



# Q2 2024 Report

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# Q2 Summary: highlights include acquisition of our main supplier and enrolment completion in the US

## Our 3 priorities

### Achieve growth in our ex-US business

- H1 net sales of **90 MSEK** (+20%<sup>1</sup>), **above our guidance** of 14-18% YoY growth
- Highest Q2 sales to date with **41 MSEK**, but lower growth (10%) compared to Q1
- Continued strong growth in other direct markets and distributor business, but weaker quarter in Germany due to temporary decline of ventilated patients in June

### Reach break-even ex-US during 2024

- **Acquisition** of our main supplier Innovatif Cekal in Malaysia expected to **add 2pp to the bottom line** over time
- Q2 Gross margin stable at **71%** (71%)
- Q2 ex-US EBITDA of **-10.8 MSEK** (-10.2), negative fx effect of 2 MSEK vs. positive fx effect of 3 MSEK last year
- Cash of **304 MSEK**

### Make headway towards US approval

- **Enrolment** of both US clinical trials **completed**
- Long-term follow up of study patients and work on dossier **on track**
- Initial **results** expected in **H2**, aiming for NDA submission in **Q1, 2025**
- **Fast Track Designation** by FDA



1 19% excl. fx

# We will acquire our main supplier Innovatif Cekal

## The deal

- We will acquire **Innovatif Cekal**, our main supplier based in Klang near Kuala Lumpur, Malaysia
- Innovatif Cekal produces our main device (**Sedaconda ACD**) and certain accessories
- Purchase price (cash and debt free): **34 MSEK**, of which **75%** are due upon closing and **25%** two years after closing
- **Closing** is expected in H2, 2024

## Strategic rationale

- The acquisition of IC is a good **strategic fit** and **financially accretive**:
- **Improved control** of the supply chain: reduce risks related to future cost fluctuations and supply disruptions, and get better control of the future scale-up of production capacity
- **Improved profitability**: the acquisition will improve margins on our main device and drive value creation, in particular over time as sales are expected to grow further

## Financial impact

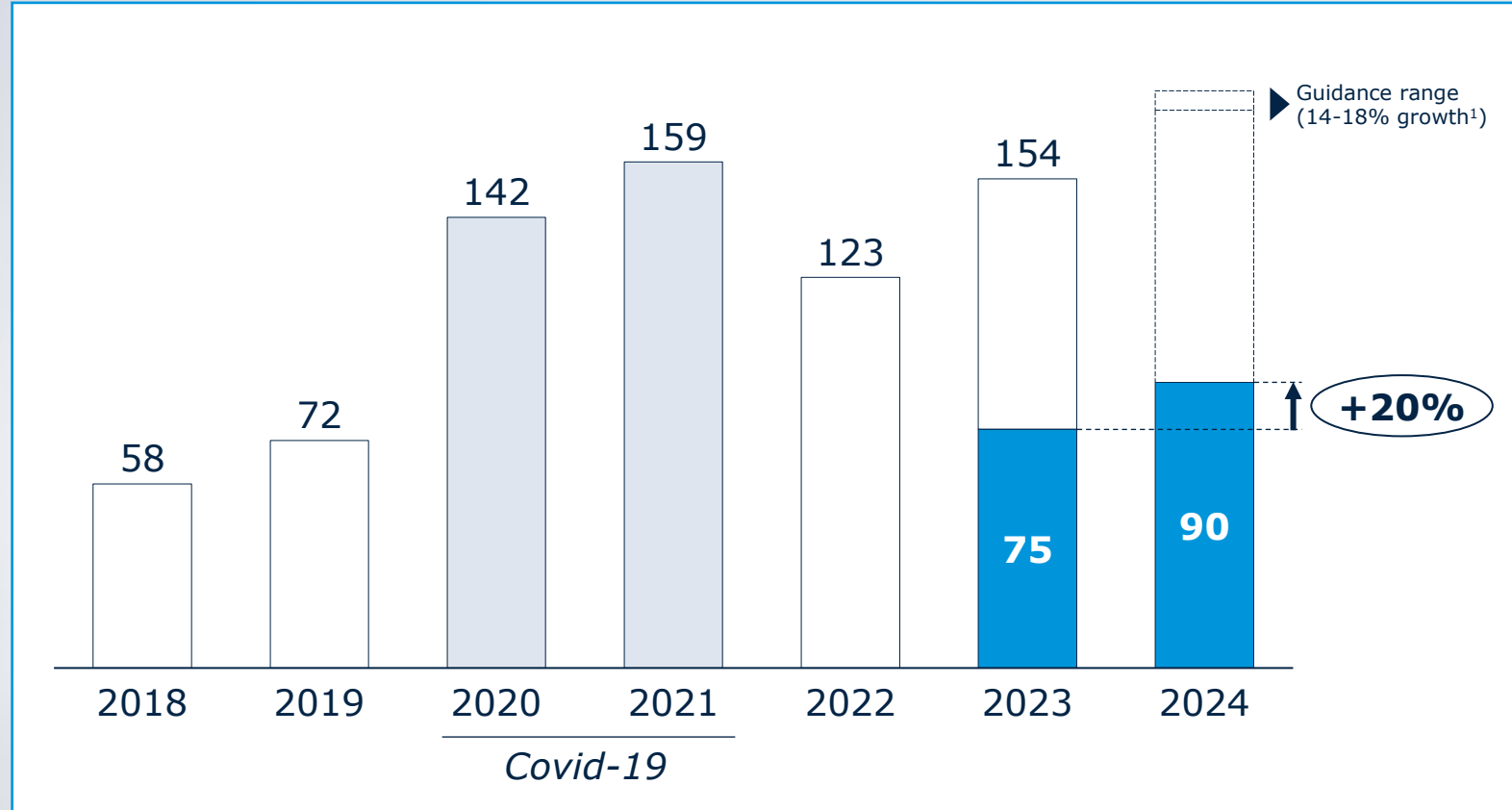
- Over time (once stock from pre-closing is depleted), the acquisition is expected to improve Sedana Medical's EBITDA margin by **2 percentage points**
- We will finance the transaction with existing cash and **continue to be financed** to execute on our strategic plan
- The acquisition is expected to have a **net positive impact** on the cash flow from operations from **2025** and a net positive impact on the cash balance from **2028**



# Sedana Medical has returned to a strong growth path

## Net sales

SEK million



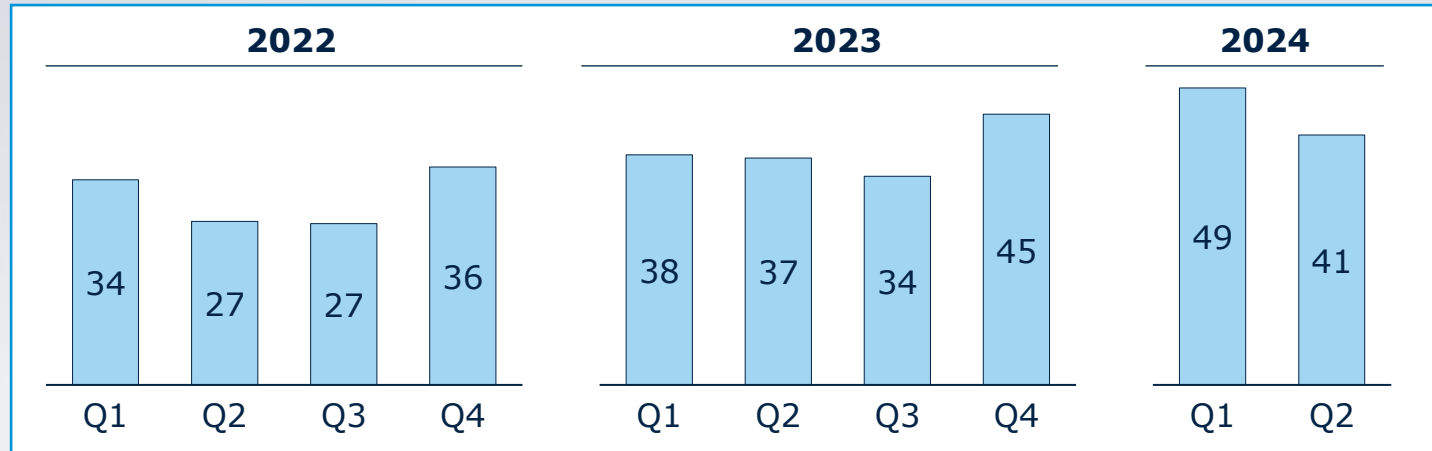
## Successful restructuring after post-Covid-19 period

- Streamlined **corporate headquarters** and improved overall **spend effectiveness**
- Shifted resources **to the frontline**
- Steered investments towards **profitable and growing** markets
- Implemented **front-line effectiveness** initiatives

<sup>1</sup> Excl. fx effects

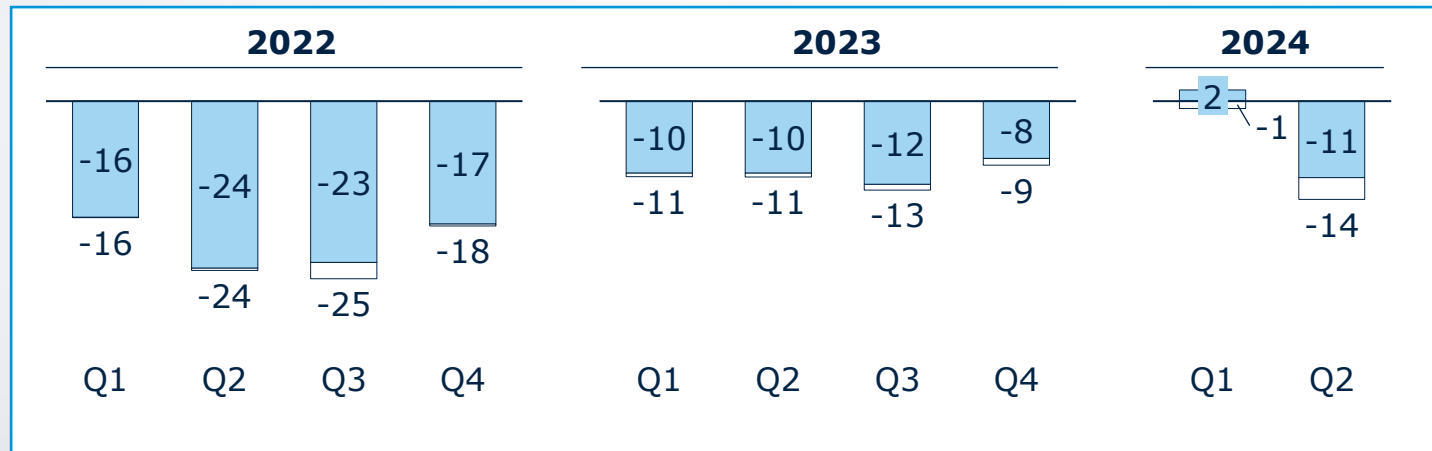
# At the same time, we have significantly improved our bottom line

## Net Sales MSEK



## EBITDA MSEK

Ex-US  
Group

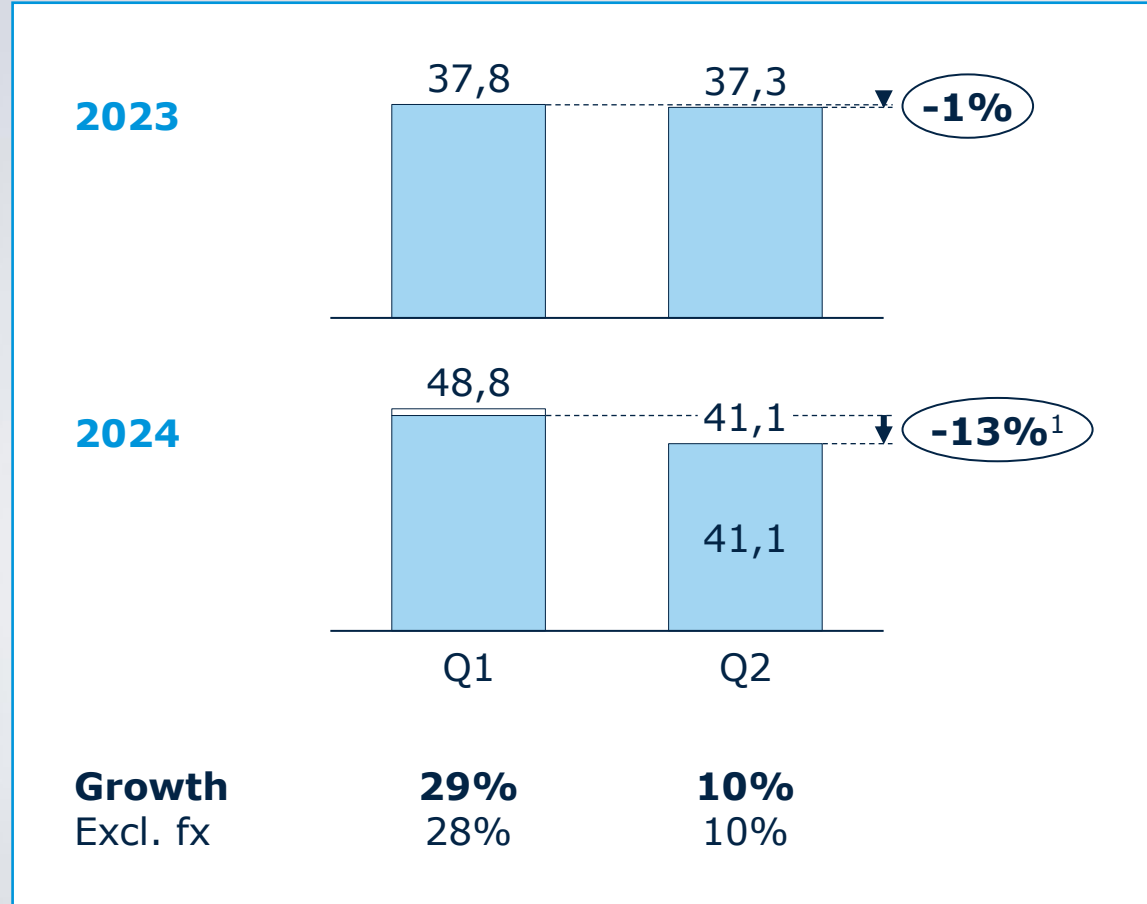


## Comments

- Restructuring measures have resulted in strong bottom line improvement after highest loss in the company's history in 2022
- Q2 EBITDA below Q1, mostly due to seasonally lower sales level, but also impacted by ~2 MSEK negative fx effect compared to a positive fx effect in Q1 of 2 MSEK

# Part of the softer growth rate in Q2 is explained by the comparator period

## Net Sales, MSEK



## Comments

- Our business is subject to seasonality as less patients require mechanical ventilation in the summer months
- On average, we see a sales decline of ~10% between Q1 and Q2 (based on 2016-22<sup>2</sup>)
- In 2023, Q1 and Q2 were on the same level, impacting the YoY comparison

<sup>1</sup> Corrected for 1.5 MSEK order from South American distributor  
<sup>2</sup> Excl. 2020 due to heavy Covid-19 effect

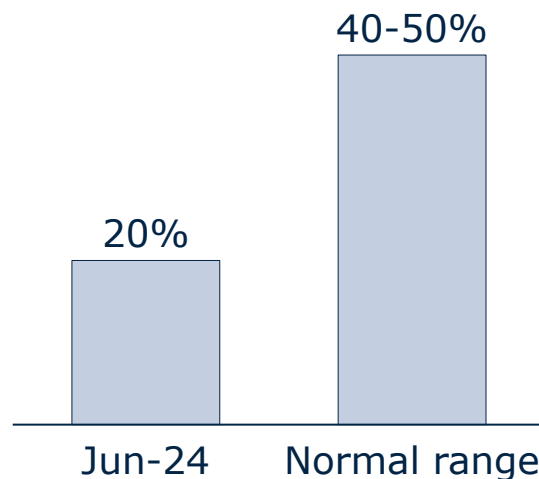
# Germany had a weak quarter due to temporary absence of ventilated patients



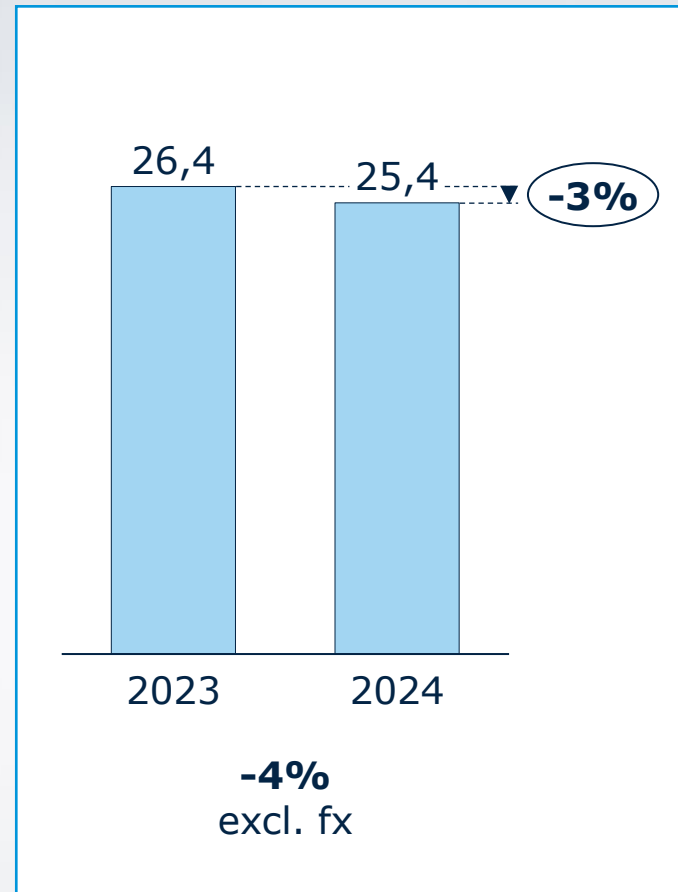
## # of mechanically ventilated patients very low in June

Results from survey of 40 German key customers (performed in June)

Share of mechanically ventilated patients relative to ventilator beds



## Net Sales Q2 MSEK



## Comments

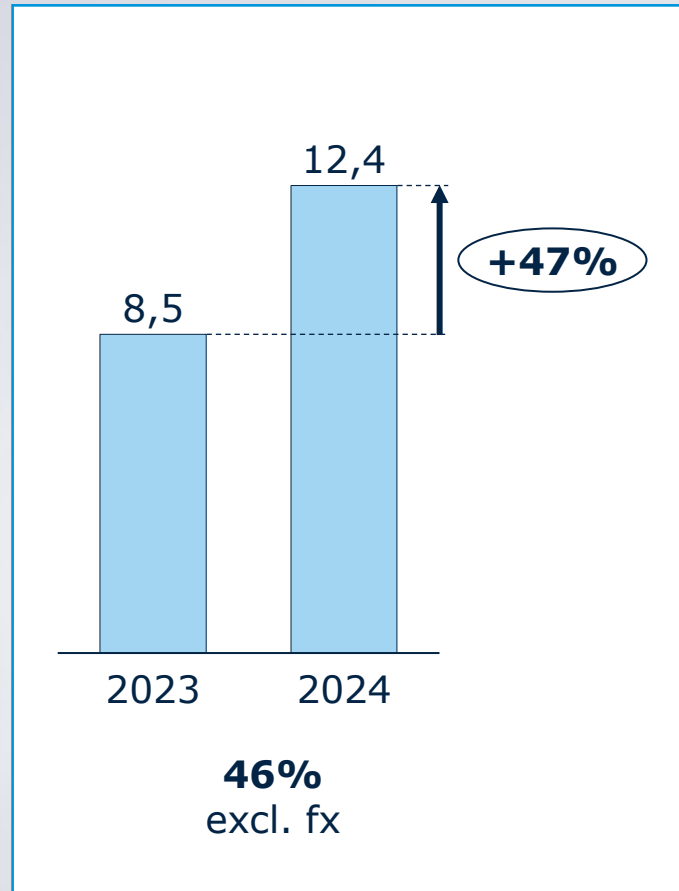
- Q2 sales were 4% lower than last year (in local currency)
- The explanation is a very weak June, with a >20% sales decline YoY
- A survey with 40 of our key customers showed that the number of mechanically ventilated patients was temporarily much lower than usual in June
- We saw growth in April/May and the first weeks of July, suggesting the effect was temporary



# Other direct markets continued on their strong growth trajectory



## Net Sales Q2, MSEK



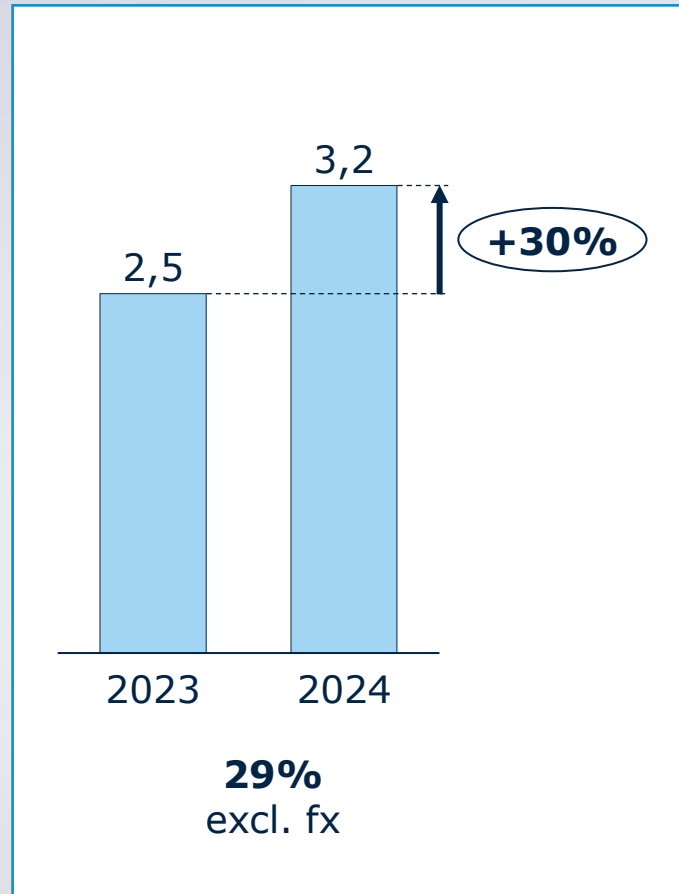
## Comments

- Among other direct markets, **Spain** continued to be the **main growth engine** in absolute terms, fuelled by new treatment guidelines and pricing & reimbursement approval. We are continuing to invest in an expansion of the team
- **UK** has seen a **significant acceleration** of demand, after receiving the **MHRA approval** in Q4, 2023, delivering the highest percentage growth rate of all markets in H1
- **France** had slightly slower growth in Q2 due to vacancies in the sales team, but poised for further growth in 2024 with **new university hospitals** starting up and promising **tenders** underway. Vacancies are being back-filled.
- All country teams have been (re-)sized to allow for **positive contribution** to company EBITDA in 2024
- Other direct markets represented **30% of Sedana Medical's sales**, up from 23% in Q2 2023

# Our distributor markets also delivered solid growth in Q2



## Net Sales Q2 2024, MSEK



## Comments

- Distributor markets showed **YoY growth for the third quarter in a row** after a long period of declining sales. Main reason for the previous decline was **high stock levels** built up during Covid-19.
- The distributor team has been **restructured** and our approach with distributor partners has been revamped, with a strong **focus on key partners** with high potential and positive momentum

# We see the company well on track to reach our financial targets

## Net Sales FY 2024

**Communicated target:**

**14-18%**

Net Sales growth (excl. fx)



**Status:**

**19%** in H1,  
putting us well on track to  
meet our targets.

## EBITDA

**Communicated target:**

**Break-even**

in our ex-US EBITDA  
during 2024



**Status:**

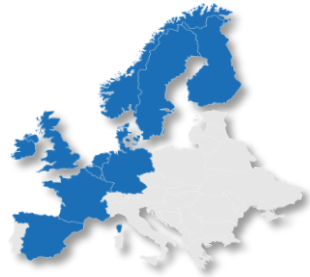
Positive ex-US EBITDA in Q1  
and seasonal EBITDA decline  
in Q2, aiming at break-even  
again in Q4<sup>1</sup>



<sup>1</sup> Excl. possible effects from acquisition of Innovatif Ceka

# We made a big step forward in our largest potential market

## The US is by far our largest commercial opportunity



**Europe** (direct markets)

~1 million

Ventilated adult  
ICU patients p.a.

Market potential  
inhaled sedation  
(low- to mid-single digit  
growth p.a.)

**3-4** BSEK

### Penetration rates 2023

- Germany: ~12%
- Best territories in Germany: >20%
- Other direct markets: <2%



**United States**

>2 million

**10-12** BSEK

### Key assumptions

- Comparable approved label as in Europe
- Assumed only modest price premium vs. Europe (10-20%) – upside if price difference in line with other sedation therapies (e.g., propofol) can be achieved

## Enrolment completed!

**INSPIRE-ICU**

- Both clinical trials in the US have completed enrolment in less than two years respectively
- 235 patients have been randomized to each study
- Primary and secondary end points are the same as in our successful European trial

# 31 prominent clinical trial sites were involved – building a strong platform for KOL engagement and launch success



## INSPIRE-ICU1



- Vanderbilt
- University of Colorado
- Cleveland Clinic
- UT Southwestern
- Brigham & Women's Hospital
- Mayo Clinic
- University of Virginia
- Intermountain
- Tufts
- Houston Methodist Hospital
- MD Anderson
- University of Cincinnati
- Emory
- University of Chicago

## INSPIRE-ICU2



- Rush University
- Columbia University
- Massachusetts General Hospital
- University of Michigan
- Beth Israel Deaconess MC
- Ohio State Wexner
- UCSD
- UCLA
- Stanford
- Virginia Commonwealth
- Long Beach Memorial
- Thomas Jefferson University
- University of Miami
- University of Maryland
- Henry Ford
- Cooper Health
- Memorial Hermann Hospital

# After enrolment completion, we are progressing towards NDA submission

## Progress



- Patient enrolment completed
- We are on track with the activities we have under our control
  - Long-term follow up (after 3 and 6 months) is underway and on schedule
  - Work on the dossier is progressing

## Target timeline

- First study results in H2
- NDA submission in Q1, 2025 (unchanged)
- Potential benefits of Fast Track Designation will be decided by FDA after submission

## Dependencies

- Meeting the timeline will require
  - Positive data read-out
  - FDA's acceptance of our analyses and submission plans
- In regular exchange with the FDA regarding our plans

# Several exciting milestones are upcoming



## Upcoming milestones (and how they will reduce the risk)

- ☑ Enrolment completion – taking out the study execution risk
- ☐ Top-line results – will increase our chances for approval, if positive
- ☐ Acceptance of analysis and submission plans by FDA – will allow us to confirm timelines (in regular exchange with the agency)
- ☐ Possible benefits from Fast Track Designation – will be decided by FDA after submission (possible upside to approval timeline)
- ☐ Approval

## Commercialization plans

- US is our highest-potential market with a concentrated customer base (~2.800 hospitals with ICUs of >10 beds)
- Therefore, we are preparing to build a commercial US subsidiary and launch our therapy ourselves
  - Keep control of our assets and capture more of the upside
  - Increase the value by achieving proof of concept
  - Strong support from prominent clinical trial sites
- Keep the option to add complementary partnership(s) if deemed attractive



# Financial result in Q2 2024

**Net sales**      **Q2'24:**    41 (37) MSEK, +10% y/y (+10% excl. fx)

- Sales in Germany decreased by 3% y/y (-4% excl. fx), driven by a decrease in ventilated patients during June.
- Other direct markets showed growth of 47% y/y (46% excl. fx), mainly driven by Spain and UK.
- Our distributor markets increased by 30% y/y (29% excl. fx) driven mainly by our prioritized distributors in Europe.

**Gross Profit**    **Q2'24:**    29 (27) MSEK

**Gross Margin**   **Q2'24:**    71 (71) %

- Rounding hides slight decrease in gross margin mainly related to proportionately higher share of Sedaconda (isoflurane) sales.

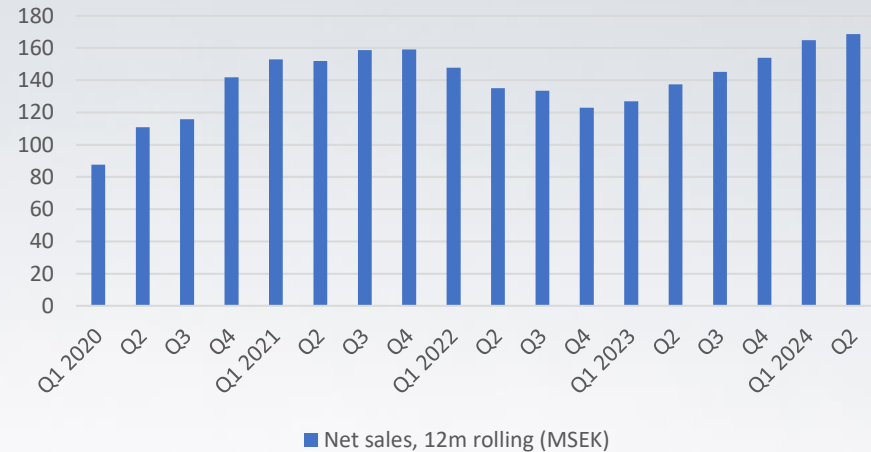
**EBITDA**        **Q2'24:**    -14 (-11) MSEK

**EBITDA Ex-US** **Q2'24:**    -11 (-10) MSEK

- Opex of 46 MSEK in Q2'24, which is in line with Q2'23. Opex is 2 MSEK higher than in Q1'24, driven by administrative costs mainly related to legal fees (IC acquisition, LTIP) and personnel, of which 1 MSEK is non-recurring.
- EBITDA in Q2'24 includes a net fx effect of -2 MSEK, compared with 3 MSEK in Q2'23 and 2 MSEK in Q1'24.

**Staff, incl consultants, per June 30 2024:** 89 (93 at June 30 2023).

## Net sales (MSEK, 12m rolling)



## Gross profit development (12m rolling)

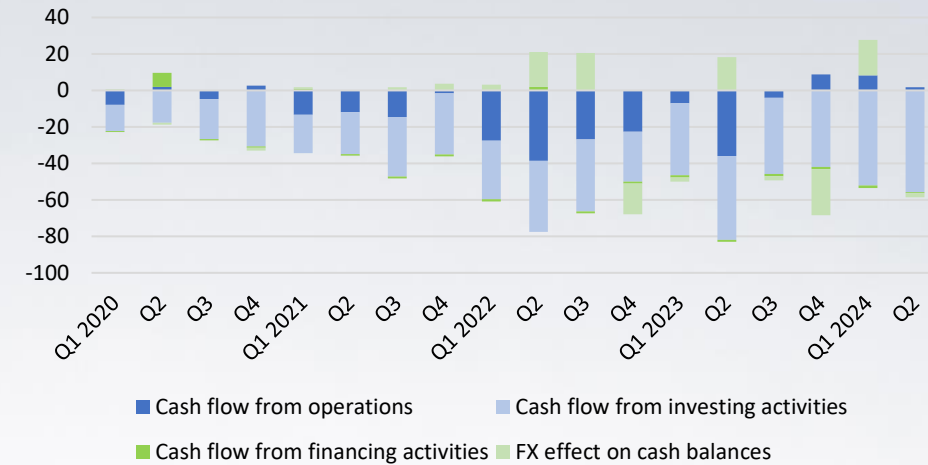




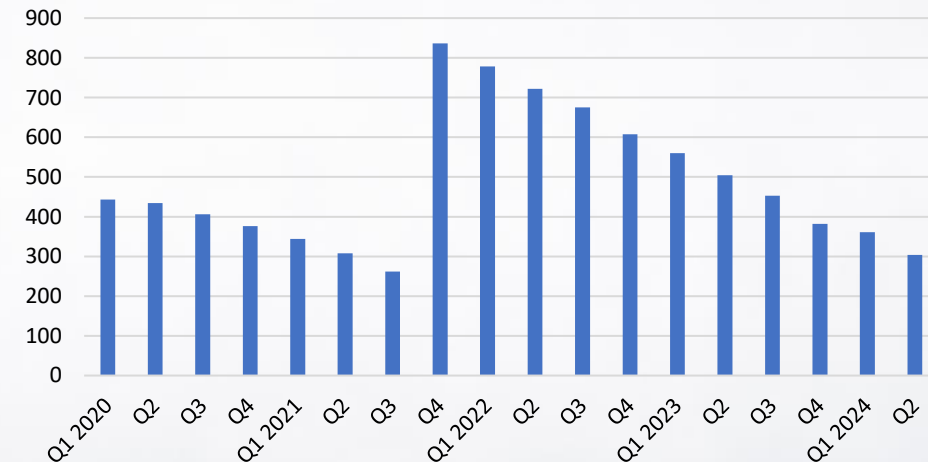
# Cash flow and available funds

- **Cash per June 30 2024:** 304 MSEK compared to 361 MSEK at the beginning of the quarter. Decrease fully driven by investments in capitalized development expenditures (mainly US clinical study).
- **Cash flow from operations Q2'24:** 2 (-36) MSEK, including a working capital effect of 14 MSEK (-17) due to timing of payments from customers and payments related to the US clinical study.
- **Cash flow from investments Q2'24:** -56 (-46) MSEK driven by our US clinical study and US registration work.
- **Total cash flow Q2'24:** -54 (-83) MSEK. Fx effect on cash balances amounted to -2 MSEK (18).
- With patient recruitment completed in our US clinical study during Q2, capex will gradually come down during 2H 2024, and in particular in 2025.
- **Liquidity management:** Approx. 80% of our available funds are in USD.
- We expect to be fully financed until break-even and to execute on our strategic plan.
- No long-term debt.

## Change in cash position (MSEK) excl 2021 cap. raise and short-term deposits



## Available funds\* (MSEK)



\* Cash and short-term deposits

# Largest shareholders June 30, 2024

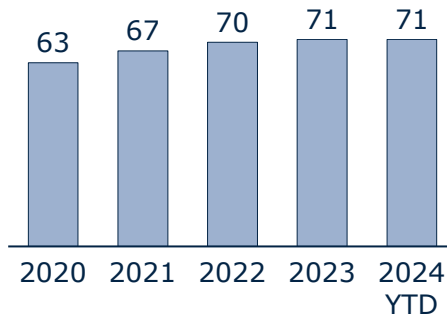
	No of shares	Share
Linc AB	10,796,076	10.9%
Anders Walldov direct and indirect (Brohuvudet AB)	10,000,000	10.1%
Swedbank Robur Funds	8,919,013	9.0%
Öhman Funds	6,978,325	7.0%
Handelsbanken Funds	5,548,598	5.6%
Ola Magnusson direct and indirect (Magiola AB)	4,312,098	4.3%
Sten Gibeck	4,196,597	4.2%
Premier Miton Investors	3,685,911	3.7%
Highclere International Investors LLP	3,380,773	3.4%
AMF Pension	2,491,000	2.5%
Amundi	1,708,952	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Avanza Pension	1,463,585	1.5%
AXA Investment Managers	1,190,132	1.2%
Berenberg Funds	1,150,411	1.2%
Fifteen largest shareholders	67,487,935	67.9%
<i>Others</i>	<i>31,849,025</i>	<i>32.1%</i>
<b>Total</b>	<b>99,336,960</b>	<b>100.0%</b>

# Investment case - why Sedana Medical?



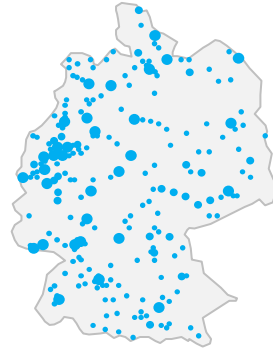
## High gross margins

GM, in percent



- Robust gross margins of our portfolio
- Limited operating expenses needed to target ICUs
- Sedana Medical can achieve attractive profits when reaching scale

## Proof of concept



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

## Growth opportunities



- Clinical benefits vs. old standard of care
- Health-economic benefits, confirmed by NICE
- Approval in 18 countries in Europe
- US launch in 2026, Fast Track Designation by FDA

## Strong balance sheet

Cash

In SEK, end of Q2

**304M**

- Financed to execute on strategic plan

# Q&A

