



## Q3 2022 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.
- 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.

# Why Sedana Medical?

## Attractive fundamentals for significant value creation

- High gross margins (70%) will yield attractive profits when we reach scale
- Proof of concept: Germany already shows a high local EBITDA margin

## Foundation laid for scale-up

- Only approved therapy for inhaled sedation in ICUs in Europe, based on unique device
  - Proven clinical benefits vs. current standard of care (intravenous sedation)
  - Health-economic benefits, confirmed by NICE
- Clinical program underway in US, our largest-potential market

## Positive momentum despite temporary market contraction

- 69% higher YTD sales than 2019 (pre-pandemic)
- Sales growth in direct markets in Q3
- ~3 new customers per week YTD and strong customer retention

## Fully financed to deliver on strategic plan

- Strong cash position of 676 MSEK, no need to raise money
- Started cost saving program in overhead and admin functions (while ring-fencing investments in sales growth)



# Q3 2022 Highlights

## Financial performance

- Net sales of **SEK 27 million** (-6%), explained by significantly lower sales in South America
- Germany, our other direct markets and distributor markets outside South America showed **positive growth**
- Gross margin of **70%** (up from 68%) despite cost pressure in the supply chain, driven by price adjustment and management of freight cost
- Cash balance of **SEK 676 million**

## Launch in Europe underway

- Sedaconda (isoflurane) now available in **Germany, Sweden, Norway, the Netherlands, France and Slovenia**
- Local pricing and reimbursement process is **progressing in Spain**, with an ambition to launch around the turn of the year
- Received approval in Switzerland, still awaiting approvals in **Poland** (expected Q4), **Italy** (expected end of year), and **UK** (delayed to 2023 due to high workload at MHRA)
- Received MDR certification for Sedaconda ACD

## U.S. studies progressing

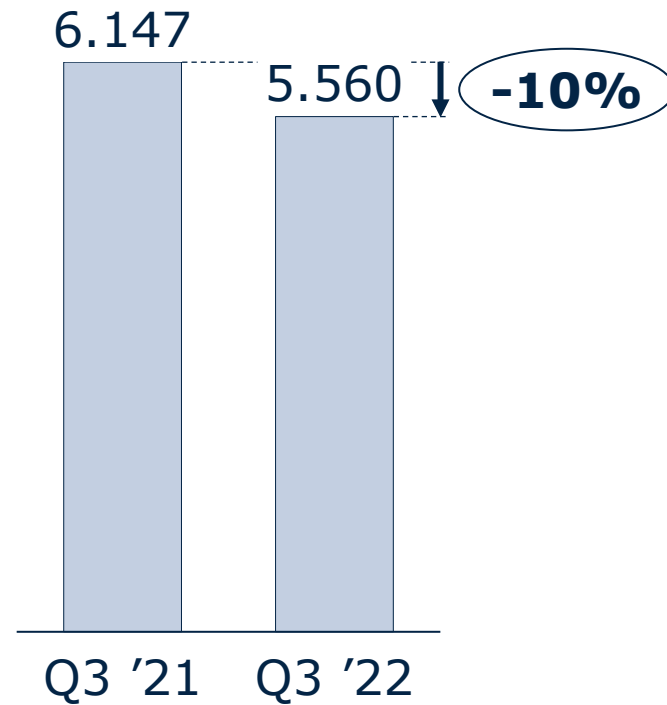
- INSPIRE-ICU trials ongoing, **majority of sites actively recruiting**
- Aiming at “last patient out” in Q4 next year and **approval in 2024** (assuming patient recruiting according to plan)



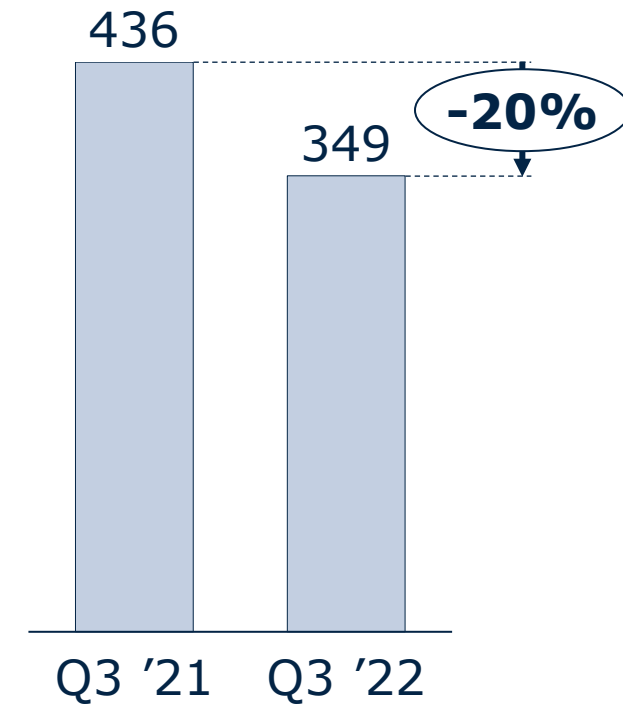
# We still see less ventilated patients in the ICU (Germany example)



**ICU patients<sup>1</sup>**  
Germany, average per day



**Ventilated Covid-19 patients**  
Germany, average per day



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

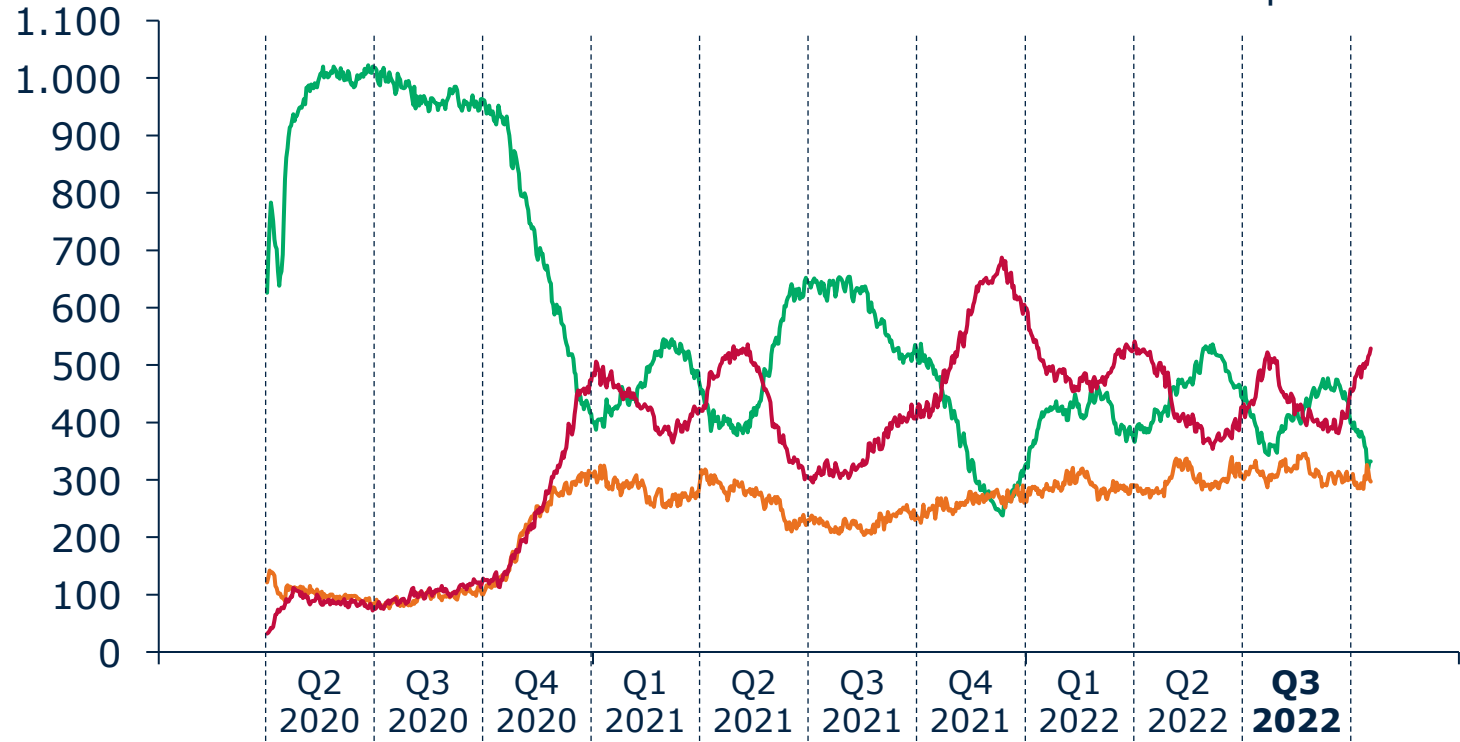
# Our ICU customers are still operating under constrained conditions (Germany example)



## Status in German ICUs

Number of ICUs

- Regular operations
- Partly restricted operations
- Restricted operations



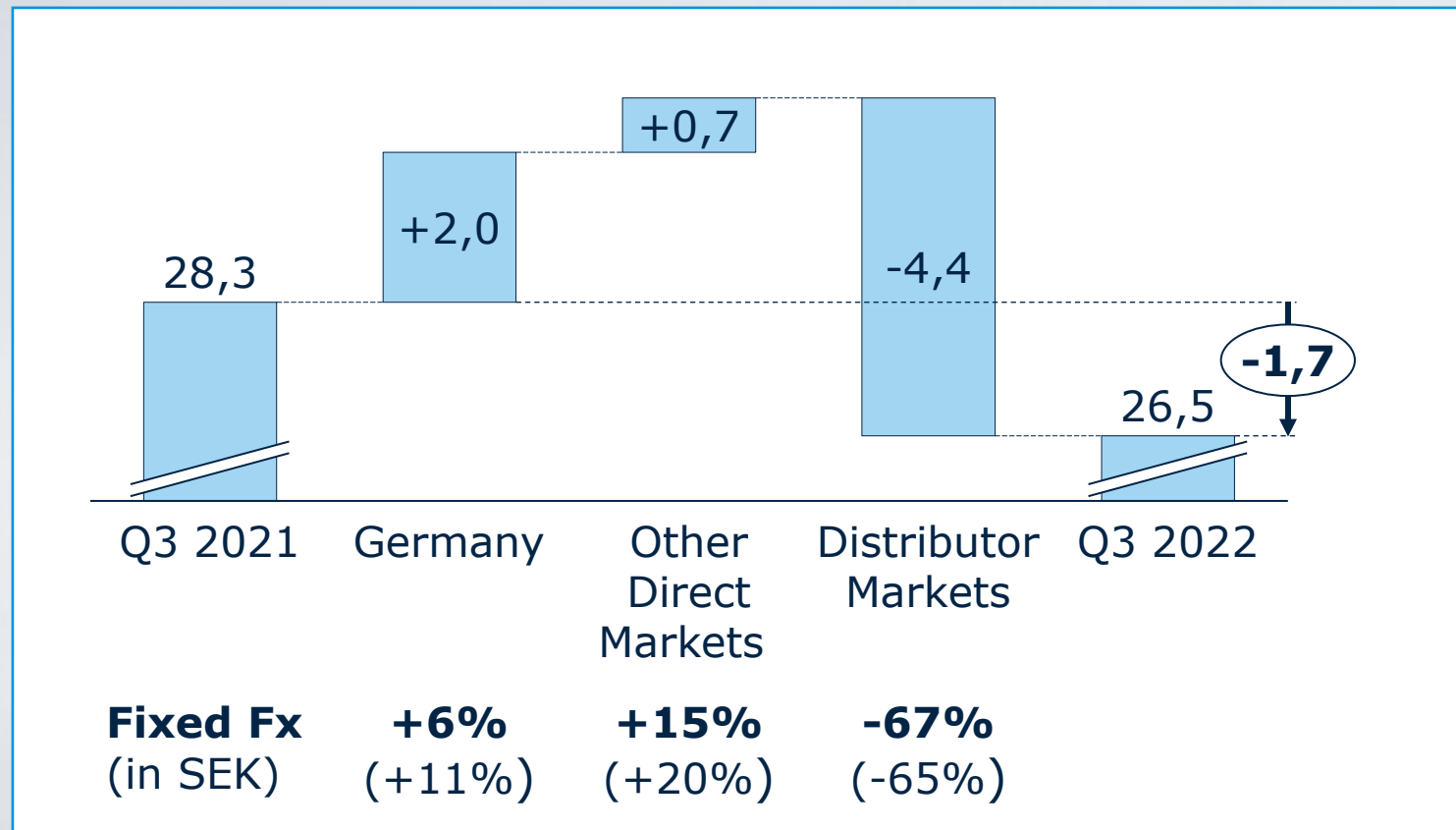
Restricted or partly restricted in Percent

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

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

## Sales bridge Q3 2022 vs. 2021

SEK million



## Comments

### Germany:

Modest growth despite continued market headwinds

### Other direct markets:

Positive momentum, especially in Spain, UK and France

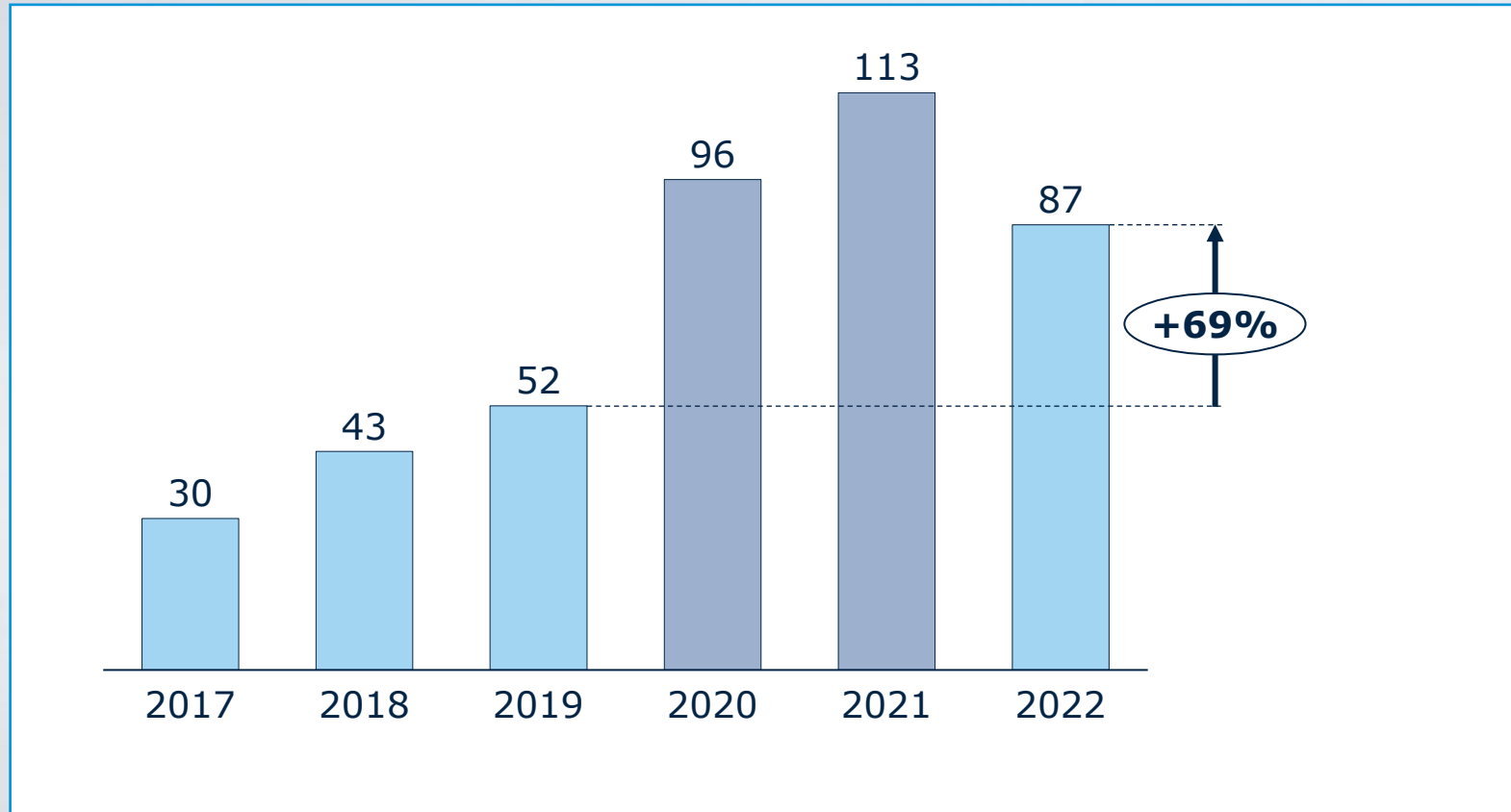
### Distributor markets:

Significant sales decline at main distributor in S. America (still high stock levels), growth in distributor markets outside S. America

# Taking a through-cycle perspective: YTD sales in 2022 were ~70% higher than pre-pandemic levels

## First 9 months net sales

SEK million



## Comments

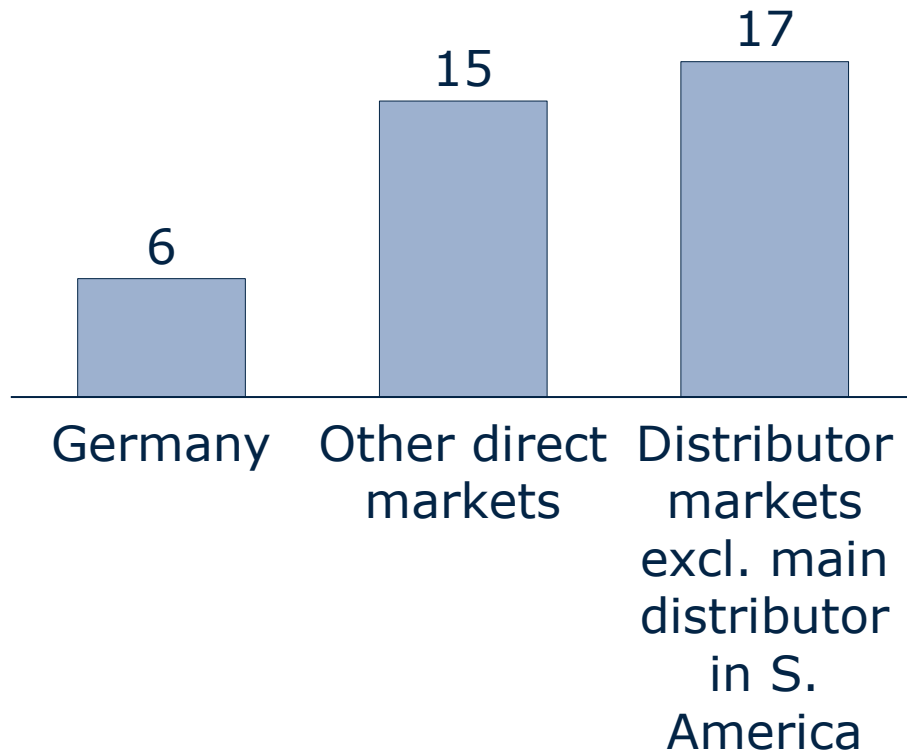
- Covid-19 resulted in a trend-break in the long-term sales development
- Lower sales in 2022 due to a significant decline in ventilated ICU patients (both Covid and non-Covid)
- But significantly higher sales than pre-pandemic levels



# Despite temporary market headwinds, there are signs of positive momentum with customers

## Q3 sales growth in several regions

In local currencies, Percent



## Continuous new customer inflow

~3

new customers per week  
(average for Sedana Medical YTD)

## Very stable customer base

100%

of Top-100 customers in Germany  
(based on 2021 sales) also bought  
in 2022

# We are making progress with the launch of Sedaconda (isoflurane) in Europe



## 6 launches to date

- Sedaconda (isoflurane) has now been launched in France
- Product is available in Germany, France, Sweden, Norway, the Netherlands (all direct) and Slovenia (through distributor)



## Ongoing P&R<sup>1</sup> processes

- Spain: local pricing and reimbursement dossier submitted and progress according to plan
- Launch of Sedaconda (isoflurane) planned for end of 2022 / early 2023 (assuming no delays by the Spanish authorities)

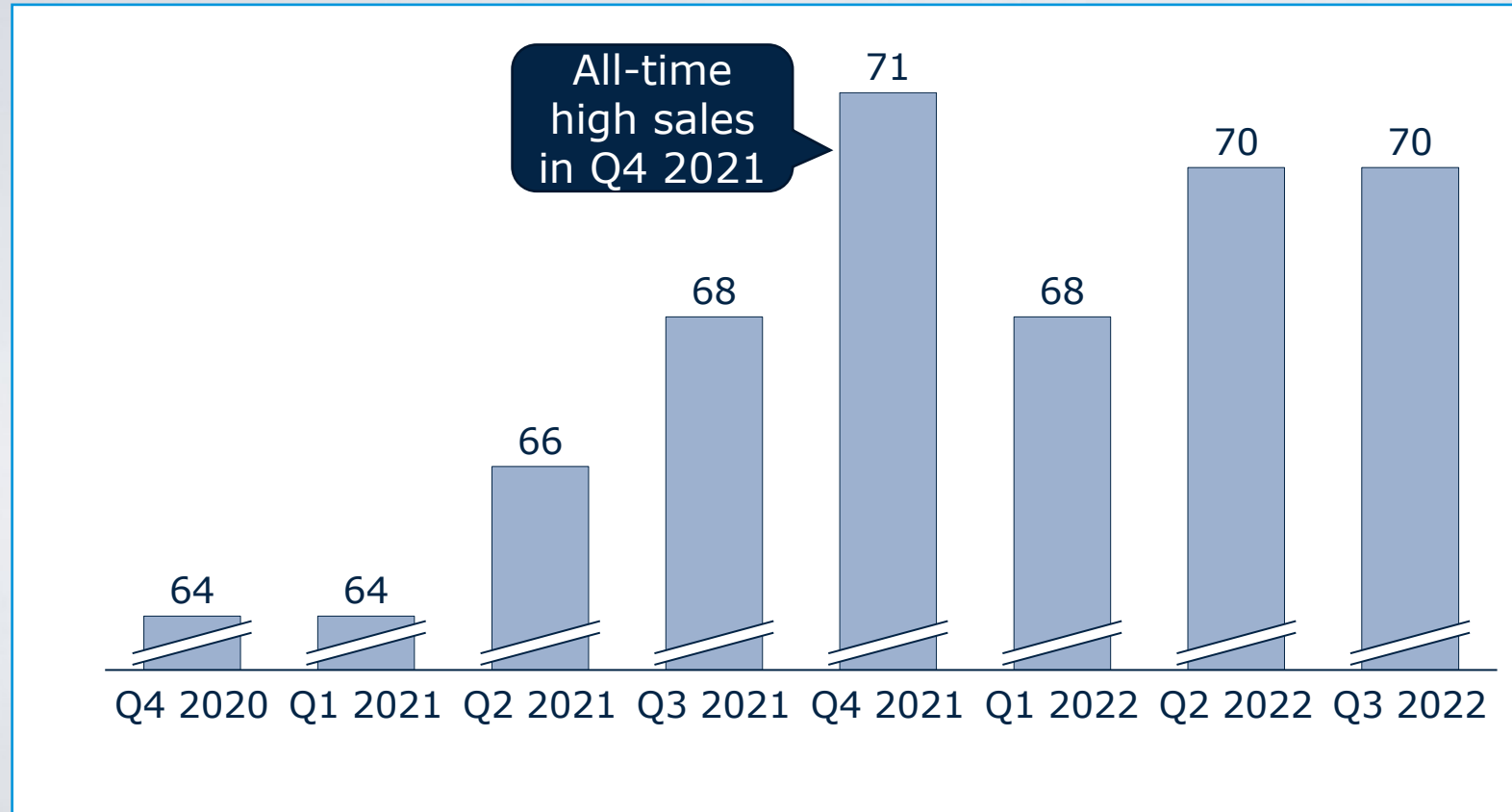
## 2nd wave countries

- Switzerland: approval by Swissmedic received in Q3 (launch planned next year)
- Poland: approval expected in Q4
- Italy: End of procedure reached in April, approval expected end of year (delay caused by internal alignment issues at Italian authorities)
- UK: approval further delayed into 2023 (update expected in January) due to high workload at MHRA

# We have increased gross margins over time, despite cost pressure in the supply chain

## Gross margin development over time

Percent of net sales



## Comments

- As all companies, Sedana Medical is currently subject to cost pressures in the supply chain
- A set of initiatives, including price adjustments and management of freight cost, have resulted in a gross margin of 70%, even at lower sales levels

# Both clinical trials are underway in the United States



## **INSPIRE-ICU\* 1**

First patient in: April 2022

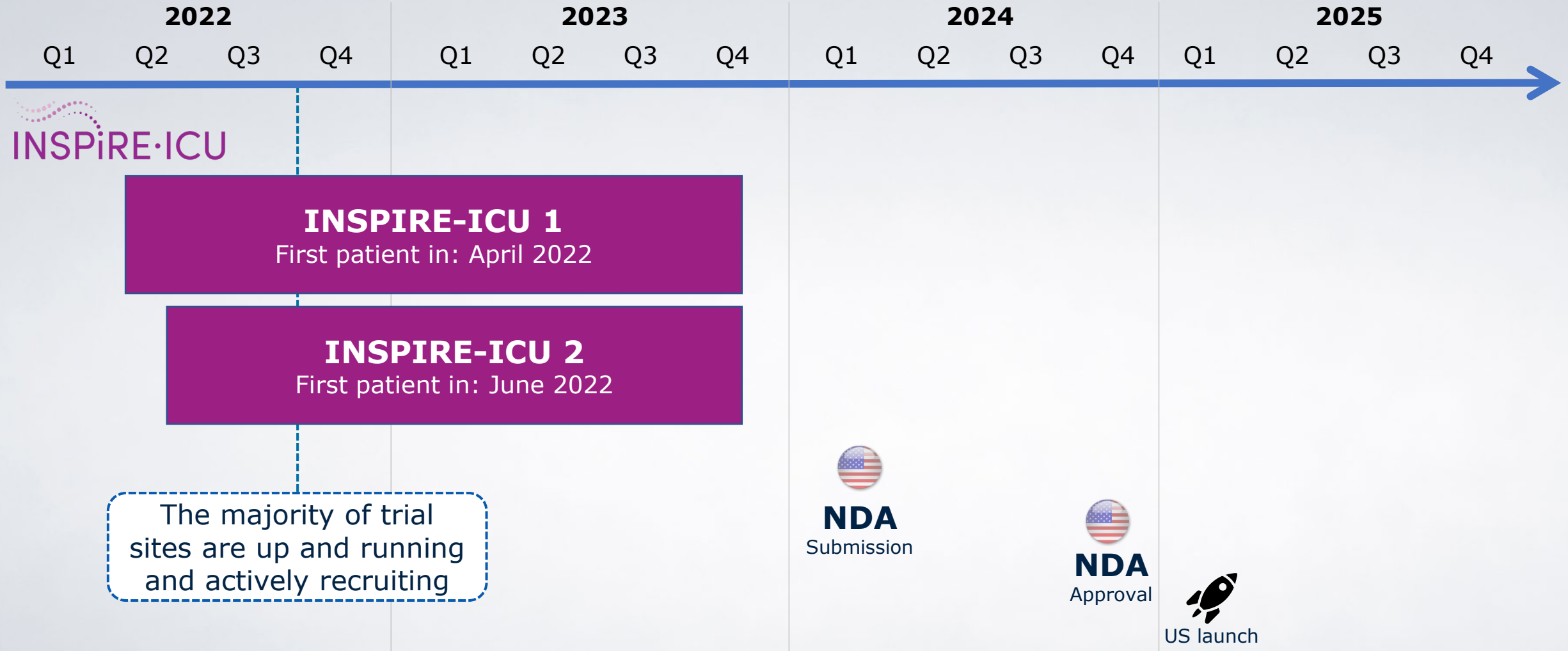
## **INSPIRE-ICU 2**

First patient in: June 2022



- Two identical phase III studies (**INSPIRE-ICU 1&2**) to confirm the efficacy and safety of inhaled isoflurane delivered via Sedaconda ACD, compared to IV propofol, for sedation of adult mechanically ventilated ICU patients
- **470 adult patients** in **approximately 25 sites** (plus 3-5 run-in patients per site)
- **Primary endpoint:** 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)
- **Key secondary endpoints:** use of opioids, wake-up time, cognitive recovery after end of sedation, and spontaneous breathing effort
- RASS will be assessed by **blinded assessors** to meet the requirements of the FDA

# US clinical program progressing according to plan



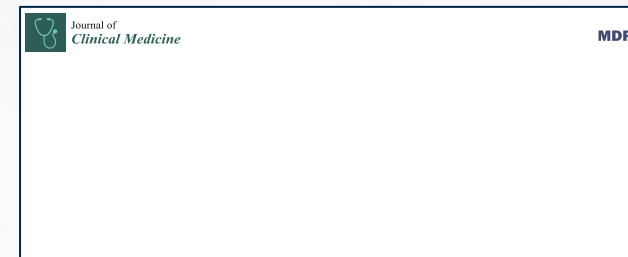


# Investigator-initiated trials underway

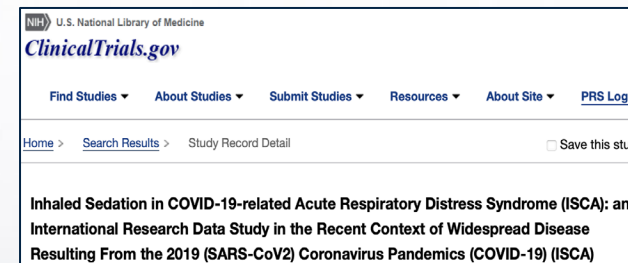
- **Isoflurane and delirium (INASED) study**
  - 110 patients recruited to date (250 planned)
  - Investigator meeting in Paris in September



- **Sevoflurane in ARDS (SESAR) study**
  - 575 patients recruited to date (700 planned)
  - Interim analysis underway
    - Safety/Futility/Superiority



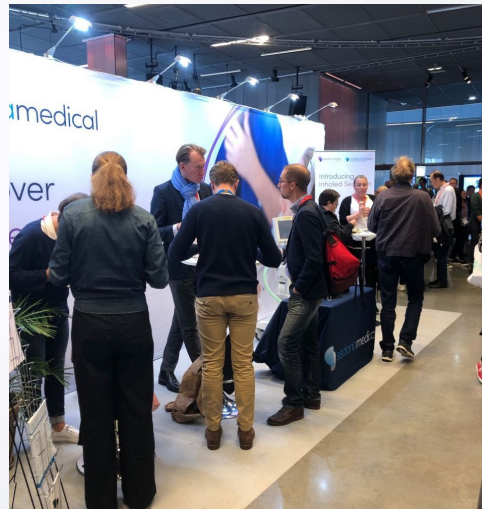
- **Inhaled sedation in Covid ARDS (ISCA) study**
  - Data collection completed (196 patients)
  - Manuscript submitted



# High activity level continued in Q3: Inhaled sedation presentations worldwide

**Inhaled sedation events in Q3** (not exhaustive)

- **Singapore:** APICS – Asia Pacific Intensive Care Symposium - Workshop
- **Bodensee:** BANIS Anesthesia and Intensive Care – F2F
- **Utrecht:** Topics in ICU Multidisciplinair congres - F2F
- **Paris:** SFAR Société Française d'Anesthésie et de Réanimation - symposium
- **Hamburg:** Hamburger Einführungskurs Intensivmedizin F2F
- **Berlin:** Hauptstadtkongress der DGAI – symposium
- **Mexico:** Reanimation in States of Shock Transdisciplinary Approach - webinar
- **Belfast:** Association of Anaesthetists in Great Britain and Ireland - F2F
- **Tiel:** MMM respiratoire insufficiëntie & beademing - F2F
- **Örebro:** SFAI – Svensk Förening för Anestesi och Intensivvård - symposium



# Financial result in Q3 2022

**Net sales**      **Q3'22:**    27 (28) MSEK, -6% y/y (-10% excl. FX)  
                   **FY'21:**    159 MSEK

- Sales in Germany increased by 11% y/y (+6% excl. FX), despite continued market headwinds (temporary decline in ventilated ICU patients and restricted ICU operations)
- Other direct markets showed growth of 20% y/y (+15% excl. FX), particularly driven by Spain, France and the United Kingdom
- Sales in South America decreased in Q3 due to high sales in 2021 and continued high inventory levels in 2022

**Gross Profit**    **Q3'22:**    18 (19) MSEK  
**Gross Margin** **Q3'22:**    70 (68) %

- The improved gross margin is mainly an effect of higher prices in the quarter compared to the third quarter last year and lower freight costs

**EBITDA**            **Q3'22:**    -25 (-14) MSEK

- Opex of 50 MSEK in Q3 2022, higher than Q3 2021 (35). The increase is driven by depreciations, US commercialization and non-recurring cost related to the Nasdaq uplisting

**Staff, incl consultants, per Sep 30, 2022:** 98 (107 at Dec 31 2021)

## Net sales (MSEK, 12m rolling)



## Gross profit development (12m rolling)



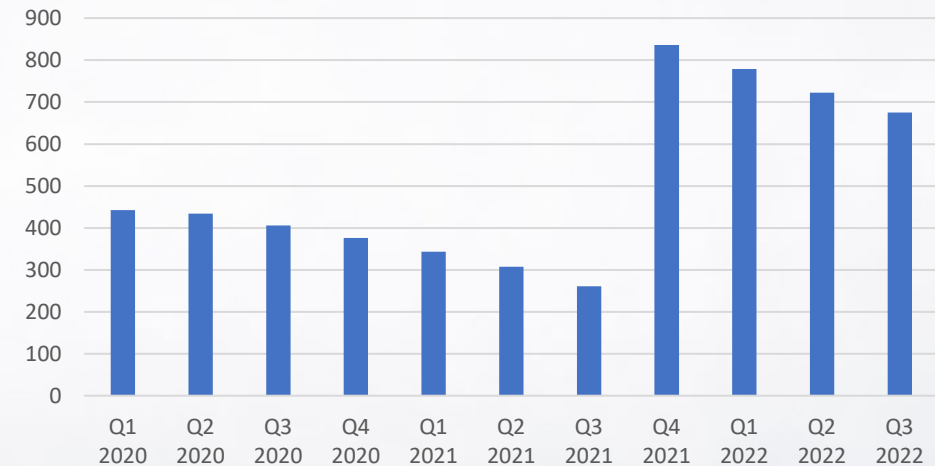
# Cash flow and cash balance

- **Cash flow from operations Q3'22:** -27 (-15) MSEK, of which cash flow from working capital of +3 MSEK mainly related to positive cash flow from accounts receivables
- **Cash flow from investments Q3'22:** -40 (-33) MSEK, related to clinical studies and registration in the United States, as well as the paediatric study in Europe
- **Cash flow for the period Q3'22:** -67 (-48) MSEK
- **Cash balance per Sep 30, 2022:** 676 MSEK compared to 722 MSEK at the beginning of the quarter (including 21 MSEK FX effect)
  - We expect to be fully financed until break-even
- **Cost saving program initiated:** Our efforts to increase efficiency in our operating cost base continue, although the progress is obscured in Q3 relative to Q2 due to non-recurring costs related to organizational changes and the upcoming move to the Nasdaq main list in Stockholm
- **No long-term debt**
- **Move to the Nasdaq main list:** progressing according to plan towards uplisting completed before year-end

## Cash development (MSEK, excl 2021 cap. raise)



## Cash position (MSEK)



# Largest shareholders September 30, 2022

	No of shares	Share
Linc AB	10 111 030	10,2%
Swedbank Robur Funds	9 519 013	9,6%
Handelsbanken Funds	9 474 757	9,5%
Anders Walldov direct and indirect (Brohuvudet AB)	8 500 000	8,6%
Ola Magnusson direct and indirect (Magiola AB)	4 552 098	4,6%
Sten Gibeck	4 286 276	4,3%
Öhman Funds	4 139 985	4,2%
Berenberg Funds	2 714 675	2,7%
Highclere International Investors LLP	2 640 192	2,7%
AMF Pension	2 491 000	2,5%
Third Swedish National Pensin Fund	1 735 989	1,7%
Tedsalus AB (Thomas Eklund)	1 666 464	1,7%
Bank of Norway	1 505 677	1,5%
Coeli	1 202 968	1,2%
Philip Earle	1 094 491	1,1%
Fifteen largest shareholders	65 634 615	66,1%
<i>Others</i>	<i>33 702 345</i>	<i>33,9%</i>
<b>Total</b>	<b>99 336 960</b>	<b>100,0%</b>



# Outlook – back to normal from 2023?

## Context

- 2022 YTD performance has been heavily influenced by a temporary contraction of our addressable market
  - Less Covid-19 patients
  - Hospital staff shortages
  - Overall lower number of ICU patients
- Comparisons vs. last years have been difficult due to Covid-19-related effects, e.g., inflated number of patients regional propofol shortages, unusual stock building patterns, etc.

## Outlook

- Q4 2021 was still heavily influenced by the last Covid-19 wave hitting the ICUs
- From Q1 2023, we expect somewhat more normalized conditions
  - Consensus among our customers appears to be that patient numbers will normalize from early 2023
  - Comparator numbers (2022) are less influenced by Covid
  - Some market headwinds (specifically staff shortages) may take longer to resolve



# Q&A

