Biotech Daily

Tuesday July 28, 2015

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: TISSUE THERAPIES UP 19%**
- GI DYNAMICS DOWN 10%

*** WEHI PARTNERING WEHI-842 TO BLOCK MALARIA CONDUCTOR PROTEIN**

*** CSL TAKES RVIII-SINGLE-CHAIN (CSL627) FOR HAEMOPHILIA A TO FDA**

*** PHYTOTECH RAISES $5m, COMPLETES MMJ MERGER, NAME CHANGE**

*** TISSUE THERAPIES CHANGES VITROGRO FROM DEVICE TO DRUG**

*** ANATARA PLAN RAISES $2m, TAKES TOTAL TO $9m**

*** ATCOR: 'AHA BACKS SPHYGMOCOR'**

*** CORRECTION: NUSEP**

*** COGSTATE SIGNS $1.6m ALZHEIMER'S DISEASE TRIAL CONTRACT**

*** UBS AG BUYS, SELLS, BORROWS, RETURNS SIRTEX SHARES TO 5%**

*** CELLMID REQUESTS CAPITAL RAISING TRADING HALT**

*** IMMURON APPOINTS DR JERRY KANELLOS COO, CSO**

MARKET REPORT

The Australian stock market slipped 0.09 percent on Tuesday July 28, 2015 with the ASX200 down 5.2 points to 5,584.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and three were untraded.

Tissue Therapies was the best, up 1.1 cents or 19.3 percent to 6.8 cents with 1.2 million shares traded. Genetic Technologies climbed 6.7 percent; Antisense and Atcor were up five percent or more; Reva was up 4.55 percent; Biotron and Starpharma rose more than three percent; with Clinuvel, Compumedics, CSL and IDT up more than one percent.

GI Dynamics led the falls, down 1.5 cents or 10 percent to 13.5 cents with 99,000 shares traded. Acrux and Optiscan lost more than eight percent; Prana shed 6.1 percent; Actinogen fell five percent; Pharmaxis fell 4.3 percent; Admedus was down 3.2 percent; Osprey and Universal Biosensors shed more than two percent; with Benitec, Bionomics, Cochlear, Impedimed, Nanosonics, Neuren, Resmed, Sirtex and Viralytics down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the first three-dimensional image capturing a critical malaria conductor protein could lead to a new class of anti-malarial drugs.

The Institute said that its researchers developed WEHI-842 to block the malaria parasite protein plasmepsin V, killing the parasite.

WEHI researcher Dr Justin Boddey said that the malaria parasite hid in the liver and red blood cells, with four walls between the bloodstream and the target protein and the Institute was collaborating with an unnamed pharmaceutical company to identify drugs that act in the same way as WEHI-842, but were able to pass through the four walls.

WEHI said that the research, led by Prof Alan Cowman, Dr Boddey, Dr Tony Hodder, Dr Brad Sleebs and Dr Peter Czabotar, was entitled 'Structural basis for plasmepsin V inhibition that blocks export of malaria proteins to human erythrocytes' and was published in the journal Nature Structural and Molecular Biology, with an abstract at: http://www.nature.com/nsmb/journal/vaop/ncurrent/full/nsmb.3061.html.

Prof Cowman said the detailed, three-dimensional molecular structure of the protein plasmepsin V was a significant step towards a new antimalarial drug.

"Plasmepsin V acts like a bus conductor, giving each protein that needs to leave the parasite a stamp of approval and a ticket to the correct destination," Prof Cowman said.

"It is an important target given its critical role in the survival of malaria parasites and expression at all stages of its lifecycle," Prof Cowman said.

"There has been significant interest in solving the structure of plasmepsin V, which has been a very tricky venture given the nature of the protein," Prof Cowman said.

"Using the potent drug WEHI-842, we were able to stabilise the protein sufficiently to detail its molecular structure, which will be critical in developing this new class of antimalarial drugs," Prof Cowman said.

Dr Boddey said that targeting plasmepsin V would effectively kill the two species of malaria that caused significant death and disease.

"WEHI-842 is a very effective agent in preventing the growth and survival of Plasmodium falciparum," Dr Boddey said.

"Plasmodium falciparum is the most deadly form of malaria parasite, causing most of the 800,000 deaths from malaria each year," Dr Boddey said.

"Plasmodium vivax is also particularly insidious because it can hide in the body for long periods of time without symptoms, causing disease relapses much later," Dr Boddey said.

Dr Boddey said malaria parasites were shape shifters, changing how they looked and acted throughout their lifecycle to evade detection and elimination in the body.

"WEHI-842 is able to strongly bind to and disrupt the function of plasmepsin V, preventing the release of proteins that are critical for shaping the parasite's environment and, effectively, killing it," Dr Boddey said.

"Plasmepsin V is expressed by the different shape shifters across the lifecycle so we should be able to kill these different forms as well," Dr Boddey said.

Prof Cowman said the biggest challenge for the team was developing an agent that could cross the barriers that protected the malaria parasite as it hid within the cell.

"The malaria parasite hides exceptionally well in the liver and red blood cells, with four walls between the bloodstream and the protein we are targeting," Dr Boddey said.

"We are now collaborating with a pharmaceutical company to identify drugs that act in the same way as WEHI-842, but are able to find a way through these four walls to access the parasite hidden deep inside the red blood cell," Dr Boddey said.

The Institute said that about half of the world's population was at risk of contracting malaria each year, with more than 200 million people infected and up to 700,000 people killed by the disease each year, predominantly children under the age of five.

CSL

CSL says that the US Food and Drug Administration has accepted for review its application for its recombinant factor VIII single-chain product for haemophilia A.
CSL said that the biologics licence application for recombinant factor VIII single-chain (rVIII-single-chain) was made through CSL Behring.
The company said that the pivotal, phase III, open-label, non-randomized, multi-center study evaluating the efficacy, safety and pharmacokinetics of rVIII-single-chain, met all its primary endpoints (BD: Jun 17, 2015).
CSL said that haemophilia A was a congenital bleeding disorder characterized by deficient or defective blood factor VIII and people with haemophilia A could experience prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs.
The company said that haemophilia A affected about one in 6,000 male births.
CSL chief scientific officer and research and development director Dr Andrew Cuthbertson said that CSL Behring had “one of the industry’s largest portfolios of biotherapies that improve the care and well-being of patients with a bleeding disorder”.
“Our scientific expertise and relationship with the bleeding disorders community led us to seek further advancements in the care and treatment of haemophilia,” Dr Cuthbertson said.
“Today, we have the only recombinant single-chain factor VIII product in late-stage development for the management of haemophilia A and we are excited to be one step closer to providing this innovative treatment to patients in the US,” Dr Cuthbertson said.
CSL said that the FDA application was based on the Affinity clinical development program, which includes a phase I/III open-label, multi-center trial examining safety and efficacy.
The company said that the program also studied the pharmacokinetics of rVIII-single-chain compared with recombinant human anti-haemophilic factor VIII (octocog alfa).
CSL said that rVIII-single-chain was specifically designed for greater molecular stability and was the first and only single-chain factor VIII product in late-stage development for the treatment of haemophilia A.
The company said that rVIII-single-chain, also known as CSL627, had a strong affinity for von Willebrand factor, leading to greater stability and integrity of factor VIII in circulation.
CSL was up $1.52 or 1.6 percent to $96.17 with 1.6 million shares traded.

PHYTOTECH MEDICAL

Phytotech says it has raised $4.8 million in a placement at 30 cents a share, has completed the acquisition MMJ Bioscience and will change its name and ASX code.
Phytotech said that shareholders approved the merger on June 29, 2015 and all regulatory approvals had been satisfied.
The company said that the acquisition was scrip based and it had issued an initial 51,000,000 ordinary shares, with up to a further 17,000,000 deferred shares that may be issued in two tranches based on the achievement of key milestones.
Phytotech said that each MMJ vendor had agreed to an escrow period of three, nine months and 15 months and the intention was for those parties to enter into structured sell-down arrangements should they decide to sell their shares.
The company said the merged entity would be called MMJ Phytotech with a change to the ASX Code to MMJ expected to occur within a few business days.
Phytotech said that the placement was led by Merchant Corporate and APP Securities.
The company said that Andreas Gedeon had been appointed as managing director and chief executive officer, with Boaz Wachtel becoming head of business development.
Phytotech was up 1.5 cents or 4.4 percent to 35.5 cents.

TISSUE THERAPIES

Tissue Therapies says it will change its approval path for its Vitrogro wound treatment from device to pharmaceutical and expects the process to take an additional year.

Tissue Therapies previously attempted to achieve European Medicines Agency approval as a device but was subjected to lengthy delays including changes to the approval pathway (BD: Mar 27, Jun 1, Aug 8, 2012; Jul 29, 2013).

Today, the company said that it intended "to develop Vitrogro ECM as a pharmaceutical worldwide for wound healing" with approval to be concurrently sought from the US Food and Drug Administration and the European Medicines Agency.

Tissue Therapies said it had reviewed the strategic and operational plan including the previous strategy of seeking Conformité Européenne (CE mark) approval following receipt of a final advice letter from the EMA, when a viable pathway for development and review as a Class III Rule 13 medical device was established in Europe.

The company said that a pharmaceutical pathway offered "the most attractive outcomes for Vitrogro … with a lesser level of approval risk" and the first step would be a meeting with the FDA for guidance on development and review.

Tissue Therapies said the FDA provided clear and specific guidance for approval pathways for products being developed for chronic cutaneous ulcer and burn wounds and Vitrogro would be "repositioned as a broad spectrum healing promoter for ulcers of all severity".

The company said that approval for venous leg ulcer and diabetic foot ulcer indications was the most commercially advantageous opportunity and it expected that subject to FDA advice it could "concurrently deliver for both indications in Europe and the US using this pathway".

Tissue Therapies said that a pharmaceutical was "more likely to realise global potential sooner and more broadly than a medical device developed specifically for Europe".

While the relative time to develop a worldwide pharmaceutical was longer than for a device in Europe, it offered "a far greater value outcome than a device in Europe" the company said.

Tissue Therapies said other advantages as a pharmaceutical product included a patent term extension of up to five years and potentially longer, at least another two to three years regulatory exclusivity, for trial data and market exclusivity subject to national law and the approval risk of a pharmaceutical was less because the development and review would focus on the whole protein rather than the insulin-like growth factor-1 (IGF-1) component, as was the case for a device approval with EMA.

The company said that the EMA device approval pathway was technically more challenging because of the need to separate the effect of the IGF-1 component from the effect of the Vitronectin component.

Tissue Therapies said that the clinical endpoints for the US would meet the requirements for approval in Europe, Asia Pacific and South America and a number of other jurisdictions and the pre-clinical and clinical work completed for CE marking remained relevant and continues to form part of the submissions.

The company said that subject to FDA guidance it expected the development and approval process "not likely to be much more than one year longer than the approval pathway … established with the EMA for a device".

Tissue Therapies acting chief executive officer Nigel Johnson said that "seeking a development partner is a critical priority" and told Biotech Daily that the company was in discussions with potential partners.

Tissue Therapies was up 1.1 cents or 19.3 percent to 6.8 cents with 1.2 million shares traded.

ANATARA LIFESCIENCES

Anatara says its oversubscribed share purchase plan at 78 cents a share has raised $2 million in addition to the two placements raising $7 million.

Earlier this month, Anatara said it had placed $4.4 million at 78 cents a share and hoped to raise a further $2.6 million in a second tranche, pending shareholder approval (BD: Jul 3, 2015).

Today, the company said that shareholders would receive about 60 percent of the allocation for which they applied, which was a similar scale-back to the placement.

Anatara said the funds were for registration trials of its pineapple stem bromelain-derived Detach pig diarrhoea treatment, proof-of-concept trials in calves and poultry, advance a pre-clinical program, safety studies and for working capital.

Anatara chairman Dr Mel Bridges said that the total of $9 million would “allow Anatara to move into both Europe and the US markets in parallel, as well as target the larger Asian markets earlier than originally forecast”.

“We will also be investigating moving into other livestock such as poultry and calves whilst advancing development of Detach’s use in humans,” Dr Bridges said.

Anatara fell two cents or 2.3 percent to 85 cents.

ATCOR MEDICAL

Atcor says the American Heart Association has published a statement on the importance and measurement of arterial stiffness.

Atcor said its non-invasive Sphygmocor system measured central aortic blood pressure and arterial stiffness.

The company said that the Association’s statement recognized “the explosive growth and progress in the field of arterial stiffness and central haemodynamics and provides new recommendations for healthcare practitioners”.

Atcor said that arterial stiffness impacted cardiovascular risk and preceded conditions including high blood pressure, diabetes and hypertension, as the elasticity, or hardening, of the arteries affected how hard the heart had to pump to circulate blood through the body.

The company reported that the American Heart Association said that the measures of arterial stiffness using carotid-femoral pulse wave velocity and central aortic pressure waveform analysis were established clinically and could be used to independently predict cardiovascular risk.

Atcor said that the Association recommended measuring carotid-femoral pulse wave velocity to provide incremental information beyond standard cardiovascular tests to determine cardiovascular risk.

The company said that central aortic blood pressure wave separation analysis was recommended when testing was focused on the role of wave reflection as either an exposure for a cardiovascular outcome or a target for intervention.

Atcor said that its Sphygmocor was the only commercial device that met all of the statement's recommended requirements for carotid-femoral pulse wave velocity, central aortic pulse wave analysis and can be performed on a single device.

Atcor chief executive officer Duncan Ross said the company “could not be more pleased by this important statement from the prestigious American Heart Association”.

“The statement further validates growing clinical awareness and application to patient care in the product-market segment pioneered and led by Atcor,” Mr Ross said.

Atcor was up one cent or 5.6 percent to 19 cents.

NUSEP

Last night's edition incorrectly said that Nusep's in-vitro trial of Spermsep would be carried out by, and paid, for the University of Newcastle (BD: Jul 27, 2015).
Today, Nusep executive chair Alison Coutts told Biotech Daily the trial would be under the direction of the University's Prof John Aitken in conjunction with in-vitro fertilization centres with no cost to Nusep apart from supplying the machines and consumables.
Ms Coutts said that the trial was not at the University and the University was not paying for the cost of the trial.
Biotech Daily apologises to Nusep and the University for the error.
The Monday sub-editor has been separated from Biotech Daily.
Nusep was untraded at 3.1 cents.

COGSTATE

Cogstate says it has a $US1.2 million ($A1.64 million) contract with an unnamed biotechnology company to use its tests in a phase II trial of Alzheimer's disease.
Cogstate said that its computerized cognition tests would be used in the trial of patients with prodromal and mild dementia.
The company said that the contract took the total value of clinical trials sales contracts signed since July 1, 2015 to $US2.3 million.
Cogstate was up 3.5 cents or 15.6 percent to 26 cents.

SIRTEX MEDICAL

The Singapore-based UBS AG and related bodies corporate says they have again returned to a substantial shareholding in Sirtex with 2,875,242 shares or 5.03 percent.
UBS AG said that between May 30 and July 23, 2015, in more than 160 separate trades, including single share trades, it bought, sold, borrowed and returned shares held for various custodians with the "power to control disposal over shares pursuant to stock borrowing and lending activities".
In March, UBS AG became substantial in Sirtex with 3,028,395 shares (5.36%), but a week later said it had reduced below five percent (BD: Mar 20, 27, 2015)
Sirtex fell 54 cents or 1.7 percent to $30.71 with 219,545 shares traded.

IMMURON

Immuron says it has appointed Dr Jerry Kanellos as chief operating and scientific officer.
Immuron said that Dr Kanellos had more than 20 years experience in the pharmaceutical and biotechnology industry and had held leadership roles in business development, project management, intellectual property portfolio management, research and development and senior management.
The company said that previously Dr Kanellos was Transbio's chief operating officer and prior to Transbio was a consultant to the biotechnology industry.
Immuron said that Dr Kanellos worked in research and development for CSL.
The company said that Dr Kanellos held a Doctorate of Philosophy in medicine from the University of Melbourne.
Earlier this month, chief executive officer Dr Leearne Hinch resigned after just three months in the position (BD: Apr 2, Jul 8, 2015)
Immuron fell one cent or four percent to 24 cents.

CELLMID

Cellmid has requested a trading halt pending an announcement “in relation to a proposed capital raising that is material to the company’s business”.

Trading will resume on July 30, 2015 or on an earlier announcement.

Cellmid last traded at four cents.