportunity to gather valuable data that will help to consolidate evidence on the safety and ease-of-use of the AnaConDa system in a large population of critically ill patients.

The study is very ambitious as it aims at enrolling 700 patients with ARDS in 31 centers in France and at assessing major and long-term outcomes in this specific population. The primary endpoint is the number of ventilator-free days at day 28 while considering death as competing event. Important secondary endpoints also include the impact of inhaled sedation on ICU-acquired delirium and weakness. Relevant long-term outcomes will be assessed at one year, which is especially exciting as these patients often have long-term effects from their critical illness, from both physical and cognitive perspectives, among others. Whatever the primary outcome result of this study, the study will therefore represent a unique opportunity to better understand the impact of inhaled sedation on the course of ARDS and on patient outcome. In addition, the study will also include a large biological collection that will further inform on the potential lung-protective effects of inhaled sevoflurane, as these effects remain largely unknown to date.

Do you have a view on how fast uptake for the AnaConDa could be?

In my view, gaining more scientific evidence on the use, and potential benefit, of inhaled ICU sedation is what will facilitate uptake. A fast uptake for a new therapy, such as inhaled sedation, surely relies on results from large studies that would ultimately support improved patient outcome.

Indeed, there are already many studies available, even if some cohorts are small and lack replication, that largely favor the use of inhaled sedation over current intravenous practice in ICU patients. However, more scientific evidence is needed before inhaled sedation can be proposed as a first line choice for sedation of ICU patients, and more data from large cohorts are needed to establish its safety and efficacy.

Hopefully, and as far as I am aware of, this will soon be the case with future results from the large German IsoConDa study and the French INASED (led by Professor L'Her at CHU Brest) and SESAR studies. I am convinced these studies will bring 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.

Even though the SESAR study is sponsored by Sedana Medical, I would like to emphasize that the company of course has no influence on the study design, conduct or analysis in the study, says professor Matthieu Jabaudon at Centre Hospitalier Universitaire (CHU) Clermont-Ferrand

Which are the hurdles for Sedana Medical?

I have always got the feeling from Sedana Medical that they are an innovative and dynamic company. They seem to have overcome most of the hurdles that I can think of over the years. For example, the equipment has been continuously improved, and it seems the company has continuously developed and adapted to clinical needs. One important aspect is that they have tried to simplify everything so that inhaled sedation is now very easy and safe to deliver to patients. Of note, I know they are preparing an outstanding e-training solution which I had the chance to test recently. It is a very efficient way for practitioners to learn everything about inhaled sedation in a very pleasant way, and most important in my opinion, to "demystify" the technology for those who have no experience yet. In particular, I don't think that the cost of the equipment needed to deliver inhaled sedation to ICU patients is a serious hurdle given its potential benefits. But again, results from ongoing and future studies will surely help to also better understand the cost-effectiveness of inhaled ICU sedation.

THE OBJECTIVE IS USA APPROVAL IN 2024

In March 2019, Sedana Medical had a so-called pre-IND meeting with the U.S. Food and Drug Administration (FDA), where the FDA proved to be in favor of registration of IsoConDa and AnaConDa as a combination product in the USA.

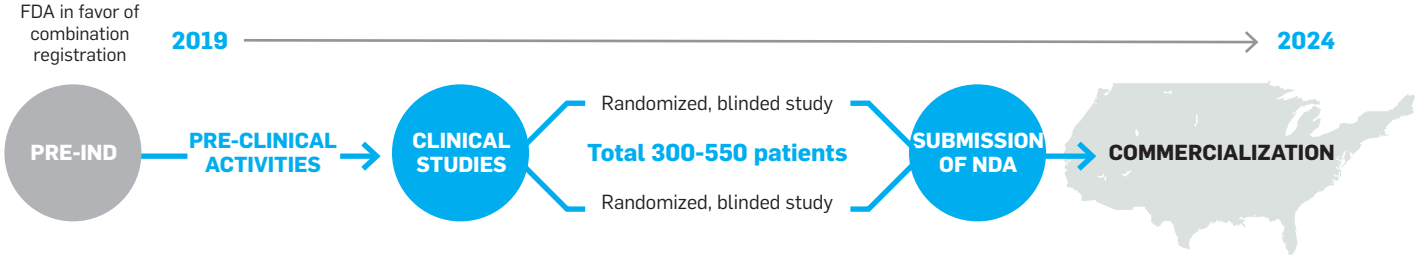
Because the drug substance isoflurane has been available for decades, the FDA accepts that Sedana medical is taking a route to registration which, in simplified terms, allows the use of previously collected data (505 (b) (2)). Registration via 505 (b) (2) is often less demanding than 505 (b) (1), which 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 toxicological animal studies. Because AnaConDa is not yet registered in the USA, a human factors validation must be performed. This validation is carried out on all advanced medical products submitted for registration and is done to exclude the human factor's effect on efficacy and safety during use.

Two clinical, randomized blind studies covering a total of 300 – 550 patients will be carried out to confirm and ensure efficacy and safety. The number of patients needed for both studies together is the same as Sedana Medical's initial requirement in the European studies, i.e. 300 – 550 patients. Because the ongoing European registration study is not blind, it will not be one of the two clinical studies required by the FDA, but it can still be used to support the NDA application and in the safety database covering 500 isoflurane patients, as required by the FDA.

Sedana Medical intends to establish a company in the USA in order to carry out the work involved in studies, registration and market access in-house. In or around 2022, the company will decide whether to launch alone or with a partner.

Preparations and work concerning the toxicological animal studies began in 2019 together with a specialist CRO company. Work with human factors validation also began in 2019 together with Beth Israel Deaconess Medical Center and Harvard Medical School in the USA.

In the fall of 2019, Sedana Medical secured financing for registration in the USA through a targeted new share issue.



NON-CLINICAL DATA

Documentation that must be supplemented with additional data for approval by the FDA
- Toxicity studies - PPND*
- Validation of human factors

CLINICAL STUDIES

Two clinical, randomized blinded 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.

COMMERCIALIZATION

Commercialization strategy decision for the USA – whether the company will launch alone or together with a local partner – around 2022.

*PPND: trends before and after birth.

INTERNATIONAL EXPANSION

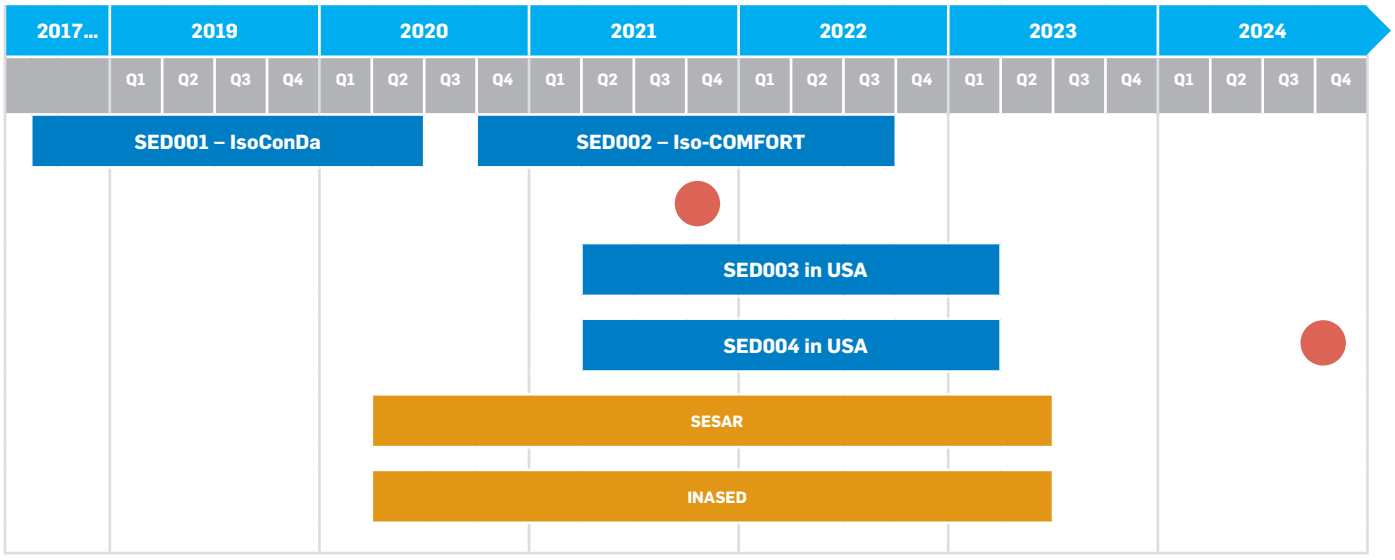
A number of advances were also made outside Europe during 2019, especially in Japan, China and India.

In Japan, the first patient was treated at the University Hospital in Shiga at the beginning of the year. AnaConDa has had market approval since November 2018, but IsoConDa is – as in Europe – not yet approved for sedation and therefore the entire therapy is classified as an off-label treatment that must first be approved by an ethics committee at each respective hospital. Sedana Medical is investigating how to register IsoConDa in Japan and is working toward a pre-IND meeting in 2020. The Japanese market potential is estimated at EUR 300 million per year.

In the case of China, Sedana Medical concluded a 10 year exclusive distributor agreement in June 2019 with the Chinese distributor Kyuan Xinhai Medical, a subsidiary of China's second biggest life-science company, the partially state-owned Shanghai Pharma. Kyuan is taking a fast-track approach in its registration work for AnaConDa in China and expects to obtain approval within less than two years, at the latest 2021. Sedana Medical estimates the Chinese market potential for sedation in intensive care to between 5 and 6 million days per year.

In August 2019, Sedana Medical concluded a distribution agreement with the Indian distributor Hansraj Nayyar Medical. Sales began during the fall in parallel with a registration process. Neither AnaConDa nor IsoConDa have market approval in India, but under current legislation and thanks to its registration in Europe, AnaConDa may be sold during the registration period. Sedana Medical estimates the Indian market potential for sedation in intensive care to around 2 million days per year.

MANY STUDIES PAVING THE WAY FOR A NEW TREATMENT STANDARD



In-house studies Investigator-initiated studies Estimated market approval in the EU (Q3 + Q4 2021) and USA (HQ3 + Q4 2024)

SED001 – IsoConDa

A randomized, controlled, open study to confirm efficacy and safety during sedation using isoflurane administered by AnaConDa in mechanically ventilated intensive care patients.

Primary objective: To demonstrate that sedation using IsoConDa administered by AnaConDa is as good as propofol in maintaining an adequate level of sedation.

Comparison: Propofol

Participating countries: Germany, Slovenia

FPI 2 July 2017

LPO Jan 2020

Study report Q1 / Q2-2020

SED002 – Iso-COMFORT

The study compares the efficacy and safety of inhaled isoflurane delivered by AnaConDa-S with intravenous midazolam during sedation of mechanically ventilated patients younger than 18 (3-17).

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

Participating countries: Spain, Germany, Sweden, France

FPI September 2020

LPO Feb 2022

Study report Q2 2022

SED003

A phase III study to confirm efficacy and safety during sedation using isoflurane administered by AnaConDa

Participating country: USA

Comparison: Propofol

Indication: Sedation during mechanical ventilation up to 48 hours.

FPI June 2021

LPO Jan 2023

Study report Q2 2023

SED004

A phase III study to confirm efficacy and safety during sedation using isoflurane administered by AnaConDa

Participating country: USA

Comparison: Propofol

Indication: Sedation during mechanical ventilation up to 48 hours.

FPI June 2021

LPO Jan 2023

Study report Q2 2023

STRATEGIC PRIORITIES CHECKED OFF

	2019	2020	2021	2022	2023	2024
EUROPE	• February – pediatrics study approved • December 2019/ January 2020 – Final patient included in the IsoConDa study at year-end.	• Q2 – IsoConDa-study concluded • Q3 – First patient in the pediatric study • Q3 – First-round registration applications submitted in 16 countries	• Second half of year – Pediatric study completed • Second half of the year – Registration approval for IsoConDa			
USA	• March– Pre-IND meeting with the FDA • Fall – non-clinical studies in pilot test	• Q3 – Conclusion of human factors validation study • Q4 – IND application preparation	• IND approval and clinical studies begin	• Decision taken to launch alone or with a partner	• NDA application	• NDA approval expected

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 using AnaConDa and IsoConDa the standard method for sedating mechanically ventilated patients in intensive care. Many important steps were taken in 2019. The chart above shows the most important steps in registration efforts in the EU and USA moving forward. In parallel with the registration work, efforts are continuing to increase the use of AnaConDa technology and establish the company in several countries.

Sedana Medical's strategic priorities

1. **Development and commercialization in Europe**
   Registration of the drug candidate IsoConDa (isoflurane) 2021. Ensure steady, robust growth of sales and prepare for the launch of IsoConDa in 2021.

2. **Development and commercialization in the USA**
   Development of registration efforts in the USA with both AnaConDa and IsoConDa for NDA approval in 2024. A decision on the commercialization strategy for the USA will be made in 2022.

3. **Development and commercialization in the rest of the world**
   Register AnaConDa and IsoConDa in relevant markets in Asia, such as Japan and China.

SUSTAINABILITY

Sedana Medical seeks 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.

In the company's code of conduct, Sedana Medical's Board of Directors has laid down the ethical business practices that form the basis on which the operation must be conducted. The code is an important tool for the prevention and detection of any violation of the law, regulations or ethics. Business activities must always comply with local and global legislation, good practice and rules.

The code of conduct covers all employees, the board, suppliers, consultants and any temporary personnel. Sedana Medical's code of conduct also includes areas such as sustainability efforts, the work environment, health and safety, the environment, equal opportunities and purchasing.

In its R&D work, Sedana Medical complies with the Helsinki Declaration covering ethical principles governing how research and development involving humans must be conducted, and international standards such as good laboratory practices (GLP) and good clinical practices (GCP).

Operations must be run in an environmentally sustainable manner on the basis of the operation's conditions. Every person in the company must carry out his or her work with as little impact on health and the environment as possible and strive for continuous improvement. Goods and services must be delivered with an awareness of, and care for, the environment.

AnaConDa technology enables very efficient reflection of anesthesia gas from expiration air; around 90 percent of the gas remains in the active charcoal filter and is re-used during the inspiration phase. The high level of reuse is positive from a sustainability standpoint and helps reduce the use of volatile anesthetics.

No form of inappropriate payment, direct or indirect, will be tolerated regardless of whether it concerns a direct bribe or other type of payment, gift, benefit, remuneration or other representation that could constitute a violation of the law or which could influence or be thought to influence judgment.

Quality management

Sedana Medical's business is quality certified according to ISO13485:2016.

Sedana Medical strives for openness and transparency in its business operations, and its sustainability management is under constant development.

RESEARCH GRANT PROMOTE MEDICAL PROGRESS

Sedana Medical Research Grant is a unique opportunity for the scientific community to increase its understanding of sedation in critically ill patients.

Sedana Medical established Sedana Medical Research Grant in 2019. This is a unique opportunity for the scientific community to increase its understanding of sedation in critically ill patients. A grant of between 10,000 to 30,000 per year for up to two years will be given to one to three induvidual academic researchers. Aimed at advancing conditions for investigator-initiated studies in our field, the ambition is for research to lead to medical advances for the benefit of patients and society.

Because of the great medical possibilities volatile anesthetics offer, interest in research into inhaled sedation is in general very high, and in 2019 we received several good applications. The winners in 2019 were three particularly interesting research projects in Italy, France and Switzerland, and each in its own way will advance therapy both scientifically and geographically.

Title: **Inhaled anaesthetic effects on Mean Pulmonary Arterial Pressure in ARDS patients**
Investigators: Dr Gabriel Parzy, Dr Jean-Marie Forel, and Dr Laurent Papazian, Professor, Medical Intensive Care Unit service, Intensive Care Unit, Hôpital Nord, Marseille, France

Title: **Feasibility and safety of inhaled sedation in ECMO patients undergoing ultra-protective low frequency ventilation.**
Investigators: Dr Giuseppe Foti, Associate professor and Director and Dr Marco Giani, Department of Anesthesia and Intensive Care Department of Monza University Hospital, Italy.

Title: **Inhaled sevoflurane for immunomodulation in patients with septic shock – a pilot study.**
Investigators: Dr Martin Schläpfer, Privatdozent, and Dr Beatrice Beck-Schimmer, Professor, Vice President Medicine, Institutes of Anesthesiology and Physiology, University and University Hospital Zurich, Switzerland.

THE COMPETITIVE SITUATION

Sedana Medical expects IsoConDa administered by AnaConDa to be the first treatment approved for inhaled sedation within intensive care. Furthermore, the company considers it to be highly unlikely that any other volatile anesthetic with the same indication is undergoing registration.

There is currently one alternative delivery system for volatile drugs known as Mirus from the German company Technologie Institut Medizin GmbH, TIM. Sedana Medical finds it unlikely that TIM would register a drug that could be combined with its product.

Intellectual property rights

Sedana Medical's freedom-to-operate analysis, which checks the risks of infringement upon the intellectual property rights of others, has not brought to light anything that prevents development of the company and commercialization of the therapy. It included a competition analysis of existing therapies and therapies under development.

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

Patent protection Since the development of AnaConDa, Sedana Medical has protected its innovations through patents. Sedana Medical's patent portfolio currently includes five patent families and two patent applications. The basic patent for the outgoing AnaConDa model (100 ml) expired in 2018. Two new patent applications were submitted in 2016 for the newly developed AnaConDa-S (50 ml). One is in respect of the unit's design and the other is intended to prevent competitors from modifying the first generation AnaConDa (100 ml) to create a product with 50 ml dead space.

Obstacles As extra protection, Sedana Medical is developing solutions where the entire process from fluid in the bottle to patient delivery as gas can be protected. Furthermore, these protections make it easier and safer to connect the AnaConDa system while also making it difficult to connect generic drugs. The protections consist of unique connections and alternative packaging solutions.

Registrations Sedana Medical will carry out full registration of IsoConDa in Europe and thus gain a 10-year exclusivity period on the European market. The registration applies to IsoConDa administered by AnaConDa. Other combinations of volatile anesthetic gases and delivery methods for sedation in intensive care will continue to be off label. Other use of volatile anesthetics such as sevoflurane and desflurane for the indication of sedation will also continue to be off label.

In addition to these three strategies, Sedana Medical has extensive knowledge about inhaled sedation generated during the past 10 years and active, successful product development. The three strategies, together with the company's knowhow and product development, provide Sedana Medical with strong protections and a stable basis for planned marketing initiatives.

SHARE INFORMATION AND SHAREHOLDERS

Sedana Medical's share was listed on Nasdaq First North Growth Market Stockholm on June 21, 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 enterprises. 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 bigger markets. 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, email: certifiedadviser@penser.se.

Share capital

The total number of shares outstanding as of December 31, 2019 amounted to 22,736,591. At year-end, share capital amounted to SEK 2,273,659. Each share entitles the holder to one vote, and every shareholder has the right to vote his or her full number of shares at the annual general meeting. All outstanding shares are fully paid. The company's share capital is reported in Swedish krona and distributed across the company's outstanding shares at a quota value of SEK 0.10 per share.

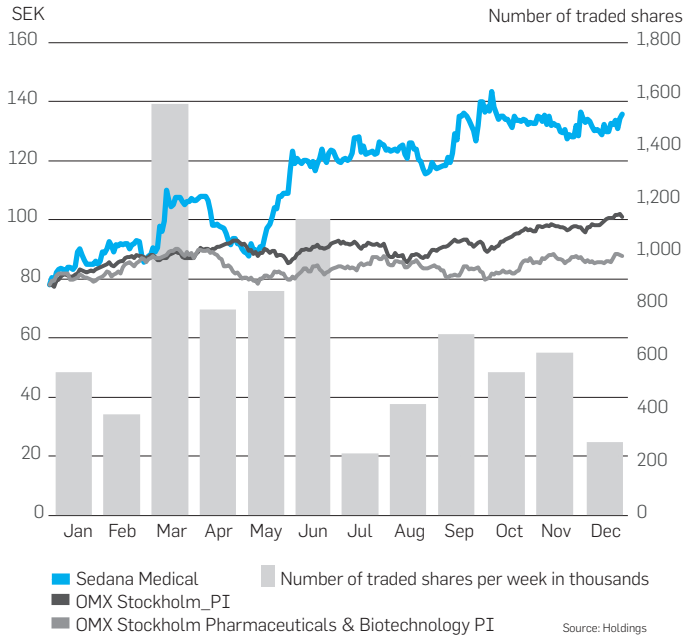
In October 2019, Sedana Medical carried out a new issue of 2,896,000 shares at a price of SEK 129.50 per share, which provided the company with SEK 375 million before transaction expenses. The share capital increased with 289 600 SEK.

Share capital development over time

Date of adoption	Event	Change in shares	Total number of shares	Change in share capital (SEK)	Total share capital (SEK)	Quota value (SEK)
2004-10-20	New formation	1,000	1,000	100,000	100,000	100
2009-10-31	New share issue	430	1,430	43,000	143,000	100
2011-05-05	New share issue	500	1,930	50,000	193,000	100
2015-09-14	New share issue	240	2,170	24,000	240,000	100
2017-04-05	Bonus issue	6,510	8,680	651,000	868,000	100
2017-04-05	Split [1)]	8,671,320	8,680,000	0	868,000	0.1
2017-06-20	Conversion of shareholder loans	613,594	9,293,594	61,359	929,359	0.1
2017-06-20	Exercised convertible bonds	1,881,509	11,175,103	188,151	1,117,510	0.1
2017-06-20	New share issue at the IPO	5,128,205	16,303,308	512,821	1,630,331	0.1
2017-07-10	Overallotment option after IPO	769,230	17,072,538	76,923	1,707,254	0.1
2018-02-05	Conversion of options to shares, program 2014/2019	208,000	17,280,538	20,800	1,728,054	0.1
2018-06-04	New share issue	1,728,053	19,008,591	172,805	1,900,859	0.1
2018-10-10	Conversion of options to shares, program 2014/2019	148,000	19,156,591	14,800	1,915,659	0.1
2019-03-27	Excercise of warrants, program 2014-2019	120,000	19,276,591	12,000	1,927,659	0.1
2019-05-24	Excercise of warrants, program 2014-2019	140,000	19,416,591	14,000	1,941,659	0.1
2019-06-14	Excercise of warrants, program 2014-2019	220,000	19,636,591	22,000	1,963,659	0.1
2019-08-05	Excercise of warrants, program 2014-2019	100,000	19,736,591	10,000	1,973,659	0.1
2019-08-26	Excercise of warrants, program 2014-2019	104,000	19,840,591	10,400	1,984,059	0.1
2019-10-24	New share issue	2,896,000	22,736,591	289,600	2,273,659	0.1

1) Share split 1:1000.

Sedana Medical's share price trend and turnover



Share trading

The introductory price at the listing on First North Growth Market 2017 was SEK 19.50. The opening price in 2019 was SEK 75.40 and at the end of the year the final payment price was SEK 135.80. During the year a total of 8 million Sedana Medical shares were traded at a value of SEK 882 million, which corresponds to a turnover rate about 35 percent. On average, 32,150 shares were traded per trading day.

Price trend

During the year, Sedana Medical stock climbed 80 percent, while the First North All Share index during the same period rose by 30.7 percent.

The highest price paid was SEK 144 noted on 7th of October 2019, and the lowest price was SEK 75,40 noted on 2nd of January 2019. At year-end 2019, Sedana Medical stock was listed at SEK 135.80, equivalent to a market capitalization of SEK 3.1 billion.

The 15 largest shareholders as of December 31, 2019

	Number of shares	Holding
Linc AB	2,116,901	9.31%
Handelsbanken funds	1,745,303	7.68%
Anders Walldow directly and indirectly (Brohuvudet AB)	1,600,000	7.04%
Sten Gibeck	1,530,744	6.73%
Swedbank Robur funds	1,376,600	6.05%
Ola Magnussion directly and indirectly (Magiola AB)	1,340,867	5.90%
Anades Ltd.	1,068,083	4.70%
Berenberg funds	865,291	3.81%
Ron Farrell	631,062	2.78%
Öhman funds	579,884	2.55%
Nordnet pensionsförsäkrings AB	511,523	2.25%
Avanza Pension	493,165	2.17%
Tredje AP-fonden	470,318	2.07%
Eklund Konsulting AB	416,616	1.83%
Alfred Berg funds	350,755	1.54%
The 15 largest shareholders	15,097,112	66.40%
Other*	7,639,479	33.60%
Total	**22,736,591**	**100.00%**

*The CEO's holding is 230,000 shares.

Source: Euroclear Sweden

Shareholder distribution by size

	Antal ägare	Antal aktier	% kapital	% ägare
1-1000	1,652	339,426	1.5%	83.7%
1001-10000	245	767,103	3.4%	12.4%
10001-100000	43	1,272,336	5.6%	2.2%
1000001-500000	22	4,880,363	21.5%	1.1%
5000001-1000000	4	2,587,760	11.4%	0.2%
1000001 -	7	10,778,498	47.4%	0.4%
Anonymous ownership	N/A	2,111,105	9.3%	N/A
Total	**1,973**	**22,736,591**	**100%**	**100%**

Source: Euroclear Sweden

Warrants program

Warrants program 2019/2022

The Sedana Medical AB (publ) AGM of May 28, 2019 resolved to carry out a new warrants program for employees (and consultants) in the Sedana Medical Group. The company thus issued 370,000 warrants in the 2019/2022 series at the AGM entitling subscription to a total of 370,000 shares, all of which were subscribed to by the company's subsidiary Sedana Medical Incentive AB for subsequent transfer to Group employees. Each warrant entitles subscription to one new share in Sedana Medical AB (publ) during the period July 1– November 30, 2022, at an issue price of SEK 142.23 per share. Full conditions apply to the warrants, including customary conversion conditions, which inter alia means that the issue price and the number of shares the warrant entitles subscription to may be restated in certain cases e.g. if the company implements changes to its share capital and/or the number of shares by issuing shares or other securities, or by consolidating or splitting shares. As of the closing date, 89,085 series 2019/2022 warrants had been transferred to Group employees, whereupon the remaining 307,208 warrants were canceled as of September 30, 2019. All transfers of warrants to Group employees took place at market value as calculated under the Black & Scholes' valuation model by an external valuer. The purchase sum for the warrants transferred as of the closing date totaled SEK 1,746,138. A precondition for acquiring warrants under the Deborah framework for the 2019/2022 warrants program was that employees undertake to sell warrants acquired back to Sedana Medical Incentive AB if their employment or assignments in the Group end before three years have passed from the acquisition date. If all of the 2019/2022 series warrants are subscribed to and transferred to employees in the Group as of the closing date, the company's share capital will rise by around SEK 8,909 through the issue of 89,085 shares in the company, equivalent to a dilution of 0.4 percent based on the number of shares in the company on the closing date.

Warrants program 2017/2021

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

Warrants program 2014/2019

As of December 31, 2018, Sedana Medical AB (publ) had 171 outstanding warrants in the 2014/2019 series, and at year end 2019, all of the warrants in the program had been converted to shares by participants in the program. These warrants were issued at the extraordinary shareholders' meeting of June 24, 2014. The warrants entitled holders to subscribe to shares in Sedana Medical AB (publ) during the period from the warrant registration date through December 31, 2019. The warrants were subject to customary conversion conditions should the company make changes to the share capital and/or the number of shares through e.g. a new share issue, bonus issue, consolidation or a share split. Each warrant entitled the holder to subscribe to 4,000 shares. In all, the total number of outstanding warrants entitled subscriptions to 1,040,000 shares at a subscription price equivalent to SEK 2.5 per share. All of the 2014/2019 series warrants were subscribed to by founders, existing shareholders, related parties and senior executives in the Group. During the year, SEK 1,710 thousand was paid in respect of the conversion of warrants to shares in the 2014/2019 warrants program. This corresponded to a total of 684,000 new shares in Sedana Medical AB (publ) and increased share capital by SEK 68 thousand. Since the conversions carried out during the year, there are no longer any warrants remaining to exercise in the 2014/2019 program, and all transferred warrants have been exercised and converted to shares in Sedana Medical AB (publ).

Facts about the Sedana Medical share

Listing	Nasdaq First North Growth Market Stockholm
Number of shares*	22 736 591
Stock market value, SEK million*	3088
Ticker	SEDANA
ISIN	SE0009947534

*As of 12/31/2019

ADMINISTRATION REPORT

The business in brief

Sedana Medical is a Swedish medical technology group that is also about to become a pharmaceutical company. The Group's operations comprise the development, manufacture and sales of medical devices and the development of products and drugs 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 anesthetics for use in anesthesia and intensive care. The Group's product portfolio currently includes AnaConDa with accessories and in the near future IsoConDa, the Group's drug candidate based on the well-known substance isoflurane.

Volatile anesthetics have long been used to anesthetize patients in connection with surgery. Complex, capital-intensive anesthesia machines that require specially trained personnel are used for this purpose. Traditional anesthesia machines lack several vital properties which means that they cannot be routinely used in an intensive care unit. The Group's AnaConDa product, which in very simple terms can be regarded as an anesthesia machine in miniature, is a solution that makes it practically and financially possible to use volatile anesthetics 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 anesthetics has shown itself in many ways to be a safer, more effective solution for sedating intensive care patients than current intravenous sedation. Despite the fact that Sedana Medical does not yet have market authorization for IsoConDa, the Group has shown rising net sales figures for several years through sales of its CE-marked product, AnaConDa. Sedana Medical's vision is to develop inhaled sedation, using IsoConDa 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 III registration study since the fall of 2016 aimed at gaining approval for the drug IsoConDa 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 via subsidiaries and affiliates to the parent company Sedana Medical AB (publ), corporate ID number 556670–2519. The operations in Germany consists of sales, storage and distribution. Until August 31, 2019, the German operations were run in a branch of the parent company. From September 1, 2019 the branch was transitioned into a wholly owned subsidiary. In Spain, sales operations are run in a branch of the parent company. Germany is by far the Group's largest market with over 85 percent of total sales. In addition to Germany and Spain, direct sales also take place in France through the wholly-owned subsidiary Sedana Medical Sarl, and in the Nordics and the United Kingdom through the parent company. In several other countries around the world, sales take place through collaborations with distributors. During 2019, the Group established new wholly-owned subsidiaries with own sales personnel in Norway, UK and the Netherlands. The Company conducts R&D in Ireland through a wholly owned subsidiary. The AnaConDa products are manufactured by subcontractors, but controlled via the Irish subsidiary. The parent company's head office and domicile is in Danderyd, Sweden. In June 2017, the company's share (ticker: SEDANA) was listed on Nasdaq First North Growth Market , Stockholm, Sweden.

Significant events January – December 2019

FIRST QUARTER

- Sedana Medical AB (publ) received approval for its planned pediatric study from the Pediatric Committee of EMA, European Medicines Agency, (PDCO).
- Sedana Medical AB (publ) secured a positive result from the interim analysis for the company's phase III study essential for registration, which showed fewer variations in effect than anticipated and will therefore only need to include a total of 300 patients instead of the initially estimated 550.

SECOND QUARTER

- At the pre-IND meeting with the American Food and Drug Administration (FDA), the FDA showed itself to be positive to the registration of IsoConDa and AnaConDa as a combination product in the USA. Thus Sedana Medical gained a clear picture of what must be done to achieve market approval in the USA. The meeting also confirmed Sedana Medical's estimation of the time and costs required for U.S. approval, which is expected to take place in 2024.
- The first patient in Japan was treated with AnaConDa, and work on the registration of IsoConDa in Japan began.
- Sedana Medical entered into an exclusive 10-year distribution agreement with Chinese distributor Kyuan Xinhai Medical, which is a subsidiary of China's second largest life science company, the partially state-owned Shanghai Pharma. Kyuan will fast-track its AnaConDa registration efforts in China, and it expects to secure approval within less than two years. The Chinese market potential for sedation within intensive care is estimated at 5 to 6 million ventilation days per year.
- The AGM of May 28, 2019, resolved to introduce a new warrant program for employees in the Sedana Medical Group.

THIRD QUARTER

- Sedana Medical concluded a distribution agreement with Indian distributor Hansraj Nayyar Medical. Sales began during the fall in parallel to a registration process. Hansraj Nayyar has committed to an initial framework order of EUR 25,000. The Indian market potential for sedation within intensive care is estimated at around 2 million sedation days per year.

- Sedana Medical secured approval from BSI Group, the European notifying body, for the use of AnaConDa in children. The approval also means AnaConDa can be used in patients with severely impaired lung function.

FOURTH QUARTER

- Sedana Medical carried out a targeted issue of 2,896,000 new shares. The issue price for the shares in the targeted new issue was SEK 129.50 per share. The targeted new share issue, which was oversubscribed many times, provided Sedana Medical with SEK 375 million before transaction expenses. Investors in the new share issue consisted of a number of Swedish and international institutional investors including AXA IM, Handelsbanken Funds, Joh. Berenberg Gossler & Co., KG (Berenberg), Swedbank Robur, Tredje AP-fonden and Öhman funds.
- Sedana Medical will sponsor two major investigator initiated studies with AnaConDa in France during 2020-2023. One of the studies the company sponsor is the world's largest multicenter study with AnaConDa, SESAR. Sedana Medical will supply the investigators with AnaConDa and accessories. The primary purpose of the study is to demonstrate that inhaled sedation with AnaConDa has lung-protective functions, shortens ventilator time and has higher survival in severely pulmonary intensive care patients.
- Sedana Medical is also supporting INASED, a major French multicenter study of isoflurane – the drug substance used in the company's drug candidate IsoConDa – which is delivered using the company's medical device, AnaConDa. The primary purpose of the study is to demonstrate a reduced occurrence of delirium in mechanically ventilated intensive care patients compared to intravenous sedation with propofol.
- Sedana Medical will no longer provide earnings targets for the period until the registration of IsoConDa in Europe, and clarifies that the sales target of SEK 500 million three years from European registration only applies to Europe. Sales outside of Europe are additional to this target.
- Sedana Medical AB (publ)'s Board Member Michael Ryan decided to resign on November 12, 2019. Sedana Medical's nomination committee started efforts to find his replacement.

Anticipated future developments

In the coming years, the Group will apply its strategy to realize its mission and vision and achieve its financial objectives.

BUSINESS CONCEPT

To provide a solution for many of the problems that today's intravenous sedation gives rise to. With AnaConDa, which is a delivery system for the volatile drug IsoConDa, which is administered via the respiratory tract, inhaled sedation is enabled, as an effective, safe, easily controllable and cost effective method for sedating mechanically ventilated patients in intensive care.

VISION

Inhaled sedation with AnaConDa and IsoConDa – a global standard method for the sedation of mechanically ventilated patients in intensive care.

FINANCIAL TARGETS

Until approval of IsoConDa is secured, the company's goal is to increase sales by an average of 20 per cent per year while also building up a larger medical, sales and marketing organization.

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

STRATEGY

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

1. Registration of IsoConDa and inhaled sedation in Europe
2. Register AnaConDa and IsoConDa in the USA
3. In close collaboration with the market, prepare for an effective, successful launch of the products and the therapy following their registration first in the EU and later in the USA.

EFFECTS OF COVID-19 PANDEMIC

Sedana Medical is affected and, like other companies, stands for currently facing the challenge of the spread of COVID-19 (novel corona virus). The company monitors developments over the spread of the virus in many countries and the implementation of measures around the world to prevent communities and business operations from being affected. As of the date of signature of this annual report Sedana Medical has seen some positive effects such as increased demand for the company's products from intensive care clinics around the world. The reason is that drugs that are administered via AnaConDa, isoflurane or sevoflurane, has lung protective effects which become especially important and useful for patients with breathing problems caused by severe viral infection by COVID-19. Sedana Medical does not only see positive effects with the COVID-19 pandemic. The company also foresee a risk of not being able to provide products in time to severe ill patients due to disruptions in the production and logistics chain. Sedana Medical works actively to dampen the effects through close cooperation with subcontractors and logistics partners. Employees work from home and communication take place via electronic tools in order to keep employees healthy and to contribute reduced risk of spread of infection in society. It is at present impossible to estimate the final impact on the Group or the parent company of the COVID-19 pandemic.

Risks

Sedana Medical's activities are affected by many factors that the company is 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 effect on the company's earnings and financial position depending on whether and how they fall out. 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 OPERATIONS

Risks related to the regulatory environment for medical devices and drugs

Sedana Medical's AnaConDa product with accessories and the forthcoming drug IsoConDa are subject to extensive regulation

worldwide and are monitored by various industry-specific supervisory authorities. In addition to such industry-specific regulation, Sedana Medical is also subject to a number of other requirements and restrictions under the provisions of environmental, health and industrial safety legislation. There may be more such requirements in the future. The cost of compliance with applicable legislation, requirements and guidelines can be great. Furthermore, the regulatory environment in general has become more stringent and extensive over time. Should these regulations not be followed, it can lead to sanctions that could significantly increase Sedana Medical's costs, entail delays in the development and the commercialization of the company's product candidates and substantially harm the ability to generate planned revenues and achieve profitability. If these risks become reality, they could have a significant adverse effect on the company's operations and financial position.

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

Before Sedana Medical's AnaConDa product and accessories may be marketed in the area of inhaled sedation treatment in intensive care in any new national or regional market, whether in combination with IsoConDa or not, the company must obtain marketing authorization or similar permits 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 revenues. In order for class II and III medical devices to be marketed in the EU, a so-called notified body must first issue a certificate confirming that the relevant regulatory requirements have been met. Under the provisions of the Medical Devices Directive (MDD), the company's current medical devices certificate is valid until May 26, 2024. Because decisions taken by notified bodies are valid for a limited time, certificates must be renewed. During the second half of 2020, Sedana Medical plan for an audit of The British Standards Institution (BSI), which is the company's notified body, to become certified according to the new medical technology regulations MDR (Medical Device Regulation). However, this renewal process can be time-consuming, especially when the original application is extended to include new treatment areas or otherwise undergoes significant changes. All of the risks described above could have a significantly 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 drug candidate IsoConDa (isoflurane) for use within the area of inhaled sedation treatment in intensive care. Completion of the study is crucial in order for the company to market its AnaConDa medical device together with IsoConDa as a 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 operational goals. The execution of clinical trials is associated with a number of risks. Among them are always the risks of delays and higher costs of the studies than estimated. Delays can occur due to problems in finding venues for studies, in gaining the necessary authority approvals for the performance of studies, with recruiting patients, with concluding satisfactory agreements with e.g. contract research companies, suppliers, and study locations etc. Not only can delays lead to increased costs, but also to late product launches which may result in the company's failure to generate revenues as planned. Increased costs can also occur due to expenditures per patient being higher than estimated or a lack of quality in the execution of the study in the hospitals where it is performed etc. Clinical studies may present negative or inadequate results in the treatment area Sedana Medical's products target. If the desired results are not achieved, it may mean the necessary market approvals fail to be issued, which can in turn jeopardize the company's ability to market and sell its products and product candidates. If the above risks become reality, they can have significant adverse effects on the company's ability to generate revenues and on its operations, financial position and earnings.

Risks related to third-party agreements in respect of e.g. the performance of clinical studies and manufacturing

Sedana Medical engages external companies such as contract research and development companies to perform clinical studies and to manufacture its products. The operations of such companies are subject to extensive requirements regarding e.g. reporting, safety and the environment. There is a risk that these companies do not comply with applicable legislation, regulation and the relevant ethical standards such as good manufacturing practices (GMP) and good clinical practices (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 can affect the development and sales of Sedana Medical's products negatively by causing delays and increasing costs. The company is not dependent on any individual contract research and 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 payers including the ability to benefit from compensation systems

Even if a product meets the requirements for market access by e.g. obtaining marketing authorization, there is a risk that the desired level of market acceptance will not be achieved from doctors, hospitals, patients, healthcare payers and the industry in general, which could prevent Sedana Medical from generating desired revenues 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 products for intensive care patients are primarily exposed to competition from sedation drugs for intravenous treatment. 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 products' ability to take market share from companies that sell drugs 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 sedation drugs for intravenous treat-

ment, there is a risk of exposure to competition within the indication inhaled sedation. The risks related to competition could have a significantly adverse effect on the company's operations, financial position and earnings.

Risks related to macro economic factors including pricing and demand for medical products

Because Sedana Medical intends to market and sell its products in several parts of the world, the company can be affected by general demand and the pricing of products for sedating intensive care patients in the relevant markets. Sedana Medical cannot foresee developments in financial markets, the economic and political climates or macro economic events such as a recession or weak growth, which may lead to stresses in the market for medical devices and drugs, leading to increasing pressure on hospitals, authorities and other healthcare payers 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 limited number of products

Today, Sedana Medical focuses mainly on sales of AnaConDa, and conducting a clinical phase III study of the IsoConDa drug candidate with the aim of obtaining marketing authorization 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, namely inhaled sedation in intensive care. Sedana Medical's operations, financial position and earnings would suffer significant adverse effects from any setback in e.g. the clinical phase III study.

Risks related to key individuals and qualified personnel

Sedana Medical is dependent on its employees, especially senior executives and other key staff. The company is dependent on its ability to recruit highly qualified personnel for the continued development of the operation. If Sedana Medical were to lose any of its key personnel or fail to recruit qualified personnel it could have a negative effect 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 form a central asset in Sedana Medical's operation and thus any future successes are largely dependent on the company's abilities to maintain existing intellectual property rights such as brands and patents and to obtain protection for submitted and future patent applications. Some of the company's patents for the old version of the AnaConDa product have run out or will run out shortly, and this may enable competitors to manufacture and sell competing products. Sedana Medical has submitted a number of patent applications related to the new AnaConDa technology. If the company's patents and other intellectual property rights were to be lost or limited, or if the company otherwise cannot maintain the necessary patent protection, it could have a negative effect on the company's operations, financial position and earnings.

Risks related to fluctuating currency rates

The company reports its financial position and earnings in Swedish krona. On the other hand, a major part of the company's operating costs and almost all revenues are in euros, and in the future the company's operating revenues and costs are expected to comprise other currencies. As a result, Sedana Medical is exposed to exchange rate risks in relation to payment flows inside and outside Sweden and the eurozone, such as fluctuations where the exchange rate changes from the time an agreement is concluded until payment takes place under said agreement, which can lead to currency transaction losses or gains (so-called transaction exposure) that the company is unable to foresee. Currency transaction losses could entail significant adverse effects on the company's future operations, financial position and profits.

Risks related to current and additional financing

The amount of resources required to implement Sedana Medical's operational plan including the development and commercialization of medical devices and drugs depends on a number of factors that are unknown at present. There is a risk that Sedana Medical will not achieve sufficient revenues 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 make competitive offers. Sedana Medical may also be forced to seek additional financing in order to continue 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 the operation according to established operational planning and objectives. If the risks associated with problems in obtaining sufficient revenues 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

In Sedana Medical's opinion, the company complies with applicable tax legislation. However, from time to time various alternative legislation may be proposed that will have a negative impact on the company's tax situation. Furthermore, 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 earlier 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 losses, Sedana Medical has major accumulated tax losses. Changes in ownership that lead to an individual's gaining a 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.

Multi-year financial overview

Group Consolidated

KSEK	2019	2018	2017	2016	2015
Net Sales	71 645,6	57 896,2	40 427,7	32 154,6	28 113,5
Gross Profit	52 413,1	42 896,5	29 661,7	21 346,4	17 849,2
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-12 978,9	-4 232,3	-736,2	994,3	-1 174,2
Earnings Before Interest and Taxes (EBIT)	-17 167,3	-8 238,2	-3 487,8	617,8	-1 386,7
Net income	-16 357,8	-6 869,1	-3 875,7	1 285,6	-1 205,4
Gross Margin (%)	73,2%	74,1%	73,4%	66,4%	63,5%
EBITDA %	-18,1%	-7,3%	-1,8%	3,1%	-4,2%
EBIT %	-24,0%	-14,2%	-8,6%	1,9%	-4,9%
Net income % of net sales	-22,8%	-11,9%	-9,6%	4,0%	-4,3%
Total assets	593 251,4	231 549,8	131 376,3	23 624,4	12 401,3
Equity ratio	96,0%	94,1%	88,6%	5,3%	3,6%
Quick ratio	2007,2%	1219,6%	640,4%	80,2%	131,8%
Average number of employees	38,6	26,1	16,5	15,7	11,0

Parent Company

KSEK	2019	2018	2017	2016	2015
Net Sales	44 929,3	55 855,7	31 494,9	27 940,0	21 261,3
Gross Profit	14 567,7	21 126,5	13 339,2	12 105,1	11 708,0
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-14 771,9	-4 888,3	1 345,5	6 088,5	164,7
Earnings Before Interest and Taxes (EBIT)	-16 050,2	-6 431,4	1 277,2	5 957,7	-830,5
Net income	-14 799,8	-3 755,2	1 659,1	6 179,5	-1 508,3
Gross Margin (%)	32,4%	37,8%	42,4%	43,3%	55,1%
EBITDA %	-32,9%	-8,8%	4,3%	21,8%	0,8%
EBIT %	-35,7%	-11,5%	4,1%	21,3%	-3,9%
Net income % of net sales	-32,9%	-6,7%	5,3%	22,1%	-7,1%
Total assets	615 476,0	257 059,7	38 328,8	31 230,9	18 734,4
Equity ratio	94,5%	89,0%	24,3%	57,6%	42,1%
Quick ratio	1443,9%	630,6%	59,6%	251,6%	81,2%
Average number of employees	23,6	17,0	8,7	7,4	7,0

Financial overview January-December 2019

REVENUES

The Group's operating revenues for the full year 2019 was SEK 73,738 thousand, which corresponds to an increase of SEK 14,367 thousand, of which net sales constituted an increase of SEK 13,749 thousand, or 24 percent. The Group's sales are exclusively in EUR, and the equivalent sales increase adjusted for currency fluctuations was 20 percent. Furthermore, the revenues include other operating revenues of SEK 2,092 thousand (1,475). Other operating revenues in 2019 comprised mainly positive exchange rate differences.

COST OF GOODS SOLD

The cost of goods sold was SEK 19,232 thousand (15,000), equivalent to an increase of 28 percent compared to the full year 2018. The increase in the cost of goods for sale depends mainly on increased sales, but also on the product mix.

OTHER EXTERNAL EXPENSES

Other external expenses for the full year 2019 totaled SEK 27,122 thousand (21,651), i.e. an increase of SEK 5,471 thousand or 25 percent compared to 2018, which is mainly due to increased expenses for sales and market. In general, other external expenses includes consultancy fees, sales and market expenses, expenses for accounting services, travel and patent expenses.

PERSONNEL EXPENSES

Personnel expenses in the Group totaled SEK 38,045 thousand (25,760) for 2019, i.e. an increase of SEK 12,285 thousand or 48 percent in comparison with 2018. During 2019, the Group had an average of 39 employees, which was an increase of 13 employees compared with the same period in 2018. The increase in personnel expenses is mainly due to a buildup of a market, sales and medical affairs organization before the registration and subsequent launch of IsoConDa.

DEPRECIATIONS, AMORTIZATIONS AND WRITE DOWNS

For the full year 2019, depreciations totaled SEK 4,188 thousand (4,006), i.e. an increase of SEK 182 thousand compared with 2018. Depreciations refer to property, plant and equipment and amortizations refer to the internally generated intangible asset, AnaConDa-S.

OPERATING INCOME

The Group's operating income for the full year was SEK -17,167 thousand (-8,328) equivalent to a decrease of SEK 8,929 thousand or 108 percent. The increased loss is explained mainly by the expenses of building up the sales, market and medical affairs organization within the Group.

FINANCIAL ITEMS

The financial net amounted to SEK 224 thousand (1,719) for the year. The financial net is mainly attributable to positive exchange rate differences.

TAXES

The Group reported a tax income of SEK 586 thousand for 2019. A tax expense of SEK 349 thousand was reported for the corresponding period in the previous year. The tax income for 2019 is attributable to changes in deferred tax. The 2018 tax expense was due mainly to an adjustment of earlier allowed tax deductions in respect of R&D in the Group's subsidiary in Ireland.

NET INCOME

The Group reported a net income of SEK -16,358 thousand (-6,869) for the year. The decrease in earnings compared to the previous year is due mainly to a lower operating income.

EQUITY AND LIABILITIES

As of December 31, 2019 equity in the Group was SEK 569,380 thousand (217,811), equivalent to an increase of SEK 351,569 thousand. The increase is mainly attributable to the new share issue during the fourth quarter which provided the company with new capital in the amount of SEK 375 million. At the end of the period, current liabilities in the Group totaled SEK 23,872 thousand (13,738) comprising mainly trade accounts payable of SEK 11,004 thousand (4,430).

CASH AND CASH EQUIVALENTS AND CASH FLOW

Cash and cash equivalents at the end of the period totaled SEK 464,560 thousand (159,351). Cash flow from operating activities before change in working capital was SEK -11,074 thousand (-2,761). Cash flow from operating activities including the change in working capital was SEK -8,700 thousand (-5,779). The negative change in working capital compared with the same period for the previous year is primarily due to an increase in operating receivables. Cash flow from investments was SEK -54,132 thousand (-29,127) comprising mainly intangible assets of which the major part concerns capitalized development expenses and where expenses for the clinical study IsoConDa EU (SED001) constitute the main part. Cash flow from financing activities showed a net of SEK 368,044 thousand (108,774) mainly due to the targeted new share issue carried out in October 2019. Cash flow from financing activities includes issue expenses of SEK 10,115 thousand. Cash flow for the full year totaled SEK 305,212 thousand (73,869).

INVESTMENTS

Investments during the 2019 financial year totaled SEK 54,132 thousand (29,127). Investments during 2019 primarily consist of:

- Capitalized expenses for development work, SEK 49,591 thousand
- Internal expenses for the preparation of patents, SEK 176 thousand
- The purchase of machinery and other technical facilities, SEK 3,728 thousand
- The purchase of fixtures, fittings and tools, SEK 163 thousand.

PARENT COMPANY

Sedana Medical AB (publ) Corporate ID number: 556670–2519, is the Group's parent company. The operation comprises clinical development, sales, administrative and company management functions. The parent company includes a branch office in Spain where operations consist of sales. Up until August 31, 2019, the parent company had a branch office in Germany. As of September 1, 2019, the German branch office's operations were transferred to a wholly-owned German subsidiary, and no longer constitutes part of the parent company.

The parent company's total revenues for the financial year were SEK 67,031 thousand (66,479). The reduction in net sales compared to the previous year is due to the fact that revenues from the German branch office no longer flow to the parent company as of September 2019.

The operating income was SEK -16,050 thousand (-6,431), which is a decrease of SEK 9,619 thousand. The financial net in 2019 was SEK 1,263 thousand (2,724). Net income for the period was SEK -14 800 thousand (-3,755).

As of December 31, 2019, equity in the parent company, Sedana Medical AB (publ), totaled SEK 581,915 thousand (228,710), an increase of SEK 353,205 thousand. Share capital totaled SEK 2,274 thousand (1,916), equivalent to an increase of SEK 358 thousand. Of this increase, SEK 290 thousand are due to the new share issue during the fourth quarter when the company was provided with new capital in the amount of SEK 375 million before transaction expenses through the issue of 2,896,000 new shares. The remaining part of the increase in share capital, SEK 68 thousand, consist of the exercise of warrants to shares in the 2014/2019 warrants program during the year. In all, the company has 22,736,591 issued shares as of December 31, 2019. At year-end 2019, there were also 399,234 outstanding warrants in two different warrants programs, namely 2017/2021 and 2019/2022.

Cash and cash equivalents totaled SEK 455,206 thousand (158,805), an increase of SEK 296,400 thousand, mainly due to the new share issue in October 2019.

Organization and Personnel

EMPLOYEES

At the end of 2019, Sedana Medical had 41 employees, of whom 22 were men, and 19 women. The corresponding figures at the end of 2018 were 30 employees, of whom 19 were men, and 11 women.

WARRANTS PROGRAM 2019/2022

The Sedana Medical AB (publ) AGM of May 28, 2019 resolved to carry out a new warrants program for employees (and consultants) in the Sedana Medical Group. The company thus issued 370,000 warrants in the 2019/2022 series at the AGM entitling subscription to a total of 370,000 shares, all of which were subscribed to by the company's subsidiary Sedana Medical Incentive AB for subsequent transfer to Group employees. Each warrant entitles subscription to one new share in Sedana Medical AB (publ) during the period July 1– November 30, 2022, at an issue price of SEK 142.23 per share. Full conditions apply to the warrants, including customary conversion conditions, which inter alia means that the issue price and the number of shares the warrant entitles subscription to may be restated in certain cases e.g. if the company implements changes to its share capital and/or the number of shares by issuing shares or other securities, or by consolidating or splitting shares. As of the closing date, 89,085 series 2019/2022 warrants had been transferred to Group employees, whereupon the remaining 307,208 warrants were canceled as of September 30, 2019. All transfers of warrants to Group employees took place at market value as calculated under the Black & Scholes' valuation model by an external valuer. The purchase sum for the warrants transferred as of the closing date totaled SEK 1,746,138. A precondition for acquiring warrants under the framework for the 2019/2022 warrants program was that employees undertake to sell warrants acquired back to Sedana Medical Incentive AB if their employment or assignments in the Group end before three years have passed from the acquisition date. If all of the 2019/2022 series warrants are subscribed to and transferred to employees in the Group as of the closing date, the company's share capital will rise by around SEK 8,909 through the issue of 89,085 shares in the company, equivalent to a dilution of 0.4 percent based on the number of shares in the company on the closing date.

WARRANTS PROGRAM 2017/2021

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

WARRANTS PROGRAM 2014/2019

As of December 31, 2018, Sedana Medical AB (publ) had 171 outstanding warrants in the 2014/2019 series, and at year end 2019, all of the warrants in the program had been exercised by participants in the program. These warrants were issued at the extraordinary shareholders' meeting of June 24, 2014. The warrants entitled holders to subscribe to shares in Sedana Medical AB (publ) during the period from the warrant registration date through December 31, 2019. The warrants were subject to customary conversion conditions should the company make changes to the share capital and/or the number of shares through e.g. a new share issue, bonus issue, consolidation or a share split. Each warrant entitled the holder to subscribe to 4,000 shares. In all, the total number of outstanding warrants entitled subscriptions to 1,040,000 shares at a subscription price equivalent to SEK 2.5 per share. All of the 2014/2019 series warrants were subscribed to by founders, existing shareholders, related parties and senior executives in the Group. During the year, SEK 1,400 thousand was paid in respect of the conversion of warrants to shares in the 2014/2019 warrants program. This corresponded to a total of 664,000 new shares in Sedana Medical AB (publ) and increased share capital by SEK 68 thousand. Since the conversions carried out during the year, there are no longer any warrants remaining to exercise in the 2014/2019 program, and all transferred warrants have been exercised and converted to shares in Sedana Medical AB (publ).

Proposed appropriations of earnings

The Board of Directors proposes no dividend for the 2019 financial year.

The amount available for appropriation at the Annual General Meeting comprises the following unrestricted reserves, profit carried forward and the profit for the year in the Parent company:

SEK	
Share premium reserve	605,702,174
Losses carried forward	-99,308,082
Loss for the year	-14,799,821
Total unrestriced reserves	**491,594,271**

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

SEK	
Share premium reserve	605,702,174
Losses carried forward	-114,107,903
Total unrestriced reserves	**491,594,271**

Statement of changes in equity

Consolidated statement of changes in equity

KSEK	Share capital	Other Equity including result for the year	Total shareholders equity
Opening balance January 1, 2018 according to balance sheet	1,707.3	114,696.0	116,403.3
Changes in the carrying amounts recognised directly in equity			
New issue of shares	208.4	112,679.5	112,887.9
Issue expenses	0.0	-4,439.4	-4,439.4
Translation difference	0.0	-171.4	-171.4
	208.4	108,068.7	108,277.1
Net income	0.0	-6,869.1	-6,869.1
Total Equity December 31, 2018	1,915.7	215,895.6	217,811.3
Opening balance January 1, 2019	1,915.7	215,895.6	217,811.3
Changes in the carrying amounts recognised directly in equity			
New issue of shares	358	376,384.0	376,742.0
Issue expenses	0.0	-10,114.9	-10,114.9
Received premium for warrant subscription	0.0	1,746.1	1,746.1
Expenses for warrant program	0.0	-329.8	-329.8
Translation difference	0.0	-117.2	-117.2
	358.0	367,568.3	367,926
Net income	0.0	-16,357.8	-16,357.8
Total Equity 31 December, 2019	**2,273.7**	**567,106.2**	**569,379.8**

Statement of changes in equity

Parent company statement of changes in equity

KSEK	Share capital	Fund for capitalized development expenses	Share premium fund	Retained earnings including profit or loss for the period	Total shareholders equity
Opening balance January 1, 2018 according to balance sheet	1,707.3	6,402.8	129,450.8	-13,614.3	123,946.5
Changes in the carrying amounts recognised directly in equity					
New issue of shares	208.4	0.0	112,679.5	0.0	112,887.9
Issue expenses	0.0	0.0	-4,439.4	0.0	-4,439.4
Translation difference	0.0	0.0	0.0	70.3	70.3
	208.4	0.0	108,240.1	70.3	108,518.7
Reallocation between items in equity					
Allocations to funds for capitalized development expenses	0.0	35,894.7	0.0	-35,894.7	0.0
	0.0	35,894.7	0.0	-35,894.7	0.0
Net income	0.0	0.0	0.0	-3,755.2	-3,755.2
Total Equity December 31, 2018	1,915.7	42,297.4	237,690.9	-53,193.9	228,710.1
Opening balance January 1, 2019	1,915.7	42,297.4	237,690.9	-53,193.9	228,710.1
Adjustments	0.0	0.0	325.8	-325.8	0.0
Adjusted opening balance January 1, 2019	1,915.7	42,297.4	238,016.7	-53,519.7	228,710.1
Changes in the carrying amounts recognised directly in equity					
New issue of shares	358.0	0.0	376,384.0	0.0	376,742.0
Issue expenses	0.0	0.0	-10,114.9	0.0	-10,114.9
Received premium for warrant subscription	0.0	0.0	1,746.1	0.0	1,746.1
Expenses for warrant program	0.0	0.0	-329.8	0.0	-329.8
Translation difference	0.0	0.0	0.0	-38.5	-38.5
	358.0	0.0	367,685.5	-38.5	368,005.0
Reallocation between items in equity					
Allocations to funds for capitalized development expenses	0.0	45,749.8	0.0	-45,749.8	0.0
	0.0	45,749.8	0.0	-45,749.8	0.0
Net income	0.0	0.0	0.0	-14,799.8	-14,799.8
Total Equity 31 December, 2019	**2,273.7**	**88,047.3**	**605,702.2**	**-114,107.9**	**581,915.2**

OTHER FINANCIAL INFORMATION

Consolidated Income Statement

Group

		1 January - 31 December	
KSEK	Note	2019	2018
Revenues			
Net sales	4	71,645.6	57,896.2
Other operating income	6	2,092.1	1,474.5
		73,737.7	59,370.7
Operating cost and expenses			
Cost of goods sold		-19,232.4	-14,999.7
External expenses	7, 23	-27,122.4	-21,651.1
Personnel expenses	8	-38,044.9	-25,760.2
Depreciation and amortisation		-4,188.4	-4,005.9
Other operating expenses	9	-2,316.9	-1,192.0
Operating income		-17,167.3	-8,238.2
Income from financial items			
Financial income	10	2,455.8	5,450.5
Financial expenses	11	-2,231.9	-3,731.9
Income after financial items		-16,943.4	-6,519.6
Income before taxes		-16,943.4	-6,519.6
Taxes	12	585.7	-349.4
Net Income		**-16,357.8**	**-6,869.1**

Consolidated Balance Sheet

Group

KSEK	Note	31 December 2019	2018
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development expenses	13	95,486.9	46,161.5
Concessions, patents, licenses, trademarks and similar	14	4,160.4	5,243.1
		99,647.3	51,404.5
Tangible assets			
Improvements on leashold properties	17	11.1	54.8
Machinery and equipment	15	4,384.9	4,128.5
Fixtures and tools	16	477.9	525.1
		4,874.0	4,708.4
Financial fixed assets			
Deferred tax receivables		2,204.6	1,590.9
Total fixed assets		**106,725.9**	**57,703.9**
Current assets			
Inventory			
Finished goods	19	7,378.3	6,294.7
		7,378.3	6,294.7
Receivables			
Trade receivables		6,467.0	4,984.7
Other current receivables		6.1	349.1
Deferred tax receivables		3,502.8	1,294.3
Prepaid expenses and accrued income		4,611.3	1,572.5
		14,587.1	8,200.5
Cash and cash equivalents	24	464,560.0	159,350.7
Total current assets		**486,525.5**	**173,845.9**
TOTAL ASSETS		**593,251.4**	**231,549.8**

KSEK	Note	31 December 2019	2018
EQUITY AND LIABILITIES			
Equity			
Share capital		2,273.7	1,915.7
Other equity including net income for the period		567,106.2	215,895.6
Equity attributable to shareholders in parent company		569,379.8	217,811.3
Total equity		**569,379.8**	**217,811.3**
Current liabilities			
Accounts payables		11,004.1	4,429.9
Tax liabilities		1,253.7	486.8
Other current liabilites	21	3,347.1	1,864.2
Accrued expenses and prepaid income	22	8,266.6	6,957.6
		23,871.6	**13,738.5**
TOTAL EQUITY AND LIABILITIES		**593,251.4**	**231,549.8**

Consolidated statement of cash flow

Group

KSEK	Note	1 January - 31 December 2019	2018
Operations			
Operating income		-17,167.3	-8,238.2
Adjustment of non cash flow items			
Depreciations and amortisations		5,558.0	5,661.3
Currency exchange rates differences		282.1	-385.4
Other non cash flow items		0.0	97.0
		-11,327.2	-2,865.3
Received interest		3.1	2.7
Paid interest		-7.0	-4.1
Paid taxes		257.3	105.5
Cash flow from operations before change in working capital		-11,073.8	-2,761.1
Cash flow from change in working capital			
Increase (-)/Decrease (+) of inventory		-1,076.6	-3,079.0
Increase (-)/Decrease (+) of operating receivables		-6,706.6	2,320.2
Increase (+)/Decrease (-) of operating liabilities		10,156.8	-2,259.1
Cash flow from operations		-8,700.2	-5,778.9
Investment activities			
Investment in intangible fixed assets		-49,839.1	-25,101.5
Investments in tangible fixed assets		-4,292.6	-4,025.1
Cash flow from investment activities		-54,131.7	-29,126.5
Financing activities			
New issue of shares		376,742.0	113,213.4
Issue expenses		-10,114.9	-4,439.4
Received premium for warrant subscription		1,746.1	0.0
Expenses for warrant program		-329.8	0.0
Cash flow from financing activities		368,043.5	108,774.0
Cash flow for the period		305,211.6	73,868.6
Liquid funds at the beginning of the period		159,350.7	85,321.6
Effects of exchange rate changes in cash		-2.3	160.5
Liquid funds at the end of the period	24	**464,560.0**	**159,350.7**

Income statement

Parent company

KSEK	Note	1 January - 31 December 2019	2018
Revenues			
Net sales	4, 5	44,929.3	55,855.7
Other operating income	5, 6	22,101.4	10,623.4
		67,030.7	66,479.1
Operating cost and expenses			
Cost of goods sold	5	-30,361.6	-34,729.2
External expenses	7, 23	-24,232.2	-16,828.9
Personnel expenses	8	-25,151.0	-18,676.1
Depreciation and amortisation		-1,278.3	-1,543.1
Other operating expenses	9	-2,057.8	-1,133.3
Operating income		-16,050.2	-6,431.4
Income from financial items			
Financial income	10	2,444.9	5,450.4
Financial income, group internal	10	964.1	995.3
Financial expenses	11	-2,146.2	-3,721.4
Income after financial items		-14,787.4	-3,707.1
Group contribution		-12.4	0.0
Income before taxes		-14,799.8	-3,707.1
Taxes	12	0.0	-48.1
Net Income		**-14,799.8**	**-3,755.2**

Balance sheet

Parent company

KSEK	Note	31 December 2019	2018
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development expenses	13	88,047.3	42,297.4
Tangible assets			
Machinery and equipment	15	839.5	2,413.6
Fixtures and tools	16	221.1	278.8
		1,060.6	2,692.4
Financial fixed assets			
Shares in group companies	18	395.3	50.0
Long term receivables in group companies		40,417.9	24,019.3
		40,813.1	24,069.3
Total fixed assets		**129,921.0**	**69,059.1**
Current assets			
Inventory			
Finished goods	19	983.6	9,227.2
Current receivables			
Trade receivables		359.3	4,380.5
Receivables in group companies		21,827.6	12,648.2
Tax receivables		3.9	349.1
Other current receivables		3,084.8	1,239.4
Prepaid expenses and accrued income		4,090.1	1,350.6
		29,365.7	19,967.8
Cash and cash equivalents	24	455,205.7	158,805.5
Total current assets		**485,555.0**	**188,000.5**
TOTAL ASSETS		**615,476.0**	**257,059.7**

KSEK	Note	31 December 2019	2018
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		2,273.7	1,915.7
Fund for capitalized development expenses		88,047.3	42,297.4
Non restricted equity			
Share premium fund		605,702.2	237,690.9
Retained earnings		-99,308.1	-49,438.7
Profit or loss for the period		-14,799.8	-3,755.2
Total Equity		**581,915.2**	**228,710.1**
Current liabilities			
Accounts payables		6,845.0	2,281.2
Liabilities to group companies		19,595.9	20,130.6
Tax liabilities		826.0	0.0
Other current liabilites	21	2,001.3	1,340.8
Accrued expenses and prepaid income	22	4,292.6	4,596.9
		33,560.8	**28,349.6**
TOTAL EQUITY AND LIABILITIES		**615,476.0**	**257,059.7**

Statement of cash flow

Parent company

		1 January - 31 December	
KSEK	Note	2019	2018
Operations			
Operating income		-16,050.2	-6,431.4
Adjustment of non cash flow items			
Depreciations and amortisations		2,252.5	3,198.5
Currency exchange rates differences		546.7	164.6
Other non cash flow items		0.0	97.0
		-13,250.9	-2,971.4
Received interest		964.1	995.3
Paid interest		-4.4	-4.0
Paid taxes		342.8	0.0
Cash flow from operations before change in working capital		-11,948.3	-1,980.1
Cash flow from change in working capital			
Increase (-)/Decrease (+) of inventory		8,217.9	-3,113.7
Increase (-)/Decrease (+) of operating receivables		-8,459.1	-5,641.1
Increase (+)/Decrease (-) of operating liabilities		5,167.8	8,328.0
Cash flow from operations		-7,021.9	-2,406.9
Investment activities			
Investment in intangible fixed assets		-45,749.8	-35,754.7
Investments in tangible fixed assets		-1,832.1	-3,007.9
Investments of financial assets		-15,529.4	7,784.9
Cash flow from investment activities		-63,111.3	-30,977.7
Financing activities			
New issue of shares		376,742.0	113,213.4
Issue expenses		-10,114.9	-4,439.4
Cash flow from financing activities		366,627.1	108,774.0
Cash flow for the period		296,494.0	75,389.5
Liquid funds at the beginning of the period		158,805.5	83,282.9
Effects of exchange rate changes in cash		-93.7	133.1
Liquid funds at the end of the period	24	**455,205.7**	**158,805.5**

NOTES

NOTE 1 GENERAL INFORMATION

Sedana Medical AB (publ), corporate ID number 556670–2519 is a public limited company domiciled in Sweden with its registered office in Danderyd, Sweden. The company's address is Vendevägen 87, SE 182 32 Danderyd, Sweden. The company develops, manufactures and sells medical devices. Sedana Medical AB (publ) is the parent company in the Sedana Medical Group.

NOTE 2 ACCOUNTING POLICIES

All amounts are reported in SEK unless otherwise indicated. As of Q3 2017, Sedana Medical AB (publ) made an exception from the K3 accounting regulation and does not gross report capitalized development expenses over other operating income but reports development expenses net as a reduction of personnel and other expensed items.

Changes in accounting compared with the year-end report 2019
In Sedana Medical's year-end report for 2019, Sedana Medical has reported the liquidity for the premium in the warrants program 2019/2022 above income statement, SEK 1,746,138. Since this accounting is not completely compatible with common principles, Sedana Medical has chosen to make a change of this accounting in the annual report for 2019. Thus, in the annual report for 2019, this liquidity is instead reported in the share premium reserve in equity in Sedana Medical AB (publ). The transaction costs incurred by the company in connection with the warrants program 2019/2022, SEK 329,782, is reported as prepaid expenses in the year-end report for 2019 but has thus changed and the reporting of this item in the annual report is now over equity in the premium reserve. This has resulted in a reduction of the profit for the year for the Group and the Parent Company by SEK 1,746,138. Furthermore, this has resulted in an increase in the premium reserve in the parent company on a net basis of 1 416 357 SEK.

General accounting policies
This Annual Report has been prepared in compliance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board's general recommendations BFNAR 2012:1 Annual accounts and consolidated financial statements (K3). Sedana Medical AB (publ), i.e. the parent company, and the Group apply the same accounting policies.

Consolidated financial statements
Subsidiaries
Subsidiaries are companies in which the parent company directly or indirectly holds more than 50 percent of the number of votes or has in some other way a controlling influence. Controlling influence means a right to determine a company's financial and operational strategies with the objective of gaining economic benefits. Business combinations are reported as a single unit of account. This means that the acquisition analysis is set up from the date the acquirer gains a controlling influence. As of this date, the acquirer and the acquired unit are regarded as a single accounting unit. Application of the single unit principle also means that all assets (including goodwill) and liabilities, as well as revenues and expenses, are taken into account in their entirety even in the case of part-owned subsidiaries. The cost of subsidiaries is calculated to the sum of fair value at the time of acquisition for the paid assets with additions for arising and acquired liabilities and the issuance of equity instruments, expenditures that are directly attributable to the business combination and any supplementary purchase price. The acquisition analysis determines the fair value, with some exceptions, at the time of acquisition of acquired identifiable assets and assumed liabilities and minority interest. Minority interest is measured at fair value at the time of acquisition. The acquired company's revenues, expenses, identifiable assets, liabilities and any goodwill or negative goodwill are included in the consolidated financial statements from the moment of acquisition.

Elimination of transactions within the Group
Group internal transactions, balance sheet items and unrealized gains and loss- es on transactions between Group companies are eliminated in their entirety.

Revenue
The inflow of financial benefits that the company has received or will receive on its own account is recognized as revenue. Revenue is measured at the fair value of what has been or will be received, less discounts.

Sale of goods
When goods are sold, revenue is recognized upon delivery.

Interest, royalties and dividends
Revenue is recognized when the financial benefits associated with the transaction are likely to accrue to the company and when the income can be reliably calculated.

Leasing – lessees
All leases are classified as operational leases. A financial lease is a lease under which the risks and benefits associated with owning an asset are in all material respects transferred from the lessor to the lessee. An operational lease is a lease that is not the financial lease.

Taxes
Tax on current year's earnings in the income statement consists of current tax and deferred tax. Current tax is income tax for the current financial year in respect of taxable earnings for the year and that part of the previous financial year's income tax not yet reported. Deferred tax is income tax for taxable earnings in respect of future financial years as a result of earlier transactions or events.

Deferred tax is calculated on temporary differences. A temporary difference exists when the carrying amount of an asset or liability differs from the taxable value. Temporary differences are not taken into account in differences attributable to investments in subsidiaries, associated companies or joint ventures if the company is able to control the date for the reversal of the temporary difference and it is not evident that the temporary difference will be reversed in the foreseeable future. Nor are differences stemming from initial recognition of goodwill or initial recognition of an asset or liability temporary differences, unless the attributable transaction is a business combination or affects tax or reported earnings.

A deferred tax asset in respect of a loss carryforward or other future tax deductions is reported to the extent it is probable that the deductions can be settled against future tax surpluses.

In the consolidated financial statements, untaxed reserves are split into deferred tax liabilities and equity.

Valuation principles etc.
Assets, provisions and liabilities have been valued at cost unless otherwise stated below.

Foreign currency
Items in foreign currency
Monetary items in foreign currency are translated at the spot rate on the closing date. Non-monetary items are not translated but entered at the acquisition date exchange rate. Transactions in foreign currencies are translated at the transaction date exchange rate.

Exchange rate differences arising when settling or translating monetary items are reported in the income statement of the financial year in which they arise either as an operational item or a financial item depending on the underlying business event.

Translation of foreign operations
Assets and liabilities, including goodwill and other group-related surplus and deficit values, are translated into the reporting currency at the closing date exchange rate. Revenues and expenses are translated at an exchange rate that constitutes an approximation of the actual exchange rate used (e.g. average exchange rate).

Exchange rate risk
Currency risk refers to the risk that the fair value or future cash flows will fluctuate as a result of changed currency rates. The company has both current and non-current receivables and liabilities in foreign currencies and is thus exposed to currency risk. In other words, exposure to currency risk stems principally from the translation of balance sheet items in foreign currency.

No hedging instruments are used.

Intangible assets
Expenditures for research and development
All expenditures that arise during the research phase are expensed as they arise.

When reporting development expenditures, the capitalization method is applied. This means expenditures arising during the development phase are reported as an asset once all of the conditions listed below are met:

- It is technically possible to complete the intangible fixed asset such that it can be used or sold.
- The intention is to complete the intangible fixed asset and use or sell it.
- Conditions exist that allow the use or sale of the intangible fixed asset.
- It is probable that the intangible fixed asset will generate future economic benefits.
- There are necessary and adequate technical, financial and other resources to complete the development and to use or sell the intangible fixed asset.
- The expenditures attributable to the intangible fixed asset can be calculated in a reliable manner.

In the acquisition value, direct costs from eg. subcontractors as well as personnel expenses incurred in the development work together with an appropriate proportion of relevant indirect expenses and borrowing costs are included.

Other intangible assets
Other intangible assets acquired by the company are reported at cost less accumulated depreciations and impairment charges. Assets are depreciated in a straight-line over the assets' estimated useful life. Useful life is retested every balance sheet date. Projects in progress are not depreciated but are tested for impairment annually. Expenditures for internally generated goodwill and trademarks are expensed in the income statement as they arise.

Depreciations
Depreciation is calculated on a straight-line basis over the asset's calculated useful life. Depreciation is reported as an expense in the income statement.

The following depreciation times are applied:

Internally developed intangible assets

	Group	Parent company
Expenditures for development and similar work brought forward	5-10 years	5-10 years

Property, plant and equipment
Property, plant and equipment are reported at cost less accumulated depreciation and impairment losses. In addition to the purchase price, cost can also include expenditures directly attributable to the acquisition.

Additional expenditures
Additional expenditures that meet the asset criterion are included in the asset's carrying amount. Expenditures in respect of running maintenance and repairs are expensed in the period in which they arise. The use of significant components has not been considered material for any of the tangible assets. Accordingly, no component depreciation has taken place.

Depreciations
Depreciation is calculated on a straight-line basis over the asset's calculated useful life as this reflects the expected pattern of consumption of the asset's future economic benefits. Depreciation is reported as an expense in the income statement. Useful life is retested on every balance sheet date.

The following depreciation times are applied:

Property, plant and equipment

	Group	Parent company
Machinery and other technical facilities	5–10 years	5 years
Equipment, tools, fixtures and fittings	5–10 years	5 years

Improvement expenditures on leased premises
Sedana Medical AB owns no real estate. Sometimes, major improvements are made to leased premises, and the improvements are capitalized. At its longest, the depreciation time on capitalized improvements coincides with the length of the lease on the premises, or 5 to 10 years.

Financial assets
Financial assets that are intended for long-term holding are reported at cost, and adjusted for currency effects where appropriate.

At least once per year, the asset is tested for the need to recognize impairment. Impairment takes place if the reduction in value is considered to be permanent. Impairment losses are reported under the income statement item Income from other securities and receivables held as non-current assets.

Inventories
Inventories are reported at the lower of cost or net realizable value. The risk of obsolescence is thus taken into account. Cost is calculated on the first-in first-out principal. In addition to purchase-related expenditures, cost also includes expenditures for bringing the goods to their current place and condition. The net realizable value has been calculated as the sales value less calculated selling expenses.

Offset of financial asset against financial liability
A financial asset and a financial liability are offset with a net amount in the balance sheet only when a legal right of offset exists and settlement with the net amount is intended to take place or when a contemporaneous disposal of the asset and liability are intended to take place.

Accounts receivable and other receivables
Receivables are reported as current assets with the exception of items with maturity dates more than twelve months from the closing date, which are reported as financial assets. Receivables are carried in the anticipated payment amounts less individually assessed doubtful receivables. Receivables that are interest free or which run with interest that deviates from market rates and have a maturity in excess of 12 months, are reported at a discounted present value and the change in the time value of money is reported as interest income in the income statement.

Loan liabilities and trade accounts payable
Loan liabilities and trade accounts payable are initially reported at cost less transaction expenses. If the reported amount differs from the amount that must be repaid on the due date, the difference is allocated over time as an interest expense over the loan's maturity period with the aid of the instrument's effective interest. By this means, the reported amount on the due date will coincide with the amount that must be repaid.

Provisions
Appropriations are reported when the Group has or can be assumed to have an obligation arising from an event and it is probable that expenditures will be required to settle the obligation. This is contingent upon the ability to make a reliable assessment of the amount that must be paid.

Employee benefits – pensions
The Group's pension plans for compensation on completion of employment are defined contribution plans. In defined contribution plans, the company pays fixed charges to a separate juridical entity. Once the charge is paid, the company has no further obligations.

Statement of cash flows
The statement of cash flows was prepared according to the indirect method. The reported cash flow includes only those transactions that entail receipts or payments. In addition to cash and bank balances, cash and cash equivalents also includes current investments that can easily be converted to a known amount and which are exposed to an insignificant risk of value fluctuation.

NOTE 3 SIGNIFICANT EVENTS AFTER THE CLOSE OF THE FINANCIAL YEAR

- In January, the last patient was included in the registration based IsoConDa study. Thus, all 300 patients have been included in the European study, which is expected to present "top-line" results in the second quarter of 2020.
- Sedana Medical's CEO Christer Ahlberg divested 30,000 shares in the company and entered into a 12-month lock-up agreement for his remaining 200,000 shares. He thus remains as a dedicated long-term owner.
- In January, Sedana Medical received market approval for AnaConDa in Mexico. The company's Mexican distributor Goba will begin sales work in the next few months and Sedana Medical will in parallel evaluate the possibility of registering the drug IsoConDa. Goba will also work for a registration of AnaConDa in Colombia.
- Sedana Medical established its own sales organization in Benelux.
- Sedana Medical donates 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 Coronavirus-affected patients.
- Sedana Medical foresee increased demand from AnaConDa as a result Covid-19 pandemic and so far, have had no significant disruptions in the supply chain due to the same. Sedana Medical forecasts a significantly higher sales increase during the first quarter of 2020 compared with the same period last year. Furthermore, the company foresee some risk that the compilation of the IsoConDa study is delayed due to the Covid-19 pandemic until the beginning of the third quarter of 2020. However, this would not necessarily mean that Sedana Medical's application for European market approval for the drug candidate IsoConDa is delayed. Sedana Medical continues to expect to keep the timetable and submit the application in the third quarter, or early in the fourth quarter of 2020, and expects approval in the second half of 2021.

NOTE 4 NET SALES

	Group		Parent company	
KSEK	2019	2018	2019	2018
Net sales				
Sedana Medical AB (publ)				
- Sales via Sweden	1,158.1	570.1	1,158.1	570.1
- Branch in Germany	42,937.8	54,530.4	42,937.8	54,530.4
- Branch in Spain	833.3	755.2	833.3	755.2
Sedana Medical Ltd, Ireland	0.0	80.0	0.0	0.0
Sedana Medical Sarl, France	2,542.0	1,960.5	-	-
Sedana Medical GmbH, Germany	24,174.3	-	-	-
Total	**71,645.6**	**57,896.2**	**44,929.3**	**55,855.7**

NOTE 5 GROUP INTERNAL PURCHASES AND SALES

	Group		Parent company	
KSEK	2019	2018	2019	2018
Proportion of sales of goods relating to group companies	-	-	1,088.1	1,014.6
Proportion of other operating income concerning services relating to group companies	-	-	18,635.9	11,109.9
Proportion of purchases of goods relating to group companies	-	-	28,602.1	34,441.4

NOTE 6 OTHER OPERATING INCOME - NONE GROUP INTERNAL

	Group		Parent company	
KSEK	2019	2018	2019	2018
Foreign exchange rate gains on operating receivables / liabilities	1,788.3	1,325.8	1,776.5	1,323.9
Other	303.8	148.7	600.9	9,299.5
Total	**2,092.1**	**1,474.5**	**2,377.4**	**10,623.4**

NOTE 7 OPERATIONAL LEASING - LESSEE

	Group		Parent company	
KSEK	2019	2018	2019	2018
Contracted future minimum lease fees for non-cancellable contracts are due:				
- Within one year	1,905.0	1,813.3	1,523.7	1,513.6
- Between one and five years	884.4	2,162.7	869.9	1,936.5
- Later than five years	0.0	0.0	0.0	0.0
Total	**2,789.3**	**3,975.9**	**2,393.5**	**3,450.0**
This year's expensed leasing fees	2,168.6	1,253.9	1,719.9	962.1
of which rent for premises	1,090.5	361.6	954.9	230.3

As of this annual report, rental costs for premises and parking spaces are included. The comparative figures are adjusted.

NOTE 8 EMPLOYEES, PERSONNEL EXPENSES AND BOARD RENUMERATION

Average number of employees

	2019			2018		
	Total	Women	Men	Total	Women	Men
Parent Company						
Sweden	15.3	8.2	7.1	7.7	3.4	4.3
Germany	6.9	2.2	4.7	8.3	2.3	6.0
Spain	1.4	0.5	0.9	1.0	1.0	0.0
Total	**23.6**	**10.9**	**12.7**	**17.0**	**6.7**	**10.3**
Group						
Ireland	7.3	1.8	5.6	6.1	2.0	4.1
France	2.9	0.1	2.8	3.0	0.0	3.0
Norway	1.7	1.0	0.7	0.0	0.0	0.0
Germany	3.1	1.3	1.8	0.0	0.0	0.0
Total	**38.6**	**15.1**	**23.6**	**26.1**	**8.7**	**17.4**

Senior Executives

	2019			2018		
	Total	Women	Men	Total	Women	Men
Board of Directors	5.0	1.0	4.0	6.0	1.0	5.0
CEO and senior executives	5.0	1.0	4.0	6.0	2.0	4.0

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

	Group		Parent company	
KSEK	2019	2018	2019	2018
Salaries and other remuneration				
Chairman of the board Thomas Eklund	283.3	218.8	283.3	218.8
Board member Sten Gibeck	50.0	58.3	50.0	58.3
Board member Bengt Julander	50.0	58.3	50.0	58.3
Board member Ola Magnusson	50.0	58.3	50.0	58.3
Board member Michael Ryan	43.3	58.3	43.3	41.7
Board member Eva Walde	100.0	58.3	100.0	58.3
CEO, Christer Ahlberg	2,095.1	1,995.5	2,095.1	1,995.5
Total	2,671.8	2,505.9	2,671.8	2,489.3
Other senior executives	8,249.1	5,964.5	5,954.0	3,248.7
Other employees	23,705.0	15,516.2	14,422.5	10,334.4
Total	31,954.1	21,480.7	20,376.5	13,583.0
Total salaries and other remuneration	**34,625.9**	**23,986.6**	**23,048.3**	**16,072.3**
Social fees by law and agreement	6,740.6	4,911.8	4,912.3	3,669.1
Pensions to the CEO and senior executives				
CEO	489.6	0.0	489.6	0.0
Senior executives	1,148.4	334.5	1,137.1	334.5
Total	**1,638.0**	**334.5**	**1,626.7**	**334.5**
Pensions to others				
Of which for other employees	1,780.9	1,032.8	1,100.7	884.1

NOTE 9 OTHER OPERATING EXPENSES

	Group		Parent company	
KSEK	2019	2018	2019	2018
Foreign exchange rate losses on operating receivables / liabilities	2,229.0	1,020.6	2,004.6	967.6
Other	87.9	171.4	53.2	165.7
Total	**2,316.9**	**1,192.0**	**2,057.8**	**1,133.3**

NOTE 10 FINANCIAL INCOME

	Group		Parent company	
KSEK	2019	2018	2019	2018
Interest income, Group companies	0.0	0.0	964.1	995.3
Interest income, Other	0.2	2.7	0.0	2.7
Foreign exchange gains	2,455.6	5,447.8	2,444.9	5,447.7
Total	**2,455.8**	**5,450.5**	**3,409.0**	**6,445.7**

NOTE 11 FINANCIAL EXPENSES

	Group		Parent company	
KSEK	2019	2018	2019	2018
Interest expenses	7.0	4.1	4.4	4.0
Foreign exchange losses	2,224.9	3,727.8	2,141.9	3,717.4
Total	**2,231.9**	**3,731.9**	**2,146.2**	**3,721.4**

NOTE 12 TAXES

	Group		Parent company	
KSEK	2019	2018	2019	2018
Current tax cost (-)/tax income (+)				
Tax cost/tax income for the year	-19.8	-228.6	0.0	-48.1
Adjustment of tax related to previous years	-8.2	-839.0	0.0	0.0
	-28.0	-1 067.6	0.0	-48.1
Deferred tax				
Deferred tax on temporary differences	613.7	718.2	0.0	0.0
	613.7	718.2	0.0	0.0
Total reported tax cost/tax income	**585.7**	**-349.4**	**0.0**	**-48.1**

Reconciliation of reported taxes

	Group		Parent company	
KSEK	2019	2018	2019	2018
Income before taxes	-16,943.4	-6,519.6	-14,799.8	-3,707.1
Tax at current tax rate for parent company	3,625.9	1,434.3	3,167.2	815.6
Tax effect of:				
- non-deductible expenses	-113.9	-88.8	-76.4	-71.2
- non-taxable income	34.0	27.5	0.0	0.0
- other tax rates for foreign subsidiaries/branches	185.3	-523.1	66.3	65.7
- increase in carry forward losses without corresponding capitalization of deferred tax	-3,769.9	-993.5	-3,157.1	-858.2
- tax related to previous years	-8.2	-839.0	0.0	0.0
- deferred tax on temporary differences	613.7	718.2	0.0	0.0
- other	18.7	-85.1	0.0	0.0
Reported effective tax	**585.7**	**-349.4**	**0.0**	**-48.1**

The Group has tax carried forward losses of 58 274 KSEK, of which 50 379 KSEK relates to the parent company.

NOTE 13 CAPITALIZED DEVELOPMENT EXPENSES

	Group		Parent company	
KSEK	2019	2018	2019	2018
Carrying amounts:				
- Opening balance	46,824.5	21,009.9	42,297.4	6,402.8
- In house development	49,590.6	24,454.8	45,749.8	35,894.6
- Acquisitions	0.0	0.0	0.0	0.0
- Translation differences	113.3	1,359.8	0.0	0.0
Closing balance	96,528.4	46,824.5	88,047.3	42,297.4
Carrying depreciations according to plan:				
- Opening balance	-663.0	-288.0	0.0	0.0
- Amortization for the year	-373.7	-362.0	0.0	0.0
- Translation differences	-4.8	-13.0	0.0	0.0
Closing balance	-1,041.5	-663.0	0.0	0.0
Carrying amount at the end of the period	**95,486.9**	**46,161.5**	**88,047.3**	**42,297.4**

NOTE 14 CONCESSIONS, PATENTS, LICENSES, TRADEMARKS AND SIMILAR

	Group		Parent company	
KSEK	2019	2018	2019	2018
Carrying amounts:				
- Opening balance	7,387.3	6,502.2	-	-
- Acquisitions	176.0	646.7	-	-
- Translation differences	155.7	238.4	-	-
Closing balance	7,718.9	7,387.3	-	-
Carrying depreciations according to plan:				
- Opening balance	-2,144.2	-758.8	-	-
- Depreciation for the year	-1,398.0	-1,350.4	-	-
- Translation differences	-16.3	-35.0	-	-
Closing balance	-3,558.5	-2,144.2	-	-
Carrying amount at the end of the period	**4,160.4**	**5,243.1**	**-**	**-**

NOTE 15 MACHINERY AND EQUIPMENT

	Group		Parent company	
KSEK	2019	2018	2019	2018
Carrying amounts:				
- Opening balance	10,348.5	5,067.9	7,963.2	5,067.9
- Acquisitions	3,728.5	3,674.6	529.7	2,818.8
- Reclassifications	-2,318.5	1,350.7	-6,621.3	-83.2
- Translation differences	56.3	255.3	0.2	159.7
Closing balance	11,814.8	10,348.5	1,871.9	7,963.2
Carrying depreciations according to plan:				
- Opening balance	-3,744.0	-1,524.4	-3,044.8	-1,524.4
- Reclassifications	-26.2		2,405.7	0.0
- Depreciation for the year	-2,290.0	-2,184.9	-393.5	-1,515.2
- Translation differences	-20.2	-34.7	0.2	-5.2
Closing balance	-6,080.3	-3,744.0	-1,032.3	-3,044.8
Carrying write downs:				
- Opening balance	-2,476.0	-718.7	-2,504.8	-718.7
- Reclassifications	2,476.0	28.8	2,504.8	0.0
- Write downs for the year	-1,369.6	-1,752.4	0.0	-1,752.4
- Translation differences	20.1	-33.7	0.0	-33.7
Closing balance	-1,349.5	-2,476.0	0.0	-2,504.8
Carrying amount at the end of the period	**4,384.9**	**4,128.5**	**839.5**	**2,413.6**
Machinery and equipment under financial lease included with the following amount:	none	none	none	none

NOT 16 FIXTURES AND TOOLS

	Group		Parent company	
KSEK	2019	2018	2019	2018
Carrying amounts:				
- Opening balance	1,728.8	2,596.1	524.7	273.3
- Acquisitions	163.4	320.4	82.1	159.0
- Reclassifications	-1,042.2	-1,350.7	-306.6	83.2
- Translation differences	6.0	163.0	0.0	9.2
Closing balance	856.0	1,728.8	300.2	524.7
Carrying depreciations according to plan:				
- Opening balance	-1,203.7	-1,163.5	-245.9	-209.1
- Reclassifications	910.9	28.8	221.2	
- Depreciation for the year	-81.5	-59.3	-54.5	-27.9
- Translation differences	-3.7	-9.7	0.0	-8.9
Closing balance	-378.0	-1,203.7	-79.1	-245.9
Carrying amount at the end of the period	**477.9**	**525.1**	**221.1**	**278.8**
Fixtures and tools under financial lease included with the following amount:	none	none	none	none

NOTE 17 IMPROVEMENTS ON LEASEHOLD PROPERTY

	Group		Parent company	
KSEK	2019	2018	2019	2018
Carrying amounts:				
- Opening balance	109.6	105.1	0.0	0.0
- Acquisitions	0.0	30.0	0.0	30.0
- Scrapping	0.0	-30.0	0.0	-30.0
- Translation differences	1.7	4.5	0.0	0.0
- Closing balance	111.3	109.6	0.0	0.0
Carrying depreciations according to plan:				
- Opening balance	-54.8	-10.5	0.0	0.0
- Depreciation for the year	-45.2	-49.3	0.0	-5.5
- Scrapping	0.0	5.5	0.0	5.5
- Translation differences	-0.2	-0.5	0.0	0.0
- Closing balance	-100.2	-54.8	0.0	0.0
Carrying amount at the end of the period	**11.1**	**54.8**	**0.0**	**0.0**

NOTE 18 SHARES IN GROUP COMPANIES

	Group		Parent company	
KSEK	2019	2018	2019	2018
Carrying amounts:				
- Opening cost	-	-	50.0	50.0
- Acquisitions	-	-	344.3	0.0
Closing accumulated cost and carrying amount at the end of the period	**-**	**-**	**394.3**	**50.0**

Information of equity and result:

KSEK	Corp reg no/ Reg office	Proportion of capital owned%	No of shares	Proportion of equity 2019	Proportion of equity2018
Sedana Medical Ltd	IE551634 / Naas, Ireland	100	1	906.6	1,274.8
Sedana Medical Incentive AB	559109-8826 / Danderyd, Sweden	100	50,000	49.3	50.0
Sedana Medical Sàrl	809 876 865 / Paris, France	100	2,000	-8,440.9	-6,162.3
Sedana Medical Norway AS	822 363 202 / Oslo, Norway	100	30,000	95.7	-
Sedana Medical UK Ltd	NI659985 / Belfast, Great Britain	100	1	-11.0	-
Sedana Medical Germany GmbH	HRB250971 / Geretsried-Gelting, Germany	100	26,000	389.2	-
Sedana Medical Netherlands B.V.	76605434 / Amsterdam, Netherlands	100	1	0.0	-

KSEK	Corp reg no/ Reg office	Proportion of the result 2019	Proportion of the result 2018
Sedana Medical Ltd	IE551634 / Naas, Ireland	-393.6	-2,961.8
Sedana Medical Incentive AB	559109-8826 / Danderyd, Sweden	0.0	0.0
Sedana Medical Sàrl	809 876 865 / Paris, France	-2,004.4	-483.3
Sedana Medical Norway AS	822 363 202 / Oslo, Norway	64.9	-
Sedana Medical UK Ltd	NI659985 / Belfast, Great Britain	-10.9	-
Sedana Medical Germany GmbH	HRB250971 / Geretsried-Gelting, Germany	84.9	-
Sedana Medical Netherlands B.V.	76605434 / Amsterdam, Netherlands	0.0	-

KSEK	Corp reg no/ Reg office	Proportion of capital owned%	No of shares	Booked value Dec. 31, 2019	Booked value Dec. 31, 2018
Shares directly owned by the parent company:					
Sedana Medical Ltd	IE551634 / Naas, Ireland	100	1	0.0	0.0
Sedana Medical Incentive AB	559109-8826 / Danderyd, Sweden	100	50,000	50.0	50.0
Sedana Medical Norway AS	822 363 202 / Oslo, Norway	100	30,000	32.5	-
Sedana Medical UK Ltd	NI659985 / Belfast, Great Britain	100	1	0.0	-
Sedana Medical Germany GmbH	HRB250971 / Geretsried-Gelting, Germany	100	26,000	311.7	-
Sedana Medical Netherlands B.V.	76605434 / Amsterdam, Netherlands	100	1	0.0	-
Shares owned by group companies:					
Sedana Medical Sàrl	809876865 / Paris, France	100	2,000		

NOTE 19 INVENTORY

	Group		Parent company	
KSEK	2019	2018	2019	2018
Finished goods and goods for sale	7,378.3	6,294.7	983.6	9,227.2
Total	**7,378.3**	**6,294.7**	**983.6**	**9,227.2**

NOTE 20 OVERDRAFT FACILITY

	Group		Parent company	
KSEK	2019	2018	2019	2018
Granted credit limit [1)]	500.0	500.0	500.0	500.0
Unutilized part	-500.0	-500.0	-500.0	-500.0
Total	**0.0**	**0.0**	**0.0**	**0.0**

1) The company has an agreement to be able to start using an overdraft facility if need arises. At present, the Company does not pay for this opportunity.

NOTE 21 OTHER CURRENT LIABILITIES

	Group		Parent company	
KSEK	2019	2018	2019	2018
VAT liabilities	53.7	164.0	23.7	164.0
Employee witholding tax	773.1	598.5	557.5	598.5
Social expenses	670.1	385.0	456.6	326.0
Other liabilities	1,850.2	716.6	963.4	252.3
Total	**3,347.1**	**1,864.2**	**2,001.3**	**1,340.8**

NOTE 22 ACCRUED EXPENSES AND PREPAID INCOME

	Group		Parent company	
KSEK	2019	2018	2019	2018
Salaries, social and other personnel expenses	4,418.3	3,663.6	1,918.2	3,663.4
Audit	467.9	245.3	350.7	169.3
Other	3,380.4	3,048.7	2,023.7	764.2
Total	**8,266.7**	**6,957.6**	**4,292.6**	**4,596.9**

NOTE 23 INFORMATION ON AUDITOR'S REMUNERATION

	Group		Parent company	
KSEK	2019	2018	2019	2018
R3 Revsionsbyrå KB				
Audit assignment	220.2	201.7	220.2	201.7
Other services	24.0	0.0	24.0	0.0
Total	244.2	201.7	244.2	201.7
Other auditors				
Audit assignment	334.3	233.8	157.5	140.5
Tax advice	158.8	97.3	103.8	97.3
Other services	0.0	0.0	0.0	0.0
Total	493.1	331.1	261.3	237.8
Total	**737.3**	**532.8**	**505.5**	**439.5**

NOTE 24 CASH AND CASH EQUIVALENTS

	Group		Parent company	
KSEK	2019	2018	2019	2018
Bank deposits	464,560.0	159,350.7	455,205.7	158,805.5

NOTE 25 PLEDGED ASSETS AND CONTINGENT LIABILITIES

	Group		Parent company	
KSEK	2019	2018	2019	2018
For own liabilities and provisions				
Other liabilities to credit institutions				
Company mortage	-	-	-	-
	-	-	-	-
Other pledged assets and contingent liabilities				
Company mortage	-	-	-	-
	-	-	-	-
Total	**-**	**-**	**-**	**-**

NOTE 26 TRANSACTIONS WITH RELATED PARTIES

	2019		2018	
KSEK	Purchase of services	Purchase of goods	Purchase of services	Purchase of goods
Parent Company				
Magiola AB	0.0	0.0	2.0	0.0
Lismed Ltd.	100.6	0.0	0.0	0.0
Total, Parent Company	**100.6**	**0.0**	**2.0**	**0.0**
Group				
Tecscan Ltd.	202.1	0.0	765.0	0.0
Lismed Ltd.	100.6	4,984.7	0.0	4,316.0
Total, Group	**302.7**	**4,984.7**	**767.0**	**4,316.0**

Magiola AB is a company related to the board member Ola Magnusson.
Purchase of services from Magiola AB concern services for project leadership for IsoConDa clinical study SED001.

Tecscan Ltd. is a company related to former board member Michael Ryan.
Purchase of services from Tecscan Ltd. concern services for business development.

Lismed Ltd. is a company related to the R&D Director Ron Farrell.
Purchase of goods from Lismed Ltd. concern the product Flurasorb and accessories which in turn are accessories to AnaConDa.
Purchase of services from Lismed Ltd. concern technical support.

NOTE 27 DEFINITIONS OF KEY RATIOS

EBITDA margin:	Operating income before depreciations and amortisations (or Earnings Before Interest Taxes Depreciatio and Amortisation) divided by Net sales.
Operating margin (EBIT-margin):	Operating income or Earnings Before Interest and Taxes divided by Net sales.
Net profit in % of Net sales:	Net profit devided by Net sales
Balance sheet total:	Total assets
Equity ratio:	Total equity plus (1 minus current tax rate) of untaxed reserves, divided by total assets.
Tax rates for parent company:	From 2019: 21,4% Before 2019: 22,0%
Quick ratio:	Current assets excluding inventory divided by current liabilities.
Average number of employees:	Average number of full-time employees during the period.
Equity per share:	Total equity divided by number of shares before dilution.
Cash flow per share:	Total cash flow divided by number of shares before dilution.

The Board of Directors' and CEO's assurance

The Board hereby certifies that this annual report provides a true and fair overview of the Group's operations, financial position and earnings. For a more detailed description of Sedana Medical's risks we refer to the Group's prospectus submitted in connection with listing on Nasdaq First North Growth Market Stockholm, Sweden.

Danderyd April 22, 2020

Thomas Eklund
Chairman of the Board

Sten Gibeck
Board member

Bengt Julander
Board member

Ola Magnusson
Board member

Eva Walde
Board member

Christer Ahlberg
CEO and Group President

My Audit Report was submitted on April 22, 2020.

Christina Kallin Sharpe
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

I have audited the annual accounts and consolidated accounts of Sedana Medical AB (publ) for the year 2019. The annual accounts and consolidated accounts of the company are included on pages 46-73 in this document.

In my opinion, the annual accounts and consolidated 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 2019 and their financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

I 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

I conducted my audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. My responsibilities under those standards are further described in the "Auditor's Responsibilities" section. I am independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled my ethical responsibilities in accordance with these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinions.

Other Information than the annual accounts and consolidated accounts

The Board of Directors and the Managing Director are responsible for the other information. The other information comprises report Årsredovisning 18 (but does not include the annual accounts, consolidated accounts and my auditor's report thereon).

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

In connection with my audit of the annual accounts and consolidated accounts, my 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 I also take into account my knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

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

Responsibilities of the Board of Directors 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. 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 intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility

My 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 my opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, I exercise professional judgment and maintain professional scepticism throughout the audit. I also:

• Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

• Obtain an understanding of the company's internal control relevant to my audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.

• Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.

• Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. I also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify my opinion about the annual accounts and consolidated accounts. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

• Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.

• Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. I am responsible for the direction, supervision and performance of the group audit. I remain solely responsible for my opinions.

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

Report on other legal and regulatory requirements

Opinions

In addition to my audit of the annual accounts and consolidated accounts, I have also audited the administration of the Board of Directors and the Managing Director of Sedana Medical AB (publ) for the year 2019 and the proposed appropriations of the company's profit or loss.

I 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 Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

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

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinions.

Responsibilities of the Board of Directors and the Managing Director

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

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

Auditor's responsibility

My objective concerning the audit of the administration, and thereby my 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.

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

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

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

Danderyd 22 April 2020

Christina Kallin Sharpe

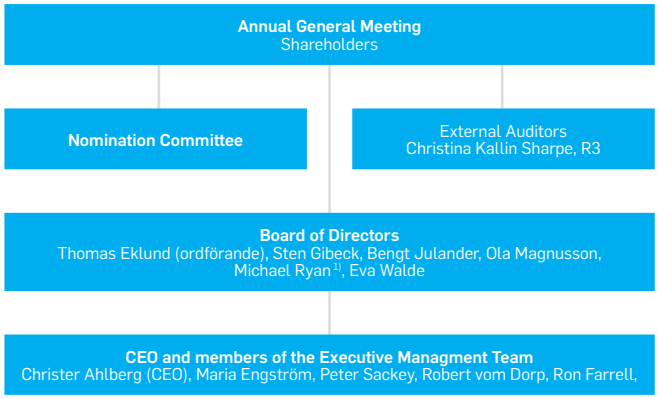
Authorized Public Accountant

CORPORATE GOVERNANCE

LEGISLATION AND THE ARTICLES OF INCORPORATION

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 June 21, 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 said governance. The articles of incorporation 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 for participating in the shareholders' meetings. The latest submitted and registered articles of incorporation were adopted at the AGM of May 19, 2017.

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



1) Resigned from the board November 12, 2019.

INTERNAL INSTRUCTIONS AND POLICIES OF IMPORTANCE FOR CORPORATE GOVERNANCE

- Articles of incorporation
- The Board's rules of procedure and CEO instructions
- Policy for financial reporting
- Authorization instructions
- Information policy
- Insider policy
- IT policy
- Conduct policy

EXTERNAL REGULATIONS THAT AFFECT THE ARTICLES OF INCORPORATION

- Swedish Companies Act
- Accounting regulations
- Nasdaq First North Growth Market's regulations

THE 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 meet its requirements.

ANNUAL GENERAL MEETING

Shareholder influence in the company is exercised at shareholders' meetings which, in accordance with the Swedish Companies Act, is the company's highest decision-making body. As the company's highest decision-making body, a shareholders' meeting can take decisions about all matters in the company that do not constitute another company body's exclusive area of competence. A shareholders' meeting has thus a superior role in relation to the company's Board of Directors and the CEO. Notices to attend, minutes and communiqués from shareholders' meetings will be kept available on the company's website. At the general shareholders' meeting (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 compensation to the Board and auditor. Shareholders may also pass resolutions at shareholders' meetings on other essential company matters such as changes to the company's articles of incorporation, and any new share issues etc. If the board finds reason to convene a shareholders' meeting before the next general shareholders' meeting, or if a company auditor or owner of a minimum of one tenth of all shares in the company so requests in writing, the Board must convene an extraordinary shareholders' meeting. Notice to attend the AGM and extraordinary shareholders' meeting where changes to the articles of incorporation will be addressed, must take place at the earliest six weeks and at the latest four weeks before the meeting. Notice to attend other extraordinary shareholders' meetings must take place 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 business daily, Dagens Industri. To participate in a shareholders' meeting, shareholders must be registered in the share ledger maintained by Euroclear Sweden AB on a record date that falls no later than five working days before the meeting, and give notice of their intention to participate in the meeting by no 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 participate in the shareholders' meeting in person or be represented by proxy or no more than two persons. There are usually opportunities for shareholders to register their participation in the meeting in a number of ways in accordance with instructions in the notice to attend. Shareholders who wish 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 no later than seven weeks before the shareholders' meeting. In order to determine who has the right to participate and vote at shareholders' meetings, Euroclear Sweden AB, upon company request, must provide the company with a list of all shareholders as of the record date in connection with each shareholders' 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 shareholders' meetings. Such registration must be completed no later than the applicable record date and cease 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 company's AGM of May 19, 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 his right to appoint a member to the nomination committee, the right is transferred to the next biggest shareholder in terms of votes, and so forth. However, no more than five additional shareholders must be contacted, unless the Chairman of the Board finds that special reasons pertain. 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 latest response date 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 chairman internally. The Chairman of the Board may not be the chairman of the nomination committee. If a member leaves the nomination committee before his 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 said shareholder no longer belongs to the three biggest 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 shareholder's meeting, 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 expenditures arising in connection with the nomination committee's work must be paid by the company on the condition that they are approved by the Chairman of the Board.

Board of directors

THE BOARD'S ASSIGNMENTS

In relation to the shareholders' meeting, the Board of Directors is the company's second highest decision-making body. The Board is also the company's highest governing body and represents the company. Furthermore, under the Swedish Companies Act, the Board is responsible for the company's organization, the administration of its affairs, the ongoing assessment of the company's and Group's financial situation, and ensuring that the company's organization 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 leading the work of the Board and making sure the Board fulfills its statutory duties. The Board's assignments include setting forth the company's overall goals and strategies, supervising major investments, ensuring the 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 characterized by openness and that they are accurate, relevant and reliable. The Board also appoints, evaluates and if necessary dismisses the company's Chief Executive Officer. In accordance with the Swedish Companies Act, the Board has set forth 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 incorporation, the Board must comprise at least three (3) and no more than six (6) members with a maximum of three (3) alternates. Members are elected annually at a general shareholders' meeting (annual general meeting) up until the end of the next general shareholders' meeting. There is no limit for how long a member may sit on the Board. As of the financial year's closing date, the company's Board consisted of five members.

CHAIRMAN OF THE BOARD

The Chairman of the Board is tasked with leading the work of the Board and ensuring that it is carried out effectively and that the Board fulfills its obligations. Through his contacts with the CEO, the Chairman must observe the company's development and make sure Board members are constantly provided with the

information they need to monitor the company's position, financial planning and development. Furthermore, the Chairman must consult with 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 owners to the Board. The Chairman does not take part in the operational work of the Board, and nor is he 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 statutory board meeting. Among other things, the rules of procedure govern the Board's functions, assignments, decision-making process and procedures, and the Chairman's assignments 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 statutory board meeting. In parallel with board meetings, the Chairman of the Board and the CEO maintain a dialog concerning the management of the company. The Board meets according to an annual timetable, and must hold at least five scheduled board meetings between each AGM.

	Attendance no. of meetings 2019	Board fees decided at the Annual General Meeting 2019	Independent in relation to:	
	Board meetings (19)	KSEK	The Group	Owners
Chairman of the board				
Thomas Eklund	19	325	Yes	Yes
Board member,s				
Sten Gibeck	18	50	Yes	Yes
Bengt Julander	19	50	Yes	Yes
Ola Magnusson	18	50	Yes	Yes
Michael Ryan	17	50	Yes	Yes
Eva Walde	18	100	Yes	Yes

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 asset management 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 CEO instructions. The Board continually evaluates the Chief Executive Officer's work. Christer Ahlberg was the company's CEO on the closing date. Otherwise, Sedana Medical's company management consisted of Chief Financial Officer Maria Engström, Chief Medical Officer Peter Sackey, Head of Sales Robert vom Dorp and Head of R&D Ron Farrell.

Internal Control and Audit

Under the Swedish Companies Act, the Board is responsible for the company's organization, the administration of its affairs, the ongoing assessment of the company's and Group's financial situation, and ensuring that the company's organization is designed such that company's accounting, asset management and the 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 website (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 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 a general shareholders' meeting in compliance with the Swedish Companies Act. Accordingly, an auditor in a Swedish limited company is engaged by, and reports to, the shareholders' meeting and may not be guided in her work by the Board or any other senior executive. According to the company's articles of incorporation, the shareholders' meeting must appoint at least one (1) and no more than two (2) auditors with no more than two (2) alternate auditors. The company's current auditor is Christina Kallin Sharpe.

Compensation to board member senior executives and auditor

Compensation to Sedana Medical's board members is resolved by the shareholders' meeting. The AGM of May 28, 2019 passed a resolution concerning annual board fees in the amount of SEK 325,000 to the chairman, and SEK 100 000 to board member Eva Walde and SEK 50,000 each to the other board members. Compensation to senior executives who are employees may consist of a basic salary, variable remunerations, pension and other benefits. In addition to his monthly salary, CEO Christer Ahlberg has the right to an annual bonus amounting to no more than six monthly salaries. The bonus is linked to the company's sales, its operating earnings before interest, tax, depreciations, impairments and goodwill depreciations and performance in relation to objectives. In addition to statutory pensions, 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 6 months on the part of the CEO and 12 months on the part of the company. Otherwise the CEO is subject to customary employment conditions containing rules on confidentiality, non-competition and non-solicitation. The total compensation to the auditor for the financial year 2019 was SEK 168.3 thousand. Compensation to the company's auditor is paid according to invoice.

BOARD OF DIRECTORS

The registered office of the company is situated in the municipality of Danderyd. The Board of Directors shall consist of not less than three (3) and not more than six (6) members.

Thomas Eklund

Chairman of the Board

Born: 1967

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

Education and work experience: Thomas holds an MBA from the Stockholm School of Economics. 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 assignments: Board member in Biotage AB, Bio-Works Technologies AB, Bio-Works Sweden AB, Boule Diagnostics AB, Caliditas Theraputics AB, Excillum Aktiebolag, Immedica Pharma Holding AB, Rodebjer Form 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 Eklund konsulting AB.

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

Sten Gibeck

Board member

Born: 1943

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

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 assignments: –

Shareholding in Sedana Medical: 1,530,744 shares.

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

Bengt Julander

Board member

Born: 1953

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

Education and work experience: Bengt is a qualified pharmacist, M. Sc. from Uppsala University. Owner and board member of Linc AB, which invests in companies in the drug and medical device segment. Operational, board and ownership experience from the industry.

Other current assignments: Chairman in Knil AB. Board member in Animal Probiotics Sweden AB, Calliditas Therapeutics AB, Cronhamn Invest AB, Linc AB, Livland Skog AB, Medivir Aktiebolag, Nefecon AB, nWise AB, Part Production Sweden AB, Reison Medical AB, Stille AB, Swevet AB and Swevet Holding AB. Board member and deputy board member in affiliates to these companies and smaller family companies.

Shareholding in Sedana Medical: 2,116,901 shares via Linc AB.

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

Ola Magnusson

Board member

Born: 1948

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

Education 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 in Pharmacia and Kabi and 20 years of experience in the medical device industry in Louis Gibeck AB (CEO) and Hudson RCI as managing director EMEA.

Other current assignments: Chairman of the boards of Eataway AB and Transcutan AB. Member of the boards of Hammarplast Medical Aktiebolag, Miris AB, Miris Holding AB (publ) and a board member in subsidiaries to these companies or small family companies.

Shareholding in Sedana Medical: 1,340,867 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

Position: Member of the Board at 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 assignments: Marketing Director in Olink AB, CEO and Chairman of the board in 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.

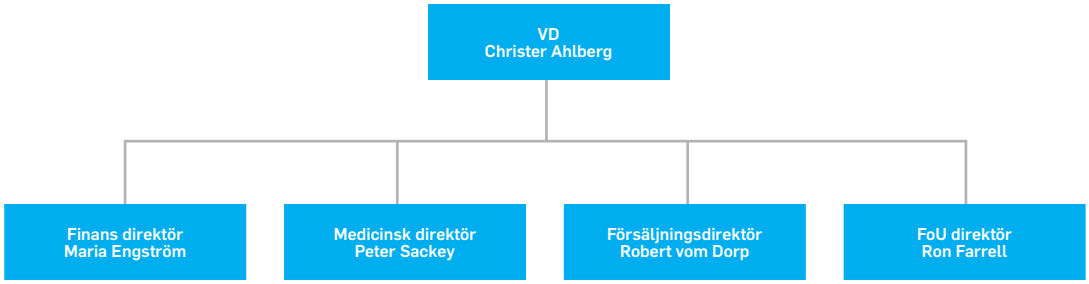
ORGANIZATION AND GROUP MANAGEMENT

Sedana Medical has personnel 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 UK, the Nordics and Spain. During 2019, the average number of employees was 39. Through its long-term, determined efforts, the Group has created a strong organization that attracts experienced personnel to the company. In the years ahead, Sedana Medical will increase the number of employees in line with Group growth and thus create an organization well prepared to introduce inhaled sedation therapy with AnaConDa and IsoConDa to the market. To achieve its operational and financial objectives, Sedana Medical will pay great attention to strengthening its product specialist organization on current and future markets and boosting pharmaceutical skills throughout the organization.

Company management

The Group's management group comprises CEO Christer Ahlberg, CFO Maria Engström, CMO Peter Sackey, Head of R&D Ron Farrell and Head of sales Robert vom Dorp.



MANAGEMENT TEAM

Christer Ahlberg

CEO and Group President

Born: 1971

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

Education and work experience: Christer holds a BSc in business administration and economics from Örebro University.Former experience in the pharmaceutical industry includes CEO at Unimedic Group (2010–2016), CEO at Eisai AB (2005–2010) a more than 10 years of experience in leading positions in sales and marketing at e.g. AstraZeneca, Meda and Wyeth.

Other current assignments: Board member in FrostPharma AB. CEO and deputy board member in Waxholm by the sea aktiebolag.

Shareholding in Sedana Medical: 200,000 shares and 184,200 warrants in program 2017/2021 representing 184,200 shares.

Maria Engström

Chief Financial Officer

Born: 1972

Position: CFO of Sedana Medical since February 2017.

Education and work experience: Maria holds a BSc in business administration and economics from Stockholm University. Former managing director at Cross Pharma AB (2015–2016) and Head of Business Control at Medivir AB (2012–2014). More than 15 years of experience in positions as finance manager, head of business control and controller at Biovitrum, Bristol Myers Squibb and Ericsson.

Other current assignments: Board Member in FAYSIT – Finance At Your Service In Tyresö AB. Deputy board member in UHT Förvaltning AB.

Shareholding in Sedana Medical: 3,850 shares and 60,782 warrants in program 2017/2021 representing 60,782 shares via FAYSIT – Finance At Your Service In Tyresö AB.

Peter Sackey

Chief Medical Officer

Born: 1971

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

Education and work experience: Peter received his doctor´s degree from Karolinska Institutet in 1997. He has worked for twenty years at the Department of Perioperative Medicine and Intensive Care, Karolinska University Hospital and is Board-certified in Anesthesiology (DESA) and Intensive Care (EDIC). He completed his PhD thesis entitled "isoflurane sedation in Intensive Care Unit patients" at Karolinska Institutet in 2006. He is an Associate professor at Karolinska Institutet, has supervised several PhD students and has active ICU-related research.

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

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

Shareholding in Sedana Medical: 975 shares, 65,167 warrants in program 2017/2021 representing 65,167 shares and 26,293 warrants in program 2019/2022 representing 26,293 shares.

Ron Farrell

Director of R&D and quality

Born: 1956

Position: Head of R&D and quality at Sedana Medical since 2011.
CEO of Sedana Medical Ltd.

Education and work experience: Ron has a graduateship of the Plastics and Rubber Institute of London (GPRI). 37 years' experience in the manufacturing industry in various managerial positions in companies such as Oral-B Laboratories, Gilette, Vistakon, Tech Group, Artema Medical and Kayfoam Woolfson. Active principally in engineering, quality assurance, supply chain, development and operational management in respect of factories.

Other current assignments: Member of the boards of Lismed Ltd. and Sedana Medical Ltd.

Shareholding in Sedana Medical: 831,062 shares.

Robert vom Dorp

Sales Director

Born: 1970

Position: Sales director for Sedana Medical since 2010, 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 the medtech industry since 2001 as account manager within anaesthesia, ventilation and intensive care at Hudson RCI and Teleflex Medical. Sales manager at Sedana Medical with responsibilities for marketing, sales, strategy and operations in Germany, Austria and Switzerland.

Other current assignments: –

Shareholding in Sedana Medical: 111,500 shares.

Literature List

Page	Source:
12-15	1 Society of Critical Care of Medicine (20-30% in the US), International Comparison in Critical Care (53.7%) and Review for the NHS Executive of Adult Care Services: An International (42-60% for seven European countries)
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	Mesnil M, Capdevila X, Bringuier S, et al. Long-term sedation in intensive care unit: A randomized comparison between inhaled sevoflurane and intravenous Propofol or midazolam. Intensive Care Med. 2011;37(6):933-941
	Hanafy MA. Clinical evaluation of inhalational sedation following coronary artery bypass grafting. Egypt J Anaesth. 2005;21(3):237-242
	Sackey P V, Martling C-R, Granath F, Radell PJ. Prolonged isoflurane sedation of intensive care unit patients with the Anesthetic Conserving Device. Crit Care Med., 2004;32(11):2241-2246.
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	4 Bellgardt, M., Bomberg, M., Dasch B. et al, Survivial after long-term isoflurane sedation as opposed to intravenous sedation in cirtically ill surgical patients, Eur J Anaesthesiol 2015; 32:1-8
	5 Sackey P V, Martling C-R, Granath F, Radell PJ. Prolonged isoflurane sedation of intensive care unit patients with the Anesthetic Conserving Device. Crit Care Med., 2004;32(11):2241-2246.
	6 Sackey, Peter V., et al. "Short-and long-term follow-up of intensive care unit patients after sedation with isoflurane and midazolam—A pilot study." Critical care medicine 36.3 (2008): 801-806.
	7 Barr, Juliana, et al. "Clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the intensive care unit." Critical care medicine 41.1 (2013): 263-306.
18-21	1 Bellgardt, M., Bomberg, M., Dasch B. et al, Survivial after long-term isoflurane sedation as opposed to intravenous sedation in cirtically ill surgical patients, Eur J Anaesthesiol 2015; 32:1-8
	2 Bittner M-I, Donnelly M, van Zanten AR, et al. How is intensive care reimbursed? A review of eight European countries. An Intensive Care. 2013;3:37
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	4 Rooke, GA., Choi JH., Bishop, MJ.: The effect of isoflurane, halothane, sevoflurane, and thiopental/nitrous oxide on respiratory system resistance after tracheal intubation, 1997 Jun;86(6):1294-9
	5 Spencer et al. Intensive Care Medicine 1992;18(7):415-21 Kong et al. BMJ 1989 13;298(6683):1277-80 Hendrickx et al. J of Clin Monit Comput 2018;32(4)
	6 Voigtsberger et al. Anesthesiology 2009;111:1238-48. Ferrando et al. Eur J Anesthesiology 2013;30:455–63. Jabaudon et al. Am J of Resp Critic Care Med 2017;195(6),792-800. Shankar et al, Intensive Care Med 2006;32;927-933. Turner et al, Respiratory Care 2012;57(11):1857-64
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	8 Mesnil M, Capdevila X, Bringuier S, et al. Long-term sedation in intensive care unit: A randomized comparison between inhaled sevoflurane and intravenous Propofol or midazolam. Intensive Care Med. 2011;37(6):933-941. Sackey, Peter V., et al. "Short-and long-term follow-up of intensive care unit patients after sedation with isoflurane and midazolam—A pilot study." Critical care medicine 36.3 (2008): 801-806. Sackey P V, Martling C-R, Granath F, Radell PJ. Prolonged isoflurane sedation of intensive care unit patients with the Anesthetic Conserving Device. Crit Care Med., 2004;32(11):2241-2246. Krannich et al, Critical Care Med 2017;45(4):e384-e390. Voigtsberger et al. Anesthesiology 2009;111:1238-48. Ferrando et al. Eur J Anesthesiology 2013;30:455–
22	63. Jabaudon et al. Am J of Resp Critic Care Med 2017;195(6),792-800. Shankar et al, Intensive Care Med 2006;32;927-933. Turner et al, Respiratory Care 2012;57(11):1857-64
33	1 Jabaudon M et al, Am J Respir Crit Care Med. 2017 Mar 15;195(6):792-800

ANNUAL GENERAL MEETING

Sedana Medical's AGM will be held at 16:00 on May 19, 2020, at Spårvagnshallarna, Birger Jarlsgatan 57 A, Stockholm. To be eligible to participate in the meeting, shareholders must be registered in the shares ledger maintained by Euroclear Sweden AB by May 15, 2020. 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 participate. Registration for the meeting begins at 15:30.

CERTIFIED ADVISER

Erik Penser Bank is the certified advisor for Sedana Medical AB (Publ).
Contact details
Telephone: +46 8 463 83 00
Mail: certifiedadviser@penser.se

FOR FURTHER INFORMATION, PLEASE CONTACT

Christer Ahlberg, CEO and Group President
+46 (0)8-124 05 200
Maria Engström, CFO +46 (0)8-124 05 200

ADDRESS INFORMATION AND CORPORATE ID NUMBER

Sedana Medical AB (publ)
Vendevägen 87,
SE-182 32 Danderyd, Sweden
Corporate ID number 556670-2519

PUBLICATIONS CALENDAR

Interim report, first quarter 2020
May 8, 2020

AGM: May 19, 2020

Interim report, second quarter 2020
August 25, 2020

Interim report, third quarter 2020
November 11, 2020.

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Sedana Medical Head office (Sweden)
Sedana Medical AB (publ)
Vendevägen 87
SE-182 32 Danderyd, Sweden

Phone: +46-8-124 05 200
E-mail: info@sedanamedical.com
Investor relation: ir@sedanamedical.com