



Biotech Daily

Wednesday October 21, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: IMMUTEP UP 12%; AMPLIA DOWN 18%**
- * **US LAW FIRMS START MESOBLAST CLASS ACTIONS**
- * **BIOTECH DAILY EDITORIAL COMMENT**
- * **CORRECTION: AMPLIA THERAPEUTICS**
- * **ANATARA RAISES \$1.7m, SHARE PLAN FOR \$750k MORE**
- * **SOMNOMED: 'Q1 IMPROVES DESPITE COVID-19'**
- * **ANTEOTECH SARS-COV-2 ANTIGEN TEST 'HIGHLY SENSITIVE' IN-VITRO**
- * **EMYRIA, SAPPHIRE PARTNER FOR MARIJUANA PATIENT DATA**
- * **RESPIRI, CIPLA LAUNCH WHEEZO IN AUSTRALIAN PHARMACIES**
- * **RESAPP ADDS HEALTH ENGINE TO SELL SLEEPCHECK**
- * **STARPHARMA RECEIVES \$5.7m R&D TAX INCENTIVE**
- * **DIMERIX RECEIVES \$2.3m R&D TAX INCENTIVE**
- * **ONCOSIL AGM: 38% 1st STRIKE REM REPORT, 30% OPPOSE CEO SHARES**
- * **PROTEOMICS REQUESTS CAPITAL RAISING TRADING HALT**
- * **REGAL FUNDS TAKES 15.2% OF OPTHEA**
- * **AUSTRALIAN ETHICAL BELOW 5% IN ANTISENSE**
- * **WALKER REDUCES TO 6.7% OF ATOMO**
- * **CELLMID LOSES CHAIR, DIRECTOR, LYRAMID CEO; ALTERNATE DIRECTOR**
- * **ONE WEEK TO AUSBIOTECH CONFERENCE, INVEST 2020**

MARKET REPORT

The Australian stock market rose 0.12 percent on Wednesday October 21, 2020, with the ASX200 up 7.2 points to 6,191.8 points. Ten of the Biotech Daily Top 40 stocks were up, 25 fell, four traded unchanged and one was untraded. All three Big Caps fell.

Immutep was best, up three cents or 12.2 percent to 27.5 cents, with 2.25 million shares traded. Patrys climbed 9.5 percent; Kazia rose 4.35 percent; Volpara was up 3.7 percent; Opthea, Pharmaxis and Pro Medicus rose more than two percent; Universal Biosensors was up 1.6 percent; with Next Science and Paradigm up by less than one percent.

Amplia led the falls, breaking its three-day, 65.0 percent winning streak, retreating six cents or 18.2 percent to 27 cents, with 1.9 million shares traded. Optiscan lost 8.7 percent; Antisense and Cyclopharm fell seven percent or more; Osprey shed 6.9 percent; Orthocell was down 5.3 percent; Alterity, Avita, Imugene and Mesoblast fell four percent or more; LBT and Oncosil were down more than three percent; Compumedics, Genetic Signatures, Nanosonics, Polynovo and Uscom shed more than two percent; with CSL, Dimerix, Nova, Starpharma and Telix down by more than one percent.

MESOBLAST

At least four US law firms have begun class actions against Mesoblast claiming the company failed to inform investors of the risk of graft-versus-host disease success. In 2013, Mesoblast said it had acquired the stem cell assets of the US-based Osiris for up to \$US100 million (\$A105.7 million) in cash and scrip (BD: Oct 11, 2013).

At that time, Osiris had been described as Mesoblast's main stem cell competitor, with some of its clinical trials results disappointing.

In 2012, the Columbia, Maryland-based Osiris claimed positive results for its Prochymal 220-patient acute myocardial infarction trial but did not directly address the listed endpoints, citing other measures, saying that "serious adverse events occurred with equal frequency in both [control and active] treatment groups" (BD: Jul 3, 4, 2012).

Mesoblast chief executive officer Prof Silviu Itescu told Biotech Daily at that time that in conducting due diligence on Osiris he was convinced that the Prochymal technology, later developed into remestemcel-L, or Ryoncil, and other Osiris stem cell assets had potential in a number of indications.

Prof Itescu said that Prochymal was available in the US under an extended access program for graft-versus-host disease, and had shown significant benefit for patients.

He said that Prochymal was also in a phase III trial for refractory Crohn's disease.

In August, Mesoblast fell as much as 32.85 percent to \$3.27 following the publication of two US Food and Drug administration documents for a planned Oncologic Drugs Advisory Committee meeting, and rebounded 39.05 percent to \$4.70 when the Committee voted nine-to-one in favor of approval (BD: Aug 11, 14, 2020).

Earlier this month, Mesoblast fell as much as 44.7 percent to \$2.81 on news that the FDA had issued a complete response letter requiring a further trial of Remestemcel-L for graft-versus-host disease (BD: Oct 2, 2020).

On October 8, New York's Bragar Egel & Squire law firm announced a class action "on behalf of investors that purchased Mesoblast ... securities between April 16, 2019 and October 1, 2020", with New York's Rosen Law Firm and Bronstein, Gewirtz & Grossman, as well as the Los Angeles-based Schall Law Firm also saying they had begun class actions against Mesoblast.

All four firms make similar claims that Mesoblast "made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the company's business, operations, and prospects".

They said that Mesoblast failed to disclose that comparative analyses between its phase III trial and three historical studies did not support the effectiveness of remestemcel-L for steroid refractory acute GvHD due to design differences between the four studies, that the FDA was reasonably likely to require further clinical studies, delaying the commercialization of remestemcel-L in the US and that positive statements about the company's business, operations and prospects were materially misleading and/or lacked a reasonable basis.

Mesoblast was contacted for a response, which had not been received at the time of publication.

Mesoblast fell 15 cents or 4.4 percent to \$3.25 with 8.1 million shares traded.

BIOTECH DAILY EDITORIAL COMMENT

Biotech Daily believes that all the data from the previous Osiris trials and the Mesoblast trial has been publicly disclosed, if somewhat tedious and difficult to find and read; and is reminded of an ancient investor dictum: Caveat emptor.

Biotech Daily editor, David Langsam, holds Mesoblast shares.

CORRECTION: AMPLIA THERAPEUTICS

Last night's article and headline incorrectly said Amplia had dosed the first cancer patients in its trial of AMP945 for difficult to treat cancers and fibrotic diseases (BD: Oct 8, 2020). In fact, the company has dosed the first healthy volunteers in the phase I trial. The error was made by the Tuesday sub-editor who said he was overwhelmed by the detail in the CSL research and development briefing, Cochlear's revenue recovery and PYC's hopes to raise \$55 million, and lost concentration. He has been given a stern warning and shown the door. Amplia fell six cents or 18.2 percent to 27 cents, with 1.9 million shares traded.

ANATARA LIFESCIENCES

Anatara says it has commitments to raise \$1.67 million through a placement at 15 cents a share and hopes to raise a further \$750,000 through a share purchase plan. Anatara said the placement, which was not underwritten, would be issued in two tranches, with the second tranche subject to shareholder approval at its 2020 annual general meeting. The company said the 15 cents placement price was a 25 percent discount to the last closing price and the share plan price would be at least 80 percent of the five-day volume weighted average price, subject to a 15 cent a share floor price. Anatara said that eligible shareholders would be able to acquire up to \$30,000 in shares under the share plan, capped at \$750,000. The company said the record date was October 20, the share plan would open on October 28 and close on November 11, 2020. Anatara said the funds would be used to progress a clinical study of its pineapple stem bromelain-based 'gastrointestinal reprogramming' (Garp) dietary supplement for irritable bowel syndrome. The company said Taylor Collison was the lead manager and bookrunner to the placement. Anatara fell two cents or 10 percent to 18 cents.

SOMNOMED

Somnomed says its performance has improved in the three months to September 30, 2020 despite the ongoing impact of Covid-19. Somnomed said unaudited revenue fell six percent to \$13.7 million compared to the previous corresponding period and it expected continued regional volatility. Somnomed managing-director Neil Verdal-Austin said the company had "a progressive return of business activity levels" in Europe, North America and the Asia-Pacific. Somnomed was up 13 cents or 5.8 percent to \$2.36.

ANTEOTECH

Anteotech says an independent in-vitro validation study found that its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigen test is "highly sensitive". Anteotech said the study, conducted by the Zaragoza, Spain-based Operon SA, used stored swab samples of the virus to detect viral deoxyribonucleic acid (DNA) associated with Sars-Cov-2 to confirm a positive sample. Anteotech said it would continue to work with Operon to generate more data. Anteotech fell 1.5 cents or 12.0 percent to 11 cents, with 20.1 million shares traded.

EMYRIA (FORMERLY EMERALD CLINICS)

Emyria says it has a partnership with the UK's Sapphire Medical Clinics, who will select and de-identify patient data for its marijuana real-world evidence platform.

In August, the company said that it had a GBP400,000 (\$A723,000) deal to develop a marijuana "real-world evidence" system for Canopy Growth subsidiary Spectrum Biomedical UK (BD: Aug 10, 2020).

Today, the company said the first 24-month commercial project under the partnership would make Sapphire its preferred UK clinical service provider.

Emyria said it would pay GBP260,000 (\$A367,578) to Sapphire based on performance milestones and would allow it to deliver the Spectrum UK data agreement.

Emyria was up 0.1 cents or 1.3 percent to eight cents.

RESPIRI

Respiri says its exclusive Australian and New Zealand distributor Cipla Australia has launched its Wheezo asthma monitor in Australian pharmacies.

In July, Respiri said it had appointed Melbourne's Cipla to market and distribute Wheezo in Australia and New Zealand for five years (BD: Jul 17, 2020).

Respiri was up half a cent or 2.5 percent to 20.5 cents, with 3.7 million shares traded.

RESAPP HEALTH

Resapp says it has a 12-month non-exclusive marketing agreement with Health Engine to add its booking technology to the company's Sleepcheck application.

Resapp said that as part of the agreement, Health Engine would promote the use of Sleepcheck to assess obstructive sleep apnoea risk.

The company said that if a Sleepcheck user was identified as at risk of obstructive sleep apnoea, the application would direct the patient to see a doctor through the Health Engine platform, which helped patients to find, book and connect with healthcare service providers through an online booking network across Australia.

The company said it would retain revenue from Sleepcheck and from Health Engine for every new patient referred through Sleepcheck.

Resapp was up half a cent or five percent to 10.5 cents, with 2.2 million shares traded.

STARPHARMA

Starpharma says it has received \$5,684,386 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Starpharma said the rebate related to research and development expenditure for the year to June 30, 2020.

Starpharma fell 2.5 cents or 1.7 percent to \$1.47.

DIMERIX

Dimerix says it has received \$2,338,254 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Dimerix said the rebate related to research and development expenditure for the year to June 30, 2020.

Dimerix fell half a cent or 1.75 percent to 28 cents.

ONCOSIL MEDICAL

Oncosil says that 38.4 percent of votes at its annual general meeting voted against the remuneration report, earning a first strike.

Oncosil said there were 88,370,796 votes (38.4%) opposed to the remuneration report, with 142,019,765 votes (61.6%) in favor, earning a 'first strike'.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election.

The company said its resolution to issue managing director Daniel Kenny up to 3,080,000 performance-dependent loan shares passed with 75,796,810 votes (30.4%) opposed and 173,890,129 votes (69.6%) in favor

Oncosil said that 69,337,468 votes (29.0%) opposed the employee share plan, with 169,770,955 votes (71.0%) in favor.

Oncosil's most recent Appendix 2A new issue announcement said the company had 832,100,898 shares on issue, meaning that the votes against the remuneration report amounted to 10.6 percent of the company, sufficient to requisition extraordinary general meetings.

The company said the resolutions to re-elect Dr Chris Roberts as a director and ratify the prior issue of placement shares passed easily.

Oncosil fell half a cent or 3.6 percent to 13.5 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested a trading halt "pending the release of an announcement regarding a capital raising".

Trading will resume on October 23, 2020 or on an earlier announcement.

Proteomics last traded at 55 cents.

OPTHEA

Regal Funds Management says it has increased its substantial shareholding in Opthea from 28,726,324 shares (10.67%) to the equivalent of 51,235,825 shares (15.17%).

The Sydney-based Regal said that it bought and sold Australian shares between June 2 and October 15, 2020, reducing its Australian share-holding by a total of 1,194,195 shares for between \$2.25 and \$3.42 a share, and on October 16 it bought 2,962,962 American depository shares (ADSs), representing 23,703,696 Australian shares, for \$US13.50 (\$A19.11) per ADS or \$2.39 per share.

Opthea was up six cents or 2.6 percent to \$2.39, with two million shares traded.

ANTISENSE THERAPEUTICS

Sydney's Australian Ethical Investment says it has ceased to be a substantial shareholder in Antisense.

Earlier this month, Australian Ethical said that it had reduced its holding in Antisense to 26,875,413 shares or 5.50 percent of the company (BD: Oct 2, 2020).

Today, Australian Ethical said that between October 7 and 19, 2020 it sold 3,194,955 shares for \$416,281 or 13.0 cents a share.

Biotech Daily calculates that Australian Ethical holds 4.8 percent of Antisense.

Antisense fell one cent or 7.4 percent to 12.5 cents, with 1.9 million shares traded.

ATOMO DIAGNOSTICS

Walker Group Holdings says it has reduced its substantial shareholding in Atomo from 46,660,718 shares (8.32%) to 37,660,718 shares (6.70%).

The Sydney-based Walker Group said that on October 19, 2020 it sold 9,000,000 shares for \$2,880,000 or 32 cents a share.

Atomo was up half a cent or 1.5 percent to 33.5 cents, with 1.1 million shares traded.

CELLMID

Cellmid says chair Dr David King, director Dr Fintan Walton and Lyramid chief executive officer Bart Wuurman have resigned, with Sarah Eck-Thompson joining as a director.

Cellmid said independent chairman Dr King would not seek re-election at the November 30, 2020 annual general meeting but had agreed to “temporarily extend his tenure to assist in the transition to a restructured board and the appointment of a new chairman, so that his resignation would be effective on December 31, 2020”.

Earlier this month, the company said it had received a notice under Section 249D of the Corporations Act 2001 calling for the removal of Dr King as a director, which it said was not valid and it would not call an extraordinary general meeting (BD: Oct 7, 2020).

Today, Cellmid said Dr Walton would retire following its November 30, 2020 annual general meeting, Mr Wuurman had resigned effective from November 30 and Ms Eck-Thompson was appointed as an alternate director to her father, Dennis Eck.

Cellmid was up 1.5 cents or 15 percent to 11.5 cents.

AUSBIOTECH

Ausbiotech says that its on-line conference and Invest 2020 are on next week with bookings open for the Auspartnering, business matching program.

Ausbiotech said that delegates could book meetings to partner during the Ausbiotech and Invest 2020.

The industry organization said bookings could be made to meet “potential new partners and investors in private, virtual rooms”.

Ausbiotech said that Auspartnering would enable “hundreds of pre-scheduled 30-minute, one-on-one meetings during the Australia’s largest life science conference”.

The organization said that Ausbiotech and Invest 2020 would be online from October 28 to 30, 2020.

To register, go to: <https://www.ausbiotechnc.org/>.