Press release (MAR)
Malmö, February 18, 2021

Acarix AB (publ) publishes Year-End Report 2020

A strong ending of an eventful year

The fourth quarter contributed strongly to our overall performance in 2020, with the market approval for CADScor® from the US Food and Drug Administration (FDA) as the outstanding achievement.

Extract from CEO Per Persson's message to the End Year Report.

Fourth quarter 2020 compared with same period 2019

- During the fourth quarter, 22 CADScor®System (10, of which 4 to clinical trials) and 1,420 (1,500, of which 840 to clinical trials) disposable patches were sold to end-users and distributors.
- Revenue amounted to SEK 966 thousand (774), with gross profit of SEK 713 thousand (607) and a gross margin of 74 percent (78).
- Operational costs amounted to SEK 12,100 thousand (10,591).
- Result before tax amounted to SEK –11,411 thousand (–9,987).
- Net cash flow from operating activities amounted to SEK –12,546 thousand (–8,122). Net cash flow for the period amounted to SEK –12,034 thousand (26,037).
- Basic earnings per share amounted to –0.08 SEK (–0.31). No dilution arose.

Financial year 2020 compared with same period 2019

- During the year a total of 51 (23, including 5 sold to clinical trials) CADScor®System and 3,540 patches (4,326, including 2,040 sold to clinical trials) were sold. In total for the year, revenues of SEK 2,170 thousand (1,857) were generated with a gross profit of SEK 1,594 thousand (1,430), corresponding to a gross margin of 73 percent (77).
- Operating costs amounted to SEK 43,025 thousand (47,873).
- Result before tax amounted to SEK –41,496 thousand (–46,434).
- Net cash flow from operating activities amounted to SEK –36,686 thousand (–44,533). Including the issue proceeds received, the period's net cash flow amounted to SEK 10,663 thousand (–11,500).
- Cash position amounted to SEK 64,113 thousand (53,747)
- Basic earnings per share amounted to –0.51 SEK (–1.83). No dilution arose.

Events in the fourth quarter, 2020

- On October 15 the company has entered into an agreement with Redeye AB regarding the position as Certified Adviser. Redeye AB has taken over as Certified Adviser on October 19, 2020.
- On November 18 Acarix announced that the company's real-life data analysis, made in co-operation with clinics in Germany and Austria, was published as a poster presentation and abstract at ISPOR, the leading European conference for health economics and outcomes research, which was held virtually November 16-19, 2020.The use in real world has demonstrated that neither patient demographics nor test results differ relevantly from the trial setting and that real-life data thus could be used for further economic modeling".
- On November 25 Acarix announced that the US Food and Drug Administration (FDA) approved the company's De Novo application for marketing approval of the CADScor®System in the US. "This is a major achievement and a significant recognition of our technology and how it can improve the diagnosis of patients with potential Coronary Artery Disease". said Per Persson, CEO of Acarix".

- On December 9 Acarix announced the last patient enrolled in Dan-NICAD II study. The Dan-NICAD II, including 1 726 patients, was initiated in January 2018 to further establish the diagnostic accuracy of the CADScor®System compared to other stratification alternatives commonly used today in parallel with securing more validated clinical data for further sophistication of the CADScor® Algorithm. The study also includes patients below the age of 40 which provides the opportunity of a possible significant expansion of the currently identified patient group, thus enable the CADScor®System to be used on patients down to 30 years of age.

Events after December 31, 2020

- On January 13 Acarix announced positive preliminary data from the exploratory SEISMO study, using its modified CADScor®System on a potential heart failure application. The SEISMO trial was initiated in June 2018 to evaluate the possibility of developing an algorithm that can differentiate patients referred with suspicion of heart failure. The study, with in total 199 patients at two sites in Denmark, included the last patient in 2020. “Completing the inclusion to the exploratory heart failure study was a great milestone for all involved. The new data looks promising for early heart failure rule out and will be important for all affected patients today waiting all too long for a final diagnosis. The data could warrant a follow-up study to consolidate findings and bring more data for algorithm development,” said Professor Peter Søgaard, MD and primary investigator. The results from the final analysis of the study data is expected to be submitted for publication in Q2 2021.

The complete Year-End report is available by link below or on www.acarix.com

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About Acarix:

Acarix was established in 2009 and is listed on Nasdaq First North Premier Growth Market (ticker: ACARIX). Acarix’s CADScor®System uses an advanced sensor placed on the skin above the heart to listen to the sounds of cardiac contraction movement and turbulent flow. It has been designed to be an all-in-one system in the sense that the heart signal will be recorded, processed, and displayed as a patient specific score, the CAD-score, on the device screen. Readout is obtained in less than 10 minutes. Safe and suitable for use in both out- and inpatient settings, the CADScor®System thus has the potential to play a major role in patient triage, avoiding the need for many patients to undergo stressful invasive diagnostic procedures.
Redeye AB (+46 (0)8 121 576 90, certifiedadviser@redeye.se) is Certified Adviser to Acarix.
For more information, please visit www.acarix.com.