Biotech Daily

Monday July 29, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ALTERITY (PRANA) UP 9%; RESONANCE DOWN 20%**

*** APPLICATIONS OPEN FOR $250k GILEAD 2020 FELLOWSHIPS**

*** ZUCERO ADDS BOWEL CANCER TO PIXATIMOD, OPDIVO COMBO TRIAL**

*** ALTERITY: 'PBT434 SAFE, TOLERATED IN ELDERLY VOLUNTEERS'**

*** NEUREN FILES 3 NNZ-2591 FDA ORPHAN APPLICATIONS**

*** TGA APPROVES PROTEOMICS PROMARKERD; INDONESIA PATENT**

*** DORSAVI RECEIPTS DOWN 13% TO $3.7m**

*** RESONANCE RECEIPTS UP 33% TO $3.5m; MAIDEN CASH-FLOW POSITIVE**

*** MEDIBIO, WELLTEQ PARTNER FOR EMPLOYERS, INSURERS**

*** ELIXINOL, PHARMACARE PARTNER FOR CANNABIDIOL CAPSULES**

*** BOD APPOINTS PCCA UK, IRELAND MARIJUANA DISTRIBUTOR**

*** RESPIRI TAKES CAPITAL RAISING HALT TO SUSPENSION**

*** KINETIC INCREASES, DILUTED BELOW 5% IN IMPEDIMED**

*** MACQUARIE TAKES 5% OF IMPEDIMED**

*** LEON SERRY, CITY CASTLE BELOW 5% IN ADALTA**

*** ANTEO CEO DEREK THOMPSON STARTS ON $280k**

MARKET REPORT

The Australian stock market was up 0.48 percent on Monday July 29, 2019, with the ASX200 up 32.4 points to 6,825.8 points. Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and one was untraded.

Alterity was the best, up 0.3 cents or 9.4 percent to 3.5 cents with 1.7 million shares traded. Avita climbed 5.3 percent; both Amplia and Imugene were up 4.2 percent; Uscom, Impedimed, Nanosonics and Oncosil improved three percent or more; Antisense, Benitec, Cyclopharm, Neuren, Prescient and Pro Medicus rose more than two percent; Ellex and Volpara were up more than one percent; with Cochlear, Compumedics, CSL and Paradigm up by less than one percent.

Resonance led the falls, down 2.5 cents or 20 percent to 10 cents with 7.7 million shares traded. LBT and Opthea lost more than seven percent; Polynovo fell 5.5 percent; Clinuvel, Cynata and Orthocell shed two percent or more; Mesoblast, Osprey, Resmed and Universal Biosensors were down more than one percent; with Medical Developments and Telix down by less than one percent.

GILEAD SCIENCES AUSTRALIA

Gilead says it will provide $250,000 through its 2020 fellowship research grants program, with a maximum amount of $60,000 for an individual project.
Gilead said it sought projects that engaged with local communities and aimed at enhancing patient outcomes in HIV, chronic viral hepatitis, haematological malignancies, non-alcoholic fatty liver disease, inflammatory diseases and invasive fungal infections.
Gilead said the fellowship grants program were in its ninth year and aimed to support projects that "often struggle to secure funding or face high competition".
The company said funding was contingent on the project being concluded in 18-months.
Gilead acting general manager and senior medical director Dr Paul Slade said the company "was founded by scientists and today science and research remains at our core, as we continue in our aspirations to cure diseases".
"Despite our size, we are one of the top 10 investors in clinical trials in Australia and we are committed to improving the lives of the people we treat through further Australian research and development projects," Dr Slade said.
Gilead said the closing date for applications was August 16, 2019 and successful applicants would be announced in January 2020.
For more information, go to: https://gileadfellowship.com.au/.

ZUCERO THERAPEUTICS

Zucero says its 20-patient, phase Ib trial of PG545 with nivolumab for advanced solid tumors has will include 30 patients with microsatellite stable metastatic colorectal cancer.
Zucero said the original 20-patient, open-label, multi-centre, phase Ib study was investigating the safety and tolerability of intravenous PG545 in combination with nivolumab in patients with advanced solid tumors and metastatic pancreatic cancer.
The company said it had approval to include patients with the bowel cancer known as microsatellite stable metastatic colorectal cancer.
In May, TBG Diagnostics, formerly Progen Pharmaceuticals, said Zucero had settled the $5,999,000 deferred payment for its PG500 assets (BD: Aug 22, 2016; May 7, 2019).
Zucero executive chairman Chris Burrell told Biotech Daily at that time that Zucero was conducting the phase Ib study of Pixatimod, or PG545, in combination with nivolumab, marketed as Opdivo, in patients with advanced solid tumors, with an expansion cohort in patients with metastatic pancreatic cancer.
Mr Burrell said that during the escalation phase of the study clinical benefit was observed in four of five metastatic colorectal cancer patients, including two patients demonstrating reductions of 86 percent and 48 percent in tumor burden.
Today, Zucero said that up to 95 percent of bowel cancers were microsatellite stable metastatic colorectal cancers and immune checkpoint inhibitors such as Opdivo failed to show any clinical activity when used alone for this specific form of bowel cancer.
The company said preliminary results from a small group of patients with advanced cancer showed evidence of immune system activation and indicated that patients with bowel cancer might benefit from the combination.
Zucero said it would begin recruitment of up to 30 new patients with microsatellite stable metastatic colorectal cancer immediately and continue to investigate the combination in pancreatic cancer.
Zucero said the study was performed by Sydney's Scientia Clinical Research with the New York-based Bristol Myers Squibb providing Opdivo.
Zucero is a public unlisted company.

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Alterity says that repeated doses of oral PBT434 in healthy and elderly volunteers are safe and well-tolerated, with adverse event rates comparable to placebo.

Alterity said PBT434 was a small molecule designed to block the accumulation and aggregation of alpha-synuclein, which was “an important biologic target” for treating neurodegenerative diseases such as Parkinson’s disease and multiple system atrophy.

In May, Alterity said that PBT434 passed through the blood-brain-barrier and was well-tolerated in healthy volunteers, with adverse event rates comparable to placebo and dose dependent systemic exposure (BD: May 6, 2019).

Today, the company said the new results included volunteers aged 65 year and above and the combined data met the primary endpoint of safety and tolerability after single and multiple oral dose administration and showed that systemic exposure to the drug was comparable between elderly and healthy volunteers.

The company said the results showed that clinically tested doses achieved concentrations in the brain that were comparable with those associated with efficacy in animal models of disease.

Alterity chief medical officer Dr David Stamler said “we are very pleased that the excellent safety and tolerability profile in the adult population has now been extended to elderly volunteers”.

“[This] data will provide the foundation for our interactions with regulatory authorities later this year as we advance the program toward a phase II clinical trial,” Dr Stamler said.

The company said it was preparing for a phase II clinical trial.

Alterity was up 0.3 cents or 9.4 percent to 3.5 cents with 1.7 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has applied for US Food and Drug Administration orphan drug status for NNZ-2591 for Phelan-McDermid, Angelman and Pitt Hopkins syndromes.

Neuren said there were no approved drug therapies for Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome.

The company said it had announced positive results for NNZ-2591 in mouse models of each of the “debilitating neuro-developmental disorders” (BD: Feb 18, May 17, 2019).

Neuren said that each disorder was caused by a mutation or deletion in a different gene or chromosomal region, but they shared “many common symptoms and an underlying impairment in the connections and signaling between brain cells”.

The company said that the aim of treatment with NNZ-2591 was to restore normal functional connectivity and signaling.

Neuren said it was currently undertaking the manufacturing development and non-clinical studies required before submitting an investigational new drug application in the US and beginning phase II clinical trials by the end of 2020.

Neuren executive chairman Dr Richard Treagus said the three orphan drug applications were “an important first interaction with the FDA as Neuren progresses the development of NNZ-2591 for these debilitating disorders”.

“We are focused on being ready to start trials in patients next year,” Dr Treagus said.

Neuren said that orphan drug designation for a rare disease or condition provided incentives, including seven years marketing exclusivity, with an additional six months if approved for paediatric use, as well as a waiver of the prescription drug user fee for a marketing application.

Neuren was up four cents or 2.7 percent to $1.525.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has Australia Therapeutics Goods Administration approval and an Indonesian patent for its Promarkerd software for diabetic kidney disease.
Proteomics said the TGA had approved Promarkerd as an in-vitro diagnostic for export use, which covered the use of the Promarkerd software algorithm across the company's platform technologies, including mass spectrometry and immunoassay formats.
The company said while awaiting further approvals, Promarkerd software could be used in clinical laboratory improvement amendments (CLIA) accredited laboratories.
Proteomics said there were more than 6,400 CLIA laboratories in the US, providing a broad network of testing facilities for the commercialization of Promarkerd.
The company said that the Indonesian patent, titled 'Biomarkers Associated with Diabetic Nephropathy' would provide coverage until September 20, 2031, and it held patents for Promarkerd in the US, Europe, Japan, Australia, Singapore, Russia and China.
Proteomics was unchanged at 33 cents.

DORSAVI

Dorsavi says that receipts from customers for the 12 months to June 30, 2019 were down 12.5 percent to $3,719,000 compared to the previous year.
Dorsavi said receipts from customers for its wearable motion analysis device for the three months to June 30, 2019 rose 85.8 percent to $1,187,000, with a cash burn of $119,000 for the three months to June 30.
The company said it had cash and cash equivalents at June 30 of $2,767,000 with an expected outflow of $1,462,000 for the three months to September 30, 2019.
Dorsavi was unchanged at five cents.

RESONANCE HEALTH

Resonance says that receipts from customers for the year to June 30, 2019 improved 33.4 percent to $3,539,000 compared to previous corresponding period.
Resonance said receipts from customers for its magnetic resonance imaging software for the three months to June 30 were up 17.0 percent to $991,000, it had cash of $3,081,000 at June 30, with an expected burn of $680,000 for the three months to September 30.
Resonance chief financial officer Agha Shahzad told Biotech Daily that the company was "cash flow positive for both the June 2019 quarter and the year to June 30, 2019 [and] the first time the company is cash-flow positive in the four consecutive quarters".
Resonance fell 2.5 cents or 20 percent to 10 cents with 7.7 million shares traded.

MEDIBIO

Medibio says it will partner with Singapore's Wellteq for a digital product using its mental health software and Wellteq's digital health platform for employers and insurers.
Medibio said the initial agreement was for the Asia Pacific, with potential for additional geographical regions on mutual agreement.
The company said Medibio and Wellteq would maintain ownership of intellectual property in their respective areas and hoped the platform would be available by the end of 2019.
Medibio chairman David Kaysen said that "the partnership is a big step forward in achieving our commercialization objective to integrate Ilumen into organizations with global distribution channels," Mr Kaysen said.
Medibio was up half a cent or 29.4 percent to 2.2 cents with 29.9 million shares traded.

ELIXINOL GLOBAL

Elixinol says it will work with Sydney's Pharmacare to develop a co-branded cannabidiol capsule range to be sold by the Nuneaton, UK-based Holland & Barrett.
Elixinol said the deal with the vitamins and supplements retailer Holland & Barrett was through its Netherlands subsidiary Elixinol BV and Pharmacare's Naturopathica.
The company said the range would include six capsules containing its cannabidiol blended with different, unspecified vitamins and minerals, and would be sold through Holland & Barrett's internet page and the company's 800 retail shops.
Elixinol said it was in the process of fulfilling a second order of 60,000 units.
Elixinol was up 16 cents or 4.9 percent to $3.45 with 805,232 shares traded.

BOD AUSTRALIA

Bod says it has appointed the Prudhoe, Newcastle, England-based PCCA to distribute its "pharmaceutical grade medical cannabis" Medicabilis in the UK and Ireland.
The company said PCCA had a network of more than 4,000 hospitals, clinics, physicians and medical specialists across the UK.
Bod said it expected its first prescriptions "in the coming months" and the companies would collaborate on packaging and distributing other medical cannabis products.
Bod fell 3.5 cents or 5.2 percent to 63.5 cents with 1.3 million shares traded.

RESPIRI

Respiri has requested a voluntary suspension to follow the trading halt requested "pending an announcement in relation to proposed capital raising initiatives" (BD: July 25, 2019).
Respiri said it expected to make an announcement regarding the proposed capital raising initiatives on or before July 31, 2019.
Respiri last traded at 12 cents.

IMPEDIMED

Kinetic Investment Partners says it has been diluted below the substantial shareholder level in Impedimed, following the recent $13.9 million capital raising (BD: Jun 27, 2019).
Last month, the Melbourne-based Kinetic said it held 21,107,504 Impedimed shares or 5.56 percent (BD: Jun 20, 2019).
Today, Kinetic said that between June 19 and July 25, 2019, it bought 4,100,000 shares for $451,000 or 11 cents a share, and Biotech Daily calculates Kinetic holds 25,207,504 shares of the company or 4.97 percent of the company.
Impedimed was up half a cent or 3.6 percent to 14.5 cents with 1.6 million shares traded.

IMPEDIMED

The Sydney-based Macquarie Group says it has become a substantial shareholder in Impedimed with 24,768,177 shares or 5.28 percent.
Macquarie Group said that in hundreds of trades between July 4 and July 24, 2019 it bought and sold shares at prices between 11 and 16 cents.

ADALTA

City Castle and director Leon Serry say their holding in Adalta has increased but been diluted from 5,311,856 shares (5.31%) to 6,031,856 shares (3.68%).
City Castle said that in July 2018 it bought 50,000 shares for $15,000 or 30 cents a share in a rights offer, acquiring a further 670,000 shares for $100,500 or 15 cents a share in May and June 2019 in a placement and rights offer and was diluted in the $7 million capital raising (BD: May 23, Jun 14, 2019)
In 2016, City Castle director Leon Serry said his company held 5,311,856 shares or 5.31 percent (BD: Aug 23, 2016).
Adalta was unchanged at 18 cents.

ANTEO DIAGNOSTICS

Anteo says it has appointed Derek Thompson as chief executive officer, by August 26, 2019, with a base salary of $280,000 a year.
Last week, Anteo said that its newly appointed chief executive officer Harley Frankfurt had stepped down for personal reasons and been replaced by former chief executive officer Mr Parker (BD: July 22, 2019).
Today, the company said Mr Thompson was currently a director of the Perth, Western Australia-based ATI Solutions group and had previously worked for KPMG, Capgemini, IBM, Oracle and Telstra.
Anteo said Mr Thompson held a Bachelor of Commerce from the University of Western Sydney and a Master of Business Administration from Sydney's Macquarie University Graduate School of Management.
The company said Mr Thompson would be entitled to a short-term incentive of up to 20 percent of his base salary paid half in cash and half in shares, along with eligibility for long-term incentives of up to 18,000,000 performance-based options.
Anteo was unchanged at 1.5 cents.