Biotech Daily

Monday July 30, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 11.5%; IMPEDIMED DOWN 5%**

*** CLINUVEL RECEIPTS UP 32% TO $23.7m, Q4 CASH-FLOW POSITIVE**

*** ACTINOGEN EXPANDS XANAMEM INDICATIONS, 3 NEW STUDIES**

*** REGENEUS: 'RGSH4K SAFE, TOLERABLE, IMMUNE RESPONSE'**

*** OPTHEA DOSES FIRST PATIENT IN OPT-302 PHASE IIa DME TRIAL**

*** PHYLOGICA PEPTIDE WITH CRE OUTPERFORMS CRE IN MICE**

*** ELIXINOL MARIJUANA REVENUE UP 103% TO $14.6m**

*** BRAIN RESOURCE RECEIPTS DOWN 3% TO $2.4m**

*** GENETIC TECHNOLOGIES APPOINTS SWISSTEC ASIA DISTRIBUTOR**

*** HYDROPONICS SCRAPS BIOFLORAL CANADA DEAL**

*** MERCHANT FUNDS TAKES 8% OF SIENNA**

*** DAVID WILLIAMS TAKES 5.6% OF SIENNA**

*** EMPERY REDUCES TO 8.2% IN IMMURON**

*** MITSUBISHI BELOW 5% IN IMPEDIMED**

*** QUEENSLAND BAUXITE REQUESTS MARIJUANA DEAL TRADING HALT**

*** IMAGION APPOINTS PROF JOHN HAZLE DIRECTOR**

*** BIO-MELBOURNE: MOLECULES, MEDICINES & MARKETS**

MARKET REPORT

The Australian stock market fell 0.35 percent on Monday July 30, 2018 with the ASX200 down 21.8 points to 6,278.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Optiscan was the best, up 0.7 cents or 11.5 percent to 6.8 cents with 50,000 shares traded. Actinogen and Clinuvel climbed more than seven percent; Immutep improved 6.25 percent; Imugene was up 4.55 percent; Factor Therapeutics was up 3.8 percent; Admedus, Airxpanders, Bionomics, Oncosil and Osprey rose more than two percent; Avita and Reva were up more than one percent; with Mesoblast and Volpara up by less than one percent.

Impedimed led the falls, down two cents or 4.6 percent to 41.5 cents with 461,721 shares traded. LBT, Pharmaxis and Universal Biosensors lost three percent or more; Nanosonics, Orthocell, Polynovo, Prana, Resmed and Uscom shed two percent or more; Cochlear, Cynata, Dimerix and Medical Developments were down one percent or more; with CSL, Neuren, Opthea, Pro Medicus, Sirtex and Starpharma down by less than one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says that receipts from customers for the 12 months to June 30, 2018 was up 32.25 percent to $23,705,000, compared to the previous corresponding period.
In its Appendix 4C quarterly report, Clinuvel said that revenue for the three months to June 30, 2018 was up 66.3 percent to $10,388,000 compared to the previous corresponding period.
The company said that all revenues were generated from its Scenesse for the orphan indication of erythropoietic protoporphyria (EPP), while the group focussed on managing its overall cost base.
Clinuvel said it had spent more than $170 million to date on research and development for Scenesse with the product approved in the European Union as the only available and first-line therapy for the treatment of EPP.
Clinuvel chief financial officer Darren Keamy said that the June quarter saw “the highest positive operating cash flow result for the company, with the increase in sales receipts influenced by the seasonal ordering of Scenesse”.
The company said it was cash flow positive in the three months to June 30, 2018 gaining $7,440,000, with cash and cash equivalents of $36,198,000 at that date and an expected cash burn for the three months to September 30, 2018 of $3,570,000, not including expected revenue.
Clinuvel was up 83 cents or 7.55 percent to $11.82.

ACTINOGEN MEDICAL

Actinogen says it will expand its program for Xanamem to include new diseases, a “target occupancy study”, a higher dose safety study and additional toxicology studies.
Actinogen said that new clinical indications for Xanamem beyond Alzheimer’s disease were under evaluation, including conditions associated with cortisol-induced cognitive impairment such as diabetes, depression, Parkinson’s disease, schizophrenia, post-traumatic stress disorder and post myocardial infarction.
Actinogen chief executive officer Dr Bill Ketelbey said the target occupancy study would investigate whether Xanamem binds to the enzyme in the human brain as it does in animal studies using positron emission tomography (PET) imaging to identify the amount binding at varying doses of the drug.
The company said the study would investigate the effect of different doses of Xanamem on the cortisone reductase, or 11beta-hydroxysteroid dehydrogenase type 1 (11b-HSD1), enzyme in the human brain, which converts inactive state cortisone to active cortisol.
Actinogen said that the initial work for the study was underway and results were expected by July 2019, in-line with the expected top-line results for the company’s safety and efficacy trial of Xanamem for Alzheimer’s disease.
The company said the higher dose safety study would expand the safety data for Xanamem and allow for higher doses of the drug to be used, if required, including in non-Alzheimer’s applications, with the human study expected to begin by the end of 2018.
Actinogen said the additional safety toxicology studies would allow for longer treatment periods as required by regulatory authorities and were expected to begin by the end of 2018.
Earlier this month, Actinogen said it had raised a total of $16.6 million through a placement and share plan, with the funds to be used to drive development of Xanamem (BD: Jul 17, 2018).
Actinogen was up 0.4 cents or seven percent to 6.1 cents with 2.5 million shares traded.

REGENEUS

Regeneus says its 12-patient, phase I trial of cancer vaccine RGSH4K has met the safety and tolerability primary endpoints and has shown an immune system response.

Regeneus said patients with various advanced solid tumors who had been “heavily pre-treated with chemotherapy or radiotherapy” were administered RGSH4K in three dose cohorts at three-week intervals.

The company said that all dose levels were “safe and well tolerated” and that it had achieved the primary endpoint, with no dose-limiting toxicities and no serious adverse events.

Regeneus said RGSH4K, which was produced from the patient’s own cancer cells, showed signs of immune stimulation, such as changes in cancer markers, immune cells and cytokines in one or more patients at all three dose levels.

The company said that the principal investigators for the trial were the St Leonard’s, Sydney-based Northern Cancer Institute’s Prof Stephen Clarke and Prof Nick Pavlakis.

Prof Clarke said that the immune response, “including favorable changes in biomarkers, coupled with the benign safety profile for RGSH4K encourages proceeding to further clinical evaluation either as a single agent or in combination with other therapies”.

Regeneus chief executive officer John Martin said that the “data obtained from this first-in-human clinical study, including the preliminary evidence of clinical activity, is encouraging and highlights the clinical potential of RGSH4K”.

“We are pleased with these results and we will use them to advance further studies and our partnering discussions with interested parties,” Mr Martin said.

In 2015, the company said it had treated the first of 21 patients in its first clinical trial of RGSH4k for solid tumors at the St Leonards, Sydney-based private hospital the Northern Cancer Institute (BD: Oct 27, 2015).

Earlier this year, Regeneus said it had a Japanese patent covering the use of a cancer vaccine technology for a range of cancers in humans and animals that would support its human RGSH4K clinical programs (BD: Feb 12, 2018).

Regeneus was unchanged at 23.5 cents with 1.8 million shares traded.

OPTHEA

Opthea says it has dosed the first patient in its 108-patient, phase IIa safety and efficacy trial of OPT-302 for diabetic macular oedema.

Opthea said the randomized, controlled trial would treat patients in a two-to-one ratio with either OPT-302 2.0mg milligrams in combination with aflibercept, marketed as Eylea, or Eylea as a monotherapy, administered on a monthly basis for three months.

Last week, the company said its nine-patient, dose-escalation phase Ib trial of OPT-302 for diabetic macular oedema met its primary objective of acceptable safety and tolerability, with dose levels “well tolerated… no dose-limiting toxicities were observed and the maximum tolerated dose was not reached” (BD: Jul 26, 2018).

Opthea chief executive officer Dr Megan Baldwin said that taking OPT-302 in combination with Elyea into a phase IIa study for diabetic macular oedema was “another important milestone in the progression of our pipeline, following the continued progress of the phase IIb study of OPT-302 in combination with Lucentis in patients with wet macular degeneration”.

Opthea fell half a cent or 0.9 percent to 55 cents.

PHYLOGICA

Phylogica says it has delivered the Cre enzyme in-vivo into the nucleus of cells across multiple types of tissue in mice, using its cell penetrating peptide, CPP1.
Phylogica said that CPP1 penetrated the nucleus of lung, liver and kidney cells in-vivo, which was “an important milestone” because Cre (cause recombination) was a large cargo and expanded the range of cargoes that its delivery platform could carry.
The company said that Cre had to be delivered into the nucleus of cells to be active and showed that the cell penetrating peptide delivered the cargo across the cell membrane and from the endosome as well as across the nuclear membrane, proving it could reach different sub-cellular destinations.
Phylogica said that delivering Cre into multiple tissue types in mice showed “the breadth of different disease indications that can be pursued using the cell-penetrating peptide] platform”.
The company said that its current lead molecule CPP2 was about twice as effective as CPP1 in-vitro and would be tested in the same animal model.
Phylogica said the delivery of the Cre cargo in-vivo was “the most significant technical challenge of the proof-of-concept cargoes” set in its 2017 strategic review and the intracellular delivery platform had been validated extensively in-vivo.
The company said it had progressed to the therapeutic application of its technology, the development of new CPP-delivered drugs and the progression of these candidates into the clinic.
Phylogica said that it tested the ability of CPP1 joined to the Cre cargo in two experiments involving a total of 24 mice including controls and found that the CPP conjugated cargo (CPP1-Cre) outperformed the Cre cargo alone with a statistical significance of $p < 0.0001$.
Phylogica was up 0.2 cents or 6.1 percent to 3.5 cents with 4.1 million shares traded.

ELIXINOL GLOBAL

Elixinol says that revenue for the six months to June 30, 2018 rose 102.8 percent to $14.6 million compared to the previous corresponding period.
Elixinol said revenue growth was primarily driven by sales of its hemp-derived cannabidiol (CBD) dietary supplements and skincare products.
In its Appendix 4C quarterly report the company said that receipts from customers for the six months to June 30, 2018 were at $13,986,000, with no comparable corresponding period due to the company’s recent listing on January 1, 2018.
The company said it had cash and cash equivalents of $14,170,000 at June 30, 2018 and an estimated cash outflow for the next three months of $13,883,000 which included the fit out and equipment of its new US facility and its investment in the Northern Colorado High Plains Producers joint venture with Kersey Ag.
Elixinol fell 3.5 cents or 2.4 percent to $1.42.

BRAIN RESOURCE

Brain Resource says that receipts from customers for the year to June 30, 2018 fell 3.4 percent to $2,347,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $6,616,000 at June 30, 2018 and an estimated cash outflow for the next three months of $3,042,000.
Brain Resource was untraded at 5.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed Melbourne's Swisstec Health Analytics as a non-exclusive distributor of its genetic screening tests for Asia.

Genetic Technologies said it had granted Swisstec the rights to deliver its genetic screening tests to hospitals in Asia in exchange for a five percent equity stake in Swisstec, with an additional five percent subject to the achievement of milestones.

The company said it would provide Swisstec $250,000 for its expansion into China.

Genetic Technologies said the agreement was in addition to its joint venture with Swisstec for blockchain technology, announced last month (BD: Jun 19, 2018).

Genetic Technologies was unchanged at 1.1 cents with 12.9 million shares traded.

THE HYDROPONICS COMPANY

Hydroponics says it has scrapped its proposed acquisition of the Laval, Quebec Canada-based Biofloral, but will cross-promote products with the company.

In January, Hydroponics said it was conducting due diligence on a then unnamed Canadian marijuana company that was "complimentary to the existing Crystal Mountain-Dragon Vision business" (BD: Jan 24, 2018).

Today, the company said the deal would not go ahead as it had decided to limit acquisitions to those that do not change the nature or scale of activities as provided in chapter 11 of the ASX listing rules.

Hydroponics said its Vancouver, Canada-based subsidiary Crystal Mountain Products would work with Biofloral to distribute respective products in Canada, as Crystal Mountain had a "strong West Coast presence" and Biofloral a "strong East Coast presence".

Hydroponics fell 1.5 cents or 2.7 percent to 54 cents.

SIENNA CANCER DIAGNOSTICS

Merchant Funds says it has become a substantial shareholder in Sienna with 16,500,000 shares, or 7.96 percent of the company.

The Perth-based Merchant Funds Management said it acquired the shares on July 20 2018 for $990,000, or six cents a share.

Earlier this month, Sienna said it had raised $1.6 million in a placement at six cents a share to Merchant Funds and Kidder Williams principal David Williams.

Sienna fell 0.1 cents or 1.3 percent to 7.8 cents.

SIENNA CANCER DIAGNOSTICS

David Williams says he has become a substantial shareholder in Sienna with 11,600,000 shares, or 5.60 percent of the company.

In his substantial shareholder notice Mr Williams said he acquired 5,000,000 shares at six cents a share through a placement on July 20, 2018 and bought the rest of the shares between August 14, 2017 and June 20, 2018, with the single largest purchase of 2,000,000 shares for $156,000,000, or 7.8 cents a share on June 8, 2018.

The substantial shareholder notice said that the registered holders of the shares were Amore Foods Pty Ltd, Kidder Peabody Pty Ltd, Moggs Creek Pty Ltd as trustee for the Moggs Creek Superannuation Fund.

IMMURON

Empery Asset Management says it has reduced its shareholding in Immuron from 13,162,744 (9.22%) to 11,717,666 (8.21%).
The New York-based Empery said it sold the shares on July 23, 2018 but did not disclose prices, as required by the Corporations Act 2001.
In the substantial shareholder notice, Empery managing member Ryan Lane said that the holders included himself, Marin Hoe, Empery Asset Management, Empery AM GP, Empery Asset Laster, Empery Tax Efficient LP and Empery Tax Efficient II LP, with Citicorp the registered holder.
Immuron fell half a cent or 1.3 percent to 37.5 cents.

IMPEDIMED

Mitsubishi says it has ceased its substantial shareholding in Impedimed, selling and returning 19,488,772 shares as well as buying and borrowing 1,724,905 shares.
Last week, the Tokyo, Japan-based Mitsubishi UFJ Financial Group said it had become substantial in Impedimed through its part holding in New York and Sydney-based Morgan Stanley, with 18,968,277 shares or 5.00 percent of the company (BD: July 27, 2018).
Today, Mitsubishi said that on July 25, 2018 it bought 24,905 shares and sold 41,000 shares for prices ranging between 42 to 43.5 cents and had borrowed 1,700,000 shares and returned 19,447,772 shares for no fee, which was the largest single change.
Impedimed fell two cents or 4.6 percent to 41.5 cents.

QUEENSLAND BAUXITE

Queensland Bauxite says it has requested a trading halt pending an announcement regarding “material developments in a collaboration deal of its subsidiary Medical Cannabis”.
Earlier this year, Queensland Bauxite said it would acquire the remaining 45 percent of its subsidiary Medical Cannabis (BD: Jun 21, 2018).
Trading will resume on August 1, 2018, or on an earlier announcement.
Queensland Bauxite last traded at 3.7 cents.

IMAGION BIOSYSTEMS

Imagion says it has formally appointed Prof John Hazle as a non-executive director, effective from today, July 30, 2018.
Imagion said that Prof Hazle was the University of Texas MD Anderson Cancer Centre professor and chair of the Department of Imaging Physics and the appointment was subject to approval from MD Anderson Cancer Centre’s conflict of interest committee, which had been obtained.
Imagion fell 0.4 cents or 6.15 percent to 6.1 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will hold its inaugural Biotech Development Lab, themed Molecules, Medicines & Markets on Friday August 10, 2018.

The Network said the full day event would include an address from a representative from the Department of Economic Development, Jobs, Transport and Resources, presentations from 12 speakers and panel discussions with the speakers and four expert panellists.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that the topics to be addressed included 'How drug development can be done differently in the 21st Century', 'How companies are attracting investment funds to go from seed to series A and beyond' and 'What are the biggest challenges for biotech in reaching that next value inflection point?'.

The Network said that more than 120 people had registered for the event which was sponsored by the Victoria State Government, Watermark, Seer Pharma and Prime Accounting and Business.

The Network said that the workshop would will be held in Lecture Theatre B, Level 7, Peter MacCallum Cancer Centre, 305 Grattan Street, Melbourne on August 10, 2018, with registration from 8.15am and presentations from 9am until 5.00pm to be followed by networking. To view the full program or register go to: https://biotechdevlab.zohobackstage.com/MoleculesMedicinesMarkets#/?lang=en.