Biotech Daily

Monday July 11, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PATRYS UP 4%; NOVA EYE DOWN 9%**

*** HEXIMA WINDING UP AFTER HXP124 FAILS NAIL FUNGUS TRIAL**

*** US FDA KNOCKS BACK LUMOS FEBRIDX**

*** EYE CO PREPARES FOR 2 FLUDROCORTISONE PHASE II TRIALS**

*** ANTERIS: DURAVR 'CLINICAL IMPROVEMENT' AT 30-DAYS**

*** TELIX ZIRCON TLX250-CDX KIDNEY CANCER IMAGING TRIAL ENROLED**

*** ALTHEA MARIJUANA RECEIPTS UP 113% TO $22m**

*** RESPIRI: UK NIHR $3.5m WHEEZO CHILD ASTHMA TRIAL**

*** IMPEDIMED: TWO RISK FACTOR PAPERS PUBLISHED**

*** ANTEO LITHIUM-ION BATTERYANTEOX 'VALIDATED'**

*** JM BELOW 5% OF UNIVERSAL BIOSENSORS**

*** CLIME REDUCES TO 7.3% OF MACH7**

*** TELIX APPOINTS KEVIN RICHARDSON AMERICAS CEO**

*** RECCE APPOINTS DR PHILLIP SUTTON TRANSLATIONAL SCIENCE HEAD**

*** ARGENICA APPOINTS PROF JEFFERY SAVER ADVISER**

MARKET REPORT

The Australian stock market fell 1.14 percent on Monday July 11, 2022, with the ASX200 down 75.8 points to 6,602.2 points. Six of the Biotech Daily Top 40 stocks were up, 24 fell, seven traded unchanged and three were untraded.

Patrys was the best, up 0.1 cents or 4.35 percent to 2.4 cents, with 1.3 million shares traded. Orthocell climbed 3.95 percent; Imugene and Starpharma rose more than two percent; Neuren and Next Science were up by more than one percent; with Cochlear and CSL up by less than one percent.

Nova Eye led the falls, down two cents or 9.3 percent to 19.5 cents, with 174,331 shares traded. Antisense, Atomo and Volpara lost more than seven percent; Paradigm was down 5.4 percent; Alcidion fell four percent; Compumedics, Genetic Signatures, Medical Developments and Pro Medicus were down more than three percent; Clinuvel and Emvision shed more than two percent; Cynata, Immutep, Impedimed, Mesoblast, Nanosonics, Opthea, Pharmaxis, Resmed, Resonance and Universal Biosensors were down more than one percent; with Avita, Polynovo and Telix down less than one percent.

HEXIMA

Hexima fell a further 48.15 percent on news that following the failure of HXP124 to show efficacy for nail fungus it had begun the process of winding-up activities.

Last month, Hexima fell 84.6 percent to four cents on news that its phase II clinical study of pezadeftide (HXP124) for onychomycosis was “inconclusive … [and did] not support moving directly into a phase III program” (BD: Jun 24, 2022).

Hexima said the results “do not appear to correlate with results observed in its prior phase I study (HXP124-ONY-001) and do not support moving directly into a phase III program”.

Last year, Hexima said it had enroled 117 patients in its phase IIb, randomized, controlled study of pezadeftide (HXP124) for onychomycosis or nail fungus (BD: Jul 26, 2021).

In 2020, Hexima returned to the ASX following a $3.3 million initial public offer at 20 cents a share to fund the HXP124 for onychomycosis trial (BD: Dec 4, 2020).

Previously, Hexima said it had it raised $40 million in an initial public offer to list on the ASX in 2007 and delisted in 2011 (BD: Nov 22, 2013).

In 2020, the company said it received $5.5 million in a placement for the phase IIb trial.

Today, Hexima said that subjects were randomised to receive once daily topical application of 2.0% (20mg/mL) pezadeftide or vehicle to all infected toenails in one of three cohorts: two treatment periods of six weeks; two treatment periods of six weeks plus once-weekly maintenance dosing for 23 weeks; five treatment periods of 6 weeks plus one treatment period of one week.

The company said that of 117 patients enrolled, 14 were withdrawn or dropped out prior to completing the study, with patients assessed for safety and efficacy at scheduled visits during the study and at the final follow-up visit at week-40.

Hexima said that pezadeftide was well-tolerated and safe, with three serious adverse events (fall, angina and depression) reported and none drug-related, with 114 adverse events primarily mild, with no unexpected treatment emergent adverse events, and were similar for pezadeftide and control patients, regardless of cohort.

The company said there was “no consistent effect observed in pezadeftide-treated patients at week-40 compared to vehicle-treated, with the best efficacy results observed in cohort 2.

Hexima said that the data provided “evidence of modest activity of pezadeftide in the treatment of onychomycosis … [but it did] not believe the data [supported] the company’s goal of developing a safe, more effective and convenient topical therapy with a shorter course of treatment”.

“Accordingly, Hexima intends to wind down its development program of pezadeftide for the treatment of onychomycosis in an orderly fashion, and will make no further significant investment,” the company said.

Hexima said it had an open investigational new drug application with the US Food and Drug Administration to begin a phase I maximal use clinical trial in the US, but that study had not begun and was on hold with no further meaningful related expenditure.

The company said it had begun a process of winding up its manufacturing and non-clinical development activities with expenses associated with non-essential employees and contractors “being managed in a cost effective and orderly manner”.

Hexima said it was exploring options to secure value for its intellectual property and residual cash of $4.0 million at June 30, 2022, with a Federal Research and Development Tax Incentive of $5.6 million expected, offset by liabilities of about $9.2 million, but did not include non-current tangible assets including its glasshouse facility, leased to a third party and valued at $900,000, for which it was seeking expressions of interest for the purchase or longer-term lease.

Hexima fell 1.3 cents or 48.15 percent to 1.4 cents with 42.4 million shares traded.

LUMOS DIAGNOSTICS

Lumos says the US Food and Drug Administration has not granted it 501(k) clearance to market its Febridx finger-prick blood test to differentiate bacterial from viral infections.
Lumos said the FDA found that Febridx "did not demonstrate substantial equivalence to the predicate device".
The company said the test had met "success criteria defined before the pandemic in accordance with the pre-submission".
Lumos said that given the number of reported cases and deaths from severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) in the US, "the FDA expressed concerns regarding the risk that false negative viral infection test results could lead to missed opportunities to treat patients or contribute to the further spread of Sars-Cov-2 infections.
The company said it was evaluating options to secure FDA clearance, which might include an appeal that would result in a decision within 90 days, or a new 510(k) submission.
Lumos said the Febridx device was registered in the UK, Europe, Canada, United Arab Emirates, Brazil and Australia.
Lumos chief executive officer Doug Ward said "clearly this was not the outcome that the company was seeking and this decision from the FDA is a significant disappointment".
"The US launch of Febridx was a key component of Lumos' future commercial plans [and] Mr Ward said he would work with the regulatory team and advisors to develop a revised commercial plan to incorporate "the unexpected development".
Lumos fell 10.8 cents or 65.45 percent to 5.7 cents with 23.05 million shares traded.

EYE CO PTY LTD

Eye Co says that following its fludrocortisone acetate for dry, age-related macular degeneration safety study it intends to proceed with two pivotal phase II studies.
Eye Co said the first study aimed to confirm fludrocortisone acetate efficacy for geographic atrophy and the second would determine efficacy as rescue therapy in patients not responding to anti-vascular endothelial growth factor (VEGF) treatment.
Last year, Eye Co said that its phase Ib study of intravitreal fludrocortisone acetate for dry, age-related macular degeneration found no evidence of any ocular or systemic adverse events (BD: Nov 1, 2021).
The company said that patients in the first-in-human study were monitored for five months following the injection with "no evidence of intra-ocular pressure spikes or cataract development commonly associated with products injected into the eye".
Eye Co said fludrocortisone acetate was a potential treatment for geographic atrophy, associated with the dry form of age-related macular degeneration and the drug had "significant potential in the treatment of other major retinal diseases".
The study, titled 'Phase 1B study of the safety and tolerability of the mineralocorticoid fludrocortisone acetate in patients with geographical atrophy' was published in Open Ophthalmology and was available at: https://bmjophth.bmj.com/content/7/1/e001032.
Eye Co said the new class of compound potentially was "able to provide the treating ophthalmologist with a powerful addition to their ability to treat retinal diseases".
The company said the class of compounds was known as mineralo-corticoids with fludrocortisone acetate an anti-inflammatory and anti-exudative addressing the pathology of diabetic macular oedema and both wet and dry age-related macular degeneration.
Eye Co said the phase Ib study suggested that in dry age-related macular degeneration fludrocortisone might retard geographic atrophy lesion spread, addressing chronic inflammation and improving rod function.
Eye Co is a private company.

ANTERIS TECHNOLOGIES

Anteris says eight patients in its second cohort of its treated cow tissue Duravr trans-catheter heart valve trial showed “clinically significant improvements” after 30 days.
In May, Anteris said the first-in-human study was conducted at Georgia’s Tbilisi Heart and Vascular Clinic (BD: May 31, 2022).
In January, the company said five patients in the first cohort of its 10-patient Duravr trial met or exceeded their study objectives (BD: Jan 24 ,2022).
Today, Anteris said there was an average 81 percent decline in mean pressure gradient (range: 89% to 75%), and an average 300 percent increase in effective orifice area (range: 217% to 582%) “denoting a marked [improvement] in the valve’s surface area and … improved blood flow”.
Anteris chief medical officer Dr Chris Meduri said “we continue to be excited about the superior haemo-dynamic performance of the Duravr system despite small annuli and complex anatomy”.
“Its remarkable flow characteristics are as close to a normal human aortic valve as we have seen, a testament to the unique [three-dimensional] tissue design,” Dr Meduri said.
Anteris fell 35 cents or 1.25 percent to $27.70.

TELIX PHARMACEUTICALS

Telix says it has dosed the final patient in its 300-patient, Zircon, phase III study of TLX250-CDx for the imaging of renal, or kidney, cancer.
In March, Telix said the 300 patients exceeded the target enrolment of 252 patients, at 34 sites in Europe, Australia, Turkey, Canada and the US (BD: Mar 8, 2022).
Today, the company said the confirmatory, prospective, multi-centre phase III zirconium imaging in renal cancer oncology (Zircon) trial would examine the diagnostic, surveillance and staging ability of TLX250-CDx, which images clear-cell renal cancer with positron emission tomography (PET).
Telix said it expected results from the study by the end of 2022.
Telix chief medical officer Dr Colin Hayward said “the completion of this trial will bring us a step closer to commercialization for this diagnostic imaging agent which may address a significant unmet need in the diagnosis and management of [clear-cell renal cancer]”.
Telix fell two cents or 0.4 percent to $5.45 with 595,766 shares traded.

ALTHEA GROUP HOLDINGS

Althea says its customer receipts for the year to June 30, 2022 were up 113 percent to $21,954,000 compared to the previous corresponding period.
Althea said for the year to June 30, 2022, it had $10.8 million in receipts from the sale of recreational marijuana products, while pharmaceutical marijuana products accounted for $11.2 million of its receipts.
The company said for the three months to June 30, 2022 it had a “record” $3.6 million in receipts from the sale of recreational marijuana products and $2.9 million from pharmaceutical marijuana products.
Althea said it had cash and cash equivalents of $6,569,000 at June 30, 2022, providing cash for 5.81 quarters.
Althea was up 1.7 cents or 21.25 percent to 9.7 cents with 3.1 million shares traded.

RESPIRI

Respiri says the UK National Institute for Health Research will fund a GBP2 million ($A3.5 million) trial of its Wheezo device with 1,464 paediatric patients with asthma.
Respiri said that London's King's College would assess the impact of the Wheezo device when combined with a standard integrated care approach for asthma, and its effectiveness and cost utility.
The company said the technology enhanced integrated asthma care (Team-care) trial was a three-arm, randomized, 30-month, 1,464 patient study aiming to assess outcomes for children with asthma using remote patient monitoring (RPM) technology.
Respiri said the primary endpoint was unscheduled health service use versus control, and that secondary endpoints included child-health related quality of life, asthma control, use of medicines and primary or secondary healthcare services use.
The company said the trial was expected to begin towards the end of 2022, with results expected by the end of 2023.
Respiri managing-director Marjan Mikel said "the world class key opinion leaders who have successfully been awarded this grant, fully understand the importance of RPM solutions in respiratory medicine, especially in children, as does the NIHR given the significant cost of asthma to the UK healthcare system".
"It is pleasing the NIHR have funded this trial, as the Team-care trial will provide robust health economic evidence for potential [National Healthcare Service] adoption of new RPM technologies like Wheezo, which we believe will show positive health outcomes for asthmatics and a lower the cost burden for government funded health systems with this major trial," Mr Mikel said.
Respiri fell 0.1 cents or two percent to five cents.

IMPEDIMED

Impedimed says a paper on the risk factors for breast cancer-related lymphoedema has been published in the journal Cancer.
Impedimed said the article, titled 'Risk factors for breast cancer-related lymphedema in patients undergoing 3 years of prospective surveillance with intervention' was available at: https://acsjournals.onlinelibrary.wiley.com/doi/10.1002/cncr.34377.
The company said the findings included: supporting the use of a prospective surveillance model of care, identifying patients who might benefit from more frequent follow-up, that residing in a rural location increased risk, and that air travel did not increase risk.
Impedimed said that an editorial, titled 'Preventive strategies for breast cancer–related lymphedema: Working toward optimal patient selection', was commissioned to be published alongside the article and was available at: https://acsjournals.onlinelibrary.wiley.com/doi/10.1002/cncr.34374.
The article said "all individuals at risk of lymphoedema following breast cancer should have access to a prospective surveillance and early intervention (PSEI) model of care".
"Risk factors … have been previously established outside of the PSEI model, and this study supports these findings within the context of the PSEI model," the articla said.
In 2018, Impedimed said a study using data from its 500-patient Prevent trial of its L-Dex device for measuring lymphoedema had been published in the journal Lymphatic Research and Biology (BD: Aug 23, 2018).
At that time, the study authors recommended "an aggressive measurement protocol consisting of an L-Dex assessment every three months, especially during the first six to 12 months post-surgery to facilitate identification of sub-clinical lymphoedema".
Impedimed fell 0.1 cents or 1.7 percent to 5.7 cents with 7.6 million shares traded.

ANTEOTECH

Anteo says two battery companies have validated the performance of its drop-in, cross-linker additive, Anteox for lithium-ion battery anodes.
Anteo said the Tokyo-based Enax Inc showed there was a “substantial uplift in electrochemical performance” as well as a higher energy density anode.
The company said an unnamed battery manufacturer showed Anteox provided benefit to binder formulations, with enhanced capacity retention for all formulations tested.
The company said it would continue to work with both parties to further validate its technology.
Anteo was up 0.4 cents or five percent to 8.4 cents with 29.8 million shares traded.

UNIVERSAL BIOSENSORS

Melbourne’s JM Financial Group says it has ceased its substantial shareholdings in Universal Biosensors.
Last month, JM said it had reduced and been diluted in Universal Biosensors to 13,443,319 shares (6.34%) (BD: Jun 17, 2022).
Today, JM said between June 8 and July 6, 2022 it sold shares, with the single largest sale of 1,000,000 shares on July 6 for $370,000 or 37 cents a share.
Universal Biosensors fell half a cent or 1.4 percent to 35 cents.

MACH7 TECHNOLOGIES

Clime Investment Management says it has reduced its substantial share-holding in Mach7 from 20,544,804 shares (8.62%) to 17,445,090 shares (7.30%).
The Sydney-based Clime said that between March 22 and July 7, 2022 it bought and sold shares at prices ranging from 51 to 80 cents a share.
Mach7 was up 2.5 cents or 4.8 percent to 55 cents.

TELIX PHARMACEUTICALS

Telix says it has appointed Kevin Richardson as chief executive officer of Telix Americas, effective from July 11, 2022.
Telix said Mr Richardson had 25 years of experience in the healthcare industry, working most recently as Uroshape Medical’s chief operating officer, as well as Sirtex Medical, St Jude Medical and Boston Scientific.
According to his Linkedin page, Mr Richardson held a Bachelor of Business Administration as well as a Master of Business Administration from the University of Texas at Arlington.

RECCE PHARMACEUTICALS

Recce says it has appointed Dr Phillip Sutton as head of translational sciences to advance its compounds across infectious disease programs.
Recce said that Dr Sutton had joined its scientific advisory committee in August 2020, and was previously CSL’s head of immunology.
The company said Dr Sutton had co-authored 99 publications; and according to his Linkedin page, Dr Sutton held a Bachelor of Science from the University of Bradford in West Yorkshire, as well as a Doctor of Philosophy from the University of Manchester.
Recce said Dr Sutton would contribute to development of its anti-infectives pipeline.
Recce fell 1.5 cents or 1.9 percent to 78.5 cents.

ARGENICA THERAPEUTICS

Argenica says it has appointed Prof Jeffery Saver to its clinical advisory committee.
Argenica said Prof Saver was a professor at the University of California Los Angeles and the director of its Comprehensive Stroke Centre, and had been involved in more than 50 trials regarding strokes.
The company said that Prof Saver held a Bachelor of Arts and a Doctor of Medicine from Boston's Harvard University.
Argenica fell half a cent or 1.1 percent to 45 cents.