

SEDANAMEDICAL

Pioneering volatile anaesthetic delivery

INTERIM REPORT Q3

JANUARY–SEPTEMBER 2019

SEDANA MEDICAL AB (PUBL)



Q1

Q2

Q3

Q4

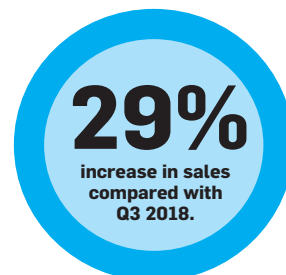
SEDANA MEDICAL, INTERIM REPORT Q3, 2019

Financial Summary July–September

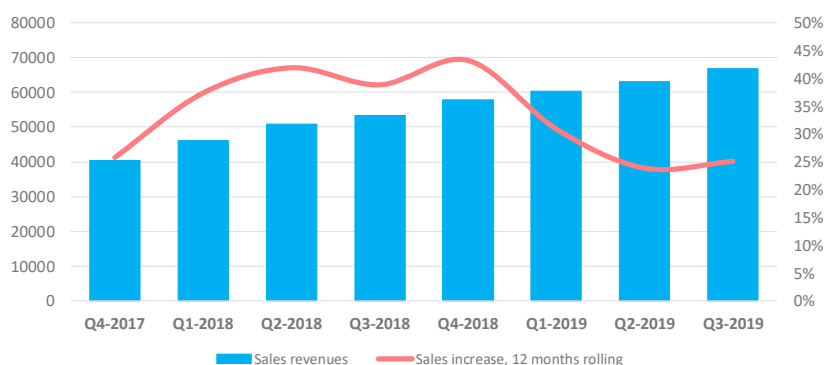
- Net sales during the third quarter amounted to KSEK 16,416 (12,682) corresponding to an increase of 29% compared with the same period in 2018.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to KSEK -4,029 (-964) KSEK. This corresponds to an EBITDA margin of -25% (-8%).
- Earnings before interest and taxes (EBIT) amounted to KSEK -5,093 (-2,051), which corresponds to an EBIT margin of -31% (-16%).
- Cash flow from operations before changes in working capital amounted to KSEK -3,913 (-301).
- Cash flow from investment activities amounted to KSEK -12,733 (-8,502).
- Cash flow for the period amounted KSEK -15,250 (-6,390).
- Liquid funds at the end of the period amounted to KSEK 122,152 (175,151).

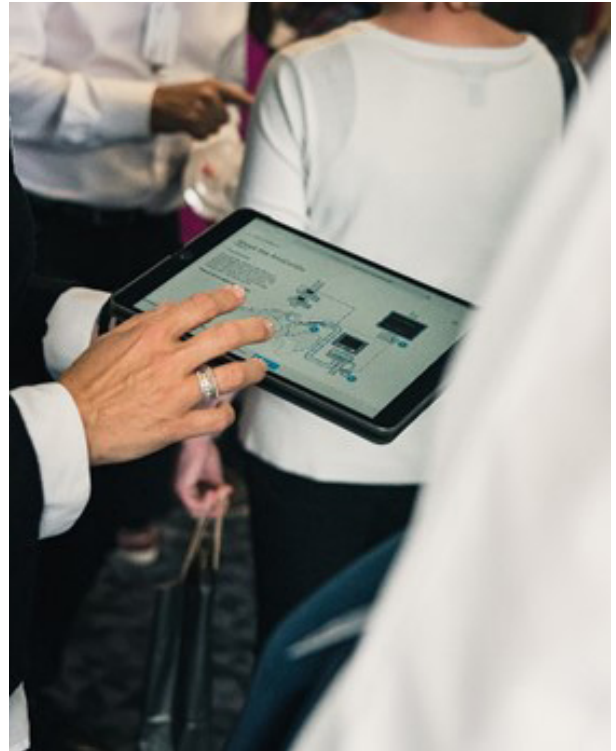
Financial Summary January–September

- Net sales during quarter 1-3 amounted to KSEK 51,589 (42,654) corresponding to an increase of 21% compared with the same period in 2018.
- Earnings before interest, taxes, depreciation and amortisation (EBITDA) amounted to KSEK -9,000 (-2,758) KSEK. This corresponds to an EBITDA margin of -17% (-7%).
- Earnings before interest and taxes (EBIT) amounted to KSEK -12,130 (-5,788), which corresponds to an EBIT margin of -24% (-14%).
- Cash flow from operations before changes in working capital amounted to KSEK -7,840 (-1,511).
- Cash flow from investment activities amounted to KSEK -36,829 (-21,696).
- Cash flow for the period amounted KSEK -37,386 (89,655).



Sales revenues, 12 months rolling





Significant events during the period

- Sedana Medical entered into a distribution agreement with the Indian distributor Hansraj Nayyar Medical. Sales will commence in the fall and a registration process will start in parallel. Hansraj Nayyar has committed to a first framework order of 25,000 euros. The Indian market potential for sedation in intensive care is estimated to be around two million ventilation days annually.
- Sedana Medical received approval for the use of AnaConDa in children by the European notifying body BSI Group. The approval also means that AnaConDa can be used in patients with severely impaired lung capacity.

Significant events after 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 Fonder.
- Sedana Medical co-finances the world's largest multi-center study with AnaConDa in France by supplying the investigators with AnaConDa and accessories. The primary purpose of the study is to show that inhalation sedation with AnaConDa has lung-protective properties, shortens ventilator time and higher survival in severely pulmonary intensive care patients.
- 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 in addition to this target.
- Sedana Medical AB (publ) 's Board Member Michael Ryan has decided to resign on November 12, 2019. The Nomination Committee of Sedana Medical will begin work to find a successor.



CEO COMMENTS

OUR THIRD QUARTER has been intense, both in terms of clinical development and preparation for our European launch. During the quarter, we also made progress in Asia through a distribution agreement in India. In terms of sales, the third quarter was a good quarter with growth of 29 percent.

The most important progress in the quarter have mainly been made in the area of clinical development and I particularly want to highlight the work on the European study. The patient recruitment proceeds as planned and the work of compiling and consolidating the results has begun. Thanks to the three Slovenian clinics that were included in August / September, we expect to be able to complete the study according to plan in December 2019 or in January 2020. With that in mind, we will be able to communicate the overall results about 3 months after the last patient in. We will be able to submit our application for a market approval in the summer of 2020 in 16 European countries in a first registration round and probably we can have a European market approval in the second half of 2021.

When it comes to the preparations for our pediatric study, they have progressed well during the quarter. The most important milestone is that we got AnaConDa approved for use in child-

ren, which is a prerequisite for starting the study in 2020.

The approval also means that AnaConDa can be used in patients with severely impaired lung function and all together, this means that we have no restrictions on the use of AnaConDa, and we can address the entire market for mechanically ventilated intensive care patients. The pediatric study ensures a complete application for registration and thus ten years of market exclusivity in the EU. We are also pleased that the European Medicines Agency EMA wants the study protocol to be designed to show that inhalation sedation via AnaConDa is better than midazolam, which is today's standard treatment for children. That means our therapy can be evaluated to be a first-hand treatment.

” We will be able to submit our application for a market approval in the summer of 2020 in 16 European countries in a first registration round and **probably we can have a European market approval in the second half of 2021.**

We also had the first meetings with the investigators in the pediatric study. At these meetings, the study protocol is reviewed and discussed in great detail in order to optimize investigators involvement. In its way, our clinical activities coincide with our commercial ones. Starting the pediatric study in several countries could be regarded as a pre-launch. We have close to 20 clinics in Germany, Sweden, France and Spain where we expect that the knowledge and interest in using our therapy will be huge at the time of launch.

In terms of our commercial work, we are now increasing the pace and we are developing our medical, sales and marketing departments in order to prepare for the launch of IsoConDa with our own sales organization in the largest European markets. This is the main reason why our expenses increased during the quarter. For example, a first major English seminar was held in Birmingham. It was very well attended by prospective customers. About 70 physicians and other healthcare professionals set aside a full day to hear about the benefits of inhalation sedation. Through the seminar we started our work in the UK seriously and we continue to participate in major international congresses. During the quarter we participated, amongst others, at ESICM in Berlin, which is one of the world's largest intensive care congresses.

After the end of the quarter, we made a successful private placement of SEK 375 million before costs. The money will primarily be used to finance the way to market approval for AnaConDa and IsoConDa in the USA. The combination registration of AnaConDa and IsoConDa includes activities such as two clinical studies involving a total of approximately 500 patients, human factors validation programs, toxicity studies, safety database, adaptation of the European pediatric study to FDA requirements and application for market approval (NDA).

We started the human factors validation program together with Harvard during the quarter and expect it to be completed in the summer of 2020. As far as the toxicity studies are concerned, we have started preparatory investigations and expect these to be ready in the summer of 2020. This enable us to plan to submit our IND application to the FDA in the fourth quarter of 2020 in order to begin clinical studies in 2021 in USA. We have already begun to find clinics that want to collaborate with us and work closely with advisory boards at each clinic. Our ambition is to have a good geographical spread at our American clinics in order to secure the commercially important regions. The plan is to reach US approval in 2024 and around 2022 we will decide whether to launch ourselves or together with local partners.

After the end of the quarter, we also announced that we are part-financing the study SESAR, the world's largest multi-center study, with AnaConDa. The purpose is to show that inhalation sedation with AnaConDa has lung protective properties. The study covers 700 patients and has the potential to dramatically change the perception of inhalation sedation in relation to intravenous sedation. The study is being conducted in France and is sponsored to a large extent by the French Ministry of Health and the EU, which we consider to be a huge success for our therapy. If the study supports the hypothesis that inhalation sedation via AnaConDa has therapeutic effects, leads to shorter ventilator treatment and a higher survival rate, it will be an important breakthrough for ICU patients worldwide with severe lung disease.

In addition to our ambition to grow 20% per year before the registration of IsoConDa in Europe, we have previously also stated that we will deliver an EBITDA result that is not significantly negative. As registration gets closer, the work of building up larger medical, sales and marketing organizations in and outside of Europe has intensified and we no longer provide an EBITDA forecast for the time before registration. We clarify that our sales turnover target of SEK 500 million and the EBITDA margin target of about 40 percent three years after the European registration of IsoConDa only apply to Europe. Sales outside Europe, for example sales in China and Japan are not included in this target and we do not communicate forecasts for these markets at this time.

In summary, we have experienced another strong quarter that takes us closer to our goals; to register IsoConDa in Europe in the second half of 2021, to obtain market approval in the US in 2024 and to establish ourselves in the major markets in Asia. The goals are a first step towards our vision of making inhalation sedation with AnaConDa and IsoConDa a standard treatment for mechanically ventilated patients in intensive care worldwide. Our estimate of the total market potential for inhalation sedation in intensive care is SEK 20-30 billion annually. Through the private placement, we got a number of new investors and I want to take this opportunity to thank you for the trust given to us by both old and new owners. I look forward to the continued journey 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 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 and South Korea, 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	2 116 901	10,67%
Sten Gibeck	1 605 744	8,09%
Anders Walldov direct and indirect (Brohuvudet AB)	1 600 000	8,06%
Handelsbanken funds	1 574 903	7,94%
Ola Magnusson direct and indirect (Magiola AB)	1 340 867	6,76%
Anades Ltd.	1 068 083	5,38%
Berenberg funds	712 731	3,59%
Ron Farrell	631 062	3,18%
Avanza Pension	476 616	2,40%
Nordnet pensionsförsäkrings AB	468 264	2,36%
Swedbank Robur funds	450 000	2,27%
Eklund Konsulting AB	416 616	2,10%
Alfred Berg funds	359 949	1,81%
Tony McCarthy	339 823	1,71%
Philip Earle	304 751	1,54%
Fifteen largest shareholders	13 466 310	67,87%
Others *	6 374 281	32,13%
Total	19 840 591	100,00%

* CEO's ownership is 230 000 shares.

BUSINESS DEVELOPMENTS 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 which is currently under way and which will form the basis of the marketing authorization.

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

REGISTRATION STUDY ISOCONDA

The clinical registration study required for a complete dossier is ongoing in Germany. During the summer of 2019, three sites in Slovenia were added to be included in the study. These three clinics have long experience of Anaconda. 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. The study only needs a total of 300 patients instead of initially estimated 550 patients.

Until the end of September 2019, the company has recruited 260 patients in the study. The company expects to include the last patient in the study in December 2019 or January 2020. This since the inclusion rate should increase during quarter 4 as the Slovenian clinics were added to the study and the fact that the summer months are over.

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 in children.

This approval is also a prerequisite for conducting the study in children. The approval 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 that 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 approval of IsoConDa comes to quickly be able to penetrate the market.

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

We intend to set up 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 quarter. 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 co-finances 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.

We also work closely to 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 25%, 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 about 40%.

Financial Summary, January – June 2019

Financial summary - Consolidated (SEK)

	Q3		Q1-Q3		Year
	2 019	2018	2019	2018	2018
Net sales	16 416 276	12 682 176	51 589 092	42 653 855	57 896 208
Gross Profit	12 017 115	9 339 506	37 785 165	31 433 462	42 896 532
Gross Margin (%)	73,2%	73,6%	73,2%	73,7%	74,1%
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-4 028 709	-963 553	-9 000 303	-2 758 035	-4 232 301
Earnings Before Interest and Taxes (EBIT)	-5 093 009	-2 050 769	-12 129 566	-5 787 946	-8 238 213
Income after financial items	-4 273 788	-2 501 973	-9 285 886	-4 120 719	-6 519 628
Net income	-4 938 345	-2 558 813	-9 632 064	-3 492 597	-6 869 062
EBITDA %	-24,5%	-7,6%	-17,4%	-6,5%	-7,3%
EBIT %	-31,0%	-16,2%	-23,5%	-13,6%	-14,2%
Net income % of net sales	-30,1%	-20,2%	-18,7%	-8,2%	-11,9%
Total assets	231 252 048	237 921 735	231 252 048	237 921 735	231 549 760
Equity	209 402 799	221 342 134	209 402 799	221 342 134	217 811 282
Equity ratio	90,6%	93,0%	90,6%	93,0%	94,1%
Quick ratio	616,0%	1095,1%	616,0%	1095,1%	1219,6%
Average number of employees	40	26	38	26	26
Average number of shares before dilution	19 738 591	19 008 591	19 498 591	18 040 565	18 114 565
Average number of shares after dilution	20 380 283	20 150 740	20 373 283	19 286 714	19 286 714
Number of shares at the end of the period before dilution	19 840 591	19 008 591	19 840 591	19 008 591	19 156 591
Number of shares at the end of the period after dilution	20 239 825	20 150 740	20 239 825	20 150 740	20 150 740
Earnings per share before dilution ¹⁾	-0,25	-0,13	-0,49	-0,19	-0,38
Earnings per share after dilution ¹⁾	-0,24	-0,13	-0,47	-0,18	-0,36

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

REVENUES

During the third quarter, the Group's revenues amounted to KSEK 17,270 (13,007), corresponding to an increase of KSEK 4,263 or 33 percent. The increase is mainly attributable to an increase in net sales of KSEK 3,734 or 29%. The Group's sales are almost exclusively in EUR and the corresponding sales increase, adjusted for currency fluctuations, was 27%. In addition, revenues for the third quarter contain other operating income of KSEK 854 (325) and consist mainly of positive exchange rate differences.

COST OF GOODS SOLD

The cost of goods sold during the third quarter amounted to KSEK 4,399 (3,343), which corresponds to an increase of KSEK 1,056 or 32%. 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.

OTHER EXTERNAL EXPENSES

Other external expenses during the quarter amounted to KSEK 7,112 (5,456), which corresponds to an increase of KSEK 1,688 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 third 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.

PERSONNEL EXPENSES

Personnel expenses in the Group amounted to KSEK 9,293 (4,887) during the third quarter, corresponding to an increase of KSEK 4,406 or 90%. During the third quarter, the Group had in average 40 employees, which was an increase of 14 employees compared to the same period in 2018. The main reason for the increase in personnel costs is the build-up of the marketing and sales organization prior to the registration and subsequent launch of IsoConDa.

DEPRECIATION AND AMORTISATION

Depreciation amounted to KSEK 1,064 (1,087) during the third quarter, which corresponds to a decrease of KSEK 23 or 2%. Depreciation relates to property, plant and equipment and amortisation of in house developed asset AnaConDa-S.

OPERATING INCOME

The Group's operating profit for the third quarter amounted to KSEK -5,093 (-2,051), which corresponds to a decreased result of KSEK 3,042 or 148%. The decreased result is mainly due to an increase in expenses for building up the sales and market organization within the Group and preparations for the IsoConDa launch.

FINANCIAL ITEMS

Net financial items amounted to KSEK 819 (-451) during the third quarter. Net financial items are partly explained by paid liquidity for the subscription of options in the warrants program 2019/2022 as well as positive exchange rate differences. At the Annual General Meeting May 28, 2019, it was resolved to introduce a new warrant program, 2019/2022, for employees of the Sedana Medical Group, see also note 3. A total of KSEK

1,330 was paid in June 2019 from employees for subscription of warrants in this program. Another KSEK 416 for the same program was paid in September 2019.

TAXES

The Group reported a tax expense of KSEK 665 (57) during the third quarter. The tax expense for the quarter is mainly explained by changes in deferred tax.

NET INCOME

The Group reported a net income of KSEK -4,938 (-2,559) for the quarter, a decrease of KSEK 2,380 or 93%. The decline in earnings compared with the previous year is mainly explained by a lower operating profit.

EQUITY AND LIABILITIES

Equity in the Group at September 30, 2019 amounted to KSEK 209,403 (221,342), corresponding to a decrease of KSEK 11,939. The decrease is due to negative results as a result of the build up of the organization prior to the IsoConDa launch.

Current liabilities in the Group amounted to KSEK 21,849 (16,580) at the end of the period and mainly comprised accrued expenses of KSEK 8,786 (10,004) and accounts payable of KSEK 7,637 (4,667).

LIQUID FUNDS AND CASH FLOW

Cash and cash equivalents at the end of the period amounted to KSEK 122,152 (175,151).

Cash flow from operating activities before changes in working capital was KSEK -3,913 (-301) the third quarter.

Cash flow from operating activities, including the change in working capital, amounted to KSEK -3,443 (1,894). The working capital's negative change compared with the same period last year is mainly due to an increase in operating receivables.

Cash flow from investments amounted to KSEK -12,733 (-8,502) and consists mainly of intangible fixed assets, the major part of which relates to capitalized development costs for the clinical study and the registration work of IsoConDa EU.

Cash flow from financing activities was KSEK 926 (218) during the quarter. KSEK 510 of the outcome during the quarter relates to new issues due to the conversion of warrants in program 2014/2019. The remaining part relates to payments from employees who have subscribed for warrants in the new program 2019/2022. The outcome for the corresponding period last year relates to new share issue following conversion of warrants in program 2014/2019.

Total cash flow for the quarter amounted to KSEK -15,250 (-6,390).

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 consist of sales of products. Until 31st of August 2019 the parent company had a branch office in Germany. The operation in the German branch has per 1st of September 2019 been incorporated into a fully owned German subsidiary.

The Parent Company's total revenues amounted to KSEK 13,474 (14,818) for the third quarter. Operating profit amounted to KSEK -5,399 (-831), which corresponds to a decrease of KSEK 4,568. Net financial items during the quarter amounted to KSEK 655 (-170). Net income for the period amounted to KSEK -4,695 (-1,001).

Equity in the Parent Company, Sedana Medical AB (publ), as of September 30, 2019 amounted to KSEK 217,876 (229,281), corresponding to a decrease of KSEK 11,405. The share capital amounted to KSEK 1,984 (1,901), an increase of KSEK 83. The increase is entirely attributable to the conversion of warrants to shares in warrant programs 2014/2019.

Cash and cash equivalents amounted to KSEK 114,986 (173,855), a decrease of KSEK 58,869, which is mainly due to investments in intangible assets but also partly to the build-up and preparation of the organization prior to the IsoConDa launch.

Other information

TRANSACTIONS WITH RELATED PARTIES

Transactions with related parties take place on market terms. During the second quarter, the subsidiary Sedana Medical Ltd. purchased goods worth KSEK 952 from Lismed Ltd., a related company to the R&D director and owner Ron Farrell.

Consolidated Income Statement

(SEK)	Note	Q3		Q1-Q3		Year
		2019	2018	2019	2018	2018
Revenues						
Net sales		16 416 276	12 682 176	51 589 092	42 653 855	57 896 208
Other operating income		854 022	325 220	2 213 553	1 041 398	1 474 482
		17 270 298	13 007 396	53 802 645	43 695 253	59 370 690
Operating cost and expenses						
Cost of goods sold		-4 399 161	-3 342 670	-13 803 927	-11 220 393	-14 999 676
External expenses		-7 112 049	-5 423 805	-20 608 771	-16 674 358	-21 651 097
Personnel expenses		-9 293 184	-4 887 130	-27 113 351	-17 753 587	-25 760 221
Depreciation and amortisation		-1 064 300	-1 087 216	-3 129 263	-3 029 911	-4 005 912
Other operating expenses		-494 613	-317 344	-1 276 899	-804 950	-1 191 997
Operating income		-5 093 009	-2 050 769	-12 129 566	-5 787 946	-8 238 213
Income from financial items						
Financial income		828 333	1 584 102	2 876 766	5 012 492	5 450 451
Financial expenses		-9 112	-2 035 306	-33 086	-3 345 265	-3 731 866
Income after financial items		-4 273 788	-2 501 973	-9 285 886	-4 120 719	-6 519 628
Income before taxes						
		-4 273 788	-2 501 973	-9 285 886	-4 120 719	-6 519 628
Taxes		-664 557	-56 840	-346 178	628 122	-349 434
Net Income		-4 938 345	-2 558 813	-9 632 064	-3 492 597	-6 869 062



Consolidated balance sheet

(SEK)	Note	30 September		31 December
		2019	2018	2018
ASSETS				
Fixed assets				
<i>Intangible assets</i>				
Capitalized development expenses		79 598 669	39 276 774	46 161 490
Concessions, patents, licenses and similar		4 632 224	4 983 722	5 243 054
		<u>84 230 893</u>	<u>44 260 496</u>	<u>51 404 544</u>
<i>Tangible assets</i>				
Building and land		22 959	91 916	54 819
Machinery and equipment		4 471 713	4 950 852	4 128 515
Fixtures and tools		788 915	375 403	525 092
		<u>5 283 587</u>	<u>5 418 171</u>	<u>4 708 426</u>
<i>Financial assets</i>				
Deferred taxes		1 306 128	1 912 172	1 590 930
		<u></u>	<u></u>	<u></u>
Total fixed assets		90 820 608	51 590 839	57 703 900
Current assets				
<i>Inventory</i>				
Finished goods		5 843 608	4 771 871	6 294 672
		<u>5 843 608</u>	<u>4 771 871</u>	<u>6 294 672</u>
<i>Receivables</i>				
Trade receivables		6 114 111	3 450 442	4 984 691
Tax receivables		6 222	626 873	349 052
Other current receivables		1 512 368	1 311 328	1 294 296
Prepaid expenses and accrued income		4 802 727	1 019 528	1 572 472
		<u>12 435 428</u>	<u>6 408 171</u>	<u>8 200 511</u>
<i>Cash and cash equivalents</i>				
		122 152 404	175 150 854	159 350 677
Total current assets		140 431 440	186 330 896	173 845 860
TOTAL ASSETS		231 252 048	237 921 735	231 549 760

(SEK)	Note	30 September		31 December
		2019	2018	2018
EQUITY AND LIABILITIES				
<i>Equity</i>				
Share capital		1 984 059	1 900 859	1 915 659
Non-registered share capital		0	14 800	0
Other equity including net income for the period		207 418 740	219 426 475	215 895 623
Equity attributable to shareholders in parent company		209 402 799	221 342 134	217 811 282
Total equity		209 402 799	221 342 134	217 811 282
<i>Current liabilities</i>				
Accounts payables		7 636 770	4 667 216	4 429 892
Tax liabilities		1 226 401	0	486 769
Other current liabilities		4 199 812	1 908 224	1 864 189
Accrued expenses and prepaid income		8 786 266	10 004 161	6 957 628
		<u>21 849 249</u>	<u>16 579 601</u>	<u>13 738 478</u>
TOTAL EQUITY AND LIABILITIES		231 252 048	237 921 735	231 549 760

Consolidated statement of changes in equity

(SEK)	Note	Q3		Q1-Q3		Year
		2019	2018	2019	2018	2018
Opening balance according to balance sheet		214 055 342	223 566 101	217 811 282	116 403 288	116 403 288
Changes in the carrying amounts recognised directly in equity						
Translation differences		-224 198	117 170	-458 738	-210 284	-496 967
Transactions with the group's owners						
New issue of shares	3	510 000	370 000	1 710 000	113 213 445	113 213 445
Issue expenses	4	0	-152 324	-27 681	-4 571 718	-4 439 422
Net income		-4 938 345	-2 558 813	-9 632 064	-3 492 597	-6 869 062
Total Equity		209 402 799	221 342 134	209 402 799	221 342 134	217 811 282

Consolidated statement of cash flow

(SEK)	Note	Q3		Q1-Q3		Year
		2 018	2017	2019	2018	2018
Operations						
Operating income		-5 093 009	-2 050 769	-12 129 566	-5 787 946	-8 238 213
<i>Adjustment of non cash flow items</i>						
Depreciations, amortisations and gains and losses on sale of fixed assets		1 181 670	1 422 866	4 235 090	4 119 979	5 661 282
Currency exchange rates differences		27 159	232 284	-239 281	62 108	-385 362
Other non cash flow items		0	96 811	0	96 811	97 018
		-3 884 180	-298 808	-8 133 757	-1 509 048	-2 865 275
Received interest		0	0	0	0	2 708
Paid interest		-489	-1 851	-3 668	-1 952	-4 080
Paid taxes		-27 962	0	297 136	0	105 517
Cash flow from operations before change in working capital		-3 912 631	-300 659	-7 840 289	-1 511 000	-2 761 130
<i>Cash flow from change in working capital</i>						
Increase (-)/Decrease (+) of inventory		108 195	12 986	494 397	-1 524 692	-3 078 972
Increase (-)/Decrease (+) of operating receivables		-3 629 188	1 066 449	-4 628 185	4 753 480	2 320 243
Increase (+)/Decrease (-) of operating liabilities		3 990 551	1 115 372	7 988 972	991 680	-2 259 071
Cash flow from operations		-3 443 072	1 894 147	-3 985 105	2 709 468	-5 778 930
Investment activities						
Investment in intangible fixed assets		-11 832 330	-7 076 206	-33 550 065	-18 080 849	-25 101 463
Investments in tangible fixed assets		-900 663	-1 426 094	-3 278 998	-3 615 105	-4 025 073
Investments of financial assets		0	0	0	0	0
Cash flow from investment activities		-12 732 993	-8 502 299	-36 829 064	-21 695 953	-29 126 536
Financing activities						
New issue of shares	3	510 000	370 000	1 710 000	113 213 445	113 213 445
Issue expenses	4	0	-152 323	-27 681	-4 571 718	-4 439 422
Received premium for warrant subscription	3	415 961	0	1 746 138	0	0
Cash flow from financing activities		925 961	217 677	3 428 457	108 641 727	108 774 023
Cash flow for the period		-15 250 104	-6 390 475	-37 385 712	89 655 242	73 868 557
Liquid funds at the beginning of the period		137 316 504	181 590 506	159 350 677	85 321 647	85 321 647
Effects of exchange rate changes on cash		86 004	-49 176	187 438	173 966	160 474
Liquid funds at the end of the period		122 152 404	175 150 854	122 152 404	175 150 854	159 350 677

Parent company income statement

(SEK)	Note	Q3		Q1-Q3		Year
		2019	2018	2019	2018	2018
Revenues						
Net sales		12 672 404	12 476 636	52 769 277	41 868 560	55 855 709
Other operating income		801 908	2 340 978	1 997 244	5 500 192	10 623 437
		13 474 312	14 817 614	54 766 521	47 368 752	66 479 146
Operating cost and expenses						
Cost of goods sold		-7 146 636	-7 881 572	-29 944 435	-26 750 403	-34 729 212
External expenses		-4 478 806	-3 263 574	-16 635 526	-11 799 551	-16 828 870
Personnel expenses		-6 416 474	-3 778 376	-19 942 151	-12 540 440	-18 676 093
Depreciation and amortisation		-337 586	-425 851	-1 149 988	-1 183 461	-1 543 114
Other operating expenses		-493 532	-299 017	-1 233 834	-778 984	-1 133 298
Operating income		-5 398 722	-830 776	-14 139 413	-5 684 087	-6 431 441
Income from financial items						
Financial income		415 390	1 865 487	1 130 628	5 722 286	6 445 723
Financial income, group internal		239 865	0	699 649	0	0
Financial expenses		-111	-2 035 414	-1 061	-3 345 272	-3 721 356
Income after financial items		-4 743 578	-1 000 703	-12 310 197	-3 307 073	-3 707 074
Group contribution		0	0	0	0	0
Income before taxes		-4 743 578	-1 000 703	-12 310 197	-3 307 073	-3 707 074
Taxes		48 135	0	0	0	-48 083
Net Income		-4 695 443	-1 000 703	-12 310 197	-3 307 073	-3 755 157



Parent company balance sheet

(SEK)	Note	30 September		31 December
		2019	2018	2018
ASSETS				
Fixed assets				
Intangible assets				
Capitalized development expenses		73 418 090	16 104 616	42 297 443
Tangible assets				
Building and land		0	26 000	0
Machinery and equipment		749 734	3 090 976	2 413 629
Fixtures and tools		215 036	128 654	278 803
		964 770	3 245 630	2 692 432
Financial fixed assets				
Shares in group companies		395 256	50 009	50 009
Long term receivables in group companies		29 085 594	40 703 240	24 019 262
		29 480 850	40 753 249	24 069 271
Total fixed assets		103 863 710	60 103 495	69 059 146
Current assets				
Inventory				
Finished goods		937 114	12 743 308	9 227 249
Receivables				
Trade receivables		708 188	3 008 726	4 380 462
Receivables in group companies		20 085 074	12 290 399	12 648 231
Tax receivables		3 980	349 704	349 052
Other current receivables		1 156 937	1 042 261	1 239 426
Prepaid expenses and accrued income		1 949 817	1 004 230	1 350 629
		23 903 996	17 695 320	19 967 800
Cash and cash equivalents				
		114 986 097	173 855 475	158 805 490
Total current assets		139 827 207	204 294 103	188 000 539
TOTAL ASSETS		243 690 917	264 397 598	257 059 685

(SEK)	Note	30 September		31 December
		2019	2018	2018
EQUITY AND LIABILITIES				
Equity				
<i>Restricted equity</i>				
Share capital		1 984 059	1 900 859	1 915 659
Non-registered share capital		0	14 800	0
Fund for capitalized development expenses		73 418 090	16 104 616	42 297 443
<i>Non restricted equity</i>				
Share premium fund		239 630 602	237 717 510	237 690 860
Retained earnings		-84 846 838	-23 150 021	-49 438 748
Profit or loss for the period		-12 310 197	-3 307 073	-3 755 157
Total Equity		217 875 716	229 280 691	228 710 057
Current liabilities				
Accounts payables		2 341 123	2 616 047	2 281 214
Liabilities to group companies		16 337 771	23 003 205	20 130 621
Tax liabilities		725 242	0	0
Other current liabilities		1 832 886	1 263 974	1 340 845
Accrued expenses and prepaid income		4 578 179	8 233 681	4 596 948
		25 815 201	35 116 907	28 349 628
TOTAL EQUITY AND LIABILITIES		243 690 917	264 397 598	257 059 685

Parent company statement of changes in equity

(SEK)	Note	Q3		Q1-Q3		Year
		2019	2018	2019	2018	2018
Opening balance according to balance sheet		222 158 874	229 869 704	228 710 057	123 946 488	123 946 488
Changes in the carrying amounts recognised directly in equity						
Translation differences		-97 715	194 014	-206 463	-451	-255 297
Transactions with the group's owners						
New issue of shares	3	510 000	370 000	1 710 000	113 213 445	113 213 445
Issue expenses	4	0	-152 324	-27 681	-4 571 718	-4 439 422
Reallocation between items in equity						
Allocations to funds for capitalized development expenses		11 587 464	-2 767 823	31 120 646	16 104 616	42 297 443
Retained earnings		-11 587 464	2 767 823	-31 120 646	-16 104 616	-42 297 443
		0	0	0	0	0
Net income		-4 695 443	-1 000 703	-12 310 197	-3 307 073	-3 755 157
Total Equity		217 875 716	229 280 691	217 875 716	229 280 691	228 710 057

Parent company statement of cash flow

(SEK)	Note	Q3		Q1-Q3		Year
		2019	2018	2019	2018	2018
Operations						
Operating income		-5 398 722	-830 776	-14 139 413	-5 684 087	-6 431 441
<i>Adjustment of non cash flow items</i>						
Depreciations, amortisations and gains and losses on sale of fixed assets		321 238	761 501	2 122 097	2 273 529	3 198 484
Currency exchange rates differences		267 632	723 516	-63 137	437 351	164 582
Other non cash flow items		0	96 773	0	96 773	97 018
		-4 809 852	751 013	-12 080 453	-2 876 435	-2 971 357
Received interest		239 865	282 590	699 649	713 930	995 272
Paid interest		-111	-1 850	-1 061	-1 850	-3 977
Paid taxes		26 358	0	342 830	0	0
Cash flow from operations before change in working capital		-4 543 740	1 031 753	-11 039 035	-2 164 355	-1 980 062
<i>Cash flow from change in working capital</i>						
Increase (-)/Decrease (+) of inventory		10 263 245	-1 650 647	8 263 715	-6 598 883	-3 113 712
Increase (-)/Decrease (+) of operating receivables		4 540 924	-526 723	-3 839 593	-3 369 785	-5 641 113
Increase (+)/Decrease (-) of operating liabilities		-14 778 323	2 639 289	-2 557 756	15 030 423	8 328 001
Cash flow from operations		-4 517 893	1 493 673	-9 172 670	2 897 400	-2 406 886
Investment activities						
Investment in intangible fixed assets		-11 587 464	-3 634 945	-31 120 647	-9 701 847	-35 754 690
Investments in tangible fixed assets		1 671 829	-841 082	-391 461	-2 507 219	-3 007 850
Investments of financial assets		-2 841 641	-1 985 221	-4 742 082	-8 899 177	7 784 889
Cash flow from investment activities		-12 757 276	-6 461 248	-36 254 190	-21 108 243	-30 977 651
Finansieringsverksamheten						
New issue of shares	3	510 000	370 001	1 710 000	113 213 445	113 213 445
Issue expenses	4	0	-152 323	-27 681	-4 571 718	-4 439 422
Cash flow from financing activities		510 000	217 677	1 682 319	108 641 727	108 774 023
Cash flow for the period		-16 765 169	-4 749 898	-43 744 541	90 430 884	75 389 485
Liquid funds at the beginning of the period		131 898 775	178 626 074	158 805 490	83 282 895	83 282 895
Effects of exchange rate changes on cash		-147 508	-20 701	-74 852	141 696	133 110
Liquid funds at the end of the period		114 986 098	173 855 475	114 986 098	173 855 475	158 805 490

Share information

	Q3		Q1-Q3		Year
	2019	2018	2019	2018	2018
Net income, SEK	-4 938 345	-2 558 813	-9 632 064	-3 492 597	-6 869 062
Cash flow, SEK	-15 250 104	-6 390 475	-37 385 712	89 655 242	73 868 557
Number of shares at the beginning of the period	19 636 591	19 008 591	19 156 591	17 072 538	17 072 538
Number of shares at the end of the period	19 840 591	19 008 591	19 840 591	19 008 591	19 156 591
Average number of shares	19 738 591	19 008 591	19 498 591	18 040 565	18 114 565
Outstanding warrants at the beginning of the period	884 149	1 142 149	1 350 149	1 350 149	1 350 149
Outstanding warrants at the end of the period	399 234	1 142 149	399 234	1 142 149	994 149
Average number of warrants	641 692	1 142 149	874 692	1 246 149	1 172 149
Share capital at the end of the period, SEK	1 984 059	1 900 859	1 984 059	1 900 860	1 915 659
Equity at the end of the period, SEK	209 402 799	221 342 134	209 402 799	221 342 134	217 811 282
<i>Earnings per share, SEK</i>					
- Earnings per share before dilution	-0,25	-0,13	-0,49	-0,19	-0,38
- Earnings per share after dilution	-0,24	-0,13	-0,47	-0,18	-0,36
Equity per share, SEK	10,55	11,64	10,55	11,64	11,37
Cash flow per share, SEK	-0,77	-0,34	-1,92	4,97	4,08

Sedana Medical share – facts

Listing	Nasdaq First North Stockholm
Number of shares *	19 840 591
Market capitalization MSEK *	2774
Ticker	SEDANA
ISIN	SE0009947534

* Per 30 September 2019

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 Group annual report 2018.

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

Average number of employees:

Average number of employees during the period

Equity ratio:

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

Quick ratio:

Current assets excluding inventory/Current liabilities

NOTE 3 NEW WARRANT PROGRAM AND EXERCISES IN CURRENT 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 warrants 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 SEK 1,746,138. 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 SEK 8,909 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 2014/2019

A total of KSEK 900 was paid in the first half of the year regarding the conversion of warrants to shares in warrants program 2014/2019. KSEK 600 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 KSEK 48.

During the third quarter, KSEK 510 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 KSEK 20.

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 TRANSACTION EXPENSES

Total transaction costs for the new share issue as a result of conversions of warrants to shares in warrant program 2014/2019 amounted to SEK 27,681 during the year.

AUDITOR'S REVIEW

The Group's auditor has reviewed the accounts in this interim 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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DATES FOR UPCOMING INFORMATION

5 Mar 2020	Year End report Q2 2019
22 April 2020	Annual report 2019
19 May 2020	Annual General Meeting 2020



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 13 November 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

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