SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

Interim Report Q3 2019 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.

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.

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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

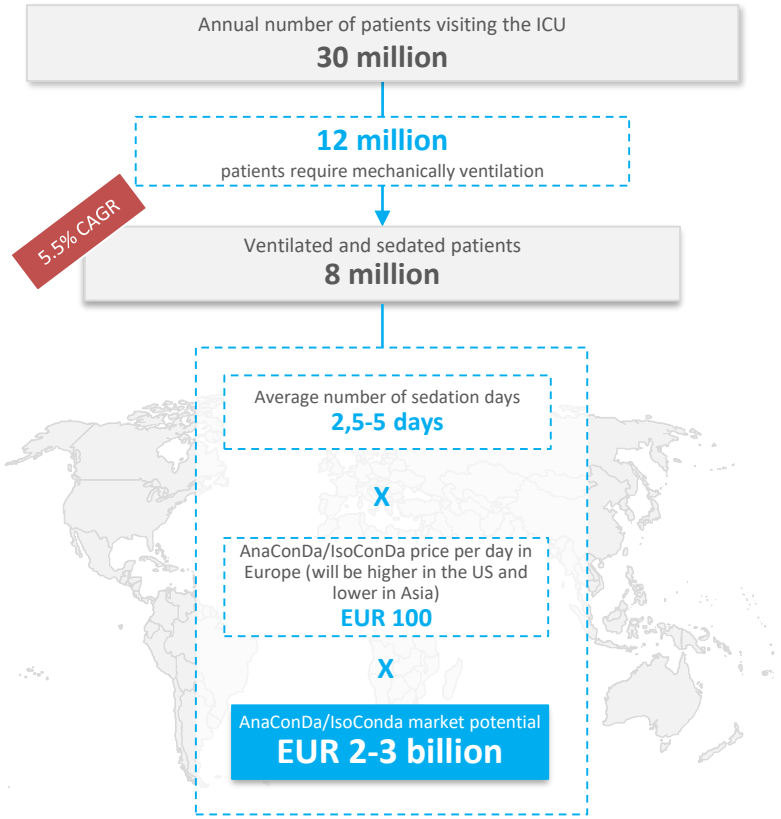
During the period up until the approval of IsoConDa is obtained, the Company's goal is to increase sales with an average of over 20 per cent per year, in parallel to building up a larger sales and market organization.

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.

Blockbuster market potential for IsoConDa/AnaConDa

Breakdown: total market potential for IsoConDa/AnaConDa*



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.

Q3 2019 Highlights

Significant events during the period

- Entered into a distribution agreement with the Indian distributor Hansraj Nayyar Medical. The Indian market potential for sedation in intensive care is estimated to be around two million ventilation days annually.
- Approval for the use of AnaConDa in children by the European notified body BSI Group. The approval also means that AnaConDa can be used in patients with severely impaired lung capacity.

Significant events after the period

- 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 Fonder.
- Co-funding the world's largest multicenter study with AnaConDa in France by supplying the investigators with AnaConDa and accessories. The primary purpose of the study is to show that inhalation sedation with AnaConDa has lung-protective properties, reduces time on the ventilator and improves survival in severely pulmonary intensive care patients.
- New financial targets 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 in addition to this target.
- Board Member Michael Ryan has decided to resign on November 12, 2019. The Nomination Committee of Sedana Medical will begin work to find a successor.

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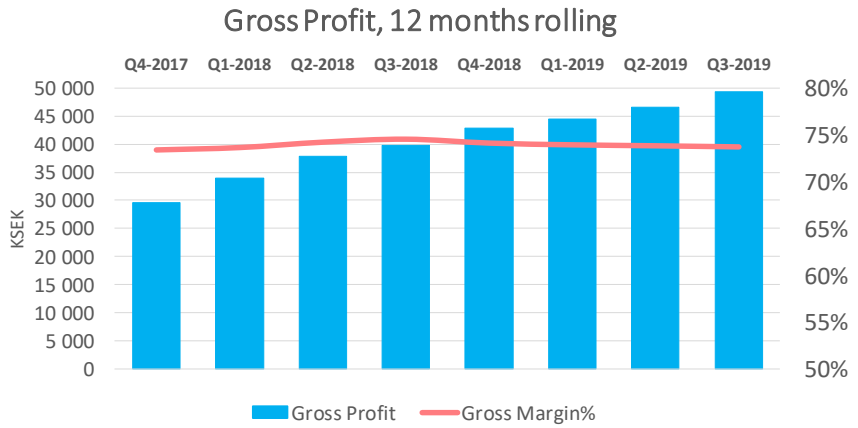
Financial highlights

Financial highlights

Q3-2019

- Net sales of 16,4 MSEK vs. 12,7 MSEK in Q3 2018, 29% growth individual quarter and 25% rolling 12 months.
- Gross margin of 12,0 MSEK or 73% vs. 9,3 MSEK or 74 % in Q2 2018.
- EBITDA -4,0 MSEK or -25% vs. -1,0 MSEK or -8% in Q1 2018.
- OPEX increased with 6 MSEK or 60% vs Q3 2018 due to build up of European organisation and preparation for IsoConDa launch which means continued medical, sales and market investments during Q3.
- 43 employees end of Q3 vs. 30 employees end of 2018 for the group in total.
- Cash flow from operations was -3,9 MSEK.
- Cash flow from investments was -12,7 of which -11,8 MSEK concern product development.
- Total cash flow for the group in Q3 was -15,3 MSEK.

Gross margin development



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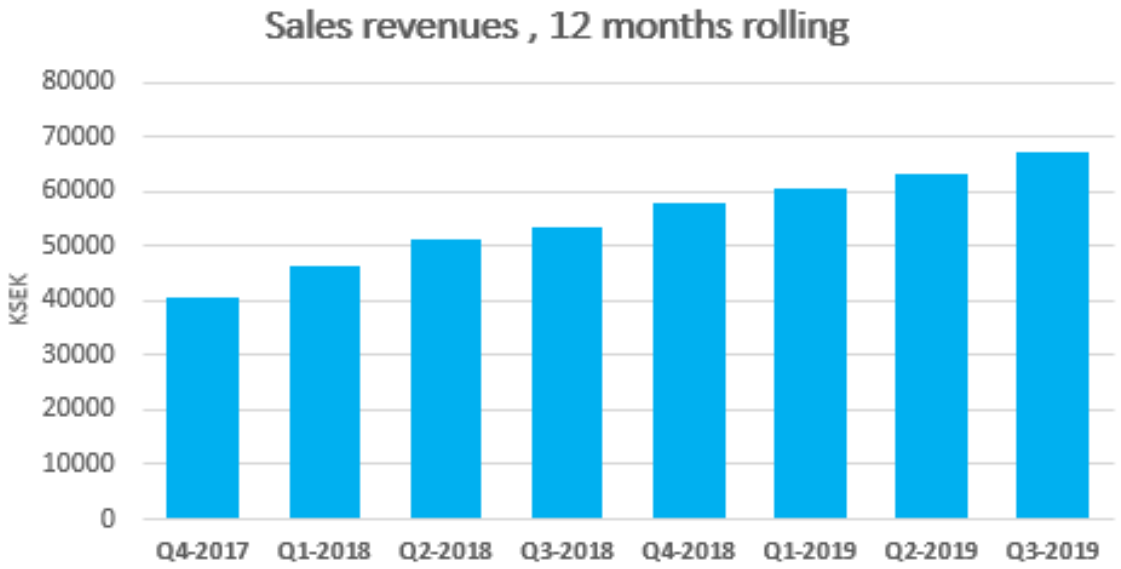
Sales Development Q3 2019



25%
Sales increase rolling 12 months

SALES DEVELOPMENT

- 29% Sales growth in Q3 2019 vs Q3 2018
- 25% Sales growth rolling 12 months
- More than 40% growth in France YTD SEP 2019
- Significant sales increase in UK and Nordic

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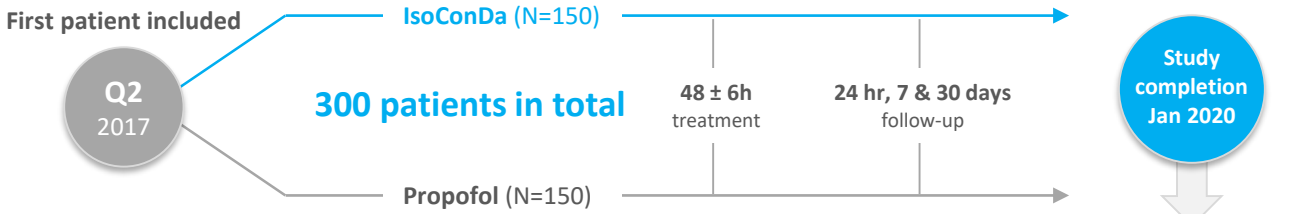
Development and commercialisation Europe

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.



Study completion Jan 2020

MAA Submission Summer 2020

After 12-16 months

Market authorization expected in EU (2021)

PRIMARY ENDPOINT

Non-inferiority: 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

EXPLORATORY ENDPOINTS

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

RECRUITMENT

- 260 patients recruited at the end of Q3 2019
- Last patient in during the turn of the year 2019/2020

STUDY SITES

21 German sites
3 Slovenian sites

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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 agreed and approved study plan for children, a so-called PIP (Paediatric Investigation Plan). The PIP is approved but the protocol is being amended to meet minor additional requests from the FDA.

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: time with adequate sedation, assessed with the COMFORT-B scale
- Preliminary duration of trial: 18 months
- Finalisation of site feasibility assessment and CRO selection underway

Planned recruitment of first patient

Q3 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.

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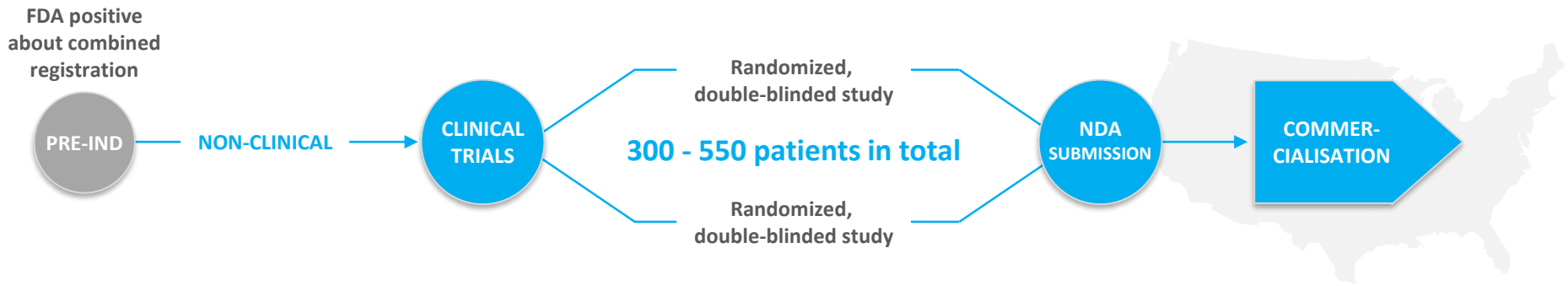
Development and commercialisation USA

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*
- Human factors validation

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.

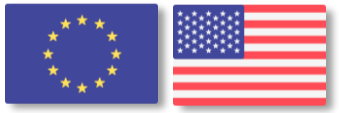
* PPND: pre- and post-natal development.

Combination registration of AnaConDa & IsoConDa in USA

Key operational activities and collaborations

- Director of clinical development for the US recruited.
- Collaboration with Harvard and HF consultant company for Human Factors Engineering Program.
- Intend to set up a company in the US for management of studies, registration and market access.
- Contract Research Organization for non-clinical studies.
- Close cooperation with relevant consultants and US key opinion leaders.
- Collaboration with academic centers in the US initiated for planning of clinical studies.

Timeline – registration activities in Europe and US



MAA Approval

NDA Approval

	2019	2020	2021	2022	2023	2024
	• **February 2019** Paediatric study approved • **Dec 2019/Jan 2020** Target inclusion of last patient in IsoConDa study around turn of the year	• **Dec 2019/Jan 2020** Target inclusion of last patient in IsoConDa study around turn of the year • **Q3 2020** Paediatric study - first patient in • **Summer 2020** Submit MAA application in Europe in a first round	• **H2 2021** Completion of paediatric study • **H2 2021** Registration approval of IsoConDa			
	• **March 2019** Pre-IND meeting with FDA • **August 2019** Pilot testing of non-clinical studies initiated	• **June 2020** Completion of Human Factors validation study • **Q4 2020** IND application	• **2021** IND approval and clinical studies begin	• **2022** Decide whether to launch the products in US ourselves or together with a local partner	• **2023** NDA application	• **2024** NDA approval expected

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Development and commercialisation RoW

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 2020

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
- 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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Financial Result

Financial results Q3 2019 vs. Q3 2018

(MSEK)

P&L	Q3	
	2019	2018
Revenues		
Net sales	16,4	12,7
Capitalized development expenses	0,0	0,0
Other operating income	0,9	0,3
	17,3	13,0
Operating cost and expenses		
Cost of goods sold	-4,4	-3,3
External expenses	-7,1	-5,4
Personnel expenses	-9,3	-4,9
Depreciation and amortisation	-1,1	-1,1
Other operating expenses	0	0
Operating income	**-5,1**	**-2,1**
Income from financial items		
Result from securities and long term receivables	0,0	0,0
Financial income	0,8	1,6
Financial expenses	0,0	-2,0
Income after financial items	**-4,3**	**-2,5**
Income before taxes	**-4,3**	**-2,5**
Taxes	-0,7	-0,1
Net Income	**-4,9**	**-2,6**

Balance Sheet	30 September	
	2019	2018
ASSETS		
Intangible assets	84,2	44,3
Tangible assets	5,3	5,4
Financial assets	1,3	1,9
Total Fixed assets	**90,8**	**51,6**
Inventory	5,8	4,8
Receivables	12,4	6,4
Cash and cash equivalents	122,2	175,2
Total current assets	**140,4**	**186,3**
TOTAL ASSETS	**231,3**	**237,9**
EQUITY & LIABILITIES		
Share capital	2,0	1,9
Other equity	207,4	219,4
Total equity	**209,4**	**221,3**
Long term liabilities	0,0	0,0
Current liabilities	21,8	16,6
TOTAL EQUITY AND LIABILITIES	**231,3**	**237,9**

Cash Flow	Q3	
	2019	2018
Cash flow from operations bef. change in w.c.	-3,9	-0,3
Change in w.c.	0,5	2,2
Cash flow from operations after change in w.c.	**-3,4**	**1,9**
Cash flow from investment activities	-12,7	-8,5
Cash flow from financing activities	0,9	0,2
Cash flow for the period	**-15,3**	**-6,4**

Largest shareholders at the end of October 2019

Below is Sedana Medical's ownership structure as of **October 31, 2019**.

Name	Number of shares	Shareholding (%)
Linc AB	2 116 901	9,31%
Handelsbanken funds	1 655 713	7,28%
Anders Walldov direct and indirect (Brohuvudet AB)	1 600 000	7,04%
Sten Gibeck	1 530 744	6,73%
Swedbank Robur funds	1 376 600	6,05%
Ola Magnussion direct and indirect (Magiola AB)	1 340 867	5,90%
Anades Ltd.	1 143 083	5,03%
Ron Farrell	631 062	2,78%
Berenberg funds	712 731	3,13%
Nordnet pensionsförsäkrings AB	490 904	2,16%
Avanza Pension	488 284	2,15%
Öhman Funds	452 671	1,99%
Eklund Konsulting AB	416 616	1,83%
Tredje AP fonden	357 069	1,57%
Tony McCarthy	339 823	1,49%
Fifteen largest shareholders	14 653 068	64,45%
***Others** *	8 083 523	35,55%
TOTAL:	**22 736 591**	**100,00%**

*Of which CEO's ownership is 230 000 shares.

Source: Modular Finance

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Questions