Revenue Ready

FY23 promises to be a transformational year for RHY with first sales revenues expected as well as potential licensing deals. With its development program completed, RHY is focusing on the commercialisation of its novel blood test, ColoSTAT®, for screening bowel/ ColoRectal Cancer (CRC).

NZ's market authorisation to registration adds to EU's

RHY has announced that ColoSTAT® has been registered with the New Zealand (NZ) national database of Medical Devices. The registration allows the sale of ColoSTAT®. In late H1FY22, RHY completed the requirements for EU's CE mark, also permitting sales of the test.

Australia to follow?

ColoSTAT® is also under review for approval by the Australian Therapeutics Goods Administration (TGA). A decision is expected by end CY22. In addition to the analytical data required for NZ and EU registration, RHY has submitted its Clinical Study 7 results to meet the TGA's requirement for supporting clinical data. The study showed that ColoSTAT® was 35% more accurate in detecting CRC than Australia's current Standard of Care (SOC) Faecal Immunochemical Test (FIT).

TGA registration to drive market uptake

In MST's view, TGA 'ratification' of the clinical data is important for market uptake. It will help inform the clinicians of how to integrate the new test within the current management paradigm. As a blood test with a higher accuracy than the faecal based FIT, ColoSTAT®, should bring significant substitution and potentially expand the current market.

Valuation, Risks, Sensitivities

MST's 12-month forward DCF valuation of $3.10 (unchanged) per share is unchanged. It 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 needed.

RHYTHM BIOSCIENCES

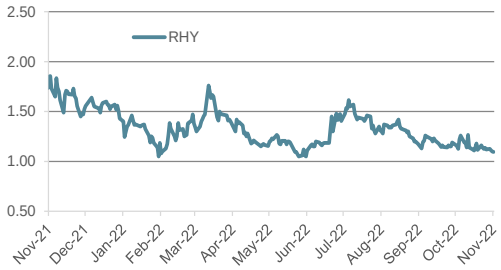
Rhythm Biosciences is an Australian medical diagnostics company. Its protein-based technology platform has been trialled in its first indication, colorectal cancer. Breast, cervical, lung, gastric and pancreatic cancer tests are included in the pipeline. The work is well credentialled. The technology reflects 13+ years of CSIRO research and to date 4+ years of RHY development. With its development program completed, RHY is 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.

Stock	RHY.AX
Price	A$1.08
Market cap	A$235m
Valuation	A$3.10 (Unchanged)

Potential Milestones

- FY23 TGA approval/ARTG expected
- FY23 First operational revenues
- FY23 Additional Regulatory Submissions
- FY23 Partnering Deals for ColoSTAT®
- Progression of RHY's Platform Technology Extension

RHY Share Price (A$)



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Financial Summary

Rhythm Biosciences Ltd — RHY-AU

Year end 30 June

MARKET DATA

Share Price	**A$/share**	**1.08**
52 week high / low	¢	1.03 - 2.00
Valuation (12 month forward)	**A$**	**3.10**
Market capitalisation	**A$m**	**235**
Shares on issue	m	217
Options	m	16
Other equity	m	-
Potential shares on issue (diluted)		233

12 month performance

INVESTMENT FUNDAMENTALS		FY20	FY21	FY22	FY23E	FY24E
EPS Reported (undiluted)	¢	(4.0)	(3.6)	(4.2)	(0.8)	3.0
EPS Underlying (undiluted)	**¢**	**(4.0)**	**(3.6)**	**(4.2)**	**(0.8)**	**3.0**
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$)		FY20	FY21	FY22	FY23E	FY24E
Forecast year end shares	m	101	202	214	217	217
Market cap (Y/E / Spot)	**$m**	**108.8**	**218.3**	**231.2**	**234.5**	**234.5**
Net debt /(cash)	$m	(1.8)	(2.2)	(7.6)	(5.9)	(12.3)
Enterprise value	**$m**	**107.0**	**216.1**	**223.7**	**228.7**	**222.2**
EV/Sales	x	#DIV/0!	195.0	92.1	29.7	10.0
EV/EBITDA	**x**	**(27.3)**	**(33.4)**	**(25.6)**	**(127.5)**	**24.4**
EV/EBIT	x	(26.3)	(32.6)	(25.4)	(121.1)	24.7
Net debt / Enterpprise Value	x	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)
Gearing (net debt / EBITDA)	**x**	**0.5**	**0.3**	**0.9**	**3.3**	**(1.4)**
Operating cash flow per share	$	(0.0)	(0.0)	(0.0)	(0.0)	0.0
Price to operating cash flow	**x**	**(39.7)**	**(40.1)**	**(35.5)**	**(142.1)**	**36.1**
Free cash flow	**$m**	**(2.8)**	**(5.5)**	**(6.5)**	**(1.7)**	**6.5**
Free cash flow per share	$	(0.03)	(0.03)	(0.03)	(0.01)	0.03
Price to free cash flow	**x**	**(39.0)**	**(39.6)**	**(35.4)**	**(139.8)**	**36.2**
Free cash flow yield	**%**	**-2.6%**	**-2.5%**	**-2.8%**	**-0.7%**	**2.8%**
Book value / share	$	0.02	0.01	0.03	0.03	0.06
Price to book (NAV)	**x**	**59.0**	**126.5**	**31.4**	**36.4**	**17.7**
NTA / share	$	0.01	0.01	0.03	0.03	0.06
Price to NTA	**x**	**80.9**	**172.7**	**33.3**	**39.0**	**18.3**
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	60.1

PROFIT AND LOSS (A$)		FY20	FY21	FY22	FY23E	FY24E
Revenue & Other Income	$m	-	1.1	2.4	7.7	22.2
Expenses	$m	(3.9)	(7.6)	(11.2)	(9.5)	(13.1)
EBITDA	**$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	$m	0.0	0.0	0.0	0.1	0.1
Pretax Profit	**$m**	**(4.0)**	**(6.6)**	**(8.8)**	**(1.7)**	**9.2**
Tax	$m	-	-	-	-	(2.7)
NPAT	**$m**	**(4.0)**	**(6.6)**	**(8.8)**	**(1.7)**	**6.4**

BALANCE SHEET (A$)		FY20	FY21	FY22	FY23E	FY24E
Cash	$m	1.8	2.2	7.6	5.9	12.3
Receivables	$m	0.1	0.2	0.1	0.3	0.9
Inventory	$m	-	-	-	0.2	0.6
PPE	$m	0.1	0.1	0.1	0.1	0.1
Intangibles	$m	0.5	0.5	0.4	0.4	0.4
Other	$m	0.1	0.1	0.3	0.3	0.3
Total Assets	**$m**	**2.6**	**3.1**	**8.4**	**7.2**	**14.6**
Accounts Payable	$m	0.7	1.2	0.6	0.3	0.9
Borrowings	$m	-	-	-	-	-
Leases	$m	0.0	-	0.2	0.2	0.2
Provisions	$m	0.1	0.1	0.3	0.3	0.3
Other	$m	-	-	-	-	-
Total Liabilities	**$m**	**0.8**	**1.3**	**1.1**	**0.8**	**1.3**
Shareholder's equity	**$m**	**1.8**	**1.7**	**7.4**	**6.4**	**13.3**

CASH FLOW (A$)		FY20	FY21	FY22	FY23E	FY24E
Receipts from customers	$m	-	-	-	6.0	20.5
Payments to suppliers and employees	$m	(3.6)	(6.6)	(9.0)	(9.5)	(13.1)
Milestones, Grants, R&D Rebates	$m	-	-	2.4	1.7	1.7
Interest	$m	0.0	0.0	0.0	0.1	0.1
Tax	$m	0.8	1.2	-	-	(2.7)
Operating cash flow	**$m**	**(2.7)**	**(5.4)**	**(6.5)**	**(1.7)**	**6.5**
Capex	$m	(0.0)	(0.1)	(0.0)	(0.0)	(0.0)
Acquisitions / Investments	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Investing cash flow	**$m**	**(0.0)**	**(0.1)**	**(0.0)**	**(0.0)**	**(0.0)**
Borrowings	$m	(0.1)	-	-	-	-
Equity	$m	-	5.9	11.9	-	-
Dividend	$m	-	-	-	-	-
Financing cash flow	**$m**	**(0.1)**	**5.9**	**11.9**	**-**	**-**
Change in Cash / FX	$m	(2.9)	0.4	5.3	(1.7)	6.5
Year end cash	**$m**	**1.8**	**2.2**	**7.6**	**5.9**	**12.3**

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 payers in the current FIT programs is also likely to be supportive.
2. Clear clinical benefit over standard of care, FIT: ColoSTAT® was shown to be 35% more accurate than FIT in detecting cancer in its Clinical Study 7.
3. User friendly: Preference of ColoSTAT® over FIT is also likely to be well supported due to the general dislike of the 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 higher acceptability and efficacy are likely to expand the current markets. It also offers convenience through incorporation with other blood tests.
4. GP based: The higher rates of screening in cervical cancer support an expanded uptake of ColoSTAT® as a GP administered test. A study of the UK FIT program reported that participants seek the involvement of their GP and prefer 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

- FY23 TGA approval/ARTG expected
- FY23 First operational revenues
- FY23 Additional Regulatory Submissions
- FY23 Partnering Deals for ColoSTAT®
- Progression of RHY's Platform Technology Extension

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 12-month forward DCF valuation is $3.10(unchanged) 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 as new protocols will need to be established and existing contracts/arrangements potentially terminated. MST's forecasts assume ColoSTAT® becomes the key CRC test in the established national FIT programs. The uptake may vary in both degree of substitution and timing.

Revenues to flow over FY23

RHY has announced that ColoSTAT®, its CRC blood-based screening test, has been registered with the New Zealand (NZ) national database of Medical Devices. RHY, as the authorized manufacturer of ColoSTAT®, can now market the test. In MST's view, it will seek partnerships to undertake the commercial activities.

Widening revenue base

The registration adds NZ to the EU, Great Britain and Northern Ireland as approved markets. In H1FY22, the company announced that ColoSTAT® had been granted Conformitè Europëenne (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.

Australian approval to support clinical evidence – key driver of uptake

RHY has also submitted ColoSTAT® for approval by Australia's Therapeutic Goods Administration (TGA) and listing on the Australian Register of Therapeutic Goods (ARTG). TGA approval of a diagnostic test is a two-step process. RHY has already met the first stage, the Manufacturer's Evidence Documentation. In addition to the detailed analytical data packages presented for the EU and NZ authorities, RHY must also provide supporting clinical data. RHY has submitted the results of its positive Clinical Study 7 as part of application. The TGA decision is expected by end CY22. A positive decision would provide first regulatory endorsement of RHY's clinical study results.

MST sees the Australian approval as a key driver of adoption of the test by clinicians. While a diagnostic test may be approved based on the analytical data – it tests what it claims - clinicians and healthcare payers often also require clinical evidence. They need to understand clinical impact/benefits of the test to determine how, when and where the test should be incorporated within the current management protocols. FIT is the current SOC for CRC screening in RHY's initial targeted markets - Australia, NZ and EU, UK and Northern Ireland. RHY's Clinical Study 7 reported that ColoSTAT® was 35% more accurate than FIT in identifying patients with CRC. In MST's view, TGA approval which includes clinical data review, will be an important endorsement and support the sales uptake.

Exhibit 1 – Potential Markets

Path to Market - Approval requirements

	Jurisdiction	Technical and Clinical Data Requirements	Timing	MST Market Estimates
√	**EU**	Conformité Européenne (CE) Mark Assessment of the test componentry and procedure No Formal Clinical trials required Supporting clinical data important for medical uptake	Submission accepted Q4CY21	US$3.9bn
√	**NZ**	(NZ) National Database of Medical Devices Assessment of the test componentry and procedure No Formal Clinical trials required Supporting clinical data important for medical uptake	Accepted for registration	US$0.15bn
	Australia			
		Manufacturer's Evidence Documentation Australian Register Therapeutics Goods Listing (ARTG)	Accepted Q3CY21 ARTG Listing expected by end Y22	US$0.2bn
	US			
	LDT* pathway	Validation of ColoSTAT® in the designated laboratory Sale of test confined to laboratory network Clinical data supportive for reimbursement submissions	Initial activities underway	US$3.6bn
	FDA	US Clinical trials and regulatory process Total US market access		

Source: RHY, FDA, TGA and European Commission
* Laboratory Developed Test

Source: Company Reports, MST Assumptions

The EU presents a key market. The US, the largest individual market by value, is predominantly based on colonoscopy. ColoSTAT®'s potential role in the colonoscopy screening regimen is yet to be determined. It is expected to offer a viable, economic alternative within the overall strategy for CRC management. It potentially reduces the economic burden and boosts compliance.

Commercialisation

First entries into significant bowel screening market opportunities

The NZ bowel screening program is similar to Australia's – a Faecal Immunochemical test (FIT) offered every two years to people aged 60 to 74 years (Australia 50-74yrs) who are eligible for publicly funded health care. The participation rate of ~58% in NZ compares to ~44% in Australia. There are ~1m people aged 60yrs+ in NZ with some 3m+ in Australia. While only a small market, the calibre of the NZ approval process augurs well for approval in other jurisdictions.

Exhibit 2 – Total Addressable Market

Market	Screened Population (m)	Unscreened Population (m)	Total Population (m)	Participation Rate	Current Screening Market ($USm)	Unrealised Market ($USm)	Total Market ($USm)
EU	53	49	102	52%	2000	1862	3862
Australia	3	4	6	44%	106	135	241
Total	55	53	108		2106	1997	4103

Source: Company Reports, MST Assumptions

Opportunity to expand current markets

As a blood test, MST believes that ColoSTAT® offers the potential to expand the current markets. The FIT test is undertaken by the participant at home. The low participation rates have been attributed to the need to handle and store faeces (See MST Report July 5 2022). RHY offers a test that can be incorporated into patients' existing routine blood testing program, under doctor's oversight. The use of ColoSTAT® in the CRC screening program would entail new administrative processes, potentially adding time for wider implementation to allow for existing contractual obligations to be met and the adoption of new regimens. In MST's view, over time greater acceptance of a blood test over a faecal one would see higher compliance rates, expanding the current markets.

Strengthens licensing opportunities

RHY is yet to confirm its commercialisation strategy. The various options include global/ regional licensing, partnerships and sale. All offer different revenue streams. In MST's view, the ongoing news of approvals strengthens RHY's licensing opportunities.

Publicly funded CRC FIT screening programs are offered in most 'advanced' nations excepting the US where colonoscopy is the SOC. In MST's view, the existing FIT programs are obvious target markets for ColoSTAT®. A potential role in conjunction with colonoscopy is likely to be explored. Rhythm has indicated that the overall pricing will be a blended model with different terms of the agreements and commercial undertakings across the different markets.

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