Biotech Daily

Tuesday July 17, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ITL UP 34%; PRANA DOWN 9%**

*** KAZIA READY FOR 1st GDC-0084 GLIOBLASTOMA DOSING**

*** FEDERAL $6m FOR SOUTH AUSTRALIAN RESEARCH**

*** ACTINOGEN SHORTFALL RAISES $560k; TOTAL $16.6m**

*** PROTEOMICS: BIOSANAPHARMA $350k CONTRACT; NEAR BREAK-EVEN**

*** ORTHOCELL 1st ITALIAN CELGRO DENTAL SALE, USE**

*** ITL EXPECTS $24.3m REVENUE, $3.5m EBITDA**

*** RECCE DESIGNS PHASE I RECCE-327 ANTIBIOTIC FOR SEPSIS TRIAL**

*** NOVITA REQUESTS 'BOOKBUILD FOR NEWLY' TRADING HALT**

*** CRESO LISTS ON FRANKFURT EXCHANGE, HIRES GERMAN ADVISOR**

MARKET REPORT

The Australian stock market fell 0.61 percent on Tuesday July 17, 2018 with the ASX200 down 37.9 points to 6,203.6 points.

Ten of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

ITL was the best, up six cents or 34.3 percent to 23.5 cents with 58,339 shares traded.

Ellex climbed 10.45 percent; Orthocell was up 6.7 percent; Actinogen improved 3.85 percent; Medical Developments, Pharmaxis, Polynovo, Starpharma and Universal Biosensors were up more than one percent; with Sirtex up 0.2 percent.

Prana led the falls, down 0.5 cents or 9.1 percent to five cents with 248,760 shares traded.

Factor Therapeutics and Neuren lost five percent or more; Airxpanders and Dimerix fell more than four percent; Cyclopharm, Cynata and Imugene were down more than three percent; Admedus, Avita, Oncosil and Telix shed two percent or more; Bionomics, Cochlear, Impedimed, Optiscan and Prescient were down more than one percent; with Clinuvel, CSL, Pro Medicus, Resmed and Volpara down by less than one percent.

KAZIA THERAPEUTICS (FORMERLY NOVOGEN)

Kazia chief executive officer Dr James Garner says the first patient is about to be dosed in its 230-patient, US, phase II trial of GDC-0084 for glioblastoma multiforme.

Dr Garner told Biotech Daily that with last week's licence of the anti-tropomyosin cancer antibody discovery research program to Trobio Therapeutics, Kazia would focus on the GDC-0084 program and continue its phase I trial of Cantrixil, also known as TRX-E-002-1, for ovarian cancer (BD: Apr 6, Sep 12, 2017; Jul 13, 2018).

Today, Dr Garner said that Trobio was a start-up founded by University of New South Wales academics, including former Novogen director and now Kazia advisor Prof Peter Gunning, "who essentially invented the [anti-tropomyosin] technology".

Dr Garner said glioblastoma multiforme was "the most common and most aggressive form of primary brain cancer" and GDC-0084 was licenced in 2016 from Roche's Genentech with data from a 47-patient, phase I, dose escalation trial (BD: Oct 31, 2016).

Dr Garner said that the Kazia, phase II, open-label trial would begin with about 12 patients in a further dose escalation stage, starting with an oral dose of 60mg of GDC-0084.

He said that Genentech took dosing to 45mg, but the drug was non-toxic and he hoped that a higher dose could result in better efficacy.

Dr Garner said that the company received US Food and Drug Administration orphan drug designation for GDC-0084 in February and pending trial results, the company could apply for accelerated approval.

He said that while the trial was open-labelled for the clinicians and patients, the magnetic resonance imaging (MRI) analysis would be blinded to the reviewers, with GDC-0084 effectively being compared to temozolomide, the main chemotherapy drug used for brain cancer, as a control.

"Two-thirds of patients do not respond to temozolomide and they have an average life expectancy of about 12 months," Dr Garner said.

"The one-third who do respond have a life expectancy of about 18 to 21 months," Dr Garner said.

He said that non-responders could be identified following first-line surgery, through a genetic switch, "the unmethylated MGMT promoter gene mutation".

Dr Garner said that the trial would enrol non-responders to temozolomide.

"We are hoping for at least six weeks of added benefit and hopefully more and that would give us an approvable product," he said.

"There are no other treatment options," Dr Garner said.

Dr Garner said that non-responding patients would complete surgery and radiotherapy before starting the GDC-0084 regime.

He said that following the first 12 patients, the next cohort of 20 patients should reveal some efficacy data and the company expected to see early results at the half-way mark of about 120 patients.

Dr Garner said that the full trial data was not expected until the end of 2021.

Dr Garner said that while the company was focussed on glioblastoma there was interest in GDC-0084 for a range of other solid tumor cancers, including metastatic brain cancer from primary breast, lung and prostate cancer, as well as melanoma.

Dr Garner said the trial was being conducted in the US by the Princeton, New Jersey-based Covance Chiltern Oncology and began in March with patient recruitment and screening, prior to surgery and radiotherapy (BD: Mar 29, 2018).

"The first patient is due to be dosed any time now," Dr Garner said.

Kazia fell 3.5 cents or 7.4 percent to 44 cents.

FEDERAL GOVERNMENT

The Federal Government says it will invest $6.1 million to fund new South Australian medical research projects.
A media release from the Federal Health Minister Greg Hunt said the funds would go to the South Australian Academic Health Science and Translation Centre, at the South Australian Health and Medical Research Institute, which conducted research into bowel cancer, cardiac rehabilitation and reduction of the risk of pre-term births.
The media release said the funding would come from the Medical Research Future Fund, in addition to the initial $2.2 million funding for the centre.
The Government said the Centre had several projects underway, including 'Beat Bowel Cancer' that aimed to achieve zero preventable deaths from bowel cancer in South Australia by better utilizing screening, as well as a project that used data from more than 5,000 pregnant women to identify those at increased risk of early pre-term birth caused by omega-3 insufficiency.
The media release said the centre's researchers were also working to ensure that by 2021 all eligible heart patients in South Australia were referred to cardiac rehabilitation services.

ACTINOGEN MEDICAL

Actinogen says it has commitments to raise $560,000 at five cents a share, in a placement from the shortfall of shares under its share purchase plan.
In May, Actinogen said it hoped to raise $2 million through a share plan following a placement that raised $15 million at five cents a share, and in July said it had raised $952,500 (BD: May 23, July 12, 2018).
Today, the company said the shortfall placement received support from existing investors, including Australian Ethical Investment and the San Francisco-based Biotechnology Value Fund LP, and was led by Bell Potter Securities.
Actinogen said the placement brought the total capital raised to $16.6 million, including the $15 million placement and the share purchase plan that raised $952,500, with the funds to be used to drive development of Xanamem, its Alzheimer's disease program.
The company said that after the placement Biotechnology Value Fund would hold 19.97 percent of the company and continue to be its largest shareholder.
Actinogen was up 0.2 cents or 3.85 percent to 5.4 cents with 2.9 million shares traded.

PROTEOMICS INTERNATIONAL

Proteomics says it has a $US260,000 ($350,259) contract with conduct comparability studies on a Biosanapharma biosimilar allergic asthma drug.
Proteomics said the work for the Amsterdam, Netherlands-based Biosanapharma was its largest analytical services contract to date and would examine the company's good manufacturing practice production run "to establish product quality by comparison against [existing] reference products".
The company said clinical trials for Biosanapharma biosimilar, or generic, monoclonal antibody, would begin January 2019.
Proteomics said it had completed licencing deals for Promarkerd in the US and Mexico in the last six weeks, with royalties expected later in 2018, and was approaching "cash-flow positive".
Proteomics was up 1.5 cents or seven percent to 23 cents.

ORTHOCELL

Orthocell says its Celgro collagen scaffold for dental bone and soft tissue repair has had its first sales and use in Italy.

Orthocell chief executive officer Paul Anderson said the company was “pleased with the rising interest [Celgro] is generating in key European markets, having now achieved first product use and sales in Italy, Poland and the UK”.

“We will continue to drive sales in Europe with support from the world-renowned experts on our medical scientific advisory board and our growing distribution network,” Mr Anderson said.

Orthocell was up two cents or 6.7 percent to 32 cents.

ITL HEALTH GROUP

ITL says it expects revenue for the year to June 30, 2018 of $24.3 million, with earnings before interest, tax, depreciation and amortization of $3.5 million

Last year, ITL said it had sold its Melbourne medical supplies packing business to Salt Lake City, Utah-based Merit Medical for $14.4 million (BD: Oct 3, 2017).

Today, the company said its operating revenue included $2.9 million revenue from its medical supplies packing business, and that its expected earnings before interest, tax, depreciation and amortization was calculated after further development funding for its chronic disease diagnostic Myhealthtest.

ITL climbed six cents or 34.3 percent to 23.5 cents.

RECCE PHARMACEUTICALS

Recce says it has a clinical trial design for a 44-patient, phase Ia trial of Reece-327 for sepsis, subject to US Food and Drug Administration approval.

Earlier this year, Recce said the FDA had provided “clear guidance around the design of a planned phase I trial” after a meeting to discuss proposed clinical and regulatory pathways for the drug (BD: Mar 8, Jun 5, 2018).

Today, the company said that clinical trial groups were evaluating a proposed randomized, double-blind, placebo-controlled study that would evaluate safety and tolerability in 44 adult participants, who would receive single ascending doses of Recce-327 at a uniform rate over 24 hours, with data expected within months of starting the study.

Recce said that, based on data from the phase Ia study, an expanded phase Ib study would follow, with both expected to be completed within 12 months of the phase Ia study commencing.

Recce was unchanged at 18 cents.

NOVITA HEALTHCARE

Novita has requested a trading halt pending a “bookbuild as part of an issue of new shares” for a Newly Pty Ltd initiative.

Novita said the new share issue would raise more than $2 million and was “in conjunction with an initiative in respect of [its] investment in Newly” (BD: Jul 24, 2017).

Trading will resume on July 19, 2018 or on an earlier announcement.

Novita last traded at 3.3 cents.

CRESO PHARMA

Creso says it has listed on the Frankfurt Stock Exchange under the code 1X8 and has hired Deutsche Gesellschaft für Wertpapieranalyse GmbH to assist it in Germany.
Creso said the Frankfurt, Germany-based DGWA was an investment and financial markets consulting firm and would assist it with German-language media and German investors, as well as help manage its listing on the Frankfurt Stock Exchange.
The company said its listing followed the launch of its marijuana food products Cannaqix and Anibidiol, as well as initial sales orders in Benelux, the union of Belgium, Netherlands and Luxemburg.
Creso was up two cents or 3.2 percent to 64 cents.