

Disclaimer

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 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





Q1 2022 Highlights

Financial performance

- Net sales of **SEK 34 million** (-25%), explained by a significant decline in the number of ventilated ICU patients in Q1
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- Gross margin of **68%** (up from 64%), driven by lower transportation costs and positive impact from the market mix
- Cash balance of SEK 779 million

Launch in Europe underway

- First bottles of Sedaconda (isoflurane) shipped to customers in Q1
- Sedaconda (isoflurane) is now available in Germany, Sweden and the Netherlands
- NICE guidance recommending inhaled sedation with Sedaconda ACD as cost-effective

U.S. studies initiated

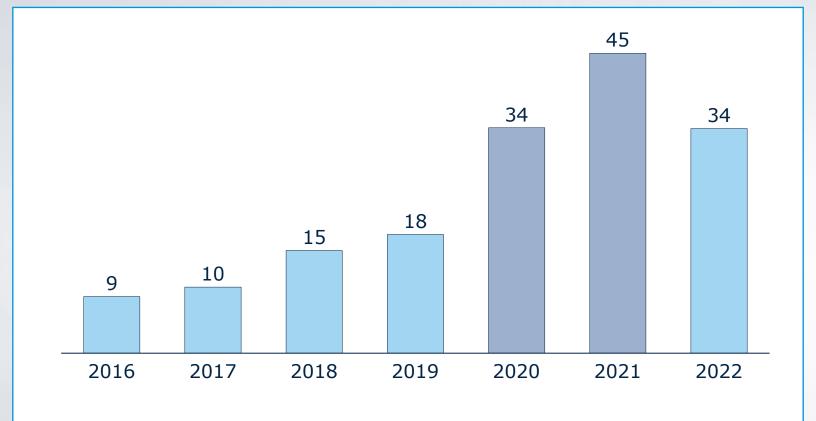
- United States represents the largest commercial opportunity
- First patient enrolled in INSPIRE-ICU 1 trial, in line with ambitious time plan
- Planning for organizational build-up in United States ongoing



In Q1, sales have declined after the Covid-19 years 2020 and 2021, but levels are higher than pre-Covid

Q1 net sales over time

SEK million



Comments

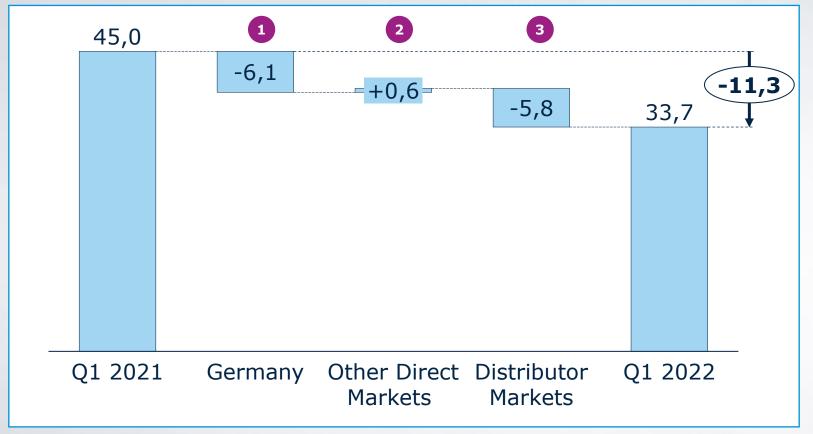
- Covid-19 resulted in a trend-break in the longterm sales development
- Lower sales in 2022 due to a significant decline in ventilated ICU patients (both Covid and non-Covid)
- Higher level than the long-term trend as Covid-19 has led to more clinics using inhaled sedation



The sales gap vs. 2021 is explained by lower sales in Germany and Distributor Markets

Sales bridge Q1 2021 vs. 2022

SEK million



Comments

- Germany:
 Q1 sales of 22.4 MSEK
 (-22% vs. Q1 last year)
- Other direct markets: Q1 sales of 5,6 MSEK (+12% vs. Q1 last year)
- **Distributor markets**: Q1 sales of 5.6 MSEK (-51% vs. Q1 last year)



Germany's performance is affected by a contraction of the addressable market

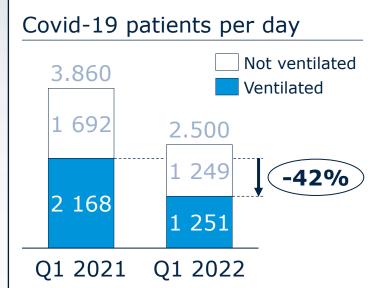
Net sales in Germany

Q1 2022, SEK million



Market dynamics

Ventilated patients in German ICUs



- Omikron variant leading to less severe cases
- Trend has continued into April (currently ~80% less ventilated patients than 2021)

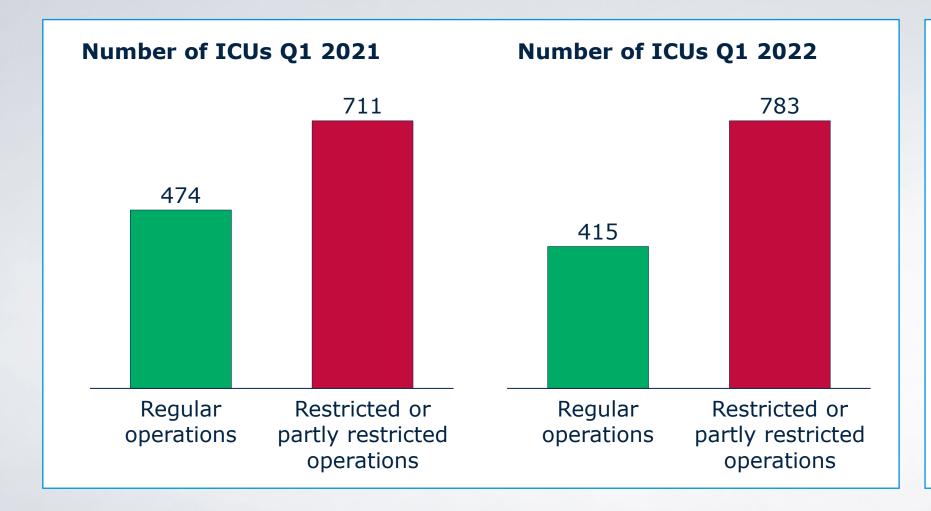
Other patients

No official statistics available, but numbers have also declined significantly for other patients

- Less elective surgeries due to high level of staff absence in hospitals
- Less community-acquired infections due to continued hygiene measures



Even more German ICUs had restricted operations in Q1 2022 than last year



- German ICUs have a maximum number of patients per nurse:
 - Day shift: 2 patients per nurse
 - Night shift: 3patients per nurse
- Due to staff shortage (omikron, burn-out, high turn-over after Covid-19), majority of ICUs had to...
 - Reduce capacity
 - Restrict access



Other direct markets: growth driven by Spain, France and UK

Net sales in Direct Markets (excl. Germany)

Q1 2022, SEK million



Market dynamics

Similar dynamics as in Germany...

- Less ventilated patients and reduced ICU capacity across direct markets
- (Partly heavily) restricted access to ICU customers

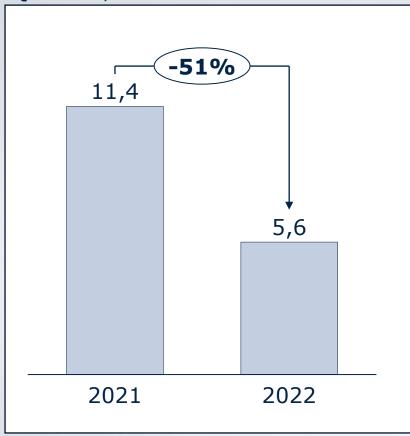
... but offset by underlying growth

- Good momentum, especially in Spain, France and UK
- Comparably low levels in some countries in Q1 2021 (due to stock-up in the first Covid-19 winter)



Distributor Markets: decline is explained by South America

Net sales in Distributor Markets Q1 2022, SEK million



Sales growth/decline Q1, 2022 vs. 21 SEK million



- Decline can be attributed to one distributor (covering Mexico, Colombia, Ecuador)
 - Artificially high sales in Q1 2021 (propofol shortage in S. America)
 - No orders in January and February 2022 due to stock-up end of 2021
- Positive growth in other distributors

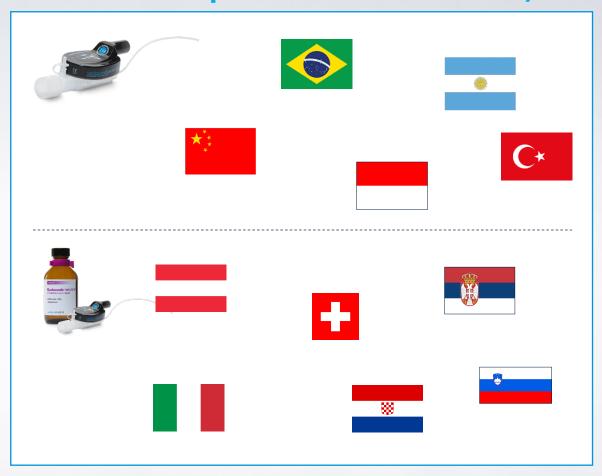


Overall, we are seeing good momentum in our distributor markets

Recent progress...



... and several possible launches in 22/23





With convincing clinical and health-economic benefits, our target is to become standard of care



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



Outlook - several growth horizons ahead



Grow 23-25

Launch 2022

Market

Company

What to expect

- Some (more) quarters may be affected by lower ICU capacity and access restrictions
- Full focus on commercial execution
- Launches of Sedaconda (isoflurane)
- Sedaconda available in all major direct markets by year end
- Increasing penetration of inhaled sedation and gradual shift to on-label isoflurane

- Normalization to pre-Covid levels and market growth in line with demographics (assuming no new wave)
- Drive towards standard of care in as many accounts as possible
- 500 MSEK sales in Europe in 2025¹
- Majority of off-label isoflurane converted

- Addition of US market (largest commercial opportunity)
- Launch in United States
- Further grow European business
- Sales guidance (incl. US) to be given closer to launch
- 40% EBITDA in steady state after US launch
- Current cash level sufficient to finance US launch



The first patient has been enrolled in our US clinical trials



First patient in.



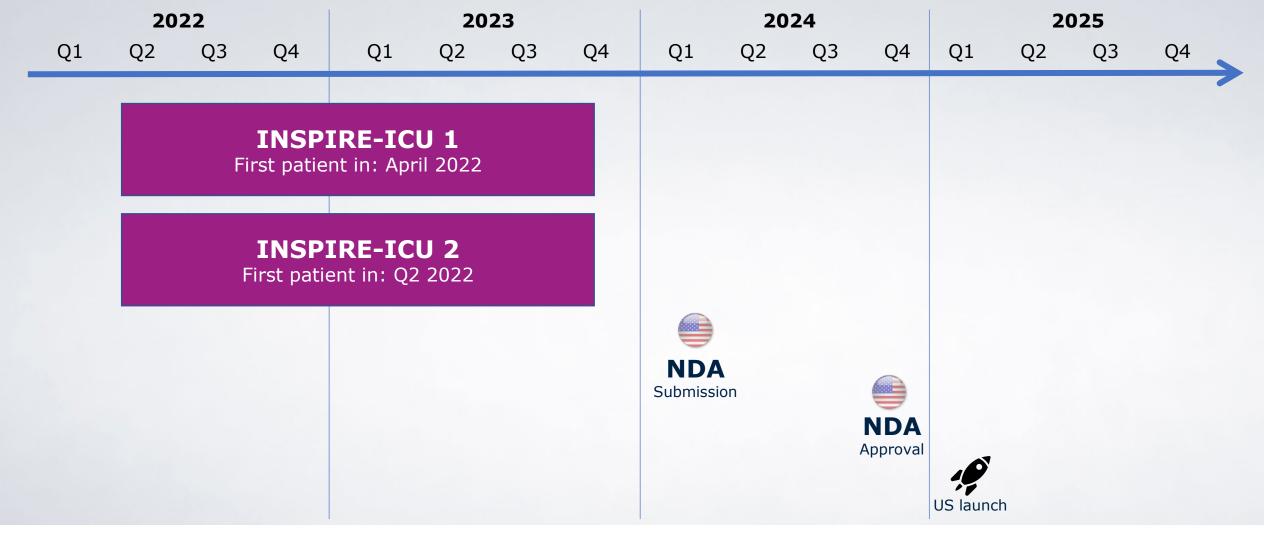
INSPIRE-ICU

- Two identical phase III studies (INSPIRE-ICU 1&2) to confirm efficacy and safety of inhaled isoflurane, delivered via Sedaconda ACD, for sedation of adult mechanically ventilated ICU patients, in comparison to IV infusion of propofol
- 470 adult patients in 25-30 sites (plus 3-5 "run-in patients" per site)
- Primary end point: proportion of time spent within the target range of sedation depth in absence of rescue sedation, as assessed according to the Richmond Agitation Sedation Scale (RASS)
- Secondary endpoints: use of opioids, wake-up time, cognitive recovery after end of sedation, and spontaneous breathing effort
- Assessments will be performed by **blinded assessors** to meet the requirements of the FDA



Development program continues to progress according to plan







Commercial impact from the war in Ukraine is limited, but need for new set-up for gas monitor business

Commercial

- No commercial presence in Ukraine
- Very limited (distributor) sales in Russia (0.1% of sales in 2021)



Gas monitor

- Sedana Medical's gas monitor is sourced from a Russian engineering company
- Not a significant sales and profit contributor, but an important enabler for inhaled sedation
- Sufficient supply on stock to satisfy demand for next 12 months
- Started project to supply alternative gas monitor





FINANCIAL HIGHLIGHTS



Financial result in Q1 2022

Net sales Q1'22: 34 (45) MSEK, -25% y/y, -28% y/y at constant FX

FY'21: 159 MSEK

- Sales in Germany decreased by 22% compared to Q1 2021, due to a decline of ventilated patients and restricted operations in intensive care units
- Sales in South America decreased due to artificially high sales in Q1 2021 due to the propofol shortage. Also, stock-up in Q4 2021 in anticipation of another Covid-19 wave that did not materialize resulted in no orders received in January-February
- Other markets: solid growth but from lower base

Gross Profit Q1'22: 23 (29) MSEK **Gross Margin Q1'22:** 68 (64) %

- Improved margin is mainly due to lower transportation costs and to some extent to a positive market mix (lower share of distributor markets)
- Lower shipping costs due to more sea freight

EBITDA Q1'22: -16 (-8) MSEK

 Opex (selling, admin, R&D, other) of 45 MSEK in Q1 2022, up vs Q1 2021 (39) but down vs Q4 2021 (51)

Staff, incl consultants, per Mar 31, 2021: 102 (107 at Dec 31 2021)

Some overlap of employees and consultants during Q4 2021

Gross profit development



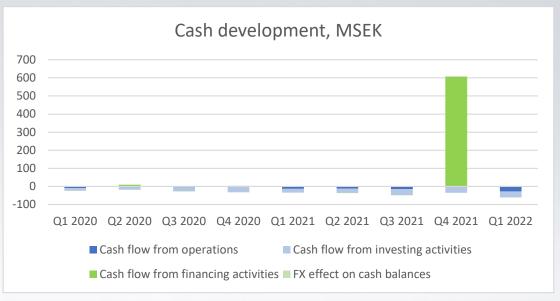
EBITDA development

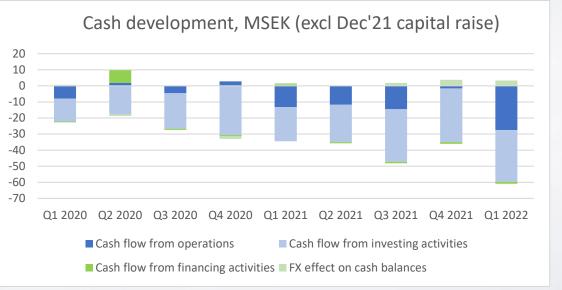




Cash flow and cash balance

- Cash flow from operations Q1'22: -28 (-13) MSEK, of which cash flow from working capital of -11 MSEK related to increased inventory levels and lower current liabilities (VAT, bonuses).
- Cash flow from investments Q1'22: -32 (-21) MSEK, of which the vast majority is related to expenses for clinical studies and 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 Q1'22: -61 (-33) MSEK
- Cash balance per Mar 31, 2022: 779 MSEK compared to 836
 MSEK at the beginning of the quarter (including 3 MSEK FX effect)
 - We expect to be fully funded until break-even and through the US launch phase
- No long-term financial loans / debt free company
- Move to Nasdaq main market in Stockholm: We have finalized an assessment and now have a tentative work plan that should lead to a main market listing end of this year







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Q&A

