Press release November 22, 2018, at 07:00 am CET

Sedana Medical AB (publ), Interim report Q3, 2018

Strong development towards our strategic objectives

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.

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 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 U.K.

Significant events after the period

- Sedana Medical AB (publ) 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 inhalation 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, President and CEO

Sedana Medical invites you to webcast telephone presentation of the company's interim report for the third quarter of 2018

Sedana Medical invites all interested parties to a webcast conference call, with presentation of the quarterly report at. 14.30 CET the 22nd November. Sedana Medical's CEO Christer Ahlberg and CMO Peter Sackey participate in the presentation held in English.

Information on how to participate:
The webcast including the presentation material, which can also be seen afterwards, is reached at:

https://tv.streamfabriken.com/sedana-medical-q3-2018

Questions can be made in writing via the webcast or verbally via the telephone conference.
To participate in the conference call, please dial one of the following numbers:

DE: +4969222229046, FI: +358981710493, FR: +33170750712, UK: +442030089809, NL: +31207168416, SE: +46856619353, US: +18557532237

The presentation material will also be available on the Sedana Medical website at www.sedanamedical.com under Investors / Presentations. From there it will also be possible to reach the webcast and see the recorded version of the webcast and the conference call afterwards.

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Sedana Medical is listed on Nasdaq First North in Stockholm
and Erik Penser Bank (+46 8 463 83 00) is certified adviser to Sedana Medical.

This information is such that Sedana Medical AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact persons above, on 22 November 2018 at 07:00 am (CET).

Sedana Medical AB (publ) has developed and sells the medical device AnaConDa, for the administration of volatile anaesthetics to mechanically ventilated patients. A major clinical registration study is currently ongoing to obtain market approval in Europe for inhalation sedation in intensive care units with the pharmaceutical IsoConDa® (isoflurane) Sedana Medical has direct sales in the Nordic countries, Germany, France, Great Britain and Spain as well as external distributors in the rest of Europe, Canada, Australia and South Korea. The company headquarters are based in Stockholm, Sweden with R&D operations in Ireland.