



## Rights Issue Investor Presentation

*Restoring value, by enhancing ColoSTAT® in  
alignment with updated regulatory and  
customer requirements*

February 2024

ASX: RHY



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# Corporate Overview

## Corporate Snapshot

ASX Code	RHY
Share Price (at 16 Feb 2024)	<b>\$0.135</b>
Shares on Issue	221.1 M
Unlisted Options	9.1 M
Market Capitalisation	<b>\$29.8 M</b>
Cash in Bank (31 Dec 2023)	\$1.2M
Top 20 Shareholders	42%

## Share Price Chart



## Board and Management

### Otto Buttula

Executive Chairman

- Extensive financial, investment, IT 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), HITIQ (ASX: HIQ) and Oncosil Medical (ASX: OSL)

### Sue MacLeman

Non-Executive Independent, Deputy Chair

- Non-Executive director of Planet Innovation Holdings, ATSE, OMICO (Australian Genomic Cancer Medicines Ltd) and Healthcare Operations Solutions T/A Smartways Logistics (and its subsidiaries)
- Member of the NSW Innovation and Productivity Council
- Fellow of the Australian Academy of Technology and Engineering (ATSE)

### Trevor Lockett PhD

Non-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) and Neural DX
- Non-Executive Director Sonic Healthcare (ASX: SHL) and Unison Housing
- Former CEO Melb Pathology & Monash IVF

# Colorectal Cancer and ColoSTAT®

## Colorectal Cancer (CRC)

Colorectal cancer (CRC) is a progressive disease associated with increased risk of mortality and substantial healthcare and societal costs

### GLOBAL BURDEN IN 2020

**1.93 million new cases** and **~940,000 deaths**, CRC is the **second largest cause of cancer death**.<sup>1</sup>

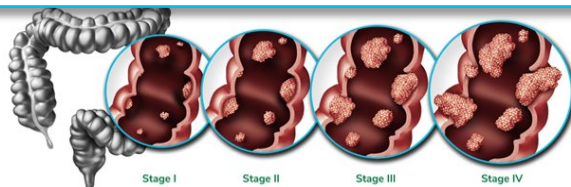
### CRC INCIDENCE IS ON THE RISE IN THE YOUNGER POPULATION

Data from major markets show that 11-15% of people diagnosed with CRC are below the age of 50,<sup>2</sup> posing a tremendous public health challenge, premature death and increased healthcare costs.<sup>1</sup>

Researchers predict that by 2030, CRC will be the leading cause of death in people aged 20-49.<sup>3</sup>

### EARLY DETECTION

**5-year survival rates** for those diagnosed at an early stage\* of CRC are **over 90%**,<sup>4</sup> but **sub-optimal screening participation rate** is the contributor to late diagnosis.



Barriers to overcome and improve participation rate include:

- “Old Persons’ Disease”
- Cultural barriers
- Physical inabilities
- “YUK” factor



### CURRENT TESTING & SCREENING REGIME

In most countries, screening is recommended for those aged between 50-74 years old, with a faecal immunochemical test (FIT), which detects for **blood** in the stool. Worldwide there is a movement to lower the screening age into the 40s.

## COLOSTAT®

ColoSTAT®, simple blood test, detects protein biomarkers indicative of an increased likelihood for CRC, can provide:

- Potential alternative or accompaniment to FIT
- Increase screening participation rate in CRC testing
- Improve early diagnosis and outcomes
- Reduce healthcare costs associated with CRC treatment

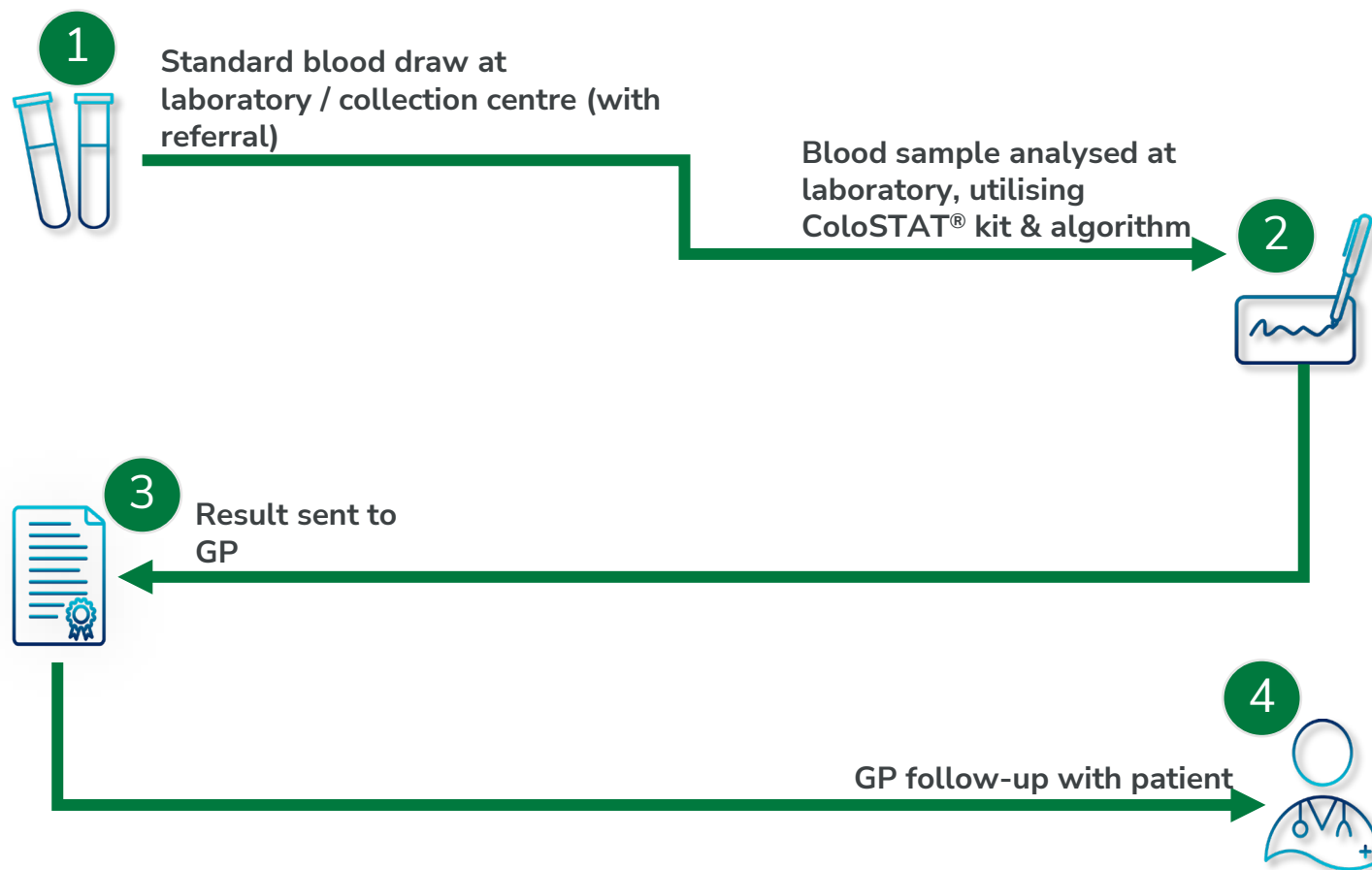
\* Stages I/II, CRC; colorectal cancer

1. Xi Y, Xu P (2021), Global colorectal cancer burden in 2020 and projections to 2040, Translational Oncology, 14(10), 101174, doi:10.1016/j.tranon.2021.101174 Epub 2021 Jul 6, 2. <https://www.cancer.net/cancer-types/colorectal-cancer/risk-factors-and-prevention#:~:text=About%2011%25%20of%20all%20colorectal,cancer%20in%20the%20United%20States>, 3. <https://www.ccalliance.org/about/never-too-young/know-the-facts>, 4. Hughes et al. J Community Health. Author manuscript; available in PMC 2016 October 25



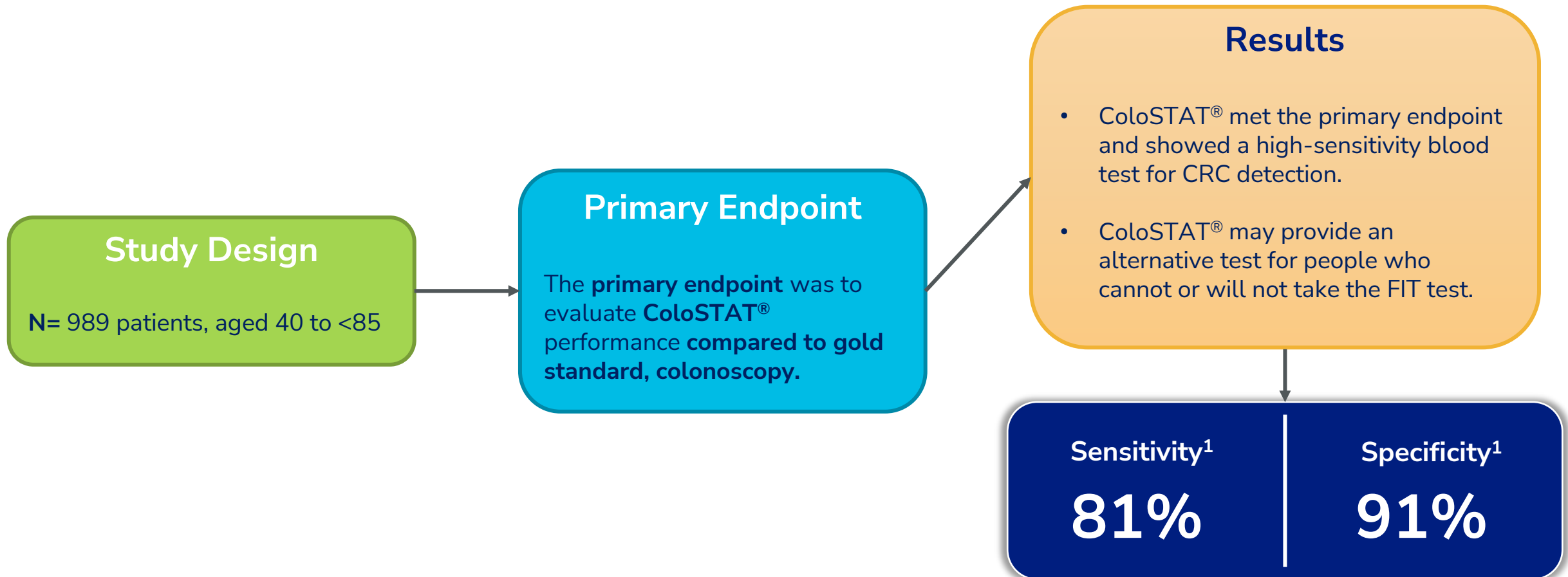
# ColoSTAT<sup>®</sup>\* - Simple Four Step Procedure

## COLOSTAT<sup>®</sup> Colorectal Cancer ELISA Test Kit

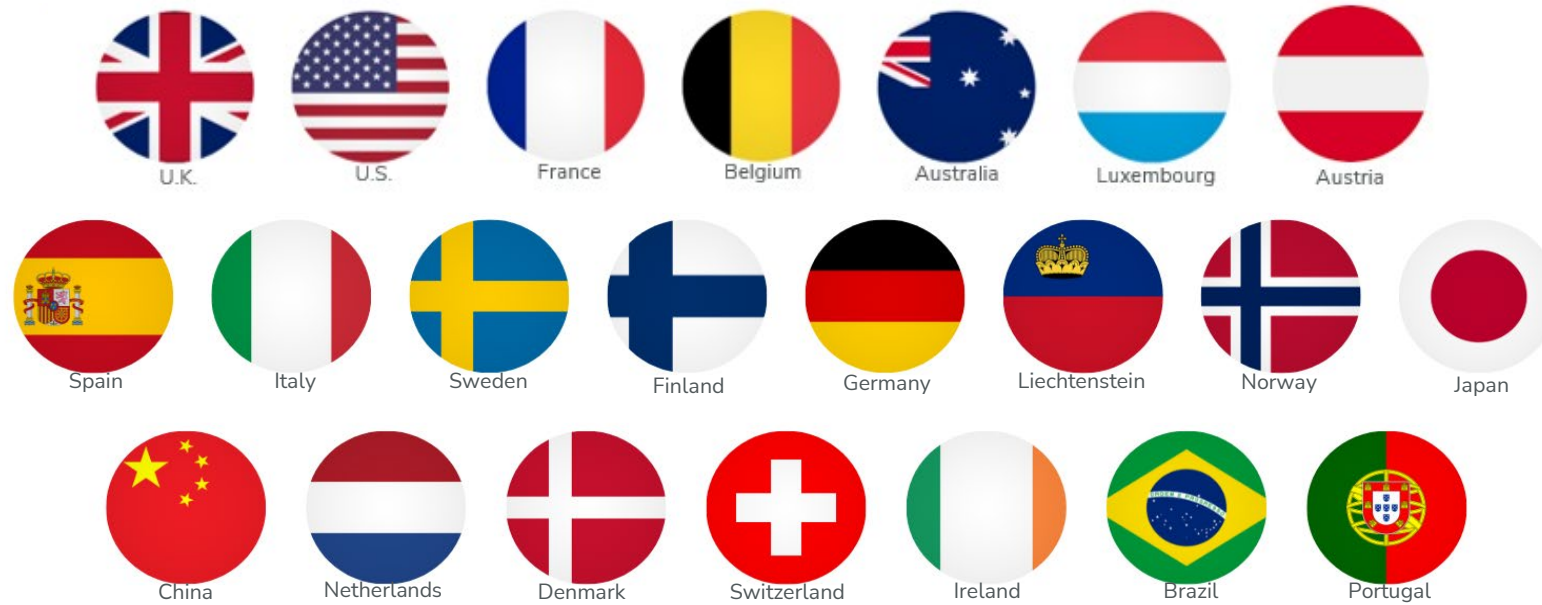


\*currently not approved for use in Australia

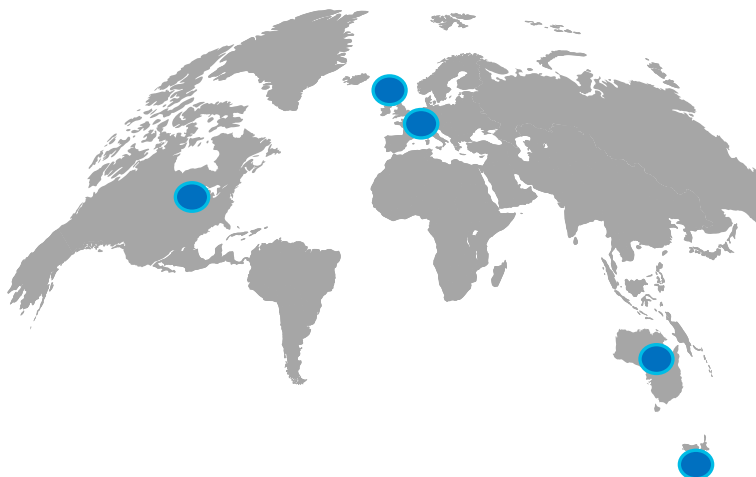
## Prospective, multi-centre study to evaluate the clinical performance of the ColoSTAT® for the detection of CRC<sup>1</sup>



# ColoSTAT® Patented in Over 20 Countries



# Market Entry Focus



Market	Population	Age – Screening Population	Screening Method	Screening Participation Rate	Unscreened Population/ Opportunity	Screening Population (40 to <85 yrs)	Testing Opportunity (40 to <85 yrs)	Incidence of CRC
Europe (EU-27) <sup>@</sup>	455.1 mill	133.5 mill (50 -74 yrs)	FIT, Colonoscopy <sup>¶</sup>	38%	82.8 mill	192.9 mill	142.2 mill	341,419
UK (England, Scotland, Wales and Northern Ireland)	67.6 mill	10.6 mill (60 -74 yrs)	FIT	67%	3.5 mill	28.1 mill	21.0 mill	52,128
New Zealand	5.1 mill	1.1 mill (60 -74 yrs)	FIT	57%*	0.5 mill	2.3 mill	1.7 mill	> 3,000
USA~	331.9 mill	161.5 mill (45 – 75+ yrs)	Undertaking broad and detailed market and competitive analysis					
Australia <sup>^</sup>	25.7 mill	7.1 mill (50 – 74yrs)	FIT	43%	4.0 mill	11.7 mill	8.8 mill	15,713
Total		306.7 mill			86.8 mill	223.3 mill	173.7 mill	

<sup>@</sup> <https://ec.europa.eu/eurostat/databrowser/view/TPS00001/default/table?lang=en>

\*Based on pilot project, recent data not available - <https://www.health.govt.nz/our-work/preventative-health-wellness/screening/bowel-screening-pilot/bowel-screening-pilot-results>

<https://www.aihw.gov.au/reports/older-people/older-australians/contents/demographic-profile>

<sup>¶</sup> Every 10 years

<sup>~</sup> <https://www.google.com/search?q=us+population>

<sup>^</sup> <https://www.aihw.gov.au/reports/older-people/older-australians/contents/demographic-profile>

FIT; faecal immunochemical test



# Strategic Review Revealed Potential Barriers



x5

**Test Development:** five different biomarker immunoassays into one kit

- Labour intensive procedure, prone to human error and higher assessment costs



**Kit production costs increased and procurement timelines difficult and unstructured**



**Lack of internal expertise for Design and Product Development – too R&D focused**



**Paper (R&D) based documentation system**

**IVDR**

**Significant regulatory changes** in Europe and Australia, and proposed changes in the USA, has resulted in a realignment in operations and resources to best realise the Company's objectives:

- Adopt the new stringent IVDR (In Vitro Diagnostic Medical Device Regulation) requirements for all products in development
- Organisational restructure – leaner team, working with outsourced developer/Contract Manufacturing Organisation
- Significant cost reduction process and the engagement of additional contracted external expertise to assist the team

# Key Decisions as a Result of the Strategic Review



Appointment of a suitably qualified  
Chief Executive Officer



The currently produced ColoSTAT® kits will be  
used for Research Use Only (RUO) and no  
commercial sales



Engagement of a US based Contract  
Manufacturing Organisation (CMO) to  
undertake all future design and development  
work on ColoSTAT®

**IVDR**

Follow on benefits are expected as the IVDR  
transition work can be applied to the  
Company's technology pipeline including  
breast, lung and gastric cancers

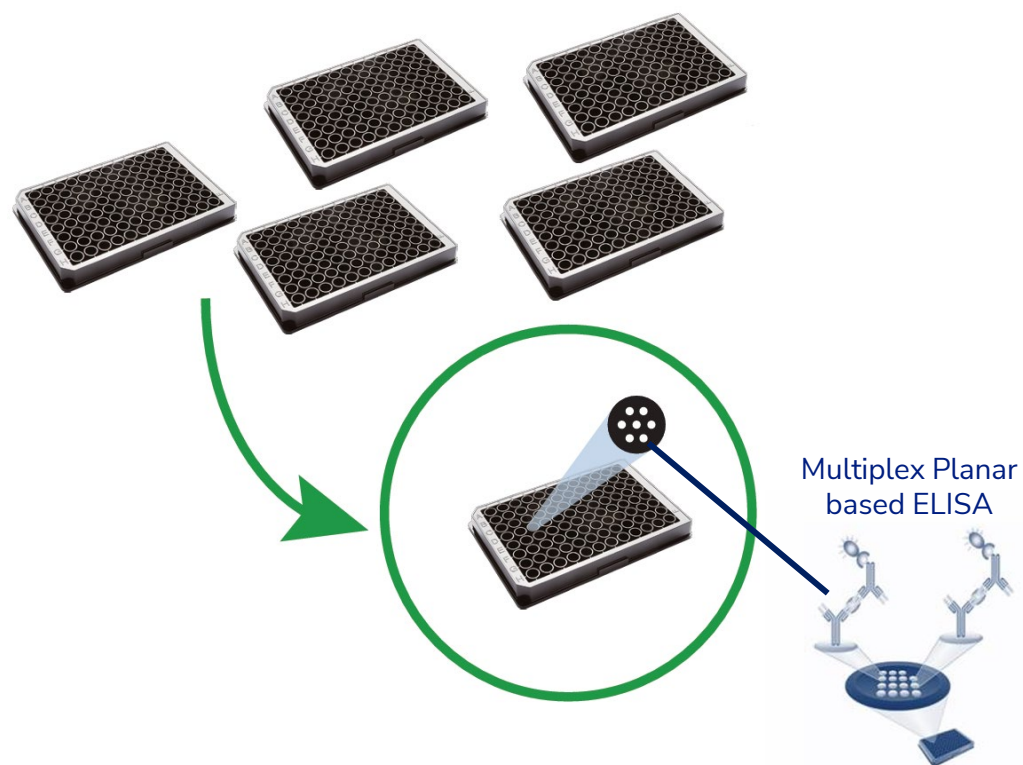


**The outsourcing of ColoSTAT®  
development/production will be cost-effective, with the  
added benefit of automation. The IVDR transition work  
is the Company's highest priority for CY24**

# Updated & Simplified ColoSTAT<sup>®</sup> Kit


Optimally, moving from:

- 5 plates to a single plate

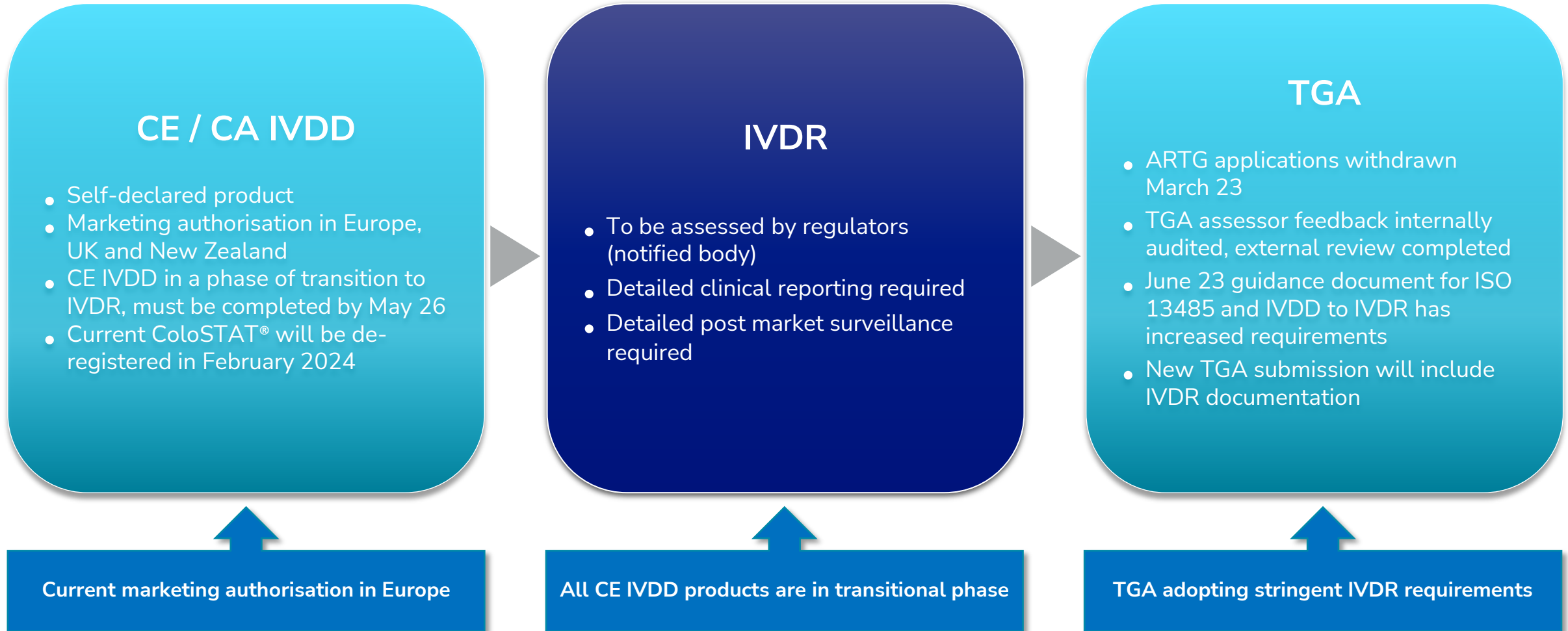


- 5 reagents to a single reagent kit



- 
- ✓ Reduced Cost – Materials, Packaging and Transport
  - ✓ Reduced Chance of Human Error
  - ✓ Embraces Increased Automation and Efficiency
  - ✓ Reduced Testing Time Required

# Regulatory Submission Pathway



IVDD; in vitro diagnostic device, TGA; therapeutic goods administration, IVDR; in vitro diagnostic medical devices regulation, ARTG; Australian register for therapeutic goods

## PHASE 1 Feasibility of New Kit Design



1

- Determine functionality of reagents
- Cross reactivity & signal to noise

## PHASE 2 Iterative Design & Characterisation



2

- Initial assay & reagent optimisation
- Specificity, sensitivity, accuracy & precision
- Linearity and recovery

## PHASE 3 Design Verification and Transfer



3

- Verify all assay specification are within the acceptable tolerance levels

## PHASE 4 Design Validation & Commercialisation



4

- Design transfer
- Production process validation
- Manufacture first lot of product in production
- QC verification of assay performance

eQMS





# Platform Technology Expansion Pipeline



STAGE 1 Progression		Theoretical Analysis of Biomarker Potential	Serum and Algorithm Analysis	Risk Analysis→ Enter Stage 2
Cancer Type	Collaborator			
Breast	Agilex Biolabs			
Lung	Baker Institute			
Gastric	Nexomics			
Cervical	ON HOLD			
Pancreatic	ON HOLD			

# Non-renounceable Rights Issue Offer

Key details of the Offer	
Offer to Eligible Shareholders	3 New Shares for every 10 Shares held at the Record Date at the Issue Price plus <ul style="list-style-type: none"><li>• 1 Option for every 2 New Shares subscribed under the Offer.</li><li>• New ASX Listed Option to purchase a Share with an exercise price of \$0.20 and an Expiry Date of 31 March 2026; and</li><li>• A Top-Up Facility for Shareholders who subscribe for their full Entitlement</li></ul>
Issue Price per New Share	\$0.10 or 10 cents per New Share payable in full on Application
Maximum number of New Shares issued under the Offer	66,342,777 New Shares
Maximum proceeds from the Offer (excluding costs associated with the Offer)	Approximately \$6.3 million (before expenses and costs of the issue)
Maximum number of Shares on issue following the Offer (refer to Section 3 below)	287,485,366 Shares

# Indicative Timetable of Rights Issue

Important dates*	
Record Date (to determine Entitlement of Eligible Shareholders to participate in the Offer)	Thursday, 22 February 2024
Opening Date of Rights Issue Offer - Dispatch of the Prospectus and Entitlement & Acceptance Form to Eligible Shareholders	Tuesday, 27 February 2024
Closing Date for acceptances under the Rights Issue Offer	5.00pm, Thursday 14 March 2024
Shortfall (if any) announced to the ASX	Monday, 18 March 2024
Issue of the New Shares and New Options	Thursday, 21 March 2024
Trading (T+2) of New Shares and Options expected to commence	Friday, 22 March 2024

\* The above dates are indicative only and subject to change. The Company reserves the right, subject to the Corporations Act and the Listing Rules, to extend the Closing Date or to withdraw the Offer at any time without prior notice, in which case all Application Monies will be refunded (without interest) as soon as practicable. Any extension of the Closing Date will have a consequential effect on the issue date of New Shares. All dates and times are references to Melbourne, Australia time.

# Use of Funds

Use of funds*	
<b>Complete new product development of ColoSTAT®</b> <i>Complete new manufacturing of kits in North America.</i>	Up to \$1.50m
<b>Re-submit for regulatory approvals for CE Mark and TGA</b> <i>Completion of renewed regulatory submissions (CE Mark and TGA), utilising external experts.</i>	Up to \$1.00m
<b>Continued R&amp;D pipeline development activities into other cancers</b> <i>Further R&amp;D studies into other cancers, including breast, lung and gastric and begin clinical trials. Commence pancreatic and Cervical R&amp;D.</i>	Up to \$1.00m
<b>Cement distributor partnerships together with marketing and sales activities</b> <i>Finalise distributor partnerships (subject to regulatory approvals).</i>	Up to \$0.50m
<b>General Working Capital and capital raising costs**</b> <i>Day to day working capital requirements and capital raising costs for the Offer</i>	Up to \$2.63m
<b>Maximum funds raised under the Offer</b>	<b>Up to \$6.63m</b>

\* The Company reserves the right to pay cash commission to AFSL Holders or authorised representatives of AFSL Holders who introduce participants to take up any or all of the Shortfall. Any such commission costs have not been taken into account in the use of funds above.

\*\* Where less than the maximum amount of \$6.63 million is raised, the Company will apply the funds raised for general working capital requirements and completion of new product development for ColoSTAT® to transition to an IVDR compliant product.

# Theoretical Value of Options

## Rights Issue Offer Discount

Current share price (as at 16 February 2024)	\$0.1350
Rights Issue offer	\$0.1000
Discount	25.9%

\$0.40

## Discount vs Volume Weighted Average (VWAP) Share Price (ASX)

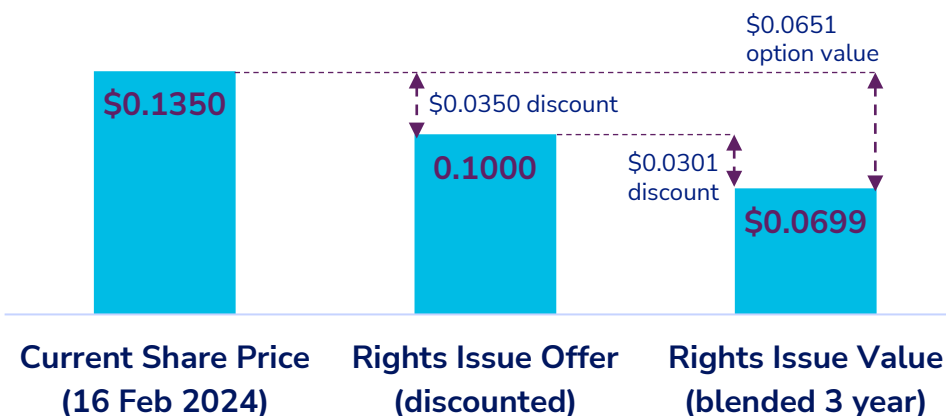
10 day VWAP - discount 22.9% #	\$0.1224
30 day VWAP - discount 20.4% #	\$0.1256
90 day VWAP - discount 43.2% #	\$0.1761

\$0.20

## Theoretical Offer of Options\* / Effective Entry Price

Theoretical Value of Option (31 Mar 2026) *	\$0.0602
Rights Issue Offer	\$0.1000
Theoretical New Issue Price (deducting Value of the Option, per New Share subscribed for)	\$0.0699

\$0.00



# Volume Weighted Average Price (VWAP) using ASX prices only to 16 February 2024.

\* Refer to Appendix 1 for detail on Black Scholes Theoretical model used to calculate value. Source: RHY & Black & Scholes Model.



**Thank You!**

# APPENDIX 1 – Rights Issue: Theoretical Option Value\*

## Theoretical Option Value – 2 year

Share price - 16 February 2024 (P)	\$0.1350
Exercise price of option (EX)	\$0.2000
Exercise period in years (t) – 31-03-26	2.00
Compounded risk-free interest rate (rf)	4.26%
Standard deviation - annualised ( $\sigma$ )	100.0%

Present value of Exercise Price (PV(EX))	\$0.1837
$\sigma \cdot t^{.5}$	\$1.0429
d1	0.4895
d2	- 0.9248
Delta N(d1) Normal cumulative density function	0.6877
Bank loan (Nd2)*PV(EX)	0.0326

Value of Call	\$0.0602
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## Summary

Value of Call (31 Mar 2026)	\$0.0602
New Share Rights Price	\$0.1000
Theoretical New Issue Price (deducting Value of the Option, per New Share subscribed for)	\$0.0699

\* Black Scholes model used. Source: RHY and Black & Scholes Model.