



Uppsala November 19th, 2020

PRESS RELEASE

AroCell AB (publ) Interim Report January 1st to September 30th, 2020

A word from the CEO

"Our work to ensure a positive outcome of our 510(k) submission to the FDA and thus the opportunity to sell the AroCell TK 210 ELISA as an IVD product in the US market continues unchanged. We have had an active dialogue with the FDA regarding our submission and the work has progressed according to plan. However, the FDA announced in October that they had to make certain priorities, which meant that the review of our 510(k) submission would initially be postponed for 90 days. It is mainly the strained situation around Covid-19 that makes the FDA need to make these priorities. It is of course a disappointment for AroCell that there will be a delay in the process of clearance of our 510(k). The work of preparing for the launch of AroCell TK 210 ELISA with primarily reimbursement plans, market access strategy, and launch activities continues. Our assessment remains that we can obtain clearance of our AroCell TK 210 ELISA from the FDA no later than the end of 2021."

Michael Brobjer, CEO

Reporting period July 1st - September 30th

- Net sales were 0 (120) KSEK
- Loss before financial items was -6 371 (-4 500) KSEK
- Cash flow from operating activities was -5 580 (-2 806) KSEK
- Earnings per share before and after dilution were -0,08 (-0,11) SEK
- Cash and cash equivalents were at the end of the period 45 848 (18 629) KSEK

Reporting period January 1st - September 30th

- Net sales were 64 (323) KSEK
- Loss before financial items was -18 040 (-14 702) KSEK
- Cash flow from operating activities was -15 068 (-11 268) KSEK
- Earnings per share before and after dilution were -0,25 (-0,37) SEK
- Cash and cash equivalents were at the end of the period 45 848 (18 629) KSEK

Events during the reporting period July 1st - September 30th

- A patent was granted by the Japanese Patent Office. The patent relates to AroCell's proprietary monoclonal antibodies used to determine the concentration of Thymidine kinase 1 in serum samples. These antibodies are used in AroCell TK 210 ELISA.



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- A patent was granted by the European Patent Office (EPO). The patent relates to AroCell's proprietary monoclonal antibodies used to determine the concentration of Thymidine kinase 1 in serum samples. These antibodies are used in AroCell TK 210 ELISA.
- AroCell implemented a change in the company's management. Cecilia Ahlin ended her employment as Chief Medical Officer (CMO). Gunnar Steineck, professor of oncology, was appointed as interim CMO.
- AroCell initiated a new collaboration with the University of Rome la Sapienza to evaluate Thymidine kinase 1 (TK1) and PSA in response to biomarkers after hormone therapy in castration-resistant prostate cancer patients. The goal is to help physicians get better treatment data by measuring TK1 as a response biomarker in castration-resistant metastatic prostate cancer patients who have been treated with hormone therapy.
- AroCell has had a dialogue with the US Food and Drug Administration (FDA) regarding the 510 (k) submission that the company submitted on May 26, 2020.

Events after the reporting period

- The FDA reports delays in the timeline for reviewing 510(k) applications, due to a large number of Emergency Use Authorization (EUA) requests they have received in in-vitro diagnostics (IVDs) due to COVID 19. Redistributions of staff and resources are expected to affect the timeline for reviewing applications. The FDA estimates the delay at about 90 days, which will delay the review of AroCell's 510(k) application.
- AroCell announced a new article published in the Journal of Immunological Methods. The article indicates that it is possible to design diagnostic algorithms for biomarkers that can help distinguish Mycoplasma pneumonia from other respiratory infections caused by bacteria or viruses.

Interim report January 1st - September 30th, 2020 (available in Swedish only) ([Link](#))

For more information:

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AroCell is obliged to make public this information pursuant to the EU Market Abuse Regulation. This information was submitted for publication through the agency of Michael Brobjer, November 19th, 2020 at 08:00.



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About AroCell

AroCell AB (publ) is a Swedish company that develops standardized modern blood tests to support the prognosis and follow up of cancer patients. AroCell's new technology is based on patented methods to measure Thymidine Kinase 1 (TK1) protein concentrations in a blood sample. The TK 210 ELISA test provides valuable information mainly about the condition of cancer patients. This may help clinicians to optimize treatment strategies and estimate the risk of recurrence of tumor disease during the monitoring of the disease. AroCell (AROC) is listed at Nasdaq First North Growth Market with Redeye AB as Certified Adviser: Certifiedadviser@redeye.se, +46 (0)8 121 576 90. For more information; www.arocell.com