



Biotech Daily

Thursday October 22, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PATRYS UP 17%; ALTERITY DOWN 11%**
- * **MESOBLAST TRIALS ENDOSCOPIC STEM CELLS FOR CROHN'S DISEASE**
- * **ONCOSIL 'FIRST COMMERCIAL SALE IN NEW ZEALAND'**
- * **ANTISENSE REQUESTS 'ATL1102 DMD ORPHAN STATUS' HALT**
- * **MOVEMBER PLANS GLOBAL PROSTATE CANCER DATABASE**
- * **PYC RIGHTS OFFER, PLACEMENT RAISE \$35.2m; \$19.6m TO GO**
- * **DORSAVI RAISES \$1.85m; RIGHTS OFFER FOR \$1.85m MORE**
- * **RESAPP: ASTRAZENECA LICENCES COUGH MONITOR SOFTWARE**
- * **EXOPHARM DOSES 1st PLECHOVAL II PATIENT; \$2.1m R&D TAX INCENTIVE**
- * **HYDRIX IMPLANTS 5th ANGEL GUARDIAN, 1st WOMAN PATIENT**
- * **GENETIC SIGNATURES Q1 RECORD \$10.5m REVENUE**
- * **CELLMID: 'AUSTRALIAN Q1 REVENUE UP 47%', RECEIPTS DOWN 20% TO \$2.1m**
- * **RHINOMED Q1 REVENUE 'UP 95%' TO \$1.2m, RECEIPTS UP TO \$641k**
- * **AUCKLAND TRUST, LANG WALKER DILUTED TO 39.5% OF NEXT SCIENCE**
- * **THORNEY, TIGA TAKE 5.7% OF LITTLE GREEN PHARMA**
- * **AZURE HEALTHCARE 'AUSTCO' NAME CHANGE AGM**
- * **LBT 6m CEO BRENT BARNES 'INCENTIVE' OPTIONS AGM**
- * **WALTER AND ELIZA HALL INSTITUTE 'BRAND' CHANGE TO 'WEHI'**

MARKET REPORT

The Australian stock market fell 0.29 percent on Thursday October 22, 2020, with the ASX200 down 18.0 points to 6,173.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and one was untraded.

Patrys was best, up 0.4 cents or 17.4 percent to 2.7 cents, with 46.2 million shares traded. Genetic Signatures climbed nine percent; Uscom improved 5.7 percent; both Optiscan and Telix were up 4.8 percent; Antisense and Pro Medicus rose two percent or more; Compumedics, Imugene, Orthocell, Pharmaxis and Universal Biosensors were up more than one percent; with Cochlear, Nanosonics and Resmed up by less than one percent.

Alterity led the falls, down 0.5 cents or 11.4 percent to 3.9 cents, with 11.1 million shares traded. Immutep lost 9.1 percent; Actinogen and Paradigm fell more than four percent; Kazia and Osprey were down three percent or more; Avita and Next Science shed more than two percent; Clinuvel, Cynata, Impedimed, Mesoblast and Volpara were down more than one percent; with CSL, Opthea, Polynovo and Starpharma down by less than one percent.

MESOBLAST

Mesoblast says it has begun an up-to 48-patient, randomized, controlled trial of remestemcel-L for medically refractory Crohn's disease and ulcerative colitis.

Mesoblast said that its mesenchymal stem cells were "delivered by an endoscope directly to the areas of inflammation and tissue injury" in the trial at Ohio's Cleveland Clinic, earlier this week.

Mesoblast chief medical officer Dr Fred Grossman said that "inflammation of the gut in Crohn's disease and ulcerative colitis closely resembles the most severe manifestation of advanced-stage, life-threatening acute graft-versus-host disease".

Dr Grossman said that the trial objective was to confirm the potential for remestemcel-L to induce luminal healing and early remission in a wider spectrum of diseases with severe inflammation of the gut, in addition to steroid-refractory acute graft-versus-host disease. Earlier this month, Mesoblast fell as much as 44.7 percent to \$2.81 on news that the US Food and Drug Administration had issued a complete response letter requiring a further trial of Remestemcel-L for graft-versus-host disease, despite an earlier Oncologic Drugs Advisory Committee meeting voting nine-to-one in favor of approval of remestemcel-L (BD: Aug 11, 14, Oct 2, 2020).

Today, the company said that mesenchymal stem cells promoted the healing of inflamed gut tissue by downregulating gut mucosal effector T-cell activity and promoting regulatory T-cell formation.

Mesoblast said that mesenchymal stem cells had been tested in clinical trials of Crohn's disease through intravenous infusions to treat the primary inflammation of Crohn's disease and local injections to treat fistulae complicating Crohn's disease.

The company said that endoscopic delivery had been "successful in pre-clinical experimental models of colitis, reducing the excessive cytokine storm in the inflamed gut and resulting in tissue healing".

Mesoblast said the Cleveland Clinic study would be the first in humans using local delivery and would enable a comparison with results from an on-going randomized, placebo-controlled trial in patients with biologic-refractory Crohn's disease where remestemcel-L was administered intravenously.

The company said that more than three million people or 1.3 percent of the US alone had inflammatory bowel disease, with more than 33,000 new cases of Crohn's disease and 38,000 new cases of ulcerative colitis diagnosed every year.

Mesoblast fell six cents or 1.85 percent to \$3.19 with 4.96 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has implanted its first commercial patient with its Oncosil device for pancreatic tumors in New Zealand, generating its maiden revenue.

Oncosil chief executive officer Daniel Kenny said the sale was "an important milestone for Oncosil as we begin transforming ourselves into a global commercial-stage medical device company".

"In Europe, our launch preparations continue to progress well with training and other critical activities well underway," Mr Kenny said.

The company said it had manufactured, dispensed, and shipped the Oncosil device system from Germany to New Zealand despite the Covid-19 pandemic, demonstrating its operational capabilities and ability to executive sales in other approved jurisdictions.

Oncosil said it expected to launch its Oncosil device and generate revenue in Europe by the end of the year.

Oncosil was unchanged at 13.5 cents with 17.4 million shares traded.

ANTISENSE THERAPEUTICS

Antisense has requested a trading halt pending an announcement on its US application for orphan drug status for ATL1102 in Duchenne muscular dystrophy.

Last year, Antisense said its nine-patient phase II trial of ATL1102 for Duchenne muscular dystrophy showed safety, tolerability and efficacy (BD: Dec 17, 2019).

Trading will resume on October 26, 2020 or on an earlier announcement.

Antisense last traded up 0.25 cents or two percent to 12.75 cents with 1.55 million shares traded.

MOVEMBER

Movember says it is launching “the world’s largest network of prostate cancer patient registries ... to transform treatment and care of the disease.

The Melbourne-based Movember, which calls for the growing of moustaches in November to support its cause, said the registries were expected to contain detailed clinical information on the diagnosis, treatment and survivorship of prostate cancer patients from more than 15 countries, with data on 250,000 men within the next five years.

The men’s health organization said the data would enable clinicians to measure and bench-mark the health of patients after treatment, providing them with information to improve the quality of prostate cancer treatment and care.

Movember said it had partnered with the Montreal, Quebec-based Dacima Software Inc electronic data company to design and develop a new registry database.

The organization said that Dacima had experience in designing registry databases for acute and chronic diseases, vaccine monitoring, infectious disease surveillance, medical procedures and devices and the upgraded system would allow data from existing patient registries to be integrated, “creating the most comprehensive and detailed prostate cancer surveillance system anywhere in the world”.

Movember said that the project would start with the Prostate Cancer Outcomes Registry – Australia and New Zealand database, which had been operating for five years and held the details of 67,570 men “to identify population-wide trends in diagnosis and treatment”.

The organization said that Movember-supported patient registries from other countries would join the network.

Movember program head Paul Villanti said that “effective clinical quality registries significantly improve the quality of life of men with prostate cancer, and offer the potential to extend survival.

“But being able to establish a super-network of registries that supports biomedical research, clinical trials, treatment quality improvement and personalized care and support for men living with prostate cancer is a major step forward and has the power to revolutionize prostate cancer treatment and care”.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says it has raised \$35.2 million in a one-for-10 entitlement offer and institutional placement at 17 cents a share, and hopes to raise a further \$19.6 million.

Earlier this week, PYC said it hoped to raise \$55 million through a \$50 million entitlement offer and a \$5 million placement (BD: Oct 20, 2020).

Today, the company said the institutional entitlement offer raised \$30.2 million and the placement raised \$5 million.

PYC fell one cent or 5.4 percent to 17.5 cents with 3.4 million shares traded.

DORSAVI

Dorsavi says it will raise \$1.85 million in a “over-subscribed” placement and hopes to raise a further \$1.85 million in a one-for-four rights offer at 3.2 cents a share.

Dorsavi said the share price of the capital raising was a 15.6 percent discount to the five-day volume weighted average price and a 11.1 percent discount to the last closing price to October 19, 2020.

The company said the additional placement applications would be under the company’s existing placement facility.

Dorsavi said the rights offer would allow shareholders to apply for one new share for every four previously held shares at the record date of October 27, with the offer opening on October 29 and closing on November 13, 2020.

The company said the funds would be used for development of its motion analysis devices, US commercialization, sales and marketing initiatives, and working capital.

Dorsavi was up 0.9 cents or 25 percent to 4.5 cents with 11.1 million shares traded.

RESAPP HEALTH

Resapp says Astrazeneca Japan has licenced its smartphone application cough analysis software for use in a study of lung cancer patients.

Resapp said the Tokyo-based Astrazeneca Japan, a subsidiary of the Cambridge, UK-based Astrazeneca Plc, had a 12-month licence for Resapps smartphone application, which used algorithms to monitor patient coughs over extended periods, and differential coughs from other background noise.

The company said that cough frequency was a key factor in monitoring respiratory disease progression and traditionally coughs were measured by subjective self-reporting or manually listening to audio recordings, which was labor intensive and inaccurate.

Resapp said it would refine the software to Astrazeneca’s requirements for the trial.

The company said Astrazeneca would pay a monthly licencing fee for each patient enrolled in the trial, but it did not expect the payment to “generate material revenue”.

Resapp chief executive officer Dr Tony Keating said that having the technology “licenced by a company of Astrazeneca’s reputation is a major achievement and provides significant validation of Resapp’s products and capability”.

Resapp was up two cents or 19.05 percent to 12.5 cents with 18.3 million shares traded.

EXOPHARM

Exopharm says it has dosed the first patient in its 15-patient Plexoval II phase I trial of its Plexaris for wound healing, and received a \$2,110,891 tax incentive.

In April, Exopharm said its Plexoval I exosome wound healing study had been disrupted by the Covid-19 outbreak and may not be completed (BD: Apr 1, 2020).

Today, the company said the Plexoval I study had been terminated and replaced by the Plexoval II randomized, double-blinded, placebo-controlled phase I study.

Exopharm said the study used its off-the-shelf Plexaris, a cell-free, allogeneic, platelet-derived exosome product, which was manufactured using the company’s ligand-based exosome affinity purification technology.

The company said it expected the study to be completed this year.

In the same announcement, Exopharm said it had received \$2,110,891 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Exopharm was unchanged at 34 cents.

HYDRIX

Hydrix says it has implanted its fifth Angel Medical Guardian cardiac arrest warning device in its first female patient in Singapore.

In August, the company said it was the exclusive distributor of the Angel Medical Guardian in eight Asia Pacific countries including Australia, Japan, and Singapore where four patient implants of the device were completed (BD: Aug 17, 2020).

Hydrix was up one cent or three percent to 34 cents with 5.7 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has record revenue for the three months to September 30, 2020 of \$10.5 million, up 50 percent on the three months to June 30, 2020.

Genetic Signatures said the revenue was a 585 percent increase on the previous corresponding period, with receipts from customers up 642.8 percent to \$11,394,000 compared to the previous corresponding period.

The company said revenue came from sales of its Easyscreen respiratory pathogen detection kit and severe acute coronavirus-2 (Sars-Cov-2) Detection Kit for Covid-19, with total Europe, Middle East and Africa sales up 70 percent on the previous quarter.

Genetic Signatures was up 17 cents or nine percent to \$2.06.

CELLMID

Cellmid says Australian consumer health revenue for the three months to September 30, 2020 “was up 47 percent on the previous corresponding period” to \$462,000.

Cellmid’s Appendix 4C quarterly reports said total customers receipts for the three months to September 30, 2020 were down 19.8 percent to \$2,087,000 compared to the three months to September 30, 2019 customer receipts of \$2,601,000.

The company said the revenue and receipts came from online sales of its personal health care products including Évolis for hair loss and its Jo-Ju branded skincare products.

Cellmid said its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) tests had “not recorded material revenues and cash outflows” (BD: Mar 30, Jul 2, 9, 2020).

Cellmid fell half a cent or 4.35 percent to 11 cents.

RHINOMED

Rhinomed says revenue for the three months to September 30, 2020 was up 95 percent to \$1.2 million, compared to the three months to June 30, 2020.

Rhinomed said the “positive movement generated throughout the first three quarters of [the year to June 30, 2020] slowed significantly in ‘the three months to June 30, 2020] ... [but] this impact was reversed in [the three months to September 30, 2020], despite this quarter historically being a seasonally softer period due to the Northern Hemisphere summer”.

The company said revenue was up 42.5 percent compared to the three months to September 30, 2019, and for the three months to September 30, 2020 customer receipts were down 13.6 percent to \$641,000 compared to the three months to June 30, 2020 “reflecting the pandemic affected [year to June 30, 2020] result”, but were up 1.1 percent compared to the three months to September 30, 2019.

The company said revenue and receipts came from sales of its Mute anti-snoring nasal dilators and its Pronto Clear nasal decongestion technology in Australia and the US.

Rhinomed was up half a cent or 2.9 percent to 18 cents.

NEXT SCIENCE

Walker Group and associates say they have increased and been diluted in Next Science from 75,510,500 shares (42.14%) to 76,072,938 shares (39.53%).

The Auckland and Sydney-based Auckland Trust, Walker Group and Lang Walker said that on April 15, 2019 they bought 550,000 shares for \$550,000 or \$1.00 each and on October 16, 2020 bought 12,438 shares for \$14,677 or \$1.18 a share.

Last week, Next Science said it had raised \$5 million in a share purchase plan at \$1.18 a share, taking the total raised to \$15 million (BD: Sep 16, Oct 14, 2020).

Next Science fell three cents or 2.4 percent to \$1.215.

LITTLE GREEN PHARMA

Melbourne's Thorney Technologies and Tiga Trading say they have become substantial in Little Green Pharma with 7,659,010 shares or 5.70 percent of the company.

Thorney and Tiga said that between October 12 and 20, 2020 they bought 4,403,823 shares at prices ranging from 29 cents to 34 cents a share.

Little Green fell 1.5 cents or 4.35 percent to 33 cents.

AZURE HEALTHCARE

Azure Healthcare says its annual general meeting will vote to change the company name to Austco Healthcare and issue 2,746,276 options to Clayton Astles.

Azure Healthcare is not related to Azure Health Technology, which acquired Invictus Biopharma and has delisted from the ASX (BD: Apr 28, Jun 11, 2020).

Azure Healthcare said it produced devices and software for healthcare clinic communication and management, including its Tacera nurse call system for communication channels between nurses, patients and monitoring alert systems.

The company said chief executive officer Mr Astles options were exercisable at 13 cents each until 2024 and would be "unconditionally issued" as soon as possible if approved.

Azure said shareholders would vote to adopt the remuneration report, re-elect director Anthony Glenning, and approve an additional 10 percent placement capacity.

The meeting will be held on November 24, 2020 at 9:30am (AEDT) as a virtual meeting at:

<https://web.lumiagm.com/?fromUrl=301743978>.

Azure was untraded at 9.6 cents.

LBT INNOVATIONS

LBT says investors will vote to chief executive officer Brent Barnes issue 6,000,000 incentive options and 354,269 shares in lieu of a portion of salary and bonuses.

LBT said Mr Barnes proposed options, exercisable at 16 cents each within five years, were based on share price growth and vesting in three equal tranches between 2023 and 2025 on the achievement of target share prices.

The company said it would issue Mr Barnes 96,869 shares prices at 10 cents each in lieu of part of his salary and 275,400 shares at 16 cents each in lieu of cash bonuses.

LBT said shareholders would vote to adopt the remuneration report, re-elect director Catherine Costello, ratify the prior issue of shares, approve a 10 percent placement facility, and approve the employee incentive plan

The meeting will be held at Thomson Geer Lawyers, Level 7, 19 Gouger Street, Adelaide, on November 25, 2020 at 11am (ACDT).

LBT was unchanged at 12.5 cents.

[THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH](#)

The Walter and Eliza Hall Institute of Medical Research says it has changed its name to the acronym WEHI, describing the change as a “new brand”.

The Institute’s director Prof Doug Hilton said the new image and name “better reflected the WEHI that its staff, students and supporters knew”.

“What I love about this new way of representing WEHI is that it pays tribute to our heritage, while also bringing a contemporary look that reflects the dynamic medical research we are known for,” Prof Hilton said.

WEHI said that it had more than 1,100 staff and students “making fundamental discoveries to advance treatments for cancer, infectious and immune diseases, developmental disorders and age-related conditions, helping people live healthier for longer”.

“WEHI isn’t just a place where discoveries are made, it’s where scientific theories are debated, investigated, pursued and celebrated,” Prof Hilton said.

“This is how we will continue to make impactful discoveries into the future,” Prof Hilton said.