SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

Interim Report Q2 2019 Presentation

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22nd of August 2019

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

Strategic Priorities

1. Registration of the pharmaceutical candidate IsoConDa (isoflurane) in Europe in 2021.

2. Development of registration work in the US with both AnaConDa and IsoConDa in 2024.

3. Ensure solid growth of the AnaConDa sales and prepare for launch of IsoConDa in Europe 2021.

4. Register AnaConDa and IsoConDa in relevant markets in Asia such as Japan and China.

Q2 2019 Highlights

“we summarize a good quarter that takes us closer to our goals;

to register IsoConDa in Europe 2021,

market approval in the US 2024

and to establish us in the major markets in Asia.

The goals are a first step towards our vision of making inhalation sedation with AnaConDa and IsoConDa a standard treatment for mechanically ventilated patients in intensive care worldwide.”

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Financial highlights

Blockbuster market potential for IsoConDa/AnaConDa

5,5% CAGR

Breakdown of total market potential for IsoConDa/AnaConDa*

Annual number of patients visiting the ICU
30 million

12 million
patients require mechanically ventilation

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)
SEK 1,000

X

AnaConDa/IsoConda market potential
SEK 20-30 billion

Regional market potential

Europe

~7,5m
ICU patients

~SEK 7 bn
European market potential

Asia/Pacific

~12,5m
ICU patients

~SEK 10bn
Asian/Pacific market potential

US

~7m
ICU patients

~SEK 9bn
US market potential depending on pricing

* Market size based on company estimates.

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 while maintaining an operating profit before depreciation and amortization (EBITDA) that is not materially negative, in parallel to building up a larger sales and market organization

Post-registration

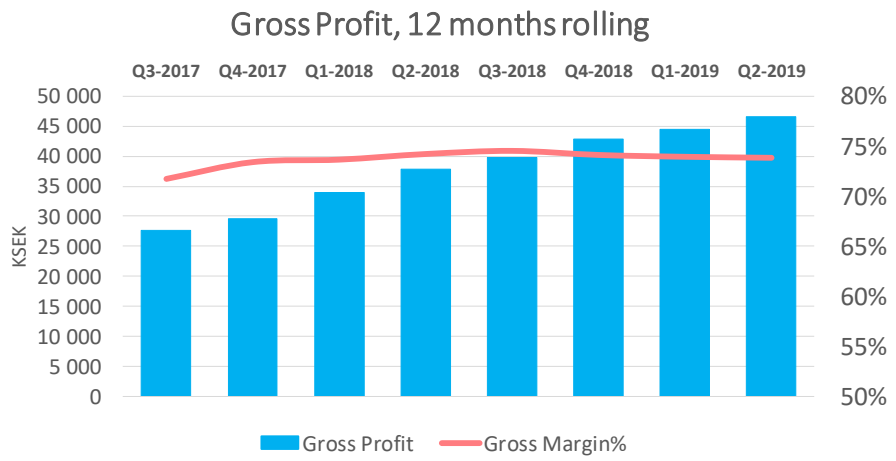
Provided that an approval of IsoConDa in Europe is obtained, the Company’s target is to reach a turnover exceeding 500 million SEK and an EBITDA margin of 40 percent three years after approval.

Financial highlights

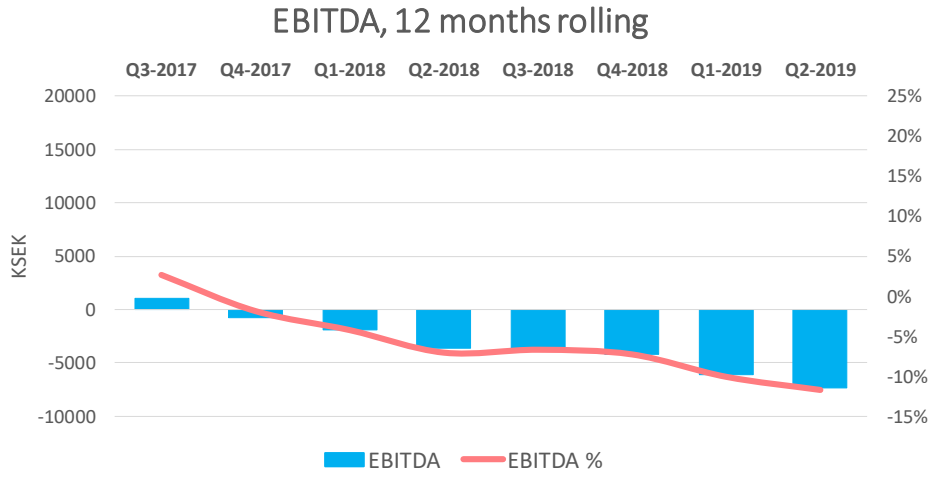
Q2-2019

- Net sales of 17,4 MSEK vs. 14,8 MSEK in Q2 2018, 20% growth individual quarter and 24% rolling 12 months.
- Gross margin of 13,4 MSEK or 77% vs. 11,3 MSEK or 78 % in Q2 2018.
- EBITDA -2,3 MSEK or -13,4% vs. -1,0 MSEK or -6,9% in Q1 2018.
- OPEX increased with 30% vs Q2 2018 due to build up of European organisation and preparation for IsoConDa launch which means continued sales and market investments during Q2.
- 40 employees in average in Q2 vs. 30 employees end of 2018 for the group in total.
- Cash flow from operations was -2,1 MSEK.
- Cash flow from investments was -13,4 of which -8,8 MSEK concern product development.
- Total cash flow for the group in Q2 was -12,6 MSEK.

Gross margin development



EBITDA development



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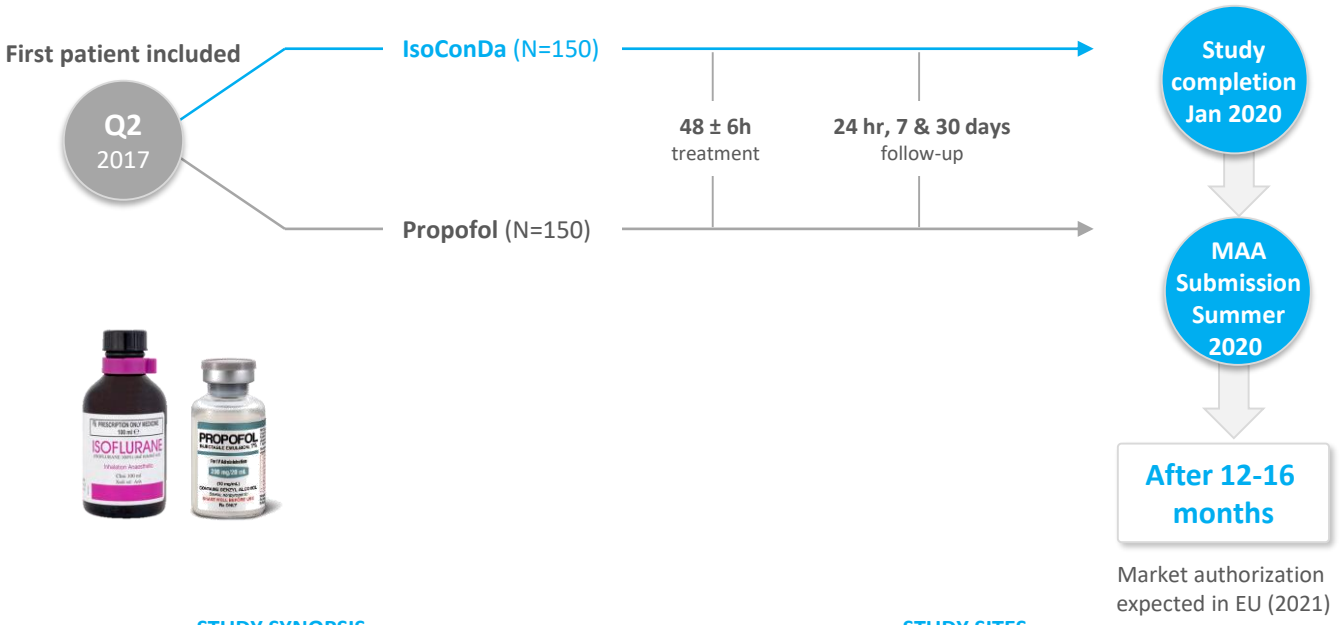
1. Registration of the pharmaceutical candidate IsoConDa (isoflurane) in Europe.

European market registration study – The IsoConDa study

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



STUDY SYNOPSIS

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 SITES

21 German sites
3 Slovenian sites

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

Marketing Authorisation Application Activities in 2019-2020

EUROPE

Recruitment of remaining 66 patients

Motivational work with current sites
Activation of three sites in Slovenia

Last patient in at the turn of 2019/2020

Study data collection completed 30 days later

Data preparation – 45 days

Final monitoring of patient data entry
Data cleaning
Query resolution
Database lock

Data analysis 45 days

- Demographics
- Primary and secondary endpoints
- Exploratory endpoints
- Adverse events

Final report for entry in eCTD 60 days

- Finalisation of study report and clinical summary
- Entry in eCTD
- Cross-referencing
- QA of full MAA
- Submission

Pediatric study (IsoCOMFORT) initiation Spring 2020

Market Authorization Approval expected 12-16 months after submission = during 2021

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The IsoCOMFORT study

- Protocol approved by EMA Pediatric Committee
- 160 patients age 3-17 years
- Isoflurane via the AnaConDa vs iv midazolam for 12-48 hours
- Primary endpoint – time with adequate sedation, assessed with the COMFORT-B scale
- Approximately 18 study sites in Spain, Germany, France and Sweden
- Finalisation of site feasibility assessment and CRO selection
- Study start spring 2020

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2. Development of registration work in the United States with both AnaConDa and IsoConDa.

US registration activities

- Initiation of Human Factors Engineering Program
  - Collaboration with Harvard and HF consultant company
  - Completion of Human Factors validation study June 2020
- Initiation of non-clinical studies
  - Contract Research Organisation for non-clinical studies
  - Pilot testing initiated in August 2019
- Planning of clinical studies initiated
  - Collaboration with academic centres in US
- IND application planned for Q4 2020
- US clinical study start in 2021

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3. Ensure solid growth of the AnaConDa sales and prepare for launch of IsoConDa.

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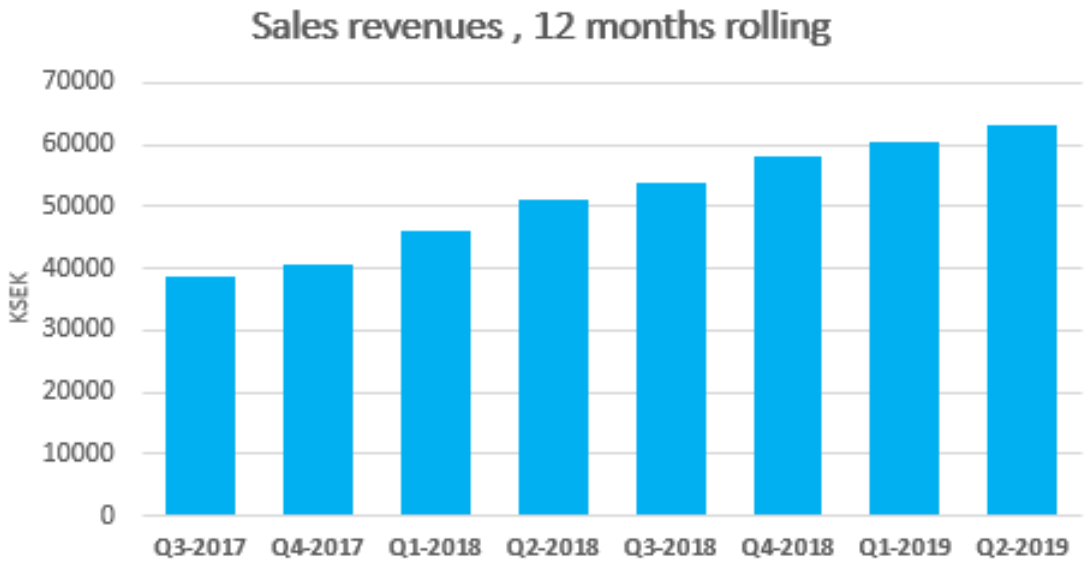
All time high sales in Q1 2019



24%

Sales increase rolling 12 months

SALES DEVELOPMENT

- ALL TIME HIGH SALES IN 1HY 2019
- 24% GROWTH ROLLING 12 MONTHS
- CLOSE TO 40% GROWTH IN FRANCE 1HY 2019
- SIGNIFICANT SALES INCREASE IN UK AND NORDIC

Introduction of Sedana Medical Research Foundation

Three research projects will receive funding from SMRF 2019 covering the area of inhaled sedation in the intensive care field.

Dr Giuseppe Foti, Associate professor and Director and dr Marco Giani, Department of Anesthesia and Intensive Care Department of Monza University Hospital, Italy.
Feasibility and safety of inhaled sedation in ECMO patients undergoing ultra-protective low frequency ventilation.
This study will investigate inhaled sedation delivered with the AnaConDa in (acute respiratory distress syndrome ARDS) patients undergoing veno-venous extracorporeal membrane oxygenation for respiratory failure with ultra-protective tidal volumes and low-frequency ventilation. Retrospective data indicate that this is possible, but positive findings may confirm that inhaled sedation, that appears to be lung-protective, may be used in patients normally considered too sick for uptake and elimination via the lungs.

Dr Gabriel Parzy, Dr Jean-Marie Forel, and Dr Laurent Papazian, Professor, Medical Intensive Care Unit service, Intensive Care Unit, Hôpital Nord, Marseille, France
Inhaled sedation effects on mean pulmonary artery pressure.
The main objective is to investigate potential reduction of pulmonary arterial pressure during inhaled sedation via the AnaConDa in moderate or severe ARDS patients. ARDS is associated with cardiopulmonary complications, including cor pulmonale and carries a high mortality. Reduced pulmonary pressures may potentially improve outcomes in these patients, however potential such effects of inhaled sedatives are not well studied previously.

Dr Martin Schläpfer, Associate professor, and Dr Beatrice Beck-Schimmer, Professor, Vice President Medicine, Institutes of Anesthesiology and Physiology, University and University Hospital Zurich, Switzerland.
Inhaled Sedation for Immunomodulation in Patients with Septic Shock – a pilot study.
This study will shed light on potential anti-inflammatory effects of inhaled sedation via the AnaConDa in septic shock. If this proves true, the implementation of this therapy may improve patient outcomes, such as mortality, in a critically ill patient group.

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

Development highlights RoW

From proven therapy to approved standard of care

- 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 1 HY 2020.
- Market potential is estimated at EUR 300 million annually.

- 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 the fast-track registration of AnaConDa.
- Estimates approval in less than two years.
- The Chinese market potential is estimated to be 5-6 million ventilation days annually.

- Exclusive distribution agreement with the Indian distributor Hansraj Nayyar Medical.
- Sales will commence in the fall and a registration process will start in parallel of AnaConDa.
- Th market potential is estimated to be 2 million ventilation days annually.

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Financial Result

Financial results Q2 2019 vs. Q2 2018

(MSEK)

P&L	Q2 2019	Q2 2018
Revenues		
Net sales	17,4	14,5
Capitalized development expenses	0,0	0,0
Other operating income	0,6	0,4
	17,9	14,8
Operating cost and expenses		
Cost of goods sold	-4,0	-3,2
External expenses	-6,7	-5,5
Personnel expenses	-9,2	-6,8
Depreciation and amortisation	-1,0	-1,0
Other operating expenses	0	0
Operating income	**-3,4**	**-2,0**
Income from financial items		
Result from securities and long term receivables	0,0	0,0
Financial income	0,7	1,3
Financial expenses	0,2	-0,9
Income after financial items	**-2,5**	**-1,6**
Income before taxes	**-2,5**	**-1,6**
Taxes	0,8	0,8
Net Income	**-1,7**	**-0,8**

Balance Sheet	30 June 2019	30 June 2018
ASSETS		
Intangible assets	72,7	38,3
Tangible assets	5,2	5,2
Financial assets	2,0	1,4
Total Fixed assets	**79,8**	**44,9**
Inventory	5,8	4,9
Receivables	8,9	7,6
Cash and cash equivalents	137,3	181,6
Total current assets	**152,0**	**194,1**
TOTAL ASSETS	**231,8**	**239,0**
EQUITY & LIABILITIES		
Share capital	2,0	1,9
Other equity	212,1	221,7
Total equity	**214,1**	**223,6**
Long term liabilities	0,0	0,0
Current liabilities	17,8	15,4
TOTAL EQUITY AND LIABILITIES	**231,8**	**239,0**

Cash Flow	Q2 2019	Q2 2018
Cash flow from operations bef. change in w.c.	-2,1	-0,4
Change in w.c.	0,7	3,6
Cash flow from operations after change in w.c.	**-1,4**	**3,2**
Cash flow from investment activities	-13,4	-8,8
Cash flow from financing activities	2,2	108,0
Cash flow for the period	**-12,6**	**102,3**

Largest shareholders at the end of June 2019

	Number of shares	Share (%)
Linc AB	2 116 901	10,78%
Sten Gibeck	1 605 744	8,33%
Handelsbanken funds	1 514 903	7,71%
Anders Walldov direct and indirect (Brohuvudet AB)	1 400 000	7,13%
Ola Magnussion direct and indirect (Magiola AB)	1 340 867	6,83%
Anades Ltd.	1 068 083	5,44%
Ron Farrell	731 062	3,72%
Berenberg funds	712 731	3,63%
Alfred Berg funds	476 648	2,43%
Nordnet Pension Insurance	470 022	2,39%
Swedbank Robur funds	450 000	2,29%
Eklund Konsulting AB	416 616	2,12%
Tony McCarthy	339 823	1,73%
Philip Earle	304 751	1,55%
Alto Invest SA	271 375	1,38%
Fifteen largest shareholders	13 219 526	67,32%
*Others **	6 417 065	*32,68%*
Total	19 636 591	100,00%

* CEO's ownership is 230 000 shares.

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Questions