Biotech Daily

Wednesday September 25, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 14%; CYCLOPHARM DOWN 6%**

*** PROBIOTEC RAISES $10.6m**

*** JCR: MESOBLAST TEMCELL FOR EPIDERMOLYSIS BULLOSA 'ON HOLD'**

*** INVITROCUE ONCO-PDO VALIDATION STUDY**

*** VICTORIA CALL FOR BIO EUROPE TRADE MISSION**

*** PHYLOGICA CPP DELIVERS ANTISENSE DRUG IN MICE OVER 4 WEEKS**

*** LBT FINALIZES APAS INDEPENDENCE CE MARK FOR MRSA**

*** INVITROCUE DIRECTORS PROF YU, MR LUI REPLY TO SPILL CLAIMS**

*** ANTEO, AXXIN WORK ON ANTEOBIND ASSAY READERS**

*** KARST PEAK REDUCES TO 8% OF AVITA**

MARKET REPORT

The Australian stock market fell 0.57 percent on Wednesday September 25, with the ASX200 down 38.7 points to 6,710.2 points.

Nine of the Biotech Daily Top 40 stocks were up, 21 fell and 10 traded unchanged. All three Big Caps were down.

Actinogen was the best, up 0.1 cents or 14.3 percent to 0.8 cents, with 3.7 million shares traded. Osprey climbed 11.1 percent; Alterity was up 7.1 percent; Optiscan improved 6.7 percent; Universal Biosensors was up 5.3 percent; Medical Developments climbed 4.3 percent; Dimerix and Volpara were up more than three percent; with Telix up 1.3 percent.

Cyclopharm led the falls, down eight cents or 6.15 percent to $1.22, with 40,599 shares traded. Pro Medicus lost 5.8 percent; Clinuvel, LBT and fell more than four percent; Ellex, Neuren, Prescient and Resonance were down more than three percent; Cynata, Nanosonics, Opthea and Paradigm shed two percent or more; Antisense, Mesoblast, Orthocell and Starpharma were down more than one percent; with Cochlear, Compumedics, CSL, Genetic Signatures, Kazia, Polynovo and Resmed down by less than one percent.

PROBIOTEC

Probiotec says it has raised $10.56 million in a placement to institutional, sophisticated and professional investors at $1.76 a share.
Probiotec said the placement was at a 4.9 percent discount to the September 24, 2019 closing price and a 0.4 percent premium to the 10-day volume weighted average price.
The company said the funds would be used to target acquisitions and strengthen its balance sheet.
Probiotec said Shaw and Partners were lead managers and Arnold Bloch Leibler was the legal adviser to the placement.
Probiotec was up four cents or 2.2 percent to $1.89.

MESOBLAST

Last week, Mesoblast's Japan partner JCR Pharmaceuticals Co withdrew its expanded Temcell marketing application for epidermolysis bullosa "for the time being".
On September 19, the Ashiya, Honshu-based JCR said that it filed the application to the Ministry of Health, Labour and Welfare for the approval of the Temcell allogeneic bone marrow-derived mesenchymal stem cells for epidermolysis bullosa in March 2019 and "had extensive discussions with the regulatory agency".
"However, in the aim to demonstrate the efficacy of Temcell for [epidermolysis bullosa] with more clarity, JCR decided to withdraw this application for the time being," JCR said.
The company said it would continue discussions with the regulator for the development of Temcell for epidermolysis bullosa, or JR-031EB.
In March, in an announcement marked as "market sensitive", Mesoblast said JCR had filed to extend marketing approval of Temcell from graft versus host disease to epidermolysis bullosa (BD: Mar 25, 2019).
Mesoblast said at that time that epidermolysis bullosa patients had fragile skin that blistered and tore from minor friction or trauma, the disease affected internal organs and bodily systems and could be lethal before 30 years of age.
The company said it would receive royalties from product sales and it would access JCR data to support remestemcel-L for epidermolysis bullosa outside Japan.
Today, Mesoblast chief executive Prof Silviu Itescu told Biotech Daily "JCR has delayed its filing and subsequent approval".
"While we don't know the exact date when they will refile for approval of their product for [epidermolysis bullosa] in Japan, it isn't material to Mesoblast given the expected revenue stream from this indication in Japan," Prof Itescu said.
Mesoblast fell three cents or 1.5 percent to $2.00 with 1.5 million shares traded.

INVITROCUE

Invitrocue says an 80-patient clinical validation study of its Onco-patient-derived organoid (PDO) test for personalized cancer treatment is underway in Germany.
Invitrocue said the 'IVQ-Rechts der Isar Validation Study 2019' would be held at the Munich's Klinikum Rechts der Isar der Technischen Universität München Cancer Centre.
The company said it would establish PDOs for its test using high-risk breast cancer patient biopsy samples from 20 patients in cohort one and 60 patients in cohort two and test the organoids against a panel of cancer drugs and compare responses to chemotherapy.
The company said initial results from the first cohort were positive with final results expected by October 2019.
Invitrocue was in a suspension and last traded at six cents.

VICTORIAN GOVERNMENT

The Victoria Government says innovative life science companies can join a trade mission to BIO Europe be held in Hamburg, Germany from November 11-15, 2019.
The Victoria Government said that trade facilitation agency Global Victoria would lead the mission to “one of the world's largest life science partnering conferences”
Global Victoria said that BIO Europe played an important role in facilitating interaction between global companies and organizations by stimulating business opportunities for 25 years in the life science sector.
Global Victoria said that its trade mission would comprise a program of business matching and networking events at BIO Europe and in Switzerland, as well as an opportunity to exhibit at its dedicated BIO Europe booth.
The agency said it would “coordinate opportunities for delegates to meet with major industry players who could potentially open doors to their export success”.
Global Victoria said that successful applicants will receive an EUR300 ($A486) discount off their BIO Europe registration fees.
The agency said applications opened on September 20 and close on October 30, 2019.
For details and to apply go to: https://bit.ly/2kWc4a1.

PHYLOGICA (TRADING AS PYC THERAPEUTICS)

Phylogica says antisense drugs delivered with its cell penetrating peptide technology continue to be effective for eye diseases in mice over four weeks.
In July, Phylogica said its cell penetrating peptides were able to deliver four times the amount of antisense oligonucleotide drug to retina targets in mice (BD: Jul 23, 2019).
In August, the company said it delivered the antisense drug into human retinal pigment epithelial cells in-vitro and administered 1.6 micrograms per eye to mice to test dosing intervals at one week, two weeks and three weeks (BD: Aug 6, Aug 22, 2019).
Today, Phylogica said it delivered 1.6 micrograms of the antisense drug to each eye using its cell penetrating peptide technology over a four-week dosing interval.
The company said the time-course evaluation of mice over four weeks achieved a positive indication for achieving an acceptable dosing regimen in humans.
Phylogica said this suggested that an effective treatment could achieve infrequent drug administration, which would increase patient compliance and treatment outcomes.
Phylogica was up 0.1 cents or 2.2 percent to 4.6 cents with 1.2 million shares traded.

LBT INNOVATIONS

LBT says its automated plate assessment system (APAS) Independence for methicillin-resistant Staphylococcus aureus is available in Europe.
LBT said it completed its declaration of conformity for APAS Independence for methicillin-resistant Staphylococcus aureus (MRSA or ‘golden staph’) as required under the existing Conformité Européenne (CE) mark registration.
Earlier this month, LBT said that APAS Independence met standards following the completion of its MRSA trial at Melbourne’s St Vincent’s Hospital meeting sensitivity and specificity requirements for clinical validation for regulatory clearance (BD: Sep 16, 2019).
LBT said it planned to develop new analysis modules for infection control screening, including for vancomycin-resistant Enterococcus and to target new applications including antibiotic susceptibility testing.
LBT fell half a cent or 4.35 percent to 11 cents.

INVITROCUE

Invitrocue directors Prof Hanry Yu and Kit Wei Lui have replied to allegations by chief executive officer Dr Steven Fang, who called for their removal.

Earlier this month, Invitrocue filed two board spill motions, one from Prof Hanry Yu, Ee Ting Ng and Kit Wei Lui to remove Dr (Boon Sing) Fang as a director and one from Dr Fang and directors Dr Gary Pace and Andreas Lindner to remove Prof Yu and Mr Lui as directors (BD: Sep 9, 2019).

The company said Prof Yu, Mr Lui and Ms Ng called a meeting to remove Dr Fang and later called a meeting to remove recently-appointed director Geoffrey Thomas and Dr Fang called a meeting to remove Prof Yu and Mr Lui (BD: Sep 10, 11, 13, 18, 2019).

Last week, Dr Fang said that the company's direction was "carefully and strategically planned by gathering key market intelligence, as well as feedback from oncologists, clinical partners and investors" in a response to the allegations from Prof Yu, Ms Ng and Mr Lui (BD: Sep 17, 2019).

Dr Fang said at that time that the "disaffected directors create a dysfunctional board [and] given the board disagreement, many items resulted in a hung decision".

"[They voted] against almost all board items, causing delay and disruption to funding but offering no viable alternative funding," Dr Fang said.

Today, Prof Yu and Mr Lui said they "refute all of the allegations … [which were] founded on an incomplete and distorted representation of circumstances and are without merit".

Prof Yu and Mr Lui said the recently appointed director Mr Thomas proposed their removal with "no first-hand knowledge of the circumstances behind the current unresolved issues".

They said Prof Yu was the founder and scientific advisor of Invitrocue and Mr Lui was a financial professional with experience in corporate capital allocation and governance.

Mr Lui said he analyzed the company's expenses and found that "disproportionately high levels of traveling and entertainment expenses have been incurred without adequate justification".

Prof Yu and Mr Lui said that the appointment of consultants, advisors and investment relations firms "without proper selection committee, approving process and KPIs" and premature expansion into overseas markets by Dr Fang "led to a significant cash drain".

They said Dr Fang proposed two potential investors with $US10 million each, with anti-dilution clauses and the board could not approve special treatment to the new investors.

Prof Yu and Mr Lui said Dr Fang "agreed to set up a committee to appoint an independent valuer" after they objected to the dilution.

They said they "requested a clear indication of the strategic purpose of the capital given Invitrocue's cash burn rate, apart from temporarily covering the cash flow shortfall".

Prof Yu and Mr Lui said they were not stopping investments from new investors but wanted "a clear indication of the strategic purposes of the capital".

They said questions about a $214,000 liability in the company's Appendix 4E were posed to Dr Fang, who would speak to auditors but no answer was forthcoming.

Prof Yu and Mr Lui said, "Steven's premature expansion into new countries has resulted in an annual expenditure increase to $SGD4 million ($A4,281,340) with no meaningful revenue generated … distracting technical staff from readying the technology for effective commercialization".

Prof Yu and Mr Lui said Invitrocue sought cross listing in Frankfurt without consulting the ASX, issued options to a related party without an announcement to the ASX, attempted to place new shares to an independent director without shareholder approval and appointed a related party as an advisor without disclosure.

ANTEO DIAGNOSTICS

Anteo says it will work with Melbourne's Axxin to develop a model assay using its particle conjugation diagnostic Anteobind on Axxin's Gen 3 readers.
Anteo said the Axxin Cubic platform technology enabled low cost, high sensitivity, hand-held and bench-top readers that delivered complex test sequences in a variety of applications.
The company said Axxin's technology was used for lateral flow and molecular quantitative assays and tests.
Anteo said collaboration results of Axxin's Gen 3 readers and its Anteobind would be published and jointly distributed and marketed to the point-of-care industry.
Anteo fell 0.1 cents or 7.1 percent to 1.3 cents with 3.85 million shares traded.

AVITA MEDICAL

Karst Peak Capital says it has reduced its substantial holding in Avita from 177,963,603 shares (9.52%) to 156,015,827 shares (8.33%).
The Hong Kong-based Karst Peak said that on September 20, 2019 it sold 21,947,776 shares on market at prices ranging from 45.04 cents to 54.92 cents a share.
Avita was unchanged at 60 cents with 7.2 million shares traded.