



Biotech Daily

Monday November 8, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: USCOM UP 12.5%; POLYNOVO DOWN 10%**
- * **AMPLIA \$5.4m PLACEMENT, \$7m RIGHTS ISSUE**
- * **NEXT SCIENCE: TGA APPROVES XPERIENCE SURGICAL SOLUTION**
- * **LIVING CELL DROPS \$4m RIGHTS ISSUE PRICE TO 0.8c**
- * **CLINUVEL ADDS NEURACTHEL TO MELANOCORTIN PORTFOLIO**
- * **CLINUVEL PLEADS SCHULTZ, 'RESEARCH NOTE' TO 17.2% FALL QUERY**
- * **PARADIGM: 'ZILOSUL FOR KNEE OSTEOARTHRITIS TO COST \$3k-\$4k PA'**
- * **CORRECTIONS: ANTISENSE THERAPEUTICS**
- * **USCOM: 2 CHINA PATENTS FOR CARDIAC MONITOR**
- * **MACH7: AI VISUALIZE ALLEGES US PATENT INFRINGEMENT**
- * **ADALTA RECEIVES NET \$894k FEDERAL R&D TAX INCENTIVE**
- * **WOKE TO DISTRIBUTE O-T-C HAVN MUSHROOM PRODUCTS**
- * **CRESO: HALUCENEX PSILOCYBIN TESTING FOR PHASE II TRIAL**
- * **PLATINUM TAKES 5.2% OF ANTISENSE**
- * **PERENNIAL REDUCES TO 8.85% OF MEDADVISOR**
- * **ALEX WAISLITZ, THORNEY-TIGA, URBAN LAND BELOW 5% IN ZELIRA**

MARKET REPORT

The Australian stock market slipped 0.06 percent on Monday November 8, 2021, with the ASX200 down 4.7 points to 7,452.2 points. Ten of Biotech Daily Top 40 stocks were up, 26 fell and four traded unchanged. All three Big Caps fell.

Uscom was the best, up 1.5 cents or 12.5 percent to 13.5 cents, with 188,412 shares traded. Actinogen climbed 8.6 percent; Universal Biosensors was up 3.3 percent; Next Science, Nova Eye, Oncosil and Patrys rose more than two percent; with Neuren, Opthea and Volpara up by less than one percent.

Polynovo led the falls, down 17 cents or 9.7 percent to \$1.585, with 14.3 million shares traded. Clinuvel and Pharmaxis lost more than eight percent; Alterity fell 6.9 percent; Prescient and Telix were down more than five percent; Antisense, Optiscan and Resonance fell more than four percent; Paradigm and Pro Medicus were down more than three percent; Amplia, Cochlear, Compumedics, Dimerix, Impedimed, Mesoblast, Nanosonics, Proteomics, Resmed and Starpharma shed more than two percent; Immutep, Kazia and Orthocell were down one percent or more; with Avita, CSL, Cyclopharm, Imugene and Medical Developments down by less than one percent.

AMPLIA THERAPEUTICS

Amplia says it has raised \$5.4 million in a placement at 18 cents a share and expects to raise \$7 million in an underwritten, one-for-four rights issue at the same price.

Amplia said the offer price was a 11.8 percent discount to the 5-day volume-weighted average price to November 3, 2021.

The company said the proceeds would be used to fund the first stage of a phase II trial for AMP945 with standard-of-care for pancreatic cancer, manufacturing and further pre-clinical studies, as well as provide working capital.

Amplia said that both the placement and share offer would include one option for every three shares acquired, exercisable at 28 cents each by December 31, 2023.

Amplia said that rights issue record date would be November 16, with the offer opening on November 19 and closing on December 7, 2021.

The company said that Taylor Collison was the lead manager and bookrunner for the placement and the underwriter for the rights issue.

Amplia fell half a cent or 2.6 percent to 19 cents.

NEXT SCIENCE

Next Science says the Australian Therapeutic Goods Administration has cleared its Xperience surgical solution.

Next Science said that Xperience was designed to remain in the surgical site after closure, affording several hours of protection against pathogens.

The company said that Xperience had US Food and Drug Administration 510(k) approval and was on sale, initially to the orthopaedic and plastic and reconstructive surgery sectors.

Next Science managing-director Judith Mitchell said that surgical site infections were “a major cause of surgical complications and increased morbidity and mortality across the world”.

“Xperience provides an enormous opportunity to help reduce surgical site infections, save lives and reduce healthcare costs that arise from perioperative infections,” Ms Mitchell said.

“We have received strong inbound interest from organizations interested in partnering with Next Science and are in the process of evaluating the commercialization options for bringing Xperience to the Australian market,” Ms Mitchell said.

Next Science was up 2.5 cents or two percent to \$1.255.

LIVING CELL TECHNOLOGIES

Living cell says it has dropped the price of its two-for-three rights issue to raise \$4 million from 0.85 cents to 0.8 cents per share (BD: Oct 19, 2021).

In October, Living Cell said the rights issue would offer one option for every three new shares, after it announced a \$3.5 million share placement at the same price.

Today, the company said that “rights issues cannot be priced at a half of a fraction of a cent” and that it would extend the record date to “on or about November 18, 2021”.

Living Cell said that because the rights issue would proceed at a lower price than the placement, it would offer one new option for every two shares to investors who had taken part in the placement who still held these shares at the rights issue record date, with the options exercisable at 1.5 cents by April 19, 2024.

Living Cell was unchanged at 0.8 cents with 10.4 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has added ACTH, or Neuracthel, to its hormone treatment portfolio and will evaluate its potential for neurological, endocrinological, and degenerative disorders. Clinuvel said it had “secured a supply” of the melanocortin adreno-cortico-tropic hormone (ACTH), to be marketed as Neuracthel, with one of its strategic partners.

The company said that melanocortins were hormones which acted on cells and could “play a role in regulating the central nervous system, energy balance, appetite, photoprotection and DNA repair, as well sexual function”.

Clinuvel said that the naturally occurring human hormone ACTH was “essential for the production of cortisol, enabling the combat of stress and regulation of immune responses, maintenance of blood pressure, moderation of blood sugar and regulation of metabolism”.

The company said that its Scenesse, approved for phototoxicity and erythropoietic protoporphyria was based on the same family of hormones as Neuracthel and the addition of the drug would build on the company’s pre-existing expertise.

Clinuvel head of scientific affairs Dr Tim Zhao said ACTH was a recognized, licenced treatment for a number of neurological and endocrinological diseases, but supply and availability had been disrupted “and its full clinical potential remains unrealized”.

“Our research and commercial expertise in melanocortin drugs and peptide drug delivery platforms means we are well placed to ensure the successful, safe and efficient development and commercialization of ACTH formulations as Neuracthel,” Dr Zhao said.

“We also know there are many more under-served patient groups who would benefit from Neuracthel treatment and we will be addressing these unmet medical needs.”

Clinuvel fell \$2.95 or 8.3 percent to \$32.55 with 308,159 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company’s share price fell 17.2 percent from \$40.56 on November 4 to \$33.58 on November 5, 2021, and noted a “significant increase” in trading volume.

Clinuvel said it was aware of a “research note by an institutional sell-side analyst of Jeffries Australia Pty Ltd ... [which] downgraded its rating of the Clinuvel from buy to hold.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its Zilosul for knee osteo-arthritis pain reduction and improved function could cost \$US2,000 (\$A2,704) to \$3,000 (\$A4,056) a year.

Paradigm said that market research, which presented the characteristics of Zilosul, or injected pentosan polysulfate sodium, without identifying the name of the drug or its manufacturer, had been conducted in the US, the UK, France, and Germany.

The company said that payers in the US “suggested funding for Zilosul as a therapy to reduce pain and improve function in [knee osteo-arthritis] would likely be acceptable at a price of \$US2,000 to \$US3,000 per year of therapy”.

Paradigm said that if the US Food and Drug Administration approved the drug “with a disease modifying label then price per year of therapy in the US could increase to \$US6,000 and potentially higher”.

The company said that US specialists had estimated that Zilosul could be prescribed to up to 50 percent of patients with knee osteo-arthritis as a second-line treatment, after the use of non-steroidal anti-inflammatories had been deemed unsatisfactory.

Paradigm fell eight cents or 3.35 percent to \$2.31 with 876,163 shares traded.

CORRECTIONS: ANTISENSE THERAPEUTICS

Friday's edition carried a comprehensive article on Antisense, unfortunately containing several minor, but important inaccuracies.

Please refer to the on-line edition for the correct version, which is available at:

https://www.biotechdaily.com.au/media/Dr%20Boreham/ANP_Nov_5_2021a.pdf.

Biotech Daily apologizes unreservedly for these intolerable inaccuracies and has seconded the Friday sub-editor to Pedants & Nit-Pickers Weekly for a refresher course in fact-checking and accuracy.

Antisense fell one cent or 4.4 percent to 21.5 cents with 4.25 million shares traded.

USCOM

Uscom says it has received two patents from the China National Intellectual Property Administration pertaining to its Uscom 1A cardiac output monitoring technology.

Uscom said the patents, titled 'Bloodflow Detection and Analysis Equipment Applicable to Ultrasonic Cardiac Output Monitor' and 'Ultrasonic Sensor Modules of Ultrasonic Cardiac Output Monitor' would provide protection for the technology in China for 10 years.

Uscom executive chair Prof Rob Phillips said the patents were "our first issued Chinese patents and it's appropriate that they are for our flagship Uscom 1A product".

The company said it had 34 active trademarks and copyrights in China, and the Uscom 1A had patent protection in Europe, the US and Australia.

Uscom was up 1.5 cents or 12.5 percent to 13.5 cents.

MACH7 TECHNOLOGIES

Mach7 says it will vigorously defend itself against allegations of patent infringement brought by the Plano, Texas-based AI Visualize, Inc.

The company said that AI Visualize alleged that Nuance Communication's Powershare Network, in combination with Mach7's Eunity diagnostic image viewing platform, infringed four US patents, which described "methods and systems for fast access to advanced visualization of medical scans and 3-dimensional views using a dedicated web portal".

Mach7 said the allegations were "wholly without merit and it remains fully committed to the continued development and support of the Eunity enterprise viewing [product]".

Mach7 chief executive officer Michael Lampron said the company looked forward "to rebutting AI Visualize's claims in court".

Mach7 fell three cents or 3.5 percent to 83 cents with 1.1 million shares traded.

ADALTA

Adalta says it has received a net \$894,329 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

In June, Adalta said it had taken out a \$1.68 million research and development tax incentive loan with Radium Capital at 14 percent interest per year (BD: Jun 25, 2021).

Today, the company said its Federal Research and Development Tax Incentive was worth \$894,329 after full repayment of its Radium Capital Facility.

Adalta said the rebate related to research and development expenditure for the year to June 30, 2021, and was additional to the \$4 million non-dilutive financing facility agreed with the Victoria Government in September (BD: Sep 20, 2021).

Adalta fell half a cent or 5.6 percent to 8.4 cents.

[WOKE PHARMACEUTICALS PTY LTD](#)

Woke says it will distribute the Havn Life's 'white label' line of mushroom-derived "natural health" products in Australia, New Zealand and China.

In October, Woke said it would work with Monash University's Medicines Manufacturing Innovation Centre to develop a low dose psilocybin, WP001, for moderate depression (BD: Oct 19, 2021).

Today, Woke said it would aim to launch and establish the retail and electronic commerce footprints of its own brand of products based on the Richmond, British Columbia-based Havn formulations.

The company said that the market for dietary supplements in Australia and New Zealand was estimated to exceed \$3.7 billion in 2020.

Woke said it had begun canvassing and assessing its options to sell in the lucrative Chinese market, which was estimated to exceed \$26 billion in 2020.

Woke chief executive officer Nick Woolf said that "the health benefits offered by naturally-derived mushroom extracts are evident, and we anticipate strong demand in our regions". Woke is a private company.

[CRESO PHARMA](#)

Creso says its Halucenex synthetic psilocybin active pharmaceutical ingredient has completed USP61 and USP62 tests and is safe for human consumption.

Creso said that the tests evaluated the total number of microbial organisms present within a sample, as well as checking for the presence of potential pathogens.

The company said that based on the positive results of the tests, it expected to begin a phase II trial of psilocybin for treatment-resistant post-traumatic stress disorder by July 2022.

Creso was up 1.5 cents or 11.1 percent to 15 cents with 26.8 million shares traded.

[ANTISENSE THERAPEUTICS](#)

Platinum Investment Management says it has become a substantial holder in Antisense with 34,406,340 shares (5.23%).

The Sydney-based Platinum said that on November 5, 2021 it bought 7,500,000 shares for \$1,800,000 or 24 cents a share.

Last week, Antisense said it had raised \$20 million at 24 cents a share and would hold a one-for-9.4 rights offer for a further \$16.8 million (BD: Nov 1, 2021).

[MEDADVISOR](#)

Perennial Value Management says it has reduced its holding in Medadvisor from 46,492,053 shares (12.32%) to 33,392,668 shares (8.85%).

The Sydney-based Perennial said that it sold shares between October 28 and November 4, 2021, with the single largest sale 8,000,000 shares for \$2,953,488 or 36.9 cents a share.

Medadvisor was up three cents or 7.9 percent to 41 cents with 1.4 million shares traded.

ZELIRA THERAPEUTICS

Alex Waislitz and Tiga Trading say they have reduced below five percent in Zelira. The Melbourne-based Mr Waislitz said that he and Tiga (Thorney Investment Group Australia) and Urban Land Nominees ceased to be substantial on November 3, 2021. Last year, Zelira said that Thorney Investment Group had become a 5.2 percent substantial shareholder having acquired 37,037,000 shares in a \$2 million private placement at 5.4 cents a share (BD: Sep 23, 2020). In a later announcement, Tiga trading said it held 59,537,000 Zelira shares. Zelira was up 0.2 cents or five percent to 4.2 cents.