Q3 Report 2021

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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 AnaConDa and IsoConDa, 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.

Our Purpose

To improve life during and beyond sedation

Our Vision

To make Inhaled Sedation a global standard therapy for critical care patients

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Q3 2021 Highlights

Solid sales growth

- 34% growth[1] in Q3 sales (28 MSEK)
- 23% growth[1] in YTD sales (113 MSEK)
- All regions incl. Germany, other direct markets, and distributor markets contributed to the growth in Q3
- Continued use of Sedaconda ACD in non-Covid-19 patient groups in Europe

Launch preparation on track

- 11 out of 15 national approvals obtained for Sedaconda (isoflurane), following the European approval in July
- Product expected on shelf in first markets towards end of the year
- Sedaconda study results published in "The Lancet Respiratory Medicine"
- Country teams staffed up and trained

U.S. preparation intensifying

- Preparations for US clinical program well on track
- IND expected in Q4, 2021
- First employees hired into Sedana Medical US organization

1 Growth in local currencies

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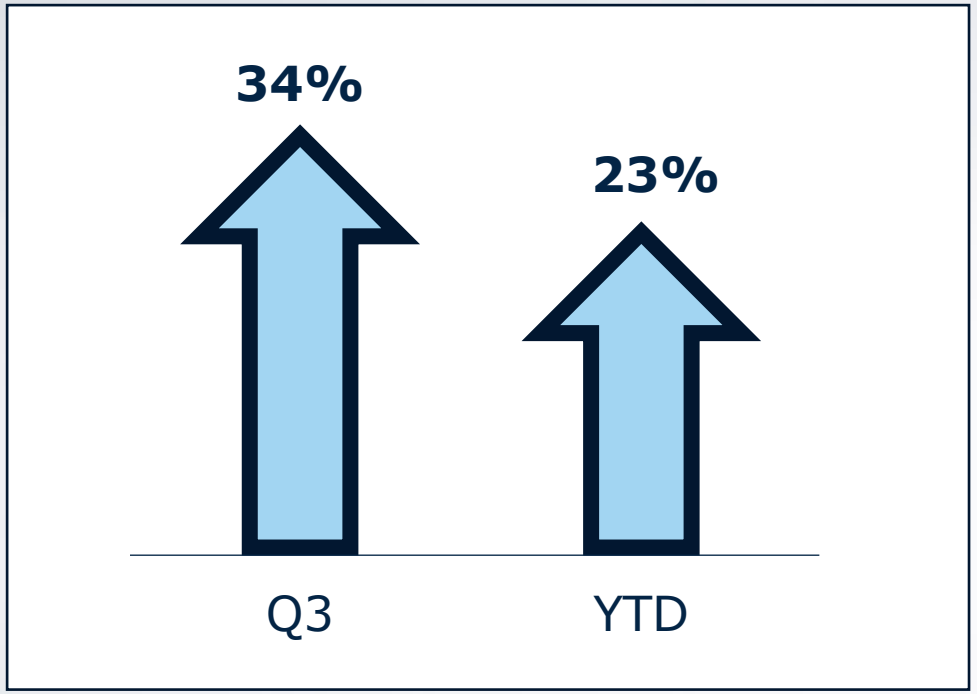
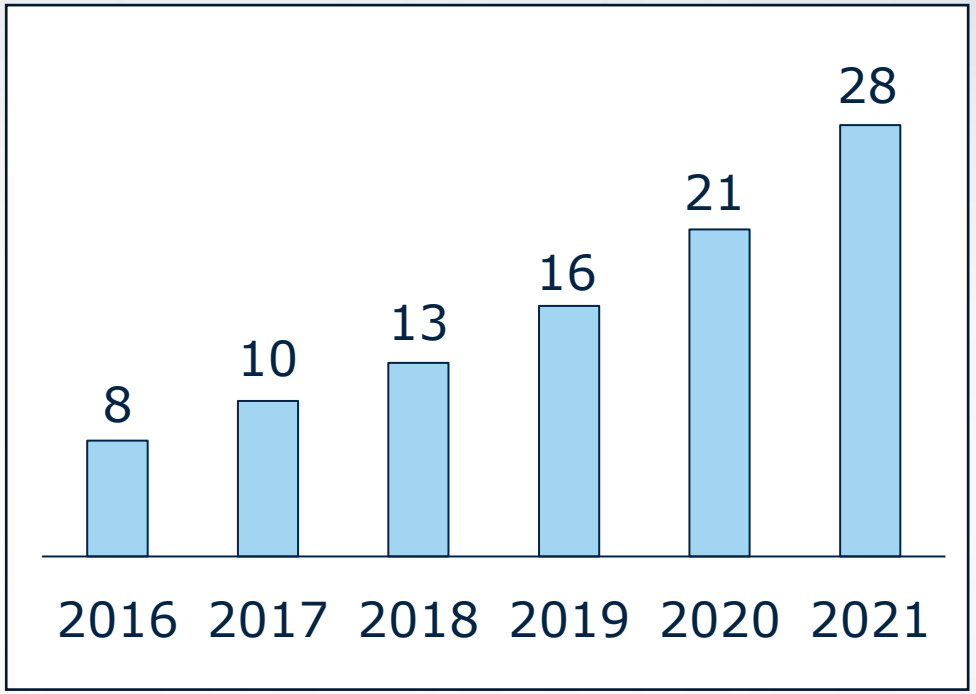
We have seen solid growth in Q3 sales, continuing on the longer-term trend

Sales growth
Percent[1]



Q3 sales over time
SEK million



1 Growth in local currencies

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Every region has contributed to the Q3 growth vs. 2020

Q3 sales and growth[1]
MSEK, Percent

Market update

Germany

- Continued growth in our main market
- Clinics continue to use Sedaconda ACD in broad patient groups beyond Covid-19

Other direct markets

- Return to YoY growth after H1 had been affected by stock building during the first Covid-19 waves in 2020
- Strong performance in Spain, France, UK

Distributor markets

- Strong demand, especially in Latin America, partly driven by Covid-19
- Colombia 2nd largest market in Q3

1 Growth in local currencies

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Use of Covid-19 as a predictor for Sedana Medical performance has limits

Actual market potential

- Patients who are
  - … in the **ICU**,
  - … **mechanically ventilated**, and
  - … **sedated**

Limitations of Covid-19 as a proxy

(Germany example)

- Covid-19 patients never exceeded 30% of ICU patients
- Not all Covid-19 patients are ventilated (currently 52%)
- Covid-19 patient demographics and treatment change over time

Our view on Covid-19

- **Some short-term impact, but long-term outlook unchanged**
  - Sales show less volatility than Covid-19, suggesting broad use outside Covid-19
  - We may see some regional fluctuation in our sales (positive or negative) due to Covid-19, but long-term potential is not affected
- **Stronger platform for launch**
  Covid-19 has led to more clinics being equipped and trained to use Sedaconda ACD

Source: own analysis based on DIVI Intensivregister

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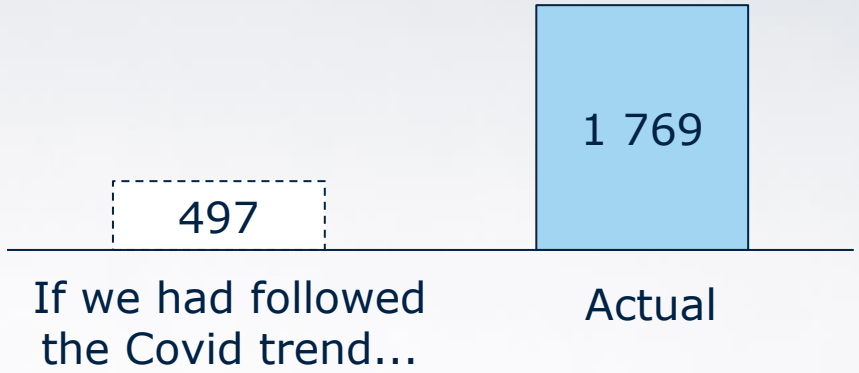
Q3 sales showed resilience versus Covid-19 trend, suggesting broad use of our products outside Covid-19 patients

Covid-19 patients in ICU
Drop from Q2 to Q3[1]

Q3 Net sales
EUR thousands

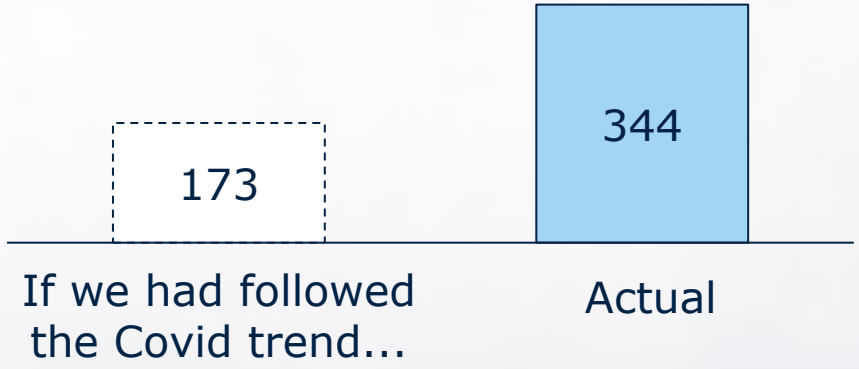
Germany

-82%



Other direct markets[2]

-55%



1 Based on average number of Covid-19 ICU patients per day
2 UK, France, Spain, Benelux, Sweden, Denmark

Source: own analysis based on European CDC and country data

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Two growth horizons ahead: Europe and the United States

Sedana Medical growth horizons

Europe

- Approval in 2021 (11 national approvals to date)
- Direct presence in Germany, UK, France, Spain, Benelux, Nordics
- Stated objective: 500 MSEK sales in 3rd year after approval

United States

- Approval anticipated before year end 2024
- Highest-potential market
  - 107.000 ICU beds[1]
  - Attractive price level
- Decision on go-to-market model in 2022

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

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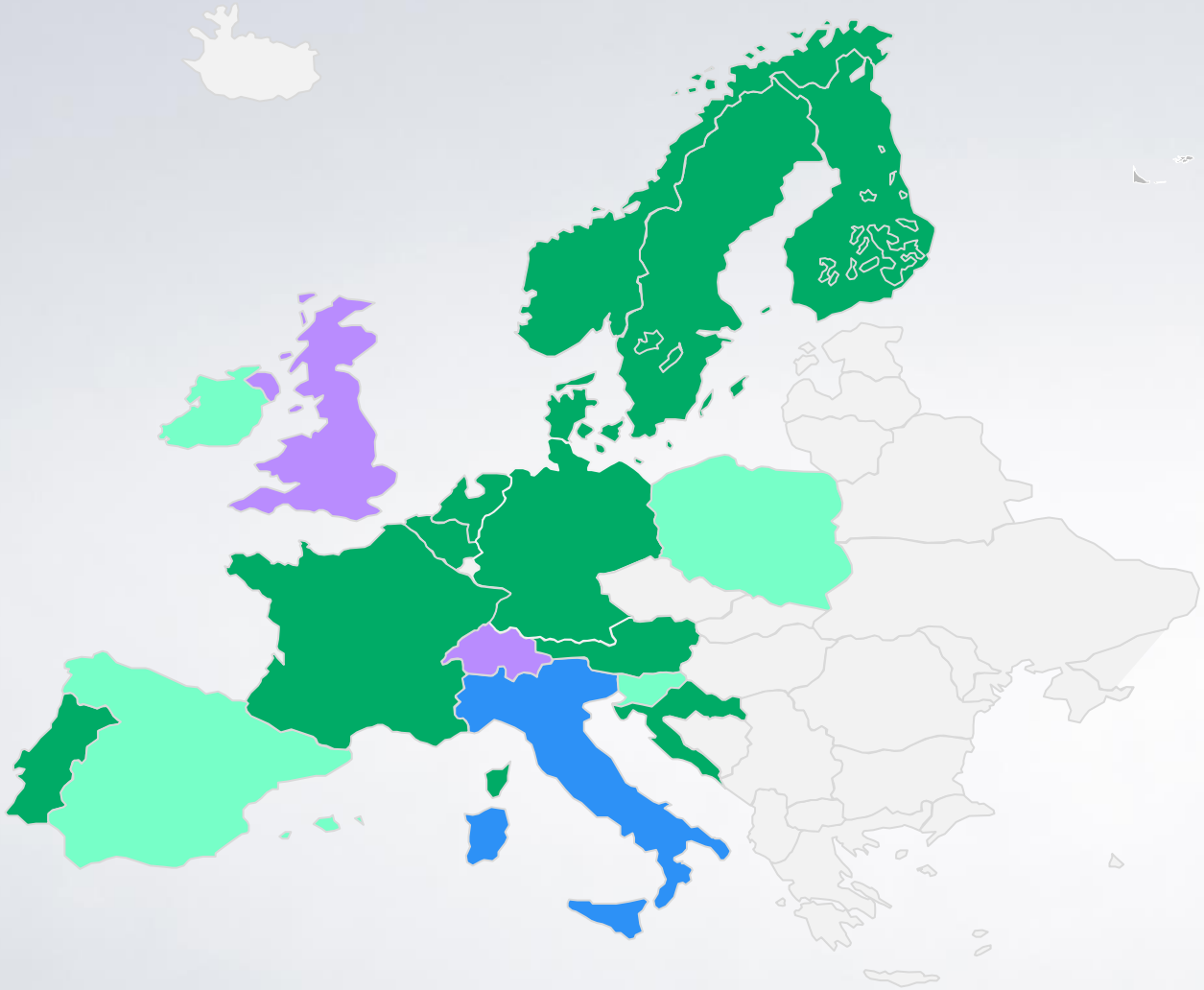
We have received national approval for Sedaconda (isoflurane) in 11 countries



- Approvals received in 11 out of 15 countries
- Approvals pending in 4 countries: Spain, Ireland, Poland & Slovenia
- Approvals anticipated in 2022: UK & Switzerland
- Submission planned for beginning of 2022: Italy

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First Sedaconda on shelf anticipated before year end

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Launch readiness in Europe is on track

Product

- First and only on-label option for inhaled sedation of mechanically ventilated adult patients in the ICU
- Strong clinical trial results and meaningful patient benefits
- Lancet publication

Market

- Existing use of inhaled sedation and Sedaconda ACD in all launch markets
- Increasing awareness through symposia and congresses, e.g., ESICM Lives and ISICEM

Company

- All country teams staffed up for launch
- KAMs trained and upskilled as pharmaceutical sales representatives

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The United States represent the largest potential market for Sedana Medical

	Germany	United States
ICU beds	~22.000	~107.000
Propofol list price Based on average propofol dose/kg from SED-001 study	EUR 47 - 57 per day	EUR 360 - 438 per day
Current penetration	10.6 MEUR sales LTM[2] (8-10% market penetration)	Approval expected in 2024

Note that discounts from list price are higher in the US[1]

1 Discounts for propofol in the range of 40-50% based on payor research conducted in 2020
2 Last twelve months

Source: ICU beds: DIVI Intensivregister, American Hospital Association
Propofol list prices: own analysis based on Lauer Taxe and Pharma14

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Preparations for the US market are intensifying

Product

- Clinical and regulatory program aligned with FDA
- IND expected in Q4, 2021
- Preparations for the clinical program ongoing (start at the turn of Q1/Q2 2022)

Market

- Top centers recruited for clinical trials, e.g., Mayo Clinic, Cleveland Clinic, Stanford, John Hopkins, etc.
- Building a network of key opinion leaders

Company

- Sedana Medical US subsidiary set-up
- First employees recruited during Q3, 2021 (clinical educators for the upcoming trials)

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MEDICAL HIGHLIGHTS

The Sedaconda Study[1]

Published in Lancet Respiratory Medicine Aug 26, 2021

Inhaled isoflurane via the anaesthetic conserving device versus propofol for sedation of invasively ventilated patients in intensive care units in Germany and Slovenia: an open-label, phase 3, randomised controlled, non-inferiority trial

Andreas Meiser, Thomas Volk, Jan Wallenborn, Ulf Guenther, Tobias Becher, Hendrik Bracht, Konrad Schwarzkopf, Rihard Knafelj, Andreas Faltlhauser, Serge C Thal, Jens Soukup, Patrick Kellner, Matthias Drüner, Heike Vogelsang, Martin Bellgardt, Peter Sackey*, on behalf of the Sedaconda study group*

1. Isoflurane was non-inferior to propofol in the primary endpoint – time within target RASS range without rescue sedation
2. Opioid requirements during treatment were 29% lower with isoflurane
3. Spontaneous breathing was more commonly observed in the isoflurane group
4. Wake-up times were shorter and more predictable with isoflurane
5. Isoflurane via Sedaconda ACD was well tolerated for sedation in the ICU

Meiser et al, Lancet Respiratory Medicine 2021, DOI:https://doi.org/10.1016/S2213-2600(21)00323-4

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A strong SmPC, describing clinical key benefits

- No 48-hour limitation for use of Sedaconda
-  Sedaconda ACD the only approved device for delivery of Sedaconda (isoflurane)
- "No effect on the exposure of isoflurane in patients with impaired hepatic and/or renal function anticipated"
- "Rapid and predictable onset of and recovery from sedation"
- "Return of wakefulness and cognitive recovery, 10 and 60 minutes after end of isoflurane administration"

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The IsoCOMFORT study – pediatric study

Approved pediatric investigation plan, hopefully also usable as US pediatric study plan

A complete Marketing Authorization Application (MAA) for drugs in EU includes a PDCO-approved study plan for children, a so-called PIP (Paediatric Investigation Plan). A complete US NDA also includes a pediatric study plan, called PSP (Pediatric study plan).

Protocol approved by EMA Paediatric Committee

2019

IsoCOMFORT Study

- 160 children, aged 3 to 17
- Isoflurane via Sedaconda ACD vs. IV Midazolam
- Sedation will last for 12-48 hours
- Primary endpoint: proportion of time with adequate sedation without rescue sedation, assessed with the COMFORT-B scale
- Preliminary duration of trial: 18 months

Recruitment of first patient

Q1 2021

~18 Sites in Spain, Germany, France & Sweden

The outcome of the study is not a requirement for obtaining an authorization for use in adults, so **the timetable for approval of Sedaconda (isoflurance) is not affected** by this decision. Estimated completion of trial by the end of 2022.

Since the filed registration documentation will now be complete – i.e. also covers children – **an approval means Sedana Medical will have ten years of market exclusivity** in Europe for the use of isoflurane in sedation in intensive care.

For the US, a pediatric study plan (PSP) is evaluated after IND, in which the adult study protocols and non-clinical data are evaluated. Substantial feedback has been given from FDA on the IsoCOMFORT study protocol, but final PSP evaluation will be after IND.

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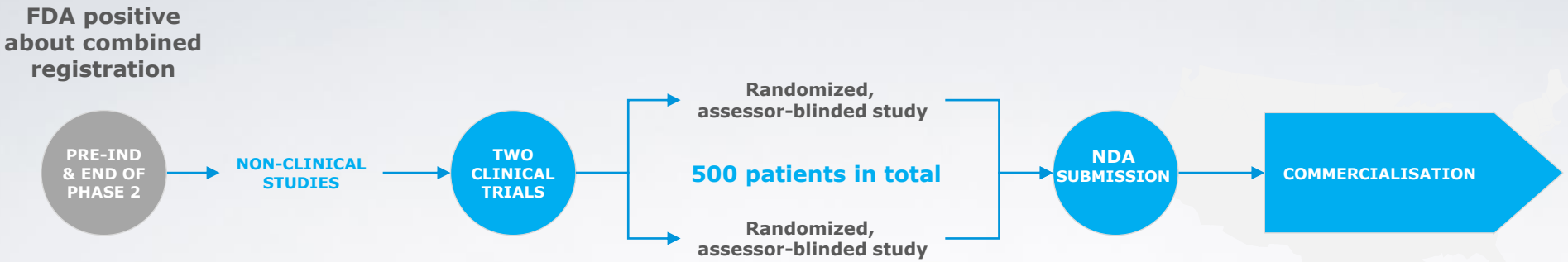
Combination registration of Sedaconda in USA

505 (b) (2) approval pathway

The FDA has accepted that Sedana Medical is taking the 505 (b) (2) path to registration, which somewhat simplifies the use of previously collected data. FDA input in 2019 and 2021 has informed the Clinical Development plan and the study designs



NON-CLINICAL STUDIES

- Non-clinical toxicity studies
- Human factors program

CLINICAL STUDIES

- Two clinical, randomized, assessor-blinded studies to be conducted to confirm the efficacy and safety of Sedaconda.
- Besides randomized patients, 3-5 run-in patients will be recruited per ICU

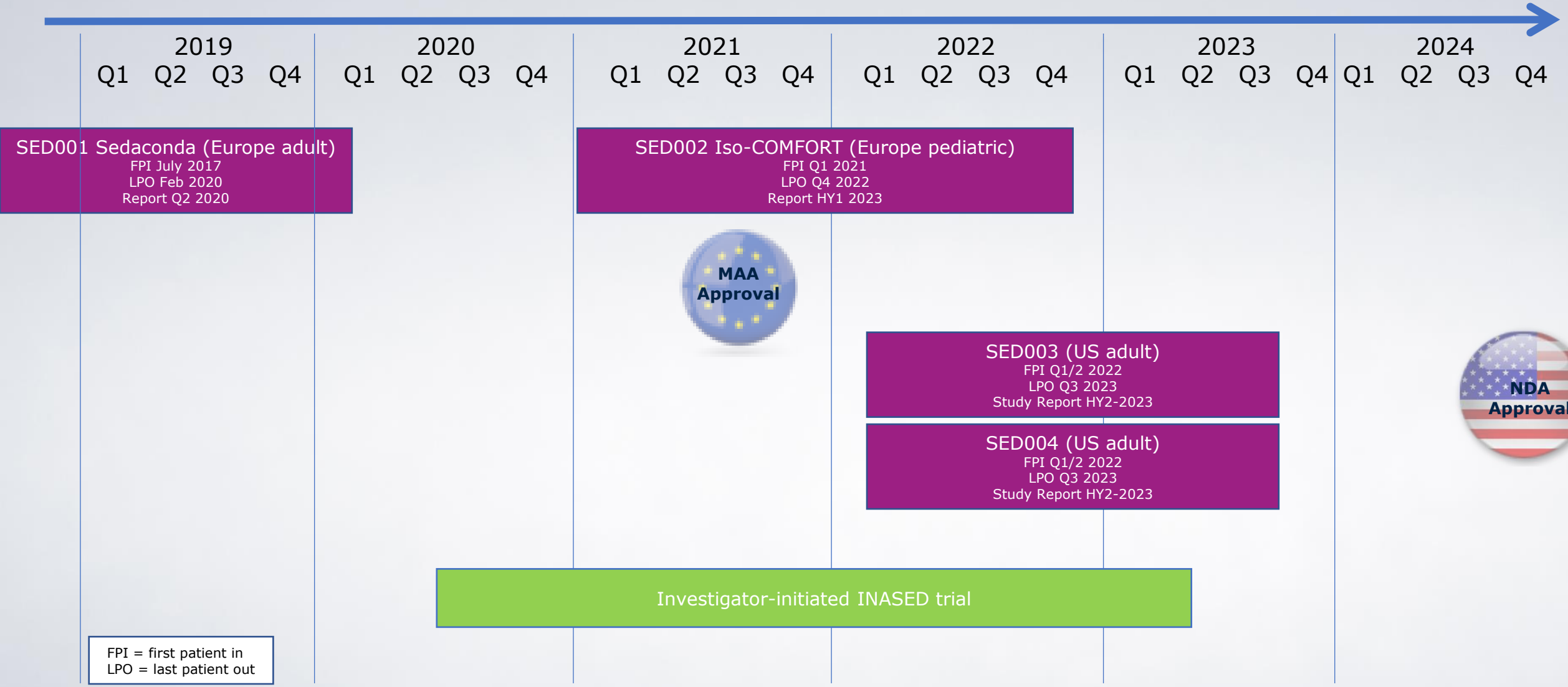
SAFETY DATABASE

Patients from the US clinical studies, and the European study will be included in the safety database of 500 isoflurane patients.

COMMERCIALISATION

Commercialisation strategy for USA – whether to launch alone or together with a local partner – to be decided during 2022.

Development program to support regulatory approvals



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Preparations for US clinical trials are ongoing

- Collaboration in study preparations with top US academic institutions, including
  - Columbia
  - Duke
  - Cleveland Clinic
  - Harvard
  - Johns Hopkins
  - Mayo
  - Vanderbilt
  - UCLA
  - University of Chicago
- Site contract negotiations and IRB applications underway
- Clinical education specialists employed for site training
- First patient in is anticipated at the turn of Q1/Q2

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FINANCIAL HIGHLIGHTS

Financial results [1)]

Investing for future

Net sales Q3'21: 28 (21) MSEK, +34% YoY in local currencies
Net sales YTD'21: 113 (96) MSEK, +23% YoY in local currencies

Gross Profit Q3'21: 19 (13) MSEK
Gross Margin Q3'21: 68 (62) %

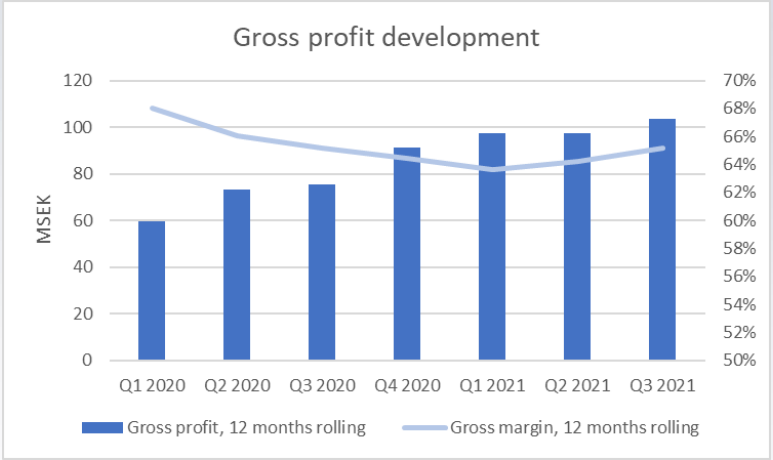
- Improved margin due to larger proportion of sea freight in the quarter. Prices for freight estimated to stay at a high rate.
- One-time positive impact of 1ppt due to reclassification to G&A.
- Market mix, increased sales in distributors markets with somewhat lower margins.

EBITDA Q3'21: -14 (-10) MSEK
EBITDA Margin Q3'21: -50 (-47) %

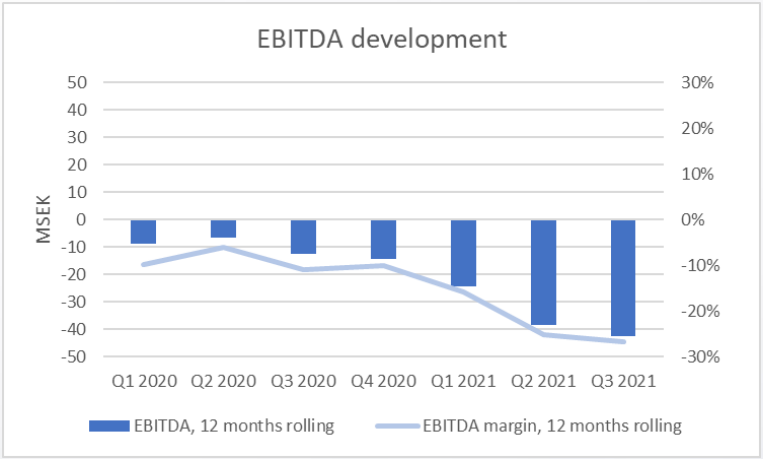
- Preparation for Sedaconda launch, including MDR-approval, results in increased OPEX, ca 2 MSEK in the quarter and 9 MSEK YTD'21.
- Build up of organisation. Now reached roughly 100 at time of Sedaconda launch. Future minor additions, mainly within Sales.

Staff, incl consultants, per Sep 30, 2021: 99 (83 at Dec 31 2020)

Gross profit development



EBITDA development



[1)] 2020 numbers are restated according to IFRS and from a P/L by cost type to function type.

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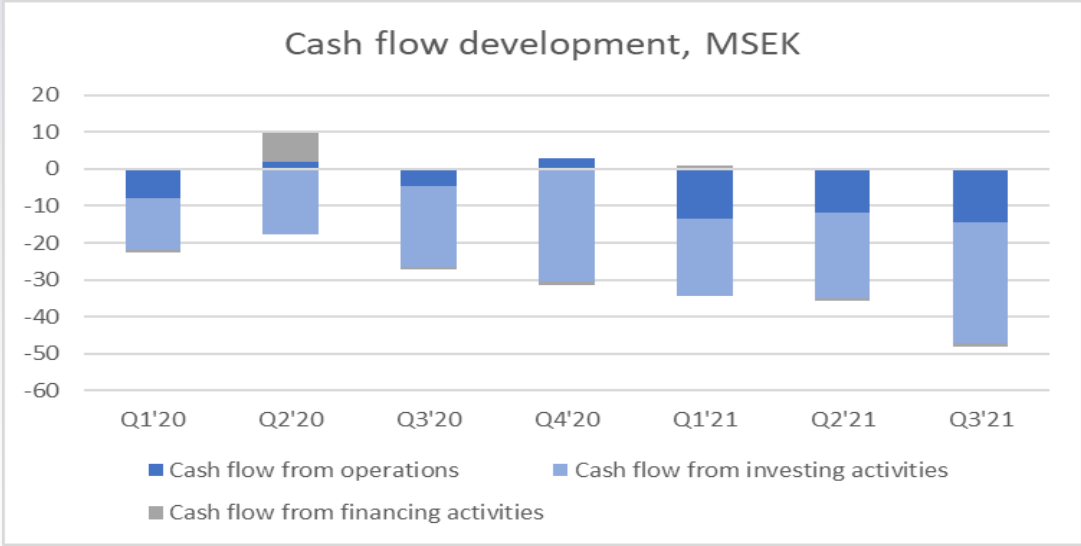
Financial balances and Cash [1)]

- **Cash flow from operations Q3'21:** -15 (-5) MSEK
  Cash flow from operations YTD'21: -40 (-11) MSEK
- **Cash flow from investments Q3'21:** -33 (-22) MSEK
  Cash flow from investments YTD'21: -77 (-54) MSEK
  of which the vast majority is related to the EU registration and US clinical studies.
- **Cash flow for the period Q3'21:** -48 (-27)
  Cash flow for the period YTD'21: -117 (-58)
- **Cash balance per Sep 30, 2021:** 262 (308) MSEK
- **No long-term financial loans / debt free company**



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Largest shareholders September 30, 2021

	No of share	Share
Handelsbanken Funds	8 580 052	9,3%
Swedbank Robur Funds	8 314 933	9,0%
Linc AB	7 598 804	8,2%
Anders Walldov direct and indirect (Brohuvudet AB)	7 200 000	7,8%
Ola Magnusson direct and indirect (Magiola AB)	4 583 728	5,0%
Sten Gibeck	4 279 776	4,6%
Öhman Funds	3 898 485	4,2%
Tredje AP-fund	2 000 000	2,2%
Avanza Pension	1 978 681	2,1%
Berenberg Funds	1 919 532	2,1%
Nordnet Pensionsförsäkring	1 743 254	1,9%
Tedsalus AB (Thomas Eklund)	1 666 464	1,8%
Highclere International Investors LLP	1 626 060	1,8%
DNCA Finance S.A	1 211 980	1,3%
Philip Earle	1 083 491	1,2%
Fifteen largest shareholders	57 685 240	62,6%
Others	*34 501 720*	*37,4%*
Total	92 186 960	100,0%

A split (4:1) was made at the end of May 2021

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QUESTIONS