Clinical Study 7 opens market opportunities

Positive Clinical Study 7 results – RHY's Clinical Study 7 reported 81% sensitivity and 91% specificity[1] of its Colo-Rectal Cancer (CRC) screening test, ColoSTAT® as compared to standard of care (SOC) diagnostic, colonoscopy. For perspective, mammography, SOC for breast cancer, sensitivity ranges from 54%-94% and specificity 90%.[2] Sensitivity, the ability to detect the disease, is key for a screening test. Despite sensitivity as low as 54%, mammogram is the SOC for breast cancer screening. In part, the wide range of results reflects the subjective nature of interpreting the mammograms. As a fully automated blood test, RHY provides for a more consistent objective measure. RHY's clinical study is likely to support regulatory requirements and market uptake.

Competitive superiority – Study 7 included Faecal Immunochemical Test (FIT), the current SOC for screening for CRC. The study showed that ColoSTAT® was 35% more accurate in identifying patients with CRC than FIT.

The positive results are expected to support the market uptake for its initial target markets of Australia, EU and US, with China and Japan to follow. Given the strong reliance on FIT testing in EU, Australia and Asia particularly, ColoSTAT®'s superior performance and its advantage as a blood test versus faecal, is likely to see strong market demand and expansion of the current FIT markets.

RHY's technology, spun out of the CSIRO, is based on protein biomarkers that can identify the presence of cancer. Biomarkers specific to the type of cancer are developed to identify the targeted cancer. RHY's pipeline includes tests for breast, cervical, lung, gastric and pancreatic cancers.

Valuation, Risks, Sensitivities

MST valuation of A3.10 (previously $2.90ps) reflects the strength of the trial results, particularly its superior performance to the current standard of care bowel cancer screening test, FIT. In MST's view, many will prefer a blood test to the current faecal test and will receive encouragement from their general practitioner to participate.

MST assumes that RHY will command a premium for its test. MST model assumes US market price of A$120 (prev A$100) and for EU and Aus market, A$60 (prev A$50). Our valuation is subject to the usual upside/downside risks of diagnostic testing including market entry timing differences, non-approval, commercial uptake variations and competitor behaviours.

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 initial 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$1.42
Market cap	A$302m
12-month valuation (per share)	A$3.10

Potential near-term milestones	
H1CY22	Commence sales, Aust. TGA submission
CY22	Commence US market entry initiatives
CY22	Confirm next target test

RHY share price (A$)

Source: FactSet.

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[1]Sensitivity and specificity are inversely proportional, meaning that as the sensitivity increases, the specificity decreases and vice versa. Comparisons are generally made with one variable constant.

[2]US National Cancer institute https://www.cancer.gov/types/breast/hp/breast-screening-pdq

Financial Data

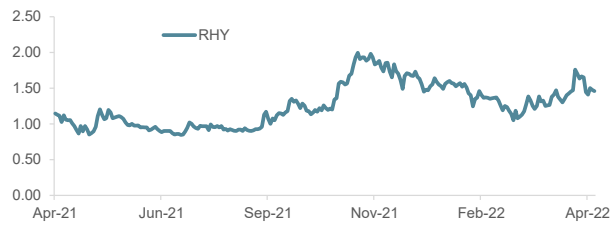
Rhythm Biosciences Ltd — RHY-AU

Year end 30 June

MARKET DATA

Share Price	**A$/share**	**1.46**
52 week high / low	¢	0.84 - 2.08
Valuation (12 month forward)	**A$**	**3.10**
Market capitalisation	**A$m**	**313**
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	4.4
EPS Underlying (undiluted)	**¢**	**(4.0)**	**(3.6)**	**(4.1)**	**0.9**	**4.4**
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**	**147.1**	**295.2**	**312.6**	**312.6**	**312.6**
Net debt /(cash)	$m	(1.8)	(2.2)	(1.0)	(2.9)	(12.2)
Enterprise value	**$m**	**145.3**	**292.9**	**311.5**	**309.6**	**300.4**
EV/Sales	x	#DIV/0!	264.3	128.3	40.2	13.8
EV/EBITDA	**x**	**(37.0)**	**(45.2)**	**(35.8)**	**106.4**	**22.0**
EV/EBIT	x	(35.7)	(44.2)	(35.3)	106.4	22.0
Net debt / Enterpprise Value	x	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Gearing (net debt / EBITDA)	**x**	**0.5**	**0.3**	**0.1**	**(1.0)**	**(0.9)**
Operating cash flow per share	$	(0.0)	(0.0)	(0.0)	0.0	0.0
Price to operating cash flow	**x**	**(53.6)**	**(54.6)**	**(47.2)**	**158.4**	**33.5**
Free cash flow	**$m**	**(2.8)**	**(5.5)**	**(6.7)**	**1.9**	**9.3**
Free cash flow per share	$	(0.03)	(0.03)	(0.03)	0.01	0.04
Price to free cash flow	**x**	**(52.8)**	**(54.0)**	**(46.8)**	**163.4**	**33.7**
Free cash flow yield	**%**	**-1.9%**	**-1.9%**	**-2.1%**	**0.6%**	**3.0%**
Book value / share	$	0.02	0.01	0.01	0.02	0.06
Price to book (NAV)	**x**	**79.8**	**171.0**	**210.0**	**85.5**	**23.4**
NTA / share	$	0.01	0.01	0.00	0.01	0.06
Price to NTA	**x**	**109.4**	**233.4**	**299.4**	**97.4**	**24.2**
EBITDA margin	%	n/m	n/m	n/m	38%	63%
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	96.9	130.0

PROFIT AND LOSS (A$)		FY20	FY21	FY22E	FY23E	FY24E
Total Revenue & Other Income	$m	-	1.1	2.4	7.7	21.8
COGS	$m	-	-	-	(1.5)	(5.1)
Gross margin	**$m**	**-**	**1.1**	**2.4**	**6.2**	**16.7**
Corporate costs	$m	(3.9)	(7.6)	(11.1)	(3.3)	(3.0)
EBITDA	**$m**	**(3.9)**	**(6.5)**	**(8.7)**	**2.9**	**13.6**
D&A	$m	(0.1)	(0.1)	(0.1)	-	-
EBIT	$m	(4.1)	(6.6)	(8.8)	2.9	13.6
Net interest	$m	0.0	0.0	0.1	0.0	0.1
Non-operating income	$m	-	-	-	-	-
Pretax Profit	$m	(4.0)	(6.6)	(8.8)	2.9	13.7
Tax	$m	-	-	-	(0.8)	(4.0)
Minorities	$m	-	-	-	-	-
Underlying NPAT	**$m**	**(4.0)**	**(6.6)**	**(8.8)**	**2.1**	**9.7**

BALANCE SHEET (A$)		FY20	FY21	FY22E	FY23E	FY24E
Cash	$m	1.8	2.2	1.0	2.9	12.2
Receivables	$m	0.1	0.2	-	0.3	0.9
Inventory	$m	-	-	-	0.2	0.5
PPE	$m	0.1	0.1	0.1	0.1	0.2
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**	**1.7**	**4.2**	**14.5**
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**	**1.5**	**3.7**	**13.3**

CASH FLOW (A$)		FY20	FY21	FY22E	FY23E	FY24E
Receipts from customers & R&D incentiv	$m	-	-	2.4	7.7	21.8
Payments to suppliers and employees	$m	(3.6)	(6.6)	(9.1)	(4.9)	(8.6)
Milestone Payments	$m	-	-	-	-	-
Interest	$m	0.0	0.0	0.1	0.0	0.1
Tax	$m	0.8	1.2	-	(0.8)	(4.0)
Operating cash flow	**$m**	**(2.7)**	**(5.4)**	**(6.6)**	**2.0**	**9.3**
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)	(0.0)	-	-	-
Equity	$m	-	5.9	5.5	-	-
Dividend / other	$m	-	-	-	-	-
Financing cash flow	**$m**	**(0.1)**	**5.9**	**5.5**	**-**	**-**
Change in Cash / FX	$m	(2.9)	0.4	(1.2)	1.9	9.3
Year end cash	**$m**	**1.8**	**2.2**	**1.0**	**2.9**	**12.2**

Investment Thesis

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

1. 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 investment thesis is built around CRC only, recognising there is further upside.

2. 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 testing either privately or with public funding. RHY's market penetration is likely to be expedited through established screening programs.

3. Clinical Trial 7 data demonstrated 81% sensitivity and 91% specificity against colonoscopy, the SOC for bowel cancer diagnosis. As a screening test, generally high sensitivity is sought to capture all 'potentials'. More specific diagnostic tests can then be conducted to determine if the disease is truly present. The 35% higher accuracy in CRC detection than FIT supports strong market uptake.

4. Preference of ColoSTAT ® to FIT is also likely to well supported due to the general dislike of the faecal test protocols and the higher cost/risk of colonoscopy. Temperatures of >35 ° render FIT inaccurate, effectively excluding much of the Asian and northern Australian zones. As a blood test, ColoSTAT® can be incorporated into current screening tests for cholesterol, glucose. The greater acceptability of a blood test coupled with higher efficacy is likely to be well received and expand the current markets.

Valuation, Risks, Sensitivities

MST valuation of A$3.10 per share (previously $2.90ps) reflects the strength of the trial results, particularly its superior performance to FIT. In MST's view, many will prefer a blood test to the current faecal test and will receive encouragement from their general practitioner to participate. Currently, most FIT testing is conducted by mail outs for participants to undertake in the home.

MST assumes that RHY will command a premium for its test. MST model is based on US market price of A$120 (prev A$100) and for EU and Aus market, A$60 (prev A$50). Our valuation is subject to the usual upside/downside risks of diagnostic testing including market entry timing differences, non-approval, commercial uptake variations and competitor behaviours. RHY is yet to confirm its commercialisation strategy. The various options include licensing globally, regionally, partnerships, sale. All offer different revenues streams and may vary to MST assumptions.

Strong support for ColoSTAT® over current test, FIT

Clinical Study 7

The Australian based trial recruited 815 patients across 11 clinical trial sites. The prospective, cross sectional, multi centred study included two cohorts. Cohort 1 included CRC-diagnosed patients who were undergoing surgery for CRC, while Cohort 2 comprised patients referred for colonoscopy by their physician.

The primary endpoint was to provide sufficient positive and negative cancer samples to confirm ColoSTAT®'s ability to accurately identify the disease. Each patient received a ColoSTAT® blood test, FIT and a colonoscopy. The primary endpoint was based on the ability of ColoSTAT® to detect the presence of CRC, as determined by the colonoscopy results.

The study also assessed the comparative performance of ColoSTAT® to FIT. From a commercial view, the comparison to FIT as the SOC for screening is a key outcome. FIT is currently used in most EU and Australian government sponsored screening programs. The superior performance of ColoSTAT® to FIT in the Study, opens the opportunity for it to become the SOC, given its other advantages.

RHY also investigated ColoSTAT®'s ability to detect early stage CRC.

Results

Clinical Study 7 reported;

- 81% sensitivity and 91% specificity for ColoSTAT®
- 35% more accurate in sensitivity than Faecal Immunochemical Test (FIT) for detecting cancer
- more accurate than the market standard Faecal Immunochemical Test (FIT) for detecting advanced adenomas (early stage colorectal cancer)

Potential Target Markets

The strong study data are expected to support the market entry activities for its nominated target markets of Australia, EU and US, China and Japan. They offer significant markets.

Market	Screened Population	Unscreened Population	Total Population	Participation Rate	Current Screening Market	Unrealised Market	Total Market
US	64.95m	29.46m	94.41m	68.8%	US$ 2,468m	US$ 1,119m	US$ 3,588m
EU	52.64m	49.0m	101.64m	51.7%	US$2,000m	US$1,862m	US$3,862m
Australia	2.78m	3.57m	6.35m	43.8%	US$106m	US$135m	US$241m
China	76.34m	331.66m	408m	18.71%	US$2,901m	US$12,603m	US$15,504m
Japan	15.84m	25.9m	41.74m	37.95%	US$602m	US$984m	US$1,586m
Overall	212.55m	439.59m	652.14m	32.6%	US$8,077m	US$16,703m	US$24,781m

Source: Participation rates – USPTF, EIHS, AIHW, International Journal of Environmental Research & Public Health, NCBI; Population – Australian Bureau Statistics , Europa, Statistics Bureau of Japan, Statista

Australian market

The Australian Therapeutic Goods Administration (TGA) approval of a diagnostic test is a two-step process. In November 2021, RHY announced it had met the first stage through compliance with the conformity assessment procedures of the Manufacturer's Evidence Documentation. The clear results of Clinical Study 7 are expected to satisfy the second stage, the clinical performance of the test and support the listing of ColoSTAT® on the Australian Register of Therapeutic Goods, with sales to follow. TGA submission is planned for 1HCY22.

EU/UK markets

In November 2021, RHY announced that it had received Conformité Européenne (CE) Mark. Under EU regulations, a company must receive the CE Mark to commence sales/marketing within the European Economic Area. In December, RHY followed with the announcement that ColoSTAT® had received UK Competent Authourity by the UK Medicines and Healthcare Products Regulatory Agency (MHRA).

While not a requirement for the CE Mark nor the UK Competent Authourity and market entry, RHY's positive Clinical Study 7 provides 'real-world' data to support its marketing activities with clinicians and negotiations with the national authorities responsible for the bowel cancer screening programs.

US Market

RHY commenced the steps to US market entry with the establishment of IchorDX Inc, its own US entity to implement its marketing strategies. The US offers two pathways for pathology tests to enter the market. Laboratory Developed Tests (LDTs) and FDA approved tests. Most tests are FDA approved, sold in 'commercial' volumes by the larger pathology laboratories and/or other healthcare facilities. However, RHY, in keeping with many developers, plans to utilise the LDT path to enter the market. It offers a faster route and lower costs. LDTs are developed for use in one pathology centre/network. Under the LDT path, RHY will be required to validate its test in the nominated laboratory. Over time RHY may choose to seek FDA approval if it is considered that it would broaden market access.

Japanese Market

In Japan, the incidence of CRC has been increasing where it is the fourth most common cancer among men and the second most common cancer among women. In 1992, a CRC screening program using FIT was incorporated into public health policy. CRC screening targets individuals 40 years and older with a screening interval of one year. Participation rate in the CRC program has been 41.4% for men and 34.5% in women, totalling ~16m people.

Chinese market

The China Anti-Cancer Association recommends regular colorectal cancer screening for the urban population, aged between 40 and 74. Currently, the participation rate for China is at 18.9%. The low penetration rate in China is primarily due to low awareness, lack of effective screening methods and insufficient capacity of colonoscopy. The penetration rate is forecast to reach 39.8% in 2030[1] through the Government's Healthy China Action-Cancer Prevention and Control Implementation Plan (2019-2022). It includes a two-step screening strategy comprising FIT and a quantitative high-risk factor questionnaire as the primary screening test, and a full colonoscopy for follow-up screening.

In MST's view, the strongly positive Clinical Study 7 data are likely to strengthen licensing partnership negotiations and marketing activities in the EU and other markets.

ColoSTAT® superiority over standard of care screening test, FIT

The clinical trial also included a 'head to head' trial of ColoSTAT® to current SOC screening test, FIT. ColoSTAT® showed a clear advantage, with 35% higher sensitivity. Despite the high burden of CRC, global participation rates of FIT screening, average at only ~32%. The contributing factors include the need to handle faecal samples, poor test efficacy and cultural

[1] Frost and Sullivan; Colorectal Cancer Screening Industry in China. 2019

reasons. For many, the convenience of CRC screening as part of routine blood tests for cholesterol, blood sugar is likely to be preferred and acceptable.

ColoSTAT® also demonstrated superiority over FIT in detecting earlier stage disease. The result is also likely to increase health regulators' interest and the market opportunity rom a competition perspective. FIT detects evidence of blood in the stool. This usually only occurs in later stage disease.

Pipeline to offer further 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. Timelines for the development of the follow-on tests are likely to be truncated through the data already established in the CRC development work.

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MST assumes that RHY will command a premium for its test. MST model assumes US market price of A$120 (prev A$100) and for EU and Aus market, A$60 (prev A$50). Our valuation is subject to the usual upside/downside risks of diagnostic testing including market entry timing differences, non-approval, commercial uptake variations and competitor behaviours. The valuation is also subject to the usual upside/downside risks of medical device development including, licensing agreements terms, timing differences, non-approval, commercial uptake variations and competitor behaviours and potential new tests. RHY is yet to confirm its commercialisation strategy. The various options include licensing globally, regionally, partnerships, sale. All offer different revenues streams and may vary to MST assumptions.

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