Biotech Daily

Wednesday July 27, 2016

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: ANTISENSE UP 15%; ATCOR DOWN 11%**

*** BURNET, GERMANY'S ARTES COMBINE FOR HEP C VACCINE**

*** ANTISENSE INTERIM DATA: 'ATL1103 ACROMEGALY SAFETY, EFFICACY'**

*** MODEL BACKS PRANA PBT2 FOR ALZHEIMER'S, HUNTINGTON'S**

*** COMPUMEDICS $3m CHINA CONTRACT, 'NUMBER 3 WORLDWIDE'**

*** ACRUX, LILLY AXIRON SALES FALL 4% TO $199m**

*** AVEXA $2.2m RIGHTS ISSUE FOR TALI**
- MARK SIMARI REPLACES BENJAMIN YEO, ALLAN TAN TO RETIRE

*** ANALYTICA RAISES $500k FROM 12% INOV8**

*** ADMEDUS REQUESTS CAPITAL RAISING TRADING HALT**

*** ALLAN GRAY TAKES MORE PROFIT TO 5.5% OF NANOSONICS**

*** JCP REDUCES, TAKES PROFIT TO 8.4% OF NANOSONICS**

*** ANTEO APPOINTS TAMARA MILLS COO**

MARKET REPORT

The Australian stock market edged up 0.04 percent on Wednesday July 27, 2016 with the ASX200 up 2.2 points to 5,539.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and two were untraded.

Antisense was the best, up 0.6 cents or 14.6 percent to 4.7 cents with 675,000 shares traded. Uscom climbed 10 percent; Oncosil was up eight percent; Compumedics and Opthea rose five percent or more; Actinogen, Avita and Prana were up more than two percent; Osprey improved 1.75 percent; with Clinuvel, Medical Developments, Resmed and Sirtex up by less than one percent.

Atcor led the falls, down 1.5 cents or 10.7 percent to 12.5 cents, with 208,673 shares traded. Acrux lost 10.2 percent; Ellex fell eight percent; Genetic Technologies, Living Cell and Neuren lost five percent or more; Starpharma fell 3.6 percent; Cellmid, Factor Therapeutics, Mesoblast, Nanosonics and Pro Medicus shed more than two percent; Airxpanders, CSL, Impedimed, Orthocell, Pharmaxis, Reva, Universal Biosensors and Viralytics lost more than one percent; with Cochlear down 0.15 percent.

THE BURNET INSTITUTE

Melbourne's Burnet Institute says that with the Langenfeld, Germany-based Artes Biotechnology it will develop a vaccine to prevent hepatitis C virus transmission.

The Burnet said the hepatitis C vaccine project would combine its Hepseevaxdelta3 technology, developed by hepatitis C team leader Prof Heidi Drummer and colleagues, with Artes' Metavax technology for the development of chimeric virus-like particle-based vaccines.

The Institute said the project aimed to develop a virus-like particle vaccine that efficiently presented hepatitis C antigens to prevent hepatitis C infection.

Prof Drummer told Biotech Daily that the research was at "the early pre-clinical stage … to obtain proof-of-concept for vaccine production and vaccine characterization, followed by immunogenicity studies to be conducted in small animals".

The Burnet said that virus-like particles would present the novel, modified envelope protein, E2, on its surface, targeting the vaccine to dendritic cells to prime and prepare the immune system to fight against hepatitis C infection.

Prof Drummer said that the Hepseevaxdelta3 technology overcame a limitation to hepatitis C vaccine development.

"The virus that causes [hepatitis C] has evolved to avoid the immune system so that in natural infection, key immune responses are delayed or distracted by irrelevant targets on the virus," Prof Drummer said.

"The same is true for conventional vaccine platforms tested previously," Prof Drummer said.

"The Hepseevaxdelta3 component of the vaccine redirects the immune response to make antibodies on the most important targets that prevent infection against the seven circulating [hepatitis C] genotypes," Prof Drummer said.

The Institute said that a hepatitis C vaccine was "urgently needed to prevent re-infection in people treated through antiviral therapies and reverse the high global mortality rates from infection-related liver cirrhosis or liver cancer".

The Institute said that the World Health Organization estimated mortality rates to be more than 500,000 people each year with more than 130 million people carrying the blood-borne virus.

Artes managing-director Dr Michael Piontek said his company was "excited" to join forces with Burnet Institute to develop a much-needed vaccine against hepatitis C, which was endemic in many countries where treatment costs were high and hepatitis C posed a significant burden on healthcare systems.

"Access to diagnosis and treatment is limited, especially in endemic countries in Africa and Asia, so there is a strong demand for a safe and low-cost vaccine to prevent hepatitis C infection," Dr Piontek said.

"After out-licencing processes for hepatitis B vaccine production worldwide, Artes is proud to take the next step together with Burnet Institute in fighting another life-threatening hepatitis infection," Dr Piontek said.

The Burnet said that the Artes' vaccine development platform Metavax in combination with the expression host Hansenula polymorpha was the preferred tool for the development of affordable vaccines.

The Institute said that the Artes development platform was a unique and economical approach to low-cost mass production of safe and effective vaccines.

The Burnet said that its Hepseevaxdelta3 technology was developed by re-engineering the major hepatitis C viral surface protein E2 and Hepseevaxdelta3 could generate high levels of antibodies to block replication of all seven genotypes of hepatitis C in laboratory tests, offering the prospect of a simple, universal vaccine to prevent hepatitis C infection.

ANTISENSE THERAPEUTICS

Antisense says an interim analysis of its high dose ATL1103 for acromegaly trial shows safety and an 18.6 percent reduction of serum insulin-like growth factor I.

Antisense said that the data came from three of four patients in the open-label study of the safety, tolerability, pharmacokinetics and effect of ATL1103 on serum insulin-like growth factor I (sIGF-I) levels.

The company said that eligible patients who satisfied the entry criterion of sIGF-I levels more than 1.3 times the upper limit of normal were dosed with ATL1103 at 300mg twice weekly, capped at a weekly dose of 6mg/kg.

Antisense said that in the previous 26 patient phase II trial, the highest dose was 200mg twice weekly with no cap on dose to weight basis, so lighter patients received up to 6.9mg/kg/week, with a secondary analysis showing that ATL1103 reduced sIGF-I in a dose dependent manner (BD: Sep 3, 2014; May 15, Nov 4, 2015).

Today, the company said that two patients completed 13 weeks of dosing and two months recovery and principal investigator Dr David Torpy had requested that the third patient continue dosing with ATL1103 and that patient was being dosed for a further 12 weeks.

The company said that an interim analysis was performed on data from all three patients after they had completed 13 weeks of dosing.

Antisense said that one patient achieved normalisation of sIGF-I and the other two had therapeutically relevant reductions.

The company said that final results were due by the end of 2016 and future trials were expected to test ATL1103 at higher doses.

Antisense said that sIGF-I levels were reduced in all three patients by an average of 18.6 percent ($p = 0.06$) at week-14, which was one week after the last dose - the primary efficacy endpoint - and an average of 26.7 percent at week-13 ($p = 0.04$).

The company said that “given that ATL1103 has consistently reduced sIGF-I levels in both animal and human studies, application of a one-sided t-test is justifiable, in which event the p-values for sIGF-I reductions at week 14 and week 13 would be $p = 0.03$ and $p = 0.02$ respectively”.

Antisense said that normalisation of sIGF-I was achieved in one patient who received the highest dose to weight ratio of 6mg/kg, which was consistent with the phase II study patients who received more drug to weight had greater reductions in sIGF-I.

The company said that the observations “need to be qualified by the relatively small number of patients in the trial, however the statistical significance levels achieved give the company confidence about the repeatability of the clinical findings that ATL1103 significantly reduces sIGF-I, the therapeutic goal for the treatment of acromegaly”.

Antisense said that ATL1103 appeared to be well-tolerated at the higher doses, no patient withdrew from the study and there were no serious adverse events reported.

The company said platelet reductions were reported for the third patient and following a reduction in dosing frequency to 300mg once weekly platelet counts stabilised, with this patient continuing to be dosed in an extended dosing phase.

Antisense managing-director Mark Diamond said that the results were “most encouraging and, importantly, consistent with our previous clinical trial results”.

“The positive safety profile … suggests that the drug may be tolerated at doses above 600mg per week … where even greater reductions in sIGF-I would be anticipated to potentially treat patients with larger body weights or those with more active disease”.

In May, the company said the enrolment of a fourth patient would depend on the interim analysis, and today Mr Diamond told Biotech Daily that the company would stop the study when the third patient completed dosing and follow up (BD: May 9, 2016).

Antisense climbed 0.6 cents or 14.6 percent to 4.7 cents.

PRANA BIOTECHNOLOGY

Prana says that testing PBT2 in the 'Alzheimer's-in-a-dish model' "significantly reduced levels of both phospho-tau (p-tau) aggregates and amyloid beta 2 fibrils".

Prana said that chief scientific advisor Prof Rudolph Tanzi presented the results of PBT2 for Huntington's disease and Alzheimer's diseases, at the Alzheimer's Association International Conference in Toronto, Canada on July 26, 2016 in a presentation entitled 'Reconstructing Alzheimer Amyloid and Tau Pathology in 3D Cell Cultures Derived from Human Stem Cells'.

The company said that in 2014, Prof Tanzi and Massachusetts General Hospital and Harvard Medical School colleague Dr Doo Yeon Kim reported in the journal Nature that they had recreated Alzheimer's disease pathology in an organoid consisting of human stem-cell derived neurons grown in three-dimensional.

Prana said that "the landmark disease model awarded with the Smithsonian 2015 American Ingenuity Award, exhibited beta-amyloid plaque deposition, neurofibrillary tangles and neuronal cell death, all major hallmarks of Alzheimer's disease".

The company said that the Alzheimer's-in-a-dish model provided the first proof-of-concept that beta-amyloid was sufficient to trigger neurofibrillary tangle formation.

Prana said that Prof Tanzi told the conference that treatment of the three-dimensional model cells with PBT2 "significantly reduced levels of both phospho-tau aggregates and [amyloid-beta-42] fibrils when compared to controls, also visible with immunostaining".

The company said that PBT2 "also led to modest improvements in neuronal cell viability in the model".

Prana said that Prof Tanzi reported that testing PBT2 in the model resulted in dose-related, statistically significant reductions in p-tau and soluble amyloid-beta-42.

The company said that the Alzheimer's model added to the evidence that PBT2 significantly reduced both p-tau and amyloid-beta-42.

Prana said that PBT2 "appears to carry great potential for targeting both the proteins at the root of Alzheimer's" and p-tau also played a role in other disorders, such as Huntington's disease.

Prana was up 0.2 cents or two percent to 10 cents.

COMPUMEDICS

Compumedics says it has a $3 million three-year contract with Beijing Bestmed to distribute its neuro-diagnostic and monitoring systems across south and central China.

In 2014, Compumedics announced a $5.5 million three year distribution contract with Bestmed (BD: Sep 15, 2014).

Today, the company said the contract would generate at least $3 million in revenue with units for the diagnosis of neurological disorders and disease costing $10,000 to $20,000

Compumedics said that Bestmed was one of seven distributors for China, Hong Kong and Macau and was complementary to its arrangements for its sleep and neurological monitoring range in other provinces in China, announced over the last 12 months.

The company said the deal included the low-cost Grael long term electro-encephalogram monitoring, which would open the smaller hospitals and private practices market.

Compumedics executive chairman Dr David Burton said the contract "places the company well and truly in the big league of neuro-diagnostics as it will mean that Compumedics will become the third biggest player in a $1.3 billion worldwide market".

"Compumedics is now the number one premium supplier of sleep diagnostic and neurological research systems in China," Dr Burton said.

Compumedics was up two cents or five percent to 42 cents.

ACRUX

Acrux says that Eli Lilly's Axiron sales revenue fell 3.9 percent to $US149.3 million ($A199.4 million) for the 12 months to June 30, 2016, compared to June 30, 2015.
For the three months to June 30, 2016, sales revenue fell 9.6 percent from $US32.4 million to $US29.3 million compared to the three months to June 30, 2014.
The sales data provided by Acrux showed a general decline in sales since July 2014, following the 2014 news that the US Food and Drug Administration was investigating cardio-vascular risks in men taking approved testosterone products (BD: Feb 4, 2014).
There have been subsequent announcements that rebut the connection between cardio-vascular risks and testosterone replacement therapy, including studies by the European Medicines Agency and one published in the Mayo Clinic Proceedings which were positive for testosterone for cardiovascular risk (BD: Mar 4, 2015).
Today, Acrux said that its US market share of 14.2 percent at June 30, 2016, was "slightly higher than that of June 2015 at 14.0 percent".
Acrux fell 8.5 cents or 10.2 percent to 74.5 cents with 2.1 million shares traded.

AVEXA

Avexa expects to raise $2.2 million in a partly-underwritten, one-for-one, non-renounceable rights issue at 2.2 cents a share.
Avexa said that the South Melbourne-based Interprac Financial Planning had underwritten the capital raising to $1.8 million.
The company said the funds would go to development of the Tali technology for diagnosing and treating developmental disabilities, including autism and would fund the remaining product and games enhancements, study trials, workshops and initial rollout (BD: Aug 12, 2015; May 3, 2016).
Avexa said that the record date would by August 4, the offer would open on August 9 and close on August 23, 2016.
The company said that Paragon Care chief executive officer Mark Simari would be appointed as an independent non-executive director on completion of the offer, Benjamin Yeo had resigned as a director effective immediately and Allan Tan would not seek re-election at the 2016 annual general meeting.
Avexa fell 0.3 cents or 9.1 percent to three cents.

ANALYTICA

Analytica says it will raise $500,000 through the placement of 71,428,571 new shares at 0.7 cents each to American Virgin Islands cornerstone investor Inov8 LLC.
Analytica said that the shares would be issued in two tranches on August 31 and September 30, 2016, giving Inov8 a holding of 12.2 percent.
Analytica chairman Dr Michael Monsour said the Inov8 investment "expresses confidence in the potential of the Pericoach system and our strategic development program".
Analytica was unchanged at 0.8 cents with 3.4 million shares traded.

ADMEDUS

Admedus has requested a trading halt "pending an announcement regarding a capital raising".
Trading will resume on July 29, 2016 or on an earlier announcement.
Admedus last traded at 45 cents.

NANOSONICS

Allan Gray Australia has reduced its substantial holding in Nanosonics from 19,290,763 shares (6.52%) to 16,184,022 shares (5.47%).
Allan Gray said that between May 31 and July 22, 2016 it sold 3,106,741 shares for $7,460,364 or an average price of $2.40 a share.
In April, Allan Gray sold 2,933,635 shares for $5,971,521 or an average price of $2.04 a share and in May sold 2,067,647 shares for $4,729,317 or an average price of $2.29 a share. (BD: Apr 14, May 31, 2016).
Allan Gray last bought Nanosonics shares at about 40 cents (BD: Aug 11, 2014).
Nanosonics fell six cents or 2.2 percent to $2.68 with one million shares traded.

NANOSONICS

JCP Investment Partners says it has reduced its substantial shareholding in Nanosonics from 26,655,463 shares (9.40%) to 24,829,090 shares (8.39%).
In April, JCP Investment Partners increased its Nanosonics holding by 2,879,710 shares with the single largest purchase 500,000 shares for $1,042,002 or $2.08 per share (BD: Apr 12, 2016).
Today, the Melbourne-based JCP said that its shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.
The substantial shareholder notice said that shares were bought and sold between April 11 and July 22, 2016 with the single largest sale 248,100 shares for $676,009 or $2.725 per share.

ANTEO DIAGNOSTICS

Anteo says that Tamara Mills has been appointed chief operating officer for Australian operations effective from August 15, 2016.
Anteo said that Ms Mills had more than 10 years' experience in the development and commercialization of medical technologies from research and development through to manufacturing, sales and marketing.
The company said that Ms Mills had worked in the pharmaceutical and medical device sectors in both technical and commercial executive positions.
Anteo said that Mr Mills was most recently the Kirkland, Quebec-based Jubilant Draximage's cardiology business division director.
According to her Linkedin profile, Ms Mills holds a Bachelor and Masters of Applied Science from the Royal Melbourne Institute of Technology, a Methods for Health Economics Research from the Harvard School of Public Health and a Masters of Business Administration from Montreal's Concordia University.
The company said that Ms Mills would be issued 2,000,000 options exercisable at 150 percent of the 10-day volume-weighted average price on the issue date within four years and vesting one year from the date of issue.
Anteo was unchanged at four cents.