AroCell AB (publ)

Interim report, 1 January – 30 September 2015

- *Net sales were TSEK 0 (0)*
- *Loss after financial items was TSEK -5,857 (-3,610)*
- *Earnings per share where SEK -0.25 (-0.19)*
- *Cash flow from operating activities was TSEK -4,676 (-3,284)*

Reporting period, 1 July – 30 September 2015

- *Net sales were TSEK 0 (0)*
- *Loss after financial items was TSEK -1,811 (-1,064)*
- *Cash flow from operating activities was TSEK -891 (-491)*
- *TK 210 ELISA test successfully passes phase 1 review of production process*
- *AroCell recognized by EU Commission and Horizon 2020*
- *CE-marking of TK 210 ELISA achieved*
- *Continued expansion to AroCell organization*

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 TK1 protein levels, which provide valuable information concerning the speed of cell turnover. A tumor has high cell turnover (speed of cell division and cell death) and as a result TK1 can be detected in the blood with a simple laboratory test, called TK 210 ELISA. The test provides valuable clinical information for prognosis and optimization of treatment strategy. The test may also be used for monitoring disease relapse. AroCell is listed on the AktieTorget marketplace in Sweden and has about 2,300 shareholders. For more information, please see www.arocell.com.

Significant events during the reporting period

- AroCell's TK 210 ELISA product successfully passed phase 1 verification review, which is a critical milestone in development of the production process for the TK 210 ELISA test. This verifies that the production process can attain full-scale product production.
- Two clinical studies have been completed and with analysis of results. Both studies indicate that the TK 210 ELISA product delivers the required performance for clinical use and for CE-marking.
- AroCell has been recognized as "one of the companies with the most innovative ideas in the world" by the EU Commission and the Horizon 2020.
- AroCell has filed TK 210 ELISA for the CE-mark registration at the Swedish Medical Products Agency (Läkemedelsverket). The CE-mark is a symbol of quality and is an essential step for the continued clinical validation needed to obtain full clinical acceptance of a diagnostic product.

Significant events after the reporting period

- AroCell reinforces the company organization with the employment of Kiran Kumar Jagarlamudi, PhD as product specialist.
- AroCell presented its TK 210 ELISA test at the annual ISOBM (International Society of Oncology and Biomarkers) congress on October 3-7, 2015 in Zakopane, Poland. The TK 210 ELISA test was presented as a robust tool for researchers and clinicians, with good sensitivity and product performance in measuring TK1 protein in serum.
- The Board of Directors has resolved on November 5, 2015, with support of the decision taken at the Annual General Meeting, a preferential rights issue of a maximum of 5 213 546 shares. Full subscription of the preferential rights issue will provide AroCell with a maximum of approximately 52.2 MSEK before issue expenses. The company has received subscription undertakings from members of the board of directors, management and the company's largest shareholders and signed agreements accordingly to fully guarantee the preferential rights issue.

Comments from Jan Stålemark, CEO of AroCell

AroCell has now achieved an historical milestone. Our TK 210 ELISA test kit has been fully developed, achieved the CE-mark and is now commercially available, primarily for research and clinical development. It is the first and only ELISA kit on the market that can measure TK1 protein in serum from a standard blood sample. This fully enables us to initiate the next step in our plan – the critical and final clinical validation to confirm the clinical value of our product. We have already demonstrated how well the product has worked in smaller clinical studies, and established that the sensitivity is now sufficient to be used for several different types of cancers.

It is a very valuable investment to conduct clinical studies with this type of product as early as possible in order to effectively drive the marketing and sales efforts based on strong evidence-based clinical results. The results from these clinical studies will also establish the basis to generate health economic data. This data in turn is critical to create opportunities to obtain health care reimbursement for the TK 210 ELISA test in health care reimbursement systems. Without reimbursement, it is extremely unlikely that the product will be used frequently and successfully on a large scale. Our clinical development efforts are therefore one of the cornerstones in our plan for a successful market introduction

The results from planned clinical studies will be presented continually during the next three year period. The first results may already be presented already during the first six months of 2016, with access to planned biobank materials as a prerequisite. These results will be based on retrospective studies, which enable a relatively short process for data collection and analysis. We plan to conduct several of these studies and present results continually during this time period. We also plan to conduct so-called prospective studies as early as possible. These studies are based on collected samples for continuous analysis during the study period, which means that these types of studies take a more significant amount of time, up to five years before final results are available.

We currently have a very good product with performance that fulfils the requirements of a highly competitive in vitro diagnostic test. During development, we have also identified good opportunities to continue to improve product performance and to reduce production costs. We therefore plan to initiate a project during 2016 to optimize production.

As we have previously reported, we have determined that this preferential rights issue will provide us with enough resources to complete the clinical development of TK 210 ELISA and will create significant value for an established in vitro diagnostic company in the large and rapidly-changing market of cancer diagnostics.

Essential risks

Financial risks
AroCell's business activities are based on external financing. To date, the company has been successful in obtaining financing, but there are no guarantees of this happening in the future in a way that is advantageous to the company's shareholders. A sufficiently serious failure in future financing may affect the company's development and market value.

Development and production risks
Development and transfer to production are always associated with risks. A product manufactured at production scale does not always display exactly the same characteristics as one manufactured at research scale. Developing future products may also prove to be more complicated and take longer than expected.

Commercialization risks
There is always a risk that the products AroCell has developed will not achieve the expected positive reception on the market and that the product will need longer to gain acceptance. Particularly in the early stages, the quantity of products sold may then be lower and the time it takes to establish the product on the market may be longer than the company allowed for in its sales estimates.

In addition, there are risks associated with patent security and how the market assesses studies, approvals and certifications. Taking risk factors into consideration in decision processes and when designing routines and drawing up documentation means that the risks are assessed and their effects can be minimised and, to some extent, avoided.

Accounting principles

The interim report has been prepared in accordance with the same accounting principles as in the company's most recent annual report, i.e. pursuant to the Swedish Annual Accounts Act and taking into consideration general guidelines, recommendations and statements issued by the Swedish Accounting Standards Board.

The share
AroCell AB (publ) was listed on the AktieTorget marketplace on 25 May 2011. At 30 September 2015, there were 23,460,960 shares (quota value SEK 0.10)

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Financial calendar

2016-02-16	Year-End report 2015
2016-05-10	Interim report no. 1 2016
2016-05-18	Annual general meeting 2016
2016-08-25	Interim report no. 2 2016
2016-11-17	Interim report no. 3 2016
2017-02-16	Year-End report 2016

The interim report has not been reviewed by the company's auditor.

Submission of interim report
Uppsala, 10 November 2015

The Board of Directors

Summary Income statement

(TSEK)	2015 Jul-Sep 3 mths	2014 Jul-Sep 3 mths	2015 Jan-Sep 9 mths	2014 Jan-Dec 9 mths	2014 Jan-Dec full year
Net sales	0	0	0	0	0
Operating expenses	-1,804	-1,054	-5,837	-3,566	-3,667
Depriciation of tangible fixed assets	-2	-8	-6	-25	-33
Operating loss	**-1,806**	**-1,062**	**-5,843**	**-3,591**	**-3,700**
Financial income	0	5	0	12	36
Financial expenses	-5	-7	-14	-31	-69
Loss after financial items	**-1,811**	**-1,064**	**-5,857**	**-3,610**	**-3,733**
Income taxes	0	0	0	0	0
Loss for the period	**-1,811**	**-1,064**	**-5,857**	**-3,610**	**-3,733**

Summary balance sheet

(TSEK)	2015 Sep 30	2014 Sep 30	2014 Dec 30
ASSETS			
Fixed assets			
Intangible assets	21,182	16,544	17,826
Tangible assets	15	23	21
Total fixed assets	**21,197**	**16,567**	**17,847**
Current asset			
Inventories	1,439	1,519	1,578
Other receivables	285	181	664
Cash and cash equivalents	10,331	4,144	18,513
Total current assets	**12,055**	**5,844**	**20,755**
Total assets	**33,252**	**22,411**	**38,602**
EQUITY AND LIABILITIES			
Share capital	2,346	1,920	2,346
Other contributed capital and reserves	33,374	22,020	39,743
Non-restricted equity	-5,857	-3,610	-6,369
Total equity	**29,863**	**20,330**	**35,720**
Long-term liabilities	0	200	150
Current liabilities	3,389	1,881	2,732
Total equity and liabilities	**33,252**	**22,411**	**38,602**

Summary cash flow statement

(TSEK)	2015 Jul-Sep 3 mths	2014 Jul-Sep 3 mths	2015 Jan-Sep 9 mths	2014 Jan-Dec 9 mths	2014 Jan-Dec full year
Cash flow from operating activities	-891	-491	-4,676	-3,284	-5,726
Cash flow from investing activities	-1,352	-2,206	-3,356	-5,411	-6,699
Cash flow from financing activities	-50	-94	-150	7,844	25,943
Cash flow from the period	**-2,293**	**-2,791**	**-8,182**	**-851**	**13,518**

Cash and cash equivalents at beginning of period	12,624	6,935	18,513	4,995	4,995
Cash and cash equivalents at end of period	**10,331**	**4,144**	**10,331**	**4,144**	**18,513**

Share data

	2015 Jan-Sep	2014 Jan-Dec	2014 Jan-Dec
Earnings per share (SEK)			
Before dilution	-0.25	-0.19	-0.32
After dilution	-0.25	-0.18	-0.32
Average number of shares			
Before dilution	23,460,960	19,035,542	19,786,428
After dilution	23,460,960	19,669,291	19,786,428
Number of shares on balance sheet date			
Before dilution	23,460,960	19,195,332	23,460,960
After dilution	23,460,960	23,460,960	23,460,960

Change in equity (TSEK)

	Share capital	Other contributed capital	Retained earnings incl. loss for the year	Total equity
Opening balance	**2,346**	**39,743**	**-6,369**	**35,720**
Allocation in accordance with resolution at AGM		-6,369	6,369	
Loss for the period			-5,857	**-5,857**
Closing balance	**2,346**	**33,374**	**-5,857**	**29,863**