# Rhythm Biosciences

## Study 7 was another success

## Share Price: A$1.41

**ASX: RHY**

**Sector: Healthcare**

**13 April 2022**

Rhythm Biosciences (ASX: RHY) has received clinical proof of its thesis that ColoSTAT was a superior way to detect colorectal cancer. The long-awaited Study 7 found ColoSTAT exhibited a very high accuracy for the detection of colorectal cancer, recording a sensitivity of 81%, a specificity of 91% and that ColoSTAT was 35% more accurate than the current market standard Faecal Immunochemical Test (FIT). RHY's ambitions to eventually target other cancers was also boosted – Study 7 found that ColoSTAT was more accurate at detecting advanced adenomas than the FIT.

### TGA approval the next near-term goal

RHY is targeting regulatory approval in Australia to facilitate ColoSTAT's commercialisation. It hopes to submit to the Therapeutic Goods Administration (TGA) by 1HCY'22 and will use the Study 7 data to make its case. RHY already has CE Mark approval, allowing it to be marketed and sold within the European Economic Area (EEA). The EEA is a significant addressable screening population for ColoSTAT of over 231 million people, with a potential combined value of ~US$12 billion. RHY anticipates inaugural revenues by the end of CY22.

### More financial runway

Since our last report on RHY, published on 7 December 2021, the company further increased its cash reserves raising $6.53m to a single, global institutional funds manager. The deal takes RHY's cash reserves to over $10.8m. RHY will use the proceeds to accelerate commercialisation of ColoSTAT including to scale up manufacturing capacity and an R&D program as part of the company's platform technology expansion for other identified cancer targets.

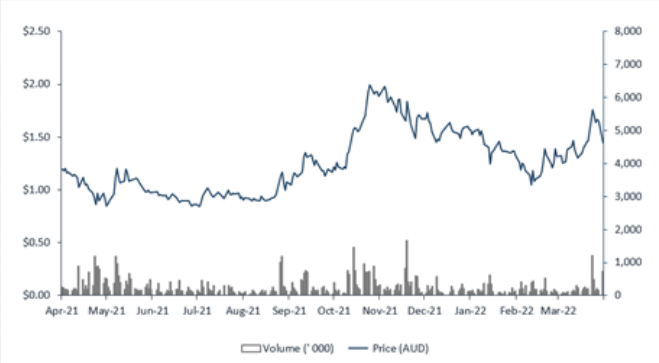
### High potential in a rapidly growing, large market

We have adjusted our DCF slightly to account for the company's recent capital raise and the recent performance of markets which affects our Risk-free rate of Return and market risk premium. Our revised valuation range is $4.32 - $9.43 per share (previous $4.19 - $9.17). We have believed all along what Study 7 showed, that in ColoSTAT RHY has a highly effective asset that could save lives and healthcare resources by detecting colorectal cancer (and potentially other cancers down the track) earlier. Please refer to page 5 for more detail on valuation and page 5 on key risks to our investment thesis.

| | |
|---|---|
| Market Cap. (A$ m) | 301.9 |
| # shares outstanding (m) | 214.1 |
| # shares fully diluted (m) | 236.2 |
| Market Cap Full. Dil. (A$m) | 333.0 |
| Free Float | 56.5% |
| 12-months high/low (A$) | 0.84/2.08 |
| Avg. daily volume ('1000) | 206.1 |
| Website | rhythmbio.com |

*Source: Company, Pitt Street Research*

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




*Source: Thomson Reuters, Pitt Street Research*

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## ColoSTAT is clinically validated

*ColoSTAT recorded a sensitivity of 81% and a specificity of 91%.*

It has been a long journey for RHY since its listing in 2017 but one of the major milestones was passing the so-called Study 7 which would provide clinical validation necessary for Australian regulatory approval. The trial was a complete success with a statistically significant and outstanding performance. ColoSTAT exhibited a very high accuracy for the detection of colorectal cancer, recording a sensitivity of 81% and a specificity of 91%. Sensitivity means the ability of the test to correctly identify those patients with colorectal cancer while specificity alludes to the ability of the test to correctly identify people who do not have colorectal cancer.

Previous testing outcomes indicated ColoSTAT was 33% more accurate than the current market standard Faecal Immunochemical Test (FIT). The trial not only confirmed this performance but in fact increased it – Study 7 found ColoSTAT is 35% more accurate than the globally adopted FIT for detecting colorectal cancer. The study also hit secondary endpoints, including the ability of the test to detect advanced adenomas. A total of 989 samples were collected across the trials 12 sites, of which 737 made up the final statistical analysis set. The difference was for varying reasons including incomplete or unavailable data, delayed colonoscopies and other typical trial related events.

## Expansion of ColoSTAT capabilities

*ColoSTAT was fund to be more accurate at detecting advanced adenomas meaning it can not only tell when a patient has cancer but if they are at risk of cancer.*

RHY has expressed intention to potentially target additional cancers. In December, it identified five additional cancer detection markets to expand its platform technology. The five additional cancers to be targeted include: breast cancer, cervical cancer, lung cancer, gastric cancer and pancreatic cancer. It also commenced a new Research and Development program designed to follow a similar development pathway to ColoSTAT.

Study 7 was critically important for these ambitions, specifically that it was more accurate at detecting advanced adenomas. Adenomas are tumors that are not cancer but can develop into cancer. This means ColoSTAT can not only tell when a patient has cancer but if they are at risk of cancer, thereby increasing its utility. These also mean unecessary colonoscopies can be avoided. Because adenomas are present in other cancers, not just colorectal cancer this gives us confidence that RHY could adjust ColoSTAT to cater for other cancers.

The Study 7 findings - combined with RHY's experience in getting to this point - mean any future programs would be substantially shorter than what it took to take ColoSTAT to its present status. Of course, the company's primary focus right now remains on ColSTAT commercialisation for colorectal cancer. But investors should watch these efforts closely and take confidence from the findings of its effectiveness in identifying adenomas.

## Eyeing TGA approval

RHY is currently closing the final clinical trial site and completing the clinical study report. The major hurdle remaining to ColoSTAT's commercialisation in Australia is TGA approval but the company expects these results will help its case.

*RHY hopes to make its final submission for TGA approval by 1HCY'22.*

RHY has already passed one step towards TGA approval – in submitting Manufacturers Evidence documentation and having it accepted. This occurred in the September quarter last year. The second step is a filing for an Australian Register of Theraprutic Goods (ARTG) listing. An ARTG listing contians further comprehensive documentation such as the product technical files and clinical evaluation reports. RHY hopes to make its final submission by 1HCY'22.

## CE Mark approval expanded

RHY was granted CE Mark certification just a few weeks prior to our last report on the company. The Conformite Europeenne (CE) Mark is the EU's mandatory conformity marking for regulating products sold within the Eurpean Economic Area (EEA). The CE Mark represents that RHY's products meet all the requirements of the relevant recognised European harmonised performance and safety standards and is compliant to its intended purpose of use. It allows RHY to roll out ColoSTAT in the EEA.

*Since our last report, RHY expanded its CE Mark registration.*

Since our last report, RHY expanded its CE Mark registration with the UK Competent Authority, the Medicines and Healthcare Products Regulation Agency (MHRA). This allows CloSTAT to be marketed and sold within Great Britain and Northern Ireland. Europe and the UK represent a significant addressable screening population for ColoSTAT of over 231 million people, with a potential combined value of ~US$12 billion. It is one of the major markets accounting for our valuation of RHY. This achievement, along with RHY's Study 7 results – which were not avaliable at the time – provides the confidence that RHY will obtain regulatory approval in Australia and potentially in other markets in the future.

## Maintaining ongoing ISO13485 certification

For the fourth consecutive year, RHY has successfully maintained ISO certification to the International Standard for In-Vitro Diagnostics and Medical Devices (ISO13485:2016) for ColoSTAT. ISO 13485:2016 is the internationally recognised quality standard to ensure the consistent design, development, manufacture and sale of medical devices that are safe for their intended purposes.

*ISO13485 certification validates the rigour, diligence and consistency of RHY's development program.*

This certification is important as part of the regulatory approvals for RHY's commercial and market entry strategies. It also validates the rigour, diligence and consistency of RHY's development program. But this particular renewal was particularly noteworthy because the certification is now valid for three years (subject to annual surveillance audits) and the scope was expanded. The scope now includes manufacturing, algorithm software development and planned development pipeline of new products.

## RHY added to the All Ordinaries Index

On March 21, RHY was added to the ASX All Ordinaries Index ('All Ords'). The All Ords containes the 500 largest ASX listed companies and is often considered a total market barometer for the Australian stock market.

*RHY's addition to the All Ordinaries Index will mean more institutional investors will be able to buy into the company*

This may appear trivial, but it is important for RHY because it will mean that more institutional investors will be able to buy into the company. Certain

institutional investors are not able to buy shares of companies outside the All Ordinaries Index due to investment mandates, but this will now change. We believe RHY will be a company for investors to look at considering its progress since its ASX listing and particularly given its future potential.

## Valuation

*Our base case assumes RHY reaches 50% of its total addressable market and would execute a licensing deal with a commercial partner.*

In our initiation report on RHY, published on 18 May 2021, we valued RHY at $1.73 per share base case and A$3.85 per share bull case. We note that RHY was 93 cents a share at the time of publication. Our base case assumed RHY reached 50% of its total addressable market, priced ColoSTAT at A$40 per test and assumed RHY would execute a licensing deal with a commercial partner in each of its target markets, with a royalty rate of 8% on gross sales post the 2% royalty payable to the CSIRO. Our bull case assumed 70% penetration, A$50 per test and a 9% royalty on gross sales. In both cases, we applied a discount rating of 14.4% and assumed 9 years of commercial exclusivity from FY23 onwards.

Our initial model did not have a terminal value because we were concerned about the company's longer term revenue sustainability after its patent expiry in 2031. But in our most recent report on RHY, published on 7 December 2021, we added a terminal value which revised our valuation range to $4.19-$9.17 per share (see Figure 1). We argued RHY would continue to invest in improving the algorithm used in ColoSTAT and thereby sustain its strong technology proposition as well as explore the potential of using ColoSTATs' lead biomarker to target indications other than colorectal cancer.

*Our new base case is $4.32 per share (previously $4.19) and our bull case is $9.43 per share previously $9.17).*

We have updated our model slightly. In light of RHY's recent capital raise have increased the company's shares on issue and decreased its net debt position. We increase the Risk-free rate of Return from 1.9% to 2.9%, to account for rise of the Australian Government 10 Year government bond (which we typically use at Pitt Street Research for the risk-free rate of return in our DCF models), and we reduce the Market risk premium from 11% to 10% in light of the markets' performance in recent months. Accordingly, our discount rate drops from 14.4% to 14.0%. We have left unadjusted the terminal growth rate (2%) as well as our assumptions about market penetration, gross royalty and test pricing. Our new base case is $4.32 per share (previously $4.19) and our bull case is $9.43 per share (previously $9.17).

**Figure 1: DCF valuation summary**

| Valuation (A$) | Base Case | Bull Case |
|---|---|---|
| PV of FCF de-risked | 399.7 | 891.9 |
| PV of terminal FCF | 608.6 | 1,325.6 |
| **Enterprise Value (A$M)** | **1,008.4** | **2,217.4** |
| Net debt (cash) | (10.8) | (10.8) |
| **Equity value (A$M)** | **1,019.2** | **2,228.2** |
| Diluted shares (M) | 236.2 | 236.2 |
| **Implied price (A$)** | **4.32** | **9.43** |
| Current price (A$) | 1.41 | 1.41 |
| *Upside (%)* | *206.1%* | *569.1%* |

*Source: Pitt Street Research*

## Catalysts

We see the following near-term events as catalysts in potentially triggering a re-rate of Rhythm's stock towards our valuation range:

- Securing further regulatory approval for ColoSTAT, in particular from the TGA.
- Securing partnerships with key sales and distribution companies;
- Securing partnerships with renowned diagnostic companies; and
- Expansion of RHY's platform technology into additional cancers.

We believe the Study 7 results have increased the likelihood of all these events occurring.

## Key risks

We see the following as key risks to our investment thesis:

1) **Regulatory risk.** Regulators may decline to approve ColoSTAT, even if Rhythm considers the data submitted to be adequate =.
2) **Commercial risk**. Rhythm may fail to secure commercial partners for ColoSTAT. However, we like Rhythms systematic approach for selecting appropriate partners for the ColoSTAT rollout and not just signing anyone.
3) **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 development. If this happens, ColoSTAT might not achieve our estimated market penetration.
4) **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 the 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 the description, the 'term' speculative can reasonable 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 the stock of any biotechnology and medical device companies mentioned in this report, including Rhythm Biosciences.

## Appendix I – Analyst Certification

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

Stuart Roberts, has been an equities analyst 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 speciality 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 over 2015–2016 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 Sciences 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 Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

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