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Q2 2023 Report

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July 21, 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.

Q2 Highlights: we have made progress against our 3 priorities for the year

2023 priorities

Q2 update

Achieve growth in our ex-US business

- **37.3 MSEK net sales** in Q2 (+39% / 27% excl. Fx)
- **36%** growth in **Germany** (49% in SEK)
- **52%** growth in **other direct markets** (65% in SEK)
- **-44%** decline in **distributor markets** (-38% in SEK) due to lack of orders from S. America

Get closer to break-even ex-US

- Gross margin of **71%** (up from 70%)
- EBITDA of -10.7 MSEK (**improved by 55%**)
- Cash and short-term deposits of **504 MSEK**

Make headway towards US approval

- INSPiRE-ICU clinical trials **progressing** according to plan
- **Fast Track Designation** by FDA
- **Adjusted submission plan** following FDA feedback (NDA submission expected Q1 '25)

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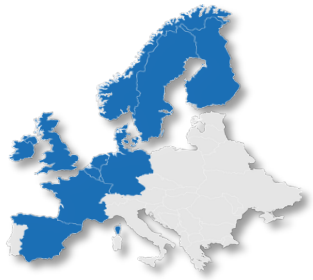
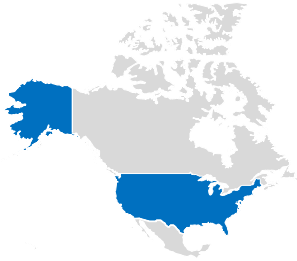
Updated market potential and financial targets

Market potential in prioritized geographies





	Europe (direct markets)	**United States**
Ventilated adult ICU patients p.a.	~1 million	>2 million
Market potential inhaled sedation (low- to mid-single digit growth p.a.)	**3-4** BSEK	**10-12** BSEK

Penetration rates 2022

- Germany: ~10%
- Best territories in Germany: ~20%
- Other direct markets: ~1%

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

145-155 MSEK
Net Sales in 2023

EBITDA

Break-even
in our ex-US business during 2024

Sources: Europe: based on publicly available data by country and Sedana Medical analysis
USA: based on market assessment performed by external consultant company (Clarion Health)

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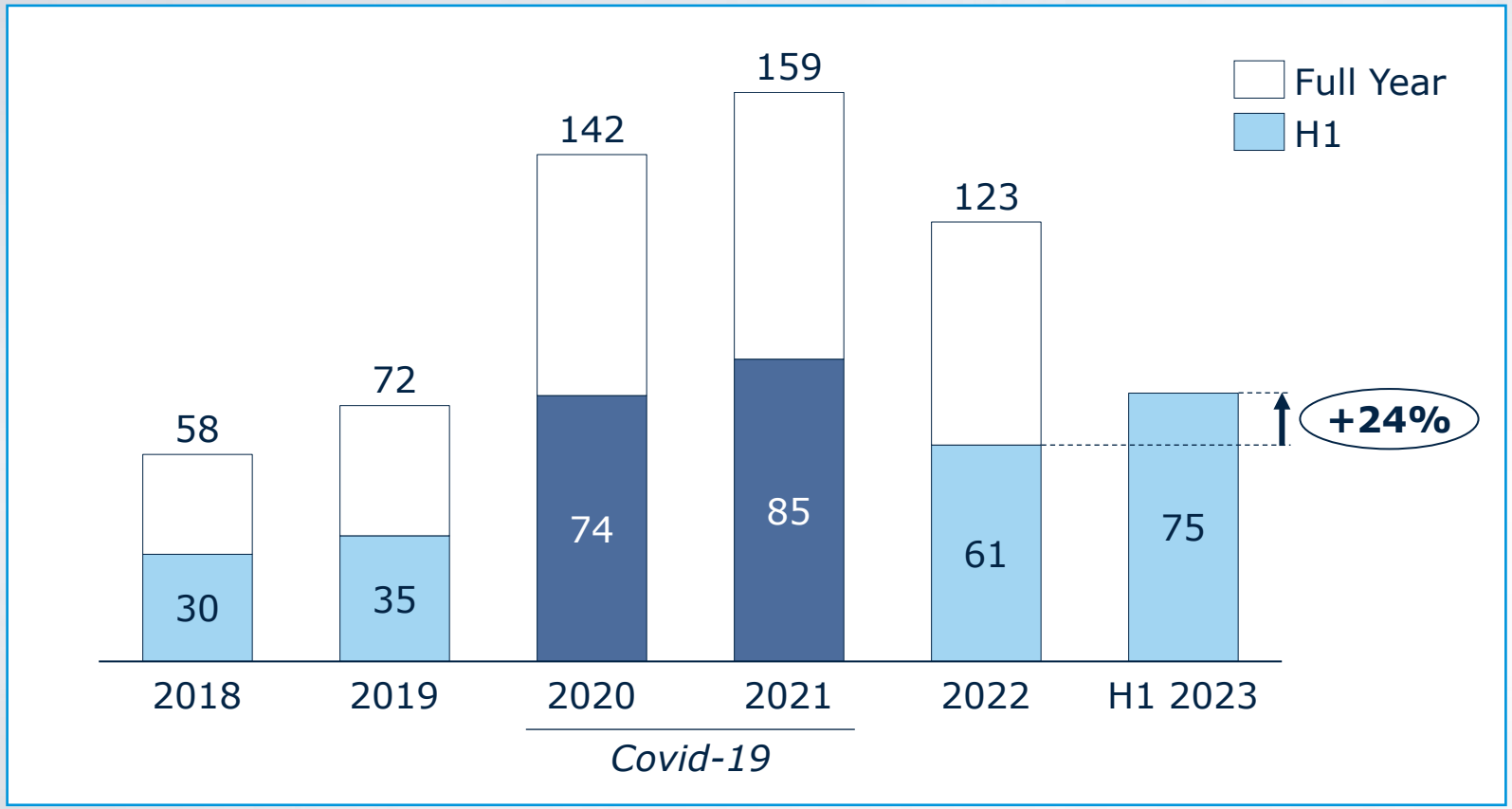
We have returned to growth after the Covid-19 pandemic

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 H1 2023 (and higher sales than the Covid-19 Year 2022)

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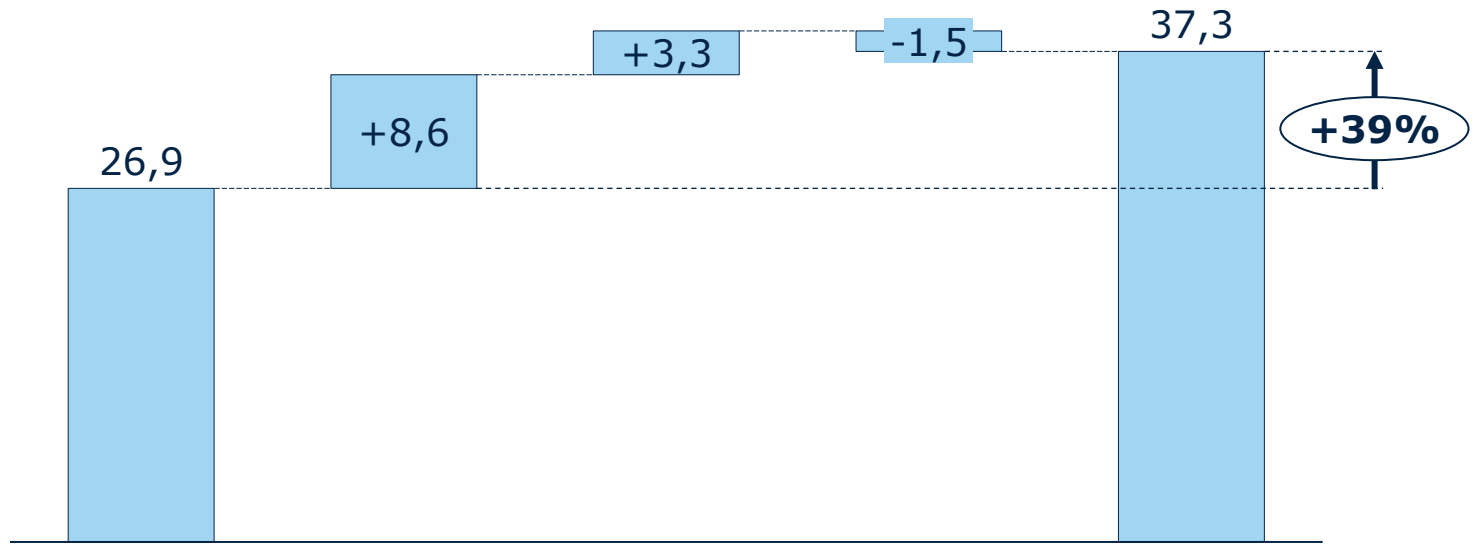
In Q2, we have shown growth in our direct markets, while distributors have declined

Sales bridge Q2 2023 vs. Q2 2022, SEK million



Performance drivers

Germany:

- Majority of YoY growth from increased penetration in existing customers
- Further positive impact from new customers

Other direct markets:

- Majority of YoY growth from new customers
- In addition, increased penetration of existing customers

Distributor markets:

- Gap explained by lack of orders from main S. American distributor
- Last order received Q2 ’22, so Q2 will be the last quarter affected by this effect

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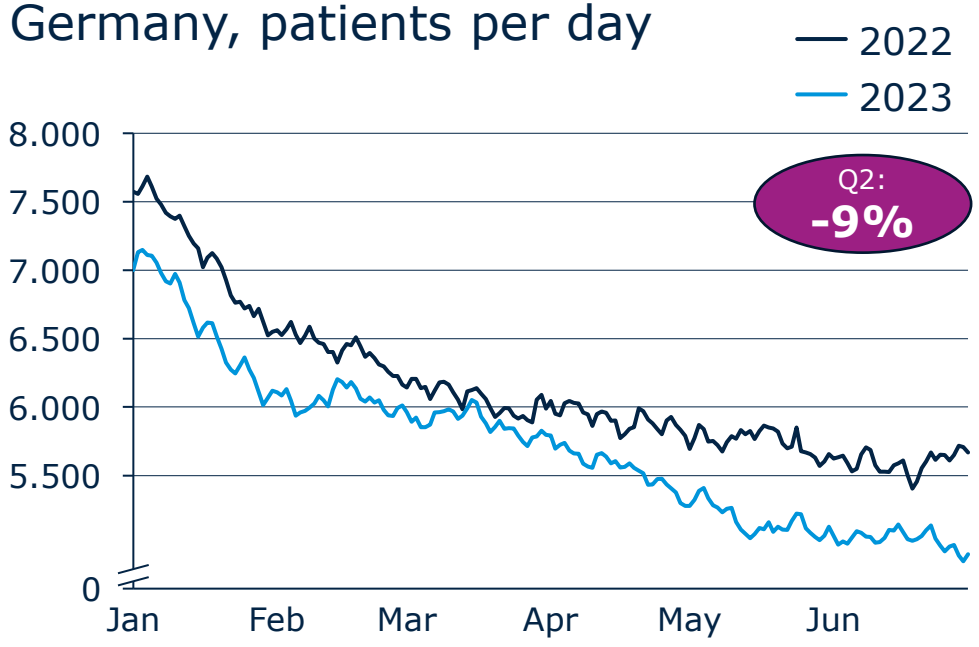
We continued to see less ventilated patients compared to 2022 in German ICUs during Q2

ICU patients[1]

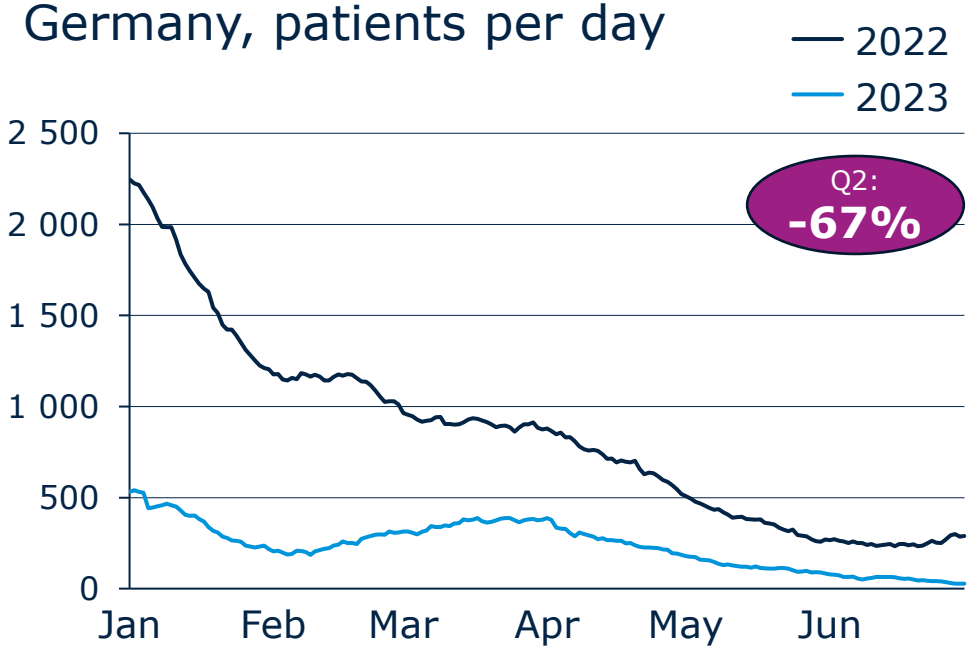
Germany, patients per day



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

Ventilated Covid-19 patients

Germany, patients per day



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

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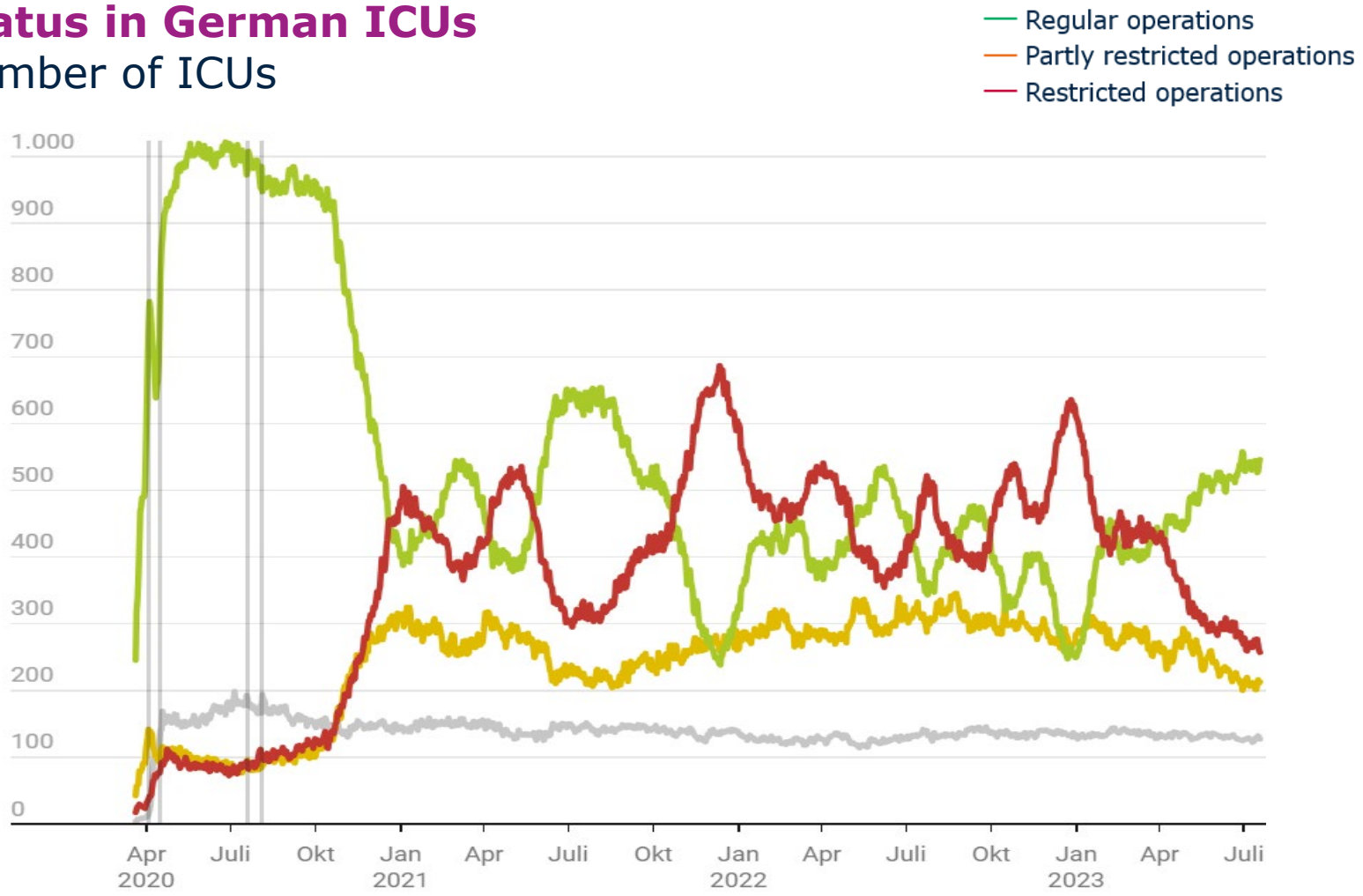
Less ICUs have reported restricted operations in Q2 due to lower patient numbers – facilitating access to customers

Status in German ICUs

Number of ICUs



Source: divi ICU survey

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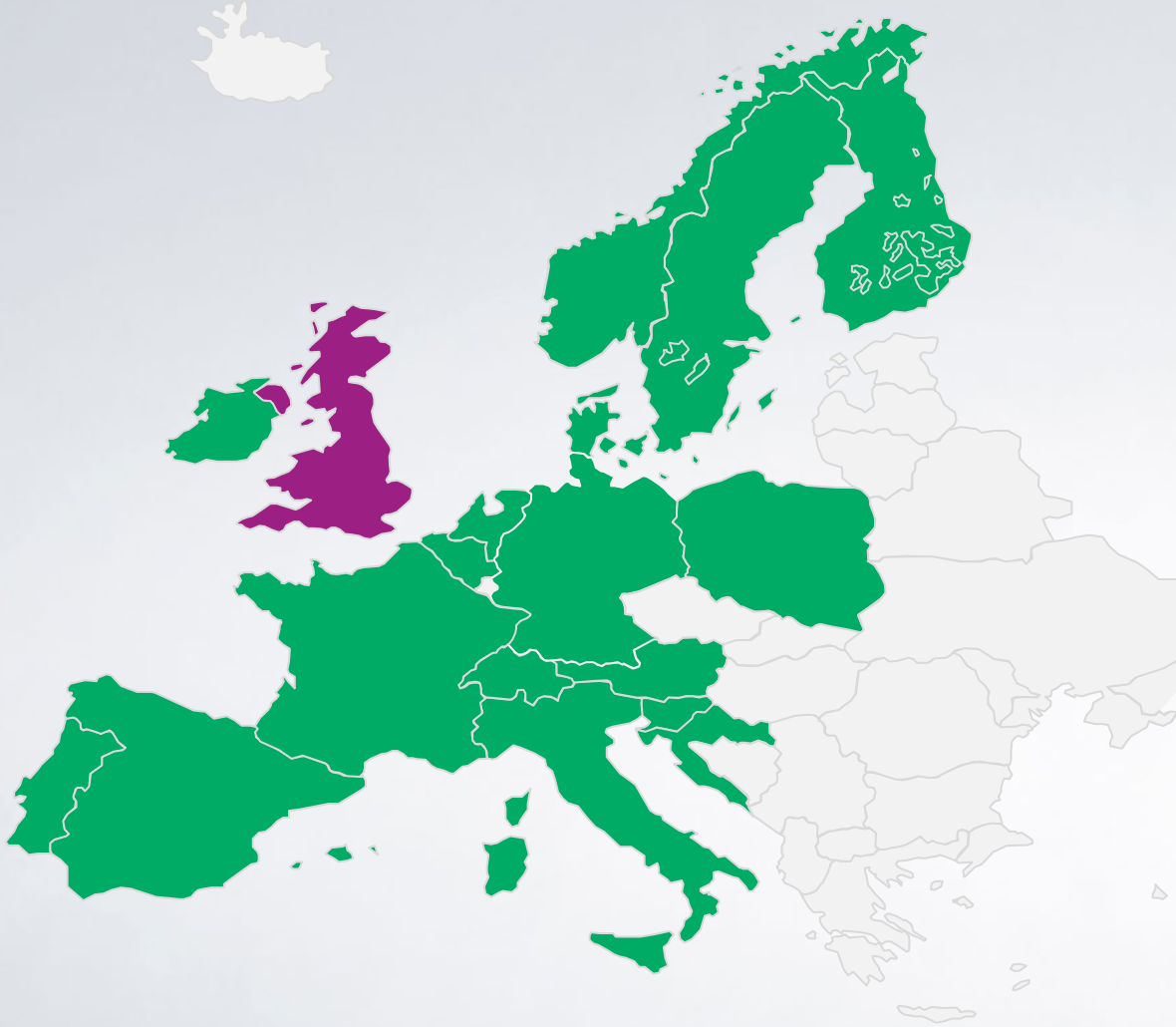
Regulatory approvals for Sedaconda (isoflurane) have been secured in 17 out of 18 countries



Key markets	Regulatory approval	Pricing/reimb. approval	Drug launch
Germany	☑	☑	☑
Spain	☑	☐	☐
France	☑	☑	☑
UK	☐	☐	☐
Nordics	☑	☑	☑
Benelux	☑	☑	☑
Italy (distr.)	☑	☑	☐

Further steps needed, decision expected in Sep

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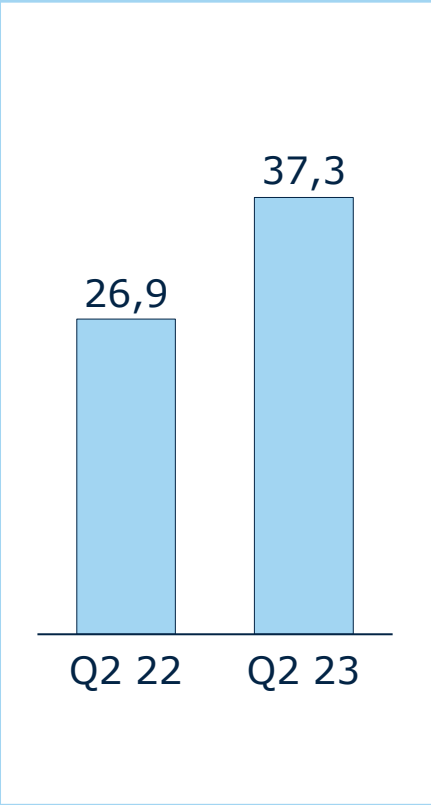
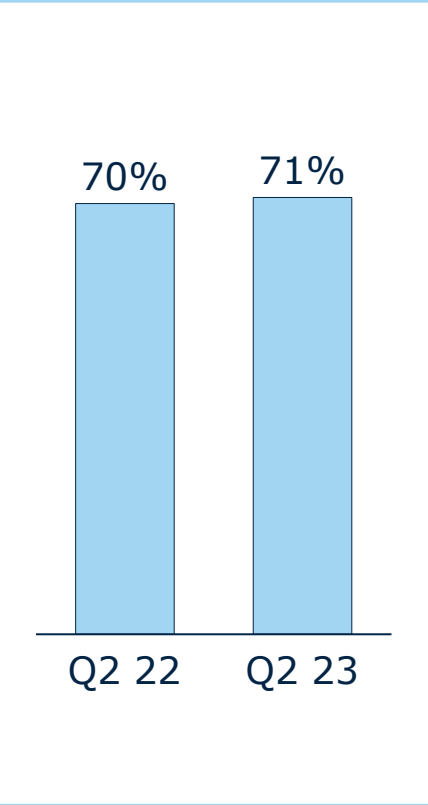
We are making progress towards break-even

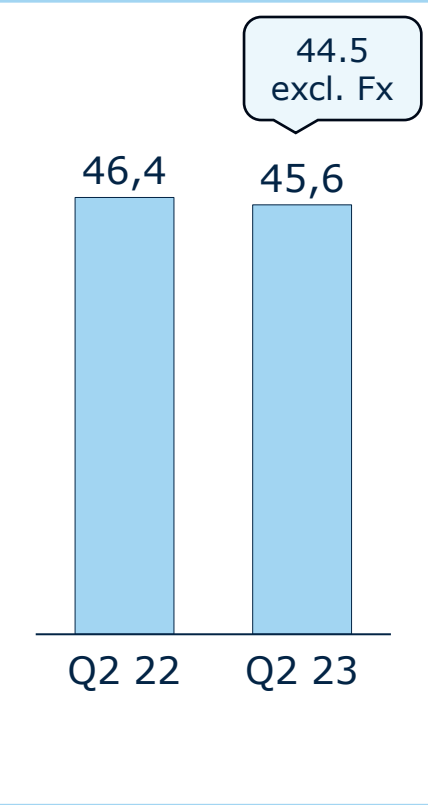
Net Sales
MSEK



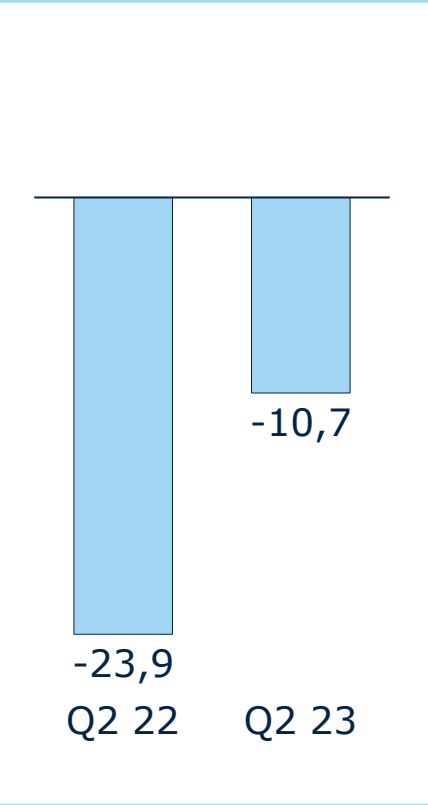
Gross margin
% of Net Sales



Opex
MSEK



EBITDA
MSEK



Our goal is to reach
EBITDA break-even ex-US during 2024

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USA: Enrolment for our clinical trials is progressing according to plan

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

We have adjusted our submission plan, following FDA feedback

Context

- The study plan for INSPIRE-ICU 1&2 includes long-term follow-up after 3(±1) and 6(±1) months
- Centralized, phone-based follow-up of cognitive, psychological and quality-of-life assessments
- Sedana Medical had previously assumed that the long-term follow-up data could be submitted separately, during the NDA review

FDA feedback

- In response to a Type D meeting request, FDA has clarified that the Clinical Study Reports and NDA submission must include all long-term follow-up data

Implications

- NDA submission is expected to shift to Q1, 2025
- Assuming standard review time, approval would be in late 2025 or early 2026
- Timeline does not consider potential benefits from Fast Track Designation
- This affects the sequence and timing, in which we can submit data, but...
  - No new data is needed
  - The risk or cost of the study is not affected

We will discuss potential benefits from FDA Fast Track Designation in a pre-NDA meeting

FTD for Sedaconda

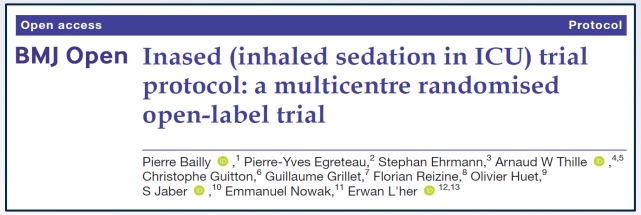
- US development program has received Fast Track Designation by FDA in January
- The purpose of an FDA Fast Track Designation is to get important new therapies to US patients earlier
- This confirms that FDA sees an unmet medical need and potential clinical benefits

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

Investigator-initiated trials – SESAR expected to complete enrollment this year

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

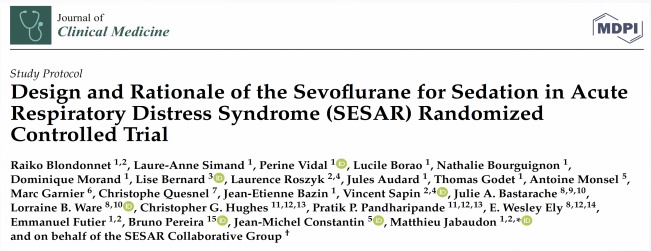

Open access Protocol

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**
  - 668 patients recruited to date (700 planned)
  - Enrollment completion expected at turn of the year


Journal of Clinical Medicine

MDPI

Study Protocol

Design and Rationale of the Sevoflurane for Sedation in Acute Respiratory Distress Syndrome (SESAR) Randomized Controlled Trial

Raiko Blondonnet [1,2], Laure-Anne Simand [1], Perine Vidal [1], Lucile Borao [1], Nathalie Bourguignon [1], Dominique Morand [1], Lise Bernard [3], Laurence Roszyk [2,4], Jules Audard [1], Thomas Godet [1], Antoine Monsel [5], Marc Garnier [6], Christophe Quesnel [7], Jean-Etienne Bazin [1], Vincent Sapin [2,4], Julie A. Bastarache [8,9,10], Lorraine B. Ware [8,10], Christopher G. Hughes [11,12,13], Pratik P. Pandharipande [11,12,13], E. Wesley Ely [8,12,14], Emmanuel Futier [1,2], Bruno Pereira [15], Jean-Michel Constantin [5], Matthieu Jabaudon [1,2,*] and on behalf of the SESAR Collaborative Group †

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Booth/symposia at meetings Q2 2023

- Symposium International Critical Care Congress Panama
- Symposium Regensburg
- 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 Intensivtheraphie“ Mönchengladbach
- Intensivpflege Kongress Kassel
- Symposium Frankfurt
- Round table SOGAMIUC congress Ferrol
- Deutsche Anästhesie Congress Düsseldorf
- DGIIN Congress Berlin
- Symposium Charité Berlin
- Symposium SEMICYUC Congress Malaga
- Symposium SRLF Paris 2023
- Nursing inhaled sedation workshop SEEIC Malaga

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Financial result in Q2 2023

Net sales **Q2'23:** 37 (27) MSEK, +39% y/y (+27% excl. FX).

- Sales in Germany increased by 49% y/y (36% excl. FX), driven mainly by increased penetration in existing accounts.
- Other direct markets showed growth of 65% y/y (52% excl. FX), driven mainly by new accounts.
- Our distributor markets decreased by 38% y/y (44% excl. FX) driven by high inventory levels in South America both at our distributor and at the hospitals. Outside South America the distributor markets showed positive growth during the period.

Gross Profit **Q2'23:** 27 (19) MSEK
Gross Margin **Q2'23:** 71 (70) %

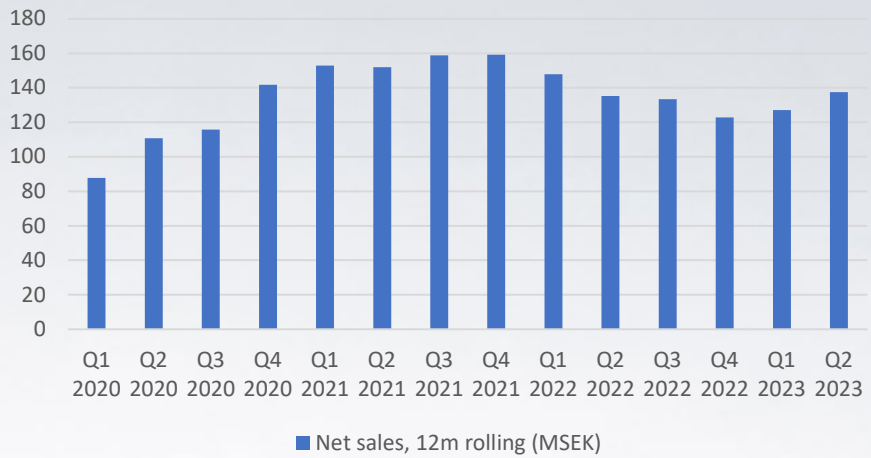
- The improved gross margin is mainly an effect of higher prices, mix effects and lower allocated central costs. Small reduction from 73% in Q1 as our price adjustments had an effect earlier than price adjustments from our suppliers. Expect to remain above 70%.

EBITDA **Q2'23:** -11 (-24) MSEK

- Opex of 46 MSEK in Q2'23, a decrease of 1 MSEK vs Q2'22. At fixed FX, the reduction is 2 MSEK (-4%).
- Streamlined admin functions (HR, IR, Accounting, Controlling).
- Reduced spending on consultants, external vendors, conferences.

Staff, incl consultants, per June 30, 2023: 93 (95 at Dec 31 2022).

Net sales (MSEK, 12m rolling)



Gross profit development (12m rolling)

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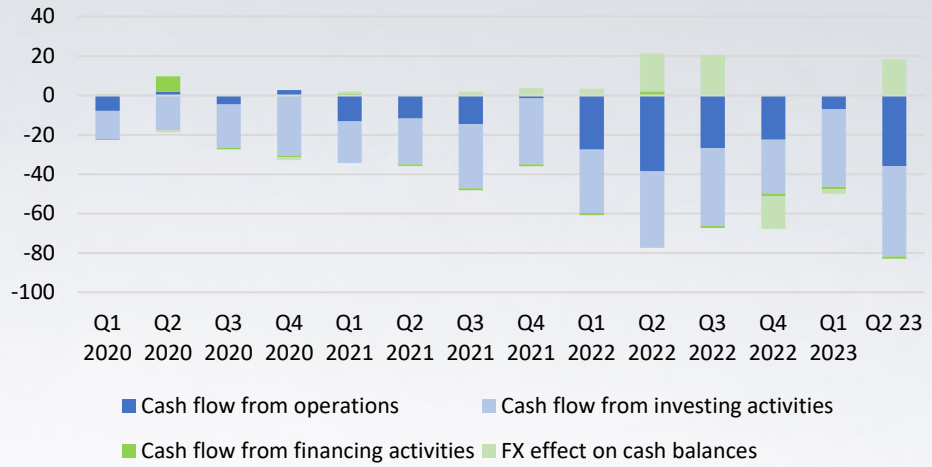
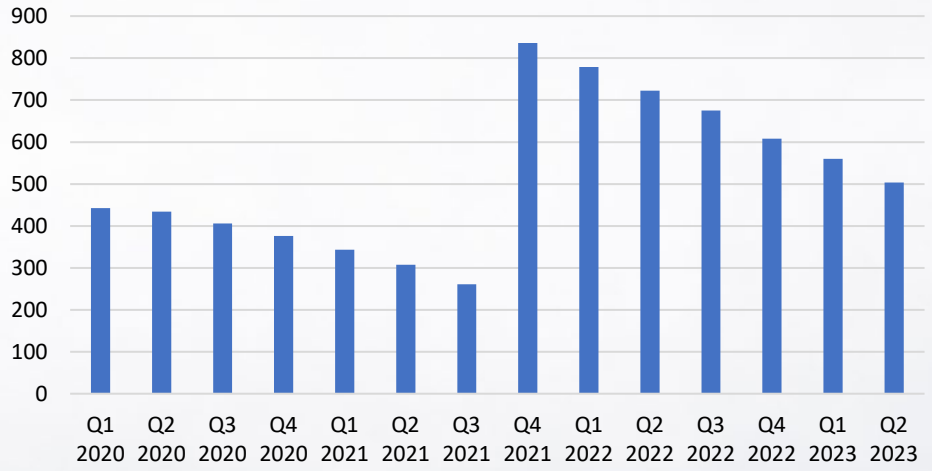
Cash flow, cash balance and short-term deposits

- **Cash flow from operations Q2'23:** -36 (-39) MSEK, of which cash flow from working capital of -17 MSEK related mainly to inventory and timing of payments for clinical studies.
- **Cash flow from investments Q2'23:** -46 (-39) MSEK, related mainly to clinical studies and registration in the United States.
- **Cash flow for the period Q2'23:** Total cash flow for the quarter was MSEK -83 (-75).
- **Cash balance and short-term deposits per June 30 2023:** 504 MSEK compared to 560 MSEK at the beginning of the quarter.
- **Liquidity management**
  - Approx. half of our cash has been converted to USD.
  - During the first quarter we placed approximately half our cash in short-term deposits for better interest rates (both SEK and USD).
- **We expect to be fully financed until break-even and to execute on our strategic plan**
  - The recent shift in US timeline relates to phasing of our submission – we do not expect any meaningful impact on the total project cost
- **No long-term debt**

Cash flow (MSEK) excl 2021 cap. raise and allocation to short-term deposits



Available funds* (MSEK)



* Cash and short-term deposits

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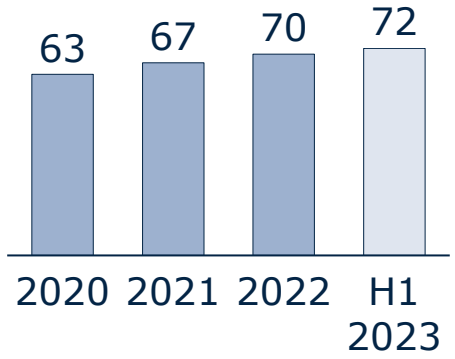
Largest shareholders June 30, 2023

	No of shares	Share
Linc AB	10 111 030	10,2%
Swedbank Robur Funds	9 519 013	9,6%
Anders Walldov direct and indirect (Brohuvudet AB)	8 500 000	8,6%
Handelsbanken Funds	7 984 846	8,0%
Ola Magnusson direct and indirect (Magiola AB)	4 462 098	4,5%
Sten Gibeck	4 286 276	4,3%
Öhman Funds	4 248 097	4,3%
Highclere International Investors LLP	3 282 254	3,3%
Bank of Norway	2 593 635	2,6%
AMF Pension	2 491 000	2,5%
Berenberg Funds	1 856 748	1,9%
Third Swedish National Pensin Fund	1 735 989	1,7%
Tedsalus AB (Thomas Eklund)	1 666 464	1,7%
Amundi	1 198 319	1,2%
Avanza Pension	1 177 488	1,2%
Fifteen largest shareholders	65 113 257	65,5%
Others	*34 223 703*	*34,5%*
Total	**99 336 960**	**100,0%**

Investment case - why Sedana Medical?

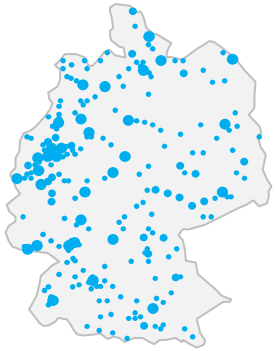
High gross margins

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 and short-term deposits
In SEK, end of Q2

504M

- 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