Q4 and Full Year 2022 Report

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February 16, 2023

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.

Q4 2022 Highlights

Financial performance

- Net sales of **36 MSEK** (-23%), explained by a significantly lower number of intubated patients compared with the pandemic
- Strongest quarter in 2022
- Gross margin of **72%** (up from 71%)
- End-of-year cash balance of **SEK 608 million**

European launches

- Sedaconda (isoflurane) now **approved in 17 countries**, only UK is pending
- **Pricing and reimbursement processes progressing**: signed agreement with German payor association for list price in Germany, received pricing and reimbursement approval in Italy, in active discussions with Spanish authorities

U.S. clinical program

- INSPiRE-ICU trials ongoing, **close to 20 sites actively recruiting**
- **Fast Track Designation** by FDA
- Aiming at **US launch in early 2025**

Other progress

- **Completed recruitment of SED-002** paediatric study
- Listed on **Nasdaq Stockholm** Main Market in January

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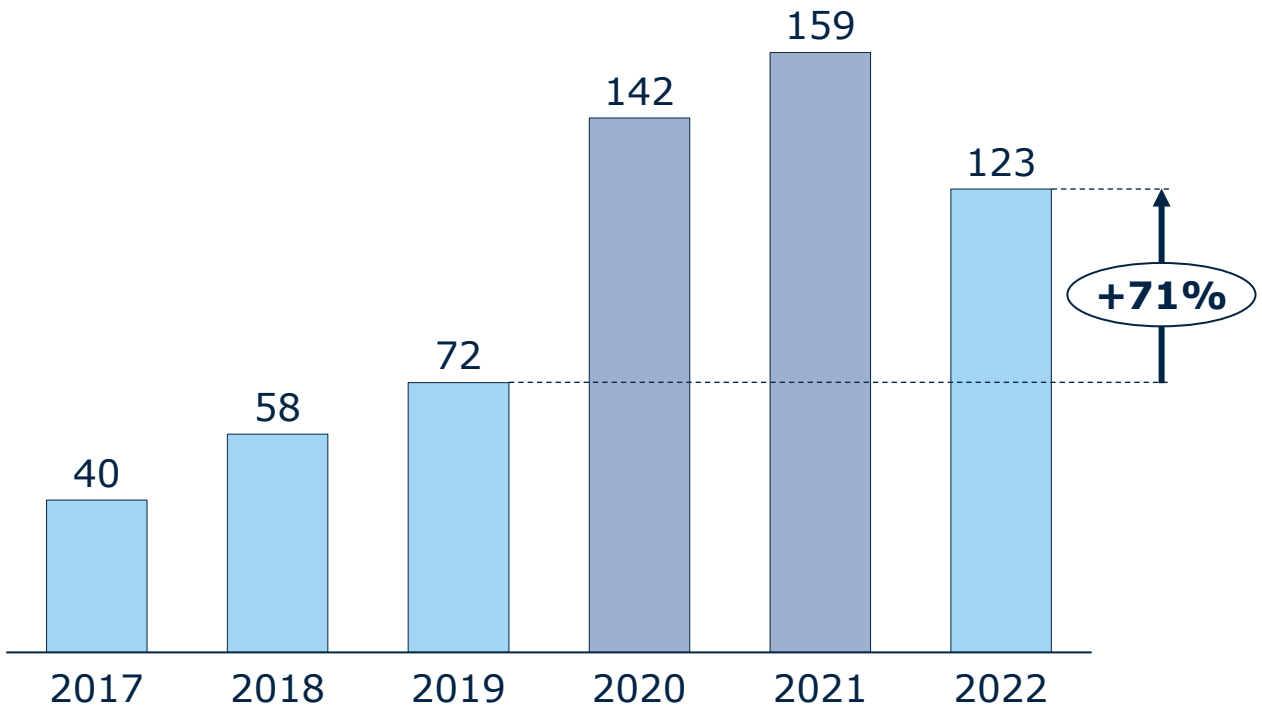
Taking a through-cycle perspective: 2022 sales were ~70% higher than pre-pandemic levels

Full year 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

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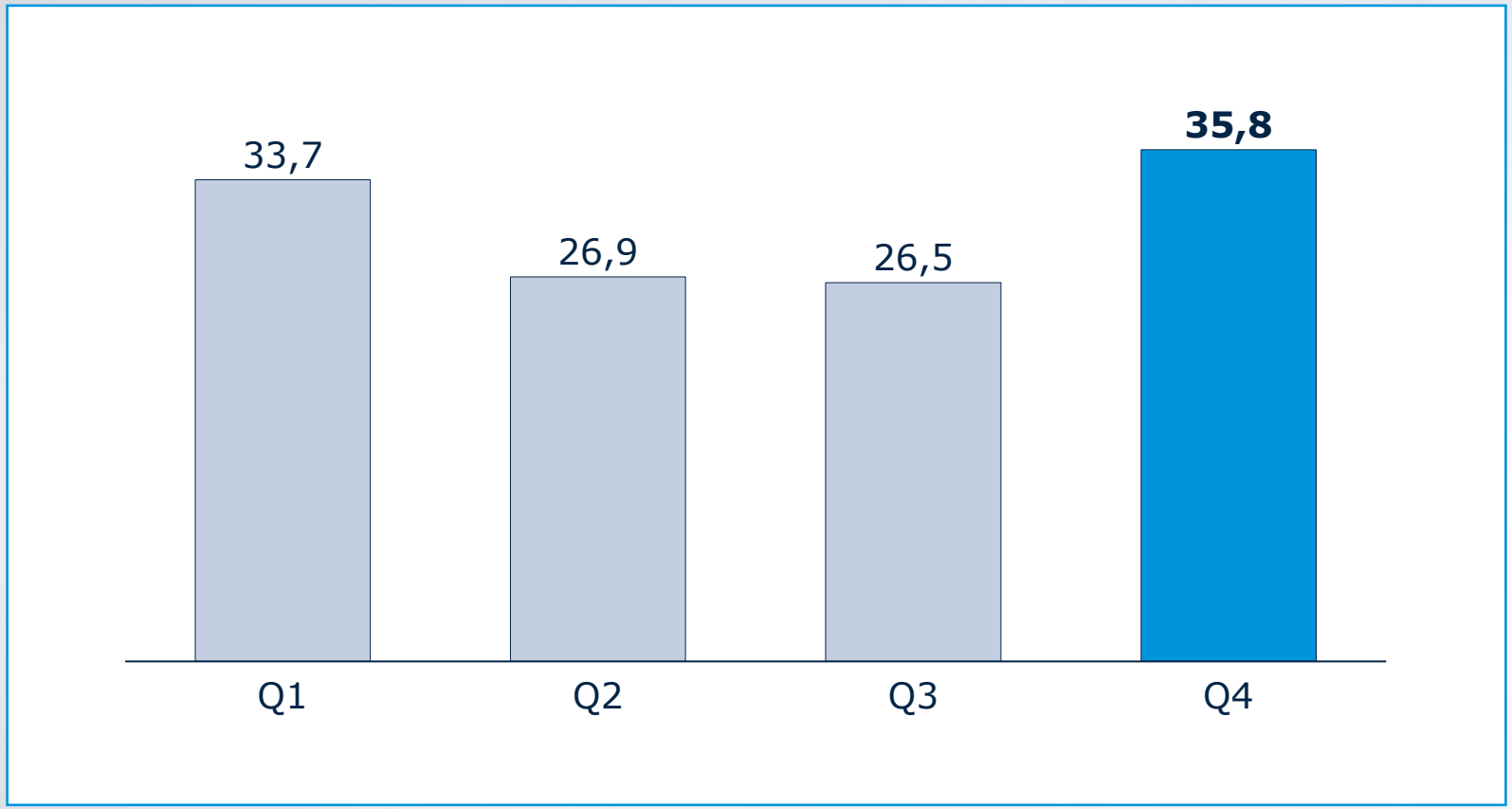
Q4 was our strongest quarter in 2022

Quarterly sales 2022

SEK million



Comments

- In general, Q1 and Q4 are the strongest quarters for Sedana Medical due to higher levels of respiratory infections
- Q2 and Q3 are weaker due to seasonality of ICU cases
- Q4 was slightly stronger than Q1 despite some remaining Covid-19 effect in Q1

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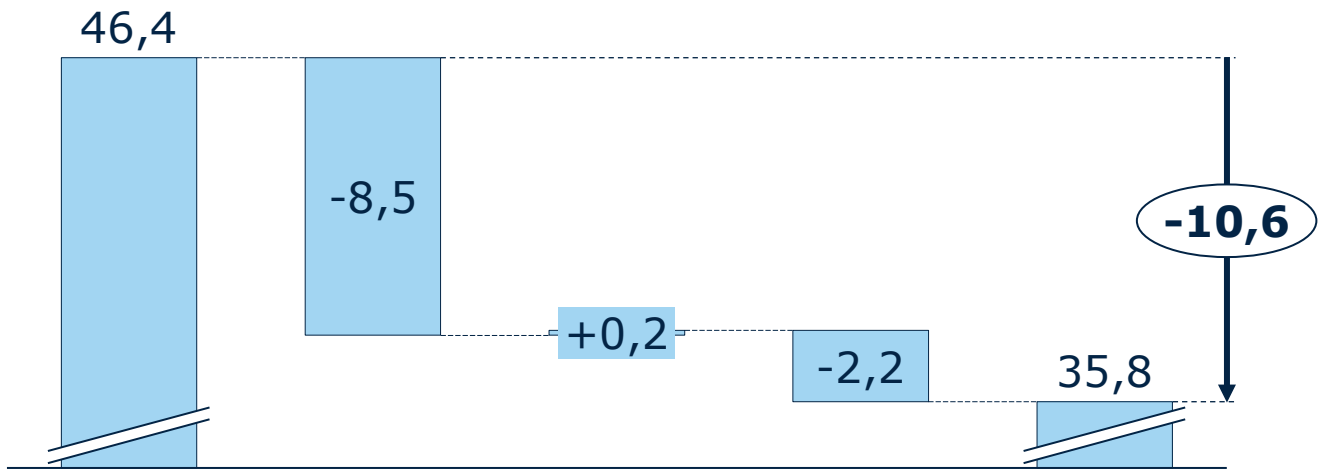
The sales gap vs. 2021 is explained by lower sales in Germany and Distributor Markets

Sales bridge Q4 2022 vs. Q4 2021

SEK million



Fixed Fx (in SEK)	**-30%** (-25%)	**-4%** (+2%)	**-47%** (-42%)

Comments

Germany:
Decline from last year's record quarter, caused by significantly less ICU patients

Other direct markets:
Flat sales development versus strong Q4 of last year, Spain showing good growth

Distributor markets:
Continued negative effect from stock levels at distributor and hospital level, primarily in select S. American countries

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Two growth horizons ahead: Europe and the US

Europe

- Direct presence in Germany, UK, France, Spain, Benelux, Nordics
- Approval in 17 European countries to date
- Sedaconda (isoflurane) available in Germany, France, Sweden, Norway, the Netherlands and Slovenia
- Registration ongoing in UK

- Clinical Phase III trials ongoing, close to 20 sites actively recruiting
- FDA Fast Track Designation
- Highest-potential market
- Launch expected early 2025
- Decided to build own US infrastructure

United States

1 Source: American Hospital Association https://www.aha.org/statistics/fast-facts-us-hospitals

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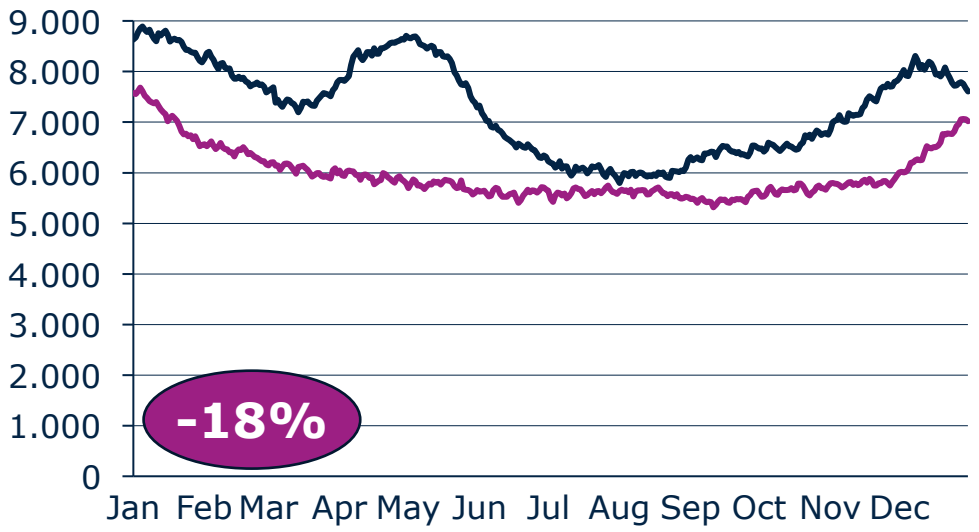
We saw less ventilated patients in the ICU throughout 2022 (Germany example)

ICU patients[1]

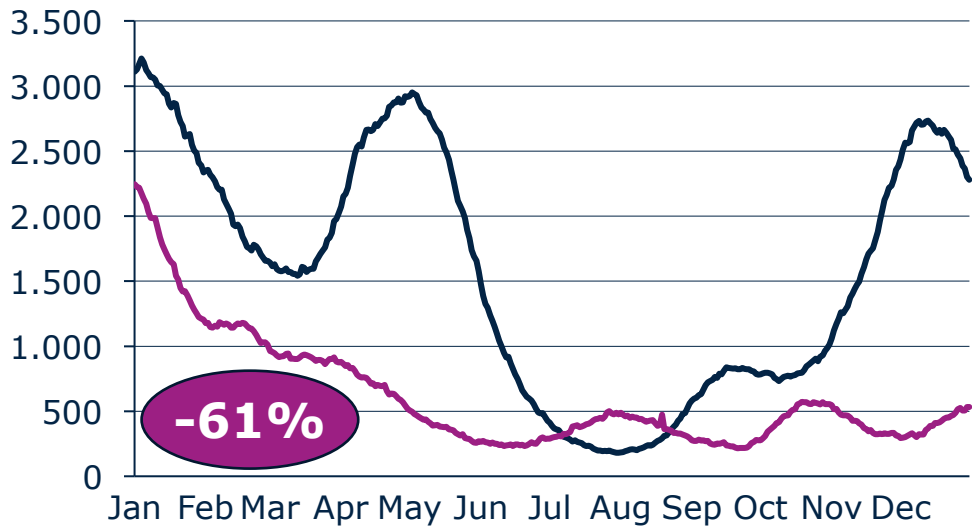
Germany, average per day



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

Ventilated Covid-19 patients

Germany, average per day



1 Includes High-Care and ECMO setting
Source: divi daily reports

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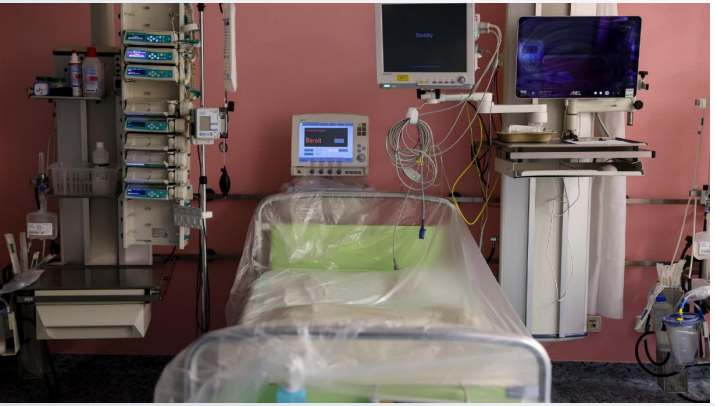
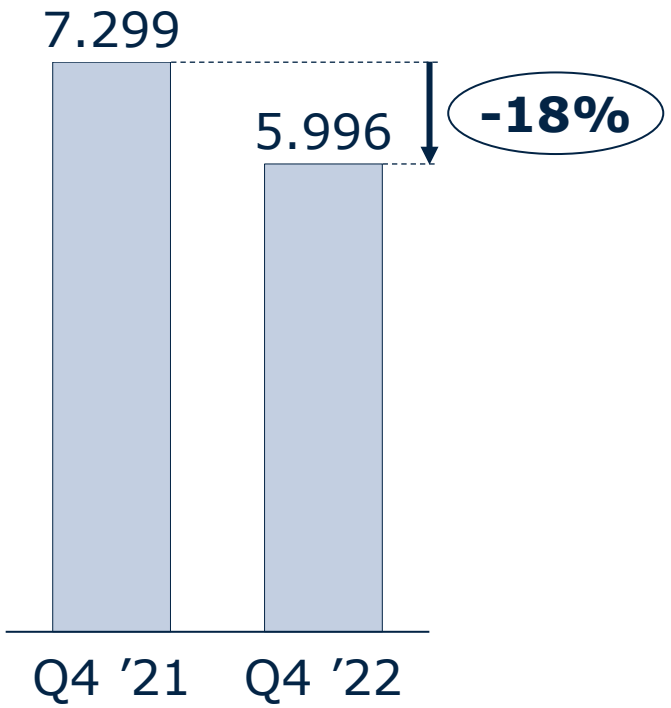
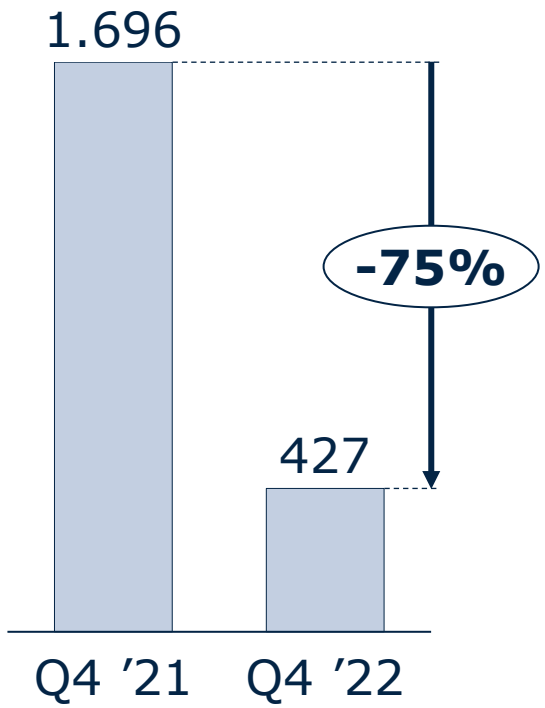
In Q4, the decline in ventilated Covid-19 patients was even more significant than in previous quarters



ICU patients[1]
Germany, average per day



Ventilated Covid-19 patients
Germany, average per day



1 Includes High-Care and ECMO setting
Source: divi daily reports

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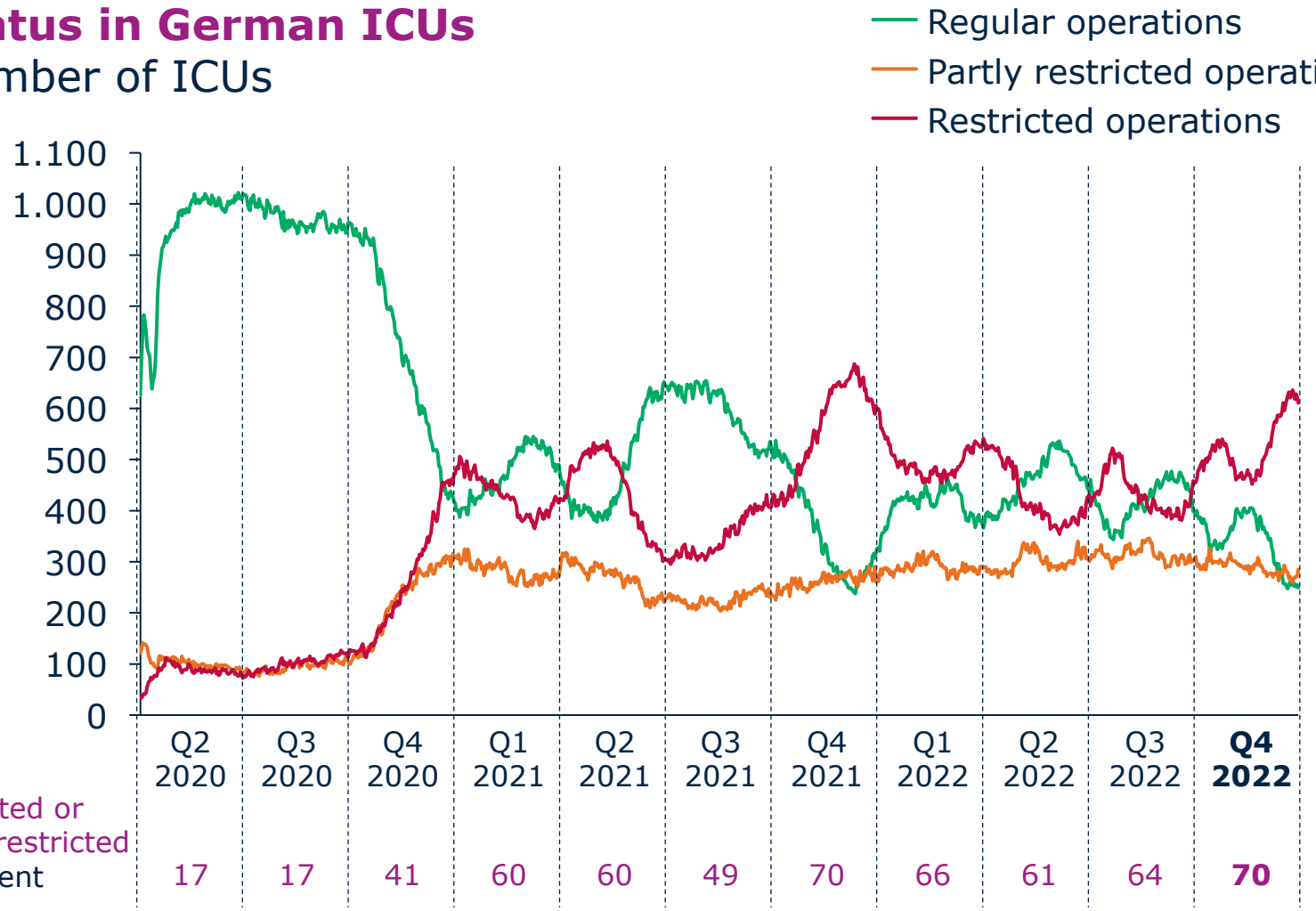
Our ICU customers are still operating under constrained conditions (Germany example)

Status in German ICUs

Number of ICUs



	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	**Q4 2022**
Restricted or partly restricted in Percent	17	17	41	60	60	49	70	66	61	64	**70**

Source: divi ICU survey

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Temporary market headwinds have affected 2022 performance

Less patients

Staff shortages

Trends

- Significantly less intubated ICU patients throughout 2022
  - Less Covid patients
  - Hygiene measures
  - Postponed surgeries
  - Lower ICU capacity

- Hospitals all over the world are plagued with staff shortages
  - Exodus during/after Covid
  - Burn-out
- Staff qualification decreasing

Implications for Sedana

- Negatively affecting sales (despite increasing market penetration)

- Less openness to introduce new therapies
- Access issues in some countries / hospitals
- Higher training need

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Outlook – customers expect a more normalized 2023

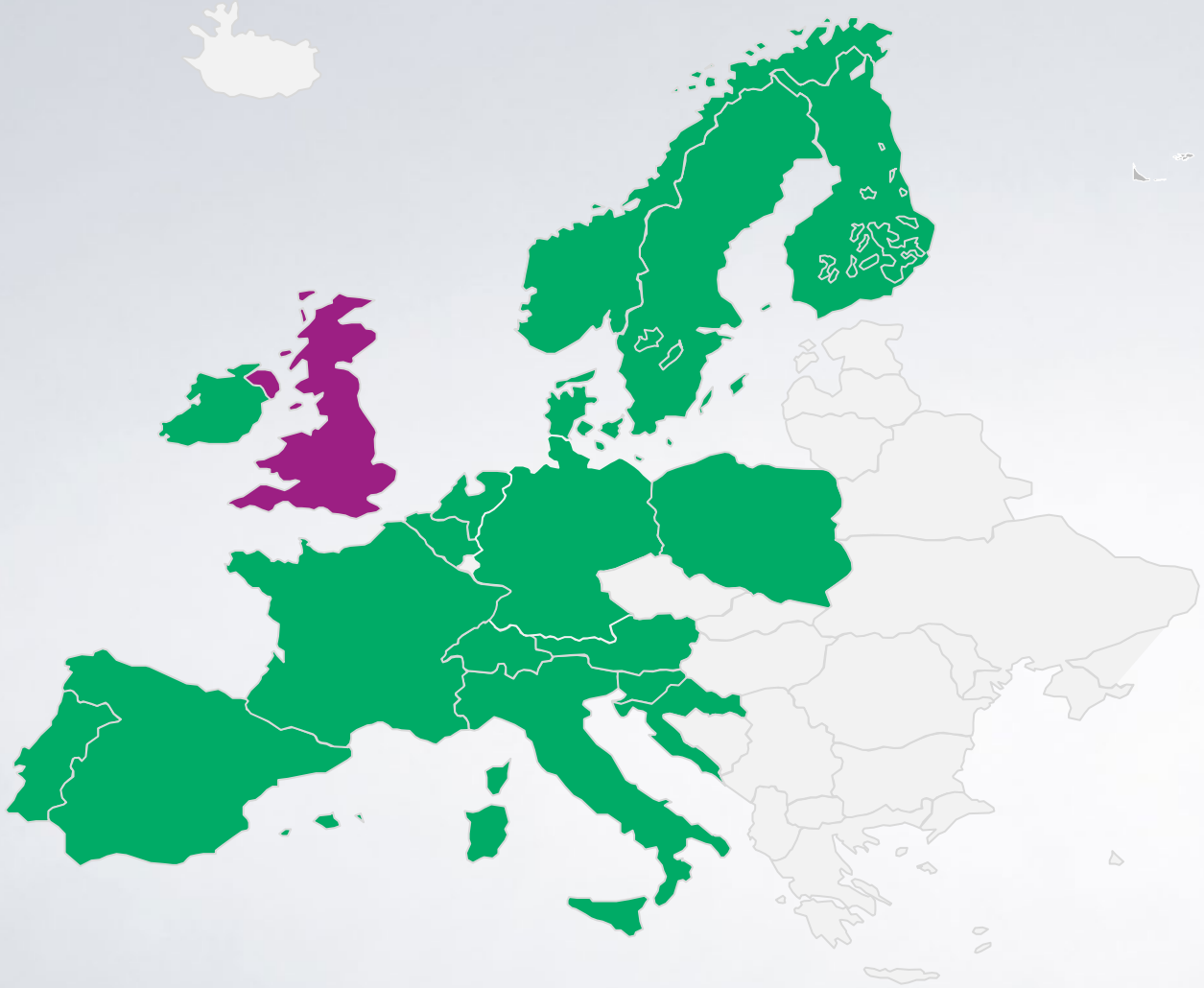
Context

- 2022 performance has been heavily influenced by a temporary contraction of our addressable market
- Comparisons vs. prior 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

- In 2023, we expect somewhat more normalized conditions
  - Consensus among our customers is that patient numbers will gradually normalize during 2023
  - Comparator numbers (2022) are generally less influenced by Covid, while Q1 2022 still saw the "tail" of the last Covid-19 wave
  - Some market headwinds (specifically staff shortages) may take longer to resolve

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



Decentralized procedure (1st wave)

- ☑ Austria
- ☑ Belgium
- ☑ Croatia
- ☑ Denmark
- ☑ Finland
- ☑ France
- ☑ Germany
- ☑ Ireland
- ☑ Netherlands
- ☑ Norway
- ☑ Poland
- ☑ Portugal
- ☑ Slovenia
- ☑ Spain
- ☑ Sweden

Second wave countries

- ☑ Switzerland
- ☑ Italy
- ☐ UK

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

Launches to date

- Product is available in Germany, France, Sweden, Norway, the Netherlands (all direct) and Slovenia (through distributor)

P&R[1] processes

- Germany: finalized contract with German payor association (GKV-SV) to set the list price for Sedaconda (isoflurane) after first year of free pricing
- Spain: in active discussions with Spanish authorities after P&R approval was not granted in Q4
- Italy: received reimbursement approval

Outstanding approval

- UK is the only outstanding regulatory approval for Sedaconda (isoflurane)
- MHRA approval further delayed (now expecting an update in March) due to continued high workload at MHRA

1 Pricing and Reimbursement

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United States: FDA has granted Sedana Medical Fast Track Designation

Update

- Our US development program has received Fast Track Designation by FDA
- 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

Two clinical trials are ongoing 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

INSPiRE·ICU

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

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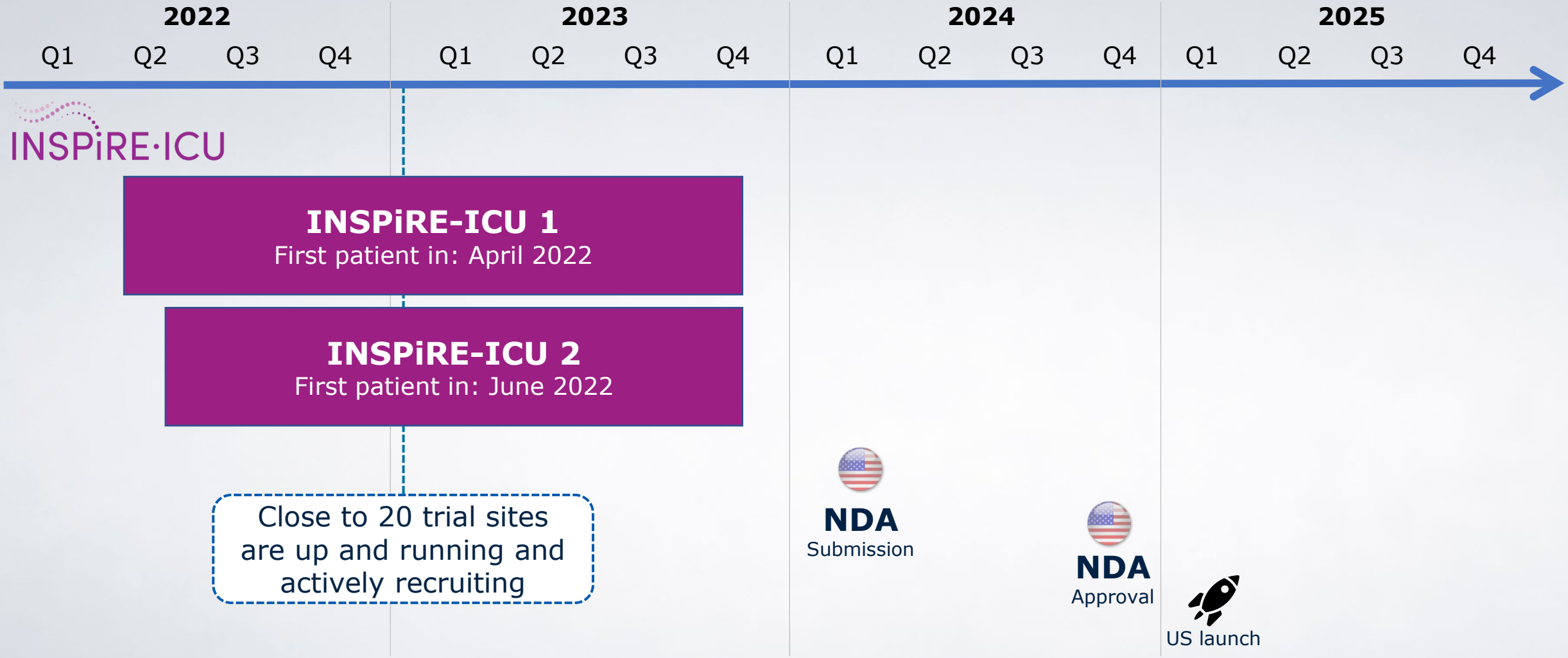
US clinical program with an aim to launch early 2025



INSPiRE·ICU

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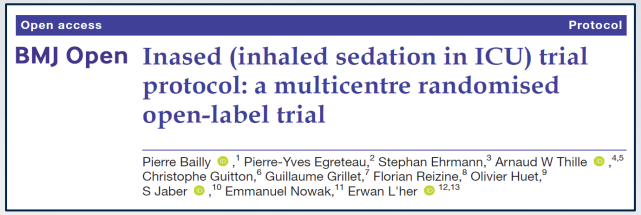
Investigator-initiated trials

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


Open access Protocol

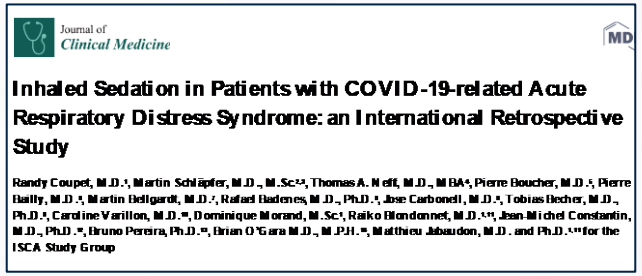
BMJ Open **Inased (inhaled sedation in ICU) trial protocol: a multicentre randomised open-label trial**

Pierre Bailly ,[1] Pierre-Yves Egreteau,[2] Stephan Ehrmann,[3] Arnaud W Thille ,[4,5] Christophe Guitton,[6] Guillaume Grillet,[7] Florian Reizine,[8] Olivier Huet,[9] S Jaber ,[10] Emmanuel Nowak,[11] Erwan L'her [12,13]

- **Sevoflurane in ARDS (SESAR) study**
  - 616 patients recruited to date (700 planned)
  - Enrollment completion expected in 2023


Journal of Clinical Medicine MDPI

- **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


Journal of Clinical Medicine

Inhaled Sedation in Patients with COVID-19-related Acute Respiratory Distress Syndrome: an International Retrospective Study

Randy Coupet, M.D.[1], Martin Schläpfer, M.D., M.Sc.[1,2], Thomas A. Neff, M.D., MBA[1], Pierre Boucher, M.D.[1], Pierre Bailly, M.D.[1], Martin Bellgardt, M.D.[1], Rafael Badenes, M.D., Ph.D.[1], Jose Carbonell, M.D.[1], Tobias Becher, M.D., Ph.D.[1], Caroline Varillon, M.D.[3], Dominique Morand, M.Sc.[1], Raiko Blondonnet, M.D.[1,4], Jean-Michel Constantin, M.D., Ph.D.[3], Bruno Pereira, Ph.D.[5], Brian O'Gara M.D., M.P.H.[6], Matthieu Jabaudon, M.D. and Ph.D.[1,4] for the ISCA Study Group

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Recruitment has been completed for our pediatric 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 in Q2 2023
- Assuming positive results, approval in Europe is expected in Q1 2024
- The data exclusivity extension to 2031 for the adult indication is independent from the paediatric indication approval

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Inhaled sedation presentations worldwide 2022
Ramp-up of live activities post-Covid restrictions

- Belfast, Ireland – Association of Anaethesists in Great Britain and Ireland F2F
- Cymdeithas Gofal, Wales – Welsh Society of Intensive Care symposium
- Panamerica and Iberia – FEPIMCTI (Critical Care): inhaled sedation webinar
- Mexico – Reanimation in States of Shock Transdisciplinary Approach webinar
- Bodensee, Germany – BANIS Anesthesia and Intensive Care – F2F
- Utrecht, Netherlands – Topics in ICU Multidisciplinair congres - F2F
- Hamburg, Germany – Hamburger Einführungskurs Intensivmedizin F2F
- Tiel, Netherlands – MMM respiratoire insiffëntie & beadming F2F
- Santiago do Compostola, Spain – SEDAR symposium
- Endhoven, Netherlands – IHTMS symposium
- Guadalajara, Mexico – COMMEC symposium
- Berlin, Germany – HAI der DGAI symposium
- Paris, France – SFAR – symposium and F2F
- Brussels, Belgium – ISICEM symposium
- Hamburg, Germany – DIVI Symposium
- Lindau, Germany – BANIS symposium
- Sevilla, Spain – SEMICYUC symposium
- Örebro, Sweden – SFAI symposium
- Paris, France – ESICM symposium
- Paris, France – SRLF symposium
- Oslo, Norway – SSAI symposium
- Singapore – APICS - Workshop
- Essen, Germany – Sedaconday

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Financial result in Q4 2022

Net sales **Q4'22:** 36 (46) MSEK, -23% y/y (-28% excl. FX)
FY'22: 123 MSEK

- Sales in Germany decreased by 25% y/y (-30% excl. FX), due to fewer ventilated ICU patients (ICUs still had high levels of ventilated Covid-19 patients in Q4'21)
- Other direct markets showed growth of 2% y/y (-4% excl. FX), despite similar market headwinds, particularly driven by Spain
- Sales in Distributor markets decreased in Q4 due to continued high stock levels after the pandemic, mainly in S. America

Gross Profit **Q4'22:** 26 (33) MSEK
Gross Margin **Q4'22:** 72 (71) %

- The improved gross margin is mainly an effect of higher prices and lower freight costs

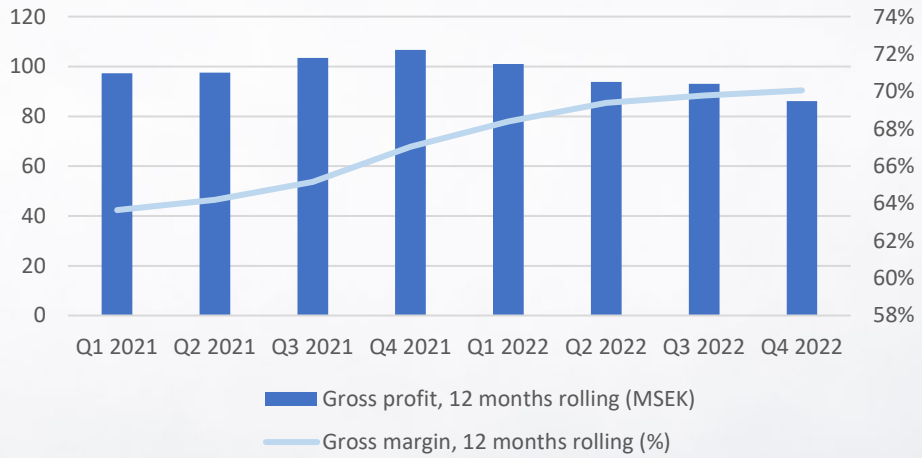
EBITDA **Q4'22:** -18 (-13) MSEK

- Opex of 49 MSEK in Q4'22, lower than Q4'21 (52). In Q4'22, the Nasdaq uplisting project accounted for 4 MSEK of opex.
- Streamlined admin functions (HR, IR, Accounting, Controlling)
- Reduced spending on consultants, external vendors, conference sponsorships

Staff, incl consultants, per Dec 31, 2022: 95 (107 at Dec 31 2021)

Net sales (MSEK, 12m rolling)

Gross profit development (12m rolling)



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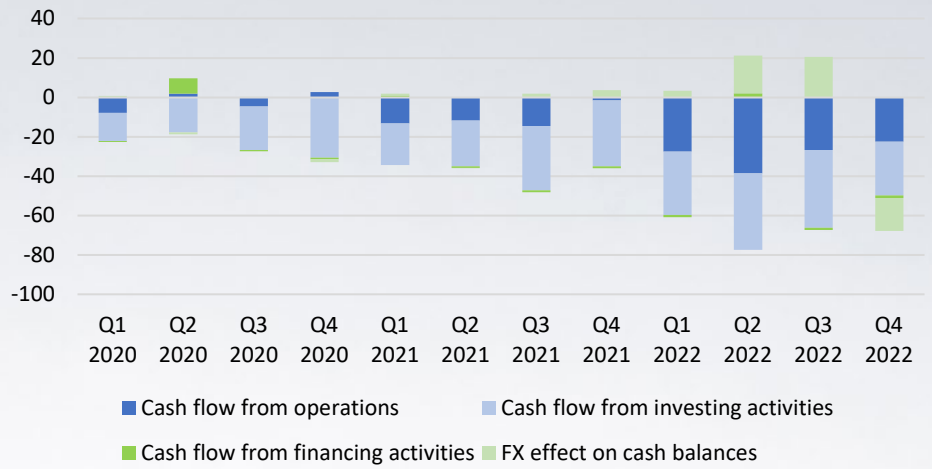
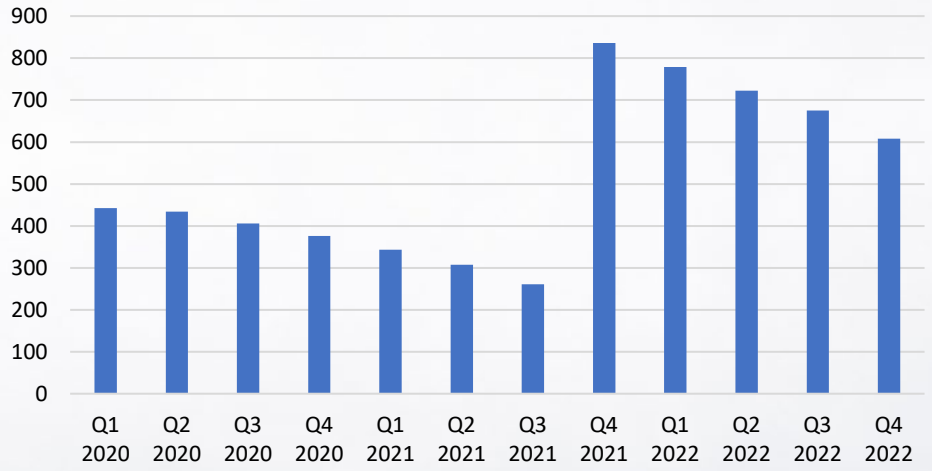
Cash flow and cash balance

- **Cash flow from operations Q4'22:** -23 (-2) MSEK, of which cash flow from working capital of -14 MSEK mainly related to negative cash flow from short-term liabilities (accrued expenses)
- **Cash flow from investments Q4'22:** -27 (-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 Q4'22:** -51 (571) MSEK
- **Cash balance per Dec 31, 2022:** 608 MSEK compared to 676 MSEK at the beginning of the quarter (including -17 MSEK FX effect)
- **Liquidity management**
  - Approx. half of our cash has been converted to USD
  - In early 2023 we placed approx. half our cash in longer-term deposits for better interest rate (both SEK and USD)
- **We expect to be fully financed until break-even and to execute on our strategic plan**
- **No long-term debt**
- **Move to the Nasdaq main list completed in January**

Cash development (MSEK, excl 2021 cap. raise)



Cash position (MSEK)



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Largest shareholders December 31, 2022

	No of shares	Share
Linc AB	10 111 030	10,2%
Swedbank Robur Funds	9 519 013	9,6%
Handelsbanken Funds	8 667 052	8,7%
Anders Walldov direct and indirect (Brohuvudet AB)	8 500 000	8,6%
Ola Magnusson direct and indirect (Magiola AB)	4 462 098	4,5%
Sten Gibeck	4 286 276	4,3%
Öhman Funds	4 139 985	4,2%
Highclere International Investors LLP	2 823 538	2,8%
Berenberg Funds	2 714 675	2,7%
Bank of Norway	2 637 258	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%
Coeli	1 235 368	1,2%
Philip Earle	1 099 491	1,1%
Fifteen largest shareholders	66 089 237	66,5%
Others	*33 247 723*	*33,5%*
Total	**99 336 960**	**100,0%**

Berenberg & DEKA shareholding reported per year-end 2021

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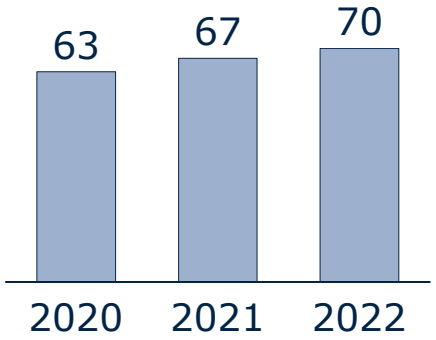
Investment case - why Sedana Medical?

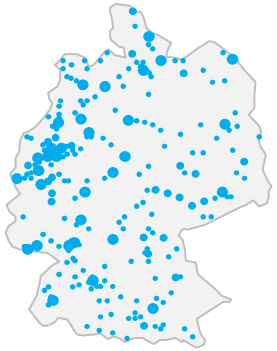
High gross margins

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 end of 2022
In SEK

608M

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

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Q&A