



# Investor Presentation

25 October 2021 [ASX:RHY](#)

*A transformative and predictive  
cancer diagnostics technology company*

[rhythmbio.com](http://rhythmbio.com)

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# Introduction



Rhythm's initial product, ColoSTAT<sup>®</sup> is a **simple, low-cost** blood test for the early detection of colorectal cancer for **global mass-market** screening.

IP protection **secured** in all major international jurisdictions.



# Investment Highlights



Disruptive and transformative technology

Significantly cheaper and easier to administer

Globally addressable market

Performance better than market standard

Manufacturing & Patents secured

Initial revenues targeted for 2022



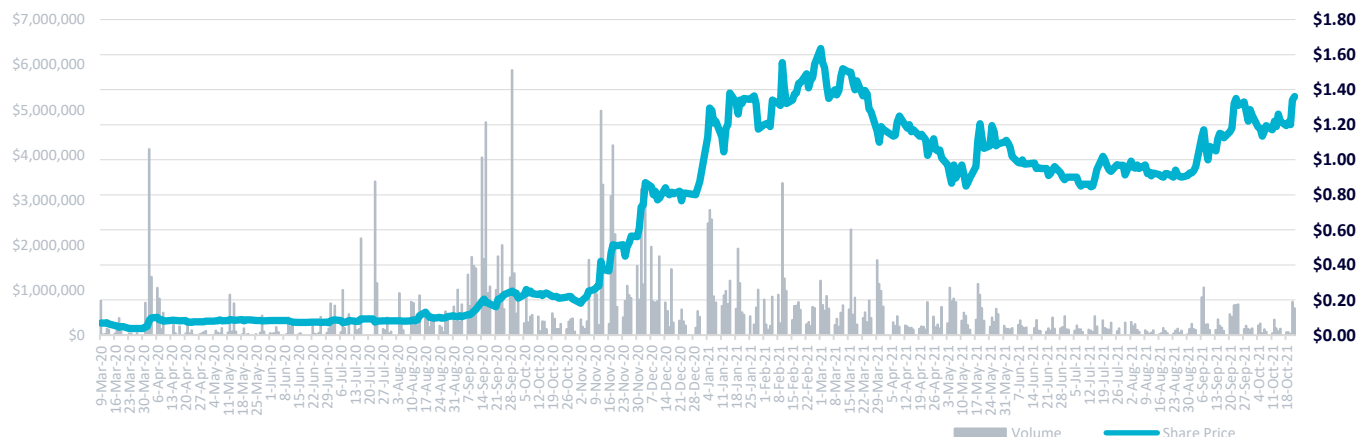
# Company Overview



## Capital Structure

ASX Code	<b>RHY</b>
<b>Share Price</b> (at 22 October 2021)	<b>\$1.36</b>
Shares on Issue	208.8 M
Unlisted Options	16.8 M
<b>Market Capitalisation</b>	<b>\$275 M</b>
Cash in bank (30 June 2021)	\$2.23 M ( <b>\$10.21 M**</b> )
Top 20 Shareholders	48%

## Share Price Chart



## Board and Management

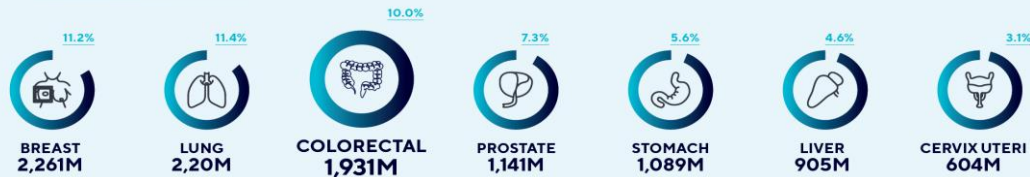
Otto Buttula	Glenn Gilbert	Trevor Lockett	Lou Panaccio	Eduardo Vom
Chairman	Chief Executive Officer	Executive-Director	Non-Executive Director	Non-Executive Director
<ul style="list-style-type: none"> <li>Extensive financial, investment and biotech experience.</li> <li>Co-Founder and CEO of IWL (ASX: IWL); Founder / former CEO of Investors Mutual.</li> <li>Formerly a Director of Imugene (ASX: IMU) and Chairman of Investofirst, now HUB (ASX: HUB).</li> <li>Chairman of HITIQ (ASX: HIQ), Non-Executive Director of Oncosil Medical (ASX: OSL).</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>Various leadership positions at CSL (ASX: CSL).</li> <li>Strong Legal, IP &amp; Operational management.</li> <li>Broad international business experience.</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>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>

\*\* additional \$7.98M (ex-costs) to be added following completed Rights Issue, Placement & FY'21 R&D tax refund (see ASX Announcement 7 September 2021 & 5 October 2021). Excludes Q1FY'22 expenditure.

# Colorectal Cancer



Globally, Colorectal Cancer is currently the 3<sup>rd</sup> largest cancer by volume with 1.9 million new cases diagnosed annually and 2<sup>nd</sup> largest cause of cancer related deaths.



## COLORECTAL CANCER RISK FACTORS

**50+**  
Aged over 50

Inherited genetic risk factor

Poor diet and lack of exercise

Smoking

A waistline of over 94cm for men and 80cm for women

A strong family history of bowel cancer

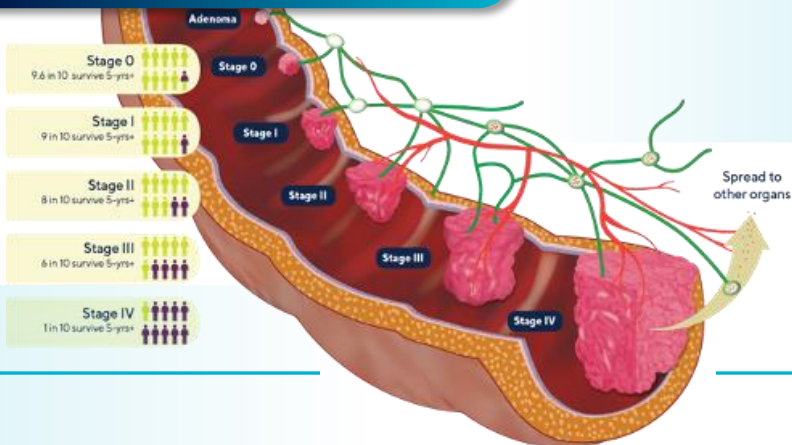
A serious inflammatory bowel disease for more than eight years

## GLOBAL BURDEN

**1.93 million** new cases **~940,000** deaths



## DIAGNOSIS BY STAGE



## 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 test (FIT), which is designed to test only for blood in the stool.

Early detection is key to survival



**>90%**

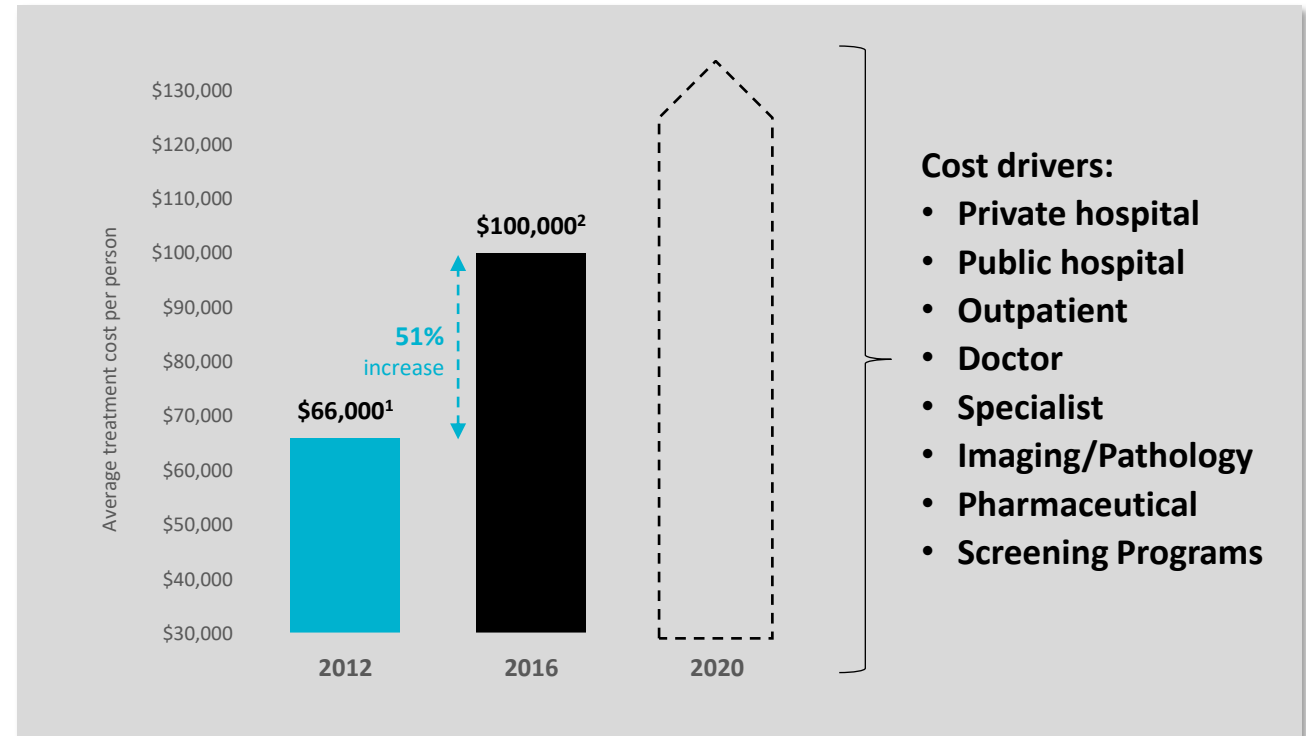
# Bowel Cancer Treatment Costs Are Increasing



ColoSTAT<sup>®</sup> is expected to increase participation, leading to earlier detection and avoiding costly treatments

“  
The National Bowel Cancer Screening Program could prevent 84,000 bowel cancer deaths by 2040 if participation rates were increased to 60% ”

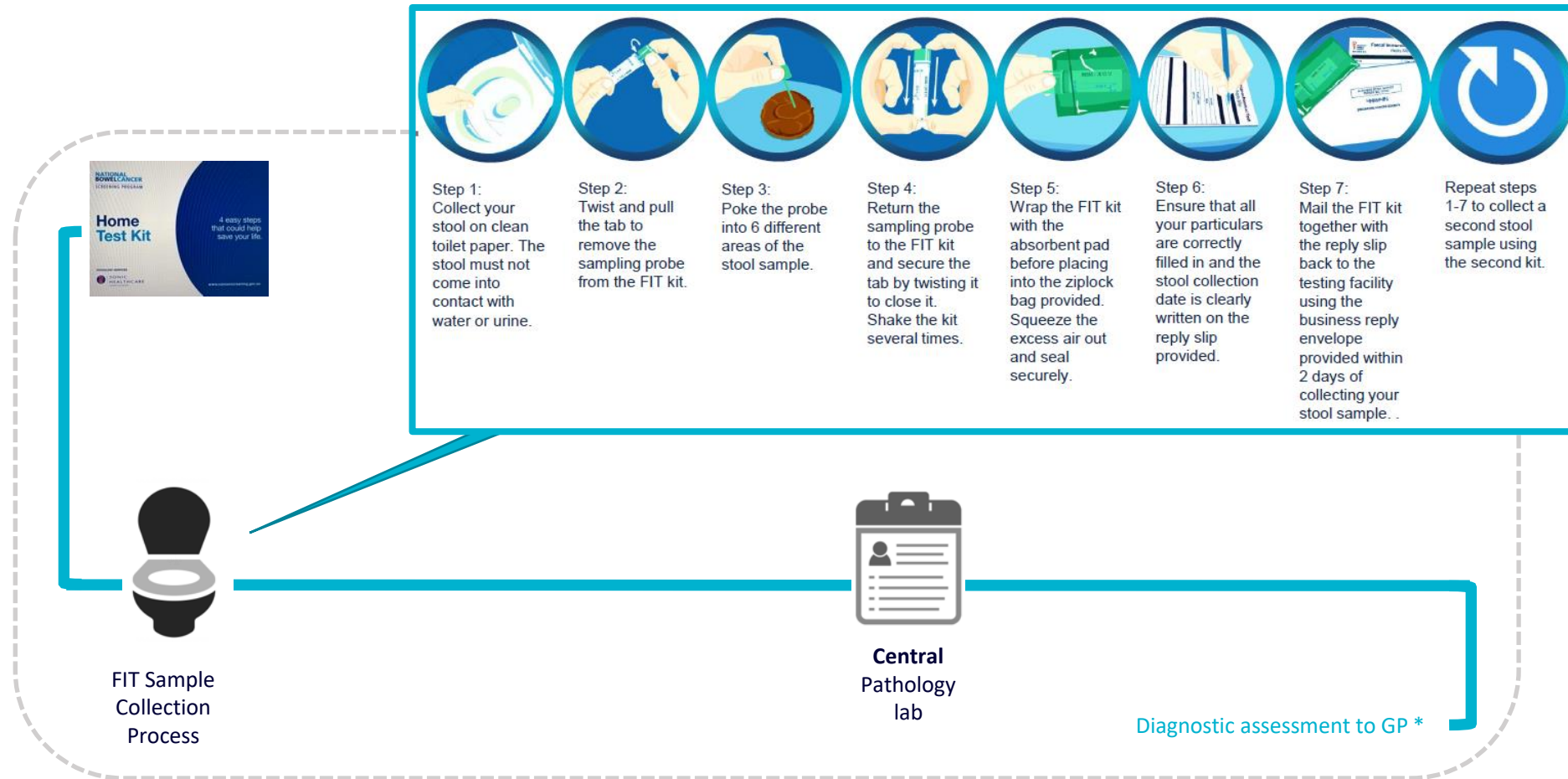
*Cancer Council Australia<sup>3</sup>*



<sup>1</sup>Cancer Council, Pre-budget submission 2012-2013. <sup>2</sup>St John & Grogan, Asia-Pacific Journal of Clinical Oncology 2016; 12: 7-9).

<sup>3</sup>Cancer Council 2021/22 Pre Budget Submission (page 6) - [https://treasury.gov.au/sites/default/files/2021-05/171663\\_cancer\\_council\\_australia.pdf](https://treasury.gov.au/sites/default/files/2021-05/171663_cancer_council_australia.pdf)

# Current FIT Pathway – Cumbersome & Not Well Adopted (<50% compliance globally)



- 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.

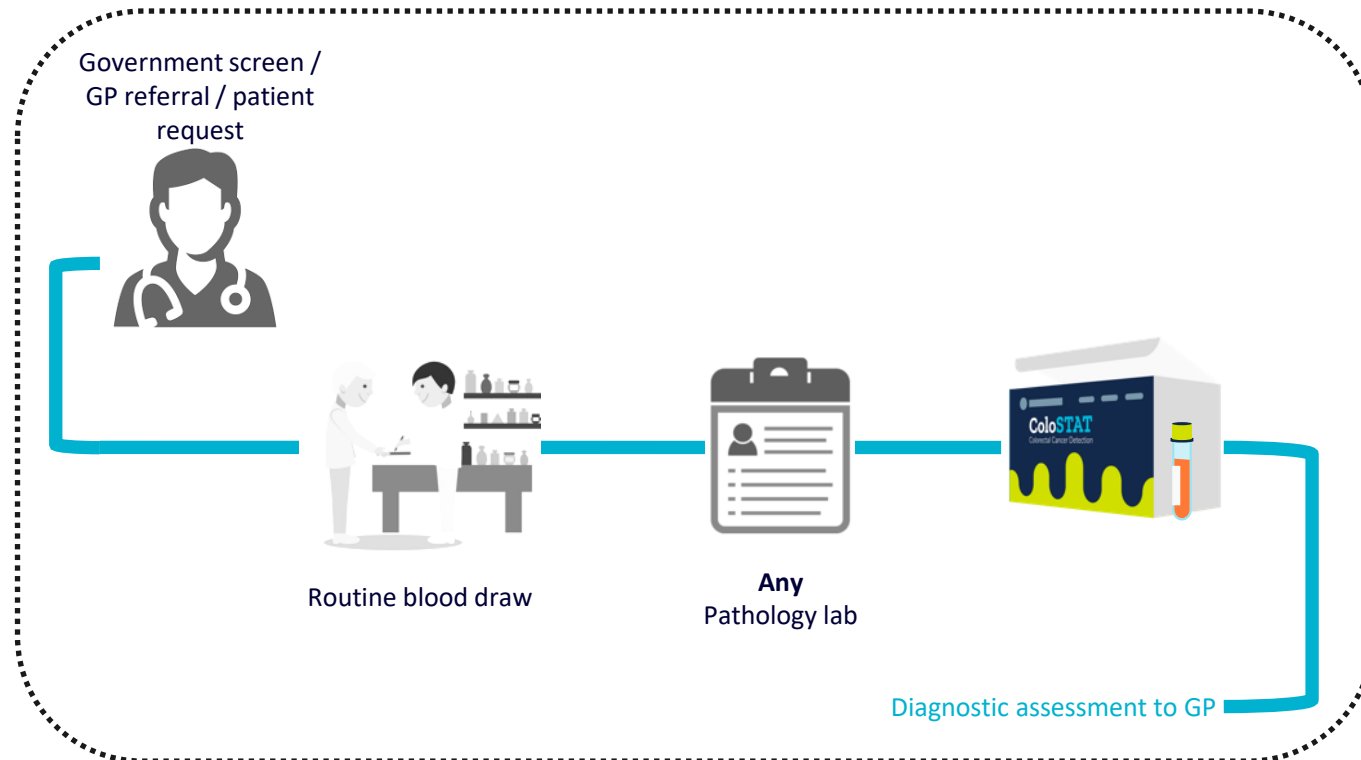


# ColoSTAT® - Patient Friendly, Increased Compliance



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

## Simple & Routine Patient Journey With ColoSTAT®



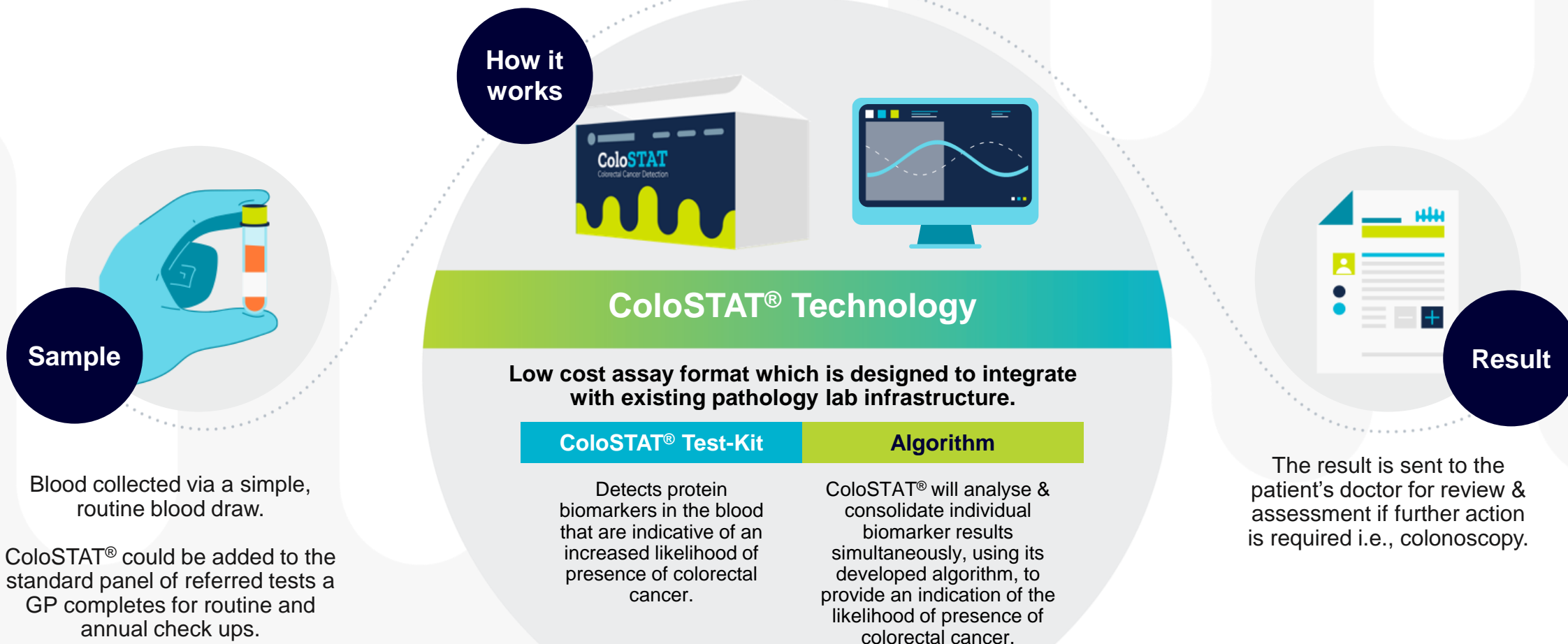
ColoSTAT® has the potential to:

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

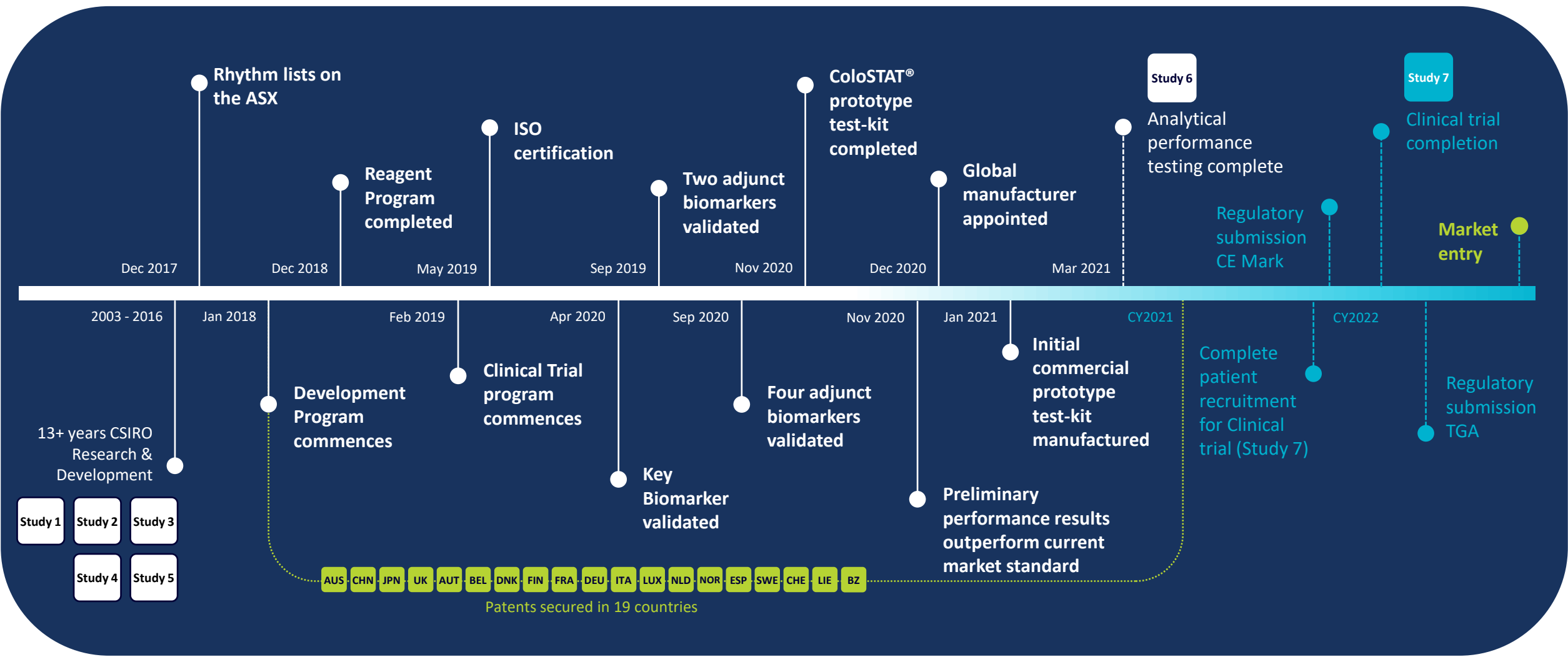
# ColoSTAT® - What Is It? How Does It Work?



Unlike the FIT, ColoSTAT® is specific for colorectal cancer – not just blood in faeces.



# ColoSTAT<sup>®</sup> - Detailed Development History



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



Trial Study Design	End Points
<p>Prospective, cross-sectional, multi-centre clinical trial.</p> <p>Two cohorts: <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> Performance of ColoSTAT® for detection of CRC relative to colonoscopy (<b>Sensitivity and Specificity</b>).</p> <p><u>Secondary:</u> ColoSTAT® performance relative to colonoscopy for:</p> <ul style="list-style-type: none"><li>➤ Advanced adenomas.</li><li>➤ Clinically actionable neoplasia.</li><li>➤ Comparison to FIT.</li></ul>

## PATIENT RECRUITMENT SUCCESSFULLY COMPLETED

### Next Steps (not exhaustive list):

- Close clinical trial sites. **Underway.**
- Testing of blood samples at Sonic Clinical Trials.
- Statistical analysis of results.
- Final clinical study report completion.
- Collation of data and study results / report in ColoSTAT® technical file.
- Submit technical file and other associated documentation to Therapeutic Goods Administration (TGA).

### 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.

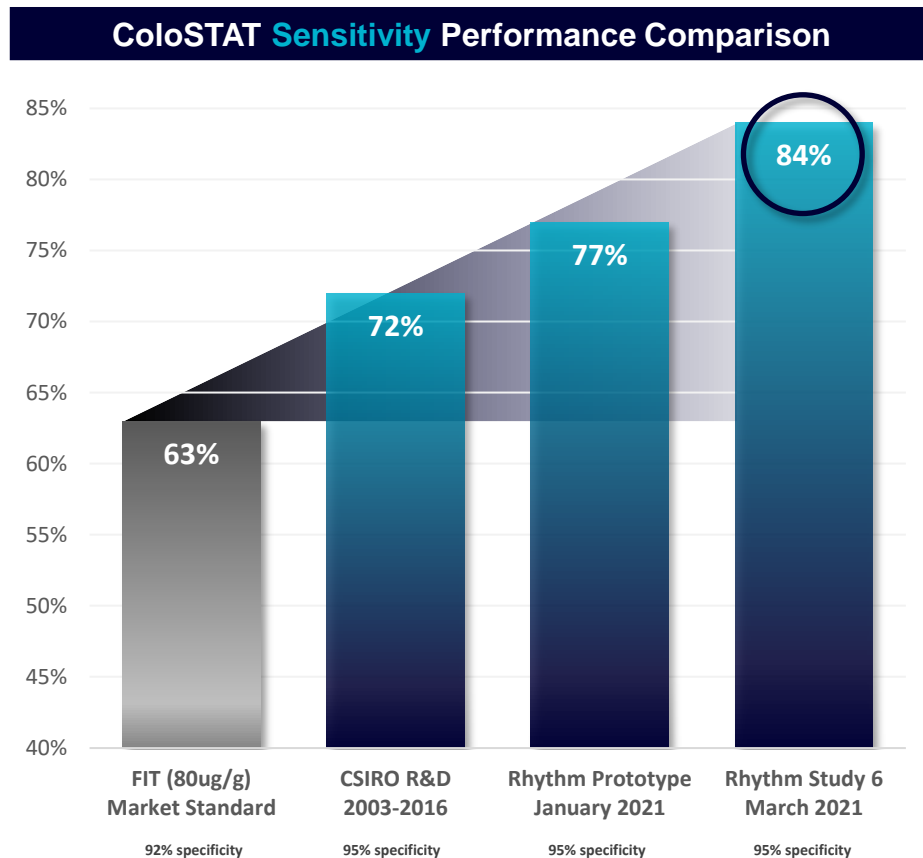
### TGA submission process requires two key filings:

- Manufacturers Evidence documentation. **Submitted and accepted;** and
- Application for an Australian Register of Therapeutic Goods (ARTG) listing.

# ColoSTAT<sup>®</sup> Performance



“83% of unscreened participants prefer a blood test over a faecal test”<sup>1</sup>



- **Highly accurate**  
ColoSTAT is 33% more accurate at detecting colorectal cancer than the current market standard Faecal Immunochemical Test (FIT).<sup>2</sup>
- **Low Cost and Simple**  
Protein biomarker led delivers a cost-efficient simple blood test that is suited to global mass market screening programs.
- **Detects Cancer**  
Disruptive technology that detects the presence of cancer in the blood whereas current FIT based testing regimes only detects the presence of blood in a stool sample.
- **Preferred**  
A blood test is preferred as a more acceptable way to participate in testing.

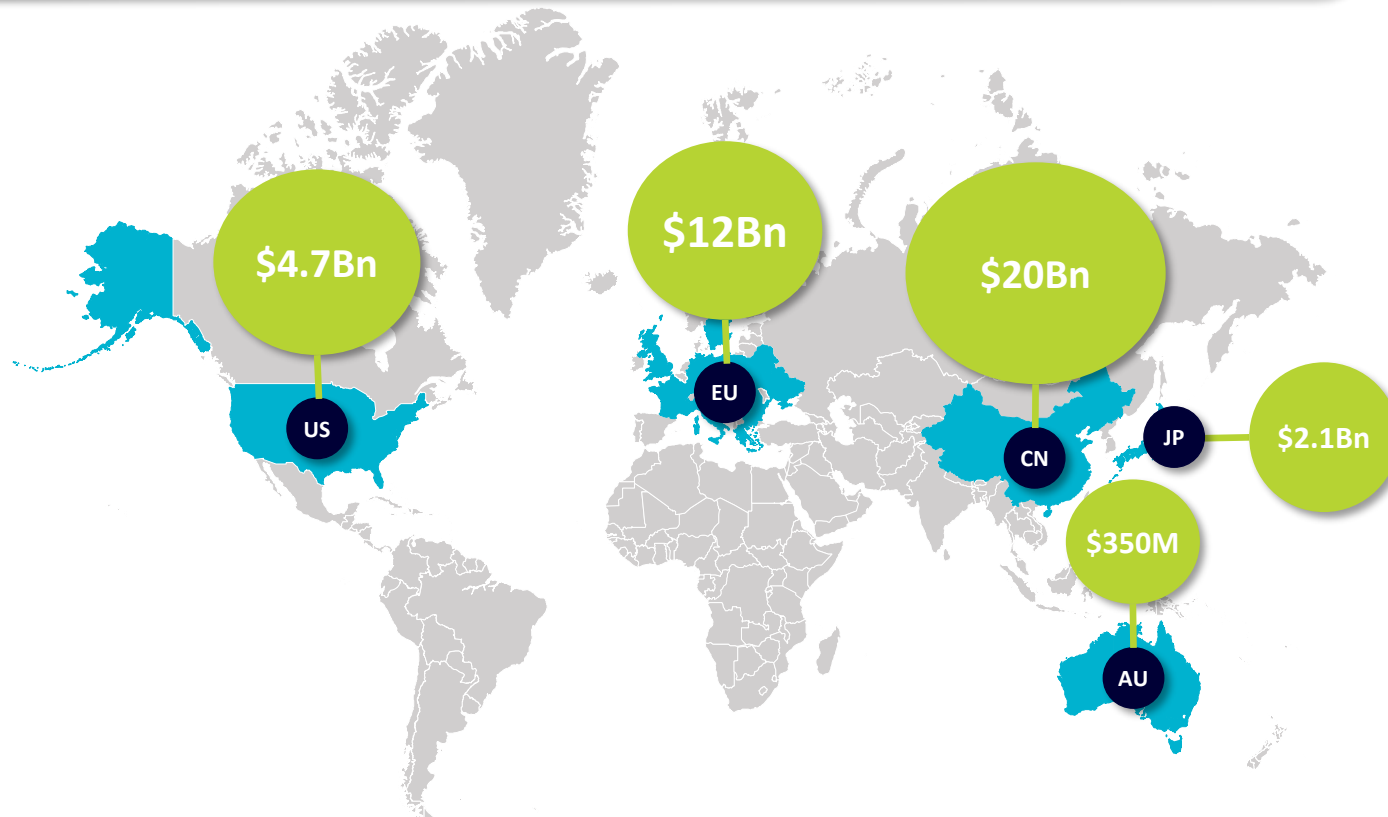
<sup>1</sup> 9. Osborne, J., Wilson, C., Moore, V., Gregory, T., Flight, I. and Young, G. (2012) Sample preference for colorectal cancer screening tests: Blood or stool?. Open Journal of Preventive Medicine, 2, 326-331. doi: 10.4236/ojpm.2012.23047.

<sup>2</sup> Symonds EL, Pedersen SK, Baker RT, Murray DH, Gaur S, Cole SR, Gopalsamy G, Mangira D, LaPointe LC, Young GP. A Blood Test for Methylated BCAT1 and IKZF1 vs. a Fecal Immunochemical Test for Detection of Colorectal Neoplasia. Clinical and Translational Gastroenterology (2016) 7, e137; doi:10.1038/ctg.2015.67.

# Market Opportunity / Addressable Market



US\$38 billion addressable screening value in priority markets<sup>1</sup>



## Colorectal Cancer Screening Market Population

Number of people over 50 years of age eligible for screening

Country	Screening participation	Addressable population
United States	63%	94 million
Europe	38%	231 million
China	19%	397 million
Japan	38%	42 million
Australia	41%	7 million
<b>Total</b>		<b>771 million people</b>

**Potential to reach ~1 billion people**  
when the screening age is lowered to 45 years old

<sup>1</sup> Based on 2021 data calculated as Eligible Screening Population (771 million) x Example Test Cost (US\$50). RHY revenue may vary.

# Market Likely To Expand Significantly



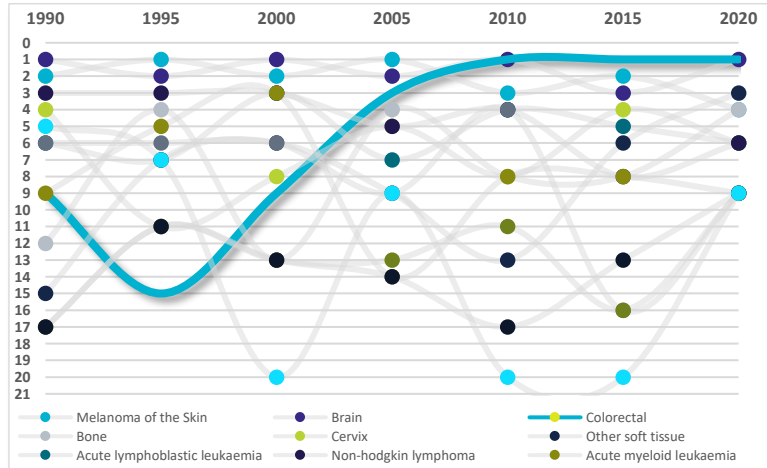
- ✓ USA Preventative Services Task Force recommends Colorectal Cancer Screening to commence at age 45. Five years younger than it previously recommended, adding circa 20 million patients to the screening population in the USA alone.
- ✓ Reduction of screening age under 50 years of age is expected to 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.
- ✓ 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.**

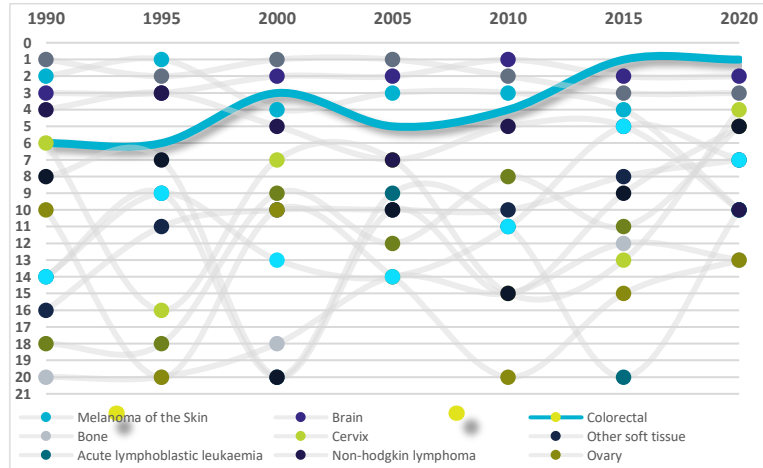
# Australia – Growth of CRC in younger age groups



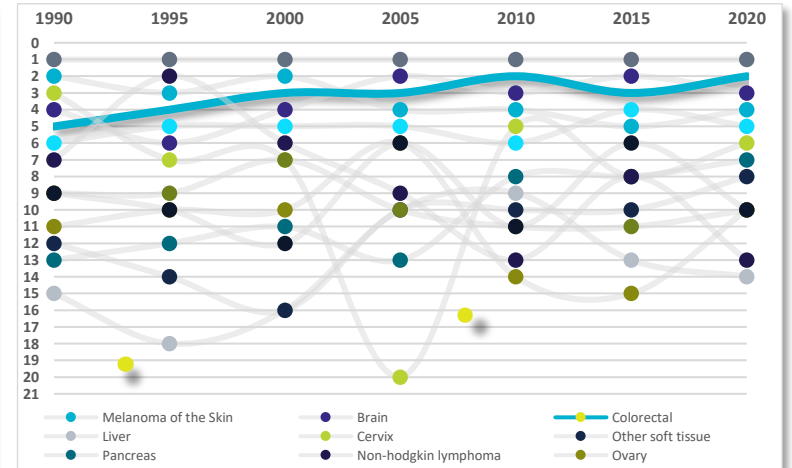
25 – 29 years old



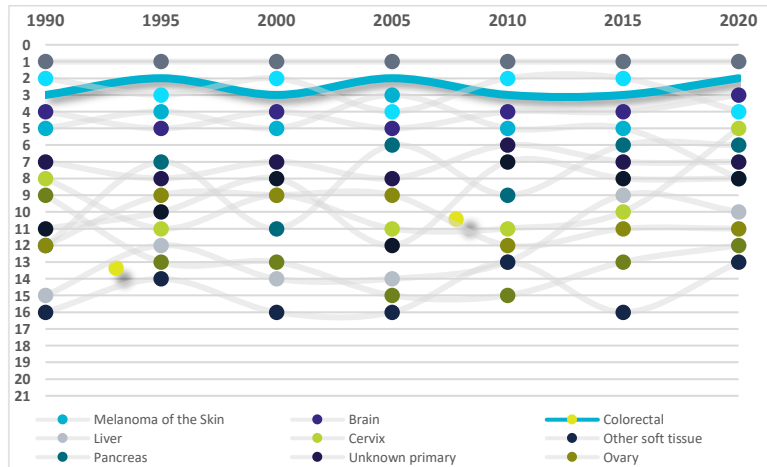
30 – 34 years old



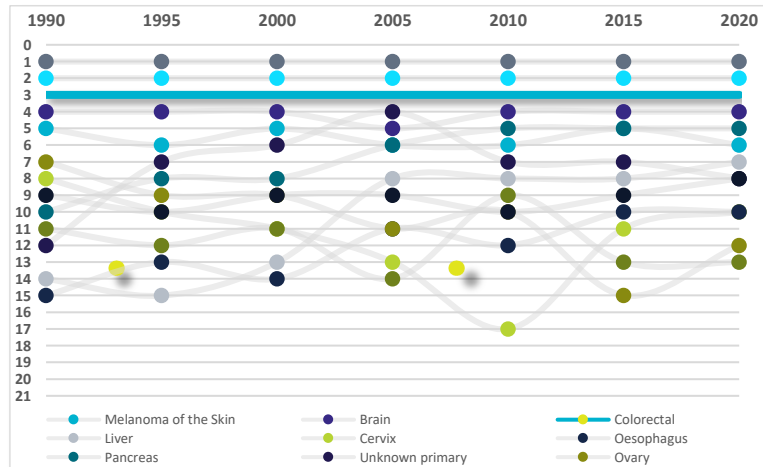
35 – 39 years old



40 – 44 years old



45 – 49 years old



**Colorectal Cancer is the #1 cause of death in 25-34 year olds.**

**Top 2 cause of cancer related deaths below the age of 50.**

Source: Australian Institute of Health and Welfare (AIHW). Cancer data in Australia - Cancer rankings data visualisation. <https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/cancer-rankings-data-visualisation> [rhythmbio.com](https://rhythmbio.com)



# Unique Opportunity To Add Significant Value



Seamless alignment across the entire value chain providing broader benefits for the health system



**Patients**



Blood test is the preferred testing method.



**Increased participation in screening.**



**Government**



Cheaper testing leads to higher availability.



**More lives saved. Reduced economic & societal burden.**



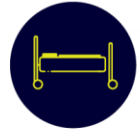
**Health Insurers**



Reduction in unnecessary colonoscopy procedures.



**Reduced claims costs. Increased member engagement.**



**Health System**



Reduction in unnecessary procedures.



**More resources and beds available to prioritise urgent cases.**



**Laboratories**



Technology fits existing pathology infrastructure.



**No additional equipment or training required.**



**GP/Doctors**



Test managed via a doctor referral.



**More relevant contact with patients for better health outcomes.**

# Market Dynamics



*Lifestyle factors increasing risk profiles*

*Low screening participation rates*

*Increased in young onset Colorectal Cancer*

*Late-Stage Bowel Cancer Treatment Costs Are Increasing >\$100k*

*US draft legislation to reduce screening age to 45 years old*

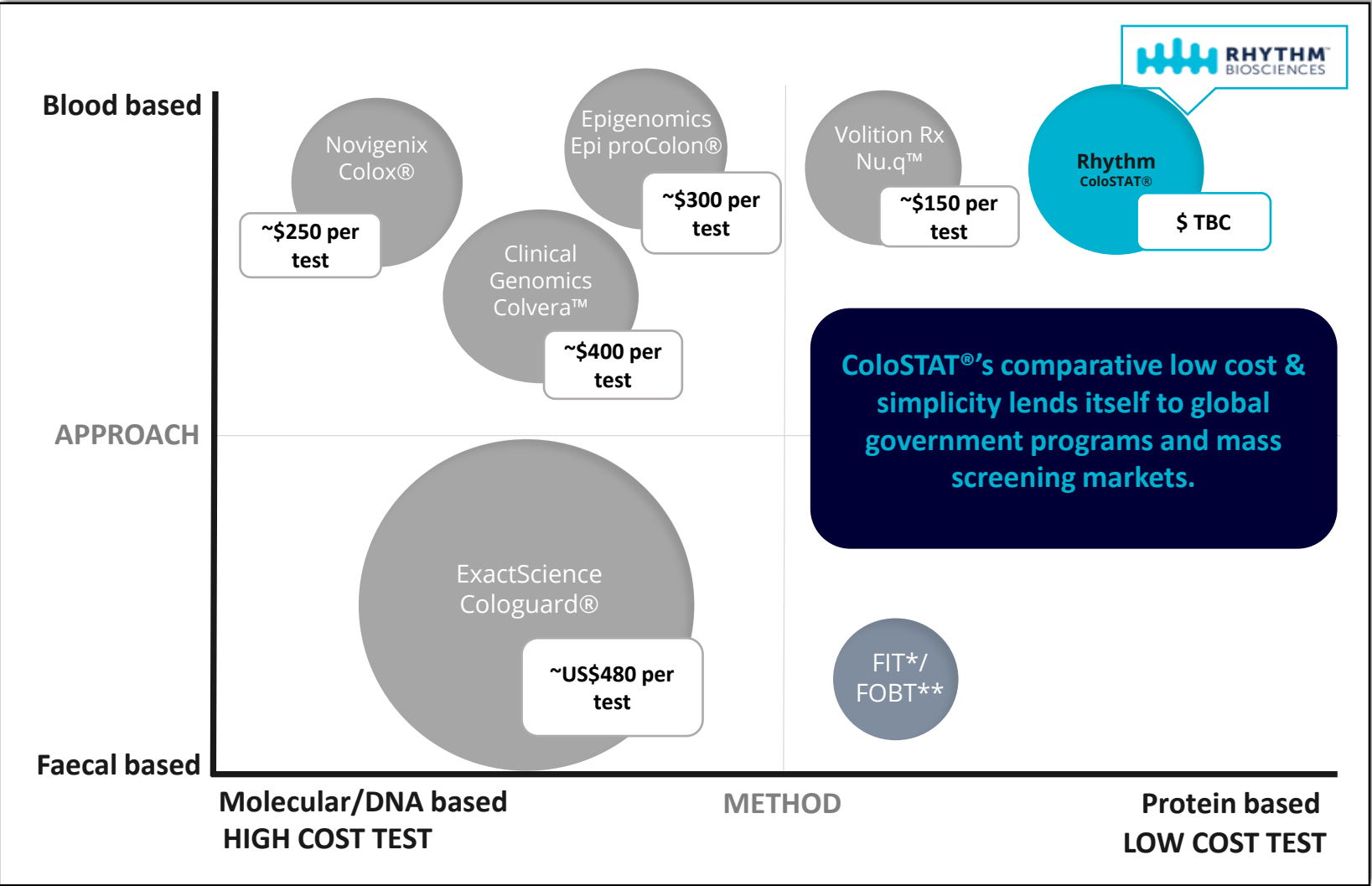
*Screening reduced during COVID-19 pandemic*

*Pressure on health resources in post-Covid environment*

*Preference for blood test rather than faecal test*

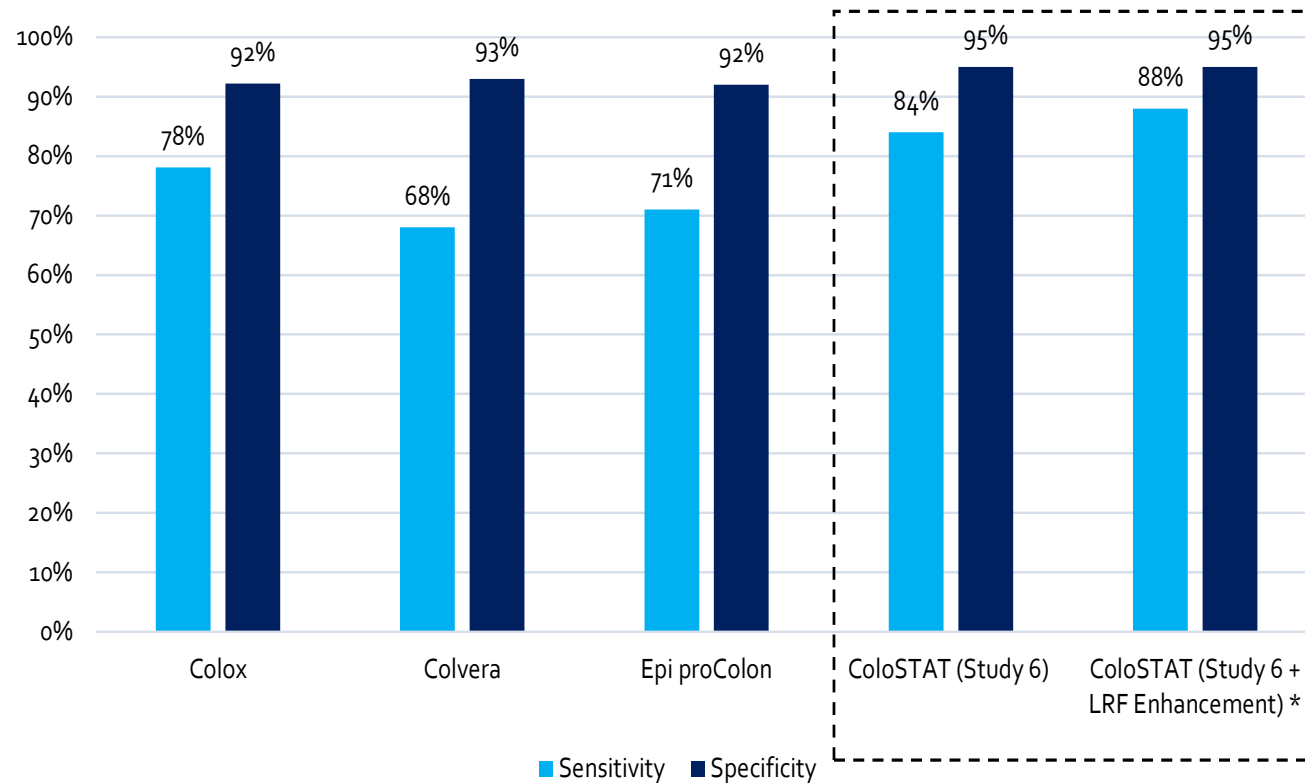
**A more effective low-cost screening process is needed to reduce the growing global burden for colorectal cancer.**

# Competitive Landscape – ColoSTAT®’s Advantage



• FIT = Faecal Immunochemical Test  
 \*\* FOBT = Faecal Occult Blood Test

# Competitive Landscape – ColoSTAT<sup>®</sup>'s Advantage

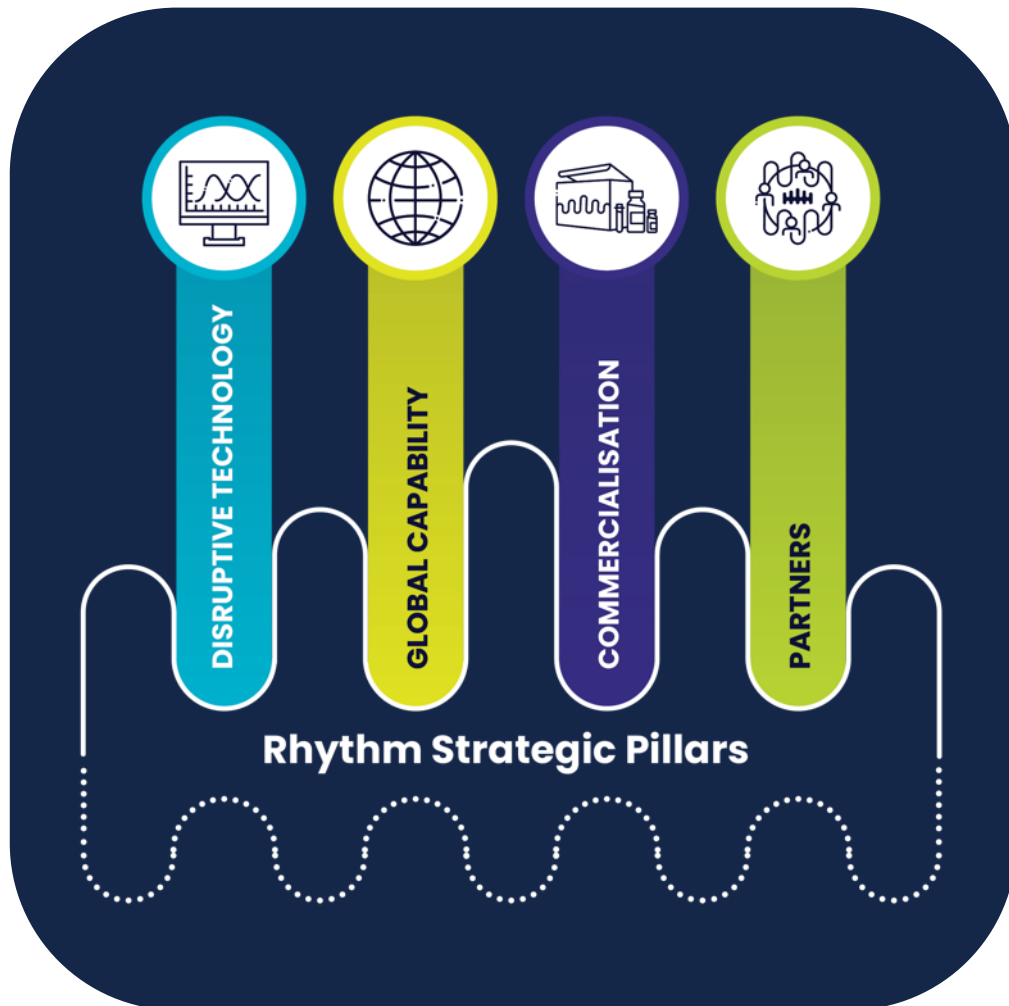


**Performance / accuracy of ColoSTAT<sup>®</sup> versus other more expensive, competitor, blood-based tests**

Source: Company websites, Gastrointest Tumors 2020, Pitt Street Research.

\*LRF Enhancement refers to Lifestyle Related Factors, which when factored into Rhythm's proprietary algorithm technology, can improve colorectal cancer detection performance

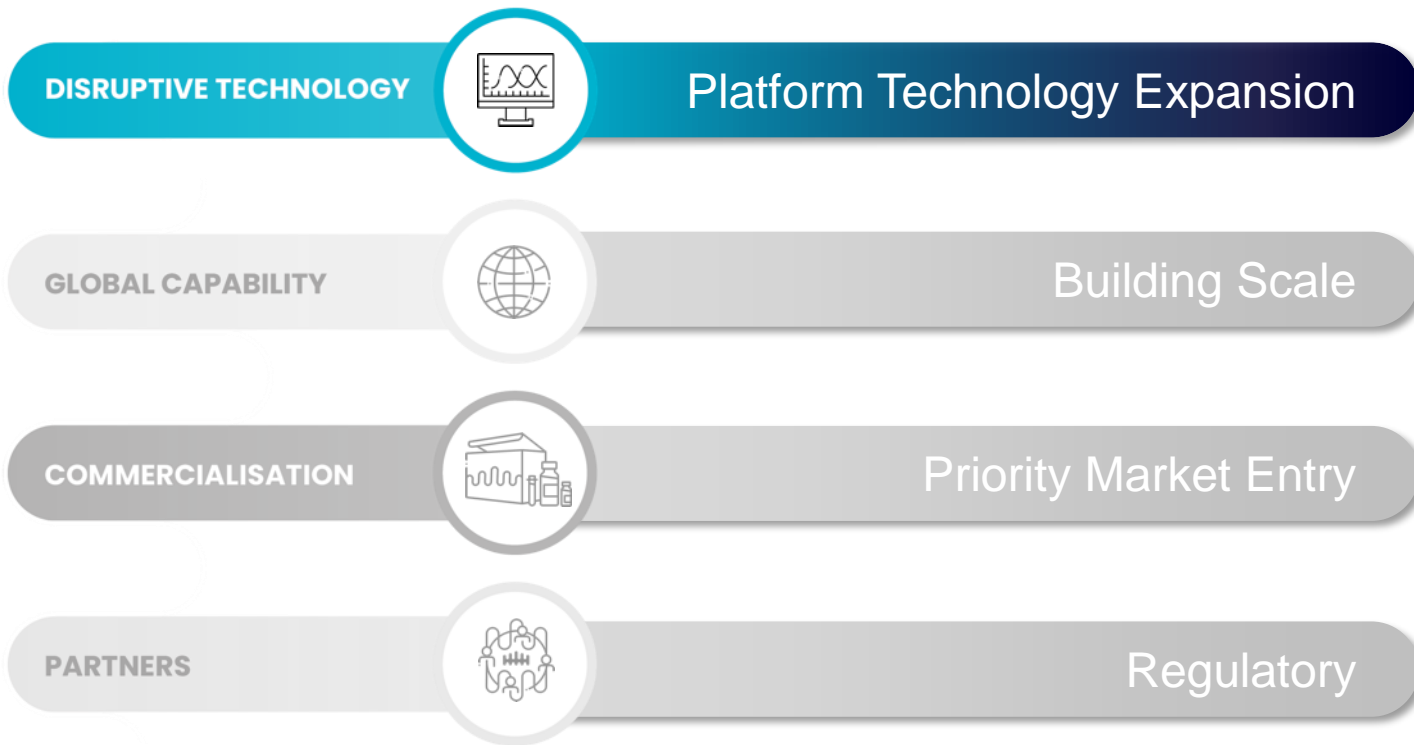
# Market Entry Strategy



Rhythm's strategy is underpinned by:

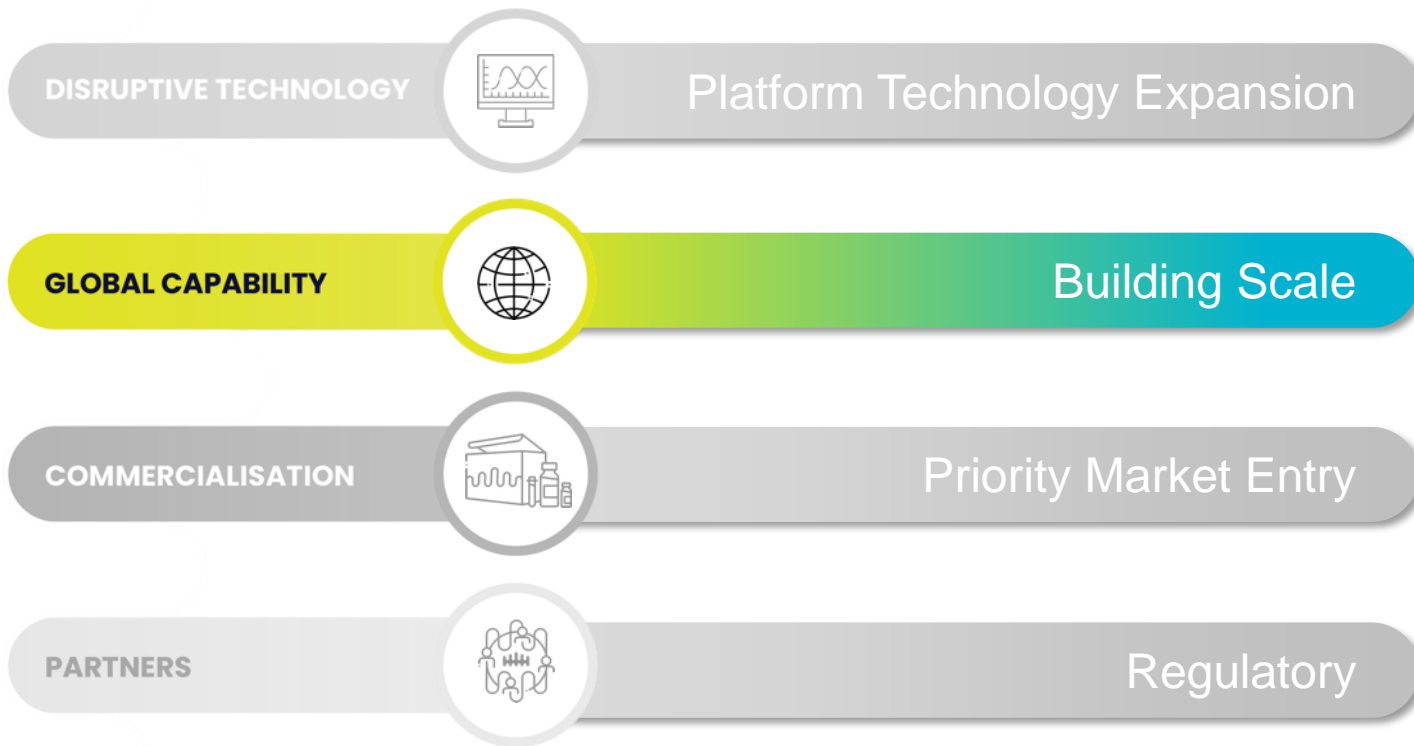
- ✓ **Proven technology;**
- ✓ **Build global manufacturing capability;**
- ✓ **Secure commercialisation pathway/s; and**
- ✓ **Establish partner networks.**

# Market Entry



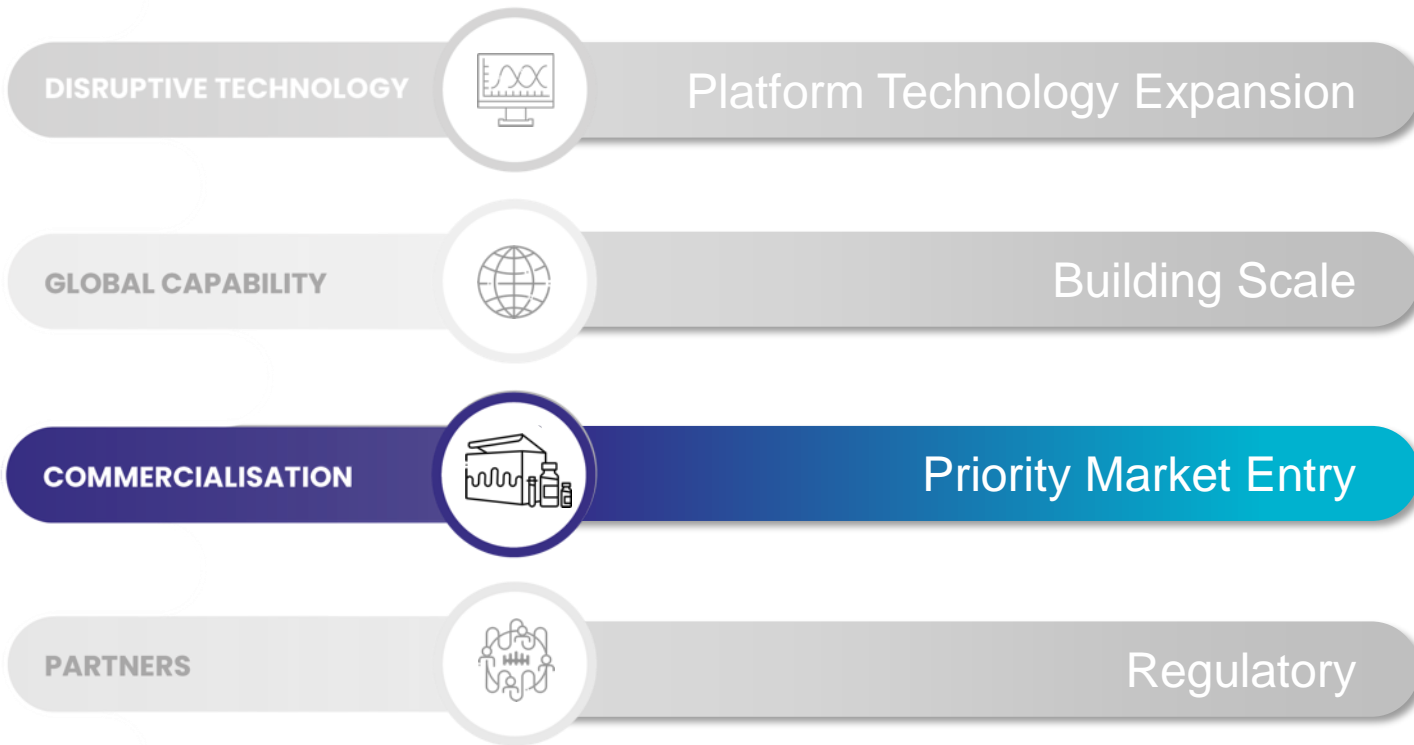
- Confirm Rhythm's key lead biomarker has global application and is highly expressed in a range of cancers.
- Shortlist target cancers to focus on.
- Complements Rhythm's simple, low-cost, mass-market cancer diagnostics strategy.
- Not expected to be capital intensive, existing biomarker tests have already been validated and established.
- Creates opportunity for collaboration and non-dilutive grants.

# Market Entry



- Confirmed test-kit manufacture in house (RHY).
- Successful transfer of core technology to global manufacturer, Biotem.
- Third party manufactured test-kits successfully produced and tested in Study 6 with exceptional results.
- GMP standard test-kits manufacturing commenced for use in Rhythm’s clinical trial.
- Building ongoing capability to support revenue ambitions.

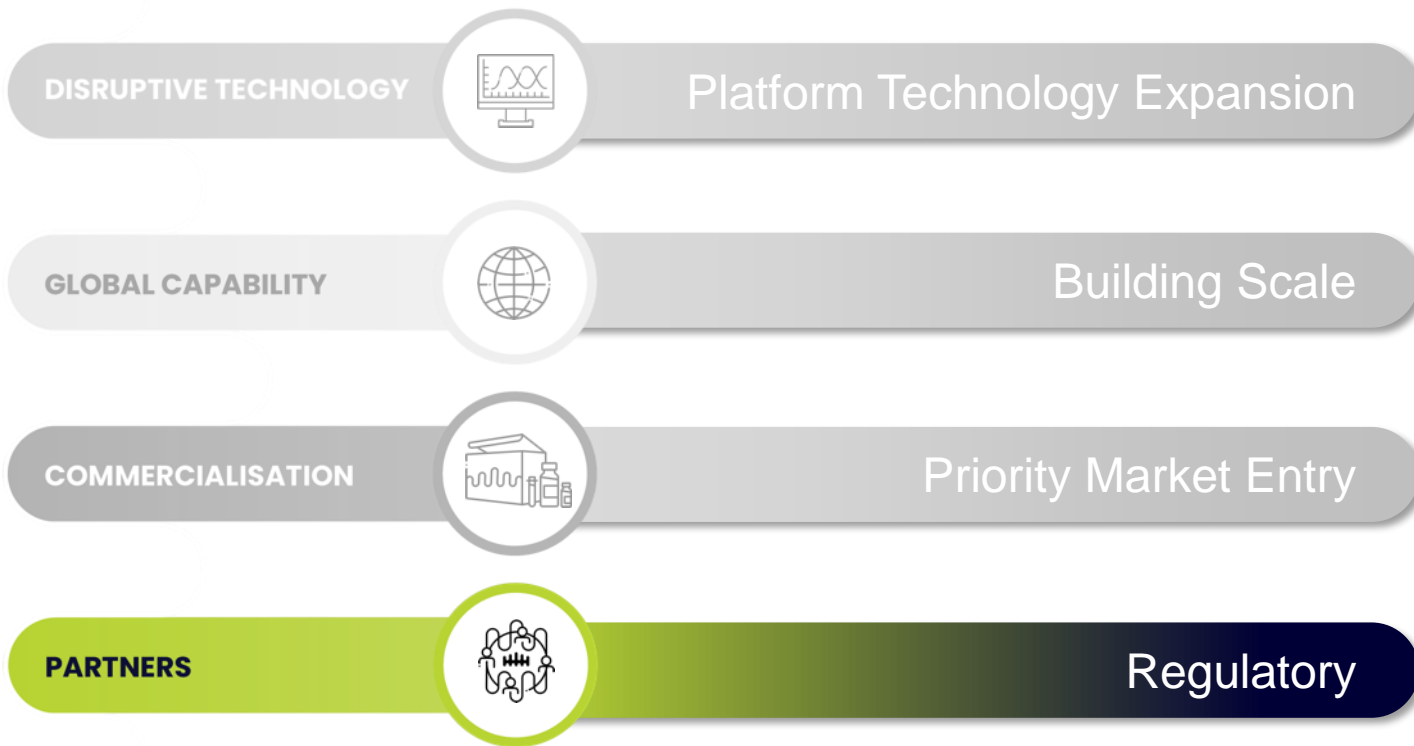
# Market Entry



- United States / Australia / Europe.
- China / Japan / Asia / ROW.
- Incorporated a 100% owned USA domiciled entity.
- Increase business development activity and appropriate partner selection.
- Target approved Clinical Laboratory Improvement Amendments (CLIA) laboratory via a lab developed test (LDT), appropriate for ColoSTAT®.



# Market Entry



- Regulatory entry for Europe (CE Mark) and Australia (TGA).
- Confirmed approach to submit application for CE Mark in advance of Study 7 completion and TGA (Australia) regulatory filing.
- CE Mark submission and approval expected in late 2021.
- Commenced engagement with TGA regarding regulatory filing in Australia.
- Commenced initial stages of US market entry, including the FDA approval pathway.

# 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.

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

\*via Rhythm's 100% owned subsidiary, Vision Tech Bio Pty Ltd

# Summary



- ✓ Disruptive and transformative technology.
- ✓ Significantly cheaper and easier to administer.
- ✓ Globally addressable market.
- ✓ Performance better than market standard.
- ✓ Patents secured.
- ✓ Manufacturing secured.
- ✓ Initial revenues targeted for late 2022.
- ✓ Commenced platform technology pipeline for additional cancer detection tests.

# Future Value Inflection Points – FY'22



- ✓ CE Mark submission and approval expected in late 2021#.
- ✓ Progression of TGA (Australia) regulatory application post clinical trial (Study 7) recruitment#.
- ✓ Development of platform technology opportunities for other cancers.
- ✓ Advance USA / European / China / Asia / ROW market entry strategies.
- ✓ Identify key sales, distribution & diagnostic companies for partnering / Explore commercialisation pathways for ColoSTAT® in various jurisdictions.



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