Biotech Daily

Tuesday August 17, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: STARPHARMA UP 3.5%; DIMERIX DOWN 10.5%**

*** BURNET SELLS 360 BIOLABS TO BIOAGILYTIX**

*** BAYMATOB: 'FDA APPROVES OLI FOR POSTPARTUM HAEMORRHAGE'**

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*** SOUTH AUSTRALIA UNI NANO-POLYMER MICELLES FOR C ALBICANS**

*** ELIXINOL H1 REVENUE DOWN 39% TO $4.8m, LOSS DOWN 87% TO $11m**

*** OSPREY H1 REVENUE UP 33% TO $1.5m, LOSS DOWN 30% TO $7.1m**

*** TELIX: GREAT ORMOND STREET TRIALS TLX66 FOR PAEDIATRIC LEUKAEMIA**

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*** PYC OPHTHALMOLOGY CLINICAL ADVISORY BOARD**

MARKET REPORT

The Australian stock market fell 0.94 percent on Tuesday August 17, 2021, with the ASX200 down 71.5 points to 7,511.0 points. Just six of the Biotech Daily Top 40 stocks were up, 27 fell and seven traded unchanged. All three Big Caps were up.

Starpharma was the best, up 4.5 cents or 3.5 percent to $1.345, with 924,447 shares traded. Antisense climbed three percent; Amplia, Kazia and Resmed rose more than two percent; Universal Biosensors was up 1.3 percent; with Cochlear, CSL and Nanosonics up by less than one percent.

Yesterday's 42.55 percent best, Dimerix, led the falls, down 3.5 cents or 10.45 percent to 30 cents, with 8.65 million shares traded. Pharmaxis fell 8.3 percent; Neuren lost 6.3 percent; Actinogen, Genetic Signatures and Prescient fell more than four percent; Compumedics, Imugene, Mesoblast, Paradigm, Telix and Uscom were down more than three percent; Cyclopharm, Immutep, Medical Developments, Optiscan, Orthocell, Patrys and Polynovo shed more than two percent; Avita, Clinuvel, Next Science, Nova Eye and Opthea were down more than one percent; with Pro Medicus, Proteomics and Volpara down by less than one percent.

BURNET INSTITUTE

The Burnet Institute says it has sold its majority-owned subsidiary 360 Biolabs to Bioagilytix Labs LLC for “several hundred million dollars”.

A spokesperson for the Burnet said that its share of the proceeds would be “more than $200 million” but the sale price was commercial-in-confidence.

The spokesperson declined to state the percentage ownership of 360 Biolabs held by the Institute.

The Institute said that the Durham, North Carolina-based Bioagilytix was a contract research laboratory focused on large molecule drug development and bioanalysis with laboratories in Boston and Hamburg, Germany.

The Burnet said that the sale would more than tripling its current budget.

The Institute said that the sale was subject to Australian Foreign Investment Review Board requirements and was expected to be completed by October 2021.

Burnet Institute director and chief executive officer Prof Brendan Crabb said it was “a transformational achievement for the Institute and welcomed the strategic focus of Bioagilytix to build on 360 Biolabs virology and immunology expertise.

“Burnet Institute is proud of its involvement in the foundation of 360 Biolabs,” Prof Crabb said.

“It is the right time, with the growing need for high quality clinical trial support, for a company of the scale, capability and reputation of 360 Biolabs to join with Bioagilytix and expand their capacity to service their customers and facilitate high quality translational medical research,” Prof Crabb said.

Prof Crabb said the sale was “another remarkable success story, not only for the Institute and the 360 Biolabs team, but also for showcasing the importance of ongoing support by Victorian and Federal governments in investing heavily in the world renown medical research sector in Melbourne and throughout Australia”.

“Both Victorian State and Federal governments have been close partners and supporters of ours over a long period of time, they have both helped build the Burnet and provide the opportunity for us to translate science in this way,” Prof Crabb said.

The Institute said that 360 Biolabs had “world-class virology and immunology expertise, with [bio-safety level] 2 and 3 laboratories, biomarker and immune monitoring capabilities with a state-of-the-art flow cytometry suite, molecular biology polymerase chain reaction (PCR) suite and expansive bioanalytical … small molecule capabilities”.

360 Biolabs co-founder and head of business development Angela Luttick said that since the 2015 launch “our strategic vision was to build a global speciality laboratory, providing support to enable future medicines for human health”.

360 Biolabs co-founder and chief executive officer Alistair Draffan said that “finding a like-minded partner, driven by a team-focused culture of excellence with an international reputation, US and European presence, will drive our strategic expansion and support our clients’ clinical development programs”.

Bioagilytix chief executive officer Jim Datin said the acquisition of 360 Biolabs was part of its strategic growth strategy to expand capacity, expertise and agility to serve customers across all geographies.

“Joining forces makes sense for our two organizations, but most importantly for our combined clients and the patients they serve,” Mr Datin said.

“Bioagilytix and 360 Biolabs are already culturally aligned in our focus on doing science right, on time, the first time,” Mr Datin said.

“Together, we will not only create significant scientific synergies but also generate new innovations and help bring future life-changing therapeutics to patients more rapidly around the globe,” Mr Datin said.

BAYMATOB PTY LTD

Baymatob says it has US Food and Drug Administration breakthrough device designation for its Oli labor monitoring device for postpartum haemorrhage.

The Sydney-based Baymatob said that the Oli device was a wearable sensor system that identify individuals during labor at higher risk of abnormal postpartum uterine bleeding or postpartum haemorrhage, before the delivery.

Baymatob said the sensors collected physiological signals from the mother and baby during labor and pregnancy, including the quality of uterine activity, maternal and foetal wellbeing, movement and exertion, with algorithms which looked for indicators that a postpartum haemorrhage was likely, after the birth.

The company said that the algorithms could identify and provide more than one hour's advance warning that a patient was likely to suffer from postpartum haemorrhage.

Baymatob said that, globally, postpartum haemorrhage was the leading cause of preventable maternal death, with a mother dying every seven minutes, with long-term and irreversible injury suffered by a percentage of mothers who survive.

The company said that in Australia, between five and 15 percent of mothers would experience postpartum haemorrhage, and in the US, between 1993 and 2014, the rate of postpartum hemorrhage requiring a blood transfusion increased from eight cases per 10,000 deliveries to 40 per 10,000 deliveries

The company said that Dr Sarah McDonald was an engineer with a Doctor of Philosophy in medicine and founded the company after the traumatic birth of her son in 2013.

The company said it had 13 staff and had been granted more than $4.4 million from the New South Wales Health Medical Devices Fund.

Baymatob said it was currently hoping to raise $8 million in a series A edition.

Baymatob is a private company.

UNIVERSITY OF QUEENSLAND

The University of Queensland says neuroscientist Dr Fatima Nasrallah aims to develop "a quick and cheap test measuring brain recovery" in sports concussion.

The University said that Dr Nasrallah was using advanced magnetic resonance imaging (MRI) at the Queensland Brain Institute to collect data on mild traumatic brain injuries and assess when an athlete's brain had fully recovered and it was safe to resume play.

"We can perform an advanced MRI scan to pick up very subtle changes in the brain and then process the data to get a deeper understanding of how the brain recovers from different types of impacts," Dr Nasrallah said.

"It's challenging for sporting bodies to make policies and guidelines around concussion when there's such a huge gap in knowledge," Dr Nasrallah said.

"By studying a wide variety of impacts, we can build up a picture of how the brain is recovering," Dr Nasrallah said.

Dr Nasrallah said the study required athletes in high-contact sports to have a baseline scan at the start of the season, another if they sustain a concussion, and subsequent scans to monitor their recovery.

"Brain scans are costly and take time," Dr Nasrallah said. "We are using them now to gather data, but ultimately we want to develop a quick, cost-effective test that can be used to judge whether someone's brain has fully recovered," Dr Nasrallah said.

The University said that Dr Nasrallah was researching changes in biomarkers when concussion occurred, which she matched to the brain scans, with the aim to identify biomarkers specific to the brain that could be monitored to distinguish whether there is a brain injury or when the brain had fully recovered.

UNIVERSITY OF SOUTH AUSTRALIA

The University of South Australia says it is developing nanoparticle micelles to treat drug-resistant fungal infections including Candida albicans.

The University of South Australia said that the micelles, developed in partnership with Melbourne's Monash University, were made of lipid molecules that arranged themselves in a spherical form in aqueous solutions, both attracting and repelling liquids, making them particularly well-suited for drug-delivery.

The University said that Candida albicans was "an opportunistic pathogenic yeast … extremely dangerous to people with compromised immune systems, particularly those in a hospital setting … [and was] notorious for its resilience to anti-fungal medicines".

The University's senior investigator Prof Clive Prestidge said that the polymer-based micelles "could revolutionize current anti-fungal medicines".

"Managing and treating invasive fungal infections is particularly challenging because so many fungal biofilms are resistant to contemporary antifungal drugs," Prof Prestidge said.

"Fungal biofilms are surface-loving microbials that thrive on implanted devices such as catheters, prostheses and heart valves, making the presence of these devices a major risk factor for infection," Prof Prestidge said.

"In places like India, which has nearly 40,000 new Covid-19 infections every day, hospital resources are severely stretched, leaving healthcare workers not only battling Covid-19, but also dealing with complacency and fatigue," Prof Prestidge said. "The unfortunate result is that infection control practices have deteriorated, putting patients on mechanical ventilation at greater risk of developing bacterial or fungal infections."

"As fungal biofilms tend to seed recurrent infections, finding ways to break and beat the infection cycle is critical," Prof Prestidge said.

Prof Prestidge said the smart micelles had the ability to break down biofilms to significantly inhibit the growth of Candida albicans.

"We estimate that the new micelles could improve the efficacy of anti-fungal medicines by 100-fold, potentially saving the lives of millions of people worldwide," Prof Prestidge said.

Co-investigator Dr Nicky Thomas said the micelles were "a breakthrough for treating invasive fungal infections".

"These micelles have a unique ability to solubilize and entrap a range of important antifungal drugs to significantly improve their performance and efficacy," Dr Thomas said.

"This is the first time that polymer-based micelles have been created with intrinsic capabilities to prevent fungal biofilm formation," Dr Thomas said.

"As our results already show that the new micelles will remove up to 70 percent of infection, this could be a real game changer for treating fungal diseases," Dr Thomas said.

ELIXINOL GLOBAL

Elixinol says revenue for the six months to June 30, 2021 was down 39.0 percent to $4,790,000 with net loss after tax down 86.7 percent to $10,828,000.

Elixinol said revenue was from its cannabidiol (CBD), dietary supplements and topical cremes, food, cosmetics and skincare products and included $2,550,000 in the Americas, $330,000 in Europe and the UK and $1,910,000 in Australia.

The company said net tangible asset backing per share fell 50.5 percent to 8.08 cents, diluted loss per share was down 94.3 percent to 3.51 cents and it had cash and cash equivalents of $18,962,000 at June 30, 2021 compared to $16,769,000 at June 30, 2020.

Elixinol has told Biotech Daily that it had ended development of marijuana for medical purposes. The company will be covered in our sister publication Ag & Vet Weekly.

Elixinol was unchanged at 12.5 cents.

OSPREY MEDICAL

Osprey says revenue for the six months to June 30, 2021 was up 33.1 percent to $US1,074,317 ($A1,471,814) with net loss after tax down 30.3 percent to $US5,181,632 ($A7,098,835).

Osprey said revenue was from its Dyevert cardiac contrast reduction and monitoring system.

The company said net tangible asset backing per Chess depository instrument (CDI) was down 33.3 percent to 0.4 US cents, diluted loss per US share was done from two US cents to zero cents.

Osprey said it had cash and cash equivalents of $US11,049,416 at June 30, 2020 compared to $US9,772,389 at June 30, 2020.

Osprey chief executive officer Mike McCormick said the first six months of 2021 was "marked by an uncertain global environment as countries around the world continue to combat the [Covid-19] pandemic to varying degrees of success".

"Despite these uncertainties, Osprey was able to generate positive momentum driven by a rebound in sales and simultaneous reduction in expenditure," Mr McCormick said.

"In the US, it was pleasing to see repeat sales through our … partners following on from initial sales earlier in the period," Mr McCormick said.

He said that recovery from Covid-19 had been slower in Europe, Australia and New Zealand.

"Consistent demand from GE Healthcare provides a positive outlook, especially when factoring in increasing vaccination rates and the recent expansion of the GE agreement to include distribution in Canada," Mr McCormick said.

Osprey was unchanged at 1.3 cents with 2.6 million shares traded.

TELIX PHARMACEUTICALS

Telix says that London's Great Ormond Street Hospital has approval for a 25-patient, phase II study of TLX66 in children with high-risk leukaemia.

Telix said that the study was independently funded by an unnamed philanthropic foundation, with Great Ormond Street Hospital as the sponsor.

The company said the open-label study would evaluate safety and efficacy of TLX66 as part of a reduced toxicity conditioning regimen in children and adolescents undergoing allogeneic haematopoietic stem cell transplantation.

Telix said that the study followed a phase I study of 10 patients with relapsed refractory leukaemia.

The company said that TLX66 targets CD662, a receptor expressed on specific types of immune and blood cells and had European orphan drug designation for bone marrow conditioning for haematopoietic stem cell transplantation, a broad clinical indication.

Telix said that in addition to paediatric leukaemia, prior phase I and II studies of TLX66 "demonstrated encouraging efficacy and safety data in multiple myeloma, and in patients with other haematological malignancies currently ineligible for stem cell transplant owing to toxicity".

The company said it recently reported top-line results from a study of TLX66 for patients with systemic amyloid light chain amyloidosis (BD: May 25, 2021).

Telix chief medical officer Dr Colin Hayward said that high-risk leukaemia "has one of the poorest prognoses amongst paediatric cancers and we will be closely monitoring progress by the team at [Great Ormond Street], in line with Telix's mission to help patients with cancer live longer, better quality lives".

Telix fell 21 cents or 3.3 percent to $6.09 with 661,171 shares traded.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved an amendment to its pivotal trial of Recell for the re-pigmentation of stable vitiligo lesions.

Avita said the new single-arm design would evaluate 23 subjects at 15 sites compared to the previously three-arm study of 84 subjects.

The company said the one-to-20 expansion ratio to be used was “the best-case scenario for patients as it requires the least amount of donor skin”.

Avita said that the decision to pursue a single cell suspension formulation was “based on data from other research efforts that suggest the improbability of meaningful clinical performance differences amongst the three cell suspensions in the initial pivotal clinical trial design”.

Avita chief executive officer Dr Mike Perry said that “the simplified study design and reduced number of study subjects reflects confidence both in the exceptional safety profile of Recell and in the anticipated high incidence of re-pigmentation with Recell treatment, as we have seen in 11 peer-reviewed publications and in the treatment of more than 1,000 patients outside the US”.

“The design change allows this program to progress in a timely and cost-effective manner toward bringing a novel therapeutic option to an underserved population,” Dr perry said.

“The program is on track, and we continue to believe we could be in a position to enter the US market with the vitiligo indication, following successful completion of the clinical trial, as early as the second half of calendar year 2023,” Dr Perry said.

Avita fell seven cents or 1.5 percent to $4.65 with 502,819 shares traded.

PHARMAXIS

Pharmaxis says Aptar Pharma has an option over the global rights to its Orbital dry powder inhaler, designed to deliver high payload dry powder to the lungs.

Pharmaxis said that the Crystal Lake, Illinois-based Aptar would pay $US250,000 ($343,100) for the 12-month option and a further $US2.5 million on exercising the option.

The company said that Aptar would evaluate the commercial applications for the Orbital device and further develop the prototype device to meet unmet market needs, and if, Aptar would pay industry standard royalties on income received for Orbital.

Pharmaxis said it retained the rights to devices containing Orbital intellectual property used to deliver inhaled mannitol.

The company said that the Orbital technology allowed powder payloads of up to 400mg or more to be inhaled by patients in divided doses without the need to reload and was originally developed as a life cycle extending product for the Pharmaxis cystic fibrosis drug Bronchitol, but could deliver high doses of other drugs, such as antibiotics, to the lungs.

Pharmaxis chief executive officer Gary Phillips said the Orbital Inhaler eliminates the need for manual reloading of multiple powder-containing capsules needed for a single dose of drug.

“The prototype device we’ve developed has been tested in phase I studies where it performed well,” Mr Phillips said.

“Any further development as a next generation Bronchitol product will be subject to commercial funding from our Bronchitol distribution partners,” Mr Phillips said.

Pharmaxis fell one cent or 8.3 percent to 11 cents with 2.1 million shares traded.

STARPHARMA

Starpharma says a 40 healthy volunteer study of its Viraleze nasal spray shows it is safe and well tolerated with the antiviral SPL7013 not absorbed into the bloodstream.
Starpharma said that the volunteers in randomized, double-blind, placebo-controlled, safety, tolerability and pharmacokinetic study used the product four times a day for 14 days.
The company said there were no notable or serious adverse events reported, and no participants discontinued product use.
Starpharma said the trial was conducted at the Perth, Western Australia-based Linear Clinical Research.
Starpharma chief executive officer Dr Jackie Fairley said that the clinical data added to "the extensive body of evidence for SPL7013, demonstrating its extremely benign safety profile and confirming lack of systemic absorption of SPL7013 in Viraleze".
"These data further support the suitability of Viraleze anti-viral nasal spray for use in everyday situations as a preventative product where individuals may be at risk of exposure to respiratory viruses," Dr Fairley said.
"An anti-viral nasal spray like Viraleze is advantageous because respiratory viruses, including [severe acute respiratory syndrome coronavirus-2] take hold by initially infecting mucosal cells in the nasal cavity, and Viraleze and SPL7013 form a barrier that traps and irreversibly inactivates viruses before they can infect cells," Dr Fairley said.
Starpharma climbed 4.5 cents or 3.5 percent to $1.345 with 924,447 shares traded.

BARD1 LIFE SCIENCES

Bard1 says that it has achieved "proof-of-concept" for its Sub-B2M-CA-125 enzyme-linked immunosorbent assay (Elisa) as a test for ovarian cancer.
In May, Bard1 said its Sub-B2M biomarker diagnostic had in-vitro feasibility for breast cancer (BD: May 25, 2021).
Today, Bard1 said that Sub-B2M with the cancer antigen-125 (CA-125) test in an assay could detect CA-125-Neu5Gc, a highly specific cancer biomarker, in blood serum in stages I to IV ovarian cancer compared to healthy controls.
The company said that previous research at Queensland's Griffith University showed that Sub-B2M on a surface plasmon resonance assay detected all stages of ovarian cancer with "100 percent sensitivity and specificity compared to healthy controls".
Bard1 said that development of a Sub-B2M-CA125 Elisa-based test had "the potential to create an accurate, reliable, and affordable test for monitoring and early detection of [ovarian cancer]".
Bard1 chief scientific officer Dr Peter French said the preliminary data was "very encouraging for development of a robust and reliable Sub-B2M-CA125 test for monitoring and early detection of ovarian cancer".
"The feasibility studies at Griffith have demonstrated that the Sub-B2M assay could be transferred from a research-use [surface plasmon resonance] platform to a commercial platform with initial design of an Elisa including key reagents and assay conditions established in both spiked-in and now patient samples". "Importantly, this initial assay development work is transferrable to our other Sub-B2M development programs including CA15-3 for breast cancer, PSA for prostate cancer and other cancers."
"These data represent a key go-decision to progress the optimization and validation of our Sub-B2M Elisa-based tests that are expected to improve existing cancer biomarker tests for ovarian, breast, prostate and other cancers," Dr French said.
Bard1 fell three cents or 2.1 percent to $1.405 with 1.1 million shares traded.

NUHEARA

Nuheara says Sydney's National Acoustics Laboratories is planning regulatory-directed clinical trials of its hearing aid products to test the safety and efficacy.

Nuheara says that trial results would allow it to meet compliance requirements set by the US Food and Drug Administration, the European Union and the Australian Therapeutic Goods Administration.

Nuheara chief executive officer Justin Miller said the trial was "the first step of our evolution to a medical device company" in the more than $US8 billion regulated hearing aid market.

Mr Miller said the company's non-regulated hearing and sound filtering products had "laid a solid foundation for our technology".

Mr Miller said the Ear ID was clinically validated and the company had pioneered embedding the hearing aid prescription protocols into its Iqbuds.

"A successful clinical trial will enable us to tackle any regulated hearing device market in the world, with our end-to-end range of affordable and accessible hearable and hearing aid devices," Mr Miller said.

Nuheara was unchanged at 3.4 cents with 3.6 million shares traded.

CSL

CSL says it has appointed University of Melbourne vice-chancellor Prof Duncan Maskell as an independent non-executive director, effective from August 18, 2021.

CSL said that Prof Maskell had experience in science and commerce, including 30 years in research, academia and entrepreneurship.

The company said that prior to the University of Melbourne Prof Maskell was England's University of Cambridge senior pro-vice-chancellor, responsible for operations planning and resources with an annual turnover of about GBP2 billion.

CSL said that Prof Maskell was a research specialist in infectious diseases and previously worked at the University of Oxford, Imperial College London and Wellcome Biotech.

The company said that Prof Maskell co-founded biotech companies, including Arrow Therapeutics and Discuva and formerly was a director of Genus Plc.

CSL said that Prof Maskell held a Master of Arts and a Doctor of Philosophy from the University of Cambridge.

CSL was up 45 cents or 0.15 percent to $297.94 with 550,098 shares traded.

PYC THERAPEUTICS

PYC says it has formed an ophthalmology clinical advisory board comprising Dr Mark Pennesi, Dr David Birch, Dr Fred Chen and Dr Jacque Duncan.

PYC was unchanged at 15.5 cents with 2.9 million shares traded.