Rhythm Biosciences

RHY.AX

A research platform of MST Financial

27 October 2023

Screening markets expanding

NEED TO KNOW

- Screening criteria expansion builds investment case
- ColoSTAT® to address current testing challenges
- Preparing for 'global' market launch

Expansion of screening program: The increasing incidence of colorectal cancer (CRC) in younger people has seen the US, UK and Australia lower the age to start CRC screening – expanding RHY's potential market.

Solution for current challenges: Current screening uptake is generally poor with an average participation rate of <50%. RHY's ColoSTAT® as a blood test will potentially offer a more 'user-acceptable' option to the current faecal based screening tests and a more affordable, lower risk option to colonoscopy.

Commercial Sales from FY25/26 (prev CY24): MST believes that significant commercial sales will only arise after RHY's resolution of the TGA[1] queries regarding its ARTG[2] listing. RHY plans to finalise the TGA / IVDR[3] process in H2FY24. Re-submission for TGA approval will trigger a decision within 255 days. In the EU, while RHY has its CE mark, it plans to undertake the IVDR pathway. IVDR is not required in the EU until May 2026. However, in MST's view, EU government funded programs are less likely to change suppliers unless they are IVDR compliant.

Investment Thesis

RHY has developed a platform technology to offer simple, low-cost, mass-market cancer screening tests with CRC as its first target. As a blood test, ColoSTAT® offers a number of advantages over the standard of care faecal test 'FIT'[4] and therefore is expected to have strong market uptake. RHY's 'lead' cancer biomarker is highly expressed in a range of cancers. RHY is also undertaking studies in gastric, breast and lung cancer.

Valuation

MST's DCF valuation of A$1.05ps versus A$1.68ps reflects the dilution effect of MSTe FY24 A$5m capital raise and muted revenues until ColoSTAT® is approved under the IVDR process in the key markets.

Risks

RHY has reported cash of $4.13m (end Sep 23). Further funding will be required to continue the planned approval/commercialisation program. MST assumes a capital raise of $5m in FY24. MST's valuation is subject to the usual upside/downside risks of medical device development including regulatory approval, commercial terms and agreements, market uptake and timing. The attractive markets bring potential competition. Timing is a key risk in the government funded programs where new protocols, systems and education programs will be required.

Equities Research Australia

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Rhythm Biosciences is an Australian medical diagnostics company. Its protein-based technology platform has been trialled in its first indication, colorectal cancer. Breast, cervical, lung, gastric and pancreatic cancer tests are included in the pipeline. The work is well credentialled. The technology reflects 13+ years of CSIRO research and to date 4+ years of RHY development. With its development program completed, RHY has been preparing for market entry in the key global markets, the US, EU and Australia. Management brings experience in both development and commercialisation of new medical products.

https://www.rhythmbio.com/

Valuation	$1.05ps (prev $1.68)
Current price	$0.17ps
Market cap	$37.6m
Cash on hand	$4.3m (Sept CY23)

Upcoming Potential Catalysts and Newsflow

2HCY23	To submit internal analytical testing to TGA
CY23	Partnering Deals for ColoSTAT®
CY23	Progress in Additional Cancer Tests

Share Price (A$) Performance

Source: FactSet, MST Access

[1] Therapeutic Goods Administration
[2] Australian Register Therapeutic Goods
[3] In Vitro Diagnostic Medical Device Regulation
[4] Faecal Immunochemical Test

Figure 1: Financial Summary

Rhythm Biosciences Ltd — RHY-AU

Year end 30 June

MARKET DATA

Share Price	**A$/share**	**0.17**
52 week high / low	A$	0.34 - 1.58
Valuation (12 month forward)	**A$**	**1.05**
Market capitalisation	**A$m**	**37.6**
Shares on issue	m	221
Options	m	12
Other equity	m	29
Potential shares on issue (diluted)		263

12 month performance

INVESTMENT FUNDAMENTALS		FY22	FY23	FY24E	FY25E	FY26E
EPS Reported (undiluted)	¢	(4.2)	(2.7)	(1.9)	1.3	12.6
EPS Underlying (undiluted)	**¢**	**(4.2)**	**(2.7)**	**(1.9)**	**1.3**	**12.6**
Underlying EPS growth	%	n/m	n/m	n/m	n/m	n/m
P/E Reported (undiluted)	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
P/E at Valuation	x	n/m	n/m	n/m	n/m	n/m
Dividend	**¢**	**-**	**-**	**-**	**-**	**-**
Payout ratio	%	0%	0%	0%	0%	0%
Yield	**%**	**-**	**-**	**-**	**-**	**-**

PROFIT AND LOSS (A$)		FY22	FY23	FY24E	FY25E	FY26E
Revenue & Other Income	$m	2.4	3.1	1.6	6.4	72.0
Expenses	$m	(11.2)	(11.4)	(6.0)	(1.8)	(27.3)
EBITDA	**$m**	**(8.7)**	**(8.3)**	**(4.4)**	**4.6**	**44.6**
D&A	$m	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)
EBIT	**$m**	**(8.8)**	**(8.4)**	**(4.6)**	**4.4**	**44.4**
Interest	$m	0.0	0.2	0.1	0.1	0.3
Tax	$m	-	-	-	(1.4)	(13.4)
NPAT	**$m**	**(8.8)**	**(8.2)**	**(4.6)**	**3.2**	**31.3**

KEY RATIOS (A$)		FY22	FY23	FY24E	FY25E	FY26E
Forecast year end shares	m	214	220	249	249	249
Market cap (Y/E / Spot)	**$m**	**246.2**	**37.4**	**42.4**	**42.4**	**42.4**
Net debt / (cash)	$m	(7.6)	(4.1)	(4.4)	(7.7)	(39.1)
Enterprise value	**$m**	**238.6**	**33.2**	**37.9**	**34.7**	**3.3**
EV/Sales	x	98.3	10.7	24.2	5.5	0.0
EV/EBITDA	**x**	**n/m**	**n/m**	**n/m**	**7.5**	**0.1**
EV/EBIT	x	n/m	n/m	n/m	7.9	0.1
Net debt / Enterprise Value	x	n/m	n/m	n/m	n/m	n/m
Gearing (net debt / EBITDA)	**x**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**
Operating cash flow per share	$	(0.0)	(0.0)	(0.0)	0.0	0.1
Price to operating cash flow	**x**	**n/m**	**n/m**	**n/m**	**12.6**	**1.3**
Free cash flow	**$m**	**(6.5)**	**(7.3)**	**(4.5)**	**3.3**	**31.4**
Free cash flow per share	$	(0.03)	(0.03)	(0.02)	0.01	0.13
Price to free cash flow	**x**	**n/m**	**n/m**	**n/m**	**13.0**	**1.3**
Free cash flow yield	**%**	**-17.9%**	**-19.5%**	**-10.6%**	**7.7%**	**74.1%**
Book value / share	$	0.03	0.03	0.02	0.03	0.17
Price to book (NAV)	**x**	**4.9**	**6.4**	**8.6**	**5.1**	**1.0**
NTA / share	$	0.03	0.02	0.02	0.03	0.16
Price to NTA	**x**	**5.2**	**6.8**	**9.4**	**5.4**	**1.0**
EBITDA margin	%	n/m	n/m	n/m	72%	62%
ROE (Average Equity)	%	n/m	n/m	n/m	n/m	n/m
ROA (EBIT)	%	n/m	n/m	n/m	n/m	n/m
Interest cover (EBIT / net interest)	x	n/m	n/m	n/m	42.2	143.4

BALANCE SHEET (A$)		FY22	FY23	FY24E	FY25E	FY26E
Cash	$m	7.6	4.1	4.4	7.7	39.1
Receivables	$m	0.1	0.1	0.1	0.3	3.0
Inventory	$m	-	2.8	0.0	0.2	1.8
PPE	$m	0.1	0.1	0.1	0.1	0.1
Intangibles	$m	0.4	0.4	0.4	0.4	0.4
Other	$m	0.3	0.2	0.2	0.2	0.2
Total Assets	**$m**	**8.4**	**7.7**	**5.3**	**8.8**	**44.6**
Accounts Payable	$m	0.6	1.5	0.1	0.3	3.0
Borrowings	$m	-	-	-	-	-
Leases	$m	0.2	0.1	0.1	0.1	0.1
Provisions	$m	0.3	0.2	0.2	0.2	0.2
Other	$m	-	-	-	-	-
Total Liabilities	**$m**	**1.1**	**1.8**	**0.4**	**0.6**	**3.3**
Shareholder's Equity	**$m**	**7.4**	**5.9**	**4.9**	**8.3**	**41.3**

CASH FLOW (A$)		FY22	FY23	FY24E	FY25E	FY26E
Receipts from customers	$m	-	-	-	4.6	72.0
Payments to suppliers and employees	$m	(9.0)	(10.3)	(6.0)	(1.8)	(27.3)
Milestones, Grants, R&D Rebates	$m	2.4	3.1	1.6	1.7	-
Interest	$m	0.0	(0.0)	0.1	0.1	0.3
Tax	$m	-	-	-	(1.4)	(13.4)
Operating cash flow	**$m**	**(6.5)**	**(7.2)**	**(4.4)**	**3.3**	**31.5**
Capex	$m	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)
Acquisitions / Investments	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Investing cash flow	**$m**	**(0.0)**	**(0.1)**	**(0.1)**	**(0.1)**	**(0.1)**
Borrowings	$m	-	(0.1)	-	-	-
Equity	$m	11.9	3.7	5.0	-	-
Dividend	$m	-	-	-	-	-
Financing cash flow	**$m**	**11.9**	**3.6**	**5.0**	**-**	**-**
Change in Cash / FX	$m	5.3	(3.7)	0.5	3.3	31.4
Year end cash	**$m**	**7.6**	**3.9**	**4.4**	**7.7**	**39.1**

Source: FactSet, MST Access Assumptions

Industry data strengthens RHY investment thesis

Rhythm Biosciences (RHY) has developed a platform technology to offer simple, affordable, mass-market cancer screening tests. The 'lead' cancer biomarker is highly expressed in a range of cancers, opening the potential for multiple applications. RHY's first target is colorectal cancer (CRC) or bowel cancer. It has developed five biomarkers which can identify CRC cells. ColoSTAT® is in late-stage development with plans to enter markets in the US, UK, Europe, Australia, New Zealand and Japan.

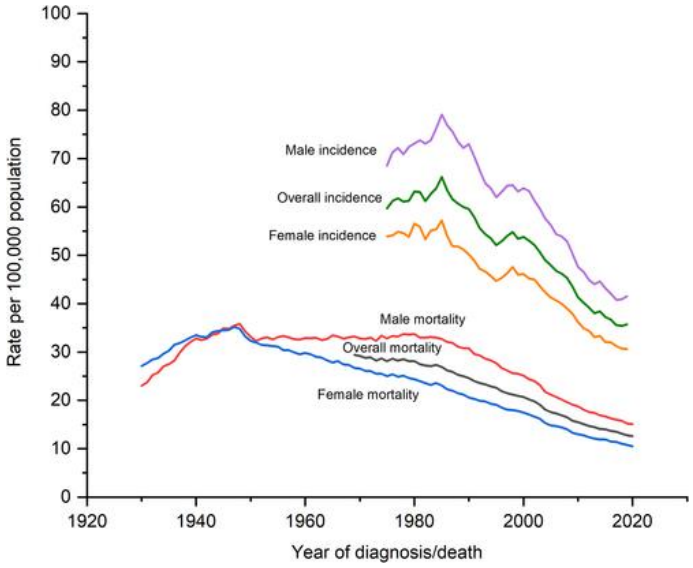
As RHY approaches its market launch, MST reviews ColoSTAT® within the current market dynamics to assess its likely performance.

1. Decreasing bowel cancer rates support continuance of screening programs

Bowel cancer is one of the most common cancers[5]. Countries including US, UK, Australia, Japan, NZ, South Africa and most of European Union member states have introduced bowel cancer screening recommendations. Most screening programs are either free or subsidised. Funding is also provided under some private health insurance schemes.

The success of the programs is well evidenced by the decline in the overall incidence of bowel cancer in individuals >50 years of age since the mid-1980s. The USA has reported a decrease of 2–3% in bowel cancer per year in men and women.[6] Similarly, in Europe, the bowel cancer mortality rate has decreased by 6.7% in men and 7.5% in women, whereas between 2008 and 2016, bowel cancer incidence rates increased by 6% annually[7]. In MST's view, the results strongly support the government funded screening programs and thereby, their continuance.

Figure 2: CRC incident rates



Source: Siegal et al. (2023)[6]

2. Expanding CRC screening markets

Most bowel cancer screening programs commence at 50 years old. The US stands out with American Cancer Society guideline changes in 2018, and more recently in 2021 when the U.S. Preventive Services Task Force (USPSTF), updated its recommendations for bowel cancer screening to start at 45 years of age, rather than 50 years[8]. The change in policy reflected US data that showed 11% of colon cancers and 15% of rectal cancers in 2020 occurred in patients < 50 years. The data compare to only 5% and 9%, respectively, in 2010. MST estimates that adoption of the 45-49 age group adds ~20-25% to the existing screening eligible cohort.

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[3]. https://www.healthdirect.gov.au/bowel-cancer
[4]. American Cancer Society. Colorectal Cancer Facts & Figures, 2017; Siegel et al., 2018
[5]. Malvezzi et al., European cancer mortality predictions for the year 2018 with focus on colorectal cancer. Annals of Oncology Vol 29, Issue 4, April 2018, Pages 1016-1022,
Increasing incidence of colorectal cancer in young adults in Europe over the last 25 years. F E Vuik et al, Gut 2019 Oct;68(10):1820-18262018;
[6]https://www.cdc.gov/cancer/colorectal/basic_info/screening/tests.htm#:~:text=The%20U.S.%20Preventive%20Services%20Task,to%20your%20doctor%20about%20screening

In the UK, more than 61% of all diagnosed bowel cancer cases are outside the screening population (60-74 years of age.) The UK is phasing in an expansion of its CRC program to start screening from 50 years old, rather than 60 years.

The 2019 *Cancer Epidemiology, Biomarkers and Prevention* study found that Australia's incidence of bowel cancer had increased by up to 9% in people aged under 50 since the 1990s. The data support the US approach of including the younger cohort.[9] The Australian Department of Health and Aged Care has reviewed the National Bowel Cancer Screening Program and recommended screening for CRC from the age of 45 (previously 50).

Further extension of screening cohort?

While the majority of US young-onset (<50 years) bowel cancer diagnoses and deaths occur in persons aged 45 to 49 years, the rate of increase in young-onset CRC is actually steepest in the very youngest patients. Colon cancer incidence is increasing by 2 percent per year in 20 to 29-year-olds, compared with 1.3 percent in 40 to 49-year-olds. Similarly, rectal cancer incidence is increasing by 3.2 percent per year in 20 to 29-year-olds and 30 to 39-year-olds, versus 2.3 percent in 40 to 49-year-olds.[10]

3. ColoSTAT® to grow market?

Figure 3: Potential CRC screening opportunities

Country	Screening Method	Age-Screening Population	Screening Participation Rate	Unscreened Population/Opportunity
Europe (EU-27)	FIT Colonoscopy	133.5m (50-74 yrs)	38%	82.8m
UK (England, Scotland, Wales and Northern Ireland)	FIT	10.6m (60-74 yrs)	67%	3.5m
USA	FIT Colonoscopy, Cologuard	161.5 (45-75+ yrs)	69%	53.3m
Japan	FIT	78.6m (>40 yrs)	20%	48.2m
South Africa	FIT	9.3m (50-74 yrs)	N/A	-
Australia	FIT	7.1m (50-74 yrs)	41%	4m
New Zealand	FIT	1.1m (60-74m)	57%	0.5m
Total		**301.7m**		**192.3m**

Source: Adapted RHY ASX released report

Most national government bowel cancer screening programs offer faecal based tests, either Faecal Occult Blood Test (FOBT) or Faecal Immunochemical Test (FIT) - noting some intersperse a colonoscopy periodically as part of the program. Uptake rates of the FOBT/FIT testing tend to be poor at sub 50%. The low response is attributed to:

Patient acceptability - As is well documented, the key deterrent is the need to handle faeces. As such, while the programs offered are clinically 'effective', uptake is poor, hence the unmet need continues.

Cost /Risk - Colonoscopy is more 'patient-acceptable' than faecal tests. However higher expense and risk see it generally unsuitable for mass screening programs. A blood test offers lower risk and cost, both are important in a screening program. For many of the eligible bowel cancer screening cohort, blood tests are already part of the medical routine. The convenience of incorporation of a bowel cancer test into the patient's current screening test program such as cholesterol and glucose is likely to be

[9] Mol Oncol. 2019 Feb; 13(2): 109–131.Published online 2018 Dec 22. doi: 10.1002/1878-0261.12417 Early-onset colorectal cancer in young individual. Gianluca Mauri, Andrea Sartore-Bianchi, Antonio-Giampiero Russo, Silvia Marsoni, Alberto Bardelli, Salvatore Siena.

[10] Rising incidence of early-onset colorectal cancer: a call for action Naohiko Akimoto et al ,Nat Rev Clin Oncol. 2021 Apr; 18(4): 230–243

appealing to the screening candidate and payer. It brings the opportunity to potentially expand the current markets.

Clinical performance- RHY's Clinical Study 7 reported that ColoSTAT® showed 81% sensitivity and 91% specificity in comparison to the gold standard, colonoscopy. The results were statistically significant. Clinical Study 7 also reported that ColoSTAT® was 35% more accurate than FIT.

As discussed, current CRC screening programs, excepting the US, have low participation rates. In MST's view, ColoSTAT® offers the potential to grow these markets. MST notes that NZ and the UK are exceptions with participation rates of 57% and 67% respectively. However, it should be taken into account that both countries offer the test to 60-74 yr olds versus the other countries which also include the younger cohort of 50-59 year olds. The higher participation rate of older cohort may reflect a 'greater' awareness of age-associated health issues. The UK program participation also benefited from the change of FOBT to FIT. FIT does not require the candidate to avoid certain foods for three days before the test. Convenience is also seemingly important. While these screening rates are already 'high', in MST's view, the participants would welcome a blood test if available, particularly as part of a patient's routine blood tests.

US evidence of impact of an 'acceptable' test on potential on market expansion

A review of US screening data provides insight into US preferences for bowel cancer screening. The preference for colonoscopy/ sigmoidoscopy over a home-based faecal test is clear.

Figure 4: Market share of various CRC tests (2018)

2021 CRC Screening Tests	Colonoscopy/graphy	FOBT	DNA
% of Screening population	67%	4%	8%

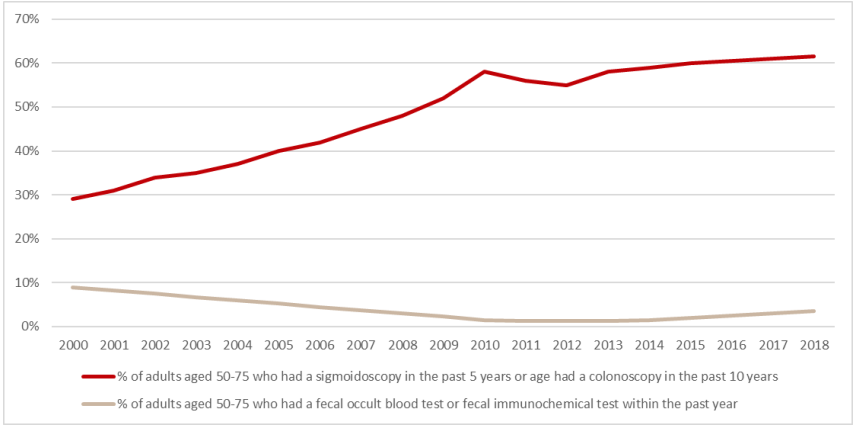
Source: National Cancer Institute

The US, without a national subsidised scheme, provides evidence of screening cohort's preferences and potential for market expansion with the right test. The National Cancer Institute Progress 2021 Report stated 79% of eligible bowel cancer screening cohort was compliant with the recommendations. In MST's view, the higher participation in comparison to other countries is attributable to US decision to fund colonoscopy – a test that is seemingly acceptable to the candidates and, despite being significantly more expensive than faecal tests, has payers' support as it offers superior efficacy. Healthcare savings of an earlier diagnosis of bowel cancer outweigh the higher cost of the test.

The rapid dissemination of colonoscopy screening, which has a greater capacity for bowel cancer prevention than other recommended tests, is credited with the steep declines in incidence rates among adults aged 50 years and older — about 3% – 5% annually in the late 2000s (Figure 5). Earlier detection allows for excision of CRC and premalignant lesions.

Medicare expansion of colonoscopy coverage to include all beneficiaries in 2001 saw significant market expansion. The growth in the screening population from 2012 – 2018 saw an additional 9.3m adults screened. The shift to colonoscopy was not simply product substitution. The introduction of colonoscopies grew the overall market. Among adults aged 50 years and older, colonoscopy use tripled from 20% in 2000 to 61% in 2018. The decline in FIT and FOBT was not commensurate, with penetration of the unrealised market rising significantly.

Figure 5: Percentage of US 50-75 yr olds who had a colonoscopy/sigmoidoscopy vs FIT



Source: Centre for Disease Control and Prevention

Implications for RHY

The review shows that the 'ideal' CRC screening test must be patient acceptable (non faecal), efficacious, affordable, convenient and low risk. With respect to ColoSTAT®, efficacy data to date include the results of RHY's Clinical Study 7. This study reported that ColoSTAT® was 35% more accurate than FIT for detecting bowel cancer. It also reported sensitivity of 81% and 91% efficacy as compared to SOC colonoscopy. The results were statistically significant.

The test also potentially offers

- **Affordability** – The price is yet to be determined but is generally expected to be at a premium to FOBT/FIT and significantly below the cost of a colonoscopy.
- **Convenience** – As a blood test, ColoSTAT®, offers an alternative for the GP to offer. There is also the opportunity to prompt their patients while in the surgery and possibly combine ColoSTAT® with other blood tests.
- **Low risk** – As a blood test, ColoSTAT® is a simple procedure with significantly lower risk than colonoscopy.
- **Patient accepting** – While some patients have needle phobias, most patients would seemingly prefer a blood test to a faecal test or a high-risk colonoscopy.

Key events to date include:

- **July 2021,** RHY established IchorDX Inc, a wholly-owned subsidiary to drive its expansion strategy into the US. While RHY is yet to confirm its plans for approval in the US, it expects first sales over the next 12 months.
- **Late CY21,** RHY completed the requirements for EU's CE mark, permitting sales of the test.
- **April 2022,** RHY announced that its Clinical Study 7 reported 81% sensitivity and 91% specificity and that ColoSTAT® was 35% more accurate than Standard of Care (SOC) FIT.
- **May 2022,** RHY filed for ARTG listing of ColoSTAT® with TGA .
- **November 2022,** ColoSTAT® registration with the New Zealand (NZ) national database of Medical Devices.
- **March 2023,** TGA raised a number of queries regarding the manufacturing process of ColoSTAT®. RHY withdrew its listing application to undertake the required testing confirmation.
- **May 23**, ColoSTAT® received UK CA mark and established strategic partnership with UK Link Medical Solutions.
- **July 23,** established a 100% fully owned subsidiary, Rhythm Biosciences UK Limited, to assist in the importation and distribution channels of ColoSTAT® into the UK and other parts of Europe where RHY has also registered ColoSTAT®.

Other activities include:

- A U.S.A based manufacturer has been engaged to deliver a pilot batch post successful feasibility manufacturing
- Automation of the ColoSTAT® immunoassay with a commercial pathology laboratory
- Build a raw material inventory, with stock on hand (~AUD$3 million) at the global CMO. This supply is expected to meet the initial unmet demand in the anticipated UK and other market entries.
- Review of further global and local Contract Manufacturing Organisation (CMO)
- Conducted an advisory board with physicians and payers from Australia and the UK.

The path from here

RHY plans to finalise plans to address the TGA application under the IVDR process in H2FY24. As RHY undertakes the TGA required production testing, management is focussing on commercialisation activities for the first targeted markets. It plans for its first commercial sales over FY24, with a focus on private markets in the UK, and South Africa. Over the next 12 months it also plans for market launch into New Zealand and the US.

RHY offers a strong pipeline

RHY's technology emerged from Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO). Its research identified ~68 proteins that vary in concentration in the blood serum of patients with and without CRC. In 2017, RHY's fully owned subsidiary, Vision Tech, entered a Licence Agreement with CSIRO which granted the company an exclusive right to the patents and patent applications. In 2019, RHY announced that it had identified a protein that enabled differentiation between cancer and healthy samples. The work established the key component of the test, the ability to detect the presence of cancer with potential use in multiple cancers. It provides RHY with a strong pipeline. Its current development focus is lung, breast, and gastric cancers.

Risks

MST's valuation is subject to the usual upside/downside risks of development of medical devices including regulatory approval, commercial terms and agreements, market uptake and timing. Many of the CRC testing programs are government funded/subsidised programs. Risk arises through acceptance into these programs and timing as many are contract based.

In addition, the TGA has requested that RHY submit test data for three different production batches of its ColoSTAT® test-kits from its overseas manufacturer. On confirmation of the batch testing, RHY is required to submit a new application to the TGA. RHY has stated it plans finalise the TGA IVDR process over H2FY24. Re submission for approval will trigger a review period of up to 255 working days.

RHY has also announced that it will seek EU approval under an IVDR application. IVDR is compulsory from May 2026. IVDR carries more comprehensive requirements than the IVDD, thereby commonly takes longer to complete.

RHY faces the usual industry upside/downside risks of medical device development including regulatory approval, commercial terms and agreements, market uptake and timing differences.

RHY will require additional capital to realise its plans for the targeted markets. Funding for its R&D program may be realised or on less favourable terms. The CRC screening markets are attractive, bringing strong competition. MST's forecasts assume ColoSTAT® becomes the key CRC test in the established national Faecal Immunochemical Test (FIT) programs. The uptake may vary in both the degree of substitution and timing from MST's forecasts.

Valuation

MST's change in its DCF valuation to A$1.05ps (prev A$1.68ps) reflects the dilution effect a A$5m capital raise in FY24 at an assumed price of A$0.17ps; slower market uptake until TGA queries are resolved and IVDR classification is gained as required in the targeted markets. Re submission for TGA approval triggers a period of review for up to 255 days, bringing upside/downside risk of further valuation revision.

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Methodology & Disclosures

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