

Approval to unlock an expanded market

RHY's Clinical Study 7 of its Colorectal cancer (CRC) screening test, ColoSTAT®, showed a 35% greater accuracy in identifying patients with CRC versus the current standard of care (SOC) screening test, Faecal Immune Test (FIT). Confirmation of Australian approval expected in H2CY22 will 'open' the door to significant current markets of ~US\$8bn with the potential for significant expansion.

Attractive Markets

Based on current screening rates in the key established markets and an assumed price of ~US\$38 per test, MST estimates the value of the total current key CRC screening markets as ~US\$8.1bn versus a ~US\$24.8bn total addressable market (TAM). We believe the advantages of ColoStat® will drive significant substitution of FIT.

We also see expansion of the current market. A UK study identified the faecal nature and home-based setting as major deterrents to participation in the current FIT screening programs. Review of cancer screening programs sees the highest participation in cervical screening. Gender does not seem to be a factor. In MST's view, doctor involvement is also an important driver. ColoSTAT® as a General Practitioner (GP) based blood test addresses the key deterrents.

ColoSTAT®'s potential to expand the CRC market

To gain some insight into the potential size of a 'more user friendly' CRC screening market, we have reviewed the Australian and UK cervical and breast cancer screening programs. The uptake of cervical screening is ~40% higher than comparable CRC screening programs. A similar screening rate across the CRC key markets would offer an additional ~US\$3.2bn market value.

Valuation, Risks, Sensitivities

FY23 promises to be a transformational year for RHY with first sales revenues and potential licensing deals. Both are likely to trigger investor interest. MST has not assigned any value to RHY's planned pipeline of screening tests in breast, cervical, gastric, lung and prostate cancers – all offer potential upside.

MST's unweighted 12-month forward DCF valuation is \$3.10 per share. It is subject to the usual upside/downside risks of medical device development including regulatory approval, commercial terms and agreements, market uptake and timing differences. The attractive markets bring potential competition. Timing is a key risk in the government funded programs. MST's forecasts assume ColoSTAT® becomes the key CRC test in the established national programs. The uptake may vary in both degree of substitution and timing.



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 is undertaking the regulatory processes to gain approval in its first markets: the US, EU and Australia. Management brings experience in both development and commercialisation of new medical products.

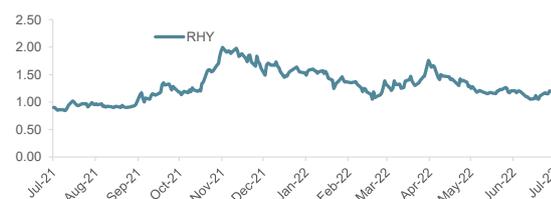
www.rhythmbio.com

Stock	RHY.ASX
Price	A\$1.19
Market cap	A\$257m
12-month valuation (per share)	A\$3.10

Potential Milestones

H2CY22	First revenues/income
H2CY22	TGA approval/ ARTG Listing
H2CY22	Partnering Deals
H2CY22	Additional Regulatory Submissions

RHY share price (A\$)



Source: FactSet.

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Financial Summary

Rhythm Biosciences Ltd

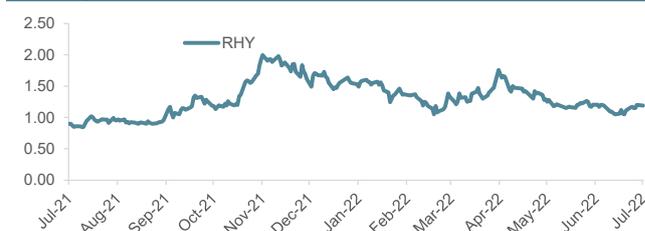
RHY-AU

Year end 30 June

MARKET DATA

Share Price	A\$/share	1.19
52 week high / low	¢	0.84 - 2.08
Valuation (12 month forward)	A\$	3.10
Market capitalisation	A\$m	255
Shares on issue	m	214
Options	m	22
Other equity	m	-
Potential shares on issue (diluted)		236

12 month performance



INVESTMENT FUNDAMENTALS		FY20	FY21	FY22E	FY23E	FY24E
EPS Reported (undiluted)	¢	(4.0)	(3.6)	(4.1)	(0.9)	2.8
EPS Underlying (undiluted)	¢	(4.0)	(3.6)	(4.1)	(0.9)	2.8
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	%	-	-	-	-	-

KEY RATIOS (A\$)		FY20	FY21	FY22E	FY23E	FY24E
Forecast year end shares	m	101	202	214	214	214
Market cap (Y/E / Spot)	\$m	119.9	240.6	254.8	254.8	254.8
Net debt / (cash)	\$m	(1.8)	(2.2)	(7.1)	(4.6)	(10.1)
Enterprise value	\$m	118.1	238.4	247.7	250.2	244.7
EV/Sales	x	#DIV/0!	215.0	102.0	32.5	11.0
EV/EBITDA	x	(30.1)	(36.8)	(28.4)	(139.5)	26.9
EV/EBIT	x	(29.1)	(36.0)	(28.1)	(130.8)	27.2
Net debt / Enterprise Value	x	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Gearing (net debt / EBITDA)	x	0.5	0.3	0.8	2.6	(1.1)
Operating cash flow per share	\$	(0.0)	(0.0)	(0.0)	(0.0)	0.0
Price to operating cash flow	x	(43.7)	(44.5)	(38.5)	(142.9)	41.1
Free cash flow	\$m	(2.8)	(5.5)	(7.0)	(2.5)	5.5
Free cash flow per share	\$	(0.03)	(0.03)	(0.03)	(0.01)	0.03
Price to free cash flow	x	(43.0)	(44.0)	(36.5)	(102.6)	46.3
Free cash flow yield	%	-2.3%	-2.3%	-2.7%	-1.0%	2.2%
Book value / share	\$	0.02	0.01	0.04	0.03	0.06
Price to book (NAV)	x	65.1	139.3	32.4	41.4	20.2
NTA / share	\$	0.01	0.01	0.03	0.03	0.06
Price to NTA	x	89.1	190.3	34.4	44.7	21.0
EBITDA margin	%	n/m	n/m	n/m	n/m	41%
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	n/m	75.2

PROFIT AND LOSS (A\$)		FY20	FY21	FY22E	FY23E	FY24E
Total Revenue & Other Income	\$m	-	1.1	2.4	7.7	22.2
COGS	\$m	-	-	-	(1.5)	(5.1)
Gross margin	\$m	-	1.1	2.4	6.2	17.1
Costs	\$m	(3.9)	(7.6)	(11.1)	(8.0)	(8.0)
EBITDA	\$m	(3.9)	(6.5)	(8.7)	(1.8)	9.1
D&A	\$m	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
EBIT	\$m	(4.1)	(6.6)	(8.8)	(1.9)	9.0
Interest	\$m	0.0	0.0	0.1	0.1	0.1
Non-operating income	\$m	-	-	-	-	-
Pretax Profit	\$m	(4.0)	(6.6)	(8.8)	(1.8)	9.1
Tax	\$m	-	-	-	-	(2.6)
Minorities	\$m	-	-	-	-	-
Underlying NPAT	\$m	(4.0)	(6.6)	(8.8)	(1.8)	6.5

BALANCE SHEET (A\$)		FY20	FY21	FY22E	FY23E	FY24E
Cash	\$m	1.8	2.2	7.1	4.6	10.1
Receivables	\$m	0.1	0.2	-	0.3	0.9
Inventory	\$m	-	-	-	0.2	0.6
PPE	\$m	0.1	0.1	0.4	0.9	1.5
Intangibles	\$m	0.5	0.5	0.4	0.4	0.4
Other	\$m	0.1	0.1	0.2	0.2	0.2
Total Assets	\$m	2.6	3.1	8.1	6.7	13.7
Accounts Payable	\$m	0.7	1.2	-	0.3	0.9
Borrowings	\$m	-	-	-	-	-
Leases	\$m	0.0	-	-	-	-
Provisions	\$m	0.1	0.1	0.2	0.2	0.2
Other	\$m	-	-	-	-	-
Total Liabilities	\$m	0.8	1.3	0.2	0.5	1.1
Shareholder's equity	\$m	1.8	1.7	7.9	6.1	12.6

CASH FLOW (A\$)		FY20	FY21	FY22E	FY23E	FY24E
Receipts from customers & R&D incentives	\$m	-	-	2.4	7.7	22.2
Payments to suppliers and employees	\$m	(3.6)	(6.6)	(9.1)	(9.6)	(13.5)
Milestone Payments	\$m	-	-	-	-	-
Interest	\$m	0.0	0.0	0.1	0.1	0.1
Tax	\$m	0.8	1.2	-	-	(2.6)
Operating cash flow	\$m	(2.7)	(5.4)	(6.6)	(1.8)	6.2
Capex	\$m	(0.0)	(0.1)	(0.4)	(0.7)	(0.7)
Acquisitions / Investments	\$m	-	-	-	-	-
Other	\$m	-	-	-	-	-
Investing cash flow	\$m	(0.0)	(0.1)	(0.4)	(0.7)	(0.7)
Borrowings	\$m	(0.1)	(0.0)	-	-	-
Equity	\$m	-	5.9	11.8	-	-
Dividend / other	\$m	-	-	-	-	-
Financing cash flow	\$m	(0.1)	5.9	11.8	-	-
Change in Cash / FX	\$m	(2.9)	0.4	4.9	(2.5)	5.5
Year end cash	\$m	1.8	2.2	7.1	4.6	10.1

Investment Thesis

Rhythm Biosciences (RHY) has developed a platform technology to offer simple, low cost, mass market cancer screening tests. CRC is the first target. It presents opportunity through:

1. **Clinical need:** CRC is the second largest cause of US cancer related death. The high burden of the disease is recognised with many countries offering bowel cancer screening programs through either private or public funding. While potentially initially slower, these programs are likely to facilitate ColoSTAT®'s market penetration. The strong involvement of health regulatory bodies and health payers in the current FIT programs is also likely to be supportive.
2. **Clear clinical benefit over standard of care, FIT:** ColoSTAT® demonstrated a 35% higher sensitivity than FIT in its Clinical Trial 7. Generally, high sensitivity is sought in a screening test to maximise capture of potential cases. More specific diagnostic tests such as colonoscopy can then be conducted to determine if the disease is truly present.
3. **User friendly:** Preference of ColoSTAT® over FIT is also likely to be well supported due to the general dislike of faecal test protocols and the higher cost/risk of colonoscopy. A UK study reported that the faecal basis of bowel screening programs was a key deterrent. ColoSTAT® also brings a solution to CRC testing in temperate/tropical areas. Temperatures of >35 ° render FIT inaccurate, effectively restricting the use of FIT testing. In MST's view, the greater acceptability of a blood test with higher efficacy is likely to be well received and expand the current markets. It also offers convenience. As a blood test, ColoSTAT® can be incorporated into current screening tests for cholesterol, glucose.
4. **GP based:** The higher rates of screening in cervical screening support expanded uptake of ColoSTAT® as based GP administered test. The FIT study reported participants seek the involvement of their GP and a medical setting.
5. **Deal friendly:** ColoSTAT® is an ELISA (enzyme-linked immunoassay) test. ELISA is a commonly used form of laboratory testing. Its universality in combination with the ColoSTAT® data, is likely to see strong interest from potential licensing partners.
6. **Strong pipeline:** The 'lead' cancer biomarker is highly expressed in a range of cancers, opening the potential for multiple applications. In addition to its initial target of CRC, RHY plans to target breast, cervical, lung, gastric and pancreatic cancers. MST's investment thesis is built around CRC only, recognising there is further upside.

Potential Milestones

- H2CY22 First revenues/income
- H2CY22 TGA approval/ Australian Register of Therapeutic Goods (ARTG) Listing
- H2CY22 Commercial Partnering Deals
- H2CY22 Additional Regulatory Submissions

Valuation, Risks, Sensitivities

MST's valuation is A\$3.10 per share. It is based on a DCF valuation of the existing key FIT markets. It assumes that RHY will receive approval in the major markets and gain higher penetration rates driven by a greater acceptability of a blood test to the current faecal test – noting some CRC screening participants will reject a blood test. As a general practitioner (GP) based test, encouragement from participants' GPs is also expected to drive higher uptake as seen in cervical cancer screening programs. Currently, most FIT testing is conducted by mail outs to participants to undertake the test in the home.

The MST model is based on US market price of A\$120 and for the EU and Australian market, A\$60. MST forecasts assume RHY will participate in the current national/regional funded programs. Generally, the products in national program demand pricing discounts. There is a risk that the price will fall below MST assumptions. There is also timing risk. The MST valuation is based on annual increments in market uptake to maturity. There may be timed entry points based on existing contracts.

RHY is yet to confirm its commercialisation strategy. The various options include global/ regional licensing, partnerships and sale. All offer different revenue streams and may vary to MST's valuation assumptions. MST forecasts assume RHY will partner with pathology service provider/s. Royalty streams commonly range 5%-15%. MST model assumes licensing agreement will be based on a 12% royalty stream for the Australian, US and EU markets. Royalties of 2% of all net sales are payable to CSIRO under the agreements. The valuation is based on a net ~10% to RHY.

The assumptions underlying the valuation are subject to the usual upside/downside risks. They include approval, pricing, market entry timing, inclusion in existing CRC screening programs, commercial terms and rates of uptake. The attractive markets bring potential competitors and as such potential loss of market share.

ColoSTAT® to expand the current CRC screening market

In April 2022, RHY announced that the Clinical Study 7 of its CRC screening test, ColoSTAT®, demonstrated 81% sensitivity and 91% specificity compared to the standard of care (SOC) diagnostic colonoscopy. The study also reported that ColoSTAT® was 35% more accurate than FIT in identifying patients with CRC. FIT is the current SOC for screening of CRC in most countries. The results are important from two perspectives:

1. Australian market approval - A clinical study is required as part of the Australian TGA's approval criteria for the listing of new tests on the Australian Register of Therapeutic Goods (ARTG). The Clinical Study 7 results formed part of RHY's application submitted in May 2022. The TGA decision is expected in H2CY22.
2. Support of marketing activities - In H1FY22, RHY announced that ColoSTAT® had been granted Conformité Européenne (CE) Mark. The CE Mark attests that the product meets EU regulations. It is mandatory for sale of products sold within the EU Economic Area (EEA). During H2FY22, the CE Mark was extended to include the Great Britain and Northern Ireland.

ARTG listing and CE Mark assess the test from a manufacturing perspective only. It provides confidence that the test measures what is stated. There is no efficacy attestation. The test can be sold, however, clinicians and payers usually also require clinical evidence. They need to understand where the test fits within the current management protocols. The comparison to FIT, the current SOC in most markets, will be important in their decision making. ColoSTAT®'s performance relative to colonoscopy may also offer value in countries such as the US, where colonoscopy is SOC. A combination approach of both colonoscopy and ColoSTAT® testing may allow for less frequent use of more costly and higher risk colonoscopy.

Exhibit 1: Estimated CRC Screening Market Opportunity

Market	Screened Population (m)	Unscreened Population (m)	Total Population (m)	Participation Rate	Current Screening Market (\$USm)	Unrealised Market (\$USm)	Total Market (\$USm)
US	64.95	29.46	94.41	68.8%	2,468	1,119	3,587
EU	52.64	49	101.64	51.7%	2,000	1,862	3,862
Australia	2.78	3.57	6.35	43.8%	106	135	241
China	76.34	331.66	408	18.7%	2,901	12,603	15,504
Japan	15.84	25.9	41.74	38.0%	602	984	1,586
Total	213	440	652	33%	8,077	16,703	24,780

1

Current market opportunity for Colostat TAM Existing FIT market

Based on the key CRC screening programs and an assumed price of US\$38 for ColoSTAT®, MST estimates the total current market value at US\$8.1bn, with a Total Addressable Market (TAM) of US\$24.8bn. RHY's initial priorities include the US, EU and Australian markets, representing an opportunity of US\$2.3bn¹. In MST's view, the current screening programs offer different opportunities for RHY. ColoSTAT®'s superior performance in Clinical Study 7 supports a strong substitution opportunity in the current predominantly FIT markets of EU, Australia and Asian countries. The US offers a significant CRC screening market, however faecal tests account for ~4.2%. In the US, colonoscopy is SOC. MST believes there may be a role for a combination approach with colonoscopy. RHY's initial focus will include EU, Australia and US. The Asian markets are planned to follow. We see a more meaningful penetration in the Asian markets as a medium-term goal. Pricing may vary. MST valuation is based predominantly on the established FIT based markets, noting a US opportunity for a combination of colonoscopy and ColoSTAT®.

Expansion of existing CRC screening market

What market penetration can ColoSTAT® achieve? We look at other cancer screening programs for insight. A current literature review shows CRC has one of the lowest screening participation rates. We look at the ColoSTAT®'s opportunity to address the current deterrents and thereby expand the existing CRC screening markets.

¹ Based on published data

Exhibit 2: Uptake in Cancer Screening Programs

Cancer	CRC		Breast		Cervical	
Country	Australia	UK	Australia	UK	Australia	UK
Participation Rate	44%	60%	50%	71%	69%*	75%
Test	FIT	gFOBT	Mammogram	Mammogram	Pap Smear	PapSmear
Screening Age Range	50-74	60-74	50-74	50-74	20-74	25-64
Administration	Home	Home	Radiology Centre	Radiology Centre	GP Surgery	GP Surgery ²

* Total cohort- 56% ; Adjusted for comparable cohort to CRC (50-74 yrs only) 69%

The Australian mammography-based breast screening program is offered to 50–74 year-old women every two years. Participation rates in Australia are estimated at ~50%, which is higher than the FIT based CRC program at 44%. The UK rates are also higher at 71% versus 60%. The breast screening programs are based on a ‘reminder system, with the onus on the participant to make an appointment at nominated radiology centres.

The Australian cervical cancer screening program includes 25 -74 year-old women. The program is transitioning from a biennial PAP smear to a 5 yearly Human Papilloma Virus (HPV) based screening program. 2017 data are presented to exclude any impact from the transition. The data show a participation rate of the 56% for the total cohort. However, adjustment of the data to include the 50-74 year-olds only, in keeping with the CRC cohort, sees a participation of ~69%. In the UK, the 2020-2021 participation rate of the total cohort was ~69%. In the 50+ year group, participation was also higher at 75%. Cervical smears tests are usually conducted by the general practitioners, noting Australia has recently commenced self-administered specimen collection.

The Prostate Specific Antigen (PSA) test is offered as a screening test for prostate cancer. However, its lower accuracy has seen a number of professional medical organizations caution against routine population screening. It is not offered as a national based testing program. It is now considered more on a case-by-case basis. It is not included in MST’s market analysis.

Why is CRC screening participation lower than breast and cervical?

Before comparing the screening uptake of the different cancers, it is important to explore the wide disparity between the UK and Australian programs. In MST’s view the overall higher rate of screening in the UK may reflect the lower level of private health insurance. 53% of Australians have private health insurance (PHI), under which Australians can undertake screening tests such as colonoscopy and mammography. PHI uptake in the UK is ~11%. Australians opting to undertake their bowel and breast cancer screening can do so through referral from their general practitioner and therefore would be not captured in the national screening programs data.

2

The higher rates of participation in both the Australian and UK cervical and breast cancer screening programs, suggest a resistance to bowel cancer screening or they may arise from a sex bias, with higher participation rates of women in health screening programs. We look more closely at the CRC, breast and cervical programs to establish the potential factors underlying the CRC lower participation rates and what role ColoSTAT® may offer. Insight into CRC screening is gained through a UK study that was undertaken to identify the drivers of resistance to its CRC screening program.

The study highlighted a number of areas:

- Faeces at home - a key deterrent

The study identified the need to sample and store faeces at home as a serious contributing factor to non-participation.

- Faecal testing was referred to as a ‘cultural taboo’. Participants viewed the storage of the kit over the several days testing period as a ‘threat, physically polluting them and/or their environment’. Many spoke of the need to undertake extreme measures to manage the perceived threats of ‘contamination’.

² <https://www.gov.uk/government/publications/cervical-screening-standards-data-report-2020-to-2021>

- Completion of the test kit within the home rather than a formal health setting was considered ‘unsettling’ and reduced perceived importance of the test. There was a preference for a doctor to do ‘such’ tests rather than home based. Participants reported ‘discomfort’ with the detachment of the faecal testing from ‘usual’ health-care settings and professionals. They expressed a preference to attend a health setting such as a GP surgery or hospital and for ‘someone else’ to undertake the screening on their behalf. Further, linked to this was a perception of ‘self-testing’ as unusual and unexpected, particularly by comparison with other screening experiences or medical interactions where ‘a professional’ is involved in the procedure. ‘If the letter had come from my GP, I would have taken it more seriously.’ The prospect of self-testing at home therefore inhibited rather than facilitated uptake.
- Participants reported putting the test to one side, implying a degree of intention to participate, but not completing it. It appeared there was no aversion to bowel testing per se, rather the method by faecal testing.
- The results were not based on gender, ethnicity, geographical location. The data thereby support that the higher screening levels in cervical and breast do not reflect a gender-based effect.³

Why is cervix screening higher than bowel and breast?

While screening ages are similar for CRC and mammography, cervical cancer programs include a younger cohort with 20-64 year olds in the UK and 20-74 year olds in the Australian programs. Screening rates tend to be higher in the older age groups. Review of the two screening programs’ data shows an uptake in 50-69 year olds of 69% in Australia. In the UK there is a similar trend with 76.4% of women aged 50-74 years old undertaking cervical screening versus 70.1% in the 25-49 yearold cohort.⁴ The higher compliance of cervical testing is not due to a higher participation rate in the younger cohort.

In MST’s view, there are a number of points to consider

- The faecal basis of the test was a key deterrent of the uptake of CRC screening.
- The higher rates of cervical and breast to CRC screening may reflect a sex bias. The comparative analyses of the UK CRC screening study found high levels of consistency in accounts for non-uptake regardless of gender, ethnicity, or geographical location. The number of men and women undertaking FIT was similar. The lower rate of CRC screening to both cervix and breast screening does not seem to be related to a general resistance of men to screening tests.
- Participants in the FIT study expressed a preference for a medical setting, rather than a home-based test. It supports ColoSTAT’s GP based format, whereby the test can be offered as part of a routine consultation.
- The study also reported a preference for results to be conveyed by medical practitioner to the participant rather than receive the results by mail to the participant.

In addition to a higher detection rate, ColoSTAT® looks to offer the desired testing characteristics – non-faecal based, GP administered, in a medical setting and doctor to receive and deliver the results.

There may be further opportunity for ColoSTAT®. The more efficacious, participant-friendly test may offer a role in conjunction with colonoscopy screening. A more economic screening regimen may be offered based on a program that sees less frequent colonoscopy testing in combination with lower cost ColoSTAT®. The combination approach may see adoption in Australia, by those currently using PHI funded colonoscopy.

Other factors to consider

GP Visits

The need for a doctor’s consultation for ColoSTAT® potentially adds some inconvenience and cost. CRC screening is generally offered to 50-74 year olds (45-74 in US). Medical visits are more frequent in the aged population allowing for the test to be part of routine visit. A recent Australian review by showed that people within the bowel cancer screening age range were generally in contact with a doctor at least once year, with many showing more than four times.

³ C K Palmer et al Reasons for non-uptake in NHS Bowel Cancer Screening Programme. *British Journal of Cancer* volume 110, pages1705–1711 (2014)

⁴ <https://www.gov.uk/government/publications/cervical-screening-standards-data-report/cervical-standards-data-report-1-april-2019-to-31-march-2020>

General Practitioner Attendance Rates

Age Group	Frequency of Visits pa			
	< 1	1-3	4-12	>12
60+ years		37%	45%	13%
45-49 years	21%	32%	38%	7%

‘Wellness’ preventative programs have become a key focus for many general practitioners/primary care physicians. Glucose testing is commonly undertaken every three years, cholesterol every 5 years. The addition of ColoSTAT® to the program is unlikely to add significantly to the burden. Ongoing doctor visits would provide the opportunity to give reminders and follow up.

Pricing

ColoSTAT® is an ELISA based test. ELISA is one of the most commonly used laboratory techniques in clinical medicine. It is offered in most diagnostic pathology laboratories promising wide application. As a highly automated test platform, it can be process large volumes efficiently.

As a screening program, cost is important. The benefit of the program needs to justify the cost. RHY has indicated a potential cost of US\$38/A\$50. Based on the strong Clinical Trial Study 7 data, MST assumes higher pricing in Australia and EU of A\$60 and in the US of \$120. This compares to US pricing of FOBT/FIT of US\$15-32 and an average price for colonoscopy of US\$2,250 as an outpatient.

In summary, ColoSTAT® is well positioned to become SOC as it

- is more efficacious than current SOC, FIT,
- is likely to be regarded as more acceptable as it is a blood test.
- requires the involvement of a GP bringing the participant reassurance.

Commercialisation Strategy

As an Australian small cap company, RHY is likely to seek licensing partners to achieve timely and effective global coverage. It may seek one global partner or seek regionally based service providers. It may choose to partner with a pathology equipment supplier. ColoSTAT® is an ELISA based test. It is well established and highly utilised testing format offering a number of partners. In MST’s view there is likely to be interest. the strongly positive Clinical Study 7 data are likely to strengthen licensing partnership negotiations and marketing activities in the EU and other markets. The pipeline of additional potential tests is likely to be attractive as well.

Pipeline to offer further significant value

RHY’s platform technology is designed to offer a range of simple, low cost, mass market cancer screening tests. It is based on a ‘lead’ cancer biomarker that is highly expressed in a range of cancers to identify the presence of cancer. In combining the ‘lead’ with cancer-specific biomarkers, the technology aims to detect and specify a range of cancers. RHY has announced it will target breast, cervical, lung, gastric and pancreatic cancers. While some may be deterred by a blood test, the frequency of blood testing and ability to combine ColoSTAT® with other routine tests is likely to driver higher compliance. Mammography for breast and PAP smear for cervical cancer carry some discomfort and radiation exposure risk in the case of breast cancer. We note the change to 5 yearly HPV screening will be seen positively.

In MST’s opinion, the ability to offer a wide range of blood-based cancer tests will assist to grow the total market with the potential for one blood draw to cover a number of the most common cancers. Timelines for the development of the follow-on tests are likely to be truncated in comparison to ColoSTAT® development through the data already established in the CRC development work.

⁵ <https://practices.hotdoc.com.au/blog/how-often-do-australians-visit-a-doctor>

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