PITT STREET RESEARCH

Rhythm Biosciences

Ticket to Europe booked

Share Price: $1.49

ASX: RHY
Sector: Healthcare
7 December 2021

Rhythm Biosciences (ASX: RHY) is a medical diagnostics technology company based in Melbourne. Currently it is developing its initial product ColoSTAT, a simple blood-based test for the efficient detection of colorectal cancer at all stages, including the early stages. The method behind this blood-based test is to detect proteins that vary in concentration in the blood of patients with and without colorectal cancer. RHY has been working diligently to turn this technology into an in-market product that could potentially serve as a frontline mass-market screen for bowel cancer globally.

CE Mark granted; clinical trial underway

RHY recently obtained its CE Mark approval for ColoSTAT, which will effectively enable its market leading product to be commercially rolled out across Europe. Our bottom-up TAM estimate for the Europe opportunity is significant (A$12bn). Given RHY's superior value proposition, we remain convinced that the company will likely capture a material portion of its TAM once its product is successfully rolled out.

Clinical trial (Study 7) is progressing well, which involves >800 patients recruited from 11 clinical sites. Management expects to complete Study 7 in 2H FY22. Patient recruitment has completed, reducing the variable costs and timeframes associated with the trial. If ColoSTAT can perform as it has in the past, it should be able to obtain the Therapeutic Goods Administration (TGA) listing, which in turn should lead to the commercial roll out of ColoSTAT across Australia. We are encouraged by the consistent, strong and positive results from the ongoing testing of commercially manufactured ColoSTAT test kits vs the current market standard Faecal Immunochemical Test which only detects blood in the faeces.

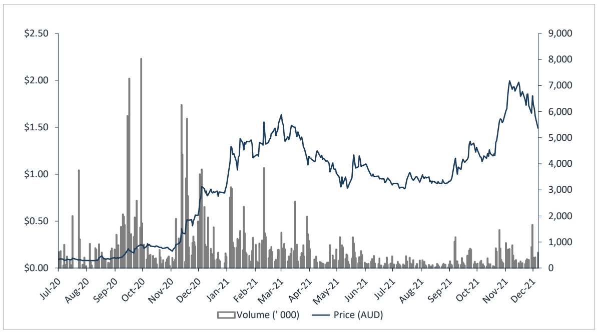
Valuation revised to $4.19 per share

We have revised our DCF to mainly incorporate: 1) a terminal value, reflecting our renewed view that RHY could potentially continue to commercialise ColoSTAT after its patent expiry (c.2031), 2) an expanded share base due to the recent rights issue, and 3) FY21 financials. Our revised valuation range is $4.19 – $9.17 per share (previous: $1.73 – 3.85), with the increase in the valuation gap attributable to the addition of a terminal value. Please refer to page 2 for more detail on valuation and page 3 on key risks to our investment thesis.

Market Cap. (A$ m)	311.2
# shares outstanding (m)	208.9
# share fully diluted	230.9
Market Cap Ful. Dil. (A$ m)	344.1
Free Float	53.4%
12 months high/low	2.08 / 0.69
Average daily volume ('000)	500.2
Website	rhythmbio.com

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)



Source: CommSec, Pitt Street Research

Valuation metrics	
DCF (A$ per share)	4.19 – 9.17
Discount rate	14.4%
Assumed terminal growth rate	2.0%

Source: Pitt Street Research

Disclosure: I own stock in Rhythm Biosciences.

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Continues to hit milestones

1H FY22 saw RHY achieving the following milestones:

- **CE Mark granted** for ColoSTAT, which will effectively enable RHY's bowel cancer detection technology to be commercialised and rolled out across Europe. Figure 1 shows our TAM matrix for the Europe opportunity which appears significant. Given RHY's superior value proposition, as detailed in our initiating coverage, we remain convinced that the company will likely capture a material portion of its TAM.

Figure 1: Bottom-up TAM for the Europe opportunity (A$bn)

		ColoSTAT Pricing (A$)				
		40	45	50	55	60
Size of the EU market - population aged 50-74 (mn)	250	10.0	11.3	12.5	13.8	15.0
	240	9.6	10.8	12.0	13.2	14.4
	230	9.2	10.4	11.5	12.7	13.8
	220	8.8	9.9	11.0	12.1	13.2
	210	8.4	9.5	10.5	11.6	12.6

Source: Pitt Street Research

- **Clinical trial (Study 7) recruitment is closed with testing and statistical analysis currently underway** which involves a total of 815 patients recruited from 11 clinical trial sites. Management expects to complete Study 7 in 2H FY22. If ColoSTAT can perform as it has in the past, it should be able to obtain the Therapeutic Goods Administration (TGA) listing, which in turn should lead to the commercial roll out of ColoSTAT across Australia. We are encouraged by the positive results from the ongoing testing of commercially manufactured ColoSTAT test kits vs the current market standard Faecal Immunochemical Test (FIT) which only detects blood in the faeces.

Valuation revised to $4.19 per share

We have incorporated the following key changes to our DCF:

- **Terminal value**: We have added a terminal value to our DCF as we have now realised the potential for RHY to continue commercialise ColoSTAT after its patent expiry (c.2031). Our initial modelling assumed 9 years of commercial exclusivity because we thought generics will step in after the expiry of RHY's patent and thereby pose a threat to the company's longer term revenue sustainability. However, upon closer scrutiny, we are now less concerned about this risk, because the expected pricing point for ColoSTAT is already low (A$40-50 per test) and therefore the possibility for generics to undercut ColoSTAT on pricing is low. We believe RHY will continue to invest in improving the algorithm used in ColoSTAT and thus sustain its strong technology proposition. Furthermore, we note that RHY has the optionality to explore the potential of ColoSTAT's lead biomarker to target indications other than bowel cancer, which should also support our terminal value argument. If we assume a terminal growth rate of 2%, we would derive a terminal value of $574.3m (c.60% of our implied EV).
- **Expanded share base**: We have updated our fully diluted share base to 230.9m to incorporate RHY's recent rights issue.
- **FY21 results**: We have updated our model based on the release of RHY's FY21 financials.

Upon revision, our revised valuation range for RHY is $4.19 – $9.17 per share (previous: $1.73 – $3.85) (Figure 2).

Figure 2: Revised DCF valuation summary

Valuation (A$)	Base Case	Bull Case
PV of FCF de-risked	391.0	870.9
PV of terminal FCF	574.3	1,244.5
Enterprise Value (A$M)	**965.3**	**2,115.4**
Net debt (cash)	(2.9)	(2.9)
Equity value (A$M)	**968.2**	**2,118.3**
Diluted shares (M)	230.9	230.9
Implied price (A$)	**4.19**	**9.17**
Current price (A$)	1.49	1.49
Upside (%)	*181.4%*	*515.6%*

Sources: Pitt Street Research

Key risks

We see five major risks for Rhythm as a company and as a listed stock:

– **Clinical risk**. Study 7 may miss its primary and secondary end-points. It may not replicate the successful outcomes achieved in Study 6. That said, any result equivalent to the faecal test will be broadly seen as a success as the preference for blood test over faecal will ensure sales are made.

– **Regulatory risk**. Regulators may decline to approve ColoSTAT, even if Rhythm considers the data submitted to be adequate.

– **Commercial risk**. Rhythm may fail to secure commercial partners for ColoSTAT. However, we like Rhythm's systematic approach for selecting appropriate partners for the ColoSTAT rollout and not just signing anyone.

– **Uptake risk**. ColoSTAT may not find significant usage in the colorectal cancer screening market as other diagnostic tools come onto the market between now and the end of ColoSTAT's clinical development. If this happens, ColoSTAT might not achieve our estimated market penetration.

– **Funding risk**. Extra funding may be required to support the clinical and commercial development of ColoSTAT, which Rhythm may not be able to secure.

Risks related to pre-revenue Life Science companies in general.

The stocks of biotechnology and medical device companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character.

Since most biotechnology and medical device companies listed on the Australian Securities Exchange fit this description, the 'term' speculative can reasonably be applied to the entire sector.

The fact that the intellectual property base of most biotechnology and medical device lies in science not generally regarded as accessible to the layman adds further to the riskiness with which the sector ought to be regarded.

Caveat emptor. Investors are advised to be cognisant of the abovementioned specific and general risks before buying any the stock of any biotechnology and medical device stock mentioned on this report, including Rhythm Biosciences.

Analysts' qualifications

Cheng Ge, lead analyst on this report, is an equity research analyst at Pitt Street Research.

- Cheng obtained a B.Com in Finance and LL.B from University of New South Wales, in 2013. He also completed all three levels of the CFA Program.
- Before joining Pitt Street Research, he worked for several financial services firms in Sydney, where his focus was on financial advice.
- He joined Pitt Street Research in January 2020.

Stuart Roberts has been covering the Life Sciences sector since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research specialty at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months in 2015 and 2016 doing Investor Relations for two ASX listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Science companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Science companies.

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