

**SEDANA**MEDICAL

Pioneering volatile anaesthetic delivery

# YEAR-END REPORT 2018

SEDANA MEDICAL AB (PUBL)



Q1 Q2 Q3

**Q4**

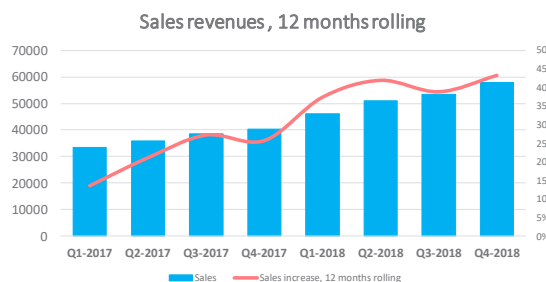
# SEDANA MEDICAL, YEAR-END REPORT 2018

## Financial Summary October-December

- Net sales during the fourth quarter amounted to 15 242 (10 796) KSEK corresponding to an increase of 41% compared with the same period in 2017.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to -1 474 (-838) KSEK. This corresponds to an EBITDA margin of -9,7% (-7,8%).
- Earnings before interest and taxes (EBIT) amounted to -2 450 (-1 912) KSEK, which corresponds to an EBIT margin of -16,1% (-17,7%).
- Cash flow from operations before changes in working capital amounted to -1 250 (-960) KSEK.
- Cash flow from investment activities amounted to -7 431 (-7 965) KSEK.
- Cash flow for the period amounted -15 787 (-4 906) KSEK.
- Liquid funds at the end of the period amounted to 159 351 (85 322) KSEK.

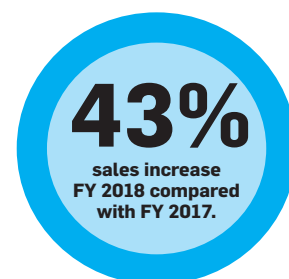
## Significant events during the period

- Sedana Medical AB (publ) received market approval for AnaConDa in Japan.
- Sedana Medical AB (publ) presented a health economic analysis at the European Conference for Health Economics and Outcomes Research 2018 (ISPOR) in Barcelona, showing clinical and economic benefits of inhaled isoflurane sedation via AnaConDa versus conventional intravenous sedation with propofol or midazolam.



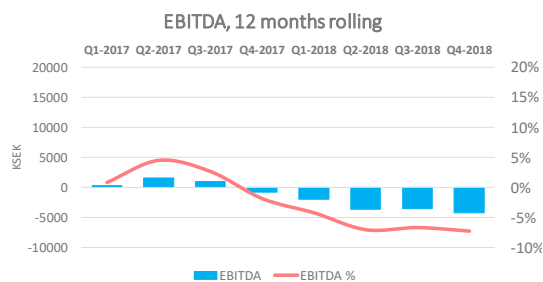
## Financial Summary January-December

- Net sales during the full year increased to 57 896 (40 428) KSEK corresponding to an increase of 43% compared with same period in 2017.
- EBITDA amounted to -4 232 (-736) KSEK and the EBITDA margin was -6,5% (0,3%).
- EBIT amounted to -8 238 (-3 488) KSEK and the EBIT margin was -14,2% (-8,6%).
- Cash flow from operations before change in working capital amounted -2 761 (-4 232) KSEK.
- Cash flow from investment activities amounted to -29 127 (-25 882) KSEK.
- Cash flow for the period amounted to 73 869 (76 953) KSEK.



## Significant events after the period

- Sedana Medical AB (publ) has been approved for its planned pediatric study from the Pediatric Committee of EMA, European Medicines Agency, (PDCO).
- Sedana Medical AB (publ) received the results of the interim analysis for the company's pivotal phase III study which shows smaller variations in efficacy than anticipated and the study will therefore only need to cover a total of 300 patients instead of initially estimated 550 patients.





“ In summary, during the fourth quarter, and throughout 2018, **we have taken a number of important development steps and built internal expertise in the company.**”

## CEO COMMENTS

---

The fourth and final quarter for 2018 is completed. A very eventful quarter and sales-wise successful. In the full year, we increased sales by 43% compared to 2017, which exceeds our ambition to increase on average 20% annually until the registration of IsoConDa in Europe.

In 2017, much of the internal work focused on making the company administratively clear for a listing. In 2018, the focus has been on the registration work of IsoConDa in Europe, AnaConDa and IsoConDa in the US and to prepare for a launch of IsoConDa in Europe. It has manifested itself in a number of ways.

To begin with, I am pleased that the organization started to become clear. In 2018 we have built a medical and clinical department in order to have the competence within the com-

pany to manage the European registration work, but also lead the work with registrations in other countries. The work with shaping the organization will of course continue in the future but began seriously in 2018.

In parallel with our marketing manager starting in the last quarter, we have continued to develop our sales organization in several countries during the year. We have expanded our sales capacity in France and Spain, but above all in Germany, where we have now employed several people who will be able

to realize Sedana Medical's vision. We have also started up sales operations in other countries on a smaller scale. I would like to mention Norway, Denmark and the UK, where we during the year opened our own direct sales.

The fact that AnaConDa was approved in Japan in November is proof that Sedana Medical as a company has a good registration competence for medical technology products, which constitutes a solid basis for the future pharmaceutical registration process. The work of launching AnaConDa in Japan has begun through our distributor.

Thanks to our targeted new share issue in the second quarter of 2018, we have also been able to initiate the work of getting our therapy approved in the US. The work of preparing the FDA meeting in March has been intensively carried out during the quarter.

Our regulatory strategy is basically to get both our medical device product and our drug approved simultaneously. Regarding the registration work for IsoConDa (isoflurane) in Europe, most things go according to plan. It is gratifying that after the end of the quarter, we received approval for our planned pediatric study from the Pediatric Committee of EMA (PDCO), which ensures 10 years of exclusivity in the EU. The only setback that affected us during the year is the pause in the clinical registration study, which is now proceeding according to plan.

An important milestone on the road to becoming a pharmaceutical company is the health economic analysis that was published during the quarter. It shows the clinical and economic benefits of inhalation sedation of isoflurane via AnaConDa compared to conventional intravenous sedation with propofol or midazolam. To become commercially viable and successful, the therapy must also be accepted as a cost-effective

alternative. In this process, the health economic study is a good start and a proof of the cost-effectiveness of therapy. Health economic documentation is needed to ensure that our proposed price level is approved in the markets we intend to launch. The health economic study also shows that we have taken the step seriously into the pharmaceutical field.

In summary, during the fourth quarter, and throughout 2018, we have taken a number of important development steps and built internal expertise in the company. We have run parallel tracks of registration work, clinical studies and health economic documentation. While we are working hard to get the therapy approved, we have built a sales and marketing organization with strategic expertise for global launch.

One of the most important steps in the registration of our therapy is the IsoConDa study, our pivotal phase III study aimed at getting the drug candidate IsoConDa (isoflurane) approved for inhalation sedation in intensive care in Europe. At the beginning of 2019, we received the interim analysis for the study, which pleasingly showed smaller variations in efficacy than anticipated and therefore the study will only need to cover a total of 300 patients instead of initially estimated 550 patients. This is very positive, and we now expect to submit an application for a market approval in the summer of 2020 in 16 European countries. If everything goes well, we can have a European market approval in the second half of 2021. The interim analysis is a milestone and we can now continue to work on the study at a rapid pace.

The fourth quarter and 2018 have been eventful, but in many ways, it is only the start of our journey. I look forward with excitement to the future.

**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 company. 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 device is sold to intensive care clinics in several countries for use in conjunction with inhalation sedation of patients, which has many medical benefits compared to intravenous sedation.

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. In Japan, AnaConDa is approved.

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 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 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	1 901 901	9,93%
Sten Gibeck	1 605 744	8,38%
Magiola Consulting	1 355 867	7,08%
Anders Walldov direct and indirect (Brohuvudet AB)	1 160 000	6,06%
Anades Ltd.	1 068 083	5,58%
State Street Bank & Trust	796 123	4,16%
Ron Farrell	731 062	3,82%
SEB	723 216	3,78%
Handelsbanken Microcap	592 990	3,10%
Eklund Konsulting AB	474 156	2,48%
BNP Paribas	457 085	2,39%
Swedbank Robur Microcap	450 000	2,35%
Avanza pension	448 709	2,34%
Nordnet pensionsförsäkrings AB	404 090	2,11%
Pershing, LLC	368 877	1,93%
<b>Fifteen largest shareholders</b>	<b>12 537 903</b>	<b>65,45%</b>
<i>Other *</i>	<i>6 618 688</i>	<i>34,55%</i>
<b>Total</b>	<b>19 156 591</b>	<b>100,00%</b>

\* CEO's ownership is 230 000 shares.

# BUSINESS DEVELOPMENT DURING THE PERIOD

---

## Registration Development

### **REGISTRATION OF THE PHARMACEUTICAL ISOCONDA® (ISOFLURAN) IN EUROPE**

In order to gain significant market share for inhalation sedation administered using the AnaConDa technology and including the pharmaceuticals the process of registering the drug candidate IsoConDa in Europe is ongoing. To succeed, the company has initiated a clinical registration study in Germany which is currently under way and which will form the basis of the marketing authorization.

A registration process to the pharmaceutical authority usually takes about 10-16 months after submission until approval is obtained depending on the questions the authority may have. The work on compiling a complete drug dossier is ongoing together with our partners in the field.

### **REGISTRATION STUDY ISOCONDA**

The clinical registration study required for a complete dossier is ongoing in Germany. The registration, based on the clinical study, is also necessary to allow us to market inhalation sedation without restrictions in Europe.

Sedana Medical has previously, for the German pharmaceutical agency BfArM, committed to include a minimum of 300 patients in the study in order to confirm the safety of IsoConDa. However, the company has previously estimated that up to 550 patients would be needed to show an equivalent effect to propofol. In March 2019, Sedana Medical received the result of the interim analysis, which did not compare the groups, but is a blinded analysis of the spread in the proportion of time with adequate sedation between the individuals in the study. The interim analysis shows a low standard deviation in the primary variable, proportion of time with adequate sedation, i.e. the effect of IsoConDa and propofol. As the study showed smaller variations in efficacy than initially expected, only 300 patients are needed to achieve the study's primary efficacy target instead of initially estimated 550 patients.

At the current rate of inclusion, Sedana Medical's assessment is that the last patient can be included in the study around the turn of the year 2019/2020, which means that the company expects to submit an application for a market approval in the summer of 2020 in 16 European countries in a first round of registration. If all goes well, Sedana Medical can have a European market approval in the second half of 2021.

The IsoConDa study is the world's largest study of inhalation sedation in intensive care. In addition to the European registration, the study will form a central part of the applications for registration in the US and other markets.

### **REGISTRATION WORK OF ANACONDA AND ISOCONDA IN US**

The market potential for inhalation sedation in intensive care in the United States is greater than SEK 6 billion annually. Work on the registration of inhalation sedation including both AnaConDa and IsoConDa has begun and representatives of the Company will meet the FDA for a first meeting in the end of March 2019 to clarify the requirements that must be met for registration. Following this meeting, when final protocol has been obtained from the FDA, the Company will be more clearly able to set out a schedule for when the therapy will be approved in the United States. The European IsoConDa study and registration dossier will be important parts of a forthcoming application for registration in the United States.

### **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 various IsoConDa registration options available to us in Japan and expect to launch AnaConDa during 2019 using our local distributor.

## Building of the market

The work to increase the use of AnaConDa technology and to establish the therapy in several European countries continues. During the quarter, we had our first patient treated with AnaConDa in Denmark. The plan is to be represented in several European markets with established networks and reference clinics when the approval of IsoConDa comes in order to quickly penetrate the market.

Even in the fourth quarter of 2018, we delivered a better sales growth rate compared with our stated ambition to deliver an annual average sales increase of more than 20% prior to the registration of IsoConDa in Europe. We will also deliver an EBITDA result that should not be significantly negative, in parallel with building a larger sales and marketing organization. Three years after the registration of IsoConDa in Europe, our ambition is for annual sales to exceed 500 MSEK and EBITDA margin to be approximately 40%.

# Financial Summary, January – December 2018

## Financial summary - Consolidated (SEK)

	Q4		Year	
	2018	2017	2018	2017
Net sales	15 242 353	10 795 764	57 896 208	40 427 741
Gross Profit	11 463 070	8 388 567	42 896 532	29 661 735
Gross Margin (%)	75,2%	77,7%	74,1%	73,4%
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-1 474 266	-837 745	-4 232 301	-736 236
Earnings Before Interest and Taxes (EBIT)	-2 450 267	-1 912 386	-8 238 213	-3 487 833
Income after financial items	-2 398 909	-826 905	-6 519 628	-4 601 153
Net income	-3 376 465	-3 465	-6 869 062	-3 875 657
EBITDA %	-9,7%	-7,8%	-7,3%	-1,8%
EBIT %	-16,1%	-17,7%	-14,2%	-8,6%
Net income % of net sales	-22,2%	0,0%	-11,9%	-9,6%
Total assets	231 549 760	131 376 324	231 549 760	131 376 324
Equity	217 811 282	116 403 288	217 811 282	116 403 288
Equity ratio	94,1%	88,6%	94,1%	88,6%
Quick ratio	1219,6%	640,4%	1219,6%	640,4%
Average number of employees	30	20	26	16
Average number of shares before dilution	19 082 591	17 072 538	18 114 565	8 537 354
Average number of shares after dilution	20 150 740	18 422 687	19 286 714	9 212 559
Number of shares at the end of the period before dilution	19 156 591	17 072 538	19 156 591	17 072 538
Number of shares at the end of the period after dilution	20 150 740	18 422 687	20 150 740	18 422 687
Earnings per share before dilution <sup>1)</sup>	-0,18	0,00	-0,38	-0,45
Earnings per share after dilution <sup>1)</sup>	-0,17	0,00	-0,36	-0,42

<sup>1)</sup> Based on average number of shares for the period.

### REVENUES

Total revenues for the Group during the fourth quarter amounted to 15 675 (11 463) KSEK which corresponds to an increase of 4 212 KSEK or 37 percent. The increase is mainly due to an increase in net sales of 4 447 (41%). The Group's sales are exclusively in EUR, and corresponding increase compared to same period previous year cleared of exchange rate effects were 35%. The revenues for the full year amounted to 59 371 which corresponded to an increase of 16 080 KSEK of which net sales was 17 468 KSEK or 43%. Cleared of exchange rate effects the corresponding increase was 35%. Revenues for the fourth quarter also contain other operating revenues of 433 (667) KSEK. Corresponding figure for the full year amounted to 1 474 (1 572) KSEK. Other operating revenues mainly consist of positive exchange rate differences. Revenues for quarter 1-3, 2017 include capitalized development expenses of 1 291 KSEK. The same item is also included in other operating expenses and illustrates the capitalization of development expenses in accordance with a gross reporting principle. As of quarter three 2017, the Group has ceased to apply this gross reporting principle and now reports capitalized development expenses on a net basis under other operating expenses. For further information see the Group's accounting principles.

### COST OF GOODS SOLD

The cost of goods sold during the fourth quarter amounted to 3 779 (2 407) KSEK, which corresponds to an increase of 1 372 KSEK or 57 %. The increase is mainly due to increased sales but also to product mix. For the full year cost of goods sold amounted to 15 000 (10 776) KSEK corresponding to an increase of 39%.

### OTHER EXTERNAL EXPENSES

Other external expenses amounted to 4 977 (4 924) KSEK during the fourth quarter, which corresponds to an increase of 53 KSEK or 1 %. The other external expenses include (among other things) consultancy fees, marketing and sales expenses, accounting expenses, travel expenses and patent costs. For the full year 2018 the other external expenses amounted to 21 651 (16 825) KSEK, an increase of 29% which mainly consist of expenses for sales and marketing.

### PERSONNEL EXPENSES

Personnel expenses in the Group amounted to 8 007 (4 798) KSEK during the fourth quarter which corresponds to an increase of 3 208 KSEK or 67 %. During the fourth quarter there were 30 employees in the Group on average, which was an increase of 10 employees compared with the same period in 2017. The main reason for the expense increase is the buildup of the marketing and sales organizations in the company prior to the launch of IsoConDa. For the full year 2018 the corresponding expenses amounted to 25 760 (16 195) KSEK, an increase of 59%.

### DEPRECIATION AND AMORTISATION

Depreciation and amortisation amounted to 926 (1 075) KSEK which corresponds to a decrease of 99 KSEK or 9 percent. For the full year 2018 the depreciations and amortisations amounted to 4 006 (2 752), an increase of 1 254 KSEK compared with same period 2017. The increase reflects the full-year effect of the amortisation of the additional acquisition of the rights of AnaConDa from Teleflex in June 2017.



#### OPERATING INCOME

The operating income for the Group amounted to -2 450 (-1 912) KSEK, during the fourth quarter, which corresponds to a lower result of 538 KSEK or 28%. The increased negative result is mainly explained by expenses for the buildup of marketing and sales organizations within the group. The operating income for the full year amounted to -8 238 (- 3 488) KSEK.

#### FINANCIAL ITEMS

Net income from financial items amounted to 51 (1 085) KSEK during the fourth quarter. The financial net is explained by positive exchange rate differences. The corresponding financial net for the full year amounted to 1 719 (-1 113) KSEK

#### TAXES

The Group reported a tax expense of 978 KSEK during the fourth quarter. Corresponding period last year a tax revenue of 823 KSEK was reported. The tax expense for the quarter is mainly explained by an adjustment of previously granted tax deductions relating to R&D in the Group's subsidiaries in Ireland. The tax revenue in the previous year related to changes in deferred tax. For the full year 2018, the Group reports a tax expense of 349 KSEK, which is attributable to the adjustment of previously granted tax deductions relating to R&D activities in Ireland. Corresponding amount for full year 2017 consisted of a tax revenue of 725 KSEK.

#### NET INCOME

The Group reported a net income after taxes of -3 376 (-3) KSEK for the fourth quarter 2018. The lower result during the fourth quarter 2018 compared with the same period previous year is mainly due to a lower operating income, a lower financial net and higher taxes. Corresponding net income for the full year was -6 869 (-3 876) KSEK.

#### EQUITY AND LIABILITIES

Equity as of 31 December 2018 amounted to 217 811 (116 403) KSEK, which corresponds to an increase of 101 408 KSEK. The increase is mainly due to the directed share issue that was carried out in the beginning of June 2018.

Current liabilities at the end of the period amounted to 13 738 (14 973) KSEK and consisted mainly of accrued expenses of 6 958 (5 005) KSEK and accounts payable of 4 430 (7 873) KSEK.

#### LIQUID FUNDS AND CASH FLOW

Liquid funds at the end of the period amounted 159 351 (85 322) KSEK.

Cash flow from operations before changes in working capital amounted to -1 250 (-960) KSEK for the fourth quarter. Cash flow from operations after changes in working capital amount-



ted to -8 488 (4 250) KSEK. The negative change compared to last year is mainly due to a decrease of operating liabilities.

Cash flow from investments amounted to -7 431 (-7 965) KSEK. The investments for the fourth quarter consist primarily of intangible fixed assets related mainly to capitalized development expenses, the majority of which concern the clinical study for IsoConDa EU SED001.

Cash flow from financing activities totalled a net of 132 (-1 091) KSEK during the fourth quarter which concern an adjustment of reserved issue expenses from a previous period.

The total cash flow for the Group for quarter four amounted to -15 787 (-4906) KSEK and the corresponding total cash flow for the full year amounted to 73 869 (76 953) KSEK.

The positive cash flow for the full year is due to the new share issue carried out in the beginning of June 2018.

#### **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 branch offices in Germany and Spain, where operations consist of sales and warehousing of products.

The parent company's total revenues amounted to 19 110 (14 299) KSEK for the fourth quarter. The operating income amounted to -747 (59) KSEK, which corresponds to a decrease of 806 KSEK. The net income from financial items amounted to 347 (1 278) KSEK during the fourth quarter. Net income amounted to -448 (2 861) KSEK for the fourth quarter. Corresponding result for the full year was - 3 755 (-4 627) KSEK.

Shareholders' equity in the Parent company, Sedana Medical AB (publ) amounted to 228 710 (123 946) KSEK as of 31 December 2018, corresponding to an increase of 104 764 KSEK. The share capital amounted to 1 916 (1 707) KSEK, an increase with 206 KSEK. 36 KSEK of the increase is due to conversion of warrants into shares in program 2014/2019. Remaining increase is referable to the new share issue in the beginning of June this year.

Liquid funds at the end of the period amounted to 158 805 (83 283) KSEK, an increase of 75 523 KSEK which is due to the directed new share issue carried out in the beginning of June 2018.

## Other information

#### **TRANSACTIONS WITH RELATED PARTIES**

Transactions with related parties are conducted on market terms. During the period, the affiliated company Sedana Medical Ltd has purchased goods at a value of 898 KSEK from Lismed Ltd., a company related to the R&D Director and owner Ron Farrell. The affiliated company Sedana Medical Ltd has further purchased services at a value of 158 KSEK during the fourth quarter from Tecscan Ltd., a company related to the board member Michael Ryan.

## Consolidated income statement

(SEK)	Note	Q4		Year	
		2018	2017	2018	2017
<b>Revenues</b>					
Net sales		15 242 353	10 795 764	57 896 208	40 427 741
Capitalized development expenses		0	0	0	1 290 937
Other operating income		433 084	667 710	1 474 482	1 571 713
		15 675 437	11 463 474	59 370 690	43 290 391
<b>Operating cost and expenses</b>					
Cost of goods sold		-3 779 283	-2 407 197	-14 999 676	-10 766 006
External expenses		-4 976 739	-4 923 981	-21 651 097	-16 825 431
Personnel expenses		-8 006 634	-4 798 347	-25 760 221	-16 194 641
Depreciation and amortisation		-976 001	-1 074 641	-4 005 912	-2 751 597
Other operating expenses		-387 047	-171 694	-1 191 997	-240 549
<b>Operating income</b>		<b>-2 450 267</b>	<b>-1 912 386</b>	<b>-8 238 213</b>	<b>-3 487 833</b>
<b>Income from financial items</b>					
Result from securities and long term receivables		0	0	0	0
Financial income		437 959	1 340 478	5 450 451	2 749 890
Financial expenses		-386 601	-254 997	-3 731 866	-3 863 210
<b>Income after financial items</b>		<b>-2 398 909</b>	<b>-826 905</b>	<b>-6 519 628</b>	<b>-4 601 153</b>
<b>Income before taxes</b>		<b>-2 398 909</b>	<b>-826 905</b>	<b>-6 519 628</b>	<b>-4 601 153</b>
Taxes		-977 556	823 440	-349 434	725 496
<b>Net Income</b>		<b>-3 376 465</b>	<b>-3 465</b>	<b>-6 869 062</b>	<b>-3 875 657</b>



## Consolidated balance sheet

(SEK)	Note	31 december	
		2018	2017
<b>ASSETS</b>			
<b>Fixed assets</b>			
<b>Intangible assets</b>			
Capitalized development expenses		46 161 490	20 721 889
Concessions, patents, licenses and similar		5 243 054	5 743 685
		51 404 544	26 465 574
<b>Tangible assets</b>			
Building and land		54 819	94 587
Machinery and equipment		4 128 515	2 824 845
Fixtures and tools		525 092	1 432 644
		4 708 426	4 352 076
<b>Financial assets</b>			
Deferred taxes		1 590 930	1 459 648
<b>Total fixed assets</b>		<b>57 703 900</b>	<b>32 277 298</b>
<b>Current assets</b>			
<b>Inventory</b>			
Finished goods		6 294 672	3 205 411
		6 294 672	3 205 411
<b>Receivables</b>			
Trade receivables		4 984 691	3 481 210
Tax receivables		349 052	406 410
Other current receivables		1 294 296	2 672 633
Prepaid expenses and accrued income		1 572 472	4 011 715
		8 200 511	10 571 968
<b>Cash and cash equivalents</b>			
		159 350 677	85 321 647
<b>Total current assets</b>		<b>173 845 860</b>	<b>99 099 026</b>
<b>TOTAL ASSETS</b>		<b>231 549 760</b>	<b>131 376 324</b>

(SEK)	Note	31 december	
		2018	2017
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital		1 915 659	1 707 254
Other equity including net income for the period		215 895 623	114 696 034
Equity attributable to shareholders in parent company		217 811 282	116 403 288
<b>Total equity</b>		<b>217 811 282</b>	<b>116 403 288</b>
<b>Current liabilities</b>			
Liabilities to credit institutions		0	3 644
Accounts payables		4 429 892	7 873 127
Tax liabilities		486 769	0
Other current liabilities		1 864 189	1 591 191
Accrued expenses and prepaid income		6 957 628	5 505 074
		13 738 478	14 973 036
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>231 549 760</b>	<b>131 376 324</b>

## Consolidated statement of changes in equity

(SEK)	Note	Q4		Year	
		2018	2017	2018	2017
<b>Opening balance according to balance sheet</b>		221 342 134	116 382 004	116 403 288	1 261 796
<b>Changes in the carrying amounts recognised directly in equity</b>					
Translation differences		-286 683	-364 253	-496 967	-340 911
<b>Transactions with the group's owners</b>					
New issue of shares		0	0	113 213 445	114 999 983
Conversion of loans		0	0	0	16 668 867
Issue expenses	3	132 295	389 002	-4 439 422	-12 310 790
Net income		-3 376 465	-3 465	-6 869 062	-3 875 657
<b>Total Equity</b>		<b>217 811 282</b>	<b>116 403 288</b>	<b>217 811 282</b>	<b>116 403 288</b>

## Consolidated statement of cash flow

(SEK)	Note	Q4		Year	
		2018	2017	2018	2017
<b>Operations</b>					
Operating income		-2 450 267	-1 912 386	-8 238 213	-3 487 833
<i>Adjustment of non cash flow items</i>					
Depreciations, amortisations and gains and losses on sale of fixed assets		1 541 303	1 074 641	5 661 282	2 751 597
Currency exchange rates differences		-447 470	-88 025	-385 362	-875 125
Provisions		0	0	0	-13 872
Other non cash flow items		207	195 417	97 018	195 417
		-1 356 227	-730 353	-2 865 275	-1 429 816
Received interest		2 708	653	2 708	654
Paid interest		-2 128	-25 042	-4 080	-2 591 545
Paid taxes		105 517	-205 282	105 517	-211 321
<b>Cash flow from operations before change in working capital</b>		<b>-1 250 130</b>	<b>-960 024</b>	<b>-2 761 130</b>	<b>-4 232 028</b>
<i>Cash flow from change in working capital</i>					
Increase (-)/Decrease (+) of inventory		-1 554 280	-396 872	-3 078 972	1 331 111
Increase (-)/Decrease (+) of operating receivables		-2 433 237	-883 587	2 320 243	-6 248 592
Increase (+)/Decrease (-) of operating liabilities		-3 250 751	6 490 364	-2 259 071	9 645 159
<b>Cash flow from operations</b>		<b>-8 488 398</b>	<b>4 249 881</b>	<b>-5 778 930</b>	<b>495 650</b>
<b>Investment activities</b>					
Investment in intangible fixed assets		-7 020 614	-6 878 092	-25 101 463	-22 105 618
Investments in tangible fixed assets		-409 968	-1 086 783	-4 025 073	-3 776 401
Investments of financial assets		0	0	0	0
<b>Cash flow from investment activities</b>		<b>-7 430 583</b>	<b>-7 964 876</b>	<b>-29 126 536</b>	<b>-25 882 019</b>
<b>Financing activities</b>					
New issue of shares		0	0	113 213 445	117 430 268
Issue expenses	3	132 295	389 002	-4 439 422	-12 310 790
Amortisation of loans		0	-1 579 959	0	-2 779 779
<b>Cash flow from financing activities</b>		<b>132 295</b>	<b>-1 190 957</b>	<b>108 774 023</b>	<b>102 339 699</b>
<b>Cash flow for the period</b>		<b>-15 786 685</b>	<b>-4 905 952</b>	<b>73 868 557</b>	<b>76 953 329</b>
<b>Liquid funds at the beginning of the period</b>		<b>175 150 854</b>	<b>90 155 963</b>	<b>85 321 647</b>	<b>8 296 432</b>
Effects of exchange rate changes on cash		-13 492	0	160 474	0
Translation difference in liquid funds		0	71 636	0	71 886
<b>Liquid funds at the end of the period</b>		<b>159 350 677</b>	<b>85 321 647</b>	<b>159 350 677</b>	<b>85 321 647</b>

## Parent company income statement

(SEK)	Note	Q4		Year	
		2018	2017	2018	2017
<b>Revenues</b>					
Net sales		13 987 149	14 261 991	55 855 709	43 129 325
Capitalized development expenses		0	0	0	1 290 937
Other operating income		5 123 245	36 694	10 623 437	121 232
		19 110 394	14 298 685	66 479 146	44 541 494
<b>Operating cost and expenses</b>					
Cost of goods sold		-7 978 809	-6 823 111	-34 729 212	-26 460 090
External expenses		-5 029 319	-3 773 855	-16 828 870	-11 595 358
Personnel expenses		-6 135 653	-3 159 949	-18 676 093	-10 523 197
Depreciation and amortisation		-359 653	-320 924	-1 543 114	-1 175 665
Other operating expenses		-354 314	-162 233	-1 133 298	-226 119
<b>Operating income</b>		<b>-747 354</b>	<b>58 613</b>	<b>-6 431 441</b>	<b>-5 438 935</b>
<b>Income from financial items</b>					
Result from securities and long term receivables		0	192 009	0	578 191
Financial income		723 437	1 347 700	6 445 723	2 749 048
Financial expenses		-376 084	-261 962	-3 721 356	-3 863 210
<b>Income after financial items</b>		<b>-400 001</b>	<b>1 336 360</b>	<b>-3 707 074</b>	<b>-5 974 906</b>
Group contribution		0	1 348 246	0	1 348 246
<b>Income before taxes</b>		<b>-400 001</b>	<b>2 684 606</b>	<b>-3 707 074</b>	<b>-4 626 660</b>
Taxes		-48 083	175 925	-48 083	0
<b>Net Income</b>		<b>-448 084</b>	<b>2 860 531</b>	<b>-3 755 157</b>	<b>-4 626 660</b>



## Parent company balance sheet

(SEK)	Note	31 December	
		2018	2017
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Intangible assets</i>			
Capitalized development expenses		42 297 443	6 402 769
<i>Tangible assets</i>			
Building and land		0	0
Machinery and equipment		2 413 629	2 824 845
Fixtures and tools		278 803	64 196
		2 692 432	2 889 041
<i>Financial fixed assets</i>			
Shares in group companies		50 009	50 009
Long term receivables in group companies		24 019 262	30 854 306
		24 069 271	30 904 315
<b>Total fixed assets</b>		<b>69 059 146</b>	<b>40 196 125</b>
<b>Current assets</b>			
<i>Inventory</i>			
Finished goods		9 227 249	6 108 574
<i>Receivables</i>			
Trade receivables		4 380 462	3 160 937
Receivables in group companies		12 648 231	7 990 913
Tax receivables		349 052	332 537
Other current receivables		1 239 426	1 314 862
Prepaid expenses and accrued income		1 350 629	1 496 634
		19 967 800	14 295 883
<i>Cash and cash equivalents</i>		158 805 490	83 282 895
<b>Total current assets</b>		<b>188 000 539</b>	<b>103 687 352</b>
<b>TOTAL ASSETS</b>		<b>257 059 685</b>	<b>143 883 477</b>

(SEK)	Note	31 December	
		2018	2017
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital		1 915 659	1 707 254
Fund for capitalized development expenses		42 297 443	6 402 769
<i>Non restricted equity</i>			
Share premium fund		237 690 860	129 450 806
Retained earnings		-49 438 748	-8 987 681
Profit or loss previous year		0	0
Profit or loss for the period		-3 755 157	-4 626 660
<b>Total Equity</b>		<b>228 710 057</b>	<b>123 946 488</b>
<b>Current liabilities</b>			
Liabilities to credit institutions		0	0
Accounts payables		2 281 214	5 045 386
Liabilities to group companies		20 130 621	10 762 117
Other current liabilities		1 340 845	976 786
Accrued expenses and prepaid income		4 596 948	3 152 700
		28 349 628	19 936 989
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>257 059 685</b>	<b>143 883 477</b>

## Parent company statement of changes in equity

(SEK)	Note	Q4		Year	
		2018	2017	2018	2017
<b>Opening balance according to balance sheet</b>		229 280 691	120 821 933	123 946 488	9 309 943
<b>Changes in the carrying amounts recognised directly in equity</b>					
Translation differences		-254 846	-124 978	-255 297	-94 855
<b>Transactions with the group's owners</b>					
New issue of shares		0	0	113 213 445	114 999 983
Conversion of loans		0	0	0	16 668 867
Issue expenses	3	132 295	389 002	-4 439 422	-12 310 790
<b>Reallocation between items in equity</b>					
Bonus issue		0	0	0	650 000
Share capital		0	0	0	-650 000
Allocations to funds for capitalized development expenses		26 192 827	3 262 584	42 297 443	6 402 769
Retained earnings		-26 192 827	-3 262 584	-42 297 443	-6 402 769
		0	0	0	0
Net income		-448 084	2 860 531	-3 755 157	-4 626 660
<b>Total Equity</b>		<b>228 710 057</b>	<b>123 946 488</b>	<b>228 710 057</b>	<b>123 946 488</b>

## Parent company statement of cash flow

(SEK)	Note	Q4		Year	
		2018	2017	2018	2017
<b>Operations</b>					
Operating income		-747 354	58 613	-6 431 441	-5 438 935
<i>Adjustment of non cash flow items</i>					
Depreciations, amortisations and gains and losses on sale of fixed assets		924 955	320 924	3 198 484	1 175 665
Currency exchange rates differences		-272 769	-1 364	164 582	-12 112
Provisions		0	0	0	0
Other non cash flow items		245	1 492 735	97 018	1 492 735
		<b>-94 922</b>	<b>1 870 908</b>	<b>-2 971 357</b>	<b>-2 782 647</b>
Received interest		281 342	192 662	995 272	578 845
Paid interest		-2 127	-25 042	-3 977	-2 591 545
Paid taxes		0	-328 983	0	-332 537
<b>Cash flow from operations before change in working capital</b>		<b>184 293</b>	<b>1 709 545</b>	<b>-1 980 062</b>	<b>-5 127 884</b>
<i>Cash flow from change in working capital</i>					
Increase (-)/Decrease (+) of inventory		3 485 171	364 300	-3 113 712	1 433 719
Increase (-)/Decrease (+) of operating receivables		-2 271 328	-6 919 045	-5 641 113	-8 481 835
Increase (+)/Decrease (-) of operating liabilities		-6 702 423	4 625 480	8 328 001	7 182 075
<b>Cash flow from operations</b>		<b>-5 304 286</b>	<b>-219 719</b>	<b>-2 406 886</b>	<b>-4 993 925</b>
<b>Investment activities</b>					
Investment in intangible fixed assets		-26 052 843	-3 262 584	-35 754 690	-4 934 053
Investments in tangible fixed assets		-500 631	-954 170	-3 007 850	-2 688 881
Investments of financial assets		16 684 066	-84 797	7 784 889	-14 204 812
<b>Cash flow from investment activities</b>		<b>-9 869 408</b>	<b>-4 301 551</b>	<b>-30 977 651</b>	<b>-21 827 746</b>
<b>Finansieringsverksamheten</b>					
New issue of shares		0	0	113 213 445	117 430 268
Issue expenses	3	132 295	389 002	-4 439 422	-12 310 790
Amortisation of loans		0	-1 579 959	0	-2 779 779
<b>Cash flow from financing activities</b>		<b>132 295</b>	<b>-1 190 957</b>	<b>108 774 023</b>	<b>102 339 699</b>
<b>Cash flow for the period</b>		<b>-15 041 399</b>	<b>-5 712 228</b>	<b>75 389 485</b>	<b>75 518 027</b>
<b>Liquid funds at the beginning of the period</b>		<b>173 855 475</b>	<b>88 936 812</b>	<b>83 282 895</b>	<b>7 711 119</b>
Effects of exchange rate changes on cash		-8 587	0	133 110	0
Translation difference in liquid funds		0	58 311	0	53 749
<b>Liquid funds at the end of the period</b>		<b>158 805 490</b>	<b>83 282 895</b>	<b>158 805 490</b>	<b>83 282 895</b>



## Share information

	Q4		Year	
	2018	2017	2018	2017
Net income, SEK	-3 376 465	-3 465	-6 869 062	-3 875 657
Cash flow, SEK	-15 786 685	-4 905 952	73 868 557	76 953 329
Number of shares at the beginning of the period	19 008 591	17 072 538	17 072 538	2 170
Number of shares at the end of the period	19 156 591	17 072 538	19 156 591	17 072 538
Average number of shares	19 082 591	17 072 538	18 114 565	8 537 354
Outstanding warrants at the beginning of the period	1 142 149	1 350 149	1 350 149	260
Outstanding warrants at the end of the period	994 149	1 350 149	994 149	1 350 149
Genomsnittligt antal teckningsoptioner	1 068 149	1 350 149	1 172 149	675 205
Share capital at the end of the period, SEK	1 915 659	1 707 254	1 915 659	1 707 254
Equity at the end of the period, SEK	217 811 282	116 403 288	217 811 282	116 403 288
<i>Earnings per share, SEK</i>				
- Earnings per share before dilution	-0,18	0,00	-0,38	-0,45
- Earnings per share after dilution	-0,17	0,00	-0,36	-0,42
Equity per share, SEK	11,37	6,82	11,37	6,82
Cash flow per share, SEK	-0,83	-0,29	4,08	9,01

## Sedana Medical share – facts

Listing	Nasdaq First North Stockholm
Number of shares *	19 156 591
Market capitalization MSEK *	1490
Ticker	SEDANA
ISIN	SE0009947534

\* Per 31 December 2018

## 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 BFNAR 2012:1 Annual report and consolidated accounts (K3). Significant accounting and valuation principles are set out in the Group annual report 2017.

A departure from the K3 regulation has occurred in the third quarter of 2017 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

#### Net profit in % of net sales:

Net profit/net sales

#### Balance sheet total:

Total assets

#### Equity ratio:

(Total equity + 78% of untaxed reserves)/Total assets

#### Quick ratio:

Current assets excluding inventory/Current liabilities

#### Quick ratio:

Current assets excluding inventory/Current liabilities

### NOTE 3 TRANSACTIONS EXPENSES

Transaction costs for the new share issue and conversion of options 2018 totaled -4 592 KSEK for the full year 2018. For the fourth quarter, an outcome of 132 KSEK is reported, which refers to the dissolution of reserves relating to late invoicing of transaction expenses for the new share issue.

## Other information

### AUDITOR'S REVIEW

The Group's auditor has 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

Christer Ahlberg, President and CEO

+46 (0)8-124 05 200

Maria Engström, CFO

+46 (0)8-124 05 200

### DATES FOR UPCOMING INFORMATION

25 Apr 2019 Annual report 2018

08 May 2019 Interim report Q1 2019

28 May 2019 Annual General Meeting 2019

22 Aug 2019 Interim report Q2 2019

13 Nov 2019 Interim report Q3 2019

### ANNUAL REPORT

Sedana Medical's annual report will be available at [www.sedanamedical.com](http://www.sedanamedical.com) from 25th of April 2019.

### DIVIDENDS

The Board proposes no distribution of dividends for the 2018 financial year.

### ANNUAL GENERAL MEETING

The Annual General Meeting will be held on 28th of May 2018 from 3-6 p.m., at the premises of Erik Penser Bank, Apelbergsgatan 27, Stockholm, Sverige.

## 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 as well as the annual report for 2017.

Danderyd 12 March 2019

**Thomas Eklund**  
Chairman of the Board

**Sten Gibeck**  
Board member

**Bengt Julander**  
Board member

**Ola Magnusson**  
Board member

**Michael Ryan**  
Board member

**Eva Walde**  
Board member

**Christer Ahlberg**  
President and CEO

Sedana Medical AB (publ), 556670–2519, Vendevägen 87,  
SE-182 32 Danderyd, Sverige.

Telefon +46 (0)8-124 05 200, [info@sedanamedical.com](mailto:info@sedanamedical.com),  
[www.sedanamedical.com](http://www.sedanamedical.com)

**SEDANA**MEDICAL  
Pioneering volatile anaesthetic delivery