

SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

Interim Report Q1 2020 Presentation

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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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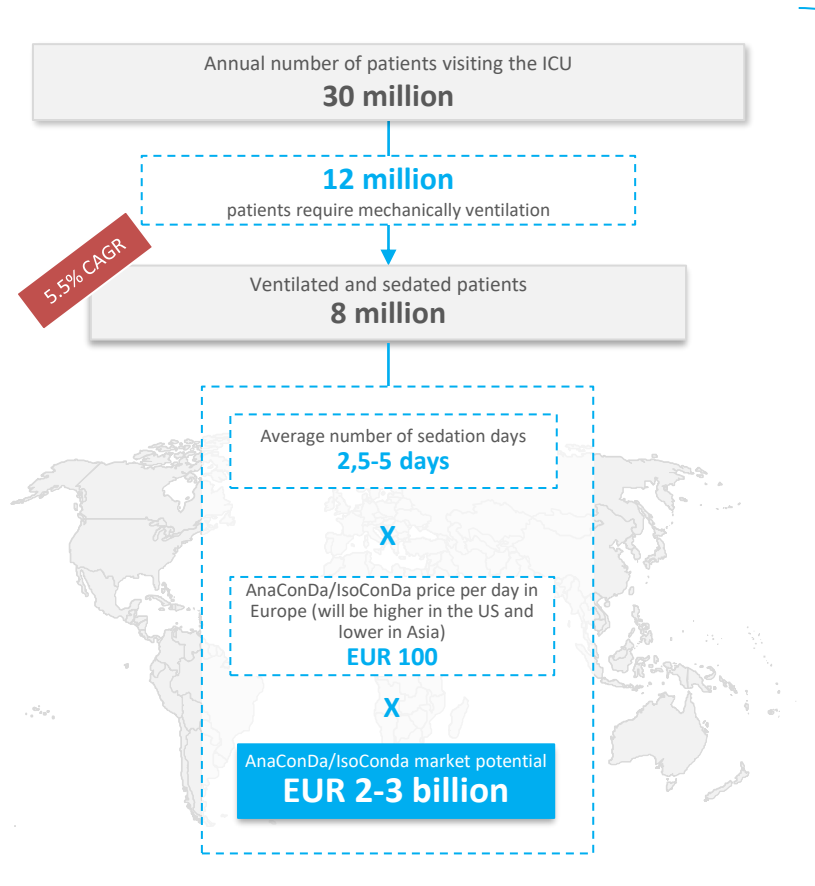
Vision

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

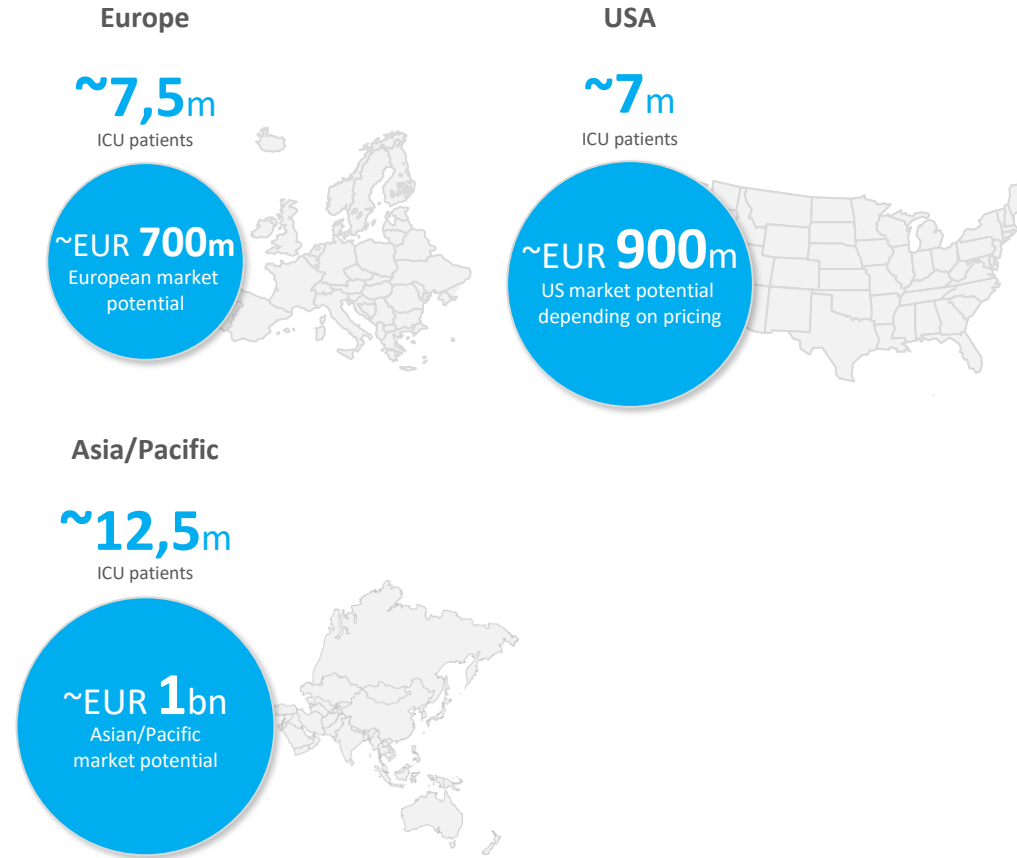
3. Large & clearly defined market opportunity for replacement of standard of care

Blockbuster market potential for IsoConDa/AnaConDa

Breakdown: total market potential for IsoConDa/AnaConDa*



Regional market potential



Strategic priorities

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

Q1 2020 Highlights

Significant events during the period

- In January, the last patient was included in the pivotal IsoConDa-study. Thus, all 300 patients have been included in the European study which is expected to show "top-line" results during Q2 2020.
- Sedana Medical obtained market approval for AnaConDa in Mexico during January. The company's Mexican distributor Goba will begin sales work in the next few months and in parallel Sedana Medical will evaluate the possibility of registering the drug IsoConDa. Goba will also work for a registration of AnaConDa in Colombia.
- Sedana Medical established its own direct sales organization in Benelux.
- Sedana Medical donated AnaConDa and accessories to two hospitals in Wuhan and Zhejiang, China, for anti-epidemic use and evaluation of the effects of inhalation sedation with AnaConDa on severely ill Corona virus affected patients.

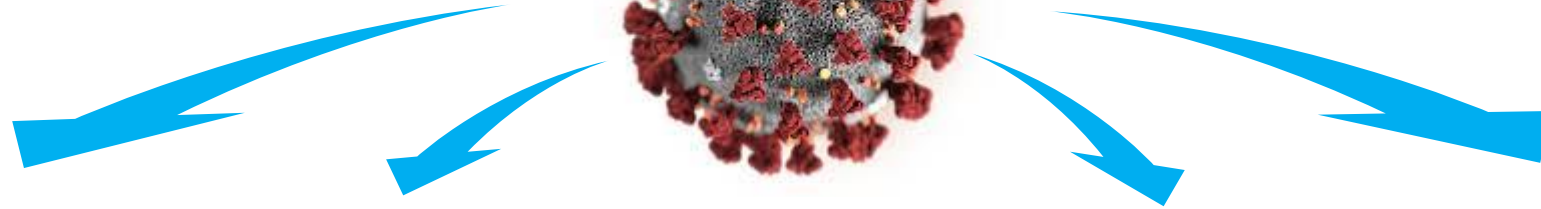
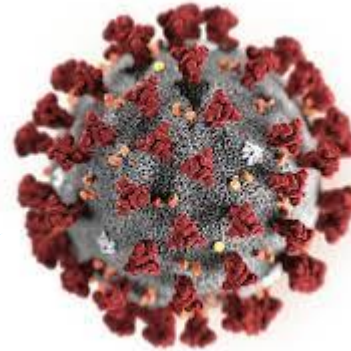
Significant events after the period

- Sedana Medical announced that the company sees increased demand for AnaConDa as a result of the Covid-19 pandemic. The company forecasts a sales for the first quarter of 2020 of SEK 34 million, which corresponds to a growth of around 90 percent compared to the same period last year.
- Due to the Covid-19 pandemic Sedana Medical sees a slight risk of delay of the compilation of the IsoConDa study until the beginning of the third quarter of 2020. However, this would not necessarily mean that Sedana Medical's application for European market approval for the drug candidate IsoConDa is delayed. Sedana Medical still expects to keep the timetable and submit the application in the third quarter, or early in the fourth quarter of 2020 and an approval during the second half of 2021.

A quarter strongly influenced by Covid-19



Covid-19 impacts on the business – current status



Sales

- ↑ Higher demand from current customers
- ↑ Deliveries to new markets and customers
- ↑ 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: May be a slight delay in top line result to early Q3 2020 and in filing of the market authorization application in EU to early Q4 2020
- ↑ No expected delay of registration of IsoConDa in EU – 2HY 2021
- ↑ Increased interest in IIT on inhaled sedation treatment

Financials

- ↑ Positive EBITDA
- ↑ Positive cash flow from operations before working capital – but an increase in Working Capital
- ↓ Higher OPEX vs. Q4

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

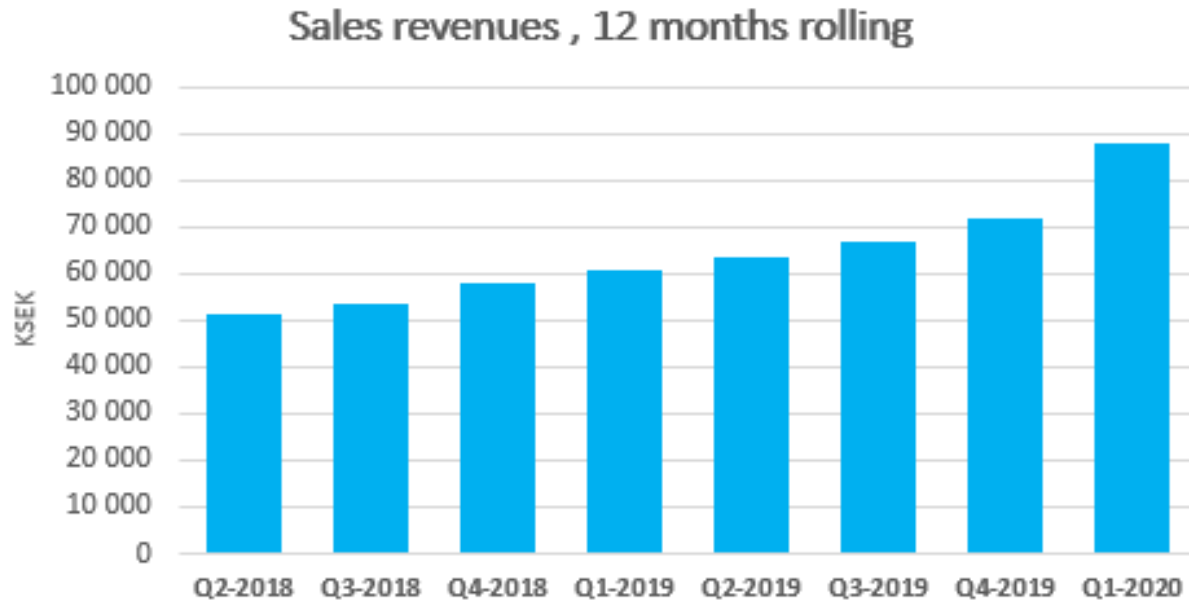
Potential pulmonary protective effects (anti-inflammatory)

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

Sales Development Q1 2020



Sales increase:

- 90% Sales growth in Q1 2020 vs Q1 2019 (86% in local currencies)
- 46% Sales growth rolling 12 months (42% in local currencies)

90%
Sales
increase
vs. Q1 2019

46%
Sales
increase
rolling 12
months

Outlook 2020

Since the end of the quarter Sedana Medical has in April seen continued positive sales growth in line with the development in March as a result of the COVID-19 pandemic. Sedana Medical is unable to make an assessment of the sales trend for the full year 2020 due to the uncertainty arising from the COVID-19 pandemic.

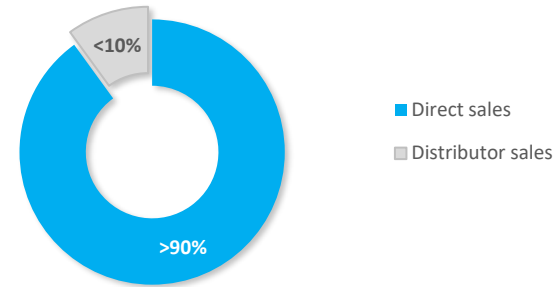
Sales organisation buildup in preparation for regulatory approval

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



SALES BREAKDOWN BY SALES TYPE



SEDANA MEDICAL DIRECT SALES ORGANISATION 2021



Q1 2020 Sales increase

Germany: >70%

Other Direct Sales markets: >200%

Distributor Markets: >50%

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 H2 2020

EUR 300m

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
- Kyuan will immediately commence fast-track registration of AnaConDa
- Estimated time to approval is under two years, by latest 2021

5-6m

Estimated ventilation days annually



India

- Exclusive distribution agreement with Hansraj Nayyar Medical
- Sales will commence in the fall 2019
- Registration process for AnaConDa will commence in parallel
- First patients treated in November 2019

2m

Estimated ventilation days annually

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Clinical Development

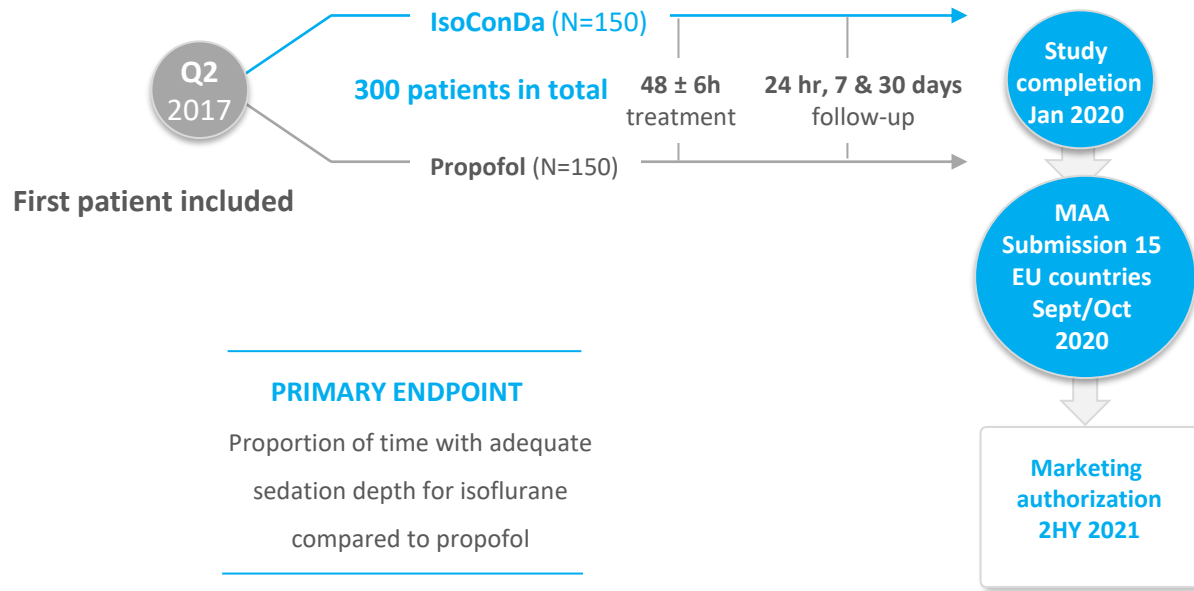


European market registration studies – the IsoConDa and IsoCOMFORT studies



IsoConDa trial:

Non-inferiority randomized controlled trial to confirm the efficacy and safety of IsoConDa in adults



PRIMARY ENDPOINT

Proportion of time with adequate sedation depth for isoflurane compared to propofol

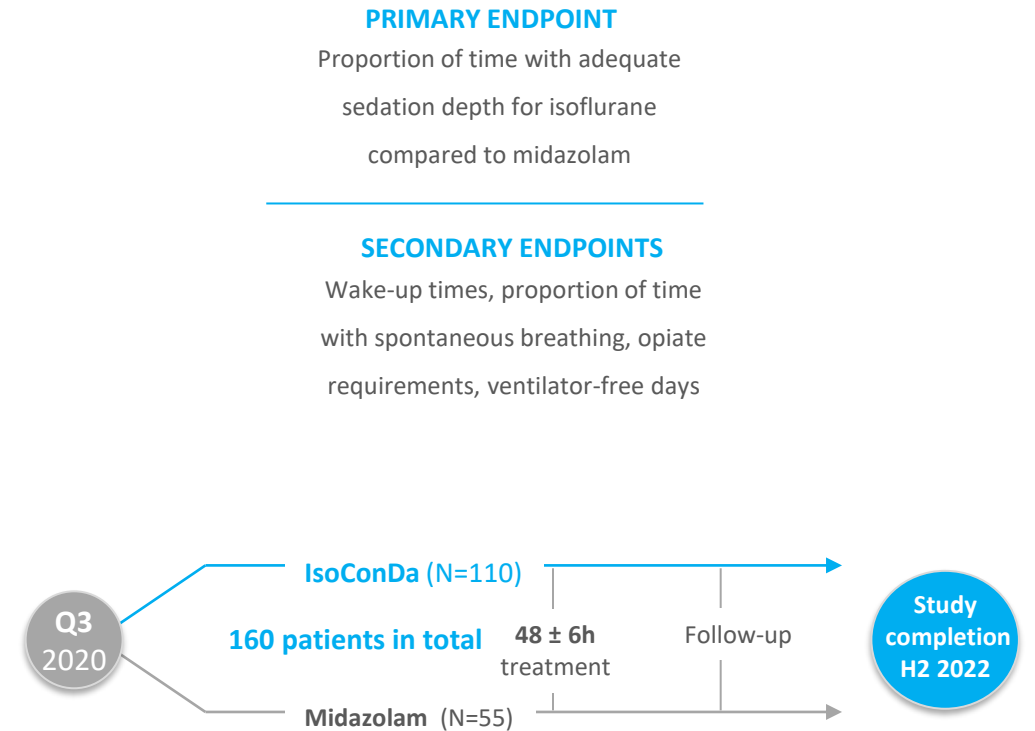
SECONDARY ENDPOINTS

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



IsoCOMFORT trial:

Superiority Randomized controlled trial of IsoConDa compared to midazolam in children



PRIMARY ENDPOINT

Proportion of time with adequate sedation depth for isoflurane compared to midazolam

SECONDARY ENDPOINTS

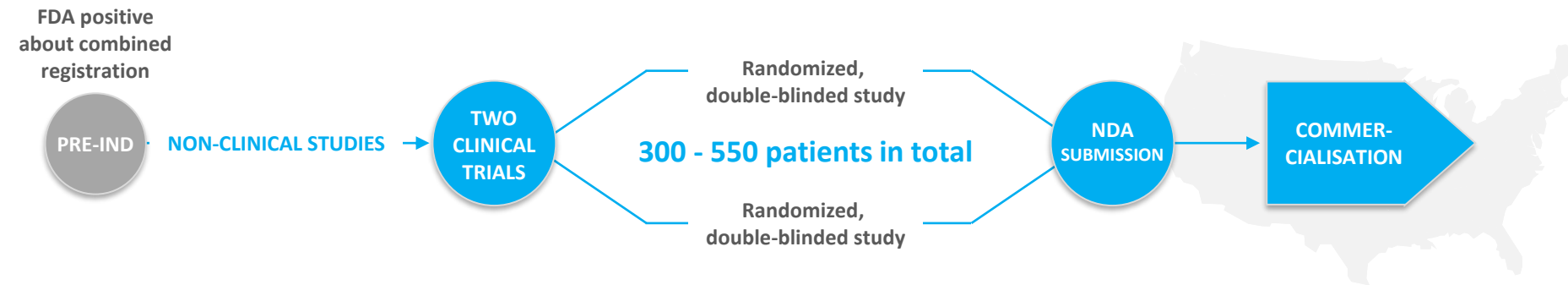
Wake-up times, proportion of time with spontaneous breathing, opiate requirements, ventilator-free days

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:

- Toxicity studies – animal and PPND* - ongoing
- Human factors validation - ongoing

CLINICAL STUDIES

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

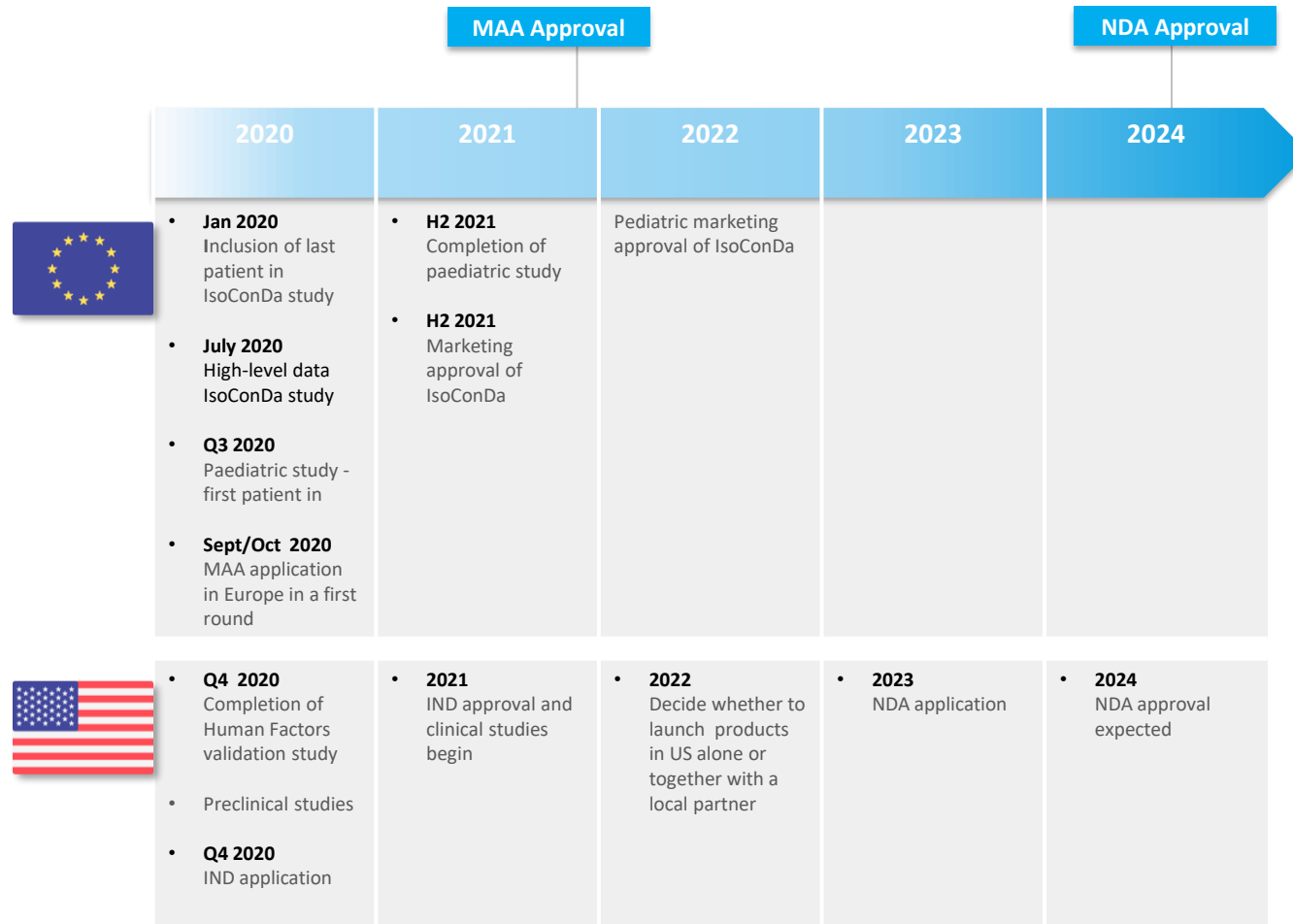
SAFETY DATABASE

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.

Timeline – registration activities in Europe and US



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Financial highlights

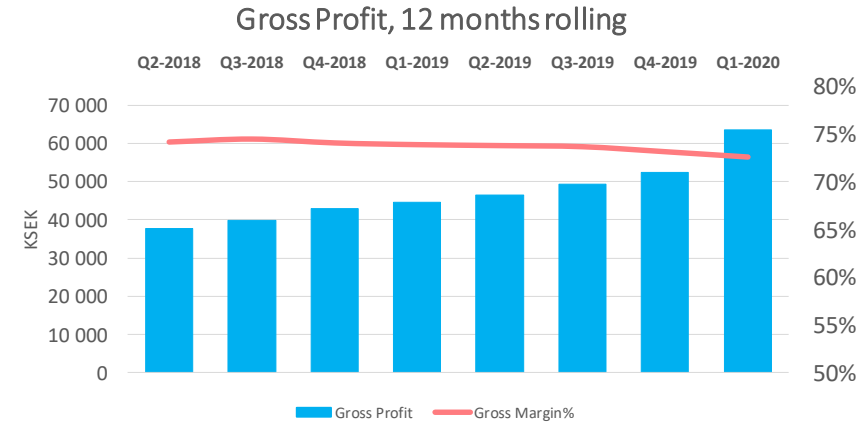
Financial highlights

Q1 -2020

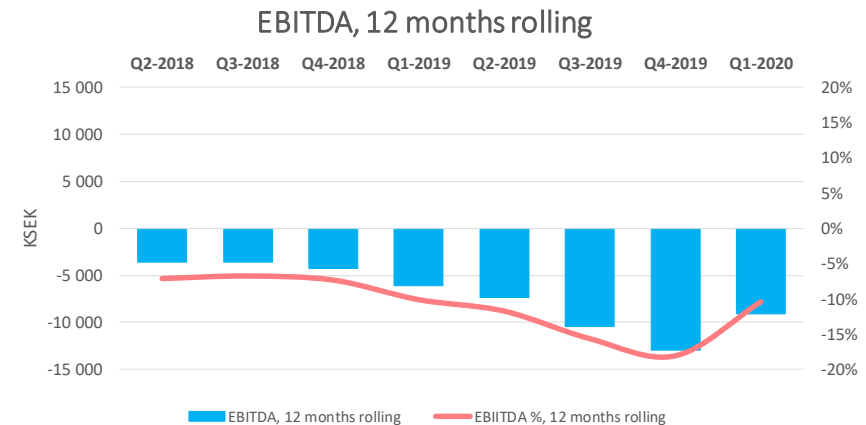
- **Net sales** of 33,8 MSEK vs. 17,8 MSEK in Q1 2019, 90% growth individual quarter and 46% rolling 12 months.
- **Gross margin** of 23,6 MSEK or 70% vs. 12,4 MSEK or 70 % in Q1 2019.
- **EBITDA** 1,2 MSEK or 3,6% vs. -2,6 MSEK or -14,8% in Q1 2019.
- **OPEX** increased with 52% vs Q1 2019 due to build up of European organisation and preparation for IsoConDa launch which means continued sales and market and medical affairs investments during Q1.
- 46 **employees** in average in Q1 vs. 37 employees Q1 2019 for the group in total.
- **Cash flow** from **operations** before change in working capital was 0,2 MSEK.
- **Cash flow** from **operations** including change in working capital was -8,5 MSEK.
- **Cash flow** from **investments** was -14,2 MSEK of which -13,4 MSEK concern product development.
- **Total cash flow** for the group in Q1 was -22,7 MSEK.



Stable gross profit



Positive EBITDA



Financial results Q1 2020 vs. Q1 2019

(MSEK)

P&L

	Q1	
	2020	2019
Revenues		
Net sales	33,8	17,8
Capitalized development expenses	0,0	0,0
Other operating income	2,2	0,8
	<u>36,0</u>	<u>18,6</u>
Operating cost and expenses		
Cost of goods sold	-10,2	-5,4
External expenses	-10,9	-6,8
Personnel expenses	-12,5	-8,6
Depreciation and amortisation	-1,1	-1,0
Other operating expenses	-1	0
Operating income	<u>0,1</u>	<u>-3,7</u>
Income from financial items		
Result from securities and long term receivables	0,0	0,0
Financial income	2,2	1,4
Financial expenses	-0,1	-0,2
Income after financial items	<u>2,2</u>	<u>-2,5</u>
Income before taxes	<u>2,2</u>	<u>-2,5</u>
Taxes	-0,5	-0,4
Net Income	<u>1,7</u>	<u>-3,0</u>
Gross Margin	23,6	12,4
%	69,8%	69,6%
EBITDA	1,2	-2,6
%	3,6%	-14,8%

Balance Sheet

	31 March	
	2020	2019
ASSETS		
Intangible assets	113,3	61,1
Tangible assets	5,0	5,1
Financial assets	1,7	1,1
Total Fixed assets	<u>120,0</u>	<u>67,3</u>
Inventory	6,0	4,2
Receivables	25,8	8,8
Cash and cash equivalents	442,6	149,8
Total current assets	<u>474,4</u>	<u>162,8</u>
TOTAL ASSETS	<u>594,4</u>	<u>230,1</u>
EQUITY & LIABILITIES		
Share capital	2,3	1,9
Other equity	567,8	213,1
Total equity	<u>570,1</u>	<u>215,0</u>
Long term liabilities	0,0	0,0
Current liabilities	24,3	15,1
TOTAL EQUITY AND LIABILITIES	<u>594,5</u>	<u>230,2</u>

Cash Flow

	Q1	
	2020	2019
Cash flow from operations bef. change in w.c.	0,2	-1,8
Change in w.c.	-8,6	2,7
Cash flow from operations after change in w.c.	<u>-8,5</u>	<u>0,8</u>
Cash flow from investment activities	-14,2	-10,7
Cash flow from financing activities	0,0	0,3
Cash flow for the period	<u>-22,7</u>	<u>-9,6</u>

Largest shareholders at the end of March 2020

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

Name	Number of shares	Shareholding (%)
Handelsbanken funds	1 933 303	8,50%
Linc AB	1 916 901	8,43%
Swedbank Robur funds	1 826 600	8,03%
Anders Walldov direct and indirect (Brohuvudet AB)	1 630 000	7,17%
Ola Magnussion direct and indirect (Magiola AB)	1 325 246	5,83%
Sten Gibeck	1 230 744	5,41%
Berenberg funds	965 149	4,24%
Öhman funds	767 680	3,38%
Ron Farrell	631 062	2,78%
Anades Ltd.	563 979	2,48%
Nordnet pensionsförsäkrings AB	503 715	2,22%
Tredje AP-fonden	498 600	2,19%
Eklund Konsulting AB	416 616	1,83%
Avanza Pension	408 516	1,80%
Alfred Berg funds	348 330	1,53%
Fifteen largest shareholders	14 966 441	65,83%
<i>Others</i> *	7 770 150	34,17%
TOTAL:	22 736 591	100,00%

*Of which CEO's ownership is 200 000 shares.

Source: Modular Finance

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Questions

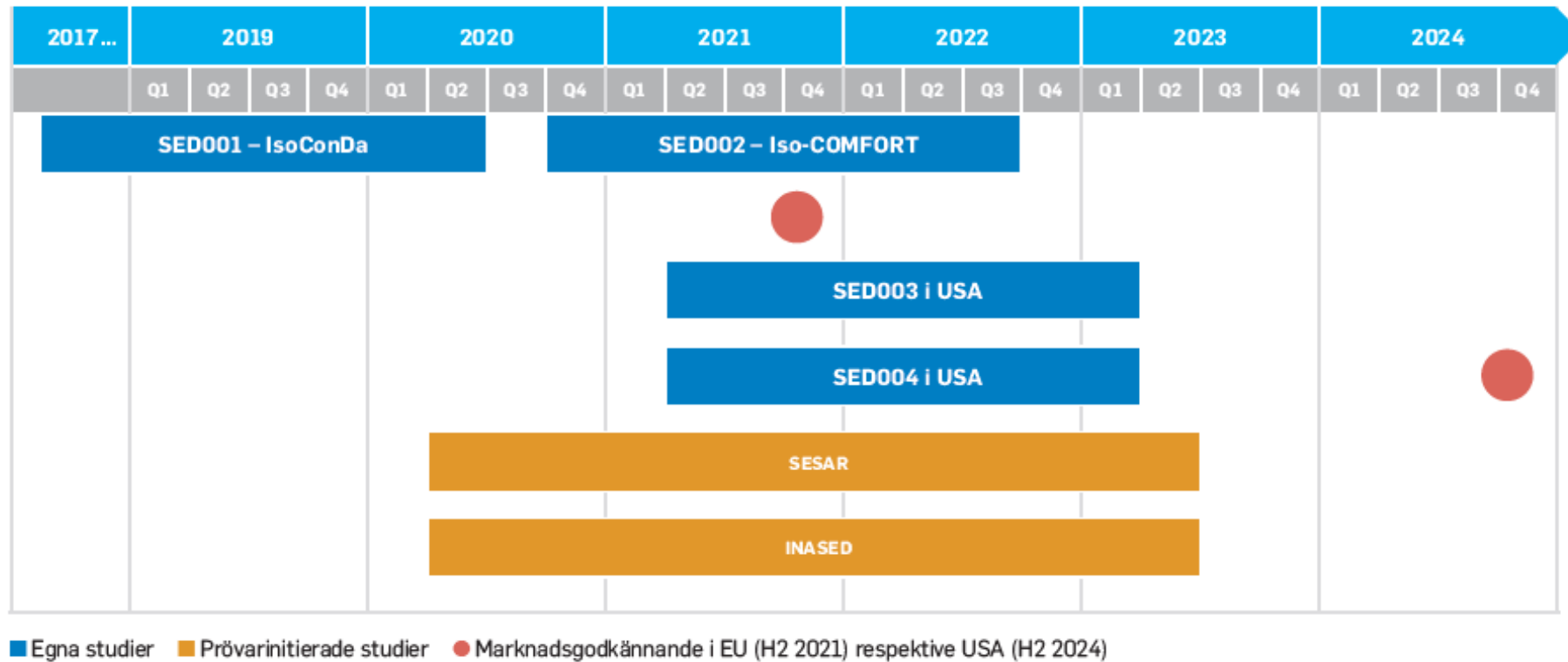


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Appendix



More studies will pave the way for a new standard of care



Therapeutical benefits by using inhaled anaesthetics



Pulmonary therapeutic effects for patients with impaired gas exchange¹¹

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



On-off effects and reliable wake-up with inhaled sedation¹²

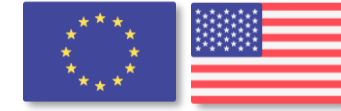
- ✓ Shorter time to extubation...
 - ✓ Shorter time to cooperation...
 - ✓ Shorter ventilator time and ICU stay...
- ...when compared with intravenous sedation



Reliable effect and safety with inhaled sedation for the distressed patient¹³

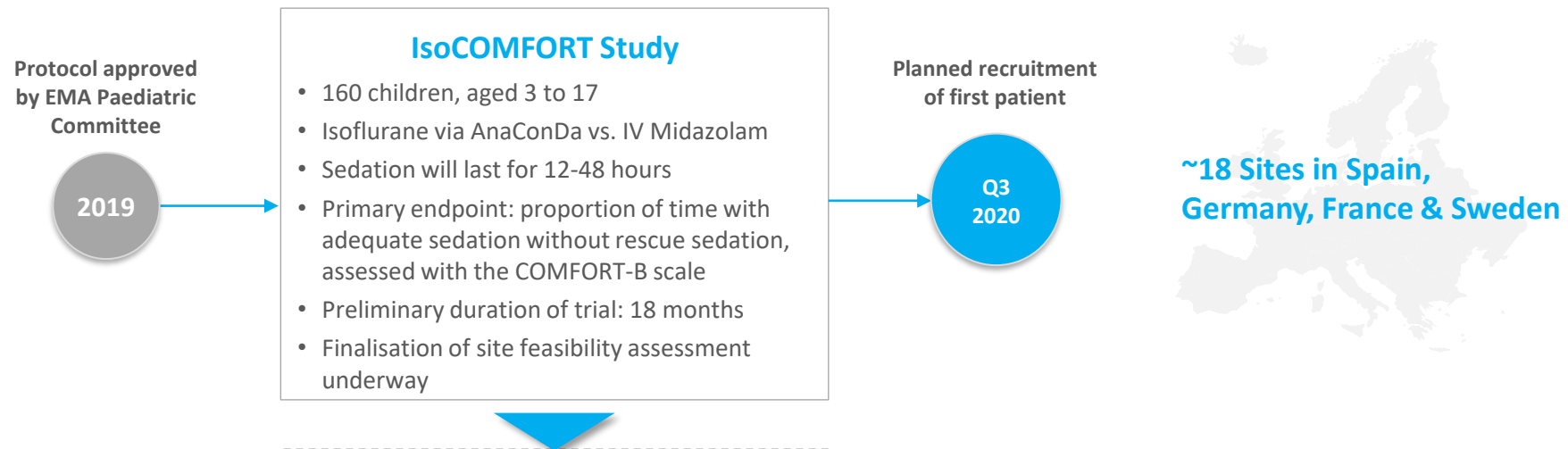
- ✓ Works in all patients – full range sedative
- ✓ No need for polypharmacy
- ✓ Few problems after wake-up
- ✓ Patients are more lucid and calm with less hallucinations and delusions
- ✓ No/low risk of tolerance development, ceiling effect and withdrawal symptoms
- ✓ Reduction of opioid use

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).



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.

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.

