



2023 AGM INVESTOR PRESENTATION

10 OCTOBER 2023



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Introduction

“*Rhythm Biosciences is committed to saving lives through early detection of cancers using simple and accurate diagnostic technology*”

- **Early detection** is critical to improving patient outcomes and reducing the global burden of cancer;
- Developing **alternative** screening solutions for specific cancers via patient friendly, simple blood tests is our primary focus; and
- Rhythm’s initial product, ColoSTAT[®] is a **simple, affordable and effective blood test** for the early detection of colorectal cancer for global mass-market screening.

Board and Management



Otto Buttula
Executive Chairman

- Extensive financial, investment, IT and biotech experience
- Co-Founder and CEO of IWL (ASX: IWL); Founder / former CEO of Investors Mutual
- Formerly a Director of Imugene (ASX: IMU) and Chairman of Investorfirst, now HUB (ASX: HUB)
- Chairman of HITIQ (ASX: HIQ) and Oncosil Medical (ASX: OSL)



Trevor Lockett PhD
Technical Director

- Former Theme Leader Colorectal Cancer and Gut Health CSIRO
- Leader – Personalised Health Group CSIRO
- Inventor on seven commercially-licensed patent families



Sue MacLeman
Independent,
Deputy Chair

- Non-executive member of Planet Innovation Holdings, ATSE and OMICO (Australian Genomic Cancer Medicines Ltd)
- Member of the NSW Innovation and Productivity Council
- Fellow of the Australian Academy of Technology and Engineering (ATSE)



Dr Rachel David
Non Exec Director

- Currently the Chief Executive Officer (CEO) of Private Healthcare Australia (PHA)
- Previously: Senior Director Government Affairs, Policy and Market Access for Johnson & Johnson
- Various senior roles with McKinsey, CSL and Pfizer (formally Wyeth)



Lou Panaccio
Non Exec Director

- Chairman of Avita Medical (ASX: AVH)
- Non-executive Director of Sonic Healthcare (ASX: SHL)
- Chairman of NeuralDX
- Non-executive Director of Adherium (ASX: ADR)
- Non-executive Director of Unison Housing
- Former CEO Melb Pathology & Monash IVF

Paul Smith
CFO / Joint
Company Secretary

Andrea Steele
Legal Counsel / Joint
Company Secretary

Darren Moulton
Head of
Operations

Elena Deak
Chief Commercial
Officer

Guy Carisbrooke
Financial
Controller

Company Overview

Capital Structure at 9 October 2023

ASX Code	RHY
Share Price	\$0.32
Shares on Issue	221.1 M
Unlisted Options	12.2 M
Market Capitalisation	\$92.8 M
Cash in bank (30 Sept 2023)	\$1.6M
Top 20 Shareholders	40.7%

Share Price Chart



Disruptive Technology

An alternative to current screening methods through a well-established ELISA based technology



Global Capacity

Manufacturing capability for our target markets



Commercialisation

Maximising sales through private markets

Automating assay to assist easier expansion into other markets

ColoSTAT® patented in 21 countries



Partners

Signed a collaborative UK partnership with LINK Medical Solutions

Developing further strategic partnerships in international jurisdictions

Why we are here and why ColoSTAT®?

Global burden in 2020:

1.93 million new cases and ~940,000 deaths, CRC is the second largest cause of cancer death¹

CURRENT TESTING & SCREENING REGIME

In most countries, screening is recommended for those aged between 50-74 years old, with a faecal immunochemical test (FIT), which detects for **blood** in the stool.



CRC INCIDENCE IS ON THE RISE IN THE YOUNGER POPULATION

Data from major markets show that 11-15% of people diagnosed with CRC are below the age of 50,² posing a tremendous public health challenge, premature death and increased healthcare costs.¹ Researchers predict that by 2030, CRC will be the leading cause of death in people aged 20-49.³

5-year survival rates for those diagnosed at an early stage* of CRC are over 90%,⁴ but sub-optimal participation rate is the contributor to late diagnosis

Barriers to overcome and improve participation rate include:

- “Old Persons’ Disease”
- Cultural barriers
- Physical disabilities
- YUK factor

ColoSTAT®, simple blood test, detects protein biomarkers indicative of an increased likelihood for CRC, can provide:

- ALTERNATIVE TO FIT
- Increase participation rate in CRC testing
- Improve early diagnosis and outcomes
- Reduce healthcare costs associated with CRC treatment

* Stages I/II, CRC; colorectal cancer

1. Xi Y, Xu P (2021), Global colorectal cancer burden in 2020 and projections to 2040, Translational Oncology, 14(10), 101174, doi:10.1016/j.tranon.2021.101174 Epub 2021 Jul 6, 2. <https://www.cancer.net/cancer-types/colorectal-cancer/risk-factors-and-prevention#:~:text=About%2011%25%20of%20all%20colorectal,cancer%20in%20the%20United%20States>, 3. <https://www.ccalliance.org/about/never-too-young/know-the-facts>, 4. Hughes et al. J Community Health. Author manuscript; available in PMC 2016 October 25

ColoSTAT® last 12 months (FY23)

Regulatory

TGA application withdrawn. June 23 guidance document for ISO 13485 and IVDD to IVDR has increased requirements

Renewed patents across 21 countries

People

Management team expanded and renewed

Product

Pipeline projects (breast, lung, gastric) initiated

Further refinement of ColoSTAT® (shelf life, stability, components, algorithm)

External focus

Australia/UK advisory meeting with Key Opinion Leaders

International recognition for ColoSTAT® at ASCO

Regulatory approval in UK and New Zealand

Strategic partnership with Link Medical Solutions in UK

Platform Technology Expansion – Stage 1



STAGE 1 Progression		Theoretical Analysis of Biomarker Potential	Serum and Algorithm Analysis	Risk Analysis → Enter Stage 2
Cancer Type	Collaborator			
Breast	Agilex Biolabs	Progression bar spanning from Theoretical Analysis to Serum and Algorithm Analysis		
Lung	Baker Institute	Progression bar spanning from Theoretical Analysis to Serum and Algorithm Analysis		
Gastric	Nexomics	Progression bar spanning from Theoretical Analysis to Serum and Algorithm Analysis		
Cervical	ON HOLD	Progression bar spanning from Theoretical Analysis to Serum and Algorithm Analysis		
Pancreatic	ON HOLD	Progression bar spanning from Theoretical Analysis to Serum and Algorithm Analysis		

Regulatory Submissions

Pathway to Regulatory Success

CE / CA IVDD

- Self-declared product
- Marketing authorisation in Europe, UK and New Zealand
- ColoSTAT[®] European approval for marketing CE IVDD will be superseded by IVDR in May 26

IVDR

- To be assessed by regulators (notified body)
- Detailed clinical reporting required
- Detailed post market surveillance required
- Target early submission to ensure continued supply in the EU CE markets

TGA

- ARTG applications withdrawn March 23
- TGA assessor feedback internally audited, external review commenced
- June 23 guidance document for ISO 13485 and IVDD to IVDR has increased requirements
- New TGA submission will include IVDR documentation

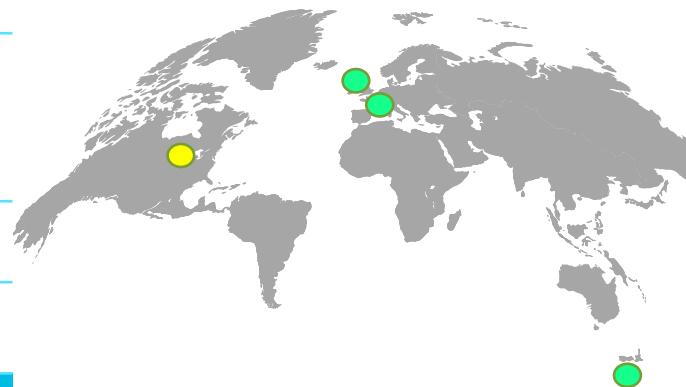
Current marketing authorisation in Europe

CE IVDR will be implemented in May 2026

TGA adopting stringent IVDR requirements

Rhythm's Focus on Market Entry

Market	Population	Age – Screening Population	Screening Method	Screening Participation Rate	Unscreened Population/ Opportunity	Screening Population based on RHY001 (40 to <85 yrs)	Screening Opportunity based on RHY001 (40 to <85 yrs)	Incidence of CRC	
Europe (EU-27) [®]	455.1 mill	133.5 mill (50 -74 yrs)	FIT, Colonoscopy [‡]	38%	82.8 mill	192.9 mill	142.2 mill	341,419	
UK (England, Scotland, Wales and Northern Ireland)	67.6 mill	10.6 mill (60 -74 yrs)	FIT	67%	3.5 mill	28.1 mill	21.0 mill	52,128	
New Zealand	5.1 mill	1.1 mill (60 -74 yrs)	FIT	57%*	0.5 mill	2.3 mill	1.7 mill	> 3,000	
USA	331.9 mill	161.5 mill (45 – 75+ yrs)	Undertaking broad and detailed market and competitive analysis						
Total		306.7 mill			86.8 mill	223.3 mill	164.9 mill		



[®] <https://ec.europa.eu/eurostat/databrowser/view/TPS00001/default/table?lang=en>

*Based on pilot project, recent data not available - <https://www.health.govt.nz/our-work/preventative-health-wellness/screening/bowel-screening-pilot/bowel-screening-pilot-results>
<https://www.aihw.gov.au/reports/older-people/older-australians/contents/demographic-profile>

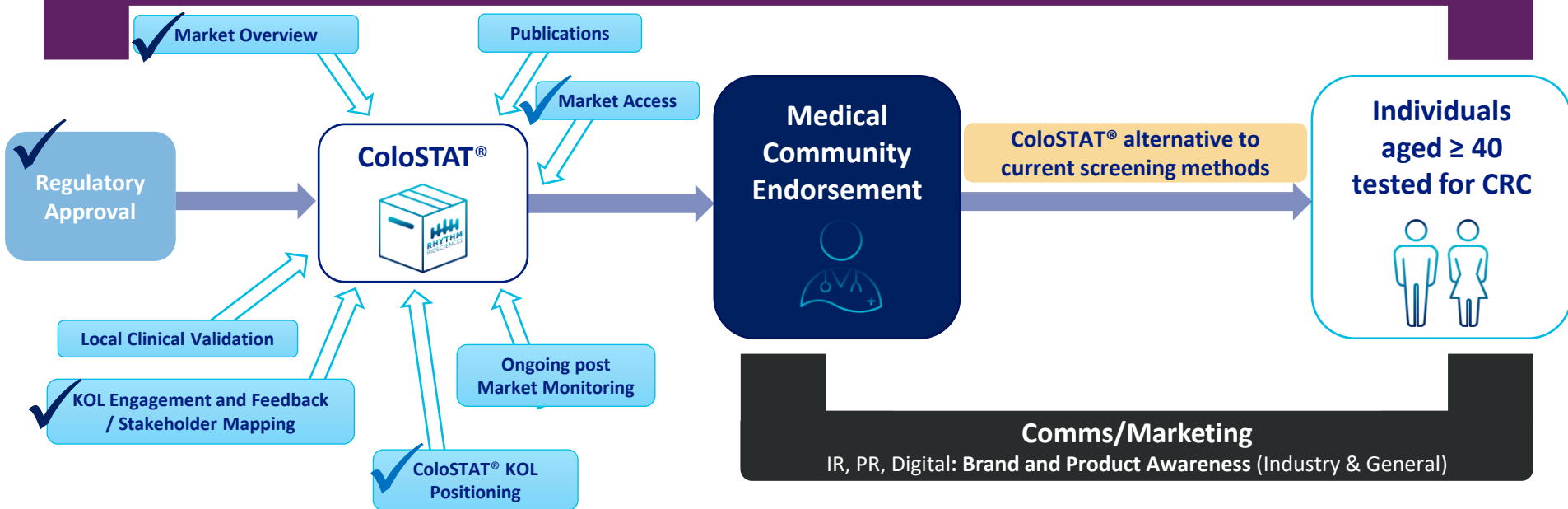
[‡] Every 10 years

https://www.google.com/search?q=us+population&riz=1C1GCEA_enAU1020AU1021&oq=US+population&gs_lcrp=EgZjaHJvbWUqDagAEAAyQxixAxiKBTIMCAAQABhDGLDGioFMgkIARAAGEMyigUyDQgCEAAygwEysQMygAQyDwgDEAAyQxiDARixAxiKBTIHCAQQABiABDIHCAUQABiABDIHCAyQABiABDIHCAcQABiABDIHCAgQABiABDIHCAkQABiABNIBCTc1MjFqMwXnagCALACAA&sourceid=chrome&ie=UTF-8

FIT; faecal immunochemical test

ColoSTAT® - UK Go-to-Market

Work with Strategic Partners



12 to 18 months process - sales revenue commence

Broader adoption and increased sales revenue

Rhythm's Focus for FY 24

H1

- ✓ Established UK Subsidiary
- ✓ Completed Stage 1 of Breast pipeline project
- ✓ Expanded and renewed management team
- ✓ UK Clinical Advisory Group commenced to evaluate ColoSTAT® positioning, validation centres
- ✓ Automation Project at Nutripath commenced
- Evaluating US Market entry strategy
- Market launch for the UK
- Lodging patent coverage in other jurisdictions
- Submit ColoSTAT® publication

H2

- Launch ColoSTAT® in additional markets
- Expand Automation Project
- Sign additional contracts
- Ongoing validation projects in UK
- Increase product shelf life
- Increase production capacity with additional CMOs
- Generate sales
- Further recognition of ColoSTAT® via new abstracts at international conferences
- Appoint CEO
- Finalise TGA / IVDR process plans

ColoSTAT® - patented in over 20 countries

