

A Medical Diagnostics Technology Company

Early detection of colorectal cancer using a simple and low cost blood test

AGM presentation October 2019





Colorectal Cancer: Introduction

Colorectal cancer is the second largest cause of cancer-related deaths in the industrialised world with over 850,000 deaths annually

Curable in over 90% of cases if detected early, this drops to around 10% if detected late, once the cancer has spread

The current standard diagnostic screening test is the Faecal Immunochemical Test (FIT), only detecting blood in the faeces





ColoSTAT® by Rhythm Biosciences

ColoSTAT® A simple, accurate & low cost blood test for early detection of colorectal cancer, suitable for the global mass market



ColoSTAT[®] is designed to detect colorectal cancer at all stages An Australian innovation pioneered & developed by CSIRO over 13 years A simple blood test using protein based biomarkers that integrates with existing pathology infrastructure

Low cost & patient friendly – suited to global mass screening market



Market Opportunity – Global screening



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The Issue with FIT: Low Participation



ColoSTAT® Effectiveness

Sensitivity of ColoSTAT[®] at Specificity of 95%



Fung et al. Blood-based protein biomarker panel for the detection of colorectal cancer. PLoS One (2015) 10 3.

Morikawa et al., Gastroenterology (2005); 129: 422-428

Specificity of 95% is the gold standard: it is an inverse measure of false positive rate, therefore a tests specificity is the ability of the test to correctly identify those without the disease (true negative rate). If you lower specificity, you may see a higher sensitivity result.



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Faecal Immunochemical Test (FIT)

Patient Preference	×
Accuracy	X
Early Stage Detection	
Affordability	
Simple Process	X
Opportunistic Screening*	×

ColoSTAT's[®] combination of advantages can potentially drive higher compliance to screening & ultimately save more lives

* ColoSTAT[®] blood test can be completed at GP clinic during a regular visit



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Competitive Landscape – ColoSTAT's® Unique Advantage



• FIT = Faecal Immunochemical Test

** FOBT = Faecal Occult Blood Test

RHYTHM

BIOSCIENCES

Potential ColoSTAT[®] Market



The colorectal cancer screening market (50-74 population)[#] across US/EU/AU/CHN/JPN \$38.49bn

*Assumption of \$50 AUD per test. RHY revenue may vary to this estimate #Total screening market = all 50-74 year olds x \$50 AUD

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RHY simple, accurate, low cost blood test will fill a unique space in the mass screening market



Go to Market Options

Multiple avenues & market segments reduce risk and support a flexible and scalable business model

National Screening Program/MBS Reimbursed

With its effectiveness & affordability, ColoSTAT[®] is well suited to mass market screening as a direct replacement for national screening programs led by government, health insurers or GPs

Private Market

- ColoSTAT[®] can be used by GPs or in hospitals as a diagnostic
- Led by health insurers, GPs, hospitals



Secondary Triage

 As a transition,
ColoSTAT[®] can be used as a follow up secondary test for those with a positive FIT test prior to an invasive colonoscopy

Global Partnerships

 Partnership, licencing, joint-venture options, market specific. Maximize IP



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- Progressed key lead biomarker development
- Commenced clinical trial recruitment (Study 7)
- ✓ ISO13485 Quality Certification achieved
- Advanced reagent development program
- Advanced kit development program
- Commenced manufacturer selection process
- Strong management & board
- Ongoing CSIRO relationship remains strong



- ✓ Test optimisation on track for completion early-mid 2020
- Reagent and test kit development on track for completion mid 2020
- Series of analytical & de-risking tests (Study 6) on track for completion mid-late 2020
- Clinical trial on track for recruitment completion mid 2020
- Regulatory documentation preparation has commenced & on track for CE & TGA regulatory submissions in FY21
- Identify key sales, distribution & diagnostic companies for partnering
- Identify and consolidate alliances with health insurers, governments



Summary

As a simple, accurate & low cost blood test, Rhythm's ColoSTAT® has potential to substantially increase global screening & save lives

1 Significant Opportunity

Mass screening market worth \$38+bn pa for people aged 50-74 in the US, EU, CH, JP & AU. Market wants change

2 Sound technology

13+ years of research & testing pioneered by CSIRO* giving confidence in the biomarkers selected

3 Simple Business Model

ColoSTAT[®] test integrates with existing pathology infrastructure (no capital spend, can reduce labour)

4 Scalable commercial model

Scalable & flexible implementation by market & segment

5 **Experienced Team**

Long tenure with successful history in both diagnostic & healthcare sectors

6 Product differentiation

Patient preference for a simple blood test

* CSIRO - Commonwealth Scientific and Industrial Research Organisation is an independent Australian federal government agency responsible for scientific research



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