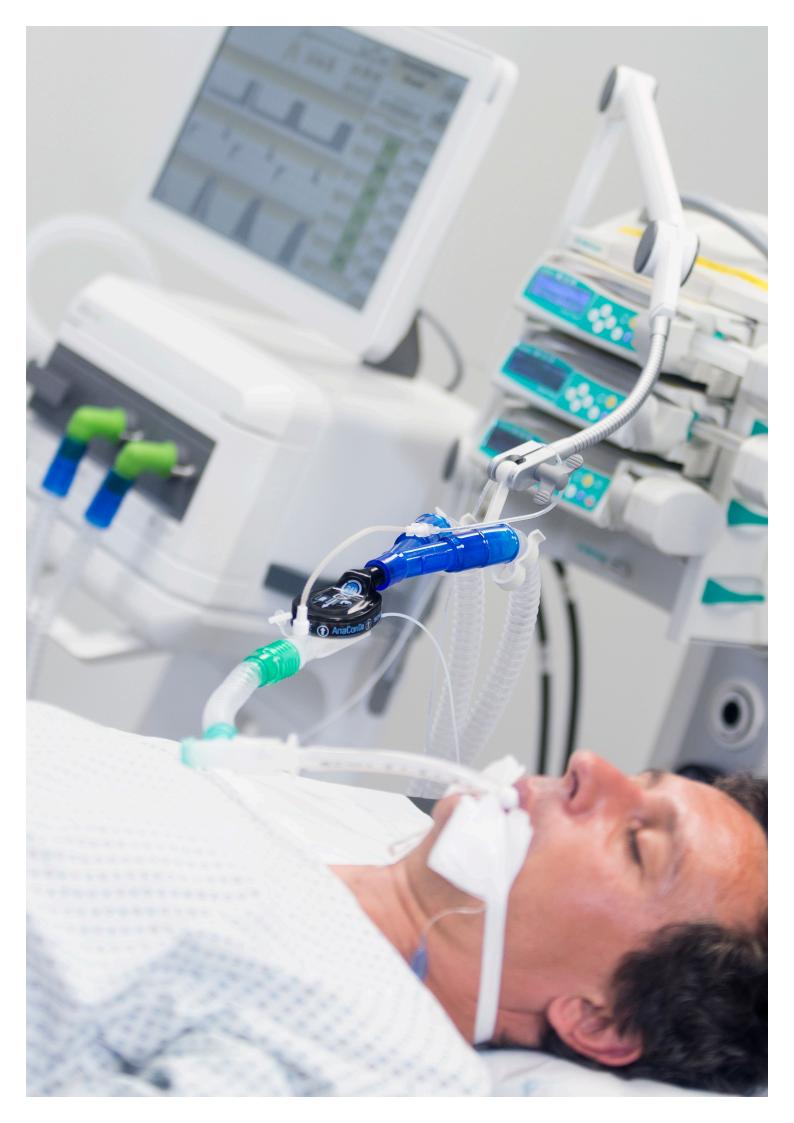


# ANNUAL REPORT 2017 SEDANA MEDICAL AB (PUBL)

Anac

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# SEDANA MEDICAL IN SUMMARY

- Sedana Medical was founded in 2005 when the AnaConDa technology was acquired. The business has since focused on developing and selling the AnaConDa medical device and related accessories.
- During 2017, Sedana Medical achieved sales of MSEK 40.4. Sales have grown by about 30 percent per year since 2010. Germany is the company's largest market.
- AnaConDa makes 'Inhalation Sedation' possible by administration of a volatile anaesthetic through the respiratory tract for the treatment of intensive care patients thereby achieving a stand-alone controllable sedation which is effective, safe and cost effective.
- Sedana Medical's vision is to develop Inhalation sedation into a global standard method for mechanically ventilated patients in intensive care throughout the world. Inhalation sedation solves many of the current problems caused by administering sedation intravenously.
- Every year, 15 million people are admitted to intensive care units worldwide. Almost half of these need help with breathing through a respirator/ventilator. In order to tolerate the "tube in the throat" as well as the necessary treatments, patients need to be sedated. About half of these patients around 3-4 million people annually are sedated for more than 24 hours and on average for 5 days.

Based on these figures, Sedana Medical estimates its global market size to be between SEK 10-20 billion and growing as populations age.

- No volatile anaesthetic is yet approved for sedation within intensive care. The company has therefore started a registration study for isoflurane, under the name IsoConDa. The purpose of the study is to obtain market approval for IsoConDa and AnaConDa for the indication of inhalation sedation in intensive care in Europe and the company's assessment is that it will be the first clinically validated therapy for inhalation sedation in intensive care.
- The company has initiated planning for introduction to the US market by mapping the registration process and the need for clinical studies. The company is also looking at the business opportunities in the largest markets in Asia, such as Japan and China.
- Sedana Medical is today a medical technology company on its way to becoming a pharmaceutical company.
- The head office is based in Danderyd, Sweden. In June 2017, the company's share (ticker: SEDANA) were listed on Nasdaq First North stock exchange. The company conducts research and development in Ireland through the wholly owned subsidiary Sedana Medical Ltd. Manufacturing is done via contract manufacturing.

# Sedana Medical's vision is to develop inhalation sedation into a global standard method for sedation of mechanically ventilated patients in intensive care throughout the world.



# **SEDANA**MEDICAL

NASDAQ FIRST NORTH

**WELCOMES** 

SEDANA MEDICAL

R. N.

# Nasdaq

Nasdag is the



**Sedana Medical's share** was listed on Nasdaq First North stock exchange on 21 June 2017.

NASDAQ

\$14.9

# SIGNIFICANT EVENTS DURING 2017

### Q1

- On 1 February 2017, Christer Ahlberg was appointed as the new CEO for the Sedana Medical Group.
- In March 2017, AnaConDa was approved in South Korea, which is the first approval on the Asian market.
- The new proprietary product AnaConDa-S was launched during the quarter.

### Q2

- A decision was made on a bonus issue and share split and on conversion to a public company at the Extraordinary General Meeting on April 5.
- The clinical protocol for the IsoConDa registration study was approved by the German Federal Institute for Drugs and Medical Devices, BfArM, as well as the ethics committee, after which the study entered an operational phase with the inclusion of the first clinic and patient.
- The Group's head office was registered in Danderyd.
- A subsidiary was established in Sweden for administration of an incentive program in Sedana Medical AB (publ).
- Sedana Medical's stock was listed on the Nasdaq First North stock exchange on 21 June 2017.
- Offering and listing on Nasdaq First North 21 June. At the offering, bids were heavily oversubscribed.
- In June 2017, a deal was concluded with Teleflex Medical Inc, which resolved all existing royalties for the AnaConDa products. Through the deal, Teleflex has no remaining rights to receive royalties relating to AnaConDa sales.



### Q3

- The first patient in Asia was treated with AnaConDa in the South Korean market.
- The process of recruiting new clinics to participate in the registration study for IsoConDa continued in Germany with approximately half of the planned number of clinics recruited by end of Q3.
- The over allotment option in the IPO was exercised.
- Start-up of direct sales to hospitals in the Nordic region were initiated through recruitment of in-house sales personnel.

### Q4

- Senior Consultant and Associate Professor Peter Sackey was recruited as Chief Medical Officer (CMO). Peter Sackey has over twenty years' clinical experience as a physician within anaesthesiology and intensive care. He joined Sedana from a position within Perioperative Medicine and Intensive Care at Karolinska University Hospital in Solna, Sweden. Sackey is one of the world's leading researchers in the field of inhalation sedation and was the first to use AnaConDa within intensive care.
- All remaining outstanding warrants in the incentive programme 2017/2021, which was initiated in conjunction with the IPO, were acquired by incoming Chief Medical Officer Peter Sackey.
- The process of recruiting patients and new clinics to the registration study for IsoConDa continued in Germany. Sixteen clinics were approved, and another two were close to approval. In addition, we had a further 10 or so clinics under evaluation or in the process of contract finalisation.
- Sedana Medical's distributor in Japan applied for registration of the medical device AnaConDa in November.
- In December, we strengthened our sales organisation with more Key Account Managers in France to meet demand.

# Significant events after the period

- Peter Sackey took office as Chief Medical Officer on 8 January 2018.
- Sedana Medical AB (publ) opened its own sales operations in Norway and Denmark.
- Sedana Medical AB (publ) announced that the schedule for patient recruitment in the ongoing Phase 3 IsoConDa study is likely to be extended.
- Sedana Medical AB (publ) reported a more than expected 60% increase in sales in the first quarter of 2018 compared to the corresponding period in 2017.

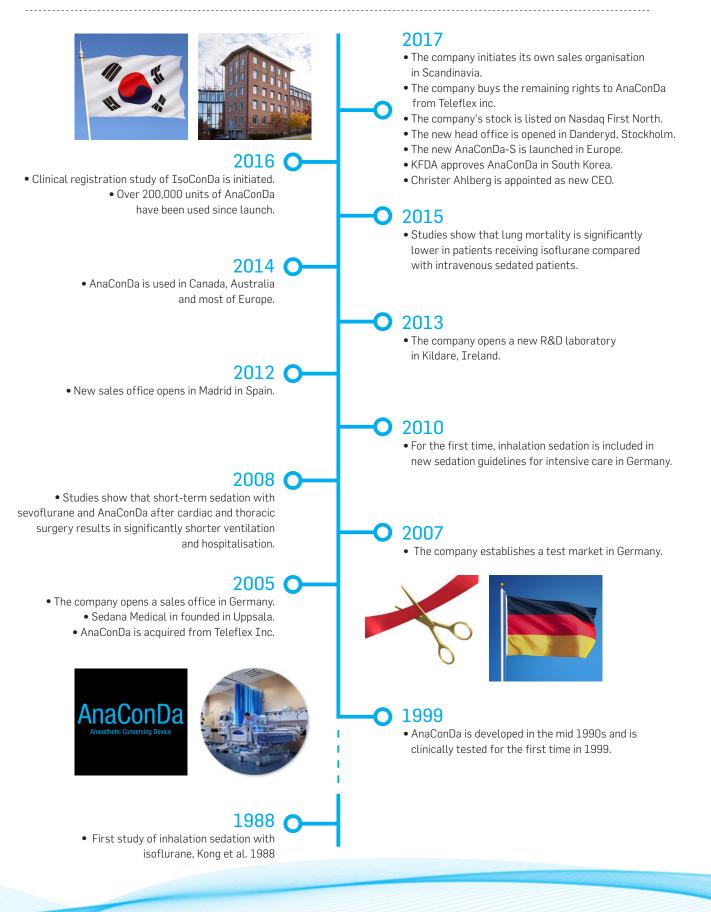
# **KEY FIGURES** FOR THE GROUP

### Financial summary - Group Consolidated

KSEK	2017	2016	2015
Net Sales	40 427,7	32 154,6	28 113,5
Gross Profit	29 661,7	21 346,4	17 849,2
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-736,2	994,3	-1 174,2
Earnings Before Interest and Taxes (EBIT)	-3 487,8	617,8	-1 386,7
Net income	-3 875,7	1 285,6	-1 205,4
Gross Margin (%)	73,4%	66,4%	63,5%
EBITDA %	-1,8%	3,1%	-4,2%
EBIT %	-8,6%	1,9%	-4,9%
Net income % of net sales	-9,6%	4,0%	-4,3%
Total assets	131 376,3	23 624,4	12 401,3
Equity ratio	88,6%	5,3%	3,6%
Quick ratio	650,2%	84,9%	131,8%
Average number of employees	16,5	15,7	11,0



# THE COMPANY'S HISTORY IN SUMMARY



# **CEO COMMENTS**

Almost 10 million people are sedated annually in an intensive care department around in the world.

Intravenous sedation, today's standard of care, often creates problems due to unpredictable wake-up times and it may take several days for the patient to wake post sedation. There are also challenges with tolerance development where higher and higher doses are required to maintain sedation as well as addiction problems such as withdrawal. Other side-effects include hallucinations and delirium which may be dangerous, unpleasant and require additional costly care.

Every additional hour and day that the patient is sedated unnecessarily increases risks to the patient and is a major additional cost for "unnecessary" care in the intensive care department.

We have identified these problems, and offer a solution where treatment is done by inhalation of the medication, so called 'inhalation sedation'. The wake-up time is significantly reduced and is approximately 15-30 minutes, thus reducing the risk of side effects and tolerance development. Studies also show organ-protecting effects.

Sedana Medical's vision is to develop inhalation sedation with our AnaConDa and IsoConDa products to a global standard method for sedation of mechanically ventilated patients in intensive care. We will achieve this ambitious vision through use of the AnaConDa technology and the drug IsoConDa (isoflurane) in offering a solution to current problems caused by intravenous sedative drugs, or those which they do not adequately address. We have a unique and leading position in the market.

In order to achieve our ambition, we are working with the following strategies:

### REGISTERING THE INHALATION SEDATION THERAPY IN INTENSIVE CARE AND THE DRUG ISOCONDA (ISOFLURANE) IN THE EU

Work on the registration process is already under way for the preparation for a complete pharmaceutical dossier. Our intention is to initially register the product in 15 European countries.

The registration study for IsoCon-Da is ongoing and we now have about 20 German clinics included in the study and another 5-8 clinics under evaluation. During 2018 we will present the results from an interim analysis, which will determine how many patients will ultimately be included in the study to achieve the desired result. Our target is that IsoConDa will be registered in Europe in 2020.

#### RAISE THE AWARENESS OF AnaConDa AND INCREASE SALES

Demand for inhalation sedation and our AnaConDa product continues to increase. Sales growth in 2017 was 26%. The number of intensive care clinics in Germany that actively use AnaConDa is increasing month-by-month, and there are currently close to 500 in more than 400 hospitals, including almost all university hospitals. We are adding more resources to marketing and sales to both raise awareness of AnaConDa and increase sales, especially in new direct sales markets such as France and in Scandinavia, and shortly in the UK. I am proud of how we have built up relationships with KOLs (Key Opinion Leaders) over the years, especially in Germany, but also in France. These close relationships yield good results. During the last part of March, we conducted our first global advisory board in Brussels. There, leading KOL's in the field of sedation in the intensive care from Europe and the US met to discuss Inhalation Sedation and Sedana Medical's current and future products.

# IMPLEMENT A REGULATORY STRATEGY FOR AnaConDa AND IsoConDa IN THE USA

The registration strategy for the USA is already under way. We are working to make an application where AnaConDa and IsoConDa are a combination product with the drug as a base. We anticipate that the products will be registered in the USA around 2022. In parallel with this process, we are investigating other means of registration that are certainly narrower. One application does not preclude the other, but is rather part of a step-by-step strategy to establish the therapy in the US market.

In Asia our distributor in Japan has applied for the registration of AnaConDa, which is a step in the right direction. Currently, we are also working on evaluating the Chinese market.

In 2017 we achieved our previously stated financial ambition of achieving an annual increase in sales of more than 20%, and an EBITDA figure that is not significantly negative in parallel with building up a larger sales and marketing organisation. It is our ambition to reach annual sales in excess of 500 MSEK and have an EBITDA margin of around 40% three years after the registration of IsoConDa in Europe. The market potential for inhalation sedation within intensive care is SEK 10–20 billion per year.

In summary, I am very satisfied with our efforts during the year, and we are well on course to achieve our challenging ambitions, in terms of our goals for both registration and growth.

Christer Ahlberg, President and CEO

# A PATIENT'S STORY – JAMES SPIEGEL

"In early September my girlfriend and I decided it was time to meet her family in Israel. It was to be a trip of a lifetime for 3 weeks visiting all the Holy Sites. About a week into the trip I

was having a very difficult time breathing and started to fatigue easily. This did not make sense as I keep myself in excellent physical condition exercising daily. Following a trip to the Dead Sea I decided to take a nap to recover from a long trip; it was a nap I almost did not wake up from."

"I had my first and hopefully last Status Asthmaticus attack."

I passed out and subsequently had to be resuscitated in the ambulance. Once at the hospital the physicians had to put me in a medical induced coma for almost 11 days.

Throughout this period the hospital attempted all conventional treatments such as propofol resulting each time in a worsening of my condition, as my  $CO_2$  markers were at a hazardous level.

At this point, my family was called because they could not find an effective treatment. The next step would have been a heart and lung machine, which the physicians believe I would not have survived.

The head of the department had one AnaCon-Da device which he had obtained as a sample, but had no accessories or follow up product and said that would be the last treatment he could try. My partner contacted Sedana Medical and explained the situation to them, briefing them on exactly what was happening. The Sedana Medical team in Germany arranged to meet her the following day in Frankfurt to provide her with product. Upon getting there they were very understanding and compas-





sionate about my situation and made sure she had the correct product and necessary accessories to return to Israel with, to save my life. Upon return the hospital physicians quickly set up

the AnaConDa delivery system and within a few hours my vitals began to stabilize and they were able to wake me up.

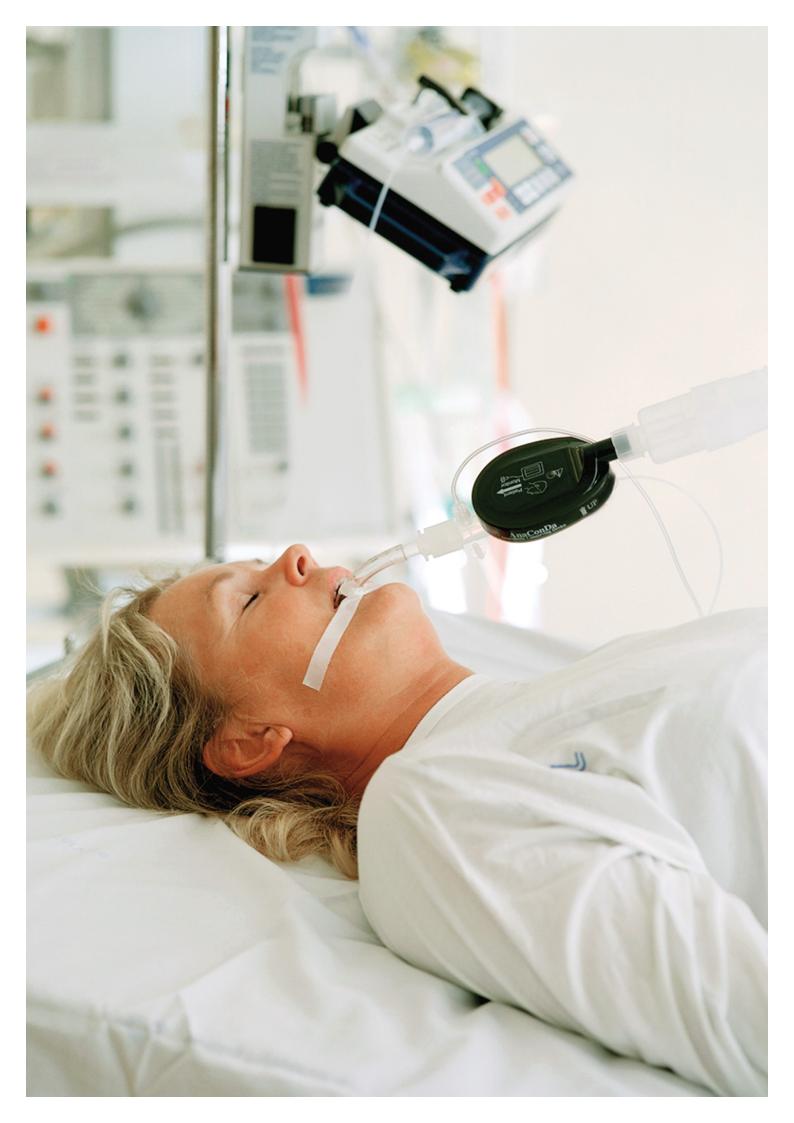
### I am not a doctor but I believe if this were available to me earlier things would not have been as serious.

"I am not a doctor but I believe if this were available to me earlier things would not have been as serious."

I will always be an advocate for Sedana Medical as this device saved not only my life but saved severe grief to my girlfriend and families lives as well. I believe that there needs to more awareness about this device and its benefits. We need to challenge conventional treatment as I strongly believe that if this had happened in the United States I would not have survived.

Upon discharge I had a long discussion with the head of the ICU whom disclosed that prior to the AnaConDa being connected, he believed I had approximately 10 hours left before he would have had to make some tough calls. I have no words to describe the gratitude I have to the team at Sedana Medical, whom even after I had woken up went above and beyond to check on my health status.

Sincerely, James Christopher Spiegel



# MARKET OVERVIEW

### Background

AnaConDa is a unique and innovative product that enables volatile anaesthetics to be administered in a simple and safe way, which previously was not possible without a so-called anaesthesia machine. Volatile anaesthetics are considered to be the ideal drugs for the sedation of mechanically ventilated intensive care patients.

The market for sedation of mechanically ventilated patients in intensive care units is today served by established and wellknown narcotic drugs such as benzodiazepines, midazolam and lorazepam, as well as propofol. These are administered intravenously and have well-known benefits, but also a number of disadvantages and challenges in terms of patient care.

Sedana Medical's market is very well defined and consists of hospitals' intensive care units that treat mechanically ventilated patients. The target group for the company's products is clear and the decision-makers aimed at by the company are intensive care professionals, intensive care nurses and decision makers who are responsible for the purchase of medical devices and medicines for these departments.

# Intensive care

Intensive care is the name given to the level of care that involves careful monitoring and advanced treatment of severely ill patients, often in life-threatening conditions. There are intensive care departments at all emergency hospitals and are characterised by a high level of staffing as well as a high-technology environment where patients are in need of more extensive supervision than in a normal ward.

Intensive care is one of the most resource-intensive areas of healthcare and is designed and equipped to provide the greatest possible chance of survival to patients whose most vital bodily functions are failing, such as breathing, blood circulation and consciousness. In intensive care departments, staff are constantly present and tests and nursing care carried out/provided at frequent intervals. The staff in intensive care departments use advanced technical equipment to monitor and treat the patient's medical status and the concentration of medical devices is therefore very high.

Every year, around 15 million patients are admitted to intensive care departments around the world, with the most common causes being respiratory failure, myocardial infarction and stroke. With an average cost of between SEK 10,000 and SEK 30,000 SEK per day in care and per patient (three to five times higher than a normal hospital department), intensive care patients are costly for hospitals. Although these patients account for only about 10 per cent of all hospital stays, they can account for almost 20 per cent of the hospital's total budget The high cost is a powerful reason for hospitals to reduce the number of days that patients spend in intensive care departments.

### Facts about sedation

Sedative drugs is a collective term for tranquillising and sometimes pain-relieving drugs used in many parts of the healthcare industry. Sedation means that a medical procedure is used to place a patient in a state of reduced consciousness to relieve apprehension, anxiety and pain. One of the main areas in which sedation is used is in intensive care where sedation is one of the more common activities being performed. The term sedation is nuanced and includes a number of levels of consciousness and there are a variety of scales to measure these (RASS, Ramsay et al.). For the sake of simplicity, we shall use here the three-stage scale defined by the American Society of Anesthesiologists:

- Light sedation
- Moderate sedation
- Deep sedation

The difference between the different levels lies in the level of consciousness, with light sedation providing a mild anxiety-relieving and relaxed state in which the patient is fully conscious without affecting the body's functions. Moderate sedation provides a condition where the patient has a lower level of consciousness, but still responds to verbal or tactile (touch) stimulation. Under moderate sedation, respiratory tract reflexes, and respiratory and cardiac function remain intact. In deep sedation, the patient is in a state beyond consciousness but responds to repeated pain stimulation. During deep sedation, cardiac function is maintained while respiratory reflexes and respiration may be impaired.

The preparations used to achieve the desired sedation level for these patients have traditionally been administered intravenously. Sedation of patients who are mechanically ventilated by means of a respirator often occurs for longer periods, usually between four and nine days. In conjunction with surgery, something that goes under the term general anaesthesia is used. General anaesthesia is a collective name for a number of ways in which medical means are used to sedate the patient far beyond consciousness and provide pain relief so that surgery can be performed. The patient does not respond to any form of stimulus. This type of sedation is so deep that the patient needs help to breathe and is a stage further than deep sedation. With general anaesthesia, an anaesthesia machine is used with which the preparation is usually administered through inahalation, which is standard, or intravenously.

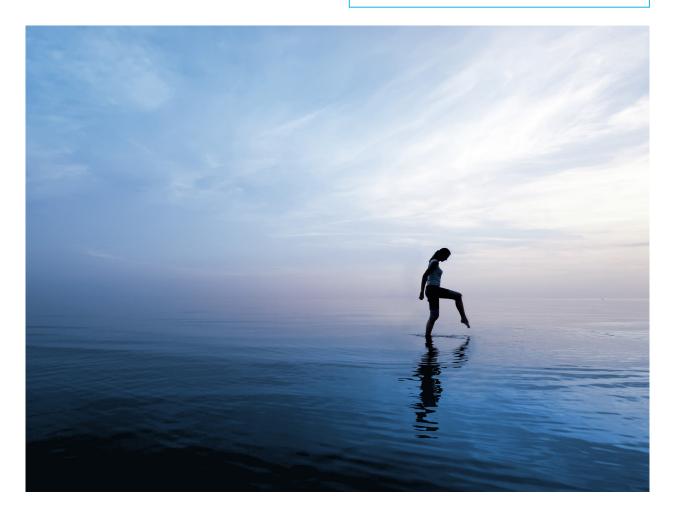
# Need for sedation in intensive care

Sedation is one of the cornerstones of intensive care and more than 85 per cent of adult patients admitted to an intensive care department are in need of and are given sedation. Many of these are in a very critical condition and most are suffering from respiratory distress, impaired lung function or other conditions that necessitate respiratory assistance. When a patient is in need of respiratory assistance, a tube is inserted into the patient's trachea through the mouth or nose, called intubation, which is then connected to a respirator (ventilator) to provide the patient with the necessary breathing assistance. This type of respiratory assistance usually goes under the name of mechanical ventilation and of the total number of patients admitted to intensive care departments, between 30 and 50 per cent are ventilated using mechanical ventilation.

Mechanical ventilation is an unpleasant experience and in order for the patient to cope with it, the patient needs to be sedated to suppress nervousness, anxiety and pain. Sedation of ventilated patients is one of the most common interventions in the field of intensive care. Sedation is also necessary for the staff to be able to perform the required treatments. The primary target group for AnaConDa is mechanically ventilated intensive care patients where sedation is expected to last for more than 24 hours, which accounts for about 50 per cent of patients. So this is the direct target group for AnaConDa. These patients are ventilated for five days on average.

### BELOW ARE THE MOST COMMON DIAGNOSES FOR MECHANICALLY VENTILATED PATIENTS IN SWEDEN.

Diagnosis	Number of patients
Acute renal failure	
Obstructive lung disease	
Severe sepsis	10.9%
Septic shock	10.5%
Cardiac arrestt9.1%	
Aortic aneurysm	5.7%
Subarachnoid haemorrhaging	
ARDS	2.6%
Acute pancreatitis	2.2%
Other	
Source: Swedish Intensive Care Registry 20	13



# Intravenous sedation and mechanical problems

Current practice for sedation of mechanically ventilated intensive care patients is the use of drugs given intravenously. Intravenous sedation means that the drug is injected directly into the patient's bloodstream via a cannula. The drugs have been established for a long time and are encumbered with a number of well-known medical problems that adversely affect patients and healthcare. The table summarises the problems associated with current treatment:

#### PROBLEMS LINKED TO THE CURRENT STANDARD OF SEDATION IN INTENSIVE CARE

Shortcomings of intravenous sedation	Effect on the quality of intensive care
The level of sedation is difficult to control and monitor	Unnecessary importance is attached to controlling sedation instead of treating the patient. Increased risk of excess and insufficient sedation.
Extended wake-up time	Longer time under ventilation, longer time for extubation* which means more time in the intensive care department.
Unpredictable wake-up	Extubation cannot be planned. Neurological assessments are difficult and more expensive.
Depending on liver metabolism and renal excreation for elimination of the sedative drug.	Intensive care patients often experience disturbances in or reduced renal and liver funtions which increases considerably the risk of excess sedation.
Development of tolerance or accumulation	Frequent increase in dose, reduced effect, need for additional drugs to maintain the quality of sedation.
Patients may experience withdrawal symptoms anxiety and delirium	Prolongs the stay in the intensive care department, in particular in elderly patients. Also prolongs the stay in hospital after the end of intensive care. Delirium has a clear association with increased mortality.

\* Extubation means removal of the tube in the throat, thus causing mechanical ventilation to cease

In general, degradation and excretion of preparations given intravenously take a long time. They are broken down in the liver and are reliant on the patient having a well-functioning metabolism. Many elderly patients have a reduced metabolism, which means that these patients should be treated carefully. In addition, many patients are critically ill and commonly have problems with their renal and hepatic function, which further delays the body's degradation and excretion of the preparations.

FASS (short for Pharmaceutical Specialities in Sweden, a summary of pharmaceutical facts from the pharmaceutical industry to different prescribers of pharmaceuticals and pharmacists) describes the following risk groups for midazolam which today is one of the most commonly used drugs for sedation:

"Particular caution should be exercised when administering midazolam to these high-risk patients:

- Adults over the age of 60
- Chronically ill or otherwise weakened patients
- Patients with chronic respiratory insufficiency
- Patients with chronic renal failure, hepatic impairment or impaired cardiac function
- Children, especially those with cardiovascular instability."

With intravenous sedation, sedation depth is difficult to monitor and control, which often leads to deep sedation, and research shows that up to 60 per cent of all sedated intensive care patients are severely sedated, which is a particularly significant problem for the above-listed high-risk patients as it takes longer for them to eliminate the preparations. Deep sedation means the patient is given an unnecessarily high dose of the drug. The difficulty in controlling sedation depth together with the slow degradation and excretion of intravenously administered preparations often leads to uncontrolled awakening, a prolonged wake-up time and undesirable side effects. There are also clear links between the use of intravenous sedative drugs and the occurrence of delirium, one of the most common causes of mortality in intensive care patients.

For sedation for shorter periods (less than 24 hours), the listed problems are less noticeable and intravenous sedation will continue to be highly significant. For longer periods of sedation, the shortcomings become more serious and there is a great need for better alternatives.

Intensive care requires a sedation drug to have the following properties:

- Easy to dose from light to deep sedation and vice versa
- Predictable and preferably with short duration of action (short wake-up time)
- No active metabolites
- No tolerance development or exposure problems
- Low cost

### Inhalation sedation

### **OVERALL BENEFITS OF INHALATION SEDATION**

Inhalation sedation means that drugs (volatile anaesthetics) are administered and are mainly eliminated via the lungs, making it easier to quickly change the dose and thereby control the sedation depth, which provides many benefits. This reduces the risk of both excess and insufficient sedation and the patient wakes up quickly and predictably upon exposure. In addition, volatile anaesthetics have no active metabolites, which results in a lower risk of accumulation of the drug, and in addition, tolerance and addiction development is limited. Many autonomic functions (features such as breathing and heartbeat) are kept intact.

### INHALATION SEDATION - HISTORY AND STATUS

The drugs used for inhalation sedation fall under the common term "volatile anaesthetics". Volatile anaesthetics such as isoflurane are potent preparations that act quickly and efficiently even at low doses and have long been approved for use in general anaesthesia. Isoflurane has been used since the early 1980s and is considered to be one of the safest preparations, which is why it is often used in patients with impaired renal and hepatic function.

Complex anaesthesia machines are used to administer isoflurane.

Anaesthesia machines are not adapted for use in intensive care environments and therefore cannot be routinely used for the treatment of intensive care patients due to:

- The built-in ventilator lacks the performance required for treating intensive care patients
- High investment cost
- High operating costs and need for specially trained staff
- Intensive care departments lack the space for additional bulky equipment

Inhalation sedation was investigated back in the 1990s in a number of clinical trials and demonstrated many medical benefits. The results of the studies could never be translated into practice as there was no practical and commercially viable solution for administering volatile anaesthetics to intensive care patients.

It wasn't until AnaConDa was introduced that it became clear that there was now a simple and safe solution for administering a volatile anaesthetic in intensive care departments. The first clinical study in which isoflurane was administered with AnaConDa was conducted at Karolinska University Hospital with promising results and was published in 2004. The interest in AnaConDa in the intensive care environment is high, and approximately 100 studies with AnaConDa and inhalation sediment have been published.

It was in 2010 when new guidelines for sedation were published in Germany (S3 Guidelines), as use was increasing on a large scale, mainly in Germany. The new guidelines were developed by the German intensive care organisations (DGAI and DIVI). The guidelines described the benefits of using inhalation sedation for some groups of patients. They therefore contributed to increased interest in the treatment

Inhalation sedation means that drugs are administered and generally eliminated via the lungs, which makes it easier and quicker to change the dose and control the sedation depth, which brings many advantages.

# Competitive situation

Information about Sedana Medical's competitors and market size for Sedana Medical's products is limited and is characterised by low transparency and large geographical differences. The information below is based on Sedana Medical's overall assessment, itself based on several sources, and Sedana Medical's best estimates derived from information received from customers, authorities and other contacts in the medical and pharmaceutical industries.

The biggest competition for Sedana Medical's AnaConDa technology is intravenous sedation medication. These are: propofol, benzodiazepines such as midazolam or lorazepam, remifentanil and dexmedetomidine. These drugs are usually generic and are sold at a low price, with the exception of dexmedetomidine, which costs around SEK 1,400 per day in Europe.

The daily cost of intravenous sedation is difficult to estimate and varies greatly from country to country. The cost calculation is complicated by the fact that different preparations are often combined (such as propofol and midazolam) to achieve the desired effect, and that the dosage may vary depending on the patient's tolerance to the preparation. These many factors contribute to the cost of intravenous sedation varying between SEK 200 and SEK 3000 per day. Sedana Medical estimates that the average cost of intravenous sedation in Europe amounts to about SEK 600 per day, which is slightly lower than the daily cost of AnaConDa and isoflurane. Costs in the USA and Canada are significantly higher, and Sedana Medical's assessment is that the average price is about three times higher than in Europe. As the cost per day of intensive care is between SEK 10,000 and SEK 30,000 per patient, Sedana Medical estimates that intensive care clinics are relatively price-insensitive when it comes to sedation drugs as they represent a relatively small part of the total cost of treatment.

The company's assessment is that propofol has the largest market share and accounts for about half of the global market for intravenous medication for sedation. The main players in the market for intravenous sedative drugs consists of both global drug giants such as Astra Zeneca, GlaxoSmithKline and Mylan and smaller generic drug manufacturers. Drugs based on benzodiazepine such as midazolam are the second-largest group of sedation drugs on the market, but are losing market shares to propofol and dexmedetomidine due to the problems associated with, inter alia, tolerance development and delirium noted in recent years. The problem has also been addressed at a higher level and in the USA, sedation guidelines recommend the use of drugs based on benzodiazepine for long-term sedation.

The company believes that competition from other inhalation solutions for volatile anaesthetics is largely non-existent. Traditional anaesthesia machines are neither practical nor commercially suitable for intensive care use and other inhalation solutions do not meet the safety and efficacy requirements required to achieve effective sedation in an intensive care environment.

### Market size and potential

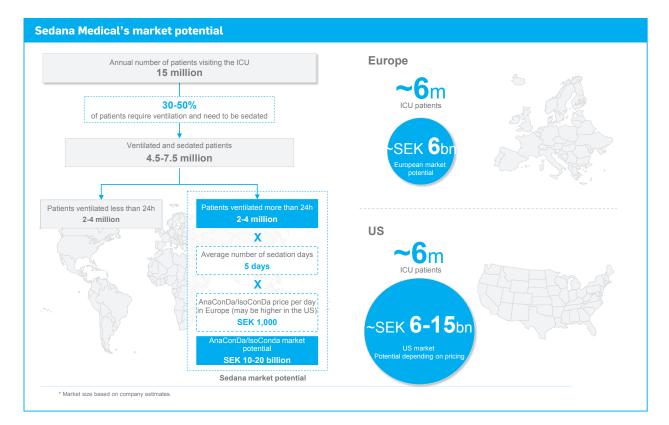
The current market for sedation drugs within intensive care is represented by intravenous drugs only. The company's assessment is that the total size of this market amounts to about SEK 20 billion per year and is dominated by propofol, midazolam, dexmedetomidine, and remifentanil.

Sedana Medical's main target group consists of mechanically ventilated intensive care patients who are sedated for a period in excess of 24 hours.

Around 15 million patients are admitted to intensive care departments around the world every year. Of these patients, approximately 30 to 50 per cent are ventilated and thus need

to be sedated. From a global perspective, this means that between 4.5 and 7.5 million patients are being ventilated and sedated. Inhalation sedation is best suited for those patients who are ventilated for more than 24 hours, which is estimated to be around half. This means that a total of between two to four million patients per year are included in the company's direct target group for IsoConDa and AnaConDa. The average time these patients are ventilated is estimated to be around five days, which means a total of 10 to 20 million days under sedation

The cost of sedation with IsoConDa and AnaConDa is estimated to be around SEK 1,000 per day, giving a total market of between SEK 10 and SEK 20 billion. Furthermore, the market is expected to grow as a result of the ageing population.



### Market drivers and trends

Sedana Medical believes there are five main market trends that affect the underlying growth of the market:

### Light sedation with daily interruption and wake-up

A broad and growing medical literature shows that it is beneficial for patients with light sedation to breathe himself/herself and to be woken daily so that vital signs can be checked. Inhalation sedation with AnaConDa is a very suitable solution as it allows the doctor to carry out investigations without being forced to use computer-tomographic examination which is both costly and resource-intensive and contains an aspect of risk as the patient must leave the intensive care department when the examination is performed in another part of the hospital.

### Increased awareness of the risk associated with

**delirium** The number of scientific studies investigating the incidence of delirium in intensive care patients has increased significantly over the past decade and delirium has been recognised as a growing public health problem in the USA. Delirium affects up to 80 per cent of all mechanically ventilated intensive care patients and the annual cost of treating intensive care patients with delirium amounts to between USD 4 and USD 16 billion in the USA alone.

**Reduced use of benzodiazepines** Several studies show that benzodiazepines used for prolonged periods can lead to a series of unwanted clinical results. Prolonged periods of ventilation, increased duration of intensive care and the presence of delirium are some of the unwanted effects that may be associated with the use of these drugs. The problems with benzodiazepines are listed in the guidelines of the American College of Critical Care Medicine, with the recommendation that benzodiazepines (midazolam and lorazepam) should be avoided when sedating mechanically ventilated intensive care patients.

**Need to reduce hospital care costs** According to PwC ("Medical Cost Trend: Behind the numbers", 2016 and 2017), total healthcare costs per patient increased by 6.5 per cent on an annual basis in the USA in 2016 and were estimated to remain at the same level in 2017.

The most costly care beds at a hospital are intensive care beds, and there is therefore a strong incentive to shorten a patient's stay in intensive care instead of increasing the number of costly intensive care beds. In view of an ageing population and a life expectancy that is expected to increase, the cost of healthcare, and intensive care in particular, is expected to continue to rise.

Ageing population Globally, but especially in Europe and the USA, there is an underlying trend of ageing populations. The number of people in Europe over 65 years is expected to rise from 16 per cent in 2010 to 27 per cent in 2050. Older people are generally in poorer health and are less able to recover after surgery or severe injury, which means that elderly people in intensive care tend to stay for a longer period than younger people. This means that although the size of the population in the developed world is generally steady or decreasing, the underlying market for Sedana Medical is still expected to increase. The poor health of elderly people also makes them vulnerable to excess or insufficient sedation, as their ability to eliminate and secrete drugs is reduced to a greater extent. The benefits of using inhalation sedation become more apparent as the population ages, and the intensive care departments are receive more and more elderly patients.

### Facts: Market drivers and trends

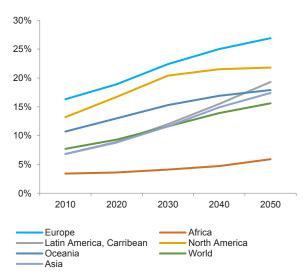
- Light sedation with daily interruption and wake-up
  Increased awareness of the risk associated
- with delirium
- Reduced use of benzodiazepines
- Need to reduce hospital care costs

**POPULATION DEVELOPMENT 2015-2050E**<sup>4</sup>

• Ageing population

6 000 5 000 4 000 3 000 2 000 1 000 0 2015 2020 2030 2050 2040 Africa Asia Europe South America - USA Oceania

PROPORTION OF POPULATION 65 OR OLDER BETWEEN 2010 AND 2050E<sup>5</sup>



<sup>3</sup> Central Office of Statistics, International summaries, Statistical Yearbook 2014
<sup>4</sup> World Statistics Organisation, March 2017.

<sup>5</sup> 3 Central Office of Statistics, International summaries, Statistical Yearbook 2014.

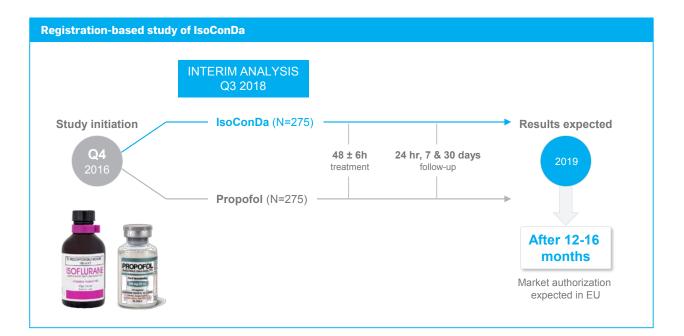
# THE ROAD TO A GLOBAL STANDARD METHOD FOR SEDATION

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

In Q4 2016, Sedana Medical initiated a clinical registration study aimed at having IsoConDa (isoflurane) approved for inhalation sedation in intensive care in Europe. The study's first patient was recruited in the middle of 2017. The study is a so-called randomised, controlled, open-label study. The purpose of the study is to confirm the efficacy and safety of sedation with isoflurane in mechanically ventilated patients using AnaConDa.

The study is a non-inferiority study, meaning its primary purpose is to prove that IsoConDa administered with AnaConDa is no worse than propofol at maintaining an adequate level of sedation. The study covers a total of up to 550 mechanically ventilated intensive care patients in need of sedation. The patients are divided into two equal groups, one of which is treated with propofol (intravenously) and the other with IsoConDa administered with AnaConDa.

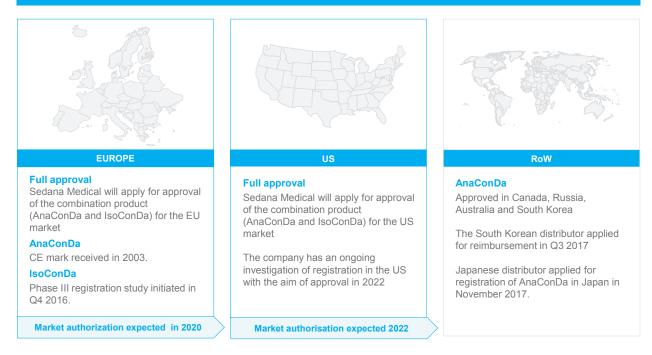
- **Primary aim:** To show that Isoflurane administered with AnaConDa is no worse than propofol. This is determined by analysing how much of the time an adequate sedation depth is maintained with isoflurane in comparison with propofol.
- Secondary aims: 1) To evaluate IsoConDa's safety profile in comparison with propofol by investigating the occurrence and frequency of side effects, delirium and changes in vital functions. 2) To show that sedation with IsoConDa leads to shorter wake-up times during daily sedation interruptions than with propofol sedation. 3) To investigate whether mortality is lower for patients treated with IsoConDa in comparison with propofol. 4) To evaluate the dosage of IsoConDa when sedated. 5) To record and evaluate any device related problems with AnaConDa. 6) To evaluate the differences between IsoConDa and propofol in the administration of rescue medicine in sedated patients. 7) To evaluate differences in the use of analgesics and to evaluate pain experienced using a pain scale. 8) To evaluate the difference regarding the ability to breathe spontaneously in sedated patients.
- **Explorative objectives:** They evaluate the difference in cost for hospitals and intensive care departments.



Sedana Medical's vision is to develop

inhalation sedation into a global standard method.

#### Summary of Sedana Medical's approval



The study is expected to be completed during 2019. During 2018, an interim analysis will be conducted to determine the final number of patients. In parallel with the study, additional documentation is required in any application for marketing authorisation, a preclinical evaluation and a pharmaceutical / technical summary. The application will also include a plan to evaluate the use of IsoConDa in children, a so-called PIP (paediatric investigation plan). When the final report for the clinical trial is available, Sedana Medical shall compile the registration documentation, which is then submitted to approximately 15 countries at the same time. The German authorities will be the reference country and lead the evaluation. Normally, the registration process takes 12-16 months from the date of application. The approval covers sedation for up to 48 hours. After approval of IsoConDa, Sedana Medical will continue to collect data for later registration of the product for longer use. Since the submitted registration documentation is complete, that is, including children, the approval means that Sedana Medical will receive ten years of market exclusivity in Europe for the use of isoflurane in intensive care. No competitor will be able to sell or market isoflurane for this purpose without having been subjected to the same procedure as Sedana Medical.

Assuming that the outcome of the registration study is good and inhalation sedation becomes an approved method of treatment in intensive care, Sedana Medical considers it likely that new guidelines for inhalation sedation will develop in the countries in question. Recommendation guidelines are expected to contribute to a further spread and general acceptance of the treatment.

#### **REGISTRATION IN THE USA**

The market potential for inhalation sedation is greater in the USA than in Europe, primarily as the price level for sedative drugs is considerably higher in the USA. There is also no similar treatment available on the US market at present. Today's method of sedation in intensive care in the USA is very similar to that in Europe, with intravenous sedation with propofol, dexmedetomidine and benzodiazepines being the usual treatment. Inhalation sedation is not yet available in the USA as AnaConDa is not approved for the US market. In 2017, Sedana Medical began the process of developing a strategy for registering the company's products in the USA. The company has established contacts with regulatory experts and KOLs in the USA. The company's assessment is that a further clinical study in the USA will be required for approval, which means that an approval will take at least another 3 years.

### REST OF THE WORLD

In Q1 2017, AnaConDa was approved in South Korea, which represents the company's first step into the Asian market. In connection with this, an agreement was established with a distributor for the South Korean market. In Q4 2017, the company's Japanese distributor also applied for registration of AnaConDa in Japan. The registration process is expected to last between 1 and 3 years. Sedana Medical is also looking into opportunities for registration in China.



# **BUSINESS OVERVIEW**

# Introduction

Sedana Medical is a medical technology company on its way to become a pharmaceutical company. The company's operations include the development and sale of medical devices and the development of products and drugs based on or having synergies with AnaConDa technology. The technology enables simple and safe conversion of liquids into gas (gasification) and reuse (reflection) of volatile anaesthetics for sedation of intensive care patients. The company's product portfolio currently includes AnaConDa with accessories and the drug candidate IsoConDa, the company's brand name for isoflurane.

Volatile anaesthetics have been used for a long time to anaesthetise patients in connection with surgery. For this purpose, anaesthesia machines are used which are complex, capital intensive and require specially trained staff. Traditional anaesthetic machines lack several vital features that make them unable to be used routinely in an intensive care department.

Very simply, the company's product AnaConDa can be seen as an anaesthesia machine in miniature. AnaConDa introduces a solution that makes it practically and economically possible to use volatile anaesthetics to sedate mechanically ventilated intensive care patients.

The market for the sedation of mechanically ventilated intensive care patients today consists of long-established drugs administered intravenously. However, sedation by inhalation, 'inhalation sedation', by volatile anaesthetics has in many ways proved to be a safer and more effective method of sedation than current intravenous sedation.

The company reported net sales in 2017 of SEK 40.4 million and operating profit before depreciation (EBITDA) of SEK -0.7 million through sales of AnaConDa with accessories. Sedana Medical had 25 employees at the end of the year. Sales are conducted through own personnel in Germany, France, Scandinavia and Spain. Sedana Medical's headquarters are located in Danderyd, Sweden, while product development is conducted from a subsidiary in Ireland. Production is mainly through contract manufacturers in Malaysia.

# **Business concept**

To provide a solution to the problems for mechanically ventilated patients in intensive care caused by today's intravenous sedative drugs by providing inhalation sedation, which involves administering a volatile drug (IsoConDa) with an administration system (AnaConDa) through the respiratory tract which allows easily controllable sedation which is efficient, safe and cost effective.

# Vision

For inhalation sedation with IsoConDa administered with AnaConDa to become a standard method for mechanically ventilated patients in all intensive care departments worldwide

# Financial goals

The company's aim until approval and registration of IsoConDa has been obtained is to increase sales by an average of more than 20 per cent per year, while maintaining an operating profit before depreciation and amortisations (EBITDA) not materially negative in parallel with building up a larger market and sales organisation.

The company's goal is, three years after the registration of IsoConDa, to achieve sales of more than SEK 500 million (excluding the USA) and an EBITDA margin of 40 per cent.

# Strategy

The company has designed and works in accordance with a strategy that can be summarised in the following four points:

# 1 Registration of IsoConDa as well as inhalation sedation in Europe

To complete the ongoing registration study and apply for approval of the IsoConDa drug within the EU.

- **2 To raise awareness and usage of AnaConDa.** Strong focus on the success of the market and sales organisation. Sales work will be carried out individually in the most important markets within the EU and through distributors in other markets inside and outside the EU. To actively participate in the major international conferences with symposia and seminars.
- **3** To implement a strategic plan for the regulatory registration of AnaConDa and IsoConDa in the USA To initiate registration activities in the USA with the aim of launching in 2022. The market has great potential, especially given the fact that the price level for intravenous drugs is about three times higher than in Europe.
- **4 To develop intellectual property protection** To establish commercial and intellectual property protection to prevent competition from copies of AnaConDa and off-label use of isoflurane after registration of IsoConDa.

# Strengths and competitive advantages

Sedana Medical believes that the company has a number of strengths and competitive advantages that have contributed to its success and put Sedana Medical in a very good position today to grow and gain market shares in the large and still untapped market for inhalation sedation within the field of intensive care.

# WELL-DEFINED MARKET AND TARGET GROUP WITH LIMITED COMPETITION

The company operates within a very well-defined market, which mainly consists of hospitals' intensive care departments. The target group is clear and the end consumers of the company's products are intensive care patients who are mechanically ventilated. The market is estimated to be worth between SEK 10 billion and SEK 20 billion per year and is expected to grow given the fact the population is ageing.

The current standard of sedation within intensive care is intravenous administration and is encumbered with a number of shortcomings that the company's treatment largely remedies. Inhalation sedation in an intensive care environment has previously not been practically possible, and thus the competition from other players is largely non-existent. As far as the company is aware, there is currently only one competitor on the market offering a solution for inhalation management in intensive care. The company estimates that the head start over this competitor as well as future competitors is significant since for several years it has been a driving force in the development of the treatment and has well-functioning product development and strategy.

# STRONG PRODUCT PORTFOLIO THAT ENABLES INHALATION SEDATION

The company's product portfolio has been developed to meet the need for better treatment of mechanically ventilated intensive care patients. The product portfolio consists mainly of the medical device AnaConDa and in the near future the drug IsoConDa (isoflurane). Through these two products, for the first time, a practical and commercially viable solution for treatment is provided for inhalation sedation by intensive care patients. The treatment is safe, effective and easy to use for healthcare professionals. In addition, intensive care clinics do not need to invest in expensive equipment, as AnaConDa can be used with existing intensive care equipment, making it easy for clinicians to implement the company's sedation solution.

### PROVEN TECHNOLOGY AND DEMAND

AnaConDa has been available on the market for 13 years and has proven to be safe and effective. Since the launch, AnaCon-Da and inhalation sedation have been described in about 100 scientific articles, highlighting the many benefits of inhalation sedation treatment. The articles show that the treatments made possible by AnaConDa technology lead, among other things, to the following improvements in the quality of sedation compared with the current standard method:

- Reduced wake-up time and extubation time
- Reduced mortality in patients sedated for a long time
- Reduced risk of delirium and hallucinations and other side effects
- Reduced risk of tolerance development and exposure problems
- Reduced need for analgesic drugs
- Organ protection

In addition to the clinical evidence validating AnaConDa, the company has also achieved a relatively large commercial success and shows that there is a large underlying demand for the treatment and the company's products. In Germany, which is the company's test market, the company estimates that approaching 500 intensive care clinics use AnaConDa.

#### **CLEAR GROWTH STRATEGY**

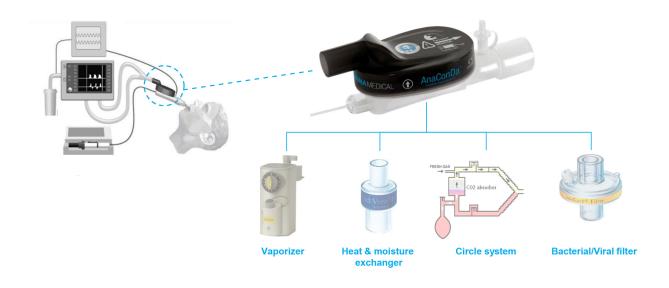
The general spread of inhalation sedation treatment and the company's sales of AnaConDa has not reached it's full potential since IsoConDa is not yet approved. An important part of the company's growth strategy is therefore to complete the ongoing registration study. The study includes the use of IsoConDa (isoflurane) and AnaConDa for intravenous care and the company expects marketing authorisation to be granted by 2020. Following approval, the company will actively promote IsoConDa and AnaConDa for its proper area of use. The company also believes that the overall acceptance of the treatment will increase significantly after approval has been obtained, which is expected to have a significant impact on the company's future sales. The company has also started mapping the market to initiate a registration process for IsoConDa and AnaConDa in the USA, thus enabling expansion into the US market. The USA represents a very interesting market and the company believes that the market potential is greater than in Europe because the price level of intravenous sedative drugs is about three times higher in the United States. The company is also working to develop the treatment in Asia, including Japan, South Korea and China.

**Sedana Medical is currently in a very good position to grow and acquire market shares** on the large and still untapped market for inhalation sedation during intensive care.

### Product description

#### AnaConDa

AnaConDa is a medical device that safely, resource- and cost-effectively enables sedation by inhalation of volatile anaesthetics as an alternative to the conventional method where the patient is instead treated by intravenous sedation. AnaConDa has been developed for the sedation of ventilated intensive care patients and consists of a small device placed between the ventilator and the patient for easy and effective administration of volatile anaesthetics, such as isoflurane and sevoflurane. The device is for single use and replaced every 24 hours, or earlier if required. Through the company's unique and patented technology, AnaConDa combines the four functions of anaesthesia machines in one and the same unit: vaporizer (required for controlled production of anaesthesia gas), reflector with a unique active carbon filter (for recirculation and preservation of anaesthesia gas), bacterial filter and a humidifier and heat exchanger. The technology enables a highly effective reflection of the anaesthesia gas from the exhalation air; over 90 per cent of the anaesthesia gas remains in the active carbon filter and is reused during the inhalation phase. The high rate of reuse contributes to reducing both the consumption of volatile anaesthetics and the spread of gas in the environment, and studies confirm that use of AnaConDa produces very low ambient concentration of inhaled anesthetic and is safe for use in intensive care clinics.



AnaConDa is designed to be easy to use and works with all modern intensive care ventilators, spray pumps and gas monitors. For most hospitals, this means they can manage without expensive new investment.

The original version of AnaConDa (100 ml) is aimed at adult intensive care patients. After further development of AnaConDa technology, Sedana Medical launched a new and 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 the dead space means that AnaConDa can now be used in patients who, for various reasons, have lower lung volume than is typical of an adult, such as children or patients who have reduced lung volume due to lung disease. The company estimates that this improvement resulted in an increase of AnaConDa's target group by around 25 per cent. In general, treatment strives to reduce the dead space for all patients, and the company believes that the new 50 ml version will dominate the market in the future.

AnaConDa provides the same functionality as traditional anaesthesia machines, but in a very compact format, without the need for large investments or expensive operating staff. Through its unique technology, AnaConDa provides an easy and effective way to make inhalation sedation the new standard method for sedating intensive care patients.

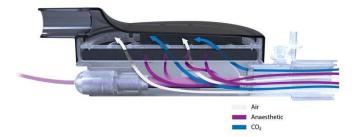
# BUSINESS OVERVIEW

### TECHNOLOGY

The AnaConDa technology is patented and AnaConDa is CE-labelled and manufactured in an ISO 13485 certified environment. Below is an illustration of AnaConDa and how the device is built and functions when used.

### **CROSS-SECTION OF AnaConDa**









# Ar Anaesthetic

### **1 START OF EXHALATION**

At the start of exhalation, the exhalation contains exhaled air from the patient's air,  $\rm CO_2$  and volatile anaesthetic.

#### 2 END OF EXHALATION

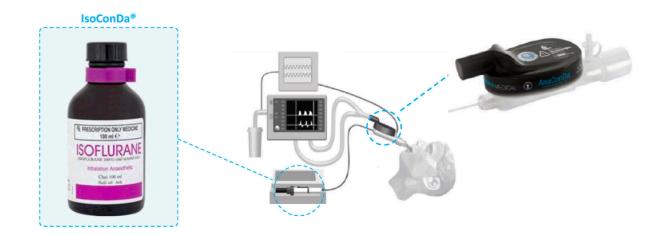
Air / oxygen and  $CO_2$  pass the active carbon filter while the majority of the volatile anesthetic is adsorbed in the active carbon filter. Exhaled air (almost exclusively air / oxygen and  $CO_2$ ) then extends through the ventilator hose and then through the ventilator exhaust.

### **3 START OF INHALATION**

When inhalation begins, air / oxygen from the ventilator passes through the AnaConDa device.

### 4 END OF INHALATION

During inhalation, anaesthetic is released from the active carbon filter where it was previously adsorbed during exhalation and transported back to the patient with air/oxygen. New anaesthetic is continuously vaporized from the mini-gasifier.



#### ISOCONDA

IsoConDa is Sedana Medical's brand name for the generic drug isoflurane. Isoflurane is a volatile anaesthetic to be used with the AnaConDa. At present, IsoConDa is not being sold and will only be sold after marketing authorisation has been obtained. Sedation with IsoConDa by administration with AnaConDa, compared to the current intravenous standard treatment, provides the patient with a range of medical benefits.

- **Shorter wake-up times.** It is important when the treatment is complete and the patient is awakened that the patient becomes lucid and cooperative as soon as possible It also makes it easier for the staff to plan their work.
- Easier to control the sedation depth. It is easier to awaken the patient every 24 hours to control the neuro-logical status of the patient and reduce the need for extra computer tomography tests.
- Can be used by patients with kidney and liver complaints. Isoflurane is both administered and eliminated through the lungs with minimal metabolism in the body.
- **Has organ-protecting qualities.** Inhalation sedation has qualities that potentially protect the heart, lungs and the brain.
- **Broncho-dilatory effect.** Improves lung function in patients with COPD and asthma.
- Reduced need for analgesic drugs (opiates). When isoflurane is used, the dose of pain relievers (opiates) can be reduced by over 35 per cent. Opiates can cause problems in elderly patients in terms of bowel function treatment and lead to dependence.
- **Clinical studies indicate that mortality is reduced**, that the frequency of delirium tends to fall and that the length of stay in intensive care are shorter.
- Clear recommendations that benzodiazepines should not be used for sedation in an intensive care setting, but alternatives are limited. IsoConDa can take their place.

Isoflurane is currently only approved for use with general anaesthesia. The company has decided to apply for approval for the use of isoflurane for the treatment of mechanically ventilated patients. For this purpose, the company initiated in Q4 2016 a registration-based Phase III clinical trial, which started in 2017. The study is currently underway at about 20 centres in Germany and is expected to be completed in 2019. The purpose of the study is to demonstrate the efficacy and safety of IsoConDa in the treatment of ventilated intensive care patients together with AnaConDa, as compared to propofol administered intravenously. See the section entitled "The road to a global standard method for sedation" for further information.

### PRODUCT ACCESSORIES

In addition to the company's main products, AnaConDa, and in the near future, IsoConDa, it also sells various accessories to facilitate and simplify the use of AnaConDa. These include syringes for supplying AnaConDa with isoflurane, special adapters for connecting the syringes with AnaConDa and the FlurAbsorb filter used to purify and remove any spread of volatile anaesthetics in the intensive care room when sedated with AnaConDa.

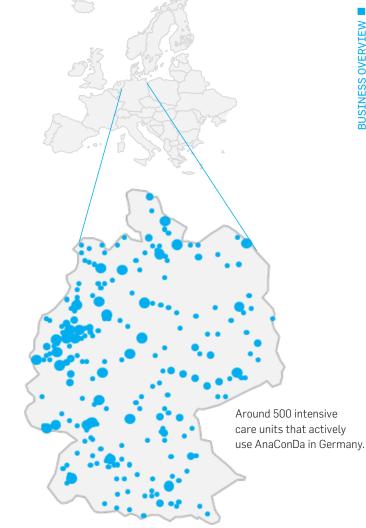
		Isoflurane is a volatile
7		anaesthetic to be used with
the	Ar	naConDa unit.

# Use of AnaConDa and isoflurane

In 2010, the new S3 guidelines for the use of sedation were published in Germany. The guidelines proposed inhalation sedation and the use of isoflurane as an alternative to intravenous sedation in intensive care for certain patient groups. The new guidelines, along with positive statements from several KOLs (key opinion leaders), have led to the extensive use of AnaConDa in Germany. The company estimates that 500 intensive care units around Germany use AnaConDa. With the help of AnaConDa, these clinics have sedated mechanically ventilated intensive care patients for about 300-400,000 days in total. The use of AnaConDa in Germany in 2017 corresponded to approximately two to three per cent of the total number of days. Between 2006 and 2017, the Company sold over 200,000 AnaConDa units in Germany alone and Sedana Medical is displaying continued strong growth.

The positive sales trend and a steadily increasing number of clinics using AnaConDa are regarded by Sedana Medical as a clear indication that existing medications for intravenous sedation is insufficient. There is a need for treatment options and inhalation sedation is a solution to that need.

When IsoConDa is approved as a drug for inhalation sedation, the company believes that IsConDa administered with AnaConDa has very good potential to become a global standard for sedation of mechanically ventilated intensive care patients.





# Clinical evidence

AnaConDa and inhalation sedation have so far been the subject of approximately 100 publications. The studies conducted show a very positive picture of inhalation sedation with the company's AnaConDa. Many of the negative side effects associated with intravenous sedation, such as a long wake-up time, occurrence of hallucinations, delirium and other side effects can be reduced with Sedana Medical's sedation solution and contribute to an improved quality of care for intensive care patients that are sedated.

Below is a summary of results from a selection of comparative studies between AnaConDa and volatile anaesthetics (isoflurane) and traditional intravenous sedation for intensive care.

#### Clinical benefits of AnaConDa-administered inhalation sedation compared with intravenous sedation

Benefits	Inhalation sedation	Intravenous sedation	Referenses	
	with AnaConDa	intravenous setation	Referenses	
Significantly reduced awakening time	10–20 min	90 min–130 hours	[1] [2] [3] [4] [5]	
Significantly reduced time for extubation *	10–35 min	150–600 min	[79,80,81,82]	
Reduced intensive care treatment in deeply sedated patients	4–16 days	6–27 days	[6] [7]	
Limited occurrence of hallucinations and delusions	2 av 10 patients	5 of 7 patients	[8]	
Reduced use of pain reliever 24h after extubation *	2,7mg/hour	4,2mg/hour	[82]	
Reduced mortality in hospitals in patients who have been ventilated for a long time (> 96h)	40%	63%	[9]	
Reduced mortality after 365 days in patients who have been ventilated for a long time (> 96h)	50%	70%	[87]	

\* Extubation means removal of the tube in the throat, thus the end of mechanical ventilation.

Note: Sources of intravenous sedation also include studies with sevoflurane, while data for inhalation sedation with AnaConDa only refer to isoflurane.

<sup>6</sup> Röhm KD, Wolf MW, Schöllhorn T, Schellhaass A, Boldt J, Piper SN. Short-term sevoflurane sedation using the anaesthetic conserving device after cardiothoracic surgery. Intensive Care Med. 2008;34(9):1683-1689.

<sup>7</sup> Mesnil M, Capdevila X, Bringuier S, et al. Long-term sedation in intensive care unit: A randomised comparison between inhaled sevoflurane and intravenous Propofol or midazolam. Intensive Care Med. 2011;37(6):933-941.

<sup>8</sup>Hanafy MA. Clinical evaluation of inhalational sedation following coronary artery bypass grafting. Egypt J Anaesth. 2005;21(3):237-242.

<sup>9</sup> 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 2004;32(11):2241-2246.

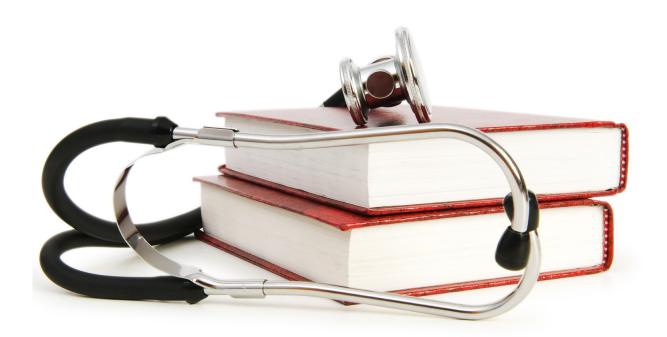
<sup>10</sup> Shelly MP, Sultan MA, Bodenham A, Park GR: Midazolam infusions in critically ill patients. Eur J Anaesthesiol 1991, 8: 21-27. <sup>11</sup>Krannich, A., Leithner, C., Engels, M. et al., "Isoflurane Sedation on the ICU in Cardiac Arrest Patients Treated With Targeted Temperature Management: An Observational Propensity-Matched Study", Society of Critical Care Medicine 45(4):e384-e390, April 2017.

<sup>12</sup> Meiser, A., Laubenthal, H., "Inhalational anaesthetics in the ICU: theory and practice of inhalational sedation in the ICU, economics, risk-benefit." Best practice & research Clinical anaesthesiology 19.3 (2005): 523-538.

<sup>13</sup> Sackey, PV., Martling, CR., Carlswärd, C. et al. Short- and long-term follow-up of intensive care unit patients after sedation with isoflurane and midazolam--a pilot study. Crit Care Med. 2008 Mar;36(3):801-6.

<sup>14</sup> 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

<sup>15</sup> 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

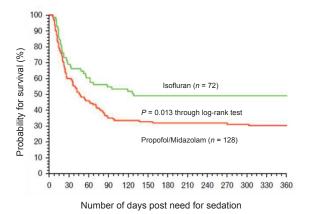


Two of the studies are presented in more detail below. The first study investigates long-term mortality with AnaCon-Da-administered isoflurane compared to intravenous sedation using propofol / midazolam. The second study examines how the lenght of mechanical ventilation and length of intensive care stay are affected by patients being treated with Ana-ConDa-administered isoflurane or midazolam administered intravenously.

#### MORTALITY

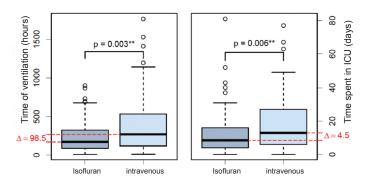
The graph shows a survival analysis for the patients undergoing long-term sedation and mechanical ventilation (> 96 hours). The green curve shows patients administered with isoflurane; the red curve, those patients who were only administered with propofol / midazolam. The study included a total of 369 patients but after excluding patients over 79 years, patients under 40 years and patients receiving a combination of different sedatives, 200 patients remained.

The study results indicate a statistically significant decrease in mortality in patients treated with isoflurane.



#### **STAY IN INTENSIVE CARE**

The graph below shows the difference in time ventilated and in an intensive care environment for patients treated with AnaConDa-administered isoflurane compared with intravenous sedation (midazolam). The study included 432 patients who survived cardiac arrest and underwent therapeutic hypothermia (cooling down) and thus required deep sedation. The patients in the study were divided into two groups, one of which was treated with AnaConDa-administered isoflurane and the other with intravenous sedation. The results from the study were statistically significant and showed that time during ventilation and intensive care was significantly lower for AnaCon-Da-administered isoflurane. The difference in the median was 98.5 hours (p = 0.003) and 4.5 days respectively (p = 0.006).<sup>16</sup>



<sup>16</sup> Krannich, A., Leithner, C., Engels, M. et al., "Isoflurane Sedation on the ICU in Cardiac Arrest Patients Treated With Targeted Temperature Management: An Observational Propensity-Matched Study", Society of Critical Care Medicine 45(4):e384-e390, April 2017.

### Development work

Sedana Medical conducts its development business from its Irish subsidiary, Sedana Medical Ltd. The staff at the Irish company have extensive experience in product development and process validation. An important success factor for Sedana Medical is to continually seek new ways through product development to facilitate and improve therapy inhalation sedation. The results of Sedana Medical's latest development work, AnaConDa-S, was launched in March 2017. The product is a further development of the first generation AnaConDa, enabling more severely ill patients to gain access to inhalation sedation and the benefits it brings with intravenous sedation.

The Development Department in Ireland focuses, inter alia, on the following areas:

- Product development of existing and new products based on or adhering to current technology
- Process development in manufacturing to reduce the cost of manufactured goods as well as to ensure the production capacity of AnaConDa and accessories
- Optimisation of packaging materials and packaging design
- Validation of processes
- Registration of Sedana Medical's products in new countries, the latest example being South Korea, where AnaConDa was registered in Q1 2017, and Japan, where the application was made at the end of 2017.
- Maintenance of quality certificates, including ISO 13485.

# Intellectual property rights

Sedana Medical has an active strategy for intellectual property rights and strives to maximise the protection of its products and technological innovations. To protect these, Sedana Medical uses a strategy that includes patent protection, aggravating measures and registrations.

**Patent protection** Since the development of AnaCon-Da, Sedana Medical has protected its innovations through patents. Sedana Medical's patent portfolio currently includes five patent families and two patent applications. The basic patents for the outgoing model of AnaConDa (100 ml) cease to apply in 2018. For the newly developed AnaConDa-S, the company filed two new patent applications in 2016. One patent application concerns the protection of the device's design (patent name: reduction of dead volume) and the other to prevent competitors from modifying the first generation AnaConDa (100 mL) to thereby create a product with 50 mL dead volume (patent name: decrease of dead volume through filler material) . **Aggravating measures** As an additional element in protecting its products and making it difficult for competitors, Sedana Medical is working on developing solutions in which the entire process of fluid in the bottle to the patient as gas can be protected. These protection will make it easier and safer to connect the AnaConDa system and at the same time complicate the connection of generic preparations. The protection will consist of unique couplings and alternative packaging solutions.

**Registrations** The company will register IsoConDa in Europe and thus receive a ten-year period of data exclusivity on the European market. As the registration applies to IsoConDa administered with AnaConDa, the company will also ensure that the summary of product characteristics states that IsoConDa should only be used with AnaConDa. The procedure means that all other uses of IsoConDa will be considered to be off-label. Any other use of volatile anaesthetics such as sevoflurane and desflurane for the indication of sedation will continue to be off-label.

As regards the US market, the company is investigating the possibility of registering AnaConDa and IsoConDa as a combination product, which means that the only way to provide inpatient sedation for intensive care in the United States will be by using Sedana Medical's two products together.

In addition to these three strategies, the company has acquired extensive knowledge of inhalation sedation and AnaConDa technology over the past ten years in the industry. The three strategies, together with the company's know-how, provide strong protection and give Sedana Medical the freedom that the company needs for its planned marketing efforts.

### Sales

Establishing a new treatment therapy in healthcare takes a long time and requires that opinion leaders within the field support the treatment. If the treatment is not anchored to these persons and expert agencies within healthcare, it is very difficult to succeed. That's why Sedana Medical has focused for a long time on making contact with these people in order to build and develop the treatment. This has been done through clinical studies, education, scientific conferences, and through the exchange of information, experiences and new guidelines. Such activities must be managed by Sedana Medical and it is therefore a clear advantage to conduct sales independently.

Sedana Medical's sales have so far been through both traditional direct sales and through distributors. The company works with product specialists who train the clinics in how the products and treatment are to be used. The product specialists employed by Sedana Medical mainly consist of nurses with a background in intensive care, which means that they possess the knowledge and experience required to educate customers.

#### DIRECT SALES

Direct sales is Sedana Medical's preferred sales channel and account for more than 90 per cent of the company's total sales. Direct sales are made primarily through own the company's own product specialists in Germany, France, Scandinavia and Spain. Direct sales are associated with higher costs than distribution sales and are usually established in larger markets where good sales through distributors have first been demonstrated. The benefits associated with direct sales are that Sedana Medical can, to a greater extent, control the sales process, while the margin is higher. According to Sedana Medical's marketing plan, its own sales organisation will cover the major European markets in connection with the registration of Isoconda in Europe.

# SEDANA MEDICAL – PLAN FOR SALES ORGANISATION UNDER ITS OWN CONTROL IN 2018



#### SALES THROUGH DISTRIBUTORS

As part of the rapid and low-risk establishment of inhalation sedation for intensive care outside the market where the company is represented with its own direct sales, the company has used distributors outside Europe. At present, the company has distribution agreements in Australia, the Middle East, Canada, Croatia, Slovenia, Japan and South Korea. In the short term, the company has no intention of establishing itself in these markets, but still considers that they may potentially be of interest from a commercial perspective in the long term.

### Customer base

Sedana Medical's customer base is primarily comprised of intensive care departments in medium-sized and large hospitals and university hospitals. The product is purchased for clinics through the hospitals' procurement departments and in many cases, Sedana Medical receives a request to participate in procurement, so-called tenders. Sedana Medical's largest market is Germany, which served as a test market to investigate the demand for treatment. In Germany, Sedana Medical has had its own organisation that trained customers to initiate treatment safely. Recently, Sedana Medical has also established its own organisation in France, Scandinavia and Spain to further expand the test market in order to identify need. Although Sedana Medical has only assisted clients in the test markets, increased demand for treatment has been noted. Sedana Medical's customers outside Germany, France and Spain are reached mainly through distributors.

The company also acquires its customers by attending trade fairs such as ESCIM, ICICEM, DIVI, DAC, SFAR, SLRS, and by leading researchers and clinics presenting their findings at scientific conferences sponsored by the company, as well as assisting with the establishment of the treatment at clinics. Sales differ between countries and regions, but throughout all markets, the ambition is to create demand from doctors and nurses who, together with intensive care patients, are the end customers of AnaConDa.

# Examples of scientific conferences that Sedana Medical participates in



Brussels Congress 2017.



Bremen Congress 2017.



Paris Congress 2018.

# As a further step in Sedana Medical's marketing,

the company participates in hospital and medical conferences, scientific conferences as well as international trade fairs to disseminate knowledge about the company's products.



Staff at Sedana Medical's lab in Ireland.

### CSR and Sustainability

Sedana Medical should be a trustworthy and reliable supplier and partner to its customers and business partners, an attractive employer and a long-term investment for its shareholders. The Board at Sedana Medical has established in the company's code of conduct the business ethics and principles that its business activities should be based on, and it is an important tool for preventing and detecting any cases where violations of laws, rules and codes of conduct occur. In all activities, local and global legislation must always be followed and good practices and rules are complied with.

The Code of Conduct covers all employees, directors, subcontractors, consultants and any temporary staff. The Sedana Medical Code of Conduct also covers areas such as sustainability, working environment, health and safety, environment, gender equality and procurement.

In its research and development work, Sedana Medical complies with the Helsinki Declaration, which includes ethical principles for conducting research and development involving people as well as international standards such as Good Laboratory Practices ("GLP") and Good Clinical Practices ("GCP").

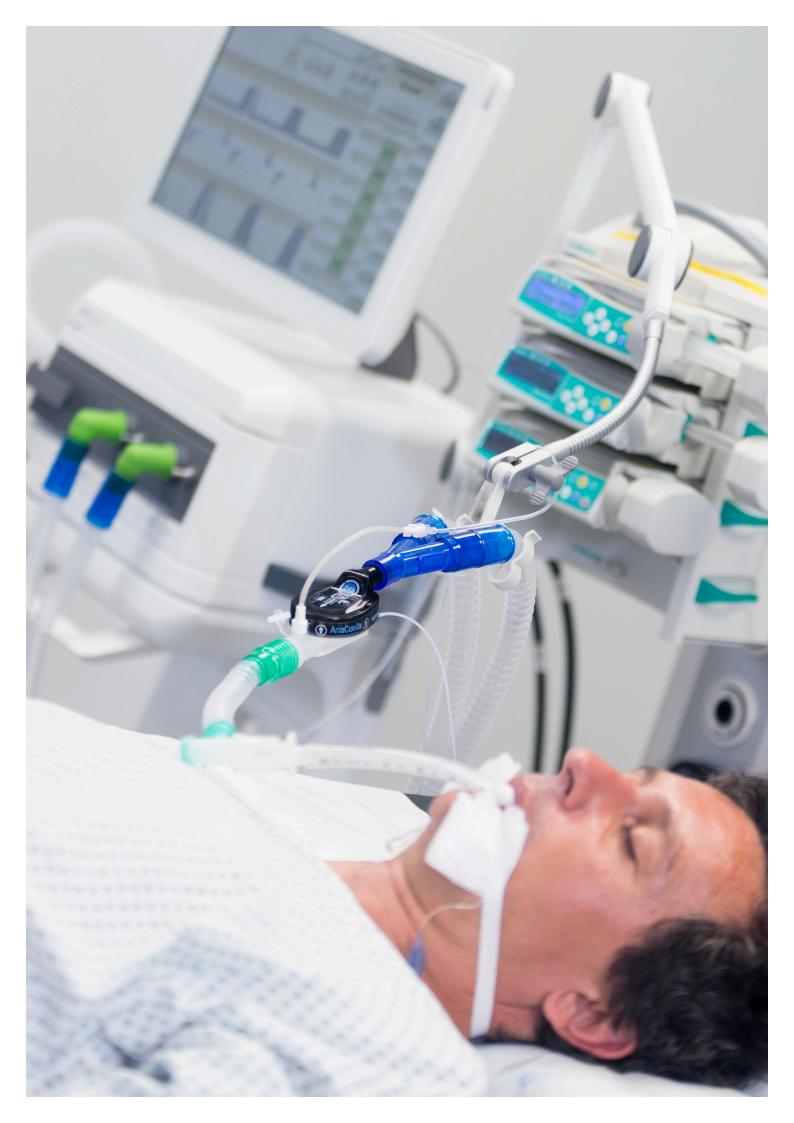
Activities must be carried out in an environmentally sustainable manner based on the requirements of the business. Everyone within the company will perform their work with minimal impact on health and the environment and strive for continuous improvement. Goods and services should be delivered in a way that demonstrates awareness of and care for environment.

No forms of direct or indirect improper payment are tolerated, whether this be a direct bribe or other kind of payment, gift, benefit, compensation or other representation that could constitute a breach of law or which could affect or seem to affect the company's reputation.

### QUALITY WORK

Sedana Medical's business is quality-assured in accordance with ISO13485:2016.

Sedana Medical strives for openness and transparency in its activities and development of sustainability work is ongoing.



# SHARE INFORMATION

### Facts about the Sedana Medical share

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

Number of shares * 17 072 538 Market capitali- sation MSEK * 649 Ticker SEDANA ISIN SE0009947534	Listing	Nasdaq First North Stockholm		
Market capitali- sation MSEK * 649 Ticker SEDANA		17 072 538		
sation MSEK * 649 Ticker SEDANA				
0257477		649		
ISIN SE0009947534	Ticker	SEDANA		
	ISIN	SE0009947534		

\* Per 31 December 2017

#### NASDAQ FIRST NORTH AND CERTIFIED ADVISER

First North is an alternative marketplace for Nordic growth companies, designed primarily for small and medium-sized companies. It does not have the same legal status as a regulated market, and the regulations are somewhat less extensive than those relating to the stock market's major marketplaces. All companies whose shares are traded on First North have a certified adviser that oversees the company's compliance with First North's regulatory framework for providing information to the market and investors. Sedana Medical's appointed certified adviser was Pareto Securities until the end of the year. From 1 January 2018, Erik Penser Bank is the certified adviser.

### SHARE CAPITAL

The total number of outstanding shares as of 31 December 2017 amounted to 17,072,538 shares. At at the end of the year, the share capital amounted to SEK 1,707,254. At the Annual General Meeting, each share entitles the holder to one vote and each shareholder is entitled to cast his or her vote in accordance with the full number of shares he or she holds. All outstanding shares are fully paid up. The company's share capital is expressed in Swedish kronor (SEK) and is distributed over the company's outstanding shares with a quota value of SEK 0.1 per share.



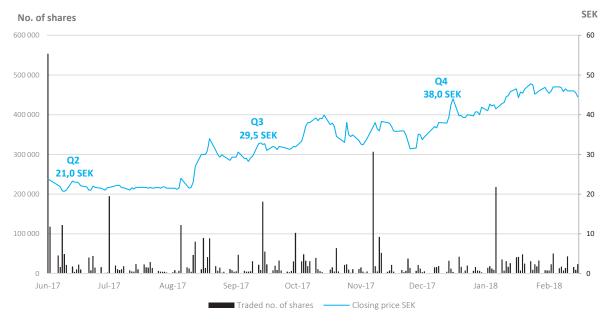
The share capital's development over time is shown below:

DATE	TRANSACTION	CHANGE NO. OF SHARES	TOTAL NO. OF SHARES	CHANGE SHARE CAPITAL (SEK)		NOMINAL VALUE (SEK)
2004-10-20	Formation of company	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	Share split <sup>1)</sup>	8 671 320	8 680 000	0	868 000	0,1
2017-06-20	Conversion of shareholder loan	613 594	9 293 594	61 359	929 359	0,1
2017-06-20	Conversion of convertible loan	1 881 509	11 175 103	188 151	1 117 510	0,1
2017-06-20	New share issue (IPO)	5 128 205	16 303 308	512 821	1 630 331	0,1
2017-07-10	IPO overallotment option exercise	769 230	17 072 538	76 923	1 707 254	0,1

<sup>1)</sup>Share split 1:1000.

#### SEDANA MEDICAL'S SHARE PRICE AND SALES

Share price and trading volume



#### TRADING IN SHARES

The introductory price was SEK 19.50. In 2017 (from the listing date of 21 June), a total of 3,511,916 million Sedana Medical shares were traded for a value of MSEK 111, corresponding to a turnover rate of 23 per cent. On average, 29,190 shares are sold per trading day. The initial payment price was SEK 23.8 and at the end of the year the closing price was SEK 38.

#### SHARE PRICE TREND

In the course of the year, the Sedana Medical share increased 95 per cent from the introductory price, while the First North All Share Index fell by 0.06 per cent in the same period.

The highest payment price was SEK 39.9 SEK recorded on 3 November 2017 and the lowest price paid was SEK 20.7 recorded on 29 June 2017.

At the end of 2017, the Sedana Medical share was listed at SEK 38, corresponding to a market capitalisation of SEK 649 million.

#### SHAREHOLDERS LOCK-UP COMMITMENT

Major shareholders, shareholders and senior executives have undertaken, with certain provisos, not to sell their respective holdings for a certain period of time after the trade on Nasdaq First North began on 21 June 2017 (the "lock-up period"). The lock-up period is 360 days for Board members, senior executives and shareholders who, prior to listing of the Sedana Medical share, had a holding of more than five per cent of the total shares and votes in the company. The lock-up period is calculated from the listing date of 21 June 2017. Shares that accrue to larger shareholders, shareholders who are Board members and senior executives in connection with the exchange / conversion of convertible bonds and shareholder loans on the listing date are also covered by the lock-up commitment. The lock-up commitment does not include any shares acquired in return for cash payment within the framework of the offer in connection with the listing.

#### THE 10 LARGEST SHAREHOLDERS AS OF 31 DECEMBER 2017

	Number of	
	shares	Share (%)
Sten Gibeck	2 105 744	12,33%
Linc AB	1 821 901	10,67%
Magiola Consulting	1 427 867	8,36%
Michael Ryan	1 108 083	6,49%
HealthInvest Partners AB	1 024 817	6,00%
Ron Farrell	906 397	5,31%
Alto Invest SA	748 228	4,38%
Brohuvudet AB	512 800	3,00%
Zaragatero Ltd	503 404	2,95%
Tony Mc Carthy	439 823	2,58%
Ten largest shareholders	10 599 064	62,08%
Others	6 473 474	37,92%
Total *	17 072 538	100,00%

\* After the end of the period the number of shares has increased with 208 000 due to excercise of warrants, program 2014/2019. The chairman of the board in Sedana Medical AB (publ) has as of the excercise of the warrants inceased his shareholding with 79 241 shares. CEO's shareholding is 260 000 shares.

#### DISTRIBUTION OF OWNERS IN SIZE CLASSES

	No. of shareholders	No. of shares	%
1-500	323	58 939	0,35%
501-1 000	64	54 028	0,32%
1 001-5 000	102	220 872	1,29%
5 001-10 000	23	162 921	0,95%
10 001-15 000	12	148 666	0,87%
15 001-20 000	10	172 699	1,01%
20 001-	58	16 254 413	95,21%
Total	592	17 072 538	100%

Source: Euroclear Sweden

#### INCENTIVE PROGRAMME

At the Annual General Meeting on 19 May 2017, it was decided to establish a warrant option-based incentive programme intended for key employees in the Company. In connection therewith, it was decided to issue a total of 310,149 warrants between 2017 and 2021, all of which were subscribed to and assigned to the Company's subsidiary Sedana Medical Incentive AB for further transfer to participants in the incentive programme. In total, 310,149 warrants have been transferred to participants in the programme. All participants are senior executives in the company. The warrants have been transferred under market conditions. The transfer price is calculated using the Black & Scholes model of an independent institution. Each warrants entitles the holder to subscribe to one share in the company at a subscription price corresponding to 130 per cent of the subscription price in the IPO offer, i.e. SEK 19.50.

The warrants may be utilised during the period 15 May 2020 to 31 January 2021. The warrants are furthermore subject to customary conversion conditions for conversion in connection with issues, etc. Upon full exercise of all warrants granted to participants in the incentive programme, the company's share capital will increase by approximately SEK 31,015 by issuing 310,149 shares, corresponding to a dilution of approximately 1.8 per cent based on the number of shares in the company on the balance sheet date.

#### WARRANT PROGRAMME

The company has 260 outstanding warrants series 2014/ 2019, which were issued at the Extraordinary General Meeting on 24 June 2014. The warrants entitle the holder to subscribe shares in Sedana Medical during the period from registration of the warrants until 31 December 2019. Customary conversion conditions apply to the warrants in the event the company carries out changes to its share capital and or the number of shares through, for example, a new issue, a bonus issue, merger or division of shares. Each warrant entitles the holder to subscribe to 4,000 shares. In total, outstanding warrants entitle the holders to subscribe to 1,040,000 shares at an issue price of SEK 2.5 per share.

All warrants in the 2014/2019 issue are subscribed to by current shareholders, related parties and senior executives in the company. After the balance sheet date, 52 warrants have been utilised and 208,000 new shares have been added, which increased the share capital by SEK 20,800, corresponding to a dilution of 1.2% based on the number of shares in the company on the balance sheet date. Following utilisation, 208 warrants in the 2014/2019 issue remain. With full utilisation of all the remaining warrants in the 2014/2019 issue, the company's share capital will increase by SEK 83,200 by issuing 832,000 shares in the company, corresponding to a dilution of 4.9 percent based on the number of shares in the Company on the balance sheet date.

# DEFINITIONS

# Glossary

#### ACUTE PANCREATITIS

Acute pancreatitis is an acute onset of inflammation of the pancreas which, among other things, leads to pain.

#### ANACONDA

AnaConDa is the trade name of Sedana Medical's medical device that makes it possible to administer volatile anaesthetics in a simple and safe manner. AnaConDa stands for anaesthetic conserving device.

#### ANAESTHESIA

Anaesthesia is another word for sedation and means prevention of the ability to perceive, or have awareness of, sensory impressions such pain, pressure, heat, cold or touch

#### ANAESTHETIC/ANAESTHETICS

Anaesthetic/anaesthetics are a drug (drugs) that sedate, anaesthetise and suppress anxiety.

#### **AORTIC ANEURYSM**

Aortic aneurysm means a rupture in a vein in a major bodily artery - aorta and is a condition where blood vessels are dilated and blood pours in due to a weakening of the vessel wall.

#### CRO

Contract Research Organisation

#### DGAI

Refers to the German organisation for intensive care doctors and stands for Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin.

#### DIVI

Refers to the German organisation Deutsche Intersiziplinäre Vereinigung für Intensiv- und Notfallmedizin.

#### EMA

European Medicines Agency

#### FDA

US Food and Drug Administration

**ICU** Intensive Care Unit

#### INHALATION

Inhalation means inhalation of e.g. gas or drugs.

#### INTRAVENOUS

Intravenous injection means that the drug is injected directly into the patient's bloodstream via a cannula.

#### ISO 13485

ISO 13485 is a standard for quality management intended for medical classification and describes how to handle and approve products intended for use in health care.

#### ISOCONDA

Brand name for Sedana Medical's drug candidate with isoflurane as a generic substance.

#### ISOFLURANE

Isoflurane is an anaesthetic and a general anaesthetic intended for inhalational anaesthesia.

KOL

Key opinion leaders

#### MECHANICALLY VENTILATED PATIENTS

Patients with breathing assistance and who breathe with the help of a respirator.

#### METABOLISM

Metabolism is the collective term for the processes in which nutrients or drugs are absorbed, converted or broken down in the body.

#### OFF-LABEL

Off-label means that a drug has not been approved by an authorised drug authority for the specific indication for which it is used, is used for an unauthorised age group, in another dosage, or is administered in a manner other than that for which the drug was originally approved. Marketing of a drug outside the areas for which it was approved is prohibited.

#### SEDATION

Sedation means that a medical procedure is used to place a patient in a state of reduced consciousness to relieve apprehension, anxiety and pain. One of the main uses for sedation is within intensive care and sedation constitutes one of the more common interventions performed there.

#### SEPSIS

Sepsis is the same as blood poisoning and indicates a potentially fatal condition which is often caused by an infection.

#### SEPTIC SHOCK

Septic shock is a life-threatening form of sepsis which occurs when the blood pressure drop that occurs during sepsis cannot be stopped by intravenous fluid delivery.

#### SUBARACHNOID HAEMORRHAGE

Subarachnoid haemorrhage is bleeding in the area between the brain and the thin tissues that cover the brain. This area is called the Subarachnoidalrummet.

#### VOLATILE

Drugs that easily go from a liquid to gaseous form and thus are easily gasified.

# **DIRECTORS REPORT**

# About the business

Sedana Medical is a Swedish medical technology company on the way to also becoming a pharmaceutical company. The Group's operations include development, manufacturing and sales of medical devices and development of products and pharmaceuticals that are based on or have synergy with the AnaConDa technology. The technology enables simple and safe conversion of volatile liquid into gas (gasification) and reuse (reflection) of volatile anaesthetics for sedation of intensive care patients. The Group's product portfolio currently includes AnaConDa with accessories and in the near future the drug candidate IsoConDa, the Group's future brand for isoflurane.

Volatile anaesthetics have long been used to sedate patients in connection with surgery. Anaesthesia machines that are complex and capital-intensive and need specially trained staff are used for this purpose. Traditional anaesthesia machines lack several vital features which enables them to be routinely used in an intensive care department. The Group's product AnaConDa, which, put simply, can be seen as an anaesthesia machine in miniature, introduces a solution which makes it practical and economically feasible to use volatile anaesthetics to sedate mechanically ventilated ICU patients. The market for sedation of mechanically ventilated ICU patients currently consists of established drugs that are given intravenously. Sedation through inhalation of volatile anaesthetics has in many ways proved to be a safer and more effective solution for sedation of ICU patients than the current intravenous sedation. Despite the fact that Sedana Medical does not yet have marketing authorisation for the IsoConDa, the Group has for many years shown an increasing net sales through selling the CE-marked product AnaConDa.

Sedana Medical's vision is to develop inhalation sedation with IsoConDa and AnaConDa into a global standard method for sedation of mechanically ventilated patients within intensive care.

To achieve this vision, the Group has been conducting a clinical phase III registration study since autumn 2016, where the drug IsoConDa and the therapy inhalation sedation is expected to be approved together with AnaConDa in the year 2020.

Sedana Medical operates its own sales from a few countries in Europe via subsidiaries and branches of the parent company Sedana Medical AB (publ), organisation number 556670–2519. In Germany, operations consist of sales, inventory and distribution, which constitutes a branch of the parent company. In Spain, sales are managed from a branch of the parent company. Germany is comfortably the Group's largest market, with more than 85% of total sales. Besides Germany and Spain, the Group manages its own sales force also in France via a wholly owned subsidiary Sedana Medical Sarl. The Company's own sales operations in the Nordic countries are managed via the parent company. For several other countries in the world, sales occur through cooperation with distributors.

The company conducts research and development in Ireland through the wholly owned subsidiary Sedana Medical Ltd. The manufacturing of AnaConDa products occurs via contract manufacturers but is controlled via the Irish subsidiary. The headquarters and the parent company's registered office are based in Danderyd, Sweden. In June 2017, the company's shares (ticker: SEDANA) were listed on the Nasdaq First North stock exchange.

# Significant events January – December 2017

# Q1

- On 1 February 2017, Christer Ahlberg was appointed as new CEO of the Sedana Medical Group.
- In March 2017, AnaConDa was approved in South Korea, which is the first approval on the Asian market.
- The newly developed product AnaConDa-S was launched during the quarter.

## **Q**2

- Decisions were made regarding a bonus issue and split of shares as well as conversion to public company at the Extraordinary General Meeting on 5 April.
- The clinical record for the registration study IsoConDa was approved by the German Drug Administration, BfArM, and by ethical committees, after which the study went into an operative phase with inclusion of the first clinics and patients.
- The Group's headquarters were registered in Danderyd.
- A subsidiary, Sedana Medical Incentive AB, was established in Sweden for the administration of an incentive programme in Sedana Medical AB (publ).
- Sedana Medical's shares were listed on the Nasdaq First North stock exchange on 21 June 2017.
- Offering and listing on Nasdaq First North 21 June. At the offering, bids were heavily oversubscribed.
- In June 2017, a settlement was entered with Teleflex Medical Inc., which means that all existing royalty rights for AnaConDa products are dissolved. Through the deal, Teleflex has no royalties for the sale of AnaConDa.

## Q3

- In South Korea, the first patients in Asia were treated using the AnaConDa device.
- The process of recruiting new clinics to the registration study for IsoConDa has continued in Germany, and around half the planned number of clinics were recruited.
- The overallotment option in the IPO was exercised.
- Direct sales to hospitals in the Nordic region were initiated through recruitment of in-house sales personnel.

# Q4

- Senior Consultant and Associate Professor Peter Sackey was recruited as Chief Medical Officer (CMO). Peter Sackey has over twenty years' clinical experience as a physician within anaesthesiology and intensive care, and joined Sedana from a position within Perioperative Medicine and Intensive Care at Karolinska University Hospital in Solna, Sweden. Sackey is one of the world's leading researchers in the field of inhalation sedation and was the first to use AnaConDa within intensive care.
- All remaining outstanding warrants in the incentive programme 2017/2021, which was initiated in conjunction with the IPO, were acquired by incoming Chief Medical Officer Peter Sackey.
- The work with recruiting patients and new clinics to the registration study IsoConDa continued in Germany.
  16 clinics were approved, and another 2 were close to approval. In addition, further 10 or so clinics were under evaluation or in the process of contract finalisation.
- In November, Sedana Medical's distributor in Japan applied for registration of the medical device AnaConDa.
- In December, the sales organisation was reinforced with more Key Account Managers in France to meet demand.

# Expected future development

In the coming years, the Group is working on realising its strategy and in doing this achieving its established financial goals.

#### FINANCIAL GOALS

The company's aim until approval and registration of IsoCon-Da has been obtained is to increase sales by an average of more than 20 per cent per year, while maintaining an operating profit before depreciation and amortisation (EBITDA) not materially negative in parallel with building up a larger market and sales organisation.

The company's goal is, three years after the registration of IsoConDa, to achieve sales of more than SEK 500 million (excluding the USA) and an EBITDA margin of 40 per cent.

#### STRATEGY

The company has designed and works in accordance with a strategy that can be summarised in the following four points:

# 1 Registration of IsoConDa for inhalation sedation in Europe

Complete the current registration study and apply for approval of the IsoConDa drug within the EU.

#### 2 To raise awareness and usage of AnaConDa.

Strong focus on the success of the market and sales organisation. Sales work will be carried out by Sedana Medical own personnel in the most important markets within the EU and through distributors in other markets inside and outside the EU. To actively participate in the major international conferences with symposia and seminars.

#### 3 Implement a strategic plan for regulatory registration of AnaConDa and IsoConDa in the USA.

To initiate registration activities in the USA with the aim of launching in 2022. The market has great potential, especially given the fact that the price level for intravenous drugs is about three times higher than in Europe.

#### 4 To develop intellectual property protection.

Establish a commercial and intellectual property protection to prevent the competition from copying AnaConDa and off-label use of isoflurane after registration of IsoConDa.

## Risks

Sedana Medical's operations are affected by many factors that the Company can in some ways partially control and in some ways not at all. These factors can also be expressed by various risks. The risks can have a more or less significant impact on the Company's earnings and position depending on whether and how they occur.

Described below are some of the risks the Company considers most important for the future development.

#### INDUSTRY AND BUSINESS-RELATED RISKS

# Risks related to the regulatory environment for medical devices and pharmaceuticals

Sedana Medical's AnaConDa products and the upcoming drug IsoConDa are subject to extensive regulations worldwide and are monitored by various industry-specific regulatory authorities. In addition to such industry-specific regulation, Sedana Medical is also subject to a number of other requirements and restrictions resulting from environmental, health and safety laws. These requirements may also be expanded in the future. The costs of complying with applicable laws, requirements and guidelines can be high. In addition, the regulatory environment has generally become more strict and comprehensive with time. If these regulations are not followed, it could result in sanctions which could significantly increase Sedana Medical's costs, lead to delays in development, the commercialisation of the Company's product candidates and significantly harm the ability to generate planned revenues and achieve profitability. If these risks are actualised, it could have a significant negative impact on the company's operations and financial position.

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

Before Sedana Medical's AnaConDa products, either in combination with IsoConDa or not, may be marketed within the treatment area inhalation sedation within intensive care in a new national or regional market, the Company must obtain marketing approval or similar permission from relevant authorities in the countries where the Company intends to market and sell its products. Changes in the process and the requirements for market access may negatively impact Sedana Medical's ability to generate desired revenues. In order for Class II and III medical devices to be marketed in the EU, it is required that a certificate be issued by a so-called "notified body" which confirms that the established regulatory requirements are met. The Company's certificate for its medical devices is valid until 2020. Because decisions made by a "notified body" are valid for a certain period, the certificate must be renewed. Such a renewal process can be time-consuming, particularly when the original application is expanded to new treatment areas or otherwise undergoes significant changes. All of the risks listed above could have a significant negative impact on the Company's operations, financial position and earnings.

# Risks related to the implementation and results of clinical studies

During Q4 2016, Sedana Medical initiated a registration-based clinical study for its drug candidate IsoConDa (isoflurane) for use in the treatment area inhalation sedation within intensive care. The implementation of the study is crucial for being able to market the Company's products AnaConDa and AnaConDa-S together with IsoConDa as therapy for inhalation sedation within intensive care in the markets which the Company plans to target. The company is thus dependent on obtaining positive results in the ongoing clinical studies to be able to achieve its long-term business goals. The implementation of clinical studies is associated with a number of risks. Amongst other things, there is always the risk of delays and that the costs of studies will be higher than estimated. Delays can arise due to problems finding places for studies, problems in obtaining the required regulatory approvals for performing studies, problems with recruitment of patients, problems reaching satisfactory agreements with, for example, contract research companies, suppliers and study sites, etc. Delays can lead to increased costs, but also to the launch of a product being delayed, which can lead to the company not generating revenues as expected. Increased costs can also arise due to the cost per patient being higher than estimated or due to a lack of quality in performing the studies at the hospitals where they are implemented, etc. Clinical studies can prove to have negative or inadequate results within the treatment area in which Sedana Medical's products are focused. If the desired results are not achieved, this can lead to the necessary marketing approvals not being obtained, which in turn may endanger the company's ability to market and sell its products and product candidates. If the risks above are realised, it could lead to a significant negative impact on its ability to generate revenues and have a significant negative impact on the company's operations, financial position and earnings.

#### Risks related to third party agreements regarding, amongst other things, the performance of clinical studies and manufacturing

Sedana Medical hires external companies such as contract research and manufacturing companies for the performance of clinical studies and for the manufacturing of its products. The operations of these companies are subject to extensive requirements regarding reporting, safety and environment. There is a risk that these companies will not comply with applicable laws, rules and relevant ethical standards such as good manufacturing practice (GMP) and good clinical practice (GCP). There is also a risk of inadequate or non-delivery of products or services from current and future recruited external companies. This can negatively affect the development and sales of Sedana Medical's products by causing delays and increased costs. The company is not dependent on any individual contract research or manufacturing company, but replacing suppliers can be both costly and time-consuming. Activation of the risks described above could have a negative impact on Sedana Medical's operations, financial position and earnings.

Risks related to unsuccessful market acceptance from caregivers, patients and healthcare payers, including the opportunity to be covered by compensation systems

Even if a product meets the requirements for market access, such as through obtaining marketing authorisation, there is a risk that the desired level of market acceptance will not be achieved from doctors, hospitals, patients, healthcare professionals and the industry in general, which could prevent Sedana Medical from generating and achieving desired revenues and could have a significant negative impact on the Company's operations, financial position and earnings.

#### **Risks related to competition**

Sedana Medical's products for inhalation sedation of ICU patients primarily faces competition from sedation drugs for intravenous treatment. Intravenous sedation is a well-established therapy method and currently standard treatment for sedation of ICU patients. Even if Sedana Medical believes in the ability of its products to take market shares from companies selling drugs for intravenous sedation, there is always a risk that the company will not achieve the desired market acceptance. Even if Sedana Medical should be successful in taking market shares from traditional treatment with sedative drugs for intravenous treatment, there is a risk of being exposed to competition within the indication inhalation sedation. The risks related to competition could lead to a significant negative impact on the Company's operations, financial position and earnings.

#### Risks related to macroeconomic factors including pricing and demand of medical products

Because Sedana Medical intends to market and sell their products in many parts of the world, the Company may be affected by the general demand and pricing of products for the treatment of ICU patients in relevant markets. Sedana Medical cannot predict the development of financial markets, economic and political climates, or predict macroeconomic events, e.g. that a low business cycle or a weak economic development may put a strain on the market for medical devices and pharmaceuticals and lead to increased pressure on hospitals, authorities and other healthcare payers to cut costs, which potentially lowers the will to pay for the products in general, Sedana Medical's products included. If the risks above are actualised, it could have a significant negative impact on the Company's operations, financial position and results.

#### Dependence on sales and development of a few products

At present, Sedana Medical is mainly focusing on sales of AnaConDa and the implementation of the a clinical phase III study of its drug candidate IsoConDa for the purposes of obtaining marketing approval for the product for use together with the Company's AnaConDa medical devices. The Company's growth target is based entirely on a technology and therapy focus: inhalation sedation within intensive care. Sedana Medical's operations, financial position and earnings could be significantly negatively affected by setbacks in the clinical phase III study.

#### Risks related to key personnel and qualified personnel

Sedana Medical is dependent on its employees, especially senior executives and other key employees. The Company is dependent on being able to recruit highly qualified staff for the continued development of its operations. If Sedana Medical should lose any of its key employees or not succeed in recruiting qualified personnel, it could have a negative effect on the Company's operations, financial position and results.

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

Patents and other intellectual property rights are a key asset in Sedana Medical's operations and thus any future successes are largely dependent on the ability to maintain existing intellectual property rights such as trademarks and patents and to obtain patent protection for filed and future patent applications. The company's patent protection for the old version of the AnaConDa product expires within a short time, which allows for competitors to manufacture and sell competing products. Sedana Medical has applied for a patent for the new improved product AnaConDa-S, which is expected to replace the old one within a short time. If the company's patents and other intellectual property rights should be lost or restricted, or if the company in general cannot maintain the required patent protection, it could significantly negatively affect its operations, earnings and financial position.

#### Risks related to fluctuating exchange rates

The Company reports its financial position and earnings in SEK. Therefore, most of the Company's operating expenses and revenues consist of EUR, and in the future it is expected that the Company's operating income and expenses will also consist of other currencies. As a result of this, Sedana Medical is subject 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 of the conclusion of an agreement to when payment is due under the agreement, which can lead to currency translation losses or gains (so-called transaction exposure) which the Company cannot predict. Currency transaction losses could lead to a significant negative effect on the Company's future operations, financial position and profits.

#### **Risks related to current and later funding**

The extent of the resources which will be required for the implementation of Sedana Medical's business plan, including development and commercialisation of medical devices and pharmaceuticals, depends on a number of factors which are not known at this time. There is a risk that Sedana Medical will not achieve sufficient income in time to be able to fund its operations and development. If the Company cannot obtain acceptable funding, it may limit the company's ability to maintain its position in the market or the competitiveness of its offerings. Sedana Medical may also be forced to seek additional funding in order to continue its operations. Such funding can be sought with external investors or existing shareholders

and occur through public or private funding initiatives. There is a risk that new capital cannot be obtained when needed or on acceptable terms or that received capital will not be enough to fund operations in accordance with the established business plan and established goals. If risks associated with problems with obtaining sufficient income or sufficient funding to maintain the Company's operations are actualised, it could have a significant negative impact on its continuing operations, financial position and results.

#### Risks related to exposure to tax requirements and changes in tax regulation

Sedana Medical assesses that the Company complies with applicable tax legislation. However, from time to time various legislative alternatives are proposed which could negatively impact the Company's tax situation. Furthermore, tax regulation is 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 in such an event. A decision by the tax authorities may change Sedana Medical's previous tax situation, which could have a negative impact on the Company's operations, financial position and earnings.

#### **Risks related to accumulated tax deficits**

As a result of the operations having generated significant deficits, Sedana Medical has high accumulated tax deficits. Ownership changes which lead to someone having a controlling influence over the Company can lead to limitations in the ability to use the deficits in the future. The ability to use the deficits in the future could also be negatively affected by changes in applicable legislation. Such restrictions and changes could have a negative impact on Sedana Medical's business and financial position.

# Financial multi-year overview

#### Financial summary - Group Consolidated

2017	2016	2015
40 427,7	32 154,6	28 113,5
29 661,7	21 346,4	17 849,2
-736,2	994,3	-1 174,2
-3 487,8	617,8	-1 386,7
-3 875,7	1 285,6	-1 205,4
73,4%	66,4%	63,5%
-1,8%	3,1%	-4,2%
-8,6%	1,9%	-4,9%
-9,6%	4,0%	-4,3%
131 376,3	23 624,4	12 401,3
88,6%	5,3%	3,6%
650,2%	84,9%	131,8%
16,5	15,7	11,0
	40 427,7 29 661,7 -736,2 -3 487,8 -3 875,7 73,4% -1,8% -8,6% -9,6% 131 376,3 88,6% 650,2%	40 427,7         32 154,6           29 661,7         21 346,4           -736,2         994,3           -3 487,8         617,8           -3 875,7         1 285,6           73,4%         66,4%           -1,8%         3,1%           -8,6%         1,9%           -9,6%         4,0%           131 376,3         23 624,4           88,6%         5,3%           650,2%         84,9%

Financial summary - Parent Company					
KSEK	2017	2016	2015	2014	2013
Net Sales	43 129,3	31 494,9	27 940,0	21 261,3	17 705,1
Gross Profit	16 669,2	13 339,2	12 105,1	11 708,0	11 768,7
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-4 263,3	1 345,5	6 088,5	164,7	331,6
Earnings Before Interest and Taxes (EBIT)	-5 438,9	1 277,2	5 957,7	-830,5	-59,4
Net income	-4 626,7	1 659,1	6 179,5	-1 508,3	-57,4
Gross Margin (%)	38,6%	42,4%	43,3%	55,1%	66,5%
EBITDA %	-9,9%	4,3%	21,8%	0,8%	1,9%
EBIT %	-12,6%	4,1%	21,3%	-3,9%	-0,3%
Net income % of net sales	-10,7%	5,3%	22,1%	-7,1%	-0,3%
Total assets	143 883,5	38 328,8	31 230,9	18 734,4	14 894,0
Equity ratio	86,1%	24,3%	57,6%	42,1%	62,7%
Quick ratio	489,4%	59,6%	251,6%	81,2%	110,1%
Average number of employees	8,7	7,4	7,0	5,0	5,0

## Financial summary January – December 2017

#### REVENUES

Revenues for the whole year amounted to 43,290 (35,667) KSEK. The increase is mainly attributable to an increase in net sales of 8,273 (26%). The Group's sales are exclusively in EUR, and corresponding sales figures cleared of exchange rate effects were 24% for the whole year of 2017. The increase in net sales is almost entirely due to increased sales in Germany. Revenues for Q1-2 include capitalised development expenses of 1,291 (1,580) KSEK. The same item is also included in other operating expenses, and illustrates the capitalisation of development expenses in accordance with a gross reporting principle. As of Q3, the Group has ceased to apply this gross reporting principle and now reports capitalised development expenses on a net basis under external and personell expenses. Please see the note on accounting principles for more information. Revenues also include other operating income of 1,572 (1,932) KSEK.

#### COST OF GOODS SOLD

Cost of goods sold amounted to 10,766 (10,808) KSEK over the whole year. During 2016, costs relating to the depreciation value of gas monitors was itemised under cost of goods sold. Gas monitors have been reclassified from current assets to fixed assets in 2017, and the depreciation is thus now reported under the item 'depreciation'.

#### **OTHER EXTERNAL EXPENSES**

Other external expenses for the period January-December amounted to 16,825 (10,606) KSEK. The increase is primarily attributable to the listing of the company's share during 2017 and the implementation of the Group's new business plan, and the associated expansion of the organisation.

#### PERSONNEL EXPENSES

Personnel expenses during the whole of 2017 amounted to 16,195 (11,670) KSEK. The increase in personnel expenses is due to a difference in the personnel structure compared with the previous year. The Group recruited a new CEO during the first quarter of 2017 and has gradually increased the number of sales employees during the year.

#### DEPRECIATION AND AMORTISATION

Depreciation for the period January-December was 2,752 (377) KSEK. The increase is due to increased depreciation of intellectual property rights and a reclassification of assets. Depreciation of intangible assets increased as a result of the acquisition of remaining intellectual property rights in relation to AnaConDa, which took place in Q2. A reclassification between current assets and fixed assets was carried out in Q3 in relation to the gas monitors owned by the Group. The entire year's effect of the reclassification of the gas monitors has been reported in Q3. Please see the section on accounting principles for more information.

#### **OPERATING INCOME**

The operating income during the period January-December amounted to -3,488 (618) KSEK. The decrease is mainly due to increased operating expenses in connection with the Group's new strategy and increased depreciation and amortisation as a result of increased intellectual property rights and a larger acquisition of gas monitors compared with 2016.

#### FINANCIAL ITEMS

Net financial items amounted to -1,113 (19) KSEK for the whole year of 2017. The negative financial net is primarily due to exchange rate changes and negative net interest. The main reason for the negative net interest is new interest-bearing borrowing during Q2 and increased interest to the owners. The increased interest to the owners occurred in connection with conversion of a shareholder loan into new shares at the time of the listing of the company's share on Nasdaq First North.

#### ТАХ

The Group reported a tax of 725 (649) KSEK during January-December. The tax charges are primarily due to changes in deferred tax.

#### NET INCOME

The Group reported a net income of -3,876 (1,286) KSEK during January-December. The decline in profit and between the years is mainly due to increased operational costs, with the Group's new strategy, a higher cost for gas monitors and a higher negative financial net.

#### EQUITY AND LIABILITIES

Equity as of 31 December 2017 amounted to 116,403 (1,262) KSEK, which corresponds to an increase of 115,120 KSEK. The increase is due to the new share issue that was carried out in connection with the listing of the company's share on Nasdaq First North, and the overallotment option that was exercised in Q3. Equity includes transaction costs associated with the listing of the company's share.

Long-term liabilities at the end of the period amounted to 0 (6,880) KSEK.

Current liabilities at the end of the period amounted to 14,973 (15,469) KSEK and consisted mainly of accounts payable of 7,873 (1,917) KSEK, as well as accrued expenses of 5,505 (2,808) KSEK.

#### CASH FLOW

Liquid funds at the end of the period amounted to 85,322 (8,296) KSEK. Cash flow from operations before changes in working capital was -4,232 (186) KSEK.

Cash flow from operations including changes in working capital amounted to 496 (-413) KSEK. The positive change in working capital is due to an increase in operating liabilities. Cash flow from investments amounted to -25,882 (-4,928) KSEK for the whole year of 2017. Cash flow from financing activities totalled a net of 102,340 (10,346) KSEK for the whole year of 2017. The new share issue in June in connection with the listing of the company's share and the exercise of the overallotment option in July were the main reasons for positive cash flow from financing activities in 2017. The period January-December generated a positive total cash flow of 76,953 (5,006) KSEK.

#### INVESTMENTS

Investments during the financial year 2017 amounted to 25,882 (4,928) KSEK. Investments in 2017 primarily relate to:

- Capitalised development expenses, 15,747 KSEK
- Acquisition of the remaining intellectual property rights from Teleflex inc., 6,359 KSEK
- Purchase of machines and other technical facilities, 2,624 KSEK
- Purchase of equipment and tools, 1,045 KSEK.
- Expenditures incurred on leasehold property, 103 KSEK

#### PARENT COMPANY

Sedana Medical AB (publ), org.no. 556670–2519, is the parent company in the Group. Its operations consist of clinical development, sales as well as administrative and management functions. The parent company also has branch offices in Germany and Spain, where operations consist of sales and warehousing of products.

The parent company's total income amounted to 44,541 (34,008) KSEK for the whole year. Operating profit amounted to -5,439 (1,277) KSEK. Net financial items amounted to -536 (382) KSEK for the whole year. The decrease in financial net income for the whole year of 2017 is related to an increase in interest-bearing liabilities compared with the same period in 2016. Net profit amounted to -4,627 (1,659) KSEK for the whole year.

Equity as of 31 December 2017 amounted to 123,946 (9,310) KSEK, which corresponds to an increase of 114,637 KSEK.

Liquid funds amounted to 83,283 (7,711) KSEK, an increase of 75,572 KSEK. This increase is due to the new share issue that was carried out in connection with the listing of the company's share on Nasdaq First North in June and the exercise of the overallotment option that took place in Q3.

# **Organisation and Staff**

#### EMPLOYEES

At the end of 2017, Sedana Medical had 25 employees. Of these, 16 employees were men and 9 employees were women. Corresponding figures at the end of 2016 were 17 employees of which 14 employees were men and 3 employees were women.

#### **INCENTIVE PROGRAMME**

At the Annual General Meeting on 19 May 2017, it was decided to introduce a subscription option-based incentive programme intended for key personnel in Sedana Medical. In connection therewith, it was decided to issue a total of 310,149 warrants between 2017 and 2021, all of which were subscribed to and assigned to the Company's subsidiary Sedana Medical Incentive AB for further transfer to participants in the incentive programme. In total, 310,149 warrants have been transferred to participants in the programme. All participants are senior executives in Sedana Medical. The warrants have been transferred under market conditions. The transfer price is calculated using the Black & Scholes model of an independent institution. Each warrant gives the right to subscription of one share in Sedana Medical AB (publ) at a subscription price corresponding to 130 per cent of the subscription price in the IPO offer, which was 19.50 SEK. The warrants can be utilised during the period 15 May 2020 to 31 January 2021. The warrants are also subject to customary conversion conditions for conversion in connection with issues etc. At full utilisation of all warrants transferred to participants in the incentive programme, the share capital in Sedana Medical AB (publ) will increase by about 31,015 SEK through issuance of 310,149 shares, corresponding to a dilution of about 1.8 per cent based on the number of shares in the Company on the closing date.

#### WARRANT PROGRAMME

Sedana Medical AB (publ) had 260 outstanding warrants series 2014/2019 as of 31 December 2017, which were issued at the Extraordinary General Meeting on 24 June 2014. The warrants entitle the holder to subscribe shares in Sedana Medical AB (publ) during the period from registration of the warrants until 31 December 2019. The warrants are subject to customary conversion conditions in the event the Company makes changes in the share capital and/or the number of shares through, for example, new issue, fund issue, consolidation or split of shares. Each warrants entitles the holder to subscribe to 4,000 shares. In total, outstanding warrants give the right to subscription of 1,040,000 shares at a subscription price corresponding to 2.5 SEK per share. All warrants series 2014/2019 are subscribed by current shareholders, related parties to these and senior executives in the Group. After the closing date, 52 warrants have been utilised and 208,000 new shares added, which increased the share capital by 20,800 SEK, corresponding to a dilution of 1.2% based on the number of shares in the Company on the closing date. After the utilisation, there were 208 remaining warrants series 2014/2019. At full utilisation of the rest of all the warrants series 2014/2019, the Company's share capital will increase by 83,200 SEK through issue of 832,000 shares in the Company, corresponding to a dilution of 4.9 per cent based on the number of shares in the Company on the closing date.

# Specification 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, 2016 according to balance sheet	217,0	231,0	448,0
Adjustments	0,0	0	0
Adjusted opening balance January 1, 2016	217,0	231,0	448,0
Changes in the carrying amounts recognised directly in equity			
Translation difference	0,0	-471,8	-471,8
	0,0	-471,8	-471,8
Net income	0,0	1 285,6	1 285,6
Total Equity December 31, 2016	217,0	1 044,8	1 261,8
Opening balance January 1, 2017	217,0	1 044,8	1 261,8
New issue of shares	512,8	99 487,2	100 000,0
Bonus issue	651,0	-651,0	0,0
Conversion of convertibles	188,2	4 515,6	4 703,8
Conversion of share holder loan	61,4	11 903,7	11 965,1
Issue expenses	0,0	-12 310,8	-12 310,8
Overallotment option	76,9	14 923,1	15 000,0
Translation difference	0,0	-340,9	-340,9
	1 490,3	117 526,9	119 017
Net income	0,0	-3 875,7	-3 875,7
Total Equity 31 December, 2017	1 707,3	114 696,0	116 403,3

#### 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, 2016 according to balance sheet	217,0	0,0	11 583,0	-4 026,7	7 773,3
Adjustments	0,0	0,0	0,0	0,0	0,0
Adjusted opening balance January 1, 2016	217,0	0,0	11 583,0	-4 026,7	7 773,3
Changes in the carrying amounts recognised directly in equity					
Translation difference	0,0	0,0	0,0	-122,4	-122,4
Reallocation between items in equity	0,0	0,0	0,0	-122,4	-122,4
Allocations to funds for capitalized development expenses	0,0	1 468,7	0,0	-1 468,7	0,0
	0,0	1 468,7	0,0	-1 468,7	0,0
Net income	0,0	0,0	0,0	1 659,1	1 659,1
Total Equity December 31, 2016	217,0	1 468,7	11 583,0	-3 958,8	9 309,9
Opening balance January 1, 2017	217,0	1 468,7	11 583,0	-3 958,8	9 309,9
Changes in the carrying amounts recognised directly in equity					
New issue of shares	512,8	0,0	99 487,2	0,0	100 000,0
Bonus issue	651,0	0,0	-651,0	0,0	0,0
Conversion of convertibles	188,2	0,0	4 515,6	0,0	4 703,8
Conversion of share holder loan	61,4	0,0	11 903,7	0,0	11 965,1
Issue expenses	0,0	0,0	-12 310,8	0,0	-12 310,8
Overallotment option	76,9	0,0	14 923,1	0,0	15 000,0
Translation difference	0,0	0,0	0,0	-94,9	-94,9
Reallocation between items in equity	1 490,3	0,0	117 867,8	-94,9	119 263,2
Allocations to funds for capitalized development expenses	0,0	4 934,1	0,0	-4 934,1	0,0
	0,0	4 934,1	0,0	-4 934,1	0,0
Net income	0,0	0,0	0,0	-4 626,7	-4 626,7
Total Equity 31 December, 2017	1 707,3	6 402,8	129 450,8	-13 614,4	123 946,5

# Proposed allocation of profits

At the disposal of the Annual General Meeting are the following free funds, balanced results and profit for the year in the parent company:

KSEK	
Share premium reserve	129 450,8
Loss carried forward	-8 987,7
Loss for the year	-4 626,7
Total unrestriced reserves	115 836,4

The Board of Directors proposes that available equity be allocated as follows:

KSEK	
Share premium reserve	129 450,8
Losses carried forward	-13 614,4
Total unrestriced reserves	115 836,4

Regarding the Group and parent company's earnings and position in general, the following income statement and balance sheet with accompanying notes are referred to.

# OTHER FINANCIAL INFORMATION

#### **Consolidated Income Statement**

		1 Januari - 31 December		
KSEK	Note	2017	2016	
Revenues				
Net sales	4	40 427,7	32 154,6	
Capitalized development expenses		1 290,9	1 579,7	
Other operating income	6	1 571,7	1 932,3	
		43 290,4	35 666,7	
Operating cost and expenses				
Cost of goods sold		-10 766,0	-10 808,3	
External expenses	7	-16 825,4	-10 606,1	
Personnel expenses	8	-16 194,6	-11 670,4	
Depreciation and amortisation		-2 751,6	-376,6	
Other operating expenses	9	-240,5	-1 587,6	
Operating income		-3 487,8	617,8	
Income from financial items				
Financial income	10	2 749,9	2 039,3	
Financial expenses	11	-3 863,2	-2 020,4	
Income after financial items		-4 601,2	636,7	
Income before taxes		-4 601,2	636,7	
Taxes	12	725,5	649,0	
Net Income		-3 875,7	1 285,6	

### Consolidated Balance Sheet

		31 December		
KSEK	Note	2017	2016	
ASSETS				
Fixed assets				
Intangible assets				
Capitalized development expenses	13	20 721,9	4 917,5	
Concessions, patents, licenses, trademarks and similar	14	5 743,7	0,0	
		26 465,6	4 917,5	
Tangible assets				
Building and land	17	94,6	0,0	
Machinery and equipment	15	2 824,8	127,1	
Fixtures and tools	16	1 432,6	911,0	
		4 352,1	1 038,1	
Total fixed assets		30 817,7	5 955,7	
Current assets				
Inventory	19			
Finished goods		3 205,4	4 264,0	
Advances to suppliers		-	272,5	
		3 205,4	4 536,5	
Receivables				
Trade receivables		3 481,2	2 867,0	
Other current receivables		3 079,0	816,9	
Deferred tax receivables		1 459,6	721,2	
Prepaid expenses and accrued income		4 011,7	430,6	
		12 031,6	4 835,7	
Cash and cash equivalents		85 321,6	8 296,4	
Total current assets		100 558,7	17 668,7	
TOTAL ASSETS		131 376,3	23 624,4	

		31 Decemb	er
KSEK	Note	2017	2016
EQUITY AND LIABILITIES			
Equity			
Share capital		1 707,3	217,0
Other equity including net income for the period		114 696,0	1 044,8
Equity attributable to shareholders in parent company		116 403,3	1 261,8
Total equity		116 403,3	1 261,8
Provisions			
Other provisions			13,9
		0,0	13,9
Long-term liabilities	20		
Liabilities to credit institutions	21	0,0	779,8
Convertible loans		0,0	4 100,0
Other long term liabilities		0,0	2 000,0
		0,0	6 879,8
Current liabilities			
Liabilities to credit institutions		3,6	38,2
Accounts payables		7 873,1	1 917,0
Tax liabilities		-	2,5
Other current liabilites	22	1 591,2	10 702,8
Accrued expenses and prepaid income	23	5 505,1	2 808,4
		14 973,0	15 468,9
TOTAL EQUITY AND LIABILITIES		131 376,3	23 624,4

### Consolidated statement of cash flow

		1 januari - 31 december		
KSEK	Not	2017	2016	
Operations				
Operating income		-3 487,8	617,8	
Adjustment of non cash flow items		0,0	0,0	
Depreciations and amortisations		2 751,6	370,0	
Currency exchange rates differences		-875,1	-386,7	
Provisions		-13,9	13,7	
Other non cash flow items		195,4	0,0	
		-1 429,8	614,8	
Received interest		0,7	0,0	
Paid interest		-2 591,5	-161,0	
Paid taxes	_	-211,3	-267,7	
Cash flow from operations before change in working capital		-4 232,0	186,1	
Cash flow from change in working capital				
Increase (-)/Decrease (+) of inventory		1 331,1	-641,0	
Increase (-)/Decrease (+) of operating receivables		-6 248,6	539,6	
Increase (+)/Decrease (-) of operating liabilities		9 645,2	-497,5	
Cash flow from operations		495,6	-412,8	
Investment activities				
Investment in intangible fixed assets		-22 105,6	-4 066,1	
Investments in tangible fixed assets		-3 776,4	-861,9	
Cash flow from investment activities		-25 882,0	-4 927,9	
Financing activities				
New issue of shares		117 430,3	0,0	
Issue expenses		-12 310,8	0,0	
Received loans		0,0	11 138,6	
Amortisation of loans		-2 779,8	-792,2	
Cash flow from financing activities		102 339,7	10 346,4	
Cash flow for the period		76 953,3	5 005,7	
Liquid funds at the beginning of the period		8 296,4	3 172,2	
Effects of exchange rate changes on cash		0,0	-14,0	
Translation difference in liquid funds		71,9	132,5	
Liquid funds at the end of the period	25	85 321,6	8 296,4	

#### Parent company income statement

		1 januari - 31 de	cember
KSEK	Note	2017	2016
Revenues			
Net sales	4,5	43 129,3	31 494,9
Capitalized development expenses		1 290,9	653,6
Other operating income	6	121,2	1 859,5
		44 541,5	34 008,0
Operating cost and expenses			
Cost of goods sold		-26 460,1	-18 155,7
External expenses	7	-11 595,4	-6 935,0
Personnel expenses	8	-10 523,2	-5 984,2
Depreciation and amortisation		-1 175,7	-68,3
Other operating expenses	9	-226,1	-1 587,6
Operating income		-5 438,9	1 277,2
Income from financial items			
Result from securities and long term receivables		578,2	0,0
Financial income	10	2 749,0	2 402,3
Financial expenses	11	-3 863,2	-2 020,4
Income after financial items		-5 974,9	1 659,1
Group contribution		1 348,2	0,0
Income before taxes		-4 626,7	1 659,1
Taxes	12	0,0	0,0
Net Income		-4 626,7	1 659,1

## Parent company balance sheet

		31 Decemb	er
KSEK	Note	2017	2016
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development expenses	13	6 402,8	1 468,7
Concessions, patents, licenses, trademarks and similar		0,0	0,0
Tangible assets			
Machinery and equipment	15	2 824,8	127,1
Fixtures and tools	16	64,2	21,4
		2 889,0	148,5
Financial fixed assets			
Shares in group companies	17	50,0	0,0
Long term receivables in group companies	18	30 854,3	15 976,6
		30 904,3	15 976,6
Total fixed assets		40 196,1	17 593,8
Current assets			
Inventory			
Finished goods	19	6 108,6	7 542,3
Kortfristiga fordringar			
Trade receivables		3 160,9	2 568,6
Receivables in group companies		7 990,9	2 121,8
Other current receivables		1 647,4	411,3
Prepaid expenses and accrued income		1 496,6	379,9
		14 295,9	5 481,6
Cash and cash equivalents		83 282,9	7 711,1
Total current assets		103 687,4	20 735,0
TOTAL ASSETS		143 883,5	38 328,8

		31 Decemb	er
KSEK	Note	2017	2016
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		1 707,3	217,0
Fund for capitalized development expenses		6 402,8	1 468,7
Non restricted equity			
Share premium fund		129 450,8	11 583,0
Retained earnings		-8 987,7	-5 617,9
Profit or loss for the period		-4 626,7	1 659,1
Total Equity		123 946,5	9 309,9
Long-term liabilities	20		
Liabilities to credit institutions	21	0,0	779,8
Convertible loans		0,0	4 100,0
Other long term liabilities		0,0	2 000,0
		0,0	6 879,8
Current liabilities			
Liabilities to credit institutions		0,0	0,0
Accounts payables		5 045,4	1 182,1
Liabilities to group companies		10 762,1	9 343,2
Other current liabilites	22	976,8	10 448,4
Accrued expenses and prepaid income	23	3 152,7	1 165,4
		19 937,0	22 139,1
TOTAL EQUITY AND LIABILITIES		143 883,5	38 328,8

### Parent company statement of cash flow

	1 Januari - 31 De	ecember
KSEK Note	2017	2016
Operations		
Operating income	-5 438,9	1 277,2
Adjustment of non cash flow items	,	,
Depreciations and amortisations	1 175,7	68,4
Currency exchange rates differences	-12,1	318,5
Provisions	0,0	329,0
Other non cash flow items	1 492,7	0,0
	-2 782,6	1 993,0
Received interest	578,8	0,0
Paid interest	-2 591,5	-161,0
Paid taxes	-332,5	0,0
Cash flow from operations before change in working capital	-5 127,9	1 832,0
Cash flow from change in working capital		
Increase (-)/Decrease (+) of inventory	1 433,7	-4 517,0
Increase (-)/Decrease (+) of operating receivables	-8 481,8	10 088,7
Increase (+)/Decrease (-) of operating liabilities	7 182,1	4 954,7
Cash flow from operations	-4 993,9	12 358,4
Investment activities		
Investment in intangible fixed assets	-4 934,1	-653,6
Investments in tangible fixed assets	-2 688,9	-288,0
Investments of financial assets	-14 204,8	-16 443,5
Cash flow from investment activities	-21 827,7	-17 385,0
Finansieringsverksamheten		
New issue of shares	117 430,3	0,0
Issue expenses	-12 310,8	0,0
Received loans	0,0	11 138,6
Amortisation of loans	-2 779,8	-548,9
Cash flow from financing activities	102 339,7	10 589,7
Cash flow for the period	75 518,0	5 563,1
Liquid funds at the beginning of the period	7 711,1	2 075,5
Effects of exchange rate changes on cash	0,0	-14,0
Translation difference in liquid funds	53,7	86,6
Liquid funds at the end of the period 25	83 282,9	7 711,1

# NOTES

#### **NOTE 1** GENERAL INFORMATION

Sedana Medical AB (publ) with organisation number 556670-2519 is a limited liability company registered in Sweden with registered office in Danderyd. The address of the main office is Berga Backe 2, 182 53 Danderyd. The purpose of the Company's operations is to develop, manufacture and sell medical devices. Sedana Medical AB (publ) is the parent company of the Sedana Medical Group.

#### **NOTE 2 ACCOUNTING PRINCIPLES**

Amounts are reported in SEK unless otherwise specified. Accounting principles are unchanged compared with previous years. A departure from the K3 regulation has occurred in Q3 when it comes to the gross reporting of capitalised development expenses. As of Q3 2017, Sedana Medical reports development costs on a net basis under personnel expenses and other operating expenses.

#### **General accounting principles**

The Financial Statements have been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board's General Guidelines BFNAR 2012:1 Annual Report and Consolidated Financial Statements (K3).

Sedana Medical AB (publ), i.e. the parent company, and the Group apply the same accounting principles.

#### **Consolidated Financial Statements**

#### Subsidiaries

Subsidiaries are companies in which the parent company directly or indirectly holds more than 50 % of the votes or otherwise have a controlling influence. Controlling influence means a right to design a company's financial and operational strategies for the purpose of obtaining economic benefits.

The accounting of business acquisitions is based on the unit view. This means the acquisition analysis is prepared at the time when the acquirer gained a controlling interest. From this time, the acquirer and the acquired unit are seen as an accounting unit. Application of the unit view also means that all assets (including goodwill) and liabilities as well as income and expenses are calculated in their entirety, including for partially owned subsidiaries.

The acquisition value of subsidiaries is calculated as the total of fair value at the time of acquisition for paid assets with the addition of accrued and assumed liabilities and issued equity instruments, expenses which are directly attributable to the business acquisition and any additional purchase price. In the acquisition analysis, the fair value is determined, with some exceptions, at the time of acquisition of the acquired identifiable assets and assumed liabilities and minority interest. Minority interest is valued at fair value at the time of acquisition. From the time of acquisition, the acquired company's income and expenses, identifiable assets and liabilities and any goodwill or negative goodwill are included in the consolidated financial statements.

#### Elimination of transactions within the Group

Intra-group transactions and balance sheet items as well as unrealised gains and losses on transactions between group companies are eliminated in their entirety.

#### Revenues

The inflow of economic benefits which the company receives or will receive on its own behalf is reported as revenues. Revenues are valued at the fair value of what is received or will be obtained less discounts.

#### Sale of goods

For sale of goods, income is reported at delivery.

#### Interest, Royalty and dividends

A revenue is reported when the economic benefits that are associated with the transaction will likely flow to the company and when the income can be calculated in a reliable way.

#### Leasing - lessee

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

#### Тах

Tax on profit for the year in the income statement consists of current tax and deferred tax. Current tax is income tax for the current financial year which relates to taxable profit for the year and the part of the previous accounting year's income tax which has not yet been reported. Deferred tax is income tax for taxable income relating to future financial years as a result of previous transactions or events.

Deferred tax is calculated for temporary differences. There is a temporary difference when the reported value of an asset or liability differs from the tax value. Temporary differences are not taken into account in differences attributable to investments in subsidiaries, associated companies or joint ventures if the company can control the date of the reversal of the temporary differences and it is not obvious that the temporary difference will be returned in the foreseeable future. Differences which originate from the initial recognition of goodwill or the initial recognition of an asset or liability do not constitute temporary differences unless the related transaction is a business acquisition or affects tax or the reported results.

Deferred tax assets relating to deficit deductions or other future tax deductions are reported in to the extent that it is likely that the deduction can be settled against future tax surpluses.

In the consolidated balance sheet, untaxed reserves are divided into deferred tax and equity.

#### Valuation principles etc.

Assets, provisions and liabilities have been valued at cost unless otherwise specified below.

#### **Foreign currency**

#### Items in foreign currency

Monetary items in foreign currency are converted to the spot rate on the closing date. Non-monetary items are not translated but are reported at the rate at the time of acquisition. Transactions in foreign currency are translated according to the spot rate on the transaction date.

Exchange rate differences arising from the adjustment or translation of monetary items are reported in the income statement in the financial year they arise, either as an operating item or a financial item based on the underlying business event.

#### Translation of foreign operations

Assets and liabilities, including goodwill and other consolidated surpluses and deficits, are translated to the accounting currency on the closing date. Income and expenses are translated to a rate that represents an approximation of the actual rate used (e.g. average rate).

#### Currency rate risk

Currency risk means the risk that fair value or future cash flows fluctuate as a result of changed exchange rates. The company has both long-term and current receivables and liabilities in foreign currencies and is thereby exposed to currency risk. In other words, exposure to currency risk mainly stems from translation of balance sheet items in foreign currency.

No hedging instruments are used.

#### Intangible assets

#### Expenses for research and development

All expenses that arise during the research phase are expensed when they arise.

When accounting for development costs, the capitalisation model is applied. This means that expenses that arise during the development phase are reported as assets when all of the following preconditions are met:

- It is technically possible to establish the intangible assets so that they can be used or sold.
- The intent is to establish the intangible assets and use or sell them.
- There are prerequisites for using or selling the intangible assets.
- It is likely that the intangible assets will generate future economic benefits.
- There are the necessary and adequate technical, economic and other resources to complete the development and to use or sell the intangible assets.
- The expenses that are attributable to the intangible assets can be measured in a reliable way.

The acquisition value includes personnel costs incurred in the development work together with the appropriate proportion of relevant costs and borrowing costs.

#### Other intangible assets

Other intangible assets that are acquired by the company are reported at cost less accumulated depreciation and amortisation. Assets are written down linearly over the estimated useful life of the assets. The useful life is reconsidered each closing date. Ongoing projects are not written down but are tested for amortisation annually. Expenses for internally generated goodwill and trademarks are reported in the income statement as a cost when they arise.

#### Depreciation

Depreciation occurs linearly over the estimated useful life of the asset. Depreciation is reported as an expense in the profit and loss statement.

The following depreciation	Group	Parent Company
periods are applied:	years	years
Internally generated intangibl	le assets;	

55	5	,	
Capitalised expenses for	<sup>-</sup> development		
and similar work		5	5

#### **Tangible assets**

Tangible assets are reported at cost less accumulated depreciation and amortisation. Beside the purchase price, the cost can include expenses which are directly attributable to the acquisition.

#### Additional expenses

Additional expenses that meet the asset criterion are included in the asset's carrying amount. Expenses for ongoing maintenance and repairs are expensed as incurred.

The consumption of significant components has not been considered significant for any of the tangible fixed assets. Component depreciation therefore does not occur.

#### Depreciation

Depreciation occurs linearly over the estimated useful life of the asset as it reflects the expected consumption of the asset's future economic benefits. Depreciation is reported as an expense in the profit and loss statement. The useful life is reconsidered each closing date.

The following depreciation periods are applied:	Group years	Parent Company years
Tangible assets: - Machines and other technical		
facilities - Equipment, tools and	5–10	5
installations	5-10	5

#### Leasehold property outlay

Sedana Medical AB owns no properties. Sometimes major improvements are made in rented premises which are capitalised. The amortisation period of that, which is capitalised, is as coinciding with the lease agreement's length at the premises or 5-10 years.

#### **Financial assets**

Financial assets intended for long-term holdings are reported at cost, after currency adjustments where appropriate.

The asset is tested at least once a year to see if there is a need for amortisation. Amortisation occurs if value decrease is assessed is permanent. Amortisation is reported in the income statement item Profit from other securities and receivables, which is a fixed asset

#### Inventories

Inventories are recognised at the lower of acquisition value and net realisable value. The obsolescence risk is thereby considered. The cost is calculated according to the first-in, first-out principle.

Besides expenses for purchase, the cost also includes expenses to bring the goods to their current location and condition. Net sales value has been calculated at the relisable value less estimated sales costs.

#### Offsetting of financial receivables and financial liabilities

A financial asset and a financial liability are offset and reported at a net amount in the balance sheet only when the legal set-off rights exist and when a regulation with a net amount is intended to occur or when a contemporary disposal of the asset and liability is intended to occur.

#### Trade and other receivables

Receivables are reported as current assets except for items with maturity more than 12 months after the closing date,

which are classified as fixed assets. Receivables are taken up to the amount which is expected to be paid less individually assessed doubtful claims. Receivables which are interestfree or which expire with interest that deviates from the market interest rate and has a maturity exceeding 12 months is reported at a discounted present value and the time value change is reported as interest income in the income statement.

#### Loan liabilities and trade payables

Loan liabilities and trade payables are initially reported at cost less transaction costs. If the reported amount differs from the amount to be refunded at the maturity date, the difference is accrued as an interest expense over the term of the loan using the instrument's effective interest rate. This way the amount reported at the maturity date and the amount to be repaid are in accordance.

#### Provisions

Provisions are reported when the Group has or may be considered to have a commitment as a result of an event that occurred and it is likely that payments will be required to fulfil the commitment. A prerequisite is that it is possible to make a reliable estimate of the amount to be paid.

#### Remuneration to employees – pensions

The Group's pension plans for remuneration after termination of employment are defined contribution. In defined contribution plans, the company pays an established fee to a separate legal entity. When the fee is paid, the Company has no further obligations.

#### Cash flow analysis

The cash flow analysis is prepared according to the indirect method. The reported cash flow only includes transactions that have resulted payments in or out. In addition to cash and bank balances, short-term investments that can easily be converted to a known amount and which are exposed to an insignificant risk of value fluctuation are also classified as liquid funds.

#### NOTE 3 SIGNIFICANT EVENTS AFTER THE END OF THE YEAR

- Peter Sackey took office as Chief Medical Officer on 8 January 2018.
- Sedana Medical AB (publ) opened its own sales operations in Norway and Denmark.
- Sedana Medical AB (publ) announced that the schedule for patient recruitment in the ongoing Phase 3 IsoConDa study is likely to be extended.
- Sedana Medical AB (publ) reported a more than expected 60% increase in sales in the first quarter of 2018 compared to the corresponding period in 2017.

#### **NOTE 4 NET SALES**

KSEK	Grou	ıp	Parent Co	mpany
	2 017	2016	2 017	2016
Net sales				
Sedana Medical AB (publ)				
- Branch in Germany	38 225,7	30 288,2	3 652,5	0,0
- Branch in Spain	577,3	473,5	38 899,5	31 021,4
Sedana Medical Ltd., Ireland	213,3	0,0	577,3	473,5
Sedana Medical Sárl, France	1 411,4	1 392,9	0,0	0,0
Total	40 427,7	32 154,6	43 129,3	31 494,9

#### NOTE 5 GROUP INTERNAL PURCHASES AND SALES

KSEK		
	2 017	2016
Proportion of sales of goods relating to group companies	1542.9	733,2
Proportion of sales of services relating to group companies	5 090,8	0,0
Proportion of purchases of goods relating to group companies	24 072,7	19 787,8

#### NOTE 6 OTHER OPERATING INCOME

KSEK	Gro	up	Parent Co	mpany
	2 017	2016	2 017	2016
Foreign exchange rate gains on operating receivables / liabilities	159,5	1 932,3	56,8	1 859,5
Payment from employee stock options	1 412,2	0,0	0,0	0,0
Other	0,0	0,0	64,4	0,0
Total	1 571,7	1 932,3	121,2	1 859,5

#### **NOTE 7 OPERATIONAL LEASING**

KSEK	Gro	up	Parent Co	ompany
	2 017	2016	2 017	2016
Minimum leasing fees	600,5	627,4	600,5	627,4
Total leasing costs	600,5	627,4	600,5	627,4
Contracted future minimum lease fees for non- cancellable contracts are due:	0,0	0,0	0,0	0,0
Within a year	614,1	556,0	614,1	556,0
Between one and five years	454,6	237,0	454,6	237,0
Total	1 068,7	793,0	1 068,7	793,0

#### NOTE 8 EMPLOYEES, PERSONNEL EXPENSES AND BOARD RENUMERATION

#### Average number of employees

		2017	
	Total	Women	Men
Parent Company			
Sweden	1,7	0,3	1,4
Germany	6,0	0,4	5,6
Spain	1,0	1,0	0,0
Total	8,7	1,7	7,0
Group			
Ireland	6,5	2,4	4,1
France	1,3	0,0	1,3
Total	16,5	4,1	12,4

#### Senior Executives

	2017			2016			
	Total	Women	Men		Total	Women	Men
Board of Directors	5,0	0	5		6	0	6
CEO and senior executives	4,0	1	3		3	0	3

Salary and other remuneration and social security expenses, including pension costs to the CEO

KSEK	Group		Parent Com	Parent Company			
Salaries and other remuneration	2 017	2016	2 017	2016			
Chairman of the board Thomas Eklund	322,7	198,8	322,7	198,8			
Board member Sten Gibeck	29,2	0,0	29,2	0,0			
Board member Bengt Julander	29,2	0,0	29,2	0,0			
Board member Ola Magnusson	693,9	293,0	693,9	293,0			
Board member Michael Ryan	1 127,0	0,0	29,2	0,0			
Former Board member Ron Farrell	0,0	0,0	0,0	0,0			
Former CEO, Michael Ryan	96,3	1 201,7	0,0	0,0			
CEO, Christer Ahlberg	1 420,2	0,0	1 420,2	0,0			
Total	3 718,4	1 693,5	2 524,2	491,8			
Other senior executives	2 567,1	2 929,8	1 596,2	1 923,6			
Other employees	7 867,1	8 980,7	4 617,6	4 478,5			
Total	10 434,3	11 910,5	6 213,7	6 402,1			
Total salaries and other remuneration	14 152,7	13 604,0	8 737,9	6 893,9			
Social fees by law and agreement	2 376,8	1 742,6	1 671,5	978,5			
Pensions to the CEO							
Of which for the former CEO	179,2	284,1	0,0	0,0			
Of which for the current CEO	333,7	0,0	333,7	0,0			
Total	512,9	284,1	333,7	0,0			
Pensions to others							
Of which for other employees	0,0	0,0	0,0	0,0			

#### **NOTE 9 OTHER OPERATING EXPENSES**

KSEK	Group		Parent Company		
	2 017	2016	2 017	2016	
Foreign exchange rate losses on operating receivables / liabilities	27,3	1 587,6	27,3	1 587,6	
Other	213,2	0,0	198,8	0,0	
Total	240,5	1 587,6	226,1	1 587,6	

#### NOTE 10 FINANCIAL INCOME

KSEK	Group		Parent Company		
	2 017	2016		2 017	2016
Interest income, Group companies	0,0	0,0		578,2	381,9
Interest income, Other	0,0	0,0		0,0	0,0
Foreign exchange gains	2 749,1	2 039,3		2 749,0	2 020,3
Total	2 749,1	2 039,3		3 327,2	2 402,3

#### NOTE 11 FINANCIAL EXPENSES

KSEK	Group		Parent Company		
	2 017	2016		2 017	2016
Interest expenses	1 837,1	585,4		1 837,1	585,4
Foreign exchange losses	2 026,1	1 429,9		2 026,1	1 429,9
Other financial expenses	0,0	5,1		0,0	5,1
Total	3 863,2	2 020,4		3 863,2	2 020,4

#### NOTE 12 TAXES

KSEK	Group		Parent Company		
	2 017	2016		2 017	2016
Current tax	0,0	72,2		0,0	0,0
Deferred tax	-725,5	-721,2		0,0	0,0
Total	-725,5	-649,0		0,0	0,0

#### Reconcilliation of reported taxes

KSEK	Group		Parent Co	ompany	
	2 017	2016		2 017	2016
Income before taxes	-4 601,5	636,7		-4 626,7	1 659,1
Tax at current tax rate 22%	-1 012,3	140,1		-1 017,9	365,0
Effect of foreign tax rates	-225,4	9,7		9,0	236,0
Non-deductible costs	487,0	49,6		39,8	16,6
Non-taxable income	-229,6	-583,7		0,0	0,0
Тах	0,0	0,0		0,0	0,0
Current tax from previous years	345,6	0,0		0,0	0,0
Changes in loss carryforwards	-90,8	-264,6		969,0	-617,6
Other	0,0	0,0		0,0	0,0
Redovisad effektiv skatt	-725,5	-649,0		0,0	0,0

The Group has a deferred, unbalanced tax receivable of KSEK 34,670, of which KSEK 29,490 relates to the Parent Company.

#### NOTE 13 CAPITALIZED DEVELOPMENT EXPENSES

KSEK	Group		Parent Co	mpany
	2 017	2016	2 017	2016
Carrying amounts:				
- Opening cost	4 917,5	815,2	1 468,2	815,2
- In house development	1 290,9	1 579,7	1 290,9	653,6
- Acquisitions	14 455,7	2 486,4	3 643,7	0,0
- Translation differences	345,8	36,3	0,0	0,0
- Closing cost	21 009,9	4 917,5	6 402,8	1 468,2
Carrying depreciations according to plan:				
- Opening depreciation	0,0	0,0	0,0	0,0
- Amortization for the year	-281,6	0,0	0,0	0,0
- Translation differences	-6,4	0	0,0	0
- Closing amortization	-288,0	0	0,0	0
Carrying amount at the end of the period	20 721,9	4 917,5	6 402,8	1 468,7

#### NOTE 14 CONCESSIONS, PATENTS, LICENSES, TRADEMARKS AND SIMILAR

KSEK	Group		Parent Co	mpany
	2 017	2016	2 017	2016
Carrying amounts:				
- Opening cost	0,0	0,0	0,0	0,0
- Acquisitions	6 358,9	0,0	0,0	0,0
- Translation differences	143,3	0,0	0,0	0,0
- Closing cost	6 502,2	0,0	0,0	0,0
Carrying depreciations according to plan:				
- Opening depreciation	0,0	0,0	0,0	0,0
- Depreciation for the year	-741,8	0,0	0,0	0,0
- Translation differences	-16,7	0,0	0,0	0,0
- Closing depreciation	-758,5	0,0	0,0	0,0
Carrying amount at the end of the period	5 743,7	0,0	0,0	0,0

#### NOTE 15 MACHINERY AND EQUIPMENT

KSEK	Group		Parent Company		
	2 017	2016	2 017	2016	
Carrying amounts:					
- Opening cost	471,9	471,5	471,9	471,5	
- Acquisitions	2 624,5	0	2 624,5	0,0	
- Reclassifications	1 873,4	0	1 873,4	0,0	
- Translation differences	98,1	0,39	98,1	0,39	
- Closing cost	5 067,9	471,9	5 067,9	471,9	
Carrying depreciations according to plan:					
- Opening depreciation	-344,8	-298,0	-344,8	-298,0	
- Reclassifications		0,0	0,0	0,0	
- Depreciation for the year	-1 154,8	-46,4	-1 154,8	-46,4	
- Translation differences	-24,8	-0,4	-24,8	-0,4	
- Closing depreciation	-1 524,4	-344,8	-1 524,4	-344,8	
Carrying write downs:					
- Opening write downs	0,0	0,0	0,0	0,0	
-Omklassificeringar	0,0	0,0	0,0	0,0	
- Write downs for the year	-702,8	0,0	-702,8	-702,8	
- Translation differences	-15,9	0,0	-15,9	-15,9	
- Closing write downs	-718,7	0,0	-718,7	-718,7	
Carrying amount at the end of the period	2 824,8	127,1	2 824,8	127,1	
Machinery and equipment under financial lease					
included with the following amount:	none	none	none	none	

#### NOTE 16 FIXTURES AND TOOLS

KSEK	Group		Parent	Company
	2 017	2016	2 017	2016
Carrying amounts:				
- Opening cost	1 485,1	586,3	207	7,0 185,2
- Acquisitions	1 044,9	861,9	60	),1 13,0
- Translation differences	66,1	36,9	6	5,2 8,9
- Closing cost	2 596,1	1 485,1	273	3,3 207,0
Carrying depreciations according to plan:				
- Opening depreciation	-574,0	-235,8	-185	i,6 -156,0
- Depreciation for the year	-559,9	-323,6	-17	-22,0
- Translation differences	-29,6	-14,6	-5	i,8 -7,6
- Closing depreciation	-1 163,5	-574,0	-209	9,1 -185,6
Carrying amount at the end of the period	1 432,6	911,0	64	,2 21,4
Fixtures and tools under financial lease included with the following amount:	none	none	no	ne none

#### NOTE 17 OUTLAYS ON LEASEHOLD PROPERTY

KSEK	Group		Parent Company	
	2 017	2016	2 017	2016
Carrying amounts:				
- Opening cost	0,0	0,0	0,0	0,0
- Acquisitions	102,8	0,0	0,0	0,0
- Translation differences	2,3	0,0	0,0	0,0
- Closing cost	105,1	0,0	0,0	0,0
Carrying depreciations according to plan:				
- Opening depreciation	0,0	0,0	0,0	0,0
- Depreciation for the year	-10,3	0,0	0,0	0,0
- Translation differences	-0,2	0,0	0,0	0,0
- Closing depreciation	-10,5	0,0	0,0	0,0
Carrying amount at the end of the period	94,6	0	0,0	0,0

#### NOTE 18 SHARES IN GROUP COMPANIES

KSEK	Group		Parent Co	Parent Company	
	2 017	2016	2 017	2016	
Carrying amounts:					
- Opening cost	0,0	0,0	0,0	0,0	
- Acquisitions	0,0	0,0	50,0	0,0	
Closing accumulated cost and carrying amount at the end of the period	0,0	0,0	50,0	0,0	

Information of equity and result:				Proportion of equity	Proportion of equity
	Corp reg no /Reg office	Proportion of capital owned%	No of shares		2016
KSEK					
	IE551634 /				
Sedana Medical Ltd	Naas, Irland	100	1	4 066,0	3 592,0
	559109-8826/				
	Danderyd,				
Sedana Medical Incentive AB	Sverige	100	50 000	50,0	-
	809876865,				
Sedana Medical Sàrl	Paris, Frankrike	100	2 000	-5 443,0	-3 178,0

		roportion of ne result	Proportion of the result
	Corp reg no /Reg office	2 017	2016
KSEK			
	IE551634 /		
Sedana Medical Ltd	Naas, Irland	360,0	3 305,0
	559109-8826/		
	Danderyd,		
Sedana Medical Incentive AB	Sverige	0,0	-
	809876865,		
Sedana Medical Sàrl	Paris, Frankrike	-2 149,0	-1 858,0

Shares directly owned by the parent com	bany:			Booked value	Booked value
	Corp reg no/ Reg office	Proportion of capital owned%	No of shares	2017-12-31	2016-12-31
KSEK					
	IE551634 /				
Sedana Medical Ltd	Naas, Irland	100	1	0,0	0,0
	559109-8826/				
	Danderyd,				
Sedana Medical Incentive AB	Sverige	100	50 000	50,0	-

#### Shares owned by group companies:

	809876865,		
Sedana Medical Sàrl	Paris, Frankrike	100	2 000

#### **NOTE 19 INVENTORY**

KSEK	Group		Parent Company		
	2 017	2016		2 017	2016
Finished goods and goods for sale	3 205,4	4 264,0		6 108,6	7 542,3
Prepayments to suppliers	0,0	272,5		0,0	0,0
Total	3 205,4	4 536,5		6 108,6	7 542,3

#### NOTE 20 LONG TERM LIABILITIES

KSEK	Group		Parent Co	mpany	
	2 017	2016		2 017	2016
Maturity, 1–5 years from balance sheet day	0,0	6 879,8		0,0	6 879,8
Maturity, more than five years from balance sheet day	0,0	0,0		0,0	0,0
Total	0,0	6 879,8		0,0	6 879,8

#### NOTE 21 OVERDRAFT FACILITY

KSEK	Group		Parent Company		
	2 017	2016		2 017	2016
Granted credit limit	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

#### **NOTE 22 OTHER CURRENT LIABILITIES**

KSEK	Group		Parent Company		
	2 017	2016		2 017	2016
Loan from owners	0,0	10 138,6		0,0	10 138,6
Other liabilities	1 591,2	564,2		976,8	309,8
Total	1 591,2	10 702,8		976,8	10 448,4

#### NOTE 23 ACCRUED EXPENSES AND PREPAID INCOME

KSEK	Group		Parent Company	
	2 017	2016	2 017	2016
Royalties	59,1	631,4	0,0	754,5
Interests	0,0	754,5	0,0	133,6
Salaries, social and other personnel expenses	3 471,4	257,5	1 426,7	143,5
Audit	453,5	143,5	453,5	133,8
Other	1 521,1	1 021,5	1 272,5	0,0
Total	5 505,1	2 808,4	3 152,7	1 165,4

#### **NOTE 24 INFORMATION ON AUDITOR'S REMUNERATION**

Group		Group Parent Co		ompany
2 017	2016	2 017	2016	
0,0	0,0	0,0	0,0	
218,8	76,9	218,8	76,9	
0,0	1,8	0,0	1,8	
60,6	11,7	60,6	11,7	
279,4	90,4	279,4	90,4	
231,2	194,1	144,5	142,0	
125,0	89,6	125,2	89,7	
93,0	309,8	35,2	28,4	
449,2	593,5	304,9	260,1	
728,6	683,9	584,3	350,5	
	2 017 0,0 218,8 0,0 60,6 279,4 231,2 125,0 93,0 449,2	2 017         2016           0,0         0,0           218,8         76,9           0,0         1,8           60,6         11,7           279,4         90,4           231,2         194,1           125,0         89,6           93,0         309,8           449,2         593,5	2 017         2016         2 017           0,0         0,0         0,0           218,8         76,9         218,8           0,0         1,8         0,0           60,6         11,7         60,6           279,4         90,4         279,4           231,2         194,1         144,5           125,0         89,6         125,2           93,0         309,8         35,2           449,2         593,5         304,9	

#### NOTE 25 CASH AND CASH EQUIVALENTS

KSEK	Group		Parent Co	Company	
	2 017	2016	2 017	2016	
Bank deposits	85 321,6	8 296,4	83 282,9	7 711,1	

#### NOTE 26 PLEDGED ASSETS AND CONTINGENT LIABILITIES

KSEK	Group		Parent Company		
	2 017	2016		2 017	2016
For own liabilities and provisions					
Other liabilities to credit institutions					
Company mortage	0,0	1 940,0		0,0	1 940,0
	0,0	1 940,0		0,0	1 940,0
Other pledged assets and contingent liabilities					
Company mortage	0,0	2 000,0		0,0	2 000,0
	0,0	2 000,0		0,0	2 000,0
Total	0,0	3 940,0		0,0	3 940,0

#### **NOTE 27 TRANSACTIONS WITH RELATED PARTIES**

KSEK	2017		
	Purchase of	Purchase of	
	services	goods	
Parent Company			
Eklund Consulting	161,0	0,0	
Magiola AB	362,9	0,0	
Total, Parent Company	523,9	0,0	
Group			
Tecscan Ltd.	1 708,3	0,0	
Lismed Ltd.	0,0	3 138,5	
Total, Group	2 232,2	3 138,5	

Eklund Consulting is a company related to the Chairman of the Board Thomas Eklund.

Purchase of services from Eklund Consulting concern consulting services in relation to the IPO in first half year 2017.

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.

Tecscan Ltd. is a company related to 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 manager Ron Farrell. Purchase of goods from Lismed Ltd. concern the product Flurasorb and accessories which in turn are accessories to AnaConDa.

#### **NOTE 28 DEFINITIONS OF KEY RATIOS**

#### EBITDA margin:

Operating income before depreciations and amortisations (or Earnings Before Interest Taxes Depreciation and Amortisation) divided by Net sales.

#### Operating margin (EBIT-margin):

Opeerating 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 78% of untaxed reserves, divided by total assets.

#### Quick ratio:

Current assets excluding inventory divided by current liabilities.

#### Average number of employees:

Average number of full-time employees during the period.

## Certification from the Board of Directors and the CEO

The Board of Directors certifies that this interim report provides a true and fair view of the Group's operations, financial position and results. For a description of Sedana Medical's risks, please refer to the Group's prospectus that was prepared for the listing on Nasdaq First North.

Danderyd 24 April 2018

**Thomas Eklund** Chairman of the Board Sten Gibeck Board member Bengt Julander Board member

**Ola Magnusson** Board member **Michael Ryan** Board member Christer Ahlberg President and CEO

My audit report has been submitted on 24 April.

**Christina Kallin Sharpe** Authorised Public Accountant



#### **AUDITOR'S REPORT**

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

#### Report on the annual accounts and consolidated accounts

#### **Opinions**

I have audited the annual accounts and consolidated accounts of Sedana Medical AB (publ) for the year 2017. The annual accounts and consolidated accounts of the company are included on pages 40-75 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 2017 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.

A corporate governance report has been prepared. The management report and the corporate governance report are consistent with the other parts of the annual report and consolidated accounts and the corporate governance report is in accordance with the Annual Accounts Act.

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 Annual Report 2017 Sedana Medical AB (publ) (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.

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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 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 2017 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 24th of April 2018

Christina Kallin Sharpe Authorized Public Accountant

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# **CORPORATE GOVERNANCE**

#### LEGISLATION AND ARTICLES OF ASSOCIATION

Sedana Medical is a Swedish public limited company and governed by Swedish legislation, primarily the Swedish Companies Act (2005:551) and the Swedish Annual Accounts Act (1995:1554). The Company's shares were listed on Nasdaq First North on 21 June 2017. After this, the Company applies Nasdaq First North's regulatory framework. In addition to legislation and Nasdaq First North's regulatory framework, the Company's Articles of Association and its internal guidelines for corporate governance form the basis for the corporate governance. The Articles of Association relate to the registered office, the direction of the business, the limits for share capital and the number of shares, and the conditions for participation in the Annual General Meeting. The most recently accepted and registered articles of association were adopted at the Annual General Meeting on 19 May 2017.

The figure below shows Sedana Medical's corporate governance model and how the various governing bodies work.



1) Peter Sackey has been appointed Chief Medical Officer after the end of the fiscal year.

#### INTERNAL INSTRUCTIONS AND POLICIES WHICH ARE SIGNIFICANT FOR CORPORATE GOVERNANCE

- Articles of Association
- The Board's rules of procedure and CEO instructions
- Policy for financial reporting
- Authorisation instructions
- Information policy
- Insider policy
- Code of Conduct

#### EXTERNAL REGULATIONS THAT AFFECT CORPORATE GOVERNANCE

- The Swedish Companies Act
- Accounting regulatory framework
- Nasdaq First North regulatory framework

#### SWEDISH CODE OF CORPORATE GOVERNANCE

The Swedish Code of Corporate Governance ("the Code") specifies a higher standard for good corporate governance than the minimum requirements of the Swedish Companies Act and shall be applied by companies whose shares are admitted to trading on a regulated market in Sweden. The Code is not currently binding on companies whose shares are listed on Nasdaq First North and is thus not binding on the Company. The Company does not follow the Code and neither does it meet its requirements.

#### ANNUAL GENERAL MEETING

The shareholders' influence in the Company is exercised at the Annual General Meeting and, in accordance with the Swedish Companies Act, is the Company's highest decision-making body. As the Company's highest decision-making body, the Annual General Meeting may make decisions on any matters in the Company which do not constitute the exclusive competence of another corporate body. The Annual General Meeting thus has a supervising role in relation to the Company's Board and Managing Director. Notices, records and communiqués from Annual General Meetings will be kept available on the Company's website. At the Annual General Meeting (AGM), which in accordance with the Swedish Companies Act shall be held within six months of the end of each financial year, decisions shall be made about the establishment of the income statement and balance sheet, appropriations of the Company's profit or loss, discharge for board members and the Managing Director, election of board members and auditors and remuneration to the Board and the auditor. At the Annual General Meeting, the shareholders also make decisions on other key matters for the Company, such as amendment of the Company's Articles of Association, any new issue of shares, etc. If the Board considers there to be reason to hold a general meeting before the next Annual General Meeting, or if an auditor in the Company or owner of at least one tenth of all shares in the Company so requests in writing, the Board shall convene an Extraordinary General Meeting. A notice of an Annual General Meeting and Extraordinary General Meeting where amendments of the Articles of Association shall be discussed should take place at the earliest six weeks and no later than four weeks before the meeting. A notice of an extraordinary general meeting shall take place at the earliest six weeks and no later than three weeks before the meeting. Notices occur through announcements in Post- och Inrikes Tidningar and on the Company's website. That a notice has occurred shall also be announced in Dagens Industri. To participate in the Annual General Meeting, shareholders must be listed in the share register kept by Euroclear Sweden AB on the record date which will be announced no later than five weekdays before the meeting, and report that they intend to attend the meeting no later than the date specified in the

notice of the meeting. This day may not be a Saturday, Sunday, public holiday, Midsummer's Eve, Christmas Eve or New Year's Eve and may not be earlier than the fifth weekday before the meeting. Shareholders can participate in the Annual General Meeting in person or be represented by a representative and can also be assisted by at most two persons. Normally there is the opportunity for shareholders to report their participation in the Annual General Meeting in several different ways in accordance with instructions in the notice. Shareholders who wish to have a matter discussed at the Annual General Meeting must present a written request to the Board of Directors. Such a request must normally be received by the Board of Directors no later than seven weeks before the Annual General Meeting. In order to determine who has the right to attend and vote at the Annual General Meeting, Euroclear Sweden AB, at the Company's request, shall supply the Company with a list of all holders of shares as of the settlement date in connection with each Annual General Meeting. Shareholders who have their shares registered to a trustee must instruct the trustee to register the shares in the shareholder's own name in order to have the right to attend and vote for their shares at the Annual General Meeting (voting registration). Such registration must be completed no later than at the applicable record date and cease to apply after the record date. Shareholders who have their shares registered directly to an account in the Euroclear system will automatically be included in the list of shareholders.

#### NOMINATION COMMITTEE

The Annual General Meeting of the Company decided on 19 May 2017 to adopt the following principles for appointment and instruction regarding nomination before the 2018 Annual General Meeting. The following principles and instructions are valid until a decision is made to change them at the Annual General Meeting. The Nomination Committee shall consist of the Chairman of the board and three members appointed by the three shareholders with the greatest number of votes at the end of the third quarter of each year. The Chairman of the Board shall annually contact the shareholders who have the right to appoint a member. If any of the shareholders elect to waive their right to appoint a member of the Nomination Committee, the right transfers to the shareholder with the next greatest number of votes, and so on. However, no more than five additional shareholders need be contacted, unless the Chairman of the Board finds there are special reasons for this. When shareholders are contacted with a request for the appointment of a member to the Nomination Committee, the Chairman of the Board shall establish the required rules of procedure such as latest response date, etc. The names of the Nomination Committee members and the names of the shareholders who have appointed the members shall be published no later than six months before the Annual General Meeting. The Nomination Committee appoints a Chairman amongst themselves. The Chairman of the Board shall not be the Chairman of the Nomination Committee. If a member leaves the

Nomination Committee before its work is completed, and the Nomination Committee believes there is a need to replace this member, replacements are appointed by the same shareholders who appointed the resigned member, or, if this shareholder no longer belongs to the three largest shareholders with the most votes, one of the shareholders belonging to this group. If shareholders who appointed a certain member significantly reduce their holdings in the Company, and the Nomination Committee does not consider it inappropriate in light of any needs for continuity ahead of the forthcoming Annual General Meeting, the member shall leave the Nomination Committee and the Nomination Committee shall offer the largest shareholder who has not appointed a member of the Nomination Committee to appoint a new member.

The Nomination Committee's members shall not receive fees from the Company. Any costs arising in connection with the Nomination Committee's work shall be paid by the Company provided that this is approved by the Chairman of the Board.

# **Board of Directors**

#### THE BOARD OF DIRECTORS' DUTIES

After the Annual General Meeting, the Board of Directors is the Company's highest decision-making body. The Board is also the Company's highest executive body and the Company's deputy. Furthermore, according to the Swedish Companies Act the Board of Directors is responsible for the Company's organisation and management of the Company's affairs. and shall continually assess the Company's and the Group's financial situation and ensure the Company's organisation is designed so that the accounting, funds management and the Company's financial position in general are controlled in a safe way. The Chairman of the Board has a special responsibility to lead the Board's work and monitor that the Board fulfils its statutory duties. Amongst the duties of the Board are to define the Company's overall goals and strategies, monitor major investments, ensure that there is satisfactory control of the Company's compliance with laws and regulations which apply to the Company's operations and the Company's compliance with internal control documents. Amongst the duties of the Board are also to ensure that the Company's information to the market and investors is characterised by openness and is properly correct, relevant and reliable, and to set, evaluate and if necessary dismiss the Company's CEO.

In accordance with the Swedish Companies Act, the Board of Directors has established written rules of procedure for its work, which is evaluated, updated and re-established each year. The Board of Directors meets regularly based on a programme set out in the rules of procedure which contains certain fixed decision points and certain decision points as needed.

#### THE BOARD'S COMPOSITION

According to the Company's Articles of Association, the Company's Board shall consist of at least three (3) and no more than six (6) members with no more than three (3) deputies. Members are elected annually at the Annual General Meeting (AGM) for the time until the next Annual General Meeting has been held. There are no limits for how long a member may sit on the Board. The Company's Board consists of five members on the closing date for the financial year.

#### CHAIRMAN OF THE BOARD

The Chairman of the Board has the duty of leading the Board's work and ensuring that the Board's work is conducted effectively and that the Board fulfils its commitments. The Chairman shall, through contacts with the CEO, monitor the Company's development and ensure that the Board's members, through the CEO, continuously receive the information needed to be able to follow the Company's position, economic planning and development. The Chairman shall also consult the CEO on strategic issues and check that the Board's decisions are executed in an effective way. The Chairman is responsible for contacts with shareholders on ownership issues and for conveying comments from the owners to the Board. The Chairman does not participate in the operational work of the Company, and is also not included in the company management.

#### THE BOARD'S WORK

The Board follows written rules of procedure to be reviewed annually and re-established at the constituent board meeting. The rules of procedure regulate the work of the Board, duties, decision-making within the Company, the Board's meeting procedures, the Chairman's duties and the division of duties between the Board and the CEO. Instructions regarding financial reporting and CEO instructions are also established in connection with the constituent board meeting. In addition to the board meetings, the Chairman and CEO have a continuous dialogue around the management of the Company. The Board meets based on a pre-determined annual plan and shall hold at least five regular board meetings between each Annual General Meeting.

	Attendance no. of meetings 2017 post AGM	Board fees decided at the Annual General Meeting 2017	Independent in relation to:	
	Board meetings (9)	KSEK	The Group	Owners
Chairman of the board, Thomas Eklund	9	150	Yes	Yes
Board member, Sten Gibeck	9	50	Yes	No
Board member, Bengt Julander	9	50	Yes	No
Board member, Ola Magnusson	9	50	No	Yes
Board member, Michael Ryan	9	50	No	Yes

# The CEO and other senior management members

In accordance with the provisions of the Swedish Companies Act, the Company's CEO is subordinate to the Board and manages the ongoing management of the Company in accordance with the Board's guidelines and instructions. Measures that are of an unusual nature with regard to the extent and nature of the Company's operations or are of great importance fall outside of "ongoing administration" and shall as a rule be prepared and presented to the Board for decisions. The Company's CEO shall also take the measures necessary so that the Company's accounting is completed in accordance with law and so that funds management is handled in a safe way. The Board's rules of procedure and written CEO instructions shall set out the division of duties between the Board and the CEO. The Board continuously evaluates the Managing Director's work. At the end of the closing date, Christer Ahlberg was CEO of the Company. Sedana Medical's company management is furthermore comprised of Chief Financial Officer Maria Engström, Head of R&D Ron Farrell and Sales Manager Robert Vom Dorp. After the end of the financial year, Peter Sackey acceded as Chief Medical Officer and is part of the company management.

# Internal controls and auditing

Furthermore, according to the Swedish Companies Act the Board of Directors is responsible for the Company's organisation and management of the Company's affairs, and shall continually assess the Company's and the Group's financial situation and ensure the Company's organisation is designed so that the accounting, funds management and the Company's financial position in general are controlled in a safe way. The rules of procedure drawn up by the Board contain instructions for internal financial reporting. All interim reports and press releases are published on the Company's website (www.sedanamedical.com) in direct connection with publication. The Company is, in the capacity of a public company, obligated to have at least one auditor for review of the Company's and the Group's annual report and accounting and the Board and the Managing Director's management. The audit shall be as thorough and comprehensive as good auditing practice requires. The Company's auditors are chosen in accordance with the Swedish Companies Act. An auditor in a Swedish limited company thus has its mission from and reports to the Annual General Meeting and may not be guided in their work by the Board or any senior executives. According to the Company's Articles of Association, the Annual General Meeting shall appoint at least one (1) and a maximum of two (2) auditors with no more than two (2) deputy auditors. The Company's current auditor is Christina Kallin Sharpe.

# Remuneration to the Board members, senior executives and auditor

Remuneration to Sedana Medical's Board members is decided by the Annual General Meeting. At the Annual General Meeting on 19 May 2017, a decision was made on a Board remuneration on an annual basis of 150,000 SEK to the Chairman and 50,000 SEK to other Board members. Remuneration to senior executives who are employed can consist of base salary, variable remuneration, pension and other benefits. In addition to their monthly salary, CEO Christer Ahlberg has the right to an annual bonus of up to a maximum of six months' salary. The bonus is linked to the Company's turnover, the Company's operating income before interest, tax, depreciation, amortisation and goodwill write-downs and performance in relation to predetermined goals. In addition to statutory pension, the Company allocates an amount corresponding to 25 per cent of the CEO's fixed monthly salary to a CEO-defined occupational pension plan. The notice period is six months upon termination of employment from the CEO's side and 12 months upon termination of employment from the Company's side. In general, the CEO is subject to customary terms of employment containing provisions on confidentiality, non-competition and non-solicitation. Chief Financial Officer Maria Engström performs her duties on a consultancy basis. The consulting agreement may be terminated with due observance of a three month mutual notice period. The consulting agreement is valid from its conclusion on 1 February 2017 and until 31 March 2018. Afterwards, the consulting agreement transfers to an employment contract. The Company's Sales Manager Robert Vom Dorp and Head of R&D Ron Farrell are employees of the Group. The notice period for Robert Vom Dorp is mutually three months. The notice period for Ron Farrell is mutually six months. Only Robert Vom Dorp has agreed severance pay which amounts to six months' salary. The right to severance pay applies no matter how the employment ended. After the end of the financial year, Peter Sackey acceded as Chief Medical Officer. The notice period for Peter Sackey is mutually four months. The total remuneration to the auditor for the financial year 2017 amounted to 279.4 KSEK. Remuneration to the Company's auditor is paid on a regular basis.

# **BOARD OF DIRECTORS**

# Thomas Eklund

(Chairman)



#### Born: 1967

Position: Board member and Chairman of the Board in Sedana Medical since 2014. Education and work experience: MBA from Stockholm School of Economics. About 25 years of experience from leading positions within, amongst other things, banking, life sciences and the healthcare sector. CEO of Investor

Growth Capital (now Patricia Industries) for the years 2002-2012, an Investor-owned private equity company with a focus on long-term investments within technology, healthcare and industry. Former board member in life sciences companies such as Swedish Orphan International AB (Chairman) and Carmel Pharma AB.

Other ongoing assignments: Chairman in Caliditas Theraputics AB, Itrim Holding AB and Moberg Pharma AB (publ). Board member in Biotage AB, Boule Diagnostics AB, Eklund konsulting AB, Excillum Aktiebolag, Memira Holding AB, Neoventa Medical AB, Rodebjer Form AB, SciBase AB, SciBase Holding AB (publ), SciBase Intressenter AB, Surgical Science Sweden AB, Swedencare AB (publ) and TEDCAP AB. Holdings in Sedana Medical: 396,215 shares and 26 warrants series 2014/2019 via his company Eklund konsulting AB. The warrants give the right to subscription of a total of 104,000 shares.

**Independent:** Independent in relation to the company and company management. Independent in relation to the company's major shareholders.

## Sten Gibeck

(Board member)



#### Born: 1943

Position: Board member in Sedana Medical since 2005. Former Chairman of the board. Education and work experience: Higher Business Administration degree at Sveriges Kontoristförening. Former owner and CEO of the medical technology company Louis Gibeck AB during its journey from being a small distribution

company to achieving a market-leading position within its area in Germany, France, Japan and the United States. Louis Gibeck AB was traded on the OTC list in Stockholm for a couple of years near the end of the century in the '90s before the Company was purchased by Hudson Respiratory Care Inc, where Sten Gibeck was a board member 1999-2004.

Other ongoing assignments: -

Holdings in Sedana Medical: 2,105,744 shares. Independent: Independent in relation to the company and company management. Not independent in relation to the Company's major shareholders.

# Bengt Julander



Born: 1953 Position: Board member in Sedana Medical since 2011. Education and work experience: Trained pharmacist, M.Sc. from Uppsala Universitet, 1978. CEO of Linc AB, which invests in companies in medicine and medical technology. Operational, management and owner experience from the industry.

Other ongoing assignments:

Chairman in Knil AB. Board member in Busulipo AB, Calliditas Therapeutics AB, Cronhamn Invest AB, Linc AB, Medivir Aktiebolag, Nefecon AB, nWise AB, Pharmalink Nordic AB, ProEquo AB, Stille AB, Swevet AB, Swevet Holding AB. Deputy Board member in Algarvefastigheter AB, Eriksbergskliniken AB, Eriksbergskliniken Gam AB, Korkyl Holding AB, Kv Eldstaden i Bromma AB, Linc Global AB, Linc International AB, Linc Trade AB **Holdings in Sedana Medical:** 1,821,901 shares through Linc AB. **Independent:** Independent in relation to the company and company management. Not independent in relation to the Company's major shareholders.

# Ola Magnusson

(Board member)



#### **Born:** 1948

**Position:** Board member in Sedana Medical since 2005. Former CEO of Sedana Medical (2005-2011).

Education and work experience: Technical College Graduate with a focus in chemistry from Tekniska gymnasiet i Göteborg, 1968. Almost 30 years of experience from the pharmaceutical industry and

20 years of experience from the medical technology industry, mainly within marketing and sales and company management. Ola Magnusson was former CEO of Louis Gibeck AB and responsible for the company's listing on the OTC list in Stockholm. Former CEO of Hudson RCI AB after its acquisition by Louis Gibeck AB. Has worked in the Pharmacia Group in the United States twice during the '80s and '90s. Started Sedana Medical 2005 and worked as CEO until 2011.

**Other ongoing assignments:** Chairman in Eataway AB, Sedana Medical Incentive AB and Transcutan AB. Board member in Hammarplast Medical Aktiebolag, Miris AB, Miris Holding AB (publ) and Magiola Consulting AB.

**Holdings in Sedana Medical:** 59,867 shares in his own name and 1,368,000 shares and 37 warrants series 2014/2019 via Magiola Consulting AB. The warrants give the right to subscription of a total of 148,000 shares.

**Independent:** Not independent in relation to the company and company management. Independent in relation to the Company's major shareholders.

# Michael Ryan

(Board member and consultant within business development)



Born: 1957 Position: Board member in Sedana Medical since 2005. Former CEO of Sedana Medical (2011-2017).

Education and work experience: Master of Industrial Engineering (1st Class Honours) from University College Dublin, 1985. More than 25 years of experience from leading positions within

the manufacturing industry and almost 15 years of experience from leading positions within the medical technology industry. Board member of Venn Life Sciences Ltd, a CRO company listed on the London stock exchange's growth market AIM. Michael Ryan is also an investor, mainly in companies in life sciences. Michael Ryan was also the main shareholder and CEO of Artema Medical AB and led the sales of Artema to Datascope Corporation in 2007. Responsible for international sales and business development in Sedana Medical.

**Other ongoing assignments:** CEO and Board member in TecScan Ireland Ltd. Board member in Sedana Medical Ltd, Irrus Investment Ltd,Salmur Ltd and Venn Life Sciences Ltd. **Holdings in Sedana Medical:** 1,108,083 shares and 35 warrants series 2014/2019 giving the right to subscription of a total of 140,000 shares.

**Independent:** Not independent in relation to the company and company management. Independent in relation to the company's major shareholders.

# ORGANISATION AND MANAGEMENT

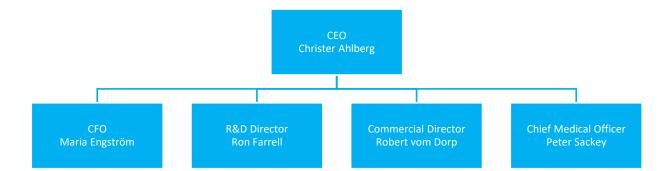
Sedana Medical has employees with a broad background and experience within business management, marketing, sales, production and research and development from both the pharmaceutical and medical technology industries.

Sedana Medical has its main offices in Dandervd, Stockholm while research and development is located in Ireland. The Group also has several employee product specialists in Germany, France, the Nordic countries and Spain. The average number of employees and consultants during 2017 amounted to 16.5 people and two consultants. Through long-term and dedicated work, the Group has created a strong organisation which attracts experienced staff to the company. In the coming years, Sedana

Medical will also increase the number of employees in line with the Group growing and thus make the organisation well prepared for the market introduction of IsoConDa. In order to reach established operational and financial goals, Sedana Medical will place a major focus on strengthening its product specialist organisation in current and future markets, and thoroughly strengthen pharmaceutical skills within the organisation.

#### COMPANY MANAGEMENT

The Group Management consists of CEO Christer Ahlberg, Chief Financial Officer Maria Engström, Director of Research and Development Ron Farrell, Commercial Director Robert Vom Dorp and Chief Medical Officer Peter Sackey.



#### Christer Ahlberg (CEO)



#### Born: 1971

Position: CEO in Sedana Medical since February 2017. Education and work experience: BSc in business administration and economics at Örebro University. Previous experience from the pharmaceutical industry, most recently as CEO within the Unimedic Group (2010-2016) and CEO of Eisai AB (2005-

2010). Before these CEO positions, Christer also has more than 10 years of experience from leading positions within sales, marketing and market access within the pharmaceutical industry, in AstraZeneca, Meda and Wyeth.

Other ongoing assignments: Anthrop Pharmaceuticals AB, Board deputy member and CEO in Waxholm by the sea limited liability company.

Holdings in Sedana Medical: 260,000 shares and 184,200 warrants series 2017/2021.

# Maria Engström

(Chief Financial Officer)



#### **Born:** 1972

Position: Chief Financial Officer in Sedana Medical since February 2017.

Education and work experience: BSc in business administration and economics from Stockholm University. Former Head of Cross Pharma AB (2015-2016) and

Head of Business Control at Medivir AB (2012-2014). Over

15 years of experience from position as a Finance manager, Head of Business Control and controller at Biovitrum, Bristol Myers Squibb and Ericsson.

Other ongoing assignments: Board member in FAYSIT -Finance At Your Service In Tyresö AB.

Holdings in Sedana Medical: 3850 shares and 60,782 warrants series 2017/2021.

# Ron Farrell

(Director of R&D)



#### **Born:** 1956

**Position:** Director of R&D in Sedana Medical since 2001. Former board member [(2012-2017)].

Education and work experience: Graduateship of the Plastics and Rubber Institute of London (GPRI) (now corresponds to Grad IOM3 from the Institute of Materials). About 37 years of experience

from the manufacturing industry at various position levels in companies such as Oral-B Laboratories, Gilette, Vistakon, Tech Group, Artema Medical and Kayfoam Woolfson. Mainly active in engineering, quality assurance, supply chain development and business management with regard to factories. **Other ongoing assignments:** Board member of Lismed Ltd. **Holdings in Sedana Medical:** 906,397 shares and 55 warrants series 2014/2019 giving the right to subscription of a total of 220,000 shares.

# Peter Sackey

(Chief Medical Officer)



#### **Born:** 1971

**Position:** Chief Medical Officer in Sedana Medical since January 2018.

Education and work experience: Peter is an adjunct professor and doctor. Peter is a Doctor of Medicine from Karolinska Institutet in Solna, Stockholm. Previously employed as Senior Physician at the Department of Intensive

Care, Perioperative medicine at Karolinska University Hospital in Sweden.

Other ongoing assignments: -

**Holdings in Sedana Medical:** 0 shares and 65,167 warrants series 2017/2021

# Auditor

According to the Company's Articles of Association, the Annual General Meeting shall appoint at least one and a maximum of two auditors with no more than two deputy auditors. The Company's current auditor is Christina Kallin Sharpe with address R3 Revisionsbyrå, Riddargatan 30, 114 57 Stockholm. Christina Kallin Sharpe is an Authorised Public Accountant and member of FAR (the Swedish trade association for accounting consultants, accountants and advisors).

# Robert Vom Dorp

(Commercial Director)



#### **Born:** 1970

**Position:** Commercial Director since 2017 and Sales Manager in Sedana Medical since 2010 (but employed since 2005).

Education and work experience: MBA in economics from the University of Applied Sciences at Hochschule Koblenz. Has also studied industrial organisation. Worked with sales in medical

technology since 2001, previously as an account manager for products within anaesthesia, ventilation and intensive care at Hudson RCI and Teleflex Medical. Responsible for marketing, strategy, sales and staff at Sedana Medical's sales office (branch office) in Germany. Also responsible for distributors in Austria and Switzerland.

Former consultant in companies that implemented ISO certifications in hospitals.

#### Other ongoing assignments: -

**Holdings in Sedana Medical:** 7,500 shares and 26 warrants series 2014/2019 giving the right to subscription of a total of 104,000 shares.



#### ANNUAL GENERAL MEETING

The Annual General Meeting in Sedana Medical will be held on 22 May 2018 at 4 p.m. CET, at the premises of Erik Penser, Apelbergsgatan 27, Stockholm. To have the right to attend the meeting, shareholders must be listed in the part of the share register kept by Euroclear Sweden on 18 May 2018. Shareholders who have registered their shares to a trustee should, in due time before this date, have the trustee temporarily register the shares in the shareholder's own name to have the right to attend the meeting. Registrations starts 3:30 p.m. CET.

#### **CERTIFIED ADVISER**

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

#### FOR FURTHER INFORMATION PLEASE CONTACT

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

Maria Engström, CFO +46 (0)8-124 05 200

#### ADDRESS INFORMATION

Sedana Medical AB (publ) Berga Backe 2, SE-182 53 Danderyd, Sverige Organisation number: 556670–2519

#### DATES FOR UPCOMING INFORMATION

Interim report Q1 2018: 22 May 2018

Interim report Q2 2018: 30 August 2018

Interim report Q3 2018: 22 November 2018

Year-end report 2018: 21 March 2019

Sedana Medical AB (publ), 556670–2519, Berga Backe 2, SE-182 53 Danderyd, Sverige.

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the AnaConDa technology people