

SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

Q1 Report 2021

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May 6th, 2021
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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.

Q1 2021 still strongly influenced by Covid-19





Our Purpose

To improve life during and beyond sedation

Vision

To make inhaled sedation a global standard therapy for critical care patients

Sedaconda®/AnaConDa provides clear benefits over current standard of care

Benefits

ON-OFF EFFECTS AND RELIABLE WAKE UP

- ✓ Significantly reduced wake-up time²
- ✓ Reduction in ICU stay duration for deep sedation patients¹⁰
- ✓ Significantly reduced time to extubation (ventilator tube removal)²

RELIABLE EFFECT AND SAFETY FOR THE DISTRESSED PATIENT

- ✓ Limits the occurrence of hallucination episodes/delirium⁶
- ✓ Reduction in use of opiates⁹

POTENTIALLY ORGAN PROTECTIVE PROPERTIES

- ✓ Reduced *in-hospital* mortality in long-term ventilated patients (>96h)⁴
- ✓ Reduced 1 year mortality in long-term ventilated patients (>96h)⁴
- ✓ Improved gas exchange/oxygenation**

Sedaconda®/AnaConDa

10-20 min

4-16 days

10-35 min

2 of 10 patients

2.7 mg/hour

40%

50%

Yes**

IV sedation

90 min – 130 h

6-27 days

150-600 min

5 of 7 patients

4.2 mg/hour

63%

70%

No**

Price per day

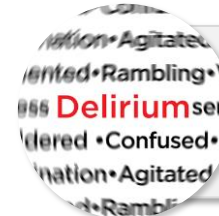
EUR 100*

EUR 20-300***



EUR 1-3k

Daily cost of an ICU bed in Europe¹⁴



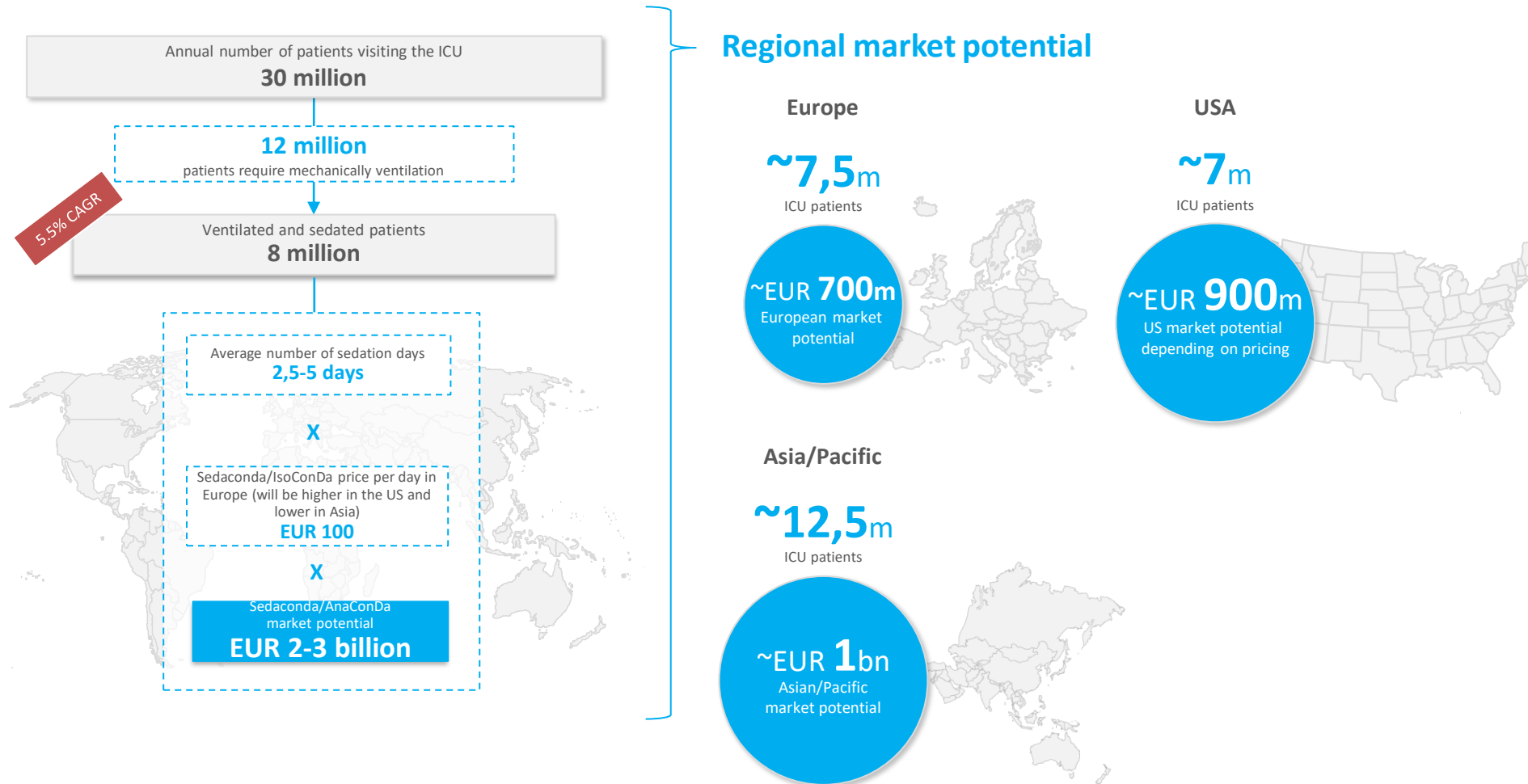
\$4-16bn

Annual cost of delirium from ventilated patients in the US¹⁵

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

Blockbuster market potential for Sedaconda/AnaConDa

Breakdown: total market potential for Sedaconda/AnaConDa*



Strategic priorities and financial objectives longterm

Strategic priorities

1

Development and commercialisation: Europe

- Registration of the pharmaceutical candidate Sedaconda (isoflurane) in 2HY 2021
- Ensure solid growth of AnaConDa sales and prepare for launch and launch of Sedaconda in 2021

2

Development and commercialisation: USA

- Development of registration work in USA with both Sedaconda and AnaConDa for NDA approval in 2024
- Preparation of Commercialisation strategy for USA to be decided ~2022.

3

Development and commercialisation: RoW

- Register AnaConDa and Sedaconda in relevant markets in Asia, such as Japan and China

Financial objectives

Pre-
registration

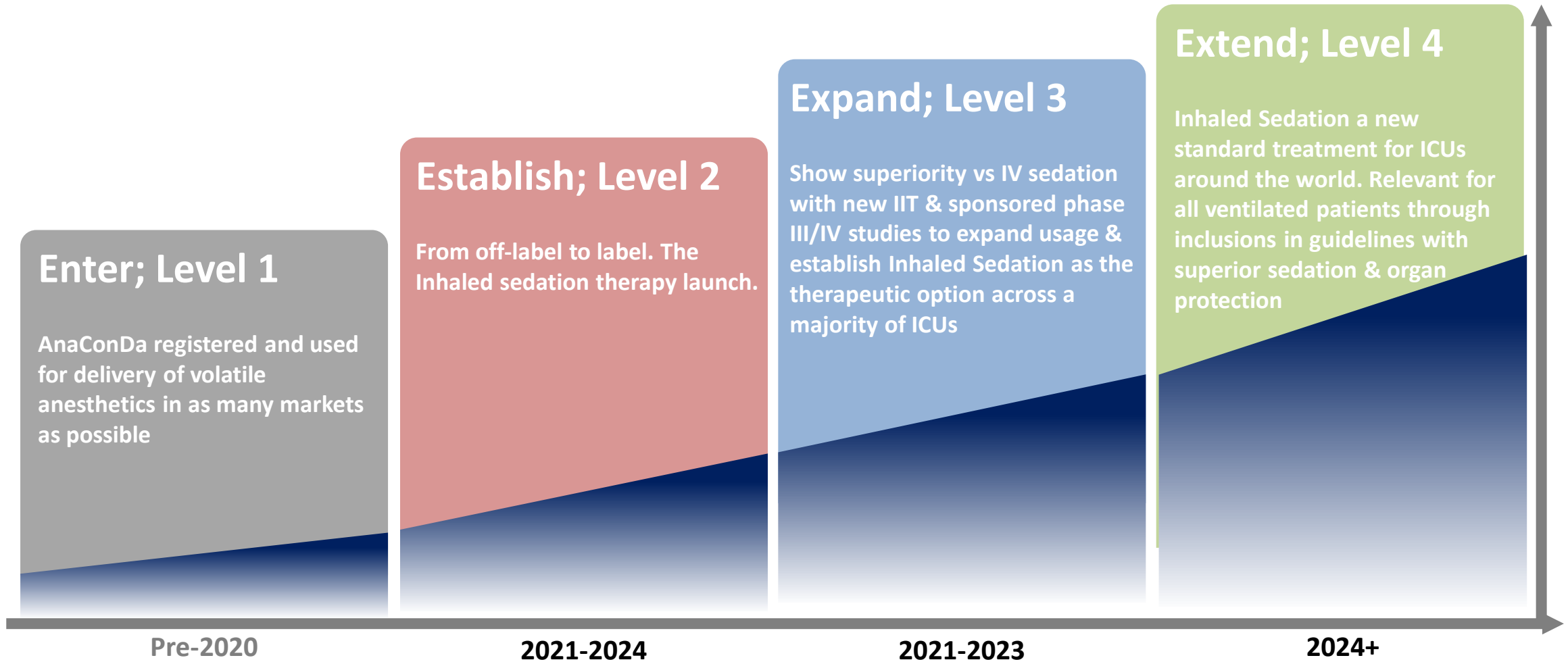
During the period up until the approval of Sedaconda is obtained, the Company's goal is to increase sales with an average of over 20 per cent per year, in parallel to building up a larger sales and market organization.

Post-
registration

Provided that an approval of Sedaconda 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.

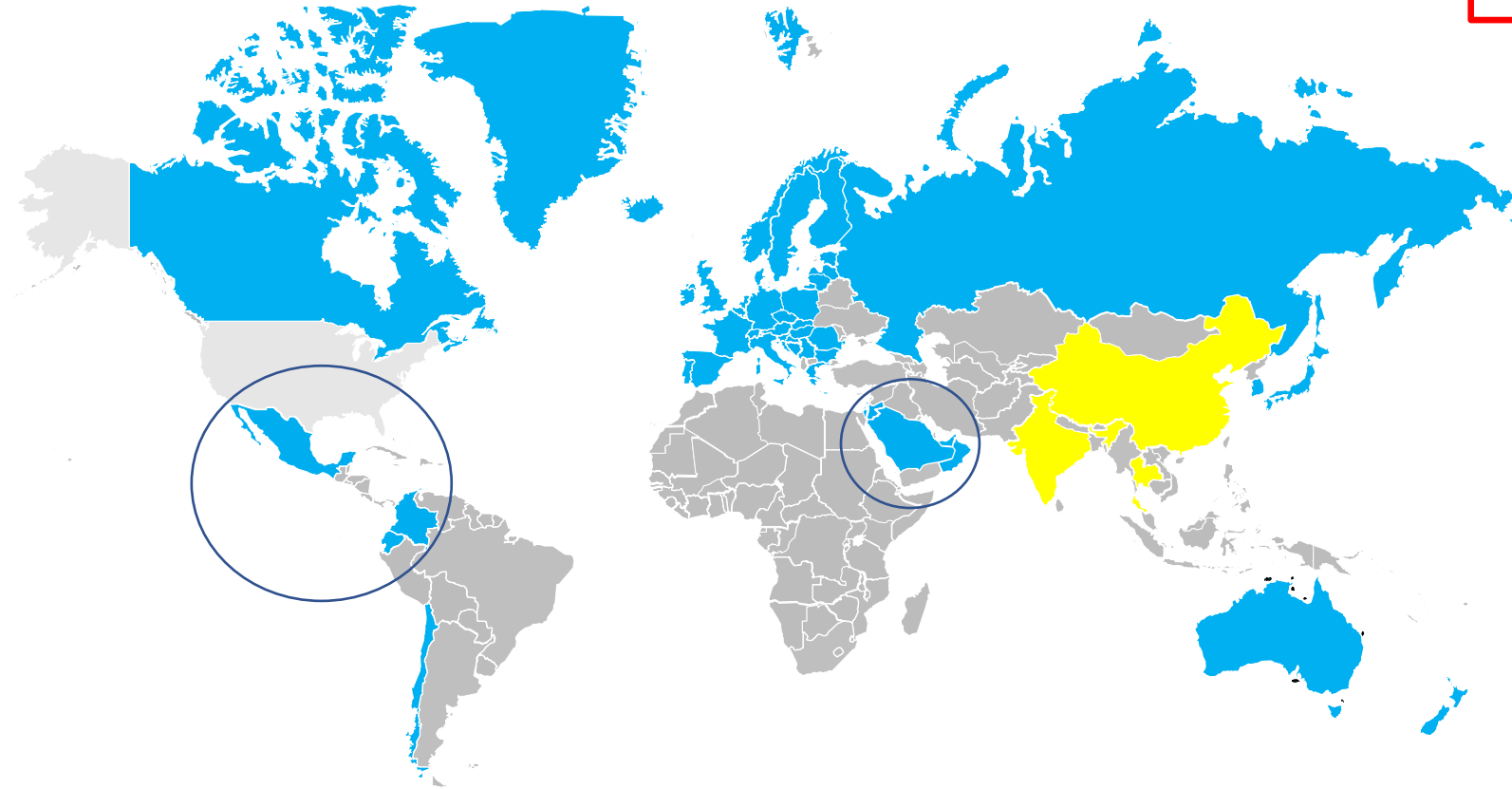
Sedana Medical Vision & Strategic Evolution

To make inhaled sedation (Sedaconda and AnaConDa),
a global standard therapy for critical care patients



Approved AnaConDa Markets

Level 1



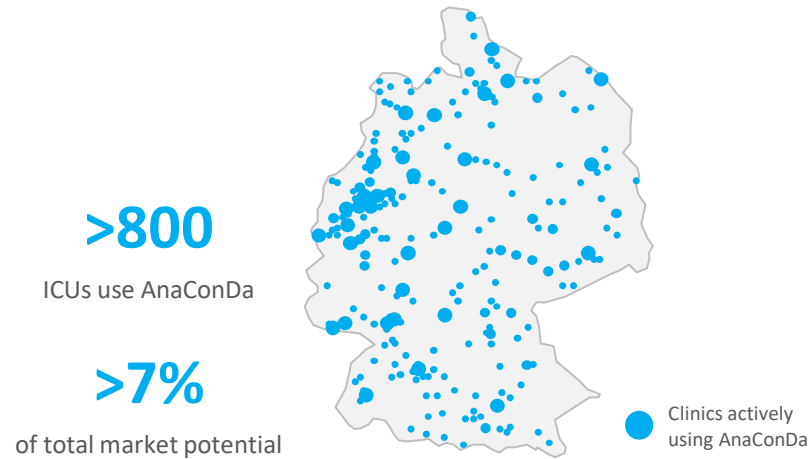
- Existing Registered AnaConDa markets
- In registration process.

Rapidly increasing adoption and usage despite off-label status

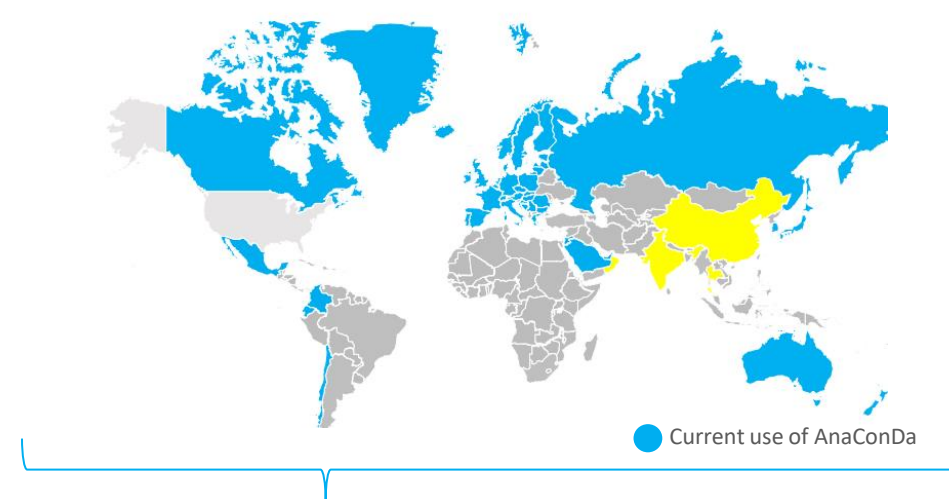
Case study: AnaConDa in Germany

- In 2010, new guidelines for sedation were published in Germany.
- The guidelines put forward inhalation sedation and the use of isoflurane as an alternative to IV sedation in intensive care for certain patient groups.
- The guidelines together with positive statements from a number of German KOLs have led to extensive use of AnaConDa in Germany.
- Sedana Medical's largest market is currently Germany, which together with other markets where it conducts direct selling, has functioned as a test market to study demand.

AnaConDa in Germany



Increasing use globally

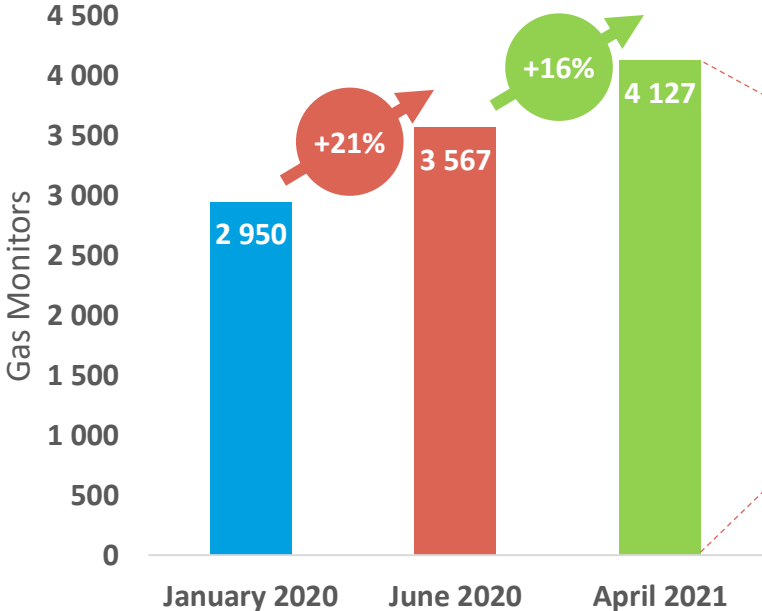


Proven in clinical practice

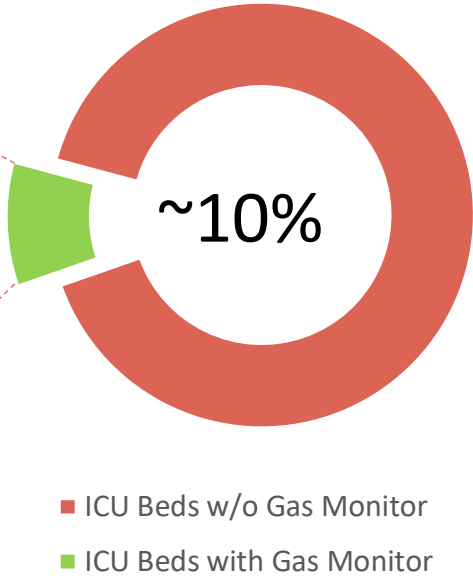


Continued increase in availability of Gas Monitors in ICUs further enabling use of inhaled sedation; with first launch of our own monitor in March

of ICU Beds with Gas Monitors in Direct Sales Markets



Share of ICU Beds in Direct Sales Markets with Gas Monitor

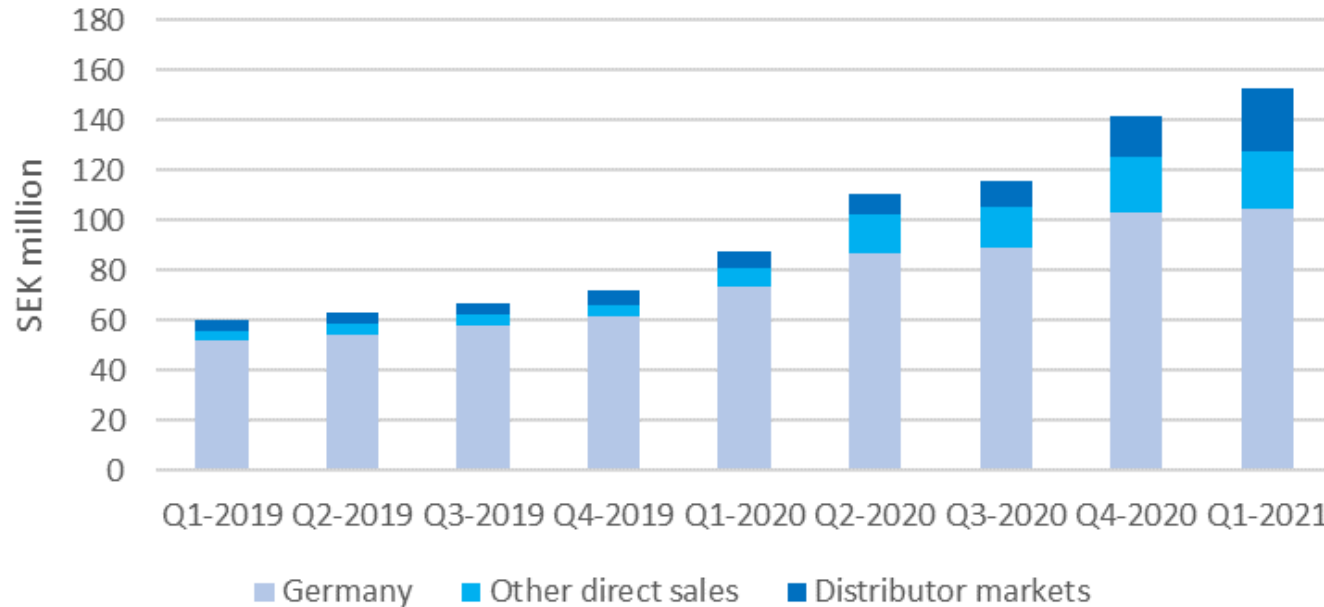


Launching the new AMG-06 Gas Monitor



Sales Development Q1 2021

Sales by area, rolling 12 months



40%
Sales growth
YoY
in local currencies

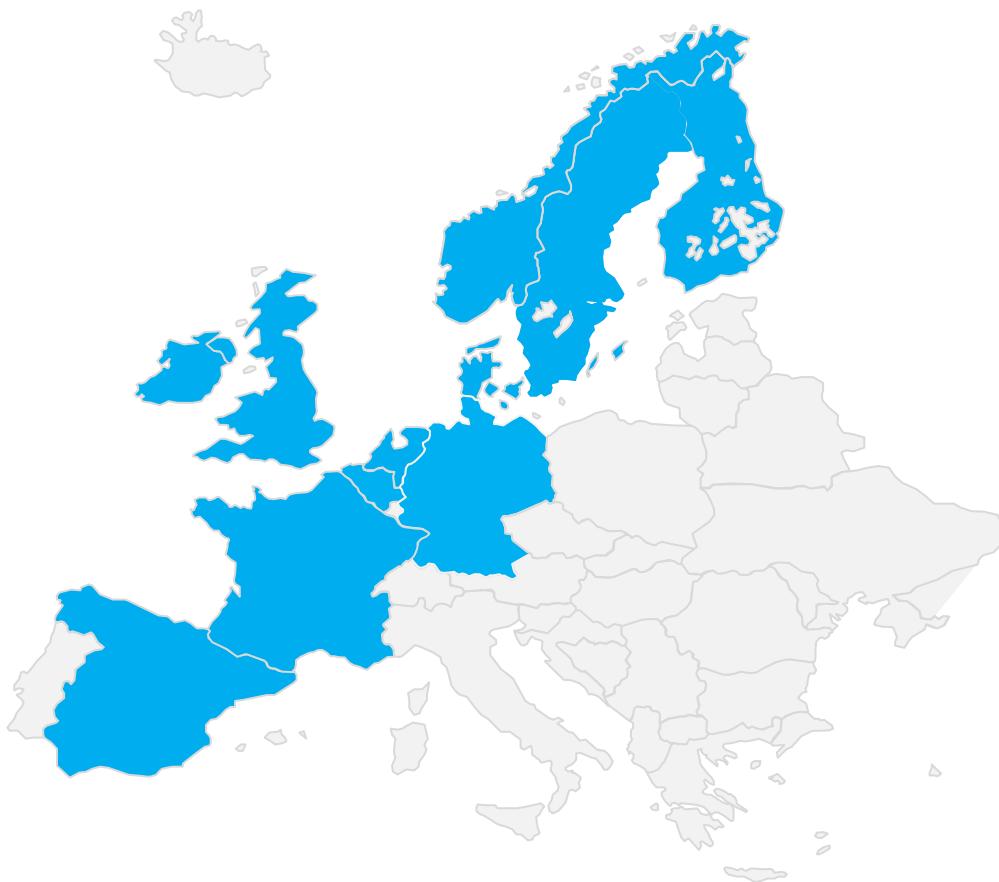
74%
Sales growth
12 months rolling
in local currencies

- Sales 45 (34) MSEK, 33% sales growth YoY, (40% in local currencies)
- Continued strong sales, fuelled by Covid-19 & new customers
- Substantial growth in Latin America

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

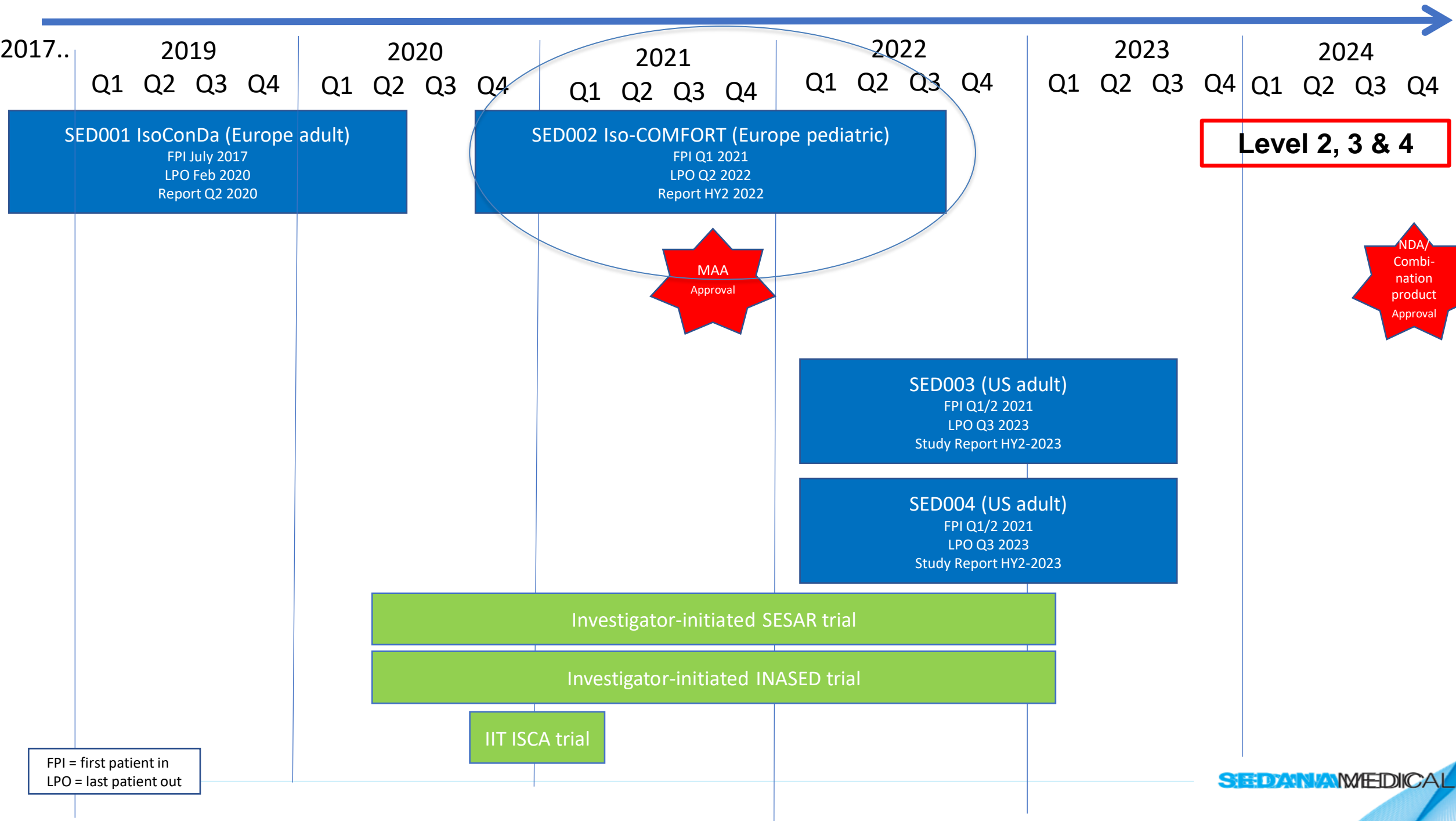


SEDACONDA LAUNCH EUROPE

- Submission in 15 EU countries November 2020
- Expected approval and launch 2HY 2021
- Submission Switzerland & UK Q1 2021
Expected approval and Launch 1HY 2022
- Second wave submission in EU after first wave approval and expected launch 6-8 months after submission.
- Investigation ongoing for additional registration countries to be added based on the European dossier.

15
COUNTRIES





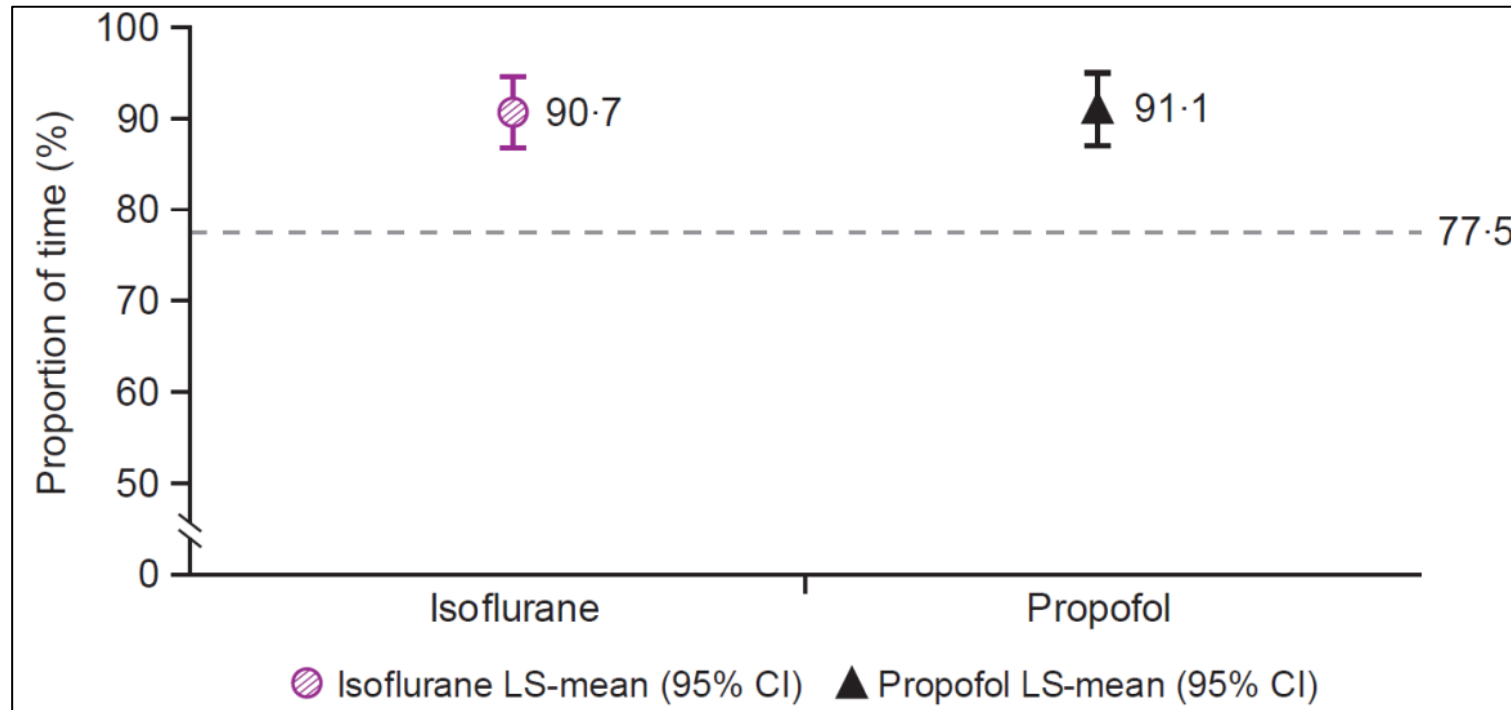
FPI = first patient in
LPO = last patient out

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Topline results from SED001 Sedaconda study

Non-inferior sedation efficacy for Sedaconda compared to propofol



Proportion of time at sedation target for isoflurane vs propofol. Mixed effect model, per protocol population. Sedation target was prespecified as RASS scores between -1 and -4. Non-inferiority analysis. Dashed line indicates non-inferiority cut-off, 15% below propofol LS-mean. CI=confidence interval. LS=least squares. RASS=Richmond Agitation-Sedation Scale.

Secondary endpoints SED001

Presented at European Society of Intensive Care Medicine 2020

1. Lower opioid requirement during sedation with isoflurane*
2. Higher proportion of spontaneous breathing with isoflurane*
3. Wake-up times
 - No difference in time to wake-up after 24 hours
 - Significantly shorter time to wake-up after 48 hours*

Safety

SAEs	No serious adverse events related to isoflurane
No safety or tolerability concerns	Adverse events generally unrelated to sedation or device No new safety concerns for isoflurane

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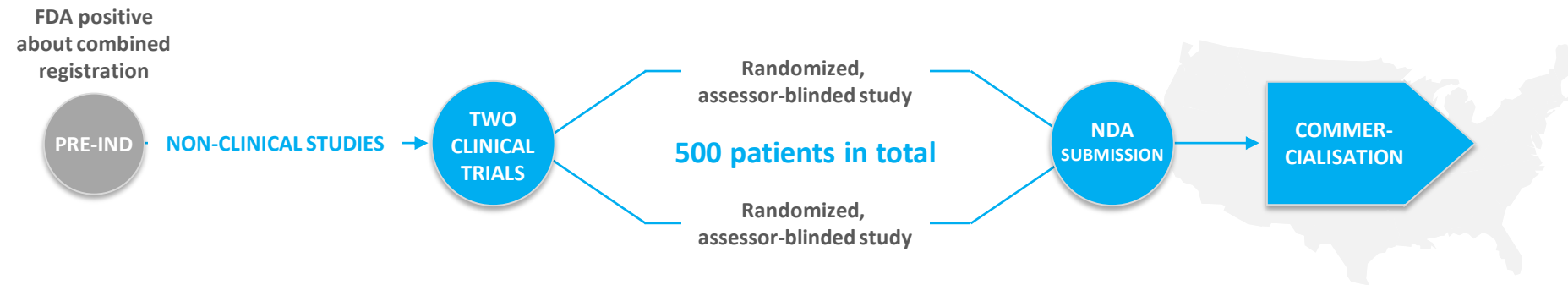
**Clinical Development
USA**



Combination registration of Sedaconda & AnaConDa 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



MAA Approval

NDA Approval

	2020	2021	2022	2023	2024
	<ul style="list-style-type: none"> Jan 2020 Inclusion of last patient in Sedaconda study July 2020 High-level data Sedaconda study Q4 2020 Paediatric study first sites opened for patient inclusion Q4 2020 MAA application in Europe in a first wave. 15 countries 	<ul style="list-style-type: none"> H2 2021 Marketing approval of Sedaconda in 15 countries IsoCOMFORT patient recruitment 	<p>H2 2022 Completion of paediatric study</p>	<p>H1 2023 Pediatric marketing approval of Sedaconda</p>	
	<p>Q4 2020</p> <ul style="list-style-type: none"> Completion of Human Factors formative study Preclinical studies 	<p>2021</p> <ul style="list-style-type: none"> Site recruitment EOP2 meeting IND approval Further preclinical studies 	<p>2022</p> <ul style="list-style-type: none"> Clinical studies start Plan launch in US - alone or together with a local partner 	<p>2023</p> <ul style="list-style-type: none"> Completion of US Clinical Trials NDA application 	<ul style="list-style-type: none"> 2024 NDA approval expected

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Financial highlights

Financial results ¹⁾

Investing for future.

Net sales Q1'21: 45 (34) MSEK, +33% YoY, +40% in local currencies

Net sales FY'20: 142 MSEK

Gross Profit Q1'21: 29 (23) MSEK, +26% YoY

Gross Margin Q1'21: 64 (67) %

- Continued high freight costs during the Covid-19 pandemic. Excl freight costs, gross profit is slightly higher YoY.
- Sales mix, increased sales in distributors markets with somewhat lower margins.

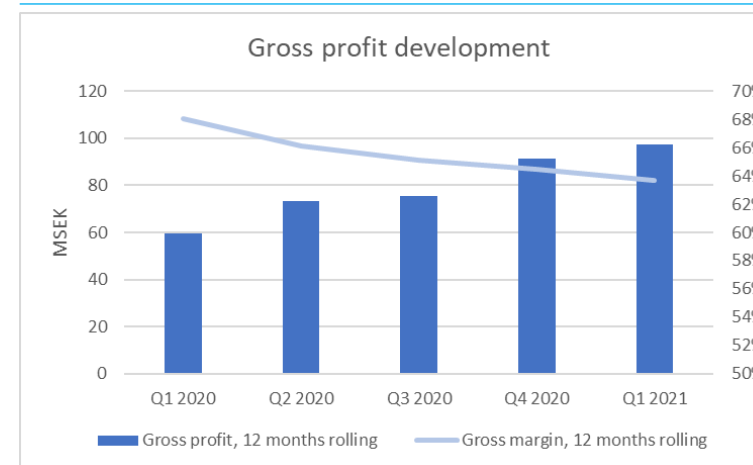
EBITDA Q1'21: -8 (2) MSEK

EBITDA Margin Q1'21: -18 (5) %

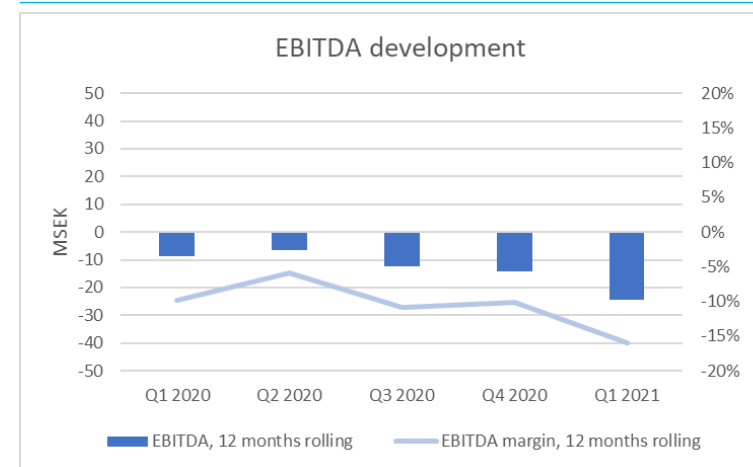
Investing now for future growth. Build up of organisation and preparation for SedaConDa launch results in increased OPEX and number of staff. Also includes some overlap in staff costs and slightly lower capitalisation rate within R&D in Q1'21. One-time impact from moving to new logistics center.

Staff, incl consultants, per 31st Mar 2021: 85 (58)

Gross profit development



EBITDA development

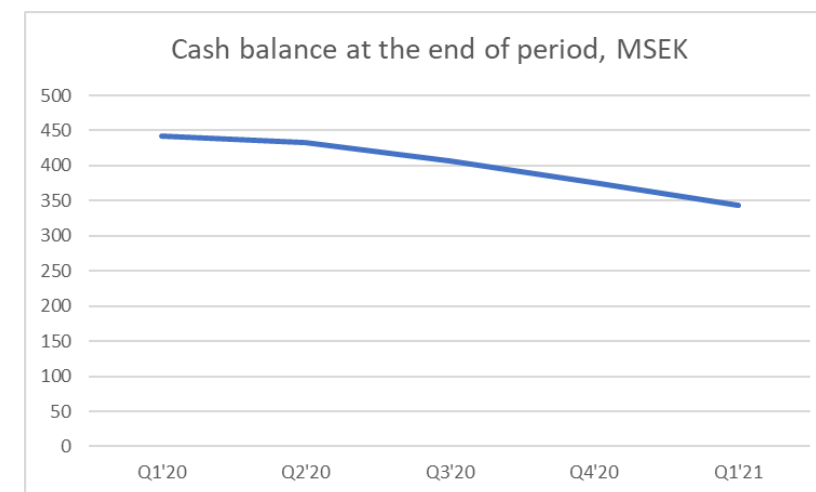
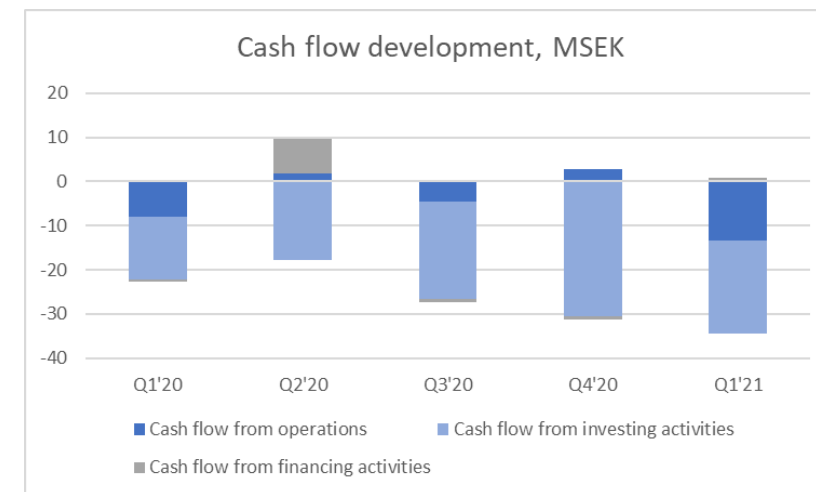


¹⁾ Numbers are restated according to IFRS and from a P/L by cost type to function type.

Financial balances and Cash ¹⁾

- **Cash flow from operations Q1'21: -13 (-8) MSEK**
- **Cash flow from investment Q1'21: -21 (-14) MSEK**
of which the vast majority is related to product development.
- **Cash flow for the period Q1'21: -33 (-23)**

- **Cash balance per 31st Mar 2021: 344 (443) MSEK**
- **No long-term financial debts / Debt free company**



¹⁾ Numbers are restated according to IFRS and from a P/L by cost type to function type.

Largest shareholders at 31st March 2021

	No of share	Share
Handelsbanken Funds	2 198 763	9,5%
Swedbank Robur Funds	2 110 895	9,2%
Linc AB	1 899 701	8,2%
Anders Walldov direct and indirect (Brohuvudet AB)	1 740 000	7,5%
Sten Gibeck	1 219 944	5,3%
Ola Magnusson direct and indirect (Magiola AB)	1 153 432	5,0%
Öhman Funds	772 659	3,4%
Berenberg Funds	609 440	2,6%
Avanza Pension	529 629	2,3%
Tredje AP-fund	475 000	2,1%
Tedsalus AB (Thomas Eklund)	416 616	1,8%
Nordnet Pensionsförsäkring	409 756	1,8%
Highclere International Investors LLP	364 376	1,6%
Philip Earle	260 500	1,1%
Christer Ahlberg	259 000	1,1%
Fifteen largest shareholders	14 419 711	62,6%
<i>Others</i>	8 627 029	37,4%
Total	23 046 740	100,0%

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Questions