

Rhythm Secures US Patent, Strengthens Global Footprint

- **US Patent has been granted for ColoSTAT®**
- **The patent secures IP protection in one of the world's largest diagnostic markets**

17 December 2020, Melbourne: Rhythm Biosciences Limited (ASX: RHY) is pleased to confirm the granting of a patent for its key ColoSTAT® biomarkers in the United States of America (US) by the US Patents and Trademarks Office (USPTO).

US PATENT

The US granted patent covers three defined core biomarkers that form part of ColoSTAT®. Further biomarkers are described in the claim which can be added to these core markers, providing optionality in the future if required. The granting of the patent is a strong outcome for Rhythm given less than 35% of diagnostic patents applications are approved by the USPTO¹.

GLOBAL MARKET OPPORTUNITY

The US represents one of the largest diagnostic markets in the world. The addition of a US patent sees Rhythm expand its global footprint and ultimately, access to a global addressable screening market of close to 800 million people. In the US, the current 50-74-year-old screening eligible population is ~94 million people. This market could grow in the short term by a further 21%, following the US Preventative Services Task Force recommendation that the colorectal cancer screening age be reduced, beginning at 45 years. As a result, where the expansion in the screening age group occurs in other markets, it is expected that the current global addressable market will also increase considerably.

Table 1: Current Global Addressable Market (number of people)²

50-74 year old population	US	EUROPE	CHINA	JAPAN	AUSTRALIA	TOTAL
	93.6M	231.2M	396.6M	41.5M	6.7M	769.6M

Rhythm's ColoSTAT® blood test will be a simple, low-cost option, that is designed to ensure the Company can effectively access the significant mass screening opportunity in each market and transform the way colorectal cancer is detected globally. Importantly, the test is designed to integrate with existing pathology infrastructure and instrumentation and be equipment agnostic.

¹ World Intellectual Property Indicators 2017

² Internal Company data

RHYTHM CEO, MR GLENN GILBERT, COMMENTED:

“The granting of this US patent further strengthens Rhythm’s global position as an emerging leader in the diagnosis of cancer, initially in the area of colorectal cancer. The significance of this patent cannot be overstated, as it expands our access to a growing global market, and importantly, with ColoSTAT® being a simple, low-cost option, means that we are in a position to access the mass market opportunity in each key country. Having patent coverage in all the major global markets is a significant value-add for the Company.”

RHYTHM GLOBAL PATENT POSITION

Rhythm has now been granted patents for the early detection of colorectal cancer in 18 countries, which represent an addressable screening population of almost 800 million people. Countries / regions include, the:

- ✓ USA
- ✓ Australia
- ✓ China
- ✓ Japan
- ✓ United Kingdom
- ✓ Europe – Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Netherlands, Norway, Spain, Sweden, and Switzerland

Patent applications are currently pending in Brazil and India.

With the authority of the Board.

For further information, please contact:

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About Rhythm Biosciences

Rhythm Biosciences (ASX: RHY) is a transformative, predictive diagnostics company, specialising in early cancer detection. Rhythm’s initial business pursuit is centred upon technology originally developed by the CSIRO and involves the development and commercialisation of a screening and diagnostic test for the early detection of colorectal cancer, the third biggest cause of cancer-related deaths globally.

Rhythm’s lead product, ColoSTAT®, is intended to be a simple, affordable, minimally invasive and effective blood test for the early detection of bowel cancer for the global mass market. It is expected to be comparable to, if not better than, the current standard of care, the faecal immunochemical test (FIT), at a lower cost. ColoSTAT® also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

ColoSTAT® is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT® has the potential to play an important role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Globally, over 850,000 people die from colorectal cancer each year. Colorectal cancer is typically diagnosed at a later stage when there is a poor prognosis for long-term survival. Annual estimated unscreened 50-74-year old’s is estimated at +130m for the US, EU and AU alone, with this market potential being more than \$6.5b.