



Biotech Daily

Wednesday May 8, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ORTHOCELL UP 377%; ACTINOGEN DOWN 7%**
- * **REDHILL NDA FOR TALICIA (RHB-105) FOR HELICOBACTER PYLORI**
- * **CLARITY RAISES \$10m**
- * **ORTHOCELL: 'CELGRO REGAINS MUSCLE FUNCTION'**
- * **COMPUMEDICS BARROW ORION LIFESPAN MEG 'LARGEST CONTRACT'**
- * **OSPREY LAUNCHES 'DYEMINISH' PATIENT REGISTRY**
- * **ANTEO 1-FOR-5 RIGHTS ISSUE FOR \$2.6m**
- * **PHARMAUST RECEIVES 25kg MONEPANTEL FOR CANCER TRIALS**
- * **BANK OF NEW YORK MELLON FILES 8 SUBSTANTIAL BIOTECH NOTICES**
- * **CREDIT SUISSE TAKES 10% OF PRESCIENT**
- * **REGAL FUNDS DILUTED BELOW 5% IN PRESCIENT**

MARKET REPORT

The Australian stock market fell 0.42 percent on Wednesday May 8, 2019, with the ASX200 down 26.6 points to 6,269.1 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and seven were untraded.

Orthocell was easily the best, leaping 41.5 cents or 377.3 percent to 52.5 cents with 76.8 million shares traded, on news that four Celgro patients with nerve injuries regained sensation and muscle function. Avita climbed 9.2 percent; Immutep was up 7.4 percent; Oncosil rose 6.85 percent; Clinuvel was up 5.5 percent; Kazia improved 4.5 percent; Starpharma was up 3.1 percent; Compumedics and Prescient rose more than two percent; with Cochlear, Medical Developments, Resmed and Volpara up by less than one percent.

Actinogen, led the falls for the second day in a row, down 0.1 cents or 6.7 percent to 1.4 cents with 42.5 million shares traded. Imugene lost 5.6 percent; Optiscan and Universal Biosensors fell four percent or more; Dimerix, Pro Medicus and Telix were down more than three percent; Genetic Signatures, Mesoblast, Pharmaust and Polynovo shed two percent or more; Nanosonics and Paradigm were down more than one percent; with CSL, Neuren and Opthea down by less than one percent.

[REDHILL BIOPHARMA](#)

Redhill says it has submitted a new drug application to the US Food and Drug Administration Talicia, or RHB-105, for Helicobacter pylori infection.

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

Today, Redhill said Talicia was an investigational new drug, not available for commercial distribution and the NDA was submitted under the 505(b)(2) regulatory pathway.

The company said that Talicia was granted qualified infectious disease product (QIDP) designation by the FDA and the application was eligible for six-month priority review.

Redhill said that if Talicia was approved it would receive an additional five years of US market exclusivity above the standard period, for a total of eight years exclusivity.

The company said that Talicia was covered by US patents which extended patent protection until at least 2034, with additional patents and applications pending in various territories worldwide.

Redhill chief operating officer Gilead Raday said the application was “a transformative milestone for Redhill and a critical step in our efforts to bring this much needed potential new therapy for [Helicobacter] pylori infection to the market”.

Mr Raday said that, pending approvals, the launch would be by the end of this year.

Redhill said the application was supported by two US phase III studies, along with two pharmacokinetic studies evaluating food effects and comparative bioavailability.

The company said the first phase III study met its primary endpoint of superiority over the historical standard-of-care eradication rate of 70 percent, demonstrating an 89.4 percent efficacy in eradicating Helicobacter pylori (H pylori) infection with Talicia ($p < 0.001$).

Redhill said that the confirmatory phase III study also met its primary endpoint, demonstrating 84 percent eradication of Talicia compared to 58 percent in the active comparator arm ($p < 0.0001$).

The company said 90 percent of subjects with confirmed blood levels of Talicia's active pharmaceutical ingredients on day-13 of treatment had confirmed eradication of H pylori.

Redhill said that low rates of eradication were obtained in patients treated with physician-directed standard-of-care therapies in the open-label parts of these studies, of 63 percent and 53 percent, respectively, consistent with the literature describing the diminished efficacy of standard-of-care therapies.

Redhill medical director Dr Ira Kalfus said that Helicobacter pylori infection was “a common and increasingly resistant and difficult to treat pathogen”.

“In our clinical study, no [Helicobacter] pylori resistance to rifabutin, one of the key ingredients in Talicia, was identified pre and post treatment,” Dr Kalfus said.

“We believe Talicia has the potential to become the new first-line, standard-of-care therapy for [Helicobacter] pylori infection,” Dr Kalfus said.

Redhill said it was strengthening its commercial management team with additional senior industry executives for the launch.

The company said that Helicobacter pylori infection affected more than 50 percent of the global population and about 35 percent of the US, with an estimated 2.5 million patients treated in the US each year.

Redhill said that Helicobacter pylori was classified as a group I carcinogen, the strongest risk factor for the development of gastric cancer and a major risk factor for development of peptic ulcer disease.

The company said that the 2018 potential market for eradication therapies was estimated at \$US4.8 billion worldwide.

On the Nasdaq, Redhill fell 14 US cents or 1.7 percent to \$US7.97 (\$A11.35) with 116,924 shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has raised \$10,000,006 at \$9.65 a share, with a \$5,000,003 placement to Genesiscare and the balance in a rights issue to new and existing shareholders.

Clarity said the funds would be used to progress the development of its pipeline of radio-pharmaceuticals, including Cu-64 Sartate and Cu-67 Sartate, which were “highly targeted theranostic [or] diagnostic and therapy pharmaceuticals with increased specificity and in-vivo stability”.

The company said that its first theranostic trial of Sartate for the brain cancer meningioma began in July 2018 and the study was expected to be completed this year.

Clarity said it would progress clinical trials with Sartate in neuro-endocrine tumors and neuro-blastoma in collaboration with US and Australian institutes.

The company said the capital raising would enable the clinical development of two other products in its pipeline, a prostate specific membrane antigen-targeting product for the diagnosis and treatment of prostate cancer and a bombesin product that targeted the gastrin-releasing peptide receptor, present within cancers, including lung, ovarian, prostate, and breast.

Clarity executive chairman Dr Alan Taylor said the capital raising included “a strategic investment from our partner Genesiscare, strong support from our current shareholder base as well as great demand from new investors”.

Dr Taylor said the capital raising coincided with the appointments of former Algeta chief executive officer Dr Thomas Ramdahl and chief medical officer Dr Gillies O’Bryan-Tear as directors, and former Algeta executive Dr Colin Biggin as chief executive officer.

Clarity is a public unlisted company.

ORTHOCELL

Orthocell says the first four patients in its 20-patient Celgro nerve regeneration trial have regained muscle function and sensation in affected limbs.

Orthocell said the trial showed that four traumatic peripheral nerve injury patients regained muscle function and sensation at 24 months, and improved muscle power by 83 percent.

The company said the pivotal trial was undertaken by the Perth-based St John of God Hospital orthopaedic nerve specialist Dr Alex O’Beirne and University of Western Australia Prof Ming Hao Zheng.

Dr O’Beirne said “the nerve injuries suffered by the patients in this study were so severe that they would not have been able to regain normal use of their injured arm and hand without microsurgery”.

“The surgery can be very complex and difficult but using Celgro has enabled us to rejoin severed nerves without tension,” Dr O’Beirne said. “Celgro increases the strength and quality of the repair and makes surgery easier.”

“I am very pleased with the patients’ progress, regaining use of affected limbs faster than I would have expected and they continue to improve,” Dr O’Beirne said.

Orthocell managing director Paul Anderson said the first patient outcomes were “very positive with early results indicating Celgro is effective in guiding and regenerating peripheral nerves”.

“This is an important step forward in the development of the Celgro platform in the area of human nerve regeneration,” Mr Anderson said.

“Celgro allows for tensionless reconnection of the damaged nerve while guiding nerve regeneration and accelerating the healing process,” Mr Anderson said.

Orthocell said it had treated 15 patients and expected to complete recruitment by July.

Orthocell leapt 41.5 cents or 377.3 percent to 52.5 cents with 76.8 million shares traded.

COMPUMEDICS

Compumedics says it the installation of the Orion Lifespan magneto-encephalography (MEG) at the Barrow Neurological Institute is the company's "largest system contract". Compumedics did not quantify the value of the contract but said the installation at the Phoenix, Arizona-based Barrow Neurological Institute, "the world's largest neurological disease treatment and research institution ... [was a] milestone ... [and] the first completely new design of a commercial MEG device to be delivered and installed in almost 20 years. The company said it was in the process of submitting a 510(k) clearance application to the US Food and Drug Administration to use the magneto-encephalography device for epilepsy and pre-surgical brain function mapping in the US.

Compumedics chief executive officer and chairman Dr David Burton said the installation and first stage commissioning was "a unique inflection point in Compumedics' evolution to date, paving the way for a major new global market for the company".

"Ultimately this new generation brain function scanner is uniquely positioned to transform brain-health and improve people's lives, worldwide," Dr Burton said.

Compumedics was up 1.5 cents or 2.8 percent to 55.5 cents.

OSPREY MEDICAL

Osprey says it has launched the Dyeminish patient registry, to evaluate its Dyevert cardiac dye reduction system.

Osprey said it would enrol up to 10,000 participants in the retrospective, large-scale, multi-centre study, with the first patient included on May 7, 2019.

The company said the registry included a core study cohort of coronary or peripheral angiography imaging procedure with use of the Dyevert system patients and a comparative health outcomes sub-study for patients without the Dyevert system.

The Edgewood, Kentucky-based St Elizabeth Heart and Vascular Institute interventional cardiologist Dr Mark Jordan said the registry would help evaluate the contrast-induced acute kidney injury prevention protocol, including an individualized assessment, procedure preparation and efforts to limit imaging contrast volume exposure with the Dyevert system. Osprey said it expected to complete the registry by late 2023.

Osprey was unchanged at 11.5 cents.

ANTEO DIAGNOSTICS

Anteo says it hopes to raise up to \$2.55 million in a one-for-five renounceable rights issue at 1.1 cents a share.

Anteo said the issue price was a discount of 37 percent to the 30-day volume weighted average price and investors would receive one listed option for every two new shares bought, exercisable at two cents a share within 18 months.

Anteo said the rights issue was underwritten to \$1 million by CPS Capital Group and sub-underwritten for \$180,000 by chairman Dr Jack Hamilton and director Matt Sanderson.

The company said that the record date for the rights issue was May 13, the offer would open on May 16 and close on May 30, 2019.

Anteo said that with an expected Research and Development Tax Incentive and a full subscription to the rights issue it would have \$4.9 million for its lithium ion battery anode program for its silicon graphite composite product; increase its point-of-care business development capability to commercialize its products and services; protect its intellectual property; expand its manufacturing capacity; and working capital.

Anteo fell 0.4 cents or 22.2 percent to 1.4 cents with 16.4 million shares traded.

PHARMAUST

Pharmaust says it has received 25 kilograms of monepantel for its human and dog cancer trials from the Greenfield, Indiana-based Elanco US.

Pharmaust was up 0.1 cents or 2.9 percent to 3.6 cents.

BANK OF NEW YORK MELLON CORP

The Bank of New York Mellon says it has become substantial in eight Australian biotechnology companies.

In separate initial substantial shareholder notices the Bank of New York Mellon said it held the shares as American depository receipts (ADR) on behalf of the named companies.

Alterity chief financial officer Kathryn Andrews told Biotech Daily that the notice was lodged by BNY Mellon as our America depository receipts depository and the 47.86 percent refers to the portion of our register held by ADR holders.

Ms Andrews said it was "a new [Australian Securities and Investments Commission] requirement and should not be read as a new substantial shareholder".

The Bank said it held ADRs equivalent to 411,960,088 shares in Alterity or 47.86 percent.

BNY Mellon said it had ADRs equivalent to 469,774,920 Avita shares (25.20%).

The Bank said it held ADRs equivalent to 38,702,125 Benitec shares (15.06%).

BNY Mellon said it had ADRs equivalent to 5,258,643 Clinuvel Pharmaceutical shares (10.74%).

The Bank said it held ADRs equivalent to 1,515,290,611 Genetic Technologies shares or (55.78%).

BNY Mellon said it had ADRs equivalent to 1,109,896,890 Immutep shares (32.80%).

The Bank said it had ADRs equivalent to 14,874,600 Immuron shares (10.39%).

BNY Mellon said it had ADRs equivalent to 16,840,686 Kazia Therapeutics shares (27.09%).

PRESCIENT THERAPEUTICS

Credit Suisse Holdings says it has become a substantial shareholder in Prescient with 38,767,904 shares or 9.83 percent.

The Sydney-based Credit Suisse said that it acquired 10,896,843 shares on April 1, and 27,770,985 shares on May 3, 2019 in the \$9.1 million capital raising at five cents a share (BD: Apr 26, 2019).

Prescient was up 0.1 cents or 2.3 percent to 4.4 cents with 1.4 million shares traded.

PRESCIENT THERAPEUTICS

Regal Funds Management says its shareholding in Prescient has been diluted below the 5.0 percent substantial level, in the recent \$9.1 million capital raising (BD: Apr 26, 2019).

Last week, the Sydney-based Regal Funds said it had returned to a substantial holding in Prescient of 16,752,422 shares or 5.79 percent (BD: May 2, 2019).

Prescient's most recent Appendix 3B new share announcement said that it had 394,260,627 shares on offer, and Biotech Daily calculated that Regal Funds retains a 4.25 percent holding.