SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

Company Presentation

CEO Christer Ahlberg

September 2020

Disclaimer

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Vision

Inhaled sedation with AnaConDa and IsoConDa;
a global standard of care therapy for mechanically ventilated ICU patients

Intensive care units and sedation: A brief introduction

Overview: Intensive care units

INTENSIVE CARE UNIT (ICU)

ICUs cater to critically ill patients with severe illnesses and injuries

Common conditions treated at ICUs include:

Trauma, multiple organ failure, sepsis and acute respiratory distress syndrome

30-50% of patients require mechanical ventilation to breathe[1]

Why are patients sedated in the ICU?

SEDATION IN THE ICU

Sedation is primarily used for mechanically ventilated patients

The purpose of sedation of mechanically ventilated ICU patients is to provide comfort via short- and long-term reduction of anxiety and distress to facilitate safety by:

Reducing autonomic stress, optimising ventilator treatment - asynchrony and avoiding self-extubation

Sedated patients are better able to tolerate many of the procedures performed during ICU care

Sedation in the ICU represents a large unmet clinical need

Current sedation methods fall short on key factors

INTRAVENOUS SEDATION

Long and unpredictable wake-up times (90 min – 130 h)[2]

Prolonging the stay in the ICU and making extubations difficult to plan

Drug level concentration is difficult to monitor

Tolerance, withdrawal symptoms or agitation/delirium (20-35% of cases)[3]

Significantly increasing ICU stay (by up to 40%)
Delirium increases the mortality risk significantly

Eliminated through the liver or kidneys

Extra burden on liver/kidneys. ICU patients frequently have impaired organ function

High mortality[4]

In long-term ventilated patients

A better sedative exists but it hasn't been possible to use

INHALATION SEDATION

Significantly reduced wake-up time (10-20 min)[5]

Improving the planning of clinical workflow and reducing time to extubation

Controlled sedation depth

With less under and over sedation

Tendency to reduce hallucination episodes/delirium[6]

Eliminated through the lungs

Inhaled sedatives such as Isoflurane are almost entirely eliminated through the lungs

Reduced mortality[4]

In long-term ventilated patients

Inhalation sedation hasn’t been practically possible in the past

The tools for administration exist but not for use in the ICU

ANESTHESIA MACHINE

Anesthesia machines are used for administration of general anaesthesia in the operating room.

These machines are capable of inhalation sedation, however, they are not approved or intended for use in the intensive care unit setting and they are not used due to their size and high capital and usage costs making them unsuitable for prolonged use.

The additional need for administration and monitoring by a specialist makes the use of these machines labour intensive and impractical for inhalation sedation.

AnaConDa finally makes inhalation sedation possible in the ICU

ANACONDA

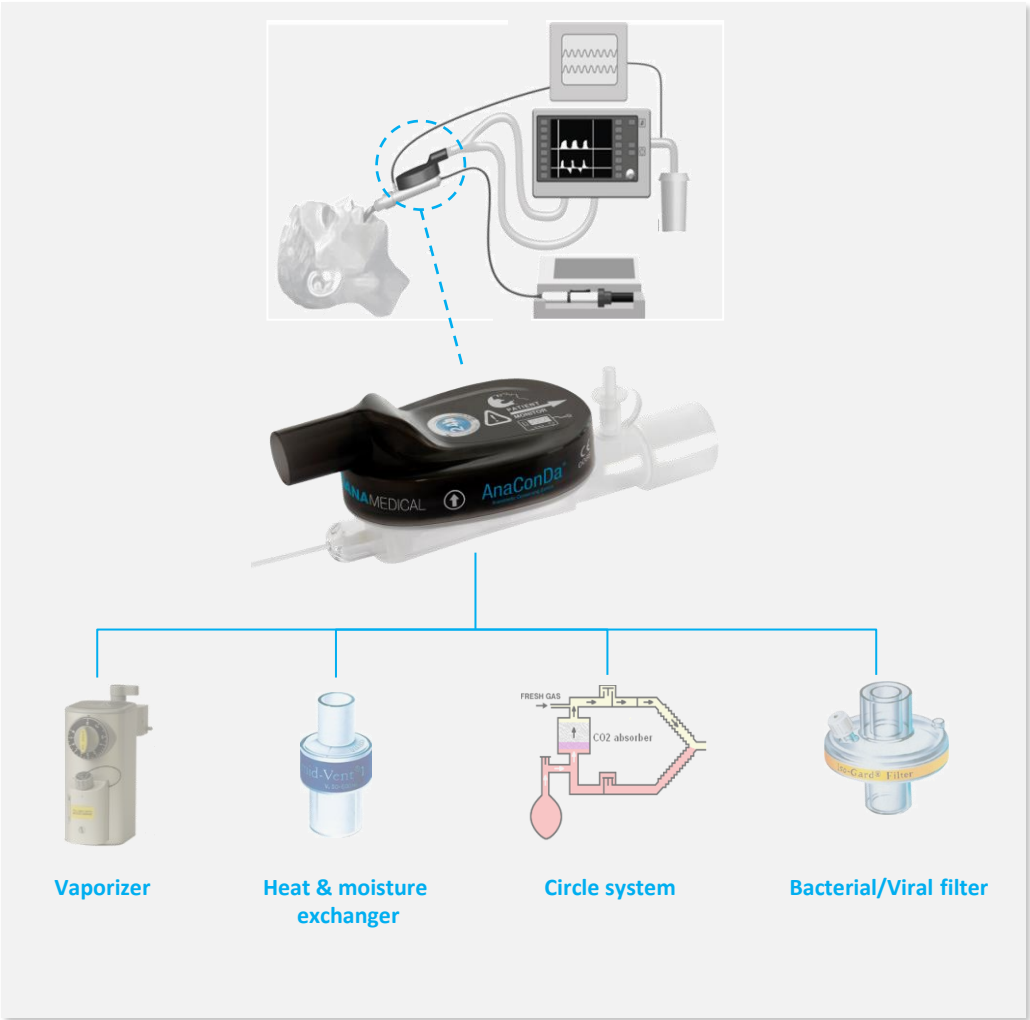
AnaConDa is a cost-effective CE marked disposable system for the delivery of inhaled sedatives built for use in the ICU.

By incorporating a vaporizer, circle system, heat & moisture exchanger and a bacterial/viral filter into a single disposable device AnaConDa is able to make inhalation sedation possible and practical in the ICU.

The AnaConDa device is simply attached to a traditional ICU ventilator in order to deliver controlled sedation to patients.

AnaConDa – making inhaled sedation possible in the ICU

Compact device encompassing the most important elements for ICU use



AnaConDa

- **Simple and convenient to administer** – can be administered by a nurse
- **Low cost disposable system** for administration of inhaled sedatives
- **Accurate patient dosing** minimizing over and under sedation
- **Compact size and convenient design** – Seamless integration into clinical workflow
- **Low consumption of sedative agent** – >90% recirculated to patient
- **Proven safety with no workplace pollution** in the ICU
- **Combines 4 functions** (vaporizing, reflecting, humidifying and filtering) disposable delivery system - no electricity or maintenance
- **CE marked** with strong sales growth in Europe, patent possible until 2036

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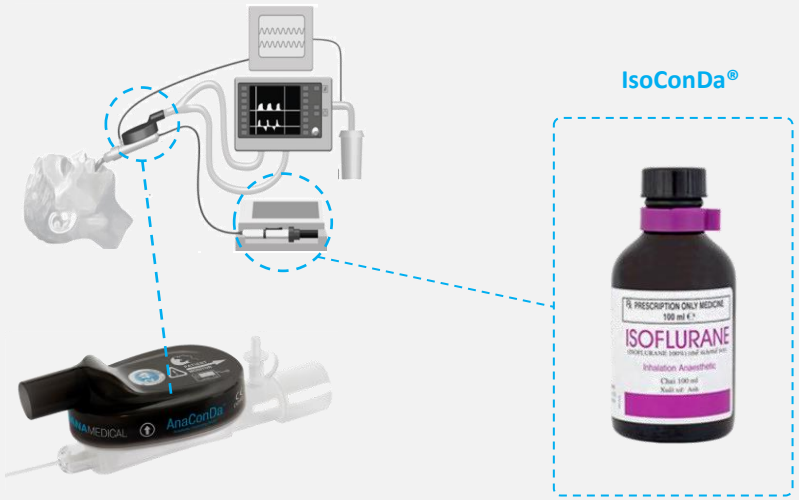
IsoConDa® – a superior inhaled sedative for use in the ICU

Safe and proven inhaled sedative administered by a practical and cost effective delivery system



- IsoConDa® (Isoflurane) is a generic volatile anaesthetic with a long record of use in the operating theatre
- Currently not approved for use as a sedative in the ICU setting but is used off label together with AnaConDa

IsoConDa® (Isoflurane)

- **Significant reduction in mortality**[4]
- **Potential for reduced ICU stay duration:** No development of tolerance, dependence, withdrawal symptoms and/or delirium and fewer hospital acquired infections (HAI): expected to lead to shorter ICU stays
- **Organ protective*:** Inhaled sedatives have potentially cardio-, neuro- and lung-protective properties[7]
- **Eliminated through the lungs** (IV drugs are metabolised in the liver and eliminated through the kidneys): isoflurane is almost 100% eliminated through the lungs
- **Bronchodilator effect:** Improves lung function for patients with COPD, ARDS, Asthma etc.[8]
- **Reduction of opiate dependency:** Reduces the need for analgesics such as remifentanil and other opioids by >35% compared to when using IV sedation, with benefits to the associated cost of sedation[9]

* Based on studies performed on mice.

IsoConDa® provides clear benefits over current standard of care

Benefits	IsoConDa®	IV sedation
ON-OFF EFFECTS AND RELIABLE WAKE UP		
✓ **Significantly reduced wake-up time**[2]	**10-20 min**	**90 min – 130 h**
✓ **Reduction in ICU stay duration for deep sedation patients**[10]	**4-16 days**	**6-27 days**
✓ Significantly reduced time to extubation (ventilator tube removal)[2]	**10-35 min**	**150-600 min**
RELIABLE EFFECT AND SAFETY FOR THE DISTRESSED PATIENT		
✓ **Limits the occurrence of hallucination episodes/delirium**[6]	**2 of 10 patients**	**5 of 7 patients**
✓ Reduction in use of opiates[9]	**2.7 mg/hour**	**4.2 mg/hour**
POTENTIALLY ORGAN PROTECTIVE PROPERTIES		
✓ **Reduced *in-hospital* mortality in long-term ventilated patients (>96h)**[4]	**40%**	**63%**
✓ Reduced *1 year* mortality in long-term ventilated patients (>96h)[4]	**50%**	**70%**
✓ Improved gas exchange**	**Yes****	**No****
Price per day	**EUR 100***	**EUR 20-300*****

EUR 1-3k

Daily cost of an ICU bed in Europe[14]

$4-16bn

Annual cost of delirium from ventilated patients in the US[15]

* Price for both AnaConDa and IsoConDa together. ** See appendix. *** Price of IV sedation is dependent on dose, number of pharmaceuticals used in the cocktail, severity of the patient and country. Excludes cost of prolonged ICU stay and additional treatment required due to complications in sedation. Cost for longer ICU –stay due to IV sedation is not included.

Blockbuster market potential for IsoConDa/AnaConDa

Breakdown: total market potential for IsoConDa/AnaConDa*

Annual number of patients visiting the ICU
30 million

12 million
patients require mechanically ventilation

5.5% CAGR

Ventilated and sedated patients
8 million

Average number of sedation days
2,5-5 days

X

AnaConDa/IsoConDa price per day in Europe (will be higher in the US and lower in Asia)
EUR 100

X

AnaConDa/IsoConda market potential
EUR 2-3 billion

Regional market potential

Europe

~7,5m
ICU patients

~EUR 700m
European market potential

USA

~7m
ICU patients

~EUR 900m
US market potential depending on pricing

Asia/Pacific

~12,5m
ICU patients

~EUR 1bn
Asian/Pacific market potential

*Market size based on company estimates.

Rapidly increasing adoption and usage despite off-label status

Case study: AnaConDa in Germany

- In 2010, new guidelines for sedation were published in Germany.
- The guidelines put forward inhalation sedation and the use of isoflurane as an alternative to IV sedation in intensive care for certain patient groups.
- The new guidelines together with positive statements from a number of German KOLs have led to extensive use of AnaConDa in Germany.
- Sedana Medical's largest market is currently Germany, which together with other markets where it conducts direct selling, has functioned as a test market to study demand.

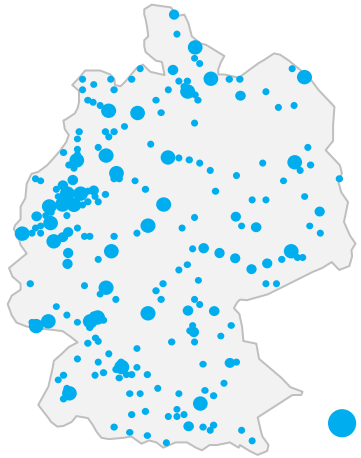
AnaConDa in Germany

~680

ICUs use AnaConDa

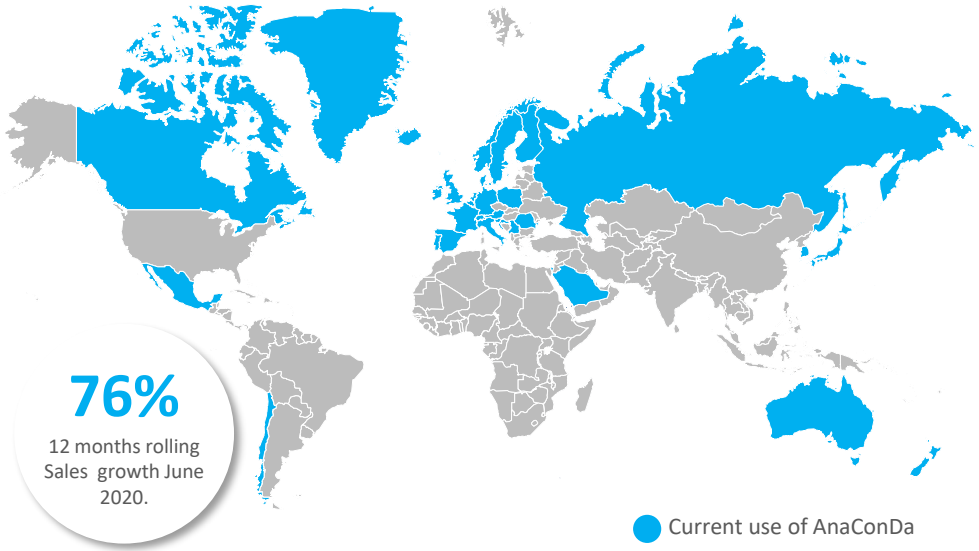
5%

of total market potential



Clinics actively using AnaConDa

Increasing use globally



Proven in clinical practice

>500,000

AnaConDa units sold

>600,000

treatment days

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Strategic priorities and financial targets

Strategic priorities

1

Development and commercialisation: Europe

- Registration of the pharmaceutical candidate IsoConDa (isoflurane) in 2021
- Ensure solid growth of AnaConDa sales and prepare for launch of IsoConDa in 2021

2

Development and commercialisation: USA

- Development of registration work in USA with both AnaConDa and IsoConDa for NDA approval in 2024
- Commercialisation strategy for USA to be decided ~2022.

3

Development and commercialisation: RoW

- Register AnaConDa and IsoConDa in relevant markets in Asia, such as Japan and China

Financial targets

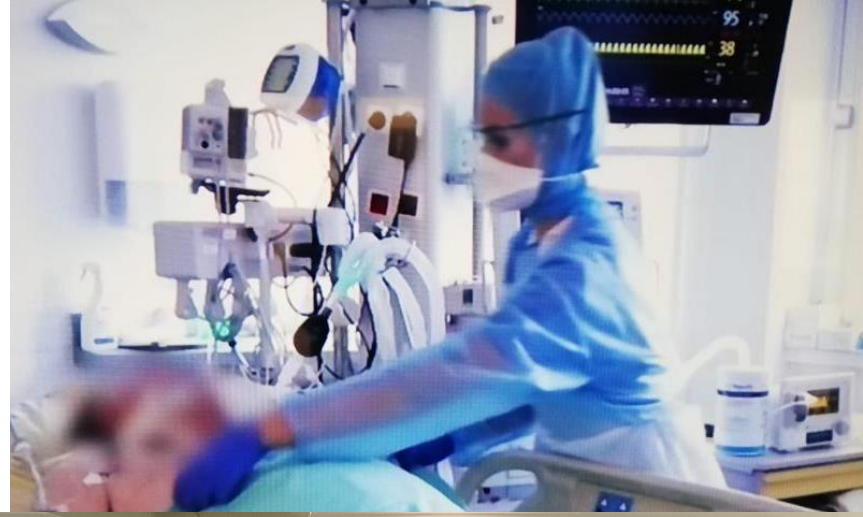
Pre-registration

During the period up until the approval of IsoConDa is obtained, the Company's goal is to increase sales with an average of over 20 per cent per year, in parallel to building up a larger sales and market organization.

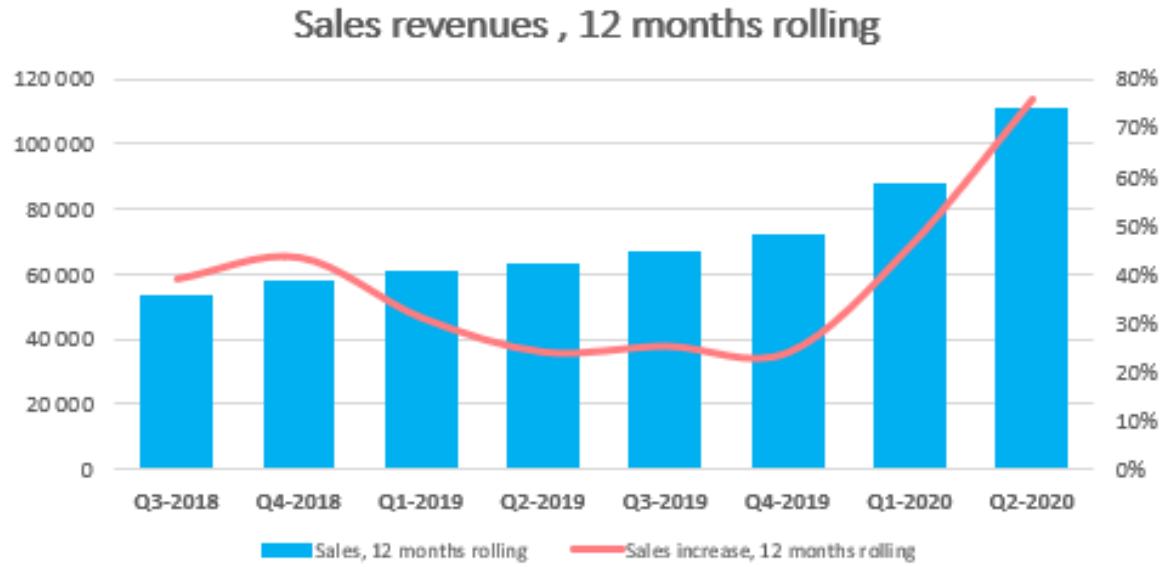
Post-registration

Provided that an approval of IsoConDa in Europe is obtained, the Company’s target is to reach a turnover in EU exceeding 500 million SEK and an EBITDA margin of 40 percent three years after approval.

H1 2020 strongly influenced by Covid-19



Sales Development Q2 2020



133%
Sales increase vs. Q2 2019

76%
Sales increase rolling 12 months

Sales increase:

- 133% sales growth in Q2 2020 vs Q2 2019 *(132% in local currencies)*
- 76% sales growth rolling 12 months (*74% in local currencies)*
  equal to 110 MSEK sales turnover annually (June 2020)
- *The sales increase comes 40% from new ICUs and 60% from established ICUs*

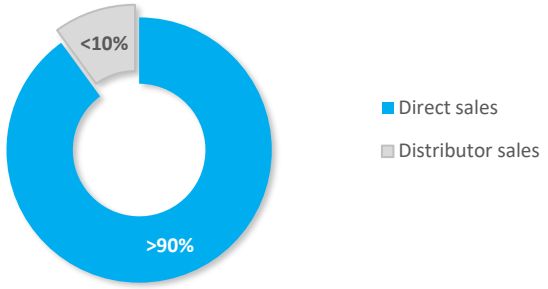
Sales organisation buildup in preparation for regulatory approval

Sedana Medical applies a direct sales model to key markets with plans to cover 15 EU countries in time for approval

SEDANA MEDICAL CURRENT DIRECT SALES ORGANISATION

SEDANA MEDICAL DIRECT SALES ORGANISATION 2021

SALES BREAKDOWN BY SALES TYPE



Q2 2020 Sales increase

Germany: >70%

Other Direct Sales markets: >500%

Distributor Markets: >250%

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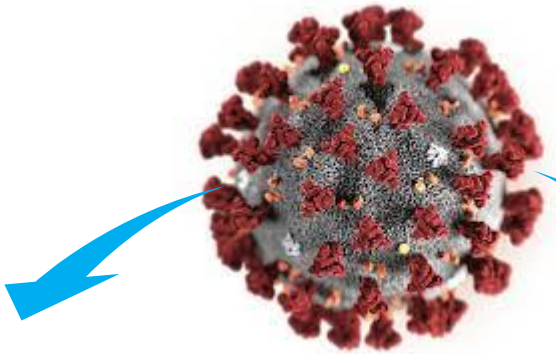
Covid-19 impacts on the business – current status



Sales

- Higher demand from current customers
- Deliveries to new markets and customers
- The sales increase comes 40% from new ICUs and 60% from established ICUs.
- Lower sales increase in the end of the Q2 vs in the beginning, but higher than normal.
- Increased interest in inhaled sedation as an alternative to IV sedation

Supply

- Higher expenses for transportation and freight
- No significant negative impact from interruptions in supply flow, but components have been the bottleneck – supporting our suppliers to ramp up
- Production – few interruptions, well structured risk mitigation and >100% ramp up in capacity

Clinical development

- IsoConDa study: Delayed top line result (July 2020) and in filing of the market authorization application in EU to Q4 2020
- No expected delay of registration of IsoConDa in EU – 2HY 2021
- No expected delay of registration work in the USA
- Increased interest in IIT on inhaled sedation treatment

Financials

- Positive EBITDA development
- Positive cash flow from operations before working capital

Development highlights RoW

From proven therapy to approved standard of care

Japan

- Approval of AnaConDa in Japan in Q4 2018
- First patient treated in Q2 2019
- Investigating the possibility for registration of IsoConDa – Pre-IND meeting during H1-2021

EUR **300**m
Estimated annual market potential

China

- 10-year exclusive distribution agreement with Kyuan Xinhai Medical, a subsidiary of partly state-owned Shanghai Pharma, the second largest life science company in China
- Ongoing registration process of AnaConDa
- Estimated time to approval is summer 2021

5-6m
Estimated ventilation days annually

India

- Exclusive distribution agreement with Hansraj Nayyar Medical
- First patients treated in November 2019
- Registration process for AnaConDa is ongoing.

2m
Estimated ventilation days annually

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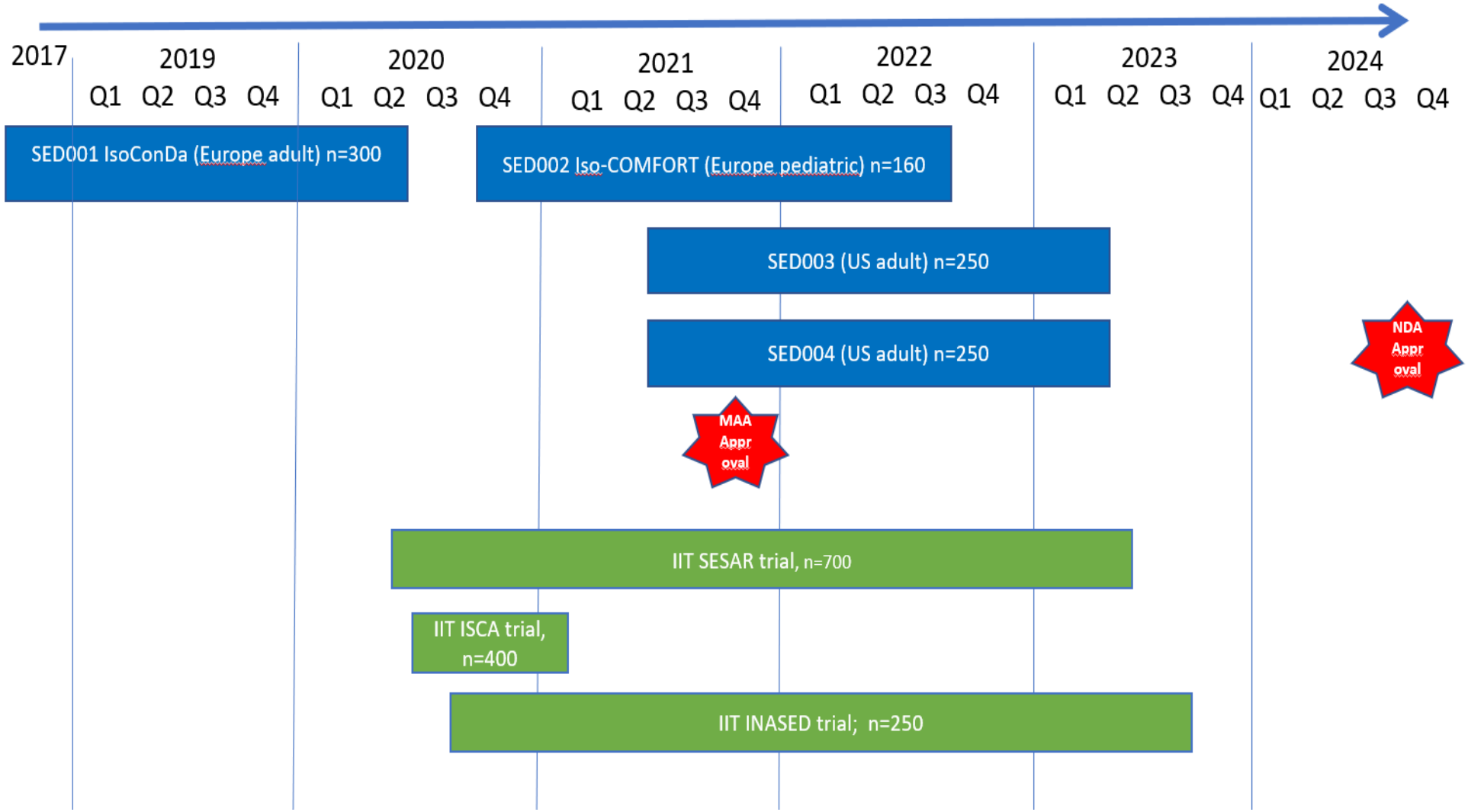
Clinical development

From proven off-label treatment to approved therapy and a new standard of care in the ICU



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The IsoConDa study
First results

.....

Sedana Medical announces positive top line result in pivotal IsoConDa study

" We are proud to have conducted the world's largest study of inhaled sedation in intensive care. This is the most significant milestone in inhaled sedation since the development of the AnaConDa…"

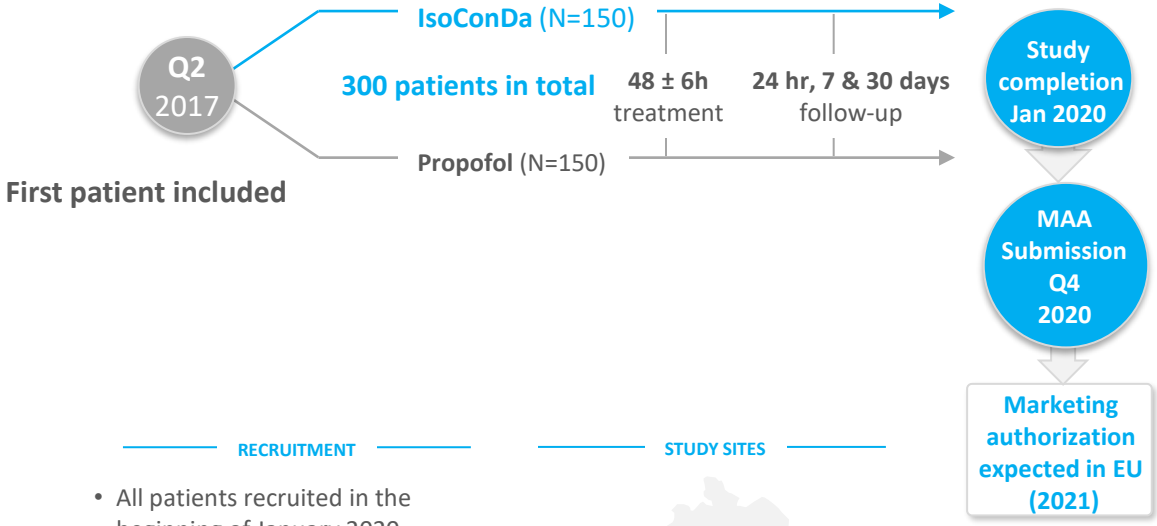
" The study results are in line with a long-standing clinical experience of many doctors all over the world. Isoflurane is safe and efficacious as a sedative for invasively ventilated critically ill patients. We hope that more patients will benefit from the advantages of inhaled sedation in the future"

"The goal we had when we initiated the work with the IsoConDa study several years ago was to be able to register inhaled sedation with IsoConDa administered with AnaConDa and thus approach our vision to make inhaled sedation a new standard method in intensive care units around the world. With these strong results as a base, we have come a giant leap closer to our vision."

European market registration study – the IsoConDa study

Phase III trial: Non-inferiority study of IsoConDa compared to propofol

A randomized, controlled, open-label study to confirm efficacy and safety of sedation with isoflurane in invasively ventilated ICU patients using the AnaConDa administration system.



PRIMARY ENDPOINT

Non-inferiority: proportion of time with adequate sedation depth for isoflurane

SECONDARY ENDPOINTS

Wake-up times, proportion of time with spontaneous breathing, opiate requirements, ventilator-free days

EXPLORATORY ENDPOINTS

Differences in Sequential Organ Failure Assessment, mortality rate in addition to IsoConDa and AnaConDa specific endpoints

RECRUITMENT

- All patients recruited in the beginning of January 2020
- Top-line results presented in Q2 2020
- Submission in 15 EU markets Q4 2020
- Approval 2HY 2021

STUDY SITES

21 German sites
3 Slovenian sites

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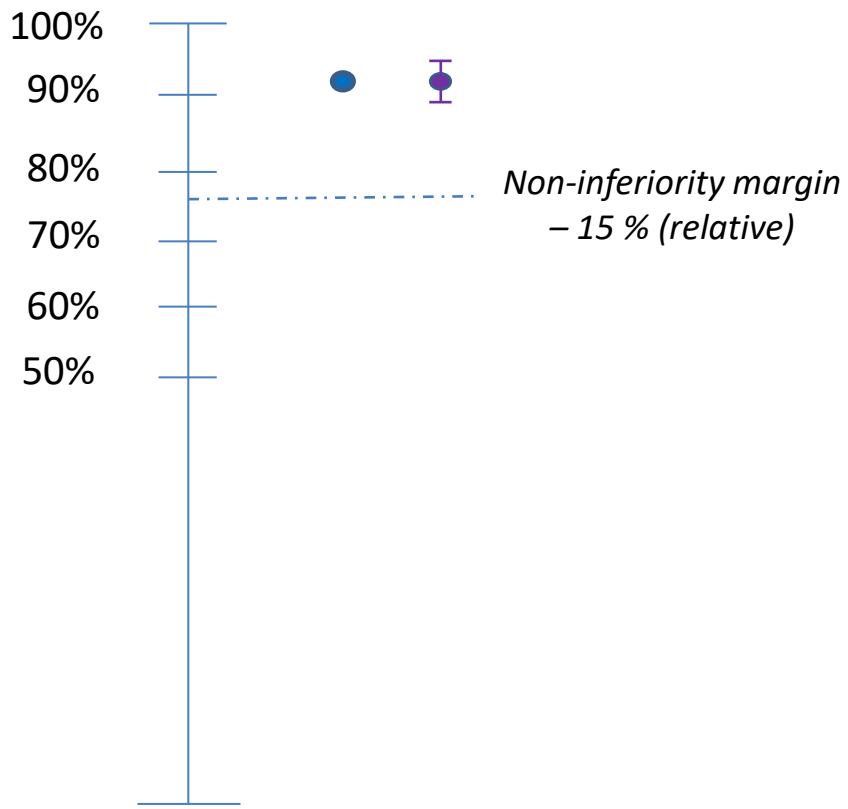
IsoConDa sedation efficacy is non-inferior to propofol

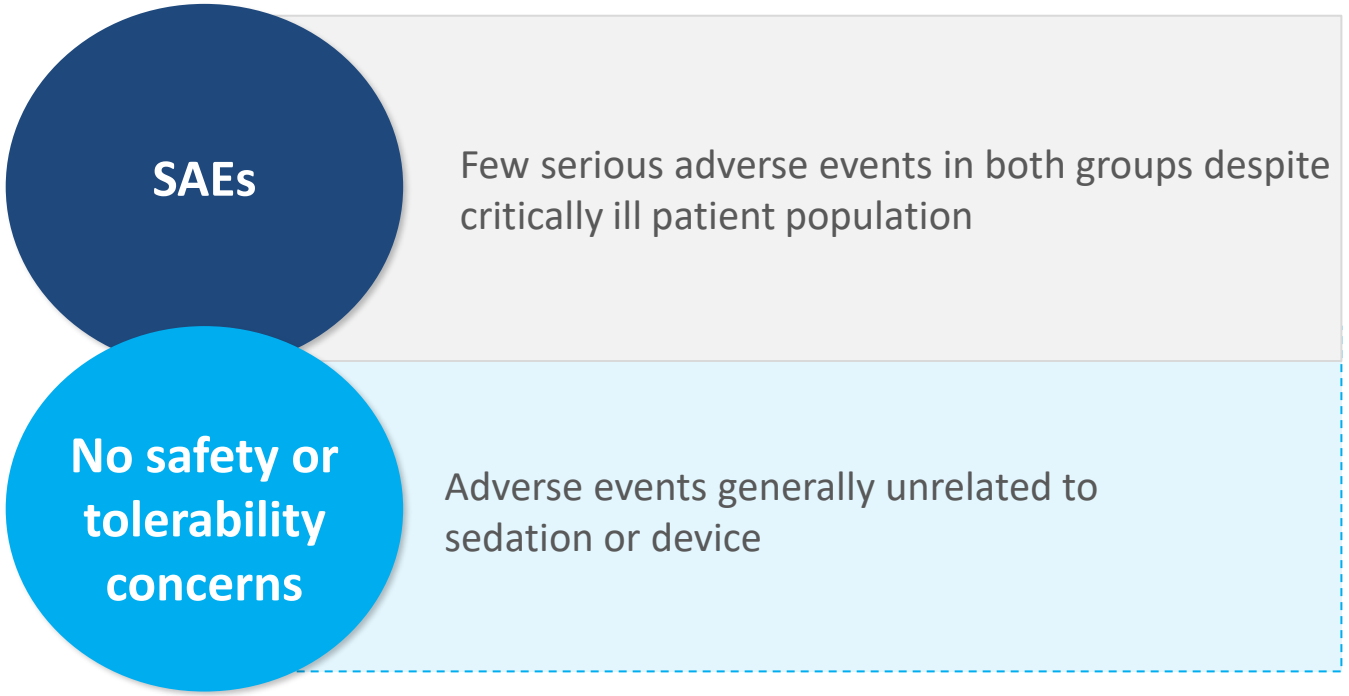


Proportion of time in target RASS (RASS -1 to -4)

Propofol
Mean proportion of time in target RASS

IsoConDa
Mean proportion and 95% confidence interval of time in target RASS

Safety


SAEs
Few serious adverse events in both groups despite critically ill patient population
No safety or tolerability concerns
Adverse events generally unrelated to sedation or device

Secondary and exploratory endpoints

Under analysis

Will be communicated together with primary endpoint and safety in peer reviewed publication

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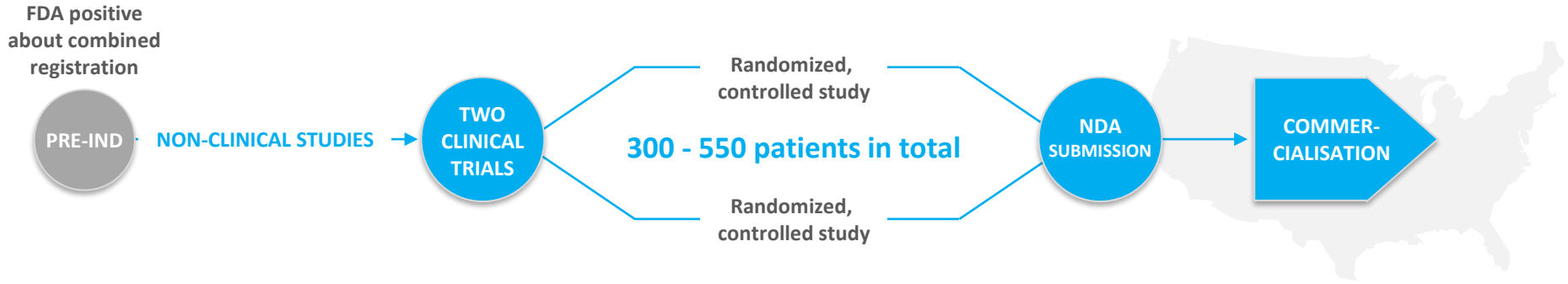
Clinical Development USA

Combination registration of AnaConDa & IsoConDa in USA

505 (b) (2) approval pathway

The FDA has accepted that Sedana Medical is taking the 505 (b) (2) path to registration, which somewhat simplifies the use of previously collected data.



NON-CLINICAL DATA

Current documentation to be complemented with more data, to be approved by FDA:

- Non-clinical toxicity studies – animal and PPND* - ongoing
- Human factors testing - ongoing

CLINICAL STUDIES

Two clinical, randomized and assessor-blinded studies to be conducted to confirm efficacy and safety.

SAFETY DATABASE

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

COMMERCIALISATION

Commercialisation strategy for USA – whether to launch alone or together with a local partner – to be decided around 2022.

* PPND: pre- and post-natal development.

Timeline – registration activities in Europe and US

MAA Approval

NDA Approval

2020	2021	2022	2023	2024
• **Jan 2020** Inclusion of last patient in IsoConDa study • **July 2020** High-level data IsoConDa study • **Q4 2020** • MAA application in Europe in a first round • **Q4 2020** Paediatric study - first patient in	• **2021** Marketing authorization of IsoConDa	• **2022** Completion of paediatric study • Pediatric marketing approval of IsoConDa		
Q4 2020 • Completion of Human Factors formative study • Completion of non-clinical studies for IND	**2021** • IND approval • Clinical studies start • Further non-clinical studies	**2022** • Decide whether to launch products in US alone or together with a local partner	**2023** • Finalise clinical trials • NDA application	• **2024** NDA approval expected

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Financial highlights

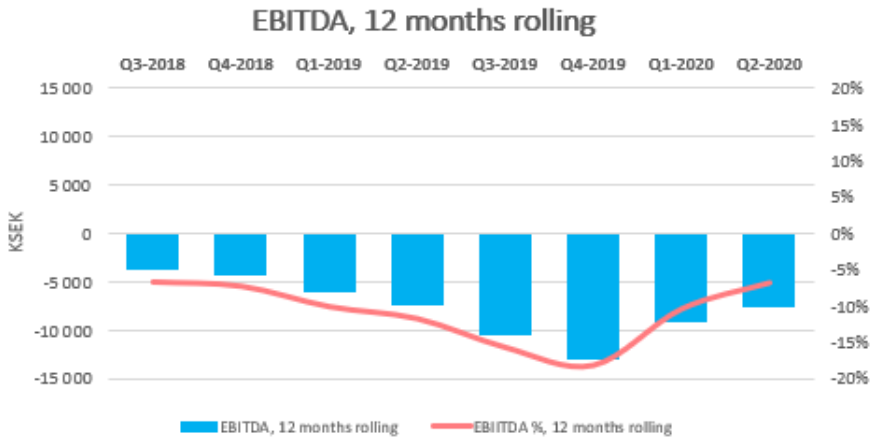
Financial highlights

Q2 -2020

- **Net sales** of 40,5 MSEK vs. 17,4 MSEK in Q2 2019, 133% growth individual quarter YoY and 76% rolling 12 months.
- **Gross margin** of 27,0 MSEK or 68% vs. 13,4 MSEK or 77 % in Q2 2019.
- **EBITDA** -0,8 MSEK or -1,9% vs. -2,3 MSEK or -13,4% in Q2 2019.
- **OPEX** increased with 68% vs Q2 2019 due to build up of European organisation and preparation for IsoConDa launch which means continued sales and market, medical affairs, regulatory affairs and quality functions investments during Q2.
- 52 **employees** in average vs. 40 employees Q2 2019 for the group in total.
- **Cash flow** from **operations** before change in working capital was 0,7 MSEK.
- **Cash flow** from **operations** including change in working capital was 1,5 MSEK.
- **Cash flow** from **investments** was -17,7 MSEK of which -15,3 MSEK concern product development.
- **Total cash flow** for the group in Q2 was -8,0 MSEK.

Slightly lower gross profit

Positive EBITDA



Financial results Q2 2020 vs. Q2 2019

(MSEK)

P&L	Q2	
	2020	2019
Revenues		
Net sales	40,5	17,4
Capitalized development expenses	0,0	0,0
Other operating income	1,3	0,6
	41,8	17,9
Operating cost and expenses		
Cost of goods sold	-13,5	-4,0
External expenses	-12,6	-6,7
Personnel expenses	-14,2	-9,2
Depreciation and amortisation	-1,1	-1,0
Other operating expenses	-2	0
Operating income	**-1,9**	**-3,4**
Income from financial items		
Result from securities and long term receivables	0,0	0,0
Financial income	0,1	0,7
Financial expenses	-2,4	0,2
Income after financial items	**-4,2**	**-2,5**
Income before taxes	**-4,2**	**-2,5**
Taxes	0,6	0,8
Net Income	**-3,6**	**-1,7**
Gross Margin	*27,0*	*13,4*
%	*66,7%*	*77,0%*
EBITDA	*-0,8*	*-2,3*
%	*-1,9%*	*-13,4%*

Balance Sheet	30 June	
	2020	2019
ASSETS		
Intangible assets	127,5	72,7
Tangible assets	5,8	5,2
Financial assets	2,4	2,0
Total Fixed assets	**135,7**	**79,8**
Inventory	8,7	5,8
Receivables	22,0	8,9
Cash and cash equivalents	433,5	137,3
Total current assets	**464,2**	**152,0**
TOTAL ASSETS	**599,9**	**231,8**
EQUITY & LIABILITIES		
Share capital	2,3	2,0
Other equity	572,9	212,1
Total equity	**575,2**	**214,1**
Long term liabilities	0,0	0,0
Current liabilities	24,7	17,8
TOTAL EQUITY AND LIABILITIES	**599,9**	**231,8**

Cash Flow	Q2	
	2020	2019
Cash flow from operations bef. change in w.c.	0,7	-2,1
Change in w.c.	0,7	0,7
Cash flow from operations after change in w.c.	**1,5**	**-1,4**
Cash flow from investment activities	-17,7	-13,4
Cash flow from financing activities	8,3	2,2
Cash flow for the period	**-8,0**	**-12,6**

Largest shareholders at the end of July 2020

Below is Sedana Medical's ownership structure as of **July 31, 2020**.

Name	Number of shares	Shareholding (%)
Handelsbanken Funds	1 933 303	8,39%
Swedbank Robur Funds	1 916 901	8,32%
Linc AB	1 826 600	7,93%
Anders Walldov direct and indirect (Brohuvudet AB)	1 630 000	7,07%
Sten Gibeck	1 325 246	5,75%
Ola Magnusson direct and indirect (Magiola AB)	1 230 744	5,34%
Berenberg Funds	965 149	4,19%
Öhman Funds	767 680	3,33%
Anades Ltd	481 478	2,09%
Tredje AP-fund	563 979	2,45%
Nordnet Pensionsförsäkring	475 506	2,06%
Avanza Pension	470 031	2,04%
Highclere International Investors LLP	396 502	1,72%
Tedsalus AB (Thomas Eklund)	408 516	1,77%
Christer Ahlberg	334 000	1,45%
Fifteen largest shareholders	**14 725 635**	**63,89%**
Others	8 321 105	36,11%
TOTAL:	**23 046 740**	**100,00%**

Source: Modular Finance

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Questions

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Appendix

Therapeutical benefits by using inhaled anaesthetics

Pulmonary therapeutic effects for patients with impaired gas exchange[11]

- ✓ Improved oxygenation
- ✓ Reduction of pulmonary inflammatory response
- ✓ Bronchodilatory effect

On-off effects and reliable wake-up with inhaled sedation[12]

- ✓ Shorter time to extubation…
- ✓ Shorter time to cooperation…
- ✓ Shorter ventilator time and ICU stay…

…when compared with intravenous sedation

Reliable effect and safety with inhaled sedation for the distressed patient[13]

- ✓ Works in all patients – full range sedative
- ✓ No need for polypharmacy
- ✓ Few problems after wake-up
- ✓ Patients are more lucid and calm with less hallucinations and delusions
- ✓ No/low risk of tolerance development, ceiling effect and withdrawal symptoms
- ✓ Reduction of opioid use

AnaConDa – increased demand in the Covid-19 crisis

Use in Covid-19 patients – clinical feedback

1. **Higher sedative and opiate requirements**
   - Very strong respiratory drive in Covid-19 ARDS
   - Prone positioning, high PEEP
2. **Potential pulmonary protective effects ***
   - Anti-inflammatory effects
   - Improved oxygenation in ARDS
3. **Multiple organ failure in many Covid-19 patients**
   - Accumulation, long, unpredictable wake-up with iv sedation
   - Delirium
   - Pharmacological advantages with inhaled anaesthetics
4. **Problems with mobilisation and ICU discharge**
   - Patients wake up very slowly after long-term iv sedation
   - Stupor and delirium make mobilization and ICU discharge difficult

Increased use in other ICU patients

Medical reasons

Reversible and effective sedation without protracted hangover effects

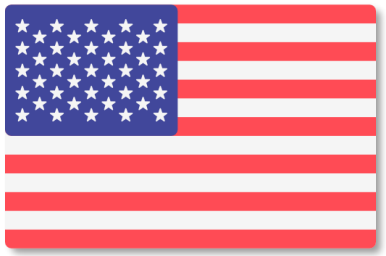
Potential pulmonary protective effects (anti-inflammatory)

Shortage of intravenous sedatives

Shortage of the most commonly used sedatives for mechanically ventilated patients

* https://bjanaesthesia.org/article/S0007-0912(20)30299-3/pdf

Ongoing US activities 2020



- ✓ Finalisation of non-clinical studies needed for IND and clinical trials
- ✓ Finalisation of US-adapted AnaConDa training program & Human Factors testing
- ✓ Selection of Contract Research Organisation (CRO) for US studies
- ✓ Finalisation of clinical study protocols together with CRO and Key Investigators
- ✓ Study site selection – currently significant interest from >30 academic centers across the US
    - Clinical trials planned to start 2HY 2021

The IsoCOMFORT study for EU and USA

Approved paediatric investigation plan

A complete Marketing Authorization Application (MAA) for drugs in EU must include a PDCO-approved study plan for children, a so-called PIP (Paediatric Investigation Plan).

Protocol approved by EMA Paediatric Committee

2019

IsoCOMFORT Study

- 160 children, aged 3 to 17
- Isoflurane via AnaConDa vs. IV Midazolam
- Sedation will last for 12-48 hours
- Primary endpoint: proportion of time with adequate sedation without rescue sedation, assessed with the COMFORT-B scale
- Preliminary duration of trial: 18 months
- Finalisation of site feasibility assessment underway

Planned recruitment of first patient

Q4 2020

~18 Sites in Spain, Germany, France & Sweden

The outcome of the study is not a requirement for obtaining an authorization for use in adults, so **the timetable for approval of IsoConDa is not affected** by this decision.

Since the filed registration documentation will now be complete – i.e. also covers children – **means Sedana Medical will receive ten years of market exclusivity** in Europe for the use of isoflurane in sedation in intensive care.

The FDA have given feedback on the study protocol as the study may merit as the pediatric study for the US program