Biotech Daily

Thursday March 30, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL BIO UP 10%, LIVING CELL DOWN 4%**

*** STARPHARMA VIVAGEL BACTERIAL VAGINOSIS RESULTS BY JULY**

*** PRANA: 'ANIMAL STUDIES BACK PBT434 FOR PARKINSON'S DISEASE'**

*** ZELDA RAISES $6m FOR MEDICAL MARIJUANA TRIALS**

*** BRAIN RAISES $1m, SHARE PLAN**

*** OPTHEA REQUESTS 'TRIAL RESULTS, CAPITAL RAISING' TRADING HALT**

*** IMUGENE INVESTORS UNDERWRITE $1.35m EXPIRING OPTIONS**

*** BOTANIX READY FOR CANNABIDIOL BTX-1503 FOR ACNE TRIALS**

*** GI DYNAMICS HOPES FOR US ENDOBARRIER TRIAL THIS YEAR**

*** NEUROTECH STARTS FDA MENTE AUTISM TALKS**

*** USCOM: 'PAPERS BACK MONITOR FOR PRE-ECLAMPSIA'**

MARKET REPORT

The Australian stock market was up 0.39 percent on Thursday March 30, 2017, with the ASX200 up 22.7 points to 5,896.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and three were untraded.

Universal Biosensors was the best, up four cents or 10.3 percent to 43 cents with 353,273 shares traded.

Cellmid and Viralytics climbed more than six percent; Uscom improved five percent; Compumedics, Oncosil and Psivida were up more than four percent; Osprey was up 3.6 percent; Reva rose 2.8 percent; Atcor, Clinuvel and Factor Therapeutics were up more than one percent; with CSL and Pro Medicus up by less than one percent.

Living Cell led the falls, down half a cent or 4.2 percent to 11.5 cents with 198,680 shares traded, followed by Avita down four percent to 9.6 cents with 40,799 shares traded.

Actinogen, Cyclopharm, IDT, Mesoblast, Orthocell and Prima lost three percent or more; Impedimed and Starpharma shed more than two percent; Acrux, Airxpanders, ITL, Pharmaxis, Polynovo and Sirtex were down more than one percent; with Ellex, Medical Developments and Cochlear down by less than one percent.

STARPHARMA HOLDINGS

Starpharma says it has completed its two phase III studies of Vivagel BV for the prevention of recurrent bacterial vaginosis, with top-line results expected by July 2017.

Starpharma said the multi-centre pivotal, double-blind, randomized, placebo-controlled trials compared the rate of bacterial vaginosis recurrence in women using Vivagel BV to the rate of recurrence in women using a placebo gel during a 16-week treatment period with the primary endpoint measured as patients completed the treatment period.

Two previous trials of Vivagel for bacterial vaginosis, a 2012 phase III "clinical cure" at two to three weeks post-treatment trial and a 2013 phase II "recurrence" trial, failed to meet their primary endpoints, with the recurrence trial described as having clinical but not statistical significance (BD: Nov 28, 29, 2012; Apr 3, 2013).

Today, Starpharma said that the phase III studies of Vivagel BV for the prevention of recurrent bacterial vaginosis were conducted at sites across the US, Europe, Canada, Mexico and Asia.

The company said it had been granted a special protocol agreement by the US Food and Drug Administration which provided binding FDA agreement on the trial design including the primary endpoint, thereby reducing the US regulatory risk "by specifying upfront the FDA's agreement with the trial design and providing certainty in the trial data required to support marketing approval".

Starpharma chief executive officer Dr Jackie Fairley said the completion of the two pivotal phase III trials for the prevention of bacterial vaginosis (BV) recurrence was "a significant milestone for Starpharma".

"The market for prevention of BV recurrence is estimated to be worth more than $US1 billion and there are currently no approved products," Dr Fairley said.

"As we look forward to the release of results in the next quarter, we are in parallel preparing our US FDA marketing applications, and are engaged in active negotiations for commercial rights to Vivage BV," Dr Fairley said.

Dr Fairley said that the granting of qualified infectious disease product (QIDP) designation and fast track status by the FDA for both treatment of, and prevention of recurrent, bacterial vaginosis in January were "important developments, attracting significant commercial interest" (BD: Jan 22, 2017).

Starpharma said that bacterial vaginosis affected about 30 percent of women in the US with about 50 to 60 percent suffering from the recurrent form and the market was estimated to be more than $US1 billion with no approved products.

The company said that Vivagel BV was approved in Europe for the treatment and relief of bacterial vaginosis symptoms and regulatory reviews including by the Australian Therapeutic Goods Administration were "well advanced".

Starpharma said that Vivagel BV had been licensed in Australia and New Zealand to Aspen Pharmacare and licencing discussions were underway, globally.

The company said it was "well advanced" in the compilation of a Vivagel BV new drug application to the FDA, which was expected to be made in the near future for the treatment of bacterial vaginosis, with the recurrent bacterial vaginosis indication to follow.

Starpharma said that its Vivagel BV marketing applications would benefit from FDA QIDP designation and fast track status, which carried "significant benefits for regulatory approval and commercialization for both indications" including priority regulatory review and an additional five years' market exclusivity.

Starpharma said that "global negotiations have been positively impacted by the recent developments in the US including revision to the FDA draft guidance for BV treatment, fast track status and the grant of QIDP designation for both indications".

Starpharma fell 1.5 cents or 2.2 percent to 68 cents.

PRANA BIOTECHNOLOGY

Prana says that mouse studies show that PBT434 is “a first-in-class disease modifying therapy for the treatment of Parkinsonian movement disorders”.

Prana said that the research, entitled ‘PBT434 prevents neuronal loss, motor function and cognitive impairment in preclinical models of movement disorders by modulation of intracellular iron’ would be presented as a poster by the Melbourne-based Florey Institute of Neuroscience and Mental Health’s Prof David Finkelstein a consultant to the company at International Conference for Alzheimer’s and Parkinson’s Diseases in Vienna from March 29 to April 2, 2017.

The company said that the poster presented in-vivo evidence of the ability of PBT434 “to prevent the loss of neurons that underpin motor and cognitive dysfunction by preventing metal-mediated degenerative processes that lead to neuronal death”.

Prana said PBT434 interceded in the production of damaging reactive oxygen species that were toxic to normal cellular function and the compound also prevented the accumulation of mis-folded forms of the tau protein, which were known to promote cell death.

The company said that as well as the beneficial impact of PBT434 on underlying neuro-degenerative processes, it was also able to prevent the iron-mediated accumulation of toxic aggregates of the protein alpha-synuclein, which was primarily found in the pre-synaptic terminals of neurons, or nerve cells.

Prana said that alpha-synuclein was of interest to researchers because aggregated forms of the protein were considered a pathological hallmark of Parkinsonian conditions and were a recognised therapeutic target.

The company said that, when orally administered to rats and dogs, PBT434 reduced alpha-synuclein in the cerebrospinal fluid, which was present in the brain and spine, demonstrating the capability for PBT434 for in-vivo target engagement.

Prana said that collectively, the ability of PBT434 to promote neuronal health by reducing oxidative stress and preventing the toxic gain of function of both tau and alpha-synuclein made PBT434 a new disease-modifying agent.

The company said that in the comprehensive pre-clinical studies, PBT434 showed a strong toxicology profile and favorable therapeutic margin and it was preparing its pre-clinical development package for PBT434 to enable human studies.

Prana was unchanged at 5.2 cents.

ZELDA THERAPEUTICS

Zelda says it has raised $6,000,000 seven cents a share in a “heavily over-subscribed” placement, with new investors in Australia and Hong Kong.

Zelda said the funds would accelerate and expand research and clinical programs and increased its cash position to about $8.3 million before costs, providing capacity “to execute its current research programs and pursue new opportunities to grow its clinical pipeline for the development of new medicinal cannabis therapies in Australia and Chile”.

Zelda said that the placement was managed by Merchant Corporate Advisory, along with the participation by clients of CPS Capital Group.

Zelda managing-director Dr Stewart Washer said the funds would be used to accelerate the eczema and insomnia clinical trials in Chile later this year and the two “relatively short and inexpensive trials” would take three to six months and, if successful, would allow Zelda to register the products for sale in Chile and Australia.

“There will be saleable products coming out of the trials, provided they are successful,” Dr Washer said.

Zelda fell half a cent or 5.1 percent to 9.3 cents with 36.5 million shares traded.

BRAIN RESOURCE

Brain says it has binding commitments to raise $1 million through a placement at eight cents a share mainly to institutional and sophisticated investors.
Brain said that staff contributed $10,000 to the placement and directors $90,000, subject to shareholder approval, which was at an 11.1 percent discount to the five-day volume weighted average share price to March 29, 2017.
The company said that the funds would support its operations with a focus on increasing revenues from its Mybrainsolutions business and to engage external expertise to help conduct a strategic review.
Brain said that the review would assess "the impact of the convertible debt on the company's ability to grow the equity value, consider the potential value of its assets to a strategic acquirer in light of recent mergers and acquisitions activity in the sector, and determine the ability to source capital in order to fund future growth opportunities".
The company said that Gleneagle Securities (Aust) was the lead manager.
Brain said it would offer a share plan for eholders at the record date of March 29, 2017.
The company said that directors Evian Gordon and Matthew Morgan participated in the placement and director Steven Koslow would invest $7,500 in the share plan.
Brain was untraded at nine cents.

OPTHEA (FORMERLY CIRCADIAN TECHNOLOGIES)

Opthea has requested a trading halt "pending … an announcement in relation to the results of [ITS] wet AMD phase I/IIa clinical trial and a potential capital raising".
Trading will resume on April 3, 2017 or on an earlier announcement.
Opthea had planned to hold an investor lunch in Sydney today, but Biotech Daily has been told that the meeting was cancelled this morning.
Opthea's share price reached $1.04 on February 3, 2017, fluctuating to 97.5 cents on March 16 and falling to 92 cents on Monday March 27 and closing at 81 cents, last night.
As Circadian, the share price highs were $1.55 in May 2007 and $4.96 in March 2000.
In its most recent half yearly report Opthea said that it had cash and cash equivalents of $13,144,174 at December 31, 2016 with expenses of $5,189,835 for the six month period.
Opthea last traded at 81 cents.

IMUGENE

Imugene says it has agreements with three existing institutional shareholders to underwrite up to $1.35 million of IMUO options expiring on March 31, 2017.
Imugene's most recent 3B new issue announcement said that there were 328,840,473 IMUO options quoted on the ASX, which were issued in relation to a $3 million capital raising in 2015 (BD: Sep 8, Oct 26, 2015).
Imugene said that the issue price for any shares issued under the underwriting agreements was 1.5 cents a share, the same price as the exercise price of the options and the total underwriting fee was about 3.8 percent of the total underwritten amount, or about $51,000.
The company said that the underwriters were Platinum Investment Management, Private Portfolio Managers and Celtic Capital and all three were existing investors.
Imugene chief executive officer Leslie Chong said that funds raised from the options would be "applied to continue our clinical development of HER-Vaxx and the preclinical work associated with the mimotope program".
Imugene was up 0.1 cents or 6.7 percent to 1.6 cents with 1.9 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has Queensland Institute for Medical Research ethics approval for its first clinical study of its synthetic cannabidiol BTX-1503 for acne.

Botanix said that recruitment of healthy volunteers for the safety and pharmacokinetic studies would begin shortly in collaboration with a Queensland clinical study provider, with data expected by July 2017.

The company said that preparation for the follow-on pilot study in acne patients would advance in parallel with the safety and pharmacokinetic studies and begin following review of the data.

Botanix executive director Matt Callahan said the company was “very pleased to have received approval … to commence our first human studies for BTX-1503”.

“These studies will be the first to be conducted anywhere in the world using synthetic cannabidiol for the treatment of skin disease, with oversight from a regulator,” Mr Callahan said.

Botanix said that approval for the studies came less than nine months after listing on the ASX and the start of formulation development and pre-clinical testing activities and provided “a clear path for the company’s two pipeline products for the treatment of psoriasis and dermatitis that also utilize synthetic cannabidiol and can leverage the work already completed for BTX-1503”.

The company said that the studies would be conducted under the Australian Therapeutic Goods Administration’s regulatory framework, with later studies under the US Food and Drug Administration drug approval process.

Botanix said that annual prescription sales of acne products in the US exceeded $US4.5 billion per annum and there had been no new drugs approved for acne in more than 20 years.

Botanix was up one cent or 17.2 percent to 6.8 cents with 48.6 million shares traded.

GI DYNAMICS

GI Dynamics hopes to confirm a new study design and begin a new US trial for Endobarrier for obesity and diabetes this year.

In a webcast, GI Dynamics chief executive officer Scott Schorer said that the company had cut costs and reviewed all of the company’s systems, as well as the safety and efficacy data form the previous closed US trial (BD: Mar 15, 2016).

Mr Schorer said that “Endobarrier is safe and effective” and that with increasing rates of type 2 diabetes, none of the therapies were without risk, but the rate of liver abscesses had been identified as primarily relating to the use of proton pump inhibitor drugs in the US trial.

Mr Schorer said that gastric bypass and insulin had greater risks than the Endobarrier.

Mr Schorer said that there were expected to be 388 million people with type 2 diabetes by 2030, implying up to one billion people with pre-diabetes at that date.

He said that the Endobarrier had Conformité Européenne (CE) mark approval and the company would focus on sales in the UK and Germany, followed by the Middle East and the rest of Europe.

Mr Schorer said the company had “no current plans to return to Australia” as it was “not financially viable”.

He said the Australian Therapeutic Goods Administration concerns with Endobarrier were not related directly to safety and efficacy but was related to incomplete paperwork and filings (BD: Jul 30, 31, 2015; Sep 14, 2016).

GI Dynamics fell 0.6 cents or 8.7 percent to 6.3 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has filed a pre-submission package with the US Food and Drug Administration for its Mente Autism device for children on the autism spectrum.
Neurotech said it had requested a meeting with the FDA to work on the regulatory and clinical plan for the neuro-feed-back device and it expected a meeting by October 2017.
Yesterday, the company said it completed enrolment of the 64-patient US paediatric randomized, double blind, controlled trial of Mente Autism (BD: Mar 29, 2017).
Neurotech said that in conjunction with World Autism Awareness Day on Sunday April 2, 2017 it would undertake marketing and public relations initiatives in Europe, focussed on the Germanic-speaking countries.
Neurotech fell one cent or 3.2 percent to 30 cents.

USCOM

Uscom says two research papers confirm the effectiveness of its ultra-sonic cardiac output monitor for diagnosing pre-eclampsia and guiding hypertensive therapy in pregnancy.
Uscom said the papers were published in the journal Ultrasound in Obstetrics and Gynaecology and authored by obstetrics and gynaecology specialists and researchers from the University of Rome, Rome's Policlinico and London's St George's Hospital.
The company said that pre-eclampsia, or high blood pressure in pregnancy, was a common complication which increased mortality and morbidity for pregnant mothers and their unborn babies, with about 10 million pregnant women developing pre-eclampsia every year and early detection and appropriate treatment improving outcomes.
Uscom said that pre-eclampsia was responsible for about 76,000 maternal and 500,000 foetal and neonatal deaths each year.
Uscom said the first study showed that abnormal maternal circulation, measured by the Uscom 1A, was associated with an eight to 10-fold increase in risk of complications at delivery and the second study showed that intra-uterine foetal growth restriction and its maternal and foetal complications could be improved by Uscom 1A guided treatment.
Uscom executive chairman Prof Rob Phillips said that "Science is value for Uscom shareholders and this science provides us with a new revenue platform as our business continues rapid growth of the back of important scientific achievement".
Prof Phillips said that the data showed that the use of Uscom in pregnancy "can improve maternal and foetal outcomes in pregnancy and support Uscom 1A use as a routine screening monitor of maternal haemodynamics, from the initial examination up to and during delivery and should be considered as a standard of care for monitoring pregnancy".
Uscom said that the first study, entitled 'Maternal cardiac output in early labour: a possible link with obstetrics risks?' concluded that Uscom could be used "not only as a screening tool in the early identification of patients at high risk of hypertensive complications, but also in the evaluation of pregnancy at term in the absence of known risk factors" and an abstract was at: https://www.ncbi.nlm.nih.gov/pubmed/28236342.
The company said that second study, entitled 'Nitric oxide (NO) donors and haemodynamic changes in foetal growth restriction' concluded that the results "might open new perspectives in the treatment of foetal growth restriction" with an abstract available at: https://www.ncbi.nlm.nih.gov/pubmed/28295749.
Uscom was up one cent or five percent to 21 cents.