

# AroCell AB (publ) Year-End Report

Report for period 1 January – 31 December 2016

- Net sales were 59 (0) KSEK
- Loss after financial items was 9,235 (-7,479) KSEK
- Earnings per share were -0.32 (-0.26) SEK
- Cash flow from operating activities was -7,168 (-9,127) KSEK

### Reporting period 1 October – 31 December 2016

- Net sales were 13 (0) KSEK
- Loss after financial items was -1,840 (-1,622) KSEK
- Cash flow from operating activities was -3,882 (-2,442) KSEK
- Work was initiated to construct a company-owned laboratory for product development use as well as customer support and service.
- Ann Hammarstrand was appointed as new CFO and Kris Rydholm Överby was appointed PR/Marketing Communication Manager.

This information is information that AroCell is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through Jan Stålemark, at 08:15 CET on 16 February 2017.

#### About AroCell

AroCell AB (AROC) 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 about 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 (AROC) is listed at Nasdaq First North and has about 2,600 shareholders. For more information, please see www.arocell.com. Redeye AB is AroCell:s Certified Adviser.



#### Significant events during the reporting period

- A clinical study using TK 210 ELISA on serum samples from breast cancer patients showed significantly higher sensitivity compared to available TK1 activity tests. The study also showed increased diagnostic sensitivity when combined with the most-used serum biomarker CA 15-3 supporting the potential of our product to be used for the purpose of better treatment planning.
- AroCell strengthens its IP protection. The European Patent Office granted AroCell a patent related to an invention relating to exposed Thymidine Kinase 1 (TK1) derived peptides, ligands and methods employing these.
- Christine Tadgell, VP Commercial Group, inVentiv Health joined the board of AroCell.
- Clinical validation for prostate cancer application started in a prospective study at Stockholm South General Hospital. The study aims to provide better information to the clinicians how to treat patients with suspected and confirmed prostate cancer. The study is expected to be concluded during autumn 2018.
- TK 210 ELISA is being validated as one of very few biomarkers available for patients with sarcoma. A clinical study regarding sarcoma cancer using TK 210 ELISA was initiated at Helsinki University Hospital in a national study in Finland to evaluate the prognostic value, monitoring of treatment effect and follow up after treatment for early detection of relapse. The study is expected to be concluded by autumn 2018 and will potentially make TK 210 ELISA a new and unique biomarker for patients with sarcoma.
- AroCell was listed on the Nasdaq First North exchange on June 30.
- An abstract on the improved performance of the 0-calibrator for TK 210 ELISA was accepted and presented at the ISOBM conference by AroCell in Chicago September, 2016. TK 210 ELISA sensitivity has thus been improved making discrimination between healthy individuals and patients with disease significantly better.
- AroCell signed a distribution agreement with Eagle Biosciences Inc. Eagle Biosciences will initially focus on cancer research centres in the North American marketplace. North America represents approximately 50% of the global IVD market.
- A chemistry laboratory was established in new facilities at the company headquarters in Uppsala. This will improve capacity of product development, quality control and customers support.
- Management team strengthened with the appointment of Martin Shaw as Business Development Manager. Martin brings over 40 years of experience in the biomarker and the IVD business. The executive management group strengthened with the appointment of new CFO Ann Hammarstrand. Her long experience in financial management and multiple executive roles in life science companies with worldwide responsibilities adds very important experience to the company as AroCell expands on the global IVD market.
- AroCell strengthens market communication and PR. Kris Rydholm Överby has been appointed as PR and Marketing Communication Manager. Kris brings more than 30 years of marketing experience from multiple international life sciences companies and



being a certified medical writer which will be important function for the company as study results become available from the clinical validation of TK 210 ELISA.

#### Significant events after the reporting period

 A scientific poster has been accepted by AARC, American Association of Cancer Research, 2017 for presentation at their annual meeting in April. Preliminary results from AroCell's TK 210 ELISA test showed significant correlation with Prostate Health Index (PHI), a new index to determine patient status for patients with suspected or confirmed prostate cancer. The study compare AroCell's TK 210 ELISA test with other commonly used test methods such as PSA, free PSA, pro PSA and PHI in men with pre-cancerous conditions and confirmed prostate cancer indicates that AroCell's TK 210 ELISA test provides valuable clinical information.

#### Comments by CEO Jan Stålemark

2016 has been a very active and rewarding year for AroCell. The continued clinical validation is a key component in our strategy to attain clinical acceptance and successfully introduce our product on the global in vitro diagnostic market for multiple applications within cancer therapy.

Two recent studies indicate that our product TK 210 ELISA adds clinical value independently and when combined with other biomarkers. This supports one of the very strong trends in the diagnostic market which is the use of biomarker panels.

The first study, published in Journal of Tumor Biology, showed that our test has higher sensitivity and specificity than one of the most currently used biomarkers for breast cancer, CA 15-3. The study also showed that our test in combination with the CA 15-3 biomarker further increases both sensitivity and specificity to identify patients with tumors. The second study compared our TK 210 ELISA with the well-known biomarkers PSA, free PSA, pro PSA and Prostate Health Index (PHI) in men with suspected or confirmed prostate cancer. TK 210 ELISA shows significant correlation with PHI which support that TK 210 ELISA can provide important clinical information on prostate cancer patients supporting the potential of our product to be used for the purpose of better treatment planning. A scientific poster on this study has been accepted by AACR (American Association for Cancer Research) 2017 for presentation at their annual meeting in April in Washington DC.

Two prospective studies are currently ongoing, in prostate cancer and sarcoma. The prostate cancer study aim to establish TK 210 ELISA as a complementary biomarker for certain prostate cancer applications. The sarcoma study will potentially make TK 210 ELISA a new and unique biomarker for patients with sarcoma. Twenty-five percent of children with cancer are diagnosed with sarcoma. Early detection of relapse may lead to curative treatment for these patients. Both studies are estimated to be finished by the end of 2018.

The company strategy to address the clinical research centres has started with the collaboration with our distributor in the US, Eagle BioSciences Inc. We are also building awareness in EU and now begin to see interest from the customers. The plan is to continue and work through distributors also in EU and other parts of the world. In the first phase, we target primarily the clinical research and pharmaceutical development segments which is in line with our strategy to build clinical evidence for our product in many applications.

Our product is the first and only CE-marked ELISA kit on the market that can measure concentrations of TK 1 protein in serum from a simple blood test. The TK 210 ELISA test

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has a standardized format that is available for use in all modern clinical chemistry laboratories which makes it very easy to introduce to new customers for our new Business Development manager.

AroCell now has positive study results in several therapeutic areas, which means we can now begin to more aggressively talk about the clinical application of TK 210 ELISA as a valid biomarker either alone or within a panel of biomarkers. We have engaged a distributor to do this in the US and a Business Development manager in the EU so that we can raise awareness and interest in our unique product. The total market for cancer diagnostics is large\* and growing and the market share potential for AroCell can be very significant.

We expect to share new interesting results in the clinical validation of our product and that we will begin to translate these results into market opportunities throughout 2017.

Jan Stålemark CEO

\* Kalorama Information 6<sup>th</sup> Edition 2014, Global IVD market for cancer was estimated to 22.6 billion US dollars

#### **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 not 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 time 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.

#### Currency risks

The company expenses are partially based in Euro, and this means that there is a risk that weakening of the Swedish krona against the Euro may lead to increased expenses for the company. A portion of the sales proceeds in future can be associated with currencies from other countries, which means that there is a risk that if the Swedish krona becomes stronger to other currencies, this may lead to decreased profits for the company in SEK.

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 minimized, and to some extent, avoided.



#### The share

AroCell AB (publ) was listed on Nasdaq First North, Stockholm, June 30 2016 under AROC. On December 31 2016 there were 28 674 506 shares (quota value SEK 0,10).

Largest shareholder	Shares	Votes %
Namn	2016-12-31	
FÖRSÄKRINGSAKTIEBOLAGET, AVANZA PENSION	3,373,889	11,77%
TRIBUKAIT, BERNHARD	1,236,796	4,31%
STAFFAN ERIKSSON MED BOLAG	1,077,862	3,76%
NORDNET PENSIONSFÖRSÄKRING AB	798,207	2,78%
JON EIKEN	650,000	2,27%
GUNVALD BERGER	634,852	2,21%
OLLE STENFORS	540,000	1,88%
UBS SWITZERLAND AG /CLIENTS ACCOUNT	497,529	1,74%
SWEDBANK	351,210	1,22%
HÅKAN ENGLUND MED BOLAG	341,478	1,19%
Övriga	19,172,683	66,86%
Total	28,674,506	100,00%

#### **Dividend proposal**

The board proposes that no dividends should be issued for the accounting year of 2016.

#### Accounting principles

This Year End Report has been prepared in accordance with the Swedish law: Årsredovisningslagen and Bokföringsnämndens allmänna råd BFNAR 2012:1 Årsredovisning och Koncernredovisning (K3).

#### **Report review**

This Year End Report has not been reviewed by the company auditor.

#### **Contact information**

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#### **The Annual General Meeting**

The Annual General Meeting will be held on Wednesday 18 May 2017 at 15.00 hours at the corporate headquarters at Virdings allé 32 B i UPPSALA.

#### **Financial information**

The Annual Report will be published on the company website <u>www.arocell.com</u> at least two weeks prior to the Annual General Meeting and will then also be available from the company at info@arocell.com.



#### **Financial calendar**

 2017-05-11
 Interim report 1 2017

 2017-05-18
 Annual General Meeting

 2017-08-24
 Interim report 2 2017

 2017-11-23
 Interim report 3 2017

 2018-02-22
 Year End Report 2017

#### Delivery of interim report

Uppsala February 15, 2017

The board of directors

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#### Summary Income statement

(TSEK)	<b>2016</b> <b>Oct-Dec</b> 3 mths	<b>2015</b> <b>Oct-Dec</b> 3 mths	2016 Jan-Dec full year	2015 Jan-Dec <sup>full</sup> year
Net sales	13	-	59	
Operating expenses	-1,904	-1,641	-9,280	-7,478
Depreciation of tangible fixed assets	-4	-1	-8	-7
Operating loss	-1,895	-1,642	-9,229	-7,485
Financial income/expenses	55	20	-6	6
Loss after financial items	-1,840	-1,622	-9,235	-7,479
Income taxes	-	-	-	-
Loss for the period	-1,840	-1,622	-9,235	-7,479
Summary balance sheet				
(TSEK)			2016	2015
			Dec 31	Dec 31
ASSETS				
Fixed assets				
Intangible assets			31,328	21,810
Tangible assets			170	14
Total fixed assets			31,498	21,824
Current asset				
Inventories			1,419	1,419
Other receivables			652	1,378
Cash and cash equivalents			32,852	49,702
Total current assets			34,923	52,499
Total assets			66,421	74,323
EQUITY AND LIABILITIES				
Share capital			2,867	2,867
Other contributed capital and reserves			69,824	77,303
Non-restricted equity			-9,235	-7,479
Total equity			63,456	72,691
Long-term liabilities			0	0
Current liabilities			2,965	1,632
Total equity and liabilities			66,421	74,323
Summary cash flow statement				
(TSEK)	2016	2015	2016	2015
、 <i>,</i>	Oct-Dec 3 mths	Oct-Dec 3 mths	Jan-Dec full year	Jan-Dec full year

	3 mths	3 mths	full year	full year
Cash flow from operating activities	-3,882	-2,442	-7,168	-9,127
Cash flow from investing activities	-2,287	-1,288	-9,682	-3,984
Cash flow from financing activities	0	18,099	0	44,300
Cash flow from the period	-6,169	14,369	-16,850	31,189
Cash and cash equivalents at beginning of				
period	39,021	4,144	49,702	18,513
Cash and cash equivalents at end of period	32,852	18,513	32,852	49,702



Share data	2016 Jan-Dec	2015 Jan-Dec
Earnings per share (SEK)		
Before dilution	-0,32	-0,26
After dilution	-0,32	-0,26
Average number of shares		
Before dilution	28,674,506	28,674,506
After dilution	28,674,506	28,674,506
Number of shares on balance sheet date		
Before dilution	28,674,506	23,797,318
After dilution	28,674,506	23,797,318