



**A Medical Diagnostics Technology Company**

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

Corporate presentation July 2019

**ASX: RHY**



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# Corporate Overview

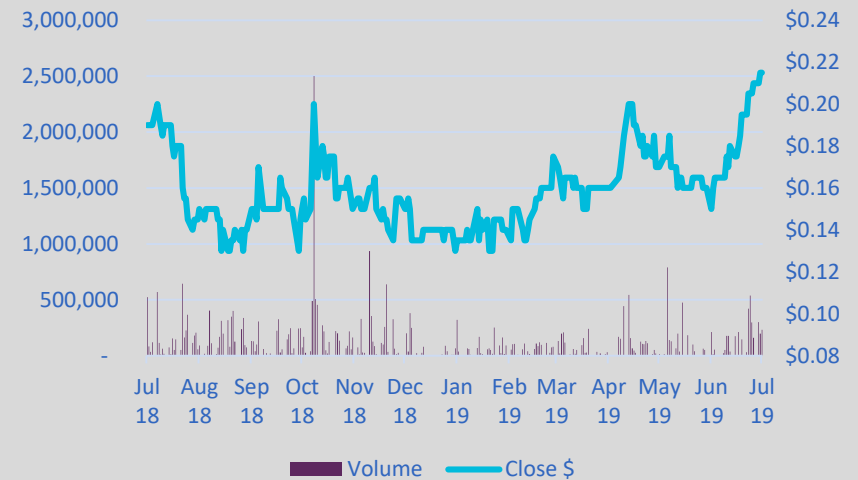
## Rhythm Biosciences – A medical diagnostics technology company

Rhythm Biosciences is positioning itself as a new generation medical diagnostics technology developer for local and international markets.

**ColoSTAT®** is the first proposed product-in-development, which is a simple, accurate and low cost blood test for the early detection of colorectal cancer, suitable for the global mass market.

Whether used as a primary or secondary triage screening test, ColoSTAT® can play an important role in reducing the economic and emotional burden of colorectal cancer.

Financial Information	
ASX Ticker	RHY
Share Price (22 Jul 2019)	\$0.21
12-Month Range	\$0.13 - 0.23
Shares on Issue	~100.7M
Market Capitalisation	~\$21M
Cash on hand (30-Jun-19)	~\$4.7m



# ColoSTAT® by Rhythm Biosciences

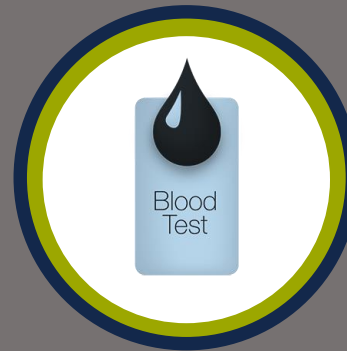
**ColoSTAT® A simple, accurate and low cost blood test for the early detection of colorectal cancer, suitable for the global mass market**



**ColoSTAT® is designed for the detection of colorectal cancer at all stages**



**An Australian innovation pioneered and developed by the CSIRO for over 13 years**



**A simple blood test using protein based bio markers that integrates with existing pathology infrastructure**



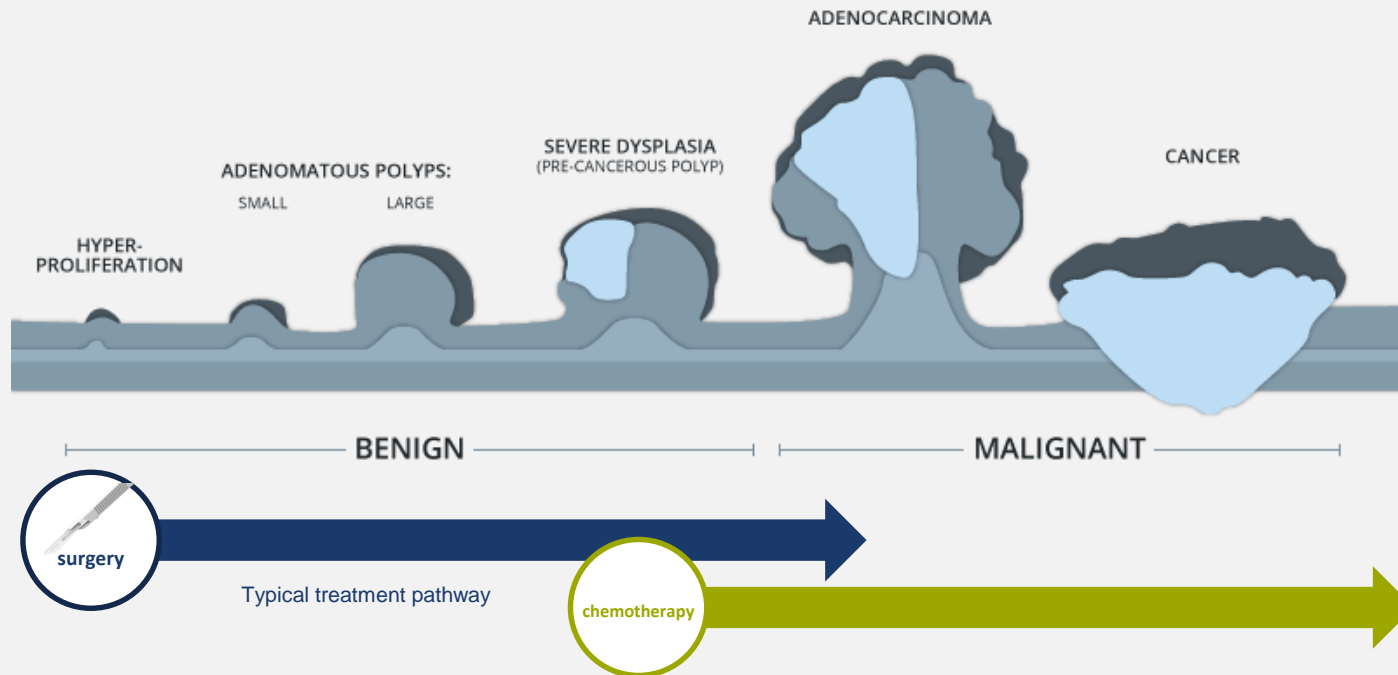
**Low cost and patient friendly - suited to the global mass screening market**

# Colorectal Cancer: Introduction









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

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

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



# Early detection is the key to survival

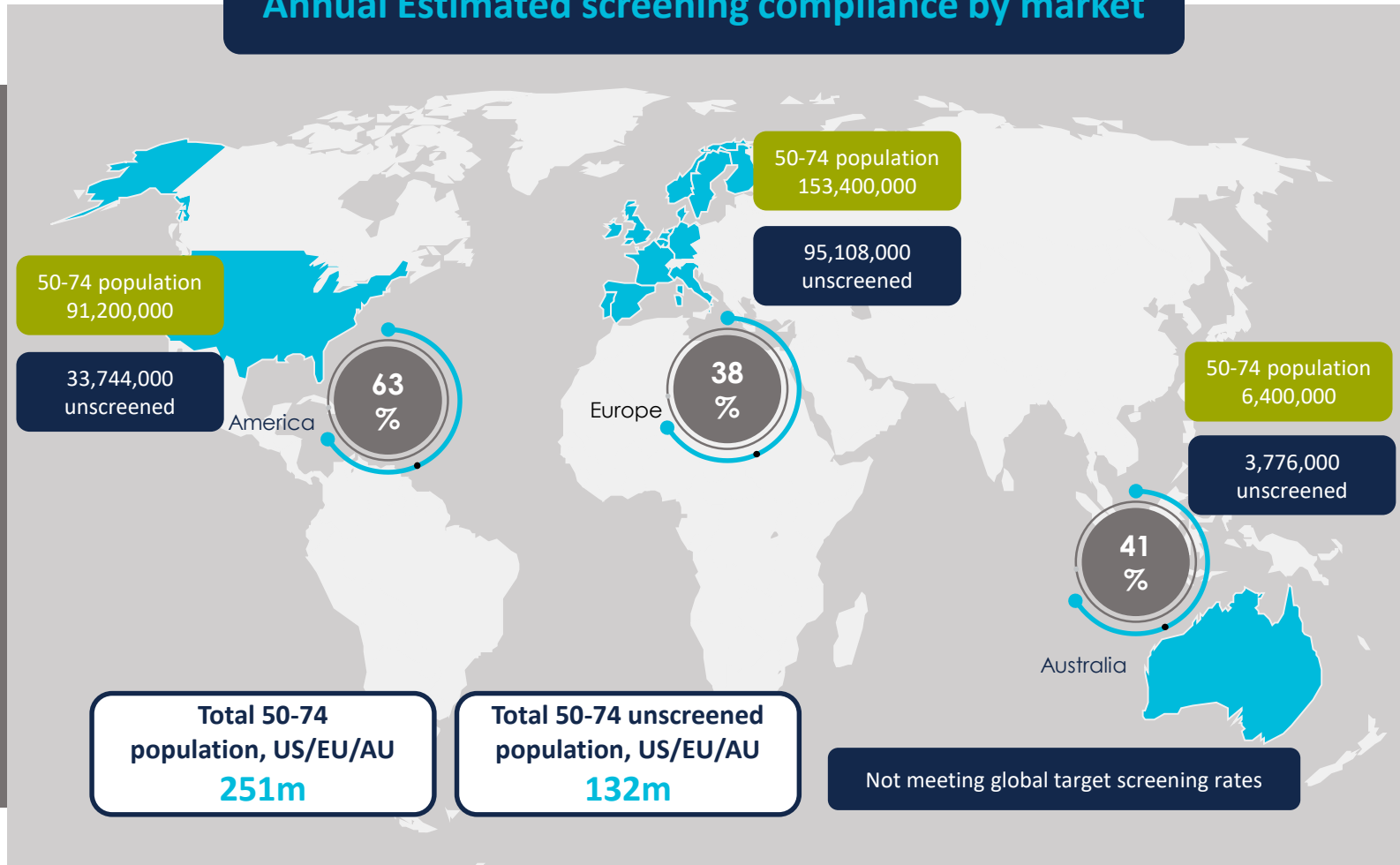
Stage	0	I	II	III	IV
<b>Description</b> 	Abnormal cells are found in the epithelium (mucosal layer) lining the bowel wall, most often outgrowths (adenomas or polyps). These abnormal cells may become cancer and spread.	Tumour has invaded beyond the epithelium of bowel into the muscle layers below but has not spread past the bowel wall.	Cancer has grown through the muscle layer of the bowel and invaded nearby tissue, but has not spread to the lymph nodes	Cancer has spread to the nearby lymph nodes but not to other parts of the body	Metastatic bowel cancer where it has spread beyond the colon and rectum to other organs such as the liver or lung.
<b>5-year % survival rate</b>	<b>&gt;96%</b>	<b>93%</b>	82%	59%	8%
<b>Treatment</b>  	Typically, surgery to remove the adenoma or local excision through a colonoscope. Removing part of the colon (partial colectomy) is occasionally needed if a tumour is larger.	Cancers of this stage require removal of the affected section of the large bowel and sometimes lymph node clearance but typically no additional treatment is necessary.	Partial colectomy along with dissection of nearby lymph nodes may be the only treatment needed. Adjuvant chemotherapy may also be required.	Partial colectomy along with dissection of nearby lymph nodes, along with adjuvant chemotherapy. If rectal, radiation therapy and/or chemo may be options for people not healthy enough for surgery.	Neoadjuvant chemotherapy to reduce tumour size, surgery and/or tumour stenting. Additional therapies also needed as well as radiation therapy and still only an 8% chance of survival.
					

**Governments currently fund screening for 50-74 year olds**

**However, there are currently over 132,628,000 million people who fall within the at-risk age not being screened each year**

# Global screening of 50-74 year olds

## Annual Estimated screening compliance by market



# Why aren't people being screened ?

Based on  
current FIT  
testing

**Acceptability:** Aversion to the handling of faeces

**Complexity:** Multiple steps, several pieces of equipment

**Avoidance:** Dislike colonoscopy and bowel preparation

**Suitability:** FIT not suitable for some populations (e.g. GI bleeding)

**Suitability:** FIT not suitable for some geographies (e.g. high temperatures)

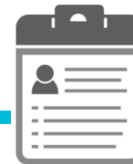


# ColoSTAT® : patient friendly = increased compliance

## Today – FIT testing



FIT Sample  
Collection  
Process



Central  
Pathology  
lab

Diagnostic assessment to GP \*

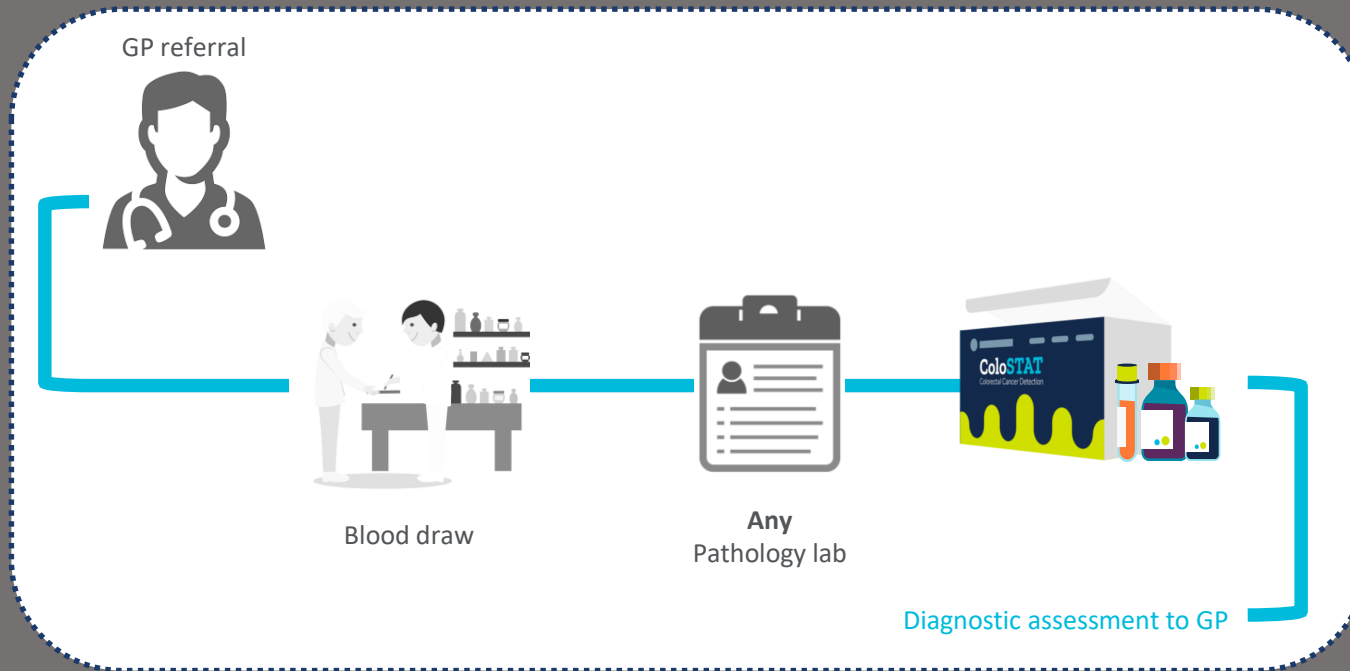
**Multi step faecal collection, packaging over at least 2 days then posting sample back to a central laboratory. Obligation on patient to sample and label correctly and to follow up the result with a GP**

*\* 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” \***

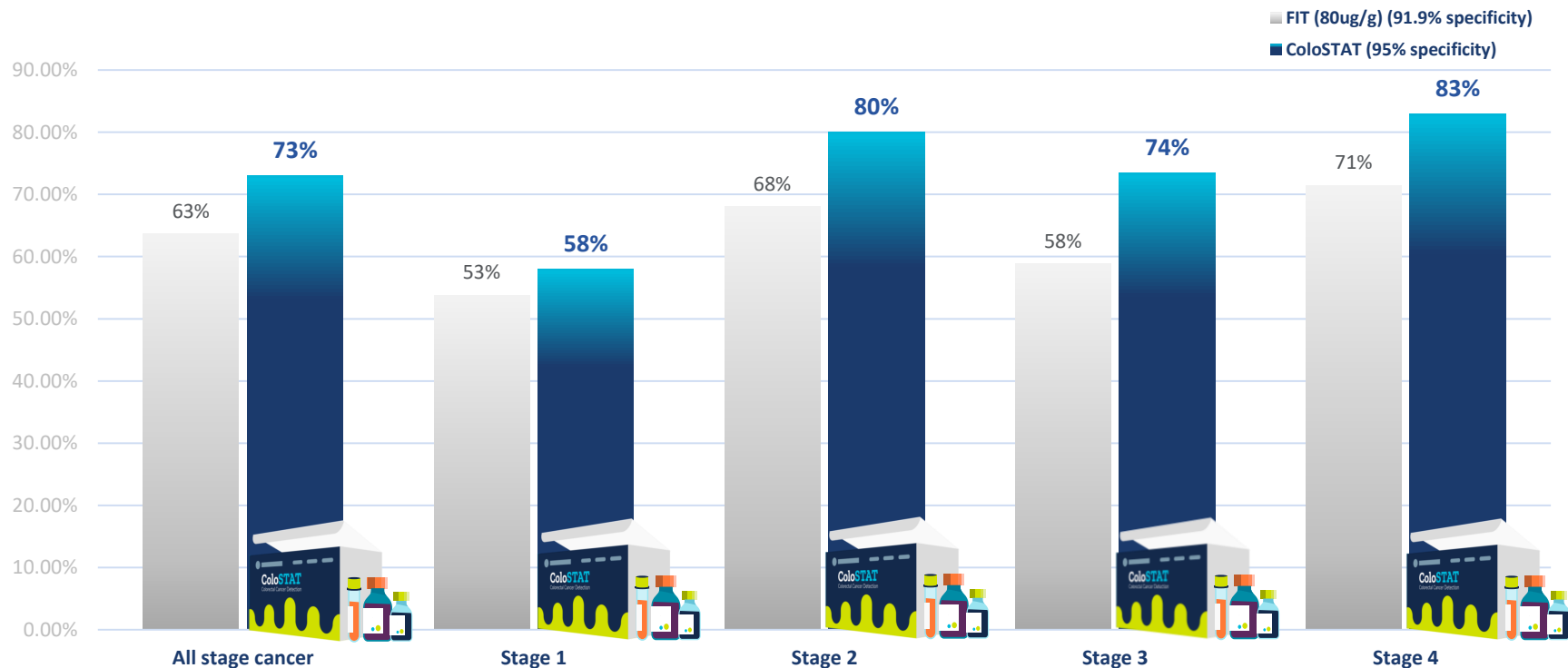
## With ColoSTAT®



ColoSTAT® - a less involved and simpler process that has the potential to increase compliance to screening, and ultimately saving more lives

\* 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.

## 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.

# ColoSTAT®'s competitive advantage

Rhythm



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

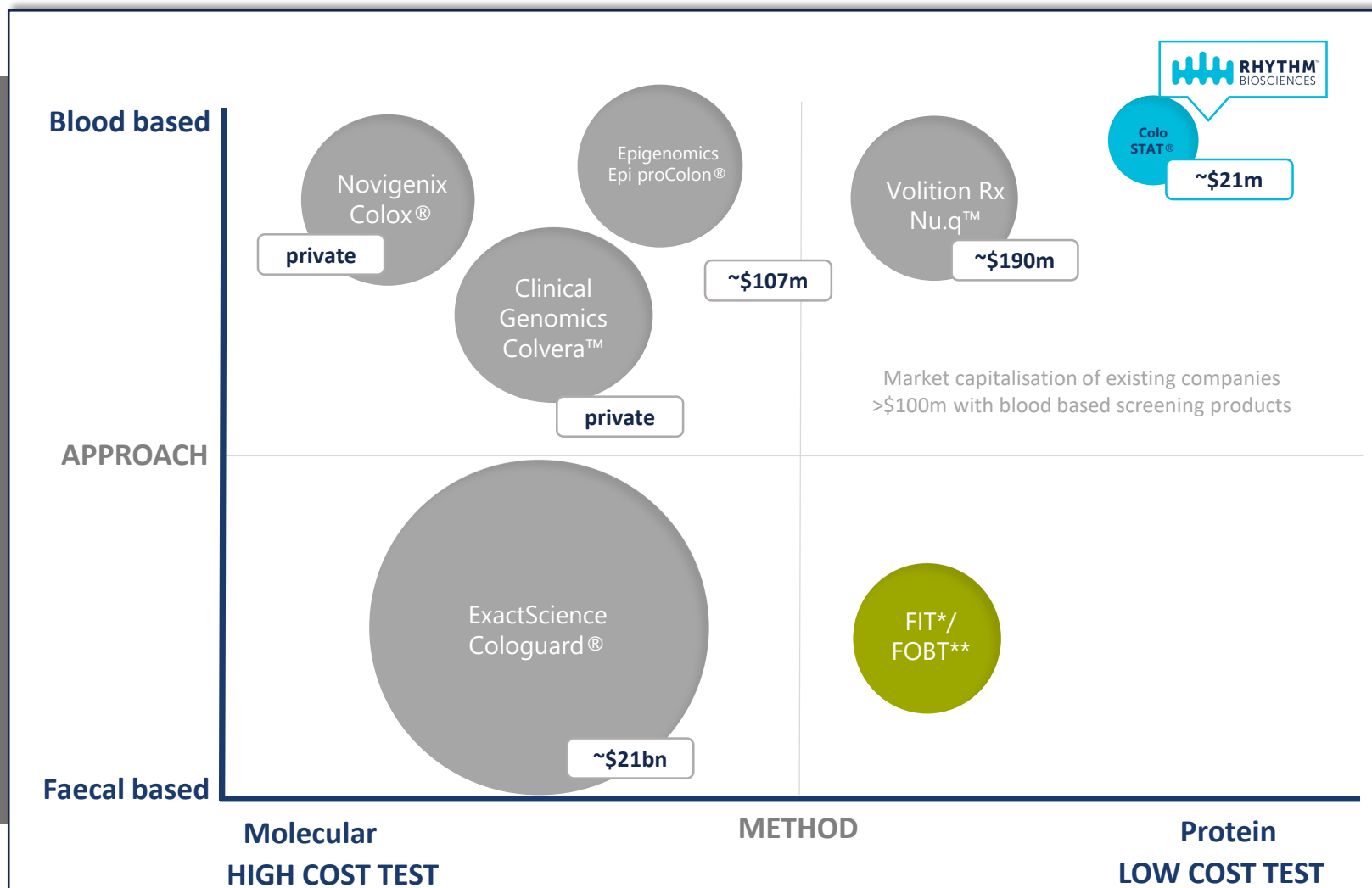
## Faecal Immunochemical Test (FIT)

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*

# Competitive Landscape – ColoSTAT®'s unique advantage

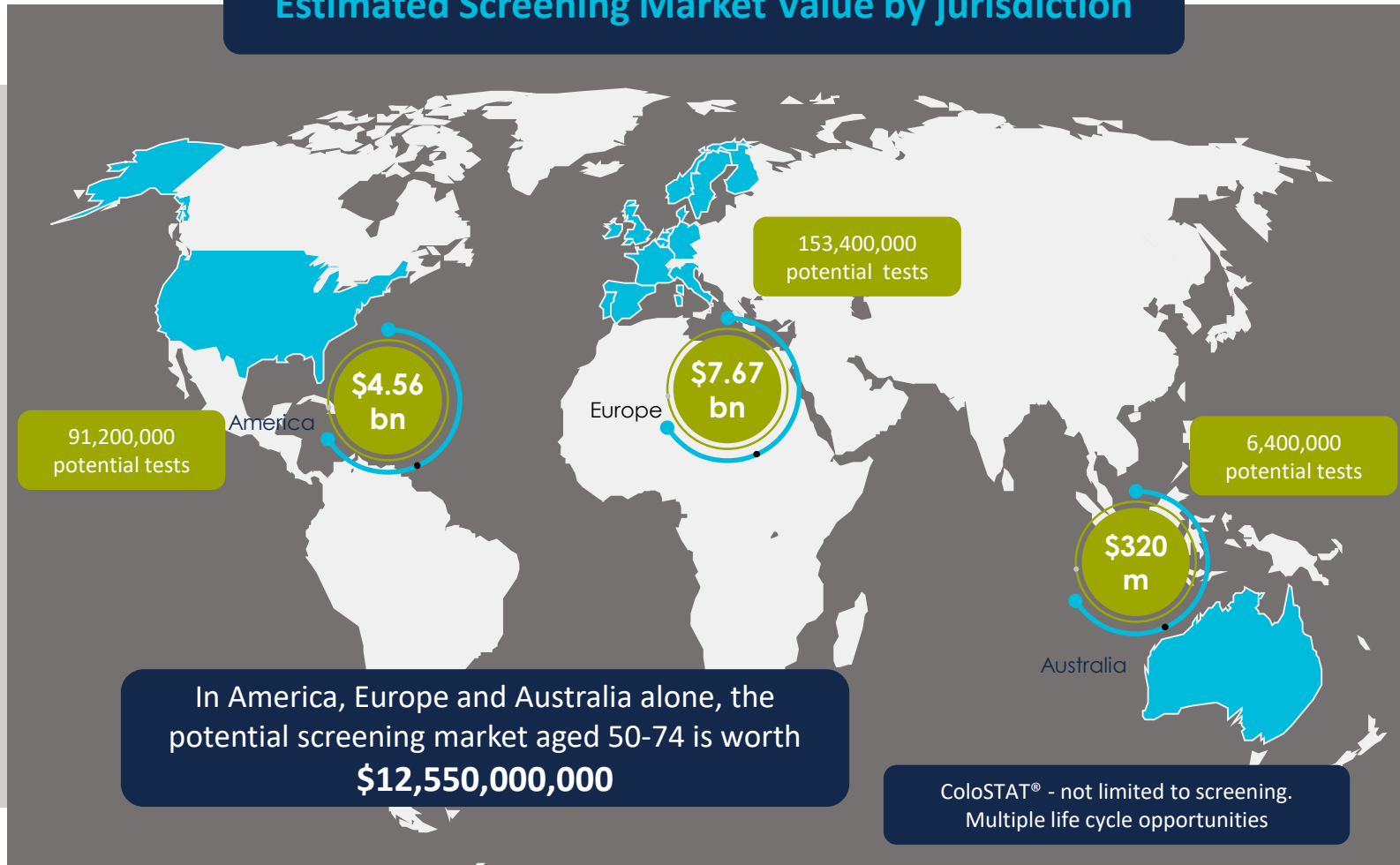


• FIT = Faecal Immunochemical Test

\*\* FOBT = Faecal Occult Blood Test

# Market Overview

## Estimated Screening Market Value by jurisdiction



\* Assumes a nominal test price point of AU\$50

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# Path to Market

**Rhythm Biosciences simple, accurate and low cost blood test will fill a unique space in the mass screening market**



**Research & development**  
(cast/control studies over 13 years)



**Reagent development**



**IVD kit development & production transfer**



**Clinical trial**



**Regulatory submissions**  
(Europe & Australia)



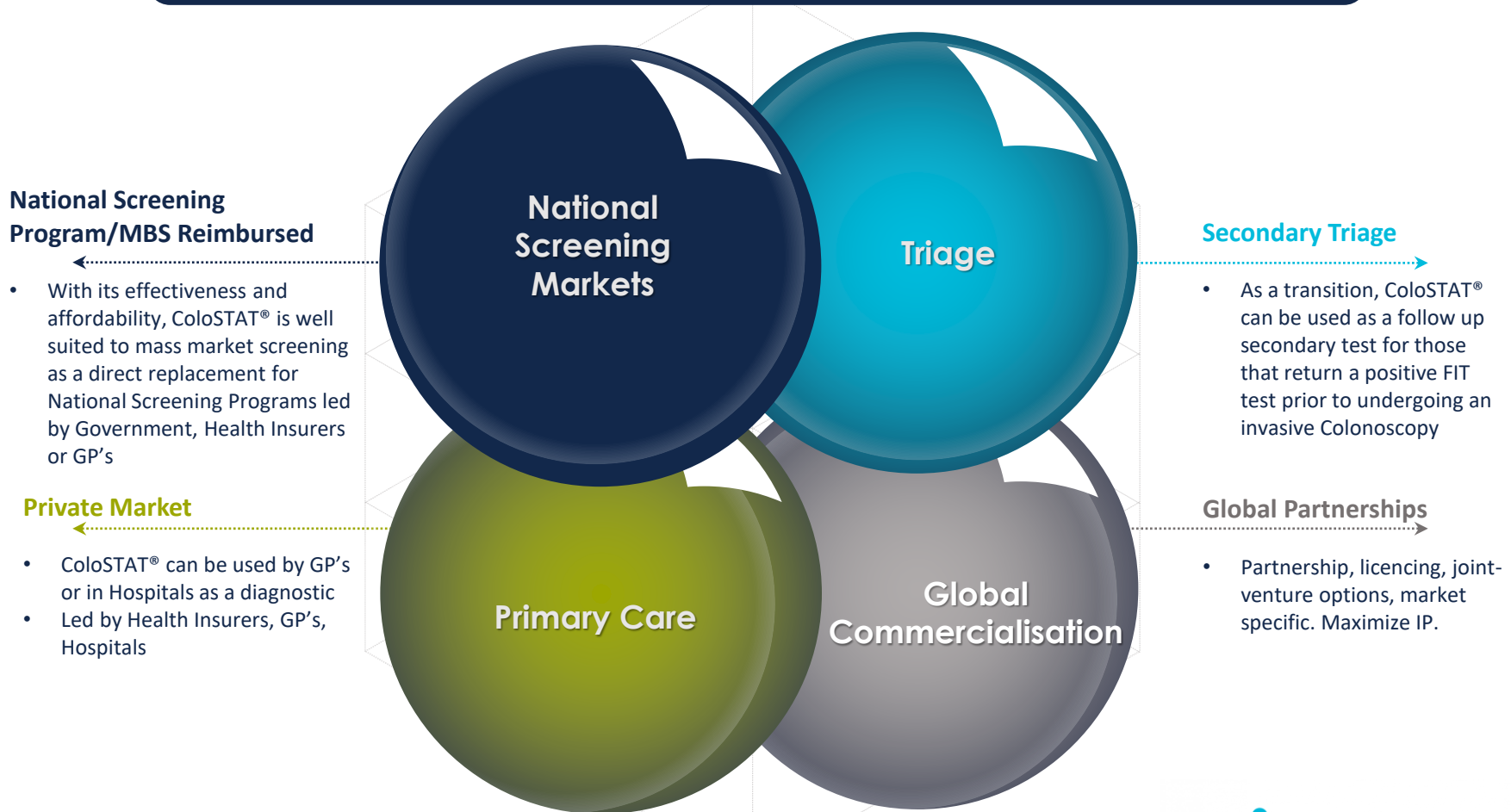
**Market entry**  
AU, EU,  
+ Others

FY20

FY21

# Go to Market Options

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





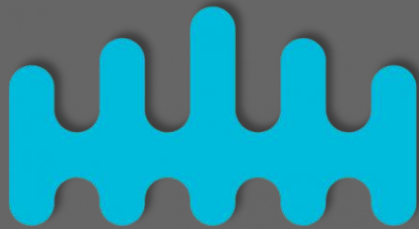
# Summary

**As a simple, accurate and low cost blood test, Rhythm's ColoSTAT® has the potential to significantly increase global screening compliance and save more lives**



- There are over 251m people aged 50-74 in the US, EU and AU alone that are at risk and should be screened for Colorectal Cancer
- Over 132m (60%) are not tested
- 850,000 people die each year, with 1.8m new cases diagnosed annually
- Patients, Insurers, Governments, Physicians want an alternative to the current faecal based test

# Why Invest in Rhythm ?



## 1 Significant Opportunity

Mass screening market worth over \$12bn for people aged 50-74 in the US, EU, and AU alone. Market wants change.

## 2 Sound technology

Over 13 years of research and testing pioneered by the CSIRO\* giving confidence in the biomarkers selected

## 3 Simple Business Model

ColoSTAT® Test integrates with existing pathology infrastructure

## 4 Scalable commercial model

Scalable and flexible implementation by market and segment

## 5 Experienced Team

Long tenure with successful history in the healthcare sector

## 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

# Board and Management

**A strong and experienced board & management team with proven commercial, operational and industry experience**



SHANE TANNER	GLENN GILBERT	TREVOR LOCKETT	LOU PANACCIO	DAVID WHITE
Chairman	Chief Executive Officer	Technical Director	Non-Executive Director	Non-Executive Director
<ul style="list-style-type: none"> <li>Chairman Paragon Care Ltd</li> <li>Chairman Zenitas Healthcare Ltd</li> <li>Director Victory Offices Ltd</li> <li>Former CEO Symbion Health</li> </ul>	<ul style="list-style-type: none"> <li>Former Rhythm COO</li> <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>Director Sonic Healthcare Ltd</li> <li>Chairman NeuralDX Ltd</li> <li>Chairman Avita Medical Ltd</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, Blue Chip Limited</li> <li>US Business Development, Planet Innovation</li> <li>Molecular Sales, GenMark Dx</li> <li>Group Marketing Manager, Advanced Staining, Leica Biosystems</li> </ul>



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