Biotech Daily

Tuesday July 18, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LIVING CELL UP 4%, PRANA DOWN 7%**

*** PRANA, TAKEDA WORK ON PBT434 FOR GUT NEURO-DEGENERATION**

*** REDHILL COMPLETES BEKINDA RHB-102 IRRITABLE BOWEL TRIAL**

*** ADALTA AD-114 SAFETY TRIALS COMPLETED, MATERIAL DELAY**

*** PRIMA DISCLOSES NOVARTIS $1.3m MILESTONE**

*** PHARMAXIS GRANTS CEO GARY PHILLIPS 770k 'PERFORMANCE' RIGHTS**

*** NUHEARA REQUESTS CAPITAL RAISING TRADING HALT**

*** CAPITAL GROUP TAKES 6% OF VIRALYTICS**

*** JIM CRAIG, BELLWETHER TAKE 6% OF BLUECHIIP**

*** ITL: 'NATIONAL DIABETES WEEK RAISED MYHEALTHTEST AWARENESS'**

MARKET REPORT

The Australian stock market fell 1.18 percent on Tuesday July 18, 2017 with the ASX200 down 68.1 points to 5,687.4 points. Eight of the Biotech Daily Top 40 stocks were up, 19 fell, 12 traded unchanged and one was untraded. All three Big Caps fell.

Living Cell was the best, up 0.5 cents or 4.35 percent to 12 cents with 144,669 shares traded.

Cellmid and Compumedics climbed four percent or more; Reva rose 2.5 percent; Ellex, Oncosil and Opthea up more than one percent; with Medical Developments up 0.4 percent.

Yesterday's 7.3 percent best, Prana, led the falls, down 0.4 cents or 6.8 percent to 5.5 cents with 115,376 shares traded.

Atcor, Dimerix, LBT and Psivida lost more than six percent; Neuren was down 3.2 percent; Airxpanders, Avita, Clinuvel, Genetic Signatures and Nanosonics shed more than two percent; Acrux, CSL, Orthocell, Osprey, Resmed, Sirtex, Universal Biosensors and Viralytics were down more than one percent; with Cochlear, Pro Medicus and Starpharma down by less than one percent.

PRANA BIOTECHNOLOGY

Prana says it will collaborate with Takeda Pharmaceuticals to study its Parkinson's drug, PBT434, to slow or prevent neuro-degeneration of the gastro-intestinal system.

Prana said one of the non-motor features of Parkinson's disease was the early presentation of impairment of gastrointestinal function and Parkinson's disease was characterised by the loss of neurons and their networks in the brain and gut.

The company said that the cause of neuro-degeneration and gastro-intestinal dysfunction in Parkinson's disease was not known, but the protein alpha-synuclein had been hypothesized to be implicated in this process.

Prana said that PBT434 showed "significant reduction of alpha-synuclein in pre-clinical models of Parkinson's disease" (BD: Jul 3, 2017).

The company said that the pre-clinical research suggested that PBT434 might reduce the formation of toxic alpha-synuclein fibrils and aggregates, rescue neurons burdened by such toxic forms of alpha-synuclein and restore motor function in animal models.

Prana said that the research collaboration with the Tokyo, Japan-based Takeda would investigate the ability of PBT434 to mitigate gastro-intestinal dysfunction; constipation, lowered colon motility and inflammation in mouse models, including an alpha-synuclein transgenic mouse.

Prana consultant and Florey Institute of Neuroscience Parkinson's disease laboratory head Prof David Finkelstein said the research was important "because our major therapeutic objective is to treat these disabling symptoms and provide an early therapeutic intervention for both motor and non-motor Parkinsonian symptoms in patients which may significantly impact on the quality of life".

The company said that PBT434 was the first of a new generation of small molecules from the quinazolinone class of drugs specifically designed to block the accumulation and aggregation of alpha-synuclein and was expected to begin human testing in a phase I trial later this year.

Prana fell 0.4 cents or 6.8 percent to 5.5 cents.

REDHILL BIOPHARMA

Redhill says it has completed treatment and follow-up of all 127 patients in its phase II study of 12mg Bekinda (RHB-102) for diarrhoea-predominant irritable bowel syndrome.

Redhill said that top-line results were expected in September 2017.

The company said Bekinda was a bimodal, extended-release, once-daily, oral formulation of the antiemetic drug ondansetron, targeting several gastrointestinal indications and the randomized, double-blind, placebo-controlled study was evaluating safety and efficacy of Bekinda for diarrhoea-predominant irritable bowel syndrome (IBS-D), with a primary endpoint of response in stool consistency as compared to baseline.

Redhill said that irritable bowel syndrome was "one of the most common gastrointestinal disorders, with up to 30 million American sufferers" with more than 50 percent having the diarrhoea-predominant illness.

The company said that the US market for IBS-D therapies increased by about 550 percent from 2013 to 2016, to an estimated $US473 million.

Redhill said that, if approved, 12mg Bekinda could be a preferred once-daily treatment for a broad segment of patients with IBS-D.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

On the Nasdaq, Redhill was up 12 US cents or 1.36 percent to $US8.93 ($A11.32) with 73,082 shares traded.

ADALTA

Adalta says it has completed two non-human primate studies evaluating half-life and safety of its AD-114 anti-fibrotic drug, but says trial material has been delayed.

Adalta said the compound was delivered subcutaneously and intravenously to better understand the pharmaco-kinetics of AD-114, or the way the compound was processed in the body.

The company said that preliminary clinical pathology safety readouts were obtained showing AD-114 was safe when dosed via either route.

Adalta said that an ascending dose safety study to find an appropriate dose range for the planned phase I human trial evaluated three ascending doses and found that AD-114 was well tolerated with no adverse effects, no study mortalities or clinical signs relating to the increasing doses observed.

The company said that in both studies AD-114 did not mobilise stem cells, unlike all other drugs which worked by antagonizing the CXCR4 receptor pathway and this finding was “a potential advantage of AD-114 for long term treatment in diseases such as fibrosis”.

Adalta’s chief executive officer Sam Cobb said that AD-114 had “the expected half-life and performs in line with our safety expectations and most importantly … [it] has been shown to have no off-target effects”.

The company said that in 2016 it appointed Fujifilm Diosynth Biotechnologies to manufacture AD-114 and sufficient material was provided to complete the pre-clinical toxicology studies (BD: Sep 12, 2016).

Adalta said that Fujifilm had reported that production of the next batch and completion of formulation studies for a third and final non-human primate study was scheduled by the end of 2017, resulting “in a short delay to the company’s phase I trial” now expected to now be completed by the end of 2018.

Ms Cobb said that the company was “ahead of schedule with the completion of the first two non-human primate studies, but will now incur a small delay to the start of our phase I trial with this news from our manufacturer”.

Adalta fell 1.5 cents or 6.0 percent to 23.5 cents.

PRIMA BIOMED

Prima says the Novartis “second undisclosed significant clinical milestone” for the IMP701 collaboration will be $US1.0 million ($A1.3 million).

Yesterday, Prima described but did not quantify the milestone payment for the IMP701 lymphocyte activation gene-3 (LAG-3) antibody collaboration (BD: Jul 17, 2017).

Today, the company posted a “financial update” which reported its cash balance at June 30, 2017 of $12.3 million, a July capital raising of $US5 million ($A6.5 million) and, finally, the amount expected to be received from Novartis (BD: Jun 30, 2017).

Prima was unchanged at 2.6 cents with 4.8 million shares traded.

PHARMAXIS

Pharmaxis says it will grant chief executive officer Gary Phillips 770,000 free “performance” rights exercisable at no cost.

Pharmaxis said that 385,000 of the rights would vest on June 30, 2019 and 385,000 would vest on June 30, 2020 provided that Mr Phillips was an employee at these times.

The company said that any shares acquired could not be traded for 12 months after vesting.

Pharmaxis was unchanged at 25.5 cents.

NUHEARA

Nuheara has requested a trading halt “pending [the] release of an announcement regarding a capital raising”.
Trading will resume on July 20, 2017 or on an earlier announcement.
In May, a Nuheara share plan, at eight cents a share, raised $247,500 of a hoped-for $2,600,000 and in March the company said it had raised $4,400,000 in an oversubscribed placement (BD: Mar 29, May 5, 2017).
Last year, Nuheara raised $4,984,000 at six cents a share to fund production and marketing of its Iqbuds sound filtering and device ear buds (BD: Oct 27, 2016).
Nuheara last traded at 9.9 cents.

VIRALYTICS

The Los Angeles, California-based Capital Group Companies says it has become a substantial holder in Viralytics with 14,000,000 shares or 5.82 percent.
Capital Group said it acquired the shares on July 14, 2017 at an average price of 95 cents a share.
Capital Group has previously said it was substantial in Cochlear, CSL, GI Dynamics and Mesoblast.
Viralytics fell 1.5 cents or 1.55 percent to 95 cents.

BLUECHIIP

Melbourne’s Bellwether Super and director Jim Craig say they have become substantial shareholders in Bluechiip with 22,134,081 shares or 5.7 percent.
Mr Craig said the shares were held by Equitas Nominees Pty Ltd and they acquired 20,634,081 shares on July 7 and 18, 2017 for $577,754 or an average price of 2.8 cents a share.
Earlier this month Bluechiip said it raised $3,422,228 in its rights issue at 2.8 cents a share and a placement to sophisticated and professional investors (BD: Jul 5, 2017).
Bluechiip was untraded at 3.6 cents.

ITL HEALTH GROUP

ITL says that National Diabetes Week increased inquiries about its Myhealthtest home blood-sugar test for diabetes.
ITL said that during National Diabetes Week from July 9 to July 15, 2017, when Diabetes Australia ran a campaign to raise awareness about the importance of early detection and early treatment for all types of diabetes.
The company said it committed to providing 1,000 free HbA1c diabetes tests but “following considerable take up of the test the company … extended the period by one week and increased the number of free tests to 2,000”.
ITL said that the consumer-based pathology testing service allowed individuals to order the test service online or from pharmacies, collect samples at home and send the samples through the mail for laboratory analysis.
ITL was unchanged at 46.5 cents.