Biotech Daily

Wednesday June 7, 2023

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: POLYNOVO UP 16%; COMPUMEDICS DOWN 10%**

*** NEUREN RECEIVES $60m ACADIA DAYBUE/TROFINETIDE MILESTONE**

*** POLYNOVO 'RECORD' $7m MAY SALES**

*** AROVELLA 'COMMITMENTS' FOR $4.1m, PLAN FOR $1m MORE**

*** VOLPARA $1.4m BREASTSCREEN VICTORIA ANALYTICS DEAL**

*** PACIFIC EDGE TO LOSE $14m CXBLADDER US MEDICARE COVERAGE**

*** VAXXAS HEXAPRO COVID-19 PATCH TRIAL: SAFE, ANTIBODY RESPONSE**

*** CSIRO $25m FOR BIOTECH INNOVATION**

*** ACRUX: FDA APPROVES GENERIC ACZONE ACNE GEL**

*** PHARMAUST MONEPANTEL 'SAFE' FOR MND**

*** AVECHO COMPLETES TPM MARIJUANA GUMMIES DEVELOPMENT**

*** CLARITY RECRUITS PHASE II 64-CU-SAR-BOMBESIN PROSTATE CANCER TRIAL**

*** QUEENSLAND, EMORY UNIS COLLABORATE ON VACCINES**

*** AVITA AGM UP-TO 15.6% DISSENT**

*** WALKER GROUP REDUCES TO 5% OF ATOMO**

*** RYDER DILUTED TO 5.8% OF LUMOS**

*** MERCHANT BELOW 5% IN HEXIMA**

*** VAXXAS APPOINTS DR ROCHELLE CHAIKEN CMO**

MARKET REPORT

The Australian stock market fell 0.16 percent on Wednesday June 7, 2023, with the ASX200 down 11.6 points to 7,118.0 points. Nineteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and two were untraded.

Polynovo was the best, up 23 cents or 15.8 percent to $1.685, with 8.6 million shares traded. Cynata climbed 11.1 percent; Paradigm was up 9.4 percent; Actinogen improved 8.7 percent; Atomo and Nova Eye were up more than seven percent; 4D Medical was up 6.7 percent, Pharmaxis and Prescient climbed more than four percent; Antisense was up 3.3 percent; Avita and Genetic Signatures rose two percent or more; Cochlear, Emvision, Immutep, Medical Developments and Volpara were up more than one percent; with Clinuvel, CSL, Neuren and Pro Medicus up by less than one percent.

Compumedics led the falls, down two cents or 9.8 percent to 18.5 cents, with 1,101 shares traded. Universal Biosensors lost eight percent; Next Science and Orthocell fell more than four percent; Kazia and Starpharma shed more than two percent; Nanosonics was down 1.6 percent; with Cyclopharm, Opthea, Resmed and Telix down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says it has received a $US40 million ($A59.9 million) payment from Acadia Pharmaceuticals for the first commercial sale of Daybue (trofinetide) for Rett syndrome.
In March, Neuren said US partner Acadia had US Food and Drug Administration approval for Daybue, or trofinetide, for Rett syndrome (BD: Mar 13, 2023).
Today, the company said it was eligible to receive ongoing royalties on net sales of trofinetide in North America as well as milestone payments of up-to $350 million on achievement of a series of four thresholds of total annual net sales.
Neuren was up 11 cents or 0.8 percent to $13.31 with 474,037 shares traded.

POLYNOVO

Polynovo says it had record sales of $7.2 million in May 2023, with US sales up 97.3 percent to $5.2 million compared to the previous corresponding period.
Polynovo said the rest of the world sales were also a record for the month up 189.3 percent to $1.9 million, including “encouragingly strong sales” in Canada, Hong Kong and India, as well as a first-time order from the Middle East.
The company said total revenue for the 11 months to May 31, 2023 was up 54.5 percent from $38.3 million in the prior corresponding period to $59.1 million
Polynovo was up 23 cents or 15.8 percent to $1.685 with 8.6 million shares traded.

AROVELLA THERAPEUTICS

Arovella says it has “firm commitments” to raise $4.1 million in a placement at 4.5 cents a share, with a $1 million share purchase plan to follow.
Arovella said the placement price of 4.5 cents was a 12.4 percent discount to the five-day volume weighted average price to June 2, 2023.
The company said the share purchase plan would not be underwritten and hoped to raise a further $1 million.
Arovella said the funds would be used to progress ALA-101 towards a phase I clinical trial for patients with cluster of differentiation-19 (CD-19)-positive non-Hodgkin’s lymphoma, strengthen its pipeline and provide general working capital.
Arovella said the share plan had a record date of June 6, would open on June 15 and close on June 29, 2023.
Arovella fell 0.4 cents or eight percent to 4.6 cents with 2.3 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has a $1.4 million, five-year, software as a service contract with Breastscreen Victoria for its Analytics software.
Volpara said the contract with Melbourne’s Breastscreen Victoria included the implementation of its Volpara Analytics software to provide quantitative measures and guidance for technologists for “optimal positioning and compression techniques, leading to a higher-quality screening program and improved personalized care for women”.
Volpara said the installation of its software at Breastscreen was expected to be completed within three to six months, and the contract included annual payments which were anticipated to contribute to revenue growth by the end of the year.
The company said that Breastscreen Victoria’s public mammography screening program diagnosed 37 percent of all breast cancers in Victoria.
Volpara was up one cent or 1.3 percent to 76 cents.

PACIFIC EDGE

Pacific Edge says its Cxbladder urine-based genomic biomarker test for bladder cancer detection will cease to be covered by Medicare in the US from July 17, 2023.

Last year, Pacific Edge said proposed changes to the US Medicare local coverage determination (LCD) had "the potential to disrupt the reimbursement of Cxbladder" in the US (BD: Aug 1, 2022).

Last week, the company said Novitas, the insurer responsible for its US laboratory, must finalize or withdraw local coverage determination and a local coverage article for reimbursement of Cxbladder tests by June 9, 2023 (BD: Jun 2, 2023).

Today, Pacific Edge said the finalized local coverage determination by its Medicare administrative contractor, the Jacksonville, Florida-based Novitas, noted the Cxbladder tests were "not considered medically reasonable and necessary".

The company said "as a direct result of the LCD, Pacific Edge's revenue is expected to reduce substantially from current levels until Cxbladder tests regain coverage".

Pacific Edge said that for the year to March 31, 2023, tests for US Medicare and Medicare Advantage were about 60 percent of its 13, 800 US commercial tests, generating $NZ15.3 million ($A13.9 million), or 77.3 percent of total operating revenue; and from July 17, 2023 "all of these tests are expected to be impacted by this determination from Novitas".

Pacific Edge chief executive officer Dr Peter Meintjes said the company was surprised and disappointed with the finalized local coverage determination.

"While Novitas appears to have reviewed all the available evidence for Cxbladder, we believe that Novitas' analysis sought to predominantly emphasize negative comments in Cxbladder publications," Dr Meintjes said.

The company said it would explore all available legal options, including a potential appeal.

Pacific Edge fell 28 cents or 73.7 percent to 10 cents with three million shares traded.

VAXXAS PTY LTD

Vaxxas says its 44-participant, phase I trial of its high-density micro-array patch (HD-MAP) with the Covid-19 Hexapro vaccine candidate shows an antibody response.

Vaxxas said that the use of its HD-MAP with Hexapro was "safe and well tolerated with positive signals of antibody responses to Sars-Cov-2".

The company said Hexapro was "a second-generation version of the spike proteins used in all US-approved Covid-19 vaccines".

Vaxxas said that its micro-array patch had "the potential to simplify vaccination logistics and administration by eliminating or reducing the need for refrigerated distribution and storage, and potentially enable self-administration".

The company said the vaccine patches "were well tolerated, with no serious or severe adverse events".

"Analysis of samples from day-28 show the HD-MAP Covid-19 vaccine increased relevant antibody levels by 8-fold on average, and the antibody responses indicated a dose dependent trend," Vaxxas said.

Vaxxas chief executive officer David Hoey said the company was "very encouraged by the compelling early data and rapid progress of our needle-free Covid-19 vaccine candidate".

"We believe our patch-based delivery of a next generation spike protein has the potential to offer best-in-class protection against Covid-19 along with cost-effective distribution without the need for extensive refrigeration," Mr Hoey said.

Vaxxas said the patch used an "ultra-high-density array of projections, invisible to the naked human eye, applied to the skin as a patch sitting inside a small applicator device".

Vaxxas is a private company.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says it has provided $25 million over the four years to 2027 for the Advanced Engineering Biology program.
The CSIRO said that the Advanced Engineering Biology program was part of its Future Science Platforms and would “harness the building blocks of life to solve intractable problems”.
CSIRO Advanced Engineering Biology director Dr Robert Speight said the program would “integrate engineering and biology to develop solutions for broad-ranging issues from the environment and energy transition to food security and human health”.
“We’re only just scratching the surface of engineering biology’s potential,” Dr Speight said.
“The field is moving fast, and there’s still a lot left to discover about the biological building blocks of life - how they work, and how we could use them,” Dr Speight said.
“The applications of engineering biology are varied and range from improving plants to sequester carbon more effectively, to manufacturing sustainable alternatives to animal proteins, petroleum fuels, and harmful pesticides, and even engineering bio-sensors that can make on-the-spot medical diagnoses,” Dr Speight said.
The CSIRO said that the program would “focus on bio-manufacturing capabilities, as well as developing the technologies that underpin engineering biology, to make it faster, more predictable, and higher performing”.

ACRUX

Acrux says it has US Food and Drug Administration approval for its generic version of Aczone gel, or dapsone, a topical treatment for acne vulgaris.
Last year, Acrux said the patent litigation case in the US district Court of New Jersey with Almirall LLC over a generic version of Almirall’s Aczone gel had “concluded in its favor” (BD: May 30, 2022).
Today, Acrux said its abbreviated new drug application (ANDA) approval would allow it to manufacture and market its generic version of dapsone in the US, and that it had a commercial partner in place to market the product.
Acrux was up 0.4 cents or 9.1 percent to 4.8 cents with 1.1 million shares traded.

PHARMAUST

Pharmaust says interim results from its trial of monepantel for motor neuron disease show that tablets were well-tolerated and reached bloodstream therapeutic levels.
Pharmaust said the 24-hour pharmacokinetic data of cohort 1 and 2 patients taking 2mg/kg and 4mg/kg doses of monepantel, respectively, showed it had been absorbed, distributed and metabolized into monepantel sulphone in the patients’ plasma.
The company said the trial safety committee observed no serious adverse events and had approved the dose escalation of cohort 1 patients to cohort 3.
Pharmaust executive chairman Dr Roger Aston said the interim trial outcome was “excellent news”.
Dr Aston said the tablet formulation showed effective absorption of monepantel and the achievement of steady-state levels of monepantel sulphone the active metabolite of monepantel.
“We are delighted that patients on our drug for over seven months have shown good tolerance and no serious adverse events,” Dr Aston said.
“We now eagerly await the analysis of the biomarkers,” Dr Aston said.
Pharmaust fell half a cent or 6.5 percent to 7.2 cents.

AVECHO BIOTECHNOLOGY

Avecho says it has developed its tocopheryl phosphate mixture (TPM)-based edible marijuana gummies for medicinal patients and consumers.

Avecho said its TPM-cannabinoid gummies "out-perform standard products with faster onset and greater magnitude of effect".

The company said marijuana gummies were chewable, jelly-like preparations and were "increasingly popular dosage forms … as they provide an alternative method to consumption to smoking and vaping without the associated respiratory issues".

Avecho chief executive officer Dr Paul Gavin said TPM enhanced drug absorption through the cheeks and into the bloodstream which improved the dosage onset.

"We have always suspected TPM had the appropriate chemistry to promote buccal absorption but have not previously worked with a dosage form appropriate for this route of administration," Dr Gavin said. "While the pharmaceutical market is our priority, the value of recreational gummies with better absorption for the North American market cannot be underestimated or ignored […and] while we won't step into this space ourselves, we are already in discussions with third parties."

Avecho was up 0.1 cents or 20 percent to 0.6 cents with 7.7 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has completed recruitment of 30 participants in its phase II, investigator-led trial of 64-copper sarcophagine (Sar)-Bombesin for prostate cancer imaging.

Last year, Clarity said that the trial at Sydney's St Vincent's Hospital would assess the safety of 64-copper Sar-Bombesin, as well the diagnostic potential for men with negative prostate specific membrane antigen (PSMA) positron emission tomography (PET) or low PSMA expression disease in patients with suspected biochemical recurrence of prostate cancer, and patients with metastatic castrate-resistant prostate cancer not eligible for PSMA therapy (BD: Aug 22, 2022).

Today, Clarity executive chair Dr Alan Taylor said the company believed that Sar-Bombesin "will not only be used as a stand-alone product for diagnosing and treating prostate cancer, but also in combination with PSMA agents to identify and treat both PSMA as well as [gastrin-releasing peptide receptor] expressing tumors for the most optimal therapeutic outcome".

Clarity was up two cents or 2.7 percent to 77 cents.

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says that Queensland "will become a major international hub for vaccine discovery and development" with Atlanta, Georgia's Emory University.

University of Queensland vice-chancellor Prof Deborah Terry said the universities would scale- up their collaboration on pandemic preparedness and regional disease prevention.

"The focus will be on rapid progression to clinical trial of a scaled-up number of vaccine candidates for the treatment of Asia-Pacific region viruses and infectious diseases, along with pandemic preparedness," Prof Terry said.

"This partnership will make Brisbane a centre for the Asia-Pacific region and [a] significant player of the burgeoning global biomedical industry," Prof Terry said.

The University said the partnership built on "more than a decade of collaboration in drug discovery" between it, Emory and the Queensland Institute of Medical Research through the Queensland Emory Development Alliance, which was renewed for a further 10 years.

AVITA MEDICAL

Avita says its annual general meeting passed all resolutions but the approval of the compensation of the company's executive officers faced 15.62 percent opposition.
Avita said there were 1,584,136 votes (15.62%) against the resolution to approve compensation to named executives and 8,557,983 votes (77.74%) in favor.
In April, the company said shareholders would vote to issue restricted stock units worth $87,500 and options to acquire shares worth $37,500 to each of six directors including chair Lou Panaccio, Prof Suzanne Crowe, Jeremy Curnock Cook, Jan Reed, Robert McNamara and Cary Vance (BD: Apr 17, 2023).
Today, Avita said the resolutions to re-elect the company's directors were passed with no opposition, but the resolutions to grant options and restricted stock units to the various directors were met with between 12.91 percent and 15.45 percent dissent.
According to the company's most recent ASX notification, it had 25,330,061 US shares or equivalents on issue.
Biotech Daily calculates that opposition to the executive pay resolution amounted to 6.3 percent of all shares on issue, sufficient to call extraordinary general meetings.
Avita was up 11 cents or 2.6 percent to $4.29 with 363,341 shares traded.

ATOMO DIAGNOSTICS

Walker Group Holdings Pty Ltd says it has reduced its substantial shareholding in Atomo from 37,660,718 shares (6.7%) to 28,818,122 shares (5.04%).
The Sydney-based Walker said that between February 9, 2023 and June 5, it sold shares in five separate transactions, with the largest sale on June 2 of 3,500,000 shares for $106,700, or 3.04 cents a share.
Atomo was up 0.2 cents or 7.7 percent to 2.8 cents.

LUMOS DIAGNOSTICS

Ryder Capital Ltd says its 17,393,032 substantial share-holding in Lumos has been diluted from 6.81 percent to 5.79 percent.
Ryder said that on five occasions between April 4 and June 2, 2023 it was diluted due to the issue of shares for the conversion of convertible notes.
Lumos fell 0.25 cents or 15.15 percent to 1.4 cents.

HEXIMA

Merchant Group Australia Pty Ltd says it has ceased to be a substantial shareholder in Hexima with the sale of 8,233,523 shares.
Yesterday, the Perth-based Merchant said that it had reduced its substantial shareholding to 12,923,523 shares, or 7.74% (BD: Jun 6, 2023).
Today, the firm said it sold 8,233,523 shares in three transactions on June 5 and 6, for $109,964 or an average of 1.34 cents a share.
Biotech Daily calculates that Merchant holds 4,690,000 shares or 2.81 percent of Hexima.
Hexima was unchanged at 1.3 cents with 2.6 million shares traded.

VAXXAS PTY LTD

Vaxxas says that it has appointed Dr Rochelle Chaiken as its chief medical officer, effective from June 6, 2023.

Vaxxas said that Dr Chaiken previously worked for Pfizer for 23 years and had "experience designing and executing late-stage clinical trials and successfully launching new products in markets".

The company said that Dr Chaiken held a Bachelor of Arts in chemistry from New York's University of Rochester and a Doctor of Medicine from Brooklyn's State University of New York.