Biotech Daily

Tuesday July 23, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MESOBLAST UP 13%; DIMERIX DOWN 8%**

*** POLYNOVO 'RECORD UNAUDITED REVENUE UP 58% TO $105m'**

*** VISIONEERING H1 RECEIPTS UP 10% TO $7.1m**

*** DIMERIX $10.8m RECEIPTS FROM ADVANZ DMX-200 LICENCE**

*** EMVISION 1st RESPONDER BRAIN SCANNER**

*** MESOBLAST: 'FDA ACCEPTS RYONCIL GvHD RE-SUBMISSION'**

*** PYC EXTENDS VP-001 SINGLE DOSE TRIAL TO MULTI-DOSE**

*** RADIOPHARM: 'FDA OKAYS RAD101 BRAIN METASTASES IND'**

*** AROA AGM 16% OPPOSE DIRECTOR SHARES**

*** ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 74%**

*** IMPEDIMED: DR PARMJOT BAINS M-D, MCGREGOR GRANT CFO, COO**

*** MELODIOL (CRESO) TO SELL MERNOVA FOR $12m**

MARKET REPORT

The Australian stock market was up 0.5 percent on Tuesday July 23, 2024, with the ASX200 up 39.4 points to 7,971.1 points. Nineteen of the Biotech Daily Top 40 were up, 14 were down, five traded unchanged and two were untraded. All three Big Caps rose.

Mesoblast was the best, up 15 cents or 13.0 percent to $1.305, with 22.5 million shares traded. Actinogen climbed 9.9 percent; Imugene and Polynovo improved more than seven percent; Avita, Clarity, Immutep, Medical Developments, Next Science and Telix were up more than three percent; 4D Medical, Cochlear, Curvebeam, Nova Eye, Pro Medicus and Proteomics rose more than two percent; with Alcidion, CSL, Nanosonics, Neuren, Opthea and Resmed up by one percent or more.

Dimerix led the falls, down 4.5 cents or 8.2 percent to 50.5 cents, with 14.0 million shares traded. Resonance lost 7.3 percent; Atomo and Starpharma were down more than three percent; Cynata, Cyclopharm, Impedimed and Syntara shed two percent or more; Medadvisor, Micro-X and Paradigm were down more than one percent; with Clinuvel, Emvision and Genetic Signatures down by less than one percent.

POLYNOVO

Polynovo says it unaudited revenue for the year to June 30, 2024 is up 57.5 percent to a record $104.8 million, compared to the previous corresponding period.

Last year, Polynovo said revenue for the year to June 30, 2023 was up 59.5 percent to $66,111,094 with net loss after tax up 312.9 percent to $4,924,539 (BD: Aug 23, 2023).

Today, the company said sales of its Novosorb biodegradable wound treatment rose 54.4 percent from $59.6 million in the prior corresponding period to $92.0 million.

Polynovo said that US sales increased 49.0 percent to $68.7 million with sales in other territories up 73.1 percent to $23.3 million, including strong performances in developed markets like the UK and Ireland, Germany, Australia and New Zealand.

The company said it had continued its surgeon education and charitable contributions, which were widely used to support patients in conflict zones.

Polynovo chair David Williams told Biotech Daily that the unaudited revenue figure was a "record".

Mr Williams said in a media release that there were many "highlights in the year just past [including] the strength of the [UK and Ireland] market from a slow start in non-burns".

Mr Williams said there was "an enormous need for our product in conflict zones and developing countries supported by [the World Health Organisation], charities and governments".

Polynovo chief executive officer Swami Raote said due to the efforts of the company's clinicians and people it continued "to make significant strides in our mission to redefine healing for our patients".

"We are proud of reaching a milestone of touching and healing over 50,000 patients across 41 countries in our relatively short commercial history," Mr Raote said.

"We are making a meaningful difference to patient outcomes, as we help reduce cost and complexity across different healthcare systems, further accelerating Novosorb adoption," Mr Raote said.

"Our clinicians continue to provide superior insights to help us take Novosorb technology across different clinical indications through our expanding product portfolio," Mr Raote said.

"Although I am proud of what our people have achieved, I remain acutely conscious of our responsibility to meet a global need to heal millions more," Mr Raote said.

Polynovo was up 19 cents or 7.9 percent to $2.60 with 6.3 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says receipts from customers for the six months to June 30, 2024 were up 10.2 percent to $US4,693,000 ($A7,070,000) compared to the prior corresponding period.

Visioneering said receipts from sales of its Naturalvue multifocal one day contact lenses for the three months to June 30, 2024 were up 17.7 percent to $US2,349,000.

The company said shipments to US eye care professionals were $US2.1 million in the three months, up four percent on the previous corresponding period.

Visioneering said shipments to US eye care professionals was an internal measure of patient-level demand reflecting sales from the company's distributors to eye care professionals in the US at the price it supplied those products to its distributors.

The company said it had a cash burn of $US872,000 for the three months to June 30, 2024, with cash and cash equivalents of $US1,825,000 at June 30, 2024 compared to $US3,267,000 at June 30, 2023.

Visioneering was untraded at 14 cents.

DIMERIX

Dimerix says that it has received $10,872,000 in receipts from customers for the year to June 30, 2024.

Earlier this year, Dimerix said the payment of EUR6.5 million ($A10.8 million) from Advanz Pharma as part of its licence agreement for DMX-200 for focal segmental glomerulosclerosis (FSGS) provided customer receipts for the six months to December 31, 2023 of $10,872,000 (BD: Jan 29, 2024).

Today, the company said it had a cash burn of $13,278,000 for the three months to June 30, 2024, with cash and cash equivalents of $22,141,000 at June 30, 2024 compared to $7,992,000 at June 30, 2023, providing 1.7 quarters cash.

Dimerix said expenditure for the three months to June 30, 2024 included a one-off cost to vendor and opening a trial site and expected to receive a research and development tax incentive as well as further funding from the exercised of 49,625,053 options at 15.4 cents each.

Dimerix fell 4.5 cents or 8.2 percent to 50.5 cents with 14.0 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has completed fabrication of its First Responder Generation 2 proof-of-concept neuro-diagnostic device for point-of-care rapid stroke detection.

Emvision said the First Responder device was “an opportunity to fundamentally transform stroke and traumatic brain injury outcomes for all patients, regardless of their location, by delivering sophisticated neuro-diagnostic technology directly to the point-of-care”.

The company said the proof-of-concept device used the principles and mode of operation of its bedside Emu brain scanner device but was “a lighter and miniaturized physical embodiment with expanded antennas, designed to provide full brain coverage in a single scan”.

Emvision said the device would be “the subject of a series of studies and developments including usability, reliability, software development, functionality and other tests intended to meet international regulatory requirements”.

The company said under its agreement with the Australian Stroke Alliance, funded by the Federal Government’s Medical Research Future Fund (MRFF), the “Ambulance Device Fabrication” milestone had been achieved.

In 2021, Emvision said it would receive a total of $8 million funded by the MRFF, in staged payments over five-years, to support the development and validation of its planned first responder device for air and road ambulances (BD: Sep 16, 2021).

Today, the company said it had submitted the required documentation to the Australian Stroke Alliance to trigger a further $600,000 non-dilutive milestone payment.

Emvision managing-director Scott Kirkland said that building the First Responder proof-of-concept device was “the culmination of years of close work with leaders in the pre-hospital sector, including the Australian Stroke Alliance and the Royal Flying Doctor Service, to ensure that we are designing and developing a scalable First Responder solution to broadly transform patient outcomes”.

“This means creating a device that aims to be economically viable, clinically powerful and attractive for pre-hospital emergency medical services worldwide,” Mr Kirkland said.

“Core to these requirements is an ultra-light scanner that can be carried in a backpack, is easy, quick and safe to use, can be operated by trained paramedics without requiring a radiographer, can integrate with tele-health solutions such as Zeus and can distinguish if a suspected ischaemic or haemorrhagic stroke has occurred,” Mr Kirkland said.

Emvision fell one cent or 0.5 percent to $1.985.

MESOBLAST

Mesoblast says the US Food and Drug Administration has accepted its resubmitted biologics licence application for Ryoncil for graft-versus-host disease (GvHD).
Earlier this year, Mesoblast said that a 2018 phase III study data "appears sufficient" for a biologics application for Ryoncil, or remestemcel-L, for paediatric steroid-refractory acute graft versus host disease (SR-aGVHD) (BD: Mar 26, 2024).
Last month, the company said it had resubmitted its biologics licence application for Ryoncil for children with graft-versus-host disease to the FDA (BD: Jul 9, 2024).
Today, Mesoblast said the FDA considered its resubmission to be "a complete response" and it expected a decision on or before the FDA's Prescription Drug User Fee Act (PDUFA) goal date of January 7, 2025.
Mesoblast managing-director Prof Silviu Itescu said the company was "pleased the FDA has accepted our [biologics licence application] resubmission for review and look forward to the potential approval of Ryoncil for children with SR-GvHD".
Mesoblast was up 15 cents or 13.0 percent to $1.305 with 22.5 million shares traded.

PYC THERAPEUTICS

PYC says it has approval for the nine patients in its single ascending dose study of VP-001 for retinitis pigmentosa type 11 (RP11) to receive multiple doses.
Earlier this month, PYC said its nine-patient, single-ascending dose study of VP-001 for the blinding eye disease RP11 showed the drug was safe and well-tolerated at the highest intravitreal dose of 75 micrograms (µg) (BD: Jul 1, 2024).
Later, the company said it had begun a six-patient, multiple-ascending dose study to assess the safety, tolerability and efficacy of VP-001 for RP11(BD Jul 10, 2024).
Today, PYC said patients who had received a single dose of the drug candidate in the single ascending dose study would rollover into an open-label extension arm of the study, called part B, and receive multiple doses of VP-001.
The company said that patients enrolling in the extension study would receive two further doses of either 30µg or 75µg of the drug candidate in the previously treated eye as their repeat dose.
PYC said the patients would receive a second dose of the drug candidate "as close as possible to a 12-week dosing interval from their original dose in the study [and] a third dose of the drug candidate about 8 weeks after the second dose".
The company said the endpoints of the extended study were safety and tolerability and efficacy throughout the course of the study.
PYC said that it expected data from the part B extension of the study "before the end of the year".
The company said the extension would allow it to expand the number of patients that safety and efficacy data would be available for, following repeat doses of the drug candidate.
PYC said data from the single dose study, the extension study and the multiple ascending dose study was expected to inform the design of a registrational trial that was expected to begin in 2025 and was directed towards supporting a new drug application and commercial launch of VP-001.
PYC was up half a cent or 4.8 percent to 11 cents with 4.6 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has investigational new drug approval from the US Food and Drug Administration to study RAD101 as a brain cancer diagnostic.

Last year, Radiopharm said it would file an investigational new drug application for a phase IIb/III trial of fluorine-18-pivalate, or RAD101, for imaging brain metastasis, with the first patients expected to be dosed before 2024 (BD: May 29, 2023).

Today, the company said pivalate, labelled with the radioisotope fluorine-18 (F18), was a small molecule that selectively targeted fatty acid synthetase, which was over-expressed in brain tumors but not in normal cells.

Radiopharm said pivalate was a novel proprietary imaging agent under clinical investigation for the detection and characterization of brain metastases.

The company said the approval was recognition by the FDA of clinical data already generated for RAD101 and was “a significant milestone towards starting a phase IIb multi-centre trial for the imaging of brain metastases”.

Radiopharm said it expected the first patient to be dosed by 2025, with the 30-patient, phase IIb read-out expected in mid-2025, to be followed by a phase III registrational study.

Radiopharm managing-director Riccardo Canevari said pivalate was “a potential new target for radio-pharmaceutical brain imaging agents, and its unique mechanism-of-action may offer eligible patients and the medical community an alternative to overcome the limitations of current standard-of-care for imaging brain metastasis”.

“We are very pleased by this FDA approval as it allows us to commence late-stage clinical studies and address the high unmet medical need in around 300,000 patients that are diagnosed with brain metastases in the US every year,” Mr Canevari said.

Radiopharm was unchanged at 3.8 cents with 17.7 million shares traded.

AROA BIOSURGERY

Aroa says its annual general meeting has passed all six resolutions but with up to 16.03 percent against the issue of shares to director Darla Hutton.

Earlier this month, Aroa said investors would vote to issue managing-director Brian Ward 961,255 performance rights and Ms Hutton 140,110 shares (BD: Jul 8, 2024).

Today, the company said the Ms Hutton’s shares were opposed by 23,216,764 votes (16.03%) with 121,661,151 votes (83.97%) in favor.

Aroa said the election of director Philip McCaw faced 2.54 percent dissent, with the election of directors John Pinion and Ms Hutton, the auditor’s remuneration and Mr Ward’s long-term incentive rights all passing easily.

According to its most recent notice, Aroa had 344,207,834 shares on issue, meaning that the 23,216,764 votes against Ms Hutton’s shares amounted to about 6.74 percent of the company, sufficient to requisition extraordinary general meetings.

Aroa was up one cent or 1.6 percent to 62 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial share-holding from 77,886,881 shares (65.12%) to 88,012,378 shares (73.58%).

In May, Allegra said Dr Hartnell would pay 0.4 cents a share in a cash bid, valuing it at $478,444; and later, filed his bidder’s statement (BD: May 27, Jun 20, 2024).

Today, Dr Hartnell said that he acquired the shares “as a result of acceptances of takeover offers made by [Allegra Innovations] dated June 20, 2024”.

Allegra was in a suspension and last traded at 2.9 cents.

IMPEDIMED

Impedimed says Dr Parmjot Bains has been appointed managing-director with executive director McGregor Grant appointed as chief financial and operating officer.
Last year, Impedimed said Dr Bains had been appointed interim managing-director with then executive chair Mr Grant interim chief financial officer (BD: Nov 20, 2023).
Today, the company said in their interim roles, Dr Bains and Mr Grant had made a number of significant changes across the business to ensure the company was "in the best position to achieve growth and profitability and ensure all patients at risk of cancer related lymphedema can access Impedimed's unique technology".
Impedimed said Dr Bains would be paid $490,000 a year and receive 8,500,000 sign-on performance rights and 8,500,000 sign-on options, exercisable at seven cents.
The company said Mr Grant would receive a salary of $430,000 a year as well as a sign-on bonus of 6,500,000 performance rights and 6,500,000 options at the same exercise price as Dr Bains' options.
Impedimed fell 0.2 cents or 2.9 percent to 6.6 cents.

MELODIOL GLOBAL HEALTH (FORMERLY CRESO PHARMA)

Melodiol says it will sell its Mernova factory and property to the Canada-based Nacerna Life Sciences Inc for $12 million in cash.
In 2018, the then Creso said it had completed the acquisition of the Halifax, Nova Scotia-based medical marijuana producer Mernova Medicinal for $C200,000 ($A201,312) and 8,300,000 Creso Canada shares (BD: Jul 27, 2017; Feb 19, 2018).
Last month, the company said it was considering "strategic alternatives" for the use of its Mernova properties, valued at $10.4 million to $12 million (BD: Jun 19, 2024).
Today, Melodiol said it would receive two earn-out provisions of $C1 million, each, subject to Nacerna reaching revenues of $C50 million within 24 months from the closing of the transaction through the sale assets and 15,000kg of cannabis being produced at the facility within 24 months of the closing of the transaction.
The company said the initial payment was "sufficient to repay all of the company's existing secured debt, significantly improving the company's balance sheet, and is expected to allow for additional working capital to be deployed to Health House and Creso Pharma Switzerland".
Melodiol said the closing of the transaction would be subject to customary conditions, including, completion of due diligence of the sale assets, receipt of corporate approvals, the execution of the definitive agreement and any ancillary agreements and the receipt of any regulatory approvals and third-party consents.
The company said that Sydney's Oakley Capital Partners was that corporate advisor to the transaction and would receive a fee of about 11 percent of the transaction, with Steinepreis Paganin acting as legal counsel.
Melodiol was up 0.1 cents or 33.3 percent to 0.4 cents with 102.9 million shares traded.