



AGM Presentation

24 November 2021 [ASX:RHY](#)

*A transformative and predictive
cancer diagnostics technology company*

rhythmbio.com

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Introduction



Rhythm's initial product, ColoSTAT[®] 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.



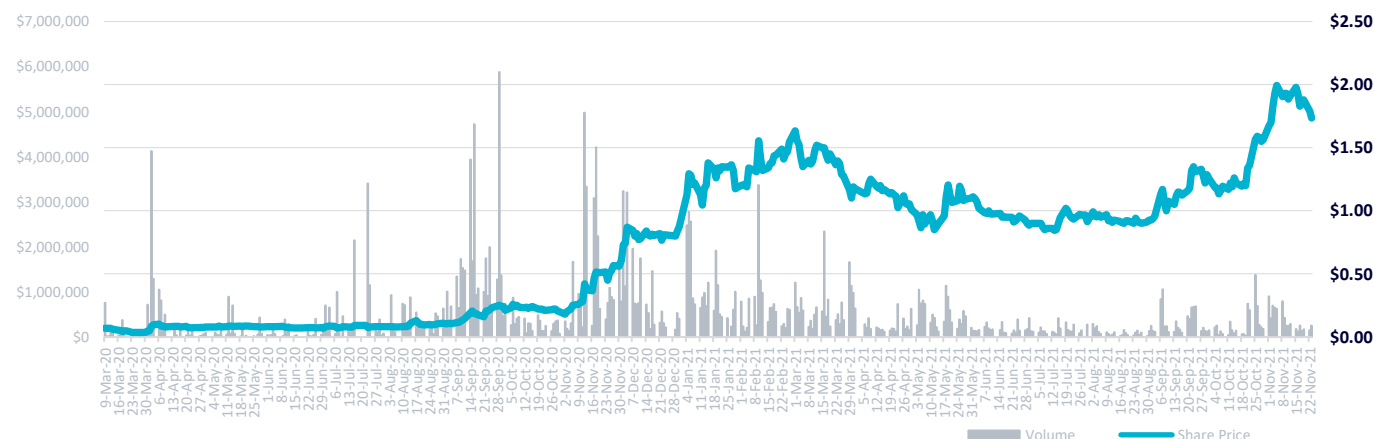
Company Overview



Capital Structure

ASX Code	RHY
Share Price (at 23 November 2021)	\$1.74
Shares on Issue	208.8 M
Unlisted Options	16.8 M
Market Capitalisation	\$363 M
Cash in bank (30 September 2021)	\$7.7 M
Top 20 Shareholders	46%

Share Price Chart



Board and Management

Otto Buttula

Chairman

- Extensive financial, investment 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 Investofirst, now HUB (ASX: HUB).
- Chairman of HITIQ (ASX: HIQ), Non-Executive Director of Oncosil Medical (ASX: OSL).

Glenn Gilbert

Chief Executive Officer

- Former Head of Global Sales, Marketing and BD at Medical Developments Int. (ASX: MVP).
- Various leadership positions at CSL (ASX: CSL).
- Strong Legal, IP & Operational management.
- Broad international business experience.

Trevor Lockett

Executive-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 Avita Medical (ASX: AVH).
- Director Sonic Healthcare (ASX: SHL).
- Chairman NeuralDX.
- Non-executive Director Unison Housing.
- Former CEO Melb Pathology & Monash IVF.

Eduardo Vom

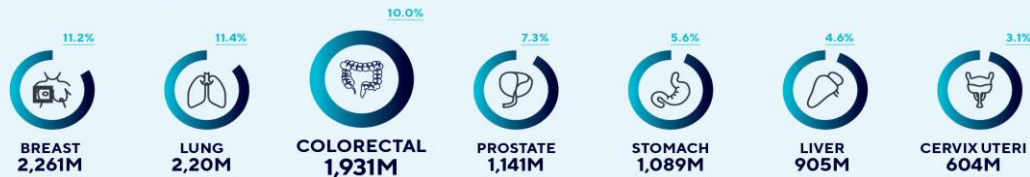
Non-Executive Director

- Co-Founder & Executive Director Planet Innovation.
- Director Atmo Biosciences.
- Former VP Innovation, Genetic Technologies.
- Various senior leadership positions Vision BioSystems.

Colorectal Cancer



Globally, Colorectal Cancer is currently the 3rd largest cancer by volume with 1.9 million new cases diagnosed annually and 2nd 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

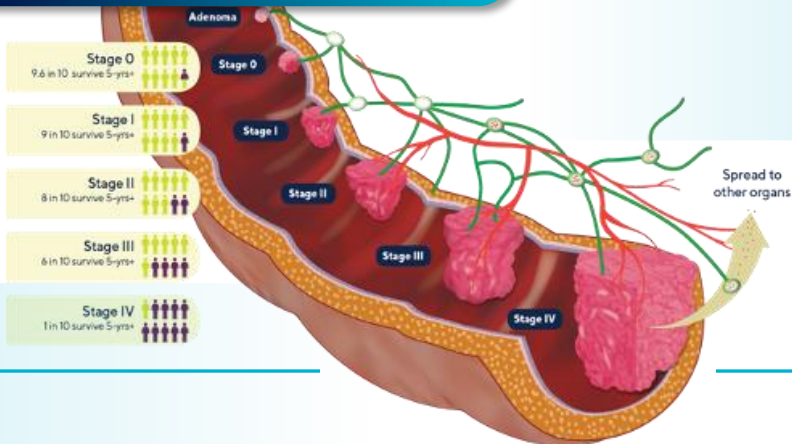
A serious inflammatory bowel disease for more than eight years

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%

Key Achievements FY'21



Completion of the ColoSTAT® prototype test-kit

Advanced the ColoSTAT® Clinical Trial (Study 7)

Patents granted in the US and China

Core technology technically validated

Global manufacturer appointed

Study 6 delivered with exceptional results

ISO certification maintained

Technology

- Technical validation of four final adjunct biomarkers supporting the key lead biomarker for ColoSTAT®;
- Stable and reproducible; and
- Ongoing enhancements – AI Learning, Lifestyle Risk Factors.

Global Capability

- Global manufacturer, Biotem appointed to manufacture ColoSTAT®; and
- Initial third-party commercial analytical test work completed.

Clinical Trial – Study 7

- 11 clinical trial sites operational;
- Patient recruitment phase completed; and
- Well understood path for regulatory approvals.

Performance

- Study 6 completed - Sensitivity of 84% at Specificity of 95%; and
- Confirms very high accuracy - 33% better than market standard.

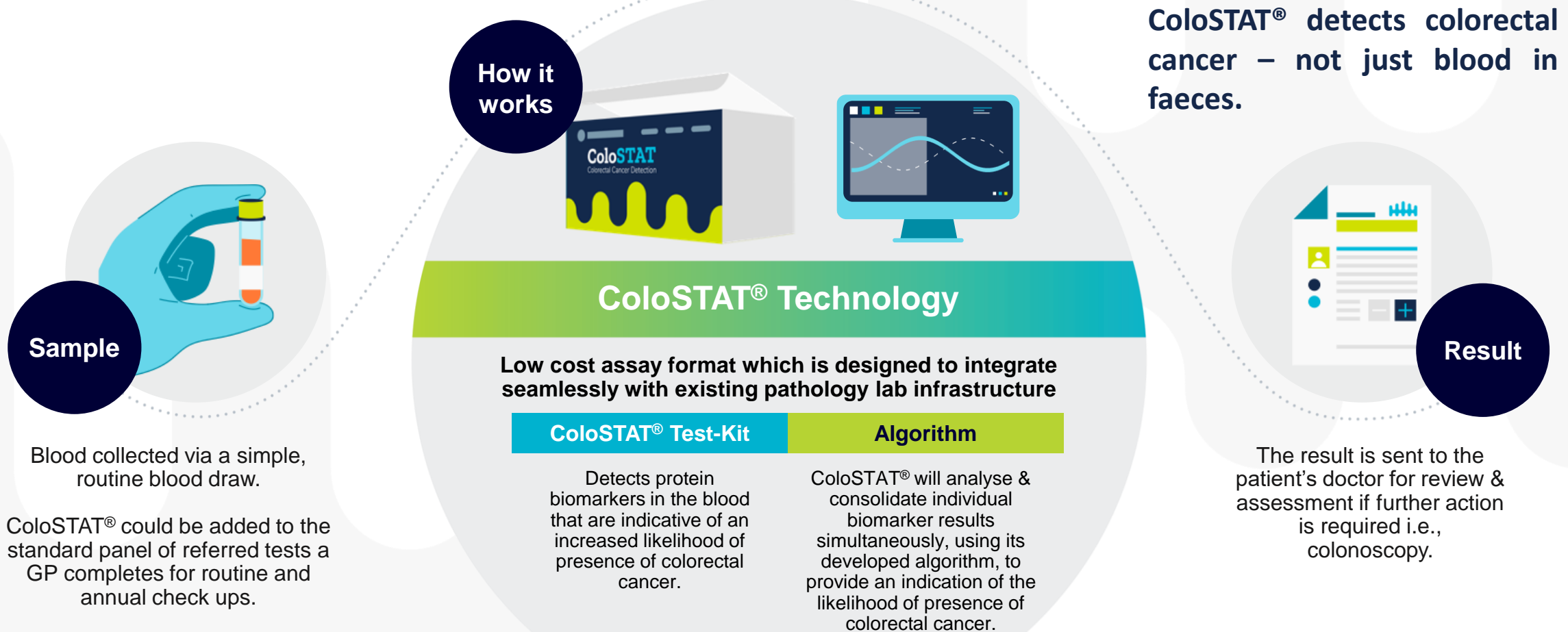
Commercialisation

- Patents now secured in all major jurisdictions;
- US market entry initiated – IchorDX Inc; and
- Government and partner discussions commenced.

Quality and Regulatory

- ISO 13485 certification maintained (assessed annually); and
- Initial TGA (Australia) application submitted and accepted.

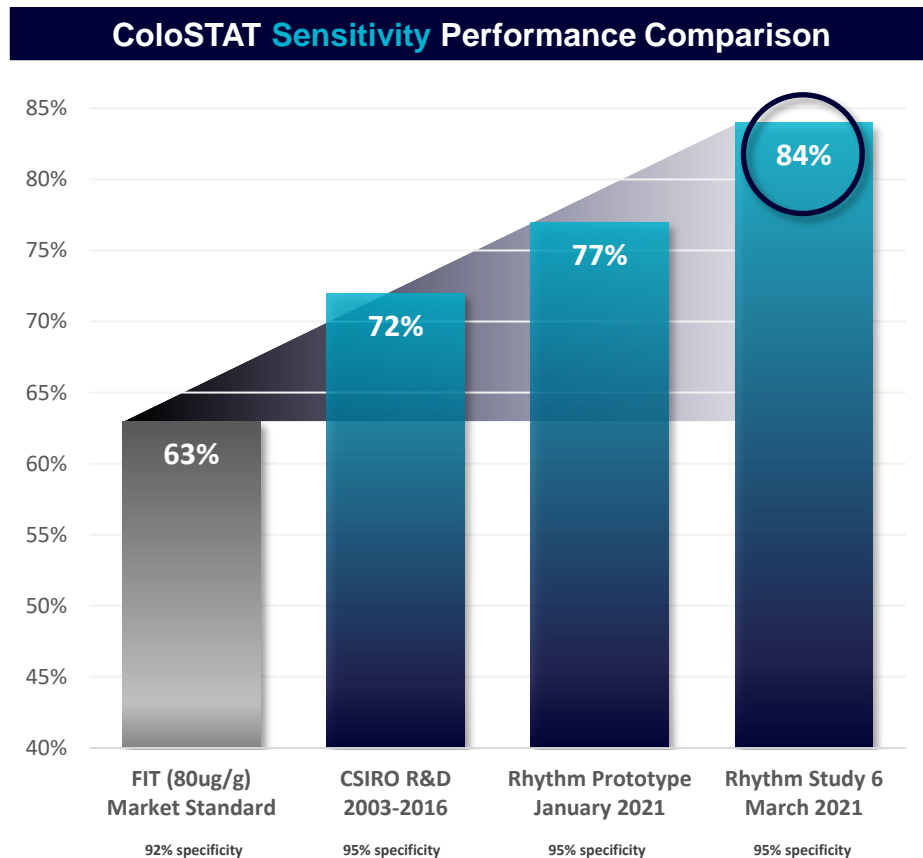
ColoSTAT® - What Is It? How Does It Work?



ColoSTAT[®] Performance



“83% of unscreened participants prefer a blood test over a faecal test”¹



- **Highly accurate**
ColoSTAT is 33% more accurate at detecting colorectal cancer than the current market standard Faecal Immunochemical Test (FIT).²
- **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.

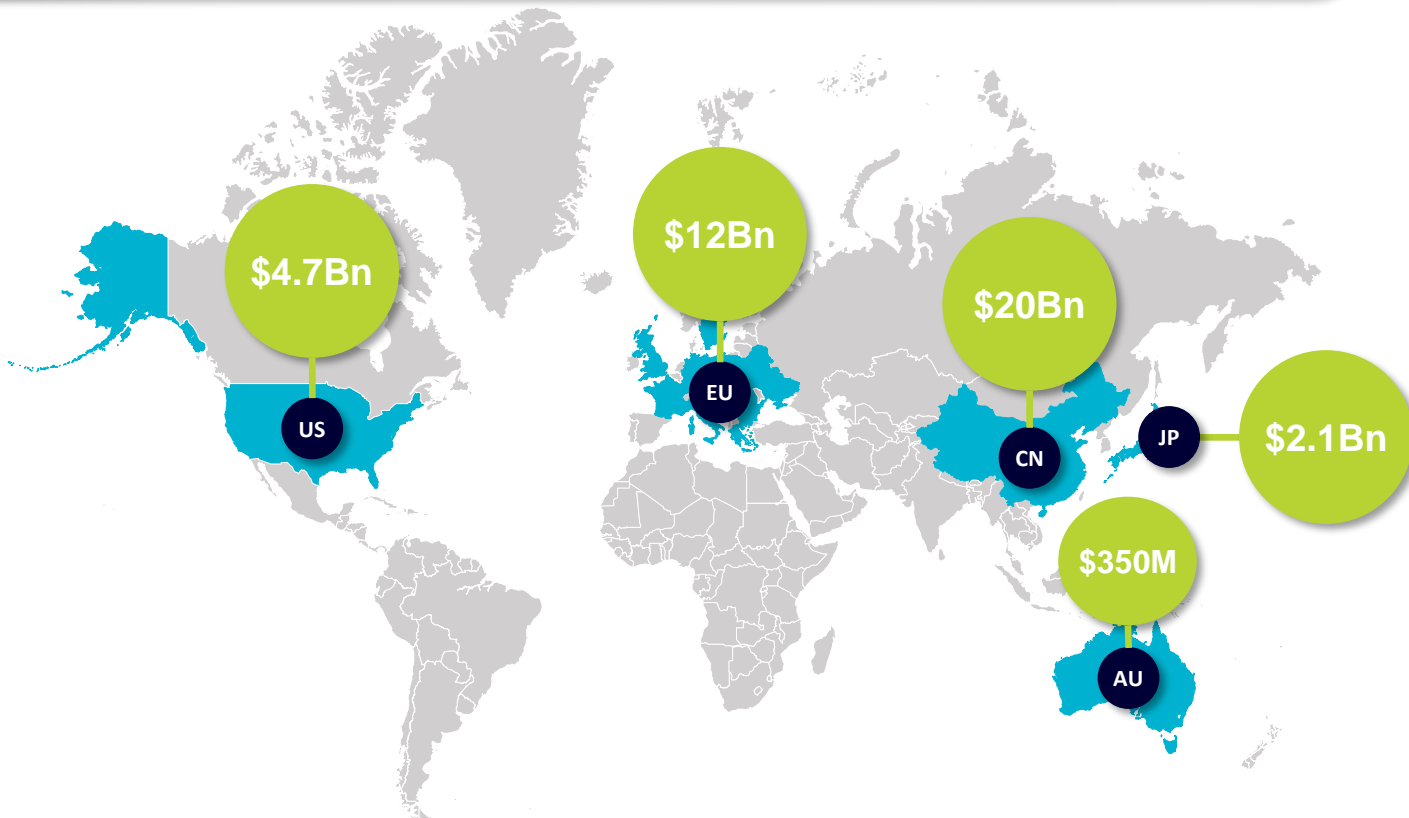
¹ 9. Osborne, J., Wilson, C., Moore, V., Gregory, T., Flight, I. and Young, G. (2012) Sample preference for colorectal cancer screening tests: Blood or stool?. Open Journal of Preventive Medicine, 2, 326-331. doi: 10.4236/ojpm.2012.23047.

² 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 markets¹



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
Total		771 million people

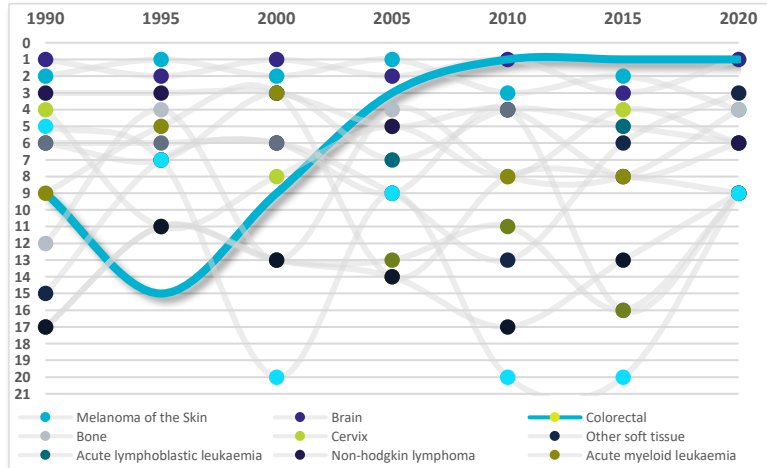
Potential to reach ~1 billion people
when the screening age is lowered to 45 years old

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

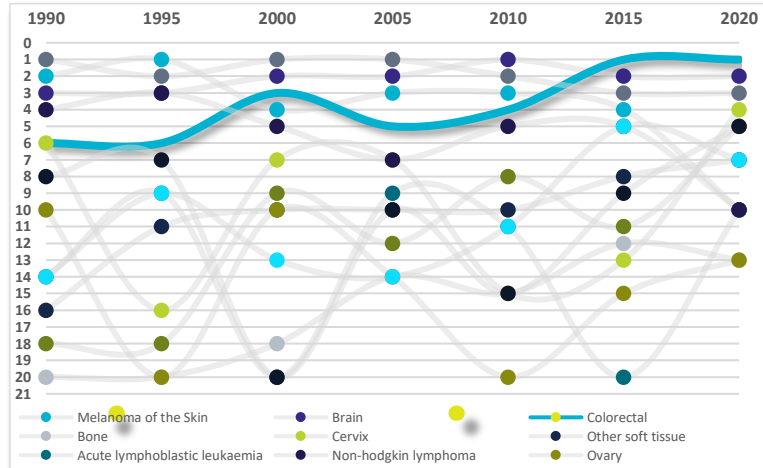
Australia – Growth of CRC in younger age groups



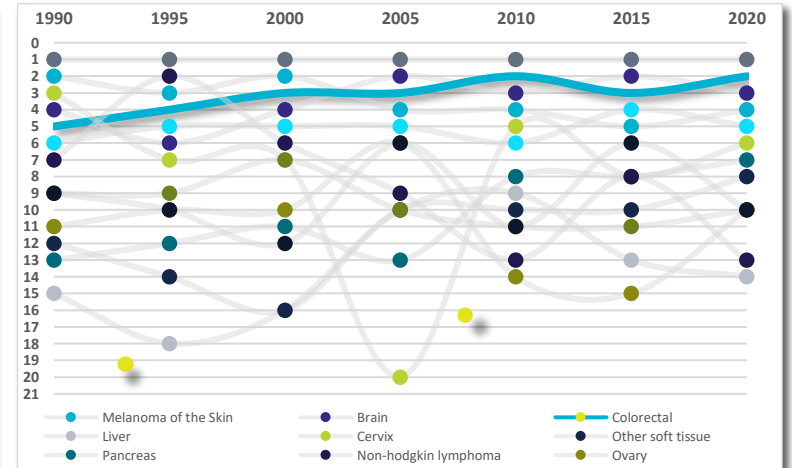
25 – 29 years old



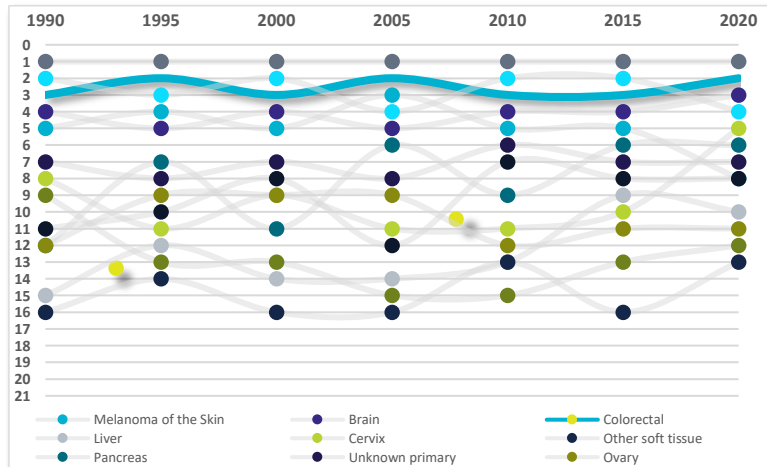
30 – 34 years old



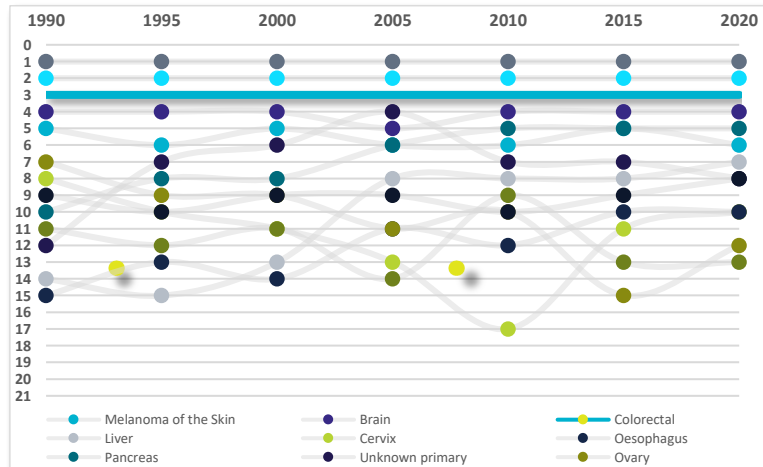
35 – 39 years old



40 – 44 years old



45 – 49 years old



Colorectal Cancer is the #1 cause of death in 25-34 year old's.

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>

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.

On Track For Future Milestones



Clinical Trial (Study 7)

- Commenced remaining clinical trial tasks;
- Reduced variability in cost and time with patient recruitment completed; and
- On track for final clinical report for H1CY'22

Distribution

- Identify key sales, distribution & diagnostic companies for partnering; and
- Explore commercialisation pathways for ColoSTAT® in various global jurisdictions.

Platform Technology Expansion

- Development of platform technology opportunities for other cancers commenced.

Regulatory

- CE Mark submission and approval expected in late 2021; and
- Progression of TGA (Australia) regulatory application post clinical trial (Study 7) on track for H1CY'22.

Market Entry

- Advance USA / European / Australian / China / Asia / ROW market entry strategies.

The Team In Action!



note: photos represent part of the entire lab team. Some team members were not present on the day these photos were taken.

Summary



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





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