sedanamedical

Q3 2023 Report

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

October 26, 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.

Q3 Highlights: during the quarter, we have made solid progress on all our 3 priorities for the year

2023 priorities

Q3 update

Achieve growth in our ex-US business

- **34.3 MSEK net sales** in Q3 (+29% / 16% excl. fx)
  - **21%** growth in **Germany** (9% in local currency)
  - **87%** growth in **other direct markets** (69% in local currencies)
  - **-11%** decline in **distributor markets** (-20% in local currencies)
- **MHRA approval** in the **UK**
- **P&R**[1] **approval** in **Spain**

Get closer to break-even ex-US

- Gross margin of **70%** (as LY)
- **Operating expenses decreased by 17%** (21% excl. currency effects)
- EBITDA of -12.6 MSEK (**improved by 50%** vs. LY)
- Cash and short-term deposits of **453 MSEK**
- Target to reach **ex-US break-even during 2024**

Make headway towards US approval

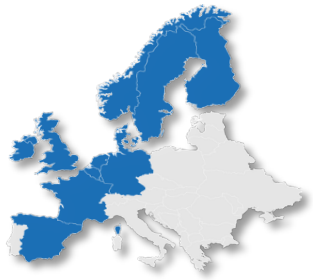
- INSPiRE-ICU clinical trials **progressing**, majority of patients enrolled in both studies
- **NDA submission** planned for Q1 2025
- **Fast Track Designation** by FDA

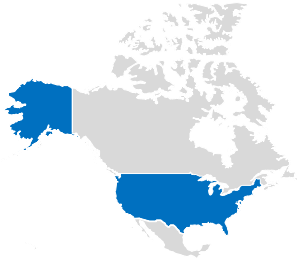
1 Pricing & Reimbursement

sedanamedical

We see the company on track to reach our 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

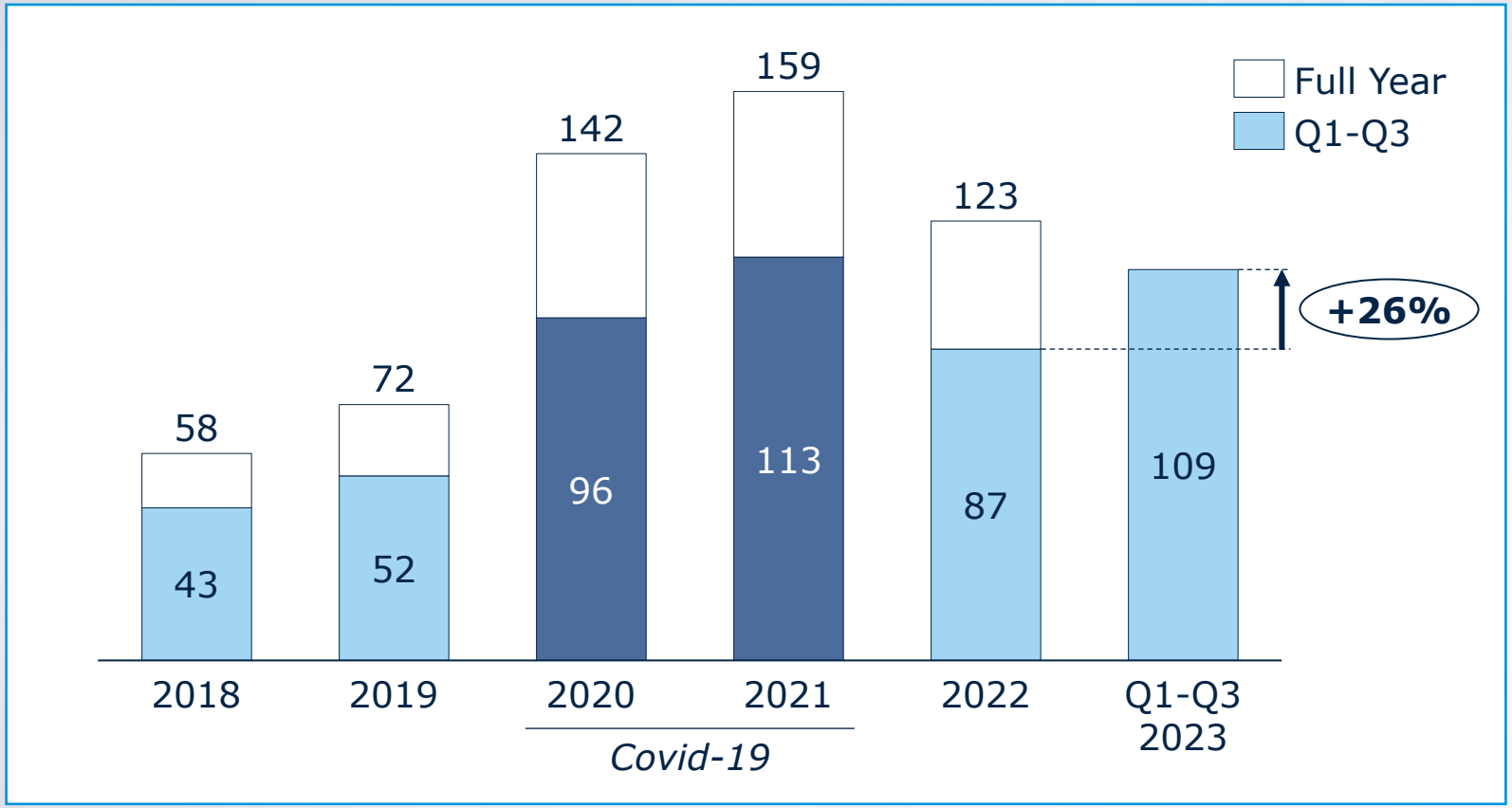
Break-even
in our ex-US business during 2024

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)

sedanamedical

We have returned to growth after the Covid-19 pandemic

Net sales
SEK million



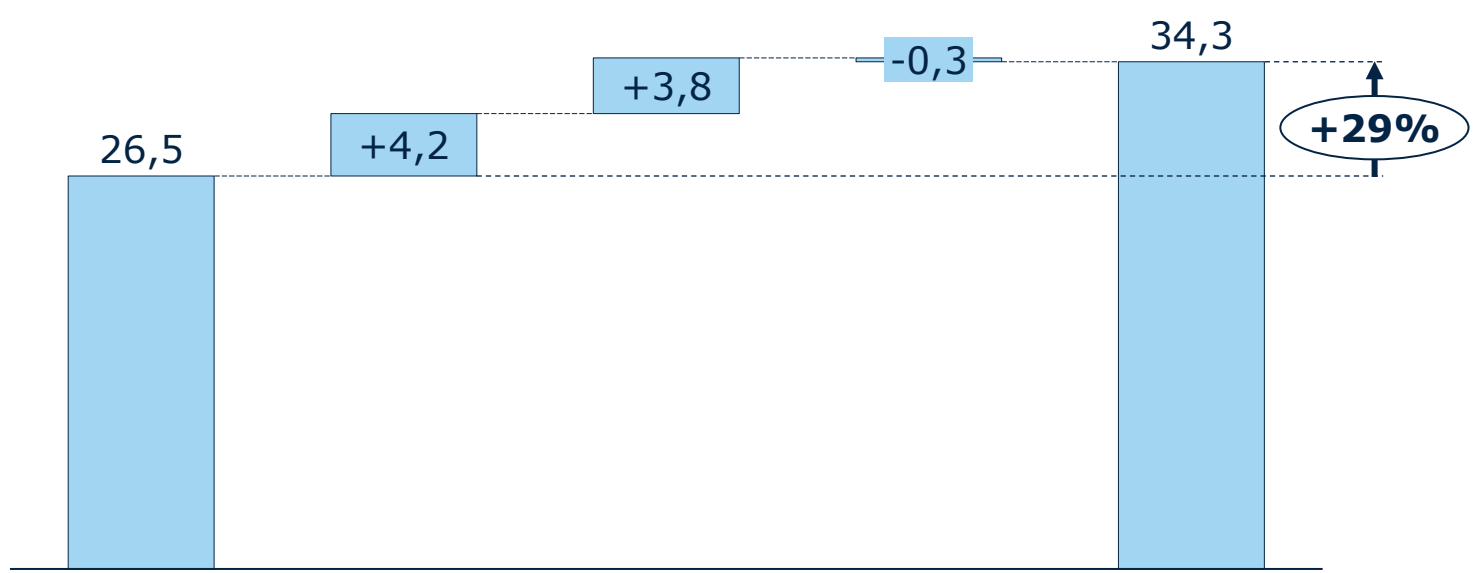
Comments

- 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 2023 (and higher sales than the Covid-19 Year 2020)

sedanamedical

In Q3, we have shown growth in our direct markets, while distributors have declined

Sales bridge Q3 2023 vs. Q3 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:

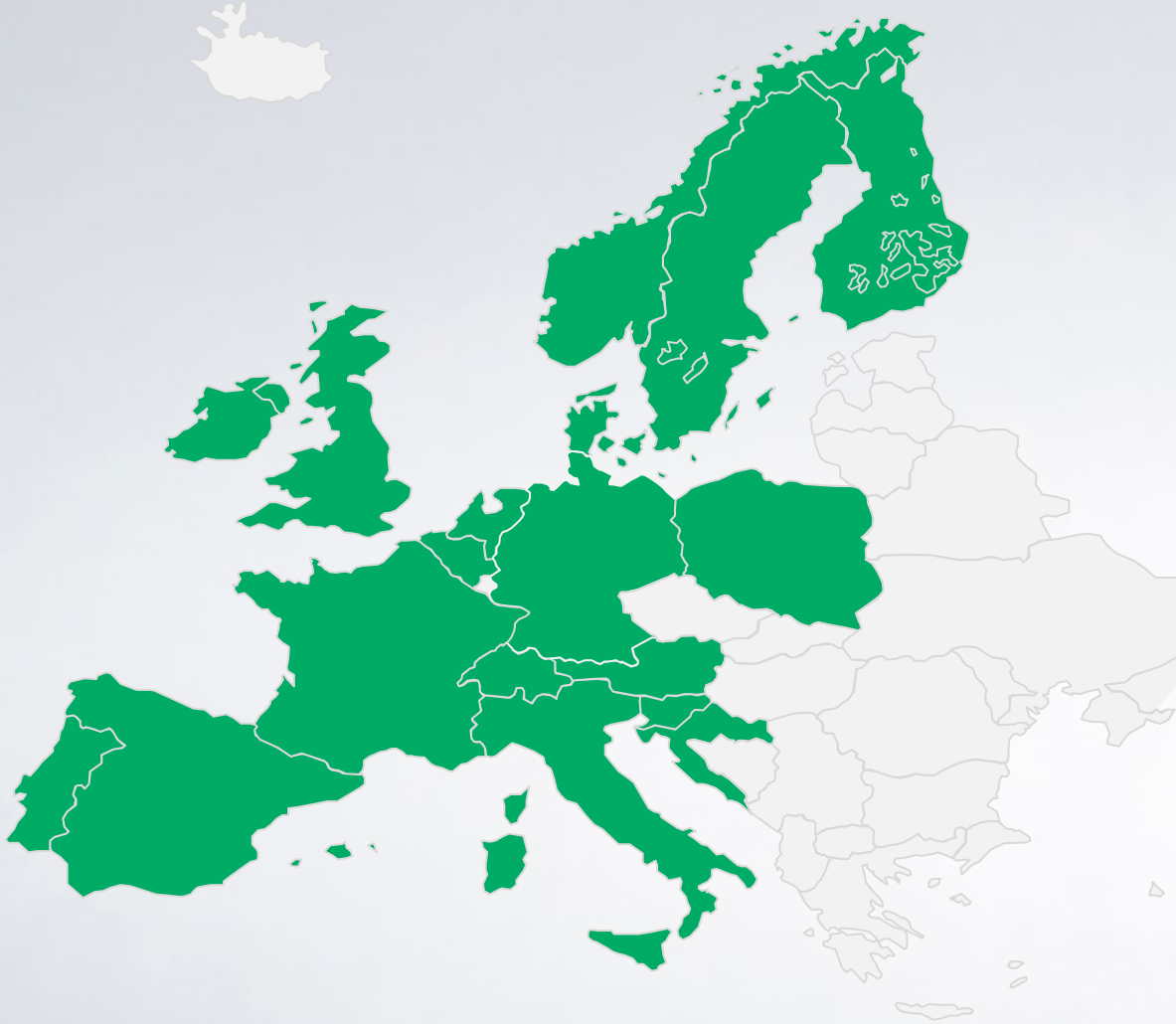
- Majority of YoY growth from new customers (Spain in the main growth engine)
- In addition, increased penetration of existing customers

Distributor markets:

- Still a gap vs. last year, but smaller than in previous quarters
- Explained by timing effects and stock levels in select markets

sedanamedical

Regulatory approvals for Sedaconda (isoflurane) have now been secured in all 18 countries



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

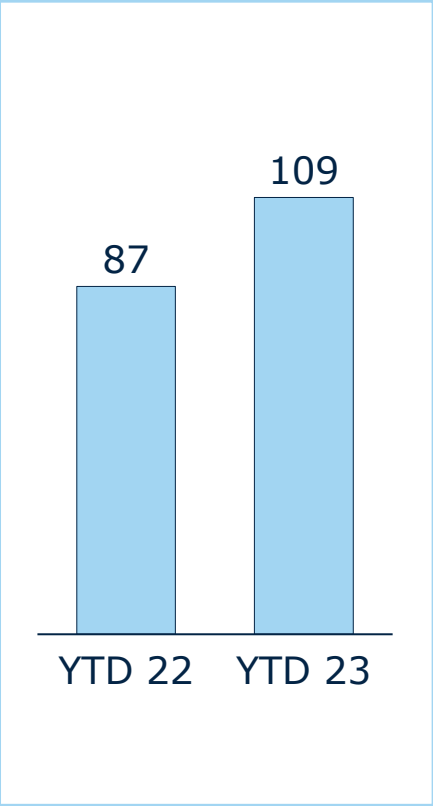
sedanamedical

We have reached two important milestones in our direct markets

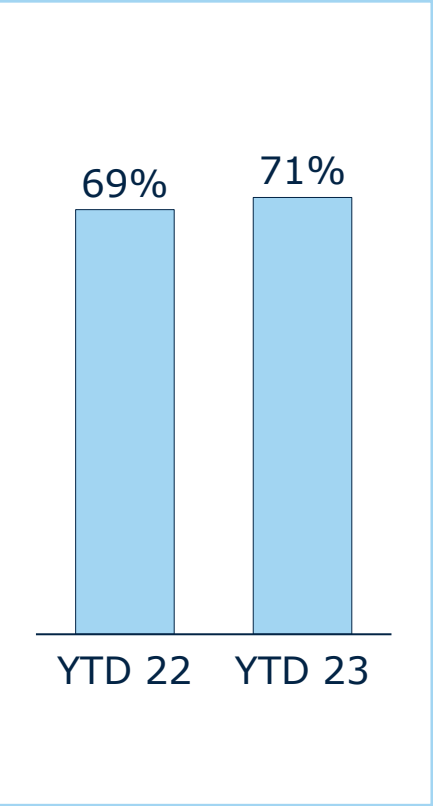
	MHRA approval in UK	Pricing & reimbursement in Spain
Update	• MHRA has approved Sedaconda (isoflurane) for inhaled sedation of mechanically ventilated patients in the ICU • The drug will be made available once supply is available (Q1 2024)	• The Spanish Ministry of Health has confirmed pricing & reimbursement approval of Sedaconda (isoflurane) • Supply is already available and can be sold from December 2023
Impact	• Inhaled sedation is now an on-label therapy also in the UK and can be actively promoted • The NICE guidance, recommending Sedaconda (isoflurane) and confirming a health economic benefit of ~3.800 GBP per patient, now applies to an approved therapy	• Numerous hospitals have awaited the pricing & reimbursement approval before implementing inhaled sedation to avoid the use of off-label isoflurane • As in all major European markets, the value of the approval is expected to come more from an acceleration of device sales than the drug itself

We are making progress towards break-even

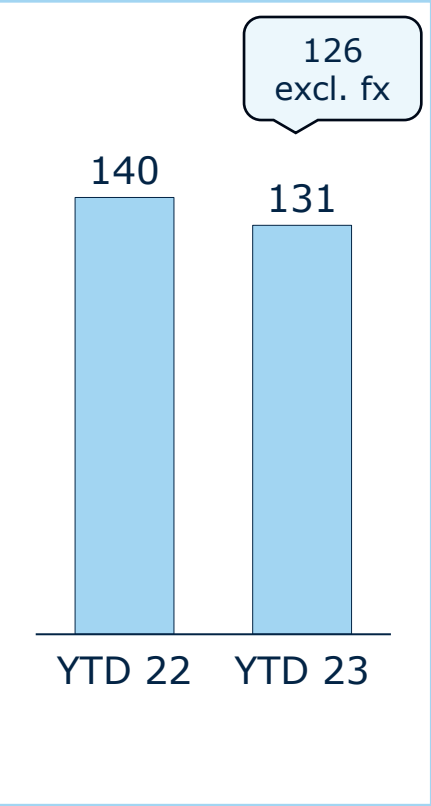
Net Sales
MSEK



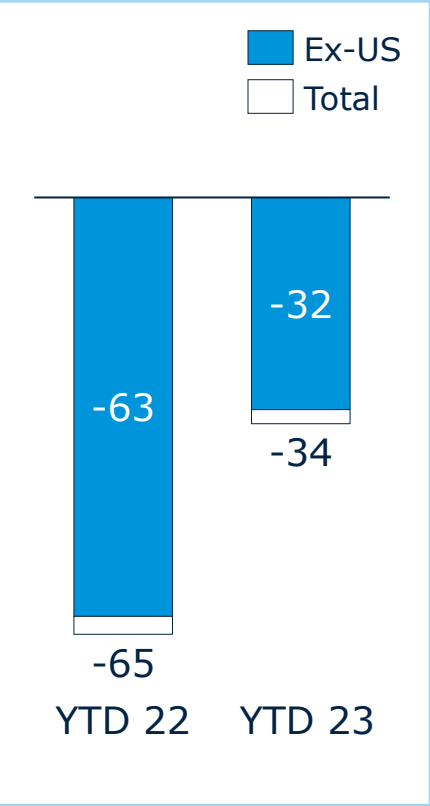
Gross margin
% of Net Sales



Opex
MSEK



EBITDA
MSEK



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

sedanamedical

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**
- Grow the organization over time, with initial focus on medical roles
- Keep the option to add complementary partnership(s) if deemed attractive

Progress

- Two phase III studies (**INSPiRE-ICU 1&2**) ongoing: 27 active sites, both trials have enrolled majority of the 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

sedanamedical

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 2023
- 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 with Sedaconda

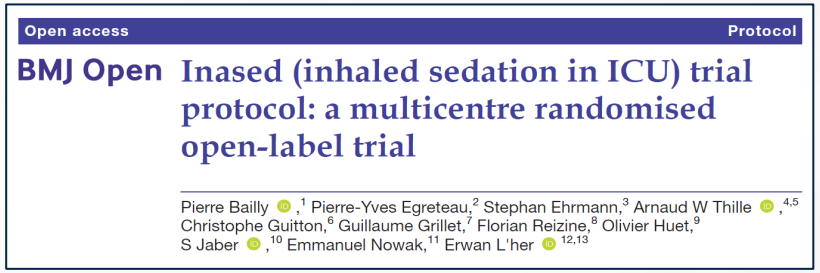
Possible benefits

- 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
- FDA's view on FTD benefits will not be known before submission

The investigator-led study SESAR has completed enrolment

- **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**
  - 165 patients recruited to date (250 planned)



sedanamedical

Recent international inhaled sedation activities

- 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
- Annual Congress of the Mexican College of Critical Care Medicine (COMMEC), Mexico
- ECMO inhaled sedation workshop, Mexico City, Mexico
- SFAR congress Paris, France
- ICU Congress St Pölten, Austria
- 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) symposium
- Inhaled sedation workshop, Istanbul, Turkey

sedanamedical

Financial result in Q3 2023

Net sales **Q3'23:** 34 (27) MSEK, +29% y/y (+16% excl. FX).

- Sales in Germany increased by 21% y/y (9% excl. FX), driven mainly by increased penetration in existing accounts.
- Other direct markets showed growth of 87% y/y (69% excl. FX), driven mainly by new accounts.
- Our distributor markets decreased by 11% y/y (-20% excl. FX) driven by timing effects and stock levels in select markets.

Gross Profit **Q3'23:** 24 (18) MSEK
Gross Margin **Q3'23:** 70 (70) %

- The gross margin of 70% is in line with last year
- We are experiencing cost increases for materials and components, and sequentially our gross margin is slightly down from 71% in Q2 2023

EBITDA **Q3'23:** -13 (-25) MSEK

- Opex of 41 MSEK in Q3'23, a decrease of 8 MSEK vs Q3'22 (-17%). At fixed FX, the reduction is 11 MSEK (-21%).
- We continue our efforts to streamline HQ functions (HR, IR, Accounting, Controlling) and reduce spending on consultants, external vendors, and conferences.

Staff, incl consultants, per September 30, 2023: 92 (95 at Dec 31 2022).

Net sales (MSEK, 12m rolling)

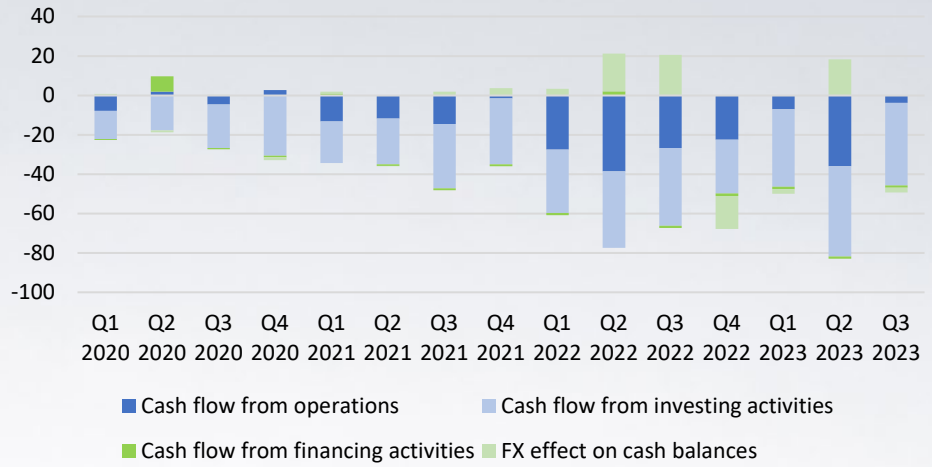
Gross profit development (12m rolling)

sedanamedical

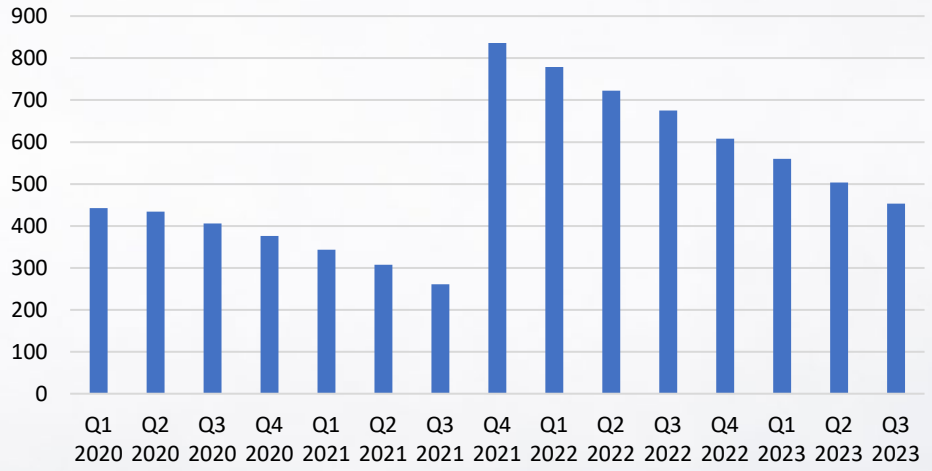
Cash flow, cash balance and short-term deposits

- **Cash and short-term deposits per September 30 2023:** 453 MSEK compared to 504 MSEK at the beginning of the quarter. Decrease driven by investments in US clinical program.
- **Cash flow from operations Q3'23:** -4 (-27) MSEK, including interest received on deposits of 6 MSEK.
- **Cash flow from investments Q3'23:** 111 (-40) MSEK, of which investments in capitalized development expenditures of -42 (-39) MSEK. Deposits made in Q1 expired in Q3 and were partially re-invested, which impacted cash flow from investments positively.
- **Total cash flow Q3'23:** 106 (-67) MSEK. Adjusted for allocation from deposits to cash, total cash flow was -47 (-67) MSEK
- **Liquidity management**
  - Approx. 75% of our available funds are in USD.
  - During the third quarter we re-invested part of our USD cash in short-term deposits for better interest rate
- **We expect to be fully financed until break-even and to execute on our strategic plan**
- **No long-term debt**

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



Available funds* (MSEK)



* Cash and short-term deposits

sedanamedical

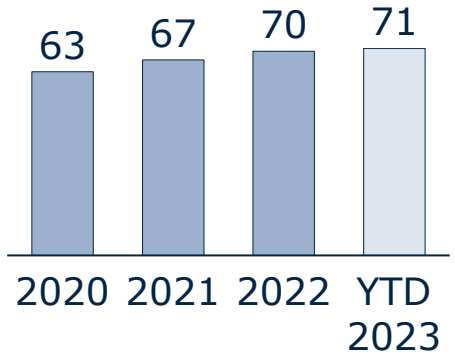
Largest shareholders Sept 30, 2023

	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)	8,900,000	9.0%
Handelsbanken Funds	7,752,386	7.8%
Ola Magnusson direct and indirect (Magiola AB)	4,362,098	4.4%
Öhman Funds	4,228,170	4.3%
Sten Gibeck	4,196,597	4.2%
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	2,019,702	2.0%
Premier Miton Investors	1,814,813	1.8%
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%
Fifteen largest shareholders	65,871,470	66.3%
Others	*33,465,490*	*33.7%*
Total	**99,336,960**	**100.0%**

Investment case - why Sedana Medical?

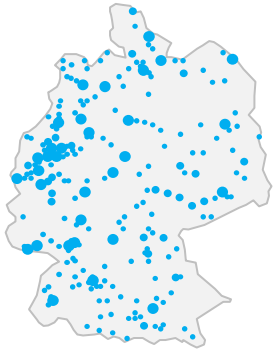
High gross margins

FY GM, in percent



- Gross margins have increased 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
- 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
- Fast Track Designation in US

Strong balance sheet

Cash and short-term deposits
In SEK, end of Q3

453M

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

sedanamedical

sedanamedical

Q&A