Biotech Daily

Tuesday April 28, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: RESONANCE UP 17%; MESOBLAST DOWN 16%**

*** IMMUTEP: 9 OF 17 TACTI-002 PATIENTS RESPOND TO IMP321, KEYTRUDA**

*** IMPEDIMED RETAIL RIGHTS RAISE $8.2m; TOTAL $18.2m of $24.9m**

*** PHARMAXIS PLANS PHASE II PXS-5505 MYELOFIBROSIS TRIAL**

*** THAILAND APPROVES MEDICAL DEVELOPMENTS PENTHROX**

*** QBIOTICS EURO LAUNCH OF STELFONTA FOR DOG CANCER**

*** IMAGION FOLLOW-ON PLACEMENT SCALED-BACK; TOTAL RAISED $2.5m**

*** AZURE, INVICTUS FAIL SPREAD RULE FOR $10m RAISING**

*** PROBIOTEC: COVID-19 SWINGS & ROUNDABOUTS**

*** MGC $3.5m PLACEMENT**

*** AUSCANN THC, CBD MARIJUANA STUDY BEGINS**

*** OVENTUS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** GI DYNAMICS HAS ONE QUARTER CASH**

*** NEUROTECH 2nd EXTENSION OF 'ASX PRICE QUERY' SUSPENSION**

*** AUSTRALIAN ETHICAL REDUCES TO 11% OF ANTISENSE**

*** REGAL TAKES 6% OF MICRO-X**

*** MGC CLAIMS 2nd ISRAEL ARTEMIC 'COVID-19' TRIAL SITE**

MARKET REPORT

The Australian stock market slipped 0.16 percent on Tuesday April 28, 2020, with the ASX200 down 8.3 points to 5,313.1 points. Twenty-six of the Biotech Daily Top 40 stocks were up, nine fell, three traded unchanged and two were untraded.

Resonance was the best, on positive third quarter results, up two cents or 16.7 percent to 14 cents, with 2.9 million shares traded. Paradigm climbed 13.0 percent; Alterity was up 11.1 percent; Avita rose 8.2 percent; Optiscan was up 7.9 percent; Actinogen, Telix and Uscom improved five percent or more; Compumedics, Imugene, Opthea, Osprey and Pharmaxis were up more than four percent; Cyclopharm was up 3.5 percent; Dimerix, Genetic Signatures, Impedimed, Polynovo and Universal Biosensors rose more than two percent; with Cynata, Nanosonics, Next Science and Volpara up more than one percent.

Mesoblast led the falls, retreating 61 cents or 15.8 percent to $3.24, with 22.3 million shares traded. Prescient lost 10.2 percent; Antisense was down 6.1 percent; both LBT and Starpharma fell 4.8 percent; Kazia shed 2.4 percent; Amplia was down 1.3 percent; with Clinuvel, CSL, Neuren and Resmed down by less than one percent.

IMMUTEP

Immutep says nine of 17 patients of up to 109-patients in its Tacti-002 trial have shown a partial response to eftilagimod alpha or IMP321 with Keytruda for cancers.

Immutep said that the further interim data from its phase II, open label, single-arm study of IMP321 with Keytruda for cancers was presented at the American Association for Cancer research meeting by principal investigator Dr Martin Firster.

Last year, Immutep said it had dosed the first of 109 patients in the phase II study to assess IMP321 in collaboration with the Kenilworth, New Jersey-based Merck & Co's programmed cell death-1 (PD-1) blocking antibody Keytruda, or pembrolizumab, on second line head and neck squamous cell carcinoma and non-small cell lung cancer patients (BD: Mar 7, 2019).

In February, Immutep said that eight of 17 patients had a response to eftilagimod alpha or IMP321 with Keytruda for cancers (BD: Feb 19,2020).

The company said, at that time, that second line head and neck squamous cell carcinoma patients in part C showed an interim overall response rate of 33 percent, with six of 18 patients reporting a response.

Today, Immutep said that two patients of the nine non-small cell lung cancer cancer patients responded after eight and 11 months and "late responders are quite unusual with pembrolizumab alone".

The company said that 12 of the 17 non-small cell lung cancer patients (NSCLC) had a target lesion decrease, a majority of patients were still under treatment at more than eight months and median progression-free survival had not been reached.

Immutep said that second line head and neck squamous cell carcinoma (HNSCC) patients in part C maintained an interim overall response rate of 33 percent, with six of 18 patients reporting a response.

The company said that nine of the 18 patients were still under treatment and median progression-free survival had not been reached.

Immutep said that 76 patients of the total target of 109 patients had been recruited.

Immutep chief scientific and medical officer Dr Frederic Triebel said the "very positive results for stage 1 demonstrate the benefits for NSCLC patients in receiving efti in combination with pembrolizumab".

"Fifty-three percent of patients are now responding and we expect [progression-free survival] to be more than nine months," Dr Triebel said.

"These consolidated results, with more tumor responses being confirmed by a second [computed tomography] scan and a longer follow up, are remarkable given that usually only 20 percent of patients respond to pembrolizumab monotherapy, if not pre-selected for high PD-L1 expression," Dr Triebel said.

"It is also encouraging to see that 33 percent of HNSCC patients are responding, almost double the proportion that respond to pembrolizumab monotherapy and that the median [progression-free survival] hasn't yet been reached for this group," Dr Triebel said.

Last year, Immutep said it dosed the first of 109 patients in its phase II Tacti-002 combination trial of IMP321 with Keytruda for head and neck or lung cancer, with the primary objective an evaluation of the objective response rate, with secondary objectives safety and tolerability, response rate, disease control rate, progression-free survival and overall survival. (BD: Mar 7, 2019).

Immutep chief executive officer Marc Voigt said the two indications were "multi-billion-dollar markets with NSCLC expected to reach $US33.9 billion and HNSCC $US2.8 billion by 2026 respectively".

Immutep was in a trading halt for a placement and last traded at 17.5 cents.

IMPEDIMED

Impedimed says its 13-for-10 retail rights offer at 3.75 cents a share has raised $8.2 million of a hoped for $14.9 million, taking the total raised to $18.2 million.

Earlier this month, Impedimed said it had raised $10 million in the institutional component of its rights offer at 3.75 cents a share and hoped to raise a further $14.9 million in the retail offer (BD: Apr 3, 2020).

Today, the company said that each share purchased in the offer would come with one free attaching unquoted option, exercisable at 3.75 cents each.

Impedimed managing-director Richard Carreon said the capital raising left the company "well capitalized with a pro-forma cash balance, after raising costs, of approximately $24 million as at March 31, 2020".

"The funds raised will assist the company in the next stage of commercialization of the Sozo digital health platform with the lymphoedema, heart failure and end stage renal disease applications," Mr Carreon said.

Impedimed was up 0.1 cents or 2.6 percent to 3.9 cents with 5.97 million shares traded.

PHARMAXIS

Pharmaxis says positive phase Ib results will take it to an up-to 30-patient, phase II study of oral anti-fibrotic pan-lysyl oxidase (LOX) inhibitor PXS-5505 for myelofibrosis by 2021.

Last year, Pharmaxis said its 40-patient, phase Ia dose-ranging trial of its LOX inhibitor, or PXS-5505, showed that it was safe, well-tolerated and demonstrated dose-related activity and expected phase Ib results in April 2020 (BD: Oct 24, 2020).

Today, the company said that its six month, 16-patient, double-blinded, placebo controlled, phase Ib long term toxicity study showed that the drug was well tolerated and identified no safety signals.

Pharmaxis said that the phase Ia and Ib trials of PXS-5505 showed "good pharmacokinetics and a dose-related strong inhibition of the lysyl oxidase family in tissue and blood".

The company said it would begin enrolment by December 31, 2020 and would provide a phase II trial design once it had final regulatory clearance, expected by October 2020.

Pharmaxis chief executive officer Gary Phillips said that with the phase Ib results, the company could move to the "six-month phase II study in myelofibrosis with meaningful clinical efficacy and safety endpoints".

"Pharmaxis believes that the current treatments for [myelofibrosis] can be augmented by the use of a pan-LOX inhibitor and be disease modifying in a marker that is conservatively worth $US1 billion per annum," Mr Phillips said.

Pharmaxis was up 0.4 cents or 4.65 percent to nine cents.

MEDICAL DEVELOPMENTS

Medical Developments says the Thailand Food and Drug Administration has approved its Penthrox for emergency relief of moderate to severe pain.

Medical Developments chairman David Williams said the approval was "an important approval as Thailand is a key market for Penthrox throughout the Asian region".

"This is the first approval we have obtained with our partners Daiichi Sankyo who are also our partners in China and Vietnam," Mr Williams said. "We expect the granting of this marketing authorization will have positive ramifications for the rest of this region and we hope this approval is a catalyst for a number of other country approvals in Asia."

Medical Developments rose four cents or 0.5 percent to $7.50 with 475,921 shares traded.

QBIOTICS GROUP

Qbiotics says its tigilanol tiglate dog cancer treatment, marketed as Stelfonta, will be available in veterinary clinics in Europe from May 2020.
In January, Qbiotics said the European Medicines Agency had registered Stelfonta for the treatment of mast cell tumors in dogs (BD: Jan 20, 2020).
Qbiotics is a public unlisted company.

IMAGION BIOSYSTEMS

Imagion says its oversubscribed rights issue follow-on placement has been scaled back to meet ASX requirements, with the total raised now $2,501,480.
Last week, Imagion said it raised $2.05 million through the rights issue at 1.0 cent a share and raised a further $964,000 through a follow-on placement (BD: Apr 23, 2020).
Today, the company said the ASX advised that all shares and options needed to be issued under listing rule 7.1 and must fit within the original 15 percent placement capacity.
Imagion said it scaled back the follow-on placement from $964,661 to $456,351.
Imagion fell 0.1 cents or 7.7 percent to 1.2 cents with 13.6 million shares traded.

AZURE HEALTH TECHNOLOGY, INVICTUS BIOPHARMA

Azure says its $10 million capital raising failed to meet the minimum 300 investors rule, the funds will be returned and it will withdraw its application for reinstatement.
In February, the company said it hoped to raise up to $10 million at 20 cents a share for a backdoor listing of Invictus Biopharma (BD: Feb 5, 2020).
In March, Azure said an extraordinary general meeting passed all resolutions to acquire Invictus and the ASX has granted an extension to its removal (BD: Mar 6, 18, 2020).
Today, Azure said that it was unable to comply to the ASX Listing Rule 1.1 Condition 8 which stated that a company must have “300 shareholders holding a parcel of shares with a value of at least $2,000”.
The company said it expected to be delisted from the ASX on May 1, 2020.

PROBIOTEC

Probiotec says the Covid-19 pandemic has led to increases in demand for respiratory virus-related products and decreases for others, resulting in no change to its revenue.
Probiotec said that “cough, cold and ’flu, analgesics and immunity products” had seen “meaningful uplifts in orders” and expected the increase to continue through the year.
The company said there had been a reduction in the demand of products relating to elective surgery and discretionary goods.
Probiotec said that international freight costs had increased and its margins had been impacted by the “rapid decline in the Australian dollar”.
The company said that new pricing had been agreed with all major customers to adjust for cost impacts, which will take effect from July 2020.
Probiotec said that Covid-19 had caused “minimal supply chain disruption” and the company had invested additional working capital to procure safety stocks to ensure supply in the case of future disruptions.
The company said it expected to meet its previously advices guidance for the year to June 30, 2020 of more than $100 million in sales revenue and earnings before interest, taxation, depreciation and amortization (Ebitda) of $16 million to $17 million.
Probiotec was up six cents or 3.1 percent to $1.97.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has commitments to raise $3.5 million in a placement at 2.7 cents a share, cornerstoned by Merchant Opportunities Fund.
MGC said that Canaccord Genuity was the lead manager of the placement.
The company said that the share price was a 6.9 percent discount to the last closing price and a 13.9 percent discount to the 10-day volume weighted average price.
MGC said that investors would receive one free attaching option for every two shares purchased, exercisable at 4.5 cents a share by August 31, 2021.
The company said the funds would be used to produce its cannabinoid-based medicines, undertake clinical trials of, and commercially develop, its Artemic supplement for Covid-19, and for general working capital.
MGC was unchanged at 2.9 cents with 13.6 million shares traded.

AUSCANN

Auscann says it has completed recruitment and started dosing in its 28 subject, phase I study of two formulations of tetrahydrocannabinol (THC) and cannabidiol (CBD).
Last month, Auscann said the randomized, open-label, cross-over bioavailability study would examine the pharmaco-kinetics of the two doses of the “balanced THC:CBD formulations” to inform dose selection (BD: Mar 31, 2020).
Today, the company said that the primary endpoints were the assessment of the pharmacokinetics of THC, CBD and the main active metabolite of THC (11-hydroxy-THC), after oral doses of 2.5mg:2.5mg and 10mg:10mg of THC:CBD.
Auscann was up half a cent or 2.6 percent to 19.5 cents with 4.05 million shares traded.

OVENTUS MEDICAL

Oventus has requested a trading halt “pending an announcement … in relation to a capital raising”.
Trading will resume on May 4, 2020 or on an earlier announcement
Oventus last traded at 28.5 cents.

GI DYNAMICS

GI Dynamics says its cash burn for the three months to March 31, 2020 was $US3,232,000 ($A5,021,880) with cash at March 31 of $US3,854,000 ($A5,988,350).
GI Dynamics said its expected net operating cash burn for the three months to June 30, 2020 was $US3,129,000 ($A4,861,630), but did not provide any further information.
GI Dynamics was unchanged at 0.3 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested a second extension to its voluntary suspension following a trading halt in relation to an ASX price query (BD: Apr 9, 14, 2020).
Neurotech’s share price increased 140 percent from five cents at the close of trading on April 6, 2020 to 12 cents at the time of the halt with more than six million shared traded.
Last week, Neurotech requested the first extension to the suspension (BD: Apr 21, 2020).
Today, Neurotech said trading would resume on May 4, 2020 or on an earlier announcement.
Neurotech last traded at 1.2 cents.

ANTISENSE THERAPEUTICS

Australian Ethical Investment says it has reduced its substantial shareholding in Antisense from 60,816,309 shares (12.44%) to 55,087,546 shares (11.27%).
The Sydney-based Australian Ethical said that on April 23, 2020 it sold 5,728,763 shares for $293,759 or 5.1 cents a share.
Antisense fell 0.3 cents or 6.1 percent to 4.6 cents with 2.5 million shares traded.

MICRO-X

Sydney's Regal Funds Management Pty Ltd says it has become a substantial shareholder in Micro-X with 18,773,972 shares or 6.01 percent of the company.
Regal Funds said it bought the shares between January 13 and April 23, 2020 at prices ranging from 14 cents to 19.6 cents a share.
Micro-X was unchanged at 14 cents with 1.6 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says Israel's Hillel Yaffe Hospital will be the second site for its phase II trial of its supplement artemisinin and curcumin-based Artemic for Covid-19 patients.
Earlier this month, MGC said it had ethics approval to begin the 14-day, 50-patient trial at Israel's Nazareth Hospital (BD: Apr 17, 2020).
MGC managing-director Roby Zomer said that "given [Artemic's] classification as a [food supplement] product and therefore requiring no further approvals or licencing, we are anticipating the ability to produce and sell Artemic within a short period of time following successful completion of the trial."