



Biotech Daily

Monday April 12, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: NEXT SCIENCE UP 9%; IMUGENE DOWN 8%**
- * **RESAPP PLACEMENT TO RAISE \$5.5m**
- * **REDHILL DSMB 4th OKAY FOR OPAGANIB FOR COVID-19**
- * **MEDLAB: 'NANABIS REDUCES CANCER PAIN 55%'**
- * **CE MARK FOR ANTEOTECH SARS-COV-2 ANTIGEN RAPID TEST**
- * **IMUGENE DATA BACK HER-VAXX COMBO, CF33 FOR CANCER**
- * **TALI, INDIAN TIMES GROUP PARTNERSHIP COMMENCED**
- * **CRESO: HALUCENEX, GTR MUSHROOM GENOME SEQUENCING DEAL**
- * **TEPIX 40% DIRECTORS POOL HIKE, \$100m REVENUE CEO OPTIONS AGM**
- * **PYC: 'PPMO DELIVERS RNA THERAPEUTIC TO MOUSE BRAINS'**
- * **ANTERIS TAKES NEW \$2.7m MERCER DRAW-DOWN EQUITY FACILITY**
- * **ALLAN GRAY INCREASES TO 10% OF IMPEDIMED**
- * **PARADICE DILUTED TO 7% OF IMPEDIMED**
- * **THORNEY, TIGA TAKE 15% OF OVENTUS**
- * **MARK LAMPERT, BVF TAKE 15.5% OF BIONOMICS**
- * **AMPLIA APPOINTS JANE BELL DIRECTOR**
- * **BOD APPOINTS MEDLAB'S ALAN DWORKIN CFO**
- * **GENETIC TECHNOLOGIES APPOINTS OPTHEA'S MICHAEL TONROE CFO**

MARKET REPORT

The Australian stock market slipped 0.05 percent on Monday April 12, 2021, with the ASX200 down 3.6 points to 6,995.2 points. Twenty of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and one was untraded. All three Big Caps fell.

Next Science was the best, up 12.5 cents or 9.1 percent to \$1.50, with 566,714 shares traded. LBT and Optiscan climbed four percent or more; Alterity was up 3.1 percent; Antisense, Cochlear and Nanosonics rose more than two percent; Volpara and Resmed were up more than one percent; with CSL, Cynata, Medical Developments, Opthea, Pro Medicus and Proteomics up by less than one percent.

Imugene led the falls, down 1.5 cents or 8.3 percent to 16.5 cents, with 123.8 million shares traded. Universal Biosensors lost 6.1 percent; Starpharma was down 5.1 percent; Nova, Oncosil and Telix fell more than four percent; Compumedics, Paradigm and Patrys were down more than three percent; Clinuvel, Genetic Signatures, Immunetep, Pharmaxis and Resonance shed more than two percent; Avita, Dimerix, Kazia and Orthocell were down one percent or more; with Neuren and Polynovo down by less than one percent.

RESAPP HEALTH

Resapp says it has firm commitments to raise \$5.5 million through a placement to institutional and sophisticated investors at 5.8 cents a share.

Resapp said that major shareholder, Fidelity International, would cornerstone the placement with \$1.5 million and hold 9.99 percent of the company after the raising.

The company said the funds would be used to progress initiatives, hire key personnel, expedite product development initiatives and for general working capital.

Resapp said it had appointed Evolution Capital Advisors as the lead manager and would issue the company six percent of the funds raised and 6,000,000 options, exercisable at seven cents each within three years, on completion of the placement.

Resapp fell 0.4 cents or 5.9 percent to 6.4 cents with 3.6 million shares traded.

REDHILL BIOPHARMA

Redhill says the independent data safety monitoring board has unanimously recommended to continue for its phase II/III study of opaganib for Covid-19.

Redhill said the fourth recommendation was based on the analysis of unblinded safety data from the first 255 patient treated for 14 days, which extended the safety base of opaganib to about 380 patients.

The company said phase II/III randomized, double-blind, parallel-arm, placebo-controlled trial was conducted on patients with severe Covid-19 pneumonia which required hospitalization and treatment with supplemental oxygen.

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

On the Nasdaq, Redhill was up 60 US cents or 8.9 percent to \$US7.31 (\$A9.61) with 318,254 shares traded.

MEDLAB CLINICAL

Medlab says interim analysis of its 119-patients enrolled observational study showed a 55 percent reduction in pain with its marijuana-based Nanabis.

Medlab said it had recruited 801 patients (40.1 percent of the intended 2,000) for its study and the study had shown "significant improvements" in quality-of-life outcomes including general activities, sleep and mood.

Medlab said the data included patients who had completed both six and 12-months of administration and preliminary analysis of brief pain inventory scores showed improvement in mean pain scores with baseline of 6.5 to 5.5 at six months and 4.7 at 12 months.

The company said that of the 119-patients to complete the six and 12-month administration, 50 percent had muscular or neuropathic pain, 32 percent had soft tissue pain with muscular pain, 11 percent had visceral pain and seven percent had other categorized pain.

Medlab managing director Dr Sean Hall said the results "validate Nanabis and strongly supports our clinical pathway and [US Food and Drug Administration] strategy, particularly as we prepare to initiate our [investigational new drug] approved phase III study in the US, UK and Australia".

Medlab fell one cent or 3.6 percent to 26.5 cents.

ANTEOTECH

Anteotech says it has Conformité Européenne (CE) approval for its Eugeni reader and in-vitro diagnostic for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

Anteotech said the CE mark would support the sales of its Eugeni reader and antigen rapid test which used its Anteobind activated europium technology to increase the test's sensitivity.

The company said its Eugeni Covid-19 antigen rapid test was a single use, disposable immuno-chromatographic diagnostic test to be used by healthcare professionals to detect the virus in nasopharyngeal specimens.

Anteotech chief executive officer Derek Thomas said the company was "delighted to have achieved this significant milestone in our strategy to become a legal manufacturer of rapid tests".

"We believe we have a superior test with high sensitivity and specificity based on our unique Anteobind technology," Mr Thomas said.

Mr Thomas said the company expected to increase its range with a Covid-19, influenza A and influenza B multiplex test.

Anteotech was up 1.5 cents or six percent to 26.5 cents with 10.6 million shares traded.

IMUGENE

Imugene says it has presented data supporting its HER-Vaxx combination treatment for human gastric cancer, and its CF33 oncolytic virus for peritoneal tumor, in mice.

Last year, Imugene said an interim analysis of its 68-patient, phase II trial of HER-Vaxx with chemotherapy for gastric cancer showed "statistically significant" benefit claiming that HER-Vaxx reduced the risk of death by 58.2 percent and the analysis resulted in "a statistically significant one-sided p-value of 0.083" (BD: Nov 23, 24, 2020).

The company said that of the 13 patients in the chemotherapy alone arm, eight had died, with four dead in the 14-patient arm receiving HER-Vaxx and chemotherapy.

Imugene said at that time the median overall survival for patients receiving HER-Vaxx plus chemotherapy was 14.2 months, compared to 8.8 months for chemotherapy alone and the trial showed a "proof-of-concept signal for HER-Vaxx when added to chemotherapy".

Today, the company said that was completed in January 2021 and a presentation to the American Association for Cancer Research said that "treatment with HER-Vaxx clearly demonstrates that all patients develop high levels of HER2- specific antibodies early in the treatment protocol [and] analysis of the antibody data reveals high levels are maintained during the treatment and maintenance phases, with only minimal booster injections of HER-Vaxx required to maintain the high levels".

Imugene said the interim data suggested the treatment was effective and well tolerated with an overall survival benefit superior to chemotherapy alone.

The company said that final tumor response, correlation of antibodies with tumor response, and final progression-free and overall survival data expected this year.

Imugene said that HER-Vaxx was a B-cell peptide cancer immunotherapy designed to treat tumors such as gastric, breast, ovarian, lung and pancreatic cancers.

In a separate announcement, Imugene said a presentation to the American Association for Cancer Research, titled 'Subcutaneous Intratumoral Administration of CF33-hNISanti-PD-L1 Eradicates Distant Peritoneal Tumors' detailed a study of the molecule's "ability to track and kill distant peritoneal metastases after local virus administration" in mice.

In 2019, the company said CF33 was "a chimeric vaccinia poxvirus ... [and came with] pre-clinical efficacy and safety, and is anticipated to enter a phase I clinical trial in 2020".

Imugene fell 1.5 cents or 8.3 percent to 16.5 cents, with 123.8 million shares traded.

TALI DIGITAL (FORMERLY NOVITA HEALTHCARE, AVEXA)

Tali says its partnership with the Times Group of India for its cognitive performance tools Tali Detect and Tali Train has begun ahead of schedule.

Last year, Tali said its Detect and Train cognitive tools for childhood attention disorders were available for sale via on-line shops in India (BD: Oct 14, 2020).

Today, the company said its direct-to-consumer versions of the products for the health and education of children between three to eight years were approved and available on the Google Play Store in India, and the Times Groups would begin print and radio initiatives later in April.

Tali managing-director Glenn Smith said the company had received \$US2 million (\$A2.6 million) from partner Brand Capital last December and was "well-positioned to capitalize on our advertising agreement with [the] Times Group that will provide [the company] with access to a network that engages with over 550 million people every month".

Tali fell 0.1 cents or 1.8 percent to 5.5 cents with 7.6 million shares traded.

CRESO PHARMA

Creso says target acquisition Halucenex has an agreement with Growing Together Research Inc for genome sequencing to better understand Psilocybe mushroom.

Creso said the agreement with the Fort Wayne, Indiana-based Growing Together was to explore genome sequencing of natural psilocybin.

The company said that Halucenex would "incorporate the use of additional psychedelic substances" including lysergic acid diethylamide (LSD), ketamine and methylene dioxy-meth-amphetamine (MDMA) for treatment-resistant depression, post-traumatic stress disorder and other mental health illnesses.

The company said Growing Together would assist in creating an intellectual property portfolio to maximize the active ingredients in various strains of magic mushrooms and investigate the elements with the best efficacy for treatment of specific conditions.

Creso chair Adam Blumenthal said Halucenex had achieved "a number of key milestones" which laid a foundation for the clinical trial schedule and development initiatives.

"The agreement with [Growing Together Research] will provide the company with a scientifically backed approach, which allows for a better understanding of the important components of psilocybin mushrooms and how particular components can be used most effectively," Mr Blumenthal said.

Creso fell one cent or 4.8 percent to 20 cents with 27.1 million shares traded.

TELIX PHARMACEUTICALS

Telix will vote to raise the directors' fees pool 40 percent to \$700,000 and issue chief executive officer Dr Chris Behrenbruch 100,708 options, pending \$100 million revenue.

Telix said that the annual general meeting would vote to increase the pool of directors' fees from \$500,000 to \$700,000, and Dr Behrenbruch's options would be exercisable at \$4.38 by January 26, 2026, but not vesting until the achievement of \$100 million in cumulative revenue, before cost of goods sold, from product sales.

Telix said that investors would vote to adopt the remuneration report, re-elect Dr Andreas Kluge as a director, approve shares related to the partnership with China Grand Pharma and the acquisition of Therapharm GmbH and adopt the equity incentive plan.

The meeting will be held virtually and at the Events Centre, Collins Square, 727 Collins Street, Melbourne, on May 12, 2021 at 11.30am.

Telix fell 18 cents or 4.2 percent to \$4.07 with 463,266 shares traded.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says that its peptide-conjugated, phosphor-rodiamidate morpholino oligomer delivers “superior levels of RNA therapeutic to cells throughout the brain” in mice.

PYC chief executive officer Sahm Nasserri said the peptide-conjugated, phosphor-rodiamidate morpholino oligomer (PPMO) technology had “broad potential to address a range of diseases” and the company first applied the technology to diseases of the eye before expanding to the central nervous system and brain.

The company said that mouse data showed the phosphor-rodiamidate morpholino oligomer delivery and antisense effect at dosages significantly lower than those reported for delivery of both antisense oligo-nucleotides and other RNA therapeutics, and using research-grade material that may under-represent the true efficacy of its PPMOs due to the lower purity, an issue it said would be overcome as it progressed to higher purity drug preparations for testing in larger animal models.

PYC said it administered either its PPMO, a naked PMO, or an antisense oligo-nucleotide of the same sequence, via intra-cerebro-ventricular injection into mice, and on day-5 following treatment, the PPMO demonstrated a dose-dependent response across the target areas of the brain including both the motor cortex and the midbrain, with no evidence of efficacy for the naked PMO, or an antisense oligo-nucleotide at any dose.

The company said that “a major barrier to development of precision medicines for neurodegenerative disease has been the poor delivery of these medicines to the brain [and insufficient depth of penetration and therefore inadequate delivery to target cells, has prevented drugs from having meaningful impact on these diseases, without causing significant toxicity”.

“These data support the expansion of our pipeline and discovery efforts to include development of assets aimed at neurodegenerative diseases and conditions of the CNS,” Mr Nasserri said. “We remain on track to name a candidate targeting a high unmet need neuro-degenerative condition in 2021”.

PYC fell half a cent or 2.9 percent to 16.5 cents.

ANTERIS (FORMERLY ADMEDUS)

Anteris says Mercer Street Global Opportunity Fund LLC has taken a third tranche of convertible notes valued at \$2.7 million but bought at \$2.5 million.

In January, Anteris said it had \$20 million finance with Mercer including a \$1 million and \$1.5 million placement, a \$1 million note and a \$16.5 million facility (BD: Jan 17, 2021).

Today, the company said that Mercer had the right to convert the notes into shares at 90 percent of the 5-day volume-weighted average price prior to the issue of a conversion notice, subject to a floor price of \$4.00.

Anteris said the notes had 16-month term, no interest was payable on unconverted drawn funds and if the notes were not converted into shares by Mercer prior to maturity, the company would be required to repay the face value of the note.

The company said any amount drawn on the convertible securities remaining unconverted would be secured against its assets, excluding the Adapt intellectual property, and ranked behind the interests held by Mitchell Asset Management Pty Ltd and Sio Partners.

Anteris said that given the floor price of \$4.00, the maximum number of shares that could be converted by the third tranche notes was 675,000 shares.

The company said that Brighton Capital Ltd would be paid an advisor’s fee of \$183,000 in cash, being six percent of the amount payable by Mercer for the placement shares plus the new third tranche notes.

Anteris fell 10 cents or one percent to \$10.01.

IMPEDIMED

Allan Gray Australia says it has increased its substantial holding in Impedimed from 76,873,268 shares (6.12%) to 147,794,622 shares (9.91%).

The Sydney-based Allan Gray Australia said that between January 19 and April 7, 2021 it bought and sold 70,921,354 shares for \$2,659,551 or an average of 3.75 cents a share.

Last week, Impedimed said it has raised \$17.9 million through the exercise of options at 3.75 cents each, as part of a rights offer in April 2020 (BD: Apr 7, 2021).

Impedimed was unchanged at 14 cents with 7.1 million shares traded.

IMPEDIMED

Paradice Investment Management says its 102,899,139 shares in Impedimed have been diluted from 8.198 percent to 6.989 percent.

Last week, Impedimed said it has raised \$17.9 million through the exercise of options at 3.75 cents each (see above).

OVENTUS MEDICAL

Thorney Technologies and Tiga Trading say they have increased their shareholding in Oventus from 22,013,646 shares (13.91%) to 23,786,561 shares (15.03%).

The Melbourne-based Thorney and Tiga said that between November 24, 2020 and April 8, 2021 they bought 1,772,915 shares at prices ranging from 20 cents to 24 cents a share.

Oventus fell one cent or 4.8 percent to 20 cents.

BIONOMICS

Mark Lampert and BVF Partners say they have increased their substantial holding in Bionomics from 119,401,557 shares (14.12%) to 155,517,432 shares (15.49%).

The San Francisco-based Mr Lampert said that the shares were acquired in last month's placement which raised \$3,065,063 14.5 cents a share, run concurrently with its \$20,000,000 rights offer (BD: Mar 17, 2021).

Bionomics was up one cent or 5.3 percent to 20 cents.

AMPLIA THERAPEUTICS

Amplia says it has appointed banking and finance lawyer Jane Bell as a non-executive director, effective from April 12, 2021.

Amplia said Ms Bell had more than 30 years' experience in law firms, financial services and corporate treasury operations.

The company said Ms Bell was currently Monash Health's deputy chair, a director at Jessie McPherson Private Hospital and a member of the Administrative Appeals Tribunal.

Amplia said Ms Bell was previously the chair of Melbourne Health and Biomedical Research Victoria, deputy chair at Westernport Water Corporation and a director of Worksafe Victoria and the Australian Red Cross (Queensland).

The company said Ms Bell held a Bachelor of Law from the University of Melbourne, a Bachelor of Economics from Melbourne's Monash University and a Master of Law from London's Kings College.

Amplia was untraded at 25.5 cents.

BOD AUSTRALIA

Bod says it has appointed Alan Dworkin as its chief financial officer, effective from May 3, 2021.

Bod said Mr Dworkin had more than 20 years' experience in finance and operations management.

Last month, Medlab said it has appointed Simon Allsop as interim chief financial officer and Drew Townsend as company secretary to replace Mr Dworkin (BD: Mar 31, 2021). The company said Mr Dworkin was previously Medlab's chief operating officer, chief financial officer and company secretary and FIT Bioceuticals chief financial officer and company secretary.

According to his LinkedIn page, Mr Dworkin holds a Bachelor of Business from Western Australia's Edith Cowan University.

Bod fell one cent or 1.9 percent to 52 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed Michael Tonroe as its chief financial officer, effective from June 28, 2021.

Genetic Technologies said Mr Tonroe had more than 25 years' experience in "overseeing finance at both management and board-level positions".

Last week, Opthea said company secretary and chief financial officer Michael Tonroe had resigned, effective from June 24, 2021 (BD: Apr 6, 2021).

The company said prior to Opthea, Mr Tonroe was previously the chief financial officer and company secretary at the Australian Synchrotron and held accounting roles at Deloitte and KPMG.

Genetic Technologies said Mr Tonroe would start on a base salary of \$300,000 a year, including superannuation, with a short-term incentive up to \$750,000 and would receive up to 60,000,000 rights subject to performance hurdles.

The company said Mr Tonroe held a Bachelor of Science from London's University of Buckingham.

Genetic Technologies was up 0.05 cents or 5.3 percent to one cent with 2.1 million shares traded.