Biotech Daily

Thursday February 13, 2014

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: TISSUE THERAPIES UP 9%, PRANA DOWN 5%**

*** ACTINOGEN BACK TO ANTIBIOTIC FUTURE**

*** PROGEN: 'PG545 ALMOST DOUBLES MEDIAN SURVIVAL IN MICE'**

*** US PATENT ALLOWED FOR BIOTRON BIT225**

*** ONQ TO DISTRIBUTE BLUECHIIP IN AUSTRALIA, NEW ZEALAND**

*** MAYNE $18m PLACEMENT AT 79.5c**

*** ALLAN GRAY TAKES 14.5% OF ACRUX**

*** UNIVERSAL BIO REVENUE DOWN 49% TO $15m, LOSS UP 27% TO $12m**

*** SUDA HIRES KAD CONSULTANTS FOR FDA ADVICE**

*** ONCOSIL APPOINTS NATALIE RUFFLES CLINICAL RESEARCH V-P**

*** MEDICAL AUSTRALIA: DARRYL ELLIS COO, BRUCE HANCOX DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.04 percent on Thursday February 13, 2014 with the S&P ASX 200 down 2.0 points to 5,308.1 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, five traded unchanged and four were untraded.

Tissue Therapies was the best, up three cents or 8.6 percent to 38 cents with 1.1 million shares traded.

Genetic Technologies climbed six percent; Phosphagenics was up 4.55 percent; Anteo, Antisense, Nanosonics and Viralytics were up more than three percent; Benitec, Compumedics, Impedimed and Prima rose two percent or more; Acrux, Bionomics, Ellex, Medical Developments, Neuren and QRX were up more than one percent; with Resmed and Sirtex up by less than one percent.

Prana led the falls, down five cents or 5.3 percent to 90 cents, with 1.9 million shares traded. Avita, GI Dynamics and Universal Biosensors fell more than four percent; Oncosil, Pharmaxis and Psivida were down more than three percent; Optiscan, Patrys and Resmed shed more than two percent; Cochlear and CSL were down more than one percent; with Alchemia, Mesoblast and Starpharma down by less than one percent.

ACTINOGEN

Actinogen says it has recommenced further research on its antibiotic project at its laboratory at Murdoch University's State Agricultural Biotechnology Centre in Perth.

Actinogen was originally developing the use of actinomycetes for antibiotics and anti-fungals and then turned its focus to bio-fuels (BD: Nov 9, 2011).

In October 2012 the company had less than three months of cash and in August 2013 failed to raise $595,000 in a rights issue (BD: Oct 29, 2012; Aug 2, 2013).

Last year, the company signed a $100,000 loan agreement with Otsana Captial and replaced the board, later raising $1.5 million (BD: Sep 24, Dec 13, 2013).

Actinogen acquired laboratory space at Murdoch University and formed a collaboration with Leaf Energy for the better production of bio-fuels (BD: Dec 20, 2013; Jan 19, 2014).

Yesterday, Actinogen said that during its operations review process, the antibiotic research program was identified as "one of the key components of the company's future strategy in the drug development area".

Actinogen said that antibiotic-resistant bacteria were an increasing global problem, with much research and investment directed to discovering new effective agents and treatment modalities.

The company said that infections caused by resistant micro-organisms often failed to respond to the standard treatment, resulting in prolonged illness and greater risk of death, with the death rate for patients with serious infections treated in hospitals about twice that in patients with infections caused by non-resistant bacteria.

Actinogen said that a high percentage of hospital-acquired infections were caused by resistant bacteria such as methicillin-resistant Staphylococcus aureus (MRSA), vancomycin resistant enterococci (VRE) and Clostridium difficile.

The company said it had identified the importance of continuing the research in this field due to the global demand for new potential agents and on the back of positive initial results conducted on numerous strains of bacteria, in particular MRSA and VRE.

Actinogen said it owned a database of more than 6,000 actinomycetes, which previously, had been screened to identify those able to produce compounds with antimicrobial activity against resistant strains.

The company said the actinomycetes were tested for activity against the MRSA panel, VRE, Candida., Pseudomonas aeruginosa and Clostridium difficile.

Actinogen said the testing panels consisted of clinical isolates of microorganisms that developed serious antibiotic resistance patterns and could be used to increase the likelihood of finding new antibiotics.

The company said that once actinomycetes with anti-microbial activity against the clinical test isolates had been identified, it tried to identify the active compound from public literature and databases and if the compound could not be matched to an existing substance, it was sent to an independent laboratory to obtain a molecular structure.

Actinogen said it had 69 isolates that had shown activity against the entire MSRA panel, 11 isolates had shown activity against the entire Candida species panel and 58 isolates have shown activity against VRE.

The company said that each compound with activity against the MRSA panel and Clostridium difficile had the potential to become a new antibiotic, but extensive further testing was required for this to be established.

Actinogen said it planned to retest the previously identified isolates with activity against MRSA, Candida and possibly Clostridium difficile, with particular interest in isolates that produced unidentifiable active compounds.

Actinogen was unchanged at 2.5 cents.

PROGEN PHARMACEUTICALS

Progen says that as a single agent for solid tumors in mice, PG545 “almost doubled median survival to 43 days”.

Progen said that when PG545 was used as part of a maintenance therapy, 90 percent of mice were alive beyond 60 days.

The company said that the data was in a poster entitled ‘PG545, a heparan sulfate mimetic, targets the tumor microenvironment to potently inhibit solid tumor growth and metastasis, alone and in combination with chemotherapy, in models of pancreatic and ovarian cancer’ presented by its director of drug development Dr Keith Dredge at the Lorne Cancer Conference in Victoria.

Progen said the presentation focused on the potent anti-tumour and anti-metastatic properties of PG545.

The poster abstract said that competitive inhibition of heparanase by PG545, in addition to its modulation of angiogenic growth factors was “considered a key differentiator from other anti-angiogenic agents”.

The poster said that using models of pancreatic adeno-carcinoma PG545 “significantly reduced solid tumor growth, metastasis and induced hypoxia but without leading to collagen deposition or epithelial-to-mesenchymal transition”.

“PG545 therapy also reduced tumor-associated macrophage and myeloid derived suppressor cell number,” the poster said.

The poster abstract said that in combination with gemacitabine PG545 showed additive anti-tumor activity in mice and as a single-agent PG545 significantly reduced tumor progression and/or ascites formation in models of ovarian cancer.

The poster said that changes in plasma vascular endothelial growth factor and/or heparanase were considered indicative of a pharmaco-dynamic effect, which was also observed following PG545 treatment to patients in a previous clinical trial, further illustrating the translational relevance of these studies.

Progen’s 2010 clinical trial was closed due to injection site reactions and the company moved to intravenously delivery (BD: Nov 15, 2010; Sep 20, 2011; Jan 22, 2012).

Today, the poster abstract said that significant additive activity was observed in combination with paclitaxel or cisplatin and/or carboplatin while imaging studies showed PG545’s utility as a maintenance therapy following cisplatin and paclitaxel.

The poster said that single agent PG545 “almost doubled median survival to 43 days [but] as part of a maintenance therapy, 90 percent of mice were alive beyond 60 days”.

The poster said that using PG545 alone and in combination, via multiple effects within the tumor microenvironment, had “the potential to provide greater long-term suppression of angiogenesis in tumors than pathway-specific inhibitors”.

“Together with Progen’s scientists, multiple academic collaborators have collaborated on investigating the activity of PG545 in two particular cancers - pancreatic and ovarian cancer,” Dr Dredge said.

“The studies reveal how PG545 interferes with some key biological processes implicated in the progression and spread of these cancers,” Dr Dredge said.

“These new data demonstrate the anti-cancer effects of PG545 when given as a single agent but importantly, also when given in combination with existing standard-of-care chemotherapies which provides critical guidance for future clinical trials in cancer patients,” Dr Dredge said

Progen acting managing director Heng Tang said the preclinical data was “the strongest evidence yet of the potential clinical utility of PG545 in many solid tumors indications”.

Progen has begun a phase I trial of PG545 for advanced cancer (BD: Oct 29, 2013).

Progen fell eight cents or 16.2 percent to 41.5 cents.

BIOTRON

Biotron says the US Patent and Trademark Office has allowed a patent application entitled 'Antiviral Compounds and Methods.

Biotron said that the patent protected the composition and use of, and methods of treatment with, its lead antiviral compound BIT225 until December 2027.

Biotron managing director Dr Michelle Miller said the patent was "a valuable addition to the existing intellectual property portfolio and enabled broad protection for the current clinical and commercial opportunity presented by BIT225".

"This patent provides Biotron exclusivity in the key USA market over its proprietary compound BIT225," Dr Miller said.

"Our trials of this compound have consistently demonstrated BIT225's first-in-class potential to be used as an adjunctive treatment for patients with hepatitis C virus and/or HIV," Dr Miller said.

Biotron said its patent for BIT225 had been granted or accepted in eight other jurisdictions, including Europe and China and extended its antiviral patent portfolio of five patent families covering its compound library, as well as screening assays against specific viral target proteins known as viroporins.

The company said BIT225 targetted the Vpu protein of HIV and the p7 protein of hepatitis C and both targets were in the viroporin class of proteins.

Biotron was up 0.9 cents or 11.5 percent to 8.7 cents.

BLUECHIIP

Bluechiip says the Melbourne-based Onq Software will sell Bluechiip products in Australia and New Zealand as part of Onq's laboratory information management software (QLIMS).

Bluechiip said that its sample chain-of-custody and temperature capability with Onq's system provided an end-to-end tracking product that was not otherwise available.

Bluechiip was up one cent or 13.3 percent to 8.5 cents.

MAYNE PHARMA

Mayne Pharma says it has completed its $18 million placement book-build at the final price of 79.5 cents per share.

Yesterday, Mayne said the funds would cover the costs of the $13.2 million acquisition of four drugs from the New York-based Forest Laboratories as well as other programs and working capital (BD: Feb 12, 2014).

Mayne was up 7.5 cents or 9.5 percent to 86.5 cents.

ACRUX

Allan Gray Australia has increased its substantial holding in Acrux from 21,590,115 shares (12.97%) to 24,108,916 shares (14.48%).

Allan Gray said that between February 5 and 11, 2014 it bought 2,518,801 shares for $4,893,725 or an average price of $1.94 a share.

Earlier this week, following news of a US Food and Drug Administration inquiry into the cardiac impacts of testosterone products, Macquarie analyst Dr Craig Collie put a $1.80 valuation on the stock, Wilson HTM analyst Dr Shane Storey said it was a hold at $3.70 and Morgans' Scott Power said Acrux was worth $2.70 a share (BD: Feb 4, 5, 2013).

Acrux was up two cents or one percent to $1.995 with 1.7 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says its net loss after tax for the 12 months to December 31, 2013 was up 27 percent to $11,633,807 on revenue down 49 percent to $15,089,672.
Universal Biosensors said that strip manufacturing revenue fell from $19.4 million in 2012 to $10.1 million in 2013 “due to the transfer of glucose test strip manufacturing to [Johnson & Johnson] Lifescan’s own facilities” and although the transfer adversely affected revenue, following a restructure, the overall profitability of its blood glucose business had improved.
Universal Biosensors said that 2012 revenue included fees earned on a $US4.5 million Lifescan feasibility program as well as $4.2 million in milestone payments from Siemens.
The company said that revenue from service fees, generated by test strips sales, increased 52 percent to $3.4 million in 2013, despite Lifescan Onetouch recall.
Universal Biosensors chief executive officer Paul Wright said that the growth in quarterly service fees was “clearly exceeding the single digit blood glucose testing industry growth rates, which we believe demonstrates the competitive attributes of the Onetouch Verio product and gives us confidence in its future growth”.
Universal Biosensors said that research and development expenses increased by 15 percent to $15.5 million reflecting “the ongoing investment in the coagulation testing products, the first of which is expected to launch in 2014”.
Universal Biosensors said that net tangible asset per share fell 26.1 percent to 17 cents at December 31, 2013 and diluted loss per share was up 16.7 percent to seven cents compared with six cents in the previous corresponding period.
Universal Biosensors said it had cash and equivalents of $23,742,422 at December 31, 2013 compared to $23,649,417 at December 31, 2012.
Universal Biosensors fell two cents or 4.2 percent to 45.5 cents.

SUDA

Suda says it has hired the Dana Point, California-based KAD Consultants as US regulatory strategy advisers.
Suda said that KAD managing partner Donald Harrigan and his team would provide regulatory advice and serve as the company’s agent for communications with the US Food and Drug Administration.
The company said that Mr Harrigan was “a seasoned regulatory pharmaceutical consultant with more than 30 years experience … [who had] guided numerous clients on their US regulatory strategy and dealings with the FDA”.
Suda fell half a cent or 7.7 percent to six cents.

ONCOSIL MEDICAL

Oncosil says it has appointed Natalie Ruffles as the vice-president of clinical research as it prepares for its registration study of Oncosil radiation therapy for pancreatic cancer.
Oncosil said that Ms Ruffles had 10 years experience in running clinical trials for medical devices and pharmaceutical investigational products and would be responsible for the management of all clinical studies and would provide guidance on clinical strategy for new clinical studies.
The company said that Ms Ruffles most recently worked for the US based Medtronic, where she was responsible for its clinical programs in Australia and New Zealand.
Oncosil said that Ms Ruffles held a Bachelor of Science and a Masters of Science from the University of Technology Sydney.
Oncosil fell half a cent or 3.85 percent to 12.5 cents.

MEDICAL AUSTRALIA

Medical Australia says that Mark Donnison has resigned as managing director with Darryl Ellis appointed chief operating officer and Bruce Hancox as a non-executive director.
Medical Australia said the changes followed the acquisition of Medivet and the intergration of its human and animal health operations (BD: Dec 10, 2013).
The company said that Mr Ellis “was educated at the Royal Military College Duntroon, where he developed strong leadership and organizational skills”.
Medical Australia said that Mr Ellis held a Master of Business Administration from the Macquarie Graduate School of Management and completed the Business Management Course at GE’s Crontonville, New York management facility.
The company said that Mr Ellis had held senior leadership positions at Alcan Australia, CSR, GE Lighting and Assa Abloy.
Medical Australia said that Mr Hancox was “an experienced company director and executive with strong financial and [merger and acquisition] skills”.
The company said that Mr Hancox was formerly a director of Brierley Investments and was currently a director of Neuren, as well as Windfall (NZ) Trust which had invested $2 million in Medical Australia.
Medical Australia chairman Gary Lewis said the company was “entering its next growth phase and it is important that we have the right mix of skills at an executive and board level”.
“The acquisition of Medivet and the subsequent capital raising have been company-transforming events and we are now focused on capitalizing on the opportunities that this transaction has brought,” Mr Lewis said.
Medical Australia was untraded at 39.5 cents.