Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 30%, NEUREN DOWN 9%**

*** OPTHEA OPT-302 'SAFE' FOR WET AMD ALONE, IN COMBINATION**

*** AVITA: REGENERCELL, RENOVACELL WOUND HEALING 'SIGNIFICANT'**

*** IMUGENE FILES FOR HONG KONG HER-VAXX GASTRIC CANCER TRIAL**

*** ORTHOCELL 'CELL FACTORY' FOR BONE REGENERATION PUBLISHED**

*** LIVING CELL NZ PLACEMENT RAISES $432k, TOTAL $3.7m**

*** RESONANCE SELLS 5m UNMARKETABLE PARCEL SHARES FOR $75k**

*** RHINOMED SIGNS PERFORMANCE BIKE, INBOX FITNESS FOR US SALES**

*** NUSEP REQUESTS 'TRANSACTION' TRADING HALT**

*** PRIMA PLEADS SCHULTZ TO ASX 23% QUERY**

*** REPRODUCTIVE HEALTH 5.75m DIRECTOR OPTIONS AGM**

*** JENNY SWAIN, ROB TRUSCOTT REPLACE ALLEGRA'S CHRIS CALAMOS**

*** REPRODUCTIVE HEALTH DIRECTOR FABIAN DWYER RESIGNS**

MARKET REPORT

The Australian stock market climbed 1.09 percent on Thursday April 21, 2016 with the ASX200 up 56.7 points to 5,272.7 points. Seventeen of the Biotech Daily Top 40 companies were up, 14 fell, six traded unchanged and three were untraded.

Prima was the best on an ASX price query, closing up 1.2 cents or 30.0 percent at 5.2 cents with 27.9 million shares traded. Avita climbed 7.7 percent; Impedimed, Mesoblast, Osprey and Universal Biosensors rose more than five percent; Cellmid was up 4.8 percent; Clinuvel, Oncosil and Pro Medicus were up more than three percent; Anteo rose 2.1 percent; Acrux, Ellex, Medical Developments, Polynovo and Prana were up more than one percent; with CSL and Sirtex up by less than one percent.

Neuren led the falls, down one cent or 8.7 percent to 10.5 cents with 1.5 million shares traded. Admedus lost 5.6 percent; Bionomics fell 4.5 percent; Actinogen, Antisense, Biotron and Orthocell shed more than two percent; Airxpanders, Compumedics, Nanosonics, Opthea and Starpharma were down more than one percent; with Cochlear, Resmed and Reva down by less than one percent.

OPTHEA (FORMERLY CIRCADIAN TECHNOLOGIES)

Opthea says its on-going, 20-patient, phase I, dose escalation trial of OPT-302 for wet age-related macular degeneration has met the primary objective of safety.

Opthea said that OPT-302 was safe and well tolerated as a mono-therapy and in combination with ranibizumab, with no dose limiting toxicities following 28-day safety review of high dose 2mg OPT-302 mono-therapy and dose escalation cohorts of 0.3mg, 1.0mg or 2mg OPT-302 in combination with 0.5mg ranibizumab, marketed as Lucentis.

The company said that OPT-302 was a novel vascular endothelial growth factor C and vascular endothelial growth factor D 'trap' therapy administered either alone or in combination with ranibizumab on a monthly basis for three months by ocular injection.

Opthea said the study was being run under an investigational new drug application program with at 14 US sites and the 28-day safety assessment period had been completed for all 20 patients in the phase I dose trial.

Opthea chief executive officer Dr Megan Baldwin told Biotech Daily that the full data from the dose-escalation trial would be released when all patients had completed the three months of treatment which was expected by October 2016.

The company said that there were no dose limiting toxicities and a maximum tolerated dose was not reached.

Opthea said that adverse events were primarily related to the intra-vitreal injection procedure and were mild and manageable.

The company said that there were no signs of infection inside the eye, or endophthalmitis, and no clinically significant changes in intraocular pressure, electrocardiograms, blood pressure or other vital signs during the safety assessment period at all dose levels of OPT-302.

The University of Southern California Eye Institute's Prof Pravin Dugel, a member of Opthea's clinical advisory board, said the investigators were "encouraged by the clinical data showing the feasibility and favorable safety profile of OPT-302 as a mono-therapy and in combination with Lucentis, particularly as a number of patients thus far have received at least two or three repeat doses on a monthly basis".

Dr Baldwin said that the results of the phase I dose escalation study to date were "very encouraging".

"Meeting the primary objective of the phase I study by demonstrating that intra-vitreally administered OPT-302 is safe and well tolerated at all dose levels tested in combination with Lucentis is a major milestone," Dr Baldwin said.

"We look forward to reporting longer term patient outcomes and secondary measures of clinical activity from the phase I dose escalation study [by October] 2016 when all 20 patients have completed dosing on a monthly basis for three months," Dr Baldwin said.

Opthea said that with the 28-day safety assessment period completed in the dose escalation trial, patient recruitment for the randomized dose expansion phase IIa study could begin.

The company said that the phase IIa trial would enrol about 30 subjects with wet age-related macular degeneration, randomized equally into two treatment groups to be given OPT-302 as a mono-therapy or in combination with Lucentis administered by intra-vitreal injection on a monthly basis for three months.

Opthea said that the primary analysis data from the phase IIa study was expected by the end of 2016.

Opthea said that wet age-related macular degeneration was the leading cause of blindness for people over the age of 50 years in the US and Europe and affected more than 1.5 million people worldwide.

Opthea fell half a cent or 1.2 percent to 42.5 cents.

AVITA MEDICAL

Avita says its Regenercell skin suspension “positively affects chronic wound size and associated pain whilst reducing the time required for wound healing”.

Avita said that data from a 52-patient, randomized, controlled trial comparing standard compression therapy to compression therapy with the Regenercell treatment showed statistically significant results for pain reduction and wound closure.

The data was presented by the Cambridge UK-based Addenbrooke’s Hospital consultant vascular surgeon Dr Paul Hayes at the Avita-hosted Fourth Annual Skin Regeneration Symposium at the University of Cambridge.

A poster co-authored by Dr Hayes, entitled ‘A Pilot Randomised Controlled Trial of Regenercell for the Treatment of Venous Leg Ulcers’ concluded that “Regenercell has shown a significant benefit for patients in terms of quality of life and ulcer healing”.

“Wounds in the Regenercell group closed on average 9.1cm^2 versus 1.2cm^2 for the control group ($p = 0.014$) [and the] subjects in the Regenercell group reported significant decrease in pain two weeks after treatments ($p = 0.017$),” the poster concluded.

The poster said that leg ulcers were chronic wounds that took more than four to six weeks to heal, the skin breaks down and does not heal due to insufficient venous return.

The poster said that venous lug ulcers required an average 24 weeks to heal once blood flow was restored followed by compression therapy, with a significant number of patients failing to heal.

The poster said that there were statistically significant improvements shown in wound size, pain and health-related quality of life, as well as positive trends in healing time, incidence of closure and all aspects of the quality of life questionnaire.

The poster said that the results would be used to design a larger, statistically powered, pivotal clinical investigation.

Dr Hayes said that most of the treated participants within the large-ulcer subgroup saw at least a 40 percent reduction in wound size by six weeks after Regenercell, whereas most of the control wounds reduced less than 40 percent.

He said that achieving 40 percent closure after six weeks was important because that threshold had been shown to be a predictor of complete wound closure.

“During the trial, we saw a real difference to overall wound size in patients treated with Regenercell, on average, their wounds reduced by 9cm^2 compared to 1cm^2 in the control group, ” Dr Hayes said.

Avita has previously told Biotech Daily that Regenercell and Renovacell used the technology first developed for Recell, in Perth by Prof Fiona Wood, of harvesting patients skin to prepare a spray-on skin or epithelial suspension at the point of care in about 30 minutes and that Recell provided up 1,920cm^2 of coverage, Renovocell covered 640 cm^2 and Regenercell covered 320 cm^2 (BD: Mar 2, 2016).

Avita said that the Symposium was told that repigmentation and scar revision could be significantly enhanced using its Renovacell skin suspension device in conjunction with other mainstream cosmetic surgical techniques.

The Cologne, Germany-based Malteser Hospital’s Dr Matthias Aust said that the combination of Renovacell and medical needling was more appropriate than using lasers and other ablative procedures.

Dr Aust said that needling triggered collagen production and healing.

“Data from a prospective study of 20 patients with hypo-pigmented scars showed that one year out, only those patients treated with needling and Renovacell showed significant improvements in pigmentation,” Dr Aust said.

Avita was up one cent or 7.7 percent to 14 cents.

IMUGENE

Imugene says it has filed a regulatory submission for its phase Ib/II study of HER-Vaxx for gastric cancer the Department of Health of Hong Kong.

Imugene said the filing, in conjunction with contract research organization Novatech, was "the first of many submissions to various regulators across Asia …given the high unmet need in this area for patients who have HER2 positive gastric cancer".

The company said that the two-part study would enrol up to 18 patients at eight sites in Asia in the phase Ib dose-escalation trial of HER-Vaxx in combination with chemotherapy to obtain safety, immunogenicity, a measure of how many of the HER2 antibodies were produced, evaluate the booster schedule and determine the optimal dose to take into the phase II study or recommended phase II dose.

Imugene said the open-label, phase II study would enrol around 68 patients randomized into two arms of either HER-Vaxx plus standard-of-care or standard-of-care alone.

The company said that the Hong Kong principal investigator would be oncologist Dr Thomas Yau.

Medical University Vienna, Austria Department of Medicine chairman and Imugene advisor Prof Christoph Zielinski said the Hong Kong application was "an important step for the clinical development of HER-Vaxx".

"This will be the first of many regulatory and ethics review submissions for the HER-Vaxx program, thanks largely to the dedicated and diligent work of Imugene in strong partnership with investigators of the Medical University of Vienna who were largely responsible for the development of the compound".

"Since inventing HER-Vaxx some years ago and our continued work to optimize it, we are thrilled to take this step forward to advance this important B-cell-based treatment of cancers," Prof Zielinski said.

Imugene was unchanged at 1.1 cents with 16.7 million shares traded.

ORTHOCELL

Orthocell says that proteins and bio-active molecules, or growth factors, derived from a 'cell factory' have a positive effect on bone regeneration.

Last year, Orthocell said that data presented at the European Bone and Joint Infection Society in Estoril, Portugal further validated the potential of combining its cell factory derived bioactive molecules with an antibiotic containing bone substitute and the bioactive molecules from bone might enhance regeneration of slow healing bone defects common in chronic osteomyelitis (BD: Sep 15, 2015)

Orthocell said at that time that the data from institutes in Sweden, Australia, Denmark, India and UK supported its intellectual property around the generation of tissue-specific growth factors for the regeneration of cartilage and bone.

In July, the company said that a rabbit study had shown that the intra-articular injection of "bioactive molecules along with chondrocyte-seeded scaffolds further enhance the repair" of sub-chondral cartilage defects (BD: Jul 16, 2015).

Today, Orthocell said the Swedish and Indian data was published in the journal 'ACS Applied Materials and Interfaces' confirming that proteins and growth factors derived from a cell factory had a positive effect on bone regeneration and led to early bone defect healing in an animal model when combined with a collagen scaffold, in this case gelatin.

Orthocell managing-director Paul Anderson said the studies supported the value of the cell factory-derived growth factors pipeline and provided "another step towards the potential for off-the-shelf tissue specific growth factors".

Orthocell fell one cent or 2.5 percent to 39 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has raised $431,644 in a placement of 8,349,010 shares at 5.17 cents to wholesale investors in New Zealand.
Living Cell said the issue price was the same as the share purchase plan which raised $482,607 (BD: Apr 4, 2016).
The company said the total $3,678,872 raised would fund the completion of implants in the phase IIb trial of NTCell for Parkinson's disease (BD: Feb, 17, Mar 24, 2016).
Living Cell was unchanged at 5.1 cents.

RESONANCE HEALTH

Resonance Health says that under its minimum holding share sale it has sold 5,000,500 shares at 1.5 cents a share. (BD: Feb 23, 2016).
Resonance said that it sold 982 unmarketable parcels, with 85 retention notices received from the total of 1,067 unmarketable parcels on the register.
The company said that prior to the sale it had about 2,110 shareholders of which 1,067 were unmarketable parcels and following the sale there were 1,108 shareholders.
Resonance said that the sale gave priority to offers from unrelated parties in preference to directors and staff and "there were … no shares available for purchase by directors or staff from the unmarketable parcels".
Resonance was untraded at 1.6 cents.

RHINOMED

Rhinomed says it has signed the Chapel Hill, North Carolina-based Performance Bike and Newark, Delaware-based Inbox Fitness as US distributors.
Rhinomed said that Performance Bike was a specialty bike retailer with 127 shops and on-line sales and it would sell Turbine sports breathing technology.
The company said that Inbox Fitness would sell the Turbine range and Mute aniti-snoring technology through its on-line health and fitness shop.
Rhinomed said that Inbox Fitness had more than 100,000 customers.
Rhinomed was unchanged at 2.3 cents.

NUSEP

Nusep has requested a trading halt "pending the outcome of commercial negotiations in relation to a transaction involving a company asset".
Trading will resume on April 26, 2016 or on an earlier announcement.
Nusep last traded at 1.2 cents.

PRIMA BIOMED

Prima 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 0.9 cents or 22.5 percent from 4.0 cents on April 20 to 4.9 cents today, April 21, 2016 and noted an increase in trading volume.
Prima said that it was recently the subject "of a favorable research report by maxim Group" which was available on its website.
Prima climbed as much as 1.4 cents or 35.0 percent to 5.4 cents before closing up 1.2 cents or 30.0 percent at 5.2 cents with 27.9 million shares traded.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health Psivida will vote to grant chief executive officer Dr Michelle Fraser and three directors 5,750,000 options and ratify a previous share issue.
Reproductive Health said it proposed to grant Dr Fraser 1,500,000 options exercisable at 20 cents or 140 percent of the 5-day volume-weighted average price (VWAP) preceding the meeting and 1,500,000 options exercisable at 25 cents or 150 percent of the 5-day VWAP, vesting on January 1, 2017 and expiring on May 31, 2020.
The company said it proposed issue 1,400,000 options to chairman David Brookes exercisable at 20 cents or 140 percent of the 5-day VWAP preceding the meeting expiring on May 31, 2020 and 675,000 options each on the same terms to directors Sue MacLeman and Johnathon Matthews.
Reproductive Health said that shareholders would vote on the re-election of Mr Brookes, the ratification of the prior issue of 2,563,984 shares to sophisticated investors and approve the 10 percent placement capacity.
The meeting will be held at Bio-SA Conference Centre, Bio-SA Incubator, 40-46 West Thebarton Road, Thebarton, Adelaide, on May 25, 2016 at 11am (ACST).
Reproductive Health fell two cents or 16.7 percent to 10 cents.

ALLEGRA ORTHOPAEDICS

Allegra says it has appointed Jenny Swain chief executive officer and Rob Truscott chief financial officer, replacing Chris Calamos with effect from May 2, 2016.
Allegra said the appointments followed “a strategy review based on the decision to place a greater emphasis on sales and marketing by outsourcing Allegra’s manufacturing activities” and was based on a recommendation from Mr Calamos who held both the chief executive officer and chief financial officer positions.
The company said that Mr Calamos would continue to provide consulting services supporting management and take the lead on a number of strategic initiatives including the commercialization of a synthetic bone substitute.
Allegra said that Ms Swain joined the company in February 2011 as national sales manager having spent 10 years in a similar role with Life Healthcare driving growth of its orthopaedic sales division.
The company said that Mr Truscott was appointed in 2015 and was an experienced professional with more than 25 years experience in senior finance roles and held a Bachelor of Commerce from the University of Western Sydney.
Allegra was untraded at 15 cents.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says that Fabian Dwyer has resigned as a non-executive director for personal reasons, effective immediately.
Reproductive Health said that Mr Dwyer acted as a consultant to the company prior to his appointment as a director on September 1, 2015.
The company said it did not plan to appoint a replacement at this time, but the decision would be re-evaluated as it progressed the commercialization of its products and services.