



## Q2 2022 Report

Johannes Doll, CEO  
Peter Sackey, CMO  
Johan Spetz, CFO

July 21st, 2022



# 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

- 72% higher H1 sales than 2019 (pre-pandemic)
- Sales have declined less than the market (suggesting higher penetration)
- Sold to more customers than 2021 (adding ~3 new customers per week in H1)

## Fully financed to deliver on strategic plan

- Strong cash position of 722 MSEK, no need to raise money
- Started cost saving program in overhead and admin functions (while ring-fencing investments in sales growth)



# Q2 2022 Highlights

## Financial performance

- Net sales of **SEK 27 million** (-32%), explained by a significant decline in the number of ventilated ICU patients
- Gross margin of **70%** (up from 66%), driven by product mix, price adjustments and reduced freight cost
- Cash balance of **SEK 722 million**

## Launch in Europe underway

- Sedaconda (isoflurane) now available in **Germany, Sweden, Norway and the Netherlands**
- Local pricing and reimbursement processes progressing, with an ambition to **launch in all major direct markets** in next 6 months
- Approval in **Poland, Italy, UK, Switzerland** expected in H2

## U.S. studies initiated

- **First patient enrolled** in INSPIRE-ICU 1 trial in April, in line with ambitious time plan. INSPIRE-ICU 2 also started during Q2
- **Site and patient recruiting** ongoing according to plan

## Cost program

- Initiated project to **reduce cost in admin and overhead** functions (sparing investment to drive sales growth)



# We see an unprecedented (but temporary) contraction of our addressable market



## Temporary drivers



- Continued staff shortage in hospitals leading to
- Reduced ICU capacity (less beds)
  - Less surgeries



- Continued work-from-home and hygiene measures (e.g., face masks) leading to less community-acquired infections (flu, pneumonia, etc.)

## Potentially permanent drivers

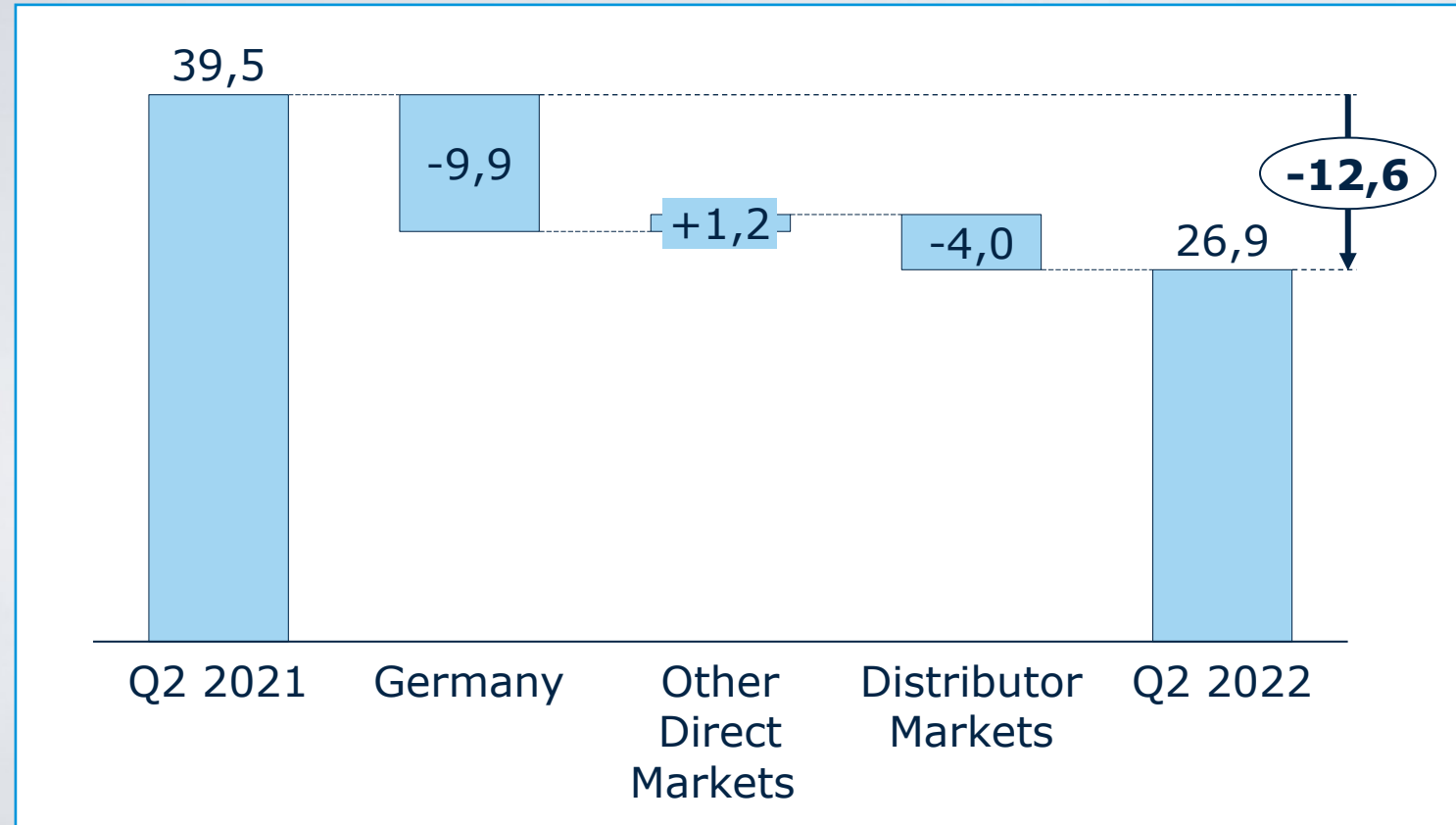


- Lower number of Covid-19 patients (as expected)

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

## Sales bridge Q2 2022 vs. 2021

SEK million



## Comments

### Germany:

36% sales decline due to temporary decline in ventilated ICU patients (by 40-50%<sup>1</sup> vs. Q2 '21)

### Other direct markets:

31% sales growth despite similar market dynamics

### Distributor markets:

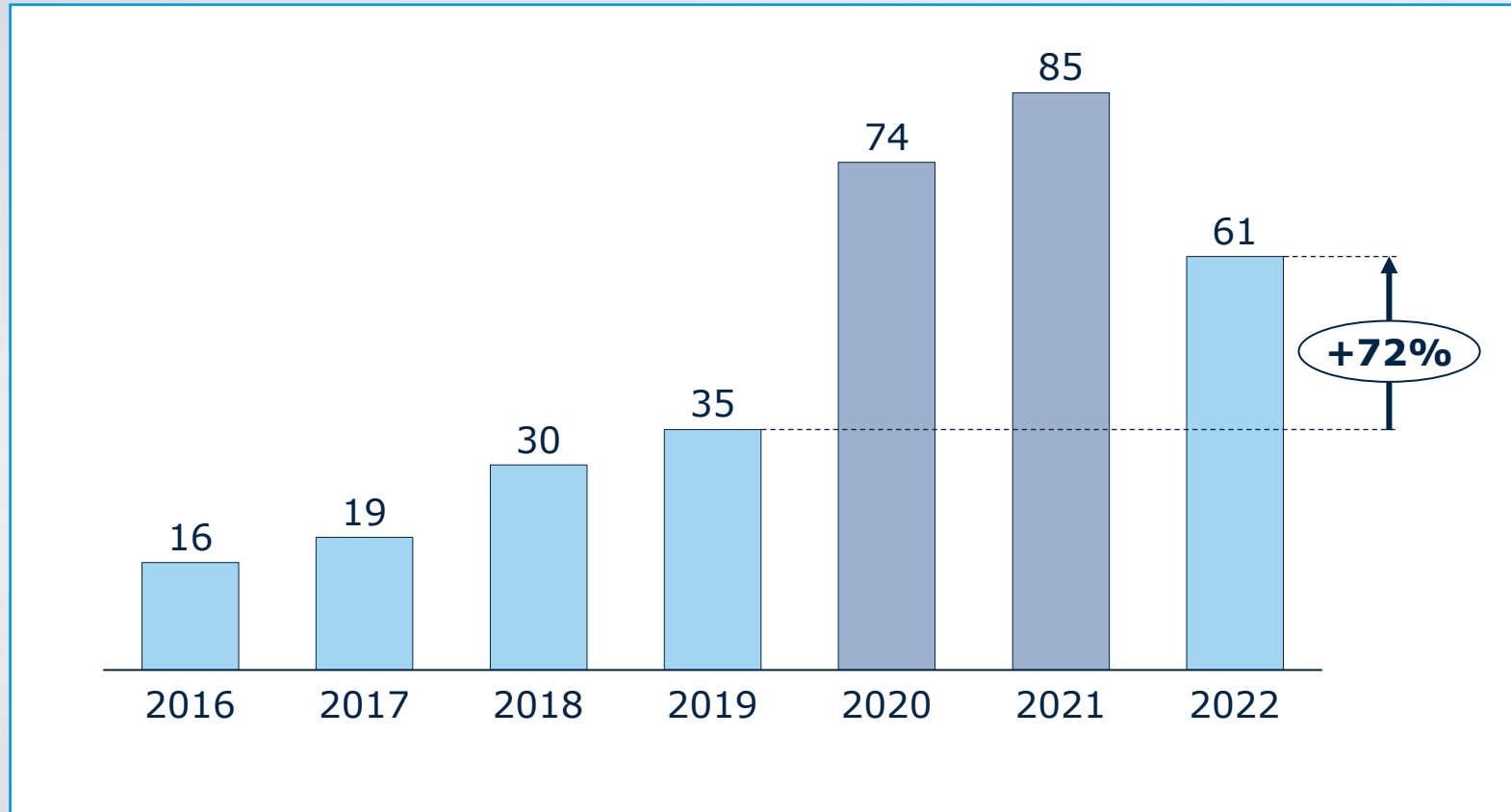
49% sales decline vs. extraordinary 2021 (propofol shortage in Latin America)

<sup>1</sup> Sedana analysis – see page 8

# Taking a through-cycle perspective: H1 sales in 2022 were >70% higher than pre-pandemic levels

## H1 net sales over time

SEK million



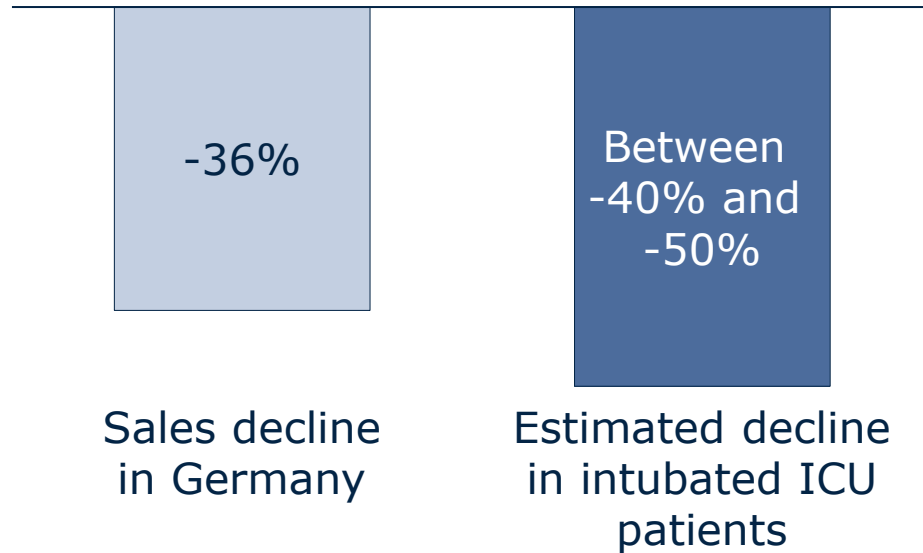
## Comments

- 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)
- Significantly higher sales than pre-pandemic levels as Covid-19 has led to more clinics using inhaled sedation

# Despite sales decline, there are clear signs of positive momentum with customers

## Sales decline lower than market decline

**Comparison Q2 '22 vs. Q2 '21**  
implying increasing market penetration



Source: Sedana analysis based on publicly available data (divi Tagesreports) and own ICU survey mid-May

## Continuous new customer inflow

~3

new customers per week  
(average for Sedana Medical in H1)

## Very stable customer base

100%

of Top-100 customers in Germany  
(based on 2021 sales) also bought  
in H1 2022



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



## 4 launches to date

- First bottles of Sedaconda (isoflurane) shipped to customers in Germany in February
- Today, also available in Sweden, Norway, and the Netherlands



## More launches in H2

- Ambition to launch in all major direct markets and several distributor markets in the next 2 quarters (assuming UK approval)
- France: Reimbursement effective (Sedaconda listed in "Journal Officiel")
- Spain: local pricing and reimbursement dossier submitted

## More approvals (2nd wave)

- Approvals expected in H2:
  - Poland: last missing national approval from DCP in July '21 (delay caused by "workload")
  - Italy: End of procedure reached in April, now in national phase (~3-5 mo)
  - UK: still no update from MHRA (significant delays due to Brexit and Covid)
  - Switzerland: approval by Swissmedic expected in Q3

# Both clinical trials are underway in the United States



## INSPIRE-ICU

### INSPIRE-ICU 1

First patient in: April 2022

### INSPIRE-ICU 2

First patient in: June 2022

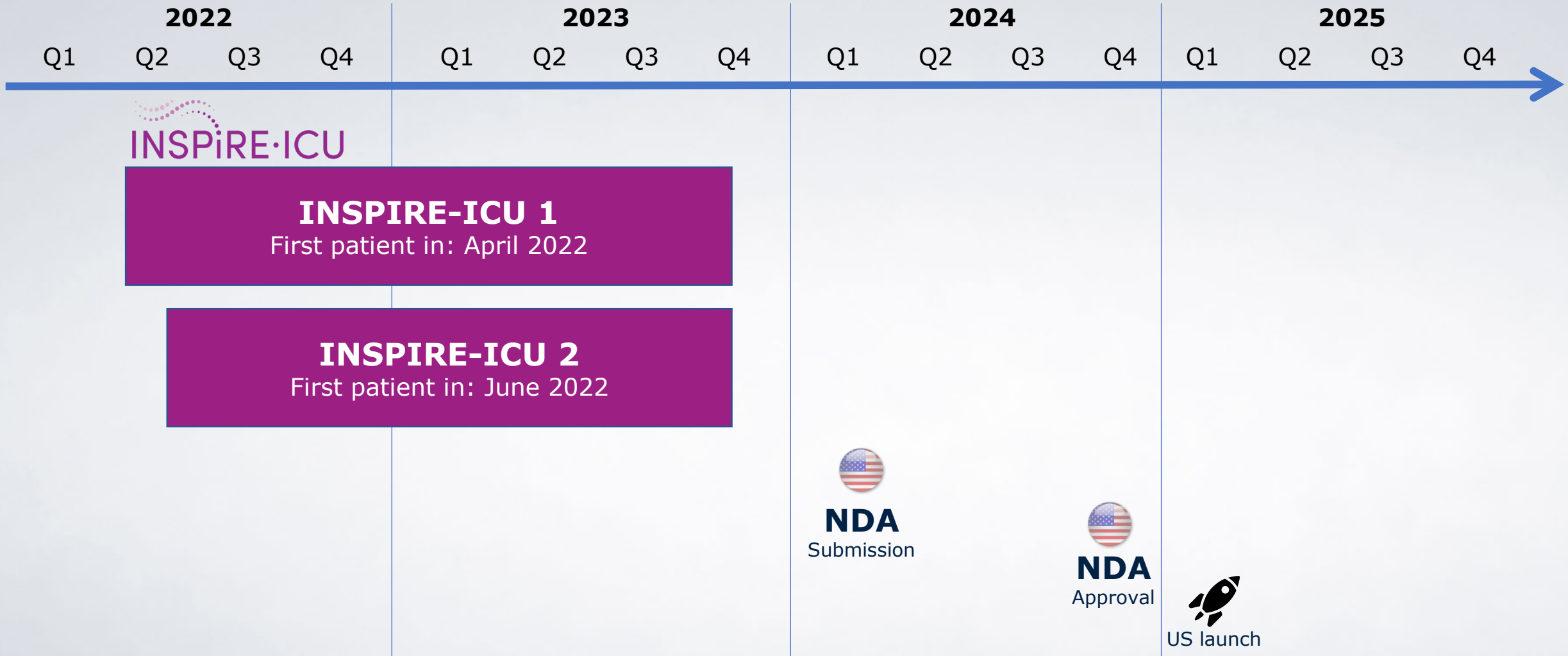
Sites activated continually throughout 2022



- Two identical phase III studies (**INSPIRE-ICU 1&2**) to confirm the 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

**INSPIRE-ICU** = Inhaled Sedation vs Propofol in REspiratory Failure in the ICU

# Development program progressing according to plan



# Successful Investigator meeting in San Francisco, 13<sup>th</sup>-14<sup>th</sup> May



- F2F kick-off meeting for all study teams, together with our Contract Research Organisation
- High in-person attendance, additional online attendance
- European long-term KOLs sharing experiences and the science behind inhaled sedation
- Hands-on Sedaconda demonstrations
- Lessons learned and best practice shared from first site initiations





# Inhaled sedation presentations worldwide - ramp-up of live activities post-Covid restrictions

## Examples for Sedaconda events (not exhaustive)

### March

- Brussels, Belgium: ISICEM symposium

### April

- Santiago do Compostela, Spain: SEDAR symposium

### May

- Cymdeithas Gofal, Wales: Welsh Society of Intensive Care symposium
- Panamerica and Iberia: FEPIMCTI (Critical Care): inhaled sedation *webinar* - 604 participants

### June

- Essen, Germany: Sedaconday
- Lindau, Germany: BANIS symposium
- Sevilla, Spain : SEMICYUC symposium
- Paris, France: SRLF symposium
- Oslo, Norway: SSAI symposium
- Eindhoven, Netherlands: IHTMS symposium

Busy meeting agenda for the autumn of 2022 – activities on 4 continents





# Financial result in Q2 2022

**Net sales**            **Q2'22:**    27 (40) MSEK, -32% y/y  
                               **FY'21:**    159 MSEK

- Sales in Germany decreased by 36% compared to Q2 2021, due to a significant temporary decline in ventilated ICU patients and restricted ICU operations
- Other direct markets showed solid growth of 31% compared to Q2 2021, particularly driven by Spain, France and the United Kingdom
- Sales in South America decreased due to artificially high sales in Q2 2021 due to the propofol shortage in the region at the time

**Gross Profit**        **Q2'22:**    19 (26) MSEK  
**Gross Margin**    **Q2'22:**    70 (66) %

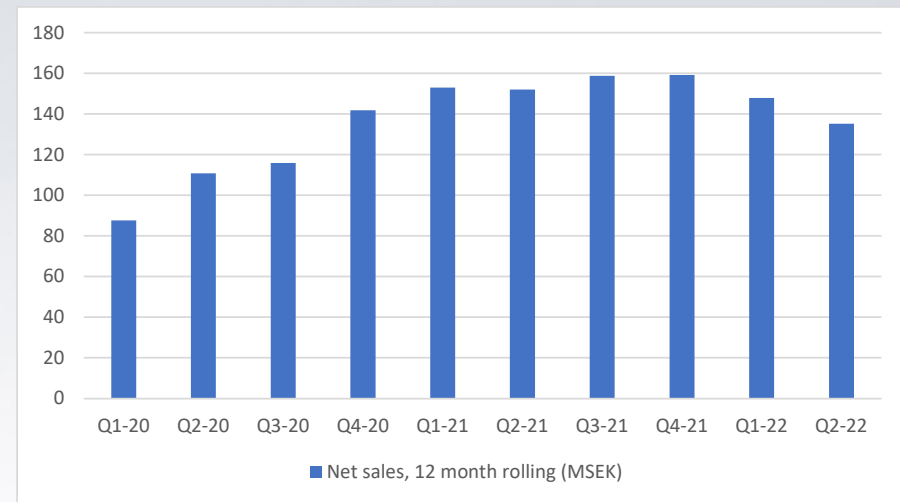
- The improved margin is mainly an effect of a positive product mix, price adjustments and initiatives to reduce freight costs

**EBITDA**            **Q2'22:**    -24 (-14) MSEK

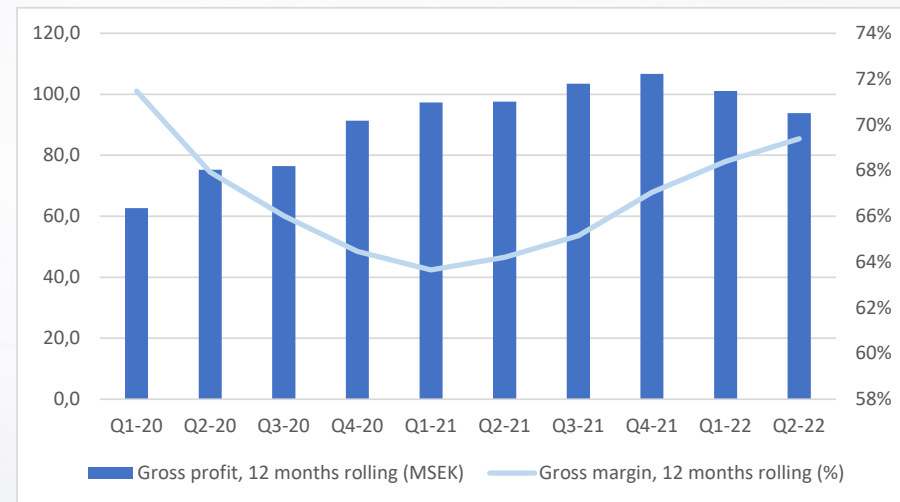
- Opex of 46 MSEK in Q2 2022, higher than Q2 2021 (43) and Q1 2022 (44) – slight increase driven by higher activity level

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

## Net sales (MSEK, 12m rolling)



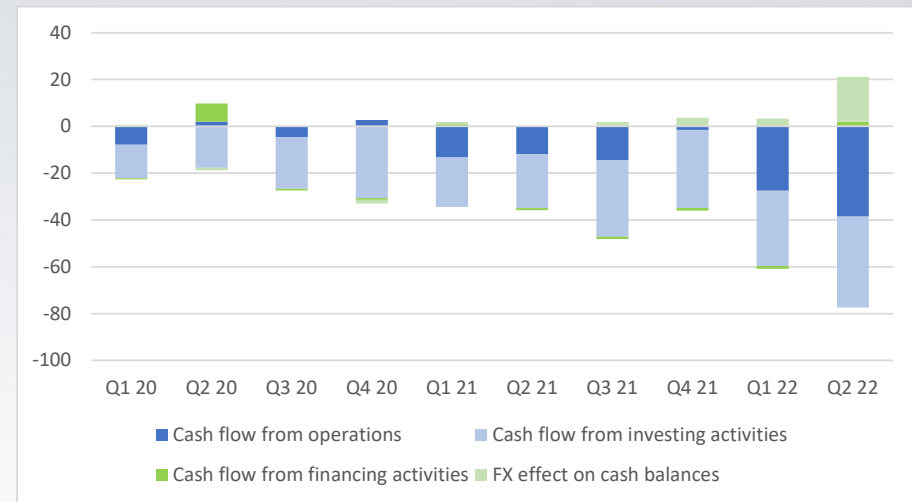
## Gross profit development (12m rolling)



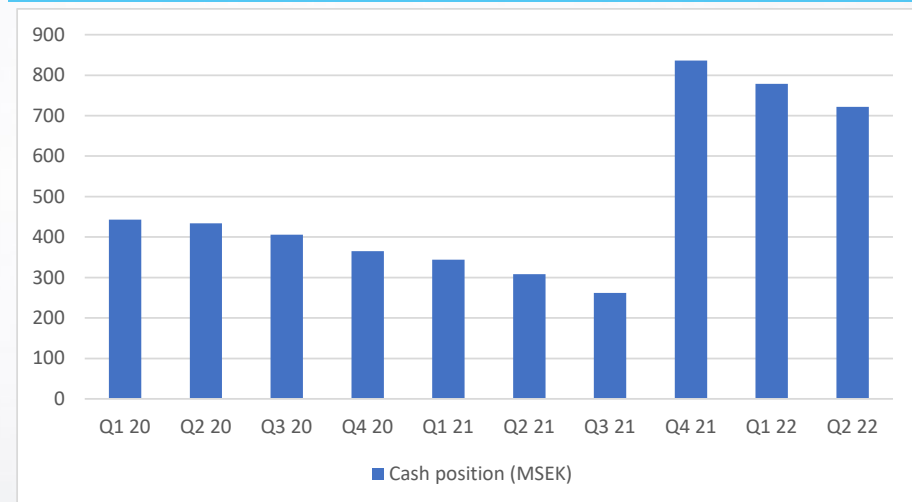
# Cash flow and cash balance

- **Cash flow from operations Q2'22:** -39 (-12) MSEK, of which cash flow from working capital of -14 MSEK related to increased inventory levels
- **Cash flow from investments Q2'22:** -39 (-23) MSEK, related to clinical studies and registration in the United States, as well as the paediatric study in Europe
- **Cash flow for the period Q2'22:** -75 (-36) MSEK
- **Cash balance per Jun 30, 2022:** 722 MSEK compared to 779 MSEK at the beginning of the quarter (including 19 MSEK FX effect)
  - We expect to be fully financed until break-even and through the US launch phase
- **Cost saving program initiated:** We are reviewing and reducing spending levels across overhead and admin functions (while ring-fencing investments in sales growth)
- **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 June 30, 2021

	No of shares	Share
Linc AB	9 983 804	10,1%
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)	4 572 098	4,6%
Sten Gibeck	4 286 276	4,3%
Öhman Funds	4 137 821	4,2%
AMF Pension	3 870 000	3,9%
Berenberg Funds	2 282 932	2,3%
Highclere International Investors LLP	2 096 488	2,1%
Third Swedish National Pensin Fund	1 735 989	1,7%
Tedsalus AB (Thomas Eklund)	1 666 464	1,7%
DNCA Finance S.A	1 597 302	1,6%
Deka Investments	1 339 540	1,3%
Avanza Pension	1 181 020	1,2%
Fifteen largest shareholders	66 243 504	66,7%
<i>Others</i>	<i>33 093 456</i>	<i>33,3%</i>
<b>Total</b>	<b>99 336 960</b>	<b>100,0%</b>

- We note that many of our top-15 shareholders have increased their holdings during Q2

# Working towards Standard-of-Care

**What if...** inhaled sedation was already standard of care?



## New entrant



“

- Not a better sedative
- Patients will need more opioids
- Less spontaneous breathing
- Longer and less predictable wake-up times
- 4 more days in the ICU

# Q&A

