Biotech Daily

Wednesday August 7, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ATOMO UP 9%; AMPLIA DOWN 4%**

*** PFIZER $150m FOR MELBOURNE ANTI-MICROBIAL PLANT**

*** LBT $4.1m ASTRAZENECA APAS DEAL**

*** NEUREN EARNS $24.6m H1 ACADIA DAYBUE ROYALTIES**

*** NEXTSENSE OPENS $75m SYDNEY HEARING, VISION LOSS CENTRE**

*** BIONICS INSTITUTE: VICTORIA $500k FOR VAGUS-ARTHRITIS DEVICE**

*** ENLITIC SELLS CXR X-RAY FOR $764k TO CLAIRVO**

*** IMRICOR TREATS 1st US ATRIAL FLUTTER TRIAL PATIENT**

*** AROVELLA: FDA OKAYS PHASE I ALA-101 BLOOD CANCER TRIAL**

*** AMPLIA WINS EU, JAPAN NARMAFOTINIB PATENTS**

*** ISLAND: FDA OKAYS PHASE IIa/b ISLA-101 PROTOCOL CHANGES**

*** NEUREN REQUESTS 'TRIAL RESULTS' TRADING HALT**

MARKET REPORT

The Australian stock market was up a further 0.25 percent on Wednesday August 7, 2024, with the ASX200 up 19.2 points to 7,699.8 points. Twenty-five of the Biotech Daily Top 40 companies were up, eight were down, six traded unchanged and one was untraded.

Atomo was the best, up 0.2 cents or 9.1 percent to 2.4 cents, with 1.4 million shares traded. Universal Biosensors climbed 8.3 percent; Curvebeam was up seven percent; Percheron climbed 6.8 percent; Emvision was up 5.3 percent; Immutep improved 3.45 percent; Actinogen, Alcidion, Aroa, Dimerix, Imugene, Nova Eye and Polynovo rose two percent or more; Avita, Clinuvel, Compumedics, Impedimed, Medadvisor, Medical Developments, Mesoblast, Orthocell and Pro Medicus were up more than one percent; with Cochlear, CSL, Nanosonics, Proteomics and SDI up by less than one percent.

Yesterday's 50 percent best, Amplia, led the falls, down 0.5 cents or 3.7 percent to 13 cents, with 4.2 million shares traded. Clarity, Resonance and Starpharma lost more than three percent; Genetic Signatures shed two percent; 4D Medical, Opthea and Telix were down one percent or more; with Resmed down by 0.09 percent.

PFIZER INC

Pfizer Inc says it has invested $150 million to upgrade its Mulgrave pharmaceutical production plant for anti-microbial treatments, in Melbourne's Eastern suburbs.

The New York-based Pfizer said the facility would offer "pharmaceutical production facilities in Australia for new anti-microbial treatments aiming to help address rising levels of anti-microbial resistance, considered one of the biggest threats to global health".

The company said investment in the Melbourne site included the construction of an additional separate facility that included two freeze-drying machines known as lyophilisers, which were used in the anti-microbial manufacturing process.

Pfizer said the products currently manufactured at the site included treatments for cancer as well as anti-microbials, anaesthetics, anti-inflammatories and other medicines which were "exported to more than 60 countries worldwide and treated up-to 15 million patients each year".

The company said the site had been "selected for a trial of artificial intelligence (A.I.) technology designed to support key site processes".

Pfizer said the installation work on the upgrades were on track to be completed and operational "by mid-2025", with commercial manufacturing expected to begin "in 2026".

Pfizer closed on the Nasdaq down 42 US cents or 1.4 percent at $US29.32 ($A44.72) with 22.8 million shares traded.

LBT INNOVATIONS

LBT says it has an up-to $4.1 million contract with Astrazeneca to provide five of its automated plate assessment systems (Apas) for imaging microbiology culture plates.

Last year, LBT said it had a $1 million partnership with Astrazeneca to develop an automated plate assessment system 'pharma analysis module' into its APAS instrument (BD: Jan 22, 2023).

Earlier this year, the company's share price climbed as much as 2.4 cents or 171.4 percent to 3.8 cents on news it had validated its automated plate assessment system (Apas) Pharma QC, which was ready for commercialization (BD: Mar 13, 2024).

Today, LBT said the contract was for five Apas instruments, as well as the continued lease of a sixth instrument used by Astrazeneca for the technology's validation, as well as annual maintenance and support services for seven years.

The company said the total contract value was between $US2.2 million ($A3.4 million) and $US2.7 million ($A4.1 million) "depending on the level of maintenance and support services selected by Astrazeneca".

LBT said most of the contract value was "to be received as the instruments are installed, scheduled over the next six months".

LBT managing-director Brent Barnes said the agreement showed "the value the Apas technology provides and unlocks an initial roll-out of five instruments across a number of their large manufacturing operations".

"This decision was made based on demonstrated performance of the technology within the Astrazeneca manufacturing processes and provides credibility for the technology more broadly," Mr Barnes said.

"This milestone provides evidence and confidence that the Apas Independence is a fully validated technology that meets the stringent requirements for environmental monitoring during drug manufacturing, applicable to all customers globally for this application," Mr Barnes said. "Pleasingly, evaluations with additional multinational pharmaceutical customers are expected to commence in the current quarter."

LBT was up 0.3 cents or 20 percent to 1.8 cents with 43.5 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says Acadia reported net sales of Daybue for the six months to June 30, 2024 to be $US160.5 million ($A244.5 million), earning it royalties of $A24.6 million.
Last year, Neuren said it had maiden customer receipts for the six months to June 30, 2023 of $59,810,000 following payment by Acadia for the US approval of trofinetide, marketed as Daybue, for Rett syndrome (BD: Jul 31, 2023).
Today, the company said Acadia expected sales for the year to December 31, 2024 to be between $US340 million and $US370 million, earning it royalties of between $A55 million to $A61 million "plus sales milestone revenue of $77 million".
Earlier this year, Neuren said New York short-sellers Culper Research estimated Daybue revenue of $US316 million in 2024 falling to $US227 million by 2030 (BD: Feb 16, 2024).
Today, Neuren managing-director Jon Pilcher said that in the three months to June 30, 2024 "Daybue sales returned to growth and our phase II trial of NNZ-2591 in Pitt Hopkins syndrome again achieved highly encouraging results".
"We are optimistic about the large global market opportunity for Daybue and our share of those revenues provides a strong financial foundation to optimize the potential of NNZ-2591 in multiple indications," Mr Pilcher said.
Neuren said it had cash and cash equivalents of $A213 million at June 30, 2024, compared to $A85,675,000 at June 30, 2023.
Neuren was in a trading halt (see below) and last traded at $17.09.

NEXTSENSE (FORMERLY THE ROYAL INSTITUTE FOR DEAF & BLIND CHILDREN)

Nextsense says it has opened a $75 million innovation centre at Sydney's Macquarie University campus for the research, education and treatment of hearing and vision loss.
The Sydney-based Nextsense said it was "Australia's second oldest not-for-profit organization" and was supported by a $12.5 million from the Federal Government.
Nextsense was formerly Sydney's Royal Institute for Deaf & Blind Children.
The organization said the centre would deliver services to people with hearing and vision loss and provide research and practical knowledge for professionals in the field.
Nextsense said the centre would be the headquarters for its national operations and would include "allied health, disability and cochlear implant services for children and adults, a school and preschool, and a major research and professional education program".
The organization said the Macquarie University precinct would bring it "closer to its key partners … such as Macquarie University Hearing, Cochlear and Hearing Australia".
Nextsense said the centre would "be an important gateway to new partnerships …[with] between researchers, industry and governments" to trial ideas and drive better outcomes.
Nextsense chief executive officer Chris Rehn said the centre was "an important investment in removing barriers for people who are deaf, hard of hearing, blind or have low vision".
"We welcome the Australian Government's significant financial support of $12.5 million to this project, it will change lives and create new opportunities for the way education and services are delivered to all people with sensory disability," Mr Rehn said.
"We've come such a long way from our beginnings in 1860 when Thomas Pattison established us as Australia's first Deaf school," Mr Rehn said.
"Since then, we have achieved many firsts, from championing compulsory education in the 1900s for children who were deaf and blind, and pioneering teacher training in the 1930s, to creating the first digital version of the Auslan dictionary, building Australia's largest cochlear implant program, and launching the world's first online braille training program," Mr Rehn said.

BIONICS INSTITUTE

The Bionics Institute says it has a $500,000 grant from the Victorian Medical Research Acceleration Fund to develop vagus nerve stimulation for rheumatoid arthritis.
The Bionics Institute said the grant would help launch a clinical trial of the device, which used electricity to dampen the body's overactive immune response and prevent long-term damage, in late 2024.
The Institute said rheumatoid arthritis was "a chronic and debilitating auto-immune condition that affects over 20 million people worldwide, including almost 500,000 Australians".
The Bionics Institute chief executive officer Robert Klupacs said the funds from the Victoria Government would "help our researchers set up a comprehensive clinical trial of our revolutionary medical device for rheumatoid arthritis".
"Our aim is to help sufferers and their loved ones by getting the technology into doctor's clinics as soon as possible," Mr Klupacs said.

ENLITIC INC

Enlitic say it has sold its CXR focal opacity chest x-ray technology for $US500,000 ($A764,000) in cash to its Tokyo-based distributor Clairvo Technologies.
Last year, Enlitic opened on the ASX up 6.0 percent at 88 cents, having raised $21 million at 83 cents to list under the code 'ENL' to commercialize its Endex and Encog imaging software (BD: Dec 19, 2023).
Today, the company said Clairvo was a wholly-owned subsidiary of Marubeni Corporation, which held 12.3 percent of Enlitic and was a related-party of director Riichi Yamada.
Enlitic said it had assigned its right, title and interest in CXR focal opacity to Clairvo and granted Clairvo "perpetual non-exclusive licenses of certain patents relevant to CXR focal opacity and to certain Enlitic background [intellectual property] as needed by Clairvo to use and practice CXR focal opacity".
The company said Clairvo remained "a distributor of Enlitic's core products in Japan".
Enlitic was up 1.5 cents or 13.6 percent to 12.5 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says Johns Hopkins Hospital has performed its first interventional cardiac magnetic resonance (ICMR)-guided atrial flutter ablation as part of its VISABL-AFL trial.
Earlier this year, Imricor said it had approval for a 91-patient trial of its cardiac ablation catheter and irrigation pump products at the Baltimore, Maryland-based Johns Hopkins Hospital, Switzerland's Lausanne University Hospital and the Cardiovascular Institute of South Paris (BD: Jan 21, Mar 8, Apr 10, 2024).
Today, the company said it was "the first real-time ICMR-guided ablation procedure to ever be performed in the US".
Imricor managing-director Steve Wedan said the company had "been fortunate to work with some of the highest calibre doctors and medical teams across Europe, and to have such an esteemed institution like Johns Hopkins be the first US hospital to use the technology is a real privilege".
"We are on track to complete enrolment in VISABL-AFL this calendar year, and we hope to have [US Food and Drug Administration] approval mid-2025, thereby making real-time ICMR ablations available to patients and physicians throughout the US," Mr Wedan said.
Imricor fell 0.75 cents or 1.4 percent to 51.5 cents.

AROVELLA THERAPEUTICS

Arovella says the US Food and Drug Administration has provided “positive feedback” for its phase I study of ALA-101 for lymphoma and leukaemia.

Earlier this year, Arovella said it had developed the manufacturing process for large-scale production of ALA-101 chimeric antigen receptor-positive invariant natural killer T-cells (CAR-INKT) (BD: Jun 5, 2024).

At that time, the company said it could proceed with engineering batches to produce material for phase I clinical trials, and that final product characteristics were consistent with the expectations of regulators such as the FDA for quality and safety.

Today, Arovella said feedback from the pre-investigational new drug (IND) meeting supported its development plans to begin a phase I, first-in-human clinical trial, with “no major changes proposed for the development program”.

The company said that “very few allogeneic CAR-INKT cells have a received an IND acceptance to start first-in-human trials, so pre-IND feedback was critical to ensure that Arovella’s development plan for ALA-101 aligns with FDA expectations”.

Arovella said ALA-101 consisted of CAR19-iNKT cells modified to produce a chimeric antigen receptor (CAR) that targeted cluster of differentiation 19 (CD19), an antigen found on the surface of numerous cancer types.

The company said the FDA guidance included a review of its chemical, manufacturing and controls program, a plan for non-clinical safety and efficacy studies and the proposed phase I clinical trial design.

Arovella said it expected to file an IND for ALA-101 by April 2025.

Arovella managing -director Dr Michael Baker said that “the valuable and positive feedback we received from the FDA was excellent and aligns clearly with our development plans for ALA-101”.

“For a complex therapeutic like off-the-shelf CAR-INKT cells, our team has done a commendable job reaching this key milestone,” Dr Baker said.

“We look forward to receiving acceptance for our IND and executing our plan to advance ALA-101 into the clinic over the coming months,” Dr Baker said.

“Due to the platform nature of Arovella’s CAR-INKT cells, the learnings for ALA-101 throughout the IND application process can be applied to our additional solid tumour programs, such as ALA-105,” Dr Baker said.

Arovella was up half a cent or 3.45 percent to 15 cents with 1.8 million shares traded.

AMPLIA THERAPEUTICS

Amplia says the European and Japanese Patent Offices have granted patents for the specific chemical form of its focal adhesion kinase (FAK)-inhibitor narmafotinib.

Amplia said that in both jurisdictions the patent was titled ‘A salt and crystal form of a FAK inhibitor’ and would protect its intellectual property until “at least 2040”.

The company said the patent described “a stable, manufacturable form of narmafotinib that provides improved drug levels upon dosing” which was the form it was using in its phase IIa trial for advanced pancreatic cancer.

Amplia managing-director Dr Chris Burns said “the granting of this patent by two of the world’s most respected patent offices bodes well for granting of the patent in other jurisdictions, including the US and Australia”.

“Importantly from a commercial perspective, this patent extends protection for narmafotinib out to at least 2040,” Dr Burns said.

Amplia fell half a cent or 3.7 percent to 13 cents with 4.2 million shares traded.

ISLAND PHARMACEUTICALS

Island says the US Food and Drug Administration has approved a change to its phase IIa/b trial of ISLA-101 for dengue fever to include a therapeutic and prophylactic arm.
Earlier this year, Island said its 24-subject, single-ascending dose study showed that ISLA-101 achieved the required levels of blood concentration; and last month, said computer models of the study had confirmed a "predicted ideal single dose" for a phase II clinical study (BD: Apr 16, Jun 3, 2024).
At that time, the company said the data "potentially obviates" the need to conduct a phase II trial at multiple doses, reducing the costs and resources needed, and that it would submit the modelling data to the FDA with the study protocol for the phase II study, including an expansion from pure prophylactic focus to a therapeutic arm.
Last month, Island said it had filed a revised phase II study protocol to the FDA and would conduct a trial site initiation visit on July 11, 2024 (BD: Jul 4, 2024).
Today, the company said the amended randomized, placebo-controlled trial would administer a single dose level, twice daily across multiple days, and include a four-patient, prophylactic, or preventative, cohort as well as a 10-patient, therapeutic cohort.
Island said the FDA had requested it to wait until "the end of mosquito season, which occurs on October 1" to start infecting participants to ensure the public was protected from unwanted transmission.
The company said it expected to begin dosing "in late September and will start infecting on or after October 1" with a full readout of the prophylactic cohort expected "before the end of this calendar year" and dosing of the treatment cohort expected "in January 2025".
Island said the trial would be funded by a $US625,000 ($A962,000) grant from a US Congressionally Directed Medical Research Programs grant, and that due to the trial protocol amendments the remaining cost of the study was about $US1,080,000 ($A1,650,000) "substantially lower than prior estimates".
Island managing-director Dr David Foster said the company was "pleased to have now locked down our protocol for the ISLA-101 … study and have it registered, in preparation for final ethics approvals".
"We have worked hard to bolster our internal capabilities and as a result have not needed to engage a [clinical research organization] for this study," Dr Foster said.
"This strategy not only has streamlined efforts on protocol revisions, FDA communications and trial execution, but has substantially reduced costs enabling us to complete the phase IIa, prophylactic cohort of the … study with existing funds," Dr Foster said.
Island was up 1.1 cents or 18.0 percent to 7.2 cents with 1.1 million shares traded.

NEUREN PHARMACEUTICALS

Neuren has requested a trading halt pending an announcement "in relation to the top line results of its phase II clinical trial of NNZ-2591 in Angelman syndrome".
Trading will resume on August 9, 2024, or on an earlier announcement.