



sedanamedical

Bringing inhaled sedation to intensive care

Interim report

January-September 2021

sedana medical ab (publ)

*"Sedaconda (isoflurane) approved in
11 European markets"*

Johannes Doll, President and CEO

Q1 Q2 **Q3** Q4

Financial summary

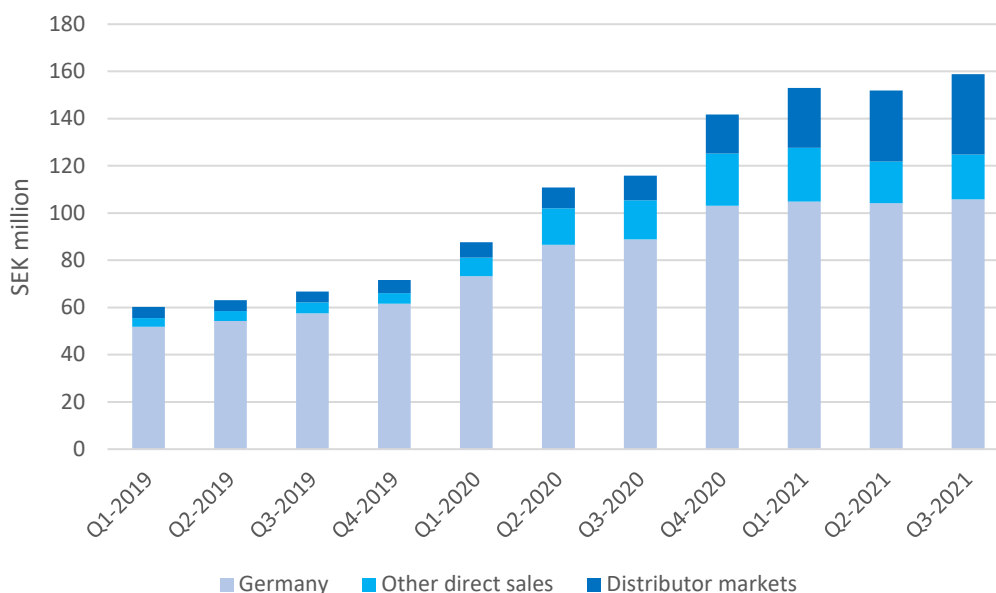
Third quarter 2021

- Net sales totalled SEK 28 M (21), equivalent to an increase of 32% compared to the third quarter of 2020. At constant exchange rates, sales increased by 34% with all regions showing positive growth.
- Gross profit was SEK 19 M (13), equivalent to a margin of 68% (62). The improved margin is primarily an effect of lower transportation costs, favorable product mix and timing effects.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled SEK -14 M (-10), equivalent to an EBITDA margin of -50% (-47).
- Operating income (EBIT) totalled SEK -16 M (-12), equivalent to an EBIT margin of -57% (-55).
- Net profit for the quarter was SEK -15 M (-13), and earnings per share before and after dilution were SEK -0.17 (-0.15).
- Cash flow from operating activities totalled SEK -15 M (-5).
- Cash flow from investing activities totalled SEK -33 M (-22).
- Cash flow for the period totalled SEK -48 M (-27).
- Cash and cash equivalents at the end of the period was SEK 262 M, compared to SEK 308 M at the beginning of the quarter.

January-September 2021

- Net sales for the period totalled SEK 113 M (96), equivalent to an increase of 18%. At constant exchange rates, sales increased by 23%.
- Gross profit was SEK 74 M (62), equivalent to a margin of 66% (65).
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) totalled SEK -37 M (-9), equivalent to an EBITDA margin of -32% (-9).
- Operating income (EBIT) totalled SEK -43 M (-13), equivalent to an EBIT margin of -38% (-14).
- Net profit for the period was SEK -41 M (-15), and earnings per share before and after dilution were SEK -0.45 (-0.17).
- Cash flow from operating activities totalled SEK -40 M (-11).
- Cash flow from investing activities totalled SEK -77 M (-54).
- Cash flow for the period totalled SEK -117 M (-58).
- Cash and cash equivalents at the end of the period was SEK 262 M, compared to SEK 376 M at the beginning of the year.

Sales by area, rolling 12 months



Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve the patient's 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.

This interim report has been prepared in accordance with IFRS with function-based income statement compared to cost-based previous year. For converted comparative periods in 2020, see pages 17-19.

CEO comment

Approval in 11 EU markets and continued sales growth provide strong platform for the upcoming launch

This third quarter report is my first as Sedana Medical's CEO. In the first weeks after joining Sedana Medical on October 1, I have made it a priority to visit intensive care units in several countries and gather first-hand feedback from our customers. I had the opportunity to speak with many physicians, nurses and hospital administrators about their views on inhaled sedation and their experience with Sedaconda ACD (previously named AnaConDa). I am inspired by the fact that the clear benefits of inhaled sedation vs. previous standard of care, which we have shown in our pivotal trial, are seen and confirmed by hospital staff for their patients every day. I find this strong feedback very encouraging as we continue our journey to make inhaled sedation the standard therapy in intensive care.

I am especially pleased to see that clinics across Europe continue to use Sedaconda ACD in broad patient groups in a time when the number of Covid-19 patients has declined significantly in ICUs across many of our European markets. This confirms that – while Covid-19 has improved our starting position for the upcoming launch as many more ICUs are now trained and equipped to use our products - Sedana Medical's long-term potential is not dependent on Covid-19.

Sales in the quarter totalled SEK 28 million, an increase of 34 percent at fixed exchange rates compared to last year. It is very positive to note that all of our businesses have contributed to the positive development. Our largest market Germany has continued to show steady growth while our other direct markets have returned to positive year-over-year growth after the first two quarters had been impacted by the extraordinary development during the first wave of the Covid-19 pandemic. We have also seen a strong increase in demand in our distributor markets, specifically from Latin America.

During the third quarter, we reached a key milestone when our proprietary pharmaceutical product Sedaconda (isoflurane) obtained European DCP approval. To date, we have received national approvals for 11 of the 15 EU countries that were included in the DCP approval. The approval in today's largest market Germany was received in the end of September. The national approvals will enable us to commercialize the full therapy for inhaled sedation of mechanically ventilated patients in the ICU, consisting of our Sedaconda ACD device, our Sedaconda isoflurane drug and different accessories. We continue to expect product on the shelf in the first launch markets towards the end of the year.

Also during the quarter, the results of our pivotal study Sedaconda (SED001) were published in the renowned scientific journal, Lancet Respiratory Medicine. This publication in the leading journal in the field is an important element for our pre-launch activities. We hosted scientific symposia at both the annual congress of the European Society of Intensive Care Medicine, ESICM Lives, and the world's largest conference for intensive care and emergency medicine, ISICEM.

The United States represent the largest commercial opportunity for Sedaconda. Preparations for the US registration have continued during the quarter with the recruitment of the first Sedana Medical employees in the United States. We are working towards obtaining an Investigational New Drug (IND) approval before year end to enable the start of our pivotal studies at the turn of Q1/Q2, 2022. On the commercial side, we are thoroughly assessing which go-to-market strategy will offer the most attractive route for Sedana Medical. A decision whether we will build up our own commercial infrastructure in the US will be communicated in 2022 at the latest.

I am excited to join my passionate and highly qualified colleagues at Sedana Medical at this important point in our company's history. With differentiated products, convincing scientific evidence and existing usage of Sedaconda ACD in 34 countries around the globe, we have a strong platform for continued success, and I look forward to getting back to you on our future progress.

Johannes Doll, President and CEO



Significant events during the period

- In January and February an application for market approval for the drug candidate Sedaconda (isoflurane), previously known as IsoConDa, for inhaled sedation in intensive care was submitted in Switzerland and the United Kingdom.
- In February the first patient was included in the company's paediatric study IsoCOMFORT (SED002), which is being conducted to study whether inhaled sedation with Sedaconda (isoflurane) delivered via Sedaconda ACD is a safe and more effective method of sedation than intravenously administered midazolam, for children below 18 years of age.
- In June the pivotal phase 3 Sedaconda study (SED001) was selected as one of the top three posters at the 52nd DGIIN & ÖGIAIN Intensive Care Conference.
- In early July, Sedana Medical's Quality Management System (QMS) received approval under the EU Medical Device Regulation (MDR) 2017/745. This approval means that Sedana Medical's Class I medical device accessories can continue to be sold with CE marking in the EU.
- In July, a successful End of Phase 2 advisory meeting was completed with the US Food and Drug Administration (FDA). The FDA accepted Sedana Medical's proposed phase 3 programme, including the study design and the primary endpoint for the studies. The positive outcome allows the company to enter phase 3 in line with the communicated timeline.
- In July, a positive outcome was obtained for the application for European marketing authorisation for the pharmaceutical product Sedaconda (isoflurane) for inhaled sedation in intensive care, what is known as DCP approval. Sedaconda is indicated for the sedation of mechanically ventilated adult intensive care patients and is to be administered only via the Sedaconda ACD medical device.
- In August, the results of the company's pivotal study Sedaconda (SED001) was published in the highly respected scientific journal The Lancet Respiratory Medicine.
- At the end of September, marketing authorisation was obtained for inhaled sedation in Germany. The application was approved by the German regulatory authority BfArM and is based on the DCP approval obtained by Sedana Medical in July.

Significant events after the period

- After being appointed by the Board in May, Johannes Doll took office as Sedana Medical's new CEO on October 1, 2021.

Financial targets

The company's target, until registration of Sedaconda (isoflurane) has been to increase revenue by an average of more than 20 percent per year while building up a larger medical, sales and marketing organisation. The target is to achieve revenue in excess of SEK 500 million in Europe and an EBITDA margin of 40 percent three years after registration of Sedaconda. European approval was obtained at the end of July 2021, and registration of Sedaconda in each country is expected in the second half of 2021.

Impact of Covid-19

Sedana Medical noted a sharp increase in demand during 2020, as a consequence of Covid-19. We have seen similar effects in some geographies also in 2021, particularly in our market segment of distributor markets, mainly in Latin America. There continues to be great uncertainty over the future development of the Covid-19 pandemic in general around the world. Its impacts range from the inclination and ability of clinics to use new sedation therapies during a time of crisis to a possible shortage of, or reduced access to, intravenous sedatives, as well as mutant virus variants and future availability of vaccines. Consequently, there may be short-term impact on sales in individual quarters, but the long-term potential of Sedana Medical's products is not dependent on Covid-19. Operationally, Covid-19 has led to a situation in which more clinics are trained and equipped to use inhaled sedation ahead of the upcoming launch of Sedaconda (isoflurane).

Business update

Getting ready for the Sedaconda® launch in Europe

Registration of the pharmaceutical product Sedaconda® (isoflurane) in Europe

The European registration of Sedana Medical's first proprietary pharmaceutical product, Sedaconda (isoflurane) represents an important milestone on the company's journey to make inhaled sedation a global standard therapy. Going forward, Sedana Medical will be able to offer the full therapy for inhaled sedation of mechanically ventilated patients in intensive care units (ICUs), consisting of the medical device Sedaconda ACD (previously known as AnaConDa) and the volatile anaesthetic, Sedaconda (isoflurane). For hospitals in Europe, Sedaconda will be the first and only on-label option for inhaled sedation in ICUs.

In July and hence ahead of the anticipated timing, we received a positive response to the application for European registration through the decentralized procedure, allowing us to apply for national approval in 15 European countries. To date, Sedana Medical has received national approval in 11 of these countries: France, Denmark, Portugal, Belgium, Sweden, Norway, Finland, Austria, Netherlands, by end of September our main market Germany and by end of October also Croatia. National approvals in Poland, Spain, Slovenia and Ireland are expected in the coming months.

In some markets, including our biggest market Germany, it is estimated that it will take about 3 months until the products are ready for delivery and sale, whereas in France, Spain and Belgium there is a slightly different procedure where we can now proceed with the price and reimbursement application process, which is expected to take 4-6 months.

During the first quarter of 2021, an application for marketing authorization was also submitted to the authorities in Switzerland and the United Kingdom, with expected approval and launch in 2022. We also plan to submit an application for Italy beginning of next year.

Publication of clinical trial results in "The Lancet"

The European submission was based on the results of the company's pivotal study Sedaconda (SED001). The results from the Sedaconda study demonstrate that Sedaconda (isoflurane) administered via Sedaconda ACD is an effective sedation therapy for mechanically ventilated intensive care patients and non-inferior to present-day standard intravenous sedation with propofol. Compared with intravenous propofol, Sedaconda reduces the need of opioids, facilitates spontaneous breathing, which improves lung function during and after ventilator treatment, and enables a faster and more predictable awakening. The study was conducted at 23 intensive care clinics in Germany and Slovenia and included 301 mechanically ventilated patients in need of sedation. Half of the patients were treated with Sedaconda administered via AnaConDa and half with propofol. The safety profile of Sedaconda was consistent with previously known findings for isoflurane.

In August, the study results were published in the highly ranked scientific journal, the Lancet Respiratory Medicine. The Lancet Lancet Respiratory Medicine is the leading journal in the field of intensive care and respiratory medicine, and the publication is considered an important step to create awareness of the benefits of the Sedaconda therapy ahead of launch.

Sedana Medical also presented the study results at both the annual congress of the European Society of Intensive Care Medicine, ESICM Lives, and the world's largest conference for intensive care and emergency medicine, ISICEM.

Launch preparations

In preparation for launch, the company has expanded their field teams in all direct markets incl. Germany, France, Spain, UK, Benelux and the Nordics. All customer-facing personnel have been intensively trained and have obtained the necessary qualifications as pharmaceutical sales representatives. The vast majority of Sedana Medical's field teams have extensive work experience in intensive care units in their respective countries.

Pediatric study SED-002

In 2019, Sedana Medical was approved for a Pediatric Investigation Plan (PIP) by the European Medicines Agency's Pediatric Committee (PDCO). This approval is important, as conducting studies in children is one of the conditions to be met to obtain 10 years of market exclusivity in Europe for Sedaconda delivered via Sedaconda ACD. The study recruited its first patients in the first quarter of 2021 and is taking place in four European countries: Sweden, Germany, France and Spain. The study does not need to be completed to obtain market exclusivity.

Preparations for the important US market

Preparing registration of Sedaconda in the US

The US represents the highest-potential market for Sedana Medical. The market potential for inhaled sedation in ICUs is estimated to reach SEK 10 billion annually.

The company is in active dialogue with the FDA and work for the US registration is underway. In July, Sedana Medical held a successful advisory meeting with the FDA, an End of Phase II Meeting, at which the FDA accepted the company's proposed phase 3 program, allowing the company to enter phase 3 in line with the communicated timetable. The company is working towards obtaining IND approval before end of 2021 and including the first patients in the studies at the turn of the quarter Q1/Q2 2022, with the objective of obtaining marketing authorisation before end of 2024.

Since the medicinal substance isoflurane has been in existence for decades, the FDA has agreed to Sedana Medical following a pathway to registration, 505 (b) (2), which, somewhat simplified, permits the use of previously collected data. As the registration requirements have been tightened over the years since isoflurane was first registered, Sedana Medical needs to supplement current documentation and add more data to be approved by the FDA, including toxicity studies and a human factors validation. Sedana Medical will also need to conduct two randomised double-blind clinical studies to confirm and ensure efficacy and safety. The number of patients needed for both studies together is the same as Sedana Medical initially had as a requirement in the European study, around 500 patients. These patients will also be included in a safety database of 500 isoflurane patients requested by the FDA. Work on human factors validation is ongoing with the Beth Israel Deaconess Medical Center (BIDMC) at Harvard Medical School in the United States. Toxicological work is in full progress and progressing according to plan.

The company aims to include approximately 30 American centres in the two clinical studies.

Starting up Sedana Medical US

During the second quarter, a subsidiary was established in the United States. The first employees who will act as clinical educators for the clinical trial sites are on board.

The company is currently performing an assessment of which go-to-market strategy will best allow Sedana Medical to capture the market potential. A decision whether we will build up our own commercial infrastructure in the US or rely on a local partner will be communicated in 2022.

Increasing interest in other geographies

While we see the highest market potential for inhaled sedation in intensive care in the United States and Europe, we have seen a clear increase in interest in Sedaconda ACD and inhaled sedation in other geographies regions, partly driven by the Covid-19 pandemic as these patients are often in great need of sedation in ICU.

Outside the market where we have established our own presence, partnerships are in place with distributors in Europe, Asia, South America, Australia/New Zealand and the Middle East. Interest in inhaled sedation is also high among customers in these markets, demonstrating the future growth potential in these markets.

Markets are being assessed on a continuous basis, where market potential, accessibility of the market and investments required justify to aim at registration of the device and/or the drug.

In November 2018, Sedana Medical obtained approval for Sedaconda ACD in Japan. The approval means that Sedaconda ACD may be marketed, sold and used for the administration of volatile anaesthetics for mechanically ventilated patients in Japan. In order to have access to the full potential of the Japanese market of over 1 million mechanically ventilated therapy days annually in intensive care, reimbursement of the price of therapy and registration of the pharmaceutical product Sedaconda would have to be ensured. The next step towards enabling the registration of Sedaconda would be an official meeting with the Japanese Pharmaceuticals and Medical Devices Agency to clarify the Japanese requirements for the approval of Sedaconda.

Financial summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Net sales	28,277	21,432	112,787	95,773	141,770
Gross profit	19,120	13,222	73,917	61,846	88,903
Gross margin %	68%	62%	66%	65%	63%
EBITDA	-14,013	-9,979	-36,604	-8,539	-14,294
EBITDA margin %	-50%	-47%	-32%	-9%	-10%
Operating income (EBIT)	-16,078	-11,682	-42,810	-13,487	-21,359
Operating margin %	-57%	-55%	-38%	-14%	-15%
Income after net financial items	-14,240	-11,418	-40,260	-13,397	-24,103
Net income	-14,921	-13,425	-41,173	-15,320	-27,138
Net income margin %	-53%	-63%	-37%	-16%	-19%
Total assets	560,403	601,282	560,403	601,282	600,097
Equity	511,424	562,367	511,424	562,367	551,094
Equity ratio %	91%	94%	91%	94%	92%
Quick ratio %	661%	1273%	661%	1273%	929%
Debt to equity ratio %	10%	7%	10%	7%	9%
Average number of full time employees for the period	73	59	70	52	55
Number of employees at balance date	85	65	85	65	69
Number of employees and consultants at balance date	99	76	99	76	83
Average number of shares before dilution ¹⁾	92,186,960	92,186,960	92,186,960	91,556,662	91,566,662
Average number of shares after dilution ¹⁾	92,734,232	92,585,780	92,660,006	92,564,540	92,564,540
Number of shares at balance date before dilution ¹⁾	92,186,960	92,186,960	92,186,960	92,186,960	92,186,960
Number of shares at balance date after dilution ¹⁾	92,734,232	92,585,780	92,734,232	92,585,780	92,585,780
Earnings per share before dilution, SEK	-0.17	-0.15	-0.45	-0.17	-0.30
Earnings per share after dilution, SEK	-0.17	-0.15	-0.45	-0.17	-0.30

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

Group performance

This interim report has been prepared in accordance with IFRS with income statement by function, compared with income statement by nature of expense as previously. For converted comparative periods in 2020, see pages 17-19.

Net sales

Net sales during the third quarter totalled KSEK 28,277 (21,432), equivalent to an increase of 32 percent. Adjusted for currency effects, the quarter showed an increase of approximately 34 percent. During the quarter, we noted that clinics and hospitals continued to broaden the use of our therapy to non-Covid-19 patients.

The majority of Group sales are in Europe, principally in Germany. In other direct markets in Europe we have seen strong increase in the use of our therapy, mainly in the United Kingdom and Spain in comparison with the previous year. In terms of distributor markets, we have seen an increase mainly in Latin America, with Colombia as our second largest market during the third quarter, partly explained by the third wave of the Covid-19 pandemic.

Net sales during the interim period totalled KSEK 112,787 (95,773), equivalent to an increase of 18 percent. Adjusted for currency effects, the increase was 23 percent. The majority of Group sales are in Europe, principally Germany. Among other countries with direct sales, France and Spain in particular have shown an increase in comparison with previous year, and in terms of distributor markets we have seen an increase mainly in Latin America, with Mexico as our second-largest market during the period.

(KSEK)	Jul-Sep			Jan-Sep			Jan-Dec
	2021	2020	%	2021	2020	%	2020
Germany	18,031	16,498	9%	74,156	71,506	4%	103,063
Other direct sales	3,514	2,126	65%	12,351	15,560	-21%	22,209
Distributor markets	6,732	2,808	140%	26,280	8,707	202%	16,498
Total net sales	28,277	21,432	32%	112,787	95,773	18%	141,770

Gross profit and margin

Gross profit for the third quarter was KSEK 19,120 (13,222), equivalent to a gross margin of 68 (62) percent. The increase is mainly an effect of lower transportation costs, as well as a positive product mix effect, while the market mix was slightly negatively impacted as sales increased in our distributor markets where margins are slightly lower. The quarter also contained a reclassification from cost of goods sold to administrative expenses, equivalent to around 1%.

Gross profit for the interim period was KSEK 73,917 (61,846), equivalent to a gross margin of 66 (65) percent. The increase is partly due to lower transportation costs but is also a mix effect with increased sales in some distribution markets with slightly lower margins.

Selling expenses

Selling expenses for the quarter totalled KSEK -20,063 (-12,962), equivalent to an increase of 55 percent. The increase is partly due to continued higher costs related to the preparations for the launch of Sedaconda (isoflurane), totalling SEK 2 million, mainly related to costs of securing price and reimbursement in each country. The higher costs are also due to a larger commercial and marketing organisation and a higher level of activities, as some trade fairs and conferences such as ISICEM and ESICM have resumed.

Selling expenses for the interim period totalled KSEK -66,817 (-40,846), equivalent to an increase of 64 percent. The increase is due partly to higher costs related to preparations for the launch of Sedaconda (isoflurane) of approximately SEK 9 million, and partly to higher costs resulting from a larger commercial and marketing organisation and a higher level of activity.

Administrative expenses

Administrative expenses for the quarter totalled KSEK -10,035 (-9,636), equivalent to an increase of 4 percent.

Administrative expenses for the interim period totalled KSEK -35,840 (-28,373), equivalent to an increase of 26 percent. The increase is due to the general growth in the company as well as expansion of office premises and associated equipment.

Research and development expenses

Research and development expenses for the quarter totalled KSEK -4,809 (-1,848), equivalent to an increase of 160 percent. The increase is mainly an effect of a somewhat larger R&D organisation than in the previous year and a lower degree of activation attributable to the EU's Medical Device Regulation (MDR) and the initial buildup of the organisation.

Research and development expenses for the interim period totalled KSEK -13,683 (-5,602), equivalent to an increase of 144 percent. Costs related to approval under the EU Medical Device Regulation (MDR), which means that Sedana Medical's medical device accessories can continue to be sold with the CE mark in the EU, totalled SEK 1.2 million for the period.

Other operating income/expenses

Other operating income consists of positive unrealised exchange rate differences on operating items. These totalled KSEK 198 (311) for the quarter. Other operating income for the interim period totalled KSEK 3,113 (1,845).

Other operating expenses principally consist of negative unrealised exchange rate differences on operating items. These totalled KSEK -490 (-769) for the quarter. Other operating expenses for the interim period totalled KSEK -3,501 (-2,357).

Net financial items and earnings per share

Net financial items for the quarter totalled KSEK 1,838 (263) and consist mainly of unrealised gain/loss on foreign exchange. For the interim period, net financial items totalled KSEK 2,550 (90).

Group tax expense for the quarter was KSEK -681 (-2,007) and mainly consists of current tax in Germany. Group tax expense for the interim period was KSEK -913 (-1,923).

Earnings per share was thus SEK -0.17 (-0.15) for the quarter and SEK -0.45 (-0.17) for the interim period.

Equity and debt

Adjusted for the share split made in May 2021, equity at 30 September was KSEK 511,424, compared to KSEK 551,094 at the beginning of the year, equivalent to SEK 5.55 (5.98) per share. Equity/assets ratio was 91 percent, compared to 92 percent at the beginning of the year.

Debt/equity ratio at 30 September was 10 percent, compared to 9 percent at the start of the year. The Group had no long-term loans as per 30 September.

Cash and cash position

Cash and cash equivalents decreased by KSEK 46,280 during the quarter and totalled KSEK 261,505 at 30 September, compared to KSEK 307,785 at the beginning of the quarter. Cash flow from operating activities before change in working

capital for the quarter was KSEK -14,299 (-8,054). Cash flow from changes in working capital was KSEK -237 (3,428), and was negatively affected during the quarter as a result of an increase in inventories and accounts receivables, which was partly offset by increased accounts payables. Cash flow from operating activities thus totalled KSEK -14,536 (-4,626). Cash flow from investing activities totalled KSEK -32,671 (-22,031). The investments mostly consist of intangible assets, mainly development expenses for work on registration of Sedaconda ACD and Sedaconda (isoflurane) in the United States and expenses related to the Sedaconda ACD paediatric study in the EU. Cash flow from financing activities totalled KSEK -924 (-721) and relates to repayment of lease liabilities. Cash flow per share for the quarter was SEK -0.52 (-0.30).

Cash and cash equivalents decreased by KSEK 114,666 during the interim period and totalled KSEK 261,505 at 30 September, compared to KSEK 376,171 at the beginning of the year. Cash flow from operating activities before change in working capital was KSEK -36,557 (-6,182) for the period. Cash flow from changes in working capital was KSEK -3,099 (-4,423), and was negatively affected during the period as a result of an increase in inventories and a decrease in accounts payable, but has been partly offset by reduced accounts receivables. Cash flow from operating activities thus totalled KSEK -39,656 (-10,605). Cash flow from investing activities totalled KSEK -76,871 (-53,984). The investments mostly consist of intangible assets, mainly work on registration of Sedaconda ACD and Sedaconda (isoflurane) in the United States and expenses related to the Sedaconda ACD paediatric study in the EU. Cash flow from financing activities totalled KSEK -819 (6,524) and relates to premiums paid for warrants in a new programme 2020/2024 and repayment of lease liabilities. Cash flow per share for the period was SEK -1.27 (-0.63).

Parent company

The Parent Company's net sales for the period totalled KSEK 112,280 (42,897), of which intra-Group sales totalled KSEK 4,199 (28,438). The increase compared to the corresponding period of the previous year is due to the Parent Company having taken over the greater part of sales in the Group with effect from the third quarter of 2020. Operating income for the period totalled KSEK -38,860 (-16,551). Net financial items were KSEK 3,710 (1,273) and relates mainly to unrealised exchange rate gains on internal loans.

Shareholders' equity in the Parent Company totalled KSEK 528,128 at 30 September 2021, compared to KSEK 561,600 at the beginning of the year, equivalent to a decrease of KSEK 33,472. Share capital totalled KSEK 2,305, which is unchanged compared to the beginning of the year.

Cash and cash equivalents totalled KSEK 245,632, compared to KSEK 365,113 at the beginning of the year, equivalent to a decrease of KSEK 119,481.

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 third quarter was SEK 9,375 million.

The price paid for Sedana Medical shares, adjusted for the split made, was SEK 85.75 at the start of the year and SEK 101.70 at the end of the third quarter. The lowest closing price for the interim period was recorded on 20 July and was SEK 66.70. The highest closing price was recorded on 3 September and was SEK 107.10.

Share information

	Jul-Sep		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Net income, KSEK	-14,921	-13,425	-41,173	-15,320	-27,138
Cash flow, KSEK	-48,131	-27,378	-117,346	-58,065	-86,678
Number of shares at balance date	92,186,960	92,186,960	92,186,960	92,186,960	92,186,960
Average number of shares	92,186,960	92,186,960	92,186,960	91,556,662	91,566,662
Outstanding warrants at balance date	547,272	398,820	547,272	398,820	398,820
Average number of warrants	547,272	398,820	473,046	997,878	997,878
Share capital at balance date, KSEK	2,305	2,305	2,305	2,305	2,305
Equity at balance date, KSEK	511,424	562,367	511,424	562,367	551,094
Earnings per share before dilution, SEK	-0.17	-0.15	-0.45	-0.17	-0.30
Earnings per share after dilution, SEK	-0.17	-0.15	-0.45	-0.17	-0.30
Equity per share, SEK	5.55	6.10	5.55	6.10	5.98
Cash flow per share, SEK	-0.52	-0.30	-1.27	-0.63	-0.95

Largest shareholders at the end of the period

	No of shares	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%

Facts about the share

Trading	Nasdaq First North Growth Market Sweden
No of shares*	92,186,960
Market cap	SEK 9,375 million
Ticker	SEDANA
ISIN	SE0015988373
LEI-code	549300FQ3NJR156LCX32
* As per 2021-09-30	

Nomination committee for the 2022 Annual General Meeting

Sedana Medical's Nomination Committee for the 2022 Annual General Meeting has been appointed and consists of Thomas Eklund, Chairman of the Board, Karl Tobieson, appointed by Linc AB, Malin Björkmo, appointed by Handelsbanken Fonder and Jan Andersson, appointed by Swedbank Robur Fonder. Karl Tobieson has been appointed Chairman of the Nomination Committee.

The Nomination Committee together represents 26.6 percent of the voting rights for all voting shares in the company as of September 30, 2021. The Nomination Committee shall submit proposals for resolution by the 2022 Annual General Meeting pertaining to the election of Chairman of the Board, fees and composition of the Board, auditors' fees and the election of auditors. Shareholders wishing to submit proposals to Sedana Medical's Nomination Committee can do so by e-mail to ir@sedanamedical.com by January 31, 2022.

Financial calendar

Year-End report 2021	17 February 2022
Annual report 2021	7 April 2022
Interim report Jan-Mar 2022	28 April 2022
Annual General Meeting 2021	11 May 2022
Interim report Jan-Jun 2022	21 July 2022
Interim report Jan-Sep 2022	25 October 2022

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 4 November 2021

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 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

Johannes Doll, President and CEO, +46 76 303 66 66
Susanne Andersson, CFO, +46 73 066 89 04
ir@sedanamedical.com

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 for the third quarter 2021

Sedana Medical presents the interim report to investors, asset managers, analysts and media on 4 November 2021 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/13795>

After the presentation, a recorded version of the webcast will be available at: [Investor Relations \(sedanamedical.com\)](https://www.sedanamedical.com/investor-relations)

Auditor's report

Sedana Medical AB (publ) reg. no. 556670-2519

Introduction

We have reviewed the condensed interim financial information (interim report) of Sedana Medical AB (publ) as of 30 September 2021 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Stockholm, November 4, 2021
Öhrlings PricewaterhouseCoopers AB

Leonard Daun
Authorized Public Accountant

Consolidated income statement, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Net sales	28,277	21,432	112,787	95,773	141,770
Cost of goods sold	-9,157	-8,210	-38,870	-33,927	-52,867
Gross profit	19,120	13,222	73,917	61,846	88,903
Selling expenses	-20,063	-12,962	-66,817	-40,846	-65,123
Administrative expenses	-10,035	-9,636	-35,840	-28,373	-37,296
Research and development expenses	-4,809	-1,848	-13,683	-5,602	-7,859
Other operating income	198	311	3,113	1,845	3,654
Other operating expenses	-490	-769	-3,501	-2,357	-3,637
Operating income	-16,078	-11,682	-42,810	-13,487	-21,359
Financial items					
Financial income	1,906	469	3,251	2,815	2,845
Financial expenses	-68	-206	-701	-2,725	-5,590
Net financial items	1,838	263	2,550	90	-2,745
Income before taxes	-14,240	-11,418	-40,260	-13,397	-24,103
Tax	-681	-2,007	-913	-1,923	-3,035
Net income	-14,921	-13,425	-41,173	-15,320	-27,138
Earnings per share, based on earnings attributable to the parent company's ordinary shareholders:					
Before dilution	-0.17	-0.15	-0.45	-0.17	-0.30
After dilution	-0.17	-0.15	-0.45	-0.17	-0.30
EBITDA	-14,013	-9,979	-36,604	-8,539	-14,294
Amortisation of intangible assets	-429	-433	-1,280	-1,325	-1,756
Depreciation of tangible assets	-1,636	-1,270	-4,926	-3,623	-5,309
Operating income (EBIT)	-16,078	-11,682	-42,810	-13,487	-21,359

Consolidated statement of other comprehensive income, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Net income	-14,921	-13,425	-41,173	-15,320	-27,138
Other comprehensive income					
Items that can later be reclassified to the income statement:					
Translation differences from foreign operations	-143	590	-257	77	624
Other comprehensive income, net after tax	-143	590	-257	77	624
Total comprehensive income	-15,064	-12,835	-41,430	-15,243	-26,514
Total comprehensive income as a whole attributable to the parent company's shareholders	-15,064	-12,835	-41,430	-15,243	-26,514

Consolidated balance sheet, summary

(KSEK)	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
ASSETS			
<i>Intangible assets</i>			
Capitalised development expenditure	238,911	141,148	166,378
Concessions, patents, licenses, etc.	2,099	4,247	2,998
<i>Tangible assets</i>			
Machinery and other technical facilities	6,146	5,627	5,711
Equipment, tools and installations	1,092	877	1,213
Rights of use	9,485	8,665	8,792
<i>Financial assets</i>			
Other long-term assets	42	43	41
<i>Deferred tax assets</i>	21	1,093	45
Total fixed assets	257,796	161,700	185,178
Inventory	12,075	12,186	9,087
Tax receivables	461	6	453
Accounts receivable	18,279	9,469	19,484
Prepayments and accrued income	6,252	6,119	5,609
Other receivables	4,035	5,456	4,115
Cash and cash equivalents	261,505	406,346	376,171
Total current assets	302,607	439,582	414,919
TOTAL ASSETS	560,403	601,282	600,097
(KSEK)	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
EQUITY AND LIABILITIES			
<i>Equity</i>			
Share capital	2,305	2,305	2,305
Other contributed capital	615,683	613,923	613,923
Translation difference	249	-40	506
Retained earnings including net profit	-106,813	-53,821	-65,640
Equity attributable to the parent company's shareholders	511,424	562,367	551,094
<i>Non-current liabilities</i>			
Leasing liabilities	5,041	5,336	5,324
Total non-current liabilities	5,041	5,336	5,324
<i>Current liabilities</i>			
Leasing liabilities	3,987	2,890	2,967
Accounts payable	13,156	7,954	16,371
Tax debt	3,981	1,985	2,718
Other liabilities	6,972	7,750	7,668
Accrued expenses and deferred income	15,842	13,000	13,955
Total current liabilities	43,938	33,579	43,679
Total liabilities	48,979	38,915	49,003
TOTAL EQUITY AND LIABILITIES	560,403	601,282	600,097

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, 2020	2,274	605,702	-117	-38,501	569,358
Net income	-	-	-	-15,320	-15,320
Other comprehensive income	-	-	77	-	77
Total comprehensive income	-	-	77	-15,320	-15,243
Transactions with the Group's owners					
New share issue	31	7,831	-	-	7,862
Issue expenses	-	-68	-	-	-68
Received premium for warrant subscription	-	515	-	-	515
Expenses for warrant program	-	-57	-	-	-57
Total transactions with the Group's owners	31	8,221	-	-	8,252
Closing equity at Sep 30, 2020	2,305	613,923	-40	-53,821	562,367
(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	-	-	-	-41,173	-41,173
Other comprehensive income	-	-	-257	-	-257
Total comprehensive income	-	-	-257	-41,173	-41,430
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 Sep 30, 2021	2,305	615,683	249	-106,813	511,424

Consolidated cash flow statement, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Operating activities					
Operating income	-16,078	-11,682	-42,810	-13,487	-21,359
<i>Adjustments for non-cash items</i>					
Depreciations and amortisations	2,065	1,703	6,206	4,948	7,065
Exchange rate differences	-261	608	-1,594	300	-363
Other non-cash items	108	2,221	1,891	3,097	7,411
Interest received	-	-	-	49	25
Interest paid	-62	-44	-178	-153	-189
Taxes paid	-71	-860	-72	-936	-869
Cash flow from operating activities before changes in working capital	-14,299	-8,054	-36,557	-6,182	-8,279
<i>Cash flow from changes in working capital</i>					
Cash flow from inventories	-1,362	-3,296	-3,278	-4,629	-1,158
Cash flow from operating receivables	-650	823	1,889	-6,601	-15,292
Cash flow from operating liabilities	1,775	5,901	-1,710	6,807	16,883
Cash flow from operating activities	-14,536	-4,626	-39,656	-10,605	-7,846
Investing activities					
Investments in intangible assets	-32,176	-18,268	-72,684	-46,952	-72,175
Investments in tangible assets	-495	-3,763	-4,187	-7,032	-12,444
Cash flow from investing activities	-32,671	-22,031	-76,871	-53,984	-84,619
Financing activities					
New share issue	-	-	-	7,862	7,862
Issue expenses	-	-5	-	-68	-68
Amortisation of leasing liabilities	-924	-716	-2,579	-1,727	-2,464
Received premium for warrant subscription	-	-	1,760	515	515
Expenses for warrant program	-	-	-	-58	-58
Cash flow from financing activities	-924	-721	-819	6,524	5,787
Cash flow for the period	-48,131	-27,378	-117,346	-58,065	-86,678
Cash and cash equivalents at the beginning of the period	307,785	433,537	376,171	464,560	464,560
Translation difference	1,851	187	2,680	-149	-1,711
Cash and cash equivalents at the end of the period	261,505	406,346	261,505	406,346	376,171

Consolidated quarterly summary, income statement

(KSEK)	2020				2021		
	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1	Quarter 2	Quarter 3
Net sales	33,832	40,509	21,432	45,997	45,000	39,510	28,277
Cost of goods sold	-11,193	-14,524	-8,210	-16,464	-16,395	-13,318	-9,157
Gross profit	22,639	25,985	13,222	29,533	28,605	26,192	19,120
<i>Gross margin</i>	67%	64%	62%	64%	64%	66%	68%
Selling expenses	-13,908	-13,976	-12,962	-24,277	-20,853	-25,901	-20,063
Administration costs	-8,527	-10,210	-9,636	-11,399	-13,611	-12,194	-10,035
Research and development costs	-1,071	-2,683	-1,848	-2,257	-4,173	-4,701	-4,809
Other operating income	1,193	341	311	1,809	2,272	643	198
Other operating expenses	-229	-1,359	-769	-1,280	-2,602	-409	-490
Operating income	96	-1,902	-11,682	-7,871	-10,362	-16,370	-16,078
<i>Operating margin</i>	0%	-5%	-55%	-17%	-23%	-41%	-57%
Financial income	2,260	86	469	30	1,651	-306	1,906
Financial expenses	-125	-2,394	-206	-2,865	-147	-486	-68
Net financial items	2,135	-2,308	263	-2,835	1,504	-792	1,838
Income before taxes	2,232	-4,210	-11,419	-10,706	-8,858	-17,162	-14,240
Tax	-532	616	-2,007	-1,113	-105	-127	-681
Net income	1,700	-3,594	-13,426	-11,819	-8,963	-17,289	-14,921
Operating income (EBIT)	96	-1,902	-11,682	-7,871	-10,362	-16,370	-16,078
Whereof depreciation of intangible assets	-446	-446	-433	-431	-425	-426	-429
Whereof depreciation of tangible assets	-1,165	-1,188	-1,270	-1,686	-1,629	-1,661	-1,636
EBITDA	1,708	-268	-9,979	-5,754	-8,308	-14,283	-14,013
<i>EBITDA margin</i>	5%	-1%	-47%	-13%	-18%	-36%	-50%

(KSEK)	2020				2021		
	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1	Quarter 2	Quarter 3
Germany	26,802	28,206	16,498	31,558	28,601	27,524	18,031
Other direct sales	4,370	9,064	2,126	6,648	4,968	3,869	3,514
Distributor markets	2,660	3,239	2,808	7,791	11,431	8,117	6,732
Total net sales	33,832	40,509	21,432	45,997	45,000	39,510	28,277

The above quarterly figures relating 2020 have been converted in accordance with IFRS and adjusted from previous cost-based income statement to function-based income statement to create comparability. In connection with the transition to a function-based income statement, costs have been redistributed to the cost of goods sold, which has reduced the gross margin by approximately 3 percentage points (given above sales volumes).

For Q4 2020, a minor adjustment has been made, which increased the cost of goods sold by approximately SEK 1 million compared with previously published figures. For Q1 2021, a reclassification of approximately SEK 2 million of previously published figures has been made from research and development expenses to selling expenses.

Consolidated quarterly summary, balance sheet

(KSEK)	2020				2021		
	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1	Quarter 2	Quarter 3
ASSETS							
<i>Intangible assets</i>							
Capitalised development expenditure	109,214	124,019	141,148	166,378	184,591	206,795	238,911
Concessions, patents, licenses, etc.	4,054	3,487	4,247	2,998	2,718	2,351	2,099
<i>Tangible assets</i>							
Machinery and other technical facilities	4,527	5,099	5,627	5,711	7,151	6,362	6,146
Equipment, tools and installations	483	696	877	1,213	1,149	1,172	1,092
Rights of use	2,628	2,094	8,665	8,792	9,067	9,667	9,485
<i>Financial assets</i>							
Other long-term assets	45	43	43	41	42	42	42
<i>Deferred tax assets</i>							
	1,742	2,371	1,093	45	83	31	21
Total fixed assets	122,693	137,809	161,700	185,178	204,801	226,420	257,796
Inventory	6,035	8,730	12,186	9,087	11,739	10,714	12,075
Tax receivables	6	6	6	453	464	457	461
Accounts receivable	18,418	11,909	9,469	19,484	17,525	18,458	18,279
Prepayments and accrued income	4,511	6,207	6,119	5,609	6,364	5,881	6,252
Other receivables	2,487	3,503	5,456	4,115	3,287	3,276	4,035
Cash and cash equivalents	442,553	433,537	406,346	376,171	343,619	307,785	261,505
Total current assets	474,010	463,892	439,582	414,919	382,998	346,571	302,607
TOTAL ASSETS	596,703	601,701	601,282	600,097	587,799	572,991	560,403
EQUITY AND LIABILITIES							
<i>Equity</i>							
Share capital	2,274	2,305	2,305	2,305	2,305	2,305	2,305
Other contributed capital	605,702	613,927	613,923	613,923	615,683	615,683	615,683
Translation difference	-1,088	-630	-40	506	211	392	249
Retained earnings including net profit	-36,801	-40,396	-53,821	-65,640	-74,603	-91,892	-106,813
Equity attributable to the parent company's shareholders	570,087	575,206	562,367	551,094	543,596	526,488	511,424
<i>Non-current liabilities</i>							
Leasing liabilities	629	540	5,336	5,324	5,224	5,414	5,041
Total non-current liabilities	629	540	5,336	5,324	5,224	5,414	5,041
<i>Current liabilities</i>							
Leasing liabilities	1,646	1,237	2,890	2,967	3,355	3,779	3,987
Accounts payable	5,862	6,444	7,954	16,371	10,288	12,577	13,156
Tax debt	1,296	853	1,985	2,718	2,705	2,949	3,981
Other liabilities	5,897	4,821	7,750	7,668	9,432	7,038	6,972
Accrued expenses and deferred income	11,286	12,600	13,000	13,955	13,199	14,746	15,842
Total current liabilities	25,987	25,955	33,579	43,679	38,979	41,089	43,938
Total liabilities	26,616	26,495	38,915	49,003	44,203	46,503	48,979
TOTAL EQUITY AND LIABILITIES	596,703	601,701	601,282	600,097	587,799	572,991	560,403

For comparison purpose, the above quarterly figures relating 2020 have been converted in accordance with IFRS.

Consolidated quarterly summary, cash flow statement

(KSEK)	2020				2021		
	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1	Quarter 2	Quarter 3
Operating activities							
Operating income	96	-1,902	-11,682	-7,871	-10,362	-16,370	-16,078
Adjustments for non-cash items							
Depreciations and amortisations	1,611	1,633	1,703	2,117	2,054	2,087	2,065
Exchange rate differences	-1,197	889	479	-534	-1,435	102	-261
Other non-cash items	295	582	2,350	4,184	1,131	652	108
Interest received	1	49	-23	-1	-	-	-
Interest paid	-96	-14	-21	-59	-50	-66	-62
Taxes paid	-63	-13	-860	67	-189	188	-71
Cash flow from operating activities before changes in working capital	648	1,224	-8,054	-2,098	-8,851	-13,407	-14,299
Cash flow from changes in working capital							
Cash flow from inventories	1,223	-2,556	-3,296	3,471	-2,942	1,026	-1,362
Cash flow from operating receivables	-10,641	3,217	823	-8,690	4,053	-1,514	-650
Cash flow from operating liabilities	860	46	5,901	10,076	-5,570	2,085	1,775
Cash flow from operating activities	-7,910	1,932	-4,626	2,759	-13,310	-11,810	-14,536
Investing activities							
Investments in intangible assets	-13,362	-15,321	-18,268	-25,223	-18,096	-22,412	-32,176
Investments in tangible assets	-881	-2,389	-3,763	-5,411	-2,982	-710	-495
Cash flow from investing activities	-14,243	-17,710	-22,031	-30,635	-21,078	-23,122	-32,671
Financing activities							
New share issue	-	7,862	-	-	-	-	-
Issue expenses	-	-65	-3	-	-	-	-
Amortisation of leasing liabilities	-546	-465	-716	-737	-814	-841	-924
Received premium for warrant subscription	-	515	-	-	1,760	-	-
Expenses for warrant program	-	-56	-2	-	-	-	-
Cash flow from financing activities	-546	7,791	-721	-737	946	-841	-924
Cash flow for the period	-22,699	-7,988	-27,378	-28,612	-33,442	-35,773	-48,131
Cash and cash equivalents at the beginning of the period	464,560	442,553	433,537	406,346	376,171	343,619	307,785
Translation difference	692	-1,028	187	-1,563	890	-61	1,851
Cash and cash equivalents at the end of the period	442,553	433,537	406,346	376,171	343,619	307,785	261,505

For comparison purpose, the above quarterly figures relating 2020 have been converted in accordance with IFRS.

Parent company income statement, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Net sales	27,759	33,450	112,280	42,897	121,238
Cost of goods sold	-11,783	-8,244	-36,205	-15,486	-38,707
Gross profit	15,976	25,206	76,075	27,411	82,531
Selling expenses	-11,690	-34,231	-39,364	-49,202	-72,666
Administration costs	-16,572	-8,247	-72,898	-24,369	-38,668
Research and development costs	-3,552	-1,027	-10,407	-2,685	-3,953
Other operating income	3,197	17,332	10,997	34,495	7,790
Other operating expenses	-1,990	-743	-3,263	-2,201	-2,611
Operating income	-14,631	-1,710	-38,860	-16,551	-27,577
Financial items					
Financial income	2,247	-1,555	4,239	1,444	1,778
Financial expenses	-6	2,188	-529	-171	-2,959
Net financial items	2,241	633	3,710	1,273	-1,181
Income after net financial items	-12,390	-1,077	-35,150	-15,278	-28,758
Group contribution	0	0	0	0	-9
Income before tax	-12,390	-1,077	-35,150	-15,278	-28,767
Income tax	0	0	0	0	-
Net income	-12,390	-1,077	-35,150	-15,278	-28,767

Parent company statement of other comprehensive income, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Net income	-12,390	-1,077	-35,150	-15,278	-28,767
Other comprehensive income					
Items that can later be reclassified to the income statement:					
Translation differences from foreign operations	-38	-56	-82	-61	200
Other comprehensive income, net after tax	-38	-56	-82	-61	200
Total comprehensive income	-12,428	-1,133	-35,232	-15,339	-28,567

Parent company balance sheet, summary

(KSEK)	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
ASSETS			
<i>Intangible assets</i>			
Capitalised development expenditure	226,706	132,693	156,261
<i>Tangible assets</i>			
Machinery and other technical facilities	5,271	1,856	4,334
Equipment, tools and installations	523	416	638
<i>Financial assets</i>			
Other long-term assets	404	394	395
Non-current receivables, group companies	43,369	40,024	38,539
Total fixed assets	276,273	175,383	200,167
Inventory	12,083	17,260	9,245
Tax receivables	5	4	4
Accounts receivable	16,960	8,222	17,925
Receivables, group companies	11,869	32,717	2,239
Prepayments and accrued income	5,973	5,773	5,575
Other receivables	2,081	4,897	3,202
Cash and cash equivalents	245,632	396,238	365,113
Total current assets	294,603	465,111	403,303
TOTAL ASSETS	570,876	640,494	603,470

(KSEK)	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
EQUITY AND LIABILITIES			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital	2,305	2,305	2,305
Fund for capitalised development expenses	220,864	131,693	154,405
<i>Non-restricted equity</i>			
Share premium fund	615,683	613,923	613,923
Retained earnings	-275,574	-157,815	-180,266
Net income	-35,150	-15,278	-28,767
Equity attributable to the parent company's shareholders	528,128	574,828	561,600
<i>Current liabilities</i>			
Accounts payable	12,891	6,796	15,469
Liabilities to group companies	12,083	45,762	10,095
Tax debt	1,754	1,026	1,387
Other liabilities	5,046	2,906	4,707
Accrued expenses and deferred income	10,974	9,176	10,212
Total current liabilities	42,748	65,666	41,870
Total liabilities	42,748	65,666	41,870
TOTAL EQUITY AND LIABILITIES	570,876	640,494	603,470

Parent company statement of changes in equity, summary

	Equity attributable to the parent company's shareholders				
	Restricted equity		Non-restricted equity		Total
(KSEK)	Share capital	Fund for capitalised development expenses	Share premium fund	Retained earnings including net income	Total equity
Opening equity at Jan 1, 2020	2,274	88,047	605,702	-114,108	581,915
Net income	-	-	-	-15,278	-15,278
Other comprehensive income	-	-	-	-61	-61
Total comprehensive income	-	-	-	-15,339	-15,339
Transactions with the parent company's owners					
New share issue	31	-	7,831	-	7,862
Issue expenses	-	-	-68	-	-68
Received premium for warrant subscription	-	-	515	-	515
Expenses for warrant program	-	-	-57	-	-57
Total transactions with the parent company's owners	31	-	8,221	-	8,252
Reallocation between items in equity					
Capitalised development expenses	-	43,646	-	-43,646	-
Total reallocations	-	43,646	-	-43,646	-
Closing equity at Sep 30, 2020	2,305	131,693	613,923	-173,093	574,828
(KSEK)	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	-	-	-	-35,150	-35,150
Other comprehensive income	-	-	-	-82	-82
Total comprehensive income	-	-	-	-35,232	-35,232
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	-	66,459	-	-66,459	-
Total reallocations	-	66,459	-	-66,459	-
Closing equity at Sep 30, 2021	2,305	220,864	615,683	-310,724	528,128

Parent company cash flow statement, summary

(KSEK)	Jul-Sep		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Operating activities					
Operating income	-14,631	-1,710	-38,860	-16,550	-27,577
<i>Adjustments for non-cash items</i>					
Depreciations and amortisations	430	220	1,458	554	969
Exchange rate differences	-267	910	-479	446	629
Other non-cash items	106	128	900	0	473
Interest received	-	298	-	1,017	1,336
Interest paid	-2	1	-13	-2	-8
Taxes paid	-49	-	-	-	-
Cash flow from operating activities before changes in working capital	-14,413	-153	-36,994	-14,535	-24,178
<i>Cash flow from changes in working capital</i>					
Cash flow from inventories	-1,298	-18,223	-2,838	-17,420	-8,262
Cash flow from operating receivables	-127,693	-46,689	-36,173	-67,156	396
Cash flow from operating liabilities	125,160	66,634	29,107	77,010	8,380
Cash flow from operating activities	-18,244	1,569	-46,898	-22,101	-23,664
Investing activities					
Investments in intangible assets	-31,285	-17,312	-70,445	-44,646	-68,213
Investments in tangible assets	-483	-896	-3,177	-1,764	-4,893
Investments in financial assets	-3,006	-108	-3,014	1,423	-283
Cash flow from investing activities	-34,774	-18,316	-76,636	-44,987	-73,389
Financing activities					
New share issue	-	-	-	7,862	7,862
Issue expenses	-	-5	-	-68	-68
Received premium for warrant subscription	-	-	1,760	515	515
Expenses for warrant program	-	-	-	-58	-58
Cash flow from financing activities	-	-5	1,760	8,251	8,251
Cash flow for the period	-53,018	-16,752	-121,774	-58,837	-88,802
Cash and cash equivalents at the beginning of the period	297,062	413,009	365,113	455,206	455,206
Translation difference	1,588	-20	2,293	-131	-1,291
Cash and cash equivalents at the end of the period	245,632	396,237	245,632	396,238	365,113

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. 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 2020 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 2020 Annual Report.

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 2020 Annual Report on pages 56–58. For information concerning our view of Covid-19 and its possible impacts on Sedana Medical, see page 4 and the CEO's Comment on page 3.

Personnel

During the interim period, the Group had an average of 70 (52) full time employees and 11 (7) full time consultants, representing an increase of 22 on the same period in 2020. At the end of the quarter, the number of employees was 85 and the number of consultants was 14 compared to 69 and 14 respectively at the start of the 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 the first quarter, Sedana Medical bought goods to a value of KSEK 4,860 (2,355) and services to a value of KSEK 37 (0) from Lismed Ltd. This company is a related party to Ron Farrell, who during the first quarter was a member of Board of the Group's Irish subsidiary. Ron Farrell left his Board position at the beginning of the second quarter. During the first quarter, Sedana Medical provided a loan amounting to SEK 300,000 to Stefan Krisch. Stefan has been part of Sedana Medical's management team since the beginning of March 2021. During the second quarter, a consulting agreement was signed between Sedana Medical and board member Claus Bjerre. No amounts have yet been invoiced or settled regarding this agreement.

Warrant programme

At the end of the period Sedana Medical had 547,272 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 acquired warrants at the end of the period	Terms*	Strike price (SEK)
2019/2022	CEO	0	0	0	0	1:1	35.56
2019/2022	Senior management	105,172	0	0	105,172	1:1	35.56
2019/2022	Other employees	251,168	0	0	251,168	1:1	35.56
2019/2022	Total	356,340	0	0	356,340	1:1	35.56
<i>Exercise period 1 July 2022 – 30 November 2022</i>							
2020/2023	CEO	0	0	0	0	1:1	83.65
2020/2023	Senior management	16,000	0	0	16,000	1:1	83.65
2020/2023	Other employees	26,480	0	0	26,480	1:1	83.65
2020/2023	Total	42,480	0	0	42,480	1:1	83.65
<i>Exercise period 1 June 2023 – 30 September 2023</i>							
2020/2024	CEO	0	0	0	0	1:1	123.88
2020/2024	Senior management	0	0	0	0	1:1	123.88
2020/2024	Other employees	0	148,452	0	148,452	1:1	123.88
2020/2024	Total	0	148,452	0	148,452	1:1	123.88
<i>Exercise period 1 February 2024 – 31 May 2024</i>							
Total	CEO	0	0	0	0		
Total	Senior management	121,172	0	0	121,172		
Total	Other employees	277,648	148,452	0	426,100		
	Total	398,820	148,452	0	547,272		

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

Explanations regarding transition to IFRS

This financial interim report for the Group is the fourth prepared in accordance with IFRS. The accounting principles stated on page 24 have been applied in the preparation of the Group's financial reports for the financial year 2020 and for the comparison year 2019 and for the Group's opening balance on 1 January 2019. In preparing the Group's opening balance sheet, amounts reported in accordance with previously applied accounting principles have been adjusted in accordance with IFRS. Explanations of how the transition from previous accounting principles to IFRS has affected the Group's financial position and financial results are set out in the following tables and explanations of the same.

What was done during the transition to accounting in accordance with IFRS

The transition to IFRS is reported in accordance with IFRS 1 First time adoption. The main rule is that all applicable IFRS and IAS standards, which have come into force and been approved by the EU as of 31 December 2020, shall be applied with retroactive effect. IFRS 1, however, contains transitional regulations that give companies a certain choice. The exceptions permitted by IFRS from full retroactive application that the company has chosen to apply in the transition from previously applied accounting principles to IFRS are listed below.

Exceptions for accumulated translation differences

IFRS 1 allows accumulated translation differences reported in equity to be reset at the time of transition to IFRS. This is a relief compared with determining accumulated translation differences in accordance with IAS 21, Effects of Changes in Foreign Exchange Rates, from the time the company's subsidiaries were formed. The company has chosen to reset all accumulated translation differences in the translation reserve and reclassify these to retained earnings at the time of the transition to IFRS as of January 1, 2019.

IFRS 16 Leasing Agreement

The Group applies IFRS 16 from 1 January 2019. The Group applies the simplified transition method, which means that rights of use are valued at an amount corresponding to the lease liability as of 1 January 2019 (adjusted for prepaid and accrued lease fees). Furthermore, the Group has made the following choices at the time of transition:

- To exclude leasing agreements whose leasing period ends within twelve months from the time of transition to IFRS (2019-01-01) and leasing agreements for which the underlying asset is of low value.
- To use estimates made retrospectively when determining the leasing period in cases where the agreement contains opportunities to extend or terminate the leasing agreement.

Reconciliation between previously applied cost-based income statement and function-based income statement

The summary below shows the effects on the income statement when changing from a cost-based income statement to a function-based one.

Change of layout form: Group income statement Jan-Sep 2020

((KSEK))	Cost-based	Other operating income	Cost of goods sold	Other external costs	Personnel costs	Depreciation	Function-based	
Net sales	95,773						95,773	Net sales
Other operating income	5,492	-5,492					0	
			-30,833	-390	-897	-1,807	-33,927	Cost of goods sold
	101,265	-5,492	-30,833	-390	-897	-1,807	61,846	Gross Profit
							0	
Cost of goods sold	-30,833		30,833				0	
Other external costs	-33,218			33,218			0	
Personnel costs	-41,200				41,200		0	
Depreciation	-3,545					3,545	0	
				-13,606	-26,115	-1,125	-40,846	Selling expenses
				-15,743	-12,059	-619	-28,421	Administrative expenses

				-3,479	-2,129	6	-5,602	Research and development expenses
		1,845					1,845	Other operating income
Other operating expenses	-6,004	3,647					-2,357	Other operating expenses
Operating income	-13,535	0	0	0	0	0	-13,535	Other operating income
Financial income	2,815						2,815	Financial income
Financial expenses	-2,674						-2,674	Financial expenses
Income after financial items	-13,394	0	0	0	0	0	-13,394	Income after financial items
Income before tax	-13,394	0	0	0	0	0	-13,394	Income before tax
Income tax	-1,923						-1,923	Tax
Net income	-15,317	0	0	0	0	0	-15,317	Net income

Reconciliation between previously applied accounting principles and IFRS

According to IFRS 1, the Group must present a reconciliation between equity and total comprehensive income reported in accordance with previously applied accounting principles and equity and total comprehensive income in accordance with IFRS. The tables below show the reconciliation between previously applied accounting principles and IFRS.

Effects on income statement, balance sheet and equity

The following summaries show the above effects on the income statement, balance sheet and equity as if IFRS had been applied in 2020.

Group income statement Jan-Sep 2020

(KSEK)	According to previous principles	Effect of IFRS 1	Effect of IFRS 16 - Leasing	According to IFRS
Net sales	95,773			95,773
Cost of goods sold	-33,927			-33,927
Gross Profit	61,846	0	0	61,846
Selling expenses	-40,846			-40,846
Administrative expenses	-28,421		48	-28,373
Research and development expenses	-5,602			-5,602
Other operating income	1,845			1,845
Other operating expenses	-2,357			-2,357
Operating income	-13,535	0	48	-13,487
Financial items				
Financial income	2,815			2,815
Financial expenses	-2,674		-51	-2,725
Net financial items	141	0	-51	90
Income before tax	-13,394	0	-3	-13,397
Tax	-1,923		0	-1,923
Net income	-15,317	0	-3	-15,320
Group's other comprehensive income Jan-Sep 2020				
Net income	-15,317	0	-3	-15,320
Other comprehensive income				

Items that can later be reclassified to the income statement:

Translation differences from foreign operations	0	77	0	77
Other comprehensive income, net after tax	0	77	0	77
Total comprehensive income	-15,317	77	-3	-15,243
Total comprehensive income as a whole attributable to the parent company's shareholders	-15,317	77	-3	-15,243

Group's balance sheet Sep 30 2020

(KSEK)	K3 2020-09-30	Effect of IFRS 1	Effect of IFRS 16 - Leasing	IFRS 2020-09-30
Assets				
Intangible assets				
Capitalised development expenditure	141,148			141,148
Concessions, patents, licenses, etc.	4,247			4,247
Tangible assets				
Machinery and other technical facilities	5,627			5,627
Equipment, tools and installations	877			877
Rights of use	0		8,665	8,665
Other long-term receivables	43			43
Deferred tax assets	1,086		7	1,093
Total fixed assets	153,028		8,672	161,700
Inventory	12,186			12,186
Tax receivables	6			6
Accounts receivable	9,469			9,469
Prepaid expenses and accrued income	6,589		-470	6,119
Other receivables	5,456			5,456
Cash and cash equivalents	406,346			406,346
Total current receivables	440,052		-470	439,582
Total assets	593,080	0	8,202	601,282
Equity and liabilities				
Equity				
Share capital	2,305			2,305
Other contributed capital	613,923			613,923
Translation difference	0	-40	0	-40
Retained earnings including net profit	-53,837	40	-24	-53,821
Equity attributable to the parent company's shareholders	562,391	0	-24	562,367
Non-current liabilities				
Non-current liabilities	0		5,336	5,336
Total non-current liabilities	0	0	5,336	5,336
Current liabilities				
Leasing liabilities	0		2,890	2,890
Accounts payable	7,954			7,954
Tax liabilities	1,985			1,985
Other liabilities	7,750			7,750
Accrued expenses and prepaid income	13,000			13,000
Total current liabilities	30,689	0	2,890	33,579
Total liabilities	30,689	0	8,226	38,915
Total equity and liabilities	593,080	0	8,202	601,282

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%