

Rhythm to Present at MST Access Investor Conference

17 June 2021, Melbourne: Rhythm Biosciences (ASX: RHY) is pleased to announce that it has been invited to present at the MST Access Australian Micro & Small Caps Conference 2021.

Presentation is to be given by CEO Mr Glenn Gilbert today, Thursday 17 June at 5pm AEST.

Please find attached the presentation. To join, please click the webinar link below:

https://mstfinancial-au.zoom.us/j/81909959774

With authority by the Board.

For further information, please contact:

Glenn Gilbert Chief Executive Officer +61 3 8256 2880

About Rhythm Biosciences

Rhythm Biosciences (ASX: RHY) is a transformative, predictive diagnostics company, specialising in early cancer detection. Rhythm's initial business pursuit is centred upon technology originally developed by the CSIRO and involves the development and commercialisation of a screening and diagnostic test for the early detection of colorectal cancer, the third biggest cause of cancer-related deaths globally.

Rhythm's lead product, ColoSTAT®, is intended to be a simple, affordable, minimally invasive and effective blood test for the early detection of bowel cancer for the global mass market. It is expected to be comparable to, if not better than, the current standard of care, the faecal immunochemical test (FIT), at a lower cost. ColoSTAT® also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

ColoSTAT® is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT® has the potential to play an important role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Globally, over 850,000 people die from colorectal cancer each year. Colorectal cancer is typically diagnosed at a later stage when there is a poor prognosis for long-term survival. Annual estimated unscreened 50-74-year old's is estimated at +130m for the US, EU and AU alone, with this market potential being more than \$6.5b.



MST ACCESS Australian Micro & Small Caps Conference 2021

Initial Product Aim = ColoSTAT®
the early detection of colorectal
cancer using a simple, accurate &
low-cost blood test, designed for
global mass-market screening.

A transformative, predictive cancer diagnostics technology company

ASX: RHY



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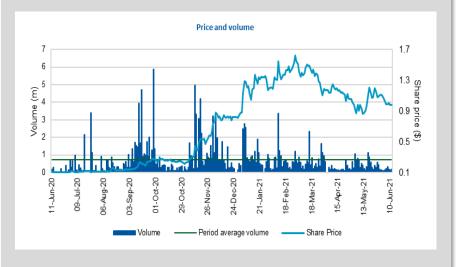
Corporate Overview

Rhythm Biosciences (ASX: RHY)

A transformative, predictive cancer diagnostics technology company

- ✓ RHY is a new-generation / disruptive cancer diagnostics technology developer, focused on building a global diagnostics business.
- ✓ ColoSTAT® is the first product in development, representing a transformative diagnostic tool, to more accurately detect colorectal cancer, via a simple, accurate, low-cost blood test, aimed at global mass-market screening.
- ✓ Used as a primary screening or secondary triage test, ColoSTAT® aims to play a vital role in reducing the global healthcare burden of colorectal cancer.

Financial Information	
ASX Code:	RHY
Share Price (14-Jun-21)	\$0.98
12-Month Range	\$0.078 - \$1.67
Shares on Issue	~202.170m
Unlisted Options on Issue	7.475m
Market Capitalisation	~\$198.13m
Cash on hand (31-Mar-21)	~\$4.57m
Enterprise Value (14-Jun-21)	~\$193.56m



Board and Management

A strong and industry experienced board and management team, with a pedigree of building successful businesses.













OTTO BUTTULA	GLENN GILBERT	TREVOR LOCKETT	LOU PANACCIO	DAVID WHITE	EDUARDO VOM
Chairman	Chief Executive Officer	Technical – Executive-Director	Non-Executive Director	Non-Executive Director	Non-Executive Director
 Extensive financial services 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) 	 Former Head of Global Sales, Marketing and BD at Medical Developments Int. (ASX: MVP) Various leadership positions at CSL Strong Legal, IP & Operational management Broad international business experience 	 Former Theme Leader Colorectal Cancer and Gut Health CSIRO Leader – Personalised Health Group CSIRO Inventor on seven commercially- licensed patent families 	 Chairman Avita Medical (ASX: AVH) Director Sonic Healthcare (ASX: SHL) Chairman NeuralDX Non-executive Director Unison Housing Former CEO Melb Pathology & Monash IVF 	 US BD&C, Bluechiip (ASX: BCT) US Business Development, Planet Innovation Molecular Sales, GenMark Dx Group Marketing Manager, Advanced Staining, Leica Biosystems 	 Co-Founder & Executive Director Planet Innovation Director Atmo Biosciences Former VP Innovation, Genetic Technologies Various senior leadership positions Vision BioSystems

Key Investment Highlights

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

- ✓ Transformative Diagnostic Company: Focused on early detection of colorectal cancer (CRC) using a simple, low-cost blood test that could revolutionise colorectal cancer detection and mass-market screening.
- ✓ Significant Opportunity: Mass-market screening marketplace worth \$38+bn p.a. in the US, EU, CH, JP and AU of 50-74 year old alone. Market wants (& needs) change in colorectal cancer detection & screening.
- ✓ Scalable & Capital-Light Commercial Model: Lean business structure. Scalable and flexible implementation by market & segment.
- ✓ Experienced Team: Long tenure with successful histories in both diagnostic and healthcare sectors, and importantly, in building sizeable, successful businesses.



Key Investment Highlights

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

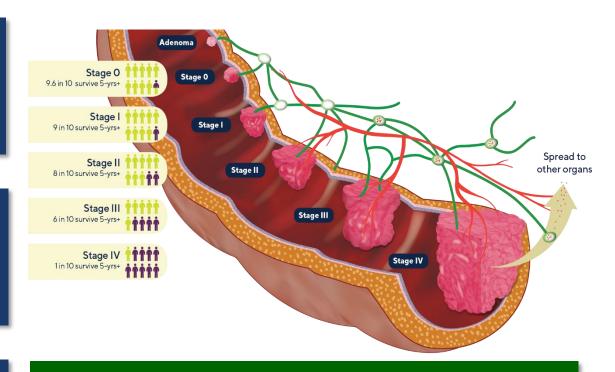
- ✓ **Sound technology:** 13 years of R&D pioneered by CSIRO[^] combined with 3 years RHY, giving robustness and confidence in the biomarkers selected.
- ✓ Key Lead Biomarker, a potential Platform Technology: Known to be highly expressed in a range of cancers, offering Rhythm a potentially deeper pipeline targeting other indications.
- ✓ Product differentiation: Patient preference for a simple blood test vs faecal test. Significant global unmet need.
- ✓ Simple Business Model: ColoSTAT® test designed to integrate with existing pathology infrastructure & instrumentation (no additional capital spend, can reduce labour and will be equipment agnostic).

Colorectal Cancer – Mass-Market Screening Is Critical

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 circa 10% if detected late and once the cancer has spread.

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

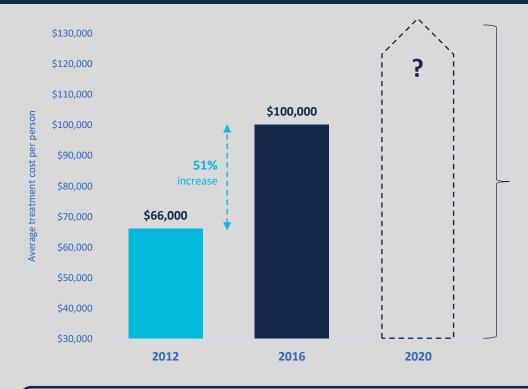


RHY's ColoSTAT® detects protein biomarkers in the blood that are indicative of an <u>increased likelihood of presence of colorectal cancer</u> via a simple, mass-screening blood test.



Bowel Cancer Treatment Costs Are Increasing

Early detection is the key to survival and reducing the cost of treatment



Cost drivers:

- Private hospital
- Public hospital
- Outpatient
- Doctor
- Specialist
- Imaging/Pathology
- Pharmaceutical
- Screening Programs

ColoSTAT® is expected to assist in lowering treatment costs through increased participation leading to detection at earlier stages



¹Cancer Council, Pre-budget submission 2012-2013

² St John & Grogan, Asia-Pacific Journal of Clinical Oncology 2016; 12: 7–9)

ColoSTAT® - What Is It? How Does It Work?

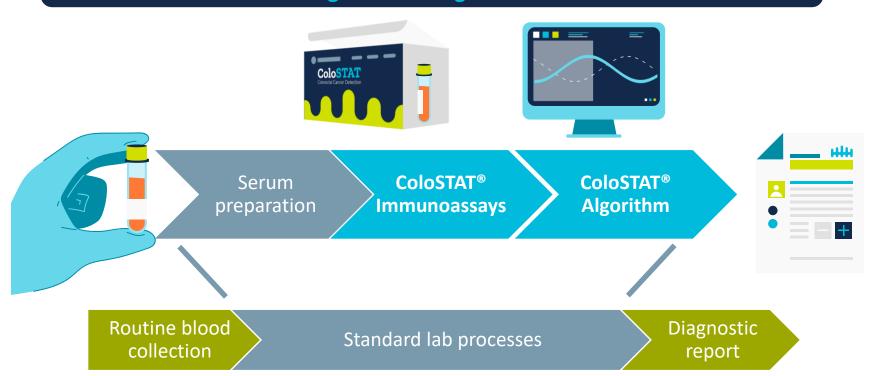
A simple, accurate, low cost blood test for the early detection of colorectal cancer designed for the global mass market

- ✓ Detects protein biomarkers in the blood that are indicative of an increased likelihood of presence of colorectal cancer. (accurate)
- ✓ Blood collected via a simple, routine and standard blood draw. (patient friendly)
- ✓ ColoSTAT® could be added to the standard panel of referred tests a GP completes for routine and annual check ups. (simple)
- ✓ ColoSTAT® will analyse & consolidate individual biomarker results simultaneously, using its developed algorithm, to provide an indication of the likelihood of presence of colorectal cancer. (innovative)
- ✓ The result is sent to the patient's healthcare practitioner for review & assessment if further diagnosis is required i.e., colonoscopy. (improved GP/patient relationship)
- ✓ Low cost assay format is designed to integrate with existing pathology lab infrastructure / equipment agnostic. (suitable for the global mass market)



ColoSTAT® - What Is It? How Does It Work?

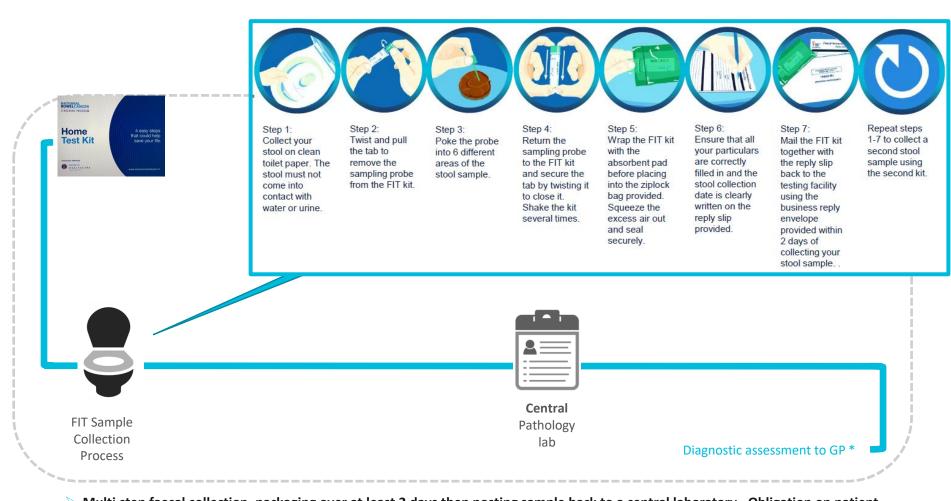
A simple, accurate, low cost blood test for the early detection of colorectal cancer designed for the global mass market



Technology designed to fit with existing pathology infrastructure



Current FIT Pathway - Cumbersome And Not Well Adopted



Multi step faecal collection, packaging over at least 2 days then posting sample back to a central laboratory. Obligation on patient to sample and label correctly and to follow up the result with a GP. Patient can determine if they will have a follow up colonoscopy.

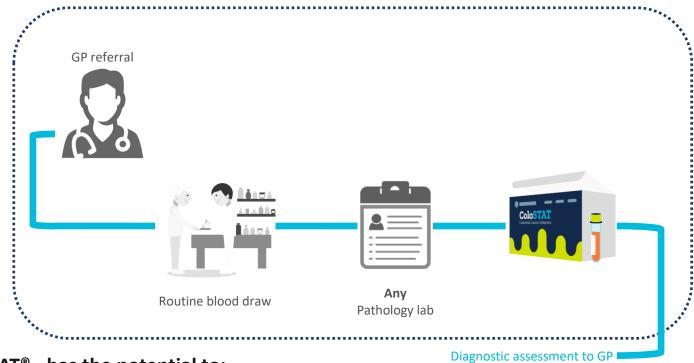


^{*} If the test is completed as part of the NBCSP the result is also sent to the patient.

ColoSTAT® - Patient Friendly - Increased Compliance

"83% of unscreened participants preferred a blood test over a faecal test" *

Simple & Routine Patient Journey With ColoSTAT®



ColoSTAT® - has the potential to:

- ✓ Significantly increase screening compliance globally.
- ✓ Save more lives, benefitting the health system and reducing the economic burden.
- ✓ Improves the doctor/patient relationship.

^{*} Source: 9. Osborne, J., Wilson, C., Moore, V., Gregory, T., Flight, I. and Young, G. (2012) Sample preference for colorectal cancer screening tests: Blood or stool?. Open Journal of Preventive Medicine, 2, 326-331. doi: 10.4236/ojpm.2012.23047.

ColoSTAT®'s - Competitive Advantage



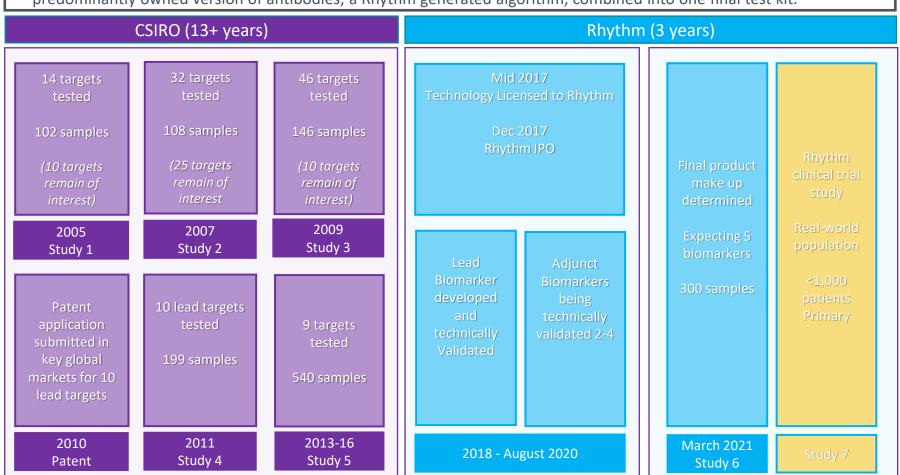
ColoSTAT®'s combination of advantages can potentially drive higher compliance to screening and ultimately save more lives



^{*} ColoSTAT® blood test can be completed at GP clinic during a regular visit

ColoSTAT® - Development History

- ColoSTAT® relies on detecting biomarkers in blood that indicate an increased likelihood of presence of colorectal cancer.
- For over 13 years CSIRO investigated over 68 potential biomarkers until a panel of 10 lead targets remained, using individually sourced commercial test kits.
- Rhythm took these 10 targets and began the work necessary to turn ColoSTAT® into a viable asset by validating Rhythm's predominantly owned version of antibodies, a Rhythm generated algorithm, combined into one final test kit.



Clinical Trial (Study 7) – Performance In A Clinical Setting

Trial Study Design	End Points
Prospective, Cross sectional, multicentre clinical trial. Two cohorts: Cohort 1: Patients with a diagnosis of CRC who are progressing to surgery. Cohort 2: Participants referred for colonoscopy by their physician. Each patient to provide: ColoSTAT® blood test Faecal (FIT) test Colonoscopy	Primary: Performance of ColoSTAT® for detection of CRC relative to colonoscopy (Sensitivity and Specificity). Secondary: ColoSTAT® performance relative to colonoscopy for: Advanced adenomas. Clinically actionable neoplasia. Non-inferiority to FIT.

ColoSTAT® Clinical Trial to confirm:

- Performance translates to a clinical setting.
- ✓ Performance against FIT head-to-head.
- Suitable for mass population screening.
- ✓ Supports TGA regulatory submission.

Key Recruitment Challenge:

Hospitals maintaining motivated key trial staff members to identify, consent and recruit suitable patients.

COVID-19 exacerbated timelines for ethics approvals, site assessments, hospital governance processes.

Improvements:

- Review of protocol and made changes to streamline process.
- ✓ Closer relationship with the trial sites.
- ✓ Non-Victorian sites appointed.
- ✓ Strategic move to include more private clinics.
- COVID restrictions softening.
- Newly appointed sites actively recruiting.



Study 7 – New Trial Sites Motivated To Recruit

"The burden of colorectal cancer and the benefits of early detection have been well recognised. The risk of colorectal cancer increases dramatically over 50 years of age, yet the majority of people in this age group remain unscreened. A blood-based diagnostic tool such as ColoSTAT® would likely enable more people to participate in screening and thereby could have a significant beneficial impact on colorectal cancer survival rates." said Professor Clingan OAM, Illawarra Health & Medical Research Institute

"We are excited to be partnering with Rhythm on the clinical trial of ColoSTAT®. A simple blood test like ColoSTAT® is the change the world needs both socially and economically, for colorectal cancer detection. The number of lives that could be saved with this test is significant, especially as it would significantly increase patient compliance and overall screening rates. We are excited to be a part of this journey" commented Jeff Wall, CEO of Northern Beaches Clinical Research.



Confidence In Performance Moving Forward

- ✓ Preliminary results from the prototype test-kit outperformed the current market standard (faecal test) and previous CSIRO test work.
- Confirmation of Study 6 results demonstrating exceptional accuracy / performance bettering the prior outperformance.
- ✓ Demonstrated **further improved performance** via incorporating Lifestyle Risk Factors (LRF) such as diet, weight, smoking, type 2 diabetes into the algorithm.
- ✓ ColoSTAT® **prototype test-kit complete** using Rhythm's proprietary algorithm that continues to improve.
- ✓ CE Mark application is expected to be submitted pre-Study 7 completion, subject to data and manufacturing requirements.
- ✓ The clinical trial (Study 7) will fulfil the compulsory requirements for some regulatory approvals (such as in Australia) and support clinical evidence for global markets.

Key Achievements - Delivered In 2020/2021

- Technically validated the key lead and four adjunct biomarkers.
- ✓ Appointed additional clinical trial (Study 7) sites.
- ✓ ISO13485 Quality Management System certification maintained.
- Completed reagent development program.
- Commenced high-volume manufacturer selection process.
- ✓ Granting of USA patent and China divisional patent.
- ✓ Granting of ColoSTAT® trademark in the USA.
- Strengthened Board and aligned management incentive program.
- ✓ Completed approx. \$6m capital raise.
- ✓ Received \$1.1m FY20 R&D tax incentive.
- Commenced design transfer of the prototype test-kit to a high-volume manufacturer.

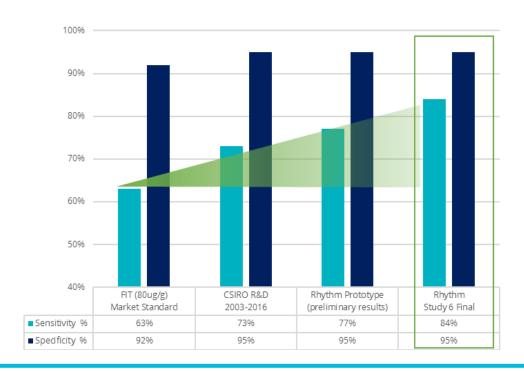
None more important than...

- ✓ ColoSTAT® prototype test-kit complete.
- ✓ Preliminary results demonstrate superior performance to faecal immunochemical test (FIT) and prior CSIRO test work.
- ✓ Completion of Study 6 with exceptional results.



Key Achievements - ColoSTAT® Performance

Prototype test-kit results outperform current global market standard



Sensitivity is the ability of the test to correctly identify those patients with colorectal cancer, that is, the percentage of people with colorectal cancer who are correctly identified as having illness.

Specificity is the ability of the test to correctly identify people who do not have colorectal cancer, that is, the percentage of people without colorectal cancer who are correctly identified as not having cancer.

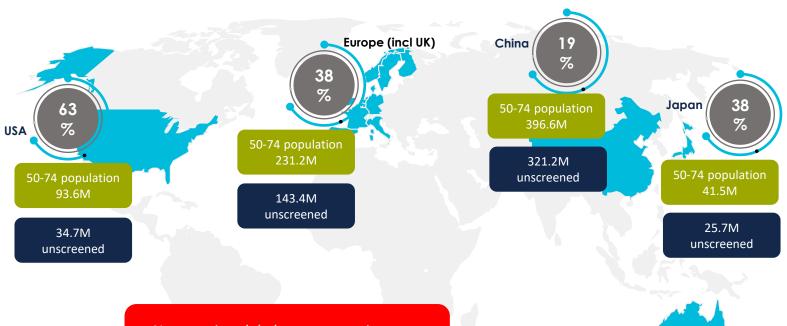
Source: Fung et al. Blood-based protein biomarker panel for the detection of colorectal cancer. PLoS One (2015) 10 3.

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



Market Opportunity – Global Screening Numbers

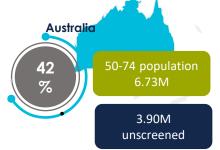
Screening compliance & opportunity by market



Not meeting global target screening rates (USA = 80%, Australia = 60%)

Total 50-74 year old population, US/EU/AU/CHN/JPN 769m

Total 50-74 year old unscreened population, US/EU/AU/CHN/JPN 529m





Market Likely To Expand Significantly

Colorectal Cancer is prevalent in younger segments of the population

- Colorectal cancer is the leading cause of cancer related deaths for 30-to-35year-olds in both males and females in Australia.
- ✓ It is also the leading cause of cancer related deaths for 45-to-49-year-olds in males in Australia.
- ✓ USA Preventative Services Task Force recommends Colorectal Cancer Screening to commence at age 45. Five years younger than it previously recommended, adding circa 20 million patients to the screening population in the USA alone.
- Reduction of screening age under 50 years of age is expected to occur in all major global markets.
- ✓ The US Centers for Medicare and Medicaid Services released a draft decision outlining the criteria for the reimbursement of current and future blood-based colorectal cancer screening tests, which included:
 - Tests must demonstrate both sensitivity greater than or equal to 74 percent and specificity greater than or equal to 90 percent.

ColoSTAT® would meet the requirements in the US based on the Study 6 performance of 84% sensitivity and 95% specificity

RHYTHM

Where Could ColoSTAT® Value Be Derived From

Who are the potential payers?

Government – National Screening Program

Government – National/Regional reimbursement

Hospital / Pathology Lab payers

Private Health Insurers

Patients

Simplified Value Story

ColoSTAT®



Increased CRC screening rates

Because the vast majority of patients prefer a blood test vs tests involving faecal handling



Increased rates of early diagnosis

Greater screening levels equates to greater early detection



Decreased rates of late stage CRC detection

Early diagnosis prevents disease progression in the majority of cases



Increased survival rates

Early diagnosis equates to a survival rate of 90%, this drops to 10% when detected at advanced stages

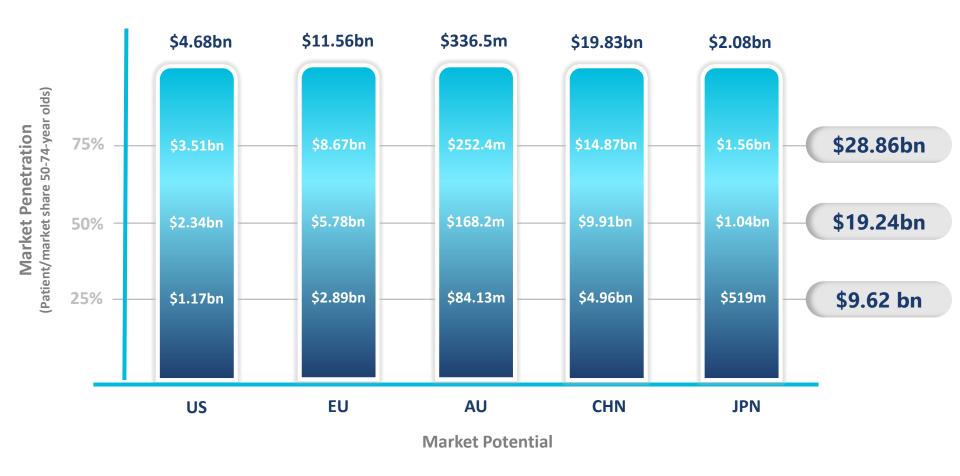


Decreased government / private healthcare expenditure

Late stage CRC involves ultra-high cost treatments



Potential ColoSTAT® Total Market Size (50-74yr old only)



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

Go To Market Options

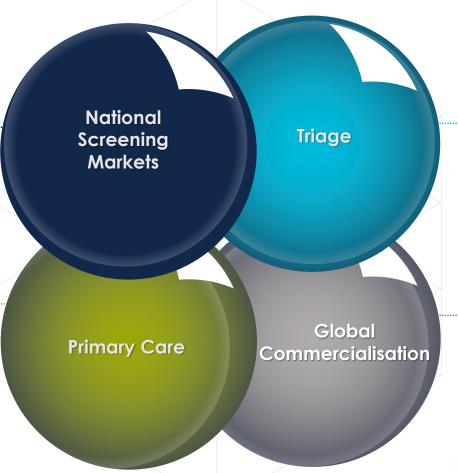
Multiple avenues and market segments reduce risk and support a flexible and scalable business model

National Screening Program/MBS Reimbursed

 With its effectiveness and affordability, ColoSTAT® is well suited to mass market screening as a complement / direct replacement for global National Screening Programs led by Government, Health Insurers or GP's.

Private Market

- ColoSTAT® can be used by GP's or in Hospitals as a diagnostic
- Led by Private Health Insurers, GP's, Hospitals.



Secondary Triage

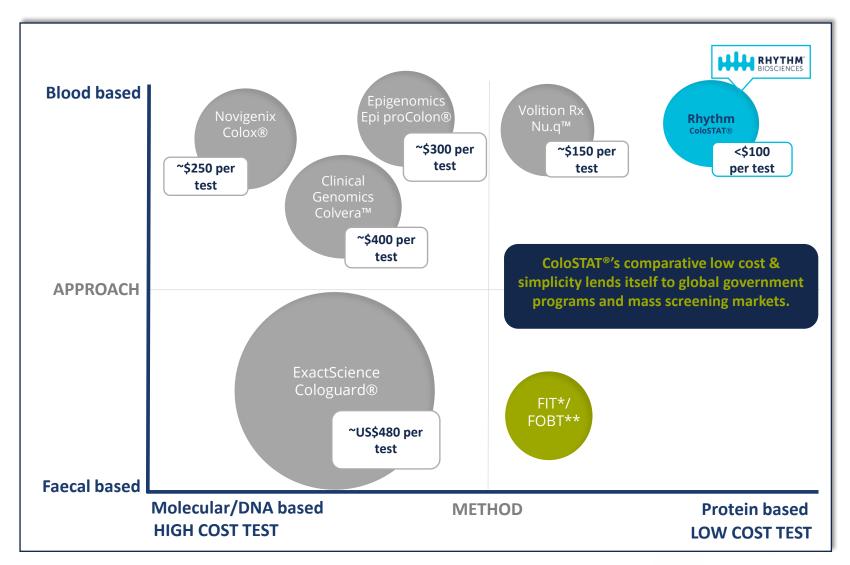
As a transition, ColoSTAT® could be used as a follow up secondary test for those that return a positive FIT test prior to invasive & costly colonoscopy, potentially reducing unnecessary colonoscopies and wait times.

Global Partnerships

 Partnership & licensing opportunities, joint-venture, market/channel specific deals. Co-development potential.



Competitive Landscape – ColoSTAT®'s Unique Advantage



[•] FIT = Faecal Immunochemical Test



25

^{**} FOBT = Faecal Occult Blood Test

IP – Patents Filed In All Major Target Markets

- Licensed from CSIRO
- Worldwide exclusive licence
- Patent wholly owned by Rhythm Biosciences Ltd*
- Expires 2031
- Methods for detecting colorectal cancer covering the combinations of 10 biomarkers
- Additional patents applications and patent extensions expected to be submitted in 2021

Gra	Pending	
United States	France	Brazil
Australia	Germany	India
China (x2)	Italy	
Japan	Luxembourg	
United Kingdom	Netherlands	
Europe	Norway	
Austria	Spain	
Belgium	Sweden	
Denmark	Switzerland & Liechtenstein	
Finland		



^{*}via Rhythm's 100% owned subsidiary, Vision Tech Bio Pty Ltd

Future Value Inflection Points – 2021

With R&D significantly de-risked, anticipated near-term value inflection points on the path to towards commercialisation include:

- Finalisation and execution of European and Australian regulatory submission pathways.
- Commence USA / European / China / Asia market entry strategies.
- Commencement of further platform technology opportunities.
- Recruitment for clinical trial (Study 7) on track for completion in 2021.#
- Progression of TGA (Australia) regulatory application post clinical trial (Study 7) recruitment.
- Planned CE Mark application in late 2021.#
- Identify key sales, distribution & diagnostic companies for partnering.







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