



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## FDA Okays Redhill Talicia (Sydney's Heliconda) For Helicobacter Pylori

Redhill says the US Food and Drug Administration has approved the Giaconda-based Talicia delayed-release capsules, for Helicobacter pylori infection.

In 2010, Israel's Redhill bought Talicia, or Heliconda (RHB-105), as well as Myoconda (RHB-104) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

The combination antibiotics were developed by Prof Tom Borody who has continued as a scientific consultant to Redhill.

Today, the company said that Helicobacter pylori bacterial infection was a group I carcinogen with the strongest risk factor for gastric cancer, and a major risk factors for peptic ulcer disease and gastric mucosa-associated lymphoid tissue lymphoma.

Redhill said that Talicia was an oral capsule, delayed-release combination of the antibiotics, amoxicillin and rifabutin, and a proton pump inhibitor, omeprazole.

The company said that Talicia was the only rifabutin-based therapy approved for the treatment of Helicobacter pylori infection and was designed to address the high resistance of Helicobacter pylori bacteria to current clarithromycin-based standard-of-care therapies.

The company said that Talicia was eligible for eight years of US market exclusivity under qualified infectious disease product designation and had patent protection until 2034.

Redhill said that more than two million patients were expected to be treated for Helicobacter pylori infection each year in the US.

Talicia phase III study lead investigator Prof David Graham said that the clinical studies for Talicia “found zero resistance to rifabutin and showed 17 percent resistance to clarithromycin, a current standard-of-care macrolide antibiotic, consistent with current data showing that clarithromycin-containing therapies fail in approximately 25-40 percent of cases”.

Redhill said it expected to launch Talicia in the US expected by April 2020.

On the Nasdaq, Redhill was up 43 US cents (62.3 Australian cents) or 6.21 percent to US\$7.35 (\$A10.65) with 5,073,628 shares traded.