Biotech Daily

Wednesday July 22, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMUGENE UP 19%; OPTISCAN DOWN 8%**

*** QBIOTICS DOSES 1st AUSTRALIAN HEAD, NECK CANCER PATIENT**

*** IMMURON TO RAISE $28m**

*** SOMNOMED RECEIPTS DOWN 5.6% TO $61.5m**

*** CELLMID RECEIPTS UP 29% TO $8.2m**

*** ATOMO RECEIPTS UP 456% TO $2.7m**

*** MICRO-X RECEIPTS UP 11% TO $2.6m**

*** LITTLE GREEN PHARMA RECEIPTS OF $1.8m**

*** CORRECTION: RESPIRI**

*** IMPEDIMED LAUNCHES SOZO FOR HEART FAILURE**

*** EMVISION IMAGING ALGORITHMS CLASSIFY STROKES**

*** IMAGION: IRON OXIDE NANOPARTICLES ENABLE LOW-FIELD MRI**

*** OSTEOPORE, QUT LICENCE FOR 3-D PRINTED BONE IMPLANT**

*** ZELIRA, CVSCM MARIJUANA DEAL FOR PAD, DIABETIC NEUROPATHY**

*** PYC COMPLETES CPP TOXICITY, MOUSE STUDIES**

*** RACE GRANTED 4th US BISANTRENE PATENT**

*** BOTANIX TELLS ASX 22% AWARE QUERY: FDA INFO HELD FOR 10 DAYS**

*** INVEX REQUESTS 'REGULATORY ADVICE' TRADING HALT**

*** MGC REQUESTS 'ARTEMIC PRE-CLINICAL RESULTS' TRADING HALT**

*** NOXOPHARM RECEIVES $130k FROM LIND, CST FACILITY**

*** ADALTA APPOINTS DR DAVID FULLER DIRECTOR**

*** TALI APPOINTS EXPERT ADVISORY BOARD**

MARKET REPORT

The Australian stock market fell 1.32 percent on Wednesday July 22, 2020, with the ASX200 down 81.2 points to 6,075.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell and eight traded unchanged. All three Big Caps fell.

Imugene was the best, up 0.8 cents or 19.05 percent to five cents, with 70.6 million shares traded.

Oncosil climbed 8.7 percent; Impedimed improved 5.6 percent; Antisense was up 4.8 percent; Amplia, LBT, Proteomics and Resonance were up more than three percent; Compumedics and Kazia rose more than two percent; with Neuren and Starpharma up by less than one percent.

Optiscan led the falls, down 0.4 cents or 8.2 percent to 4.5 cents, with 46,237 shares traded.

Prescient lost 7.5 percent; Mesoblast and Pro Medicus retreated more than six percent; Avita, Cynata, Nova (Ellex), Pharmaxis and Polynovo were down five percent or more; Cyclopharm, Genetic Signatures and Immutep fell four percent or more; Clinuvel, Cochlear, CSL and Nanosonics were down more than three percent; Alterity, Resmed, Telix and Volpara were down more than one percent; with Medical Developments, Next Science and Opthea down by less than one percent.

QBIOTICS GROUP

Qbiotics says it has dosed the first Australian patient in its phase I/II trial evaluating the dose and safety of tigilanol tiglate for head and neck squamous cell carcinoma.
Last year, Qbiotics said that four of 22 patients in its phase I trial of tigilanol tiglate, or EBC-46, for solid tumors had shown a complete response, with no maximum dose reached (BD: Dec 10, 2019).
In December, the company announced the start of the up-to 40-patients, phase I/II, multi-centre, open-label, dose-escalation head and neck cancer trial.
Today, Qbiotics said the study had so far treated four patients in India.
The company said that the trial was designed to determine the maximum tolerated dose and recommended dose level for further studies.
Qbiotics said the trial would investigate safety, tolerability and tumor response following a single, two or three doses of tigilanol tiglate.
Qbiotics chief executive officer Dr Victoria Gordon said the company had treated the first Australian patient at Sydney's Kinghorn Cancer Centre, a joint facility of Sydney's St Vincent's Hospital and the Garvan Institute of Medical Research.
Dr Gordon said the trial, known as the QB46C-H03 study, was being conducted in Sydney and at the Kolkata, India Tata Medical Centre and Mumbai's Tata Memorial Hospital.
Qbiotics said that tigilanol tiglate was administered directly into the tumor mass, limiting exposure and damage to surrounding healthy tissues and reducing the risk of functional or cosmetic impairment as well as reduced systemic toxicity.
"Cancers of the head and neck are challenging and frequent, with more than two million new cases each year," Dr Gordon said.
"We hope that with tigilanol tiglate, we might be able to bring a much-needed new treatment to patients who currently have few other options," Dr Gordon said.
Qbiotics is a public unlisted company.

IMMURON

Immuron says it expects to raise up to $US20 million ($A28 million) with “definitive agreements with several healthcare-focused institutional investors”.
Immuron said the investors would buy up to 1,066,668 American depositary shares (ADSs), representing 42,666,720 shares, at $US18.75 per ADS or 46.9 US cents a share.
The company said the proceeds would be used for research and development, preclinical and clinical programs, to support marketing initiatives for Travelan and for ongoing working capital.
Immuron said H C Wainwright & Co was the placement agent for the offer.
Immuron fell 29.5 cents or 34.5 percent to 56 cents with 25.8 million shares traded.

SOMNOMED

Somnomed says receipts from customers for the year to June 30, 2020 were down 5.6 percent to $61,465,000 compared to the previous corresponding period.
Somnomed said receipts from customers for the three months to June 30, 2020 fell 32.6 percent to $12,090,000.
The company said receipts were from its Somnodent sleep apnoea mouth guard device.
Somnomed said it had cash and cash equivalents of $30,174,000 at June 30, 2020 compared to $8,006,000 at June 30, 2019 and it had an estimated 43.09 quarters of funding.
Somnomed fell seven cents or five percent to $1.32.

CELLMID

Cellmid says receipts from customers for the year to June 30, 2020 were up 29.1 percent to $8,238,000 compared to the previous corresponding period.
Cellmid said receipts from customers for the three months to June 30, 2020 fell 15.9 percent to $1,097,000.
The company said receipts were from sales of its hair loss products in Australia, the US and Japan, as well as the Wondfo Covid-19 antibody test.
Cellmid said it had cash and cash equivalents of $6,970,000 at June 30, 2020 compared to $3,082,000 at June 30, 2019 and it had an estimated 4.1 quarters of funding.
Cellmid was up half a cent or 3.7 percent to 14 cents.

ATOMO DIAGNOSTICS

Atomo says receipts from customers for the year to June 30, 2020 was up 456.4 percent to $2,654,000 compared to the previous corresponding period.
Atomo said receipts from customers for sales of its Covid-19 antibody rapid diagnostic test for the three months to June 30, 2020 were $1,837,000.
The company said the sales included an order from France’s NG Biotech for more than 1.75 million devices (BD: Apr 16, May 7, 2020).
Atomo said it had cash and cash equivalents of $27,104,000 at June 30, 2020 and an estimated 10 quarters of funding.
Atomo fell one cent or 2.6 percent to 38 cents with 6.1 million shares traded.

MICRO-X

Micro-X says receipts from customers for the year to June 30, 2020 were up 10.7 percent to $2,569,000 compared to the previous corresponding period.
Micro-X said receipts from customers from sales of its Carestream DRX Revolution Nano for the three months to June 30, 2020 rose 75.5 percent to $1,651,000.
The company said it had cash and cash equivalents of $18,323,000 at June 30, 2020 compared to $1,603,000 at June 30, 2019 and it had an estimated five quarters of funding.
Micro-X was unchanged at 16 cents with 1.1 million shares traded.

LITTLE GREEN PHARMA

Little Green Pharma says it had receipts from customers for the year to June 30, 2020 $1,792,000 and $667,000 for the three months to June 30, 2020.
Little Green said receipts were from sales of its medical marijuana oil products.
The company said it had cash and cash equivalents of $4,274,000 at June 30, 2020 and an estimated 5.7 quarters of funding.
Little Green Pharma was unchanged at 37.5 cents.

CORRECTION: RESPIRI

Last night's edition incorrectly said that Respiri Zip Co customers will pay $14 per week for six months or $336 compared to $229 upfront for its Wheezo asthma monitor.
In fact, the Wheezo upfront cost is $299, but it comes with an $8 per month subscription fee, taking its total price for six months to $347, effectively giving the buy-now-pay-later customers an $11 advantage.
Both Tuesday sub-editors have been required to telephone Centrelink and not return until they have spoken with a JobSeeker consultant.
Respiri fell half a cent or 3.3 percent to 14.5 cents with 3.2 million shares traded.

IMPEDIMED

Impedimed says it has launched its Sozo fluid analysis software for heart failure following improvements in collaboration with the San Diego-based Scripps Health.
Impedimed said its fluid analysis software used its heart failure index, or HF-Dex, to measure extracellular fluid as a percent total of body water and these improvements incorporated color-coded reference ranges for extracellular, intracellular, total body fluid volumes and weight.
The company said the updates improved usability and data visualization for cardiologists.
Impedimed said that clinicians typically had "poor tools for determining the degree of congestion in heart failure … [leading] to costly hospital admissions … and re-admissions after discharge".
Heart failure home study co-investigator Dr Andrew Accardi said the "initial clinical trial experience with Sozo has been very positive".
Impedimed chief executive officer Richard Carreon said that with the "software-based approach to product improvements, we can respond quickly and act on critical feedback, which will help to ensure the commercial launch of our heart failure application".
Impedimed was up 0.4 cents or 5.6 percent to 7.5 cents with 10.7 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says a selection of its imaging algorithms were able to detect, localize and classify haemorrhagic strokes in preliminary results from its 30-patient pilot trial.
Emvision said the primary endpoint of the trial was to generate a dataset of stroke patient scans that improved the understanding of strokes on electromagnetic scattering effects in the brain, in order to select optimal imaging algorithms.
The company said that the conductivity, permittivity and related electromagnetic values identified differed from previous ischaemic stoke patient datasets, which demonstrated the potential to classify strokes (BD: Apr 21, 2020).
Emvision chief executive officer Dr Ron Weinberger said the “preliminary images support the approach we are taking to deliver a unique bedside device for stroke monitoring, and in the future, pre-hospital, to assist clinicians with earlier interventions”.
“We now have shown the ability to identify both stroke types [an ischaemic blockage or haemorrhagic bleed], and importantly, distinguish between them,” Dr Weinberger said.
Dr Weinberger said the results were preliminary but provided validation of the principles.
The company said it expected to complete trial enrolment by October 2020.
Separately, Emvision requested a trading halt “pending an announcement by the company regarding a proposed capital raising”.
Trading will resume on July 24, 2020 or on an earlier announcement.
Emvision last traded at $1.69.

IMAGION BIOSYSTEMS

Imagion says its iron oxide nanoparticles enable low-field magnetic resonance imaging, reducing costs and improving accessibility.
Imagion said a research study, led by the University of Sydney, titled ‘High-sensitivity in vivo contrast for ultra-low field magnetic resonance imaging using superparamagnetic iron oxide nanoparticles’ was published in Science Advances, with the full article available at: https://advances.sciencemag.org/content/6/29/eabb0998.
The company said the research was a collaboration with Boston’s Low-field MRI and Hyperpolarized Media Laboratory and its nanoparticles successfully yielded high-contrast images without compromising acquisition sensitivity, even with ultra-low magnetic fields.
Imagion said magnetic resonance imaging (MRI) contrast was dominated by chelated agents, such as gadolinium, which had issues with brain and kidney toxicity, but its iron oxide nanoparticles provided better contrast than gadolinium in ultra-low-field MRI.
Imagion was up 1.4 cents or 29.2 percent to 6.2 cents with 132.4 million shares traded.

OSTEOPORE

Osteopore says it will pay $40,000 for an exclusive licence with the Queensland University of Technology for a three-dimensional printed modular bone implant.
Osteopore said the Queensland University of Technology would provide a further $100,000 in non-dilutive grant funding for a clinical development program in two stages to gather clinical data and for US Food and Drug Administration, Australian Therapeutic Goods Administration and European regulatory approval and commercialization.
The company said that under a future commercial agreement, it would be required to pay a $100,000 market entry fee and royalties of between two and six percent.
Osteopore said the technology had shown early stage results for regrowth of long bone defects in patients who had lost more than six centimetres of bone to injury or disease.
Osteopore was up two cents or 3.2 percent to 64.5 cents with two million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has an agreement with Cardiovascular Solutions of Central Mississippi to develop marijuana products for peripheral arterial disease and diabetic neuropathy.
Zelira said the five-year binding product development agreement with the Cleveland, Mississippi-based Cardiovascular Solutions of Central Mississippi (CVSCM) develop products based on cannabidiol and other cannabinoids derived from hemp for associated ischemic neuropathies and diabetic neuropathies.
The company said it would receive an undisclosed, immaterial, non-refundable upfront fee and royalties on resulting commercialized products, with all costs borne by CVSCM.
Zelira said CVSCM would retain exclusive marketing rights in the US and it would hold the rights to all other markets, with the agreement renewable for additional five-year periods.
The company said it could not fully quantify the impact of the contract on the price of its securities at this stage, but it did not expect the upfront licence fee to be material.
Zelira said that peripheral arterial disease was the leading cause of non-traumatic amputations.
Zelira chief executive officer Dr Oludare Odumosu said the partnership was “in-line with our mission to target indications where cannabinoid-based medicines can be used as safe, effective and accessible options”.
“This collaboration represents the first of its kind in this field and allows us to focus on the impact of [peripheral arterial disease] on quality of life for patients,” Dr Odumosu said.
Zelira was up 0.4 cents or 7.55 percent to 5.7 cents with 4.4 million shares traded.

PYC THERAPEUTICS

PYC says its cell penetrating peptide phosphoro-diamidate morpholino oligomer (CPP-PMO) technology has no toxicity and shows a clear dose dependent response in mice.
PYC said it used a maximum of 6.4 micrograms, 16 times the dose used by a competitor antisense oligonucleotides technology, and found no statistical difference between dose cohorts, indicating a lack of toxicity at expected therapeutic doses and doses substantially higher than expected for humans.
The company said there was a clear relationship between its CPP technology delivery method and the targeted gene effect, showing that efficacy increased with dosing levels.
PYC said it would begin dosing in rabbits in August and pending mouse, rabbit and monkey trials, expected to submit a first-in-human phase I program by the end of 2021.
PYC was unchanged at 12.5 cents with two million shares traded.

RACE ONCOLOGY

Race says that the US Patent and Trademarks Office has granted its fourth US patent for Bisantrene.
Race said the patent, entitled ‘Compositions to improve the therapeutic benefit of Bisantrene and analogs and derivatives thereof’, would protect its intellectual property until May 31, 2038.
Race chief executive officer Dr Daniel Tillett said that the new patent allowed “additional claims around the use of bisantrene that improve the therapeutic benefit of bisantrene and related chemical structures”.
The company said that the patent addressed the expanded therapeutic utility of bisantrene and related chemical structures, in particular, methods and compositions for improving the therapeutic efficacy of bisantrene and reducing side effects.
Race fell one cent or one percent to 96.5 cents.

BOTANIX PHARMACEUTICALS

Botanix says it had US Food and Drug Administration minutes regarding an end of phase II meeting and a phase III acne trial for 10 days before announcing it.

The ASX noted that prior to the Friday July 17, 2020 announcement, the Botanix share price increased 21.7 percent from 4.6 cents to 5.6 cents on July 16 with a “significant increase” in trading volumes on July 15 and July 16, and asked when the company first became aware of the information.

Botanix said that the FDA meeting was held on July 2, and its regulatory advisers received the minutes of the meeting on July 7.

The company said that it considered suggestions for amendments to the minutes between July 8 and July 16, when “a strategic decision was made not to pursue any amendments to the minutes” and it made the announcement the next day.

Botanix said that it did not previously release the information in relation to the FDA meeting and “only four board directors” [executive chair Vince Ippolito, Matt Callahan, Dr Michael Thurn and Dr Bill Bosch] were aware of the meeting minutes information, along with Botanix's regulatory advisers and two key opinion leaders who attended the telephonic meeting”.

The company said the information was material and it was complying with the Listing Rules, in particular Listing Rule 3.1.

Botanix was up 0.1 cents or two percent to five cents with 3.9 million shares traded.

INVEX THERAPEUTICS

Invex has requested a trading halt pending an announcement on advice “regarding its proposed development plans for Presendin in idiopathic intracranial hypertension”.

Trading will resume on July 24, 2020 or on an earlier announcement.

Invex last traded at $1.14.

MGC PHARMACEUTICALS

MGC has requested a trading halt “pending the release of an announcement by the company in relation to safety and toxicity pre-clinical study results for Atremic” [sic].

Trading will resume on July 24, 2020 or on an earlier announcement.

MGC last traded at 2.4 cents.

NOXOPHARM

Noxopharm says it has received $129,764 from 811,022 collateral shares at 16 cents a share, issued to the New York-based Lind Partners LLC and CST Investment Fund.

Noxopharm said it had previously issued 4.5 million shares to Lind and CST under a convertible security agreement, which was terminated in February, and in April, received $409,477, including $159,727 from CST to reduce the CST liability from 2.25 million shares to 811,022 shares (BD: Feb 14, Apr 21, 2020).

Today, the company said the lenders were required to pay the collateralization price in cash by December 20, 2021 but all collateral shares had now been paid.

Noxopharm fell two cents or 5.5 percent to 34.5 cents with 2.2 million shares traded.

ADALTA

Adalta says it has appointed Dr David Fuller as a non-executive director.
Adalta said Dr Fuller was currently the head of clinical development for Syneos Health's oncology business unit, a director of Epiaxis Therapeutics and Perth's Linear Clinical Research and was previously the chair of Dimerix.
The company said Dr Fuller had led five product approvals in the US and European Union, and had designed multiple phase I to phase III trials in the US, EU and Asia.
Adalta said Dr Fuller held a Bachelor of Medicine, Bachelor of Surgery and Bachelor of Pharmacy from the University of Sydney.
Adalta fell 0.3 cents or 3.1 percent to 9.4 cents.

TALI DIGITAL

Tali says it has appointed Sarah Michel, Dr Phil Lambert, Prof Con Stough and Dr Scott Kollins as expert and scientific advisors to its advisory board.
Tali chair Sue MacLeman said the expert advisory board was a "shift in how our advisory board operates by balancing scientific excellence with commercial acumen".
"The board will assist with guiding our scientific programs and support the team as we grow and scale in major markets," Ms MacLeman said.
Tali fell 0.2 cents or 6.9 percent to 2.7 cents with 3.1 million shares traded.