Biotech Daily

Tuesday May 25, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: IMUGENE UP 12%; PATRYS DOWN 11%**

*** VIVAZOME, RENERVE WORK ON EXOSOME SPINAL CORD REPAIR**

*** ANTERIS PLACEMENT TO RAISE $2.3m**

*** PARADIGM: FDA QUESTIONS PPS FOR OSTEOARTHRITIS TRIAL**

*** TELIX: 'TLX66 AMYLOIDOSIS TRIAL MEETS ENDPOINTS'**

*** TELIX DOSES 1st PATIENT IN JAPAN TLX591-CDx PROSTATE IMAGING TRIAL**

*** INVION: INV-043 EFFECTIVE AGAINST MULTIPLE CANCERS, IN MICE**

*** CLARITY SIGNS CU-67 SUPPLY DEAL WITH NORTHSTAR**

*** AROA REVENUE DOWN 11% TO $21m; LOSS UP 222% TO $18m**

*** IMUGENE CHAIR PAUL HOPPER, M-D LESLIE CHONG EXERCISE $2.6m OPTIONS**

*** CHIMERIC DOSES 1st PATIENT IN GLIOBLASTOMA 2nd COHORT**

*** VISIONEERING 100-TO-1 CONSOLIDATION AGM**

*** BARD1: PRELIMINARY SUB-B2M TEST SHOWS 'FEASIBILITY' FOR CANCER**

*** NEUROTECH DOLCE BEATS CBD FOR MS NEURO-MARKERS, IN VITRO**

*** ACTINOGEN PLEADS SCHULTZ TO ASX 54% QUERY**

*** IMPEDIMED RELEASES SOZO VERSION 4**

*** MEMPHASYS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** MERCER STREET BELOW 5% IN ANTERIS**

MARKET REPORT

The Australian stock market was up 0.98 percent on Tuesday May 25, 2021, with the ASX200 up 69.3 points to 7,115.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 22 fell and five traded unchanged. All three Big Caps were up.

Imugene was the best, up five cents or 12.35 percent to 45.5 cents, with 81.4 million shares traded. Telix climbed eight percent; LBT was up 5.1 percent; Immutep improved 4.4 percent; Proteomics and Uscom were up more than three percent; Cochlear, Dimerix and Resonance rose more than two percent; Cyclopharm, Pharmaxis, Polynovo, Pro Medicus and Volpara were up more than one percent; with CSL and Resmed up by less than one percent.

Patrys led the falls, down 0.3 cents or 11.1 percent to 2.4 cents, with 9.9 million shares traded. Actinogen retreated 10.4 percent; Paradigm was down 9.05 percent; Alterity and Osprey lost more than six percent; both Antisense and Prescient fell 4.8 percent; Genetic Signatures, Kazia and Universal Biosensors were down three percent or more; Amplia and Avita shed more than two percent; Opthea, Optiscan and Orthocell were down one percent or more; with Clinuvel, Cynata, Medical Developments, Nanosonics, Neuren, Next Science and Starpharma down by less than one percent.

VIVAZOME THERAPEUTICS PTY LTD, RENERVE LTD

Vivazome says it will combine its exosome technologies with Renerve's Nervalign nerve cuff scaffolds for the repair of spinal cord injuries.
Vivazome said the companies would share costs to take the program to pre-clinical proof-of-concept and would "explore the potential of combining the … Nervalign nerve cuff with Vivazome's proprietary exosomes to enhance nerve regrowth in damaged spinal cords".
The company said the Nervalign cuff had potential to facilitate localized delivery of regenerative factors to damaged nerves while protecting the healing process, while the Vivazome exosomes had potential to stimulate the regeneration of functional neural tissue and reduce inflammation.
Vivazome chief executive officer Dr David Haylock said his company had identified neurological disorders as "a key area of strategic interest for Vivazome's exosome products" and there were about 250,000 people in the US living with spinal cord injuries, with about 17,500 new cases each year.
Vivazome said treatment options for people with spinal cord injury were limited, and safe, innovative solutions were needed to achieve meaningful improvements in their quality of life.
The company said it hoped to begin pre-clinical studies this year.
Vivazome is a private company and Renerve is a public unlisted company.

ANTERIS TECHNOLOGIES

Anteris says it has commitments for a $2.3 million placement at $7.50 a share, a nine percent discount to the 5-day volume-weighted average price.
Anteris said that placement investors would receive one unlisted option for every two new shares acquired, exercisable at $11.50 within two years, pending shareholder approval.
The company said the funds would be used as additional working capital.
Anteris said the placement was led by Evolution Capital Advisors, would receive $81,739 as fees and 50,000 unlisted options exercisable at $11.50 within two years, also subject to shareholder approval.
Anteris fell 55 cents or 6.9 percent to $7.45.

PARADIGM BIOPHARMACEUTICALS

Paradigm says the US Food and Drug Administration has asked questions regarding its investigational new drug application for pentosan polysulfate sodium for osteoarthritis.
Paradigm said the FDA feedback "contained its positions and questions principally in relation to recently completed non-clinical studies".
The company did not detail the questions, its answers. nor the FDA "feedback".
Paradigm said that the FDA provided its "suggested mitigation strategies to address its positions and questions, which included further detailed clinical monitoring".
The company said it would include mitigation strategies as well as "clarification of existing study data".
Paradigm said it expected to submit its complete response to the FDA within 30 days and a further review and response from the FDA would be due within 30 days of the receipt of the company's response.
The company said it was continuing its phase III study start-up preparation at sites in the US and Australia and additional sites might be added to ensure completion of the study, within the planned commercialization timelines.
Paradigm fell 21 cents or 9.05 percent to $2.11 with one million shares traded.

TELIX PHARMACEUTICALS

Telix says its nine-patient, phase I/IIa trial of TLX66 for systemic amyloid light chain amyloidosis has met its study objectives of safety.

Telix said the targeted radiotherapy for amyloid light (AL) amyloidosis (Trala) trial evaluated the safety and toxicity of TLX66 (90-yttrium-besilesomab) as the only bone marrow conditioning agent prior to autologous haematopoietic stem cell transplantation in patients with AL amyloidosis patients.

Last year, the company said it had completed its acquisition of Therapharm and with it an agreement for a data package from the University of Southampton for 90-yttrium-besilesomab (BD: Dec 14, 2020).

Today, Telix said the Trala trial was sponsored by the University of Southampton and was conducted at four centers, Southampton, University College Hospital London, Royal Free Hospital London, and Queen Elizabeth Hospital Birmingham.

The company said all nine-patients in the trial showed a “favorable” safety profile and tolerated the bone marrow conditioning agent “well”.

Telix said the patients were “successfully” engrafted following bone-marrow-conditioning with TLX66 and had autologous haematopoietic stem cell transplantation without any chemotherapy.

The company said the disease response, measured by the fall in clonal free light chains, was seen in seven of the nine patients, with two complete responses and five partial responses in the first 100 days after the transplant.

Telix said that in two of the patients achieving partial responses, the clonal free light chains continued to fall, with one patient achieving a complete response with no further treatment and all nine-patients were alive at a median follow-up of 31 months.

Telix chief medical officer Dr Colin Hayward said the results “indicate that TLX66 may offer a new approach to bone marrow conditioning in patients who could benefit from [hematopoietic stem cell transplantation] such as those with AL amyloidosis, providing new hope to patients with this rare disease and with few effective treatment options”.

“TLX66 was well-tolerated, enabling successful engraftment of the patients’ own transplanted stem cells without the need for toxic chemotherapy,” Dr Hayward said.

“With all patients remaining alive, and most not requiring further therapy, we believe these data support taking TLX66 forward into a pivotal registration program in this rare disease indication,” Dr Hayward said.

Telix was up 32 cents or eight percent to $4.32 with 1.7 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has dosed the first patient in its 10-patient Japanese phase I trial of its TLX591-CDx for prostate cancer imaging.

In February, Telix said the Japanese regulator cleared its phase I trial of TLX591-CDx and last year, the company began its collaboration with Kanazawa University for the trial using positron emission tomography and 68-gallium-prostate-specific membrane antigen 11 (Ga-PSMA-11) (BD: Dec 14, 2020; Feb 22, 2021).

Today, Telix head of Japan Dr Shintaro Nishimura said, “this is the first study in Japan where a gallium based [prostate-specific membrane antigen] imaging agent is being systematically evaluated.”

“Dosing the first patient represents a significant first step for the Japanese domestic medicine community to deliver innovative benefits to Japanese prostate cancer patients,” Dr Nishimura said.

INVION

Invion says a proof-of-concept study shows its INV-043 with its Photosoft technology is effective against multiple cancer types, in mice.

Last month, Invion said that work with Melbourne's Hudson Institute on immune deficient mouse models of T-cell lymphoma, triple negative breast and pancreatic cancers had provided early indications that INV-043 had superior anti-cancer activity and cancer-targeting characteristics than previous compounds (BD: Apr 27, 2021).

Today, the company said the proof-of-concept studies showed that INV-043 had about 50 times greater phototoxicity that its previous active pharmaceutical ingredient IVX-P03 and about 600 times greater than the widely-used photosensitizer, Talaporfin sodium.

Invion said the study showed INV-043 was selectively retained in malignant tissues and no toxicity issues were identified in up to 50 times the therapeutic dosage.

The company said "significant regression" was observed in T-cell lymphoma, triple negative breast and pancreatic cancer mouse models.

The company said its INV-043 showed fluorescence characteristics under blue light which illuminated tumor growths.

Invion chair Thian Chew said that "by using our latest [active pharmaceutical ingredient], these initial proof-of-concept results demonstrate the potential of Photosoft technology's applications in cancer treatment".

"Our next steps include performing further proof-of-concept studies looking at INV-043's effect on the immune response as well as exploring its potential to work together with other therapies," Mr Chew said.

Invion was up 0.1 cents or 10 percent to 1.1 cents with 94.4 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has a long-term exclusive deal with the Beloit, Wisconsin-based Northstar Medical Radioisotopes to supply the therapeutic radioisotope copper-67 (Cu-67).

Clarity did not detail the term or value of the agreement, but said NorthStar would supply Cu-67 exclusively to Clarity as an active pharmaceutical ingredient to support its targeted copper diagnostic and therapy programs, including clinical development and commercial supply for neuroblastoma, breast, prostate and other cancers.

The company said that Cu-67 was a beta-emitting radioisotope with clinical applications as a radio-pharmaceutical to target and deliver therapeutic doses of radiation to destroy cancer cells in patients with serious disease.

Northstar chief executive officer Stephen Merrick said that "previously, the lack of an effective copper chelating technology has limited the clinical development of Cu-67 products and subsequent commercial production of Cu-67".

Mr Merrick said that Clarity's "unique copper-chelating technology has enabled it to advance its product pipeline into a range of [diagnostic and therapeutic] clinical trials" that use copper-64 (Cu-64) for diagnostic imaging and Cu-67 as therapy.

Northstar said Cu-67 had "an optimal half-life for a therapeutic radiopharmaceutical, was produced in the US without a nuclear reactor, had no long-lived contaminants or bi-products from the manufacturing process, and base material, zinc, was readily available.

Clarity executive chair Dr Alan Taylor said that access to large, commercial supply of Cu-67 at a suitable price-point "enables us to apply our … approach not only to rare diseases such as neuroblastoma in children, but also other cancers with very large patient populations such as prostate and breast cancers".

Clarity is a public unlisted company.

AROA BIOSURGERY

Aroa says revenue for the year to March 31, 2021 was down 11.0 percent to $NZ22,342,000 ($A20,808,522), with net loss after tax up 222.4 percent to $NZ19,209,000 ($A17,893,821).

Aroa said revenue came primarily from sales of its sheep-stomach-derived Myriad for soft tissue repair and Symphony for wound closure, with remaining revenue from royalties and project fees and it had a non-cash, one-off loss of $NZ8 million for the fair value adjustment of pre-offer shares which were issued in February and May 2020.

The company said its diluted loss per share fell from $NZ2.1263 in the year to March 31, 2020 to 6.39 NZ cents in the year to March 31,2021 and net tangible asset backing per share has been converted from a negative $NZ4.98 in the year to March 31, 2020 to 11 NZ cents in the year to March 31, 2021.

Aroa said it had cash and cash equivalents of $NZ15,381,000 at March 31, 2021 compared to $NZ3,850,000 at March 31, 2020.

Aroa was up four cents or 3.4 percent to $1.22 with 1.2 million shares traded.

IMUGENE

Imugene says executive chair Paul Hopper has exercised 25 million options for $1,070,000, with managing-director Leslie Chong exercising 36.2 million options for $1,517,000.

Ms Chong told Biotech Daily the options were exercisable at a range of prices and she expected to exercise her remaining 13.8 million options “in the near future”.

Imugene said the funds raised would further research and development activities.

Imugene was up five cents or 12.35 percent to 45.5 cents with 81.4 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has dosed the first patient in the second cohort of City of Hope’s up to 36-patient phase I trial of chlorotoxin chimeric antigen receptor T-cells therapy.

Last month, Chimeric said the first cohort received 44 million CAR-T-cells in the trial of chlorotoxin chimeric antigen receptor T-cells (CLTX-CAR-T) and at the 28-day follow-up showed no “dose-limiting toxicities” (BD: Apr 22, 2021).

Today, the company said the second cohort would receive a total target dose of 88 million CLTX-CAR-T cells administered by both intracranial intra-tumoral and intracranial intra-ventricular routes.

Chimeric fell half a cent or 1.7 percent to 28.5 cents with one million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it annual general meeting will vote on a 100-to-one consolidation of its stock, to elect directors and approve a 10 percent placement facility.

Visioneering said that if approved the number of shares and Chess depository interests (CDIs) on issue would be reduced from 2,363,512,855 to about 23,635,129.

The company said its 2,800,000 convertible notes convertible to CDIs at 2.8 cents would be deemed a conversion price of $2.80 if the consolidation was approved.

Visioneering said the meeting would vote to elect Jean Franchi and Andrew Silverberg as directors and approve the 10 percent placement facility.

The meeting will be held online on June 8, 2021 at 8am (AEST).

Visioneering was unchanged at 1.2 cents with 5.1 million shares traded.

BARD1 LIFE SCIENCES (MERGED WITH SIENNA CANCER DIAGNOSTICS)

Bard1 says its preliminary test of the “pan-cancer probe” protein Sub-B2m showed feasibility in an immuno-histochemistry in-vitro study on breast cancer tissue.

Last year, Sienna chief executive officer Carl Stubbings told Biotech Daily that Sub-B2M was “the B subunit of Subtilase cytotoxin (SubB) produced by Shiga toxigenic [Escherichia coli and] it specifically targets and binds to Neu5gc, which are tumor biomarkers” (BD: Apr 20, Jul 29, 2020).

Today, the company said the study compared the staining pattern of cancer issue from an invasive ductal breast cancer tumor biopsy to a non-cancer breast tissue biopsy which showed Sub-B2M-based immuno-histochemistry had a differential staining pattern in invasive breast cancer compared to the non-cancer tissue.

Bard1 said that after optimizing the staining for breast cancer tissue, it planned to extend its Sub-B2M immuno-histochemistry studies to other cancer applications

Bard1 chief scientific officer Dr Peter French said that “this is the first time Sub-B2M has been used in a histopathology application, and it demonstrated both initial feasibility in an [immunohistochemistry] application for breast cancer and compatibility with an automated staining instrument.”

Bard1 fell 23 cents or 9.5 percent to $2.19 with 851,119 shares traded.

NEUROTECH INTERNATIONAL

Neurotech says that in-vitro testing shows that its Dolce marijuana strains are “significantly more potent” than cannabidiol alone for multiple sclerosis neuro-markers.

Neurotech said that the research at the Royal Melbourne Institute of Technology showed that Dolce strains, comprising extracts of CBDA, CBGA, CBDB, CBDP and less than three percent tetrahydrocannabinol (THC) were superior to CBD alone.

The company said that Dolce marijuana reduced granulocyte-macrophage colony-stimulating factor by 40 percent and tumor necrosis factor by 30 percent, while cannabidiol alone had “no significant effect”.

Neurotech said the studies paved the way for further expansion and analysis of other neuro-markers involved in multiple sclerosis.

Neurotech chair Brian Leedman said there were “a number of very powerful neuro-markers that are currently being used to assess disease onset and progression”.

“To be able to suppress or regulate these markers may be very beneficial in the overall disease management,” Mr Leedman said.

Neurotech fell 0.3 cents or 5.2 percent to 5.5 cents with 1.2 million shares traded.

ACTINOGEN MEDICAL

Actinogen 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 rose 3.4 cents or 54.0 percent from 6.3 cents to 9.7 cents on May 24, 2021 and noted a “significant increase” in the trading volume.

During the course of trading, yesterday, Actinogen’s share price reached 9.9 cents.

Today, Actinogen retreated one cent or 10.4 percent to 8.6 cents with 51.7 million shares traded.

IMPEDIMED

Impedimed says it has “officially” released version 4.0 software of its Sozo digital health platform for patient health monitoring.
Impedimed said the version 4.0 had improved its user interface, added body composition reference ranges and segmental analysis, option to enter notes and tags, alignment of the Apple Iphone operating system and Android software for support, and enhanced privacy and security through multi-factor authentication and single sign on.
Impedimed was unchanged at 12.5 cents with 1.55 million shares traded.

MEMPHASYS

Memphasys has requested a trading halt in connection with “a potential capital raising”.
Trading will resume on May 27, 2021 or when the announcement is released to the market.
Memphasys last traded at 5.2 cents.

ANTERIS TECHNOLOGIES

New York’s Mercer Street Global Opportunity Fund says it has ceased its substantial shareholding in Anteris.
Mercer Street said that it sold 9,838 shares for $79,612 or $8.09 a share.
Biotech Daily calculates that Mercer Street holds 325,545 shares or 4.91 percent of