



Biotech Daily

Monday October 10, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ACTINOGEN UP 25%; PARADIGM DOWN 10%**
- * **ACTINOGEN XANAMEM ALZHEIMER'S BIOMARKER EFFECT**
- * **ANTERIS RECEIVES \$1.6m FEDERAL R&D TAX INCENTIVE**
- * **SHENG LI WANG REDUCES TO 6.4% OF INVION**
- * **SIMARI, SAM REPLACE IDT DIRECTORS BURRILL, KOTSANIS**
- * **QUIRIN, SCOTT REPLACE CRESO'S BLUMENTHAL; NAME CHANGE**
- * **GENETIC TECHNOLOGIES APPOINTS TONY DI PIETRO CFO, CO SEC**
- * **SMARTZ SENSOR NAPPY WINS MTA INNOVATION GONG**

MARKET REPORT

The Australian stock market fell 1.4 percent on Monday October 10, with the ASX200 down 95.0 points to 6,667.8 points.

Twelve of the Biotech Daily Top 40 companies were up, 19 fell, five traded unchanged and four were untraded. All three Big Caps fell.

Actinogen was the best, up 2.4 cents or 25 percent to 12 cents, with 37.2 million shares traded. Mesoblast climbed 8.2 percent; Universal Biosensors was up 7.7 percent; Amplia improved five percent; Antisense was up 4.65 percent; Atomo, Emvision, Oncosil and Starpharma were up more than three percent; Medical Developments rose 1.2 percent; with Neuren and Volpara up by less than one percent.

Paradigm led the falls, down 16 cents or 9.55 percent to \$1.515, with 884,471 shares traded.

Imugene, Micro-X and Uscom lost more than seven percent; Clinuvel and Impedimed fell more than six percent; Nanosonics and Polynovo were down more than five percent; Avita, Compumedics, Opthea and Pro Medicus fell more than four percent; Cochlear, Dimerix and Immutep were down three percent or more; CSL, Orthocell and Proteomics shed two percent or more; with Cyclopharm, Cynata, Resmed and Telix down by more than one percent.

ACTINOGEN MEDICAL

Actinogen says a 72-patient phase IIa Alzheimer's disease biomarker study shows Xanamem has "a therapeutic effect in patients with a biomarker-positive blood profile". Actinogen said that the 72-patient, double-blind, pre-specified, biomarker study used blood biomarker samples from the prior phase IIa placebo-controlled 'Xanadu' study of 185 patients diagnosed with mild Alzheimer's disease who were treated with Xanamem 10mg or placebo once daily for 12 weeks.

In 2019, the company fell as much as 70.8 percent on news that its 186-patient, phase II Xanadu trial of Xanamem for Alzheimer's disease "did not achieve statistical significance" (BD: May 7, 2019).

At that time, Actinogen said that despite missing primary and secondary efficacy endpoints the "results provide great encouragement to pursue higher dose and longer duration studies, consistent with ongoing Xanamem safety and target occupancy studies". Today, Actinogen said that the endpoints of its biomarker study were to measure Xanamem effects in patients with biomarker-positive Alzheimer's and establish short-term effects of Xanamem on the levels of blood biomarkers.

The company said the study found that the Alzheimer's disease diagnostic biomarker, phosphorylated tau (pTau) blood levels were above the median value of 6.74 picograms per milliliter (pg/ml) in 34 patients, or 10.2pg/ml in nine patients who had a "clinically significant therapeutic benefit" from Xanamem.

Actinogen said that there was an average effect size of 0.6 to 0.8 points on the cognition and function clinical dementia rating-sum of boxes (CDR-SB) scale, which compared to 0.45 reported for the anti-amyloid antibody lecanemab.

The company said that it used Cohen's "d" statistic of effect size for treatment compared to placebo ($p = 0.09$), representing a 60 percent reduction in progression compared with placebo treatment, and that based on CDR-SB scores, twice as many patients in the Xanamem group were stable or improved compared with those in the placebo group. Actinogen said that the findings confirmed that CDR-SB was a suitable endpoint for measuring Xanamem's therapeutic effect in trials of biomarker-positive Alzheimer's patients over a period as short as 12 weeks.

The company said that it had a "clear and uncontroversial" regulatory pathway with CDR-SB following the trial, which would be its primary endpoint in a planned phase IIb study and the findings "significantly de-risk and improve [Alzheimer's disease] program efficiency".

Actinogen chief medical officer Prof Paul Rolan said "these clinical results provide further validation of our Alzheimer's disease program and are a significant step forward in the development of Xanamem as a new treatment for Alzheimer's disease with a novel, amyloid-independent mechanism of action".

Actinogen managing-director Dr Steven Gourlay said the company was "very pleased to see such positive clinical data for patients with biomarker-positive, mild Alzheimer's disease.

"The results extend findings of therapeutic effects on cognition in two prior trials of cognitively normal, older volunteers to patients with early Alzheimer's disease," Dr Gourlay said.

"The data also validates the dose range planned for our upcoming trials in Alzheimer's disease and depression," Dr Gourlay said.

"Xanamem has the potential to be a novel daily oral therapy for Alzheimer's disease and other conditions that could be safely used alone or in combination with other therapies," Dr Gourlay said.

Actinogen climbed 2.4 cents or 25 percent to 12 cents with 37.2 million shares traded.

ANTERIS

Anteris says it has received \$1,600,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Anteris said the rebate related to expenditure for the year to December 31, 2021.

Anteris was up 40 cents or 1.6 percent to \$24.90.

INVION

Sheng Li Wang and associates says they have decreased their substantial holding in Invion from 681,440,371 shares (10.63%) to 408,940,371 shares (6.37%).

The Hong Kong-based Sheng Li Wang and associates said that on September 21, 2022 they conducted an off-market transfer of 272,500,000 shares at 0.013 cents a share.

Invion was up 0.05 cents or 4.55 percent to 1.15 cents.

IDT AUSTRALIA

IDT says Mark Simari and Geoffrey Sam will replace Hugh Burrill and Michael Kotsanis, as non-executive directors.

IDT said that Mr Burrill was appointed in 2015 and resigned, effective from today with Mr Kotsanis, Acrux's current chief executive officer, to resign at the 2022 annual meeting.

The company said Mr Simari had more than 15 years of experience as a director in the healthcare industry, and was currently the chair of Careteq and Tali Digital and was the co-founder and managing director of Paragon Care.

IDT said Mr Sam was co-founder of Healthe Care Australia Pty Ltd, managing-director of Nova Health and a company director.

IDT said that Mr Sam held a Bachelor of Commerce and a Master of Health Administration from Sydney's University of New South Wales and a Master of Arts from the University of Manchester in England.

IDT was up 0.7 cents or 7.5 percent to 10 cents.

CRESO PHARMA

Creso says Ben Quirin and Jodi Scott will replace founder Adam Blumenthal as directors and it intends to change its name to Melodial Global Health.

Creso said that Mr Blumenthal had resigned effective from October 10, 2022.

The company said Mr Quirin was formerly a Canopy Growth Corp executive, and it would seek shareholder approval to issue him 2,000,000 options, exercisable at four each by October 10, 2024 as an equity-based incentive component to his remuneration package.

Creso said that as part of its Sierra Sage Herbs LLC acquisition in August, it appointed Ms Scott as an executive director and that Ms Scott had been employed as head of US operations of Sierra (BD: Aug 29, 2022).

The company said Ms Scott held a Master of Science from Texas State University.

Creso said that pending shareholder approval it intended to change its name to Melodiol Global Health to "assist in best capturing the essence of the diversified operations of the group" stemming from a number of recent acquisitions and a broader strategy to position it for further merger and acquisition opportunities in the US and other markets.

The company said that Melodiol was a nod to its "focus on combining traditional plant-derived remedies with modern scientific expertise to bring safe, natural and efficacious products to market for a growing group of source-conscious consumers".

Creso fell 0.4 cents or 10 percent to 3.6 cents with 21.6 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed Tony Di Pietro as chief financial officer and company secretary.

In July, Genetic Technologies said chief financial officer and company secretary Michael Tonroe had resigned to “pursue other opportunities” (BD: Jul 5, 2022).

Last week, Inoviq said chief financial officer and company secretary Mr Di Pietro would resign effective from November 11, 2022 (BD: Oct 6, 2022).

Today, Genetic Technologies said Mr Di Pietro had 18 years of experience in the biotechnology industry, most recently working at Inoviq where he oversaw the merger between Bard1 Life Sciences and Sienna Cancer Diagnostics.

Genetic Technologies was untraded at 81.5 cents.

SMARTZ AG (FORMERLY SIMAVITA)

Smartz AG, formerly Simavita, says its “intelligent” sensor equipped nappy won the 2022 Kerrin Rennie Medical Technology Association Innovation Award.

The Sydney-based Smartz said that it won the Medical Technology Association of Australia innovation award for “medical developments improving quality of life”.

The company said that its nappy was “a low-cost, [internet] cloud-based wearable technology which uses advanced sensors and analytics to deliver personalized and precise treatment for people with incontinence”.

Smartz said that the sensor sent alerts when the nappy needed changing which optimized the use of nappies and could lead to cost and time savings, fewer changes and reduced waste disposal.

The company said that “multiple clinical studies have confirmed it leads to an improvement in health outcomes, dignity and peace of mind for the wearer”.

Smartz chief executive officer Michael Spooner said the award “recognizes the profound significance of the platform in enhancing care where it is needed the most... [and] it reinforces our confidence in our mission to improve the quality of life of millions”.

Smartz is a private company.