RHYTHM™ BIOSCIENCES

Company Overview

BIOSHARES 25 July 2023
Otto Buttula – Executive Chairman

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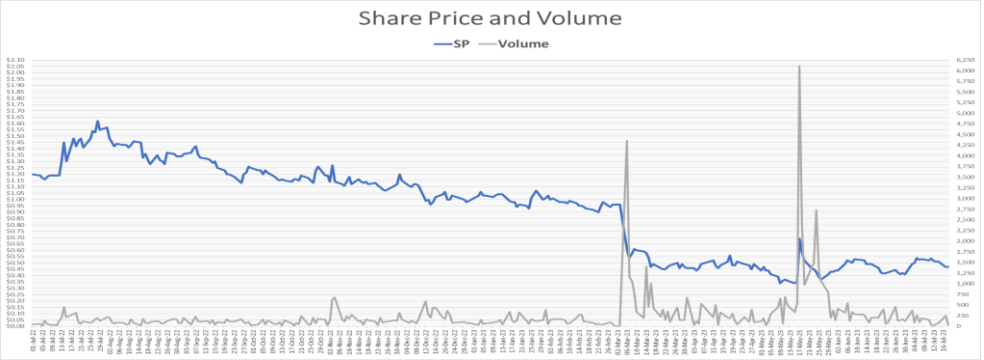
Company Overview

Capital Structure	
ASX Code	RHY
Share Price (at 18 July 2023)	**$0.47**
Shares on Issue	219.8 M
Unlisted Options	12.9 M
Market Capitalisation	**$109 M**
Cash in bank (31 March 2023)	$6.8M
Top 20 Shareholders	41%

Share Price Chart



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
Executive – Technical Director

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

Lou Panaccio
Non-Executive 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.

Rachel David
Non-Executive 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).

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).

Agenda

- Rhythm Biosciences – Our Goal
- The Burden of Colorectal Cancer
- ColoSTAT® - a simple screening alternative
- Clinical Data
- Historical Challenges
- Rhythm’s 12 Month Focus
- Rhythm’s Long-term Focus

Our Company's Goal

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

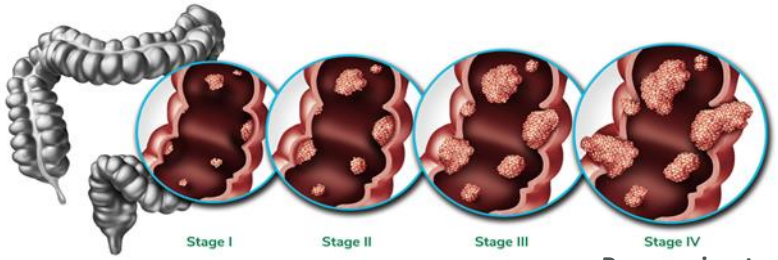
Early detection is critical to improving patient outcomes and reducing the global burden of cancer;

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 blood test** for the early detection of colorectal cancer for global mass-market screening.

Colorectal cancer (CRC) is treatable and often curable, yet is the second leading cause of cancer death globally

CRC is a progressive disease in which epithelial cells in the colon or rectum grow out of control[2]



Disease progression of colorectal cancer[3]

Progression to other organs

- CRC is generally asymptomatic; more than 50% of CRC cases are diagnosed at an advanced stage[4-6]
- CRC grows slowly over many years and has the potential to be detected early[7]
- When localised to the bowel, CRC is highly treatable and often curable[8]

Global burden in 2020:

1.93 million new cases and **~940,000 deaths**[1]

CURRENT TESTING & SCREENING REGIME

In most countries, screening is recommended for those aged between 50-74 years old, with the primary method being a faecal immunochemical test (FIT), which is designed to test only for blood in the stool.

CRC INCIDENCE IS ON THE RISE IN THE YOUNGER POPULATION

Major markets show that **11-15% of people diagnosed with CRC are below the age of 50**[9], posing a public health challenge, premature death and increased healthcare costs.[1, 10]

Abbreviations: CRC, colorectal cancer

Participation in CRC screening remains suboptimal despite national programmes being in place in many countries worldwide

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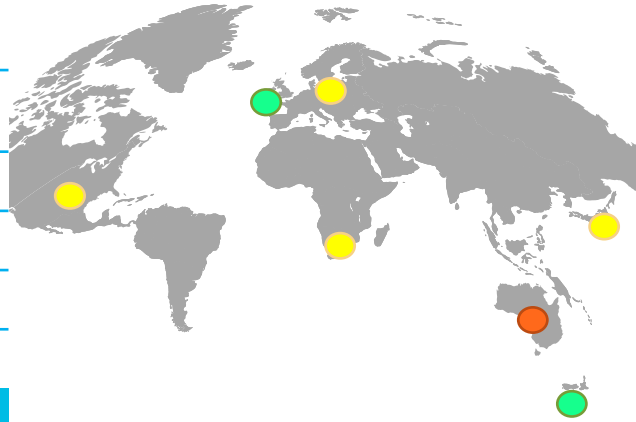
Market	Population	Age – Screening Population	Screening Method	Screening Participation Rate	Unscreened Population/ Opportunity	Screening Population based on RHY001 (40 to <85 yrs)	Screening Opportunity based on RHY001 (40 to <85 yrs)	Incidence of CRC
Europe (EU-27)@	455.1 mill	133.5 mill (50 -74 yrs)	FIT, Colonoscopy¶	**38%**	**143.0 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
USA	331.9 mill	161.5 mill (45 – 75+ yrs)	FIT, Colonoscopy, ¶ Cologuard	**61%**	**62.9 mill**	181.3 mill	**82.8 mill**	153,020
Japan	123.3 mill¥	78.6 mill (> 40 yrs) ¥	FIT	**20%**	**48.2 mill**	71.3 mill¥	**55.6 mill**	148,505
South Africa	59.4 mill	9.3 mill (50 -74 yrs)	FIT	**NA**		17.6 mill	**17.6 mill**	8,671**
Australia	25.7 mill	7.1 mill (50 – 74yrs)	FIT	**43%**	**4.0 mill**	11.7 mill	**8.8 mill**	15,713
New Zealand	5.1 mill	1.1 mill (60 -74 yrs)	FIT	**57%***	**0.5 mill**	2.3 mill	**1.7 mill**	> 3,000
Total		**301.7 mill**			**216.8 mill**	**505.2 mill**	**329.6 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://journals.lww.com/ajg/Fulltext/2021/10001/S342_Evaluating_Trends_of_Colorectal_Cancer.342.aspx
¥ https://www.populationpyramid.net/japan/2023/
https://www.aihw.gov.au/reports/older-people/older-australians/contents/demographic-profile
¶ Every 10 years
FIT; faecal immunochemical test, NA; not available

Blood tests, such as ColoSTAT®, are preferred by patients over FIT as they provide a more acceptable way to participate in testing

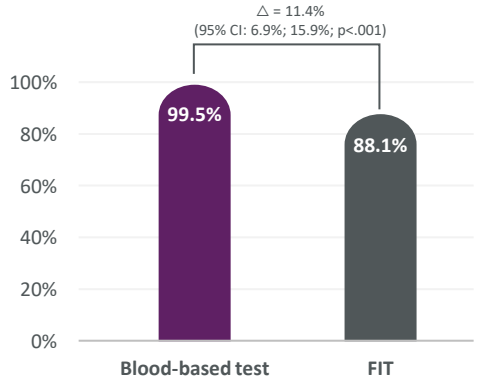
Blood-based tests are **preferred** over **faecal tests (FIT)** by **78–94%** of people who are offered CRC testing[1-5], with **ease** and **convenience** being the main reasons for their preference[3-4]

In an observational study among 460 people in the US who were offered CRC testing[1]:

Opted for a **blood-based test**† over FIT[1]

In a randomized controlled trial, **test uptake** was **significantly higher** with a **blood-based test**† than with FIT (p<0.001)[2]

Test uptake (%) in people who were offered CRC testing in the US (n=413)[2]



Reasons for preferring blood-based options[3-4]:

- **Convenience of a blood draw** in the physician's office (74%; 67/90 patients)
- **Ease/comfort of a blood test** (78%; 71/90 patients)
- **Lower time requirement** vs FIT (48%; 43/90 patients)

Abbreviations: CRC, colorectal cancer; FIT, faecal immunochemical test †Blood-based test offered was Septin9 DNA blood test (Epi proColon®)

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3.Lamb YN, Dhillon S. Epi proColon((R)) 2.0 CE: A Blood-Based Screening Test for Colorectal Cancer. Mol Diagn Ther. 2017 Apr;21(2):225-32.
4.Adler A, Geiger S, Keil A, Bias H, Schatz P, deVos T, et al. Improving compliance to colorectal cancer screening using blood and stool based tests in patients refusing screening colonoscopy in Germany. BMC Gastroenterol. 2014 Oct 17;14:183.
5.Osborne JM, Wilson C, Moore V, Gregory T, Flight I, Young G. Sample preference for colorectal cancer screening tests: Blood or stool? Open Journal of Preventive Medicine. 2012;2(3):326-31.

ColoSTAT® - patented in 21 countries

bsi EN ISO 13485 Medical Device Quality Management CERTIFIED

UK CA

CE

MEDSAFE New Zealand Medicines and Medical Devices Safety Authority

ColoSTAT® - test kit explained

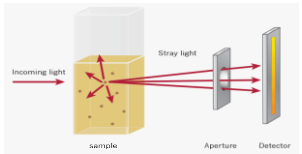
ColoSTAT® - indicated to screen adults, aged 40 to <85, at average risk for developing CRC. The test measures 5 specific biomarkers in the blood that either increase/decrease in concentration when CRC tumours are present.

ELISA Assay Plate testing of 5 Biomarkers

Optical Density (OD) Plate – measuring of concentration level of the biomarkers

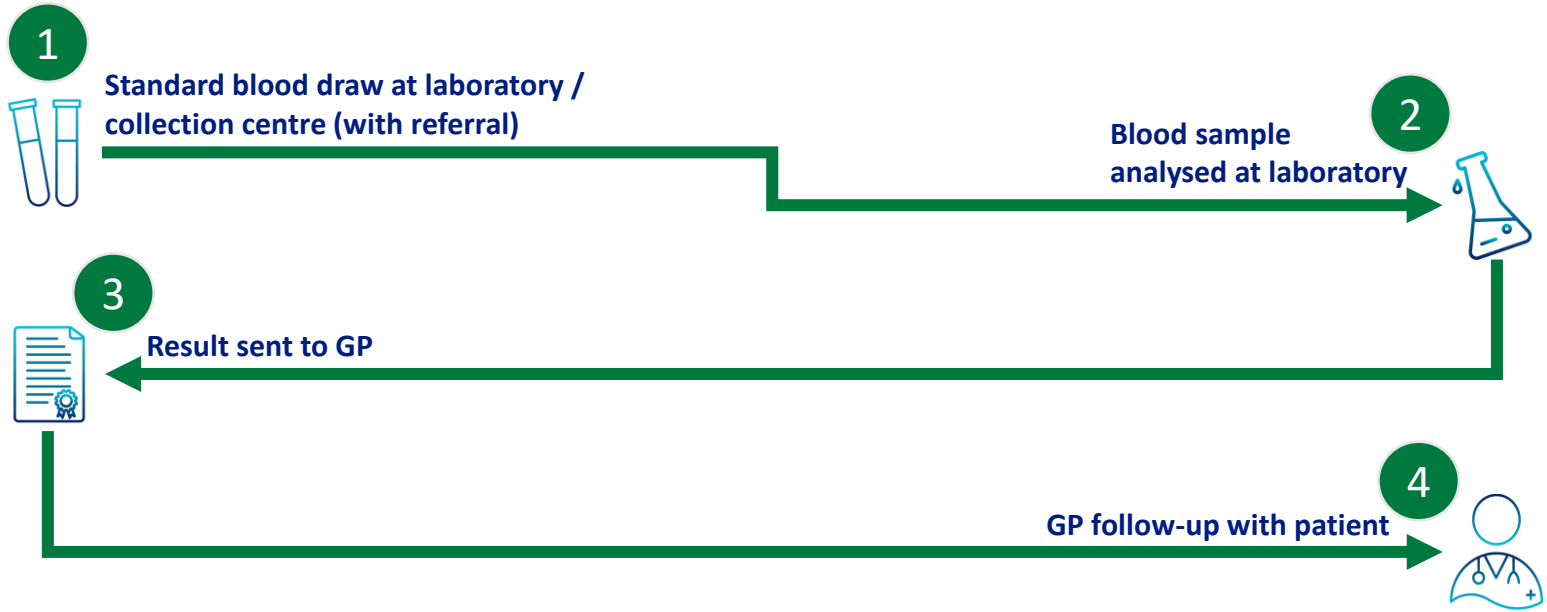
Analyse results. Biomarker concentrations inputted into ColoSTAT® Algorithm

Generated data, along with the individual's age and sex, is entered into the ColoSTAT® proprietary algorithm software, producing a **CRC 'likelihood score'** and the result is sent to the GP



ColoSTAT®* - simple four step procedure

COLOSTAT®



*currently not approved for use in Australia

Our Clinical Data - prospective, multi-centre study to evaluate the clinical performance of the ColoSTAT® for the detection of CRC[1]

Study Design

- The **primary endpoint** was to evaluate **ColoSTAT®** performance **compared to gold standard, colonoscopy.**
- 989 patients, aged 40 to <85 were included in the study.

Results

- ColoSTAT® met the primary endpoint and showed a high-sensitivity blood test for CRC detection.
- ColoSTAT® may provide an alternative test for people who cannot, or will not take the FIT test.

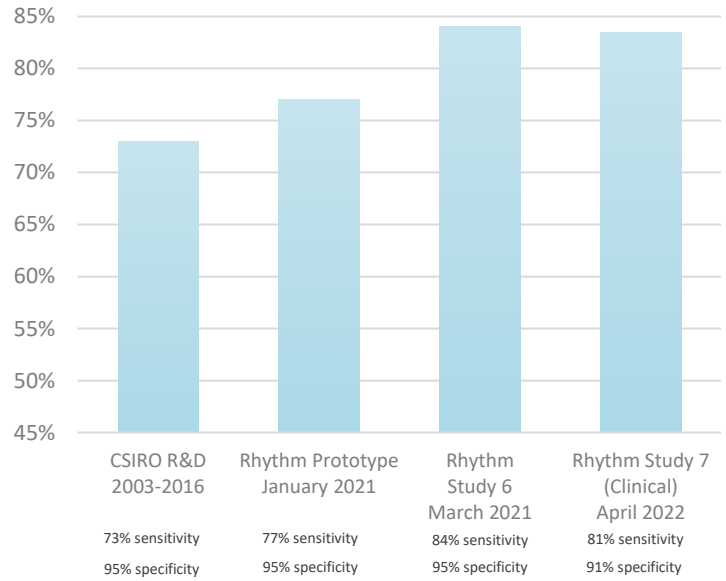
Sensitivity[1]	Specificity[1]
81%	91%

CRC; colorectal cancer, FIT; faecal immunochemical test
1.He et al DOI: 10.1200/JCO.2023.41.16_suppl.3529

ColoSTAT® - development journey

ColoSTAT® is expected to increase participation, leading to earlier detection

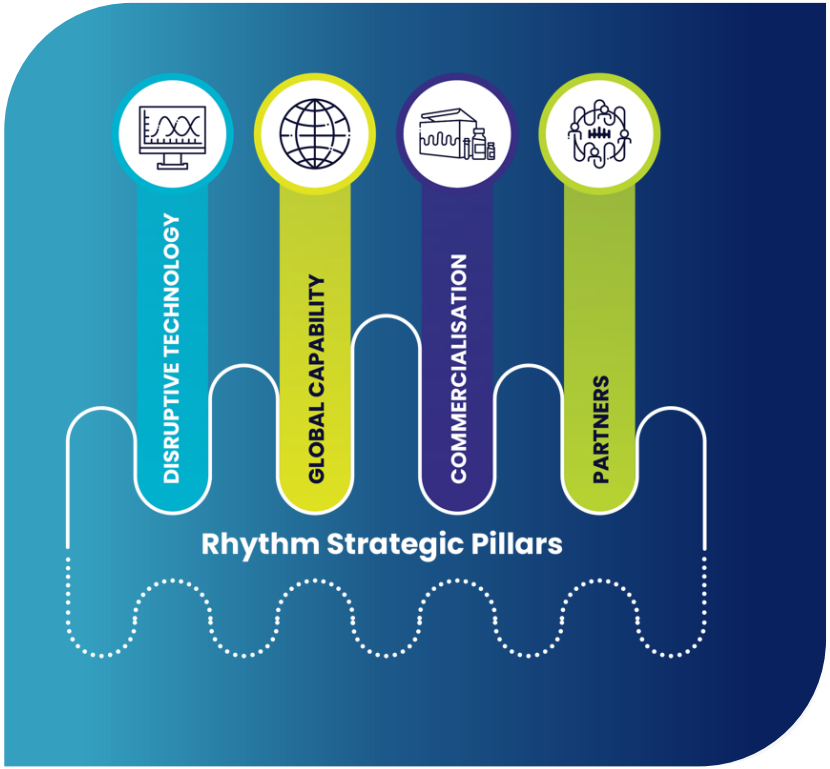
ColoSTAT® Sensitivity Performance



- **Accurate**
  ColoSTAT® obtains a qualitative likelihood of CRC presence based on 5 protein biomarker levels in the blood, compared to FIT (detects blood in the stool).
- **Affordable and Simple**
  Cost-efficient simple blood test that may suited to screening programs.
- **Preferred**
  A blood test is preferred over FIT because of ease and convenience.[2,3]
- **Patient Friendly**
  Convenient and can be part of routine health examination.

1. He et al DOI: 10.1200/JCO.2023.41.16_suppl.3529
2.Lamb YN, Dhillon S. Epi proColon((R)) 2.0 CE: A Blood-Based Screening Test for Colorectal Cancer. Mol Diagn Ther. 2017 Apr;21(2):225-32.
3.Adler A, Geiger S, Keil A, Bias H, Schatz P, deVos T, et al. Improving compliance to colorectal cancer screening using blood and stool based tests in patients refusing screening colonoscopy in Germany. BMC Gastroenterol. 2014 Oct 17;14:183.

Strategic Pillars and Direction



DISRUPTIVE TECHNOLOGY

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

GLOBAL CAPABILITY

- Manufacturing capability for our target markets.
- Increase production capacity with further international and local CMOs.

COMMERCIALISATION

- Commercial due diligence into international jurisdictions underway.
- USA – commercialisation pathway:
  - Lab Developed Test (LDT) via a CLIA Lab.
- Review additional regulatory requirements for IVDR and TGA submission.
- Raise awareness among younger demographics as 11-15% of patients diagnosed with colorectal cancers are less than 50 years of age.

PARTNERS

- Signed a collaborative UK partnership with LINK Medical Solutions.
- Developing further strategic partnerships in international jurisdictions.

Historical Challenges

- Test development - combining 5 different biomarker immunoassays into one kit
  - transitioning from research to commercial.

- Pandemic impact on:
  - Study recruitment; and
  - Manufacturing scale up.

- Market awareness:
  - Blood-based vs current screening methods, which have been in market for the past 3-4 decades.

Rhythm's 12 Month Focus

- FY'24 commercial sales – initially focused on ~1% of addressable market.

- UK market launch:
  - Establish ColoSTAT® as an alternative to FIT;
  - Developing partnerships with key labs for growth; and
  - Maximising sales revenue through the private market
    - Over 61% of CRC detected, are outside the current screening age.

- South African market entry;
- New Zealand market entry;
- USA market launch and strategy – finalise approach;
- Australian market - progression of regulatory approval;
- Transfer immunoassay to automated platform; and
- Development of other platform technologies.

Platform Technology Expansion – Stage 1

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Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
Initiation: Opportunity and Risk Analysis	Formulation: Concept and Feasibility	Design & Development: Verification, Validation, & Clinical Trials	Final Validation: Product Launch Preparation	Product Launch & Post-Launch Assessment

STAGE 1 Progression		Theoretical Analysis of Biomarker Potential	Serum and Algorithm Analysis	Risk Analysis→ Enter Stage 2
Cancer Type	**Collaborator**			
Breast	Agilex Biolabs			
Lung	Baker Institute			
Stomach	Nexomics			
Cervical	TBD			
Pancreatic	TBD			

Rhythm's Long-term Focus

- Establish ColoSTAT® as test of choice in CRC.
  - Expand test in diagnosis of advanced adenomas.
- Increase participation rate in CRC testing and reduce late diagnosis.
- Market awareness, widen CRC screening participation in individuals aged 40 and above.
- Machine agnostic.
- Recurring revenues across multiple markets.
- Expansion of platform technology to include multiple cancers.

Thank you

References

Slide 5

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4. Australia colorectal cancer statistics. Available at: https://ncci.canceraustralia.gov.au/diagnosis/distribution-cancer-stage/distribution-cancer-stage
5. ACS. Colorectal cancer facts and figure. Available at: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-andfigures/colorectal-cancer-facts-and-figures-2020-2022.pdf
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