Biotech Daily

Thursday July 28, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OSPREY UP 21%; ACTINOGEN DOWN 5%**

*** PSIVIDA: 'MEDIDUR STOPS POSTERIOR UVEITIS RETURN, p < 0.00000001'**

*** ACTINOGEN: 'AIBL STUDY BACKS XANAMEM MODE OF ACTION'**

*** ELLEX UNAUDITED REVENUE UP 16% TO $73m, PRE-TAX PROFIT $4m**

*** BIOXYNE PROBIOTIC SALES UP 31% TO $2m**

*** IMPEDIMED EXPANDS MAYO BIS TRIAL AGREEMENT TO DEVELOPMENT**

*** ASTRAZENECA EXPANDS STARPHARMA DEP PROGRAM**

*** DIMERIX BEGINS DMX-250 FOR NASH PROGRAM**

*** INVITROCUE, UNIVERSITY OF SINGAPORE HEPATITIS B COLLABORATION**

*** REGAL FUNDS REDUCES, DILUTED TO 6% OF ADHERIUM**

*** COCHLEAR APPOINTS FIVE SENIOR EXECUTIVES**

*** RECCE PRODUCES 9L RECCE-327, SYDNEY HQ, LAB**

MARKET REPORT

The Australian stock market was up 0.31 percent on Thursday July 28, 2016 with the ASX200 up 16.9 points to 5,556.6 points. Nineteen of the Biotech Daily Top 40 stocks were up, nine fell, 11 traded unchanged and one was untraded.

Osprey was the best, up six cents or 20.7 percent to 35 cents with 1.9 million shares traded. Ellex climbed 8.7 percent; Psivida was up 7.3 percent; IDT rose 6.25 percent; Atcor and Impedimed were up four percent or more; Benitec, Oncosil, Polynovo, Starpharma and Uscom were up three percent or more; Antisense, Cellmid, Nanosonics, Opthea and Pro Medicus rose more than two percent; Medical Developments and Viralytics were up more than one percent; with Cochlear and Mesoblast up by less than one percent.

Actinogen led the falls, down 0.4 cents or 5.33 percent to 7.1 cents, with 3.7 million shares traded, followed by Genetic Technologies down 5.26 percent to 1.8 cents with 3.6 million shares traded. Clinuvel fell four percent; Orthocell and Prana lost three percent or more; Biotron and Resmed were down more than one percent; with Airxpanders, CSL and Sirtex down by less than one percent.

PSIVIDA CORP

Psivida says its first phase III trial of Medidur for posterior uveitis met its primary endpoint with high statistical significance at 12 months follow-up.

Psivida said that the primary endpoint of prevention of recurrence of disease was met with a significance value of $p < 0.00000001$.

The company said that posterior uveitis was much less likely to recur in eyes treated with a Medidur injection than those receiving a sham injection through 12 months of 26.4 percent compared to 85.7 percent.

Psivida said the average increase in intraocular pressure at 12 months was 0.6mmHg more in Medidur-treated eyes than control eyes of 1.3mmHg compared to 0.7mmHg.

In March, Psivida said that six-month data from the trial showed “a small average increase in intraocular pressure” with the increase in intraocular pressure for Medidur-treated eyes lower than that observed in the same trial period for the two approved sustained release treatments for posterior uveitis Ozurdex and Retisert (BD: Mar 16, 2016).

Psivida said at that time that intraocular pressure (IOP) in Medidur-treated eyes increased 1.1mmHg more than control eyes, with an IOP of 1.8mmHg compared to 0.7mmHg.

Today, the Durham, North Carolina-based Duke University ophthalmology professor and principal investigator Prof Glenn Jaffe said that “the continued high efficacy and favorable safety results of Medidur in the treatment of posterior uveitis are impressive”.

“Particularly encouraging is the effectiveness of Medidur in controlling recurrence of disease over the longer 12-month period,” Prof Jaffe said. “Medidur-treated eyes were over 5.2 times more likely to be free of recurrence through 12 months than control eyes.”

Psivida said that Medidur was generally well-tolerated through the last follow-up visit and the incremental risk of elevation of IOP for Medidur-treated eyes compared to control eyes was lower than it was through six months.

The company said that elevated IOP was generally well treated with eye drops, and the percentage of eyes requiring incisional surgery to reduce IOP was essentially the same in Medidur-treated and control eyes through the last follow-up.

Psivida chief executive officer Dr Paul Ashton said the results show “the potential for treating posterior uveitis by delivering a very small amount of drug directly to the back of the eye over an extended period with a single injection”.

“We were pleased to see that over 80 percent of the Medidur-treated patients who were on systemic [drugs] at baseline were able to come off of them entirely through 12 months,” Dr Ashton said.

Psivida said that at 12 months follow-up 22.9 percent of Medidur-treated eyes and 11.9 percent of control eyes showed improvement in visual acuity gaining 15 or more letters from baseline and the improvement in visual acuity in Medidur-treated eyes seen at six months was maintained at 12 months and was twice that of control eyes.

The company said that of the 65 patients receiving systemic therapy of steroids, immune suppressants and biologics at baseline, 52.4 percent of control patients compared to 18.2 percent of Medidur-treated patients were still being administered systemic treatment at 12 months.

Psivida said that of the study eyes with a natural lens at baseline, 45.2 percent of Medidur-treated eyes compared to 9.5 percent of control eyes required cataract surgery through the last follow-up visit.

The company said cataracts were a side effect of treatment with steroids and a natural consequence of posterior uveitis.

Psivida said that patients would be followed for three years from injection at six-month intervals.

Psivida climbed 33 cents or 7.3 percent to $4.83.

ACTINOGEN MEDICAL

Actinogen says that Xanamem inhibits cortisol production which has been independently shown to correlate with the development of Alzheimer's disease.

Actinogen said that it presented its pre-clinical and phase I data at the Alzheimer's Association International Conference in Toronto from July 24 to 28, 2016 along with a separate presentation from the Australian Imaging, Biomarker & Lifestyle Flagship Study of Ageing (AIBL), sponsored by the Commonwealth Scientific and Industrial Research Organisation and several Australian universities.

The company said that the 416-patient AIBL study concluded that "targeting ways to lower excess cortisol should be undertaken in battling Alzheimer's disease in the elderly".

Actinogen said that its pre-clinical and clinical data showed "a correlation between elevated cortisol in the blood of a healthy aged population and the subsequent development of Alzheimer's disease in these individuals".

The company said that a novel, orally administered 11-beta-hydroxysteroid dehydrogenase (11-beta-HSD1) inhibitor demonstrated in its phase I study that it significantly inhibited production of cortisol in healthy volunteers and successfully crossed the blood-brain barrier.

Actinogen said that when individuals evidenced a broad build-up of beta-amyloid plaques in the brain, their chances of developing Alzheimer's disease increased.

The Cleveland Clinic Brain Health director Prof Jeffrey Cummings said that study results "demonstrate both the importance of understanding the pathological processes in Alzheimer's and the compelling need for new approaches to treatment".

"To my eyes, AIBL has provided the most important validation to date for controlling excess cortisol production in individuals at risk for developing dementia," Prof Cummings said.

"Development of new therapies to inhibit cortisol can show us the impact of blocking this mechanism on disease progression," Prof Cummings said.

Actinogen chief executive officer Dr Bill Ketelbey said that the findings from the AIBL study "linking excess cortisol with the development of Alzheimer's disease, provides further strong validation of our ongoing development of Xanamem".

"Independent validation is clearly emerging that excess cortisol is a key target for treating the disease and our Xanadu trial aims to demonstrate that inhibiting cortisol in the brain with Xanamem is an effective treatment option for patients with mild Alzheimer's disease," Dr Ketelbey said.

Florey Institute of Neuroscience and Mental Health neuro-degeneration division co-head, AIBL study co-author and Actinogen advisor Prof Colin Masters said that "while the presence of aberrant beta-amyloid and tau proteins in the brain, combined with neural death and cognitive decline, are recognized as the hallmarks of Alzheimer's disease, there is still substantial speculation as to the underlying triggers for the disease".

"We have demonstrated that when levels of cortisol, the stress hormone, become chronically elevated in the blood, there is a strong correlation with the subsequent development of Alzheimer's disease," Prof Masters said.

"This finding, and the results showing synergy with the build-up of beta-amyloid plaques in the brain, suggests a compelling new area of research for the treatment of Alzheimer's," Prof Masters said.

The presentations are at: http://bit.ly/AIBLposter and http://bit.ly/XanamemPoster.

Actinogen was up 0.4 cents or 5.3 percent to 7.1 cents with 3.7 million shares traded.

ELLEX MEDICAL LASERS

Ellex expects to report revenue for the 12 months to June 30, 2016 up 16.1 percent to $72.9 million with profit before tax up 61.5 percent to $4.2 million.
Ellex said that sales increased in the US, Asia and Europe, margins improved and there was a benefit from a fall in the Australian dollar compared to some of the other currencies.
The company said it expected to report audited accounts by August 26, 2016.
Ellex was up nine cents or 8.7 percent to $1.12.

BIOXYNE

Bioxyne says that unaudited revenue from sales of its PCC probiotics for the year to June 30, 2016 were up 31.1 percent to $1,919,000.
Bioxyne was up 0.1 cents or 4.2 percent to 2.5 cents.

IMPEDIMED

Impedimed says it has a three-year development agreement with the Mayo Clinic for its fluid status and body composition monitoring technology in additional indications.
Impedimed's bio-impedance spectroscopy (BIS) was first developed to measure post-breast cancer lymphoedema of the arms and has been expanded to lymphoedema in the legs, with the company recently announcing new indications including congestive heart failure (Jun 12, 2008; Apr 7, 2010; Oct 26, Nov 3, 2016).
In May, Impedimed said it had a five-year clinical trial agreement with the Rochester, Minnesota-based Mayo Clinic to explore additional indications for its spectroscopy technology (BD: May 30, 2016).
Today, Impedimed chief executive officer Richard Carreon said there were "multiple clinical areas where fluid management is critical".
Mr Carreon said that the goal of working with the Mayo Clinic was to uncover new products to increase the quality of life for patients.
"In order to achieve this, we must develop solutions that are both clinically relevant and cost efficient," Mr Carreon said.
Impedimed said that its technology sent 256 unique frequencies through the body to assess both intra- and extracellular fluid and by detecting small amounts of fluid changes it could help health care providers better detect and manage chronic disease in patients.
The company said that relevant to any market where fluid burden and body composition were important, there was a wide range of applications for bio-impedance spectroscopy, potentially including cardiology and nephrology.
Impedimed said that under the agreement, the Mayo Clinic and Impedimed would jointly develop new products for patients with chronic diseases while improving the quality, outcomes and costs of patient care.
Mayo Clinic Ventures vice-chair Andy Danielsen said that by working with Impedimed "we hope to continue to improve care and reduce costs, across additional episodes of care."
Impedimed said that since 2015, the Mayo Clinic hospital in Florida had participated in the randomized, controlled study analyzing the bio-impedance spectroscopy technology's effectiveness in the early identification of lymphoedema.
Impedimed was up 5.5 cents or 4.3 percent to $1.33 with 1.1 million shares traded.

STARPHARMA HOLDINGS

Starpharma says it has a new but undisclosed dendrimer-enhanced product drug delivery program for a further compound from Astrazeneca's portfolio.
Starpharma said the new program was outside the licence signed last year and was in addition to the current programs (BD: Sep 7, Dec 2, 2015).
The company did not provide any details of the program.
Starpharma said its dendrimer-enhanced product (DEP) technology was designed to improve the performance of pharmaceuticals.
The company said that preclinical and early clinical data had shown DEP versions of drugs to be enhanced in a variety of ways compared to the unmodified drugs.
Starpharma said it had a number of internal DEP candidates, including DEP docetaxel, which was in the advanced stages of phase I clinical testing (BD: Apr 30, 2016).
The company said there were a number of partnered DEP programs underway in which the technology was being applied to partners' drugs to improve product performance and formulation characteristics
Starpharma chief executive officer Dr Jackie Fairley said it was "very pleasing to see a further expansion of our partnered DEP programs with Astrazeneca to evaluate new therapeutic candidates in addition to the existing licence agreement".
Starpharma was up two cents or three percent to 69 cents.

DIMERIX

Dimerix says it has begun its second development program investigating DMX-250 targeting fibrosis in patients with non-alcoholic steato-hepatitis or fatty liver disease.
Dimerix said the DMX-250 pre-clinical program was exploring the use of combinations of angiotensin receptor blockers and propagermanium, a CCR2 receptor antagonist.
The company said that it had observed a positive effect with DMX-250 in a mouse model based on evaluation of industry accepted endpoints, warranting further investigation.
Dimerix said the angiotensin receptor blocker and propagermanium combinations had been selected using its receptor-heteromer investigation technology, Receptor-Hit.
The company said that both the angiotensin receptor and the chemokine 2 receptor were members of a group of receptors called G-protein coupled receptors.
Dimerix said that non-alcoholic fatty liver disease was a severe and increasingly recognized non-viral, progressive liver disease affecting about six million people in the US alone, in many cases undiagnosed.
The company said that non-alcoholic steato-hepatitis (NASH) carried a risk of progression to liver fibrosis and hepatocellular carcinoma, with no established treatments
Dimerix executive chairman Dr James Williams said that animal model studies had provided "valuable insights into how an optimal NASH therapeutic program using our DMX-250 heterodimer approach could be developed for this common liver disease".
"Our early data shows signs of predicted synergies between the components of DXB-250 in the model and further pre-clinical studies are currently being planned to confirm these observations," Dr Williams said.
Dimerix said that by applying its Receptor-Hit technology to receptors such as G-protein coupled receptors it was able to identify potential pharmacological effects when receptors interacted as heterodimers, indicating new and more effective routes for therapeutic intervention compared with the traditional target development against a single receptor.
The company said the Receptor-Hit technology was used to identify the company's lead compound DMX-200 which was in a phase II trial for chronic kidney disease.
Dimerix was up 0.3 cents or 42.9 percent to one cent with 15.7 million shares traded.

INVITROCUE

Invitrocue has signed a hepatitis B research collaboration program with the National University of Singapore's Yong Loo Lin School of Medicine.

Invitrocue said that the program would focus on its three-dimensional human liver process to model an in-vitro system for the study of chronic hepatitis B infection.

The company said that if the program delivered promising data and results by 2018, it would offer it as a value-added service to bio-pharmaceutical clients for paradigm anti-hepatitis B drug and vaccine developments.

Invitrocue executive director Dr Steven Fang has previously told Biotech Daily that the company had grown liver cells in its scaffold system to measure their response to chemicals and had used the same system to grow cancer cells for testing anti-cancer drugs (BD: May 25, 2016).

Invitrocue said that the pluripotent stem cell-derived hepatocyte-like cells (hPSC-HLCs) were functionally enhanced by culturing the cells in three-dimensional cellulosic scaffolds.

The company said the research showed that the cells could be maintained and differentiated in the three-dimensional (3-D) cellulosic scaffolding technology due to the physical properties of the scaffolds and optimised media conditions.

Today, Dr Fang said that the company was "making important progress in the infectious disease niche market".

"To date, there is no reliable model for the study of many aspects of hepatitis B infection and there is still an urgent need for new in vitro infection models and systems," Dr Fang said.

"With better awareness, understanding and management many deaths caused by viral hepatitis can be prevented," Dr Fang said.

Invitrocue was up half a cent or 7.7 percent to seven cents.

ADHERIUM

Regal Funds Management says it has reduced its substantial holding in Adherium and been diluted from 10,333,783 shares (7.20%) to 10,235,108 shares (6.12%).

The Sydney based Regal Funds said that it bought 30,000 at 52 cents each on April 8, sold 128,675 shares at 50 cents each on July 20 and was diluted in the $8,023,049 placement at 50 cents each with Fidelity International (BD: Jul 20, 2016).

Adherium was up 2.5 cents or 5.3 percent to 49.5 cents.

COCHLEAR

Cochlear says it has appointed Stuart Sayers, Dr Richard Toselli, Dig Howitt, Anthony Bishop and Dean Phizacklea as senior executives.

Cochlear chief executive officer Chris Smith said the company had "focused our business priorities on the customer with activities aimed at strengthening our market leadership position".

"At the same time we are building our servicing capability to provide products, programmes and services to support the lifetime relationship we have with recipients," Mr Smith said.

Mr Smith said that Stuart Sayers had been appointed the head of services, with Dr Richard Toselli as chief medical officer, Dig Howitt as chief operating officer, Anthony Bishop as head of Asia Pacific and Dean Phizacklea as head of marketing.

Cochlear climbed 71 cents or 0.55 percent to $130.33 with 211,337 shares traded.

RECCE

Recce says its Perth facility has produced more than nine litres of its Recce-327 antibiotic for pre-clinical studies.

Recce said it had established a Sydney head office and a second laboratory in Macquarie Technology Park to manufacture Recce-327 for human trials, with a planned facility in Boston, Massachusetts deferred.

The company said that executive director James Graham would be based in Sydney, where future board meetings would be held.

Recce was untraded at 24 cents.