



Biotech Daily

Tuesday April 14, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: AMPLIA, OPTISCAN UP 25%; ALTERITY DOWN 10%**
- * **TGA APPROVES GENETIC SIGNATURES SARS-COV-2 TEST KIT**
- * **CELLMID RECEIVES 12k WONDFO CHINA COVID-19 ANTIBODY TESTS**
- * **FDA WAIVES CYCLOPHARM \$4.5m TECHNEGAS NDA FEE**
- * **AVECHO, PURISYS DEAL FOR TPM MARIJUANA**
- * **PAINCHEK FDA PRE-DE NOVO APPLICATION**
- * **BIOXYNE DIRECTORS 50% PAY CUT, REVENUE UP 7%**
- * **RESPIRI, PHENIX PARTNER FOR WHEEZO TELEHEALTH**
- * **ESENSE EVERBLU LOAN NOTES, PLACEMENT RAISE \$1.15m**
- * **CRESO ISSUES 10.8m COLLATERAL SHARES TO L1 CAPITAL**
- * **BOD LAUNCHES 4 MARIJUANA CBD CAPSULES IN UK**
- * **ADMEDUS 2nd NAME CHANGE (TO ANTERIS), STAFF INCENTIVES AGM**
- * **TELIX 200k CEO OPTIONS AGM**
- * **CRESO, HIGHNOON, ROUTE 2 PAKISTAN MARIJUANA DISTRIBUTORS**
- * **G MEDICAL RECONSIDERING NASDAQ LISTING**
- * **JENCAY TAKES 8% OF ELLEX**
- * **NEUROTECH TAKES 'ASX PRICE QUERY' TRADING HALT TO SUSPENSION**
- * **ADHERIUM APPOINTS JAMES WARD-LILLEY CHAIR, MIKE MOTION COO**

MARKET REPORT

The Australian stock market climbed 1.87 percent on Tuesday April 14, 2020, with the ASX200 up 100.8 points to 5,488.1 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell and nine traded unchanged.

Amplia and Optiscan were the best, both up 25 percent to eight cents and three cents, respectively, with 90,847 shares and 1.5 million shares traded, respectively. Paradigm climbed 19.5 percent; Medical Developments was up 13.8 percent; Dimerix was up 11.1 percent; Polynovo was up 9.05 percent; both Cyclopharm and Patrys improved 7.7 percent; Volpara was up 5.4 percent; Cochlear and LBT climbed more than four percent; Clinuvel and Pro Medicus were up 3.2 percent; Genetic Signatures, Orthocell, Prescient and Starpharma rose more than two percent; Next Science, Proteomics and Resmed were up more than one percent; with Avita, Cynata and Neuren up less than one percent.

Alterity led the falls, down 0.2 cents or 10 percent to 1.8 cents, with 120,000 shares traded. Imugene fell 7.4 percent; Mesoblast and Uscom lost six percent or more; Compumedics was down 3.4 percent; Antisense and shed two percent or more; Ellex fell 1.8 percent; with CSL, Nanosonics and Opthea down by less than one percent.

GENETIC SIGNATURES

Genetic Signatures says the Australia Therapeutic Goods Administration has approved its Sars-Cov-2 detection kit, which has identified eight viral mutations.

In February, Genetic Signatures said its Easyscreen respiratory pathogen targeted an assay for all known coronaviruses, including severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), the disease which caused Covid-19 (BD: Feb 26, 2020).

Earlier this month, the company said it has received Conformité Européenne mark approval for its Easyscreen Sars-Cov-2 detection kit (BD: Apr 1, 2020).

Today, Genetic Signatures said that “as more sequencing of the Sars-Cov-2 virus is published it is apparent that the viral mutations are occurring and there are at least eight different strains already identified”.

The company said that the Sars-Cov-2 detection kit in conjunction with the company’s highest throughput instrument, GS-1000, would provide laboratories with the ability to process about 1,500 samples in a 24-hour period.

Genetic Signatures said that the Sars-Cov-2 detection kit could be used on its own or alongside its Easyscreen respiratory pathogen detection kit.

Genetic Signatures was up five cents or 2.8 percent to \$1.85 with 935,923 shares traded.

CELLMID

Cellmid says it has received its first shipment of 12,000 Covid-19 rapid antibody diagnostic tests from the Guangzhou, Guangdong-based Wondfo Biotech.

In March, Cellmid said it had a supply agreement to distribute Wondfo Biotech’s diagnostic test for Covid-19, the disease caused by Sars-Cov-2 (BD: Mar 30, 2020).

Today, the company said the shipment was intended to be sold to medical practitioners subject to the completion of internal testing.

Cellmid said it expected the test to primarily be used to facilitate return-to-work programs, with a limited number of tests to be held for external testing and research purposes.

The company said that Wondfo test kit was manufactured in a facility certified by the Australian Therapeutic Goods Administration, the US Food and Drug Administration and the Chinese National Medical Products Administration and is authorized by the Chinese Administration to export its devices to Australia.

Cellmid fell 4.5 cents or 15 percent to 25.5 cents with 11.8 million shares traded.

CYCLOPHARM

Cyclopharm says the US Food and Drug Administration has waived application fees of \$US2.9 million (\$A4.51 million) for its Technegas new drug application.

Last month, Cyclopharm said it had lodged the application for its Technegas nuclear medicine lung ventilation imaging agent following reports of increased use of Technegas to differentiate between Covid-19 and pulmonary embolism where laboratory tests results were not fast enough (BD: Mar 24, 30, 2020).

Today, the company said the FDA could waive the application fee for the first human drug application of a small business. defined as fewer than 500 employees.

Cyclopharm chief executive officer James McBrayer said that the company was confident that it was eligible for a fee waiver but it was “very grateful to the US FDA in their support of small business and the speed at which our application was granted”.

“What normally takes three to four months to review, our request was granted at two months,” Mr McBrayer said.

Cyclopharm was up 10 cents or 7.7 percent to \$1.40.

[AVECHO \(FORMERLY PHOSPHAGENICS\)](#)

Avecho says Purisys LLC will supply pharmaceutical grade synthetic marijuana for combination with its tocopheryl phosphate mixture (TPM) vitamin E technology.

Avecho said it would combine the Athens, Georgia-based Purisys cannabidiol and dronabinol with its vitamin-E TPM to develop new oral cannabidiol products.

The company said its TPM was “proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients”.

Avecho said it would use Purisys’ cannabidiol and dronabinol for the research and development of TPM-enhanced cannabidiol products for specific clinical indications and regulatory approval and would “purchase future commercial supply from Purisys upon the commercialization of specific cannabidiol products”.

The company said that the decision to develop TPM-enhanced cannabidiol products followed “corroborating experiments conducted at Purisys demonstrating that TPM can increase the solubility of cannabinoids”.

Avecho chief scientific officer Dr Paul Gavin said that TPM had “been shown to reproducibly increase bioavailability and duration of absorption of orally ingested lipid, as well as increasing their solubility in aqueous mediums”.

Avecho executive chairman Dr Greg Collier said the medical and consumer cannabis markets were “attracting enormous interest and investment, and with it, growing interest from cannabinoid manufacturers and suppliers seeking truly differentiated products”.

“At present, the cannabis extracts entering these spaces are very similar,” Dr Collier said. “We believe the addition of TPM will provide commercially advantageous differentiation.”

Avecho was up 0.1 cents or 25 percent to 0.5 cents with 31.2 million shares traded.

[PAINCHEK](#)

Painchek says it has asked the US Food and Drug Administration for feedback on “human factors validation testing and clinical trials protocols”.

Painchek said that the testing and protocols were developed by its research partners the Toronto-based Human Healthcare Factors and Rome’s Donawa Lifesciences and it was seeking FDA confirmation that the studies would provide the necessary data to support a successful de-novo application for its pain monitoring mobile application.

The company said that given the impact of Covid-19, the US studies may be delayed.

Painchek chief executive officer Philip Daffas said the company had Australian Therapeutic Goods Administration and Conformité Européene mark clearance and FDA clearance would provide access to more than 70 percent of the medical device market.

Painchek was up 1.1 cents or 11.1 percent to 11 cents with six million shares traded.

[BIOXYNE](#)

Bioxyne says its directors will take a 50 percent pay cut until June 30, 2020 as Covid-19 slows sales in Malaysia and Indonesia.

Bioxyne said that sales revenue from probiotic *Lactobacillus fermentum* VRI-003, or Progastrim, was up seven percent to \$1.6 million for the nine months to March 31, 2020.

The company said that most of its revenue was earned in the US and a proportion of the improvement was attributable to the recent weakening of the Australian dollar and it expected that “demand for [Progastrim] will continue in the current Covid-19 environment”.

The company said that it expected sales in Malaysia and Indonesia to slow as direct sales rely on face-to-face meetings which were restricted due to Covid-19 lockdown measures.

Bioxyne was up 0.4 cents or 36.4 percent to 1.5 cents.

[RESPIRI](#)

Respiri says it has a joint development agreement with Phenix Health to integrate its Wheezo asthma test into the Phenix telehealth platform.

Respiri said that the agreement would integrate its Wheezo monitor with the Brisbane-based Phenix's patient dashboards and asthma management plans to provide patients access to Wheezo to help monitor their condition.

Respiri chief executive officer Marjan Mikel said the agreement underscored the company's "commitment to patients with asthma and related respiratory disease in Australia during the Covid-19 pandemic".

Respiri was up 1.3 cents or 17.6 percent to 8.7 cents with 2.7 million shares traded.

[ESENSE-LAB](#)

Esense says it has raised \$250,000 through the issue of unsecured loan notes and \$895,000 in a placement of Chess Depository Interest (CDIs) at four cents each.

Esense said each loan note had a face value of one cent with a coupon rate of 12 percent per annum and a maturity date of September 1, 2020.

The company said that noteholders would receive one free attaching option for every two CDIs issued on conversion of notes, exercisable at one cent each within 18 months and if shareholders did not approve the conversion of notes into CDIs the notes will be repayable in cash and the maturity date would be extended to December 1, 2020.

The company said that for every two CDIs bought in the placement, holders would receive one free attaching option at the same terms as the notes, subject to shareholder approval.

Esense said Everblu Capital was the lead manager of the capital raising and the funds would be used for research and development, business development, and working capital. Esense was up 0.3 cents or 42.9 percent to one cent with 2.9 million shares traded.

[CRESO PHARMA](#)

Creso says it will issue 10,812,526 additional collateral shares to L1 Capital Global Opportunities Master Fund, in accordance with the convertible note agreement.

In February, Creso said it had a convertible note agreement with L1 Capital for up to \$17,482,500, wherein Creso could request an initial \$1,750,000 advance in two equal tranches in exchange for 9,000,000 collateral shares prior to receiving the first tranche, paying L1 Capital a four percent fee of the advance, and potentially issuing up to an additional 11,000,000 collateral shares (BD: Feb 5, 2020).

Today, the company the additional collateral shares would top up L1 Capital's outstanding balance of collateral shares.

Creso said the number of the first tranche convertible notes held by a nominee had been reduced from 1,666,667 notes to 1,319,747 notes through L1 Capital's decision to purchase a reduction in the number of collateral shares.

Creso fell half a cent or 5.4 percent to 8.8 cents with 3.7 million shares traded.

[BOD AUSTRALIA](#)

Bod says it has launched four cannabidiol-based soft gel capsules for stress, anxiety, anti-inflammation, general wellness and liver protection in the UK.

Bod said the capsules were under the Hong Kong-based Health & Happiness Group's CBII brand and were available through electronic commerce.

Bod was up 1.5 cents or 6.5 percent to 24.5 cents.

ADMEDUS

Admedus will vote to change its name, again, this time to Anteris Technologies, as well as approve an employee incentive plan and re-elect director Stephen Denaro.

In 2013, the then Allied Healthcare Group changed its name to Admedus saying that as it expanded into international jurisdictions it was unable to consistently use the current name and Admedus would provide “a unique and recognizable brand and clearly distinguish [it] and its products in international markets” (BD: Oct 21, Nov 21, 2013).

In 2011, the then Andrew Forrest-run Allied Medical merged with Biomed to become Allied Healthcare Group to be “a full-service health care company” combining Biomed’s Adapt cardiac tissue patches with Allied’s healthcare distribution network and an investment in Prof Ian Fraser’s Cordion group, developing anti-virus vaccines including for herpes simplex 2 and Epstein-Barr virus, which is better known as the cause of glandular fever (BD: May 19, Jun 29, 2011).

In February, the company said it would hold a second consolidation, this time at 100-to-one, reducing the number of shares on offer from 590,842,817 shares to 5,908,428 shares and increasing the price per share from about seven cents to about \$7.00, but equivalent to an original pre-consolidation share price of about 0.7 cents (BD: Feb 26, 2020).

The first consolidation, at 10-to-one in November 2015 raised the company’s then trading price from 6.7 cents to 67 cents (BD: Oct 14, Nov 16, 2015).

Just before the market closed for the Easter holiday, Admedus filed its annual report and notice of meeting, disclosing the name change proposal.

The company said that the change of name to Anteris was because “the nature of the company’s business has changed ... from a diversified medical product development, medical technology and distribution business to a company predominantly focused on delivering clinically superior solutions to healthcare professionals in the structural heart sector”.

“Anteris’ is a genus of wasps symbolizing agility and aggression but also ingenuity and industrious team orientation,” Admedus said.

“Wasps are also exceptional engineers with ability to build lasting structures,” the company said.

The sale of 60 percent of the Coridon business, itself renamed Admedus Vaccines, to the Hong Kong-based Star Bright fell through last year and the company was put in administration (BD: Apr 27, 2018; Apr 23, 2019).

In May last year, BTC Health said it would buy the hospital infusion kit business from Admedus for \$6.3 million (BD: May 13, 2019).

In October, Admedus said it had sold the distribution rights of its Adapt tissue technologies Cardiocel and Vascucel to Lemaitre Vascular for up to \$36.2 million, but retained manufacturing rights for Cardiocel and Vascucel for three years and retained all Adapt intellectual property rights (BD: Oct 14, 2019).

The company’s notice of meeting said that shareholders would vote to approve the remuneration report and the 10 percent placement capacity and re-elect director Stephen Denaro.

Admedus said that shareholders would vote to approve the employee incentive plan, allowing for the issue of up to 295,515 shares - equivalent to 29,515,000 pre-consolidation shares and equivalent to 295,150,000 pre-first-consolidation shares.

The meeting will be held at the Hotel Grand Chancellor, 23 Leichhardt Street, Spring Hill Brisbane, Queensland on May 15, 2020 at 10am (AEST).

Admedus was up 30 cents or 3.8 percent to \$8.13, equivalent to 8.13 cents pre-2020 consolidation and 0.8 cents pre-2015 consolidation.

TELEX PHARMACEUTICALS

Telex says its annual general meeting will vote on a resolution to issue chief executive officer Dr Christian Behrenbruch 200,000 options exercisable at \$2.23 each.

Telex said the option price was a 43 percent premium on the five-day volume weighted average to the date of the offer, and the options were exercisable by January 12, 2024.

The company said it would vote to adopt the remuneration report, re-elect directors Kevin McCann, Oliver Buck and Dr Mark Nelson, approve 30,770,000 placement shares, renew proportional takeover bid provisions in the company constitution and approve a 10 percent placement facility.

The meeting will be held at the Telex Pharmaceuticals, Suite 401, 55 Flemington Road, North Melbourne on May 12, 2020 at 11:30am (AEST).

Telex fell 2.5 cents or 2.1 percent to \$1.17.

CRESO PHARMA

Creso says it has an agreement with Highnoon Laboratories and Route 2 Health to expand the distribution of its hemp-derived products in Pakistan.

Creso said that it would collaborate with the Lahore-based Highnoon and Route 2 to bring its products to Pakistan, which had a population of more than 200 million and a "wide range of unmet needs" that could be addressed by Creso's product portfolio.

The company said the collaboration could extend to deliver its products to Afghanistan, Azerbaijan, Bangladesh, Cambodia, Georgia, the Maldives, Myanmar, the Philippines, Tajikistan, Turkmenistan, Uzbekistan and Vietnam.

The company said that a definitive agreement would "be executed in the next three months".

Creso chief executive officer Dr Miri Halperin Wernli said that the company was "delighted to announce this partnership with Highnoon Laboratories and Route 2 Health, leading players in Pakistan's pharmaceutical and nutritional supplement sectors".

G (GEVA) MEDICAL INNOVATIONS HOLDINGS

G Medical says it is "re-considering a listing on the Nasdaq stock exchange to unlock additional value for shareholders".

Last year, G Medical said it hoped to raise \$US17,000,000 (\$A24,570,907) and list its American depository shares on the Nasdaq, and in August said it would withdraw its Nasdaq registration statement and pursue an Over-The-Counter Quality Exchange second board listing, as the "Nasdaq listing, and associated capital raising, was not in the best interest of its shareholders" (BD: May 20, Aug 26, 2019).

Today, the company said that it was in discussions with "various third parties" and there was no certainty that the Nasdaq listing would proceed.

G Medical was unchanged at 10.5 cents with 10.8 million shares traded.

ELLEX MEDICAL LASERS

Jencay Capital says it has increased its substantial shareholding in Ellex from 9,565,041 shares (6.66%) to 11,465,423 shares (7.98%).

The Alexandria, New South Wales-based Jencay said that on April 8, 2020 it acquired 1,900,382 shares for \$1,269,097 or 66.8 cents a share.

Ellex fell one cent or 1.8 percent to 55.5 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested a voluntary suspension to follow the trading halt requested “pending a response to a price query issued by [the] ASX” (BD: Apr 9, 2020).

Neurotech’s share price increased 140 percent from five cents at the close of trading on April 6, 2020 to 12 cents at the time of the halt with more than six million shares traded. Neurotech said trading would resume on April 21, 2020 or on an earlier announcement. Neurotech last traded at 1.2 cents.

ADHERIUM

Adherium says it has appointed James Ward-Lilley as chairman, replacing the late Thomas Lynch, and has promoted Mike Motion to chief operating officer.

Last week, Adherium announced the death of Thomas Lynch who had been chairman since September 2016 (BD: Apr 8, 2020).

Today, the company said that Mr Ward-Lilley was a consultant for Adherium and would continue in that role until the end of June 2020, at which time he would become a non-executive director and chair.

Adherium said Mr Ward-Lilley had more than 28 years’ experience in the pharmaceutical industry and was previously the chief executive officer at Vectura and a senior employee of AstraZeneca.

The company said Mr Ward-Lilley would receive 10,000,000 options exercisable at four cents, vesting over three years and expiring on April 14, 2027.

Adherium said Mr Motion joined the company in November 2018 as chief commercial officer and had more than 35 years’ experience in the life science industry.

Adherium was up 0.1 cents or 4.35 percent to 2.4 cents.