



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Redhill Biopharma

By TIM BOREHAM

Nasdaq: RDHL

TASE (Tel Aviv): RDHL

Share price (Nasdaq): \$US8.47 (\$A11.94)

Market cap: \$US180.8 million (\$A254.8 million)

Shares on issue: 213,439,434 Israeli shares (equivalent to 21,343,943 American depository shares trading on Nasdaq).

Financials (June quarter 2018): revenue \$US2.4 million (up 380%), gross profit \$US1.6 million (up 700%), operating loss \$US9.6 million (down 29%), cash balance \$US43 million, including a \$US25 million rights raising in August

Executive chairman: Dror Ben-Asher

Board: Dror Ben-Asher, Dan Suesskind, Eric Swenden, Dr Kenneth Reed, Rick Scruggs, Dr Shmuel Cabilly, Ofer Tsimchi, Nurit Benjamini, Nicolas Weinstein

Identifiable major shareholders: management reports there are no controlling shareholders but numerous "long term supporters."

With matters Israel the hot political topic this week, Aussie investors should know that Redhill is a paradigm case of The One That Got Away.

That's because the Tel Aviv-based Redhill's development activities are largely based on three compounds acquired from Giaconda, which was 70 percent owned by Sydney gastroenterologist Prof Thomas Borody.

Giaconda listed on the ASX in 2005, but in 2010 sold the development drugs to Redhill for a princely \$US500,000 (plus 7.0 percent of net sales and 20 percent of sub-licencing receipts, post development costs).

Giaconda went into voluntary administration in February 2011, but still exists as a private company, majority-owned by Prof Borody, who is on Redhill's scientific advisory board.

Given Giaconda was named over a glass from a Victorian winery - an industry known for chewing through money – o we guess it was always going to end in tears. The winery was, in turn, named after Leonardo da Vinci's Mona Lisa Giocondo.

"Giaconda had three excellent assets," says Redhill's head of business development Adi Frish.

"From our perspective there was a lot of science and [Giaconda's] focus was on what we were looking ... to develop in the US market."

Redhill is focused on developing and commercializing late stage drug candidates for gastrointestinal diseases and cancer.

It also has four approved drugs in the US for indications including irritable bowel syndrome, gastric reflux and diarrhoea in HIV/AIDS patients.

From kibbutz to clinic

Redhill was founded in 2009 by Ben-Asher and Ori Shilo, childhood friends who grew up on the same kibbutz.

Wondering about the name? according to The Times of Israel, Givat Brenner "overlooks a soothing earth-red hill, sun-drenched and dotted with green shrubs that became the inspiration for the name of their company."

Ben-Asher served in an elite Israeli air force unit before getting law degrees at Oxford and then Harvard (when you're on a roll ...)

Similarly, Shilo served in an elite special forces unit, travelled the world and obtained economics and business degrees. An out-of-the-blue phone call from old mate Ben-Asher set the Redhill ball rolling.

Redhill listed in Israel in Feb 2011 after an IPO raised \$US14 million. The company listed on the Nasdaq in December 2012.

A new approach to old drugs

Instead of creating drugs from scratch Redhill takes new and existing drugs to create new therapies that work differently to the old treatment.

That way, there's lots of data from old programs to complement the new work.

Redhill chief operating officer Gilead Raday says: "We can conduct complex phase III studies in a way that lowers the cost relative to the industry average and increases the probability of success."

In 2017 the company opened an office in North Carolina and subsequently acquired the rights to four other gastroenteric products.

In effect, this developed Redhill's sales and other infrastructure as a precursor to selling any future drugs off its own bat.

"As far as the US market is concerned we will commercialize the products ourselves, but would look to distribution partnerships elsewhere," Mr Raday says.

Packed clinical program

The most advanced drug in Redhill's packed clinical program RHB-105 (formerly Heliconda, now called Talicia), to treat gastric cancer.

Its successful phase III trial zeroed-in on the *Helicobacter pylori* (H pylori) bacteria that causes peptic ulcers and is a root cause of gastric cancer.

The Talicia program draws on the work of Aussie scientists Dr Robin Warren and Prof Barry Marshall, who snared the 2005 Nobel Prize in Physiology or Medicine for identifying H pylori and its role in stomach ulcers and inflammations.

The treatment is based on combining two antibiotics with a proton pump inhibitor. The company is now carrying out a 455-patient confirmatory phase III US trial with results expected by the end of calendar 2018 and a US Food and Drug Administration application in early 2019.

Targeting the difficult to treat Crohn's disease, RHB-104 (formerly Myoconda) managed positive top-line results from a 331-patient phase III study. The company is now discussing approval procedures with the FDA, although more trials are likely.

With Crohn's disease the treatment paradigms are not well established, addressing the symptoms (inflammation) rather than the underlying cause.

The treatments are also expensive and can have side effects such as malignancies and serious infection.

Meanwhile Redhill's Bekinda (RHB-102) targets nausea and vomiting associated with chemotherapy, as well as the common irritable bowel syndrome.

Similarly, top line phase III results for Bekinda were positive in a 321-patient study for irritable bowel syndrome.

Once again, Redhill has met with the FDA and agreed on a single confirmatory phase III study, which is likely to enroll several hundred patients.

Slightly further behind the evolutionary curve, the company plans a pivotal phase II study for RHB-204 to treat non-tuberculosis mycobacteria, or NTM.

NTM is a mainly pulmonary infection caused by Mycobacterium avium complex, a drug-resistant bacterium related to tuberculosis.

RHB-204 is subject to a pivotal phase III expected to start by April 2019, "subject to completion of a supportive non-clinical program and additional input from the FDA".

Mr Raday describes NTM as the low-hanging fruit that is a "synergistic indication" to Crohn's disease.

"We have an opportunity to take this straight through to phase III in a small trial, with potential to get market in 2020," he says.

And we're not done yet.

Yeliva is a potential treatment for multiple oncology and inflammation indications. The drug has orphan indication status for cholangio-carcinoma (bile duct cancer) which is subject to an ongoing phase IIa study.

Rosy finances

In August this year Redhill raised \$US25 million through an underwritten offer of 4.16 million American depositary shares at \$US6.00 a share. The loot will be used to fund programs including the phase III study of RHB104 for Crohn's disease, as well as the phase III study for NTM.

Management believes it is sufficiently funded to get the Talicia and Crohn's trials up and running.

"All in all, we are in a good position to execute our current plans," Mr Frish says. "As well as the cash we hope to secure out-licencing transactions outside of the US."

Then there's the revenue from the four drugs on market, which contributed a handy \$US2.35 million in the June quarter for a gross profit of \$US1.625 million.

About one third of Redhill stock that is traded changes hands on the Tel Aviv bourse, the rest on Nasdaq.

"We are happy to be listed on Nasdaq," Mr Frish says. "We are focused on the US market and our development primarily is done in the US."

Dr Boreham's diagnosis:

We reckon that almost every ASX-listed biotech would give away their newly-born to be on the cusp of commercializing multiple treatments.

Redhill is addressing massive unmet needs: its latest presentation cites a potential \$US4.83 billion market for Talicia, \$US10 billion for Crohn's disease and \$US500 million for NTM.

Of course, getting approval and nailing the sales is no cinch.

Asking management what product they most prefer is like asking which of their children they are most fond of, but the H. pylori program is the most developed and addresses the pressing issue of antibiotics resistance.

"We have the right product and the right time to meet this unmet need," Mr Frish says.

With so many drugs in its pipeline and cash to run trials, Redhill is a paradigm case of great Australian invention seized on the cheap by the far deeper pockets of off-shore companies.

Redhill's register, by the way, includes more than a smattering of Australian shareholders. For those who want to join them - and don't take this as a recommendation - Nasdaq shares can be readily traded via facilities offered by most brokers.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He would be happy to try the biotechnology products of any winery - Giaconda or other - and has no intention of moving to Jerusalem in the immediate future.