



Q4 and FY 2023 Report

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February 15, 2024



Disclaimer

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Q4 Highlights: during the quarter, we have made strong progress on all of our 3 priorities

Our 3 priorities



Achieve growth in our ex-US business

- Q4 net sales: **44.5 MSEK** (+24% / +18% excl. Fx)
- FY net sales: **153.9 MSEK** (+25% / +16% excl. Fx), upper end of our financial guidance (145-155 MSEK)
- **MHRA approval** in the **UK**
- **P&R¹ approval** in **Spain**

Reach break-even ex-US during 2024

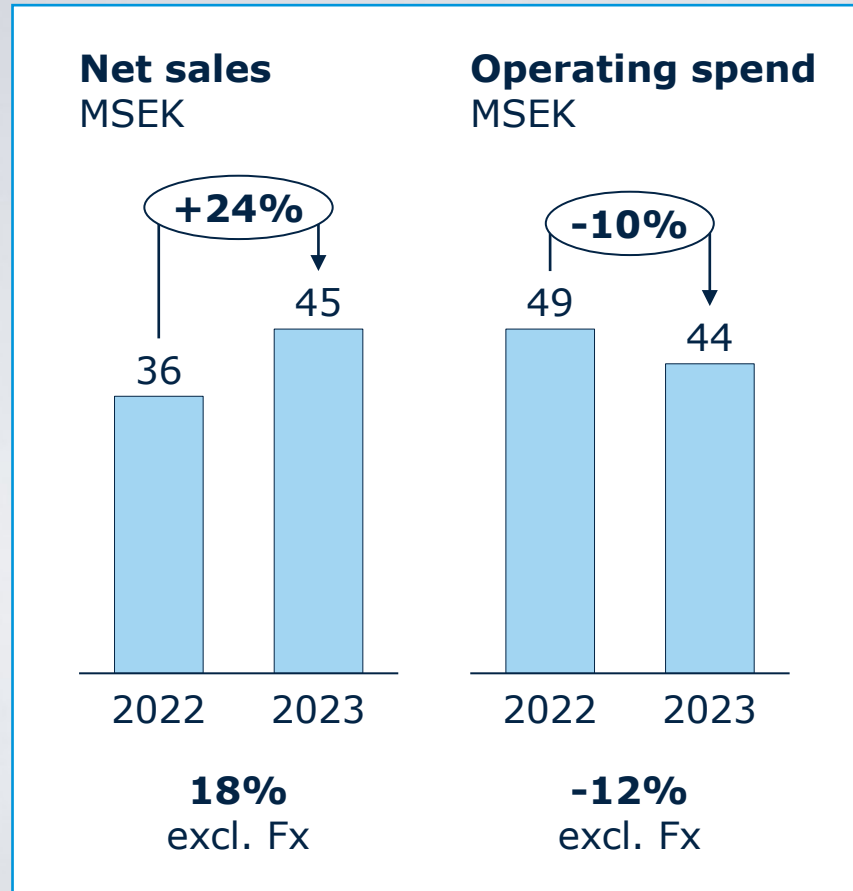
- Gross margin of **70%** (72%)
- **Operating expenses decreased by 10%** (12% excl. currency effects)
- Ex-US EBITDA of -8,1 MSEK in Q4 (**improved by 54%** vs. LY)
- Cash and short-term deposits of **382 MSEK**

Make headway towards US approval

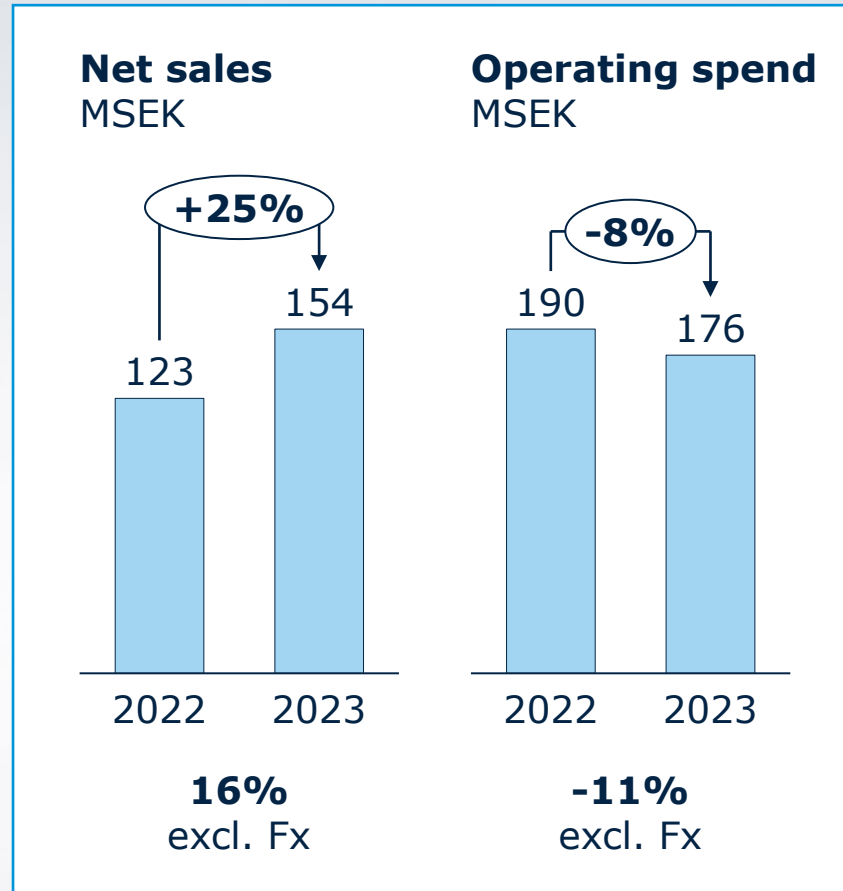
- US clinical trials **progressing**: >200 (of 235) patients recruited for INSPIRE ICU-1
- **NDA submission** planned for Q1 2025 (unchanged)
- **Fast Track Designation** by FDA

In Q4, we have continued on our path towards profitability, achieving sales growth and cost cuts at the same time

Q4 2023



Full Year 2023



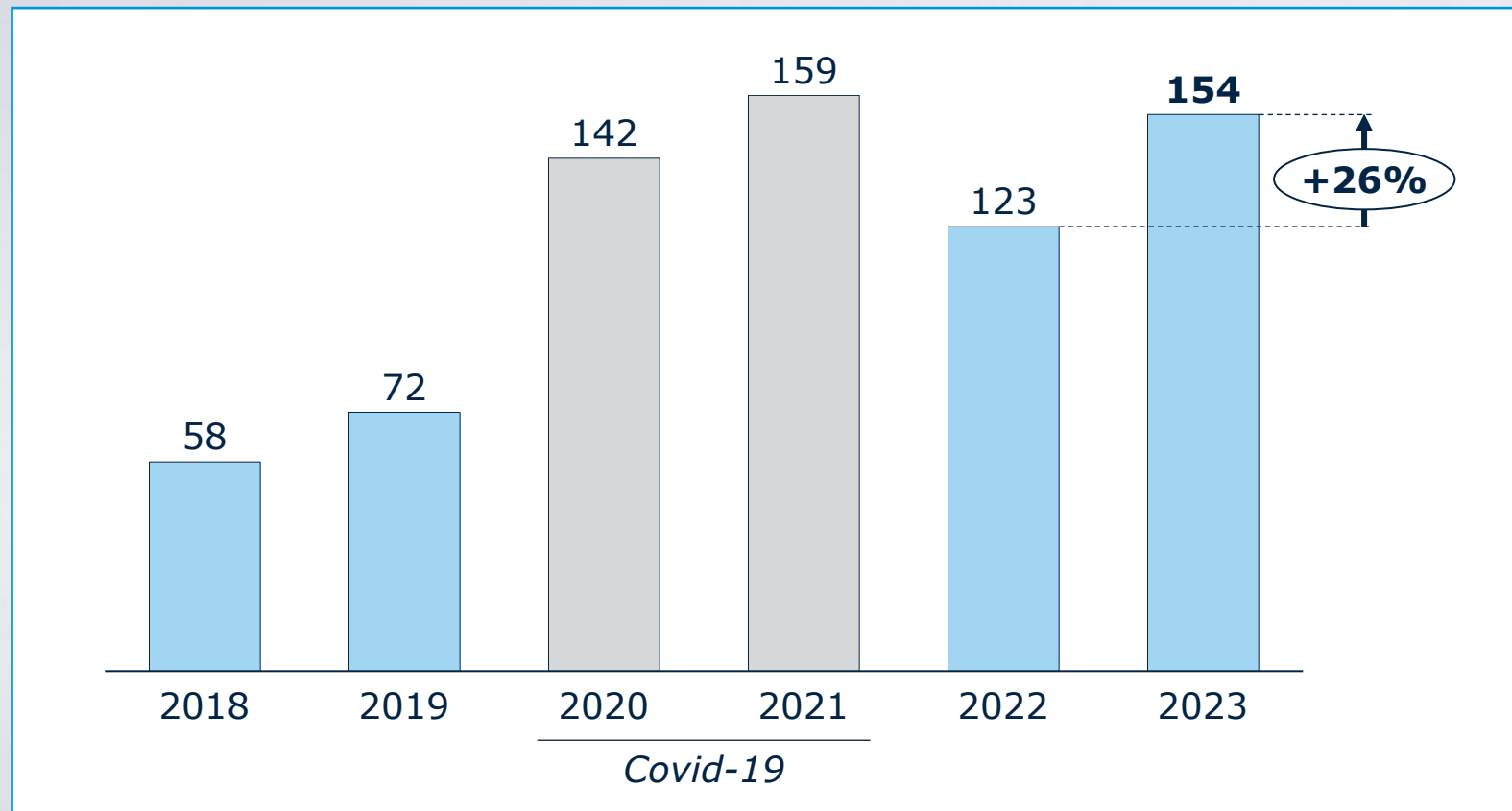
Key measures

- Implemented **front-line effectiveness** initiatives
- Steered investments towards **profitable and growing** markets
- Streamlined **corporate headquarters**
- Improved overall **spend effectiveness**

In 2023, we have returned to growth after the difficult post-Covid-19 period

Net sales

SEK million



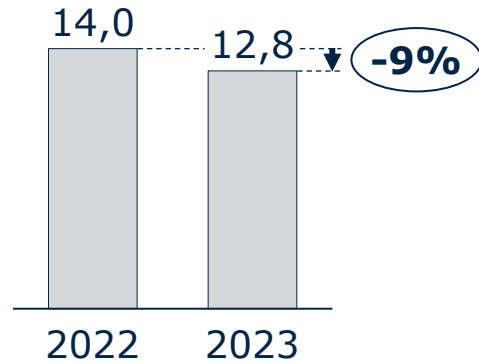
Comments

- 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 2023 and higher FY sales than in the Covid-19 Year 2020

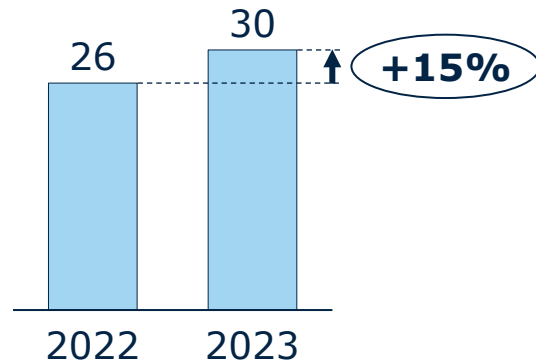
Despite a further decline in ICU patients, Germany continued to show solid growth

Ø number of ICU patients
Per day, per ICU¹

Q4 2023

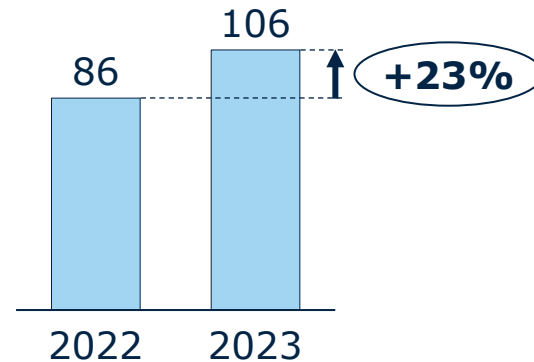
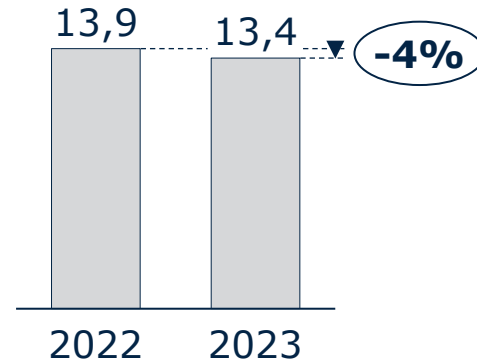


Net sales
MSEK



9%
excl. Fx

Full Year 2023



14%
excl. Fx

Comments

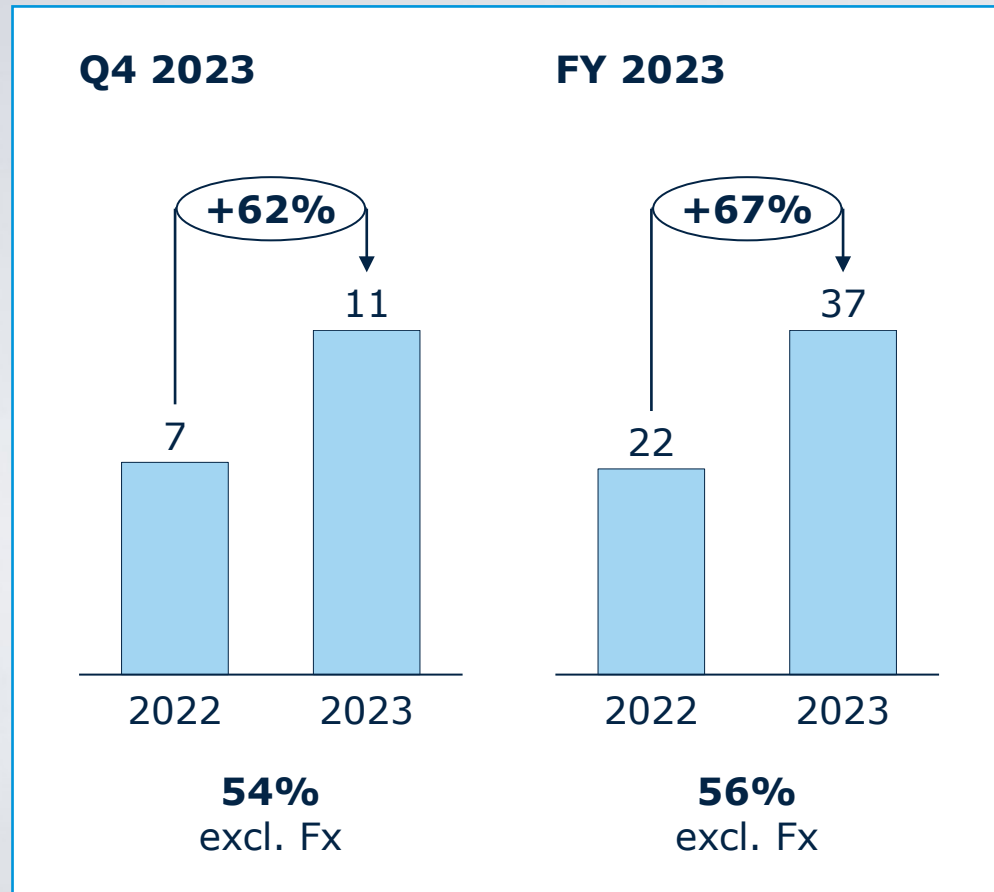
- Number of patients in German intensive care units saw a **further decline** in 2023
- Against that trend, our German business showed **solid growth**
- Healthy balance of growth from existing customers and **~120 new/re-activated customers**
- Our **market penetration** increased **to 12%**, up from 10% the year before

¹ Source: divi Intensivregister

Other direct markets continued strong growth trajectory

Net Sales

MSEK



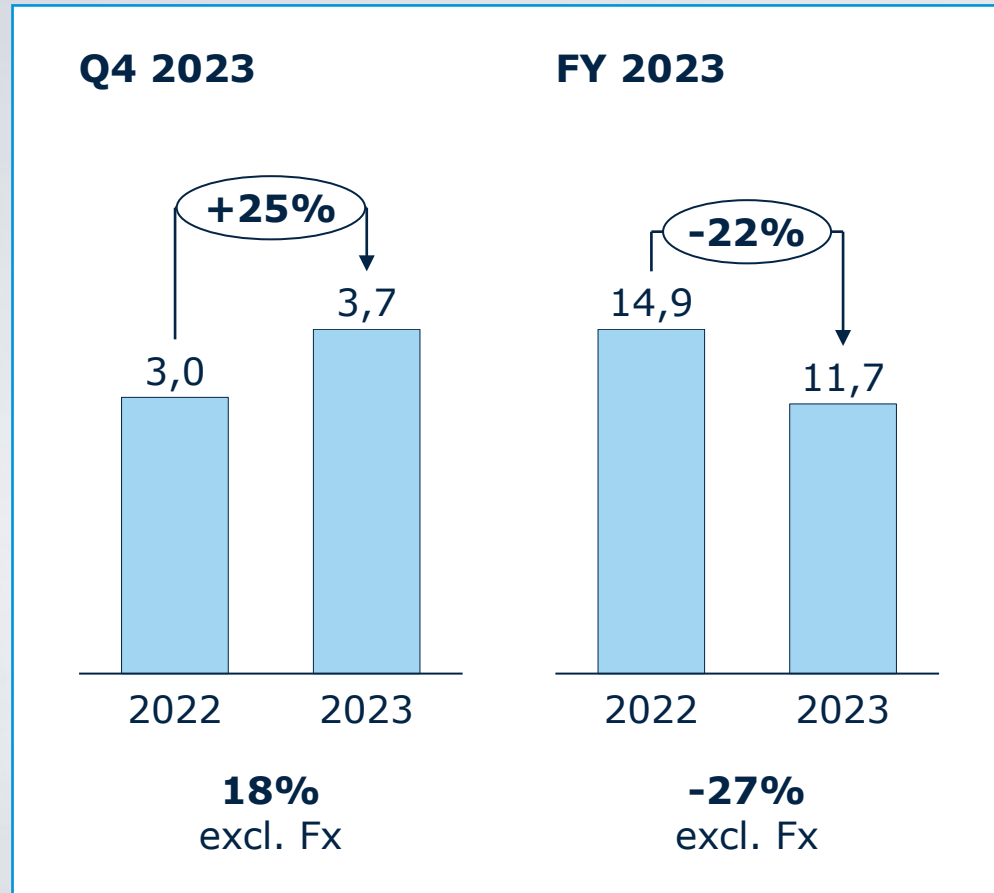
Comments

- **Spain** was the **main growth motor** among other direct markets in 2023, fuelled by new treatment guidelines and pricing & reimbursement approval
- **France** poised for further growth in 2024 with **new university hospitals** starting up and promising **tenders** underway
- **UK** expected to accelerate growth, after **MHRA approval** in Q4, 2023
- All country teams have been (re-)sized to allow for **positive contribution** to company EBITDA in 2024
- Good balance of growth from existing customers and **~80 new / re-activated customers** in 2023
- Other direct markets represented **24% of Sedana Medical's sales** in 2023, up from 18%

Distributor Markets showed growth for the first time since 2021

Net Sales

MSEK

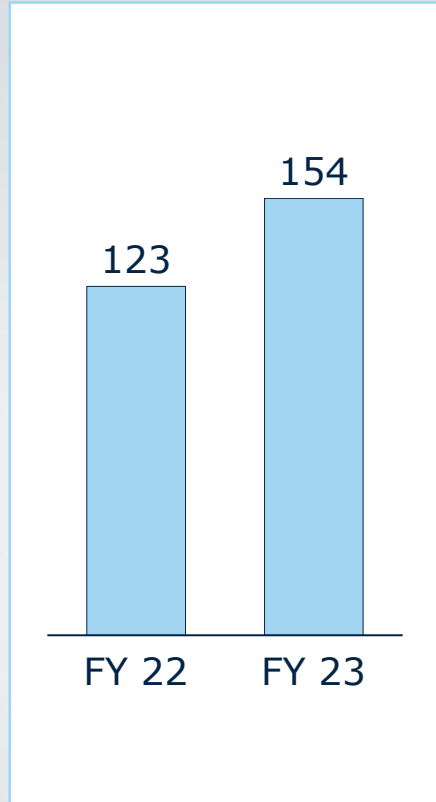


Comments

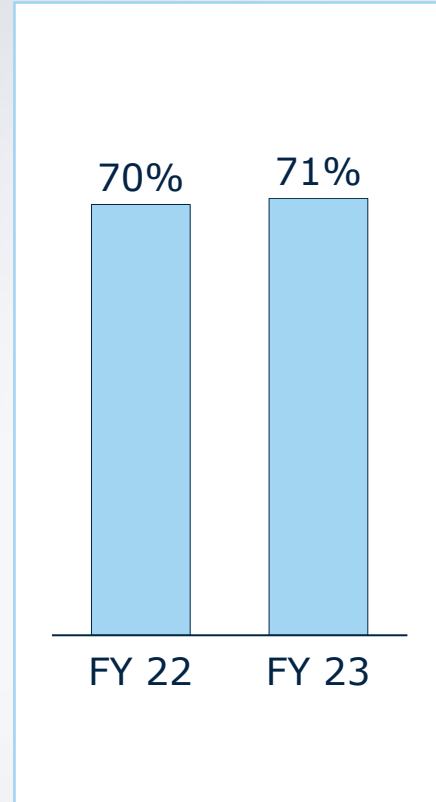
- Q4 was the **first quarter with positive growth** for our distributor business since Q3, 2021
- Main reason for the previous decline was **high stock levels** built up during Covid-19
- Lack of orders from our leading **S. American distributor** alone had a negative impact of 4.6 MSEK in 2023 vs. 2022
- **Revamped our distributor model**, with new leadership and intensified focus on key partners with highest growth prospects

We are making progress towards break-even ex-US

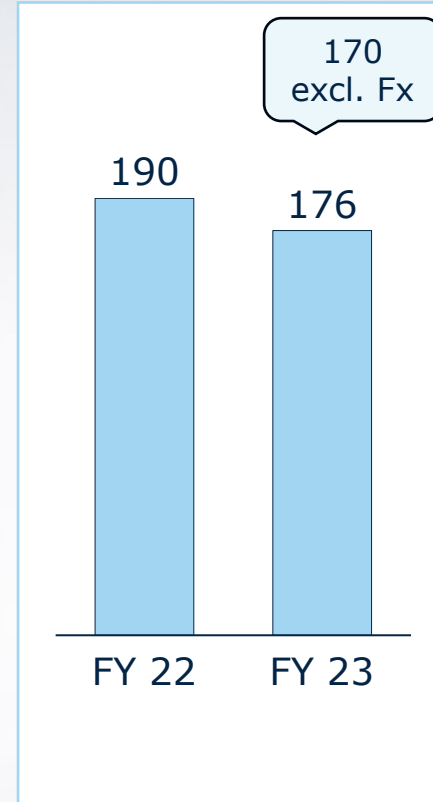
Net Sales
MSEK



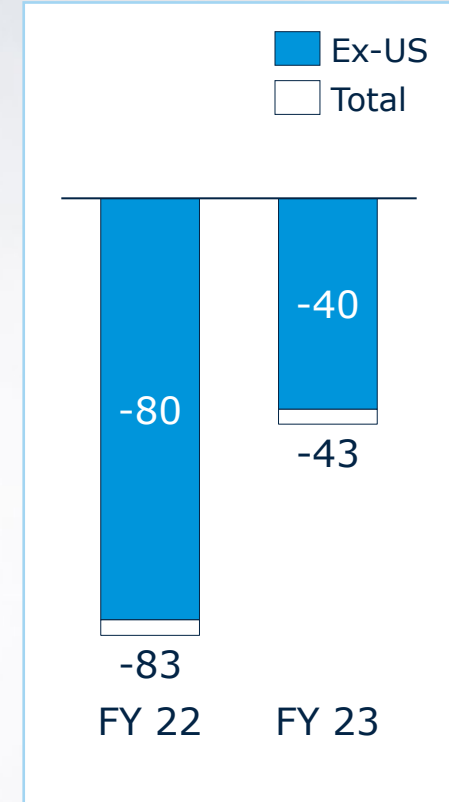
Gross margin
% of Net Sales



Opex
MSEK



EBITDA
MSEK



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

Net Sales FY 2023

Communicated target:

145-155 MSEK
Net Sales in 2023



Result:

154 MSEK
(upper end of the guidance)

EBITDA

Communicated target:

Break-even
in our ex-US business
during 2024



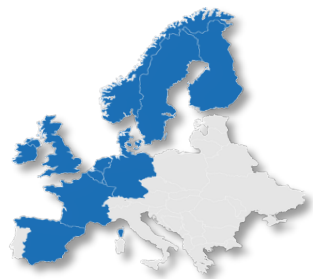
Status:

- Q4 ex-US EBITDA **improved by 54%** (-8 MSEK, of which ~2 MSEK were severance payments)
- **Positive operating cash flow** in Q4 / in balance excl. interest income



We have updated our sales guidance for 2024

Market potential in prioritized geographies



Europe (direct markets)

Ventilated adult
ICU patients p.a.

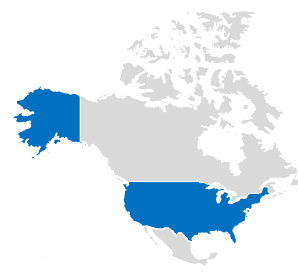
~1 million

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

Short-term targets

Net sales growth FY 2024

14-18%

(excl. Fx),
compared to 16% in 2023

EBITDA

Break-even

in our ex-US business
during 2024

The United States represent our next growth horizon

Market

- US is clearly the **largest potential** market
 - 5x more ICU beds than Germany
 - ~2-4x the propofol net price level compared to Europe
- **Concentrated customer base:**
~4.860 hospitals with ICU care (of which ~2.800 with >10 beds)¹

Strategy

- Build **in-house commercial infrastructure for launch**
- Keep the **option to add complementary partnership(s)** if deemed attractive

Progress

- Two phase III studies (**INSPIRE-ICU 1&2**) ongoing: 29 active sites, INSPIRE-ICU 1 has surpassed 200 (of 235) randomized patients
- NDA submission planned **Q1 2025**, standard review time is 10 months
- Received **Fast Track Designation** by FDA in January 2023



¹ Source: American Hospital Association

Besides the clinical benefits, inhaled sedation is well positioned for the US market access landscape



Fit with hospital reimbursement mechanism

- DRG (“diagnoses-related groups”) is the dominant payment mechanism (hospital is paid with pre-set rate based on patient’s diagnoses and procedures)
- The hospital will benefit financially, if patients ...
 - Wake up faster
 - Spend less time on the ventilator
 - Leave the ICU faster
- All are potential benefits of inhaled sedation



Wide-spread preference for opioid sparing therapies

- Much higher awareness of opioid risks in the US, due to the opioid epidemic with >100,000 drug overdose deaths p.a.
- In SED001 (European study), inhaled sedation patients needed ~30% less opioids without having more pain
- In SED002 (paediatric study), inhaled sedation patients needed ~50% less opioids without indications of more pain



Fit with existing treatment recommendations

- CDC’s “Wake up and Breathe” collaborative intends to get patients off the ventilator sooner and improve recovery time
- Benefits of inhaled sedation, including rapid wake-up, return of cognitive function and more spontaneous breathing, create opportunities to be well positioned in treatment guidelines

Our US trials have the same primary and secondary end points as our successful European trial (SED-001)

INSPIRE-ICU

INSPIRE-ICU* 1

First patient in: April 2022

INSPIRE-ICU 2

First patient in: June 2022



- **Two identical phase III studies** 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
- **230 randomized patients in each study**
- **Primary endpoint:** proportion of time at target sedation level, assessed with Richmond Agitation Sedation Scale (RASS)
- **Key secondary endpoints:**
 - Opioid dosing during sedation
 - Time to wake-up after sedation
 - Cognitive recovery after sedation
 - Proportion of time with spontaneous breathing

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

29 sites are enrolling in our US trials – 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

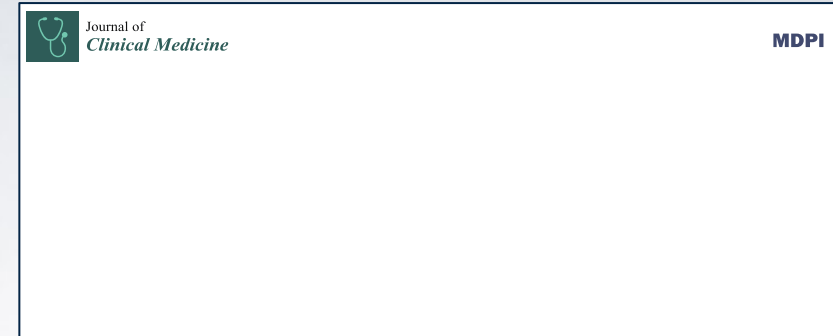
During 2023, we have engaged the KOL and medical community with very positive response

- Stuttgarter Intensivkongress F2F Germany
- ISICEM – F2F, Inhaled sedation workshop, Frontiers in sedation meeting Brussels
- Forum Interdisziplinäre Intensivmedizin F2F Berlin, Germany
- Symposium Intensivmedizin 2023 – F2F and symposium Bremen, Germany
- SOVAMICYUC – symposium Valencia, Spain
- INSPiRE-ICU Investigator Meeting Boston
- SOCMIC Inhaled sedation Workshop, Lleida, Spain
- Leicester, UK – Sedation matters study day
- Barretos, Brazil – workshop
- Society of Critical Care Medicine Congress San Francisco
- Panama - Symposium International Critical Care Congress Panama
- Regensburg - Symposium Regensburg
- France: - Live-web symposium "Two cities" Paris & Clermont Ferrand
- Symposium Bayreuth
- Bielefelder Intensiv- und Infektiologie-Tag Bielefeld
- Sedaconday Greifswald
- SEMICYUC inhaled sedation Webinar Spain
- Tag der Intensivtherapie“ Mönchengladbach
- Intensivpflege Kongress Kassel
- Round table SOGAMIUC congress Ferrol
- Deutsche Anästhesie Congress Düsseldorf
- DGIIN Congress Berlin
- Symposium Charité Berlin
- Symposium SEMICYUC Congress Malaga
- Annual Congress of the Mexican College of Critical Care Medicine (COMMEC), Mexico
- XII International Symposium on Critical Care and Ventilatory Support, Colombia
- XLIX Annual Refresher Course in Anesthesiology and Operative Medicine Mexico
- European Society of Intensive Care Medicine (ESICM) offsite symposium
- Symposium SRLF Paris
- Nursing inhaled sedation workshop SEEIC Malaga
- ECMO round table London, UK
- Bavaria Anaesthesia Days, Germany
- ABSSAT – Anaesthesia days Berlin and Eastern Regions, Germany
- Weimar Sepsis Update, Weimar, Germany
- East Midlands Critical Care Conference, UK
- ECMO inhaled sedation workshop, Mexico City, Mexico
- SFAR congress Paris, France
- ICU Congress St Pölten, Austria
- Inhaled sedation workshop, Istanbul, Turkey
- Congreso de Medicina, Veracruz, Mexico
- Sociedad Castellano-Leonesa de Medicina Intensiva Spain
- SOMIANA: Sociedad Madrileña Intensiva
- DIVI Congress Germany
- Symposium Frankfurt

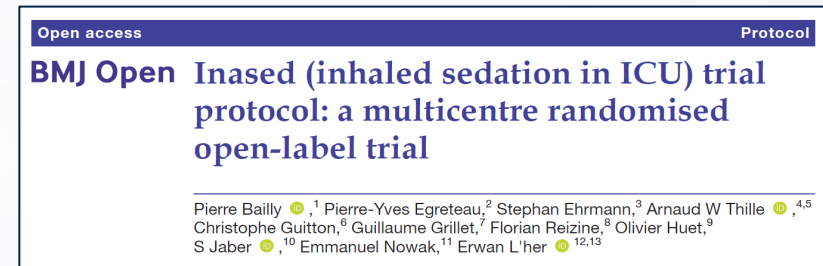


The investigator-led study SESAR was completed in Q4, 2023

- **Sevoflurane in ARDS (SESAR) study**
 - Enrolment completed (700 patients)
 - Results expected in HY2 2024
 - Sedana Medical not involved in analysis



-
- **Isoflurane and delirium (INASED) study**
 - 180 patients recruited to date (250 planned)



Financial result in Q4 2023

Net sales **Q4'23:** 45 (36) MSEK, +24% y/y (+18% excl. FX).

- Sales in Germany increased by 15% y/y (9% excl. FX), driven by a mix of growth from existing and new/re-activated customers.
- Other direct markets showed growth of 62% y/y (54% excl. FX), also driven by a mix of growth from existing and new/re-activated customers.
- Our distributor markets increased by 25% y/y (18% excl. FX) driven mainly by European distributors.

Gross Profit **Q4'23:** 31 (26) MSEK

Gross Margin **Q4'23:** 70 (72) %

- We have experienced cost increases for materials and components, and our gross margin is slightly down from 72% in Q4 2022.
- Sequentially the gross margin of 70% is in line with our previous quarter.

EBITDA **Q4'23:** -9 (-18) MSEK

- Opex of 44 MSEK in Q4'23, a decrease of 5 MSEK vs Q4'22 (-10%). At fixed FX, the reduction is 6 MSEK (-12%). In Q4, close to 2 MSEK were related to severance payments.
- We continue our efforts to streamline HQ functions and reduce spending on consultants, external vendors, and conferences.

Staff, incl consultants, per Dec 31 2023: 86 (95 at Dec 31 2022).

Net sales (MSEK, 12m rolling)



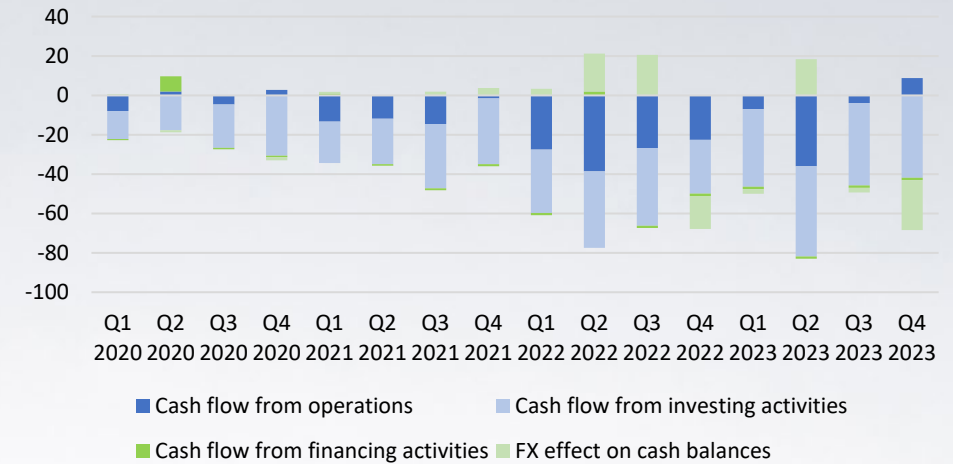
Gross profit development (12m rolling)



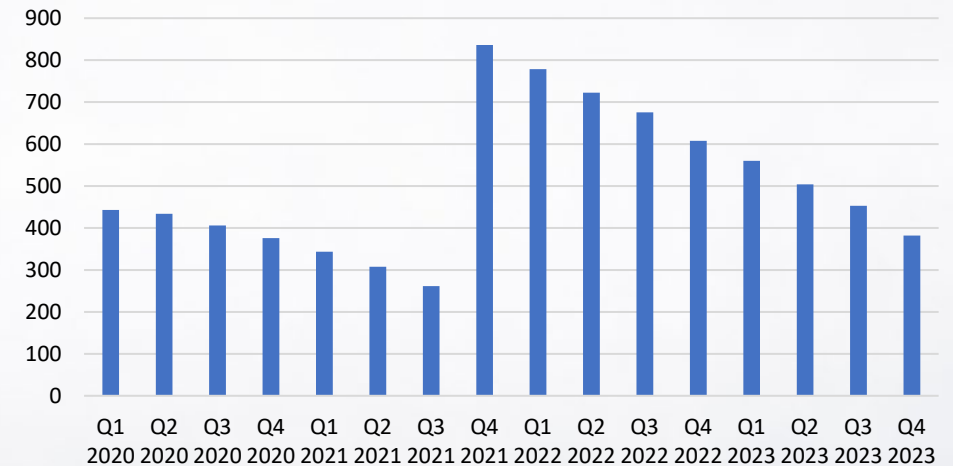
Cash flow, cash balance and short-term deposits

- **Cash and short-term deposits per December 31 2023:** 382 MSEK compared to 453 MSEK at the beginning of the quarter. Decrease driven by investments in capitalized development expenditures.
- **Cash flow from operations Q4'23:** 9 (-23) MSEK, including interest received of 9 MSEK.
- **Cash flow from investments Q4'23:** -42 (-27) MSEK, whereof the majority are investments in capitalized development expenditures.
- **Total cash flow Q4'23:** -34 (-51) MSEK.
- **Liquidity management**
 - Approx. 75% 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 Dec 31, 2023

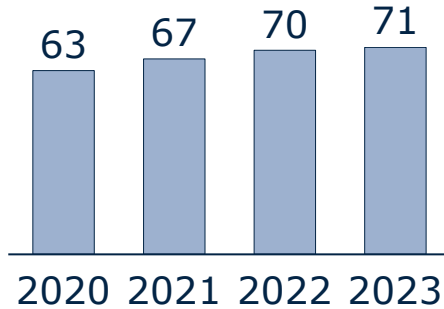
	No of shares	Share
Linc AB	10,111,030	10.2%
Anders Walldov direct and indirect (Brohuvudet AB)	10,000,000	10.1%
Swedbank Robur Funds	9,519,013	9.6%
Handelsbanken Funds	6,268,654	6.3%
Öhman Funds	4,382,095	4.4%
Ola Magnusson direct and indirect (Magiola AB)	4,312,098	4.3%
Sten Gibeck	4,196,597	4.2%
Highclere International Investors LLP	3,310,435	3.3%
Premier Miton Investors	2,671,820	2.7%
AMF Pension	2,491,000	2.5%
Berenberg Funds	1,983,744	2.0%
Third Swedish National Pensis Fund	1,735,989	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Amundi	1,344,738	1.4%
Avanza Pension	1,177,928	1.2%
Fifteen largest shareholders	65,171,605	65.6%
<i>Others</i>	<i>34,165,355</i>	<i>34.4%</i>
Total	99,336,960	100.0%

Investment case - why Sedana Medical?



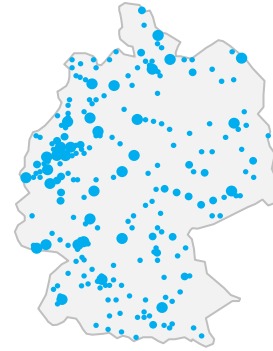
High gross margins

FY GM, in percent



- Robust gross margins of our portfolio
- 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 and short-term deposits

In SEK, end of Q4

382M

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

Q&A

