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Pioneering volatile anaesthetic delivery

Interim Report Q2 2020 Presentation

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25th Aug 2020

Disclaimer

Forward-looking statements

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Sedana Medical's business, financial condition and results of operations. The terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realized. Factors that could cause these differences include, but are not limited to, implementation of Sedana Medical's strategy and its ability to further grow, risks associated with the development and/or approval of Sedana Medical's products candidates, ongoing clinical trials and expected trial results, the ability to further commercialize AnaConDa and IsoConDa, technology changes and new products in Sedana Medical's potential market and industry, the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

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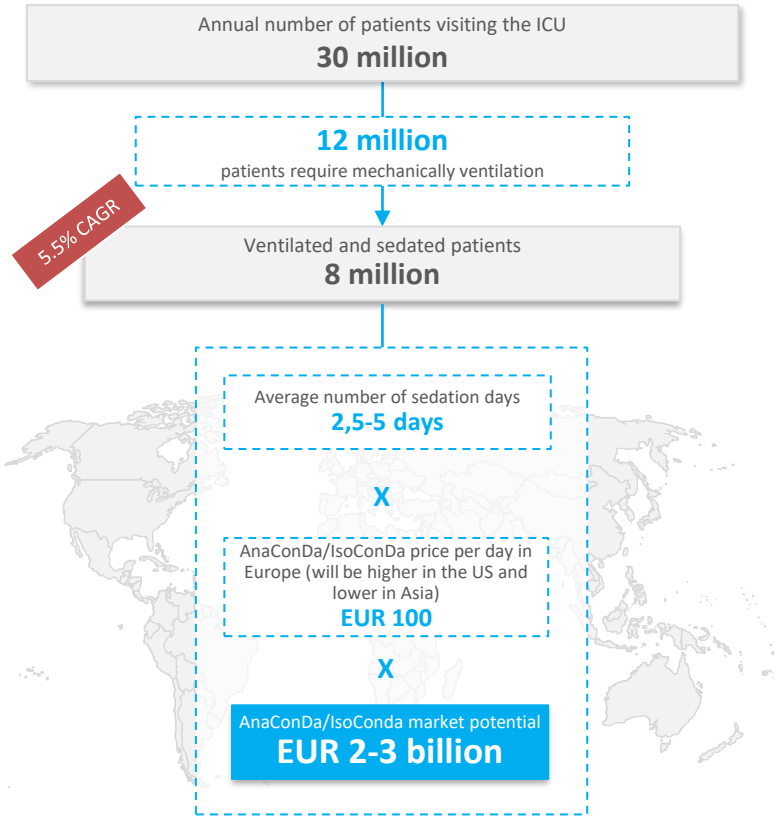
Vision

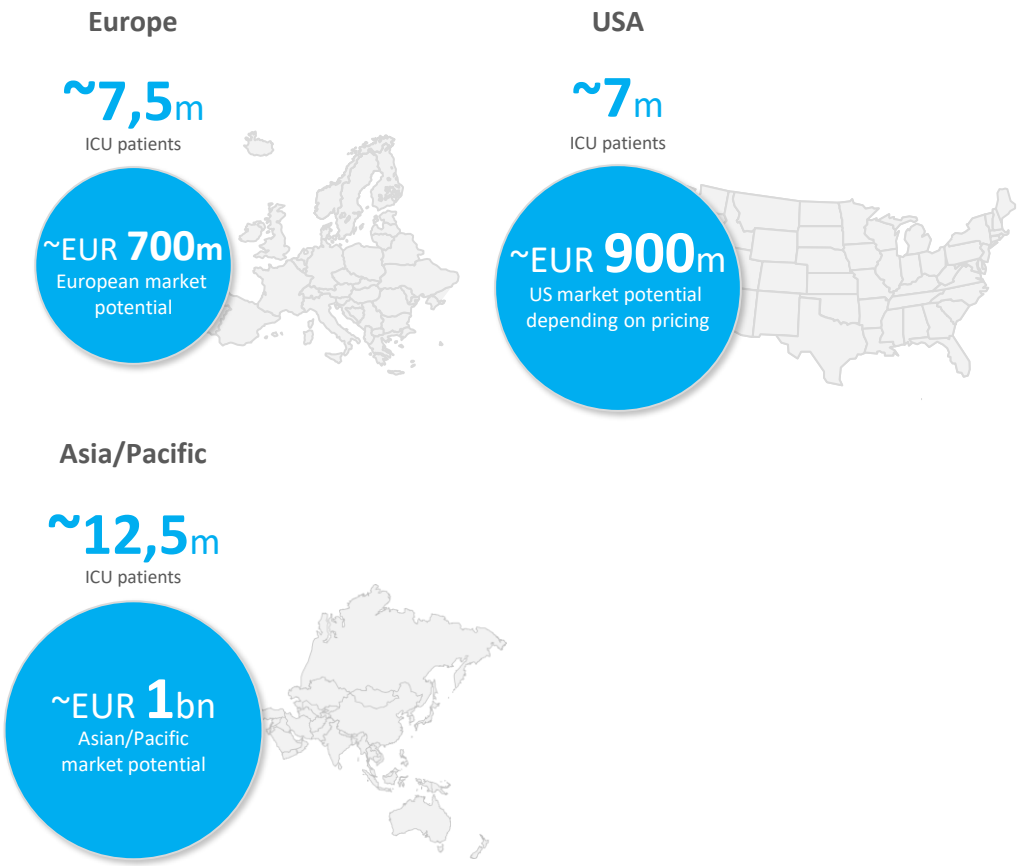
Inhaled sedation with AnaConDa and IsoConDa;
a global standard of care therapy for mechanically ventilated ICU patients

Blockbuster market potential for IsoConDa/AnaConDa

Breakdown: total market potential for IsoConDa/AnaConDa*



Regional market potential



*Market size based on company estimates.

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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.

Q2 2020 Highlights

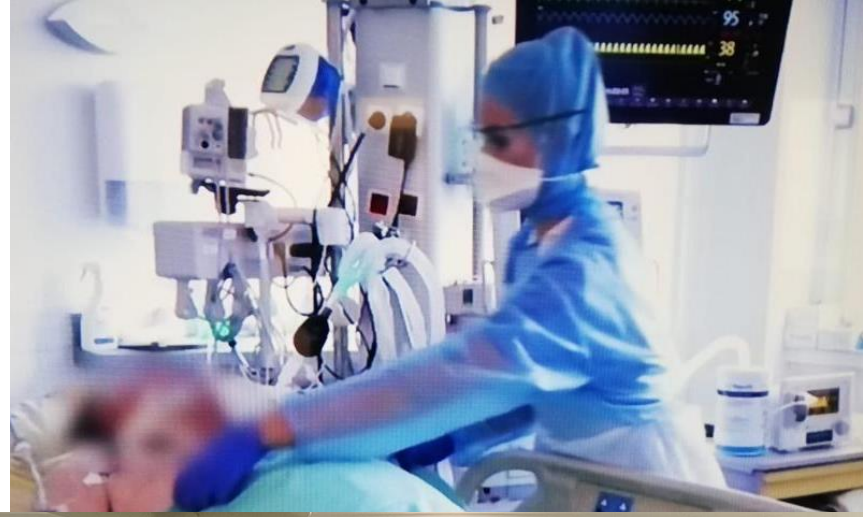
Significant events during the period

- Sedana Medical announced that the company will support a multinational study of inhaled sedation in covid-19-related ARDS, the ISCA study. The study is conducted in intensive care units in several European countries.
- The first patient was enrolled in SESAR, a study comparing inhaled sedation and intravenous sedation for patients with Acute Respiratory Distress Syndrome, ARDS. Sedana Medical contributes with financial support and study material.
- Sedana Medical signed during the quarter sales agreements with distributors in Eastern Europe.

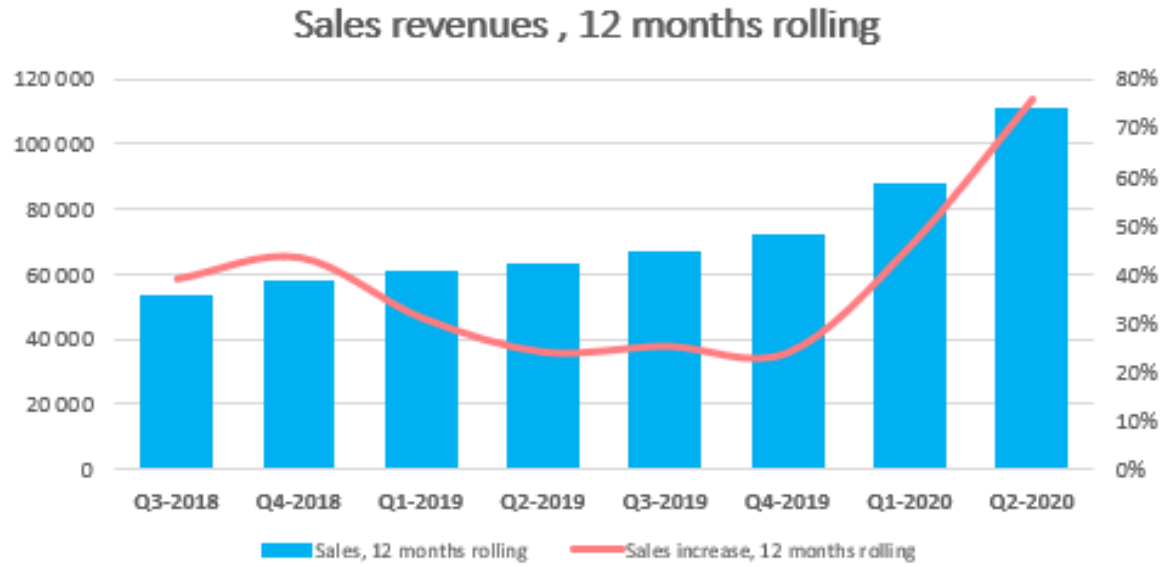
Significant events after the period

- The company announced that it had received market approval in Saudi Arabia for AnaConDa, and that distribution agreements had been concluded with distributors in Saudi Arabia, the United Arab Emirates and Oman.
- On July 10, Sedana Medical announced top line result for the company’s registration-based phase 3 study for the drug IsoConDa. The study reached its primary endpoint; to show that IsoConDa (isoflurane), administered with AnaConDa, is an effective sedation method, for ventilator-intensive care patients, which is non-inferior to propofol.The results indicate that IsoConDa is an effective and safe sedation method and will form the basis for the company's application for European market approval later during 2020.
- On August 19, the company announced that it has signed a distribution agreement for sales in Australia and New Zealand

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*

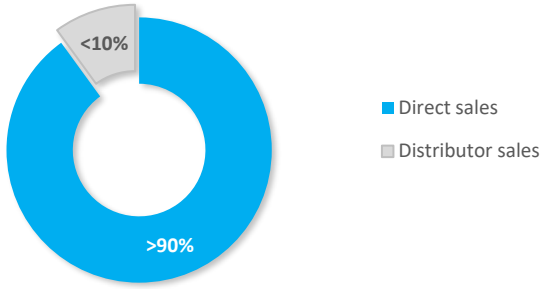
Sales organisation buildup in preparation for regulatory approval

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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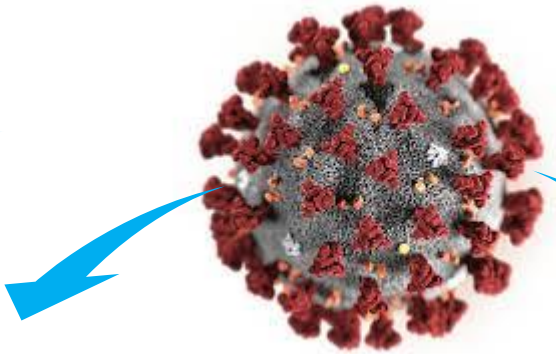
Covid-19 impacts on the business – current status



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.

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

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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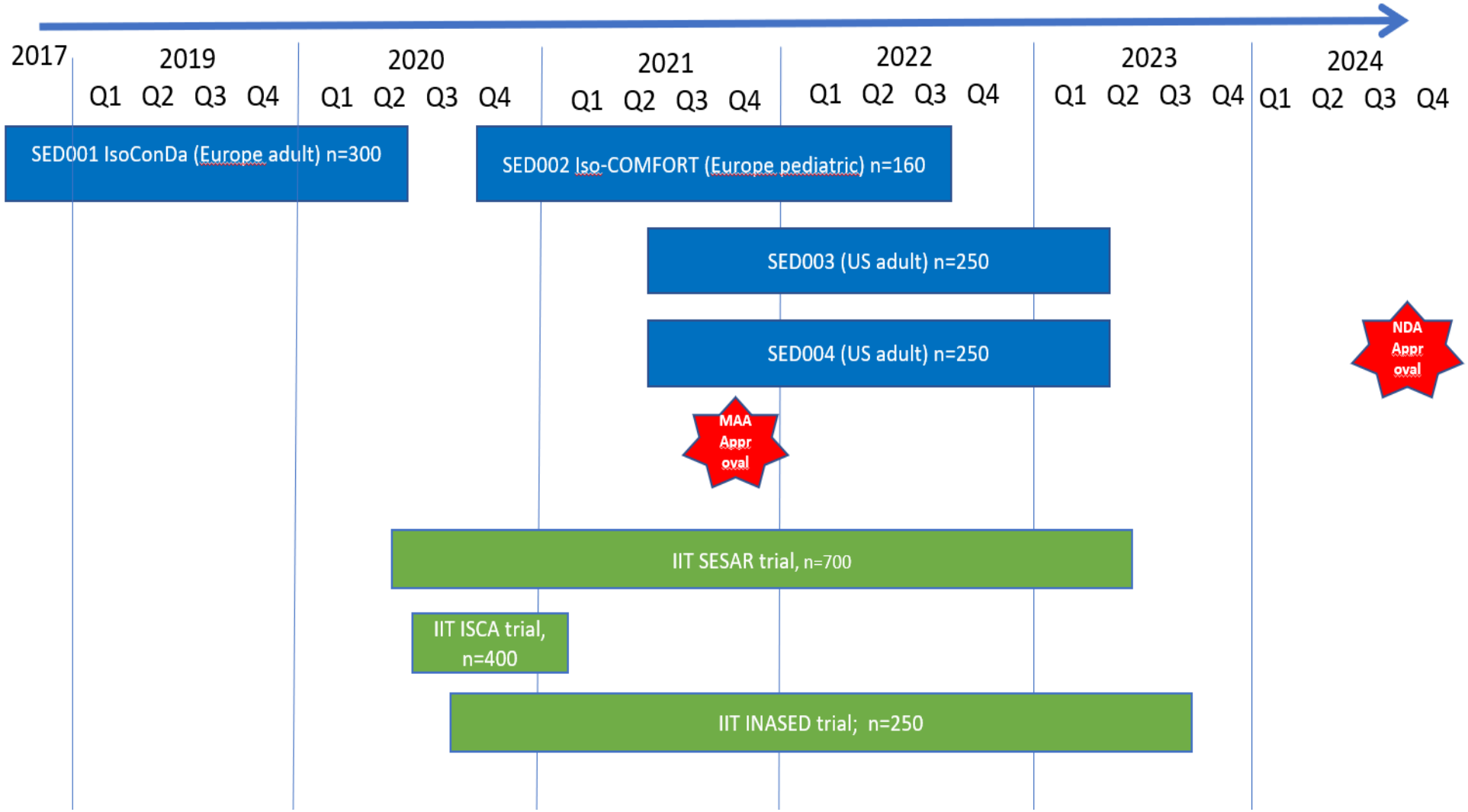
Clinical development

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

.....

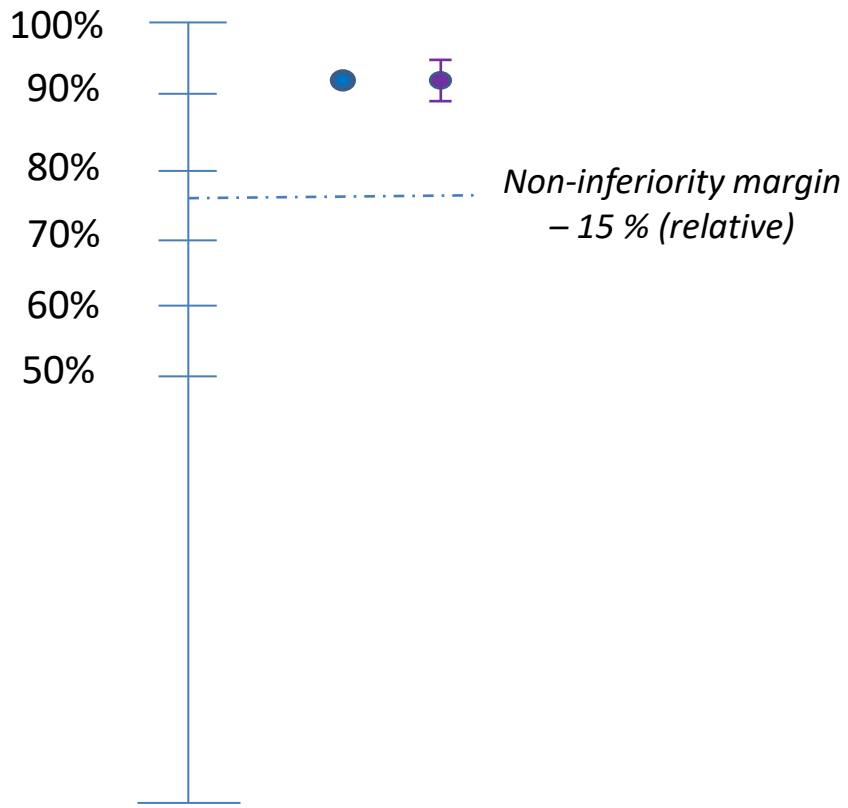
Sedana Medical announces positive top line result in pivotal IsoConDa study

" 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."

IsoConDa sedation efficacy is non-inferior to propofol

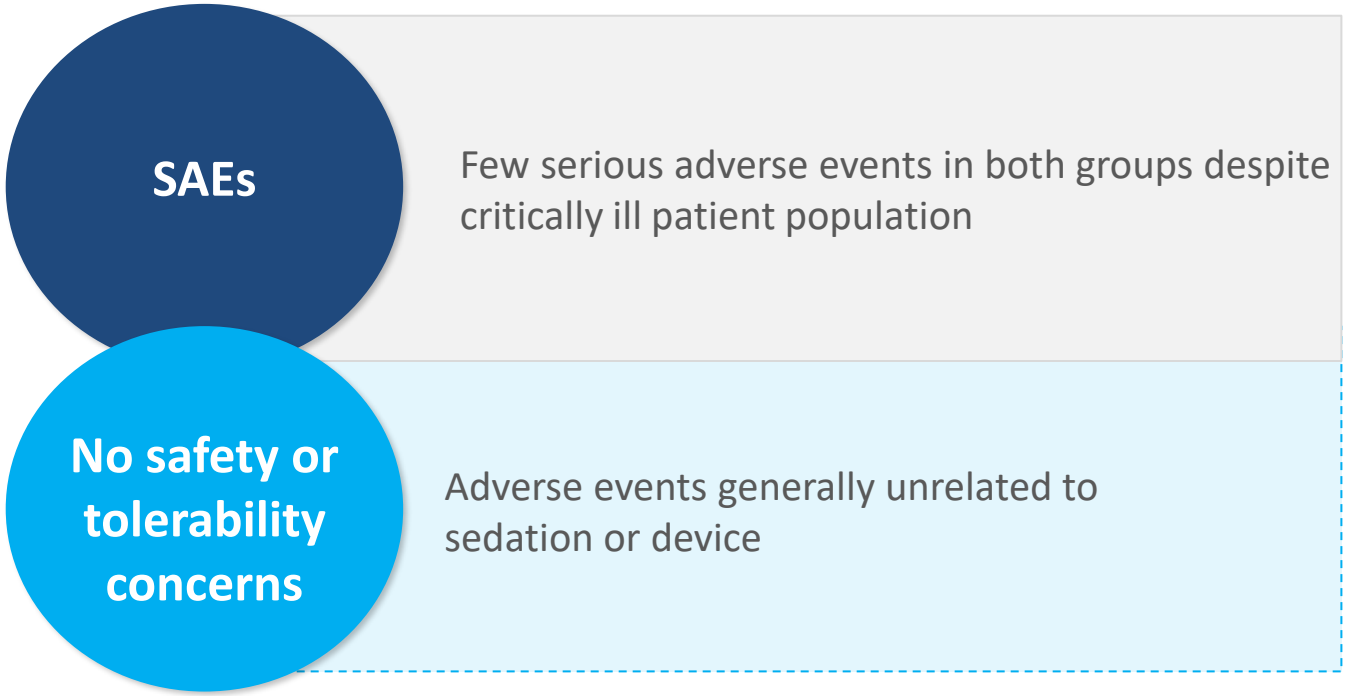


Proportion of time in target RASS
(RASS -1 to -4)

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

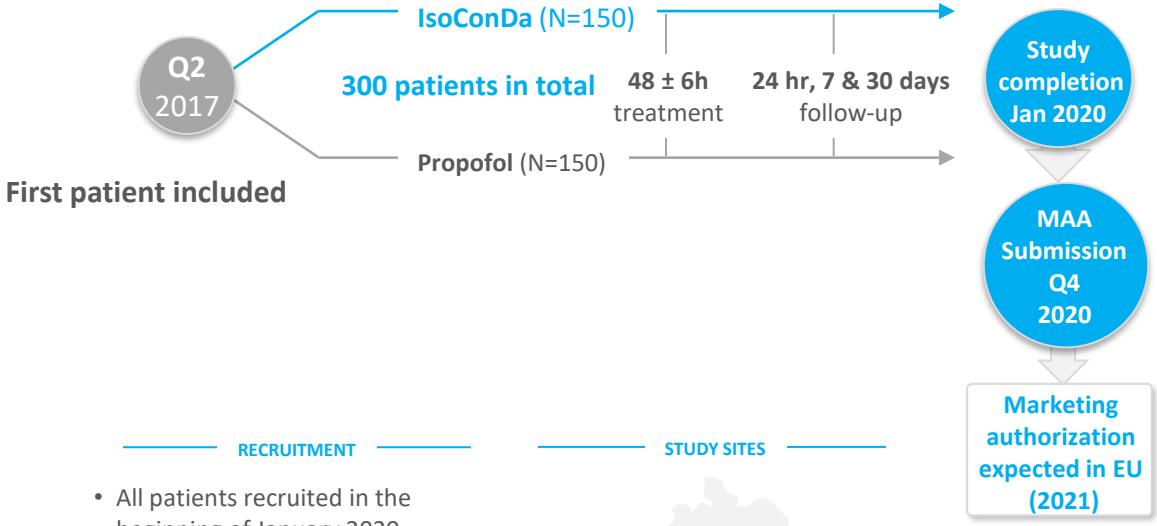
Under analysis

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

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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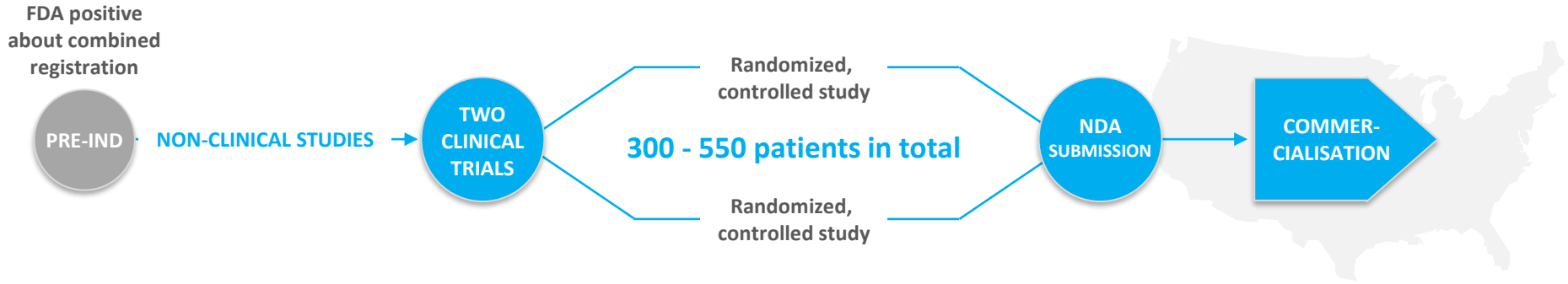
Clinical Development USA

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

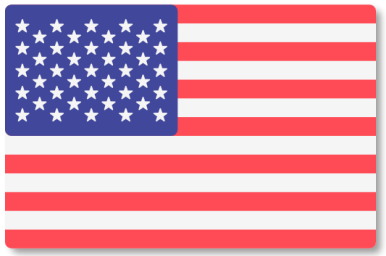
Patients from these clinical studies, as well as patients from the European study will be included in the safety database of 500 isoflurane patients.

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.

Ongoing US activities 2020

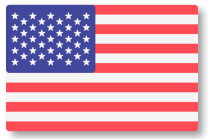


- ✓ Finalisation of non-clinical studies needed for IND and clinical trials
- ✓ Finalisation of US-adapted AnaConDa training program & Human Factors testing
- ✓ Selection of Contract Research Organisation (CRO) for US studies
- ✓ Finalisation of clinical study protocols together with CRO and Key Investigators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

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

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 – **an approval 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

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Financial highlights

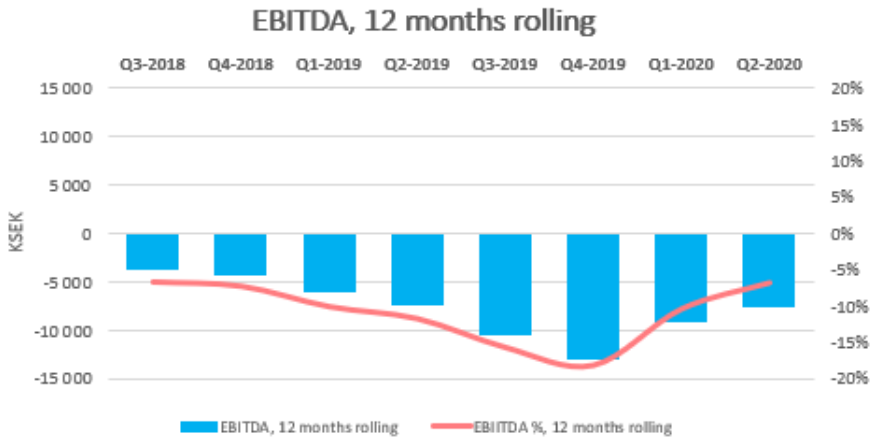
Financial highlights

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	Q2 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	30 June 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	Q2 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