Biotech Daily

Monday July 22, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMUGENE UP 12%; ACTINOGEN DOWN 10%**

*** KAZIA, SLOAN KETTERING GDC-0084, RADIATION FOR BRAIN METASTASES**

*** PATRYS: 'PAT-DX1, RADIATION REDUCES TUMORS, NO TOX, IN MICE'**

*** CORRECTIONS: PHARMAXIS**

*** TELIX: DENMARK FOR EUROPE TLX591-CDX REFERENCE**

*** EXOPHARM: EXOSOME WOUND TRIAL, 'CAPITAL RAISING' HALT**

*** BIONOMICS FURTHER $1.3m FEDERAL R&D TAX INCENTIVE; TOTAL $7.9m**

*** SHAREROOT SHORTFALL, PLACEMENT RAISE $780k; TOTAL $1.3m**

*** REGENEUS: 'PROGENZA FOR OA PAIN FOCUS, DROP ANIMAL HEALTH'**

*** EURO PATENT FOR SUDA'S ANAGRELIDE**

*** ALTHEA REQUESTS 'ACQUISITION, CAPITAL RAISING' TRADING HALT**

*** ELIXINOL BUYS MICROENCAPSULATION IP FOR HEMP PRODUCTS**

*** TOTAL BRAIN JOINS AMERICAN HEART STUDY**

*** INVION COO CRAIG NEWTON TO CEO, DR GREG COLLIER DIRECTOR**

*** ANTEO LOSES CEO HARLEY FRANKFURT, CHRISTOPHER PARKER BACK**

*** SIMON GLOVER REPLACES MEDADVISOR CFO CARLO CAMPICIANO**

MARKET REPORT

The Australian stock market fell 0.14 percent on Monday July 22, 2019, with the ASX200 down 9.1points to 6,691.2 points. Sixteen of the Biotech Daily Top 40 stocks were up, 21 fell and three traded unchanged. All three Big Caps fell.

Imugene was the best, up 0.2 cents or 11.8 percent to 1.9 cents, with 10 million shares traded, followed by Resonance up 11.5 percent to 14.5 cents with 4.9 million shares traded. Compumedics and Amplia climbed more than eight percent; Clinuvel and Kazia were up more than five percent; Ellex, Immutep and Patrys improved more than four percent; Alterity and Opthea were up more than three percent; Mesoblast, Pharmaxis and Prescient rose more than two percent; with Cynata up 1.4 percent.

Actinogen led the falls, down 0.1 cents or 10 percent to 0.9 cents, with 1.3 million shares traded. Dimerix lost 9.1 percent; Universal Biosensors shed eight percent; Optiscan fell 6.1 percent; Osprey retreated 5.1 percent; Antisense, Genetic Signatures and Orthocell fell more than four percent; Avita and Oncosil lost more than three percent; Paradigm, Proteomics and Volpara shed more than two percent; Benitec, Cochlear, CSL, Medical Developments, Nanosonics, Resmed and Telix were down more than one percent; with Cyclopharm, Neuren, Polynovo and Starpharma down less than one percent.

KAZIA THERAPEUTICS

Kazia says it will begin an up-to 30 patient, phase I trial of GDC-0084, with radiotherapy for brain cancer metastases led by New York's Sloan Kettering Cancer Center.

Kazia said it expected recruitment to begin by the end of 2019 and the trial was expected to take about two years to complete, with Kazia providing financial support and the study drug and Sloan Kettering filing the investigational new drug application to the US Food and Drug Administration.

The company said the first part of the study would determine the maximum tolerated dose of GDC-0084 when combined with radiotherapy, and the second part of the study would enroll an additional 12 patients and explore preliminary signals of efficacy.

Kazia said that patients with brain metastases would be genetically tested for a specific alteration in the PI3K pathway and only those with a relevant mutation will be enrolled.

Kazia chief executive officer Dr James Garner said that many cancers had "the potential to spread to the brain and they become very difficult to treat when they do".

"The work being done at [Sloane Kettering] will investigate whether GDC-0084 has the potential to enhance the effects of radiotherapy, which remains the current standard of care in most cases," Dr Garner said.

Kazia was up two cents or 5.1 percent to 41 cents.

PATRYS

Patrys says PAT-DX1 with single low dose radiation increases tumor suppression and improves survival for glioblastoma multiforme in mice, with no toxicity observed.

Patrys said the study, completed at the New Haven, Connecticut-based Yale School of Medicine, "used a highly aggressive human [glioblastoma] tumor explant" in mice and tested the effects of PAT-DX1 and low dose radiation on tumor growth and mouse survival across four different regimes.

The company said the study compared a control vehicle delivered three times a week; control with a single low dose radiation treatment; PAT-DX1 alone three times a week; and a combination of PAT-DX1 and a single low dose radiation treatment.

Patrys said that PAT-DX1 alone out-performed low dose radiation in tumor suppression and extended survival and that when PAT-DX1 was used in combination with low dose radiation, an even greater reduction in tumor size and survival was achieved.

The company said that low dose radiation reduced tumors by 52 percent compared to controls, PAT-DX1 alone reduced tumors by 87 percent and the combination of PAT-DX1 and low dose radiation reduced tumors by 93 percent.

The company said that radiation alone extended mouse survival by 24 percent ($p = 0.04$), as a single agent PAT-DX1 extended survival by 41 percent ($p = 0.01$) and PAT-DX1 used in combination with low dose radiation extended survival by 71 percent ($p = 0.002$).

Patrys said no toxicity associated with PAT-DX1 treatment was observed.

The company said additional studies would be conducted to explore the interactions between different radiation and PAT-DX1 dosing regimes and this data would inform and guide the design of clinical trials to test PAT-DX1 against glioblastoma in humans.

Patrys chief executive officer Dr James Campbell said "radiation therapy plays an important role in treating [glioblastoma]".

"However, radiation therapy often results in significant morbidity and severe side effects, particularly in elderly populations", Dr Campbell said.

"The ability to improve clinical outcomes by reducing the dose of radiation required could be an important advancement in the treatment of [glioblastoma]" Dr Campbell said.

Patrys was up 0.1 cents or 4.2 percent to 2.5 cents with 39.9 million shares traded.

CORRECTIONS: PHARMAXIS

Friday's Pharmaxis article contained several errors that slipped by the former sub-editor.
In 2012, Pharmaxis won the appeal against the 2011 European Bronchitol rejection and in 2015 Chiesi spent $35 million on the US-required study.
The AOC3 inhibitor BI 1467335, acquired by Boehringer Ingelheim, targets non-alcoholic steatohepatitis (NASH) and diabetic retinopathy, not nephropathy as stated.
The US FDA approved Aridol in 2011, and with the upgrade and move of the Pharmaxis manufacturing facility, the company found it uneconomic at that time to continue US Aridol sales, but that has changed and the new facility is manufacturing Aridol for the US.
The former Friday sub-editor has been despatched with extreme, but humane, prejudice.
Pharmaxis was up half a cent or 2.2 percent to 23.5 cents.

TELIX PHARMACEUTICALS

Telix says the Danish Medicines Agency will be its European reference for TLX591-CDx for the imaging of metastatic prostate cancer with positron emission tomography.
Telix said the scientific advisory meeting, with wholly-owned subsidiary Advanced Nuclear Medicine Ingredients, would support a European marketing authorization application for TLX591-CDx.
The company said the Danish Medicines Agency "was specifically approached as a reference authority because of extensive expertise in reviewing medical imaging and radiopharmaceutical product submissions".
Telix said the agency broadly indicated support for the company's approach to the European marketing authorization and was "willing to serve as a reference authority for the … process".
The company said the Danish Medicines Agency supported the dosing approach, the "rationale and extent of the product's non-clinical package", and the overall clinical and regulatory product strategy.
Telix said it expected to complete the submission in the next six months.
Telix fell three cents or 1.8 percent to $1.635 with 707,059 shares traded.

EXOPHARM

Exopharm says it is ready for a 20-patient phase I trial of its Plexaris exosomo treatment for would healing, and has requesting a trading halt for a capital raising.
Exopharm said it had been approved by the Melbourne Health ethics committee to begin its 'Ploxoval' trial of autologous, or one's own, exosomos derived from blood platelets.
The company said the exosome product was purified using its Leap technology which was a "manufacturing process to isolate and purify exosomes from adult stem cells and other sources".
Exopharm said the prospective, open-label, single dose, proof-of-concept study would track participants for 42 days after dosing to evaluate the safety, tolerability and biological activity of platelet-derived extracellular vesicles on the augmentation of wound healing.
The company said the primary endpoints of the study were safety and efficacy in wound closure and scar formation.
Exopharm chief executive officer Dr Ian Dixon said "exosomes represent a new modality to treat a variety of conditions and the Plexoval study will be a world-first to apply this type of product in a phase I study looking at both safety and signs of efficacy."
Exopharm said trading would resume on July 24, 2019 or on an earlier announcement.
Exopharm last traded at 44.5 cents.

BIONOMICS

Bionomics says it has received a further $1,342,052 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Bionomics said the payment included an interest payment of $17,593.
Last year, the company said it received a $6,568,808 Research and Development Tax Incentive for expenditure for the year to June 30, 2018 (BD: Dec 11, 2018).
Bionomics was unchanged at 4.1 cents with 1.3 million shares traded.

SHAREROOT

Shareroot says it has raised $780,000 through shortfall shares and a placement, raising a total of $1,289,612.
Last week, Shareroot said it raised $509,612 of a hoped-for $954,342 and aimed to raise the remaining $444,731 from the placement of shortfall shares (BD: Jul 17, 2019).
Today, the company said it raised $444,731 through the issue of the shortfall shares for 0.1 cents a share and a further $335,269 through a placement at 0.1 cents a share.
The company said the funds would be used to expand its digital client services, launch new products, marketing campaigns and change its name to “reposition the company within the target market”.
Shareroot fell 0.05 cents or 25 percent to 0.15 cents with 5.1 million shares traded.

REGENEUS

Regeneus says chief executive officer Leo Lee’s has reviewed the company and it will “develop therapies to treat pain and modify the underlying diseases”.
Regeneus said its key priority was a phase II trial of its allogeneic Progenza fat-derived stem cells for osteoarthritis and the commercialization of the treatment Japan, as well as exploring additional therapies in pain.
In 2017, Regeneus said its 20-patient phase I trial of Progenza for osteoarthritis showed the stem cells were safe, tolerated and reduced pain (BD: May 22, 2017).
Today, the company said it was “on the cusp of securing a commercial licencing deal with a major Japanese company to take the product through a phase II clinical trial … towards bringing a commercial product to market by 2023”
Regeneus said it would focus on licencing Progenza for osteoarthritis in Japan, the US and Europe, and then Asia, the Middle East and Eastern Europe.
The company said they was “considering a range of options to monetize its RGSH4K cancer vaccine and animal health platforms in order to extract the value already created”.
Regeneus was up 2.4 cents or 29.6 percent to 10.5 cents.

SUDA PHARMACEUTICALS

Suda says the European Patent Office intends to grant a patent for the blood disorder drug anagrelide for use in cancer.
Suda said the patent, titled ‘Use of Anagrelide for Treating Cancer’ would provide intellectual property protection until December 2035.
The company said the patent would cover the use of anagrelide in the treatment or prevention of metastatic disease in the bone or lung in patients with a high platelet count and a solid cancer across “broad routes of administration beyond … oro-mucosal and hydrotrope technologies, including transdermal patches and creams, lotions and gels”.
Suda was up 0.1 cents or 33.3 percent to 0.4 cents with 91.7 million shares traded.

ALTHEA GROUP

Althea has requested a trading halt pending the release of an announcement in relation to an acquisition and a capital raise.
Trading will resume on July 24, 2019 or on an earlier announcement.
Althea last traded at $1.195.

ELIXINOL GLOBAL

Elixinol says it has acquired the rights to microencapsulated technology developed by Bionova SL for its hemp-based food, beverage and food additive formulations.
Elixinol said the intellectual property acquisition would include the Madrid-based Bionova as the exclusive manufacturer and supplier within the European Union of Elixinol products developed using the microencapsulated technology.
The company said it would pay an annual fixed amount of EUR25,000 ($A39,825) for each non-European Union country in which Elixinol used the technology until patent rights over the technology were granted in that country and the payment would increase to EUR50,000 a year once patent rights were granted.
The company said the technology could be used for increased absorption into the human body and efficacy of active ingredients within a product, masking of unpleasant flavors or odors in finished products, added protection against environmental factors inside the human body once ingested, and better storage preservation of the encapsulated active ingredients.
Elixinol chief executive officer Stratos Karousos said the company was “focused on developing new technologies, formulations and delivery systems to maximize bioavailability of our hemp derived cannabidiol products”.
Elixinol was up nine cents or 2.3 percent to $3.93 with 311,136 shares traded.

TOTAL BRAIN

Total Brain says it will work with the American Heart Association to study the validity and reliability of continuous heart rate variability monitoring.
Total Brain said it would use the data from the signals to “measure and affect stress and high blood pressure”.
The company said data from the study would contribute to its mental health and fitness platform.
Total Brain fell 0.1 cents or 3.85 percent to 2.5 cents.

INVION

Invion says Craig Newton will replace Dr Greg Collier as chief executive officer effective from November 1, 2019, with Dr Collier to continue as a director.
Invion said Dr Collier would step down as chief executive officer effective October 31, 2019 to “to focus on other areas and companies of interest”.
The company said Mr Newton joined the company in April 2018 as chief operating officer and had previously held business and operational roles at CSL, Serono UK, Bio Nova International, Avax Australia and Cryptome Pharmaceuticals.
Invion said Mr Newton held a Bachelor of Applied Science from the University of South Australia, a Graduate Diploma in Marketing from Melbourne’s Monash University and a Graduate Diploma in Management from the Royal Melbourne Institute of Technology.
Invion was unchanged at 1.5 cents with 2.8 million shares traded.

ANTEO DIAGNOSTICS

Anteo says that recently appointed chief executive officer Harley Frankfurt will be replaced by former chief executive officer Christopher Parker effective immediately.
In April, Anteo said it had appointed Harley Frankfurt as its chief executive officer on $280,000 a year, effective from April 23, 2019, with Christopher Parker to transition to executive director to focus on the company's life sciences division (BD: Apr 15, 2019).
Today, the company said Mr Frankfurt would leave is role for "personal reasons".
Anteo said the board had begun the process to appoint a suitably qualified and experienced chief executive officer.
Anteo fell 0.1 cents or 6.7 percent to 1.4 cents with 7.4 million shares traded.

MEDADVISOR

Medadvisor says Simon Glover will replace Carlo Campiciano as chief financial officer, with Mr Campiciano continuing as company secretary.
Medadvisor said Mr Glover had held financial roles at Jetstar, Tabcorp and Coles Group, and had pharmaceutical experience at Mayne Pharma.
Medadvisor fell 0.05 cents or 1.1 percent to 4.55 cents.