Biotech Daily

Thursday September 26, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 12.5%; CYCLOPHARM DOWN 11.5%**

*** BRANDON $14m FOR DENTERIC PORPHYROMONAS GINGIVALIS VACCINE**

*** CYNATA RECEIVES FUJIFILM $4.4m SIGNING FEE**

*** IMMUTEP: 'POSITIVE DATA, IMP321 TACTI-002 NSCLC TRIAL GO AHEAD'**

*** ADALTA INVOICES GE HEALTHCARE $183k FOR IMAGING**

*** VISIONEERING CLAIMS 1st HONG KONG NATURALVUE SALE**

*** CE MARK FOR RESAPP VERSION 2 RESPIRATORY DIAGNOSTIC**

*** DIMERIX RECRUITS DMX-200 DIABETIC KIDNEY DISEASE TRIAL**

*** FDA APPROVES STARPHARMA, ASTRAZENECA AZD0466 TRIAL**

*** BIONOMICS REFORMULATED BNC210 ACHIEVES BLOOD LEVELS**

*** ELIXINOL APPOINTS HARMONIA LIFE FINLAND HEMP DISTRIBUTOR**

*** PROBIOTEC RELEASES 1.95m ESCROW SHARES**

*** GENETIC TECHNOLOGIES EGM 14% OPPOSE SHARE ISSUE**

*** PAC PARTNERS REDUCED TO 6% OF ALTHEA**

*** NIV DAGAN, FREEDOM TRADER, 10 BOLIVIANOS TAKE 7% OF LIFESPOT**

MARKET REPORT

The Australian stock market fell 0.49 percent on Thursday September 26, with the ASX200 down 32.6 points to 6,677.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and one was untraded.

Actinogen was the best for the second day in a row, up 0.1 cents or 12.5 percent to 0.9 cents, with 3.0 million shares traded. Immutep climbed 8.7 percent; Starpharma was up 7.8 percent; Oncosil, Paradigm and Volpara were up more than three percent; Clinuvel, Mesoblast and Pro Medicus rose two percent or more; Compumedics, Neuren and Orthocell were up more than one percent; with Cynata and Resmed up by less than one percent.

Cyclopharm led the falls for the second day in a row, down 14 cents or 11.5 percent to $1.08, with 25,000 shares traded. Prescient lost 8.3 percent; Alterity, Avita, Impedimed and Kazia fell more than three percent; Genetic Signatures, Next Science and Pharmaxis shed more than two percent; Antisense, Cochlear, CSL, Opthea and Telix were down one percent or more; with Medical Developments, Nanosonics and Polynovo down by less than one percent.

BRANDON CAPITAL, DENTERIC PTY LTD

Brandon says it has invested $14 million in University of Melbourne spin-out Denteric Pty Ltd to develop a vaccine for periodontal gum disease.

Brandon Capital said the funding was through its Medical Research Commercialization Fund's Biomedical Translation Fund for Denteric to develop and commercialize the research of a program originating from the University in collaboration with CSL.

The company said that Denteric would develop a therapeutic vaccine for treating Porphyromonas gingivalis, which was implicated in periodontal disease, a debilitating and painful form of gum disease which affects one in three people globally.

Brandon partner and Denteric director Dr Ingmar Wahlqvist told Biotech Daily that the vaccine had shown "very encouraging safety and efficacy data in mouse and non-human primate models".

"The next steps will be optimization, selecting lead candidates and formal preclinical studies including toxicology," Dr Wahlqvist said.

Brandon said that the disease damaged periodontal soft tissue and alveolar bones, which support teeth, due to an accumulation of bacteria, and severe periodontitis affected more than 50 percent of Australians over the age of 65 and was associated with diabetes, heart disease, rheumatoid arthritis, dementia and certain cancers.

The company said that poor oral hygiene was the leading cause of periodontitis but there were no cures available.

The University of Melbourne's Prof Eric Reynolds, who was also the founder and chief executive officer of the Oral Health co-operative research centre (CRC) said that Denteric was "the perfect example of public-private collaboration within the thriving Melbourne biomedical precinct".

"My team has been developing this critical treatment for periodontal disease over many years at the University of Melbourne," Prof Reynolds says.

"Today, in a true partnership with the Australian Government and private capital, we have launched a company which will bring a Melbourne-developed gum disease therapy to market," Prof Reynolds said.

Brandon Capital managing-director and Medical Research Commercialization Fund (MRCF) chief executive officer Dr Chris Nave said that a treatment for periodontal disease was much-needed.

"Current methods for treating periodontal disease are archaic and painful," Dr Nave said.

"Looking at the science and market opportunity for Denteric, the Porphyromonas gingivalis vaccine research program has great promise and the vaccine would be a blockbuster if it comes to market," Dr Nave says.

CSL head of research Dr Andrew Nash said the group had seen "significant potential in this treatment from the early days and we are pleased to continue our support for the program through series A investment into Denteric".

The Brandon Capital media release said the $14 million investment would go towards progressing the vaccine research program, which was a lead program at the Oral Health CRC, funded under the Federal Government's cooperative research centres program from 2003 to 2018.

The media release said that the Oral Health CRC, was supported by the Victoria Government, Federal Government, CSL and the University of Melbourne, but was no longer part of the CRC Program.

The company said the Oral Health CRC had become the University of Melbourne's Centre for Oral Health Research, under the Melbourne Dental School.

The company said it expected the first human trial in the next two to three years.

Denteric is a private company.

CYNATA THERAPEUTICS

Cynata says it has received $US3 million ($A4,445,370) in an upfront fee from Japan's Fujifilm for the graft versus host disease licence agreement.
Last week, Cynata said Fujifilm would pay up to $US46 million to licence its CYP-001 mesenchymal stem cell product for graft versus host disease.
Cynata was up half a cent or 0.32 percent to $1.59.

IMMUTEP

Immutep says positive interim data for non-small cell lung cancer in cohort 1 will take its phase II Tacti-002 trial of IMP321 with Keytruda to the second cohort.
In March, Immutep said it had dosed the first of 109 patients in the phase II study to assess eftilagimod alpha, or IMP321, in a collaboration with the Kenilworth, New Jersey-based Merck & Co's programmed cell death-1 (PD-1) blocking antibody Keytruda, or pembrolizumab, on second line head and neck squamous cell carcinoma and non-small cell lung cancer patients (BD: Mar 7, 2019).
Today, the company said 17 patients in cohort one of part A with non-small cell lung cancer were given IMP321 with Keytruda at trial sites in the US, Europe and Australia.
Immutep said seven of 17 patients (41.2%) showed a partial response and six patients showed disease stabilization, with a disease control rate of 76.5 percent.
The company said 12 patients were currently continuing treatment and it expected final best overall response numbers in December 2019.
Immutep said the data monitoring committee made the decision to open cohort 2 after a review of preliminary safety and efficacy data.
The company said it exceeded the requisite number of predefined patient responses in cohort one for first line non-small cell lung cancer and it would now recruit a further 19 patients for cohort 2 of part A.
Immutep said recruitment was ongoing for part B of the trial for second line non-small cell lung cancer and for part C for second line head and neck squamous cell carcinoma.
Immutep chief scientific and medical officer Dr Frederic Triebel said the company was "encouraged by the early signals of efficacy seen in the more advanced part A of the study that appear to be consistent with the synergistic efficacy seen in combining efti with pembrolizumab in the TACTI-mel clinical trial".
"We very much look forward to presenting more detailed and more mature data … in November," Dr Triebel said.
Immutep was up 0.2 cents or 8.7 percent to 2.5 cents with 29.7 million shares traded.

ADALTA

Adalta says it has sent a GBP100,000 ($A183,167) invoice to the Chicago, Illinois-based GE Healthcare for its collaboration to develop diagnostic imaging.
Last week, Adalta said it had an agreement with GE Healthcare for its i-body platform to develop positron-emission tomography diagnostic imaging but did not disclose financial terms (BD: Sep 16, 2019).
Today, the company said GE Healthcare would pay research costs of the initial proof-of-concept program, expected to be for 11 to 14 months, would have the option to continue the program and fund it into subsequent phases to commercialization.
Adalta said it could receive royalties if the program continued and it retained the rights to pursue therapeutic applications and to any programs not continued by GE Healthcare.
Adalta fell one cent or 6.45 percent to 14.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering says it has sold its Naturalvue multifocal one day contact lens for paediatric myopia and presbyopia in Hong Kong.
In July, Visioneering said the Hong Kong Department of Health had granted approval for its Naturalvue lenses, which would allow it to sell to regulated channels such as hospitals and it would enter Asia through Hong Kong this year (BD: Jul 24, 2019).
Today, the company said the contact lenses for near-sightedness in children and over-40-year old adults with presbyopia, or losing the ability to see things up close.
Visioneering said the first lenses had been fitted and dispensed by Hong Kong Polytechnic University graduate and optometrist Dr Forrest Ng.
Visioneering was untraded at 6.2 cents.

RESAPP HEALTH

Resapp says it has Conformité Européenne (CE) mark approval for the second version of its Resappdx-EU diagnostic test for adult and paediatric respiratory disease.
In August, Resapp said the first version of its Resappdx-EU smartphone test mobile application had received CE mark certification as a class IIa medical device to analyze cough sounds to diagnose lower respiratory tract disease (BD: Aug 23, 2019).
Today, the company said version two of the test was a software-only product to address respiratory disease in both adults and children.
Resapp was up one cent or 4.55 percent to 23 cents with 3.9 million shares traded.

DIMERIX

Dimerix says it has completed enrolment of its 40-patient phase II trial of DMX-200 for diabetic kidney disease, with no safety concerns to date.
Last November, Dimerix said it recruited the first of 40 patients in the 12-week, phase II, double-blind, randomized, placebo-controlled, crossover study to evaluate safety and efficacy of DMX-200 (BD: Nov 19, 2018; Jun 26, 2019).
The company said patients would receive two treatment blocks of 12 weeks of either placebo or DMX-200, separated by a six-week washout period, followed by the alternative in the second treatment block.
Dimerix said patients would receive 300mg of irbesartan daily for at least three months prior to screening so that reduction in proteinuria could be attributed solely to DMX-200.
Today, the company said it expected to complete the study by July 2020.
Dimerix was unchanged at 9.2 cents.

STARPHARMA HOLDINGS

Starpharma says the US Food and Drug Administration has approved the first human trial of its dendrimer enhanced product in Astrazeneca's AZD0466 for cancer.
In 2017, Starpharma said AZD0466 was a nanomedicine formulation of a dual B-cell lymphoma-extra-large Bcl-2 and Bcl-xL (Bcl2/xL) inhibitor that used its DEP technology and was being evaluated for both solid tumors and blood cancers (BD: Sep 28, 2017).
Today, Starpharma chief executive officer Dr Jackie Fairley said AZD0466 was the first partnered DEP product to receive investigational new drug (IND) clearance from the FDA.
The company said the trial of AZD0466 was expected to begin "later this year".
Starpharma was up 8.5 cents or 7.8 percent to $1.18 with 994,004 shares traded.

BIONOMICS

Bionomics says the new solid dose formulation of BNC210 has achieved the blood levels necessary to meet efficacy endpoints for post-traumatic stress disorder.

Last year, Bionomics said its 193-patient, phase II post-traumatic stress disorder (PTSD) trial "did not meet [the] primary endpoint", but in June this year said it intended to change the formulation to raise BNC210 blood levels (BD: Oct 2, 2018; Jun 26, 2019).

In February, the company said data from a drug exposure-response analysis by the Uppsala, Sweden-based Pharmetheus AB showed a statistically significant response of BNC210 for PTSD and meant it could seek US Food and Drug Administration (FDA) guidance (BD: Feb 18, 2019).

Last week, Bionomics said it had submitted a fast track designation application to the FDA for a single, ascending dose, pharmacokinetic study of BNC210 for PTSD that could achieve the blood levels necessary to meet primary efficacy endpoints using the new solid dose formulation (BD: Sep 19, 2019).

Today, the company said results from a pharmacokinetic study in healthy volunteers showed an exposure-response relationship between BNC210 blood levels and clinician-administered PTSD scale for DSM-5 (CAPS-5) scores, the primary endpoint measure in PTSD trials.

The company said BNC210 was well tolerated at a 300mg dose, which reached plasma exposure of 11mg hours per litre (h/L), at 600mg exposure was 20mgh/l, at 900mg exposure was 27mgh/L and at 1200 mg exposure was 38 mgh/L.

Bionomics said this showed that the solid dose formulation could overcome the "food effect" and reach the blood levels required to give statistically significant results.

Bionomics was up 2.6 cents or 44.8 percent to 8.4 cents with 52.1 million shares traded.

ELIXINOL GLOBAL

Elixinol says it has a five-year exclusive distribution agreement with Harmonia Life Oy for its Elixinol branded hemp and hemp-derived cannabidiol products in Finland.

Elixinol said the agreement with Helsinki's Harmonia Life was "based on achievement of minimum annual sales targets", but did not provide details of the minimum sales targets.

The company said that the expected contribution to Elixinol's revenue would be "not material in the short term", but would represent "continued execution of its global expansion strategy and is an extension of Elixinol's current European footprint".

Elixinol chief executive officer Stratos Karousos said the agreement would allow "Elixinol to further expand our European operations and launch Elixinol branded products throughout various retail channels in Finland."

Elixinol was up 11.5 cents or 5.9 percent to $2.07 with 731,252 shares traded.

PROBIOTEC

Probiotec says that 1,950,000 shares will be released from voluntary escrow on October 4, 2019.

In 2017, Probiotec said 3,950,000 shares were issued to an entity associated with the founder of South Park Laboratories, which it acquired, with 50 percent to be held under escrow for one year and 50 percent in escrow for two years (BD: Sep 21, 2017).

Probiotec chief financial officer Jared Stringer told Biotech Daily that following the release of the shares and the completion of yesterday's $10.56 million placement, the company would have 66,028,870 shares available for trading.

Probiotec fell 3.5 cents or 1.85 percent to $1.855.

GENETIC TECHNOLOGIES

The Genetic Technologies extraordinary general meeting passed all resolutions but with up to 14.1 percent opposition to the issue of placement shares to Kentgrove.
In 2018, Genetic Technologies said it had a $20 million “equity placement facility” with the Melbourne-based Kentgrove Capital Growth Fund, and that Kentgrove Capital could provide up to $20 million in a series of placements of up to $1.0 million over the next 20 months until April 7, 2020. (BD: Aug 8, 2018).
Today, Genetic Technologies said that 13,248,616 votes (14.1%) opposed the issue of 72,596,869 shares to Kentgrove with 80,697,064 votes (85.9%) in favor, with similar opposition to the issue of 100,000,000 shares also to Kentgrove.
Genetic Technologies said that the other placement share issues to Kentgrove Capital and a placement to Aegis Capital were passed by much wider margins.
The company’s most recent Appendix 3B new issue announcement said it had 2,938,134,143 shares on issue, meaning that the 13,248,616 votes against the placement amounted to 0.45 percent of the company, not sufficient to requisition extraordinary general meetings.
Genetic Technologies was unchanged at 0.5 cents.

ALTHEA GROUP HOLDINGS

PAC Partners Securities says it has reduced its substantial shareholding in Althea from 21,409,852 shares (10.5%) to 14,029,902 shares (6.0%).
The Melbourne-based PAC Partners said that between February 11 and August 13, 2019 it bought and sold shares, with a single largest sale of 400,000 shares for $161,000 or 40.25 cents a share.
PAC Partners said it was diluted on August 9, 2019 in the $30 million placement at $1.00 a share (BD: Jul 25, 2019).
Althea was unchanged at 73.5 cents.

LIFESPOT HEALTH

Niv Dagan, Freedom Trader and 10 Bolivianos say they have increased their holding in Lifespot Health from 4,241,719 shares (5.47%) to 5,344,361 shares (6.88%).
The Melbourne-based Mr Dagan, Freedom Trader and 10 Bolivianos said that between January 3 and September 25, 2019, they bought and transferred shares with the single largest purchase 166,600 shares for $9,996 or 6.0 cents a share.
Lifespot fell 0.2 cents or 3.6 percent to 5.3 cents.