



Interim report

January–March 2022

sedana medical ab (publ)



"First patient enrolled in US clinical program"

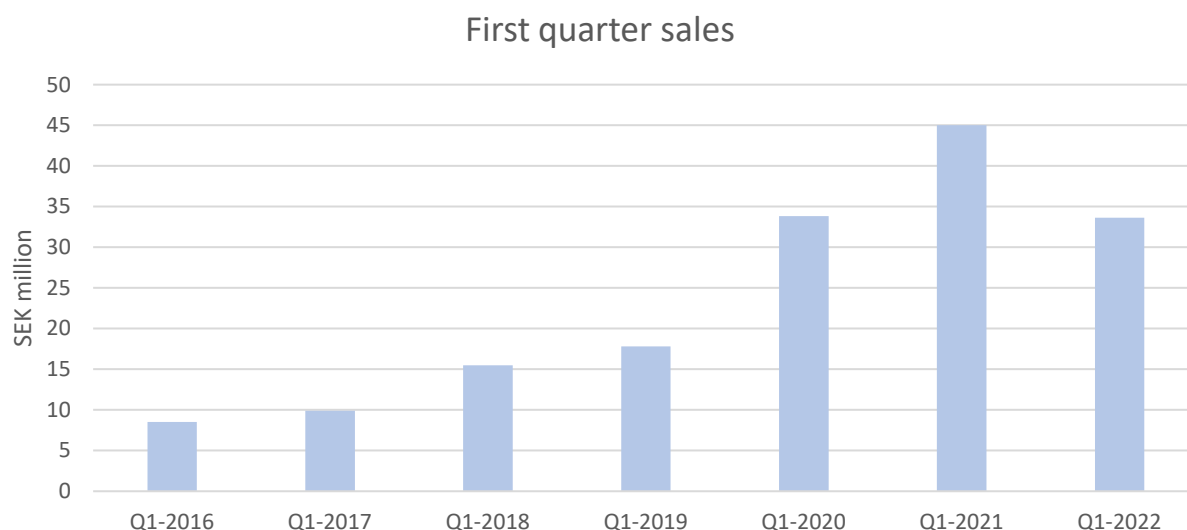
Johannes Doll, President and CEO

Q1 Q2 Q3 Q4

Financial summary

First quarter 2022

- Net sales totalled MSEK 34 (45), equivalent to a decrease of 25% compared to the first quarter of 2021. At constant exchange rates, sales decreased by 28%. The development is a consequence of a significant decline in ventilated patients in intensive care units.
- Gross profit was MSEK 23 (29), equivalent to a margin of 68% (64%). The improved margin is principally due to lower transportation costs and to some extent to a positive market mix.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled MSEK -16 (-8), equivalent to an EBITDA margin of -49% (-18%).
- Operating income (EBIT) totalled MSEK -22 (-10) equivalent to an EBIT margin of -66% (-23%).
- Net profit for the quarter was MSEK -19 (-9), and earnings per share before and after dilution was SEK -0.19 (-0.10).
- Cash flow from operating activities totalled MSEK -28 (-13).
- Cash flow from investing activities totalled MSEK -32 (-21).
- Total cash flow was MSEK -61 (-33).
- Cash and cash equivalents at the end of the quarter totalled MSEK 779, compared to MSEK 836 at the start of the quarter.



Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve patients' life during and beyond sedation. Through the combined strengths of the medical device Sedaconda ACD and the pharmaceutical Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated patients in intensive care. Sedana Medical was founded in 2005 and is listed on Nasdaq First North Growth Market. The company's head office is in Stockholm, Sweden.

CEO comments

First patient enrolled in US clinical program, sales impacted by significant decline in ventilated patients

During the first quarter of 2022, we have continued to make progress on both of our main priorities: we have launched Sedaconda (isoflurane) in Europe and are excited to initiate our clinical program in the United States. On the business side, our sales were affected by a significant decline of ventilated patients and restricted operations in intensive care units, however, sales still clearly exceed pre-Covid levels as more clinics are now equipped to use inhaled sedation.

Sales in the quarter amounted to SEK 34 million, a decline of 25% versus last year. The decline is explained by lower sales in Germany and in South America, while our other markets showed solid growth.

In Germany, our sales decreased by 22%. The primary reason is that we saw a significant decline of ventilated patients in German ICUs but restricted operations at ICU's also contributed:

- The number of Covid-19 patients alone decreased by 42% compared to Q1 2021, a decline of more than 80,000 ventilator days in the first quarter. Today (end of April), the number of ventilated Covid-19 patients is 75-80% lower than last year. While no statistics are publicly available for ventilated patients with other indications, we saw those patient groups decline as well.
- Like most parts of society, hospitals were heavily hit by high levels of staff absence in Q1, on top of the generally high turn-over and burn-out rates among nursing staff. Consequently, two thirds of German ICUs reported restricted or partly restricted operations in Q1, leading to reduced capacity, less surgeries and access restrictions to ICUs. Furthermore, the continued hygiene measures like the use of face masks helped avoid respiratory infections.



In our other direct markets, we saw similar effects including less ventilated ICU patients and restricted access to hospitals. However, the underlying growth, in particular in Spain, France and the UK, together with the comparably low sales levels last year, resulted in a 12% sales increase versus last year.

The reasons for the decline in South America are twofold: Firstly, we saw artificially high sales in Q1 last year due to the propofol shortage in the region at the time. Secondly, we saw a stock-up in Q4 in anticipation of another Covid-19 wave that did not materialize and therefore no orders were received in January and February. Orders have to some extent picked up again and we received approval for Sedaconda ACD in Brazil, so I am looking forward to the continued development of this important region. During Q1, we have also obtained marketing approval for Sedaconda ACD in Indonesia. With 26,000 and 30,000 ICU beds respectively, Brazil and Indonesia represent sizeable potential markets.

With the launch of Sedaconda (isoflurane) in Germany during the quarter, we can now offer the first and only on-label therapy for inhaled sedation in the ICU. The team is working on switching accounts from off-label generics to our approved product. While initial customer reactions have been promising, we continue to expect a gradual ramp-up over time as we are working through our customers' purchasing processes. Since April, the drug is also available in Sweden and the Netherlands and we will add more countries throughout the year.

On the US side, the focus in the first quarter has been on preparing the clinical program. Following the IND approval in December, we could start working with the individual trial sites to ensure all necessary approvals, finalize contracts and start training. I am very pleased to report that the first patient has been included in the clinical trial in April, in line with our ambitious time plan. Assuming rapid recruitment and a successful trial, we continue to expect the NDA submission in 2024 and a launch in early 2025.

Of course, we are following the terrible events in Ukraine. The short-term impact on Sedana Medical is however manageable. We have no presence in Ukraine and minimal (distributor) sales in Russia. The more relevant business implication is that our gas monitor is being manufactured by a Russian engineering company. While the sales contribution is fairly small, gas monitors are an important enabler for our therapy. In the short-term, we have sufficient stock available to meet our customers' demand. In anticipation of longer-term trade restrictions, we have however started a project to ensure availability of alternative gas monitors going forward.

Overall, I am pleased with the progress we have made during the quarter. Short term, we are facing some uncertainty regarding what the "new normal" after Covid-19 will look like, when access restrictions will be lifted, for how long ICU operations will be constrained and to what extent ICU capacities will continue to be scaled back after the pandemic. This short-term uncertainty does of course not change our belief in the long-term potential of inhaled sedation and we remain fully focused on executing our strategy. Based on convincing clinical data and strong health economic arguments, we will continue to work on our vision to make inhaled sedation the standard of care in ICUs.

Johannes Doll, President and CEO

Significant events during the period

- In January, the National Institute for Health and Care Excellence (NICE) in the UK, issued positive guidance recommending Sedaconda ACD as a cost-saving option for delivering inhaled sedation in intensive care as an alternative to intravenous sedation.
- In February the first bottles of Sedaconda (isoflurane) were delivered to customers in Germany, the company's largest market.
- In March, a post hoc analysis on the Sedaconda study was presented as a poster at ISICEM, one of the world's largest conference for intensive care and emergency medicine, concluding that isoflurane sedation as the primary sedative during mechanical ventilation in the first 30 days after randomisation, was associated with significantly more ICU-free days than propofol sedation, with a difference of four days. The company also hosted a symposium at the conference.
- During Q1, Sedaconda ACD was approved in Brazil and in Indonesia. With 26,000 and 30,000 ICU beds respectively, both countries represent sizeable potential markets.

Significant events after the period

- In April, end of procedure was reached in Italy, an important milestone in the approval process for Sedaconda. Approval is expected in the second half of 2022.
- In April the first patient has been included in the US clinical program.

Impact of Covid-19

Throughout the pandemic, Covid-19 has affected Sedana Medical's business. The impact included both positive effects, primarily the higher numbers of ventilated patients in ICUs, but also negative effects, such as restricted access to hospital customers. During that time, Sedana Medical achieved a step-change in sales. We anticipate that part of this positive development is sustainable as more customers are now familiar with inhaled sedation. At the same time, there is still significant uncertainty around what the "new normal" post Covid-19 will look like, e.g., when access restrictions will be lifted, for how long ICU operations will be constrained due to staff shortages and to what extent ICU capacities will continue to be scaled back after the pandemic.

Financial targets

The company aims at achieving revenue in excess of SEK 500 million in Europe in 2025 and an EBITDA margin of 40 percent when the company has reached a steady state following the launch phase in the United States.

The revenue target has been postponed by one year compared to previous communication. The reason is that access restrictions and capacity constraints in ICUs are slowing down launch execution and national pricing and reimbursement processes for Sedaconda (Isoflurane) in some countries have taken longer than anticipated.

Business update

First shipments of Sedaconda® (isoflurane) in Q1

In February, Sedana Medical shipped the first bottles of its pharmaceutical product Sedaconda (isoflurane) to costumers in Germany. This represents an important milestone on the company's journey to make inhaled sedation a global standard therapy in intensive care. In the countries where Sedaconda (isoflurane) is approved, Sedana Medical can offer the full therapy for inhaled sedation of mechanically ventilated patients in intensive care, consisting of the medical device Sedaconda ACD, the volatile anaesthetic Sedaconda (isoflurane), as well as accessories.

Additional national market approvals in Europe for Sedaconda (isoflurane)

The sales launch of Sedaconda (isoflurane) was enabled by the approval for European registration through the decentralized procedure received in July 2021. The general European approval allows the company to apply for approval in European countries according to separate national processes. To date, Sedana Medical has received national approval in 14 European countries: Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Ireland, Netherlands, Norway, Portugal, Slovenia, Spain and Sweden. In 2022, the company expects national approvals in four additional markets: the UK, Switzerland, Poland and Italy. The launch timelines after national approval vary, depending on the supply schedule and the speed of local pricing and reimbursement processes that are required in some countries. For example, Sedana Medical received a positive outcome for its registration application in Italy in April, which means that the company can now apply for the national market authorisation in the country. Overall, Sedana Medical aims to launch Sedaconda (isoflurane) in all its major direct markets during 2022 (Germany, France, Spain, UK, Nordics, Belgium and Netherlands), as well as several distributor markets.

NICE recommendation strengthens marketing message further

In January, the UK's National Institute for Health and Care Excellence (NICE) issued positive guidance recommending Sedaconda ACD as a cost-saving option for delivering inhaled sedation in intensive care as an alternative to intravenous sedation (in England and Wales). Evidence-based cost modelling performed by NICE shows cost savings compared to intravenous sedation of approximately £3,800 per adult patient (30-day time horizon for adult patients needing mechanical ventilation for 24 hours or longer in intensive care). The Sedaconda study (SED001) showed meaningful benefits of Sedaconda (isoflurane), administered via Sedaconda ACD, versus intravenous sedation, and the NICE recommendation has now shown that the use of Sedaconda ACD also leads to considerable cost savings compared to intravenous sedation.

In March, a post hoc analysis on the Sedaconda study was presented as a poster at one of the world's largest conferences for intensive care and emergency medicine, ISICEM, in Brussels. The poster "ICU-free and ventilator-free days with Isoflurane or Propofol as a primary sedative – a post hoc analysis of the Sedaconda study" concludes that isoflurane sedation as the primary sedative during mechanical ventilation in the first 30 days after randomisation, was associated with significantly more ICU-free days than propofol sedation, with a difference of four days. The findings support the use of isoflurane as a sole sedative in patients with need for prolonged sedation. These results were also an important part of the documentation on which NICE's recommendation was based.

US activities ramping up as first patient is included in clinical study

The US has over 100,000 intensive care beds and significantly higher price levels of sedation therapies than in Europe, making the US the highest-potential market for Sedana Medical. To obtain market approval in the US, Sedana Medical will conduct two randomised double-blind clinical studies to confirm and ensure efficacy and safety. The total number of patients included in the two studies is around 470 and the company aims to include approximately 25-30 clinics. Sedana Medical received Investigational New Drug (IND) clearance from the FDA in December 2021 and officially started the trial on 27 April by including the first patients in the studies. The objective remains to obtain market approval in the US before the end of 2024.

During the autumn of 2021, Sedana Medical took the strategic decision to build its own commercial operations in the US to retain the most value for shareholders. To ensure that Sedana Medical has the financial strength and flexibility required to prepare for a commercial launch in the US, the company successfully raised approximately SEK 615 million before transaction-related costs in a directed share issue in December 2021.

Adding new geographical markets

Sedana Medical is experiencing a steadily increasing interest in inhaled sedation in intensive care and the medical device Sedaconda ACD from around the world. New markets are being assessed on a continuous basis based on market potential, accessibility and expected return on investment. During Q1, Sedana Medical received approval for the medical device Sedaconda ACD in Brazil and Indonesia, two high-potential markets for the company. For reference, Brazil has 26,000 ICU beds and Indonesia has 30,000 ICU beds, which can be compared to Germany's 22,000 ICU beds.

Financial summary

(KSEK)	Jan-Mar		Jan-Dec
	2022	2021	2021
Net sales	33,654	45,000	159,152
Gross profit	22,990	28,605	106,706
Gross margin %	68%	64%	67%
EBITDA	-16,444	-8,308	-50,093
EBITDA margin %	-49%	-18%	-31%
Operating income (EBIT)	-22,061	-10,362	-61,493
Operating margin %	-66%	-23%	-39%
Income after net financial items	-18,826	-8,858	-57,371
Net income	-18,973	-8,963	-57,966
Net income margin %	-56%	-20%	-36%
Total assets	1,141,361	587,799	1,167,580
Equity	1,082,203	543,596	1,101,456
Equity ratio %	95%	92%	94%
Quick ratio %	1492%	952%	1414%
Debt to equity ratio %	5%	8%	6%
Average number of full-time employees for the period	87	66	73
Number of employees at balance date	94	74	90
Number of employees and consultants at balance date	102	88	107
Average number of shares before dilution ¹⁾	99,336,960	92,186,960	92,774,631
Average number of shares after dilution ¹⁾	99,490,544	92,660,006	92,964,711
Number of shares at balance date before dilution ¹⁾	99,336,960	92,186,960	99,336,960
Number of shares at balance date after dilution ¹⁾	99,490,544	92,734,232	99,548,704
Earnings per share before dilution, SEK	-0.19	-0.10	-0.62
Earnings per share after dilution, SEK	-0.19	-0.10	-0.62

¹⁾ Comparative periods have been adjusted for the share split that was carried out in May 2021

Group performance

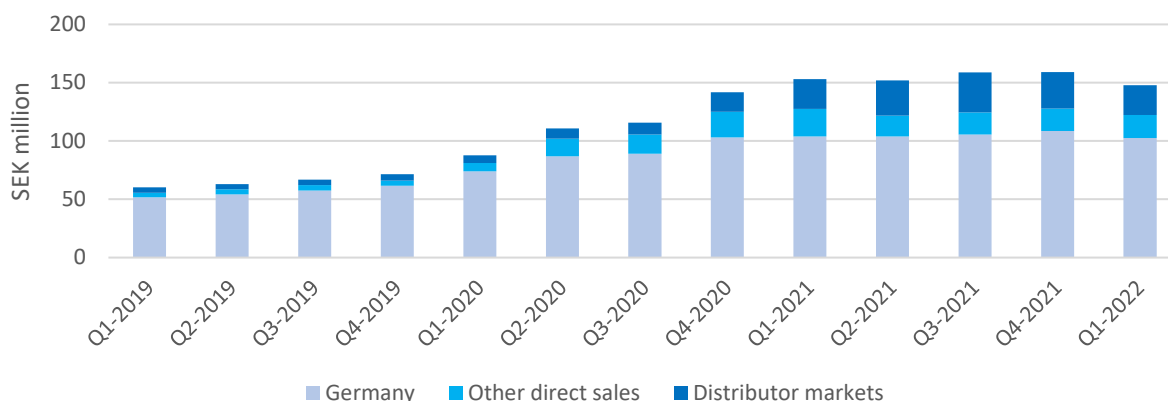
Net sales

Net sales during the first quarter totalled KSEK 33,654 (45,000), equivalent to a decrease of 25 percent. Adjusted for currency effects, the quarter showed a decrease of 28 percent.

The majority of the Group's sales are in Europe, mainly Germany, where the decrease was 22 percent, mainly due to reduced capacity in intensive care as hospitals were badly affected by staff absence during the quarter. The decrease is also partly explained by fewer ventilator days than in the first quarter of last year as a consequence of the milder Omicron variant of Covid-19. In other direct markets in Europe we have seen similar effects in some countries with fewer ventilated intensive care patients and limited access to hospitals. However, this was offset by good underlying growth particularly in Spain, France and the United Kingdom, leading to an overall increase in sales of 12 percent in our other direct markets. Regarding distributor markets, the decrease mainly relates to South America, where we firstly had a sharp increase in sales in the first quarter of the previous year, driven partly by a shortage of propofol, and secondly a build-up of stocks in the fourth quarter of 2021 in expectation of a further wave of Covid-19 which did not happen. Other regions in our distributor markets showed good growth. Altogether, the decrease in the distributor markets was 51 percent from the high level of sales in the first quarter last year.

(KSEK)	Jan-Mar		%	Jan-Dec
	2022	2021		2021
Germany	22,384	28,531	-22%	108,699
Other direct sales	5,625	5,038	12%	19,062
Distributor markets	5,645	11,431	-51%	31,391
Total net sales	33,654	45,000	-25%	159,152

Sales by area, rolling 12 months



Gross profit and margin

Gross profit for the quarter was KSEK 22,990 (28 605), equivalent to a gross margin of 68 (64) percent. The increase is mainly due to lower transportation costs, but also to some extent to a positive market mix whereas distributor markets with somewhat lower margins contributed relatively less to net sales than for the first quarter last year.

Selling expenses

Selling expenses for the quarter totalled KSEK -26,597 (-20,853), equivalent to an increase of 28 percent. The increase is due partly to costs related to the launch of Sedaconda (isoflurane), a larger commercial and marketing organisation and a higher level of activity, as the first quarter of the previous year was greatly affected by Covid-19 restrictions. The higher expenses are also a result of commencement of amortisation relating to the EU registration project of approximately MSEK 3 in the quarter.

Administrative expenses

Administrative expenses for the quarter totalled KSEK -12,561 (-13,611), equivalent to a decrease of 8 percent. The lower expenses are mainly related to efficiency improvements within the finance function.

Research and development expenses

Research and development expenses for the quarter totalled KSEK -5,314 (-4,173), equivalent to an increase of 27 percent. The increase is mainly due to higher regulatory expenses related to sale of pharmaceutical products rather than solely medical devices, as previously.

Other operating income/expenses

Other operating income mainly consists of positive unrealised exchange rate differences on operating items. These totalled KSEK 6,233 (2,272) for the quarter.

Other operating expenses mainly consist of negative unrealised exchange rate differences on operating items. These totalled KSEK -6,812 (-2,602) for the quarter.

Net financial items and earnings per share

Net financial items for the quarter totalled KSEK 3,235 (1,504) and consist mainly of unrealised exchange rate differences.

Group tax expense for the quarter was KSEK -147 (-105) and consists mainly of current tax in Germany. Consequently, earnings per share amounted to SEK -0.19 (-0.10) for the quarter.

Equity and debt

Adjusted for the share split made in May 2021 and including the new share issue made in December 2021, equity at 31 March was KSEK 1,082,203, compared to KSEK 1,101,456 at the beginning of the year. This corresponds to SEK 10.89 (5.90) per share. Equity/assets ratio was 95 percent, compared to 94 percent at the beginning of the year.

Debt/equity ratio at 31 March was 5 percent, compared to 6 percent at the beginning of the year. The Group had no long-term debt at 31 March.

Cash and cash position

Cash and cash equivalents decreased by KSEK 57,564 during the quarter and were KSEK 778,617 at 31 March, compared to KSEK 836,181 at the beginning of the quarter. Cash flow from operating activities before change in working capital for the quarter was KSEK -16,288 (-8,851). Cash flow from change in working capital totalled

KSEK -11,239 (-4,459), which was negatively impacted during the quarter by increased stock levels and lower current liabilities. Cash flow from operating activities thus totalled KSEK -27,527 (-13,310).

Cash flow from investing activities totalled KSEK -32,145 (-21,078). The investments mostly consist of intangible assets, principally development expenses for clinical studies and work on registration of Sedaconda ACD and Sedaconda (isoflurane) in the United States and investments related to the company's paediatric study IsoCOMFORT (SED002).

Cash flow from financing activities totalled KSEK -1,204 (946) and is mainly related to amortisation of lease liabilities but also related to repurchase of warrants.

Cash flow per share for the quarter was SEK -0.61 (-0.36).

Parent company

The Parent Company's net sales for the quarter totalled KSEK 33,626 (44,967), of which intra-group sales totalled KSEK 1,653 (1,308).

Operating income for the period totalled KSEK -17,388 (-9,782). Net financial items were KSEK 3,544 (1,861) and relate mainly to unrealised exchange gains on internal loans.

Shareholders' equity in the Parent Company totalled KSEK 1,092,524 at 31 March 2022, compared to KSEK 1,106,528 at the beginning of the year. This corresponds to a decrease of KSEK 14,004. Share capital totalled KSEK 2,483, compared to KSEK 2,483 at the beginning of the year.

Cash and cash equivalents totalled KSEK 765,449, compared to KSEK 816,279 at the beginning of the year.

The Sedana Medical share

Sedana Medical shares have been listed on Nasdaq First North Growth Market Stockholm since June 2017. Market capitalisation at the end of the first quarter was SEK 6,745 million.

The price paid for Sedana Medical shares, adjusted for the split made, was SEK 98.05 at the start of the year and SEK 67.90 at the end of the quarter. The lowest closing price for the interim period was recorded on 21 February and was SEK 57.75. The highest closing price was recorded on 3 January and was SEK 95.60.

Share information

	Jan-Mar		Jan-Dec
	2022	2021	2021
Net income, KSEK	-18,973	-8,963	-57,966
Cash flow, KSEK	-60,876	-33,442	453,595
Number of shares at balance date	99,336,960	92,186,960	99,336,960
Average number of shares	99,336,960	92,186,960	92,774,631
Outstanding warrants at balance date	505,368	547,272	513,368
Average number of warrants	509,368	473,046	456,094
Share capital at balance date, KSEK	2,483	2,305	2,483
Equity at balance date, KSEK	1,082,203	543,596	1,101,456
Earnings per share before dilution, SEK	-0.19	-0.10	-0.62
Earnings per share after dilution, SEK	-0.19	-0.10	-0.62
Equity per share, SEK	10.89	5.90	11.09
Cash flow per share, SEK	-0.61	-0.36	4.89

Largest shareholders at the end of the period

	No of shares	Share
Swedbank Robur Funds	9,444,013	9.5%
Handelsbanken Funds	9,270,212	9.3%
Linc AB	8,064,804	8.1%
Anders Walldov direct and indirect (Brohuvudet AB)	8,000,000	8.1%
Ola Magnusson direct and indirect (Magiola AB)	4,572,098	4.6%
Sten Gibeck	4,283,276	4.3%
Öhman Funds	4,137,821	4.2%
AMF Pension	3,870,000	3.9%
Berenberg Funds	1,849,456	1.9%
Avanza Pension	1,767,814	1.8%
Third Swedish National Pensin Fund	1,735,989	1.7%
Tedsalus AB (Thomas Eklund)	1,666,464	1.7%
Highclere International Investors LLP	1,640,367	1.7%
DNCA Finance S.A	1,592,761	1.6%
Deka Investments	1,339,540	1.3%
Fifteen largest shareholders	63,234,615	63.7%
Others	36,102,345	36.3%
Total	99,336,960	100.0%

Facts about the share

Trading
Nasdaq First North Growth Market
Sweden

No of shares as per Mar 31, 2022
99,336,960

Market cap as per Mar 31, 2022
SEK 6,745 million

Ticker
SEDANA

ISIN
SE0015988373

LEI-kod
549300FQ3NJRI56LCX32

Certification from the Board of Directors and the CEO

The Board of Directors and the Chief Executive Officer certify that this interim report presents a true and fair view of the operations, financial position and earnings of the parent company and the Group and describes material risks and uncertainties faced by the parent company and the companies forming part of the Group.

Danderyd 28 April 2022

Thomas Eklund
Chairman of the Board

Claus Bjerre
Board member

Bengt Julander
Board member

Ola Magnusson
Board member

Eva Walde
Board member

Christoffer Rosenblad
Board member

Johannes Doll
President and CEO

This interim report has not been subject to review by the company's auditors. This document has been prepared in Swedish and English versions. In the event of any discrepancies between the Swedish and English versions, the Swedish version will take precedence.

Contacts and invitation to presentation

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Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm.
The company's Certified Adviser is Erik Penser Bank, +46 8 463 83 00, certifiedadviser@penser.se

Presentation of the interim report

Sedana Medical presents the interim report to investors, asset managers, analysts and media on 28 April 2022 at 13.30. The presentation will be held in English and takes place via telephone conference and audio webcast. More information is available at: <https://financialhearings.com/event/43300>

After the presentation, a recorded version of the webcast will be available at: [Presentations | Sedana Medical](#)

Financial calendar

Annual general meeting	11 May 2022
Interim report Jan-Jun, 2022	21 July 2022
Interim report Jan-Sep, 2022	25 October 2022

Consolidated income statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2022	2021	2021
Net sales	33,654	45,000	159,152
Cost of goods sold	-10,664	-16,395	-52,446
Gross profit	22,990	28,605	106,706
Selling expenses	-26,597	-20,853	-96,573
Administrative expenses	-12,561	-13,611	-51,736
Research and development expenses	-5,314	-4,173	-19,704
Other operating income	6,233	2,272	4,013
Other operating expenses	-6,812	-2,602	-4,199
Operating income	-22,061	-10,362	-61,493
Financial items			
Financial income	3,455	1,651	11,285
Financial expenses	-220	-147	-7,163
Net financial items	3,235	1,504	4,122
Income before taxes	-18,826	-8,858	-57,371
Tax	-147	-105	-595
Net income	-18,973	-8,963	-57,966
Earnings per share, based on earnings attributable to the parent company's ordinary shareholders:			
Before dilution	-0.19	-0.10	-0.62
After dilution	-0.19	-0.10	-0.62
EBITDA	-16,444	-8,308	-50,093
Amortisation of intangible assets	-3,806	-425	-4,720
Depreciation of tangible assets	-1,811	-1,629	-6,680
Operating income (EBIT)	-22,061	-10,362	-61,493

Consolidated statement of other comprehensive income, summary

(KSEK)	Jan-Mar		Jan-Dec
	2022	2021	2021
Net income	-18,973	-8,963	-57,966
Other comprehensive income			
Items that can later be reclassified to the income statement:			
Translation differences from foreign operations	-183	-295	-322
Other comprehensive income, net after tax	-183	-295	-322
Total comprehensive income	-19,156	-9,258	-58,288
Total comprehensive income as a whole attributable to the parent company's shareholders	-19,156	-9,258	-58,288

Consolidated balance sheet, summary

(KSEK)	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
ASSETS			
Intangible assets			
Capitalised development expenditure	295,391	184,591	268,201
Concessions, patents, licenses, etc.	2,595	2,718	1,786
Tangible assets			
Machinery and other technical facilities	1,195	7,151	1,309
Equipment, tools and installations	5,984	1,149	6,154
Rights of use	10,344	9,067	9,324
Financial assets			
Other long-term assets	42	42	42
Deferred tax assets			
	26	83	23
Total fixed assets	315,577	204,801	286,839
Inventory	18,498	11,739	11,093
Tax receivables	712	464	410
Accounts receivable	15,187	17,525	20,345
Prepayments and accrued income	7,771	6,364	7,115
Other receivables	4,999	3,287	5,597
Cash and cash equivalents	778,617	343,619	836,181
Total current assets	825,784	382,998	880,741
TOTAL ASSETS	1,141,361	587,799	1,167,580

(KSEK)	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
EQUITY AND LIABILITIES			
Equity			
Share capital	2,483	2,305	2,483
Other contributed capital	1,222,298	615,683	1,222,395
Translation difference	1	211	184
Retained earnings including net profit	-142,579	-74,603	-123,606
Equity attributable to the parent company's shareholders	1,082,203	543,596	1,101,456
Non-current liabilities			
Leasing liabilities	5,059	5,224	4,642
Total non-current liabilities	5,059	5,224	4,642
Current liabilities			
Leasing liabilities	4,805	3,355	4,232
Accounts payable	12,927	10,288	15,036
Tax debt	2,655	2,705	3,997
Other liabilities	11,676	9,432	18,473
Accrued expenses and deferred income	22,036	13,199	19,744
Total current liabilities	54,099	38,979	61,482
Total liabilities	59,158	44,203	66,124
TOTAL EQUITY AND LIABILITIES	1,141,361	587,799	1,167,580

Consolidated statement of changes in equity, summary

Equity attributable to parent company shareholders

(KSEK)	Share capital	Other contributed capital	Translation difference	Retained earnings including net profit	Total
Opening equity at Jan 1, 2021	2,305	613,923	506	-65,640	551,094
Net income	-	-	-	-8,963	-8,963
Other comprehensive income	-	-	-295	-	-295
Total comprehensive income	-	-	-295	-8,963	-9,258
Transactions with the Group's owners					
Received premium for warrant subscription	-	1,760	-	-	1,760
Total transactions with the Group's owners	-	1,760	-	-	1,760
Closing equity at Mar 31, 2021	2,305	615,683	211	-74,603	543,596

(KSEK)	Share capital	Other contributed capital	Translation difference	Retained earnings including net profit	Total
Opening equity at Jan 1, 2022	2,483	1,222,395	184	-123,606	1,101,456
Net income	-	-	-	-18,973	-18,973
Other comprehensive income	-	-	-183	-	-183
Total comprehensive income	-	-	-183	-18,973	-19,156
Transactions with the Group's owners					
Repurchase of warrants	-	-97	-	-	-97
Total transactions with the Group's owners	-	-97	-	-	-97
Closing equity at Mar 31, 2022	2,483	1,222,298	1	-142,579	1,082,203

Consolidated cash flow statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2022	2021	2021
Operating activities			
Operating income	-22,061	-10,362	-61,493
<i>Adjustments for non-cash items</i>			
Depreciations and amortisations	5,617	2,054	11,400
Exchange rate differences	236	-1,435	-4,080
Other non-cash items	114	1,131	1,927
Interest received	0	0	0
Interest paid	-63	-50	-243
Taxes paid	-131	-189	-320
Cash flow from operating activities before changes in working capital	-16,288	-8,851	-52,809
<i>Cash flow from changes in working capital</i>			
Cash flow from inventories	-6,346	-2,942	-2,296
Cash flow from operating receivables	3,135	4,053	-2,169
Cash flow from operating liabilities	-8,028	-5,570	16,053
Cash flow from operating activities	-27,527	-13,310	-41,221
Investing activities			
Investments in intangible assets	-31,660	-18,096	-105,063
Investments in tangible assets	-485	-2,982	-5,192
Cash flow from investing activities	-32,145	-21,078	-110,255
Financing activities			
New share issue	-	-	614,900
Issue expenses	-	-	-7,946
Amortisation of leasing liabilities	-1,107	-814	-3,579
Received premium for warrant subscription	-	1,760	1,696
Repurchase of warrants	-97	-	-
Cash flow from financing activities	-1,204	946	605,071
Cash flow for the period	-60,876	-33,442	453,595
Cash and cash equivalents at the beginning of the period	836,181	376,171	376,171
Translation difference	3,312	890	6,415
Cash and cash equivalents at the end of the period	778,617	343,619	836,181

Consolidated quarterly summary, income statement

(KSEK)	2021				2022
	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1
Net sales	45,000	39,510	28,277	46,365	33,654
Cost of goods sold	-16,395	-13,318	-9,157	-13,576	-10,664
Gross profit	28,605	26,192	19,120	32,789	22,990
<i>Gross margin</i>	64%	66%	68%	71%	68%
Selling expenses	-20,853	-25,901	-20,063	-29,756	-26,597
Administration costs	-13,611	-12,194	-10,035	-15,896	-12,561
Research and development costs	-4,173	-4,701	-4,809	-6,021	-5,314
Other operating income	2,272	643	198	900	6,233
Other operating expenses	-2,602	-409	-489	-699	-6,812
Operating income	-10,362	-16,370	-16,078	-18,683	-22,061
<i>Operating margin</i>	-23%	-41%	-57%	-40%	-66%
Financial income	1,651	-306	1,906	8,034	3,455
Financial expenses	-147	-486	-68	-6,462	-220
Net financial items	1,504	-792	1,838	1,572	3,235
Income before taxes	-8,858	-17,162	-14,240	-17,111	-18,826
Tax	-105	-127	-681	318	-147
Net income	-8,963	-17,289	-14,921	-16,793	-18,973
Operating income (EBIT)	-10,362	-16,370	-16,078	-18,683	-22,061
Whereof depreciation of intangible assets	-425	-426	-429	-3,440	-3,806
Whereof depreciation of tangible assets	-1,629	-1,661	-1,636	-1,754	-1,811
EBITDA	-8,308	-14,283	-14,013	-13,489	-16,444
<i>EBITDA margin</i>	-18%	-36%	-50%	-29%	-49%

(KSEK)	2021				2022
	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1
Germany	28,531	27,597	18,031	34,540	22,384
Other direct sales	5,038	3,875	3,514	6,635	5,625
Distributor markets	11,431	8,038	6,732	5,190	5,645
Total net sales	45,000	39,510	28,277	46,365	33,654

Consolidated quarterly summary, balance sheet

(KSEK)	2021				2022
	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1
ASSETS					
Intangible assets					
Capitalised development expenditure	184,591	206,795	238,911	268,201	295,391
Concessions, patents, licenses, etc.	2,718	2,351	2,099	1,786	2,595
Tangible assets					
Machinery and other technical facilities	7,151	6,362	6,146	1,309	1,195
Equipment, tools and installations	1,149	1,172	1,092	6,154	5,984
Rights of use	9,067	9,667	9,485	9,324	10,344
Financial assets					
Other long-term assets	42	42	42	42	42
Deferred tax assets					
	83	31	21	23	26
Total fixed assets	204,801	226,420	257,796	286,839	315,577
Inventory	11,739	10,714	12,075	11,093	18,498
Tax receivables	464	457	461	410	712
Accounts receivable	17,525	18,458	18,279	20,345	15,187
Prepayments and accrued income	6,364	5,881	6,252	7,115	7,771
Other receivables	3,287	3,276	4,035	5,597	4,999
Cash and cash equivalents	343,619	307,785	261,505	836,181	778,617
Total current assets	382,998	346,571	302,607	880,741	825,784
TOTAL ASSETS	587,799	572,991	560,403	1,167,580	1,141,361
EQUITY AND LIABILITIES					
Equity					
Share capital	2,305	2,305	2,305	2,483	2,483
Other contributed capital	615,683	615,683	615,683	1,222,395	1,222,298
Translation difference	211	392	249	184	1
Retained earnings including net profit	-74,603	-91,892	-106,813	-123,606	-142,579
Equity attributable to the parent company's shareholders	543,596	526,488	511,424	1,101,456	1,082,203
Non-current liabilities					
Leasing liabilities	5,224	5,414	5,041	4,642	5,059
Total non-current liabilities	5,224	5,414	5,041	4,642	5,059
Current liabilities					
Leasing liabilities	3,355	3,779	3,987	4,232	4,805
Accounts payable	10,288	12,577	13,156	15,036	12,927
Tax debt	2,705	2,949	3,981	3,997	2,655
Other liabilities	9,432	7,038	6,972	18,473	11,676
Accrued expenses and deferred income	13,199	14,746	15,842	19,744	22,036
Total current liabilities	38,979	41,089	43,938	61,482	54,099
Total liabilities	44,203	46,503	48,979	66,124	59,158
TOTAL EQUITY AND LIABILITIES	587,799	572,991	560,403	1,167,580	1,141,361

Consolidated quarterly summary, cash flow statement

(KSEK)	2021				2022
	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1
Operating activities					
Operating income	-10,362	-16,370	-16,078	-18,683	-22,061
Adjustments for non-cash items					
Depreciations and amortisations	2,054	2,087	2,065	5,194	5,617
Exchange rate differences	-1,435	102	-261	-2,486	236
Other non-cash items	1,131	652	108	36	114
Interest received	0	0	0	0	0
Interest paid	-50	-66	-62	-65	-63
Taxes paid	-189	188	-71	-248	-131
Cash flow from operating activities before changes in working capital	-8,851	-13,407	-14,299	-16,252	-16,288
Cash flow from changes in working capital					
Cash flow from inventories	-2,942	1,026	-1,362	982	-6,346
Cash flow from operating receivables	4,053	-1,514	-650	-4,058	3,135
Cash flow from operating liabilities	-5,570	2,085	1,775	17,763	-8,028
Cash flow from operating activities	-13,310	-11,810	-14,536	-1,565	-27,527
Investing activities					
Investments in intangible assets	-18,096	-22,412	-32,176	-32,379	-31,660
Investments in tangible assets	-2,982	-710	-495	-1,005	-485
Cash flow from investing activities	-21,078	-23,122	-32,671	-33,384	-32,145
Financing activities					
New share issue	-	-	-	614,900	-
Issue expenses	-	-	-	-7,946	-
Amortisation of leasing liabilities	-814	-841	-924	-1,000	-1,107
Received premium for warrant subscription	1,760	-	-	-64	-
Repurchase of warrants	-	-	-	-	-97
Cash flow from financing activities	946	-841	-924	605,890	-1,204
Cash flow for the period	-33,442	-35,773	-48,131	570,941	-60,876
Cash and cash equivalents at the beginning of the period	376,171	343,619	307,785	261,505	836,181
Translation difference	890	-61	1,851	3,735	3,312
Cash and cash equivalents at the end of the period	343,619	307,785	261,505	836,181	778,617

Parent company income statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2022	2021	2021
Net sales	33,626	44,967	159,107
Cost of goods sold	-9,735	-14,935	-49,662
Gross profit	23,891	30,032	109,445
Selling expenses	-15,382	-10,317	-58,487
Administration costs	-26,901	-27,825	-102,312
Research and development costs	-4,361	-4,309	-15,592
Other operating income	11,961	3,514	15,766
Other operating expenses	-6,596	-877	-3,981
Operating income	-17,388	-9,782	-55,161
Financial items			
Financial income	3,699	1,958	12,621
Financial expenses	-155	-97	-21,088
Net financial items	3,544	1,861	-8,467
Income after net financial items	-13,844	-7,921	-63,628
Group contribution	-	-	-1
Income before tax	-13,844	-7,921	-63,629
Income tax	-	-	0
Net income	-13,844	-7,921	-63,629

Parent company statement of other comprehensive income, summary

(KSEK)	Jan-Mar		Jan-Dec
	2022	2021	2021
Net income	-13,844	-7,921	-63,629
Other comprehensive income			
Items that can later be reclassified to the income statement:			
Translation differences from foreign operations	-63	-100	-93
	-63	-100	-93
Other comprehensive income, net after tax			
Total comprehensive income	-13,907	-8,021	-63,722

Parent company balance sheet, summary

(KSEK)	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
ASSETS			
Intangible assets			
Capitalised development expenditure	279,575	173,800	253,928
Tangible assets			
Machinery and other technical facilities	815	5,964	835
Equipment, tools and installations	5,312	609	5,389
Financial assets			
Other long-term assets	404	395	404
Non-current receivables, group companies	30,530	39,755	29,819
Total fixed assets	316,636	220,523	290,375
Inventory	18,498	11,788	11,093
Tax receivables	19	5	4
Accounts receivable	13,172	16,072	17,934
Receivables, group companies	41,973	4,457	19,158
Prepayments and accrued income	7,105	6,350	5,721
Other receivables	4,421	2,207	4,336
Cash and cash equivalents	765,449	329,969	816,279
Total current assets	850,637	370,848	874,525
TOTAL ASSETS	1,167,273	591,371	1,164,900

(KSEK)	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	2,483	2,305	2,483
Fund for capitalised development expenses	272,270	171,921	246,451
<i>Non-restricted equity</i>			
Share premium fund	1,222,298	615,683	1,222,395
Retained earnings	-390,683	-226,649	-301,172
Net income	-13,844	-7,921	-63,629
Equity attributable to the parent company's shareholders	1,092,524	555,339	1,106,528
Current liabilities			
Accounts payable	12,063	9,835	13,662
Liabilities to group companies	34,039	8,768	10,937
Tax debt	1,568	1,201	2,118
Other liabilities	7,928	5,453	16,027
Accrued expenses and deferred income	19,151	10,775	15,628
Total current liabilities	74,749	36,032	58,372
Total liabilities	74,749	36,032	58,372
TOTAL EQUITY AND LIABILITIES	1,167,273	591,371	1,164,900

Parent company statement of changes in equity, summary

(KSEK)	Equity attributable to the parent company's shareholders				
	Restricted equity		Non-restricted equity		Total
	Share capital	Fund for capitalised development expenses	Share premium fund	Retained earnings including net income	Total equity
Opening equity at Jan 1, 2021	2,305	154,405	613,923	-209,033	561,600
Net income	-	-	-	-7,921	-7,921
Other comprehensive income	-	-	-	-100	-100
Total comprehensive income	-	-	-	-8,021	-8,021
Transactions with the parent company's owners					
Received premium for warrant subscription	-	-	1,760	-	1,760
Total transactions with the parent company's owners	-	-	1,760	-	1,760
Reallocation between items in equity					
Capitalised development expenses	-	17,516	-	-17,516	-
Total reallocations	-	17,516	-	-17,516	-
Closing equity at Mar 31, 2021	2,305	171,921	615,683	-234,570	555,339
(KSEK)	Share capital	Fund for capitalised development expenses	Share premium fund	Retained earnings including net income	Total equity
Opening equity at Jan 1, 2022	2,483	246,451	1,222,395	-364,801	1,106,528
Net income	-	-	-	-13,844	-13,844
Other comprehensive income	-	-	-	-63	-63
Total comprehensive income	-	-	-	-13,907	-13,907
Transactions with the parent company's owners					
Repurchase of warrants	-	-	-97	-	-97
Total transactions with the parent company's owners	-	-	-97	-	-97
Reallocation between items in equity					
Capitalised development expenses	-	25,819	-	-25,819	-
Total reallocations	-	25,819	-	-25,819	-
Closing equity at Mar 31, 2022	2,483	272,270	1,222,298	-404,527	1,092,524

Parent company cash flow statement, summary

(KSEK)	Jan-Mar		Jan-Dec
	2022	2021	2021
Operating activities			
Operating income	-17,388	-9,782	-55,161
<i>Adjustments for non-cash items</i>			
Depreciations and amortisations	3,741	523	4,911
Exchange rate differences	197	-2,347	-2,671
Other non-cash items	75	432	936
Interest received	-	-	-
Interest paid	-	-	-23
Taxes paid	-	-188	-
Cash flow from operating activities before changes in working capital	-13,375	-11,362	-52,008
<i>Cash flow from changes in working capital</i>			
Cash flow from inventories	-7,405	-2,831	-1,848
Cash flow from operating receivables	-19,560	-5,191	-26,003
Cash flow from operating liabilities	16,376	1,646	24,296
Cash flow from operating activities	-23,964	-17,738	-55,563
Investing activities			
Investments in intangible assets	-28,855	-17,539	-100,581
Investments in tangible assets	-486	-2,264	-4,183
Investments in financial assets	-	-	-3,046
Cash flow from investing activities	-29,341	-19,803	-107,810
Financing activities			
New share issue	-	-	614,900
Issue expenses	-	-	-7,946
Received premium for warrant subscription	-	1,760	1,696
Repurchase of warrants	-97	-	-
Cash flow from financing activities	-97	1,760	608,650
Cash flow for the period	-53,402	-35,781	445,277
Cash and cash equivalents at the beginning of the period	816,279	365,113	365,113
Translation difference	2,572	637	5,889
Cash and cash equivalents at the end of the period	765,449	329,969	816,279

Other information

General information

Sedana Medical (publ), with corporate identity number 556670-2519, is a limited company registered in Sweden with registered office in Danderyd. The address of the head office is Vendevägen 89, SE-182 32 Danderyd, Sweden. The object of the company's operations is to develop, manufacture and sell medical devices and pharmaceuticals. Sedana Medical AB is the Parent Company of the Sedana Medical Group. Unless otherwise indicated, all amounts are stated in thousands of Swedish kronor (KSEK). All amounts, unless otherwise indicated, are rounded to the nearest thousand. Figures in brackets relate to the comparative year.

For the Group's financial assets and liabilities, their carrying amount is considered to be a reasonable estimate of fair value as they essentially refer to current receivables and liabilities, so that the discounting effect is insignificant.

Accounting principles

This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting. The parent company interim report has been prepared in accordance with the Annual Accounts Act and Swedish Financial Reporting Board recommendation RFR 2. Applied accounting policies agree with those described in the 2021 Annual Report of Sedana Medical.

Important estimates

Estimates and judgements are evaluated regularly and based on historical experience and other factors, including expectations of future events considered reasonable under prevailing circumstances. For further information, see the Group's 2021 Annual Report.

Alternative performance measures

Alternative performance measures relate to financial performance indicators used by the senior management and investors to assess the Group's earnings and financial position which cannot be read or derived directly from the financial statements. These financial performance indicators are intended to facilitate analysis of the Group's development. The alternative performance measures should accordingly be regarded as complementing the financial reporting prepared in accordance with IFRS. The financial performance indicators presented in this report may differ from similar indicators used by other companies. For further information regarding definitions, see page 24.

Risk

Sedana Medical's operations, earnings and financial position are affected by a number of risk factors. These are principally related to demand for medical devices, fluctuating exchange rates and access to funding. More information about Sedana Medical's risks and management of these risks can be found in the 2021 Annual Report on pages 43.45. For information concerning our view of Covid-19 and its possible impacts on Sedana Medical, see page 4 and the CEO's Comments on page 3.

Personnel

During the period, the Group had an average of 87 (66) full time employees and 10 (12) full time consultants, representing an increase of 19 on the same period in 2021. At the end of the quarter, the total number of employees was 94 and the total number of consultants was 8 compared to 74 and 14 respectively at the end of the first quarter last year. The main reason for the increase in personnel is a build-up of functions such as sales, marketing, medical affairs and regulatory and quality functions prior to the registration and launch of Sedaconda (isoflurane).

Transactions with related parties

Transactions with related parties take place on market terms. During 2021, Sedana Medical provided a loan amounting to SEK 300,000 to Stefan Krisch. Stefan is, since last year, part of Sedana Medical's management team. During 2021, a consulting agreement was also signed between Sedana Medical and board member Claus Bjerre. During the first quarter 2022 50 KSEK regarding this agreement was settled.

Warrant programme

At the end of the period Sedana Medical had 505,368 outstanding warrants where 1 warrant equals 1 share at conversion.

Programme	Position	Number of acquired warrants at the beginning of the period	Number of acquired warrants during the period	Number of exercised warrants during the period	Number of exercised repurchased during the period	Number of acquired warrants at the end of the period	Terms*	Strike price (SEK)
2019/2022	CEO	0	0	0	0	0	1:1	35.56
2019/2022	Senior management	105,172	0	0	0	105,172	1:1	35.56
2019/2022	Other employees	217,264	0	0	0	217,264	1:1	35.56
2019/2022	Total	322,436	0	0	0	322,436	1:1	35.56
<i>Exercise period 1 July 2022 – 30 November 2022</i>								
2020/2023	CEO	0	0	0	0	0	1:1	83.65
2020/2023	Senior management	16,000	0	0	8,000	8,000	1:1	83.65
2020/2023	Other employees	26,480	0	0	0	26,480	1:1	83.65
2020/2023	Total	42,480	0	0	8,000	34,480	1:1	83.65
<i>Exercise period 1 June 2023 – 30 September 2023</i>								
2020/2024	CEO	0	0	0	0	0	1:1	123.88
2020/2024	Senior management	25,200	0	0	0	25,200	1:1	123.88
2020/2024	Other employees	123,252	0	0	0	123,252	1:1	123.88
2020/2024	Total	148,452	0	0	0	148,452	1:1	123.88
<i>Exercise period 1 February 2024 – 31 May 2024</i>								
Total	CEO	0	0	0	0	0		
Total	Senior management	146,372	0	0	8,000	138,372		
Total	Other employees	366,996	0	0	0	366,996		
	Total	513,368	0	0	8,000	505,368		

* 1:1 = 1 warrant = 1 share at conversion

Definitions

Average number of full-time employees during the period

Number of full-time employees at the end of each period divided by number of periods

Balance sheet total

Total assets

Cash flow per share

Cash flow for the period divided by average number of shares before dilution

Debt to equity ratio

Total liabilities divided by total equity

EBIT

Operating income/Earnings before interest and taxes

EBITDA

Earnings before interest, taxes, depreciation and amortisation

EBITDA margin

EBITDA divided by net sales

Equity to assets ratio

Total equity divided by total assets

Equity per share

Equity divided by number of shares at the end of the period, before dilution

Gross margin

Gross profit divided by net sales

Net income margin

Net income divided by net sales

Operating margin

Operating income divided by net sales

Quick ratio

Current assets excluding inventories divided by current liabilities

Tax rates for the parent company

2021: 20.6%

Before 2021: 21.4%