Biotech Daily

Tuesday February 10, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GI DYNAMICS UP 14%, TISSUE THERA DOWN 6%**

*** FEDERAL PARLIAMENT PASSES IP AMENDMENT BILL**

*** VAXXAS RAISES $25m**

*** COCHLEAR RECORD H1 REVENUE, PROFIT UP**

*** MESOBLAST US DISC REPAIR, RECONSTITUTION PATENT**

*** US PATENT FOR DRAWBRIDGE PHAXAN ANAESTHETIC, SEDATIVE**

*** OTIFEX: 'BETAHISTINE FOR GLUE EAR SAFE, TOLERATED'**

*** UNILIFE H1 REVENUE UP 0.3% TO $9m, LOSS UP 44% TO $54m**

*** CORRECTION: PRESCIENT**

*** MAYNE TO RAISE $115m FOR DORYX, DRUGS, US DIVISION**

*** BPH SHARE PLAN FOR UP TO $200k**

*** CYTOMATRIX: PROF ALAN TROUNSON, PROF MILES PRINCE ADVISORS**

MARKET REPORT

The Australian stock market fell 0.25 percent on Tuesday February 10, 2015 with the S&P ASX 200 down 14.3 points to 5,800.6 points. Ten of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and three were untraded. All three Big Caps fell.

GI Dynamics was the best, up three cents or 14.3 percent to 24 cents with 292,182 shares traded. Mesoblast climbed 4.2 percent; Atcor and Ellex were up more than three percent; Cellmid, Oncosil, Optiscan and Prima rose two percent or more; Anteo was up 1.1 percent; with Sirtex up 0.35 percent.

Tissue Therapies led the falls, down 1.5 cents or 6.4 percent to 22 cents with 1.1 million shares traded, followed by Medical Developments down 6.2 percent to $1.745 with 136,250 shares traded. Analytica and Bionomics fell four percent or more; Genetic Technologies, Starpharma and Viralytics lost more than three percent; Alchemia, Benitec, Nanosonics and Prana shed more than two percent; Cochlear, Impedimed, Living Cell, Phosphagenics and Resmed lost one percent or more; with Acrux, Clinuvel and CSL down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says the Intellectual Property Laws Amendment Bill 2015 was passed by the Senate last night simplifying intellectual property rights.

A media release from the Parliamentary Secretary to the Minister for Industry and Science Karen Andrews said the Bill simplified aspects of Australia's intellectual property system, to "make it cheaper and easier to protect and enforce certain ... rights, and make it simpler for developing countries to get help in dealing with major public health crises".

"This new legislation will streamline business between Australia and New Zealand by simplifying the process for innovators seeking to patent the same invention in both countries," Ms Andrews said.

"It allows for a single patent attorney regime and a single patent application and examination process, making it easier for businesses to protect their [intellectual property] in both countries," Ms Andrews said.

Ms Andrews said it the changes would assist people who worked with new plant varieties, "as the plant breeders who supply these industries will now have simpler and more cost-effective means of enforcing their rights in the Federal Circuit Court".

Ms Andrews said that the Act could also help people in developing countries who faced life-threatening illnesses such as malaria, HIV/AIDS or tuberculosis, with generic drug manufacturers able to apply to Australia's Federal Court for permission to manufacture patented drugs that would otherwise be too costly and export the medicine to a developing country facing a health crisis.

The media release said that more information about the Intellectual Property Laws Amendment Bill 2015 was at: www.ipaustralia.gov.au.

The Bill will come into force as an Act when the Governor-General signs Royal Assent, expected in the coming days.

VAXXAS

Vaxxas says it has raised $25 million from new and existing investors to develop a pipeline of vaccine products using its Nanopatch vaccination platform.

The Brisbane-based Vaxxas said that the "Series B venture financing" brought the total capital raised to $40 million.

Vaxxas chief executive officer David Hoey said the company was ready to begin its clinical Nanopatch needle-free vaccination programs.

The company said that the Nanopatch induced a "robust immune system activation by targeting vaccine to the abundant immunological cells immediately below the surface of the skin".

Vaxxas said it intended to apply its technology against major diseases, such as influenza, polio, bacterial infections and cancer.

Vaxxas chairman and Oneventures managing director Dr Paul Kelly said that Oneventures lead the financing.

The company said that it was founded in August 2011 with a $15 million capital raising led by Oneventures with co-investors Brandon Capital, the Medical Research Commercialisation Fund and the US-based Healthcare Ventures.

Vaxxas said it had a collaboration with the US-based Merck & Co to evaluate, develop and commercialize the Nanopatch platform for undisclosed vaccine candidates developed by Merck.

Vaxxas is a private company.

COCHLEAR

Cochlear says that in the six months to December 31, 2014 revenue was up 18.1 percent to $438.3 million and net profit after tax up 240.0 percent to $71.4 million.

Cochlear said that the profit for the six months to December 31, 2013 included a patent provision of $22.5 million before tax and $15.8 million after tax.

The company said that before adjustment for the patent provision, the net profit after tax was up 94.0 percent.

Cochlear said that diluted earnings per share climbed 238.5 percent from 36.9 cents to $1.249 with net tangible assets per share up 22.5 percent to $1.579 at December 31, 2014.

The company said a partly franked interim dividend of 90.0 cents a share would be paid on March 26, 2015, down 29.1 percent on the previous corresponding period for a record date of March 5, 2015.

Cochlear said research and development expenditure was down 5.7 percent to $61,360,000 compared to the previous period's $65,057,000 or 14.0 percent compared to 17.5 percent of total revenue.

Cochlear chief executive officer Dr Chris Roberts told a teleconference that the previous year's expenditure "was high, but R and D spend will stay in double digits".

Dr Roberts said that while there were significant costs in developing products it was also expensive to launch them.

"We are trying to keep it in check but not by starving marketing," Dr Roberts said.

"That's the turbo-charger of a company like this," Dr Roberts said.

Dr Roberts said that the previously recalled CI-512 had returned as the Nucleus Profile, the thinnest implant available and in two models.

Dr Roberts said that the platform of the Nucleus Profile was available with the Slim Straight electrode in Europe and with the Contour Advance electrode in the US.

He said the Nucleus Profile implants were being manufactured at the plant at Macquarie University in Sydney and the US Food and Drug Administration approval for the plant was a significant achievement.

Dr Roberts said that sales in the Americas were up 29.8 percent to $195.3 million, with Asia Pacific sales up 9.8 percent to $63.6 million and sales in Europe, Middle East and Africa were up 7.4 percent to $181.6 million.

In a media release, Cochlear said that no China Central Government tender sale had been booked in either the six months to December 31, 2013 or December 31, 2014, but about 1,900 units were expected to be delivered by July 2015, as part of a Government tender, which was similar to the number supplied in the six months to June 30, 2014.

Cochlear said that implant sales revenue was up 15.7 percent to $383.0 million of which sound processor upgrades contributed $82.2 million, reflecting "strong market enthusiasm for the Nucleus 6 sound processor".

The company said that Cochlear implant unit sales were 11,689, in line with the previous corresponding period and stronger in developed countries, with Western Europe up eight percent and North America up 17 percent, offset by sales in developing countries.

Cochlear said that Bone Anchored Solutions, including acoustic implant sales, were up 25 percent to $57.5 million and the depreciation of the Australian dollar against the US dollar benefited sales by $7.3 million, offset by $2.2 million in foreign exchange contract losses.

The company said that net debt was up 3.2 percent to $171.6 million compared to December 31, 2013, but down 5.35 percent compared with June 30, 2014, while cash and cash equivalents at December 31, 2014 was $58,871,000 compared to $56,127,000 at June 30, 2014.

Cochlear fell 84 cents or 0.96 percent to $86.76 with 678,658 shares traded.

MESOBLAST

Mesoblast says the US Patent and Trademark Office has granted a patent covering its mesenchymal precursor cells for degenerated inter-vertebral discs.
The USPTO website said that the patent was entitled 'Repair and/or reconstitution of invertebral discs' and the invention related "to a method for repair and reconstitution of invertebral discs in a subject which involves administration of STRO-1.sup [human stem cells and] multipotent cells".
"The method of the invention is useful in the treatment of spinal conditions characterized by degeneration of the invertebral disc," the USPTO website said.
Mesoblast said that the patent provided rights to June 2029 with the potential for patent term and regulatory exclusivity extensions.
The company said that the patent was one of a suite of patents that provided "multiple layers of protection for its product candidates in the treatment of low back pain due to degenerating discs".
Mesoblast said that US patents had been granted covering its product candidates for repair and regeneration of inter-vertebral discs and for spinal fusion, including product compositions and methods of use.
The company said it had pending applications for additional claims to broaden and extend protection for its product candidates for the treatment of chronic low back pain.
Mesoblast said that it had begun a US phase III program using mesenchymal precursor cells in patients with chronic discogenic low back pain with the objective of confirming the positive outcomes seen in its 100-patient phase II trial (BD Jan 18, 2015).
The company said that in the phase II trial, product candidate MPC-06-ID demonstrated potential to provide durable improvement in pain and function for patients with chronic discogenic low back pain due to degenerative disc disease (BD: Jan 30, 2014).
Mesoblast said the primary endpoint for the phase III was to confirm the phase II benefit for MPC-06-ID compared to saline control using a composite of durable improvement in pain and function.
Mesoblast said that more than four million patients in the US suffered from with chronic discogenic low back pain with total costs of low back pain estimated to be up to $US200 billion a year.
Mesoblast was up 18 cents or 4.2 percent to $4.46 with 374,312 shares traded.

DRAWBRIDGE PHARMACEUTICALS

Drawbridge says the US Patent and Trademark Office has allowed a patent entitled 'Anaesthetic Formulation' covering neuro-active steroid anaesthetic/sedative compounds.
Drawbridge chief medical officer Prof Colin Goodchild said that neuro-active steroids as a class possessed "useful properties with respect to the pharmacological management of several [central nervous system] diseases".
"The expansion of the library of compounds available to us now opens up other development programs for Drawbridge," Prof Goodchild said.
Drawbridge said that its patent portfolio included patents granted in the US, UK, Australia, New Zealand, Hong Kong, Singapore, South Africa and China for Phaxan anaesthesia and sedation.
The company said that the allowance of the US divisional patent extended the coverage to 2031 for the use of a larger group of neuro-active steroids and preparations for sedation and anaesthesia in critical care situations and complimented divisional patents granted in the UK and Australia.
Drawbridge is a private company.

OTIFEX THERAPEUTICS

Otifex says its phase Ia trial has shown its betahistine nasal spray is safe and well tolerated as a single dose in healthy adult volunteers at all the doses tested.

Otifex said that the randomized, placebo-controlled, double-blind, single ascending dose, trial in healthy volunteers examined safety, tolerability and drug distribution characteristics.

The company said that volunteers receive a single nasal spray dose and once safety was established, doses were increased in subsequent groups of volunteers.

Otifex said that the betahistine nasal spray was being developed for otitis media with effusion, or glue ear, the most common cause of acquired hearing loss in childhood.

Otifex chief executive officer Dr Christopher Wraight said the company was “very pleased with the performance of our betahistine nasal spray in our first clinical trial”.

“While betahistine tablets have been safely used by over 130 million people worldwide, it was important to demonstrate the safety and tolerability of this novel form of the drug for a new disease indication,” Dr Wraight said.

Otifex said that otitis media with effusion affected five million US children each year with more than 500,000 children treated surgically with the insertion of tympanostomy tubes, or grommets, following a “watchful waiting” period when the treating physician assesses whether middle ear fluid shows any signs of clearing naturally.

The company said that there were no treatments available to improve the clearance rate and the strategy was to address the unmet medical need and it was preparing for a phase Ib study in a patient population to address repeat dose safety, tolerability and efficacy.

Otifex is a private company backed by Uniseed and the Brandon Capital-managed Medical Research Commercialisation Fund.

PRESCIENT THERAPEUTICS (FORMERLY VIRAX HOLDINGS)

Last night’s edition described Prescient’s PTX-100 RAS inhibitor candidate as a “renin-angiotensin system (RAS) inhibitor”.

Prescient managing director Dr Robert Crombie has told Biotech Daily that the PTX-100 ”RAS” is an abbreviation of “rat sarcoma, reflecting the way the first members of the protein family were discovered”.

Biotech Daily understands that renin-angiotensin system inhibitors play a role in hypertension or high blood pressure but not in the cancer indications pursued by Prescient.

Biotech Daily’s Prime Fact-Checker apologies unreservedly and says he has been tested and will be much more consultative in future, if given more time to listen to his colleagues.

Prescient fell half a cent or 4.35 percent to 11 cents.

UNILIFE

Unilife says that revenue for the six months to December 31, 2014, was up 0.3 percent to $US6,783,000 ($A8,667,520) with net loss after tax up 43.7 percent to $US42,346,000 ($A54,115,320).

Unilife said that research and development expenses increased from $US14.2 million to $US22.3 million, while “selling, general and administrative” increased from $US13.2 million to $US17.7 million.

The company said it had raised $US44.7 million and at December 31, 2014 it had cash and cash equivalents of $US8,448,000, compared to $$US8,368,000 at June 30, 2014.

Unilife said that diluted loss per share increased 34.5 percent to 39 cents.

Unilife fell four cents or 4.5 percent to 84.5 cents.

MAYNE PHARMA

Mayne Pharma says it will raise $115 million to acquire the Doryx brand acquire rights to two other drugs and fund the start-up costs of a US specialty brands division.

Mayne said that the fully underwritten equity raising comprised a one-for-3.45 accelerated non-renounceable entitlement offer at 61 cents a share to raise about $105.0 million and an institutional placement to raise about $10.0 million.

The company said the balance of the proceeds would fund working capital and general corporate purposes, including for its existing pipeline and potential acquisitions.

Mayne said that it would acquire Doryx and related assets in the US from distribution partner Actavis for $US50 million, payable at completion expected on February 26, 2015.

The company said that Doryx was a delayed-release oral tablet formulation of doxycycline hyclate used as an adjunctive therapy for severe acne and as a treatment for certain bacterial infections and Actavis reported Doryx net revenues of $US60.1 million in the 12 months to December 31, 2014.

Mayne chief executive officer Scott Richards said the Doryx acquisition “transforms the current US business platform into a diversified and integrated pharmaceutical business with exciting growth platforms in generics, contract services and now, specialty brands”.

“Mayne Pharma will now market and distribute the Doryx product in addition to manufacturing it,” Mr Richards said. “We know the Doryx product well and have been manufacturing different formulations of the product for the past 30 years.”

Mayne said it also had agreements to acquire the Butalbital, acetaminophen and caffeine (BAC) capsule and the methamphetamine tablet abbreviated new drug application for up to $US15.7 million.

The company said that methamphetamine tablets were indicated for the treatment of attention deficit disorder and BAC capsules were used to treat tension headaches or migraines and it was currently selling both products and had legacy profit share arrangements with third parties, which for BAC has been amended and for Methamphetamine has been terminated.

Mayne said that the markets for these products ware attractive with limited generic competition and the two transactions were expected to deliver an additional $US300,000 in earnings per month on average from July 2015.

The company said that the entitlement offer and placement are underwritten by Credit Suisse (Australia) and UBS AG, Australia with Credit Suisse Emerging Companies (Australia) acting as financial advisor on the Doryx acquisition.

Mayne was in a trading halt and last traded at 70 cents.

BPH ENERGY

BPH hopes to raise funds through a share plan at about 0.5 cents a share.

BPH said the maximum number of shares to be issued was up to 30 percent of its issued capital, priced at a 20 percent discount to its five-day volume weighted average price to February 9, 2015.

The company closed at 0.5 cents today and its most recent annual report said the company had 172,562,245 shares on offer, implying that it could raise about $200,000.

BPH said the record date was February 9, 2015, the offer would open on February 12 and close on March 6, 2015.

BPH said the proceeds would contribute to the continuing exploration, development and commercialization of investee company assets, including the Cortical Dynamics brain anaesthesia response (BAR) monitor and Avent Energy’s seismic activities.

BPH was unchanged at 0.5 cents.

CYTOMATRIX

Cytomatrix says it has appointed Prof Alan Trounson and Prof Miles Prince to its scientific advisory board.

Cytomatrix said that Prof Trounson and Prof Prince would assist development of its scalable, off-the-shelf, haemopoietic stem cells for bone marrow transplantations and high dose chemotherapy.

The company said that Prof Trounson was “an internationally recognized leader in stem cell research”.

Cytomatrix said that Prof Trounson was formerly the president of the California Institute for Regenerative Medicine and previously the director of Monash Immunology and Stem Cell Laboratories.

The company said that Prof Prince was a haematologist and a professor at both the University of Melbourne and Monash University.

Cytomatrix said that Prof Prince held Australian, American and European research grants and had published more than 300 journal articles.

The company said that Prof Prince would assist in the design and planning of clinical trials.

Cytomatrix chief executive officer Bob Atwill said the three-dimensional expansion technology was making “excellent progress”.

“The appointments of two highly distinguished and globally recognized specialists will provide invaluable input to the future developments of the company,” Mr Atwill said.

Cytomatrix is a private company.