Biotech Daily

Tuesday July 4, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ATOMO UP 131%; PATRYS DOWN 10%**

*** CLARITY: FDA POSITIVE ON 64-CU SAR-BIS-PSMA PHASE III TRIAL**

*** ACRUX: FDA ACCEPTS ANAL OINTMENT APPLICATION**

*** PARADIGM RECRUITS STAGE 1, PHASE III PPS KNEE ARTHRITIS TRIAL**

*** PHARMAUST: 'MONEPANTEL MAY SUPPRESS MND INFLAMMATION'**

*** VOLPARA REDUCES CREDIT FACILITY TO $2.3m**

*** ATOMO PRE-EMPTIVE SCHULTZ TO 100% PRICE JUMP; 2 DAYS – UP 277%**

*** CORRECTION: POLYNOVO**

*** CORRECTION: LBT INNOVATIONS**

*** NEUROSCIENCE RESEARCH: PROF MATTHEW KIERNAN CEO, DIRECTOR**

*** RHYTHM PROMOTES DIRECTOR SUE MACLEMAN TO DEPUTY CHAIR**

MARKET REPORT

The Australian stock market was up 0.45 percent on Tuesday July 4, 2023, with the ASX200 up 32.9 points to 7,279.0 points. Twenty-five of the Biotech Daily Top 40 stocks were up, 11 fell and four traded unchanged.

Atomo was the best for the second day in a row (see below), up 4.7 cents or 130.6 percent to 8.3 cents, with 108.7 million shares traded. Dimerix climbed 17.4 percent; Opthea was up 15.3 percent; Volpara rose 11.8 percent; Impedimed improved 8.1 percent; Kazia was up 6.1 percent; 4D Medical, Antisense and Cyclopharm were up more than five percent; Alcidion, Cynata and Resonance climbed more than four percent; Medical Developments and Neuren rose more than three percent; Amplia, Emvision, Immutep, Imugene, Mesoblast, Nanosonics, Nova Eye, Polynovo, Prescient and Starpharma were up one percent or more; with Cochlear, CSL and Telix up by less than one percent.

Patrys led the falls, down 0.1 cents or 10 percent to 0.9 cents, with 1.3 million shares traded. Both Micro-X and Universal Biosensors lost 8.3 percent; Pharmaxis fell 5.45 percent; Avita was down 3.9 percent; Orthocell, Paradigm and Proteomics shed more than two percent; Clinuvel, Genetic Signatures and Resmed were down more than one percent; with CSL down by 0.2 percent.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration supports its planned 383-patient phase III copper-64-Sar-Bis-PSMA positron emission tomography prostate cancer trial.
Clarity said the trial would be a pivotal, non-randomized, single-arm, open-label, multi-centre study using positron emission tomography (PET) scans with its copper-64 isotopes in participants with high-risk prostate cancer, prior to radical prostatectomy surgery.
The company said the aim of the 'Clarify' study was to assess the diagnostic performance of copper-64 with PET scans to detect prostate cancer within the pelvic lymph nodes, and was expected to begin by the end of this year.
Clarity executive chair Dr Alan Taylor said the positive results from previous trials showed that the isotopes were safe and that their uptake in PSMA-expressing cancer lesions was significantly higher compared to the approved standard-of-care imaging agent.
"This may enable diagnosis of additional and smaller lesions, especially when coupled with the opportunity for delayed imaging, a characteristic not available to the first generation of PSMA imaging agents that exhibit high specificity but low sensitivity," Dr Taylor said.
"We believe that the additional shelf-life of up-to 48 hours could not only allow clinics greater flexibility in scheduling the scans, but also improve patients' access to care in clinics and geographic areas," Dr Taylor said.
Clarity was up 2.5 cents or 3.4 percent to 76.5 cents.

ACRUX

Acrux says the US Food and Drug Administration has accepted its abbreviated new drug application (ANDA) for generic nitro-glycerine ointment for anal fissures.
The company said the application marked the company's seventh ANDA to be accepted for review.
Acrux chief executive officer and managing director Michael Kotsanis said the company was "extremely pleased to advance another product" from its pipeline to FDA regulatory review.
"Our key focus is on the continuing evolution of Acrux into a company with a diversified on-market portfolio and a well-planned pipeline of commercially valued products," Mr Kotsanis said.
"Today's advancement of nitro-glycerine ointment 0.4 percent through to the regulatory submission stage is a great example of our strategy in action," Mr Kotsanis said.
Acrux was up 0.3 cents or 7.1 percent to 4.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has recruited all 468 patients in stage 1 of its phase III trial comparing injectable pentosan polysulfate sodium to placebo for knee arthritis joint pain.
Paradigm said it expected the final stage 1 patients to be screened and randomized by October 2023, and conclude dose selection 84 days after initial treatment.
The company said it had activated the targeted 120 clinical trial sites in seven countries, including Australia, the US, Canada, UK, Belgium, Poland and Czechia.
The company said the timeline for its new drug application with the US Food and Drug Administration remained on track and that an independent data monitoring committee recommended the trial proceed to a pivotal phase III without modification.
Paradigm fell 2.5 cents or 2.4 percent to $1.025.

PHARMAUST

Pharmaust says data from its seven patient, phase I/II trial of monepantel shows the drug might suppress the inflammation responsible for motor neuron disease.

Last week, Pharmaust said it had dosed all 12 patients in cohort 3 of its open label trial of monepantel for motor neuron disease (BD: Jun 27, 2023).

Today, the company said monepantel tablets were intended to inhibit the mammalian target of rapamycin (mTOR) signaling pathway, which regulates cell proliferation, autophagy and apoptosis in the body, in the blood of patients.

Pharmaust said there was “a clear correlation” between reduced biomarkers with monepantel treatment.

Pharmaust executive chair Dr Roger Aston said that molecular and cellular pathways of neurodegeneration in motor neuron disease were complex, but “it appears that oxidative stress, protein misfolding and aggregation may be underlying causes for the inflammation associated in neurons during [motor neuron disease] progression”.

Pharmaust was up 0.7 cents or 9.6 percent to eight cents with three million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has reduced its revolving credit facility from $NZ10 million ($A9.22 million) to $NZ2.5 million ($A2.3 million) following increased revenue and cash flow.

Volpara said the facility was “no longer considered necessary” after its revised business strategy from July 2022 had resulted in three consecutive three-month periods of cash inflows and “repeatable operating cash flow positivity”.

Volpara was up nine cents or 11.8 percent to 85.5 cents.

ATOMO DIAGNOSTICS

Atomo says it is not aware of any information it has not announced to the market which, if known, could explain recent trading in its securities.

Atomo said its share price climbed from 3.6 cents at the close on July 3 to 7.2 cents at the time of the announcement.

According to Commsec data, Atomo’s share price was 2.2 cents at the close on Friday, June 30 and reached a peak of 10 cents during trading today, a rise of 354.5 percent.

The company said that on July 3, partner Lumos Diagnostics said it had US Food and Drug Administration Approval for its Febridx test, which used Atomo’s integrated Pascal test platform “making Atomo a critical supplier to Lumos for this approved product [ad it was] possible that the price movement … could be attributed to the … announcement”.

Atomo closed up 4.7 cents or 130.6 percent at 8.3 cents with 108.7 million shares traded.

CORRECTION: POLYNOVO

Friday’s edition incorrectly said that AOD9604 “was central to the drug scandals engulfing the Essendon and Cronulla football clubs in 2013”.

In fact, AOD9604 was one of several molecules involved in the Essendon Football Club drugs scandal and there is no evidence that it was used at Cronulla.

The article has been corrected to say that AOD9604 “was associated with the drug scandal engulfing the Essendon Football Club in 2013”.

The Friday sub-editor has been admonished for failing to fact-check, but was only 12-years-old at the time and barracks for Collingwood, anyway, so what can you expect?

Polynovo was up 1.5 cents or one percent to $1.535 with 983,620 shares traded.

CORRECTION: LBT INNOVATIONS

Last night's edition said that LBT had appointed director Rebecca Wilson as its chair but failed to provide the previous chair's surname in the article.
The headline was correct that LBT's former chair was Joanne Moss.
The Monday Millennial sub-editor said she was copying the mainstream media's increasingly very lax policy of referring to people by first names only.
It is so hard to find good hired help these days.
Biotech Daily apologizes unreservedly.
LBT was up 0.3 cents or 10 percent to 3.3 cents.

NEUROSCIENCE RESEARCH AUSTRALIA

Neuroscience Research Australia says it has appointed Prof Matthew Kiernan as its chief executive officer and institute director.
The organization said that Prof Kiernan was appointed a professor of neuroscience at the University of New South Wales with a clinical appointment in neurology within the local health district and Prince of Wales Hospital.
Neuroscience Research Australia said Prof Kiernan was currently co-director of the Brain and Mind Centre and was the chair of neurology at the Royal Prince Alfred Hospital and the University of Sydney.
Neuroscience Research Australia said Prof Kiernan held a Bachelor of Medicine and a Bachelor of Surgery from the University of Sydney and a Doctor of Philosophy and a Doctor of Science from the University of New South Wales.

RHYTHM BIOSCIENCES

Rhythm says it has promoted non-executive director Sue MacLeman to independent deputy chair.
Earlier this year, Rhythm said it had appointed Ms MacLeman as an independent, non-executive director (BD: Jan 31, 2023).
Rhythm was up one cent or two percent to 50 cents.