

SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

Interim Report Q4 2019 Presentation

CEO Christer Ahlberg
CMO Peter Sackey
CFO Maria Engström

5th March 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.

No assurance can be given that such expectations will prove to have been correct. Sedana Medical disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

SEDANA MEDICAL



Vision

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

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.

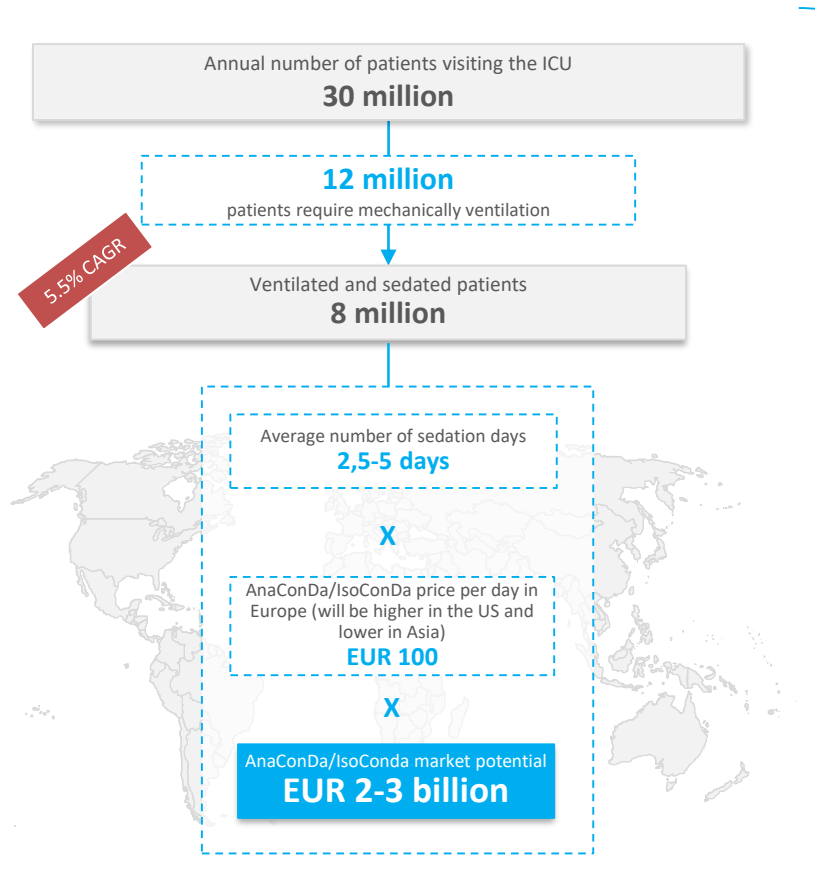
Post-registration

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.

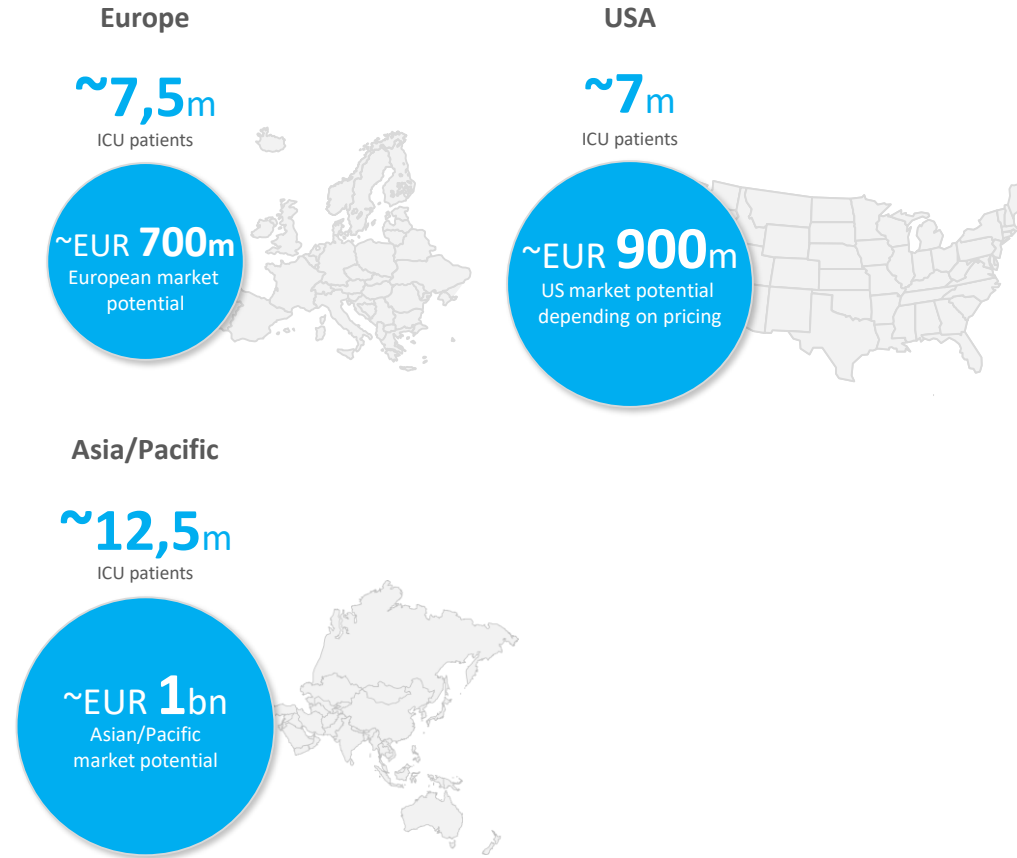
3. Large & clearly defined market opportunity for replacement of standard of care

Blockbuster market potential for IsoConDa/AnaConDa

Breakdown: total market potential for IsoConDa/AnaConDa*



Regional market potential



Q4 2019 Highlights

Significant events during the period

- Sedana Medical completed a private placement of 2 896 000 shares. The subscription price for the shares in the private placement was SEK 129.50 per share. Through the targeted new issue, which was several times oversubscribed, Sedana Medical received SEK 375 million before transaction costs. Investors in the new share issue consisted of a number of Swedish and international institutional investors, including AXA IM, Handelsbanken fonder, Joh. Berenberg Gossler & Co. KG (Berenberg), Swedbank Robur, Third AP fund and Öhman funds.
- Sedana Medical will sponsor two major investigator initiated studies with AnaConDa in France during 2020-2023. One of the studies the company sponsor is the world's largest multicenter study with AnaConDa, SESAR. Sedana Medical will supply the investigators with AnaConDa and accessories. The primary purpose of the study is to demonstrate that inhalation sedation with AnaConDa has lung-protective functions, shortens ventilator time and has higher survival in severely pulmonary intensive care patients. Sedana Medical also supports INASED, a large French multicenter study with isoflurane – the substance in the company's drug candidate IsoConDa – delivered with the company's medical device AnaConDa. The aim is mainly to show a reduced incidence of delirium in mechanically ventilated intensive care patients compared to intravenous sedation with propofol.
- Sedana Medical no longer communicates profit targets for the period leading up to the registration of IsoConDa in Europe and clarifies that the sales target of SEK 500 million three years after the European registration only applies to Europe. Sales outside Europe will be added in addition to this target.
- Sedana Medical AB (publ)'s Board Member Michael Ryan decided to resign on November 12, 2019. The Nomination Committee of Sedana Medical will begin work to find a successor.

Significant events after 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 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 donates 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

SEDANAMEDICAL



Financial highlights

Financial highlights

Q4 -2019

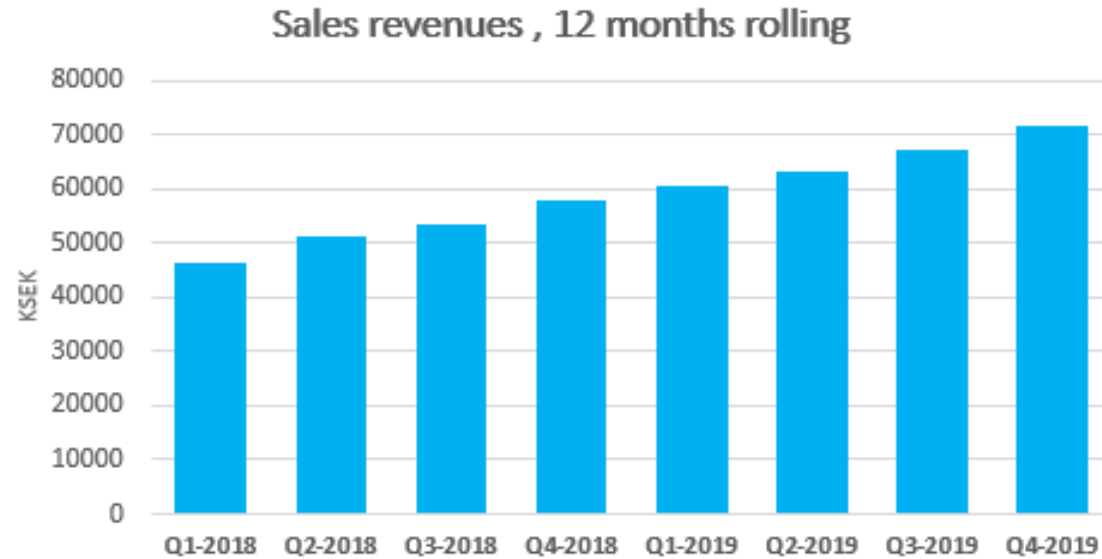
- **Net sales** of 20,1 MSEK vs. 15,2 MSEK in Q4 2018, 32% growth individual quarter and 24% rolling 12 months.
- **Gross margin** of 14,6 MSEK or 73% vs. 11,5 MSEK or 75 % in Q4 2018.
- **EBITDA** -4,0 MSEK or -19,8% vs. -1,5 MSEK or -9,7% in Q4 2018.
- **OPEX** increased with 34% vs Q4 2018 due to build up of European organisation and preparation for IsoConDa launch which means continued sales and market and medical affairs investments during Q4.
- **40 employees** in average in Q4 vs. 30 employees Q4 2018 for the group in total.
- **Cash flow from operations** was -3,2 MSEK.
- **Cash flow from investments** was -17,3 MSEK of which -16,3 MSEK concern product development.
- **Cash flow for financing** activities was 364,9 MSEK.
- **Total cash flow** for the group in Q4 was 342,6 MSEK.

FY -2019

- **Net sales** of 71,6 MSEK vs. 57,9 MSEK in 2018, 24% growth individual quarter vs. 2018.
- **Gross margin** of 52,4 MSEK or 73% vs. 42,9 MSEK or 74 % in 2018.
- **EBITDA** -13,0 MSEK or -18,1% vs. -4,2 MSEK or -7,3% in 2018.
- **OPEX** increased with 37% vs 2018 due to build up of European organisation and preparation for IsoConDa launch which means continued sales and market and medical affairs investments during the year.
- **39 employees** in average in 2019 vs. 26 employees 2018 for the group in total.
- **Cash flow from operations** was -11,1 MSEK.
- **Cash flow from investments** was -54,1 MSEK of which -49,8 MSEK concern product development.
- **Cash flow from financing** activities was 368,4 MSEK.
- **Total cash flow** for the group in was 305,2 MSEK.



Sales Development Q4 2019



24%
Sales
increase
rolling 12
months

SALES DEVELOPMENT

- 32% Sales growth in Q4 2019 vs Q4 2018
- 24% Sales growth rolling 12 months

SEDANAMEDICAL



Development and commercialization Europe

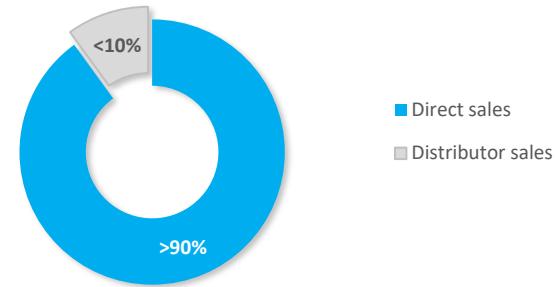
Sales organisation buildup in preparation for regulatory approval

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

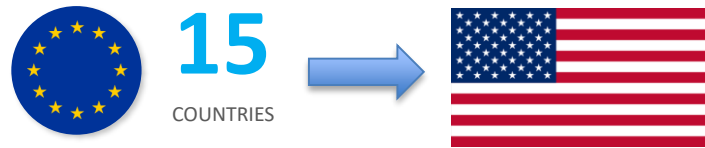
SEDANA MEDICAL CURRENT DIRECT SALES ORGANISATION



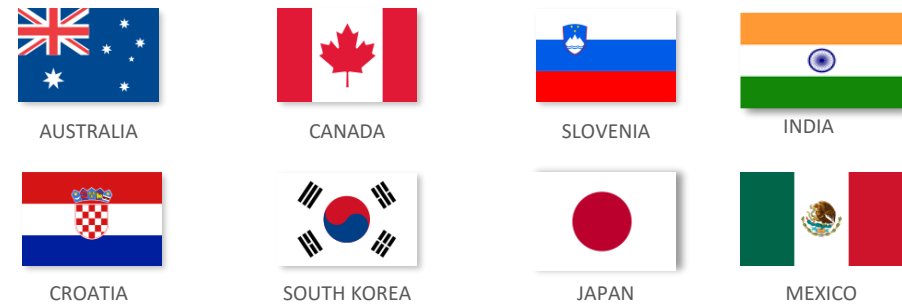
SALES BREAKDOWN BY SALES TYPE



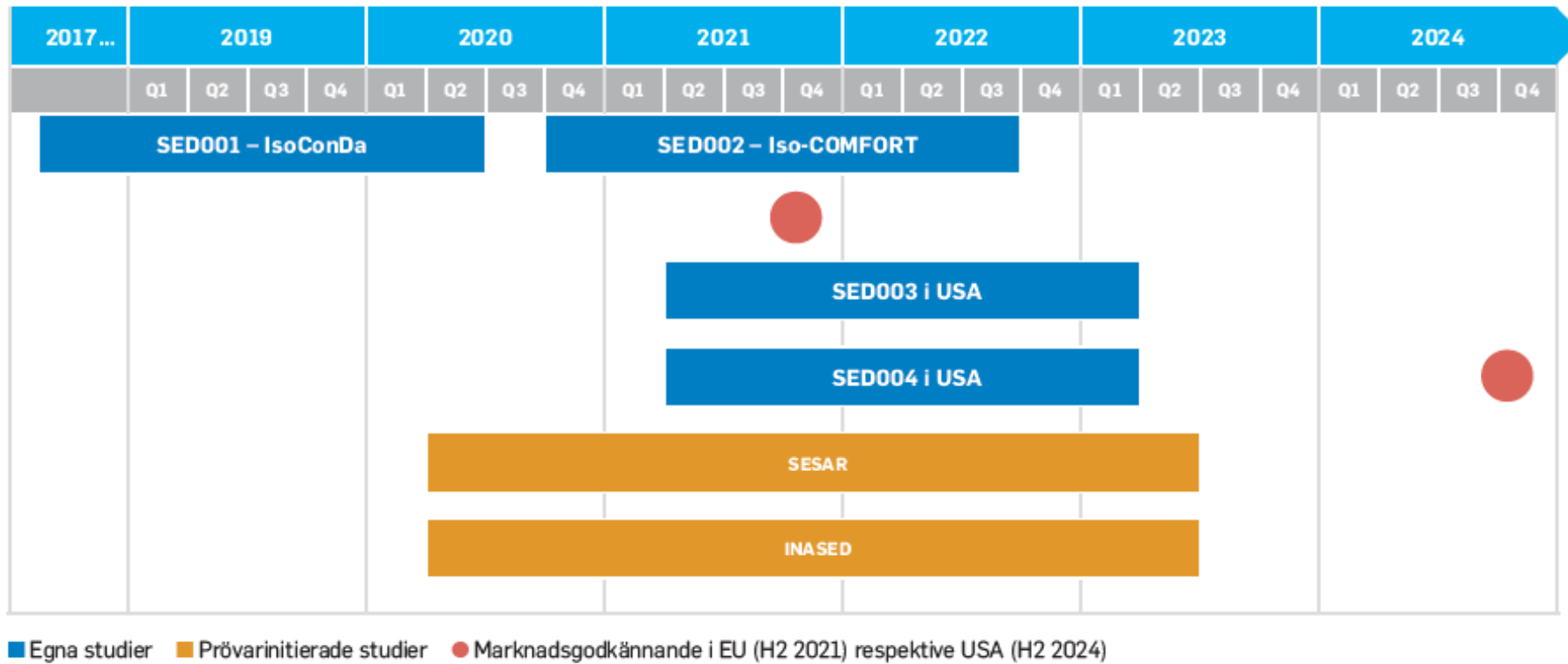
SEDANA MEDICAL DIRECT SALES ORGANISATION 2021



COUNTRIES SERVICED BY DISTRIBUTORS OUTSIDE EU15



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

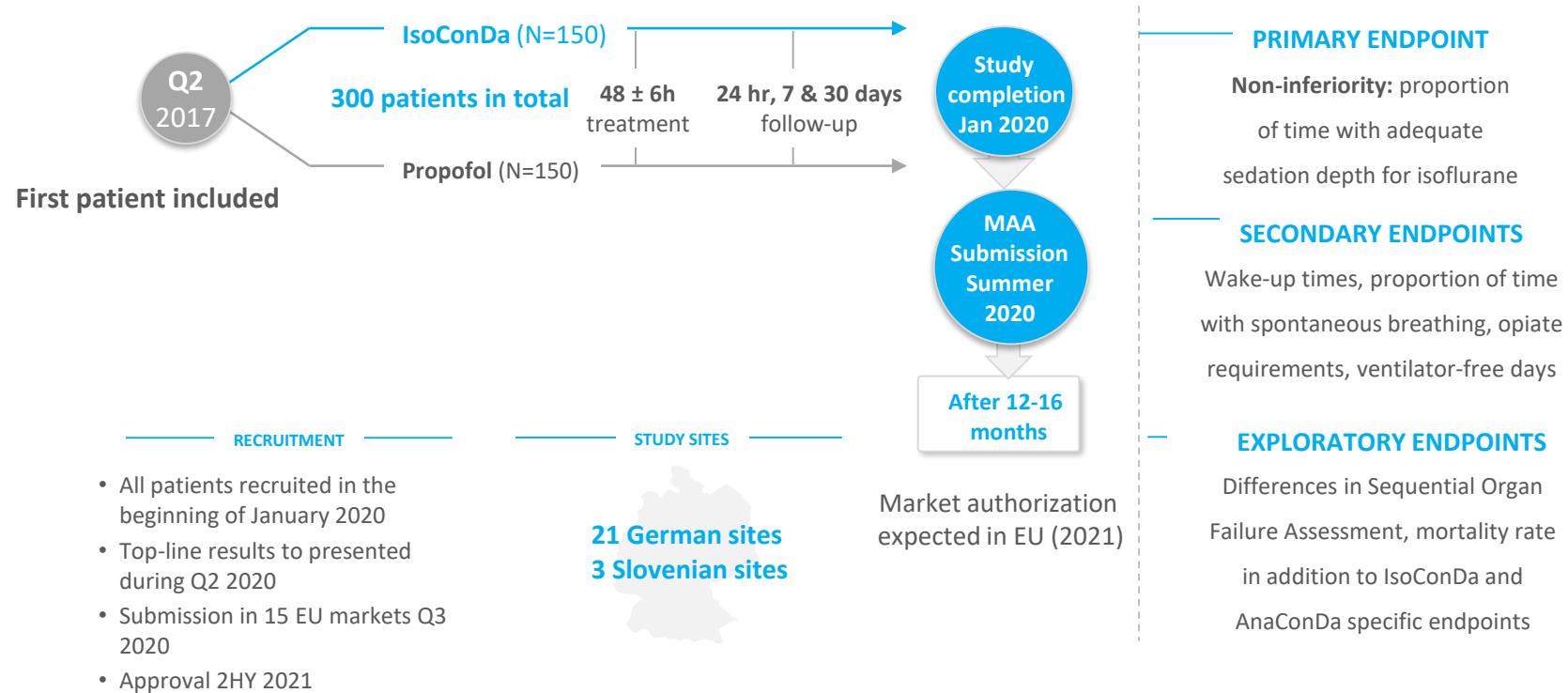


European market registration study – the IsoConDa study

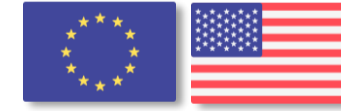


Phase III trial: Non-inferiority study of IsoConDa compared to propofol

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.

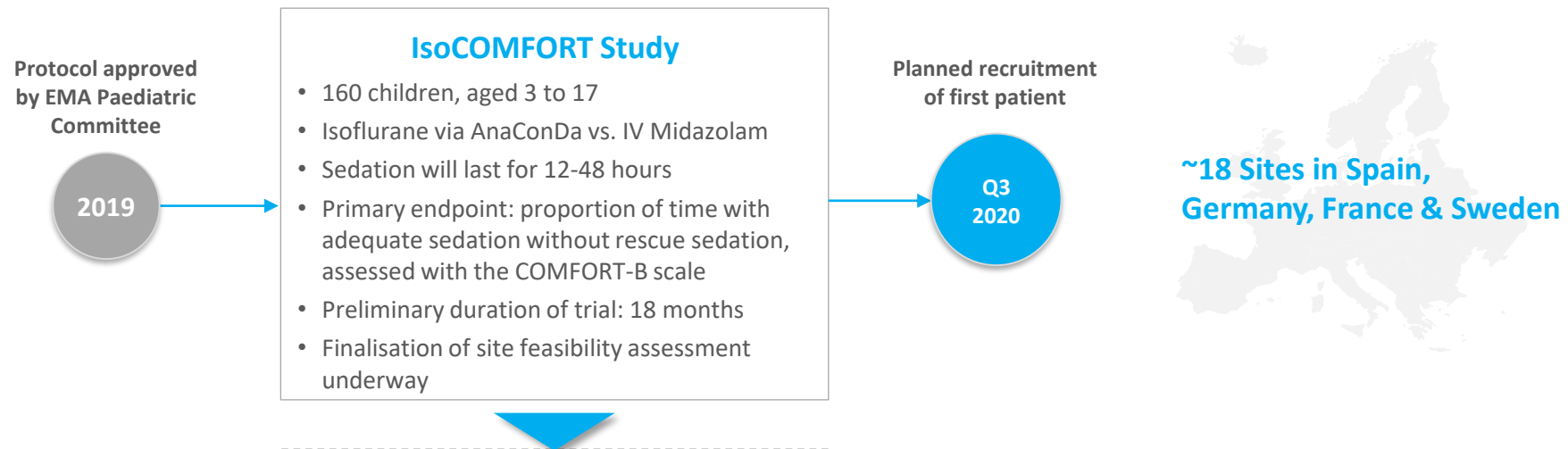


The IsoCOMFORT study for EU and USA



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.

SEDANAMEDICAL



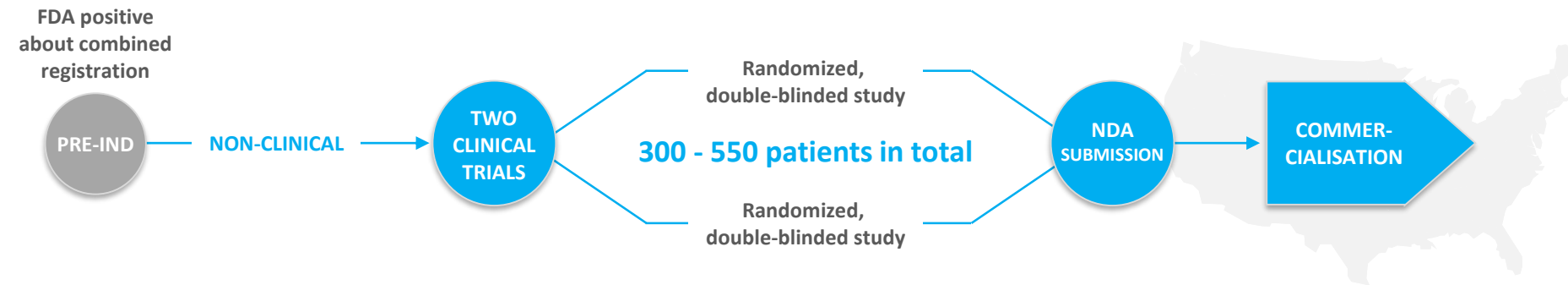
Development and commercialization USA

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:

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

CLINICAL STUDIES

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

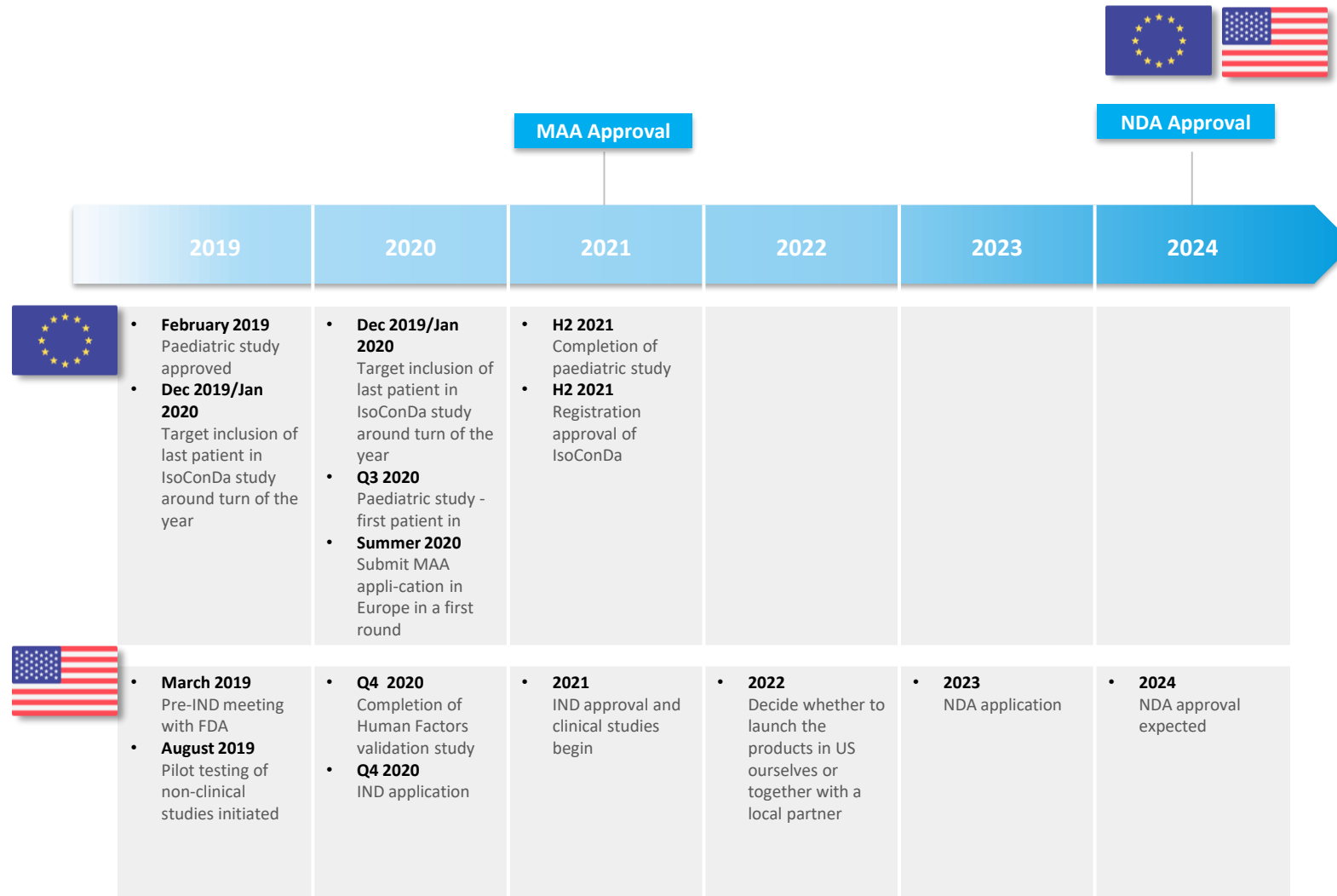
SAFETY DATABASE

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

COMMERCIALISATION

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

Timeline – registration activities in Europe and US



SEDANAMEDICAL



Development and commercialization RoW

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

Sedana Medical donates AnaConDa to hospitals in Wuhan, China



THU, FEB 27, 2020 08:00 CET


Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company is donating the medical device AnaConDa and accessories for anti-epidemic use and evaluation of the effects of inhalation sedation with AnaConDa on severely ill Corona virus affected patients to two hospitals in Wuhan and Zhejiang, China.

Sedana Medical is a pioneer in making volatile anaesthetics available to critically ill mechanically ventilated patients via the medical device AnaConDa. In the current situation, with the outbreak of the novel coronavirus (2019-nCoV), Sedana Medical wants to contribute by sharing knowledge on alternative treatment options for these patients. With volatile anaesthetics administered via the AnaConDa there is an opportunity to improve the care and outcome of patients with acute respiratory failure.


"In this situation, which potentially affects us all, available data on the pathogenesis of the 2019-nCoV has urged us to contribute to improved care and outcome of the affected patients. To begin with, we will donate 300 AnaConDa and related accessories to evaluate the effects of inhalation sedation with AnaConDa on severely ill Corona virus infected patients." said Christer Ahlberg, CEO of Sedana Medical.

The novel coronavirus (2019-nCoV) mainly affects the lungs. A recent study published in the Lancet (Huang C et al., 2020) describes the first 41 hospitalized patients with 2019-nCoV infection in Wuhan, China. The infection was associated with ICU admission and high mortality. All the patients had pneumonia and 30 percent developed acute respiratory distress syndrome (ARDS). The article describes a "cytokine storm" that leads to severely impaired gas exchange in the ICU admitted patients. This form of pulmonary inflammation is the most extreme and lethal consequence of a coronavirus disease.

"Clinical studies have shown that in patients with ARDS, use of volatile anaesthetics exert anti-inflammatory effects and improve oxygenation. The cytokine storm in novel coronavirus ARDS is driven by the very same cytokines that are attenuated by inhaled anaesthetics, even in sedation doses. Thus, the use of inhaled anaesthetics such as isoflurane, for sedation in mechanically ventilated adults with coronavirus ARDS may potentially impact clinical outcomes" said Peter Sackey, CMO of Sedana Medical.

 **Subscribe**



 **Documents & Links**

 [Release](#)

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

SEDANAMEDICAL

.....

Financial Result

Financial results Q4 2019 vs. Q4 2018

(MSEK)

P&L

	Q4	
	2019	2018
Revenues		
Net sales	20,1	15,2
Capitalized development expenses	0,0	0,0
Other operating income	-0,1	0,4
	19,9	15,7
Operating cost and expenses		
Cost of goods sold	-5,4	-3,8
External expenses	-6,5	-5,0
Personnel expenses	-10,9	-8,0
Depreciation and amortisation	-1,1	-1,0
Other operating expenses	-1	0
Operating income	-5,0	-2,5
Income from financial items		
Result from securities and long term receivables	0,0	0,0
Financial income	1,3	0,4
Financial expenses	-2,2	-0,4
Income after financial items	-5,9	-2,4
Income before taxes	-5,9	-2,4
Taxes	0,9	-1,0
Net Income	-5,0	-3,4

Balance Sheet

	31 December	
	2019	2018
ASSETS		
Intangible assets	99,6	51,4
Tangible assets	4,9	4,7
Financial assets	2,2	1,6
Total Fixed assets	106,7	57,7
Inventory	7,4	6,3
Receivables	14,9	8,2
Cash and cash equivalents	464,6	159,4
Total current assets	486,9	173,8
TOTAL ASSETS	593,6	231,5
EQUITY & LIABILITIES		
Share capital	2,3	1,9
Other equity	567,4	215,9
Total equity	569,7	217,8
Long term liabilities	0,0	0,0
Current liabilities	23,9	13,7
TOTAL EQUITY AND LIABILITIES	593,6	231,5

Cash Flow

	Q4	
	2019	2018
Cash flow from operations bef. change in w.c.	-3,2	-1,3
Change in w.c.	-1,8	-7,2
Cash flow from operations after change in w.c.	-5,0	-8,5
Cash flow from investment activities	-17,3	-7,4
Cash flow from financing activities	364,9	0,1
Cash flow for the period	342,6	-15,8

Largest shareholders at the end of January 2020

Name	Number of shares	Shareholding (%)
Linc AB	2 116 901	9,31%
Swedbank Robur funds	1 806 600	7,95%
Handelsbanken funds	1 745 303	7,68%
Anders Walldov direct and indirect (Brohuvudet AB)	1 600 000	7,04%
Sten Gibeck	1 530 744	6,73%
Ola Magnusson direct and indirect (Magiola AB)	1 323 746	5,82%
Berenberg funds	865 291	3,81%
Öhman funds	635 069	2,79%
Ron Farrell	631 062	2,78%
Anades Ltd.	568 083	2,50%
Nordnet pensionsförsäkrings AB	508 193	2,24%
Tredje AP-fonden	497 613	2,19%
Avanza Pension	486 217	2,14%
Eklund Konsulting AB	416 616	1,83%
Alfred Berg funds	348 879	1,53%
Fifteen largest shareholders	15 080 317	66,33%
Others *	7 656 274	33,67%
TOTAL:	22 736 591	100,00%

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

Source: Modular Finance

October 9, 2019 Sedana Medical completed a directed new share issue of 2,896,000 shares at a subscription price of SEK 129.50 per share. Through the directed new share issue, Sedana Medical received proceeds amounting to SEK 375 million before transaction costs.

Investors in the new share issue were a number of Swedish and international institutional investors, including AXA IM, Handelsbanken Fonder, Joh. Berenberg Gossler & Co. KG (Berenberg), Swedbank Robur, the Third Swedish National Pension Fund and Öhman Fonder.

SEDANAMEDICAL

.....

Questions