



# Biotech Daily

Friday October 19, 2018

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian Stock Market slipped 0.05 percent on Friday October 19, 2018 with the ASX200 down 2.9 points to 5,939.5 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and five were untraded. All three Big Caps fell.

Telix was the best, on the first day this week it didn't announce positive news, up 11 cents or 12.8 percent to 97 cents with 1.9 million shares traded. Immutep climbed 6.7 percent; Actinogen and Imugene improved more than four percent; Ellex, Prescient and Starpharma rose more than three percent; Compumedics and Optiscan were up more than one percent; with Opthea, Pro Medicus and Volpara up by less than one percent.

Avita led the falls, down 0.6 cents or 5.7 percent to 9.9 cents, with 14.1 million shares traded. Airxpanders, Cynata and Impedimed fell four percent or more; Benitec, Clinuvel and Genetic Signatures lost more than three percent; Bionomics, Cochlear, Orthocell and Paradigm shed more than two percent; Factor, Mesoblast, Nanosonics, Osprey and Polynovo were down more than one percent; with CSL, Medical Developments and Resmed down by less than one percent.

## [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.***

### [MGC \(MEDICAL GRADE CANNABIS\) PHARMACEUTICALS](#)

MGC says its sale of MGC Derma to Canada's Cannaglobal has been delayed with the completion date extended to October 31, 2018.

In September, MGC said it would sell the subsidiary for \$C12.5 million (\$A13.25 million) in equity, a \$C2.5 million loan repayment and a five-year supply agreement, which included an upfront \$C1 million order and payment for the initial order, with funds to be received within 10 business days (BD: Sep 27, 2018).

Today, MGC said that the companies "mutually agreed to extend the completion date". MGC fell 0.3 cents or 4.2 percent to 6.8 cents with 10.4 million shares traded.

### [QUEENSLAND BAUXITE](#)

Queensland Bauxite says subsidiary Medcan Australia will form a joint venture with Israel's Pharmocann to distribute the Israeli medical marijuana products.

Queensland Bauxite said that its soon-to-be wholly-owned subsidiary Medcan would work with the Israeli marijuana grower, which had proprietary products, intellectual property and expertise.

The company said that Medcan would manufacture Pharmocann's products for global distribution and the two would collaborate on clinical trials in Israel and Australia.

Queensland Bauxite said that Pharmocann would provide intellectual property, standard operating procedures, recipes and manufacturing techniques including existing Israeli clinical trial data and Medcan would be responsible for the manufacturing facility, Australian licences and the raw marijuana for product manufacture and export.

The company said that Pharmocann had supplied more than 4,500 registered patients medicinal cannabis dried flower, oils and ointments, for more than 10 years.

Queensland Bauxite was in a suspension at 3.7 cents.

### [FACTOR THERAPEUTICS](#)

Factor says its net operating cash burn for the three months to September 30, 2018 was \$2,436,000 with cash at the end of the quarter of \$4,047,000.

Factor said its expected burn for the coming three months was \$2,489,000.

Factor chief executive officer Dr Rosalind Wilson told Biotech Daily that "expenditure will drop-off dramatically after the conclusion of the pivotal VF001 diabetic foot ulcer trial in November".

Factor fell 0.1 cents or 1.3 percent to 7.6 cents with 2.6 million shares traded.

### [BRAIN RESOURCE](#)

Brain says its estimated cash outflow for the three months to December 31, 2018 was \$3,056,000 with cash at September 30, 2018 of \$4,445,000.

Brain said its net operating cash burn for the three months to September 30, 2018 was \$1,870,000, with \$919,000 in receipts from customers.

Brain director Matt Morgan told Biotech Daily that the company was "expecting a significant increase in revenue".

Brain was up 0.4 cents or 11.1 percent to four cents.

## PHARMAXIS

Pharmaxis shareholders will vote to grant chief executive officer Gary Phillips 690,000 free 10-year performance rights.

In 2017, the company said that 7,316,502 votes (9.74%) opposed the performance rights to Mr Phillips, but votes against the issue of the rights amounted to 2.3 percent of the company, not sufficient to requisition extraordinary general meetings.

In 2016, Pharmaxis overwhelmingly supported the issue of the rights to Mr Phillips but in 2015, Pharmaxis investors voted 8.9 percent dissent against the issue of 1,626,000 free performance rights to Mr Phillips (BD: Oct 16, 2015).

The opposition represented 2.2 percent of the shares on issue at that time.

Today, the Pharmaxis notice of annual general meeting said that shareholders would vote to approve the remuneration report, re-elect chairman Malcolm McComas and renew the proportional takeover provisions.

The meeting will be held at the Computershare, Level 4, 60 Carrington Street, Sydney on November 22, 2018 at 2.30pm (AEDT).

Pharmaxis was unchanged at 29.5 cents.

## PRESCIENT THERAPEUTICS

Prescient will vote to grant chief executive officer Steven Yatomi-Clarke 2,000,000 options exercisable at 145 percent above the 5-day volume-weighted average price at issue.

Prescient said the options would expire four years from issue.

The company said the annual general meeting would vote on the remuneration report, prior issue of shares, the 10 percent placement and to re-elect director Paul Hopper.

The meeting will be held at Chartered Accountants Australia and New Zealand, Level 18, 600 Bourke Street, Melbourne on November 20, 2018 at 10am (AEDT).

Prescient was up 0.3 cents or 3.4 percent to 9.1 cents.

## RACE ONCOLOGY

Race will vote to grant director Dr John Cullity and former director Dr Brendan De Kauwe 2,000,000 options each.

Race said that half of Dr De Kauwe's options would be exercisable at 49 cents and half at 65 cents by November 22, 2019.

The company said that Dr de Kauwe was issued 2,000,000 options last year provided that if he ceased to be a director, the options would expire within 60 days,

Race said that Dr Kauwe left his position as a director, "for commercial reasons unrelated to his performance as a director at the request of the company" and at that time the share price was below the exercise price and the options expired.

The company said that to restore the options it sought approval for the issue of 2,000,000 options "in consideration for services provided by ... Dr de Kauwe".

The company said that Dr Cullity's options would be exercisable at a 75 percent premium to the 5-day volume weighted average price to the date of issue within three years.

Race said that shareholders would vote on the remuneration report, the election of directors Dr William Garner and Dr Cullity, the employee share plan, the proportional takeover provisions, the ratification of the prior issue of 6,420,000 options and the 10 percent placement capacity.

The meeting will be held at the ISC Room, Royal Automobile Club of Australia, 89 Macquarie Street, Sydney, on November 27, 2018 at 11am (AEDT).

Race fell one cent or 6.7 percent to 14 cents with 4.9 million shares traded.

### LIVING CELL TECHNOLOGIES

Living Cell has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 176.7 percent from 3.0 cents on October 15 to 8.3 cents today, October 19, 2018, and noted a "significant increase" in the trading volume.

Living Cell closed up 1.8 cents or 43.9 percent to 5.9 cents with 55.7 million shares traded.

### STEMCELL UNITED

Stemcell has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 27.6 percent from 2.9 cents on October 18 to 3.7 cents today, October 19, 2018 and noted a "significant increase" in trading volume.

Stemcell was up half a cent or 17.2 percent to 3.4 cents with 62.1 million shares traded.

### RESPIRI

Respiri says it has appointed Sydney marketing company M&C Saatchi Lida Australia to help launch its second-generation asthma wheeze detector.

Respiri said M&C Saatchi conducted "a naming survey" including research in the UK, Australia and Singapore which concluded that Wheezo was "the preferred brand name" for the device, previously known as the Wheezometer (BD: Sep 24, 2009).

The company said that the study found "high product appeal and purchase intent".

Respiri fell half a cent or 5.3 percent to nine cents with 1.4 million shares traded.