



Press release (MAR)  
Malmö, May 14, 2020

## **Acarix AB (publ) publishes Interim Report, January – March 2020**

# Continued focus on strategic key priorities

During the quarter we have kept focus on our priorities along with managing the impact from the global Covid-19 situation. We have been in continued dialogue with both the US Food and Drug Administration, FDA, for our US market approval, and the German G-BA for the German reimbursement process.

*Extract from CEO Per Persson's message to the Interim Report.*

### **First quarter 2020 compared with same period 2019**

- During the first quarter, one CADScor®System was rented (5 systems were sold) and 370 (640) disposable patches were sold. Additionally, 240 patches were delivered for clinical trials.
- Revenue amounted to 121 kSEK (299), with gross profit of 109 kSEK (209) and a gross margin of 90 percent (70).
- Operational costs amounted 10,904 kSEK (13,038).
- Result before tax amounted to –10,815 kSEK (–12,822).
- Net cash flow from operating activities amounted to –8,575 kSEK (–13,101).
- Cash at the end of the period was 45,019 kSEK (51,581).
- Basic earnings per share amounted to –0.21 SEK (–0.56). No dilution arose.

### **Events in the first quarter, 2020**

- On January 14, 2020, the company announced the first commercial usage of the CADScor®System in the UK. Dr Amrit Takhar and his team at Wansford and Kingscliffe Practice, near Peterborough, UK, is the first clinic in the UK to use the unique CADScor technology to assess patients suffering from stable chest pain.
- On February 18, 2020, the company announced the initiation of the randomized, multi-center clinical study FILTER-SCAD to examine the cost effectiveness and safety of adding the CADScor®System as a rule-out test in patients referred with symptoms suggestive of stable coronary artery disease. In the FILTER-SCAD study, 2,000 patients referred on suspected stable coronary disease are to be consecutively enrolled at four hospitals in Denmark and Lund's University Hospital in Sweden.
- On March 12, 2020, the company received encouraging feedback from the German authorities, the Federal Joint Committee, G-BA, on its submission for reimbursement of the CADScor®System in Germany. "They conclude that the CADScor®System represents a promising technology and they see a potential fit with the German health care system which is positive," said Per Persson, CEO Acarix. "Now, our submission process will proceed to the next step whereby G-BA will review Acarix's latest updates in clinical evidence and ongoing studies, or as an alternative, suggest a local German confirmatory study. We are expecting additional comments by mid-year."
- During the first quarter of 2020, the Covid-19 pandemic broke out and the consequences of the outbreak have had a negative impact on Acarix since March, and there is a risk that this could lead to a negative financial impact on the Group. At Acarix, we are working to ensure that the business continues to operate to the best of our ability, but also with a focus on our employees' health. We do this primarily through a call to the company's staff to work from home and a travel ban. In our assessment of the immediate effects, we can conclude that the



patient recruitment in our ongoing clinical studies The Filter Scad Study and the Dan-NICAD II study have stopped which may delay the completion of the studies. In addition, the company has submitted a DeNovo application to the FDA (American Food and Drug Administration) for product approval prior to the launch of the CADScor®System in the US market. There is a risk that the approval process will be delayed.

With regard to the reimbursement process in Germany, it is ongoing with the G-BA (Federal Joint Committee). At the beginning of 2020, we received positive feedback from G-BA, which expected to return with further information in mid-2020. There is a risk that G-BA's feedback may be delayed.

Since most hospitals, health centers and even private clinics have restricted access to commercial operations, sales and markets are also affected to a great extent as long as the Covid-19 situation remains. Both international and national congresses and educational meetings have been suspended or postponed until the latter part of the year. All in all, this means that a large part of our commercial activities are affected by the corresponding shift as long as the Covid-19 crisis lasts. However, given the uncertain situation at present, it is not possible to estimate the full potential impact for Acarix.

### **Events after March 31, 2020**

- On May 11, 2020, the company announced that the last patient was included in the exploratory SEISMO study, which is evaluating the possibility of developing an early heart failure detection algorithm.

The complete interim report is available by link below or on [www.acarix.com](http://www.acarix.com)

### **For further information, please contact:**

Per Persson, CEO  
mail: [per.persson@acarix.com](mailto:per.persson@acarix.com):  
+46 736 005 990

Christian Lindholm, CFO  
mail: [christian.lindholm@acarix.com](mailto:christian.lindholm@acarix.com)  
tel: +46 705 118 333

### **About Acarix**

Acarix was established in 2009 and is listed on Nasdaq First North Premier. 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. Readings are obtained in less than 8 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 and invasive diagnostic procedures.

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