Biotech Daily

Tuesday September 10, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MESOBLAST UP 22%; PARADIGM DOWN 10%**

*** MESOBLAST: 'GRÜNENTHAL UP TO $219m FOR MPC-06-ID FOR PAIN'**

*** PARADIGM FDA 'COMPASSIONATE USE' CLEARANCE FOR PPS**

*** ESENSE: MARIJUANA FOR WOUNDS, PARKINSON'S, ALZHEIMER'S**

*** USCOM UNMARKETABLE PARCEL BUYBACK**

*** LIVING CELL MEMBERS BOARD CHANGE CALL**

*** PHARMAUST, WERRIBEE ANIMAL HOSPITAL JOINS DOG CANCER TRIAL**

*** MEMPHASYS 21m DIRECTORS INCENTIVE, IN LIEU OPTIONS EGM**

*** G MEDICAL TAKES 'ASX QUERY' TRADING HALT TO SUSPENSION**

*** CYNATA RELEASE 2.5m VOLUNTARY ESCROW SHARES**

*** ALLAN GRAY TAKES 14% OF STARPHARMA**

*** INVITROCUE APPOINTS GEOFFREY THOMAS DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.51 percent on Tuesday September 10, 2019, with the ASX200 down 33.9 points to 6,614.1 points. Ten of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and four were untraded. All three Big Caps fell.

Mesoblast was the best, up 32.5 cents or 22.3 percent to $1.78 with 5.8 million shares traded. Impedimed climbed 10.7 percent; Neuren was up 7.4 percent; Actinogen and Prescient were up more than six percent; Proteomics was up 5.9 percent; Ellex rose 4.4 percent; with Cyclopharm, Starpharma and Telix up more than one percent.

Paradigm led the falls, down 21.5 cents or 10.2 percent to $1.885, with 1.9 million shares traded. Universal Biosensors lost 9.8 percent; Opthea was down 7.25 percent; Clinuvel shed 6.2 percent; Medical Developments, Patrys and Resmed fell more than four percent; Amplia, Compumedics, Dimerix and Genetic Signatures were down more than three percent; Cochlear, CSL, Nanosonics, Oncosil, Optiscan, Orthocell, Osprey, Pharmaxis, Pro Medicus and Volpara shed more than two percent; with Cynata, Next Science and Polynovo down by less than one percent.

MESOBLAST

Mesoblast says Grünenthal will pay up to $US150 million ($A218.9 million) to commercialize its mesenchymal precursor cell MPC-06-ID for lower back pain.

Mesoblast said that MPC-06-ID was a “phase III allogeneic cell therapy candidate for the treatment of chronic low back pain due to degenerative disc disease in patients who have exhausted conservative treatment options”.

The company said the Aachen, Germany-based Grünenthal would have exclusive commercialization rights to MPC-06-ID in Europe and Latin America.

Mesoblast said it would receive $US15 million ($A21.9 million) on signing, $US20 million ($A29.2 million) on regulatory approval to begin a confirmatory phase III trial in Europe, and $US10 million ($A14.6 million) for undisclosed clinical and manufacturing outcomes, and cumulative milestone payments “could exceed $US1 billion depending on the final outcome of phase III studies and patient adoption”.

The company said it would receive “tiered double-digit royalties on product sales”.

Mesoblast said it was completing a phase III trial for MPC-06-ID in the US and expected results in 2020.

Last year, the company said it had completed enrolment in its 404-patient, randomized, placebo-controlled, phase III trial of MPC-06-ID for chronic low back pain due to degenerative disc disease (BD: Mar 29, 2018).

Mesoblast said at that time that patients received a single intra-discal injection of MPC-06-ID to determine whether it could alleviate pain and improve function in patients who did not receive adequate relief from current standard of care therapies such as non-steroidal anti-inflammatory drugs, epidural steroid injections or opioids.

The company said the US Food and Drug Administration-agreed primary endpoint specified the use of a composite measurement showing significant clinical improvement in pain and function at 12 months and 24 months, pre-specified thresholds for determining significant improvement in pain, with patients who had additional interventions at the treated level considered treatment failures.

Mesoblast said that a 100-patient, phase II trial showed that a single intra-discal injection of 6 million MPC-06-ID cells alleviated pain and improved function for up to three years in patients whose symptoms were not adequately treated with current standard of care therapies (BD: Jan 30, Nov 13, 2014; Aug 1, 2016; Mar 15, 2017).

Today, the company said it had agreed with Grünenthal on an overall development plan for MPC-06-ID to meet European regulatory requirements, which included collaborating on a design for the confirmatory phase III trial.

Mesoblast said the results of the phase III and confirmatory phase III trials were expected to support both the US Food and Drug Administration and European Medicines Administration regulatory approvals for MPC-06-ID in degenerative disc disease chronic low back pain.

Grünenthal chief executive officer Gabriel Baertschi said that “cell-based therapies … can potentially deliver meaningful lasting improvements to patients beyond symptomatic treatment by maintaining or even restoring physiological function”.

Mesoblast chief executive Prof Silviu Itescu said that with Grünenthal, the company planned to “bring an important new class of therapy for pain management to the many patients suffering with degenerative disc disease”.

“This partnership is in line with our corporate strategy to team up with best in category commercial leaders to maximize market access for our innovative cellular medicines for the treatment of patients suffering from debilitating or life-threatening inflammatory conditions,” Prof Itescu said.

Mesoblast climbed 32.5 cents or 22.3 percent to $1.78 with 5.8 million shares traded.

PARADIGM

Paradigm says it has US Food and Drug Administration ‘compassionate use’ clearance for its pentosan polysulfate sodium for knee osteoarthritis pain.

Paradigm said the FDA had approved its expanded access investigational new drug application for pentosan polysulfate sodium (PPS) for the treatment of about 10 patients with knee osteoarthritis-related pain with concurrent bone marrow lesions where patients had failed to respond to standard of care.

The company said the FDA clearance was “validation of Paradigm’s safety data, the finished product’s quality and confirmation of an unmet medical need”.

Last year, Paradigm said its 112-patient, phase IIb trial showed that its injectable PPS significantly reduced knee osteoarthritis pain compared to placebo ($p = 0.031$).

Today, the company said that the FDA expanded access, or compassionate use, allowed patients to gain “access to investigational drugs, biologics, and medical devices used to diagnose, monitor, or treat patients with serious diseases or conditions for which there are no comparable or satisfactory therapy options available”.

Paradigm chief executive officer Paul Rennie said that the FDA clearance showed “the need for effective and safe therapies for the serious chronic disease of osteoarthritis”.

“It also provides validation of the Paradigm dossier which contained information about our non-clinical and toxicology, our manufacturing and our clinical data and data about the previous human experience with the drug,” Mr Rennie said.

Paradigm fell 21.5 cents or 10.2 percent to $1.885 with 1.9 million shares traded.

ESENSE LAB

Esense says it will explore its marijuana derivatives, terpenes and cannabinoids for diabetes-related wounds, Parkinson’s disease and Alzheimer’s disease.

Esense said it was developing “a neuronal cell system that will model both Parkinson’s and Alzheimer’s diseases … [and] serve as a screening platform to select the most effective terpene-cannabinoid combinations to be used in such diseases”.

Esense said it was “developing a wound model derived from fibroblast skin cells that will mimic chronic wounds in a high glucose environment … [to] select the effective terpene-cannabinoid combinations with accelerated wound healing characteristic”.

The company said that diabetes-related wounds, Parkinson’s and Alzheimer’s diseases had “an estimated collective market size of more than $US30 billion by 2026”.

Esense said the potential market would be $US32.6 billion ($A47.5 billion) by 2026 including wound care worth $US14.89 billion, Alzheimer’s expected to reach $US12.43 billion, and Parkinson’s expected to be worth $US5.28 billion.

Esense fell 0.3 cents or 14.3 percent to 1.8 cents with 2.7 million shares traded.

USCOM

Uscom says it has a share sale facility for holders of unmarketable parcels of its shares, worth less than $500, at 11 cents a share, for holders at August 30, 2019.

Uscom said there were 252 holders of unmarketable parcels, with a total of 424,528 shares.

The company said that investors with unmarketable parcels could opt-out of the buy-back.

Uscom said the facility would allow holders of unmarketable parcels to sell their shares without brokerage or handling costs.

The company said the closing date would be October 22, 2019.

Uscom was untraded at 12.5 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has received a call to replace directors Dr Ken Taylor, Robert Willcocks and Laurie Hunter with Dr Andrew Kelly and Dr Roland Toder.
Living Cell said it received the notice from unnamed members who collectively held about 5.26 percent of the company, but gave no reasons for the proposal.
In May, Living Cell said Mr Hunter intended to retire at the November annual general meeting (BD: May 7, 2019).
Living Cell fell half a cent or 21.7 percent to 1.8 cents with 8.15 million shares traded.

PHARMAUST

Pharmaust says the veterinary clinic at the University of Melbourne's Werribee Animal Hospital has joined the trial of monepantel for dogs with B-cell lymphoma.
Yesterday, Pharmaust said it had begun a multi-site, trial of monepantel in an undisclosed number of dogs (BD: Sep 9, 2019, Jun 27, Sep 20, 2017).
Pharmaust fell half a cent or 3.45 percent to 14 cents with 1.8 million shares traded.

MEMPHASYS

Memphasys shareholders will vote to grant 18,000,000 free incentive options to executive chair Alison Coutts and grant directors 3,298,938 options in lieu of fees.
Memphasys said the extraordinary general meeting would vote to grant directors Andrew Goodall, Marjan Mikel and Shane Harting 1,099,646 options each in lieu of 50 percent of their $50,000 directors fees.
The company said Ms Coutts' options would be exercisable at a 34 percent premium to the 5-day volume-weighted average price prior to the meeting and within two years.
Memphasys said the other director options would vest in 12 equal amounts over 12 months from issue, exercisable at a 34 percent premium to the 5-day volume-weighted average price prior to the meeting and within 24 months of issue.
The company said shareholders would also vote to ratify the prior issue of shares, grant shares to directors for debt repayment and for participation in the recent $4.2 million placement (BD: July 9, 2019).
The meeting will be held at 30 Richmond Road, Homebush West, Sydney on October 21, 2019 at 11am (AEDT).
Memphasys was up 0.7 cents or 15.2 percent to 5.3 cents with 6.1 million shares traded.

CYNATA THERAPEUTICS

Cynata says 2,500,000 shares held by chief executive officer Dr Ross Macdonald and director Dr Stewart Washer will be released from voluntary escrow on September 25, 2019.
Cynata's most recent Appendix 3B said it had 102,335,053 shares available for trading.
Cynata fell 2.5 cents or 1.4 percent to $1.72.

STARPHARMA HOLDINGS

Allan Gray Australia says it has increased its holding in Starpharma from 49,041,042 shares (13.36%) to 53,431,698 shares (14.37%).
Allan Gray said that between September 28, 2016 and September 5, 2019 it bought and sold shares, buying 1,192,405 shares on June 19, 2019 for $1,526,278 or $1.28 a share.
Starpharma was up 1.5 cents or 1.35 percent to $1.125.

G MEDICAL INNOVATIONS

G Medical has requested a voluntary suspension to follow the trading halt requested on September 6, pending “a response to an ASX query” (BD: Sep 6, 2019).
Last year, G Medical answered ASX questions regarding missed milestones for its mobile telephone electronic health devices (BD: Mar 28, 2018).
Today, the company said its securities would be suspended until after the expected announcement or until the market opened on September 17, 2019.
G Medical last traded at 8.1 cents.

INVITROCUE

Invitrocue says it has appointed Geoffrey Thomas as a non-executive director.
Invitrocue said Mr Thomas was a principal at Adelaide’s Axant Corporate Advisory and previously held executive positions at funds management companies including Paragon Private Equity and Playford Capital.
Yesterday, the company said it had two requisitions of meeting; one from directors Prof Hanry Yu, Mr Lui, and Ee Ting Ng to remove executive chairman Dr Steven (Boon Sing) Fang and the other from Dr Fang and directors Gary Pace and Andreas Lindner for the removal of Prof Yu and Mr Lui as directors (BD: Sep 9, 2019).
Invitrocue was in a suspension and last traded at six cents.