Biotech Daily

Monday August 12, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 10%; ACTINOGEN DOWN 59%**

*** ACTINOGEN: XANACIDD FAILS PRIMARY ENDPOINT, MEETS SECONDARY**

*** PYC: '2 MORE VP-001 PATIENTS SHOW IMPROVED VISION'**

*** TRYPTAMINE: 'TRP-8802 IMPROVES FIBRO-MYALGIA PAIN IN 5 PATIENTS'**

*** ALLEGRA TAKEOVER 'UNCONDITIONAL, ACCEPT OFFER'**

*** AMPLIA RECEIVES $3.2m FEDERAL R&D TAX INCENTIVE**

*** NEUROTECH HOPES FOR PARTNERSHIPS**

MARKET REPORT

The Australian stock market was up 0.46 percent on Monday August 12, 2024, with the ASX200 up 36.0 points to 7,813.7 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and two were untraded. All three Big Caps were up.

Avita was the best for the second trading day in a row, up a further 27 cents or 10 percent to $2.97, with 635,991 shares traded.

Syntara climbed 7.1 percent; Medical Developments improved 6.1 percent; Polynovo was up 4.5 percent; Clarity and Emvision were up more than three percent; Alcidion, Curvebeam, Mesoblast, Opthea and SDI rose more than two percent; Compumedics, Dimerix, Medadvisor, Proteomics, Resmed and Telix were up more than one percent; with Clinuvel, Cochlear, CSL, Cyclopharm, Nanosonics, Neuren and Pro Medicus up by less than one percent.

Actinogen led the falls, down 4.5 cents or 59.2 percent to 3.1 cents, with 147.5 million shares traded.

Atomo lost 13 percent; Aroa, Imugene and Orthocell were down more than three percent; Genetic Signatures and Paradigm shed two percent or more; with Immutep, Micro-X and Prescient down by more than one percent.

ACTINOGEN MEDICAL

Actinogen fell as much as 67.1 percent to 2.5 cents on its 165-patient, phase IIa trial of Xanamem for depression missing primary endpoints, but meeting secondary endpoints.

Actinogen said the trial showed its Xanamem did not meet its primary endpoint of a superiority to placebo in a cognitive 'attention composite' of three Cogstate computerized tests due to an "unexpectedly large improvement in the placebo group".

In 2022, the company said a six-week, phase II, proof-of-concept study of daily oral 10mg Xanamem cortisol synthesis inhibitor would be compared to placebo and anti-depressant therapy, for effects on depression and cognition (BD: Jun 14, 2022).

Today, Actinogen said the mean improvements in scores from three Cogstate computerized tests measuring attention and working memory were 0.3 for Xanamem and 0.4 for the placebo group with the p-value "not significant".

The company said an "unexpectedly large placebo mean improvement may have impaired the ability of the trial to observe any short-term pro-cognitive effects of Xanamem".

Actinogen said Xanamem was statistically significant for the endpoint of "clinically significant benefits" in changes from baseline on the Montgomery-Asberg Depression Rating Scale (MADRS) compared to placebo after six weeks of treatment ($p = 0.11$) and statistically significant four weeks after the end of treatment ($p = 0.02$) with an improvement of 26 percent from baseline in the placebo group, which was "within the expected range for trials of this type".

The company said that a greater benefit on MADRS scores was "evident in the pre-specified group of 81 patients with less severe depression", both at the end of six weeks treatment ($p = 0.02$) and four weeks later ($p = 0.03$).

Actinogen said there was a greater improvement in MADRS scores in a pre-specified group of 31 patients taking the drug as a monotherapy at the end of treatment ($p = 0.06$), but not four weeks after treatment, with typically reported MADRS improvements in approved anti-depressants averaging about two to three points compared to placebo.

Actinogen chief executive officer Dr Steven Gourlay told Biotech Daily that the company was "very pleased to see this trial validate that inhibiting tissue cortisol synthesis in the brain works for patients with depression".

"The trial results show that Xanamem resulted in a clinically meaningful reduction of depression symptoms," Dr Gourlay said. "The MADRS depression score was the key secondary endpoint and showed statistical significance at 10 weeks, that is four weeks after six weeks of treatment with 10mg oral Xanamem."

"In the overall population of mild and moderate depression, the benefit was in the range of many approved anti-depressant drugs, with Xanamem having none of the side effects of anti-depressants," Dr Gourlay said.

"In patients with mild depression the benefit was statistically significant at six weeks and 10 weeks, and larger than many approved anti-depressants," Dr Gourlay said.

"We have shown that oral 10mg Xanamem improves cognition in healthy people, has activity to slow Alzheimer's disease and also reduces depression," Dr Gourlay said.

The company said Xanamem was safe and well tolerated, with other secondary endpoints subject to ongoing analysis including "an executive function cognitive composite, memory function cognitive composite, proportions of responders and global clinical assessment".

Dr Gourlay said the Xanamem trial for Alzheimer's disease was expected to be extended to the US next month with interim results expected in mid-2025 and final results in 2026.

Actinogen the endpoints for the Alzheimer's disease trial focused on "a broader range of tests validated in the Alzheimer's field" (BD: Apr 15, 2024).

Actinogen closed down 4.5 cents or 59.2 percent at 3.1 cents with 147.5 million shares traded.

PYC THERAPEUTICS

PYC says two of three retinitis pigmentosa type-11 patients in cohort four of its single-ascending dose trial have improved vision following a 75 microgram dose of VP-001.
Last year, PYC said it had dosed the first of nine patients in the phase I study; and later, said it conducted a safety review of the first three doses of three micrograms, 10 micrograms and 30 micrograms, with a fourth cohort of three patients expected to receive the final 75 microgram dose by June trial (BD: Jun 30, 2023, Apr 29, 2024).
Last week, the company said two patients in the third cohort of the study had shown further vision improvement at four months post-dosing (BD: Aug 5, 2024).
Today, PYC said the two patients in the fourth cohort showed enhanced retinal sensitivity in the "entire macula" three months after treatment compared to baseline.
The company said all three fourth cohort patients had enrolled in its extension study and would receive multiple doses of VP-001, with one patient receiving a second dose.
PYC said the patient, who had not seen a "quantifiable visual functional improvement" was reporting visual improvement in their treated eye and had received a second dose.
The company said the third patient in cohort three of the study had completed six-month follow-up and showed "a marginally slower rate of disease progression in the treated eye when compared to the untreated eye".
PYC fell half a cent or 4.55 percent to 10.5 cents with 1.5 million shares traded.

TRYPTAMINE THERAPEUTICS (FORMERLY EXPOHARM)

Tryptamine says all five patients in its phase IIa trial of TRP-8802 oral psilocybin showed improved fibro-myalgia pain severity, sleep and pain interference one month after dosing.
In July, Tryptamine said it had dosed all five patients in the open-label phase IIa trial of TRP-8802 with psycho-therapy for fibro-myalgia associated with pain (BD: Jul 10, 2024).
Today, the company said patients were dosed with 15mg psilocybin and a second 25mg dose two weeks apart with psycho-therapy, with the combination safe and well-tolerated.
Tryptamine said four of five patients reported a clinically meaningful reduction in anxiety and improved cognitive ability and one patient reported that their sense of smell had returned following a Covid-19 diagnosis in 2021.
The company said that "whilst appreciating the limitations of the small number of patients and the open label nature of the 'signal' style study, the results are highly encouraging and considerably strengthen [its] … intellectual property position".
Tryptamine said the results validated its approach targeting "nociplastic" pain with an initial focus on fibro-myalgia and will inform an additional clinical study using intra-venous-infused TRP-8803 psilocin, which was expected to being before June 30, 2025.
The company said the results were presented by the University of Michigan researchers at the International Association for the Study of Pain 2024 World Congress held in Amsterdam, the Netherlands on August 9, 2024.
Tryptamine chief executive officer Jason Carroll said that while still early, the results highlighted "that psychedelic-assisted therapy may achieve an improved patient outcome through treating the cause of fibromyalgia rather than the limited relief to select symptoms provided from the treatment choices presently open to them".
"Through this trial we have demonstrated that psychedelic-assisted therapy may offer an improved future for fibro-myalgia patients across Australia and globally," Mr Carroll said.
"These findings will be incorporated into planning now underway for an additional trial utilising TRP-8803, Tryp's innovative and scalable [intra-venous]-infused psilocin formulation," Mr Carroll said.
Tryptamine fell 0.2 cents or 9.5 percent to 1.9 cents with 8.75 million shares traded.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra says Allegra Innovations Pty Ltd holds 80.6 percent of the company, with shareholders who had accepted the offer to be paid within 10 days of acceptance.
In May, Allegra said Allegra Innovations, a related party of director Dr Nicholas Hartnell, would pay 0.4 cents a share in a cash bid, valuing it at $478,444 (BD: May 27, 2024).
On Friday, Allegra Innovations said it met "all of the outstanding conditions... of the bidder's statement" and its acquisition of Allegra was "unconditional" (BD: Aug 9, 2024).
Today, the company said shareholders who accepted Allegra Innovation's offer would be paid within 10 days from August 8, with the offer set to expire August 19.
Allegra said it strongly encouraged "all remaining shareholders who have not yet accepted to do so before the expiry date as they may not be able to sell their holdings on-market once the offer period expires".
The company said Allegra Innovations intended to have Allegra Medical Technologies' shares removed from the official list of ASX following the acquisition.
Allegra was in a suspension and last traded at 2.9 cents.

AMPLIA THERAPEUTICS

Amplia says it has received $3,177,718 from the Australian Taxation Officer under the Federal Government's Research and Development Tax Incentive program.
Amplia said the incentive related to research and development expenditure from its "ongoing phase Ib/IIa clinical trial of narmafotinib in advanced pancreatic cancer patients" for the year to March 31, 2024.
The company said it would use the funds to fully repay its $1,467,000 loan from director Dr Robert Peach with accrued interest and progress its trial and other research and development activities.
Amplia was unchanged at 13 cents with 3.9 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it hopes for "one or more strategic partnerships" to develop its NTI164 marijuana in the US, Europe and "certain Asian territories" including Japan.
Neurotech said the potential partnerships would support clinical, regulatory development, manufacturing and future commercialization.
The company said the partnerships "may take the form of licencing transactions, equity-based investments or mergers and acquisitions".
Neurotech said a partnership would "minimize the financial, clinical and regulatory risks for Neurotech shareholders" and, if successful, potential partnerships would allow it to focus financial resources and expertise towards registration of NTI164 in Australia.
Neurotech was up 0.1 cents or 1.5 percent to 6.6 cents with 1.6 million shares traded.