Biotech Daily

Monday March 16, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN BIGLY: ALTERITY UP 25%; PARADIGM DOWN 23%**

*** COCHLEAR WITHDRAWS GUIDANCE, FREEZES HIRING, SPENDING**

*** POLYNOVO FILES NOVOSORB BTM BURN STUDY RESULTS TO FDA**

*** PATRYS: PAT-DX1 BLOOD BRAIN BARRIER MECHANISM CONFIRMED**

*** TELIX: $500k R&D GRANT FOR RADIATION CANCER DRUGS**

*** GENETIC TECHNOLOGIES APPEALS NASDAQ EQUITY NON-COMPLIANCE**

*** NEUROSCIENTIFIC REQUESTS 'POSITIVE RESULTS' TRADING HALT**

*** REGAL FUNDS TAKES 7% OF MEDICAL DEVELOPMENTS**

*** CEO PAUL RENNIE INCREASES, DILUTED TO 12% IN PARADIGM**

*** MASON STEVENS BELOW 5% OF PATRYS**

*** W WHITNEY GEORGE TAKES 29% OF RHINOMED**

*** SIENNA APPOINTS PROF GEOFF MCCAUGHAN ADVISOR**

MARKET REPORT

The Australian stock market lost 9.7 percent on Monday March 16, 2020, with the ASX200 down 537.3 points to 5,002.0 points. Five of the Biotech Daily Top 40 stocks were up, 29 fell and six traded unchanged. All three Big Caps fell.

Alterity (Prana) continued to yo-yo from best to worst, up 0.3 cents or 25 percent to 1.5 cents, with 39,000 shares traded. Patrys climbed 16.7 percent; Kazia was up 5.45 percent; Cynata improved 3.4 percent; with Uscom up 2.1 percent.

Paradigm led the falls, down 45 cents or 22.8 percent to $1.525 with 3.5 million shares traded. Mesoblast lost 20.1 percent; Avita and Cochlear fell more than 19 percent; Opthea shed 18 percent; Imugene and Polynovo were down more than 15 percent; Medical Developments and Telix fell more than 14 percent; Pharmaxis was down 13 percent; Amplia, Prescient and Starpharma shed more than 12 percent; Neuren, Oncosil and Proteomics lost more than 11 percent; CSL, Nanosonics and Neuren were down more than 10 percent; Clinuvel fell 8.0 percent; Dimerix was down 7.4 percent; Cyclopharm and Pro Medicus were down more than six percent; Actinogen and Ellex fell more than five percent; Resonance lost 4.8 percent; Genetic Technologies and Orthocell were down more than three percent; Antisense and Compumedics shed more than two percent; with Immutep and Resmed down by more than one percent.

COCHLEAR

Cochlear says it withdrawn its earnings guidance for the year to June 30, 2020, has implemented a hiring freeze and reduced all non-essential spending.
Last month, Cochlear said it expected a net profit of $270 million to $290 million for the year to June 30, 2020 (BD: Feb 11, 18, 2020).
Today, Cochlear company said it expected the coronavirus to "have a substantial, short-term negative impact on … surgeries, particularly in the US and Western Europe".
Cochlear chief executive officer Dig Howitt said that "a growing number of health authorities either recommend or enforce surgery deferrals".
"Over the weekend, the US Surgeon-General has urged hospitals and healthcare systems to consider suspending elective surgical procedures in an effort to reduce the strain on the healthcare system until the rate of infection of Covid-19 is under control," Mr Howitt said.
"With regard to China, after a delay to surgeries during February, a small but growing number of surgeries have recommenced over the past few weeks, although they remain well below the pre-virus run rates," Mr Howitt said.
"Cochlear's Chinese suppliers have resumed production of components, which are used primarily for sound processors and accessories," Mr Howitt said.
"The business continues to carry at least three months inventory of most components and is managing distribution carefully to enable continued supply of products," Mr Howitt said.
Mr Howitt said that due to the uncertainty of the coronavirus, the company was "not in a position to provide an earnings outlook to the market" and withdrew the previous earnings guidance for the year to June 30, 2020.
Cochlear said it had a "conservatively-geared balance sheet, headroom in existing debt facilities and is confident it can arrange increased debt facilities to assist with meeting future cash requirements".
The company said it had "no plans to reduce the workforce with expectations the disruption will be temporary".
Cochlear fell $41.60 or 19.25 percent to $174.51 with 827,687 shares traded.

POLYNOVO

Polynovo says its 15-patient Novosorb for full thickness burns results will be filed to the US Food and Drug Administration with its investigational device exemption application.
Polynovo said that once the FDA had the documents it could release them publicly.
The company said the 12-month CP-002 prospective, multi-centre, single-arm, open label feasibility study of Novosorb biodegradable temporizing matrix (BTM) study for full thickness burns covering 10 percent to 70 percent of total body surface would be submitted to the FDA for review.
Polynovo said the co-primary effectiveness endpoints were the BTM 'take' rate assessed after integration and at the time of sealing membrane removal, and the split-thickness skin graft 'take' rate at seven to 10 days after application.
The company said that the FDA granted it 'breakthrough device' designation in November 2019 and it expected "approval for the larger pivotal trial IDE in June 2020".
Polynovo said that the pivotal trial would support a submission leading to pre-market approval for a full thickness burn indication in the US.
Polynovo chief executive officer Paul Brennan said that "the results of the feasibility trial mean we are on track with the clinical program".
"Novosorb BTM is already approved for full thickness burns outside of the US and this trial will add significantly to the gravitas of our improved outcomes," Mr Brennan said.
Polynovo fell 28.5 cents or 16.0 percent to $1.50 with 14.7 million shares traded.

PATRYS

Patrys says mouse and in-vitro data shows that PAT-DX1 crosses the blood-brain barrier via the equilibrative nucleoside transporter 2 (ENT2) pathway.

Patrys said the data would support its planned US Food and Drug Administration investigational new drug for trials of PAT-DX1 for brain tumors, metastases and other cancers.

The company said that Yale School of Medicine's Dr James Hansen and Dr Jiangbing Zhou completed new in-vitro and mouse studies that established the mechanism by which PAT-DX1 crossed the blood-brain barrier, supporting previous pre-clinical studies where PAT-DX1 increased tumor suppression in brain cancers and metastases, further strengthening the biologic rationale to enter the clinic.

Previously, Patrys has said PAT-DX1-NP crossed the blood-brain-barrier and targeted triple-negative breast cancer brain metastases in mice, with a Yale School of Medicine study showing PAT-DX1-NP improved delivery of nanoparticles across the blood brain barrier by 260 percent compared to the unconjugated nanoparticles, and it was "specifically targeting regions of the brain where more metastatic tissue was localized" (BD: May 30, 2019; Mar 2, 2020).

Today, Patrys chief executive officer Dr James Campbell said the blood-brain barrier prevented antibodies and the majority of small molecule therapeutics from entering the central nervous system.

"PAT-DX1 has proven to be an exception to this rule and has shown activity against brain tumors in mouse models of glioblastoma and triple negative breast cancer brain metastases," Dr Campbell said.

"The study data clearly illustrates how PAT-DX1 is able to achieve these outcomes, and provides compelling evidence of an ENT2-mediated method of [blood-brain barrier] penetration by PAT-DX1," Dr Campbell said.

Patrys said the investigation by Dr Hansen and Dr Zhou showed that co-treatment with a small molecule inhibitor of ENT2 blocked the transport.

The company said the research tested the ability of PAT-DX1 to cross the blood-brain barrier in the presence or absence of an ENT2 inhibitor.

Patrys said that in the absence of the ENT2 inhibitor, PAT-DX1 crossed the blood-brain barrier efficiently, while other molecules of similar molecular weight were blocked.

The company said that the addition of the ENT2 inhibitor significantly impaired PAT-DX1 transport across the blood-brain barrier, demonstrating that PAT-DX1 crossed the barrier through the ENT2 pathway.

Patrys said that Dr Hansen and Dr Zhou completed a mouse study that showed that PAT-DX1 crosses the blood-brain barrier and localized to orthotopic brain tumors in mice, and that co-treatment of mice with a small molecule inhibitor of ENT2 blocked the activity.

The company said that the mouse study used "a highly aggressive human glioblastoma tumor explant to generate brain tumors in mice" with four mice per group randomized to tail vein treatment with either control vehicle, fluorescently-labelled PAT-DX1 or fluorescently-labelled PAT-DX1 with the small molecule ENT2 inhibitor.

Patrys said that 24 hours after treatment the localization of PAT-DX1 to brain tumors was visualized by the fluorescence signal, with a strong fluorescence signal detected in the brain tumors in mice treated with PAT-DX1 alone and the signal was reduced by more than 50 percent in mice co-treated with ENT2 inhibitor.

The company said the study data strengthened the planned FDA filing, provided a biologic rationale to advance PAT-DX1 to the clinic, particularly against brain tumors and metastases, and would be part of the data package for future strategic discussions.

Patrys was up 0.2 cents or 16.7 percent to 1.4 cents with 4.6 million shares traded.

TELIX PHARMACEUTICAL

Telix says it is a co-recipient of a $500,000 research and development grant to improve Australian manufacturing of molecularly-targeted radiation drugs for cancer.

Telix said the funds from the Federal Government Innovative Manufacturing Cooperative Research Centre (IMCRC) were shared between the University of Melbourne, the Bio-21 Institute, Cyclotek, Genesiscare and Iphase Technologies.

The company said the grant would enable the development of manufacturing processes for a series of molecularly targeted radiation drugs intended the imaging and treatment of prostate, kidney and neuroendocrine cancers, using zirconium-89 and lutetium-177.

Telix head of research and development Dr Michael Wheatcroft said it was a “challenge” to develop diagnostic and therapeutic molecularly-targeted radiation drugs that “lend themselves to manufacture and distribution beyond the hospital walls to allow them to be made available to patients across the country, regardless of geography”.

“We expect this IMCRC funded project, which employs carrier compounds designed for use with longer half-life radioisotopes, will capitalize on the extraordinary radio-pharmaceutical expertise we have in Australia,” Dr Wheatcroft said.

“This work will enable this new approach to the diagnosis and treatment of cancer to be offered to many more patients in need, including via export of radiopharmaceutical products from Australia with a far longer shelf-life,” Dr Wheatcroft said.

Telix fell 16 cents or 14.2 percent to 97 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it will appeal a determination letter from the Nasdaq indicating that it did not comply with the Listing Rule 5550(b) the Equity Rule.

Genetic Technologies said continued listing on the Nasdaq required the company to have a minimum of $US2,500,000 ($A4,074,472) in stockholders’ equity or a market value of listed securities of $US35 million or net income from continuing operations of $US500,000 in the most recent fiscal year or two of the last three most recently completed fiscal years.

In May last year, the company said it was below the minimum market capitalization at December 31, 2018 and in October raised $4.5 million in a capital raising to comply with Nasdaq listing requirements (BD: May 3; Oct 27, 2019).

Today, Genetic Technologies said the Nasdaq letter stated that since the company was out of compliance with the Equity Rule within one year of the receiving the compliance letter, the company would not be allowed to submit a plan of compliance.

The company said it had requested a hearing before a panel before 4pm (US EST) on March 20, 2020 (7am, March 21, 2020 AEDT) to review the delisting determination.

Genetic Technologies said that pending the panel’s decision, the Nasdaq would delay the suspension and the filing of the Form 25-NSE, removing the company from the Nasdaq.

The company said there was no assurance that the panel would grant the request or that the company would meet the Equity Rule during any compliance period or in the future.

Genetic Technologies fell 0.1 cents or 20 percent to 0.4 cents with 30.5 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific has requested a trading halt “pending release of the positive results from the company’s pre-clinical study in multiple sclerosis model”.

Trading will resume on March 18, 2020 or on an earlier announcement.

Neuroscientific last traded at 14.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Regal Funds Management says it has increased its substantial shareholding in Medical Developments from 3,301,082 shares (5.03%) to 4,668,764 (7.12%).
The Sydney-based Regal Funds said it bought and sold shares between December 20, 2019 and March 11, 2020 with the single largest purchase 1,282,484 shares for $8,425,920 or $6.57 a share on March 11, 2020.
Medical Developments fell 87 cents or 14.95 percent to $4.95 with 587,988 shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm chief executive officer Paul Rennie says he has increased and been diluted from 23,612,290 shares (12.14%) to 23,640,790 shares (11.95%).
The Adelaide-based Mr Rennie said that on March 13, 2020 he acquired 28,500 shares for $49,786 or $1.75 a share through an on-market trade.
A Paradigm Appendix 3B new issue announcement subsequent to Mr Rennie's most recent substantial shareholder notice said that 625,000 options were exercised at 40 cents each and 1,000,000 options were exercised at 45 cents each.
Paradigm fell 45 cents or 22.8 percent to $1.525 with 3.5 million shares traded.

PATRYS

Sydney's Mason Stevens says it has ceased its substantial shareholding in Patrys.
Last year, Mason Stevens said it held with 66,254,192 shares or 6.18 percent, buying 62,057,414 shares for $1,463,162 or 2.36 cents a share (BD: July 12, 2019).
Today, Mason Stevens said it made more than 150 trades between July 29, 2019 and March 12, 2020, with the largest sale 1,418,424 shares for $32,624 or 2.3 cents a share and the largest transfer in and out of 4,335,069 shares for $101,874 or 2.35 cents a share.
Patrys was up 0.2 cents or 16.7 percent to 1.4 cents with 4.6 million shares traded.

RHINOMED

W Whitney George says he has increased his substantial shareholding in Rhinomed from 46,291,546 shares (27.36%) to 49,291,543 shares (29.13%).
The Carlsbad, California-based Mr George said that between February 10 and March 12, 2020 he bought 2,999,997 shares for $US295,873 ($A482,211) or 9.9 US cents (16.1 Australian cents) a share.
Rhinomed was up one cent or 10 percent to 11 cents.

SIENNA DIAGNOSTICS

Sienna says it has appointed Prof Geoff McCaughan to its clinical advisory board.
Sienna said Prof McCaughan was the head of the University of Sydney's Centenary Institute liver injury and cancer program and head of Sydney's Royal Prince Alfred Hospital's gastroenterology and liver centre.
Sienna fell 0.4 cents or 13.8 percent to 2.5 cents with 1.3 million shares traded.