Biotech Daily

Wednesday October 4, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTHEA UP 9%; CYCLOPHARM DOWN 11%**

*** CARB-X $2.75m FOR DOHERTY (ALTERITY) PBT2 FOR PNEUMONIA**

*** UNIVERSAL BIOSENSORS: EU APPROVES XPRECIA BLOOD SELF-TEST**

*** AROA: 'MYRIAD HEALS WOUNDS IN 14-TO-33 DAYS'**

*** PYC: PYC-001 'SAFE, EFFECTIVE' FOR ADOA, IN-VITRO, PRIMATES**

*** NOXOPHARM: CRO-67 FOR PANCREATIC CANCER FDA ORPHAN STATUS**

*** ALTERITY FILES $80m US SEC F-3 'AT-THE-MARKET' FORM**

*** CARDIEX STAFF CUTS; RECOUP $6m; $1.4m Q1 REVENUE; $516k GRANT**

*** DIMERIX REQUESTS 'LICENCING AGREEMENT' TRADING HALT**

*** NEUROTECH REQUESTS 'TRIAL RESULTS' TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.77 percent on Wednesday October 4, 2023, with the ASX200 down 53.2 points to 6,890.2 points. Nine of the Biotech Daily Top 40 stocks were up, 21 fell, six traded unchanged and four were untraded. All three Big Caps fell.

Opthea was the best, up three cents or 9.4 percent to 35 cents, with 133,822 shares traded. Universal Biosensors climbed 7.4 percent; Actinogen was up 5.3 percent; Pharmaxis rose 2.9 percent; Genetic Signatures, Next Science and Volpara were up one percent or more; with Neuren and Proteomics up by less than one percent.

Cyclopharm led the falls, down 33 cents or 11.4 percent to $2.57, with 197,586 shares traded, followed by 4D Medical down 11.1 percent to 48 cents, with 277,861 shares traded.

Cynata lost 7.4 percent; Imugene was down 6.4 percent; Polynovo shed 5.2 percent; Atomo, Emvision and Mesoblast fell four percent or more; Immutep, Impedimed, Micro-X, Nanosonics and Starpharma were down more than three percent; Alcidion, Avita, Orthocell and Paradigm shed two percent or more; Antisense and Clinuvel were down more than one percent; with Cochlear, Pro Medicus, Resmed and Telix down by less than one percent.

CARB-X, THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Boston's Carb-X says it will award $US1.75 million ($A2.75m) to the University of Melbourne and Doherty Institute to develop PBT2 for drug-resistant bacterial pneumonia.

The Boston University based not-for-profit Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (Carb-X) said PBT2 was originally developed to restore brain activity in patients with neurodegenerative disease, including Alzheimer's disease, but it was discovered that it disarmed "key pathways" by which bacteria become antibiotic resistant.

The company said the research team led by the Doherty Institute's Prof Christopher McDevitt aimed to use PBT2 to restore the ability of common antibiotics to eliminate bacteria.

"We were screening ionophore molecules for their antibiotic resistance breaking properties with a view to identifying the best candidate for future clinical trials until we realized that next door, at the Florey Institute and Alterity, they had also developed one, PBT2," Prof McDevitt told Biotech Daily.

"While PBT2 had been unsuccessful in treating neurological diseases, it was an ideal candidate to explore its potential in being repurposed for antimicrobial applications," Prof McDevitt said.

"We applied to Carb-X for funding to progress development of PBT2 in combination with amoxicillin or doxycycline to restore the efficacy of these antibiotics against drug resistant pathogens that cause community acquired bacterial pneumonia," Prof McDevitt said.

"In terms of stage of development, we're in the final stage of lead optimization with Carb-X, building on our prior in-vitro and mouse studies," Prof McDevitt said.

"We aim to progress into pharmacology and toxicology preclinical studies in the next two years, with human clinical trials to follow," Prof McDevitt said.

In 2020, the University of Queensland said that PBT2 had proven "effective at treating some of the most persistent, life-threatening antibiotic-resistant bacteria" in mice and had been shown to be "effective at disrupting and killing … Gram-negative bacteria that [caused] … pneumonia, bloodstream infections and meningitis" (BD: Nov 19, 2020).

In late December 2020, Alterity said it had licenced a technology from Uniquest to develop and commercial therapies to "combat antimicrobial resistance in superbugs", combining its PBT2 and other zinc ionophores with commonly used antibiotics to treat infections caused by multi-drug resistant bacteria (BD: Jan 17, 2021).

Prana had been developing PBT2 for Alzheimer's disease, with phase IIa efficacy data in 2008, but in 2014 an imaging trial of PBT2 for Alzheimer's disease did not meet its primary endpoint of reducing amyloid beta plaques (BD: Jul 30, 2008; Apr 1, 2014).

In March this year, Alterity said that it had been granted a US patent for acyl hydrazone compounds and licenced them and PBT2 to the Florey Institute of Neuroscience's Prof Colin Masters, who would "advance these compounds for the treatment of Alzheimer's and related diseases" and it had granted the rights and licence in exchange for future royalties of net sales (BD: Mar 14, 2023).

Prof Masters told Biotech Daily that PBT2 was developed from the anti-protozoal and anti-fungal clioquinol, or iodochlorhydroxyquin, so its repurpose for antibiotic resistance was not unusual.

Carb-X said the award was the first of its 2022-'23 funding rounds, with additional rounds for the development of further oral antibiotics, vaccines and rapid diagnostics to be announced this year.

The company said lower respiratory tract infections, including drug-resistant, community-acquired bacterial pneumonia, killed about 2.6 million people in 2019.

UNIVERSAL BIOSENSORS

Universal Biosensors says its Xprecia Prime 4U blood coagulation self-test monitoring device has been approved for sale in Europe.

The company said the approval by its notified body TÜV SÜD Product Service GmbH was through the EU Technical Documentation Assessment Certificate for in-vitro diagnostic medical devices for patient self-testing or near patient testing.

Universal Biosensors chief executive officer John Sharman said the company had "been working on the development and approval of the new Xprecia Prime 4U device for more than 18 months and this approval is an important step towards building a meaningful Xprecia business in Europe".

"The patient self-testing market is the fastest growing [prothrombin time test] market in Europe and when combined with the use of [prothrombin time test] devices and test strips in hospitals and clinic, we estimate the market is worth $365 million [a year]," Mr Sharman said. "More importantly, many of the hospitals and governments will only award tender 'wins' to products that have the approval for patients to take the device home and test themselves."

Universal Biosensors was up two cents or 7.4 percent to 29 cents.

AROA BIOSURGERY

Aroa says a 10-patient study shows its Myriad Matrix and Myriad Morcells sheep gut-derived product heals contaminated soft tissue wounds in 14 to 33 days.

Aroa said the study assessed 13 complex traumatic wounds, including injuries from motor vehicle accidents, abdominal dehiscence following hernia repair, Fournier's gangrene, compartment syndrome and pressure injuries, at a US trauma center between January 2021 and February 2023.

The study said the 13 wounds had a mean defect age of 3.5 weeks and a mean area of 217.3 square centimetres and were treated with ovine forestomach matrix, or Myriad products, as part of their inpatient surgical management and had a mean time to 100 percent granulation tissue formation of 23.4 days.

The study said it also used staged reconstruction in seven of 13 wounds, with the remaining six wounds left to heal via secondary intention using standard wound care protocols.

The study said there were no major postoperative infections of adverse events at a mean follow-up of 7.4 weeks.

The study said Myriad had shown "clinical success in the surgical management of soft tissue defects, especially in contaminated fields, and provides an effective option for immediate coverage of exposed vital structures before definitive closure".

The company said the study built on an increasing body of evidence demonstrating its Myriad products could be used to facilitate the formation of well vascularized soft tissue in patients with traumatic injuries.

Aroa said the study, titled 'Ovine Forestomach Matrix in the Surgical Management of Complex Volumetric Soft Tissue Defects: A Retrospective Pilot Case Series' was published in Eplasty and was available at: https://bit.ly/3LHMqPl.

Aroa chief executive officer Brian Ward said "with a [total addressable market] of $US740 million ($A1.2 billion), we expect the Myriad portfolio to continue driving strong growth".

"Based on our estimates, over 86,000 trauma procedures are performed in the US each year, and the [total addressable market] for those procedures is about $US300 million," Mr Ward said.

Aroa fell one cent or 1.3 percent to 76 cents.

PYC THERAPEUTICS

PYC says a single 16 microgram dose of PYC-001 for autosomal dominant optic atrophy (ADOA) was safe and effective in non-human primates and patient-derived models.
In April, PYC said that in-vitro and in-vivo data supported human trials of PYC-001 for autosomal dominant optic atrophy, pending formal toxicology studies (BD: Apr 3, 2023).
At that time, the company said its program for retinitis pigmentosa gave it a “very clear template and substantial read-through insight” for fast tracking the drug to human studies.
Today, PYC said autosomal dominant optic atrophy was a progressive blinding eye disease in children and PYC-001 addressed the “underlying cause”.
The company said PYC-001 had increased the amount of OPA1 protein in the retina of non-human primates at a safe and well-tolerated dose, and together with in-vitro results, the primate study provided a “comprehensive pre-clinical data pack in support of the clinical translational potential of the drug candidate in autosomal dominant optic atrophy”.
PYC said it was preparing an investigational new drug application to the US Food and Drug Administration for approval to begin human trials in 2024.
PYC chief executive officer Dr Rohan Hockings said “drugs targeting monogenic diseases already have the highest likelihood of success in human trials”.
“Now we can link this data from non-human primates with the results that we have generated in the ‘retina in a dish’ models from patients with autosomal dominant optic atrophy to demonstrate a fully integrated data pack suggesting that we can stop [the disease] … in its tracks,” Dr Hockings said.
PYC fell half a cent or 8.2 percent to 5.6 cents.

NOXOPHARM

Noxopharm says the US Food and Drug Administration has granted orphan drug designation for its CRO-67 dual-cell drug candidate for pancreatic cancer.
Last month, Noxopharm said that CRO-67 reduced pancreatic tumor volume by 56.7 percent (0.0013) and slowed growth rate by 48 percent, in mice (BD: Sep 28, 2023).
At that time, the company said CRO-67 targeted “pancreatic cancer in a different and innovative way” by killing tumor cells as well as the dense barrier cells surrounding them.
Noxopharm has not disclosed the derivation of CRO-67 nor its mechanism of action.
Today, the company said the designation was for drugs treating rare diseases or conditions, with benefits including tax credits for qualified clinical trials, exemption from fees such as FDA application fees as well as up to seven years of market exclusivity.
Noxopharm chief executive officer Dr Gisela Mautner said that “for CRO-67 to achieve an [orphan drug designation] is a significant milestone”.
Noxopharm was up 3.8 cents or 61.3 percent to 10 cents with 30.2 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has filed a US Securities and Exchange Commission F-3 form, allowing it to offer up-to $US50 million ($A79.4 million) in American depositary shares and warrants.
Alterity said each American depository share (ADS) was equivalent to 600 ordinary Australian shares and it might offer the shares “from time to time” in one or more series or issuances, with the shares listed on the Nasdaq under the ticker code ATHE.
Alterity chair Geoffrey Kempler told Biotech Daily the facility replaced an expiring facility, which it had done “for many years and it provides us the opportunity to use the ‘at-the-market’ facility or to do a direct raising”.
Alterity was unchanged at 0.7 cents with 2.65 million shares traded.

CARDIEX

Cardiex says it will cut costs and staff, attempt to recoup $6,408,000 Clinichain trial payments, has $1.4 million first quarter revenue and a $US325,000 ($A516,000) grant.

Cardiex said it would reduce two full-time roles in customer care and sales support, restructure employee pay plans towards shares rather than cash, transition two employees to hourly based contracts with about 50 percent pay reductions and temporarily “furloughed … some staff members”.

Last week, the company said it had withdrawn its registration with the US Securities and Exchange Commission and Nasdaq initial public offering, with executive director Jarrod White resigning (BD: Sep 28, 2023).

Today, Cardiex said it continued to review operations to reduce operating costs and had outsourced all financial operations, integrated its Conneqt and Atcor medical businesses into one operating business, and restructured some operational roles and resources.

The company’s last six Appendix 4C Quarterly reports said that on each occasion it had less than two quarters of cash but reported debt funding, convertible notes and an ability to raise capital, as well as receiving funds from operations.

Last year, Cardiex said the Almere, Netherlands-based trial support and procurement business Clinichain BV would use its Atcor Xcel devices and data management services in a 30-month, multi-site trial for the assessment of arterial health (BD: Dec 9, 2022).

At that time, the company said Clinichain had placed two orders with a total expected revenue to be “twice the 2021-’22 revenues for the entire business”.

In a corporate update on June 30, 2023, Cardiex said it had received more than $2,000,000 under the Clinichain agreement, but during May 2023 it was advised there were likely to be trial delays due to the changing requirements of the underlying customer.

The company said it was later advised the trial would conclude earlier than expected and it was in “commercially sensitive discussions” on how the agreement could be finalized given the provision of its Xcel Sphygmocor devices and data management services were non-cancellable.

At that time, Cardiex said it was “not expecting any material changes to the agreement including the originally estimated revenues and net cash receipts from the trial”.

Today, Cardiex said pursuant to its contract with Clinichain its services were non-cancellable and that it was enforcing its contractual rights through settlement discussions to recoup all outstanding contractual payments, worth about $6,408,000.

The company said that unaudited revenue for the three months to September 31, 2023 was up 143 percent to $1.36 million, primarily driven by its “traditional business” as well as sales and lease of its Xcel and Oscar 2 devices to pharmaceutical companies, research institutions and specialist clinicians.

Cardiex said US and Asia Pacific sales were more than doubled during the period as a result through expanded sales lead generation and data-driven targeting of prospective customers, and it expected increased revenue “to accelerate throughout the year with the recent addition of two new executive leads with proven success in lead generation and sales marketing”.

Cardiex said as part of the US National Institutes of Health’s Rapid Acceleration of Diagnostics Tech for Maternal Health Challenge it had received $US325,000 as an interim milestone cash payment for the technology assessment phase of the challenge, taking the total awarded to date to $US415,000.

The company said the Challenge was designed to accelerate the development and commercialization of a remote patient monitoring product for pregnant women or women who recently gave birth, with a further $US525,000 to come if successful in the final round.

Cardiex was in a voluntary suspension and last traded at 13.5 cents.

DIMERIX

Dimerix has requested a trading halt “pending the release of an announcement regarding a licensing agreement”.
Trading will resume on October 6, 2023 or on an earlier announcement.
Dimerix last traded at 6.1 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested a trading halt pending results from its phase I/II trial of marijuana-based NTI164 for paediatric autoimmune neuro-psychiatric disorders.
Trading will resume on October 6, 2023 or on an earlier announcement.
Neurotech last traded at 6.7 cents.