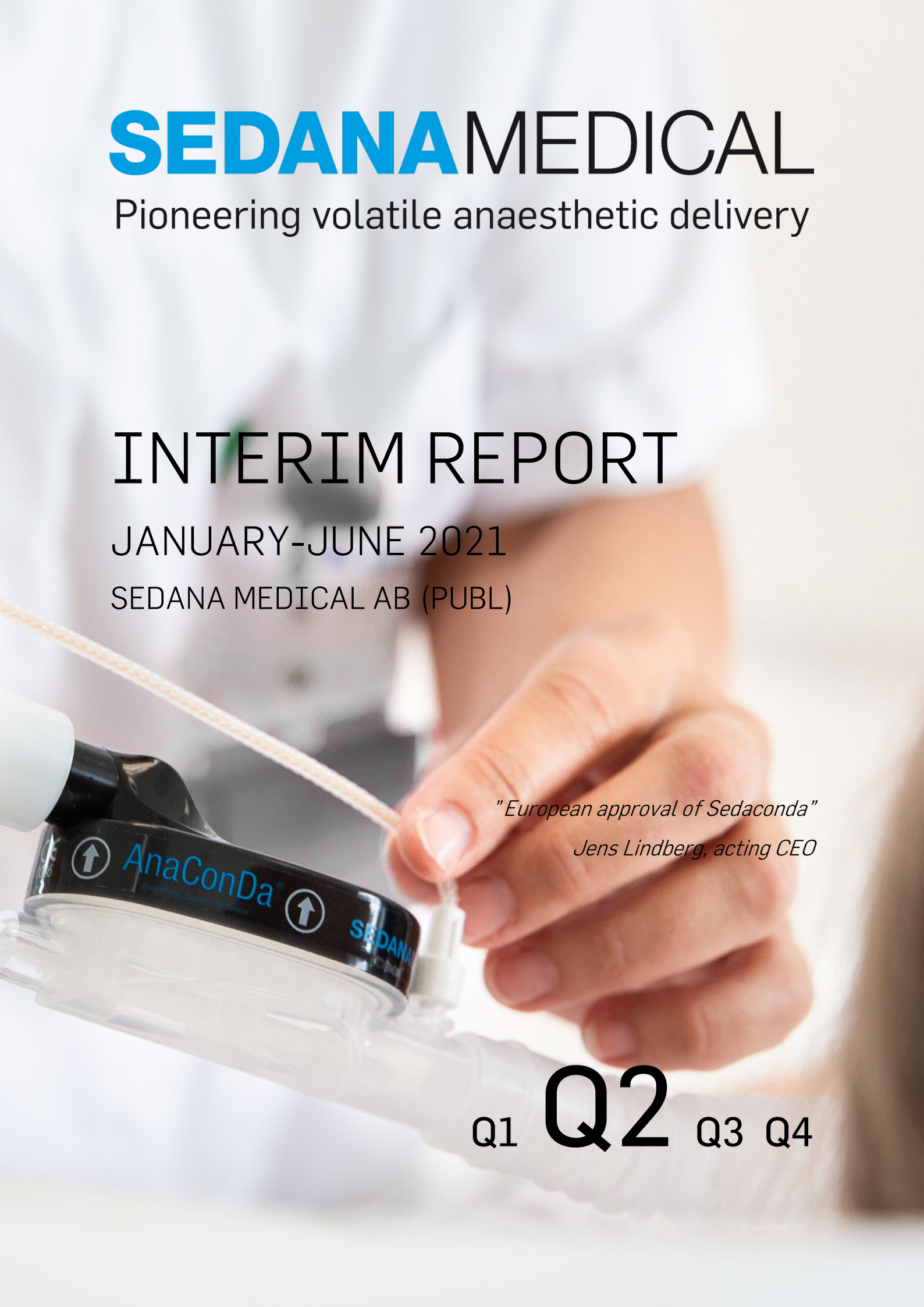
SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

INTERIM REPORT

JANUARY-JUNE 2021

SEDANA MEDICAL AB (PUBL)



"European approval of Sedaconda"

Jens Lindberg, acting CEO

Q1 **Q2** Q3 Q4

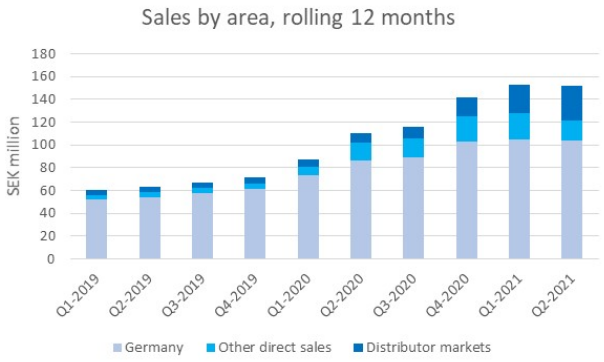
Financial summary

Second quarter 2021

- Net sales totalled MSEK 40 (41), equivalent to a decrease of 2 percent compared to the second quarter of 2020. At constant exchange rates, sales increased by 3%. In May and June, we saw a slowdown in the third wave of the pandemic in Europe, while it is increasing in Latin America and other regions in our distributor markets.
- Gross profit was MSEK 26 (26), equivalent to a margin of 66% (64%). The improved margin is mainly an effect of lower transport costs during the quarter as a larger share of freight was carried by sea rather than by air.
- In connection with the transition to a function-based income statement, costs have been redistributed to cost of goods sold, which has reduced gross margin by approximately 3 percentage points. These costs consist of depreciation and costs related to logistics. With increased sales and economies of scale, the effect of these costs on gross margin will diminish.
- EBITDA totalled MSEK -14 (0), equivalent to an EBITDA margin of -36% (-1%). Also the second quarter was notable for preparations for our European launch of Sedaconda (isoflurane), which has impacted profit by approximately SEK -5 million in non-recurring launch costs.
- Earnings before interest and taxes (EBIT) totalled MSEK -16 (-2), equivalent to an EBIT margin of -41% (-5%).
- Net profit for the quarter was MSEK -17 (4), and earnings per share before/after dilution were SEK -0.19 (-0.04).
- Cash flow from operating activities totalled MSEK -12 (2).
- Cash flow from investing activities totalled MSEK -23 (-18).
- Total cash flow for the quarter amounted to MSEK -36 (-8).
- Cash and cash equivalents at the end of the quarter amounted to MSEK 308, compared to MSEK 344 at the start of the year.

January-June 2021

- Net sales for the interim period totalled MSEK 85 (74), equivalent to an increase of 14%. At constant exchange rates, net sales increased by 20%.
- Gross profit was MSEK 55 (49), equivalent to a margin of 65% (65%).
- In connection with the transition to a function-based income statement, costs have been redistributed to cost of goods sold, which has reduced gross margin by approximately 3 percentage points. These costs consist of depreciation and costs related to logistics. With increased sales and economies of scale, the effect of these costs on gross margin will diminish.
- EBITDA totalled MSEK -23 (1), equivalent to an EBITDA margin of -27% (2%).
- Earnings before interest and taxes (EBIT) totalled MSEK -27 (2), equivalent to an EBIT margin of -32% (-2%).
- Net profit for the interim period was MSEK -26 (-2), and earnings per share before/after dilution were SEK -0.28 (-0.02).
- Cash flow from operating activities totalled MSEK -25 (-6).
- Cash flow from investing activities totalled MSEK -44 (-32).
- Total cash flow for the interim period amounted to MSEK -69 (-31).
- Cash and cash equivalents at the end of the interim period amounted to MSEK 308, compared to MSEK 376 at the start of the year.



Sedana Medical AB (publ) develops and sells the medical device AnaConDa for administration of volatile anaesthetics. Through a combination therapy of AnaConDa and the drug candidate Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated intensive care patients.
Sedana Medical was established in 2005 and is listed on Nasdaq First North Growth Market. The company's head office is in Danderyd, Stockholm.

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

CEO comments

European approval of Sedaconda (isoflurane) and increased sales despite declining number of Covid-19 patients in Europe

At the end of July, an important milestone was reached with the gratifying news that we received - earlier than expected - DCP approval for the pharmaceutical product Sedaconda (isoflurane), as well as the treatment inhaled sedation. As a result, we are now seeking national approvals to launch the inhaled sedation therapy in 15 European countries. These national processes are expected to take about 1-3 months. Further encouraging news was announced on 13 August when Sedaconda[1] received its first national approval, from the French medicines agency ANSM.

Sales in the quarter totalled SEK 40 million, an increase of about 3 percent at fixed exchange rates compared to last year. The gross margin for the quarter was 66 percent, up 2 percentage points year-on-year as a result of lower transport costs in the quarter as a greater proportion of freight was carried by sea rather than by air.

In Germany, our largest market, we saw continued strong momentum with sales up year-on-year and almost in line with Q1, despite a sharp downturn in the number of Covid-19 intensive care patients in May-June. This is a positive sign that clinics are continuing to broaden use beyond Covid-19 patients.

Other direct sales in Europe decreased compared to last year as a result of the slowing third wave of the pandemic. The previous year was notable for a massive increase in sales during April-May, at the start of the pandemic. These countries, which have a substantially smaller customer base than Germany, are even more affected in terms of sales by the decreasing number of Covid-19 patients in the ICU. However, we are seeing continued momentum here too, with existing and new hospital customers beginning to broaden use to other patient groups. These relationships will be very valuable for future marketing authorisations.

Sedana Medical operates according to a clear strategy based on several steps to develop inhaled sedation into a global standard therapy in intensive care.

The first step in the strategy is to establish AnaConDa (to be renamed Sedaconda ACD) in selected markets. During the quarter, we continued to strengthen our presence in our distributor markets, particularly in Latin America. Sales increased sharply compared to the previous year, and Mexico is our second largest market in the second quarter. Latin America is one of the regions in the world where the pandemic has put the greatest strain on health systems, with acute shortages of propofol in many countries. Our success can also be largely attributed to our local distributor, one of Latin America's leading distributors of healthcare products. There is strong interest in launching and selling AnaConDa/Sedaconda ACD in the markets we do not cover ourselves, which gives us the opportunity to work with the best distributors in each country.

With regard to the second step in our strategy, having the pharmaceutical product Sedaconda and inhaled sedation therapy approved, it was very pleasing to obtain DCP approval in July, as well as the first national marketing authorisation in France in August. Now that we are approaching commercialisation in Europe, our work has been concentrated on pre-launch activities. We are focusing on the pricing, procurement and reimbursement processes in each country, which is sometimes resource-intensive work, but acceptance by purchasers in healthcare systems is a key factor for successful commercialisation. In addition, despite continued shutdowns in many of our markets, we have managed to step up our level of activity at local congresses and meetings. We have also organised our own well-attended symposia in conjunction with these congresses. All in all, our level of activity has increased and will increase further as we come closer to the start of sales.

Part of the work ahead of the launch is the change of name for our medical device AnaConDa to Sedaconda ACD, which stands for Anaesthetic Conserving Device. The name strengthens the link to Sedana Medical and the unique area of use of sedation. The pharmaceutical product Sedaconda (isoflurane) is to be administered via AnaConDa/Sedaconda ACD, together making up the inhaled sedation therapy. The name change will be launched on 1 October.

[1] Sedaconda will be marketed in France under the brand name Cedaconda.

Preparations ahead of our American registration were intense during the quarter. Shortly after the end of the quarter, we were able to announce that we had held an End of Phase II meeting with the US Food and Drug Administration (FDA). The purpose of this advisory meeting was to discuss the documentation ahead of phase 3 and to agree on the plan and design of the phase 3 studies. The meeting was successful - the FDA accepted our proposed phase 3 programme, including the study design and the primary endpoint for the studies - and means that we are able to enter phase 3 in line with the previously communicated timetable.

We are now working to submit an Investigational New Drug (IND) application in the autumn to allow us to start clinical studies and enrol the first patients in the studies at the turn of Q1/Q2 2022. There has been significant interest in participating in the studies from a large number of leading US centres. We aim to include around 30 centres and look forward to starting the inclusion of patients. We have established a subsidiary and recruited employees in the United States who will be involved in the studies. By successfully carrying out two randomised controlled trials, each including around 250 patients, we plan to obtain marketing authorisation before the end of 2024.

With regard to the third step in our strategy; With the aid of more studies, securing medical evidence showing that inhaled sedation is a better and more cost-effective treatment than today's intravenous standard therapy, it was very pleasing to be able to report during the quarter that the Sedaconda study (SED001) was named one of the three best posters at the 52nd DGIIN & ÖGIAIN intensive care conference from 16 to 18 June 2021. DGIIN & ÖGIAIN is the joint annual congress of the German and Austrian acute and intensive care associations. It is highly positive that the study is receiving attention in Germany, which is our largest market.

All in all, we look back on yet another intensive quarter with success in all the steps in our strategy. On 1 October, I will be handing over the baton to our incoming President and CEO Johannes Doll and will continue in my role as Commercial Director. We look forward to coming back to you.

Jens Lindberg, acting CEO and President

Significant events during the period

First quarter

- An application for market approval for the candidate drug Sedaconda (isoflurane), previously known as IsoConDa, for inhaled sedation in intensive care was submitted in Switzerland and the United Kingdom.
- 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 AnaConDa is a safe and more effective method of sedation than intravenously administered midazolam, for children below 18 years of age.
- Sedana Medical's CEO, Christer Ahlberg, announced that he is stepping down as CEO to become the CEO of Cinclus Pharma AB.

Second quarter

- In May, the Board appointed Johannes Doll as the new CEO. Johannes will take up duties on 1 October 2021. Sedana Medical's Commercial Director Jens Lindberg has been appointed by the Board as acting CEO.
- The Annual General Meeting in May resolved, in line with the Board's proposal, to split the company's shares, with each existing share being divided into four new shares of the same class (4:1 split). The split was completed at the end of May.
- 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 June 2021.

Significant events after the period

- 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 devices can continue to be sold with CE marking in the EU.
- A successful End of Phase II 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.
- At the end of July, a positive outcome was received for the application for European marketing authorisation for the pharmaceutical product Sedaconda (isoflurane) for inhaled sedation in intensive care. Sedaconda is indicated for the sedation of mechanically ventilated adult intensive care patients and is to be administered only via the AnaConDa medical device.
- On 13 August, the first market approval for inhaled sedation was obtained in France. The application was approved by the French Medicines Agency, L'Agence nationale de sécurité du médicament et des produits de santé (ANSM) and is based on the DCP approval Sedana Medical received in July.

Financial targets

The company's target, until registration of Sedaconda (isoflurane) has been obtained, is 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 saw a positive trend in sales during the quarter, partly as a consequence of the Covid-19 pandemic. During the first half of 2020 demand increased significantly, as our therapy leads to potentially fewer side effects and better oxygen uptake in the lungs, which is especially good for Covid-19 patients. During the first half of 2021, we noted an increased demand in our market segment Other distributor markets, mainly in Latin America with a shortage of propofol, while we noted a small decline in Europe mainly at the end of the second quarter 2021. 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.

Business development

Development of registration

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

The process of registering the pharmaceutical product Sedaconda in Europe is now in its final phase, with the process moving faster than expected. Together with AnaConDa (which will be renamed Sedaconda ACD from 1 October), this will give us access to the full potential of the inhaled sedation market. To succeed in this, the company has completed a pivotal phase 3 study in Germany and Slovenia. In July 2020, the company announced that the study had reached its primary endpoint: to show that Sedaconda delivered via AnaConDa/Sedaconda ACD, is an effective sedation therapy for mechanically ventilated intensive care patients and non-inferior to present-day standard intravenous sedation with propofol.

The results of the study formed the basis for the application for marketing authorisation for Sedaconda for inhaled sedation in intensive care, that was submitted to the German regulatory authority BfArM and a number of other European regulatory authorities under what is known as a DCP procedure in November 2020.The application marked the starting point for the review process for Sedaconda in 15 EU Member States, including Norway.

In July 2021, we announced that we had received a positive response to this application for European registration through the decentralised procedure. This outcome means that we can proceed to apply for national approval in the 15 countries, which is expected to take 1-3 months. After that, it is estimated that it will take about 3 months until the products are ready for delivery and sale.

On 13 August 2021, we announced that the first national approval for Sedaconda had been obtained in France, which means that we can proceed with the price and reimbursement application process, which is expected to take 4-6 months in France. Spain and Belgium also have similar processes that take 4-6 months, while these processes are considerably faster in other European countries.

During the first quarter of 2021, an application for marketing authorisation was also submitted to the authorities in Switzerland and the United Kingdom, with expected approval and launch in 2022. We also plan to submit applications for additional EU countries over the next six months.

Registration study SED-001

The company's pivotal phase 3 study is necessary for a complete dossier and to register the pharmaceutical product as well as the entire therapy. The study was completed in 2020 and formed the basis for the European application.

The SED001 study was designed as a non-inferiority study, which means that its primary purpose and objective is to show that inhaled sedation with isoflurane is not inferior to propofol in maintaining an adequate sedation level. SED001 was an open-label, randomised study that included 300 patients treated with either inhaled sedation with isoflurane delivered via AnaConDa/Sedaconda ACD or with intravenous propofol. The top line results of the study published in early July 2020 showed that the primary endpoints had been reached, allowing us to proceed with the marketing authorisation application for Sedaconda in Europe.

The results for some of the secondary endpoints in the study were presented at the ESICM congress in December 2020. The secondary endpoints show that Sedaconda (isoflurane) 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 Sedaconda study also attracted attention at the annual joint intensive care conference in Germany and Austria in June 2021, where it was named one of the top three posters. The full results of the study will be presented in a scientific journal in 2021.

Pediatric study SED-002

In 2019, Sedana Medical was approved for a Paediatric Investigation Plan (PIP) by the European Medicines Agency's Paediatric 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 AnaConDa/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. This approval also means that AnaConDa/Sedaconda ACD can be used in patients with severely impaired lung function.

Work on registration of Sedaconda and AnaConDa in the US

The market potential for inhaled sedation in intensive care in the United States is around SEK 10 billion annually. Work on the registration of inhaled sedation including both Sedaconda and AnaConDa/Sedaconda ACD is fully under way. During 2019, the company was able to announce the outcome of the 'pre-IND meeting' held at the FDA in March of the same year. The FDA was broadly positive towards the registration of Sedaconda and AnaConDa/Sedaconda ACD as a combination product in the United States. The meeting confirmed the company's estimate of the time and cost involved in a registration, which is expected to be possible in 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[2] . 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 is working towards obtaining IND approval during the autumn 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 the end of 2024.
The company announced in July 2021 that it had 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 process of selecting a CRO has been completed, and the company is currently putting all its efforts into preparing a study protocol and recruiting clinics to take part in the studies. The company aims to include approximately 30 American centres in the two clinical studies. During the second quarter, a subsidiary was established in the United States; the first employees have been recruited and will join in Q3 2021. They will be involved in the conduct of our phase 3 trials. Around 2022 we will decide whether we intend to launch on our own or together with a local partner.

Work on registration of Sedaconda and AnaConDa in Japan

In November 2018, Sedana Medical obtained approval for AnaConDa/Seconda ACD in Japan. The approval means that AnaConDa/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 must also be ensured. We are now examining the various registration options for Sedaconda available to us in Japan. The next step towards enabling the registration of Sedaconda is an official meeting with the Japanese Pharmaceuticals and Medical Devices Agency to clarify the Japanese requirements for the approval of Sedaconda.

Building the market

The total market potential for inhaled sedation in intensive care in the United States estimated by the company is around SEK 20–30 billion annually. Europe and the United States are the two most important markets for Sedana Medical. However, patients sedated due to mechanical ventilation in intensive care are evenly distributed globally between the United States, Europe and Asia.
Efforts aimed at increasing awareness and use of AnaConDa/Sedaconda ACD and establishing a presence in several countries in Europe are continuing. The plan is to be represented in selected European markets with established networks and reference clinics when the company receives national marketing authorisation for Sedaconda, in order to be able to penetrate the markets quickly. As a result of clarification in the registration process in the United States and the scheduling for Europe, as well as the success in Asia, we are now able to carry on working at a fast pace according to an established plan for Europe, the United States and Asia.
In 2020-2021, we have seen a clear increase in interest in AnaConDa/Sedaconda ACD and inhaled sedation in new regions, partly driven by the Covid-19 pandemic as these patients are often in great need of sedation in ICU. This has meant establishing partnerships with distributors in Latin America, Australia/New Zealand and the Middle East, in addition to the regions mentioned above. Interest in inhaled sedation is also high among customers in these markets, contributing positively to further market penetration.
Our research foundation, the Sedana Medical Research Grant, represents a unique opportunity for the scientific community to increase knowledge on the sedation of critically ill patients.
We are continuously working closely with the academy to find interesting projects in order to highlight the benefits of the therapy compared to intravenous sedation. One example is that the company is sponsoring the world's largest multicentre study for inhaled sedation with AnaConDa/Sedaconda ACD in France. The primary purpose of the study is to demonstrate that inhaled sedation with AnaConDa/Sedaconda ACD has lung-protective characteristics, shortens ventilator time, and leads to greater survival in intensive-care patients with severe respiratory disease compared to intravenous sedation.
We are also making active efforts to establish closer ties with key opinion leaders in intensive care and academia to better understand regional differences and gain a deeper understanding of the clinical processes in each country.
From a market point of view, we regularly attend national and international scientific intensive-care conferences and congresses, where we often arrange well-attended scientific symposia in the field of inhaled sedation.

[2] Human factors-validation means that Sedana Medical tests, develops and validates the users' learning and practical application of Sedana Medical's therapy inhaled sedation.

Financial summary

	Apr-Jun		Jan-Jun		Jan-Dec
(KSEK)	2021	2020	2021	2020	2020
Net sales	39,510	40,509	84,510	74,341	141,770
Gross profit	26,192	25,985	54,797	48,624	88,903
Gross margin %	66%	64%	65%	65%	63%
EBITDA	-14,283	-268	-22,591	1,440	-14,294
EBITDA margin %	-36%	-1%	-27%	2%	-10%
Operating income (EBIT)	-16,370	-1,902	-26,732	-1,806	-21,359
Operating margin %	-41%	-5%	-32%	-2%	-15%
Income after net financial items	-17,162	-4,210	-26,020	-1,979	-24,103
Net income	-17,289	-3,594	-26,252	-1,895	-27,138
Net income margin %	-44%	-9%	-31%	-3%	-19%
Total assets	572,991	601,701	572,991	601,701	600,097
Equity	526,488	575,206	526,488	575,206	551,094
Equity ratio %	92%	96%	92%	96%	92%
Quick ratio %	817%	1754%	817%	1754%	929%
Debt to equity ratio %	9%	5%	9%	5%	9%
Average number of full time employees for the period	70	52	68	48	55
Number of employees at balance date	79	57	79	57	69
Number of employees and consultants at balance date	91	64	91	64	83
Average number of shares before dilution [1)]	92,186,960	91,556,662	92,186,960	91,556,662	91,566,662
Average number of shares after dilution [1)]	92,734,232	92,564,540	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 [2)]	-0.19	-0.04	-0.28	-0.02	-0.30
Earnings per share after dilution, SEK [2)]	-0.19	-0.04	-0.28	-0.02	-0.30

1) Comparative periods have been adjusted for the share split that was carried out in May 2021
2) Based on average number of shares for the period

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 second quarter totalled KSEK 39,510 (40,509), equivalent to a decrease of 2 percent. Adjusted for currency effects, the second quarter showed an increase of about 3 percent. In May and June 2021, we saw a slowdown in the third wave of the pandemic in Europe, while it is increasing in Latin America and other regions in our distributor markets. This compares to April and May 2020, which saw a massive increase in sales in Europe at the start of the pandemic. During the quarter, we noted in Europe, mainly in Germany, that clinics and hospitals have significantly broadened the use of our therapy to non-Covid patients, which has had a positive impact on sales.

The majority of Group sales are in Europe, mainly in Germany with steady sales. In other countries with direct sales, Spain in particular has increased compared to the previous year, while it has been difficult to reach customers in some markets such as the United Kingdom during lock-downs. Other direct sales also decreased slightly compared to the first quarter due to a previous build-up of stocks at hospitals. In terms of distributor markets, we have seen an increase mainly in Latin America, with Mexico as our second largest market. The increase is largely attributable to the third wave of the Covid-19 pandemic.

Net sales during the interim period totalled KSEK 84,510 (74,341), equivalent to an increase of 14 percent. Adjusted for currency effects, the increase was 20 percent. The majority of Group sales are in Europe, mainly Germany. Among other

countries with direct sales, Spain in particular has shown an increase in comparison with previous year, and in terms of distributor markets we have seen an increase mainly in Latin America.

	Apr-Jun			Jan-Jun			Jan-Dec
(KSEK)	2021	2020	%	2021	2020	%	2020
Germany	27,524	28,206	-2%	56,125	55,008	2%	103,063
Other direct sales	3,869	9,064	-57%	8,837	13,434	-34%	22,209
Distributor markets	8,117	3,239	151%	19,548	5,899	231%	16,498
Total net sales	**39,510**	**40,509**	**-2%**	**84,510**	**74,341**	**14%**	**141,770**

Gross profit and margin

Gross profit for the second quarter was KSEK 26,192 (25,985), equivalent to a gross margin of 66 (64) percent. The increase is mainly an effect of lower transport costs during the quarter as a higher proportion of freight was carried by sea rather than by air, while the sales mix affected the margin slightly negatively as sales increased in our distributor markets where margins are somewhat lower.

Gross profit for the interim period was KSEK 54,797 (48,624), equivalent to a gross margin of 65 (65) percent. The increase is partly due to higher sales but is also a mix effect with increased sales in some distributor markets with slightly lower margins.

Selling expenses

Selling expenses for the quarter totalled KSEK -25,901 (-13,976), equivalent to an increase of 85 percent. The increase is due in equal parts to higher costs related to preparations for the launch of Sedaconda, of approximately MSEK 5, and higher costs resulting from a larger commercial and marketing organisation and a higher level of activity. The launch costs relate mainly to the costs of securing price and reimbursement in each country.

Selling expenses for the interim period totalled KSEK -46 754 (-27 884), equivalent to an increase of 68 percent. The increase is due to higher costs related to preparations for the launch of Sedaconda, of approximately SEK 7 million, and 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 -12 194 (-10 210), equivalent to an increase of 19 percent. The increase is a result of the general growth in the company and expansion of office premises and associated equipment.

Administrative expenses for the interim period totalled KSEK -25 805 (-18 737), equivalent to an increase of 38 percent.

Research and development expenses

Research and development expenses for the quarter totalled KSEK -4,701 (-2,683), equivalent to an increase of 75 percent. The increase is an effect of a slightly larger R&D organisation and MSEK 0.7 related to approval under the EU Medical Device Regulation (MDR), which means that Sedana Medical's medical devices can continue to be sold with CE marking in the EU.

Research and development expenses for the interim period totalled KSEK -8,874 (-3,754), equivalent to an increase of 136 percent. Costs related to the MDR approval totalled MSEK 1.2 for the period.

Other operating income/expenses

Other operating income mainly consists of positive unrealised exchange rate differences on operating items. These totalled KSEK 643 (341) for the quarter. Other operating income for the interim period totalled KSEK 2,915 (1,534).

Other operating expenses mainly consist of negative unrealised exchange rate differences on operating items. These totalled KSEK -409 (-1,359) for the quarter. Other operating expenses for the interim period totalled KSEK -3,011 (-1,588).

Net financial items and earnings per share

Net financial items for the quarter totalled KSEK -792 (-2,308) and consist mainly of unrealised gain/loss on foreign exchange. Net financial income for the interim period totalled KSEK 712 (-173).
Group tax expense for the quarter was KSEK -127 (616) and mainly consists of current tax in Germany. Group tax expense for the interim period was KSEK -232 (84).
Earnings per share was thus SEK -0.19 (0.04) for the quarter and SEK -0.28 (-0.02) for the interim period.

Equity and debt

Adjusted for the split carried out in May 2021, equity at 30 June was KSEK 526 488, compared with KSEK 551 094 at the start of the year, equivalent to SEK 5.71 (5.98) per share. Equity/assets ratio was 92 percent, compared with 92 percent at the start of the year.
Debt/equity ratio at 30 June was 9 percent, compared with 9 percent at the start of the year. The Group had no non-current liabilities at 30 June.

Cash position and cash flow

Cash and cash equivalents decreased by KSEK 35,834 during the quarter and totalled KSEK 307,785 at 30 June, compared to KSEK 343,619 at the start of the quarter. Cash flow from operating activities before changes in working capital for the quarter was KSEK -13,407 (1,224). Cash flow from changes in working capital was KSEK 1 597 (707). The lower tied up working capital is mainly due to higher trade payables at the end of the quarter. Cash flow from operating activities thus totalled KSEK -11,810 (1,931).
Cash flow from investing activities totalled KSEK -23,122 (-17,710). The investments mostly consist of intangible assets, mainly development expenses for the clinical study SED001, registration work for AnaConDa and Sedaconda in the United States and expenses related to the AnaConDa paediatric study in the EU.
Cash flow from financing activities totalled KSEK -841 (7,791) and relates to repayment of lease liabilities.
Cash flow per share for the quarter was SEK -0.39 (-0.10).

Cash and cash equivalents decreased by KSEK 68 386 during the interim period and totalled KSEK 307,785 at 30 June, compared to KSEK 376,171 at the start of the year. Cash flow from operating activities before changes in working capital for the quarter was KSEK -22,258 (1,872) for the interim period. Cash flow from changes in working capital totalled KSEK -2,862 (-7,851). The lower tied up working capital is mainly due to payments of accounts receivable. Cash flow from operating activities thus totalled KSEK -25,120 (-5,980).
Cash flow from investing activities totalled KSEK -44,200 (-31,953). The investments mostly consist of intangible assets, mainly development expenses for the clinical study SED001, registration work for AnaConDa and Sedaconda in the United States and expenses related to the AnaConDa paediatric study in the EU.
Cash flow from financing activities totalled KSEK 105 (7,245) and relates to premiums paid for warrants in a new programme 2020/2024 and repayment of lease liabilities.
Cash flow per share for the interim period was SEK -0.75 (-0.35).

Parent company

The Parent Company's net sales for the interim period totalled KSEK 84,521 (9,447), of which intra-group sales was KSEK 4,396 (854). The increase compared with the same interim 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 profit for the interim period totalled KSEK -24,229 (-14,841). Net financial items were KSEK 1,469 (640) and relate mainly to unrealised foreign exchange gains on internal loans.
Shareholders' equity in the Parent Company totalled KSEK 540,556 at 30 June 2021, compared with KSEK 561,600 at the start of the year, equivalent to a decrease of KSEK 21,044. Share capital totalled KSEK 2,305, which is unchanged compared to the beginning of the year.
Cash and cash equivalents totalled KSEK 297,062, compared with KSEK 365,113 at the start of the year, equivalent to a decrease of KSEK 68,051.

The Sedana Medical share

Sedana Medical shares are listed on Nasdaq First North Growth Market Stockholm. Market capitalisation at the end of the second quarter was MSEK 6 582.

The price paid for Sedana Medical shares at the start of the year, adjusted for the share split that was carried out in May, was SEK 85.75 and at the end of the second quarter was SEK 71.40. The lowest closing price for the interim period was recorded on 24 June and was SEK 69.70. The highest closing price was recorded on 16 February and was SEK 98.38.

Share information

	Apr-Jun		Jan-Jun		Jan-Dec
	2021	2020	2021	2020	2020
Net income, KSEK	-17,289	-3,594	-26,252	-1,895	-27,138
Cash flow, KSEK	-35,773	-7,988	-69,215	-30,688	-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	91,556,662	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	997,878	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	526,488	575,206	526,488	575,206	551,094
Earnings per share before dilution, SEK	-0.19	-0.04	-0.28	-0.02	-0.30
Earnings per share after dilution, SEK	-0.19	-0.04	-0.28	-0.02	-0.30
Equity per share, SEK	5.71	6.24	5.71	6.24	5.98
Cash flow per share, SEK	-0.39	-0.10	-0.75	-0.35	-0.95

Largest shareholders at the end of the period

	No of shares	Share
Handelsbanken Funds	8,495,052	9.2%
Swedbank Robur Funds	8,314,933	9.0%
Linc AB	7,598,804	8.2%
Anders Walldov direct and indirect (Brohuvudet AB)	7,100,000	7.7%
Ola Magnusson direct and indirect (Magiola AB)	4,613,728	5.0%
Sten Gibeck	4,279,776	4.6%
Öhman Funds	3,902,588	4.2%
Berenberg Funds	2,162,344	2.3%
Avanza Pension	1,947,394	2.1%
Tredje AP-fund	1,900,000	2.1%
Nordnet Pensionsförsäkring	1,840,198	2.0%
Tedsalus AB (Thomas Eklund)	1,666,464	1.8%
Highclere International Investors LLP	1,626,060	1.8%
Philip Earle	1,010,000	1.1%
DNCA Finance S.A	975,980	1.1%
Fifteen largest shareholders	57,433,321	62.3%
Others	*34,753,639*	*37.7%*
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	6,582 SEK million
Ticker	SEDANA
ISIN	SE0015988373
LEI-code	549300FQ3NJRI56LCX32

* As per 2021-06-30

Financial calendar

Interim report Jan-Sep 2021	4 November 2021

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 19 August 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

Jens Lindberg
Acting President and CEO

This report has not been the object of 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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The company's Certified Adviser is Erik Penser Bank, +46 8 463 83 00, certifiedadviser@penser.se

Presentation of the interim report for the second quarter 2021

Sedana Medical presents the interim report to investors, asset managers, analysts and media on 19 August 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/13794

After the presentation, a recorded version of the webcast will be available at: Investors - Sedana Medical

Consolidated income statement, summary

(KSEK)	Apr-Jun 2021	Apr-Jun 2020	Jan-Jun 2021	Jan-Jun 2020	Jan-Dec 2020
Net sales	39,510	40,509	84,510	74,341	141,770
Cost of goods sold	-13,318	-14,524	-29,713	-25,717	-52,867
Gross profit	**26,192**	**25,985**	**54,797**	**48,624**	**88,903**
Selling expenses	-25,901	-13,976	-46,754	-27,884	-65,123
Administrative expenses	-12,194	-10,210	-25,805	-18,737	-37,296
Research and development expenses	-4,701	-2,683	-8,874	-3,754	-7,859
Other operating income	643	341	2,915	1,534	3,654
Other operating expenses	-409	-1,359	-3,011	-1,588	-3,637
Operating income	**-16,370**	**-1,902**	**-26,732**	**-1,806**	**-21,359**
Financial items					
Financial income	-306	86	1,345	2,346	2,845
Financial expenses	-486	-2,394	-633	-2,519	-5,590
Net financial items	**-792**	**-2,308**	**712**	**-173**	**-2,745**
Income before taxes	**-17,162**	**-4,210**	**-26,020**	**-1,979**	**-24,103**
Tax	-127	616	-232	84	-3,035
Net income	**-17,289**	**-3,594**	**-26,252**	**-1,895**	**-27,138**
Earnings per share, based on earnings attributable to the parent company's ordinary shareholders:					
Before dilution	-0.19	-0.04	-0.28	-0.02	-0.30
After dilution	-0.19	-0.04	-0.28	-0.02	-0.30
EBITDA	**-14,283**	**-268**	**-22,591**	**1,440**	**-14,294**
Amortisation of intangible assets	-426	-446	-851	-892	-1,756
Depreciation of tangible assets	-1,661	-1,188	-3,290	-2,353	-5,309
Operating income (EBIT)	**-16,370**	**-1,902**	**-26,732**	**-1,806**	**-21,359**

Consolidated statement of other comprehensive income, summary

(KSEK)	Apr-Jun 2021	Apr-Jun 2020	Jan-Jun 2021	Jan-Jun 2020	Jan-Dec 2020
Net income	**-17,289**	**-3,594**	**-26,252**	**-1,895**	**-27,138**
Other comprehensive income					
Items that can later be reclassified to the income statement:					
Translation differences from foreign operations	181	458	-114	-513	624
Other comprehensive income, net after tax	**181**	**458**	**-114**	**-513**	**624**
Total comprehensive income	**-17,108**	**-3,136**	**-26,366**	**-2,408**	**-26,514**
Total comprehensive income as a whole attributabe to the parent company's shareholders	**-17,108**	**-3,136**	**-26,366**	**-2,408**	**-26,514**

Consolidated balance sheet, summary

(KSEK)	Jun 30, 2021	Jun 30, 2020	Dec 31, 2020
ASSETS			
Intangible assets			
Capitalised development expenditure	206,795	124,019	166,378
Concessions, patents, licenses, etc.	2,351	3,487	2,998
Tangible assets			
Machinery and other technical facilities	6,362	5,099	5,711
Equipment, tools and installations	1,172	696	1,213
Rights of use	9,667	2,094	8,792
Financial assets			
Other long term assets	42	43	41
Deferred tax assets	*31*	*2,371*	*45*
Total fixed assets	**226,420**	**137,809**	**185,178**
Inventory	10,714	8,730	9,087
Tax receivables	457	6	453
Accounts receivable	18,458	11,909	19,484
Prepayments and accrued income	5,881	6,207	5,609
Other receivables	3,276	3,503	4,115
Cash and cash equivalents	307,785	433,537	376,171
Total current assets	**346,571**	**463,892**	**414,919**
TOTAL ASSETS	**572,991**	**601,701**	**600,097**

(KSEK)	Jun 30, 2021	Jun 30, 2020	Dec 31, 2020
EQUITY AND LIABILITIES			
Equity			
Share capital	2,305	2,305	2,305
Other contributed capital	615,683	613,927	613,923
Translation difference	392	-630	506
Retained earnings including net profit	-91,892	-40,396	-65,640
Equity attributable to the parent company's shareholders	**526,488**	**575,206**	**551,094**
Non-current liabilities			
Leasing liabilities	5,414	540	5,324
Total non-current liabilities	**5,414**	**540**	**5,324**
Current liabilities			
Leasing liabilities	3,779	1,237	2,967
Accounts payable	12,577	6,444	16,371
Tax debt	2,949	853	2,718
Other liabilities	7,038	4,821	7,668
Accrued expenses and deferred income	14,746	12,600	13,955
Total current liabilities	**41,089**	**25,955**	**43,679**
Total liabilities	**46,503**	**26,495**	**49,003**
TOTAL EQUITY AND LIABILITIES	**572,991**	**601,701**	**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	-	-	-	-1,895	-1,895
Other comprehensive income	-	-	-513	-	-513
Total comprehensive income	**-**	**-**	**-513**	**-1,895**	**-2,408**
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	-	-53	-	-	-53
Total transactions with the Group's owners	**31**	**8,225**	**-**	**-**	**8,256**
Closing equity at Jun 30, 2020	2,305	613,927	-630	-40,396	575,206

(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	-	-	-	-26,252	-26,252
Other comprehensive income	-	-	-114	-	-114
Total comprehensive income	**-**	**-**	**-114**	**-26,252**	**-26,366**
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 Jun 30, 2021	2,305	615,683	392	-91,892	526,488

Consolidated cash flow statement, summary

	Apr-Jun		Jan-Jun		Jan-Dec
(KSEK)	2021	2020	2021	2020	2020
Operating activities					
Operating income	-16,370	-1,902	-26,732	-1,806	-21,359
Adjustments for non-cash items					
Depreciations and amortisations	2,087	1,634	4,141	3,245	7,065
Exchange rate differences	102	889	-1,333	-308	-363
Other non-cash items	652	581	1,783	876	7,411
Interest received	0	48	0	49	25
Interest paid	-66	-13	-116	-109	-189
Taxes paid	188	-13	-1	-76	-869
Cash flow from operating activities before changes in working capital	**-13,407**	**1,224**	**-22,258**	**1,872**	**-8,279**
Cash flow from changes in working capital					
Cash flow from inventories	1,026	-2,556	-1,916	-1,333	-1,158
Cash flow from operating receivables	-1,514	3,217	2,539	-7,424	-15,292
Cash flow from operating liabilities	2,085	46	-3,485	906	16,883
Cash flow from operating activities	**-11,810**	**1,931**	**-25,120**	**-5,980**	**-7,846**
Investing activities					
Investments in intangible assets	-22,412	-15,322	-40,508	-28,684	-72,175
Investments in tangible assets	-710	-2,388	-3,692	-3,269	-12,444
Cash flow from investing activities	**-23,122**	**-17,710**	**-44,200**	**-31,953**	**-84,619**
Financing activities					
New share issue	0	7,862	0	7,862	7,862
Issue expenses	0	-63	0	-63	-68
Amortisation of leasing liabilities	-841	-465	-1,655	-1,011	-2,464
Received premium for warrant subscription	0	515	1,760	515	515
Expenses for warrant program	0	-58	0	-58	-58
Cash flow from financing activites	**-841**	**7,791**	**105**	**7,245**	**5,787**
Cash flow for the period	**-35,773**	**-7,988**	**-69,215**	**-30,688**	**-86,678**
Cash and cash equivalents at the beginning of the period	**343,619**	**442,553**	**376,171**	**464,560**	**464,560**
Translation difference	-61	-1,028	829	-336	-1,711
Cash and cash equivalents at the end of the period	**307,785**	**433,537**	**307,785**	**433,537**	**376,171**

Consolidated quarterly summary, income statement

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

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

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 MSEK 1 compared with previously published figures. For Q1 2021, a reclassification of approximately MSEK 2 of previously published figures has been made from research and development expenses to selling expenses.

Consolidated quarterly summary, balance sheet

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

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

Consolidated quarterly summary, cash flow statement

(KSEK)	2020 Quarter 1	Quarter 2	Quarter 3	Quarter 4	2021 Quarter 1	Quarter 2
Operating activities						
Operating income	96	-1,902	-11,682	-7,871	-10,362	-16,370
Adjustments for non-cash items						
Depreciations and amortisations	1,611	1,633	1,703	2,117	2,054	2,087
Exchange rate differences	-1,197	889	479	-534	-1,435	102
Other non-cash items	295	582	2,350	4,184	1,131	652
Interest received	1	49	-23	-1	0	0
Interest paid	-96	-14	-21	-59	-50	-66
Taxes paid	-63	-13	-860	67	-189	188
Cash flow from operating activities before changes in working capital	**648**	**1,224**	**-8,054**	**-2,098**	**-8,851**	**-13,407**
Cash flow from changes in working capital						
Cash flow from inventories	1,223	-2,556	-3,296	3,471	-2,942	1,026
Cash flow from operating receivables	-10,641	3,217	823	-8,690	4,053	-1,514
Cash flow from operating liabilities	860	46	5,901	10,076	-5,570	2,085
Cash flow from operating activities	**-7,910**	**1,932**	**-4,626**	**2,759**	**-13,310**	**-11,810**
Investing activities						
Investments in intangible assets	-13,362	-15,321	-18,268	-25,223	-18,096	-22,412
Investments in tangible assets	-881	-2,389	-3,763	-5,411	-2,982	-710
Cash flow from investing activities	**-14,243**	**-17,710**	**-22,031**	**-30,635**	**-21,078**	**-23,122**
Financing activities						
New share issue	0	7,862	0	0	0	0
Issue expenses	0	-65	-3	0	0	0
Amortisation of leasing liabilities	-546	-465	-716	-737	-814	-841
Received premium for warrant subscription	0	515	0	0	1,760	0
Expenses for warrant program	0	-56	-2	0	0	0
Cash flow from financing activites	**-546**	**7,791**	**-721**	**-737**	**946**	**-841**
Cash flow for the period	**-22,699**	**-7,988**	**-27,378**	**-28,612**	**-33,442**	**-35,773**
Cash and cash equivalents at the beginning of the period	**464,560**	**442,553**	**433,537**	**406,346**	**376,171**	**343,619**
Translation difference	692	-1,028	187	-1,563	890	-61
Cash and cash equivalents at the end of the period	**442,553**	**433,537**	**406,346**	**376,171**	**343,619**	**307,785**

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

Parent company income statement, summary

	Apr-Jun		Jan-Jun		Jan-Dec
(KSEK)	2021	2020	2021	2020	2020
Net sales	39,554	6,324	84,521	9,447	121,238
Cost of goods sold	-9,487	-4,410	-24,422	-7,242	-38,707
Gross profit	**30,067**	**1,914**	**60,099**	**2,205**	**82,531**
Selling expenses	-16,401	-7,982	-27,674	-14,971	-72,666
Administration costs	-28,501	-9,009	-56,326	-16,122	-38,668
Research and development costs	-3,502	-1,536	-6,855	-1,658	-3,953
Other operating income	4,286	8,586	7,800	17,163	7,790
Other operating expenses	-396	-1,279	-1,273	-1,458	-2,611
Operating income	**-14,447**	**-9,306**	**-24,229**	**-14,841**	**-27,577**
Financial items					
Financial income	34	427	1,992	2,999	1,778
Financial expenses	-426	-2,366	-523	-2,359	-2,959
Net financial items	**-392**	**-1,939**	**1,469**	**640**	**-1,181**
Income after net financial items	**-14,839**	**-11,245**	**-22,760**	**-14,201**	**-28,758**
Group contribution	0	0	0	0	-9
Income before tax	**-14,839**	**-11,245**	**-22,760**	**-14,201**	**-28,767**
Income tax	0	0	0	0	0
Net income	**-14,839**	**-11,245**	**-22,760**	**-14,201**	**-28,767**

Parent company statement of other comprehensive income, summary

	Apr-Jun		Jan-Jun		Jan-Dec
(KSEK)	2021	2020	2021	2020	2020
Net income	**-14,839**	**-11,245**	**-22,760**	**-14,201**	**-28,767**
Other comprehensive income					
Items that can later be reclassified to the income statement:					
Translation differences from foreign operations	56	373	-44	-5	200
	56	**373**	**-44**	**-5**	**200**
Other comprehensive income, net after tax					
Total comprehensive income	**-14,783**	**-10,872**	**-22,804**	**-14,206**	**-28,567**

Parent company balance sheet, summary

(KSEK)	Jun 30, 2021	Jun 30, 2020	Dec 31, 2020
ASSETS			
Intangible assets			
Capitalised development expenditure	195,420	115,381	156,261
Tangible assets			
Machinery and other technical facilities	5,276	1,314	4,334
Equipment, tools and installations	568	279	638
Financial assets			
Other long term assets	404	394	395
Non-current receivables, group companies	39,648	39,502	38,539
Total fixed assets	**241,316**	**156,870**	**200,167**
Inventory	10,786	180	9,245
Tax receivables	4	4	4
Accounts receivable	17,383	3,972	17,925
Receivables, group companies	20,390	37,953	2,239
Prepayments and accrued income	5,237	5,112	5,575
Other receivables	2,207	2,794	3,202
Cash and cash equivalents	297,062	413,009	365,113
Total current assets	**353,069**	**463,024**	**403,303**
TOTAL ASSETS	**594,385**	**619,894**	**603,470**

(KSEK)	Jun 30, 2021	Jun 30, 2020	Dec 31, 2020
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	2,305	2,305	2,305
Fund for capitalised development expenses	191,653	115,381	154,405
Non-restricted equity			
Share premium fund	615,683	613,927	613,923
Retained earnings	-246,325	-141,448	-180,266
Net income	-22,760	-14,201	-28,767
Equity attributable to the parent company's shareholders	**540,556**	**575,964**	**561,600**
Current liabilities			
Accounts payable	11,957	3,766	15,469
Liabilities to group comapnies	23,713	28,535	10,095
Tax debt	1,436	803	1,387
Other liabilities	4,501	2,268	4,707
Accrued expenses and deferred income	12,222	8,558	10,212
Total current liabilities	**53,829**	**43,930**	**41,870**
Total liabilities	**53,829**	**43,930**	**41,870**
TOTAL EQUITY AND LIABILITIES	**594,385**	**619,894**	**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	-	-	-	-14,201	-14,201
Other comprehensive income	-	-	-	-5	-5
Total comprehensive income	**-**	**-**	**-**	**-14,206**	**-14,206**
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	-	-	-53	-	-53
Total transactions with the parent company's owners	**31**	**-**	**8,225**	**-**	**8,256**
Reallocation between items in equity					
Capitalised development expenses	-	27,334	-	-27,334	-
Total reallocations	**-**	**27,334**	**-**	**-27,334**	**-**
Closing equity at Jun 30, 2020	**2,305**	**115,381**	**613,927**	**-155,648**	**575,965**

(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	-	-	-	-22,760	-22,760
Other comprehensive income	-	-	-	-44	-44
Total comprehensive income	**-**	**-**	**-**	**-22,804**	**-22,804**
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	-	37,248	-	-37,248	-
Total reallocations	**-**	**37,248**	**-**	**-37,248**	**-**
Closing equity at Jun 30, 2021	**2,305**	**191,653**	**615,683**	**-269,085**	**540,556**

Parent company cash flow statement, summary

	Apr-Jun		Jan-Jun		Jan-Dec
(KSEK)	2021	2020	2021	2020	2020
Operating activities					
Operating income	-14,447	-9,306	-24,229	-14,841	-27,577
Adjustments for non-cash items					
Depreciations and amortisations	505	186	1,028	334	969
Exchange rate differences	2,135	638	-212	-464	629
Other non-cash items	362	-128	794	-128	473
Interest received	0	373	0	719	1,336
Interest paid	-11	0	-11	-3	-8
Taxes paid	237	0	49	0	0
Cash flow from operating activities before changes in working capital	**-11,219**	**-8,237**	**-22,581**	**-14,383**	**-24,178**
Cash flow from changes in working capital					
Cash flow from inventories	1,291	88	-1,540	803	-8,262
Cash flow from operating receivables	96,711	-10,642	91,520	-20,467	396
Cash flow from operating liabilities	-97,699	10,575	-96,053	10,376	8,380
Cash flow from operating activities	**-10,916**	**-8,216**	**-28,654**	**-23,671**	**-23,664**
Investing activities					
Investments in intangible assets	-21,621	-14,674	-39,160	-27,334	-68,213
Investments in tangible assets	-430	-620	-2,694	-868	-4,893
Investments in financial assets	-8	2,389	-8	1,531	-283
Cash flow from investing activities	**-22,059**	**-12,905**	**-41,862**	**-26,671**	**-73,389**
Financing activities					
New share issue	0	7,862	0	7,862	7,862
Issue expenses	0	-63	0	-63	-68
Received premium for warrant subscription	0	515	1,760	515	515
Expenses for warrant program	0	-58	0	-58	-58
Cash flow from financing activites	**0**	**8,256**	**1,760**	**8,256**	**8,251**
Cash flow for the period	**-32,975**	**-12,865**	**-68,756**	**-42,086**	**-88,802**
Cash and cash equivalents at the beginning of the period	**329,969**	**426,014**	**365,113**	**455,206**	**455,206**
Translation difference	68	-140	705	-111	-1,291
Cash and cash equivalents at the end of the period	**297,062**	**413,009**	**297,062**	**413,009**	**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 policies

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 Coid-19 and its possible impacts on Sedana Medical, see page 5 and the CEO's Comments on pages 3-4.

Personnel

During the interim period, the Group had an average of 68 (48) full time employees and 11 (6) full time consultants, representing an increase of 25 on the same period in 2020. At the end of the quarter, the number of employees was 79 and the number of consultants was 12 compared to 69 and 14 respectively at the start of the year. The main reason for the increase in personnel costs 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.

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 Farell 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**
Exercise period 1 July 2022 – 30 November 2022							
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**
*Exercise period **1 June 2023 – 30 September 2023***							
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**
*Exercise period **1 February 2024 – 31 May 2024***							
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.

The table above shows warrants held by the acting CEO on the line for other senior executives.

Explanations regarding transition to IFRS

This financial report for the Group is the second 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-Jun 2020

(KSEK)	Cost-based	Other operating income	Cost of goods sold	Other external costs	Personnel costs	Depreciation	Function-based	
Net sales	74,341						74,341	Net sales
Other operating income	3,459	-3,459					0	
			-23,694	-141	-623	-1,258	-25,716	Cost of goods sold
	77,800	**-3,459**	**-23,694**	**-141**	**-623**	**-1,258**	**48,625**	**Gross Profit**
							0	
Cost of goods sold	-23,694		23,694				0	
Other external costs	-23,454			23,454			0	
Personnel costs	-26,710				26,710		0	
Depreciation	-2,263					2,263	0	
				-9,401	-17,171	-1,312	-27,884	Selling expenses
				-10,595	-7,524	-647	-18,766	Administrative expenses
				-2,305	-1,392	-57	-3,754	Research and development expenses
		1,534					1,534	Other operating income

Other operating expenses	-3,514	1,925					-1,589	Other operating expenses
Operating income	**-1,835**	**0**	**0**	**1,012**	**0**	**-1,011**	**-1,834**	**Other operating income**
Financial income	2,346						2,346	Financial income
Financial expenses	-2,489						-2,489	Financial expenses
Income after financial items	**-1,978**	**0**	**0**	**1,012**	**0**	**-1,011**	**-1,977**	**Income after financial items**
Income before tax	**-1,978**	**0**	**0**	**1,012**	**0**	**-1,011**	**-1,977**	**Income before tax**
Income tax	84						84	Tax
Net income	**-1,894**	**0**	**0**	**1,012**	**0**	**-1,011**	**-1,893**	**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-Jun 2020

(KSEK)	According to previous principles	Effect of IFRS 1	Effect of IFRS 16 - Leasing	According to IFRS
Net sales	74,341			74,341
Cost of goods sold	-25,716			-25,717
Gross Profit	**48,625**	**0**	**0**	**48,624**
Selling expenses	-27,884			-27,884
Administrative expenses	-18,766		29	-18,737
Research and development expenses	-3,754			-3,754
Other operating income	1,534			1,534
Other operating expenses	-1,589			-1,588
Operating income	**-1,834**	**0**	**29**	**-1,806**
Financial items				
Financial income	2,346			2,346
Financial expenses	-2,489		-30	-2,519
Net financial items	**-143**	**0**	**-30**	**-173**
Income before tax	**-1,977**	**0**	**-2**	**-1,979**
Tax	84		0	84
Net income	**-1,893**	**0**	**-2**	**-1,895**
Group's other comprehensive income Jan-Mar 2020				
Net income	-1,893	0	-2	-1,895
Other comprehensive income				
Items that can later be reclassified to the income statement:				
Translation differences from foreign operations	0	-513	0	-513
Other comprehensive income, net after tax	**0**	**-513**	**0**	**-513**

Total comprehensive income	**-1,893**	**-513**	**-2**	**-2,408**
Total comprehensive income as a whole attributabe to the parent company's shareholders	**-1,893**	**-513**	**-2**	**-2,408**

Group's balance sheet June 30 2020

(KSEK)	K3 2020-06-30	Effect of IFRS 1	Effect of IFRS 16 - Leasing	IFRS 2020-06-30
Assets				
Intangible assets				
Capitalised development expenditure	124,019			124,019
Concessions, patents, licenses, etc.	3,487			3,487
Tangible assets				
Machinery and other technical facilities	5,099			5,099
Equipment, tools and installations	696			696
Rights of use	0		2,094	2,094
Other long term receivables	43			43
Deferred tax assets	2,365		6	2,371
Total fixed assets	**135,709**		**2,100**	**137,809**
Inventory	8,730			8,730
Tax receivables	6			6
Accounts receivable	11,909			11,909
Prepaid expenses and accrued income	6,554		-347	6,207
Other receivables	3,503			3,503
Cash and cash equivalents	433,537			433,537
Total current receivables	**464,239**		**-347**	**463,892**
Total assets	**599,948**	**0**	**1,753**	**601,701**
Equity and liabilities				
Equity				
Share capital	2,305			2,305
Other contributed capital	613,927			613,927
Translation difference	0	-630	0	-630
Retained earnings including net profit	-41,002	630	-24	-40,396
Equity attributable to the parent company's shareholders	**575,230**	**0**	**-24**	**575,206**
Non-current liabilities				
Non-current liabilities	0		540	540
Total non-current liabilities	**0**	**0**	**540**	**540**
Current liabilites				
Leasing liabilities	0		1,237	1,237
Accounts payable	6,444			6,444
Tax liabilities	853			853
Other liabilities	4,821			4,821
Accrued expenses and prepaid income	12,600			12,600
Total current liabilities	**24,718**	**0**	**1,237**	**25,955**
Total liabilities	**24,718**	**0**	**1,777**	**26,495**
Total equity and liabilities	**599,948**	**0**	**1,753**	**601,701**

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%