Biotech Daily

Monday August 8, 2022

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: ANTISENSE UP 17%; MEDICAL DEVELOPMENTS DOWN 19%**

*** LUMOS APPEALS US FDA FEBRIDX; HALTS $17m VICTORIA FACTORY**

*** MEDICAL DEVELOPMENTS INSTOS RAISE $20m; RETAIL FOR $10m MORE**

*** HYDRIX LOYALTY, PIGGYBACK OPTIONS TO RAISE $11.6m**

*** MAYNE: FDA (FINALLY) APPROVES NUVARING GENERIC CONTRACEPTIVE**

*** KAZIA: '9 OF 12 BRAIN METASTASES PATIENTS RESPOND TO PAXALISIB'**

*** IMUGENE: 'PD1-VAXX SAFE, 1 COMPLETE, 1 PARTIAL RESPONSE'**

*** VECTUS: 30mg VB0004 'SAFE, WELL-TOLERATED'**

*** NEUREN STARTS NNZ-2591 PHELAN-MCDERMID, PITT HOPKINS TRIALS**

*** PARADIGM TRIALS PPS, STEM CELLS FOR MPS-I**

*** FDA ACCEPTS ACRUX GENERIC COLD SORE CREAM APPLICATION**

*** ZELIRA TO ASX FURTHER AWARE QUERY: 'APPROVAL NEWS INFORMAL'**

*** BIONOMICS RECEIVES $2.1m R&D TAX INCENTIVE**

*** MESOBLAST TAKES 'PRIVATE PLACEMENT' HALT TO SUSPENSION**

*** PROTEOMICS TAKES PROMARKERD 'US LICENCE' HALT TO SUSPENSION**

*** SIO REDUCES, DILUTED TO 7% OF ANTERIS**

*** PATRYS TO LOSE CHAIR JOHN READ; MICHAEL STORK INTERIM**

*** MEDLAB APPOINTS MOHIT GUPTA DIRECTOR**

*** EPSILON LOSES EXECUTIVE DIRECTOR ROB JENNY**

MARKET REPORT

The Australian stock market edged up 0.07 percent on Monday August 8, 2022, with the ASX200 up 5.0 points to 7,020.6 points. Twenty of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and three were untraded.

Antisense was the best for the second trading day in a row, on no news, up 1.5 cents or 16.7 percent to 10.5 cents, with 2.3 million shares traded. Avita improved 13.2 percent; Paradigm was up 10.8 percent; Imugene improved 9.6 percent; Neuren climbed 6.4 percent; Polynovo was up 5.8 percent; Kazia and Resonance rose four percent or more; Actinogen, Opthea and Volpara were up three percent or more; Cyclopharm, Nanosonics and Starpharma rose more than two percent; Atomo, Cynata, Genetic Signatures, Immutep, Pharmaxis and Telix were up more than one percent; with Cochlear and Resmed up by less than one percent.

Medical Developments led the falls, down 46 cents or 19.2 percent to $1.94, with 1.2 million shares traded. Micro-X lost 10.7 percent; Orthocell fell 5.7 percent; Nova Eye shed 4.8 percent; Impedimed and Oncosil lost more than three percent; Next Science and Prescient shed two percent or more; with Clinuvel and Pro Medicus down by more than one percent.

LUMOS DIAGNOSTICS

Lumos says it has filed an appeal to the US Food and Drug Administration over the decision not to grant 510(k) clearance to market Febridx in the US.

In July, Lumos said that the FDA had “concerns regarding possible risks associated with false negative viral infection test results … [and] determined that Febridx did not demonstrate equivalence to the predicate device and consequently it was not granted clearance for marketing in the US (BD: Jul 11, 2022).

Today, the company said that it “continues to believe that Febridx has an important role as an aid to differentiate bacterial from viral infections and to assist with initiatives focused on improving antibiotic stewardship”.

Lumos said it would continue “to pursue options to secure regulatory clearance to market Febridx in the US, including the filing of this appeal” expecting an outcome this year.

Lumos chief executive officer Doug Ward said that Febridx was “a key asset in our Lumos-branded product portfolio”.

“At this time, there is no rapid, point-of-care test available in the US that clinicians can use to help distinguish a bacterial respiratory infection from a viral infection,” Mr Ward said.

“We continue to believe that Febridx has an important role in correctly identifying patients who will benefit from antibiotics and, as such, has a role in initiatives to improve antibiotic stewardship,” Mr Ward said.

In a separate announcement Lumos said it would not participate in the establishment of a $17.2 million diagnostics manufacturing facility in Victoria.

In February, the company said the Victoria Government would support a factory to produce up-to 50 million severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen tests a year (BD: Feb 2, 2022).

Today, Lumos said it was not “in a position where it can commit to providing the capital investment and human resources required to support the establishment of such a facility within the intended timeframes” and had told the Victoria Government that it could not participate in the establishment of the facility at this time.

In its Appendix 4C quarterly report for the three months to June 30, 2022, Lumos said it had receipts from customers of $US2,266,000 ($A3,271,000), a cash burn of $US4,660,000, cash and equivalents of $US7,974,000 providing 1.71 quarters of funding available, and it was “cost-cutting and right-sizing” and would explore financing options.

Lumos was up 0.3 cents or 5.8 percent to 5.5 cents with 1.7 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has raised $20 million in its fully-underwritten, one for 9.5 pro-rata non-renounceable institutional offer and placement at $2.00 a share.

Last week, Medical Developments said it expected to raise $30 million in the placement and one-for-9.5 rights offer (BD: Aug 4, 2022).

At that time, the company said the offer price was a 16.4 percent discount to the 10-day volume-weighted average price to August 3, 2022, with one option exercisable at $2.80 by September 30, 2024, attaching to every 2.5 shares acquired under the capital raising.

The company said it intended to use the funds for business expansion, European growth strategy and investment in growth strategy”.

Today, Medical Developments said the placement raised about $15 million and the institutional rights offer raised about $5 million, with a take-up of 87 percent.

Medical Developments said the retail component would open on August 11 and close on August 25, to raise an additional $10 million.

Medical Developments fell 46 cents or 19.2 percent to $1.94 with 1.2 million shares traded.

HYDRIX

Hydrix says it will offer shareholders one loyalty option for each eight shares held at 0.5 cents each, with “piggyback” options to raise up to $11.6 million.
Hydrix said that if all the loyalty options were exercised at 12 cents each by December 31, 2023 it would raise $5.5 million.
The company said that for every two loyalty options exercised, investors would receive one “piggyback” option exercisable at 28 cents each by April 30, 2025 and if all of those were exercised it would raise a further $6.1 million.
Hydrix said the offer timetable would be issued “in the coming weeks”, with the funds to go to sales growth, improve margins and target profitability for the coming financial year.
Hydrix said the offer was fully underwritten by Adelaide’s Baker Young.
Hydrix was untraded at eight cents.

MAYNE PHARMA GROUP

Mayne says the US Food and Drug Administration has approved the abbreviated new drug application for its Haloette generic intra-vaginal hormonal contraceptive ring.
In 2018, Mayne said the FDA had accepted its abbreviated new drug application for generic Nuvaring intra-vaginal hormonal contraceptive device combined etonogestrel and ethinyl estradiol delivered over a three-week period (BD: Mar 20, 2018).
Last year, the company said the FDA had rejected its response to a complete response letter for its generic version of the Nuvaring (BD: Oct 7, 2021).
At that time, Mayne told Biotech Daily that the Nuvaring application was refiled with its development partner the Liège, Belgium-based Mithra Pharmaceuticals in March 2021.
Today, Mayne said that Haloette was its generic version of Nuvaring and it expected the commercial launch early next year.
The company said that under its agreement, it would pay Mithra EUR6 million ($A8.8 million) as a result of the FDA approval, and EUR1.6 million on the US commercial launch.
Mayne chief executive officer Scott Richards said the company was “very pleased to announce the approval of Haloette in the US and look forward to bringing this drug-device generic to market”.
Mayne was up half a cent or 1.5 percent to 34 cents with 4.6 million shares traded.

KAZIA THERAPEUTICS

Kazia says nine of 12 patients in its phase I trial of paxalisib for treatment of brain metastases experienced “complete or partial responses”.
Kazia said the up-to 36-patient, single-arm, dose-escalation, phase I trial of paxalisib (formerly GDC-0084) with whole brain radiotherapy for brain metastases was in two stages and had the primary endpoint of safety and tolerability (BD: Jul 22, 2019).
The company said that interim data from the first stage of the study showed that “all nine evaluable patients experienced complete or partial response, representing an overall response rate of 100 percent”.
Kazia said that it expected preliminary data from the second stage of the trial in 2023.
Kazia chief executive officer Dr James Garner said the company was “encouraged by this data and by the potential benefit it may indicate to this substantial and high-need group”.
“Radiotherapy is a ubiquitous component of the treatment paradigm for brain metastases, but resistance is common,” Dr Garner said. “[The] study has shown a very promising signal that paxalisib may help to potentiate the effect of radiotherapy.”
Kazia was up one cent or four percent to 26 cents with 1.3 million shares traded.

IMUGENE

Imugene says its PD1-Vaxx IMU-201 for non-small-cell lung cancer is generally safe and well tolerated, with one complete and one partial response in 14 patients.

In 2020, Imugene said it had dosed the first of 32 patients in its trial of the PD1-Vaxx checkpoint immunotherapy candidate for non-small cell lung cancer (BD: Dec 1, 2020).

Today, Imugene said four patients were in the 10µg/dose cohort, with one having a complete response; six were in the 50µg/dose cohort, with two having stable disease; and four were in the 100µg/dose cohort, with one a partial response and two stable.

The company said that by week-6, antibodies to IMU-201 were generated and sustained at high titers during treatment with 100µg PD1-Vaxx, with a dose dependent increase in antibody production in patients receiving the 100µg dose.

Imugene managing-director Leslie Chong said she was "encouraged that we are seeing positive signals with correlative biomarker data at such an early stage of our PD1-Vaxx phase I trial and we are now progressing to the phase Ib combination studies in treatment naïve patients".

"It's particularly gratifying to have followed a patient in the trial for over 18 months where their tumor burden has been reduced to zero," Ms Chong said.

"For such a late-stage patient, having a chemo-free alternative could mean a very real difference to their quality of life," Ms Chong said.

The poster concluded that IMU-201 was generally safe and well tolerated; the potential for immune related adverse events required evaluation of additional patients; IMU-201 monotherapy had an anti-tumor effect; and exploratory biomarker data indicated that IMU-201 was immunogenic and stimulated a sustained, antibody response.

The poster concluded that the data supported further evaluation of IMU-201 in non-small-cell lung cancer and the next steps were to evaluate the immune-mediated response to IMU-201 and to combine it with the check point inhibitor, atezolizumab.

Imugene was up 2.5 cents or 9.6 percent to 28.5 cents with 52.2 million shares traded.

VECTUS BIOSYSTEMS

Vectus says the second cohort dosed with VB0004 in its phase I/Ib trial in up-to 88-patients with hypertension, showed safety and tolerability, with no adverse events.

In May, Vectus said it had begun a multiple ascending dose cohort of its 40-volunteer phase I trial of VB0004, following the completion of all five single ascending dose cohorts (BD: May 25, 2022).

Today, the company said the single-center, randomized, double-blind, placebo-controlled sequential phase I/Ib study would assess the safety, tolerability and pharmaco-kinetics of VB0004 in healthy volunteers and patients with mild to moderate hypertension and low cardiovascular risk.

Vectus said that patients received a 30mg dose of VB0004 for 14 consecutive days, with no significant adverse events reported, and that the interim pharmaco-kinetic analysis "confirmed that the time to achieve the maximal concentration of VB0004 occurred six to eight hours after dosing, and the plasma half-life was between 10 and 15 hours on both days one and 14".

Vectus said that the data suggested that "little to no accumulation of VB0004 occurred with time, in normal individuals".

The company said that it had permission for the third and final cohort to proceed, in which participants would receive 100mg of VB0004 per day for 14 days, with four participants already enrolled and starting the 14-day study.

Vectus was untraded at 84.5 cents.

NEUREN PHARMACEUTICALS

Neuren says it has begun two phase II trials of up-to 20 children each, for NNZ-2591 for Phelan-McDermid syndrome and Pitt Hopkins syndrome.

In March, Neuren said it had US Food and Drug Administration approval for the two trials of NNZ-2591 for Phelan-McDermid syndrome and Pitt Hopkins syndrome, and expected top-line results by July 2023 (BD: Mar 23; 25, 2022).

Today, the company said the trials would examine the safety, tolerability, pharmaco-kinetics and efficacy of 13 weeks of treatment with twice-daily, oral NNZ-2591, with titration up to the target dose during the first six weeks of treatment, followed by four weeks of observation, and an assessment two weeks after the end of treatment.

Neuren said the primary endpoints for each trial were safety and tolerability, as well as the severity and frequency of adverse events, and measure of standard pharmaco-kinetic parameters, with secondary outcomes to explore efficacy measures.

Neuren chief executive officer Jon Pilcher said the “seriously debilitating conditions have no approved medicines and we are eager to assess the potential impact of NNZ-2591, having observed highly encouraging effects in mouse models of each syndrome”.

Neuren was up 35 cents or 6.4 percent to $5.80 with 200,728 shares traded.

PARADIGM BIOPHARMA

Paradigm says that Adelaide Women and Children’s Hospital is evaluating pentosan polysulfate sodium in four muco-poly-saccharidosis type I (MPS-I) patients.

Paradigm said pentosan polysulfate sodium (PPS) was being trialed “as an adjunctive therapy to enzyme replacement therapy and/or haematopoietic stem cell transplantation in an open-label, single-centre, phase II trial”.

Paradigm chair Paul Rennie told Biotech Daily that PPS had been trialed in enzyme replacement, but this was the first time it had been studied with stem cell replacement.

The company said the study would evaluate safety and tolerability of PPS over an initial 48-week period, with a six-month treatment extension available, in patients treated with the current standard of care; with secondary and exploratory objectives included examining the effects of PPS on pain, function, and quality of life, pharmacokinetics, biomarkers, and inflammatory processes.

Paradigm said that three of four patients had completed the 48-week treatment regimen with no serious adverse events reported to date.

The company said that interim results indicated an overall trend toward providing meaningful improvements in pain, function, activities of daily living, and overall improvement in quality of life, and was well-tolerated at weekly doses of 0.75mg/kg and 1.5mg/kg for 47 weeks.

Paradigm said the results were expected to be presented in February 2023, by the Adelaide Women and Children’s hospital head of the metabolic clinic Dr Drago Bratkovic.

The company said that MPS-1 was “a relentlessly progressive and potentially fatal rare genetic disorder with a spectrum of disease”, caused by a reduction or absence in the amount of enzyme responsible for the catabolism, or break down, of glycosaminoglycans, resulting in the progressive accumulation of glycosaminoglycans in tissues.

Paradigm said the disorder caused problems with neurological, skeletal, and cardiovascular development, there was no cure and children born with the most severe form of MPS-I do not typically survive beyond 10 years of age, without treatment.

The company said that the current standard treatments included bone marrow transplant and enzyme replacement therapy to address the underlying cause of the disease.

Paradigm was up 18.5 cents or 10.8 percent to $1.905 with 1.1 million shares traded.

ACRUX

Acrux says the US Food and Drug Administration has accepted its abbreviated new drug application for its generic version of the acyclovir cream cold sore treatment.
Acrux said that the generic 5 percent acyclovir cream was used to treat herpes simplex virus-1, with the reference listed drug Zovirax Cream.
The company said the FDA notified it that its application was “sufficiently complete to be accepted for review” and was its sixth generic application accepted by the FDA.
Acrux managing-director Michael Kotsanis said his company was “extremely pleased to advance another product from its pipeline to FDA regulatory review”.
“Our key focus is on the continuing transformation of Acrux into a company with a diversified on-market portfolio and a well-planned pipeline of commercially valued products,” Mr Kotsanis said. “We have … two new product launches expected in the current financial year along with two further expected regulatory approvals that will subsequently be commercialized.”
Acrux was unchanged at 5.5 cents.

ZELIRA (FORMERLY ZELDA) THERAPEUTICS

Zelira has again told the ASX that a July 11 email preceding an announcement of German approval for its marijuana-based Zenivol for insomnia was “informal”.
In July, Zelira told an ASX price query that more buyers than sellers may have pushed its share price 94.1 percent, as investors began to better understand the company, prior to announcing German approval for Zenivol for insomnia. (BD: Jul 13, 2022).
The ASX said at that time that Zelira’s shares rose 94.1 percent from $1.02 on July 6 to $1.98 on July 12, 2022, prior to announcing German approval for its marijuana-based Zenivol for insomnia
After the market closed on July 18, Zelira says it was aware of German regulatory approval by way of an “informal email” and received formal approval for Zenivol for insomnia, on July 11 at 8pm (AWST) (BD: Jul 19, 2020).
Last Friday, August 5, after the market closed, Zelira published a letter dated August 4, responding to an ASX ‘Further aware query’ dated August 2, 2022.
The ASX asked Zelira to “provide a copy of the email received by ZLD at approximately 8.00pm (WST) on 11 July 2022 by which ZLD states it first became aware it had received formal regulatory approval in Germany (‘Email’) (not for release to the market)”.
Zelira said the email had been provided but did not publish that email.
The company said the first July 11 email was “informal as: the email took the form of an informal conversation between the sender and Mr Greg Blake of Zelira; the email was not clear on what was meant by federal authority, local authority and what steps remained in order to be in a position to announce; it was the company’s view that it was important it understood the distinction its partner was making before it announced the … approval”.
“As such, until this issue was satisfactorily clarified, there was uncertainty and the company was not in a position to announce,” Zelira told the ASX.
The company said that about 6am on July 13, it “received an email from its commercial partner, that did not raise any concerns regarding the content of the announcement but noted its commercial partner may have comments on the wording”.
“Following receipt of this email, Zelira was satisfied that the information within the announcement was sufficiently definite to warrant disclosure,” the company said.
“The company confirms that in its opinion it is, and has been at all times, in compliance with Listing Rule 3.1,” Zelira said.
Zelira fell 10 cents or 5.3 percent to $1.78.

BIONOMICS

Bionomics says it has received $2,085,453 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program.
Bionomics said the rebate related to research and development expenditure for the year to June 30, 2021.
Bionomics was unchanged at 5.2 cents.

MESOBLAST

Mesoblast has requested a voluntary suspension to follow last week's trading halt for an announcement "in relation to a proposed private placement" (BD: Aug 4, 2022).
Trading will resume on August 10, 2022 or on an earlier announcement.
Mesoblast last traded at 93 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested a voluntary suspension to follow its trading halt for an "announcement regarding licencing of the Promarkerd test in the US" (BD: Aug 4, 2022).
Trading will resume on August 9, 2022 or on an earlier announcement.
Proteomics last traded at 89 cents.

ANTERIS TECHNOLOGIES

The New York-based Sio Capital Management LLC says it has reduced and been diluted in Anteris, from 1,274,966 shares (12.61%) to 974,966 shares (7.02%).
Sio Capital said that on August 4, 2022 it sold 300,000 shares at $24.00 a share.
Last week, Anteris said Mercer Street Global Opportunity Fund had converted a portion of the $1,350,000 third tranche of its convertible shares but did not disclose how many shares were to be converted.
Anteris fell 44 cents or 1.6 percent to $27.16.

PATRYS

Patrys says non-executive chair and director John Read will retire, effective from the close of business on August 31, 2022, with Michael Stork as interim chair.
Patrys said Mr Read was its inaugural chair when it listed on the ASX in 2007.
Patrys managing-director Dr James Campbell said that Mr Read had made a "sustained and significant contribution to Patrys since his appointment as chair in May 2007".
"Patrys has transformed considerably under John's stewardship, and he leaves the company in a strong position and with a clear trajectory to becoming a clinical-stage company," Dr Campbell said.
"On behalf of the board, I would like to extend my heartfelt thanks to John and wish him every success in his future endeavors," Dr Campbell said.
The company said it had begun a search for a replacement chair.
Patrys was unchanged at 2.5 cents with 3.3 million shares traded.

MEDLAB CLINICAL

Medlab says it has appointed Mohit Gupta as a non-executive director, effective from August 8, 2022.
Medlab said Mr Mohit had spent the last 10 years in pharmaceutical companies, including at Viatris Pharmaceuticals.
The company said Mr Mohit had a Bachelor of Commerce from India's Delhi University and a Master of Business Administration from the Birla Institute of Technology and Science in Pilani, India.
Medlab was up $1.40 or 13.9 percent to $11.50.

EPSILON HEALTHCARE

Epsilon says Dr Rob Jenny has resigned as executive director, effective from August 7, 2022.
Epsilon said Dr Jenny had been an executive director since August 2021, as part of an arrangement between it and Melbourne's Cannvalate Pty Ltd marijuana company to secure a "broader strategic alignment".
The company said it would not consider a new appointment to its board at this time.
Epsilon fell 0.2 cents or 5.1 percent to 3.7 cents.