Biotech Daily

Monday June 29, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MEDICAL DEVELOPMENTS UP 14%**
- VIRALYTICS DOWN 8%

*** NOVARTIS BUYS SPINIFEX FOR $916m**

*** MEDICAL DEVELOPMENTS $71.5m+ EUROPE SALES DEAL**

*** US PATENT FOR CELLMID MIDKINE C-DOMAIN**

*** PRESCIENT NOTIFIES FDA OF PTX-200 IND TRANSFER**

*** INVION COMPLETES INV102 FOR SMOKING CESSATION DOSING**

*** ACTINOGEN CHAIRMAN MARTIN ROGERS EXECUTIVE ON $80k**

*** IMUGENE PROPOSES 5m OPTIONS FOR DIRECTOR DR AXEL HOOS**

*** TISSUE THERAPIES LOSES CSO PROF ZEE UPTON**

MARKET REPORT

The Australian stock market fell 2.23 percent on Monday June 29, 2015 with the S&P ASX 200 down 123.4 points to 5,522.5 points.

Only one of the Biotech Daily Top 40 stocks was up, 25 fell, 12 traded unchanged and two were untraded. All three Big Caps fell.

Medical Developments was the sole company to rise today, up 34 cents or 14.1 percent to $2.75, with 347,030 shares traded. Congratulations John Sharman and David Williams !

Viralytics led the falls, down 6.5 cents or 9.4 percent to 62.5 cents with 236,631 shares traded.

IDT lost eight percent; Compumedics fell 7.1 percent; Avita and Genetic Technologies lost more than six percent; Atcor, Oncosil and Prima fell four percent or more; GI Dynamics, Mesoblast, Nanosonics, Osprey and Prana were down more than three percent; Acrux, Actinogen, Bionomics, CSL, Optiscan, Sirtex and Tissue Therapies shed more than two percent; with Admedus, Anteo, Cochlear, Impedimed and Resmed down more than one percent.

SPINIFEX PHARMACEUTICALS

Spinifex says it will be acquired by the Basel, Switzerland-based Novartis International AG for $US200 million upfront as well as development and regulatory milestones.

Biotech Daily understands that the additional payments and potential royalties amount to about $US500 million making the total $US700 million ($A915.9 million) buy-out Australia's single largest biotechnology deal.

Spinifex said that the technology behind its lead compound EMA401, for the treatment of pain and hypersensitivity in peripheral nerve injury patients and the treatment of pain and hypersensitivity in cancer chemotherapy patients, around which Spinifex was founded was developed by the University of Queensland's Prof Maree Smith and Dr Bruce Wyse.

The company said it was spun-out in 2005 and was backed by the University's commercialization arm Uniquest, Uniseed and GBS Venture Partners, with Brandon Capital later joining the funding, helping to raise $12 million in 2008 and a further $6.25 million in 2011 (BD: Sep 3, 2008; Aug 24, 2011).

Brandon Capital managing director Dr Chris Nave told Biotech Daily that Spinifex had initial support from the University of Queensland along with about $6 million to $8 million in Federal Government funding through the Innovation Investment Funds and the Pre-Seed Funds.

Dr Nave said that Spinifex raised a further $46 million last year with continued Government support through these funds and the introduction of leading US venture firms Novo Ventures and Canaan Partners (BD: Apr 11, 2014).

Spinifex said that last year it the Lancet published positive results from its phase II trial in post-herpetic neuralgia, a condition that can develop following herpes zoster or shingles paving the way for the major raising.

The company said that Novartis would continue the development of the company's programs and was planning to undertake phase IIb clinical trials in patients with post-herpetic neuralgia and painful diabetic neuropathy and intended to build on the two indications to pursue a broad peripheral neuropathic pain.

Spinifex chief executive officer Dr Tom McCarthy said he thanked "all Spinifex investors throughout this journey".

"I thank Prof Maree Smith and her colleagues for their foundational [intellectual property], Uniquest for shepherding this into Spinifex and fostering Uniseed and GBS's Series A syndicate support," Dr McCarthy said.

"The Australian support base was further strengthened by Brandon Capital at the Series B, and then Novo and Canaan in the Series C financing," Dr McCarthy said.

"As with all successful outcomes, it needed the support of many," Dr McCarthy said.

"I would also like to remember Dr Andrew Baker who led GBS's initial investment and was past Spinifex chairman," Dr McCarthy said.

"From the time I joined the company in November 2006 through to Andrew's passing, he was a great support to Spinifex and me personally and I know at this time he would be very proud of us all," Dr McCarthy said (BD: Mar 19, 2012).

Spinifex said that the acquisition was "a great example of the combination of world leading Australian medical research, the dedication and hard work of Dr McCarthy and his team over many years and the successful co-operation of the Australian venture community in identifying the potential of, and helping to developing this company.

The company said that each of the Australian investors thanked the "limited partners" who supported each of the funds, as well as the Australian Government programs which made the outcome possible including the Pre-Seed Funds, Innovation Investment Funds, Innovation Investment Follow-On Funds, Commercial Ready and the R&D Tax Incentive.

Spinifex was a private company.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it expects to sign a European Penthrox inhaled analgesic distribution deal worth potentially more than $US54.5 million ($A71.5 million).
Medical Developments said that the agreement was with an unnamed pharmaceutical company with expertize in pain management products which would distribute Penthrox in the 28 member states of the European Union, except for the UK, Ireland, and Hungary where the company had existing distribution agreements, and other European countries.
The company said it would receive $US7.0 million on signing, which was expected in about eight weeks' time, $US3.0 million on receiving marketing authorization in France and $US7.0 million on receiving reimbursement in Germany, Italy, Spain and France.
Medical Developments said it expected to receive a further $US37.5 million for sales milestones potentially earned over the term of the deal and it would further receive a gross margin on product sold to the distributor and royalties based on net sales.
Medical Developments chief executive officer John Sharman said it was "a very significant deal and potentially underwrites the future success of Penthrox in Europe".
"Our partner estimates peak sales could be circa 10 million units per annum and it will be responsible for investing into the development of Penthrox and registering Penthrox throughout Europe," Mr Sharman said.
Medical Developments chairman David Williams said that Penthrox globally would "satisfy world demand for an inhaled, fast acting, non-addictive, non-narcotic trauma and acute pain drug".
"There are a large number of opportunities for Penthrox globally," Mr Williams said.
"We have now turned our attention to registration in North America where we have started work and there is already interest from companies wanting to represent us there," Mr Williams said.
Medical Developments was up 34 cents or 14.1 percent to $2.75.

CELLMID

Cellmid says that US Patent Office has allowed a patent application entitled 'Antibody recognising C-domain of midkine'.
Cellmid said that the granted claims covered antibodies and antibody fragments which bound to the important functional C-domain of growth factor midkine, in particular, antibodies of any kind that bind to key midkine C-domain epitopes.
The company said that the patent included composition of matter claims for midkine specific antibodies, including its lead humanized antibody CAB102.
Cellmid said that the granted claims covered the use of the antibodies for prevention and treatment of cancer, autoimmune diseases, inflammatory diseases, and any disease or disorder attributed to cell migration.
The company said that the midkine C-domain was the key region promoting signalling and pathology attributed to midkine and blocking the C-domain was "a powerful potential treatment option" in midkine-related diseases.
Cellmid chief executive officer Maria Halasz said that having the US granted patent "across such a wide array of diseases is a tremendous commercial outcome [and] patent adds to already covered territories of Europe, Japan and Australia," Ms Halasz said.
"This family gives Cellmid strong and exclusive rights to develop MK antibodies unencumbered by competition," Ms Halasz said.
"Cellmid's patent coverage for its therapeutic antibodies now extends across cancer, inflammatory and autoimmune diseases, and surgical adhesion," Ms Halasz said.
Cellmid was unchanged at 2.7 cents with 2.6 million shares traded.

PRESCIENT THERAPEUTICS (FORMERLY VIRAX HOLDINGS)

Prescient says it has told the US Food and Drug Administration it has transferred an investigational new drug application for trial of PTX-200 for ovarian cancer.

Prescient said that the application for a phase Ib/II trial of PTX200, formerly known as TCN-P, for the treatment of metastatic ovarian cancer had been transferred from the Tampa, Florida-based Moffitt Cancer Center, following the acquisition of the drug from Aktivate Therapeutics in late 2014.

The company said that the phase Ib/II trial of PTX200 in combination with the current standard of care cisplatin was underway, with six patients with recurrent or persistent platinum resistant ovarian cancer recruited, at the Moffitt Cancer Center and initially funded by the US Department of Defense.

Prescient managing director Dr Robert Crombie told Biotech Daily the trial would recruit a total of about 30 patients.

The company said that early studies suggested that PTX-200, which targetted the AKT tumor survival pathway, might help minimise the problem of chemotherapy resistance, a major problem in the treatment of ovarian cancer and linked to poor survival rates.

Prescient said that ovarian cancer was the fifth leading cause of cancer deaths in women in the US and about half of those diagnosed would die from metastatic disease.

Prescient managing director Dr Robert Crombie said that “despite decades of research focused on the role of surgery and cytotoxic chemotherapy for epithelial ovarian cancer, current treatments make little substantive impact on cure rates for the disease”.

“There is a vital need for new therapies that may be used in conjunction with current standards of care and we are committed to unlocking the value of this highly promising drug candidate that has great potential as a new treatment for this difficult to treat cancer,” Dr Crombie said.

Earlier this month, Prescient said the FDA had reactivated its application for a phase Ib trial of PTX-100 for metastatic breast cancer and today said it was planning a phase Ib/II trial of PTX-200 for acute myeloid leukaemia in late 2015. (BD: Jun 10, 2015).

Prescient was up 0.8 cents or 12.9 percent to seven cents.

INVION

Invion says it has completed dosing in its 155-patient, double-blind, randomized, placebo-controlled phase IIb trial of INV102, or nadolol, for smoking cessation.

Invion said that the trial known as INVSC001 was entitled ‘Efficacy and safety of beta-adrenoceptor inverse agonist, nadolol, in smoking cessation of patients with pre-existing [chronic obstructive pulmonary disease]’.

The company said that completing dosing was “an important milestone” ahead of the release of headline study data, expected by October 2015.

Last month, Invion said that INV102, was safe for smokers trying to quit tobacco products as well as patients with chronic obstructive pulmonary disease patients and that interim trial data showed that smokers with chronic cough who had not been formally diagnosed with chronic obstructive pulmonary disease (COPD) had similar airways damage to those who had been diagnosed with COPD, thereby expanding the market opportunity for INV102 for smoking cessation (BD: May 20, 2015).

Today, the company said that the results could pave the way for a new approach to the treatment of chronic respiratory diseases like COPD, cystic fibrosis and severe asthma and could provide novel intellectual property if correlations provided insights to safety or efficacy linking nadolol use to specific profiles of biomarkers.

Invion was up 0.2 cents or 12.5 percent to 1.8 cents with 2.4 million shares traded.

ACTINOGEN

Actinogen says it the role and duties of chairman Martin Rogers are more accurately characterized as those of an executive.

Actinogen said that it had entered into an executive services agreement with Mr Rogers effective form his appointment as a director on November 28, 2014, with a base salary of $80,000 per annum exclusive of superannuation and taxes, performance-based bonuses at the company's discretion and a notice period of one month.

Actinogen fell 0.2 cents or 2.9 percent to 6.8 cents.

IMUGENE

Imugene says it will issue director Dr Axel Hoos 5,000,000 options, half exercisable at 1.25 cents and half at 1.75 cents within four years, subject to shareholder approval.

Imugene said that Dr Hoos was "a highly qualified and internationally respected medical research professional who has played a key role in the development of Imugene's HER-2+ gastric and breast cancer therapies and his on-going involvement and incentivization is critical for Imugene as it focusses on delivering key milestones".

The company said that the proposed issue of options would be a cost effective incentive based form of remuneration.

Imugene said that 2,500,000 options exercisable at 1.25 cents each would vest on recruitment of the first patient for a phase Ib trial, with the 2,500,000 options exercisable at 1.75 cents each vesting on recruitment of the first patient for a phase II trial, with any options not vested lapsing if Dr Hoos ceases to be a director.

Imugene fell 0.2 cents or 16.7 percent to one cent with 3.1 million shares traded.

TISSUE THERAPIES

Tissue Therapies says that Prof Zee Upton will retire as consulting chief scientific officer form June 30, 2015 continuing as an adviser on scientific matters.

Tissue Therapies said that research and development director Dr Gary Shooter would be responsible for scientific operations.

The company said that Dr Shooter had worked closely with Prof Upton since 2004 and had been involved in the development of the Vitrogro technology and was "well-positioned to ensure continuity".

Tissue Therapies said that Prof Upton had been appointed as Singapore's Agency for Science Technology and Research Institute of Medical Biology research director.

Tissue Therapies interim chairman Dr Cherrell Hirst said that the company expressed "its sincere thanks to Prof Upton for her significant contribution to [Tissue Therapies] over the years since 2003 and for her role in fostering our relationships with the scientific community".

Tissue Therapies fell 0.1 cents or 2.6 percent to 3.7 cents.