

Q4 and Full Year Report 2021

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- 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.



Our Purpose

To improve life during and beyond sedation

Our Vision

To make Inhaled Sedation a global standard therapy for critical care patients





Q4 2021 Highlights

Strong financial performance

- All-time-high sales for the quarter and the full year
 - 2% growth¹ in Q4 sales (46 MSEK)
 - 16% growth¹ in FY sales (159 MSEK)
- Gross margin of 71% in Q4 (up from 64% in Q4 2020)

Launch in Europe on track

- 14 out of 15 national approvals obtained for Sedaconda (isoflurane), following the European approval in July
- First bottles of **Sedaconda (isoflurane) shipped** to customers in Q1, 2022
- NICE guidance recommending inhaled sedation with Sedaconda ACD as cost-effective

U.S. preparation intensifying

- Decided to build **own commercial operations** in United States
- **IND approved** in December 2021
- Preparations for **clinical trial on track**, first patient in the clinical trial expected in April

1 Growth in local currencies



We have seen an all-time-high in sales for both the quarter and the full year

Q4 sales over time SEK million

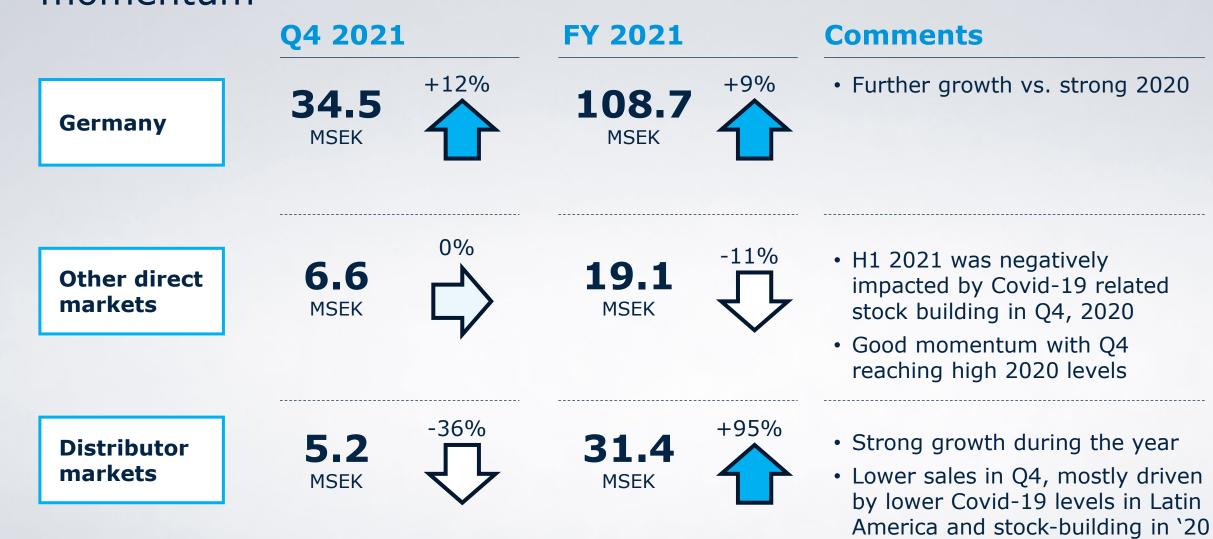


Full year sales over time SEK million





Strong performance in Germany, other direct markets gaining momentum



1 Growth in local currencies



Two growth horizons ahead: Europe and the US

Europe

- Approval of Sedaconda (isoflurane) in 14 countries to date
- Offering the first and only on-label therapy for inhaled sedation in the **ICU**
- Direct presence in Germany, UK, France, Spain, Benelux, Nordics



- 107,000 ICU beds¹
- Attractive price level
- IND approved
- Clinical program to start in April
- Decided to build own US infrastructure

United States

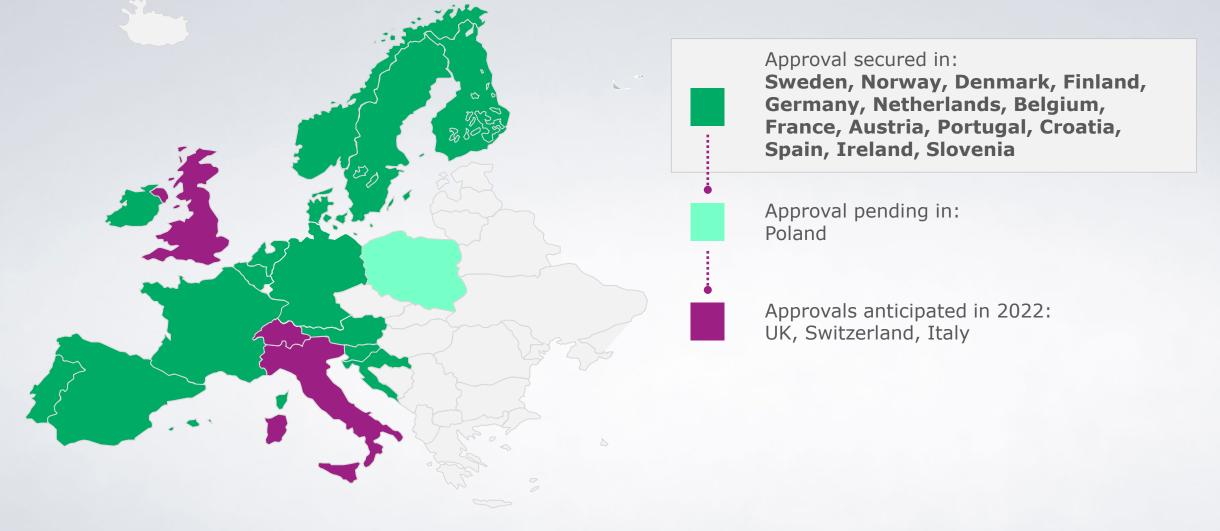






National approval for sedaconda (isoflurane) has been secured in 14 countries







The first bottles of Sedaconda (isoflurane) have been shipped to customers



Launch update

- First sales in Germany in February 2022
- More countries will launch over the next months, timing depending on local pricing and reimbursement
- Assuming UK approval, all direct markets will launch in 2022

Outlook

- Aim in all countries is to convert a significant part of off-label volatile anaesthetics to Sedaconda (isoflurane)
- Level and speed of conversion will differ by country
- We anticipate a gradual ramp-up
 - More countries will come on board over time
 - Sales processes in individual accounts take time



inhalation vapour, liqui

NICE has issued a recommendation for Sedaconda ACD



NICE National Institute for Health and Care Excellence



Sedaconda ACD-S for sedation with volatile anaesthetics in intensive care

Information for the public Published: 27 January 2022 www.nice.org.uk

NICE has said that Sedaconda anaethestic conserving device-S (Sedaconda ACD-S) can be used in the NHS for delivering inhaled sedation to adults and children who are mechanically ventilated in an intensive care unit.

Sedaconda ACD-S may reduce the amount of time a person stays on mechanical ventilation and allow them to wake up quicker than with intravenous sedatives, which may shorten the length of time in intensive care.

More research is needed to identify which groups of patients and which health conditions would benefit most from inhaled sedation with Sedaconda ACD-S.

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- NICE¹ has issued a Medical Technologies
 Guidance, recommending Sedaconda ACD
 and showing significant cost saving vs.
 intravenous sedation
- Based on a thorough assessment (>1 year) and review of available evidence including 21 studies
- NICE guidances come with an implementation expectation for health care personnel
- NICE guidances typically get international recognition



With the NICE recommendation, our therapy has proven clinical and health-economic benefits





Clinical benefits (SED-001 2021)



- Non-inferior sedation to propofol
 - 29% lower opioid requirements during treatment
 - More commonly observed spontaneous breathing
 - Shorter and more predictable wake-up times
 - Well tolerated for sedation in the ICU



Health-economic benefits (NICE 2022)

- Sedaconda ACD is recommended as a cost-saving option for delivering inhaled sedation in an intensive care setting
- Cost savings compared with intravenous sedation of almost £3,834 per adult patient¹



The United States represent the largest potential market for Sedana Medical





¹ Discounts for propofol in the range of 40-50% based on payor research conducted in 2020 2 Last twelve months



We have decided to build own commercial operations in the United States



Facts

- US is clearly the largest potential market
 - 5x more ICU beds than Germany
 - ~3-4x the propofol net price level
- Concentrated customer base: ~4.860 hospitals with ICU care (of which ~2.800 with >10 beds)¹

US Strategy

- Build in-house commercial infrastructure
- Grow the organization over time, with initial focus on medical roles
- Keep the option to add complementary partnership(s) to enhance reach if deemed attractive





We have received approval for our IND application in the United States





United States Update

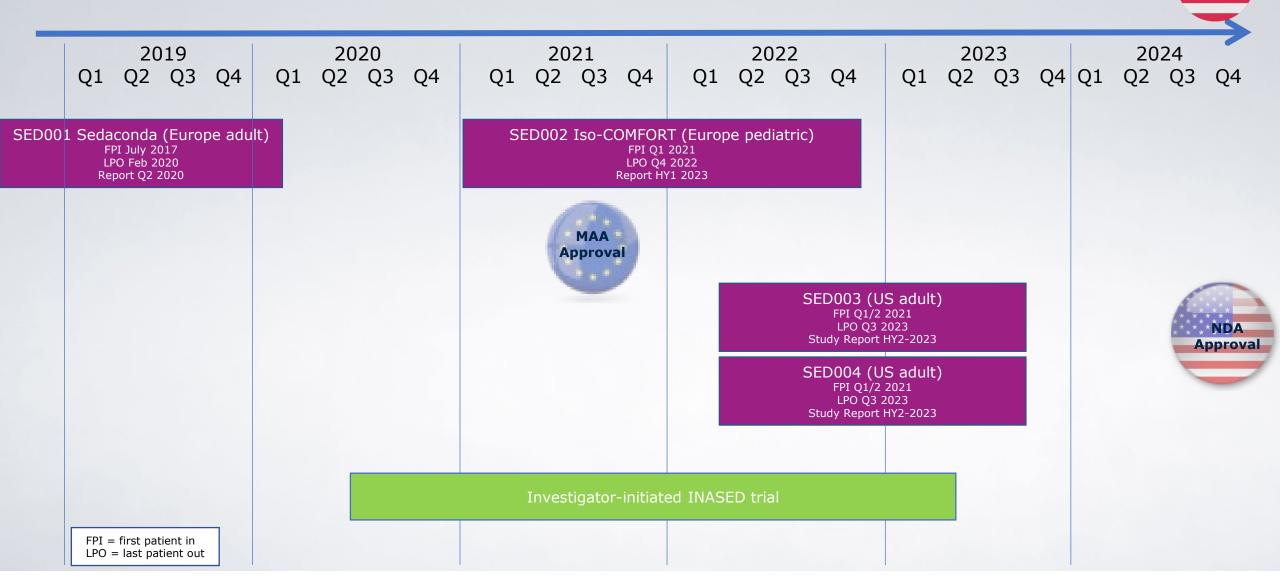
- IND (Investigational New Drug Application) was approved in December 2021
- Central IRB (Institutional Review Board) approvals for clinical trial sites progressing according to plan
- Site trainings ongoing
- First patient expected to be enrolled in April, 2022



INhaled Sedation vs Propopfol In REspiratory failure



Development program is progressing according to plan





We also had progress in countries outside Europe and US

Progress US during Q4...



 Approval of Sedaconda ACD in Turkey (10.000 ICU beds)



 Approval of Sedaconda ACD in Argentina (8.000 ICU beds)



 Filed for Marketing Authorization of Sedaconda ACD in China (frame contract worth SEK 16MSEK with our partner Kyuan)



 Filed for Marketing Authorization of Sedaconda ACD in Brazil (26.000 ICU beds)

... further growing our global presence





Supply: We have taken the first steps in our Dual sourcing project

Objectives

- Establish second source production for main products
 - Reduce dependency on individual suppliers
 - Reduce exposure to risks related to shipment from Asia

Status

 Started EU production of Sedaconda
 Syringes in Q4, 2021



Aim is to start EU production of other core products during 2022





FINANCIAL HIGHLIGHTS



Financial results

Net sales Q4'21: 46 (46) MSEK, +2% YoY in local currencies

YTD'21: 159 (142) MSEK, +16% YoY in local currencies

Sales in Germany contributed with 9 percent growth for the full year.

 Other direct markets showed a decrease of 11 percent from the previous year. This is due to the fact that the first two quarters of 2021 were negatively affected by significant Covid-19driven stock-building in 2020 and consequently less and lower orders in the first half of 2021.

Gross Profit Q4'21: 33 (30) MSEK **Gross Margin Q4'21:** 71 (64) %

- Improved margin is mainly an effect of a positive market mix where markets with higher gross margins had a relatively higher share of the quarter's sales.
- Lower shipping costs due to more sea freight also contributed positively to the gross margin.

EBITDA Q4'21: -13 (-6) MSEK **EBITDA Margin Q4'21:** -29 (-13) %

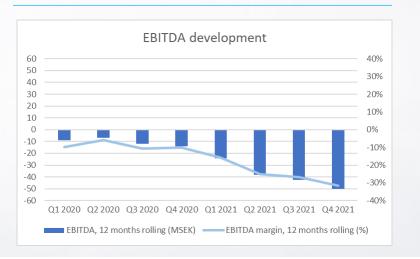
- Increased selling expenses due to higher costs related to the pre-launch activities of Sedaconda (isoflurane), a larger commercial and market organization and a higher level of activity as certain trade fairs and conferences have resumed.
- Increased R&D expenses mainly due to a lower degree of capitalization attributable to the initial scale up of the organization.

Staff, incl consultants, per Dec 31, 2021: 107 (83 at Dec 31 2020)

Gross profit development



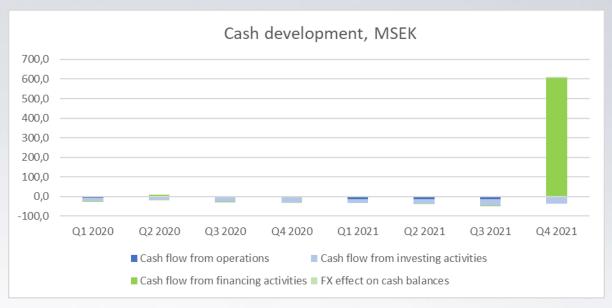
EBITDA development

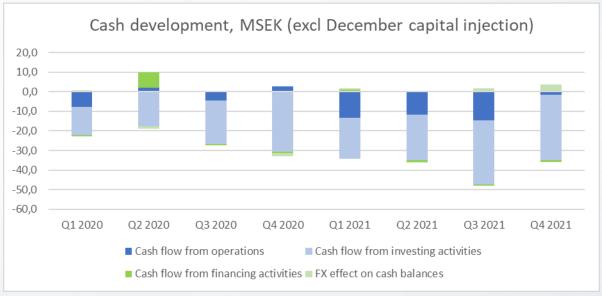




Financial balances and Cash

- Cash flow from operations Q4'21: -2 (3) MSEK
 Cash flow from operations YTD'21: -41 (-8) MSEK and a cash flow from working capital of 12 MSEK mainly due to high levels of accounts receivables at year-end 2020.
- Cash flow from investments Q4'21: -33 (-31) MSEK Cash flow from investments YTD'21: -110 (-85) MSEK of which the vast majority is related to expenses for clinical studies, work on registration of Sedaconda ACD and Sedaconda (isoflurane) in the United States, as well as investments related to the paediatric study in the EU.
- Cash flow for the period Q4'21: 571 (-29) MSEK
 Cash flow for the period YTD'21: 454 (-87) MSEK whereof
 607 MSEK is the net amount related to the new share issue completed in December.
- Cash balance per Dec 31, 2021: 836 MSEK compared to 262 MSEK at the beginning of the quarter
- No long-term financial loans / debt free company

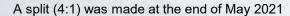






Largest shareholders December 31, 2021

	No of shares	Share
Swedbank Robur Funds	9,329,589	9.4%
Handelsbanken Funds	9,087,712	9.1%
Linc AB	8,064,804	8.1%
Anders Walldov direct and indirect (Brohuvudet AB	7,662,018	7.7%
Ola Magnusson direct and indirect (Magiola AB)	4,572,098	4.6%
Sten Gibeck	4,279,776	4.3%
Öhman Funds	4,087,019	4.1%
AMF Pension	3,870,000	3.9%
Berenberg Funds	1,905,101	1.9%
Avanza Pension	1,867,828	1.9%
Nordnet Pensionsförsäkring	1,803,870	1.8%
Tredje AP-fund	1,735,989	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Highclere International Investors LLP	1,492,630	1.5%
DNCA Finance S.A	1,379,980	1.4%
Fifteen largest shareholders	62,804,878	63.2%
Others	36,532,082	36.8%
Total	99,336,960	100.0%





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QUESTIONS

