

Platform Expansion: Breast Cancer Diagnostic Test Update

Highlights

- ✓ Preliminary results from Agilex Stage 1 study show positive results.
- ✓ Rhythm has identified four biomarkers with preliminary results of 83% Sensitivity and 90% Specificity.

Rhythm Biosciences Ltd (ASX: RHY) (“Rhythm” or the “Company”) is pleased to provide an update on its cancer diagnostics technology platform expansion program in breast cancer. As previously announced (ASX: RHY - 19 June 2023), together with Agilex Biolabs, Rhythm has identified 4 biomarkers that exhibit a strong correlation with specific breast cancer subtypes.

The preliminary assessment of the potential biomarkers was performed by Agilex in a “research use only” immunoassay study to evaluate these blood-based biomarkers from 100 breast cancer patients and 100 healthy volunteers. This early-stage R&D has identified important biomarker combinations that can distinguish between patients with breast cancer and healthy controls, with a **83% sensitivity and a 90% specificity** ($P \leq 0.0003$).

Breast cancer subtypes and stages identified in this study are in the following table.

BC Subtypes and Controls	Stage 0	Stage I	Stage II	Stage III	Stage IV	Total
Healthy Controls						100
Infiltrating Ductal Carcinoma		26	25	16	7	74
Infiltrating Lobular Carcinoma		1	7	3		11
Infiltrating Ductal and Lobular Carcinoma		1	2			3
Infiltrating Tubular Carcinoma			1			1
Carcinoma in Situ	5					5
Mucinous Carcinoma		1	2			3
Acinar cell Carcinoma		1				1
Cribiform Carcinoma			1			1
Metaplastic Carcinoma				1		1
Total	5	30	38	20	7	200

The 5-year survival rate for Stage 1 (early) breast cancer is, on average, 100% and Stage 2 is 95%. For locally advanced cancers (known as Stage 3) the survival rate is 81%, while the 5-year survival rate for Stage 4 (metastatic breast cancer) is significantly lower at 32%. – National Breast Cancer Foundation

These encouraging results warrant confirmation in a larger sample set and justify the continuation and advancement of the project.

Verification of these results would support the case for investment in a new R&D program to develop, validate, clinically evaluate the performance of the biomarkers, and translate these results into a commercially scalable, proprietary blood test for the early detection of breast cancer.

Globally, breast cancer has become the most diagnosed cancer, with 2.3 million women affected by the disease each year.¹ Over the 5 years from 2016 - 2020, there were 7.8 million women that were diagnosed with breast cancer, making it the world’s most prevalent cancer.²

In 2019 - 2020, 3.5 million women were invited to participate into the BreastScreen Australia Program. 1.8 million (~50%) women participated in the program.³

There is a clear need to improve the participation rate and the potential to save lives with an alternative to current screening practices. Not unlike, ColoSTAT®, which is aimed at providing a simple blood test for the early detection of colorectal cancer, the team at Rhythm will look to advance this project to provide a simple blood test for the early detection of breast cancer.

- ENDS -

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of Rhythm Biosciences Limited.

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About Rhythm Biosciences

Rhythm Biosciences Ltd (ASX: RHY) is an Australian innovative, medical diagnostics company aimed at delivering simple, affordable blood tests for accurate and early detection of cancers. Rhythm is focused on improving patient outcomes through detection at the earliest possible stage, reducing the global burden of cancer and saving lives.

Rhythm Biosciences is committed to working with likeminded global partners to achieve commercialisation and distribution of these simple solutions.

The company was founded in 2017 and is headquartered in Melbourne, Australia. For more information, visit rhythmbio.com and follow the company on LinkedIn and Twitter.

About ColoSTAT®

Colorectal cancer (CRC), also referred to as bowel cancer, is the second leading cause of cancer deaths globally. If diagnosed early, colorectal cancer is curable.

The ColoSTAT® Test-Kit is Rhythm Bioscience's simple blood test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood presence of CRC. The test can be used as an alternative for individuals who are unable or unwilling to participate in current screening programs.

The ColoSTAT® Test-Kit is based on research from Australia's CSIRO and is patent protected internationally. It has the potential to play a key role in reducing the mortality rate and healthcare costs associated with colorectal cancer.

1. <https://www.breastcancertrials.org.au/breast-cancer-resources/breast-cancer-statistics/#:~:text=Breast%20Cancer%3A%20The%20Most%20Common,commonly%20diagnosed%20cancer%20in%20women>
2. <https://www.who.int/news-room/fact-sheets/detail/breast-cancer>
3. <https://www.aihw.gov.au/reports/cancer-screening/national-cancer-screening-programs-participation/contents/breastscreen-australia/participation>