Biotech Daily

Tuesday September 29, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 30%, ONCOSIL DOWN 13%**

*** POLYNOVO WINS UP TO $38m BARDA BURNS TRIALS CONTRACT**

*** COGSTATE $4.5m ALZHEIMER'S CONTRACT EXTENSION**

*** ACTINOGEN: 'XANAMEM FOR ALZHEIMER'S DELIVERED TO BRAIN'**

*** PSIVIDA: 'FDA WILL ACCEPT SIX MONTH MEDIDUR DATA FOR UVEITIS'**

*** NEUREN COMPLETES FRAGILE X TRIAL PATIENT VISITS**

*** PATRYS PAT-SC1 DEAL, PAT-SM6 ON HOLD, CAR T-CELL CLOSED**

*** DORSAVI $9m UK YOURPHYSIOPLAN VIMOVE DEAL**

*** PHARMAUST'S EPICHEM MOVES INTO NEW LAB**

*** HUNTER HALL REDUCES TO 6% OF SIRTEX**

*** CBA, RELATED PARTIES SELL, RETURN BELOW 5% OF SIRTEX**

*** BIONOMICS APPOINTS DR ALAN DUNTON DIRECTOR**

*** ALLEGRA SHRINKS, LOSES CEO TOM MILICEVIC**

MARKET REPORT

The Australian stock market fell 3.82 percent on Tuesday September 29, 2015 with the ASX200 down 195.1 points to 4,918.4 points. Eight of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and four were untraded. All three Big Caps fell.

Actinogen was the best, up 1.5 cents or 30 percent to 6.5 cents with 24.3 million shares traded, followed by Polynovo up 20.8 percent to 14.5 cents with 1.8 million shares traded. Reva was up 10.3 percent; Admedus and Antisense were up more than three percent; Avita and Pharmaxis rose more than two percent; with Anteo up 1.1 percent.

Oncosil led the falls, down two cents or 12.9 percent to 13.5 cents with 7.4 million shares traded. Atcor fell 8.2 percent; Benitec, Clinuvel and Prima lost more than seven percent; Cellmid was down 6.25 percent; Orthocell fell 5.1 percent; Cochlear and Mesoblast fell more than four percent; CSL, Medical Developments, Neuren, Osprey, Starpharma and Viralytics were down three percent or more; Impedimed, Nanosonics, Resmed, Sirtex and Universal Biosensors shed more than two percent; Bionomics and Ellex were down more than one percent; with Acrux down 0.8 percent.

POLYNOVO

Polynovo says it has won a US Government contract worth up to $US26.2 million ($A37.7 million) for a trials of its biodegradable temporising matrix for burns.

Polynovo said that it would receive $US8.2 million ($A11.8 million), on a reimbursement for activity basis, for a 10-patient trial of the biodegradable temporising matrix for full thickness burns from the Biomedical Advanced Research and Development Authority (BARDA).

The company said the trial would be conducted at four centres and if completed successfully BARDA could provide a further $US18 million ($A25.9 million) for a 150-patient trial, fully-funding a pre-market authorization US Food and Drug Administration pathway.

Polynovo said that BARDA was a division of the US Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response and supported research, development and procurement of medical counter-measures against security and public health threats.

The company said that many mass casualties resulted in burn injuries with long treatment and rehabilitation pathways, imposing significant resource demands on the health system.

Polynovo said that its Novosorb based biodegradable temporising matrix (BTM) had advantages over the current standard of care in its ability to generate a neo-dermis.

The company said that the matrix was “scalable in production, robust, yet easy to handle and apply [and] delivers outstanding cosmetic and functional outcomes”.

Polynovo said that BTM provided a temporary scaffold allowing a new full dermis to be generated and then biodegraded leaving the patient’s own tissue fully repaired.

The company said that it provided BARDA “an opportunity to explore, through rigorous clinical testing, the delivery of a new approach to mass burn management whilst improving the healed outcomes”.

Polynovo said that the Wilmington, North Carolina-based contract research organization PPD would conduct the feasibility trial.

Polynovo chief executive officer Paul Brennan said the company would “work closely with BARDA and the FDA to prove our [matrix] has the capability to treat a large number of burns victims in the event of a disaster”.

“Being a fully synthetic product our capacity to quickly provide large volumes of product in response to a disaster makes our product attractive in emergencies and acute medical treatment,” Mr Brennan said.

Polynovo was up 2.5 cents or 20.8 percent to 14.5 cents with 1.8 million shares traded.

COGSTATE

Cogstate says an unnamed pharmaceutical company has extended its contract services for a phase III Alzheimer’s disease trial by $US3.1 million ($A4.5 million).

Cogstate said that the original contract was signed in August 2014 and the extension takes the total value to $US12.3 million, of which $US2.7 million had been invoiced (BD Sep 11, 2014).

The company said that the services provided included scientific consulting, project management, data management and statistical analysis in support of scales and other neuropsychological tests to measure the efficacy of a novel compound in mild Alzheimer’s disease.

Cogstate was up one cent or 4.8 percent to 22 cents.

ACTINOGEN MEDICAL

Actinogen says its final phase I trial of Xanamem for Alzheimer's disease shows the drug crosses the blood-brain barrier and is effectively delivered to the brain.

Actinogen said the four-patients in the trial underwent lumbar puncture to confirm central nervous system pharmaco-kinetics as well as plasma and cerebro-spinal fluid levels after taking Xanamem for five days (BD: Mar 31, Apr 14, Jun 11, 2015).

The company said that the results confirmed that Xanamem reached the brain in concentrations that were predicted to inhibit the 11beta-hydroxysteroid dehydrogenase type 1 (11beta-HSD1) enzyme in the brain.

Actinogen said that the 11beta-HSD1 enzyme produced the stress hormone cortisol and excess cortisol in the brain was associated with memory loss, amyloid plaque accumulation and neural death, which were the hallmarks of Alzheimer's disease.

The company said that inhibition of the 11beta-HSD1 enzyme had been shown to decrease cortisol levels, reverse memory loss and the amyloid plaque accumulation in the brain in human and rodents.

Actinogen adviser, the University of Edinburgh's Prof Brian Walker, discovered and developed the compound formerly known as UE2343 and said that "unlike other 11beta-HSD1 inhibitors in development for type 2 diabetes, Xanamem was designed with the explicit goal of maximizing penetration of the drug into the brain".

"These results confirm that this goal has been achieved in humans," Prof Walker said.

"Xanamem is therefore an excellent drug with which to evaluate the benefits of 11beta-HSD1 inhibition in patients with memory loss," Prof Walker said.

Actinogen chief executive officer Dr Bill Ketelbey told Biotech Daily that the company was preparing for a US phase II trial to demonstrate the effectiveness of Xanamem in treating patients suffering from mild Alzheimer's disease, expected to begin by July 2016.

Actinogen was up 1.5 cents or 30 percent to 6.5 cents with 24.3 million shares traded.

PSIVIDA

Psivida says the US Food and Drug Administration has advised that it will accept six-month efficacy data from its two phase III trials of Medidur for posterior uveitis.

Psivida said that the FDA had advised that six-month data would be acceptable for review and the company would file a new drug application to the agency.

The company said that it previously planned to use 12-month efficacy data from the first trial and six-month efficacy data from the second trial.

Psivida said that six-month visits for the first trial would be completed this month and top-line results from the first phase III trial were expected in December 2015.

The company said that enrolment in the second phase III trial was expected to be completed by July 2016, with a new drug application expected by July 2017.

Psivida chief executive officer Dr Paul Ashton said the company was "very pleased that the FDA has agreed to review an NDA for posterior uveitis based on six-month efficacy data".

"The primary end-point of the phase III trials is recurrence of disease, which in the majority of patients occurs typically within six months," Dr Ashton said. "We believe therefore that six-month data from our two trials will show safety and efficacy."

Psivida said that Medidur was an injectable micro-insert providing sustained release over three years of the corticosteroid flucinolone acetonide and was effectively the same as Iluvien licenced to Alimera Sciences and approved for diabetic macular oedema in the US and 17 European Union EU countries.

Psivida was untraded at $5.19.

NEUREN PHARMACEUTICALS

Neuren says it has completed the last subject visit in its 72-patient phase II trial of trofinetide for Fragile X syndrome (BD: Oct 18, 2013; Jul 29, 2015.

Neuren said it was on-track to release top-line results from the trial in December 2015.

The company said that eight more subjects were required to complete the target enrolment of 260 subjects in its phase II trial of trofinetide (formerly NNZ-2566) for moderate to severe traumatic brain injury.

Neuren said that patients were treated with trofinetide or placebo in hospital for 72 hours and followed-up for up to three months after randomization, with results expected "in early 2016".

Last year, the US Army granted a further $US3 million for the phase II 'Intrepid' trial of NNZ-2566 for moderate to severe traumatic brain injury and the phase II trial of NNZ-2566 in mild traumatic brain injury or concussion (BD: Jul 17, 2014).

Neuren fell 0.3 cents or 3.5 percent to 8.2 cents.

PATRYS

Patrys says it has completed licencing of PAT-SC1 for gastric cancer to China's Hefei Co-source Biomedical Co and received the first milestone payment.

In June, Patrys said the key terms of the deal were confidential, but were "on par for similar transactions of this type in this territory, including potential back-loaded payments, sharing of revenue and double digit royalties on end sales and it would receive an upfront payment when the agreement was executed and Patrys retained the right to commercialize PAT-SC1 outside China (BD: Jun 25, 2015).

Patrys chief executive officer Dr James Campbell said the company was "delighted to have finalised the agreement with Hefei Co-source and are looking forward to building a strong working relationship with [chief executive officer Dr Shanchun] Zhang and his team as they commence the development program for PAT-SC1".

Patrys said it would not approach German regulatory agency the Paul Ehrlich Institut for advice on the developments of PAT-SM6.

In June, the company said that the production run of PAT-SM6 immunoglobulin M (IgM) did not produce an adequate mass of antibody meeting release specifications, delaying a planned trial and "as the variability in the yield and consistency of the end product is unresolved, the initiation of the proposed combination trial of PAT-SM6 in refractory multiple myeloma patients remains on hold" (BD Nov 7, 2014; Jun 11, 2015).

Today, the company said it was in discussions with its manufacturer about the causes of variation in manufacturing that led to the variability in the yield and consistency and had has sought extensive input from its consultant and other experts and decided not approach the scientific advisory board of the Paul Ehrlich Institut as it did not believe that clinically meaningful doses of acceptable material were available.

Patrys said that the PAT-SM6 antibody produced was not able to be used for the proposed combination trial of PAT-SM6 in refractory multiple myeloma patients and it was investigating whether a cost effective, timely and reliable manufacturing process was viable for PAT-SM6.

The company said that chimeric antigen receptor T-cell program feasibility studies had been completed and the anti-cancer collaboration had been discontinued.

Patrys said it was exploring alternative avenues for deriving value from its IgM library.

Patrys fell 0.2 cents or 14.3 percent to 1.2 cents with seven million shares traded.

DORSAVI

Dorsavi says it will earn more than $9 million over three years from a deal with Britain's Yourphysioplan marketing and selling Vimove body sensors in the UK and Ireland.

Dorsavi said that the three-year deal included minimum sales targets of 100, 300 and 600 Vimove units to be purchased or leased consecutively each year over this period.

The company said it had the right to exit the contract if the minimum sales targets were not met and it had retained direct sales for Vimove in the UK and Ireland to hospitals, medical centres, universities, companies, and elite sports groups.

Dorsavi said that Yourphysioplan was a national network of more than 100 member clinics allowing members to pay a monthly payment to a health and care plan for physiotherapy services.

In June, Dorsavi said that Yourphysioplan had bought an initial 10 Vimove devices and the success of the program led to the new agreement (BD: Jun 2, 2015).

Dorsavi chief operating officer for Europe Zoe Whyatt said the partnership "provided an opportunity for Dorsavi to establish a strong foothold in the private UK market".

"This is a very significant milestone for Dorsavi and will allow us to tap into a large and growing network of clinicians and patients who will have access to our Vimove product," Ms Whyatt said.

Dorsavi was untraded at 28 cents.

PHARMAUST

Pharmaust says that subsidiary Epichem's laboratory in Western Australia's Technology Park became fully operational on September 11, 2015.

Pharmaust said that laboratory at Bentley in Perth adjacent to Curtin University was more than twice the size of its previous laboratory at Murdoch University and had provision for additional expansion in the future.

Epichem managing director Dr Wayne Best said the laboratory provided significant extra capacity and its improved design "offers significant improvements in efficiency".

"The timing couldn't be better for the expansion," Dr Best said. "With most of Epichem's business being for the export market, the current low Australian dollar adds significantly to our competitiveness and profitability."

Pharmaust was unchanged at 0.5 cents with 5.5 million shares traded.

SIRTEX MEDICAL

Hunter Hall Investment Management has reduced its substantial holding in Sirtex from 4,214,004 shares (7.37%) to 3,565,058 shares (6.24%).

In March, following the failure of the Sirflox trial to meet its primary endpoint, the Sirtex share price fell as much as 55 percent and Hunter Hall bought 1,251,375 shares for $21,829,457 or $17.44 a share, the first time Hunter Hall had bought Sirtex shares since May 2013 when it reached an internal maximum (BD: Mar 17, 19, 2015)

Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at $2.35 a share and has sold shares at prices ranging up to $34 a share (BD: Mar 5, 2009).

Today, Hunter Hall said that it sold Sirtex shares between August 26 and September 25, 2015, with the single largest sale 128,250 shares for $4,407,072 or $34.36 a share.

Sirtex fell 95 cents or 2.8 percent to $32.45 with 290,079 shares traded.

SIRTEX MEDICAL

The Commonwealth Bank of Australian and a large number of related parties say they have reduced their holding below the five percent substantial level in Sirtex.
Last month, the CBA said the group had reduced their holding to 2,988,845 shares (5.21%), naming scores of related companies and said it bought, sold, borrowed and returned shares in a large number of trades requiring more than 240 pages to report the trades, with some shares subject to share lending agreements (BD: Aug 26, 2015).
Today, the CBA said that it had bought, sold and increased and decreased borrowings, requiring more than 100 pages to report the trades.

BIONOMICS

Bionomics says it has appointed Dr Alan Dunton as a non-executive director.
Bionomics chairman Graeme Kaufman said that Dr Dunton had "enormous drug development and clinical research experience as well as his tenured career in the pharmaceutical industry".
The company said that Dr Dunton had drug discovery, development and regulatory experience across all functional areas and played a key role in the development of more than 20 products through to regulatory approval.
Bionomics said that Dr Dunton was formerly the Janssen Research Foundation's managing-director Metaphore Pharmaceuticals chief executive officer and the founder of consultancy Danerius LLC.
The company said that Dr Dunton was currently a director of Palatin Technologies, Oragenics and Sancilio Pharma.
Bionomics said that Dr Dunton held a Doctor of Medicine degree from New York University School of Medicine.
Bionomics fell half a cent or one percent to 47.5 cents.

ALLEGRA ORTHOPAEDICS (ADVANCED SURGICAL DESIGN & MANUFACTURE)

Allegra says that chief executive officer and chief financial officer Tom Milicevic has resigned effective on October 9, 2015.
Allegra said it would "undertake a management restructure that reflects the size of its business" over the next six months.
The company said that managing director Peter Welsh would subsume the chief executive officer role and a consultant had been hired to support financial and accounting resources.
Advanced Surgical Design & Manufacture listed on the ASX in November 2007 to commercialize a range of orthopaedic equipment including its own Active Total Knee reconstruction kit, hip replacement cup and the Peripheral Access Device to increase lower limb perfusion to prevent amputation (BD: Feb 13, 2008; Apr 9, 2010).
In 2012, founder Dr Greg Roger resigned and was replaced by Mr Milicevic, with Mr Welsh appointed as a director (BD: Mar 26, 2012).
Allegra was untraded at 25 cents.