



*A transformative, predictive cancer diagnostics technology company*

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

Investor Presentation  
19 November 2020

**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® could play an important role in reducing the global healthcare burden of colorectal cancer.

### Financial Information

ASX Code:	RHY
Share Price (18 November 2020)	\$0. 515
12-Month Range	\$0.041 - \$0.580
Shares on Issue	~201.496m
Unlisted Options on Issue	6.650m
Market Capitalisation	~\$103.770m
Cash on hand (30-Sep-20)	~\$6.169m
Enterprise Value (18-Nov-20)	~\$97.601m



# 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
<ul style="list-style-type: none"> <li>Extensive financial services and biotech experience</li> <li>Co-Founder and CEO of IWL (ASX: IWL); Founder / former CEO of Investors Mutual</li> <li>Formerly a Director of Imugene (ASX: IMU) and Chairman of Investorfirst, now HUB (ASX: HUB)</li> </ul>	<ul style="list-style-type: none"> <li>Former Head of Global Sales, Marketing and BD at Medical Developments Int. (ASX: MVP)</li> <li>Strong international business experience</li> <li>Strong Legal, IP &amp; operational management</li> </ul>	<ul style="list-style-type: none"> <li>Former Theme Leader Colorectal Cancer and Gut Health CSIRO</li> <li>Leader – Personalised Health Group CSIRO</li> <li>Inventor on seven commercially-licensed patent families</li> </ul>	<ul style="list-style-type: none"> <li>Chairman Avita Medical (ASX: AVH)</li> <li>Director Sonic Healthcare (ASX: SHL)</li> <li>Chairman NeuralDX</li> <li>Non-executive Director Unison Housing</li> <li>Former CEO Melb Pathology &amp; Monash IVF</li> </ul>	<ul style="list-style-type: none"> <li>US BD&amp;C, Bluechiip (ASX: BCT)</li> <li>US Business Development, Planet Innovation</li> <li>Molecular Sales, GenMark Dx</li> <li>Group Marketing Manager, Advanced Staining, Leica Biosystems</li> </ul>	<ul style="list-style-type: none"> <li>Co-Founder &amp; Executive Director Planet Innovation</li> <li>Director Atmo Biosciences</li> <li>Former VP Innovation, Genetic Technologies</li> <li>Various senior leadership positions Vision BioSystems</li> </ul>

# 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 & mass-market screening.
- ✓ **Significant Opportunity:** Mass-market screening marketplace worth \$38+bn p.a. in the US, EU, CH, JP & 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 & flexible implementation by market & segment.
- ✓ **Experienced Team:** Long tenure with successful history in both diagnostic & healthcare sectors and importantly in building sizeable, successful businesses.

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

# 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<sup>^</sup> combined with 3 years RHY, giving 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 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).

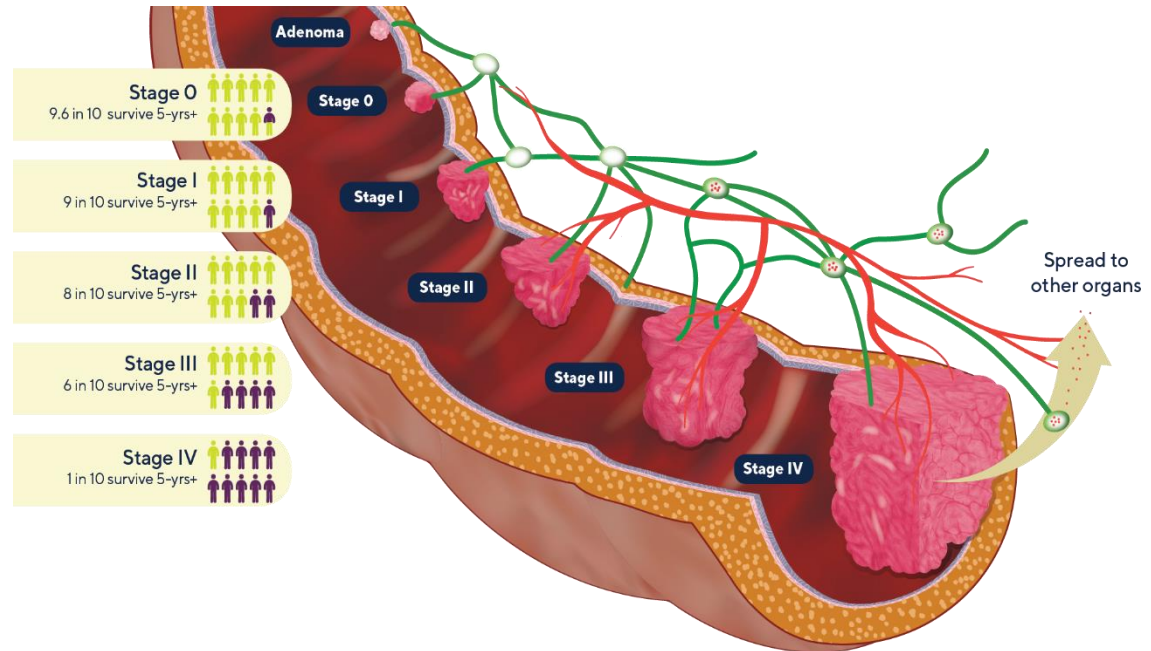
<sup>^</sup> CSIRO - Commonwealth Scientific and Industrial Research Organisation is an independent Australian federal government agency responsible for scientific research.

# 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 increased likelihood of presence of colorectal cancer via a simple, mass-screening blood test.



# Late-Stage Bowel Cancer Treatment Costs Are Increasing

Early detection is the key to survival and reducing the healthcare burden

\$66,000  
per patient<sup>1</sup>  
(2012-13)

\$71,156  
per patient<sup>2</sup>  
(2016)

\$100,000  
per patient  
& rising<sup>3</sup>  
(2016)

ColoSTAT<sup>®</sup> is expected to deliver a significant cost / benefit factor to assist the penetration of both domestic and international markets.

1. Cancer Council, Pre-budget submission 2012-2013 2. Ananda et al, Asia-Pacific Journal of Clinical Oncology, Vol. 12, Issue 1, pages 33-40; March 2016) 3. St John & Grogan, Asia-Pacific Journal of Clinical Oncology 2016; 12: 7-9)



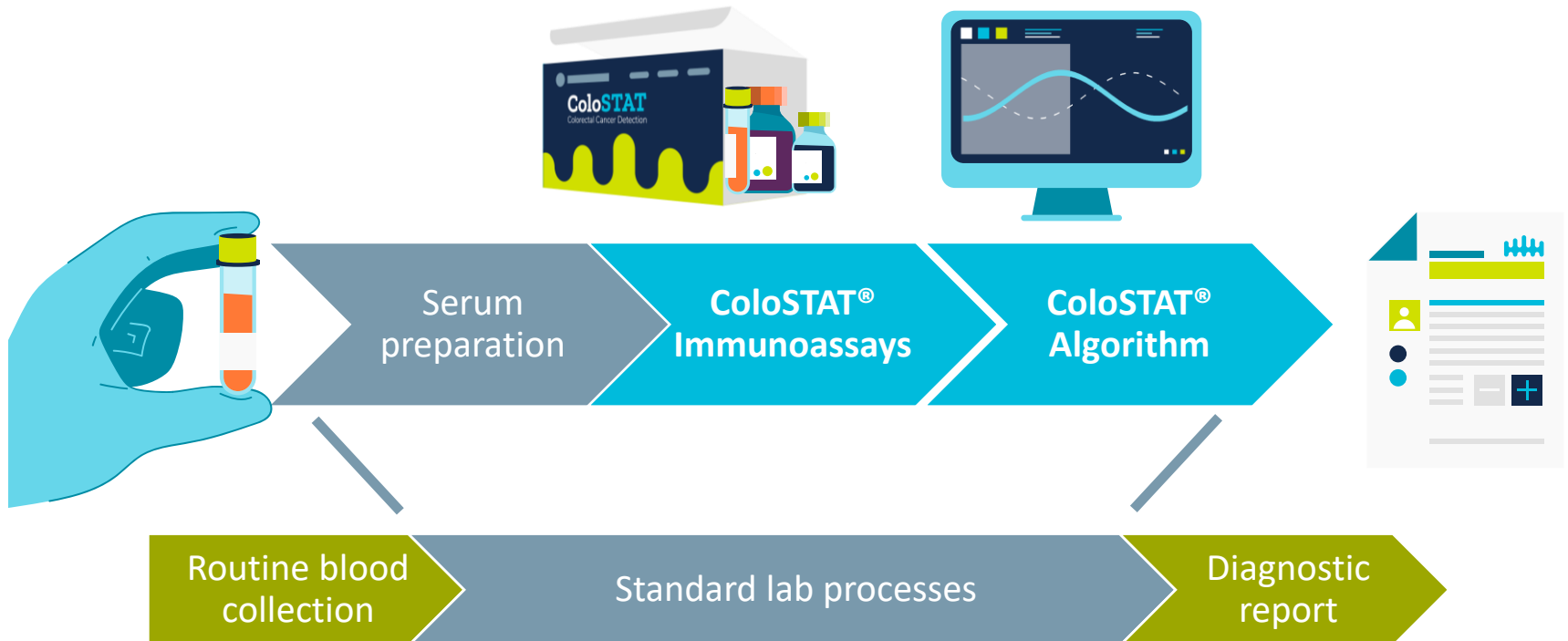
# ColoSTAT® - What Is It? How Does It Work?

**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)**

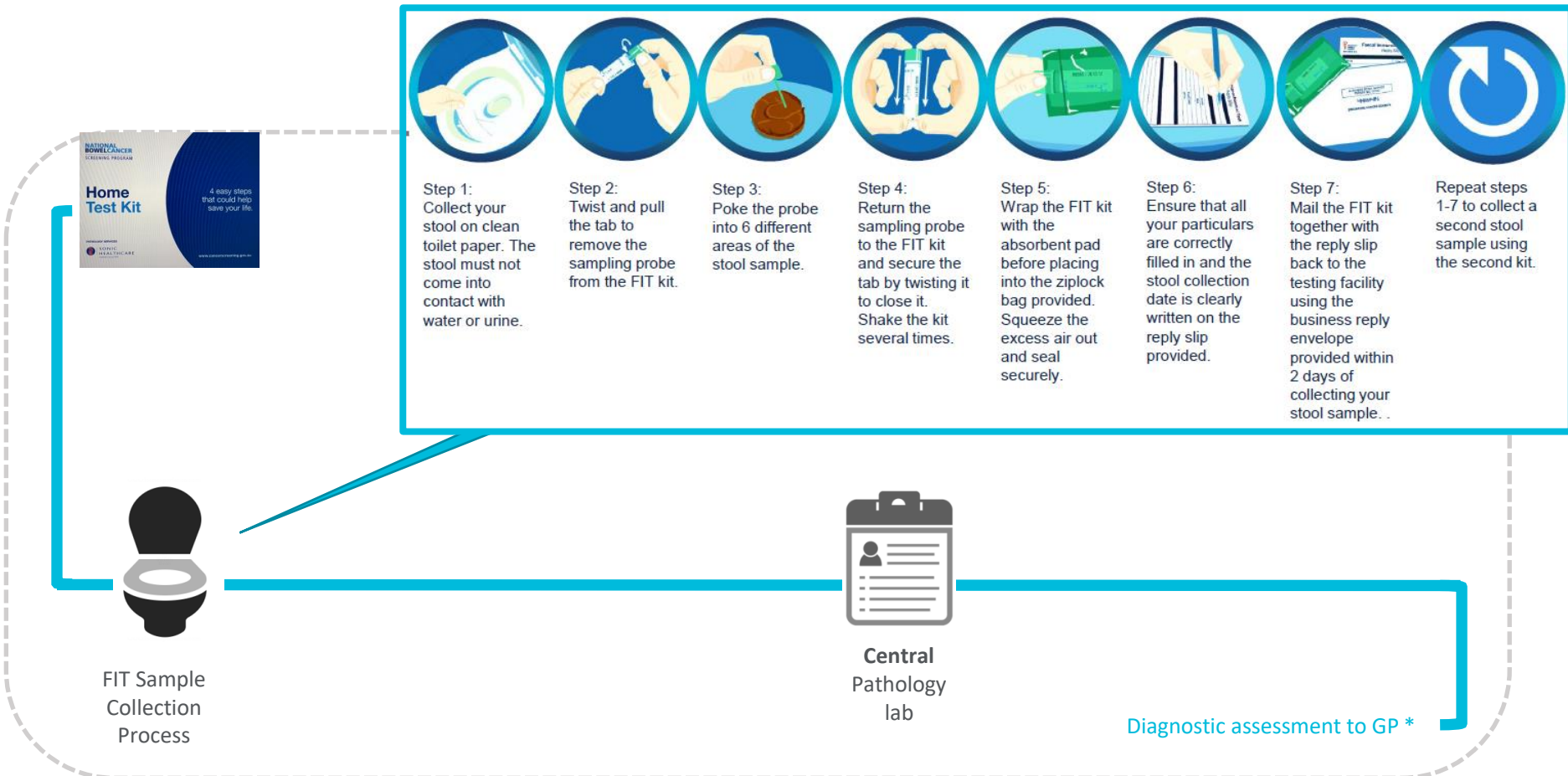
# ColoSTAT® - What Is It? How Does It Work?

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



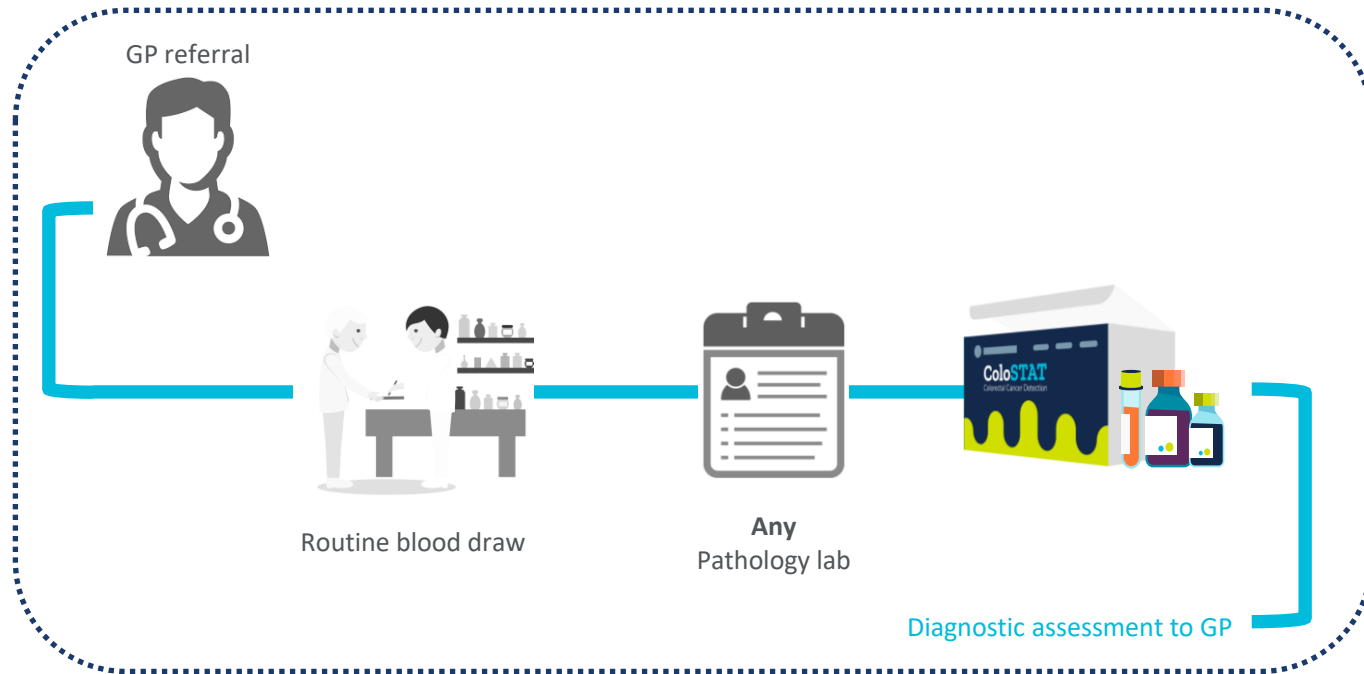
- **Multi step faecal collection, packaging over at least 2 days then posting sample back to a central laboratory. Obligation on patient to sample and label correctly and to follow up the result with a GP. Patient can determine if they will have a follow up colonoscopy.**

\* 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 increase screening compliance, saving more lives and benefitting the health system overall. Improves 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

Rhythm



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

## Faecal Immunochemical Test (FIT)

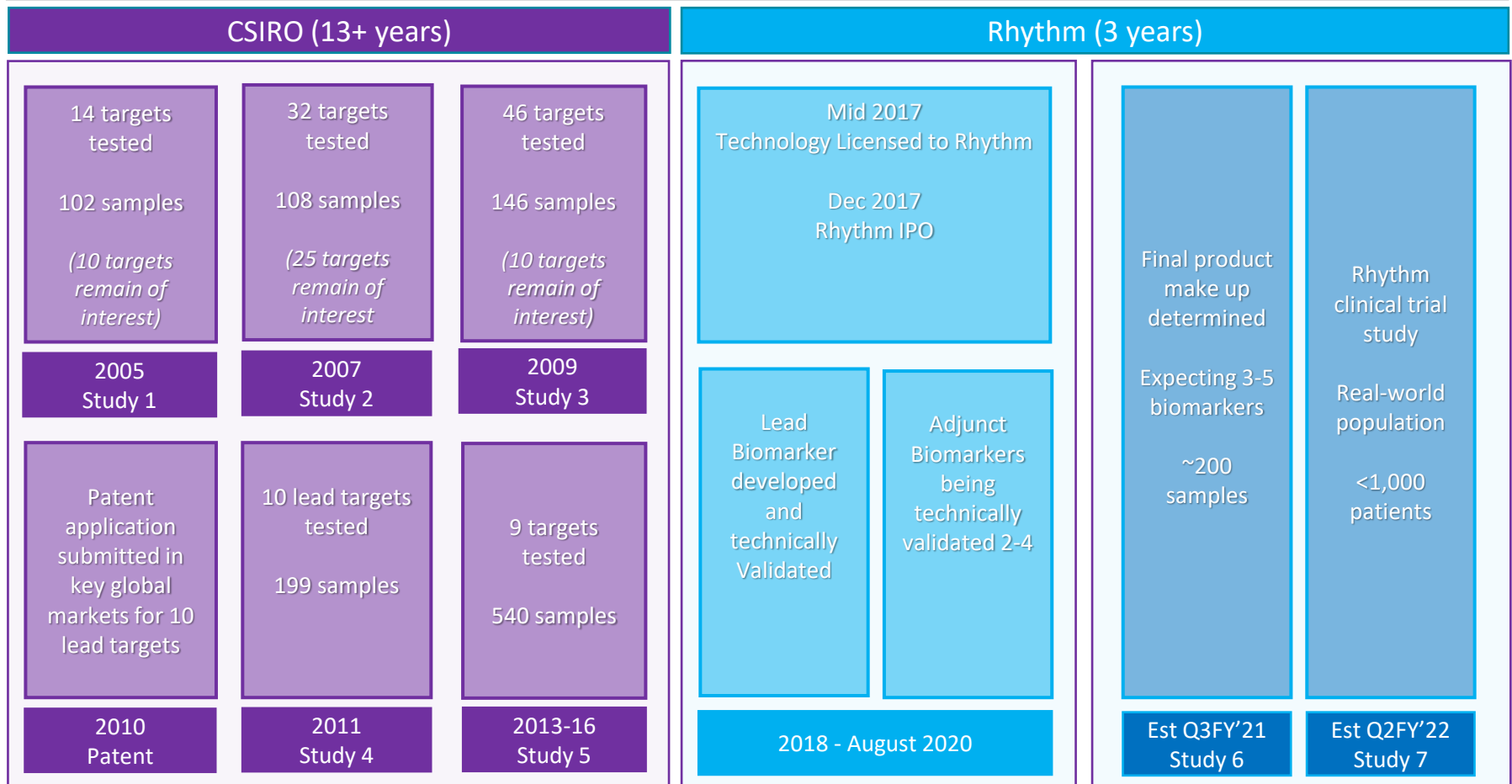
Patient Preference	✗
Accuracy	✗
Early Stage Detection	✓
Affordability	✓
Simple Process	✗
Opportunistic Screening*	✗

**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 licensed 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
<p>Prospective, Cross sectional, multicentre clinical trial.</p> <p>Two cohorts:</p> <p><u>Cohort 1:</u> Patients with a diagnosis of CRC who are progressing to surgery.</p> <p><u>Cohort 2:</u> Participants referred for colonoscopy by their physician.</p> <p>Each patient to provide:</p> <ul style="list-style-type: none"><li>➤ ColoSTAT® blood test</li><li>➤ Faecal (FIT) test</li><li>➤ Colonoscopy</li></ul>	<p><u>Primary:</u></p> <p>Performance of ColoSTAT® for detection of CRC relative to colonoscopy (<b>Sensitivity and Specificity</b>).</p> <p><u>Secondary:</u></p> <p>ColoSTAT® performance relative to colonoscopy for:</p> <ul style="list-style-type: none"><li>➤ Advanced adenomas.</li><li>➤ Clinically actionable neoplasia.</li><li>➤ Non-inferiority to FIT.</li></ul>

## ColoSTAT® Clinical Trial to confirm:

- ✓ Performance translates to a clinical setting.
- ✓ Works at least as well as FIT head-to-head.
- ✓ Suitable for mass population screening.

## 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

- ✓ ColoSTAT® **prototype test-kit complete** using Rhythm's proprietary algorithm that continue to improve.
- ✓ Preliminary results from the prototype test-kit **outperform current market standard** (faecal test) and previous CSIRO test work.
- ✓ CE Mark application may be submitted post Study 6 (prior to 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 in global markets. It will also provide some head to head data vs FIT.

# Key Achievements - Delivered In 2020

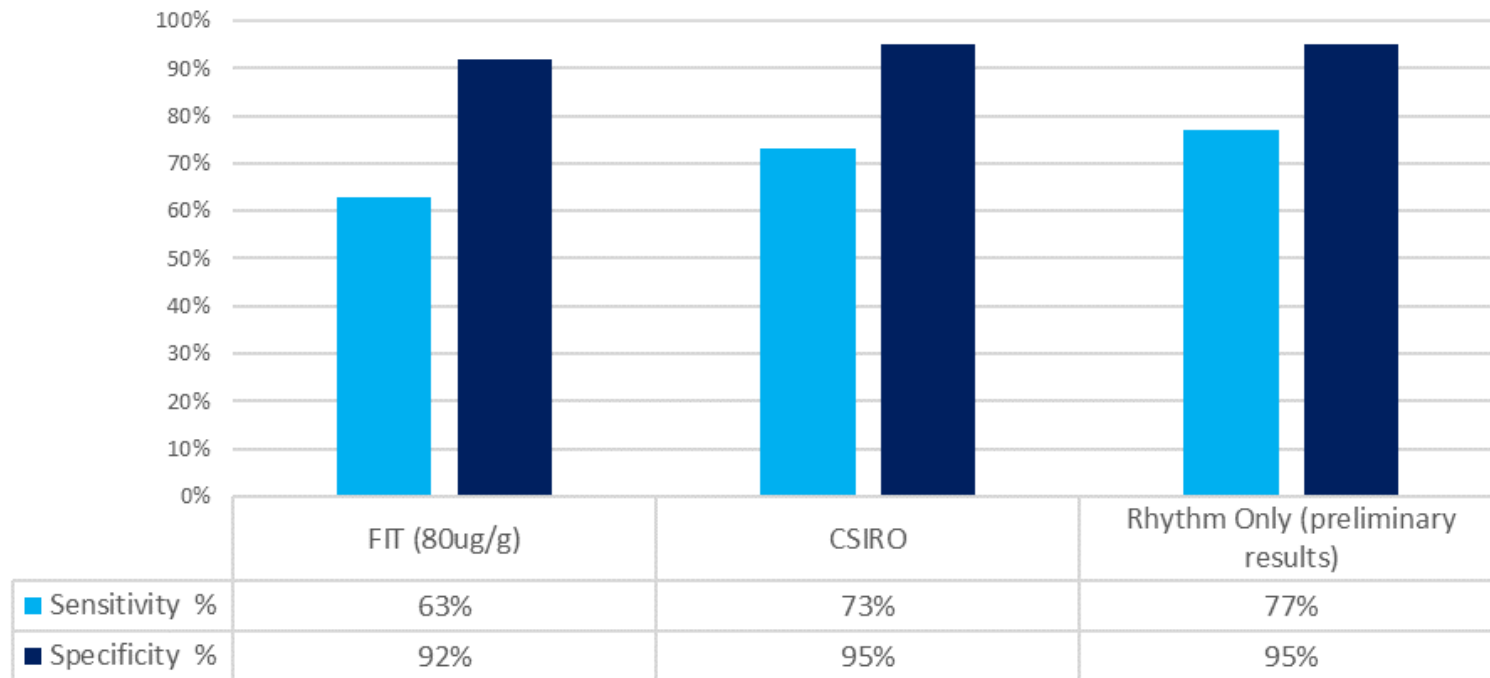
- ✓ Technically validated the key lead and four adjunct biomarkers.
- ✓ Appointed additional clinical trial (Study 7) sites.
- ✓ ISO13485 Quality Management System certification maintained.
- ✓ Completed reagent development program.
- ✓ Commenced high-volume manufacturer selection process.
- ✓ Granting of 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.

## None more important than...

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

# 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.

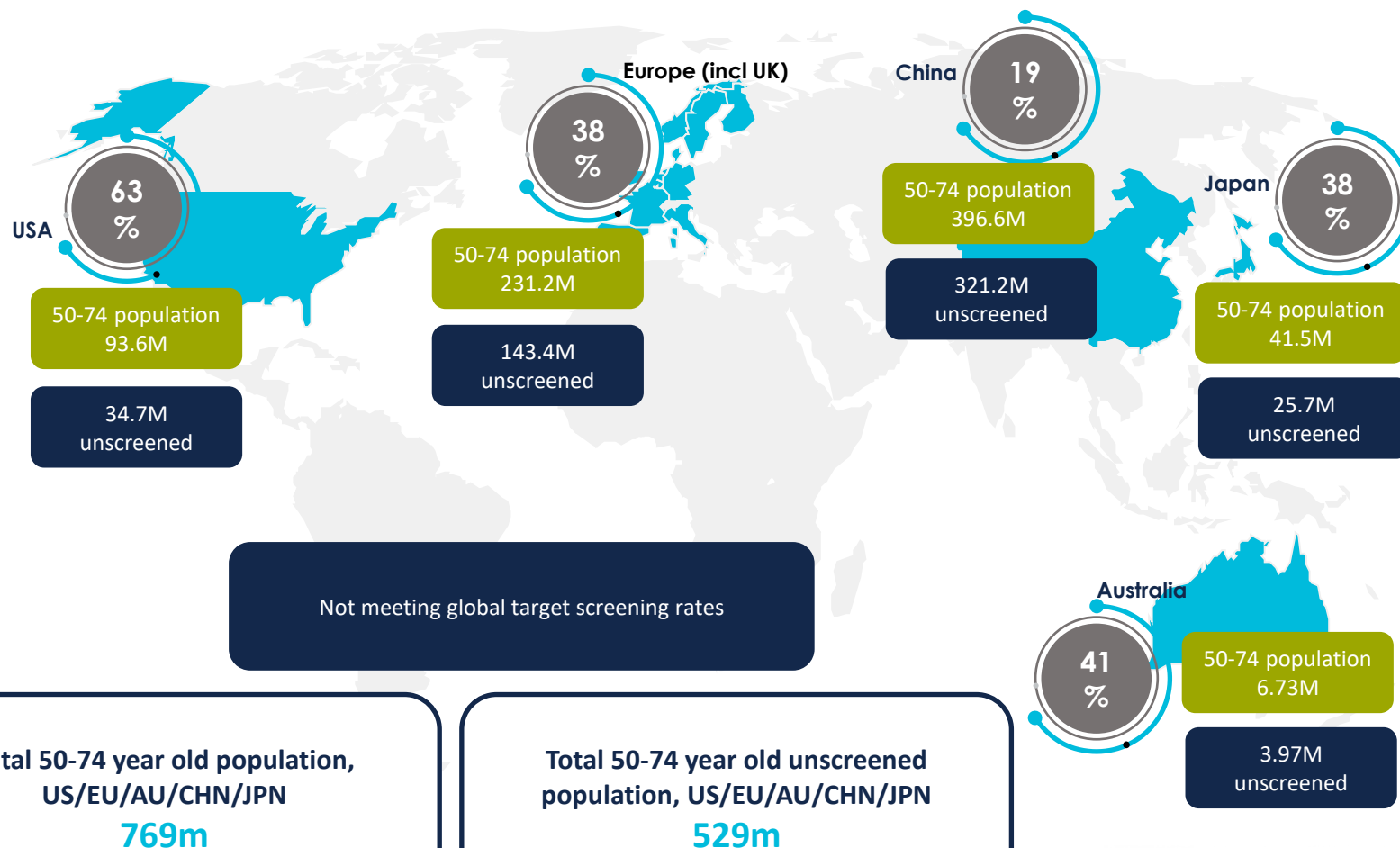
**Specificity** is the ability of the test to correctly identify people who do not have colorectal cancer, that is, the percentage of people without colorectal cancer who are correctly identified as not having cancer.

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



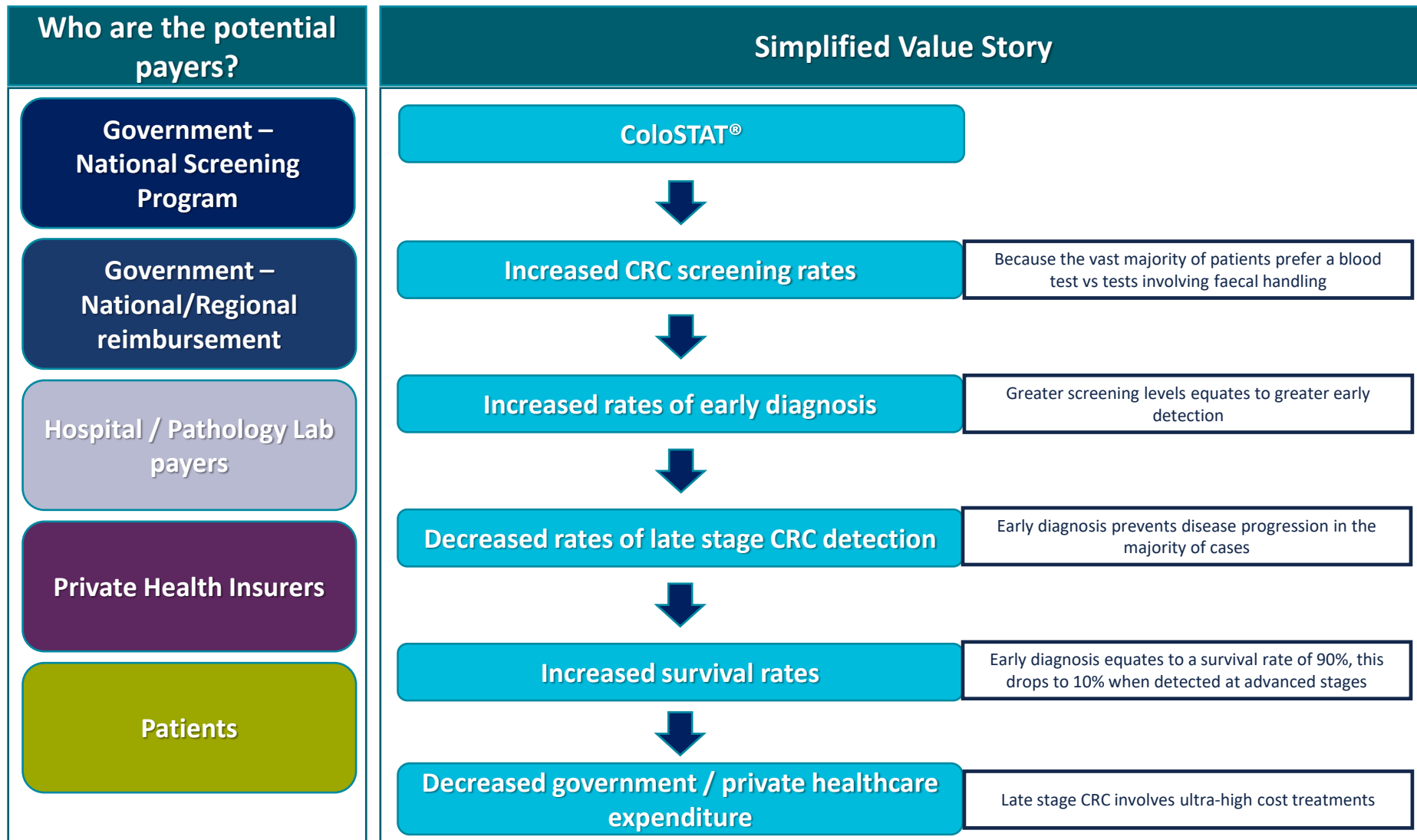
# Market Likely To Expand Significantly

## Colorectal Cancer is also prevalent in younger segments of the population

- ✓ Colorectal cancer is the leading cause of cancer related deaths for 30-to-35-year-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.

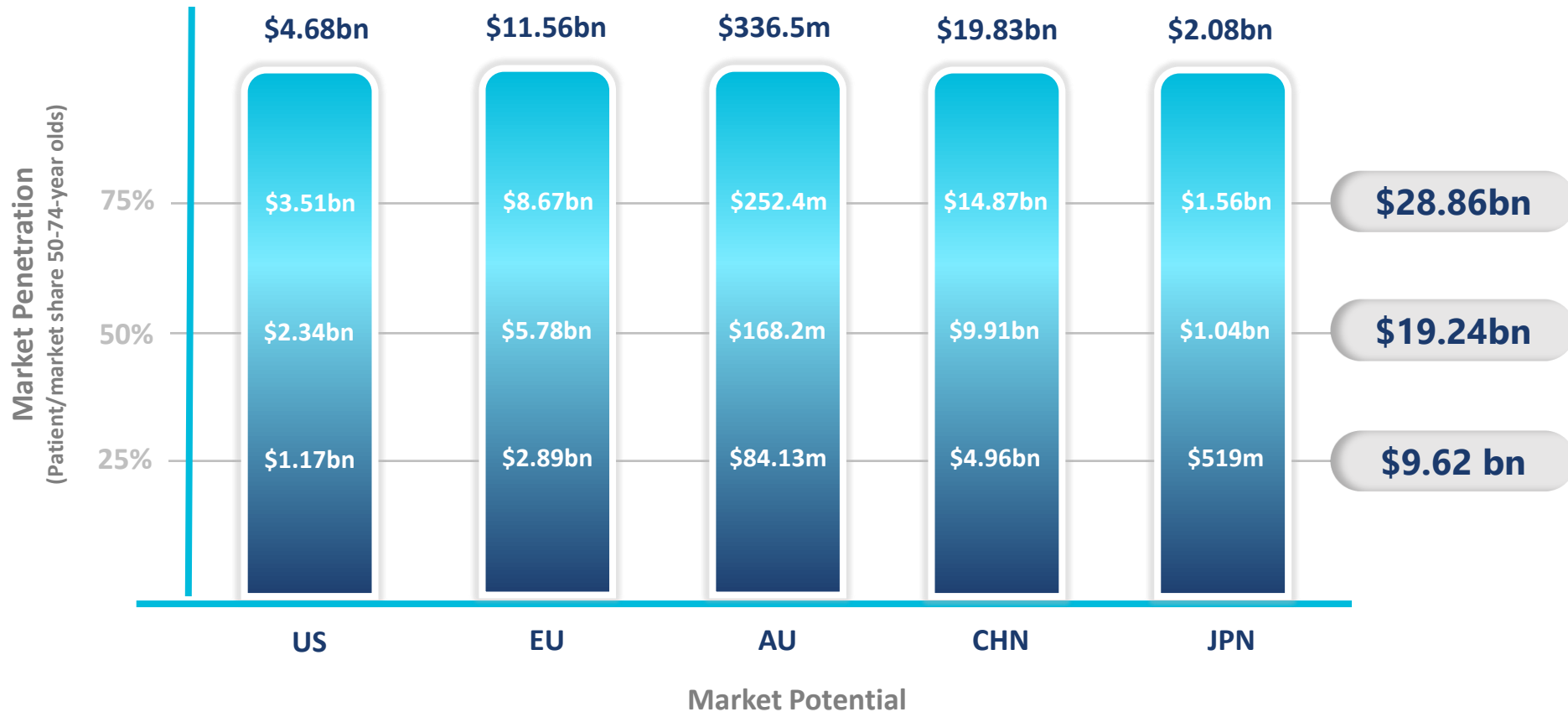
Source: <https://www.aihw.gov.au/getmedia/8c9fcf52-0055-41a0-96d9-f81b0feb98cf/aihw-can-123.pdf.aspx?inline=true>

# Where Could ColoSTAT<sup>®</sup> Value Be Derived From





# Potential ColoSTAT<sup>®</sup> Total Market Size (50-74yr old only)



The colorectal cancer screening market (50-74 population)<sup>#</sup> across US/EU/AU/CHN/JPN  
**\$38.49bn**

\*Assumption of \$50 AUD per test. RHY revenue may vary to this estimate

<sup>#</sup>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.

National  
Screening  
Markets

Triage

## 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.

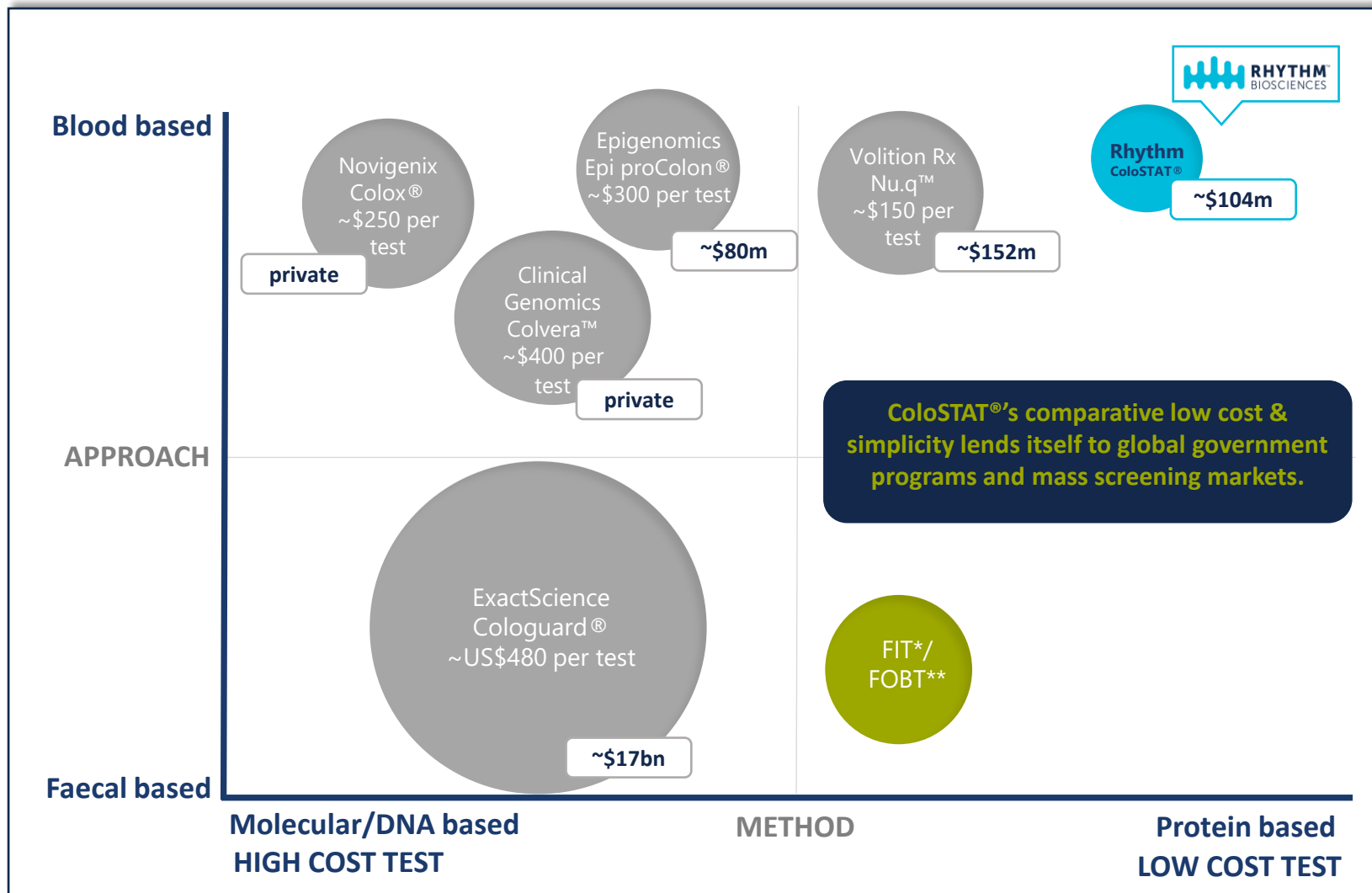
## Global Partnerships

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

Primary Care

Global  
Commercialisation

# Competitive Landscape – ColoSTAT®'s Unique Advantage



\* FIT = Faecal Immunochemical Test

\*\* FOBT = Faecal Occult Blood Test

# IP – Patents Filed In All Major Target Markets

- Licensed from CSIRO
- Worldwide exclusive licence
- Patent wholly owned by Vision Tech Bio Pty 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

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

\*Vision Tech Bio Pty Ltd is a 100% owned subsidiary of Rhythm Biosciences Ltd

# Future Value Inflection Points – 2020-2021

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

- Further clinical trial sites to be appointed to accelerate recruitment.
- Design transfer of the ColoSTAT® prototype test-kit to a high-volume manufacturer.
- Series of cancerous & healthy blood sample tests on third-party kits (Study 6) on track for completion Q3FY'21.
- Biomarker panel finalisation on track for completion Q3FY'21.
- Issuance of USA patent.
- Clinical trial on track for recruitment completion in 2021.#
- CE Mark application.\*#
- Identify key sales, distribution & diagnostic companies for partnering.

\*CE Mark submission may be undertaken prior to Study 7 completion, subject to data generated

# Subject to COVID-19, government restrictions, hospital protocols & staff, 3<sup>rd</sup> party limitations, global supply chain impacts and the like



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A stylized illustration of a human torso in light gray. The digestive system is highlighted in a vibrant blue, showing the esophagus, stomach, and a coiled section of the small intestine.

**Thank you**