



## Q1 2023 Report

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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 Sedaconda ACD and Sedconda (isoflurane), 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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# Q1 Highlights: we have made progress against all 3 priorities for the year

2023 priorities

Progress in Q1

## Bring Sedana Medical back on a growth path

- First growth quarter post-Covid-19: **37.8 MSEK** net sales (+12%)
- Organic **growth in all direct markets**, sales decline in distributor markets
- Pricing and reimbursement **approval in Spain**
- Regulatory and pricing/ reimbursement **approval in Italy**
- MHRA approval in UK still outstanding

## Get closer to break-even ex-US

- Gross margin of **73%** (up from 68%)
- EBITDA loss of -10.7 MSEK (**reduced by 35%**)
- Cash and short-term deposits of **560 MSEK**

## Make headway towards US approval

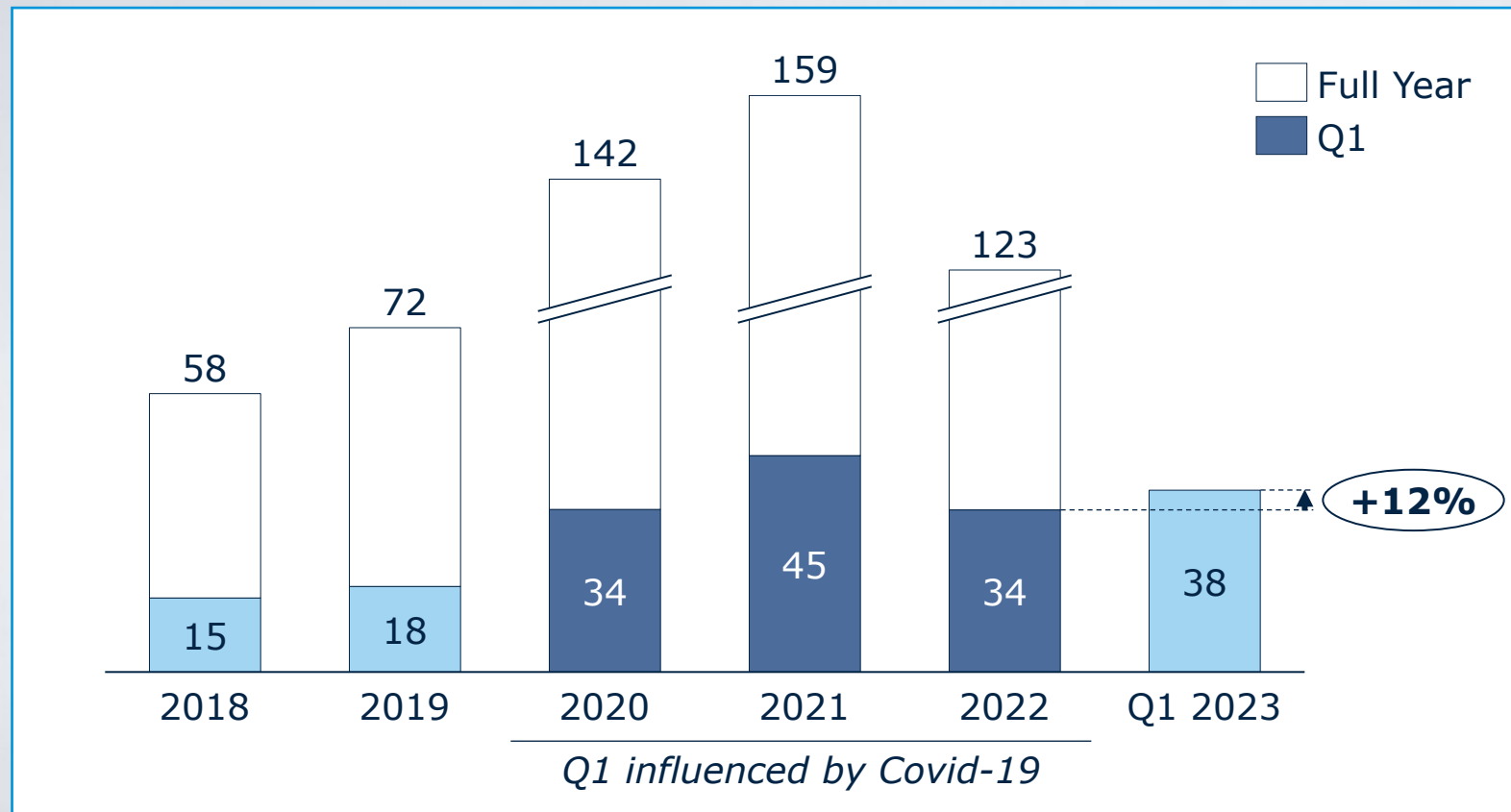
- INSPIRE-ICU clinical trials **progressing** according to plan
- **Fast Track Designation** by FDA
- Aiming at **US launch in early 2025**



# Q1 2023 was the first growth quarter after Covid-19

## Net sales

SEK million



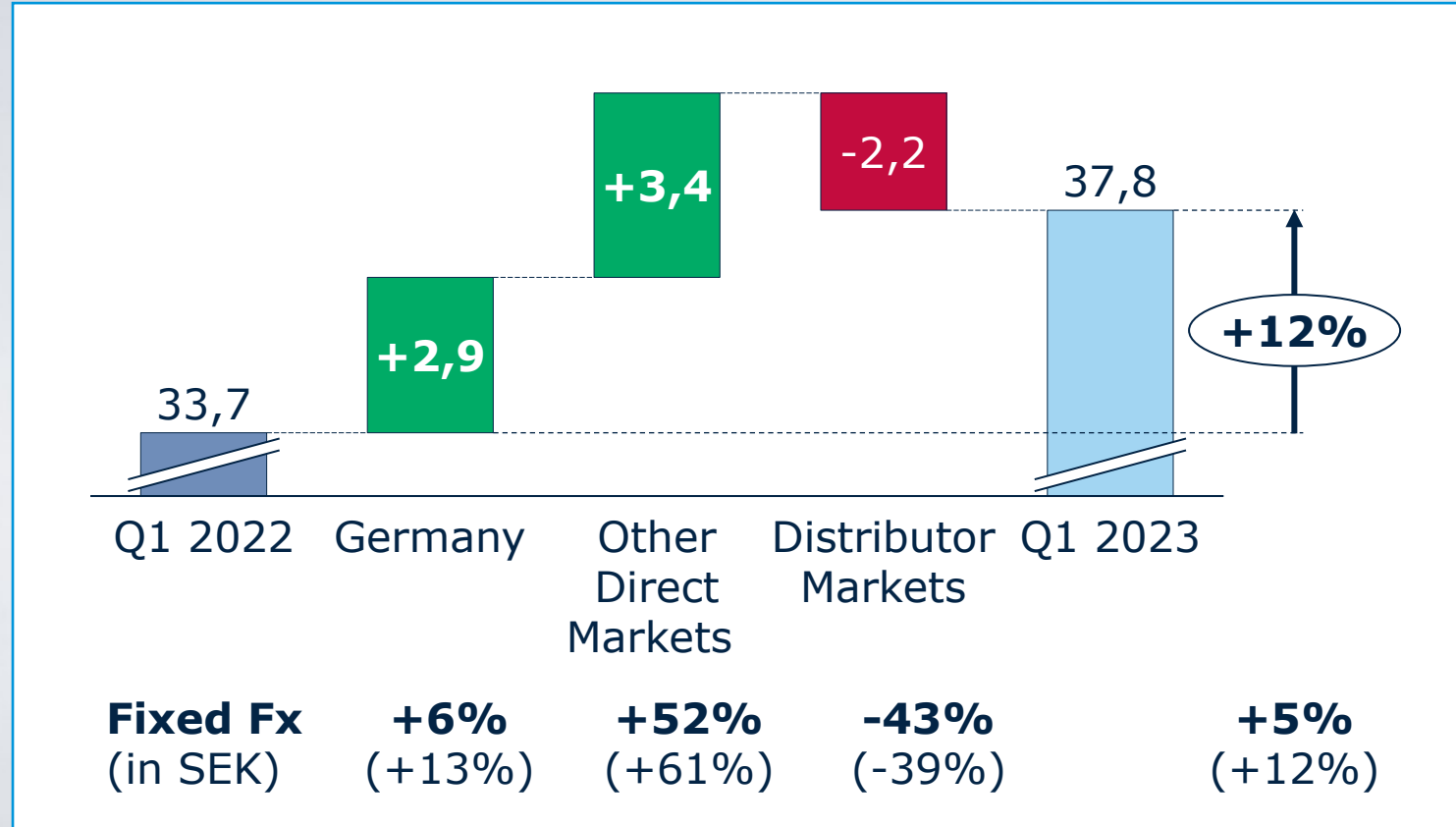
## Comments

- Covid-19 resulted in a trend-break in the long-term sales development
- Lower sales in 2022 due to a significant decline in ventilated ICU patients (both Covid and non-Covid)
- Back to growth post Covid-19 in Q1 2023 (and higher sales than the Covid-19 quarters Q1 2020 and Q1 2022)

# In Q1, we show growth in all our direct markets

## Sales bridge Q1 2023 vs. Q1 2022

SEK million



## Comments

### Germany:

Return to organic growth despite less ICU patients

### Other direct markets:

Positive organic growth in all direct markets, strongest growth in Spain

### Distributor markets:

Continued lack of orders from distributor in S. America due to overstocking (last sizeable order received in Q2 2022). Remaining distributor markets showing growth in aggregate.

# Market dynamics: patient numbers gradually normalize, but some headwinds remain



## Less patients

### Market dynamics in 2022

- Significantly less intubated ICU patients throughout 2022 (both Covid and non-Covid)

### Update

- Still less ventilated ICU patients in Q1 compared to last year, but gap is narrowing



## Staff shortages

- Hospitals all over the world were plagued with staff shortages
- Staff qualification decreasing

- Staff shortages remain (and will remain) an issue
- Still, access to hospitals has eased vs. Covid-19



## Strikes

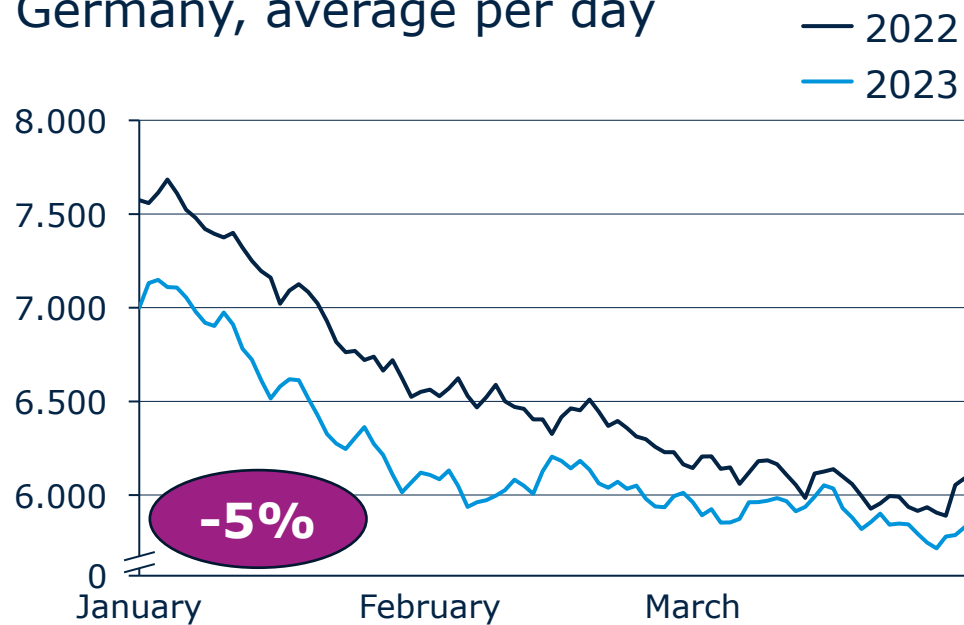
- Occasional / regional strikes of healthcare staff for better pay and work conditions
- Limited impact on ICUs in '22

- Strikes have intensified and now also affect ICUs (both nurses and doctors), primarily in UK and France

# In Q1, we continued to see less ICU patients and ventilated Covid-19 patients, but gaps are narrowing

## ICU patients<sup>1</sup>

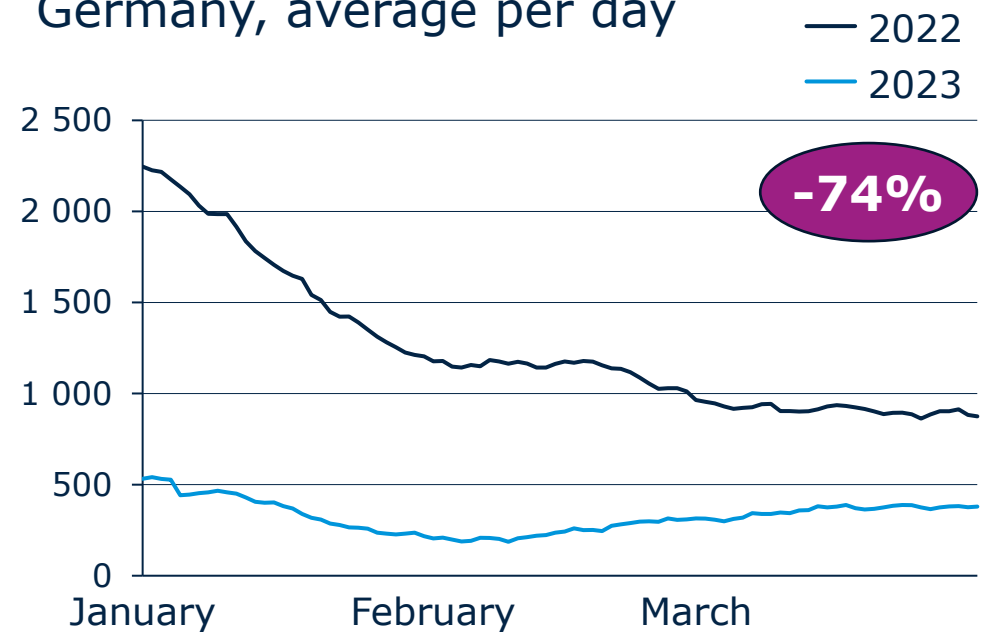
Germany, average per day



Note that ICU patients include both ventilated and non-ventilated patients

## Ventilated Covid-19 patients

Germany, average per day



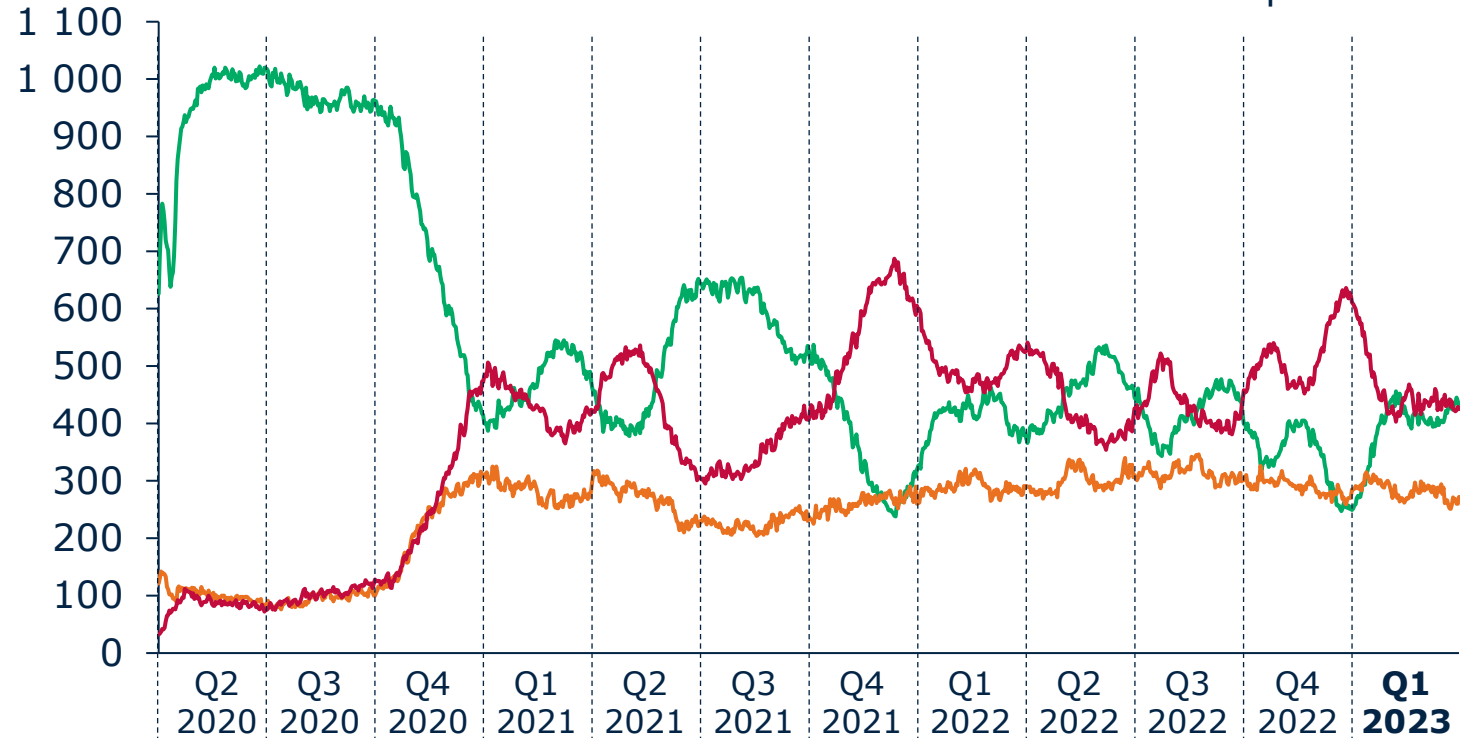
<sup>1</sup> Includes High-Care and ECMO setting  
Source: divi daily reports

# Despite some recent improvement, ICUs are still operating under constrained conditions (Germany example)

## Status in German ICUs

Number of ICUs

- Regular operations
- Partly restricted operations
- Restricted operations



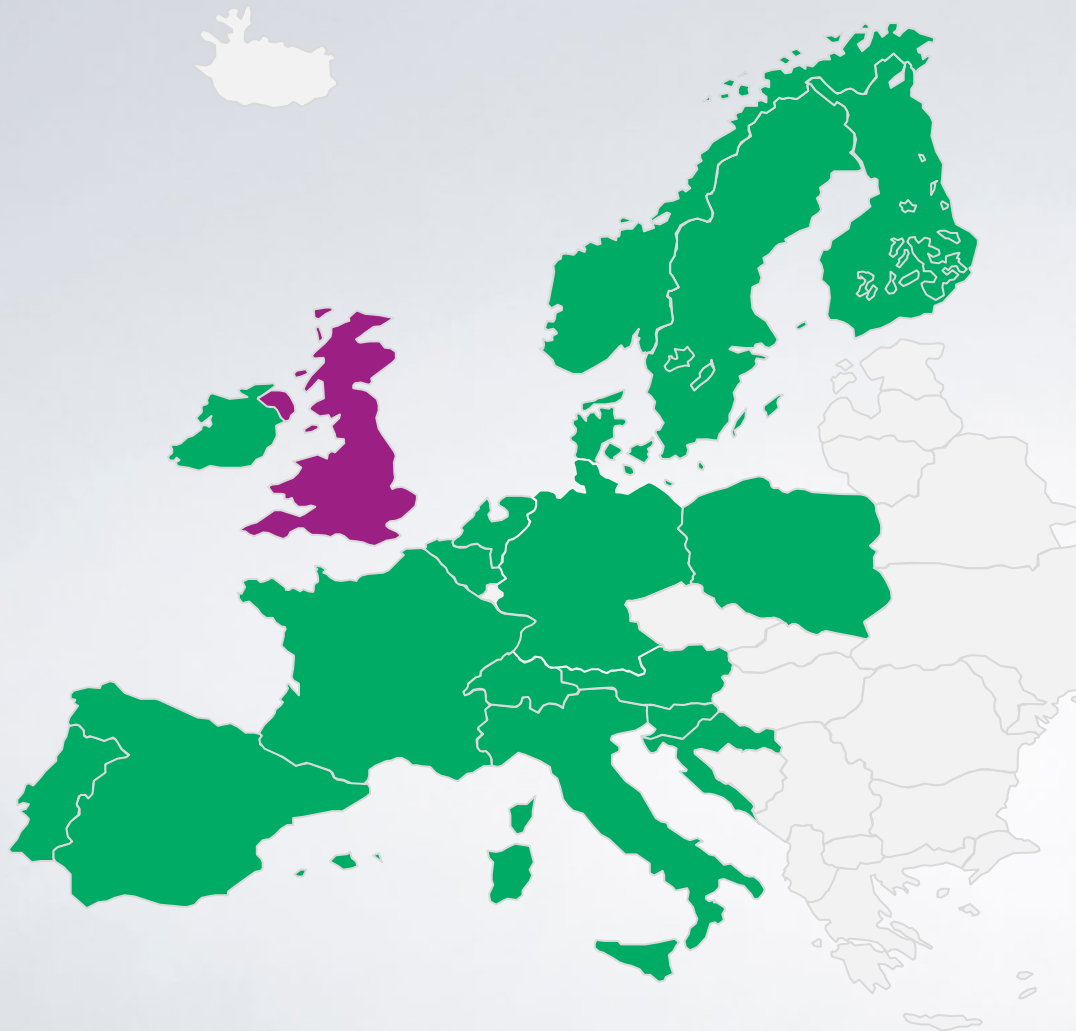
Restricted or partly restricted in Percent

17 17 41 60 60 49 70 66 61 64 70 65





# Regulatory approvals for Sedaconda (isoflurane) have been secured in 17 out of 18 countries



Key markets	Regulatory approval	Pricing/reimb. approval	Drug launch
Germany	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Spain	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> Q2/3
France	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
UK	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nordics	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Benelux	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Italy (distr.)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> H2

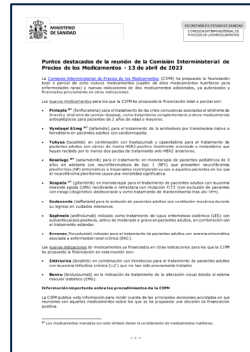
# Good progress in Spain with Pricing/Reimbursement approval and updated treatment recommendations

## Pricing and reimbursement

- In April, the Spanish Ministry of Health has granted Sedaconda (isoflurane) pricing and reimbursement approval
- Some administrative steps remain, before we can launch the drug in Q2/Q3

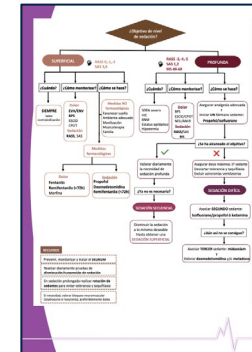
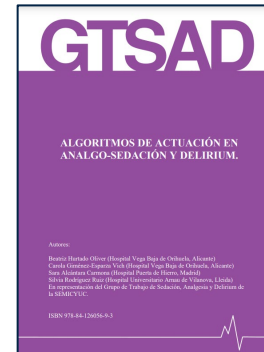


MINISTERIO DE SANIDAD



## Treatment algorithm

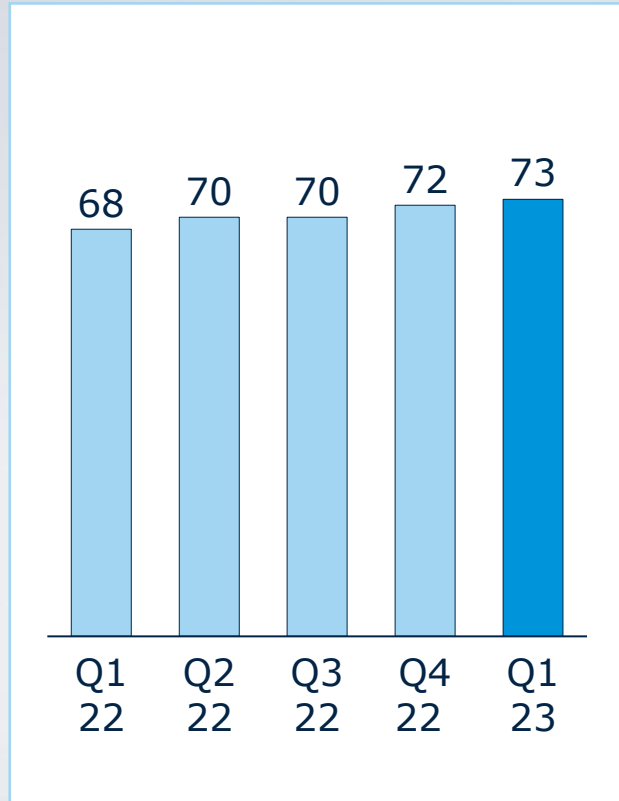
- The Spanish intensive care society SEMICYUC has issued new treatment recommendations
- Inhaled sedation with isoflurane is recommended as first-line option, on the same level as propofol, for moderate and deep sedation



# We are making progress towards break-even

## Gross margin

Percent of net sales



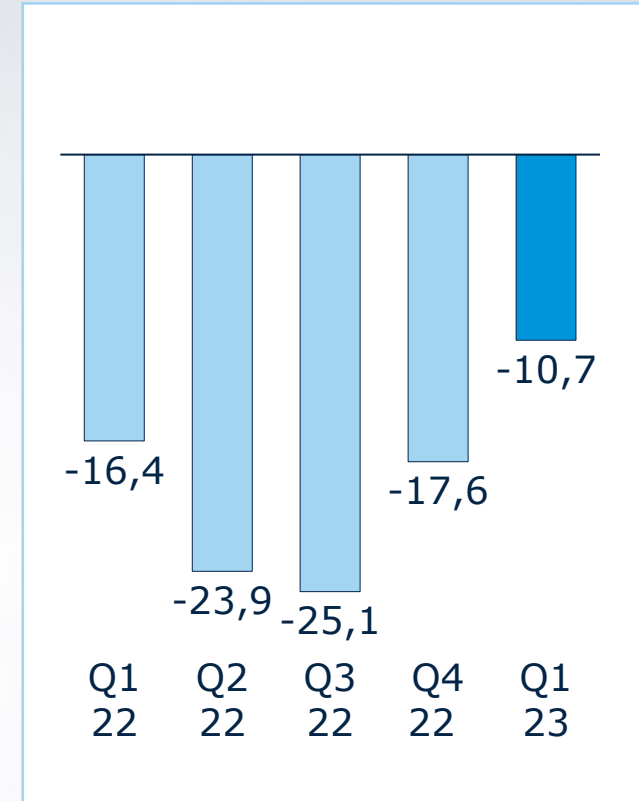
## Operating expenses<sup>1</sup>

MSEK



## EBITDA

MSEK



Our goal is to reach break-even ex-US before we launch in the United States

<sup>1</sup> Excluding depreciation

# United States: FDA has granted Sedana Medical Fast Track Designation (FTD)



## FTD for Sedaconda

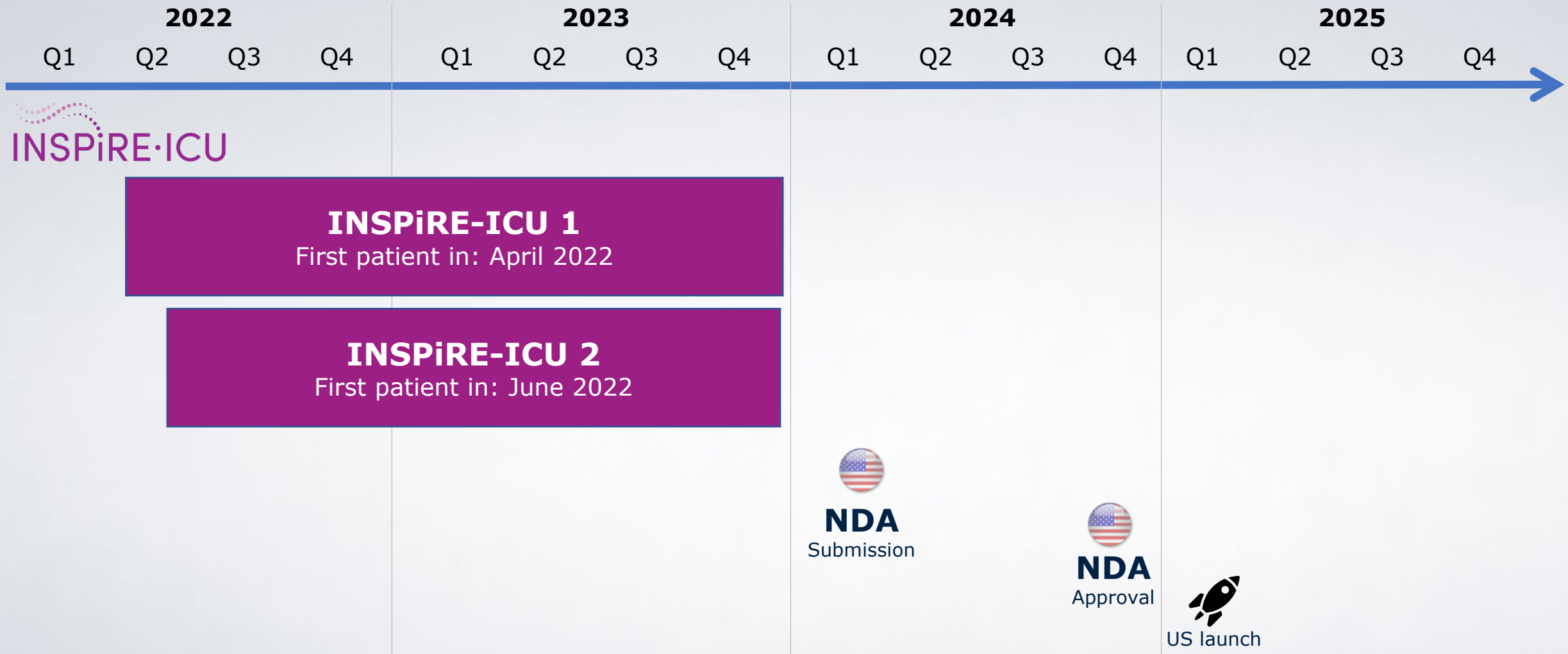
- US development program has received Fast Track Designation by FDA in January
- The purpose of an FDA Fast Track Designation is to get important new therapies to US patients earlier
- This confirms that FDA sees an unmet medical need and potential clinical benefits

## Possible benefits

- Clinical programs with Fast Track Designation may benefit from
  - Frequent communication with the FDA throughout the development and review process
  - Accelerated Approval
  - Priority Review
  - Rolling Review



# Our INSPIRE-ICU trials are progressing according to plan, and we still aim at a launch in early 2025



INSPIRE-ICU

**INSPIRE-ICU 1**  
First patient in: April 2022

**INSPIRE-ICU 2**  
First patient in: June 2022

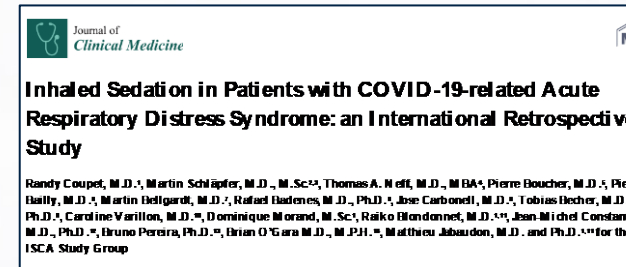
  
**NDA**  
Submission

  
**NDA**  
Approval

  
US launch

# Investigator-initiated trials – SESAR expected to complete enrollment this year

- **Isoflurane and delirium (INASED) study**
  - 145 patients recruited to date (250 planned)
- **Sevoflurane in ARDS (SESAR) study**
  - 639 patients recruited to date (700 planned)
  - Enrollment completion expected in 2023
- **Inhaled sedation in Covid ARDS (ISCA) study**
  - Retrospective cohort study of 196 patients with COVID-19 ARDS
  - Results published in Jan 2023:
    - Use of inhaled sedation with sevoflurane or isoflurane was not associated with improved clinical outcomes
    - Inhaled sedation was feasible and safe, while reducing requirements for other sedative agents



# Recruitment has been completed for our paediatric study (IsoCOMFORT)

## IsoCOMFORT study

- The IsoCOMFORT study compares the efficacy and safety of inhaled sedation with IV midazolam for sedation of mechanically ventilated ICU patients in the age group of 3–17 years
- The aim is two-fold:
  - To obtain market authorization for a vulnerable and difficult-to-sedate patient population
  - To secure data exclusivity/market protection for the adult indication until 2031

## Updates

- The last IsoCOMFORT patient was enrolled in January
- High-level results expected in Q2 2023
- Assuming successful review, approval in Europe is expected in H1 2024
- The data exclusivity extension to 2031 for the adult indication is independent from the paediatric indication approval
- The IsoCOMFORT study is included as part of the approved US Pediatric study plan, together with ongoing juvenile non-clinical studies



# Medical presence at meetings Q1 2023

- Stuttgart, Germany - Stuttgarter Intensivkongress F2F
- Brussels, Belgium – ISICEM – F2F, Inhaled sedation workshop, Frontiers in sedation meeting
- Berlin, Germany Forum Interdisziplinäre Intensivmedizin F2F
- Bremen, Germany Symposium Intensivmedizin 2023 – F2F and symposium
- Valencia, Spain – SOVAMICYUC – symposium
- Lleida, Spain – SOCMIC Inhaled sedation Workshop
- Leicester, UK – Sedation matters study day
- Barretos, Brazil – workshop
- San Francisco, US - Society of Critical Care Medicine Congress – F2F and presentation





# Financial result in Q1 2023

**Net sales**     **Q1'23:** 38 (34) MSEK, +12% y/y (+5% excl. FX).

- Sales in Germany increased by 13% y/y (6% excl. FX), despite fewer ventilated ICU patients.
- Other direct markets showed growth of 61% y/y (52% excl. FX), and all regions contributed positively.
- Our distributor markets decreased by 39% y/y (43% excl. FX) driven by high inventory levels in South America both at our distributor and at the hospitals. Outside South America the distributor markets showed positive growth during the period.

**Gross Profit**     **Q1'23:** 27 (23) MSEK

**Gross Margin**     **Q1'23:** 73 (68) %

- The improved gross margin is mainly an effect of higher prices, mix effects and lower allocated central costs.

**EBITDA**             **Q1'23:** -11 (-16) MSEK

- Opex of 44 MSEK in Q1'23, lower than Q1'22 (45).
- Streamlined admin functions (HR, IR, Accounting, Controlling).
- Reduced spending on consultants, external vendors, conference sponsorships.

**Staff, incl consultants, per March 31, 2023:** 92 (95 at Dec 31 2022).

## Net sales (MSEK, 12m rolling)



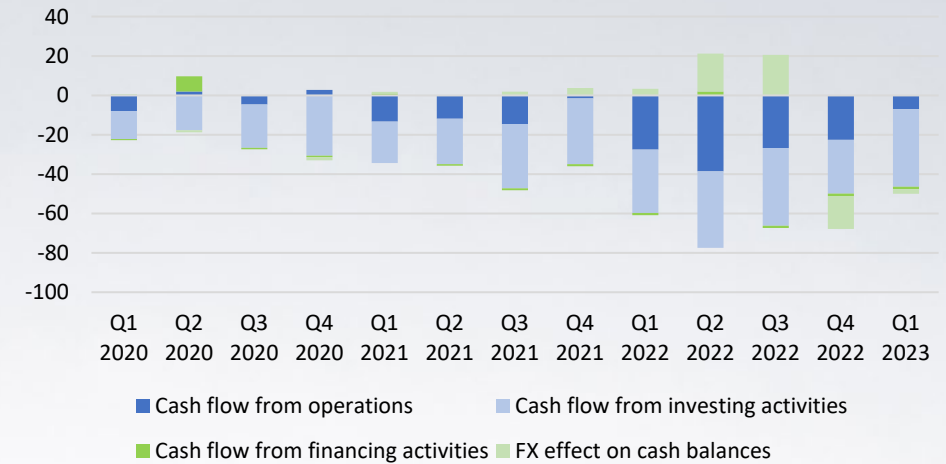
## Gross profit development (12m rolling)



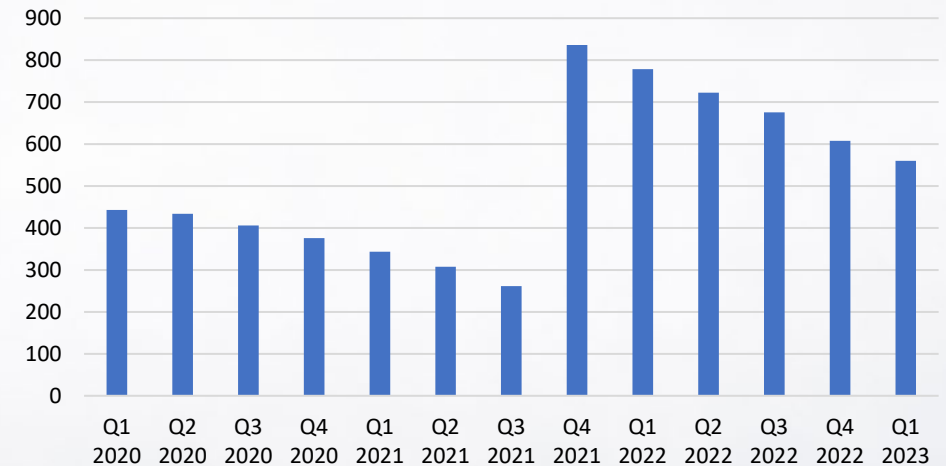
# Cash flow, cash balance and short-term deposits

- **Cash flow from operations Q1'23:** -7 (-28) MSEK, of which cash flow from working capital of +3 MSEK mainly related to payments from customers.
- **Cash flow from investments Q1'23:** In order to favor from better interest rates, investments in short-term deposits of MSEK -306 were made during the quarter. Cash flow from investing activities thus totalled MSEK -346 (-32).
- **Cash flow for the period Q1'23:** Total cash flow for the quarter was MSEK -354 (-61). Adjusted for the allocation of cash to deposits, total cash flow was MSEK -48 (-61).
- **Cash balance and short-term deposits per March 31, 2023:** 560 MSEK compared to 608 MSEK at the beginning of the quarter.
- **Liquidity management**
  - Approx. half of our cash has been converted to USD.
  - During the first quarter we placed approximately half our cash in short-term deposits for better interest rates (both SEK and USD).
- **We expect to be fully financed until break-even and to execute on our strategic plan**
- **No long-term debt**

## Cash flow (MSEK) excl 2021 cap. raise and allocation to short-term deposits



## Available funds\* (MSEK)



\* Cash and short-term deposits

# Largest shareholders March 31, 2023

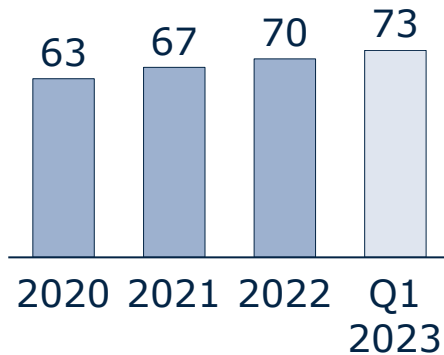
	No of shares	Share
Linc AB	10,111,030	10.2%
Swedbank Robur Funds	9,519,013	9.6%
Anders Walldov direct and indirect (Brohuvudet AB)	8,500,000	8.6%
Handelsbanken Funds	7,300,000	7.3%
Ola Magnusson direct and indirect (Magiola AB)	4,462,098	4.5%
Sten Gibeck	4,286,276	4.3%
Öhman Funds	4,150,984	4.2%
Highclere International Investors LLP	2,382,254	2.4%
Bank of Norway	2,690,924	2.7%
AMF Pension	2,491,000	2.5%
Berenberg Funds	1,823,547	1.8%
Third Swedish National Pensis Fund	1,735,989	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Amundi	1,190,512	1.2%
Philip Earle	1,104,456	1.1%
Fifteen largest shareholders	63,414,547	63.8%
<i>Others</i>	<i>35,922,413</i>	<i>36.2%</i>
<b>Total</b>	<b>99,336,960</b>	<b>100.0%</b>

# Investment case - why Sedana Medical?



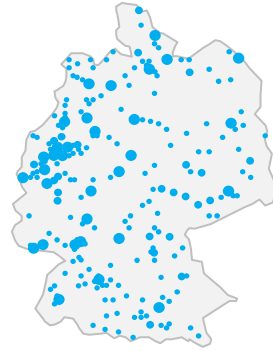
## High gross margins

FY GM, in percent



- Gross margins have increased to >70% despite pressures in the supply chain
- Sedana Medical can achieve attractive profits when reaching scale

## Proof of concept



- Majority of German ICUs are customers already
- German subsidiary operating with high local EBITDA margins

## Growth opportunities



- Clinical benefits vs. old standard of care
- Health-economic benefits, confirmed by NICE
- Approval in 17 countries in Europe
- Fast Track Designation in US

## Strong balance sheet

Cash and short-term deposits  
In SEK

**560M**

- Financed to execute on strategic plan
- Cost saving program in administrative and headquarter functions to free up further cash

# Q&A

