

SEDANAMEDICAL

Pioneering volatile anaesthetic delivery

YEAR-END REPORT 2019

SEDANA MEDICAL AB (PUBL)



Q1 Q2 Q3

Q4

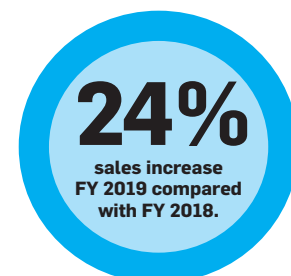
SEDANA MEDICAL, YEAR-END REPORT 2019

Financial Summary October-December

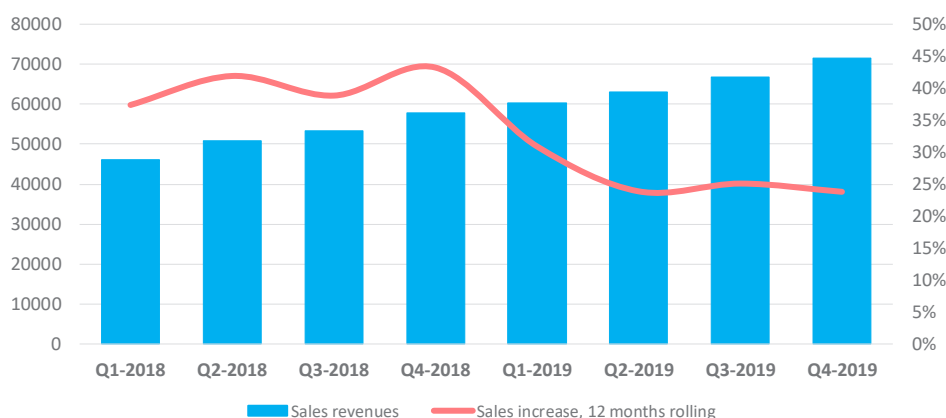
- Net sales during the fourth quarter amounted to 20 056 (15 242) KSEK corresponding to an increase of 32% compared with the same period in 2018.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to -3 979 (-1 474) KSEK. This corresponds to an EBITDA margin of -20% (-10%).
- Earnings before interest and taxes (EBIT) amounted to -5 038 (-2 450) KSEK which corresponds to an EBIT margin of -25% (-16%).
- Cash flow from operations before changes in working capital amounted to -3 234 (-1 250) KSEK.
- Cash flow from investment activities amounted to -17 303 (-7 431) KSEK.
- Cash flow for the period amounted to 342 597 (-15 787) KSEK.
- Liquid funds at the end of the period amounted to 464 560 (159 351) KSEK.

Financial Summary January-December

- Net sales during the full year increased to 71 646 (57 896) KSEK corresponding to an increase of 24% compared with same period in 2018.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to -12 979 (-4 232) KSEK. This corresponds to an EBITDA margin of -18% (-7%).
- Earnings before interest and taxes (EBIT) amounted to -17 167 (-8 238) KSEK, which corresponds to an EBIT margin of -24% (-14%).
- Cash flow from operations before changes in working capital amounted to -11 074 (-2 761) KSEK.
- Cash flow from investment activities amounted to -54 132 (-29 127) KSEK.
- Cash flow for the period amounted to 305 212 (73 869) KSEK.



Sales revenues, 12 months rolling



Significant events during the period

- Sedana Medical completed a private placement of 2 896 000 shares. The subscription price for the shares in the private placement was SEK 129.50 per share. Through the targeted new issue, which was several times oversubscribed, Sedana Medical received SEK 375 million before transaction costs. Investors in the new share issue consisted of a number of Swedish and international institutional investors, including AXA IM, Handelsbanken fonder, Joh. Berenberg Gossler & Co. KG (Berenberg), Swedbank Robur, Third AP fund and Öhman funds.
- Sedana Medical will sponsor two major investigator initiated studies with AnaConDa in France during 2020-2023. One of the studies the company sponsors is the world's largest multicenter study with AnaConDa, SESAR. Sedana Medical will supply the investigators with AnaConDa and accessories. The primary purpose of the study is to demonstrate that inhalation sedation with AnaConDa has lung-protective functions, shortens ventilator time and has higher survival in severely pulmonary intensive care patients.
- Sedana Medical also supports INASED, a large French multicenter study with isoflurane – the substance in the company's drug candidate IsoConDa – delivered with the company's medical device AnaConDa. The aim is mainly to show a reduced incidence of delirium in mechanically ventilated intensive care patients compared to intravenous sedation with propofol.
- Sedana Medical no longer communicates profit targets for the period leading up to the registration of IsoConDa in Europe and clarifies that the sales target of SEK 500 million three years after the European registration only applies to Europe. Sales outside Europe will be added in addition to this target.
- Sedana Medical AB (publ)'s Board Member Michael Ryan decided to resign on November 12, 2019. The Nomination Committee of Sedana Medical will begin work to find a successor.



Significant events after the period

- In January, the last patient was included in the pivotal IsoConDa-study. Thus, all 300 patients have been included in the European study which is expected to show "top-line" results during Q2 2020.
- Sedana Medical's CEO Christer Ahlberg sold 30 000 shares in the company, and entered a 12 month lock-up agreement for his remaining 200 000 shares. He thereby remains as a committed long-term owner.
- Sedana Medical obtained market approval for AnaConDa in Mexico during January. The company's Mexican distributor Goba will begin sales work in the next few months and in parallel Sedana Medical will evaluate the possibility of registering the drug IsoConDa. Goba will also work for a registration of AnaConDa in Colombia.
- Sedana Medical established its own direct sales organization in Benelux.
- Sedana Medical donates AnaConDa and accessories to two hospitals in Wuhan and Zhejiang, China, for anti-epidemic use and evaluation of the effects of inhalation sedation with AnaConDa on severely ill Corona virus affected patients.





“ When it comes to our commercial activities, it was gratifying to see our strong sales figures. **Growth was 32 percent in the quarter.**”

CEO COMMENTS

Based on our future scenario and our priorities, the fourth quarter is our strongest ever. We build quickly according to plan to meet our long-term goals. During the quarter we announced that we are sponsoring two large studies that, if successful, will be able to generate a paradigm shift in sedation in intensive care. In addition, during the quarter we succeeded in securing funding for the work to obtain market approval for our therapy in the US. Finally, after the end of the quarter, we have passed an important milestone by completing recruitment for our pivotal IsoConDa study. Overall, I am really proud that the entire organization delivers and continues to build a solid foundation for our continued journey.

When it comes to our commercial activities, it was gratifying to see our strong sales figures.

Growth was 32 percent in the quarter. Germany remains the natural growth locomotive, but sales have also increased steadily in many other European direct sales markets, such as France and the UK. All in all, we meet the goals we have communicated and deliver well on our ambition to grow 20 percent per year before the registration of IsoConDa in Europe. After the end of the quarter, we announced that we are also opening up direct sales in Benelux by hiring sales personnel.

The co-financing of the two large multicenter studies SESAR and INASED is really gratifying. As a company, having the opportunity to contribute to medical development in this way is really a benefit. The studies are done partly to show that inhalation sedation with AnaConDa has lung protective properties (SESAR) with increased survival as a result and partly to show a reduced incidence of delirium (INASED) which is a

major problem in intensive care. Positive results would significantly strengthen our clinical base and the studies have each separately the potential to dramatically change the perception of inhalation sedation in relation to intravenous sedation.

Through this type of study we gather evidence that, if positive, can be the basis for a paradigm shift in intensive care. These investigator-initiated studies are not only an important support in our continued regulatory and commercial expansion, but also provide a clue as to the great potential of our therapy. Our own studies will also provide greater evidence that is not only a prerequisite for regulatory approval, but which will also be of great commercial use.

The quarter was largely characterized by securing US registration. The money from the targeted new share issue that closed in the quarter - SEK 375 million before costs - will primarily be used to finance the way to a market approval of AnaConDa and IsoConDa in the USA. That we succeeded in raising so much money I see as a sign of strength and I want to take this opportunity to thank you for the trust given to us by both old and new owners.

After meeting with the US Medicines Agency, the FDA, we have a good picture of what we have to deliver to obtain market approval in the US. The combination registration of AnaConDa and IsoConDa includes activities such as two clinical studies involving a total of approximately 500 patients, human factors validation, toxicity studies, safety database, adaptation of the European pediatric study to the FDA's requirements and application for market approval (NDA). Work has intensified during the quarter and is proceeding according to plan. In 2022, we will decide how to commercialize the therapy; alone or together with a partner.

We achieved a major and important milestone shortly after the end of the quarter when we were able to announce that the last patient has been included in our pivotal IsoConDa study. The study with 300 patients has been conducted at more than twenty centers in Germany and Slovenia. To begin with, it is of course extremely gratifying that we keep the schedule in the world's largest study of inhalation sedation in intensive care. But above all, the study is crucial in order to move forward with our European application for market approval.

We are expecting to present "top-line" results in the second quarter 2020. This will enable the submission of an application for European market approval in 16 European countries in a first registration round in the third quarter of 2020. If everything goes according to plan, we expect an approval in the second half of 2021.

In order to carry out a complete application for marketing authorization, an approved pediatric study plan is also needed, which we received already in early 2019. The work to start the pediatric study, Iso-COMFORT, in 2020 began during the quarter. The outcome of the pediatric study is not a requirement for obtaining approval for use in adults, so the schedule for market approval of IsoConDa is not influenced by the Iso-COMFORT study.

To sum up, we are summarizing another strong quarter and I look forward to the continued journey together with you all.

Christer Ahlberg, President and CEO



SEDANA MEDICAL IN BRIEF

SEDANA MEDICAL is a Swedish medical technology group on its way of also becoming a pharma group. Sedana Medical develops, manufactures and sells the medical device AnaConDa and its associated accessories. AnaConDa is based on patented technology involving the vaporisation and reflection of anaesthetic gases. The product is approved for the administration of volatile anesthetics in several countries in the world and is among others, used by intensive care clinics.

A major clinical registration study is currently under way with the aim of having the pharmaceutical candidate IsoConDa® (isoflurane) approved for inhalation sedation within intensive care in Europe, together with AnaConDa. The company has initiated a registration work for AnaConDa and IsoConDa in the United States and is currently reviewing the possibilities for registration of IsoConDa® in Japan.

Sedana Medical operates from several countries in Europe via subsidiaries and branch offices of the parent company, Sedana Medical AB (publ). Germany is comfortably the group's largest market, with more than 85% of total group sales.

The company conducts research and development in Ireland and has its head office in Stockholm, Sweden. In June 2017, the company's share was listed on the Nasdaq First North Growth Market Sweden's stock exchange.

LARGEST SHAREHOLDERS AT THE END OF THE PERIOD

Shareholders in the company at the end of the period:

	Number of shares	Share (%)
Linc AB	2 116 901	9,31%
Handelsbanken funds	1 745 303	7,68%
Anders Walldov direct and indirect (Brohuvudet AB)	1 600 000	7,04%
Sten Gibeck	1 530 744	6,73%
Swedbank Robur funds	1 376 600	6,05%
Ola Magnusson direct and indirect (Magiola AB)	1 340 867	5,90%
Anades Ltd.	1 068 083	4,70%
Berenberg funds	865 291	3,81%
Ron Farrell	631 062	2,78%
Öhman funds	579 884	2,55%
Nordnet pensionsförsäkrings AB	511 523	2,25%
Avanza Pension	493 165	2,17%
Tredje AP-fonden	470 318	2,07%
Eklund Konsulting AB	416 616	1,83%
Alfred Berg funds	349 362	1,54%
Fifteen largest shareholders	15 095 719	66,39%
Others *	7 640 872	33,61%
Total	22 736 591	100,00%

* CEO's ownership is 230 000 shares.



BUSINESS DEVELOPMENT DURING THE PERIOD

Registration Development

REGISTRATION OF THE PHARMACEUTICAL ISOCONDA® (ISOFLURAN) IN EUROPE

The work concerning registration of the drug candidate IsoConDa in Europe is ongoing. Together AnaConDa and IsoConDa will give us access to the full potential of the inhalation sedation market. To succeed, the company has initiated a clinical registration study in Germany and Slovenia where after the end of the year 2019/2020 it was announced that the last patient had been recruited. The results of the clinical trial is estimated to be presented during Q2 2020 and form the basis for the application for marketing authorization.

The company plans to submit the application for market approval of IsoConDa in 16 European countries in a first round during the third quarter 2020 and expects a registration approval of IsoConDa in Europe in the second half of 2021.

REGISTRATION STUDY ISOCONDA

For the clinical registration study, which is necessary for a complete dossier, an additional work is now underway in order to compile and analyse. The study is also necessary to allow us to market inhaled sedation without restrictions in Europe. The interim analysis for our registration-based Phase III study (which aims to get IsoConDa approved for inhaled sedation in intensive care in Europe) showed smaller variations in effect than expected. It was concluded that the study would only need a total of 300 patients instead of initially estimated 550 patients. In January 2020, the last patient was recruited in the study, an important milestone for the company.

In February, Sedana Medical was approved for the Pediatric Investigation Plan (PIP) by the European Medicines Agency's pediatric committee, PDCO. The approval is important as it is one of the prerequisites for a European market approval for IsoConDa. As the submitted registration documentation will now be complete, that is, also include a PIP, an approval will mean that Sedana Medical receives ten years of market exclusivity in Europe for the use of isoflurane in sedation in intensive care. The study will be initiated in 2020 in four European countries. AnaConDa has also received the approval of the European certification body (notifying body) BSI Group for use on children. This approval is also a prerequisite for conducting the study in children and means that AnaConDa can be used in patients with severe impaired lung function.

REGISTRATION WORK OF ANACONDA AND ISOCONDA IN US

The market potential for inhalation sedation in intensive care in the United States is approximately SEK 10 billion annually. Work on the registration of inhalation sedation including both AnaConDa and IsoConDa is ongoing. During 2019, the company was able to announce the result of the pre-IND meeting conducted at the FDA in March. Overall, the FDA was positive in respect to the registration of IsoConDa and AnaConDa as a combination product in the United States. The meeting confirmed the company's estimate of the time and cost of a registration which is expected to occur in 2024.

Since the drug substance isoflurane has been around for decades, the FDA has accepted that Sedana Medical is taking a path to registration, 505 (b) (2), which somewhat simplifies the use of previously collected data. Since registration

requirements have been tightened over the years since isoflurane was first registered. Sedana Medical needs to complete current documentation and add more data to be approved by the FDA; including toxicological animal studies and a human factors validation. Sedana Medical will also need to do two clinical, randomized and double-blinded 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, i.e. 300-550 patients. These patients will also be included in a safety database of 500 isoflurane patients. Work on human factors validation began during the quarter with Harvard in the US. Preparation for the tox studies has also begun during the quarter together with a specialist CRO company.

REGISTRATION OF ANACONDA AND ISOCONDA IN JAPAN

In November 2018, the company received approval of AnaConDa in Japan. The approval means that AnaConDa may be marketed, sold and used for the administration of volatile anesthetics for mechanically ventilated patients in Japan. In order to have access to the full potential of the Japanese market of over 1 million ventilated days a year in the field of intensive care, reimbursement of the price of therapy and registration of the drug candidate IsoConDa must be ensured. We are now investigating the different IsoConDa registration options available to us in Japan and expect to meet with the Japanese Medicines Agency at an official meeting in 2020 to clarify the Japanese requirements for IsoConDa approval.

Building of the market

During the spring, the estimated total market potential for inhalation sedation in intensive care was updated to SEK 20-30 billion annually by the Company. Europe and the US are two important markets. However, patients sedated due to mechanical ventilation in intensive care are equally distributed globally between the United States, Europe and Asia

The work to increase awareness and use of AnaConDa technology and to establish in several countries in Europe is continuing. The plan is to be represented in several European markets with established networks and reference clinics when the company receive approval of IsoConDa in order to quickly be able to penetrate the market.

Due to clarification in the registration process in the US and time planning schedule for Europe as well as the success in Asia, we can now work fast according to the established plan for both Europe, USA and Asia.

We intend to establish a company in the USA to be able to carry out the work on studies, registration and market access on our own. Around 2022 we will decide whether we intend to launch the products ourselves or together with a local partner.

During the year, we started a research foundation, the Sedana Medical Research Foundation, which constitutes a unique opportunity for the scientific community to increase knowledge about sedation of critically ill patients.

Sedana Medical Research Foundation fellows for 2019 were appointed during the year. This year's winners among many applications are three particularly interesting research projects in Italy, France and Switzerland, each of which will in its own way take the therapy forward both scientifically and geographically.

We are continuously working close with the academy to find more interesting projects in order to highlight the benefits of the therapy compared to intravenous treatment. The latest example is that the company sponsors the world's largest multicenter study with AnaConDa in France. The primary purpose of the study is to demonstrate that inhalation sedation with AnaConDa has lung-protective capacities, shortens ventilator time, and higher survival in severe lung-ill intensive care patients compared to IV treatment.

Sedana Medical work closely with key opinion leaders and the academy in order 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 participate in national and international scientific intensive care conferences and congresses where we often arrange well-attended scientific symposia in the area of inhalation sedation.

The total sales increase for the last twelve months was 24%, well in line with our goal of growing 20% per year until the registration of IsoConDa in Europe.

Three years after the registration of IsoConDa in Europe, our ambition is for annual sales to exceed SEK 500 million in Europe and the EBITDA margin to be around 40%.

Financial Summary, January – December 2019

Financial summary - Consolidated (SEK)

	Q4		Year	
	2019	2018	2019	2018
Net sales	20 056 468	15 242 353	71 645 560	57 896 208
Gross Profit	14 627 973	11 463 070	52 413 138	42 896 532
Gross Margin (%)	72,9%	75,2%	73,2%	74,1%
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-3 978 628	-1 474 266	-12 978 931	-4 232 301
Earnings Before Interest and Taxes (EBIT)	-5 037 772	-2 450 267	-17 167 338	-8 238 213
Income after financial items	-5 911 423	-2 398 909	-15 197 309	-6 519 628
Net income	-4 979 569	-3 376 465	-14 611 633	-6 869 062
EBITDA %	-19,8%	-9,7%	-18,1%	-7,3%
EBIT %	-25,1%	-16,1%	-24,0%	-14,2%
Net income % of net sales	-24,8%	-22,2%	-20,4%	-11,9%
Total assets	593 581 174	231 549 760	593 581 174	231 549 760
Equity	569 709 602	217 811 282	569 709 602	217 811 282
Equity ratio	96,0%	94,1%	96,0%	94,1%
Quick ratio	2008,6%	1219,6%	2008,6%	1219,6%
Average number of employees	40	30	39	26
Average number of shares before dilution	22 736 591	19 082 591	20 946 591	18 114 565
Average number of shares after dilution	23 730 740	20 150 740	21 940 740	19 286 714
Number of shares at the end of the period before dilution	22 736 591	19 156 591	22 736 591	19 156 591
Number of shares at the end of the period after dilution	23 730 740	20 150 740	23 730 740	20 150 740
Earnings per share before dilution ¹⁾	-0,22	-0,18	-0,70	-0,38
Earnings per share after dilution ¹⁾	-0,22	-0,18	-0,70	-0,38

¹⁾ Based on average number of shares for the period.

REVENUES

During the fourth quarter, the group's revenues amounted to 19 935 (15 675) KSEK, corresponding to an increase of 4 260 KSEK or 27%. The increase is mainly attributable to an increase in net sales of 4 814 KSEK or 32%. The Group's sales are almost exclusively in EUR and the corresponding sales increase, adjusted for currency fluctuations, was 28%. The revenues for the full year amounted to 73 738 (59 371) KSEK which corresponded to an increase of 14 367 KSEK or 24% of which net sales was 13 749 KSEK or 24%. In addition, revenues for the fourth quarter contain other operating revenues of -121 (433) KSEK, and the corresponding amount for the full year was 2 092 (1 474) KSEK. Other operating revenues consist mainly of positive exchange rate differences. The negative other operating revenues for the fourth quarter are explained by government grants received in Ireland during third quarter, which in the fourth quarter have been reclassified to other external expenses.

COST OF GOODS SOLD

The cost of goods sold during the fourth quarter amounted to 5 428 (3 779) KSEK, which corresponds to an increase of 1 649 KSEK or 44%. The increase in cost of goods sold is mainly due to increased sales but also somewhat higher cost for purchasing and logistics. The product mix compared to the same period last year has also negatively impacted the cost of goods sold. For the full year cost of goods sold amounted to 19 232 (15 000) KSEK corresponding to an increase of 28%. The same explanation for the deviation apply for the full year.

OTHER EXTERNAL EXPENSES

Other external expenses amounted to 6 514 (4 977) KSEK during the fourth quarter, which corresponds to an increase of 1 537 KSEK or 31%. Other external expenses include consulting fees, sales and marketing expenses, expenses for accounting services and auditing, travel expenses, patent costs and certain material costs for research. The increase in the item Other external expenses during the fourth quarter is mainly due to an increase in expenses for sales and market. Generally, there is also an increase in other types of external expenses as the company is growing and preparing for the launch of IsoConDa. For the full year 2019 the corresponding cost item amounted to 27 122 (21 651) KSEK, an increase of 25%.

PERSONNEL EXPENSES

Personnel expenses in the group amounted to 10 932 (8 007) KSEK during the fourth quarter, which corresponds to an increase of 2 925 KSEK or 37%. During the fourth quarter there were 40 employees in the group on average, which was an increase of 10 employees compared with the same period 2018. The main reason for the expense increase is the build-up of the marketing and sales organizations, as well as medical affairs, regulatory and quality functions, prior to the registration and subsequent launch of IsoConDa. For the full year 2019 the corresponding expenses amounted to 38 045 (25 760) KSEK, an increase of 48%. Average number of employees for the full year was 39 (26).



DEPRECIATIONS AND OCH AMORTISATIONS

Depreciations amounted to 1 059 (976) KSEK during the fourth quarter, corresponding to an increase of 83 KSEK or 9%. For the full year 2019 depreciations amounted to 4 188 (4 006) KSEK, an increase of 182 KSEK or 5%. Depreciations relate to property, plant and equipment and amortisation of in-house developed asset AnaConDa-S.

OPERATING INCOME

The group's operating profit for the fourth quarter amounted to -5 038 (-2 450) KSEK, which corresponds to a decreased result of 2 588 KSEK or 106%. The decreased result is mainly due to an increase in operating expenses for building up the functions for sales, marketing, medical affairs, regulatory and quality organization within the group and preparations for the IsoConDa launch. The operating result for the full year amounted to -17 167 (-8 238) KSEK, a decrease of 8 929 KSEK or 108%.

FINANCIAL ITEMS

Net financial items amounted to -874 (51) KSEK during the fourth quarter. The financial net is explained by negative exchange rate differences. The corresponding financial net for the full year amounted to 1 970 (1 719) KSEK.

TAXES

The group reported a tax income of 932 (-978) KSEK for the fourth quarter. The tax income for the quarter is mainly explained by changes in deferred tax. For the full year 2019 the group reports a tax income of 586 (-349) KSEK.

NET INCOME

The group reported a net income after taxes of -4 980 (-3 376) KSEK for the quarter, a decrease of 1 603 KSEK or 47%. Corresponding net income for the full year was -14 612 (-6 869) KSEK. The decline in earnings compared with the previous year is mainly explained by a lower operating profit.

EQUITY AND LIABILITIES

Equity in the group as of 31 December 2019 amounted to 569 710 (217 811) KSEK, which corresponds to an increase of 351 898 KSEK. The increase is mainly explained by the new share issue that was carried out in during the fourth quarter, when the company raised a capital of 375 MSEK.

Current liabilities at the end of the period amounted to 23 872 (13 738) KSEK and consisted mainly of accounts payables of 11 004 (4 430) KSEK.

LIQUID FUNDS AND CASH FLOW

Liquid funds at the end of the period amounted to 464 560 (159 351) KSEK.

Cash flow from operating activities before change in working capital was -3 234 (-1 250) KSEK for the fourth quarter.

Cash flow from operating activities, including the change in working capital, amounted to -5 045 (-8 488) KSEK. The change in working capital compared with the same period last year is mainly due to an increase in operating liabilities.

Cash flow from investments amounted to -17 303 (-7 431) KSEK and consists mainly of intangible fixed assets, the major part of which relates to capitalized development costs for the clinical study SED001 and the registration work of IsoConDa EU.

Cash flow from financing activities was 364 945 (132) KSEK during the quarter. The new share issue accounted for 375 032 KSEK before transaction costs.

Total cash flow for the quarter amounted to 342 597 (-15 787) KSEK. For the full year 2019 total cash flow was 305 212 (73 869) KSEK.

PARENT COMPANY

Sedana Medical AB (publ), corporate identity number 556670-2519, is the parent company in the group. Its operations consist of clinical development, sales and administrative and management functions. The parent company has a branch office in Spain where operations consists of sales of products. The parent company had until 31 August 2019 a branch office in Germany. As of 1 September 2019, the German branch's operations were merged into a wholly owned German subsidiary and is no longer part of the parent company.

The parent company's total revenues amounted to 12 264 (19 110) KSEK for the fourth quarter, of which net sales amounted to 688 (13 987) KSEK. The reason for the decrease in net sales is that the German branch's revenues are no longer included in the parent company from September 2019.

Operating income amounted to -1 911 (-747) KSEK which corresponds to a decrease of 1 163 KSEK.

Net financial items during the quarter amounted to -566 (347) KSEK. Net income for the fourth quarter amounted to -743 (-448) KSEK. Corresponding result for the full year was -13 054 (-3 755) KSEK.

Shareholders' equity in the Parent company, Sedana Medical AB (publ), amounted to 582 245 (228 710) KSEK as of 31 December 2019, corresponding to an increase of 353 535 KSEK. The share capital amounted to 2 274 (1 916) KSEK, an increase of 358 KSEK. 290 KSEK of the increase is due to the completed directed share issue during the fourth quarter when the company raised new capital of a total of 375 MSEK before transaction costs through the issue of 2 896 000 new shares. The remaining part of the increase in share capital, 68 KSEK, is due to the conversion of warrants to shares in the warrant program 2014/2019 during the year. In total, the company now has 22 736 591 issued shares as of December 31, 2019. Furthermore, at the end of 2019, 994 149 warrants are outstanding in two different programs, 2017/2021 and 2019/2022.

Liquid funds at the end of the year amounted to 455 206 (158 805) KSEK, an increase of 296 400 KSEK which is mainly due to the new share issue.

Other information

TRANSACTIONS WITH RELATED PARTIES

Transactions with related parties take place on market terms. During the fourth quarter, the affiliated company Sedana Medical Ltd has purchased goods at a value of 2 308 KSEK and services at a value of 101 KSEK from Lismed Ltd., a company related to the R&D Director and owner Ron Farrell.

Consolidated income statement

(SEK)	Note	Q4		Year	
		2019	2018	2019	2018
Revenues					
Net sales		20 056 468	15 242 353	71 645 560	57 896 208
Other operating income		-121 462	433 084	2 092 091	1 474 482
		19 935 006	15 675 437	73 737 651	59 370 690
Operating cost and expenses					
Cost of goods sold		-5 428 495	-3 779 283	-19 232 422	-14 999 676
External expenses		-6 513 613	-4 976 739	-27 122 384	-21 651 097
Personnel expenses		-10 931 522	-8 006 634	-38 044 873	-25 760 221
Depreciation and amortisation		-1 059 144	-976 001	-4 188 407	-4 005 912
Other operating expenses		-1 040 004	-387 047	-2 316 903	-1 191 997
Operating income		-5 037 772	-2 450 267	-17 167 338	-8 238 213
Income from financial items					
Financial income		1 325 176	437 959	4 201 942	5 450 451
Financial expenses		-2 198 827	-386 601	-2 231 913	-3 731 866
Income after financial items		-5 911 423	-2 398 909	-15 197 309	-6 519 628
Income before taxes					
		-5 911 423	-2 398 909	-15 197 309	-6 519 628
Taxes		931 854	-977 556	585 676	-349 434
Net Income		-4 979 569	-3 376 465	-14 611 633	-6 869 062



Consolidated balance sheet

(SEK)	Note	31 December	
		2019	2018
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development expenses		95 486 865	46 161 490
Concessions, patents, licenses and similar		4 160 440	5 243 054
		99 647 305	51 404 544
Tangible assets			
Building and land		11 133	54 819
Machinery and equipment		4 384 935	4 128 515
Fixtures and tools		477 945	525 092
		4 874 013	4 708 426
Financial assets			
Deferred taxes		2 204 593	1 590 930
Total fixed assets		106 725 911	57 703 900
Current assets			
Inventory			
Finished goods		7 378 333	6 294 672
		7 378 333	6 294 672
Receivables			
Trade receivables		6 467 002	4 984 691
Tax receivables		6 052	349 052
Other current receivables		3 502 816	1 294 296
Prepaid expenses and accrued income		4 941 047	1 572 472
		14 916 917	8 200 511
Cash and cash equivalents			
		464 560 013	159 350 677
Total current assets		486 855 263	173 845 860
TOTAL ASSETS		593 581 174	231 549 760

(SEK)	Note	31 december	
		2019	2018
EQUITY AND LIABILITIES			
Equity			
Share capital	4	2 273 659	1 915 659
Other equity including net income for the period		567 435 943	215 895 623
Equity attributable to shareholders in parent company		569 709 602	217 811 282
Total equity		569 709 602	217 811 282
Current liabilities			
Accounts payables		11 004 088	4 429 892
Tax liabilities		1 253 731	486 769
Other current liabilities		3 347 110	1 864 189
Accrued expenses and prepaid income		8 266 643	6 957 628
		23 871 572	13 738 478
TOTAL EQUITY AND LIABILITIES		593 581 174	231 549 760

Consolidated statement of changes in equity

(SEK)	Note	Q4		Year	
		2019	2018	2019	2018
Opening balance according to balance sheet		209 402 799	221 342 134	217 811 282	116 403 288
Changes in the carrying amounts recognised directly in equity					
Translation differences		341 557	-286 683	-117 181	-496 967
Transactions with the group's owners					
New issue of shares	4	375 032 000	0	376 742 000	113 213 445
Issue expenses	5	-10 087 185	132 295	-10 114 866	-4 439 422
Net income		-4 979 569	-3 376 465	-14 611 633	-6 869 062
Total Equity		569 709 602	217 811 282	569 709 602	217 811 282

Consolidated statement of cash flow

(SEK)	Note	Q4		Year	
		2019	2018	2019	2018
Operations					
Operating income		-5 037 772	-2 450 267	-17 167 338	-8 238 213
<i>Adjustment of non cash flow items</i>		0	0	0	0
Depreciations, amortisations and gains and losses on sale of fixed assets		1 322 956	1 541 303	5 558 046	5 661 282
Currency exchange rates differences		521 334	-447 470	282 053	-385 362
Other non cash flow items		0	207	0	97 018
		-3 193 482	-1 356 227	-11 327 239	-2 865 275
Received interest		3 074	2 708	3 074	2 708
Paid interest		-3 282	-2 128	-6 950	-4 080
Paid taxes		-39 864	105 517	257 272	105 517
Cash flow from operations before change in working capital		-3 233 554	-1 250 130	-11 073 843	-2 761 130
<i>Cash flow from change in working capital</i>					
Increase (-)/Decrease (+) of inventory		-1 570 983	-1 554 280	-1 076 586	-3 078 972
Increase (-)/Decrease (+) of operating receivables		-2 408 159	-2 433 237	-7 036 345	2 320 243
Increase (+)/Decrease (-) of operating liabilities		2 167 816	-3 250 751	10 156 788	-2 259 071
Cash flow from operations		-5 044 881	-8 488 398	-9 029 986	-5 778 930
Investment activities					
Investment in intangible fixed assets		-16 288 991	-7 020 614	-49 839 056	-25 101 463
Investments in tangible fixed assets		-1 013 643	-409 968	-4 292 642	-4 025 073
Investments of financial assets		0	0	0	0
Cash flow from investment activities		-17 302 634	-7 430 583	-54 131 698	-29 126 536
Financing activities					
New issue of shares	4	375 032 000	0	376 742 000	113 213 445
Issue expenses	5	-10 087 185	132 295	-10 114 866	-4 439 422
Received premium for warrant subscription	3	0	0	1 746 138	0
Cash flow from financing activities		364 944 815	132 295	368 373 272	108 774 023
Cash flow for the period		342 597 301	-15 786 685	305 211 589	73 868 557
Liquid funds at the beginning of the period		122 152 404	175 150 854	159 350 677	85 321 647
Effects of exchange rate changes on cash		-189 691	-13 492	-2 252	160 474
Liquid funds at the end of the period		464 560 013	159 350 677	464 560 013	159 350 677

Parent company income statement

(SEK)	Note	Q4		Year	
		2019	2018	2019	2018
Revenues					
Net sales		688 429	13 987 149	44 929 252	55 855 709
Other operating income		11 575 746	5 123 245	22 101 444	10 623 437
				67 030 696	66 479 146
Operating cost and expenses					
Cost of goods sold		0	0	0	0
External expenses		-417 117	-7 978 809	-30 361 552	-34 729 212
Personnel expenses		-7 596 713	-5 029 319	-24 232 239	-16 828 870
Depreciation and amortisation		-5 208 882	-6 135 653	-25 151 033	-18 676 093
Other operating expenses		-128 274	-359 653	-1 278 262	-1 543 114
		-823 979	-354 314	-2 057 813	-1 133 298
Operating income		-1 910 790	-747 354	-16 050 203	-6 431 441
Income from financial items					
Financial income		1 314 227	723 437	2 444 855	6 445 723
Financial income, group internal		264 486	0	964 135	0
Financial expenses		-2 145 173	-376 084	-2 146 234	-3 721 356
Income after financial items		-2 477 250	-400 001	-14 787 447	-3 707 074
Group contribution		1 733 764	0	1 733 764	0
Income before taxes		-743 486	-400 001	-13 053 683	-3 707 074
Taxes		0	-48 083	0	-48 083
Net Income		-743 486	-448 084	-13 053 683	-3 755 157



Parent company balance sheet

(SEK)	Note	31 December	
		2019	2018
ASSETS			
Fixed assets			
<i>Intangible assets</i>			
Capitalized development expenses		88 047 280	42 297 443
<i>Tangible assets</i>			
Machinery and equipment		839 514	2 413 629
Fixtures and tools		221 080	278 803
		1 060 594	2 692 432
<i>Financial fixed assets</i>			
Shares in group companies		395 267	50 009
Long term receivables in group companies		40 417 881	24 019 262
		40 813 148	24 069 271
Total fixed assets		129 921 022	69 059 146
Current assets			
<i>Inventory</i>			
Finished goods		983 571	9 227 249
<i>Receivables</i>			
Trade receivables		359 308	4 380 462
Receivables in group companies		21 815 260	12 648 231
Tax receivables		3 871	349 052
Other current receivables		3 084 769	1 239 426
Prepaid expenses and accrued income		4 419 871	1 350 629
		29 683 079	19 967 800
<i>Cash and cash equivalents</i>			
		455 205 728	158 805 490
Total current assets		485 872 378	188 000 539
TOTAL ASSETS		615 793 400	257 059 685

(SEK)	Note	31 December	
		2019	2018
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	4	2 273 659	1 915 659
Fund for capitalized development expenses		88 047 280	42 297 443
<i>Non restricted equity</i>			
Share premium fund		604 285 817	237 690 860
Retained earnings		-99 308 082	-49 438 748
Profit or loss for the period		-13 053 683	-3 755 157
Total Equity		582 244 991	228 710 057
Current liabilities			
Accounts payables		6 844 984	2 281 214
Liabilities to group companies		19 583 532	20 130 621
Tax liabilities		825 995	0
Other current liabilities		2 001 347	1 340 845
Accrued expenses and prepaid income		4 292 551	4 596 948
		33 548 409	28 349 628
TOTAL EQUITY AND LIABILITIES		615 793 400	257 059 685

Parent company statement of changes in equity

(SEK)	Note	Q4		Year	
		2019	2018	2019	2018
Opening balance according to balance sheet		217 875 716	229 280 691	228 710 057	123 946 488
Changes in the carrying amounts recognised directly in equity					
Translation differences		167 946	-254 846	-38 517	-255 297
Transactions with the group's owners					
New issue of shares	4	375 032 000	0	376 742 000	113 213 445
Issue expenses	5	-10 087 185	132 295	-10 114 866	-4 439 422
Reallocation between items in equity					
Allocations to funds for capitalized development expenses		14 629 190	26 192 827	45 749 836	42 297 443
Retained earnings		-14 629 190	-26 192 827	-45 749 836	-42 297 443
		0	0	0	0
Net income		-743 486	-448 084	-13 053 683	-3 755 157
Total Equity		582 244 991	228 710 057	582 244 991	228 710 057

Parent company statement of cash flow

(SEK)	Note	Q4		Year	
		2019	2018	2019	2018
Operations					
Operating income		-1 910 790	-747 354	-16 050 203	-6 431 441
<i>Adjustment of non cash flow items</i>					
Depreciations, amortisations and gains and losses on sale of fixed assets		130 445	924 955	2 252 543	3 198 484
Currency exchange rates differences		634 617	-272 769	571 479	164 582
Other non cash flow items		0	245	0	97 018
		-1 145 728	-94 922	-13 226 181	-2 971 357
Received interest		264 486	281 342	964 135	995 272
Paid interest		-3 314	-2 127	-4 375	-3 977
Paid taxes		0	0	342 830	0
Cash flow from operations before change in working capital		-884 556	184 293	-11 923 592	-1 980 062
<i>Cash flow from change in working capital</i>					
Increase (-)/Decrease (+) of inventory		-45 843	3 485 171	8 217 872	-3 113 712
Increase (-)/Decrease (+) of operating receivables		-6 353 319	-2 271 328	-10 192 912	-5 641 113
Increase (+)/Decrease (-) of operating liabilities		7 700 771	-6 702 423	5 143 015	8 328 001
Cash flow from operations		417 053	-5 304 286	-8 755 617	-2 406 886
Investment activities					
Investment in intangible fixed assets		-14 629 190	-26 052 843	-45 749 837	-35 754 690
Investments in tangible fixed assets		-1 440 643	-500 631	-1 832 103	-3 007 850
Investments of financial assets		-10 787 280	16 684 066	-15 529 363	7 784 889
Cash flow from investment activities		-26 857 114	-9 869 408	-63 111 304	-30 977 651
Finansieringsverksamheten					
New issue of shares	4	375 032 000	0	376 742 000	113 213 445
Issue expenses	5	-10 087 185	132 295	-10 114 866	-4 439 422
Group contribution		1 733 764	0	1 733 764	0
Cash flow from financing activities		366 678 579	132 295	368 360 898	108 774 023
Cash flow for the period		340 238 519	-15 041 399	296 493 977	75 389 485
Liquid funds at the beginning of the period		114 986 097	173 855 475	158 805 490	83 282 895
Effects of exchange rate changes on cash		-18 888	-8 587	-93 739	133 110
Liquid funds at the end of the period		455 205 728	158 805 490	455 205 728	158 805 490

Sedana Medical share - facts

Listing	Nasdaq First North Growth Market Sweden
Number of shares *	22 736 591
Market capitalization MSEK *	3088
Ticker	SEDANA
ISIN	SE0009947534

* Per 31 December 2019

Number of shares and development of share capital during the year

DATE	TRANSACTION	CHANGE NO. OF SHARES	TOTAL NO. OF SHARES	CHANGE SHARE CAPITAL (SEK)	TOTAL SHARE CAPITAL (SEK)	NOMINAL VALUE (SEK)
2018-12-31	Opening balance 2019		19 156 591		1 915 659	0,1
2019-03-27	Excercise of warrants, program 2014/2019	120 000	19 276 591	12 000	1 927 659	0,1
2019-05-24	Excercise of warrants, program 2014/2019	140 000	19 416 591	14 000	1 941 659	0,1
2019-06-14	Excercise of warrants, program 2014/2019	220 000	19 636 591	22 000	1 963 659	0,1
2019-08-05	Excercise of warrants, program 2014/2019	100 000	19 736 591	10 000	1 973 659	0,1
2019-08-26	Excercise of warrants, program 2014/2019	104 000	19 840 591	10 400	1 984 059	0,1
2019-10-24	New share issue	2 896 000	22 736 591	289 600	2 273 659	0,1
2018-12-31	Closing balance 2019		22 736 591		2 273 659	0,1

Share information

	Q4		Year	
	2019	2018	2019	2018
Net income, SEK	-4 979 569	-3 376 465	-14 611 633	-6 869 062
Cash flow, SEK	342 597 301	-15 786 685	305 211 589	73 868 557
Number of shares at the beginning of the period	22 736 591	19 008 591	19 156 591	17 072 538
Number of shares at the end of the period	22 736 591	19 156 591	22 736 591	19 156 591
Average number of shares	22 736 591	19 082 591	20 946 591	18 114 565
Outstanding warrants at the beginning of the period	994 149	1 142 149	994 149	1 350 149
Outstanding warrants at the end of the period	994 149	994 149	994 149	994 149
Average number of warrants	994 149	1 068 149	994 149	1 172 149
Share capital at the end of the period, SEK	2 273 659	1 915 659	2 273 659	1 915 659
Equity at the end of the period, SEK	569 709 602	217 811 282	569 709 602	217 811 282
<i>Earnings per share, SEK</i>				
- Earnings per share before dilution	-0,22	-0,18	-0,70	-0,38
- Earnings per share after dilution	-0,22	-0,18	-0,70	-0,38
Equity per share, SEK	25,06	11,37	25,06	11,37
Cash flow per share, SEK	15,07	-0,83	14,57	4,08

Notes to the financial information

NOTE 1 ACCOUNTING PRINCIPLES

Sedana Medical AB (publ) and the group applies the Swedish Accounting Standard Board's (BFN's) general guidelines BFNR 2012:1 Annual report and consolidated accounts (K3). Significant accounting and valuation principles are set out in the group annual report 2018.

A departure from the K3 regulation has occurred when it comes to the gross reporting of capitalized development expenses. As of Q3 2017, Sedana Medical reports development costs on a net basis under personnel expenses and other operating expenses.

NOTE 2 DEFINITION OF RATIOS

EBITDA margin:

Operating income before depreciation and amortisation /net sales

EBIT-margin:

Operating income/net sales

Balance sheet total:

Total assets

Net profit in % of net sales:

Net profit/net sales

Average number of employees:

Average number of employees during the period

Equity ratio:

(Total equity + (1-tax rate) of untaxed reserves)/Total assets

Quick ratio:

Current assets excluding inventory/Current liabilities

Equity per share:

Total equity/number of shares before dilution

Cash flow per share:

Total cash flow/number of shares before dilution

NOTE 3 NEW WARRANT PROGRAM

New Warrants Program 2019/2022

The Annual General Meeting on 28 May 2019 in Sedana Medical AB (publ) decided to implement a new warrants program for employees (employees and consultants) in the Sedana Medical Group. The company thus issued 370 000 warrants in the 2019/2022 series, entitled to subscribe for a total of 370 000 shares, all of which were subscribed by the company's subsidiary Sedana Medical Incentive AB for later transfer to employees in the Group. Each warrant entitles to subscribe for a new share in Sedana Medical AB (publ) during the period 1 July to 30 November 2022 at a subscription price of SEK 142,23 per share. Full conditions apply to the warrants, including customary conversion terms, which mean, among other things, that the subscription price as well as the number of shares that the warrants qualify for subscription may in some cases be recalculated, e.g. in the event that the

company makes changes in the share capital and / or the number of shares through, for example, issue of shares or other securities, aggregation or division of shares.

As of the balance sheet date, 89 085 warrants series 2019/2022 have been assigned to employees in the group, with the remaining 307 208 warrants being canceled as of 30 September 2019. All transfers of warrants to employees in the group have been made at market value, calculated according to the Black & Scholes valuation model by an external valuator. The total purchase sum for the warrants transferred on the balance sheet date amounts to 1 746 138 SEK.

A prerequisite for acquiring warrants within the framework of the warrants program 2019/2022 is that employees vis-a-vis Sedana Medical Incentive AB, among others undertakes to resell acquired warrants if the employee's employment or assignment in the group expires before three years have elapsed from the date of acquisition.

Upon full exercise of all series 2019/2022 warrants outstanding as of the balance sheet date, the company's share capital will increase by 8 909 SEK through the issue of 89 085 new shares, corresponding to a dilution of approximately 0,4 percent based on the number of shares in the company on the balance sheet date.

Warrant Program 2017/2021

The annual general meeting of May 19, 2017 resolved to establish a warrant-based incentive program aimed at key company personnel. In this context, a resolution was adopted on the issue of a total of 310 149 2017/2021 series warrants, all of which were subscribed to and allocated to the Company's subsidiary Sedana Medical Incentives AB for onward transfer to the participants in the incentive program. A total of 310 149 warrants were transferred to the participants in the program. All participants are senior executives in the company. The warrants were transferred under market terms. The transfer price was calculated with the aid of the Black & Scholes model by an independent institute. Each warrant entitles the holder to subscribe to one share in the company at a subscription price equivalent to 130 percent of the issue price in the IPO, i.e. 19,50 SEK.

The warrants may be exercised during the period May 15, 2020 through January 31, 2021. The warrants are also subject to customary conditions for conversion in connection with new issues etc.

If all of the warrants transferred to participants in the incentive program are exercised, the company's share capital will increase by around 31 015 SEK through the issue of 310 149 shares, equivalent to a dilution of around 1,4 percent based on the number of shares in the company on the closing date.

Warrant Program 2014/2019

A total of 900 KSEK was paid in the first half of the year regarding the conversion of warrants to shares in warrants program 2014/2019. 600 KSEK concerned the second quarter. This corresponds to a total of 460 000 new shares in Sedana Medical AB (publ) and increased the share capital by 48 KSEK.

During the third quarter, 510 KSEK was paid, corresponding to 204 000 new shares in Sedana Medical AB (publ) as a result of the conversion of warrants to shares in warrants program 2014/2019. Share capital increased by 20 KSEK.

As of the conversion during the third quarter, there are no outstanding warrants to exercise in the 2014/2019 program. All transferred warrants in this program have been exercised and converted into shares in Sedana Medical AB (publ).

NOTE 4 DEVELOPMENT OF SHARE CAPITAL

During the fourth quarter, a private placement was carried out, bringing the company 375 032 000 SEK and 2 896 000 new shares, which increased the share capital by 289 600 SEK. During the year, warrants were also converted to shares in the 2014/2019 program, which provided the company with 1 710 000 SEK and 684 000 new shares. The conversion of warrants to shares increased the share capital by 68 400 SEK.

NOTE 5 TRANSACTION COSTS

Total transaction costs for the new share issue and the warrant program amounted to 10 115 KSEK for the full year 2019.

Other information

AUDITOR'S REVIEW

The group's auditor has not reviewed the accounts in this year-end report.

CERTIFIED ADVISER

Erik Penser Bank, +46 8 463 83 00, certifiedadviser@penser.se, is the certified adviser for Sedana Medical AB (publ).

FOR FURTHER INFORMATION PLEASE CONTACT

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Maria Engström, CFO,

+46 (0)8-124 05 200

DATES FOR UPCOMING INFORMATION

22 April 2020 Annual report 2019

8 May 2020 Interim report Q1 2020

19 May 2020 Annual General Meeting 2020

25 Aug 2020 Interim report Q2 2020

11 Nov 2020 Interim report Q3 2020

ANNUAL REPORT

Sedana Medical's annual report will be available at www.sedanamedical.com from 22nd of april 2020.

DIVIDENDS

The Board proposes no distribution of dividends for the 2019 financial year.

ANNUAL GENERAL MEETING

The Annual General Meeting will be held on 19th of May 2020 at 16:00 in premises in Konferens Spårvagnshallarna, Birger Jarlsgatan 57 A, Stockholm.

Certification from the Board of Directors and the CEO

The Board of Directors certifies that this interim report provides a true and fair view of the group's operations, financial position and results. For a description of Sedana Medical's risks, please refer to the group's prospectus that was prepared for the listing on Nasdaq First North 2017 as well as the annual report for 2018.

Danderyd 5 March 2020

Thomas Eklund
Chairman of the Board

Sten Gibeck
Board member

Bengt Julander
Board member

Ola Magnusson
Board member

Eva Walde
Board member

Christer Ahlberg
President and CEO



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