Biotech Daily

Thursday October 18, 2018

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: FACTOR UP 10%; REVA DOWN 12%**

*** TELIX STARTS TLX101, RADIOTHERAPY GLIOBLASTOMA TRIAL**

*** CYNATA STEM CELLS IMPACT BRAIN, SKIN CANCERS IN-VITRO, MICE**

*** KAZIA RAISES $3.4m, SHARE PLAN**

*** ELIXINOL TO ADD MEDICAL MARIJUANA TO OTC HEMP FOODS 'SOON'**

*** AVITA 1st US RECELL SALES**

*** OVENTUS TRIALS SHOW SIGNIFICANT O2VENT BENEFIT**

*** EUROPEAN PATENT FOR REGENEUS PROGENZA FAT STEM CELLS**

*** ESENSE TELLS ASX AWARE QUERY $25k SALES 'NOT MATERIAL'**

*** CSL 16% OPPOSE $8.5m CEO PAUL PERREAULT SHARES, AGAIN**

*** CHARTER LIFE SCIENCES DILUTED TO 20% OF VISIONEERING**

*** NOVITA COMPLETES SALE OF NEWLY TO HEALTHCARELINK**

*** MEMPHASYS PLEADS SCHULTZ TO ASX 65% QUERY; ASX MISSES 148%**

*** ELLEX APPOINTS DR DAVID LUBECK CMO**

MARKET REPORT

The Australian Stock Market edged up 0.06 percent on Thursday October 18, 2018 with the ASX200 up 3.3 points to 5,942.4 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and four were untraded. All three Big Caps fell.

Factor Therapeutics was the best, up 0.7 cents or 10 percent to 7.7 cents with 2.4 million shares traded. Optiscan climbed 9.1 percent; Neuren and Telix were up more than six percent; LBT improved five percent; Cynata and Genetic Signatures were up more than four percent; Benitec and Pharmaxis rose more than three percent; with Clinuvel, Immutep, ITL, Orthocell and Polynovo up by more than two percent.

Reva led the falls, down three cents or 12.2 percent to 21.5 cents, with 43,358 shares traded. Prana lost 6.4 percent; both Airxpanders and Bionomics fell 5.6 percent; Dimerix and Imugene shed more than four percent; Impedimed, Mesoblast and Pro Medicus lost more than three percent; CSL, Oncosil, Opthea, Paradigm, Prescient and Starpharma were down more than two percent; Cochlear and Nanosonics were down more than one percent; with Medical Developments, Resmed and Volpara down less than one percent.

TELIX PHARMACEUTICALS

Telix says it has its first European approval for its 45-patient phase I/II trial of injected TLX101 with radiotherapy for recurrent glioblastoma, and has begun recruitment.

In September, Telix said it had ethics approval from the Linz, Austria-based Kepler University and the University Hospital Vienna, with sites in Belgium, the Netherlands, Germany, Switzerland and Australia to follow, pending approvals (BD: Sep 4, 2018).

Today, Telix said the multi-centre, open-label, dose-ranging Ipax-1 would evaluate the safety, tolerability, dosing schedule and preliminary efficacy of carrier-added 4-L-[131I] iodo-phenylalanine (131I-IPA) or TLX101 as single or repeated injections in patients with recurrent glioblastoma multiforme with external radiotherapy.

The company said the first authority to approve the trial was the Austrian Bundesamt für Sicherheit im Gesundheitswesen, (the Federal Office for Safety in Health Care).

Telix chief executive officer Dr Christian Behrenbruch said the company was “very pleased to have this first approval”.

“We have been able to attract the interest of some excellent neuro-oncology sites to this study and we are excited to be further evaluating the clinical utility of this very promising therapy,” Dr Behrenbruch said.

Telix was up five cents or 6.2 percent to 86 cents.

CYNATA THERAPEUTICS

Cynata says that engineered Cymerus human mesenchymal stem cells have anti-glioblastoma and anti-melanoma effects in-vitro, with anti-glioblastoma benefit in mice.

Cynata said the first stage of the program found that Cymerus stem cells could be modified using its lenti-viral engineering process to express transgenes, or genes from other cells and to express a protein known to exert anti-cancer effects.

Cynata chief executive officer Dr Ross Macdonald told Biotech Daily that the “Cymerus human cells were engineered to carry a gene for an oncolytic toxin”.

“The stem cells migrate into the tumor and once inside, the gene expresses the toxin which destroys the tumor,” Dr Macdonald said.

In its media release, the company said the modified Cymerus cells expressed transgenes that persisted in mice long enough to facilitate a statistically significant therapeutic effect glioblastoma, or brain cancer, in mice.

Cynata said the second stage of the program found that its engineered cells caused a significant reduction in the viability of human glioblastoma cells in-vitro compared to either control ($p < 0.005$) or to direct administration of the therapeutic protein ($p < 0.05$), and a significant reduction in the viability of melanoma cells compared to control ($p < 0.005$).

The company said that in a mouse model of glioblastoma, tumor progression was slower in mice that received the engineered Cymerus mesenchymal stem cells compared to those receiving the control.

Study director Prof Khalid Shah said the results “validated the use of this cell-based approach, as it provides a continuous pool of therapeutic protein around the tumor cells, circumventing the protein short half-lives”.

Cynata head of product development Dr Kilian Kelly said that the “highly encouraging results suggest that the Cymerus platform can be exploited to produce targeted anti-cancer therapies, which may have significant advantages over conventional cancer treatments, from both a safety and efficacy perspective”.

“This engineering technique could also facilitate the creation of novel engineered therapies for areas of high unmet need in other therapeutic areas,” Dr Kelly said.

Cynata was up five cents or 4.2 percent to $1.25.

KAZIA THERAPEUTICS

Kazia says it has raised $3.4 million at 38 cents a share in a placement to institutional investors and will offer a share purchase plan.
Kazia said funds would progress its phase II study of GDC-0084 for glioblastoma multiforme, its phase I study of Cantrixil for ovarian cancer and for working capital.
The company said the placement was at a 11.6 percent discount to its closing price on October 12, 2018.
Kazia said that investors at the record date of October 17 could apply for up to $15,000 in shares, with the plan opening on October 23 and closing on November 16, 2018.
The company said the London and Sydney-based WG Partners was the lead manager to the placement.
Kazia was untraded at 43 cents.

ELIXINOL GLOBAL

Elixinol chief executive officer Paul Benhaim says he expects Australian marijuana licences “soon” and then a year to build a growing and manufacturing facility.
In Melbourne as part of an investor and media roadshow, Mr Benhaim said that while waiting for medical marijuana licences the company was able to sell over-the-counter hemp-based human and animal dietary supplements in the US under the Elixinol label as well as hemp foods including seeds, flour and protein in Australia, under the brand Hemp Foods Australia.
In August, Elixinol said that sales for the six months to June 30, 2018 was up 110.8 percent to $14,886,000 with a maiden net profit after tax of $120,000 (BD: Aug 28, 2018).
Elixinol said that the revenue and profit comparison figures were pro-forma as the group was formed last year and listed on the ASX in January and Elixinol chief financial officer Ron Dufficy told Biotech Daily that underlying net profit after tax was $599,000 compared to the previous period pro forma loss of $329,000 (BD: Jan 21, 2018).
In a teleconference, Elixinol chief executive officer Paul Benhaim said that the revenue from marijuana/hemp based dietary supplements sales in the US was $12,544,000 with hemp foods and skin-care in Australia comprising $2,342,000.
Today, Mr Benhaim told Biotech Daily that the over-the-counter US products included delivery through topical oils, vaporizer liquids and lyposome.
Mr Benhaim said that the US products were generally regarded as safe and not allowed to make any claims, but customers have reported using the products for pain, including pain related to inflammation, as well as anxiety and sleep disorders.
He said that he expected to have some of the same products made available in Australia, but they would not be over-the-counter, requiring medical practitioner prescriptions and more information on the products and the brand would also be available “soon”.
“We have experience growing hemp and taking it through to stable products and are the largest importer and exporter in Australia,” Mr Behaim said.
“We have applied to the Australian Office of Drug Control for cultivation and manufacturing licences and expect to have those licences soon,” Mr Benhaim said.
“It could be this year but we have no control,” Mr Benhaim said.
Mr Benhaim said that once the licences were approved the New South Wales facility would take a year to build.
Previously, Mr Benhaim said that Elixinol would grow marijuana, produce finished medicinal goods and the company was developing specific formulation for specific indications but said he could not elaborate at this stage of the development.
Elixinol was up 2.5 cents or 1.3 percent to $1.95.

AVITA MEDICAL

Avita says it has its first commercial US burns centre sales orders and begun shipment of its Recell autologous cell harvesting device.

Last month, Avita said that the US Food and Drug Administration approved Recell for severe thermal burns in patients 18 years and older (BD: Sep 20, 2018).

Today, Avita chief commercial officer Erin Liberto said the company was “pleased to have fulfilled multiple orders for the Recell system in such a short period of time following FDA approval and in advance of our national US market launch”.

Avita said that 24 of 134 US burns centres had used Recell in clinical trials and through compassionate use and continued access and the 24 centres were “estimated to treat over 30 percent of the US burn patients annually”.

Avita was unchanged at 10.5 cents with 18.9 million shares traded.

OVENTUS MEDICAL

Oventus says data from 170 sleep apnoea patients in four clinical trials found that its devices treated 75 percent of patients without continuous positive airway pressure.

Oventus said that patients with nasal obstruction who would normally struggle with treatment were found to benefit from its O2Vent ‘mouthguard’ airway technology, which acted “as a second nose, enabling the patient to breathe freely overnight”.

The company said that patients who failed prior therapies had benefit from its airway.

Oventus said that adding positive end expiratory pressure (PEEP) valve technology, to be called Exvent, to the O2Vent airway duck bill delivered a 30 percent ($p < 0.01$) increase in efficacy and the addition of the Oventus oro-nasal PEEP valve, to be be called Onepap, increased efficacy by 50 percent ($p < 0.01$).

The company said its airway technology improved treatment outcomes for continuous positive airway pressure (CPAP) users by reducing pressure requirements by 40 to 50 percent ($p < 0.001$) and eliminating the need for full-face masks.

Oventus said that a new finding from a physiologic study predicting response to its airway showed improved treatment outcomes for female patients ($p < 0.02$).

Oventus chief executive officer Dr Chris Hart said the clinical trials showed “a dramatic improvement in our patients”.

“The technology in these devices eliminates the need for full face masks and greatly improves treatments for the majority,” Dr Hart said.

“We have been consistently delighted with the results,” Dr Hart said.

Oventus said the data was being presented at the Sleep Downunder meeting in Brisbane from October 17 to 20, 2018.

Oventus was unchanged at 29.5 cents.

REGENEUS

Regeneus says the European Patent Office intends to grant a patent for its Progenza fat-derived mesenchymal stem cells.

Regeneus said the patent, titled ‘Therapeutics using adipose cells and cell secretion’ would provide commercial rights in up to 38 European member states of the European Patent Office until March 15, 2032, with corresponding patents already granted in Australia, New Zealand, Japan and the US.

Regeneus chief executive officer John Martin said the notification was “a significant milestone for Progenza”.

Regeneus was up 1.5 cents or 8.1 percent to 20 cents.

ESENSE-LAB

Esense has told an ASX aware query that it did not consider its UK sales of Super Lemon Haze marijuana strain valued at $US18,000 ($A25,267) to be material.

The ASX asked Esense when it had "first become aware that the UK based company had purchased seven litres of [Esense's] Super Lemon Haze strain" and if Esense was aware of the purchase before it announced a $3.15 million capital raising (BD: Oct 15, 2018).

Esense told the ASX that it had been aware of the sales to the UK since March and that the sales were a part of an ongoing testing and pilot program that was underway when it announced its capital raising.

The company said that because of the confidential nature, uncertain outcome and low value of the pilot testing program, it had not announced the UK sales to the market before October 16, 2018 and at this time could not name the UK company (BD: Oct 16, 2018).

Esense said that it had announced a commercial sales trading halt on October 16 to "update the market on aspects of the company's ongoing commercial activities".

The company said it was currently negotiating with the UK party to finalize a commercial supply agreement.

Esense was up 3.5 cents or 53.85 percent to 10 cents with 10.3 million shares traded.

CSL

All resolutions at the CSL annual general meeting were passed, but with up to 16.11 percent opposition to the grant of stock to chief executive officer Paul Perreault.

In previous years, CSL has faced increasing opposition to the issue of performance rights and options, including a "first strike" against the 2016 remuneration report.

In 2017, CSL said that 18.3 percent of votes opposed the issue of $6,786,729 performance shares to Mr Perreault and the remuneration report was opposed by 12.2 percent of votes at the meeting (BD: Oct 18, 2017).

In 2016, the company said it had a remuneration report first strike with the meeting voting 65,666,474 votes (26.02%) against the report, with 33.82 percent opposed to an increase in the directors' fee pool and the director fee hike 27.25 percent of votes opposed to performance shares and options worth $6,636,637 for Mr Perreault (BD: Oct 12, 2016).

In 2015, all CSL resolutions were passed, with 11.03 percent opposition to the grant of options and rights worth up to $5,146,184) stock to Mr Perreault (BD: Oct 15, 2015).

In 2014, the CSL meeting passed all resolutions but with 10.7 percent against the grant of the free options and rights worth up to $3,358,560 (BD: Sep 12, Oct 15, 2014).

Today, CSL said that the proposal to grant Mr Perreault free 'performance' rights worth up to $US6,128,500 ($A8,510,935) was supported by 219,444,916 votes (83.89%) and opposed by 42,134,292 votes (16.11%).

The company said that the remuneration report was opposed by 26,269,715 votes (10.04%) with 235,270,374 votes in favor (89.96%); the performance rights plan was passed by 91.27 percent to 8.73 percent; the employee share plan was passed with 95.44 percent in favor; with the takeover provisions and the election of directors, chairman Dr Brian McNamee, chief scientific officer Dr Andrew Cuthbertson and Abbas Hussain, passed by more than 99.2 percent.

CSL's most recent Appendix 3B said the company had 452,958,087 shares on issue meaning that the largest opposition vote, to Mr Perreault's options and rights, amounted to 9.3 percent, an increase in proportion of the company's total shares on issue from previous results of 6.3 percent and 5.8 percent, and sufficient to requisition extraordinary general meetings.

CSL fell $4.19 or 2.2 percent to $188.81 with 1.2 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says Charter Life Sciences and its associated parties' 50,564,752 share substantial holding has been diluted from 25.66 percent to 20.37 percent.
Visioneering said the Ohio-based Charter Life Science's dilution was caused by its $8,856,000 August placement and $344,399 share plan (BD: Aug 15, Sep 12, 2018).
Visioneering was unchanged at 18.5 cents.

NOVITA HEALTHCARE

Novita says that it has completed the sale of its subsidiary Newly to Healthcarelink.
In July, Novita said it would divest its holding in Newly to Healthcarelink in return for shares and would take a cash subscription of $400,000 in an equity raising by Healthcarelink of up to $1.4 million, after which it would hold 10 percent of the company (BD: Jul 20, 2018).
Novita was up 0.1 cents or three percent to 3.4 cents.

MEMPHASYS

Memphasys has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 64.7 percent from 1.7 cents to 2.8 cents today October 18, 2018 and noted a "significant increase" in trading volume.
Memphasys was up 3.4 cents or 212.5 percent to five cents with 184.9 million shares traded.

ELLEX MEDICAL LASERS

Ellex says it has appointed cataract, corneal and refractive surgeon Dr David Lubeck as its chief medical officer.
Ellex said the Dr Lubeck currently worked at the Chicago-based Arbor Centers for Eye Care.
The company said Dr Lubeck received his medical training at the Evanston, Illinois-based Northwestern University, undertook an ophthalmology residency at the University of Illinois Eye and Ear Infirmary and served a fellowship in corneal surgery at the Adelaide-based Flinders Medical Center.
Ellex was unchanged at 62 cents.