# **SEDANA**MEDICAL

the AnaConDa technology people

# INTERIM REPORT Q3

JANUARY - SEPTEMBER 2018 SEDANA MEDICAL AB (PUBL)



# SEDANA MEDICAL, INTERIM REPORT Q3, JANUARY – SEPTEMBER 2018

# Financial Summary July-September

- Net sales during the third quarter amounted to 12 682 (10 191) KSEK corresponding to an increase of 24% compared with the same period in 2017.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to -964 (-980) KSEK. This corresponds to an EBITDA margin of -7,6% (-9,6%).
- Earnings before interest and taxes (EBIT) amounted to -2 051 (-2 254) KSEK, which corresponds to an EBIT margin of -16,2% (-22,1%)
- Cash flow from operations before changes in working capital amounted to -301 (-1 862) KSEK.
- Cash flow from investment activities amounted to -8 502 (-2 305) KSEK.
- Cash flow for the period amounted -6 390 (-10 483) KSEK.
- Liquid funds at the end of the period amounted to 175 151 (90 156) KSEK.

### Significant events during the period

- Sedana Medical AB (publ) announced on the 26th of July that the company has received approval from the central ethical committee for its pivotal phase 3-study in Germany, IsoConDa, to continue to use the original study protocol after certain clarifications. This means that the study will resume in full after it was restricted in April this year.
- Sedana Medical AB (publ) first direct sales of AnaConDa in the LLK



# Financial Summary January-September

 Net sales during the first nine months increased to 42 654 (29 632) KSEK corresponding to an increase of 44% compared with same period in 2017.

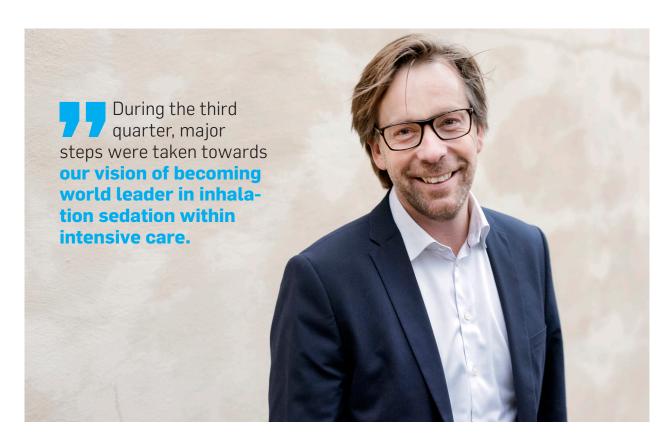


- EBITDA amounted to -2 758 (102) KSEK and the EBITDA margin was -6,5% (0,3%).
- EBIT amounted to -5 788 (-1 575) KSEK and the EBIT margin was -13,6% (-5,3%).
- Cash flow from operations before change in working capital amounted -1 511 (-3 045) KSEK.
- Cash flow from investment activities amounted to till -21 696 (-16 604) KSEK.
- Cash flow for the period amounted to 89 655 (81 926) KSEK.

#### Significant events after the period

- Sedana Medical AB (publ) (Sedana Medical or the company) announced that the company has 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.





# **CEO COMMENTS**

During the third quarter, major steps were taken towards our vision of becoming world leader in inhalation sedation within intensive care.

In order to fully sell inhalation sedation, you must have a medical device that administers the volatile drugs to the patient and have the medicine approved for intensive care. In Europe, our medical device AnaConDa is approved for the administration of volatile drugs. However, our drug candidate IsoConDa has not yet been approved for intensive care. In the United States neither AnaConDa nor IsoConDa are approved.

The work to increase the use of AnaConDa technology and to establish ourselves in several European countries continues. During the quarter, we set up our own sales organization in the UK and we have now delivered AnaConDa to intensive care clinics in Liverpool and Hull. 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. With the establishment of our own direct sales channel in the UK, we are now well on our way towards our plan, which is very pleasing.

Sales growth for the quarter was 24% compared with the same period last year despite the fact that the drug has not yet been approved. This underlines the medical value of inha-

lation sedation. The rate of the increase is also in line with our stated ambition to have an average annual sales increase of more than 20% until the registration of IsoConDa takes place.

That the increase is lower than in the first half of the year is mainly explained by the seasonal pattern. During the winter, more patients are usually placed on intensive care units for sedation. Just this year, during the winter season and early spring, the trend was clearer than usual with an extreme influenza epidemic in most parts of Europe, while the summer was both longer and warmer than usual in many European countries.

EBITDA in Q3 was MSEK -964, which is in line with our plans as operational costs increase as we develop the organization and increase our market presence.

Our ongoing clinical registration study in Germany, to receive the IsoConDa drug approved for inhalation sedation in intensive care in Europe, continues. At the beginning of April, the study was limited after the Central Ethics Committee requested some clarifications, but after the summer the study could resume. It is a relief that the break was so limited, and we are now recruiting all types of mechanically ventilated patients. For each day, we will take another step closer to a registration of the drug IsoConDa, which also significantly increases the potential of our AnaConDa product.

We expect the interim analysis for the study to end before the turn of the year and that we can communicate the results of the analysis in the first quarter 2019. The purpose of the interim analysis is to determine how many patients are ultimately needed to show the result requested in order to apply for marketing approval of IsoConDa in Europe. The results of the interim analysis will also give us an indication of when we will be able to launch IsoConDa in Europe.

The registration work for both pharmaceutical and medical device has begun in the United States and we have now been notified that our first meeting with the US Food and Drug Administration (FDA) will take place in the end of March 2019. The meeting will clarify the requirements we must meet for to have both products approved in the United States. Only after the meeting, when final protocol has been obtained from the FDA, we will be able to communicate a schedule of when the therapy can be approved in the United States.

We thought we would meet the FDA around the turn of the year 2018/19. The fact that the meeting is expected to happen later does not affect the estimated time to market, but instead means that we will have more material for the FDA at the meeting. Our European interim analysis will be an important piece in the puzzle.

It is gratifying that after the end of the quarter we 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. We are now working to provide our Japanese distributor with the necessary tools, including price reimbursement, to launch AnaConDa. As in Europe, IsoConDa is still not approved and it is also necessary to initiate a registration process for the drug in order to reach the full potential of the market. We estimate that patients in Japan require over 1 million mechanically ventilated days per annum.

After the end of the quarter, we presented a health economics study at the European Congress ISPOR in Barcelona. The study showed significant clinical and economic benefits of long-term sedation with AnaConDa and isoflurane versus intravenous sedation with propofol or midazolam. The study involved surgical intensive care patients who require prolonged sedation (> 96 hours) and mechanical ventilation.

In summary, I am very pleased with our work during the quarter. We have good development in all our three focus areas; the registration work of the IsoConDa drug in Europe, the development of US registration with both AnaConDa and IsoConDa, and market build up and preparation for effective and successful launch in Europe at the time of the registration of the therapy.

Christer Ahlberg, VD och koncernchef





# 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 AnaCon-Da 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.

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. Direct sales via in-house personnel also take place in France, Spain, Great Britain and the Nordic region.

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 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	10,01%
Sten Gibeck	1 585 744	8,34%
Magiola Consulting	1 207 867	6,35%
Michael Ryan	1 068 083	5,62%
Brohuvudet AB	852 635	4,49%
State Street Bank & Trust	774 177	4,07%
Ron Farrell	898 897	4,73%
SEB	710 971	3,74%
Alto Invest SA	524 436	2,76%
Avanza pension	496 784	2,61%
Swedbank Robur Microcap	475 000	2,50%
Eklund Konsulting AB	474 156	2,49%
BNP Paribas	463 400	2,44%
JP Morgan Europe Ltd	460 431	2,42%
Nordnet Pensionsförsäkring AB	371 991	1,96%
Fifteen largest shareholders	12 266 473	64,53%
Other *	6 742 118	35,47%
Total	19 008 591	100,00%

<sup>\*</sup> 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 study is also necessary to allow us to market inhalation sedation without restrictions in Europe. The leading ethics committee, in Saarbrücken, Germany, for the registration study IsoConDa, finally approved a modification of the study protocol, which Sedana Medical applied for after the summer. The application was a result of the issues raised by the Ethics Committee in connection with an inspection earlier this year, which was communicated by the Company via a press release on April 10. The changes mainly consist of clarifications in the protocol on the patients and the consent procedure. The new protocol has also been approved by the inspectors previously critical, as well as by the German drug authority BfArM. The company has then resumed the study after including the study centers on the updated study protocol during the third quarter.

We expect the interim analysis for the study to end before the turn of the year and that we can communicate the results in first quarter 2019. The purpose of the interim analysis is to determine how many patients are ultimately needed to show the result requested to apply for a marketing approval of IsoConDa in Europe. The results of the interim analysis will also give us an indication of when we will be able to launch IsoConDa in Europe.

#### 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 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. Probably another study will be required to register the therapy in the United States. The company is working to achieve a registration in the United States in 2022/23.

#### **REGISTRATION OF ANACONDA AND ISOCONDA IN JAPAN**

After the end of the quarter, the company has 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 by 2019 using our local distributor.

#### Building of the market

The work to increase the use of AnaConDa technology and to establish ourselves in several European countries continues. During the quarter, we set up our own sales organization in the UK and we have now delivered AnaConDa to intensive care clinics in Liverpool and Hull. 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 third quarter of 2018, we deliver a better sales growth rate compared with our stated ambition to deliver an annual average sales increase of more than 20% until 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%.

The work to increase the use of AnaConDa technology and to establish ourselves in several European countries continues.

### Financial Summary, January - September 2018

Financial summary - Consolidated	Q	3	Q1-	Year	
(SEK)	2 018	2017	2018	2017	2017
Net sales	12 682 176	10 191 491	42 653 855	29 631 977	40 427 741
Gross Profit	9 339 506	7 323 173	31 433 462	21 273 168	29 661 735
Gross Margin (%)	73,6%	71,9%	73,7%	71,8%	73,4%
Earnings before interest, taxes, depreciation and amortization					
(EBITDA)	-963 553	-979 555	-2 758 035	101 509	-736 236
Earnings Before Interest and Taxes (EBIT)	-2 050 769	-2 253 623	-5 787 946	-1 575 447	-3 487 833
Income after financial items	-2 501 973	-3 086 709	-4 120 719	-3 774 248	-4 601 153
Net income	-2 558 813	-2 818 972	-3 492 597	-3 872 192	-3 875 657
EBITDA %	-7,6%	-9,6%	-6,5%	0,3%	-1,8%
EBIT %	-16,2%	-22,1%	-13,6%	-5,3%	-8,6%
Net income % of net sales	-20,2%	-27,7%	-8,2%	-13,1%	-9,6%
Total assets	237 921 735	126 833 637	237 921 735	126 833 637	131 376 324
Equity	221 342 134	116 382 004	221 342 134	116 382 004	116 403 288
Equity ratio	93,0%	91,8%	93,0%	91,8%	88,6%
Quick ratio	1095,1%	1123,1%	1095,1%	1123,1%	640,4%
Average number of employees	26	18	25	16	16
Average number of shares before dilution	19 008 591	16 687 923	18 040 565	8 537 354	8 537 354
Average number of shares after dilution	20 150 740	18 038 072	19 286 714	9 212 559	9 212 559
Number of shares at the end of the period before dilution	19 008 591	17 072 538	19 008 591	17 072 538	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	18 422 687
Earnings per share before dilution 1)	-0,13	-0,17	-0,19	-0,45	-0,45
Earnings per share after dilution 1)	-0,13	-0,16	-0,18	-0,42	-0,42

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

#### **REVENUES**

Total revenues for the Group during the third quarter amounted to 13 007 (10 225) KSEK which corresponds to an increase of 2 782 KSEK or 27 percent. The increase is mainly due to an increase in net sales of 2 491 (24%). The Group's sales are exclusively in EUR, and corresponding increase compared to same period previous year cleared of exchange rate effects were 14%. The revenues for guarter 1-3 amounted to 43 695 which corresponded to an increase of 11 868 KSEK of which net sales was 13 022 KSEK or 44%. Revenues for the third quarter also contain other operating revenues of 325 (34) KSEK. Corresponding figure for quarter 1–3 amounted to 1 041 (904) KSEK. Other operating revenues mainly consist of positive exchange rate differences. Revenues for guarter 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 third quarter amounted to 3 343 (2 868) KSEK, which corresponds to an increase of 474 KSEK or 17 %. The increase is mainly due to increased sales.

#### OTHER EXTERNAL EXPENSES

Other external expenses amounted to 5 424 (4 180) KSEK, which corresponds to an increase of 1 244 KSEK or 30 %. The other external expenses include (among other things) consul-

tancy fees, marketing and sales expenses, accounting expenses, travel expenses and patent costs. The increase is primarily attributable to an increase in marketing and sales expenses which is in line with the strategy of the Group.

#### PERSONNEL EXPENSES

Personnel expenses in the Group amounted to 4 887 (4 121) KSEK during the third quarter which corresponds to an increase of 766 KSEK or 19 %. During the third quarter there were 26 employees in the Group on average, which was an increase of 8 employees compared with the same period in 2017. The increase in personnel expenses in quarter 3 compared to the previous quarters in 2018 was lower. The main explanation is that a higher proportion of expenses related to development programs have been capitalized.

#### DEPRECIATION AND AMORTISATION

Depreciation and amortisation amounted to 1 087 (1 274) KSEK which corresponds to a decrease of 187 KSEK or 15 percent. The decrease is due to the reclassification between current assets and fixed assets that was carried out in Q3 2017 in relation to the gas monitors owned by the Group. The entire year's effect of the reclassification of the gas monitors has been reported in Q3 2017. For further information see the Group's accounting principles.

#### OPERATING INCOME

The operating income for the Group amounted -2 051 (-2 254) KSEK, during the third quarter, which corresponds to an increase of 203 KSEK or 9%. The increase is explained by increased sales.

#### **FINANCIAL ITEMS**

Net income from financial items amounted to -451 (-833) KSEK during the third quarter. The financial net is explained by negative exchange rate differences.

#### **TAXES**

The Group reported a tax expense of 57 KSEK during the third quarter. Corresponding period last year a tax revenue of 268 KSEK was reported. The tax expense is mainly due to an adjustment of earlier filed corporate tax allowances in the Group's affiliate in Ireland. The tax revenue previous year are primarily due to changes in deferred tax.

#### **NET INCOME**

The Group reported a net income after taxes of -2 559 (-2 819) KSEK for the third quarter. The increase during the third quarter 2018 compared with the same period previous year is mainly due to a higher operating income and lower financial net.

#### **EQUITY AND LIABILITIES**

Equity as of 30 September 2018 amounted to 221 342 (116 382) KSEK, which corresponds to an increase of 104 960 KSEK. The increase is mainly due to the directed share issue that was carried out in the beginning of June 2018.

Long-term liabilities at the end of the period amounted to 0 (1 580) KSEK.

Current liabilities at the end of the period amounted to  $16\,579$  (8 872) KSEK and consisted mainly of accrued expenses of  $10\,004$  (1 997) KSEK and accounts payable of 4 667 (4 283) KSEK.

#### **LIQUID FUNDS AND CASH FLOW**

Liquid funds at the end of the period amounted 175 151 (90 156) KSEK.

Cash flow from operations before changes in working capital amounted to -301 (-1 862) KSEK for the third quarter. Cash flow from operations after changes in working capital amounted to 1 894 (-16 047) KSEK. The positive change compared to last year is mainly due to a decrease of operating receivables and an increase of operating liabilities. Cash flow from investments amounted to -8 502 (-2 305) KSEK. The investments for the third quarter consist primarily of intangible fixed assets related mainly to capitalized development expenses, the majority of which concern the clinical study for IsoConDa. Cash flow from financing activities totalled a net

of 218 (7 869) KSEK. 370 KSEK of this concern paid capital attributable to an ongoing conversion of warrants into shares in program 2014/2019. -152 KSEK of this concern expenses for the share issue in June 2018, see further notes 4 and 5 in the section "Notes to the financial information". The total cash flow for the Group was negative of -6 390 (-10 483) 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 branch offices in Germany and Spain, where operations consist of sales and warehousing of products.

The parent company's total revenues amounted to 14 818 (10 063) KSEK for the third quarter. The operating income amounted to -831 (-2 544) KSEK, which corresponds to an increase of 1 713 KSEK. The net income from financial items amounted to -170 (-657) KSEK during the third quarter. The increase is due to positive exchange rate differences. Net income amounted to -1 001 (-3 246) KSEK for the third quarter.

Shareholders' equity in the Parent company, Sedana Medical AB (publ), amounted to 229 280 (120 822) KSEK as of 30 September 2018, corresponding to an increase of 108 459 KSEK. The share capital increased during quarter 1–3, 2018 by 208 KSEK of which 36 KSEK is due to conversion of warrants into shares in program 2014/2019. Out of these, 14 KSEK concern paid but not registered share capital at the end of the third quarter. 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 173 855 (88 937) KSEK, an increase of 84 919 KSEK which is due to the directed new share issue carried out in the beginning of June 2018.

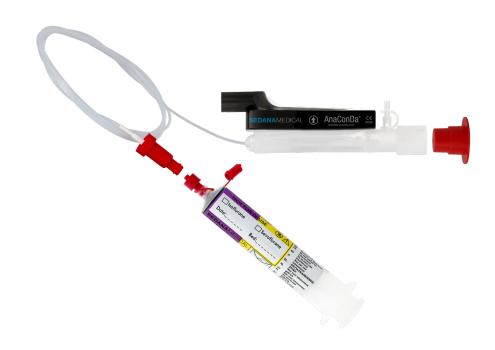
#### Other information

#### 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 921 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 182 KSEK during the third quarter from Tecscan Ltd., a company related to the board member Michael Ryan.

### Consolidated income statement

	Q	Q3		Q1-Q3		
(SEK)	2 018	2017	2018	2017	2017	
Revenues						
Net sales	12 682 176	10 191 491	42 653 855	29 631 977	40 427 741	
Capitalized development expenses	0	0	0	1 290 937	1 290 937	
Other operating income	325 220	33 930	1 041 398	904 003	1 571 713	
	13 007 396	10 225 421	43 695 253	31 826 917	43 290 391	
Operating cost and expenses						
Cost of goods sold	-3 342 670	-2 868 318	-11 220 393	-8 358 809	-10 766 006	
External expenses	-5 423 805	-4 180 173	-16 674 358	-11 901 450	-16 825 431	
Personnel expenses	-4 887 130	-4 121 473	-17 753 587	-11 396 294	-16 194 641	
Depreciation and amortisation	-1 087 216	-1 274 068	-3 029 911	-1 676 956	-2 751 597	
Other operating expenses	-317 344	-35 012	-804 950	-68 855	-240 549	
Operating income	-2 050 769	-2 253 623	-5 787 946	-1 575 447	-3 487 833	
Income from financial items						
Result from securities and long term receivables	0	629	0	0	0	
Financial income	1 584 102	332 051	5 012 492	1 409 412	2 749 890	
Financial expenses	-2 035 306	-1 165 766	-3 345 265	-3 608 213	-3 863 210	
Income after financial items	-2 501 973	-3 086 709	-4 120 719	-3 774 248	-4 601 153	
Income before taxes	-2 501 973	-3 086 709	-4 120 719	-3 774 248	-4 601 153	
Taxes	-56 840	267 737	628 122	-97 944	725 496	
Net Income	-2 558 813	-2 818 972	-3 492 597	-3 872 192	-3 875 657	



## Consolidated balance sheet

	30 september				
(SEK)	lote 2 018	2017	2017		
ASSETS					
Fixed assets					
Intangible assets					
Capitalized development expenses	39 276 774	13 990 639	20 721 889		
Concessions, patents, licenses and similar	4 983 722	5 894 479	5 743 685		
	44 260 496	19 885 118	26 465 574		
Tangible assets					
Building and land	91 916	0	94 587		
Machinery and equipment	4 950 852	2 183 764	2 824 845		
Fixtures and tools	375 403	1 511 000	1 432 644		
	5 418 171	3 694 764	4 352 076		
Financial assets					
Deferred taxes	1 912 172	806 154	1 459 648		
		_			
Total fixed assets	51 590 839	24 386 036	32 277 298		
Current assets					
Inventory					
Finished goods	4 771 871	2 808 539	3 205 411		
	4 771 871	2 808 539	3 205 411		
Receivables					
Trade receivables	3 450 442	2 881 552	3 481 210		
Tax receivables	626 873	201 128	406 410		
Other current receivables	1 311 328	3 186 045	2 672 633		
Prepaid expenses and accrued income	1 019 528	3 214 374	4 011 715		
	6 408 171	9 483 099	10 571 968		
Cash and cash equivalents	175 150 854	90 155 963	85 321 647		
Total current assets	186 330 896	102 447 601	99 099 026		
TOTAL ASSETS	237 921 735	126 833 637	131 376 324		

		30 sep	31 December	
(SEK)	Note	2 018	2017	2017
EQUITY AND LIABILITIES				
Equity				
Share capital		1 900 859	1 056 254	1 707 254
Non-registered share capital	3	14 800	0	0
Other equity including net income for the period		219 426 475	115 325 750	114 696 034
Equity attributable to shareholders in parent company		221 342 134	116 382 004	116 403 288
Total equity		221 342 134	116 382 004	116 403 288
Long-term liabilities				
Liabilities to credit institutions		0	179 959	0
Convertible loans		0	0	0
Other long term liabilities		0	1 400 000	0
		0	1 579 959	0
Current liabilities				
Liabilities to credit institutions		0	359 892	3 644
Accounts payables		4 667 216	4 282 922	7 873 127
Tax liabilities		0	0	0
Other current liabilites		1 908 224	2 232 132	1 591 191
Accrued expenses and prepaid income		10 004 161	1 996 728	5 505 074
		16 579 601	8 871 674	14 973 036
TOTAL EQUITY AND LIABILITIES		237 921 735	126 833 637	131 376 324

## Consolidated statement of changes in equity

		Q3	3	Q1-0	23	Year	
(SEK)	Note	2 018	2017	2018	2017	2017	
Opening balance according to balance sheet		223 566 101	104 870 376	116 403 288	1 261 796	1 261 796	
Changes in the carrying amounts recognised directly in equity							
Translation differences		117 170	201 477	-210 284	23 342	-340 911	
Transactions with the group's owners							
New issue of shares	3	370 000	14 129 123	113 213 445	118 969 058	114 999 983	
Conversion of loans		0	0	0	0	16 668 867	
Issue expenses	4	-152 324	0	-4 571 718	0	-12 310 790	
Net income		-2 558 813	-2 818 972	-3 492 597	-3 872 192	-3 875 657	
Total Equity		221 342 134	116 382 004	221 342 134	116 382 004	116 403 288	

### Consolidated statement of cash flow

	Qŝ	3	Q1-	Q3	Year
(SEK) Not	e 2 018	2017	2018	2017	2017
Operations					
Operating income	-2 050 769	-2 253 623	-5 787 946	-1 575 447	-3 487 833
Adjustment of non cash flow items					
Depreciations, amortisations and gains and losses on sale of fixed					
assets	1 422 866	1 274 613	4 119 979	1 685 249	2 751 597
Currency exchange rates differences	232 284	-742 478	62 108	-382 775	-875 125
Provisions	0	0	0	-13 784	-13 872
Other non cash flow items	96 811	0	96 811	0	195 417
	-298 808	-1 721 488	-1 509 048	-286 757	-1 429 816
Received interest	0	0	0	1	654
Paid interest	-1 851	-88 553	-1 952	-2 566 803	-2 591 545
Paid taxes	0	-52 019	0	-191 298	-211 321
Cash flow from operations before change in working capital	-300 659	-1 862 060	-1 511 000	-3 044 857	-4 232 028
Cash flow from change in working capital					
Increase (-)/Decrease (+) of inventory	12 986	-1 129 534	-1 524 692	-1 272 370	1 331 111
Increase (-)/Decrease (+) of inventory  Increase (-)/Decrease (+) of operating receivables	1 066 449	-1 129 534 -2 458 034	4 753 480	-1 2/2 3/0 -5 433 107	-6 248 592
Increase (+)/Decrease (+) of operating receivables  Increase (+)/Decrease (-) of operating liabilities	1 115 372	-10 597 494	991 680		9 645 159
Cash flow from operations	1 894 147	-10 397 494	2 709 468	4 123 577 -5 626 757	495 650
Cash now from operations	1 034 147	-10 047 122	2 703 408	-3 020 737	493 030
Investment activities					
Investment in intangible fixed assets	-7 076 206	-2 489 769	-18 080 849	-15 292 593	-22 105 618
Investments in tangible fixed assets	-1 426 094	-385 586	-3 615 105	-1 609 645	-3 776 401
Investments of financial assets	0	570 156	0	298 094	0
Cash flow from investment activities	-8 502 299	-2 305 199	-21 695 953	-16 604 144	-25 882 019
Financing activities					
New issue of shares 3	370 000	14 129 123	113 213 445	118 969 059	117 430 268
Issue expenses 4	-152 323	0	-4 571 718	0	-12 310 790
Received loans	0	0	0	6 002 763	0
Amortisation of loans	0	-6 259 982	0	-20 814 997	-2 779 779
Cash flow from financing activities	217 677	7 869 141	108 641 727	104 156 825	102 339 699
Cash flow for the period	-6 390 475	-10 483 180	89 655 242	81 925 924	76 953 329
Liquid funds at the beginning of the period	181 590 506	100 738 385	85 321 647	8 296 432	8 296 432
Effects of exchange rate changes on cash	-49 176	-36 166	173 966	-6 942	0
Translation difference in liquid funds	0	-63 076	0	-59 451	71 886
Liquid funds at the end of the period	175 150 854	90 155 963	175 150 854	90 155 963	85 321 647

## Parent company income statement

	a	Q3		Q1-Q3		
(SEK)	2 018	2017	2018	2017	2017	
Revenues						
Net sales	12 476 636	10 029 341	41 868 560	28 867 334	43 129 325	
Capitalized development expenses	0	0	0	1 290 937	1 290 937	
Other operating income	2 340 978	33 930	5 500 192	84 538	121 232	
	14 817 614	10 063 271	47 368 752	30 242 809	44 541 494	
Operating cost and expenses						
Cost of goods sold	-7 881 572	-6 251 996	-26 750 403	-19 636 979	-26 460 090	
External expenses	-3 263 574	-2 586 074	-11 799 551	-7 821 503	-11 595 358	
Personnel expenses	-3 778 376	-2 920 765	-12 540 440	-7 363 248	-10 523 197	
Depreciation and amortisation	-425 851	-818 519	-1 183 461	-854 741	-1 175 665	
Other operating expenses	-299 017	-30 043	-778 984	-63 886	-226 119	
Operating income	-830 776	-2 544 126	-5 684 087	-5 497 548	-5 438 935	
Income from financial items						
Result from securities and long term receivables	0	184 728	0	386 182	578 191	
Financial income	1 865 487	323 991	5 722 286	1 401 348	2 749 048	
Financial expenses	-2 035 414	-1 165 756	-3 345 272	-3 601 248	-3 863 210	
Income after financial items	-1 000 703	-3 201 163	-3 307 073	-7 311 266	-5 974 906	
Group contribution	0	0	0	0	1 348 246	
Income before taxes	-1 000 703	-3 201 163	-3 307 073	-7 311 266	-4 626 660	
Taxes	0	-45 061	0	-175 925	0	
Net Income	-1 000 703	-3 246 224	-3 307 073	-7 487 191	-4 626 660	





# Parent company balance sheet

	30 septe	31 December	
(SEK)	Note 2 018	2017	2017
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development expenses	16 104 616	3 140 185	6 402 769
Tangible assets			
Building and land	26000	0	0
Machinery and equipment	3 090 976	2 183 764	2 824 845
Fixtures and tools	128 654	71 637	64 196
	3 245 630	2 255 401	2 889 041
Financial fixed assets			
Shares in group companies	50 009	50 009	50 009
Long term receivables in group companies	40 703 240	29 683 771	30 854 306
	40 753 249	29 733 780	30 904 315
Total fixed assets	60 103 495	35 129 366	40 196 125
Current assets			
Inventory			
Finished goods	12 743 308	6 472 874	6 108 574
Receivables			
Trade receivables	3 008 726	2 589 612	3 160 937
Receivables in group companies	12 290 399	2 719 867	7 990 913
Tax receivables	349 704	3 554	332 537
Other current receivables	1 042 261	708 990	1 314 862
Prepaid expenses and accrued income	1 004 230	763 324	1 496 634
	17 695 320	6 785 347	14 295 883
Cash and cash equivalents	173 855 475	88 936 812	83 282 895
Total current assets	204 294 103	102 195 033	103 687 352
TOTAL ASSETS	264 397 598	137 324 399	143 883 477

		30 september			
(SEK)	Note	2 018	2017	2017	
EQUITY AND LIABILITIES					
Equity					
Restricted equity					
Share capital		1 900 859	1 056 254	1 707 254	
Non-registered share capital	3	14 800	0	0	
Fund for capitalized development expenses		16 104 616	3 140 185	6 402 769	
Non restricted equity					
Share premium fund		237 717 510	129 712 804	129 450 806	
Retained earnings		-23 150 021	-5 633 801	-8 987 681	
Profit or loss previous year		0	-4 207 285	0	
Profit or loss for the period		-3 307 073	-3 246 224	-4 626 660	
Total Equity		229 280 691	120 821 933	123 946 488	
Long-term liabilities					
Liabilities to credit institutions		0	179 959	0	
Other long term liabilities		0	1 400 000	0	
		0	1 579 959	0	
Current liabilities					
Liabilities to credit institutions		0	359 892	0	
Accounts payables		2 616 047	1 608 360	5 045 386	
Liabilities to group companies		23 003 205	10 433 738	10 762 117	
Other current liabilites		1 263 974	1 579 322	976 786	
Accrued expenses and prepaid income		8 233 681	941 195	3 152 700	
		35 116 907	14 922 507	19 936 989	
TOTAL EQUITY AND LIABILITIES		264 397 598	137 324 399	143 883 477	

# Parent company statement of changes in equity

	(	Q3	Q1-	Q3	Year
(SEK)	lote 2 018	2017	2018	2017	2017
Opening balance according to balance sheet	229 869 704	109 878 608	123 946 488	9 309 943	9 309 943
Changes in the carrying amounts recognised directly in equity					
Translation differences	194 014	60 426	-451	30 123	-94 855
Transactions with the group's owners					
New issue of shares	3 370 000	14 129 123	113 213 445	118 969 058	114 999 983
Conversion of loans	0	0	0	0	16 668 867
Issue expenses	4 -152 324	0	-4 571 718	0	-12 310 790
Reallocation between items in equity					
Bonus issue	0	0	0	0	650 000
Share capital	0	0	0	0	-650 000
Allocations to funds for capitalized development expenses	-2 767 823	380 532	16 104 616	1 671 469	6 402 769
Retained earnings	2 767 823	-380 532	-16 104 616	-1 671 469	-6 402 769
	0	0	0	0	0
Net income	-1 000 703	-3 246 224	-3 307 073	-7 487 191	-4 626 660
Total Equity	229 280 691	120 821 933	229 280 691	120 821 933	123 946 488

# Parent company statement of cash flow

		Q3	3	Q1-0	13	Year
(SEK)	Note	2 018	2017	2018	2017	2017
Operations						
Operating income		-830 776	-2 544 126	-5 684 087	-5 497 548	-5 438 935
Adjustment of non cash flow items						
Depreciations, amortisations and gains and losses on sale of fixed						
assets		761 501	818 519	2 273 529	854 741	1 175 665
Currency exchange rates differences		723 516	-750 528	437 351	-384 018	-12 112
Provisions		0	0	0	0	0
Other non cash flow items		96 773	0	96 773	0	1 492 735
		751 013	-2 476 135	-2 876 435	-5 026 825	-2 782 647
Received interest		282 590	0	713 930	1	578 845
Paid interest		-1 850	-88 553	-1 850	-2 566 803	-2 591 545
Paid taxes		0	-45 061	0	-179 564	-332 537
Cash flow from operations before change in working capital						
cash how home operations before change in working capital		1 031 753	-2 609 749	-2 164 355	-7 773 191	-5 127 884
Cash flow from change in working capital						
Increase (-)/Decrease (+) of inventory		-1 650 647	-2 866 314	-6 598 883	-1 867 656	1 433 719
Increase (-)/Decrease (+) of operating receivables		-526 723	444 508	-3 369 785	-1 113 045	-8 481 835
Increase (+)/Decrease (-) of operating liabilities		2 639 289	-6 269 687	15 030 423	-3 245 794	7 182 075
Cash flow from operations		1 493 673	-11 301 242	2 897 400	-13 999 686	-4 993 925
Investment activities						
Investment in intangible fixed assets		-3 634 945	-380 532	-9 701 847	-1 671 469	-4 934 053
Investments in tangible fixed assets		-841 082	-3 598	-2 507 219	-332 558	-2 688 881
Investments of financial assets		-1 985 221	-5 284 384	-8 899 177	-13 719 349	-14 204 812
Cash flow from investment activities		-6 461 248	-5 668 514	-21 108 243	-15 723 376	-21 827 746
Finansieringsverksamheten						
New issue of shares	3	370 001	14 129 123	113 213 445	118 969 059	117 430 268
Issue expenses	4	-152 323	0	-4 571 718	0	-12 310 790
Received loans		0	0	0	6 751 534	0
Increase (+)/Decrease (-) of current financial liabilites		0	0	0	6 000 000	0
Amortisation of loans		0	-6 259 982	0	-20 774 033	-2 779 779
Cash flow from financing activities		217 677	7 869 141	108 641 727	110 946 560	102 339 699
Cash flow for the period		-4 749 898	-9 100 615	90 430 884	81 223 498	75 518 027
Liquid funds at the beginning of the period		178 626 074	98 095 509	83 282 895	7 711 119	7 711 119
Effects of exchange rate changes on cash		-20 701	-36 166	141 696	-6 942	0
Translation difference in liquid funds		0	-21 916	0	9 137	53 749
Liquid funds at the end of the period		173 855 475	88 936 812	173 855 475	88 936 812	83 282 895

#### Share information

	Q	Q3		Q1-Q3	
	2 018	2017	2018	2017	2017
Net income, SEK	-2 558 813	-2 818 972	-3 492 597	-3 872 192	-3 875 657
Cash flow, SEK	-6 390 475	-10 483 180	89 655 242	81 925 924	76 953 329
Number of shares at the beginning of the period	19 008 591	16 303 308	17 072 538	2 170	2 170
Number of shares at the end of the period	19 008 591	17 072 538	19 008 591	17 072 538	17 072 538
Average number of shares	19 008 591	16 687 923	18 040 565	8 537 354	8 537 354
Outstanding warrants at the beginning of the period	1 142 149	1 350 149	1 350 149	260	260
Outstanding warrants at the end of the period	1 142 149	1 350 149	1 142 149	1 350 149	1 350 149
Genomsnittligt antal teckningsoptioner	1 142 149	1 350 149	1 246 149	675 205	675 205
Share capital at the end of the period, SEK	1 900 859	1 056 254	1 900 859	1 056 254	1 707 254
Equity at the end of the period, SEK	221 342 134	116 382 004	221 342 134	116 382 004	116 403 288
Earnings per share, SEK					
- Earnings per share before dilution	-0,13	-0,17	-0,19	-0,45	-0,45
- Earnings per share after dilution	-0,13	-0,16	-0,18	-0,42	-0,42
Equity per share, SEK	11,64	6,82	11,64	6,82	6,82
Cash flow per share, SEK	-0,34	-0,63	4,97	9,60	9,01

#### Sedana Medical share – facts

Listing	Nasdaq First North Stockholm
Number of shares *	0
Market capitalization MSEK *	0
Ticker	SEDANA
ISIN	SE0009947534

<sup>\*</sup> Per 30 September 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 on pages 13-17 of the Group annual report 2016.

A departure from the K3 regulation has occurred in the third quarter 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:

 $\hbox{\it Current assets excluding inventory/Current liabilities}$ 

#### **NOTE 3 CONVERSION OF WARRANTS**

In Sedana Medical AB (publ) there was a non-registered share capital of 14 800 SEK booked in the balance sheet at the end of the third quarter. This concern an ongoing conversion of warrants to shares in program 2014/2019. A capital of 370 000 SEK has been paid to the company in accordance with this during the third quarter, but the share capital and the warrant conversion were not registered by the Swedish Companies Registration Office per 30 September 2018.

#### **NOTE 4 EXPENSES FOR ISSUE OF SHARES**

The amount of -152 323 SEK concern expenses for the issue of shares in June 2018.

#### Other information

#### **AUDITOR'S REVIEW**

The Group's auditor has reviewed the accounts in this interim report.

#### CERTIFIED ADVISER

Erik Penser Bank 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

Year-end report 2018: 21 March 2019

#### 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 22 November 2018

Thomas Eklund	Sten Gibeck	Bengt Julander
Chairman of the Board	Board member	Board member
Ola Magnusson	Michael Ryan	Eva Walde
Board member	Board member	Board member
	Christer Ahlberg	
	President and CEO	

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# **SEDANA**MEDICAL

the AnaConDa technology people