Biotech Daily

Monday February 28, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PATRYS UP 13%; DIMERIX DOWN 18%**

*** CLARITY: CHINA GRAND OPTION, $1.75 OPTIONS LAPSE**

*** HYDRIX PLACEMENT RAISES $2.8m**

*** KAZIA: PAXALISIB, METFORMIN, KETOGENIC DIET GLIOBLASTOMA TRIAL**

*** PATRYS PAT-DX3 STABLE PRODUCTION CELL LINE**

*** LUMOS H1 REVENUE DOWN 38% to $7m, LOSS UP 234% TO $15m; FEBRIDX**

*** TOTAL BRAIN H1 REVENUE UP 171% TO $5.4m, LOSS DOWN 36% TO $2.6m**

*** ANTERIS REVENUE UP 10% TO $8m, LOSS UP 50% TO $23m**

*** NUHEARA H1 REVENUE DOWN 57% TO $3m, LOSS UP 614% TO $6m**

*** RESONANCE H1 REVENUE DOWN 8% TO $1.9m, PROFIT TO $225k LOSS**

*** OSPREY REVENUE UP 17% TO $2.7m, LOSS DOWN 25% TO $14m**

*** UNIVERSAL BIOSENSORS: XPRECIA PRIME COAGULATION TEST CE MARK**

*** DIMERIX: REMAP-CAP TRIAL PAUSE; NO DMX-200 IMPLICATION**

*** NOXOPHARM STARTS VEYONDA COMBO SARCOMA TRIAL**

*** CRESO: CANADA APPROVES PSILOCYBIN FOR PTSD TRIAL**

*** ORTHOCELL PLANS 100k PA STRIATE DENTAL MEMBRANE UNITS**

*** CHINA PATENT FOR CYNATA CYMERUS STEM CELLS**

*** INCANNEX LISTS ADRs ON NASDAQ**

*** PROBIOTEC CEO WESLEY STINGER SELLS 1m SHARES, HOLDS 6.4%**

*** NANOMAB TAKES 10.7% IN RADIOPHARM**

*** JASON PETERSON BELOW 5% IN ZELIRA**

*** MESOBLAST LOSES 18-YEAR DIRECTOR DONAL O'DWYER**

*** LINDA JENKINSON REPLACES MEDADVISOR DIRECTOR, CHAIR CHRIS RIDD**

MARKET REPORT

The Australian stock market was up 0.73 percent on Monday February 28, 2022, with the ASX200 up 51.3 points to 7,049.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and one was untraded.

Patrys was the best, up 0.3 cents or 13.0 percent to 2.6 cents, with 11.5 million shares traded. Clinuvel climbed 8.1 percent; Uscom improved 6.7 percent; Orthocell was up 5.1 percent; Amplia, Avita, Cochlear, Compumedics, Kazia and Volpara climbed three percent or more; Alcidion, Mesoblast, Nova Eye and Universal Biosensors rose two percent or more; Immutep, Pro Medicus and Resmed were up more than one percent; with Emvision and Nanosonics up by less than one percent.

Dimerix led the falls, down four cents or 18.2 percent to 18 cents, with 6.2 million shares traded. Impedimed shed 5.9 percent; Genetic Signatures, Opthea, Paradigm and Telix fell more than four percent; Atomo, Cyclopharm, Medical Developments, Prescient, Neuren and Next Science were down three percent or more; Oncosil, Pharmaxis, Polynovo, Proteomics and Starpharma shed two percent or more; with CSL down by 0.5 percent.

CLARITY PHARMACEUTICALS

Clarity says the China Grand Pharmaceutical and Healthcare option to commercialize products in China has lapsed, along with 25,543,912 options, exercisable at $1.75 each.
Clarity said that China Grand had agreed to exclusive discussions for the grant of a licence to develop, manufacture and commercialize one or more of its products in the Greater China territory.
The company said that in consideration for exclusivity, China Grand entered into an option deed on July 1, 2021, with an expiration date on the earlier of a number of events including a period of six months from the date of listing on the ASX, and was issued 25,543,912 options exercisable at $1.75 each.
Clarity said that “those options lapsed and were cancelled at 5pm on February 25, 2022 … being six months from Clarity’s listing date and the exclusivity period for the licencing negotiations also expired at that time”.
The company said it was “clear to negotiate the Greater China territory on a non-exclusive basis”.
Clarity fell two cents or 3.1 percent to 63 cents.

HYDRIX

Hydrix says it has raised $2.82 million in a placement at 10 cents a share, to develop its cardiac devices and business development.
Hydrix said that the placement price was a 20 percent discount to the last closing price.
The company said that each new share would have an attaching option, exercisable at 18 cents by March 31, 2024.
Hydrix said that it had about 19 million listed 12 cent options which would expire on July 31, 2022 and provide a further $2.24 million if exercised.
The company said that Bell Potter Securities and Baker Young were joint lead managers and bookrunners to the placement, with Holding Redlich the legal adviser.
Hydrix fell 1.5 cents or 12 percent to 11 cents.

KAZIA THERAPEUTICS

Kazia says the first of up-to 60 patients has been screened in its phase II study of paxalisib, with metformin and a ketogenic diet for new and recurrent glioblastoma.
Kazia said that the first arm of the trial, at New York's Weill Cornell Medicine, would include patients with newly diagnosed glioblastoma who had unmethylated O-6-methylguanine-DNA methyl-transferase (MGMT) promotor status, who had "historically responded poorly to the current standard of care, temozolomide".
The company said the second arm included patients with recurrent disease, regardless of MGMT methylation status, who had progressed after taking standard-of-care therapy.
Kazia said that in each arm, paxalisib would be combined with metformin and with a ketogenic diet, with an initial 16 patients recruited to each of the two arms, and if there were signals of activity in a given arm, that arm would be expanded to about 30 patients.
The company said the primary endpoint would be progression-free survival at six months, and the study would examine safety, efficacy and a range of metabolic, pharmacodynamic and novel radiographic imaging biomarkers to inform future research and clinical practice.
Kazia said the study was expected to take about two years to complete.
The company said research had shown that a low-insulin state might enhance the activity of PI3K inhibitors, such as paxalisib, and inducing a 'ketogenic' state, in which the body was fueled by fats and proteins rather than by glucose, as an effective way to reduce insulin levels.
Kazia chief executive officer Dr James Garner said that beginning the study was an "important milestone" with paxalisib in eight separate trials "with at least six potential data read-outs anticipated over the course of 2022".
Kazia climbed 3.5 cents or 3.6 percent to $1.01.

PATRYS

Patrys says it has identified and selected an optimized stable cell line for commercial scale production of its full-sized immunoglobulin G (IgG) deoxymab, PAT-DX3.
Patrys said it could begin work on developing a commercial scale manufacturing process for good manufacturing practice grade PAT-DX3 deoxymab for its clinical development.
The company said that a stable, PAT-DX3-producing cell line was "an important milestone … [it had] achieved ahead of its scheduled timeline".
Patrys said PAT-DX3 was able to cross the blood brain barrier in animal models of brain cancer and penetrate cancer cells; and was able to be used as a targeting agent to deliver an anti-cancer drug in an animal model of human breast cancer.
The company said it was "actively exploring partnering opportunities for PAT-DX3 to be used in antibody drug conjugates for the targeted intra-cellular delivery of cancer drugs and a range of other payloads such as nucleic acids".
Patrys managing director Dr James Campbell said the company was "delighted to have identified a high-yielding stable cell line for the production of PAT-DX3 significantly ahead of schedule".
"There is a lot of interest in PAT-DX3 both as a therapeutic agent in its own right and for the intracellular delivery of therapeutic payloads into brain and other cells," Dr Campbell said.
"Most of the therapeutic antibodies in the market today are full-sized IgGs which should provide a rich experience base for facilitating the development of a process for the large-scale production of clinical grade PAT-DX3 deoxymab," Dr Campbell said.
Patrys was up 0.3 cents or 13.0 percent to 2.6 cents with 11.5 million shares traded.

LUMOS DIAGNOSTICS

Lumos says that revenue for the six months to December 31, 2021 fell 38.1 percent to $US5,202,000 ($A7,234,310) with net loss after tax up 234.1 percent to $US11,088,000 ($A15,443,588).

Lumos listed on the ASX last year to commercialize its Febridx point-of-care test to differentiate viral from bacterial infections and develop its Covidx severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen test (BD: Jul 9, 2021).

The company said diluted loss per share was up 92.2 percent to 7.38 US cents, with net tangible asset backing per share down 39.9 percent to 12.70 US cents, and it had cash and equivalents of $US10,464,000 at December 31, 2021.

Separately, the company said the Brazil's Health Regulatory Agency had granted market authorization for its Febridx test, which was approved in the UK, Europe, Canada, Australia and United Arab Emirates, with an application to the US Food and Drug Administration under review.

Lumos fell nine cents or 15.25 percent to 50 cents.

TOTAL BRAIN

Total Brain says revenue for the six months to December 31, 2021 was up 170.5 percent to $5,406,682 with net loss after tax down 36.2 percent to $2,586,984.

Total Brain said revenue increase came from sales and data licencing of its brain training devices and mental health platform, with the majority of revenue coming from the US.

The company said diluted loss per share fell 46.1 percent to 2.02 cents with net tangible assets per share down 44.8 percent to 2.33 cents, and it had cash and equivalents of $4,606,737 at December 31, 2021 compared to $3,707,272 at December 31, 2020.

Total Brain was unchanged at 12 cents.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

Anteris says revenue for the year to December 31, 2021 was up 10.1 percent to $7,790,975 with net loss after tax up 50.0 percent to $22,907,027.

Anteris said revenue came from manufacturing Cardiocel and Vascucel patches for heart tissue repair under its agreement with Lemaitre Vascular Inc (BD: Oct 14, 15, 2019).

Anteris said diluted loss per share was up 19.8 percent to $3.09 a share with net tangible asset backing per share up from 0.16 cents to $1.19, and it had cash and equivalents of $21,299,864 at December 31, 2021 compared to $4,354,355 at December 31, 2020.

Anteris fell 92 cents or 4.7 percent to $18.67.

NUHEARA

Nuheara says revenue for the six months to December 31, 2021 was down 57.0 percent to $2,973,759 with net loss after tax up 613.5 percent to $6,008,723.

Nuheara said its revenue came primarily from the sale of hearing and sound filtering devices, as well as medical device hearing final, but the Omicron Covid-19 surge meant that "tradition retail store hours in the US were limited throughout December".

Nuheara said diluted loss per share was up 350.0 percent from 0.06 cents in the previous year to 0.27 cents in the six months to December 31, 2021, with net tangible asset backing per share unchanged at 0.2 cents, and it had cash and cash equivalents of $6,252,569 at December 31, 2021, compared to $2,395,864 at December 31, 2020.

Nuheara was unchanged at 1.4 cents with eight million shares traded.

RESONANCE HEALTH

Resonance says revenue for the six months to December 31, 2021 fell 7.6 percent to $1,882,843 with the previous $769,665 profit turned to a $225,409 loss after tax.
Resonance said revenue was from sales of its Ferriscan, Ferrismart liver iron diagnostics and Hepafat AI (artificial intelligence), with its Liversmart device for liver iron and fat, receiving US approval in December, 2021 (BD: Jan 16, 2022).
The company said the previous 0.17 cents diluted earnings per share turned to a 0.05 cent diluted loss per share, net tangible assets per share was up 1.6 percent to 1.92 cents, and it had cash and equivalents of $7,835,059 at December 31, 2021 compared to $8,107,186 at December 31, 2020.
Resonance was unchanged at 14 cents.

OSPREY MEDICAL

Osprey says revenue for the year to December 31, 2021 was up 17.25 percent to $US1,960,265 ($A2,730,296) with net loss after tax down 24.9 percent to $US10,046,481 ($A13,990,754).
Osprey said that revenue came primarily from sales of its cardiac contrast reducing Dyevert system.
The company said that diluted loss per share was down 63.7 percent to 82 US cents with net tangible assets per share was down 24.9 percent to 40.1 US cents.
Osprey said it had cash and cash equivalents of $US5,386,483 at December 31, 2021 $US5,787,030 compared to at December 31, 2020.
Osprey was up 2.5 cents or 7.6 percent to 35.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has Conformité Européenne (CE) mark approval for its Xprecia Prime hand-held blood coagulation test.
Universal Biosensors said the approval meant the prothrombin time, international normalized ratio (PT-INR) test could be sold in 32 countries that recognized the CE mark.
The company said that the approval covered all components of the Xprecia Prime PT-INR coagulation system including the analyzer, controls and test strips.
Universal Biosensors said the approval was “the second milestone in [its] … growth strategy for PT-INR testing” and followed the purchase of the distribution network of more than 50 distribution relationships from Siemens Healthineers.
The company said that the annual European market for PT-INR testing was estimated at $370 million and it had more than 3,500 of its first generation Xprecia Stride analyzers being used in 36 countries, with about 2,000,000 PT-INR biosensor test strips manufactured and sold each year.
Universal Biosensors said that Xprecia Prime had a superior performance and expected to increase the installed base of Xprecia analyzers in Europe and increase the number of test strips sold.
The company said it had begun regulatory-directed Xprecia Prime clinical trials in the US (BD: Oct 27, 2021).
Universal Biosensors chief executive officer John Sharman said the company had “spent seven years and tens of millions of dollars developing Xprecia Prime which we believe will prove itself as the best performing PT-INR point-of-care device available anywhere in the world”.
Universal Biosensors was up two cents or 2.25 percent to 91 cents.

DIMERIX

Dimerix says that with 779 of about 800 patients recruited, the Remap-Cap Covid-19 trial has been paused, but safety concerns do not relate to its DMX-200.

In 2020, Dimerix said DMX-200 for kidney disease would be included in the Remap-Cap protocol for Covid-19 acute respiratory distress syndrome (BD: Jun 4, 2020).

The company said at that time that the randomized, embedded, multifactorial adaptive platform trial for community-acquired pneumonia (Remap-Cap) first began in 2013 and started recruitment in 2016.

Today, Dimerix said the trial had four arms with patients receiving angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), an ARB with DMX-200, or no renin angiotensin system (RAS) modulation, with all arms receiving standard-of-care.

Dimerix said that the Remap-Cap independent data safety monitoring board conducted a scheduled interim safety assessment to determine if the treatments were safe in patients with both severe and moderate Covid-19 and found safety concerns related to the use of ACE inhibitors and ARBs in patients with severe COVID-19.

Dimerix chief executive officer Dr Nina Webster told Biotech Daily that the severe patients were on ventilators in intensive care units and no safety signal had been detected relating to the use of the Dimerix drug DMX-200.

Dr Webster said the Remap-Cap trial had been paused pending further investigations but the pause had no impact on the Dimerix trials of DMX-200.

In the media release, the company said that of the 779 patients recruited into the study domain, 564 patients were assessed across the four treatment arms.

Dimerix said that the Board recommended that recruitment of patients with severe Covid-19 to all available interventions in this domain be suspended, and the trial would also temporarily pause enrolment of patients with moderate Covid-19 to allow review of additional data prior to potentially resuming enrolment.

The company said that complete assessment of data from patients with severe disease would be undertaken and be reported “as soon as available”.

Dimerix said that the preliminary finding was “unlikely to impact the Clarity 2.0 study of DMX-200 and an ARB in patients with moderate Covid-19 respiratory complications, … [and] does not impact the Action3 study of DMX-200 in [focal segmental glomerulo-sclerosis] patients, where ARBs are part of existing standard of care”.

The company said that the Remap-Cap study used adaptive analysis to examine the data for safety and efficacy, considering whether any of the study drugs should be stopped to avoid giving patients an ineffective therapy, particularly if there are side effects.

Dimerix said that after a further data review, the study might continue treating patients, including with those receiving an ARB and DMX-200, until it reaches a pre-specified statistical threshold for determining efficacy among patients who are moderately ill with Covid-19.

Dimerix fell four cents or 18.2 percent to 18 cents with 6.2 million shares traded.

NOXOPHARM

Noxopharm says it has treated the first of 30 patients in its phase I trial of Veyonda, or NOX66, with doxorubicin for the treatment of metastatic soft tissue sarcoma.

Noxopharm said the open-label, dose-escalation and dose-expansion study of Veyonda was being conducted with the Duarte, California-based City of Hope Cancer Centre.

Noxopharm fell four cents or 11.1 percent to 32 cents.

CRESO PHARMA

Creso says Health Canada has approved subsidiary Halucenex's planned up-to 20-patient trial of psilocybin for treatment-resistant post-traumatic stress disorder.

Creso said that the phase II, single-arm, open-lab[el] trial would begin recruitment of 18 to 20 patients to test the efficacy of psilocybin on treatment-resistant, post-traumatic stress disorder (PTSD) and "determine the feasibility of future trials of psilocybin in this indication".

Creso said it was working with Wolfville, Nova Scotia, Canada-based, Acadia University "towards clinical trial design and ethics approval" and expected the trial to begin by July 2022.

Creso fell 0.2 cents or 2.9 percent to 6.7 cents with 9.85 million shares traded.

ORTHOCELL

Orthocell says it expects to be able to manufacture more than 100,000 units a year of its Striate+ dental membrane by the end of 2022.

Orthocell said that following US Food and Drug Administration approval for dental bone and tissue regeneration procedures for the device, it had approvals to upgrade its existing facility and scale-up the Striate+ manufacturing capacity.

The company said it had developed a 'key opinion leader' network and had 18 opinion leaders in the European Union, UK, US and Australian who were "actively representing the company as product ambassadors and using Striate+ in their dental surgeries".

Orthocell said it had sold more than 1,500 Striate+ units through the US opinion leaders alone.

Orthocell managing-director Paul Anderson said the company had made "significant progress towards US market entry, forming a strong clinical network validating Striate+ as a premium dental membrane".

"We are now well-positioned to secure a US distributor," Mr Anderson said.

Orthocell was up two cents or 5.1 percent to 41 cents.

CYNATA THERAPEUTICS

Cynata says the State Intellectual Property Office of the People's Republic of China will grant a patent covering its Cymerus mesenchymal stem cell technology.

Cynata said that the patent application, titled 'Colony Forming Medium and Use Thereof' would build on its patent estate around the Cymerus manufacturing platform and its ability to yield highly consistent mesenchymal stem cells at scale, from a single donation, to create therapeutic stem cell products.

The company said that the patent would provide coverage until March 14, 2037.

Cynata chief executive officer Dr Ross Macdonald said that China was "an enormously important market as its economy continues to grow and the central government accelerates the pace of adoption of sophisticated, cutting-edge medicines".

"This achievement will be of significant assistance in our ongoing engagement with potential partners in China," Dr Macdonald said.

Cynata said that the inventors named on the patent were the company's founder Prof Igor Slukvin, along with Dr Gene Uenishi, Diana Drier and Dr Derek He.

Cynata was untraded at 41 cents.

INCANNEX HEALTHCARE

Incannex says it has listed American depositary shares on the Nasdaq global market under the ticker symbol IXHL, each equivalent to 25 Australian shares.
Incannex fell 1.5 cents or 2.4 percent to 61.5 cents with 6.8 million shares traded.

PROBIOTEC

Probiotec says chief executive officer Wesley Stringer has sold 1,011,904 shares or about 1.2 percent of the company, retaining 5,195,873 shares or about 6.40 percent.
Probiotec said the sale was to "fund a renovation of Mr Stringer's family home, to repay the company loan attached to the shares which have been sold and to fund the resulting personal tax obligations in connection with the sale".
The company said that Mr Stringer did not intend to sell any further shares in the foreseeable future.
Probiotec fell two cents or 0.9 percent to $2.18.

RADIOPHARM THERANOSTICS

Nanomab Technology says it has increased its substantial holdings in Radiopharm from 21,111,111 shares (8.33%) to 26,999,909 shares (10.7%).
The Hong Kong-based Nanomab Technology said that on January 27, 1,927,177 shares were acquired through an intellectual property sale (see below) and between February 14 and 22, 2022 it bought 3,962,621 shares for $1,308,358 or an average of 33 cents a share.
In January, Radiopharm said it paid Shanghai's Nanomab Technologies $US500,000 ($A696,000) in shares to acquire three of its radio-pharmaceutical nano-particle patents (BD: Jan 24, 2022).
Radiopharm fell one cent or 2.9 percent to 33 cents.

ZELIRA THERAPEUTICS

Former Zelira director, Jason Peterson says he has ceased his substantial holdings in Zelira on February 21, 2022 due to a dilution.
According to Zelira's most recent application for quotation of securities, 372,840,936 shares were issued following the conversion of performance rights valued at 2.08 cents each.
Zelira was unchanged at 2.2 cents with 1.3 million shares traded.

MESOBLAST

In an Appendix 3Z final director's interest notice, Mesoblast 18-year director Donal O'Dwyer says he ceased to be a director on February 25, 2022.
In its second quarter financial results and operational highlights, published on Friday February 25, 2022, Mesoblast said that "as foreshadowed at the annual general meeting in November 2021, the two long standing Australia-based non-executive directors will retire from the board over a six to 12-month period … as such, Mr Donal O'Dwyer retires from the board today".
Mesoblast was up 2.5 cents or 2.3 percent to $1.105 with 1.6 million shares traded.

MEDADVISOR

Medadvisor says it has appointed Linda Jenkinson as a non-executive director and chair, replacing Chris Ridd as a director and chair.

Medadvisor said that Ms Jenkinson had been based in the US for the past 30 years, spending equal time in the US and Australia-New Zealand.

The company said that Ms Jenkinson was an experienced director and chief executive officer and previously was a director of the Guild Group.

Medadvisor said that Mr Ridd was retiring having taken company through the acquisition and integration of Adheris.

The company said that Ms Jenkinson co-founded five companies, including Dispatch Management Services and was the third woman to list a company on the Nasdaq.

Medadviser said that prior to Dispatch Management, Ms Jenkinson was a partner with AT Kearney for 11 years and had worked for Price Waterhouse.

The company said that Ms Jenkinson was currently a director of the Eclipx Group and Harbour Asset Management and chair of Jaxsta and Guild Trustee Services Pty Ltd.

Medadvisor fell half a cent or 1.5 percent to 32.5 cents.