Biotech Daily

Friday March 27, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IDT UP 14%, PHOSPHAGENICS DOWN 9%**

*** PSIVIDA COMPLETES MEDIDUR POSTERIOR UVEITIS TRIAL ENROLMENT**

*** DORSAVI POSTS FIRST UK VIMOVE SALES**

*** MESOBLAST ALLOWED JAPAN ISCHEMIA STEM CELL PATENT**

*** SUDA RAISES $5.3m**

*** VICTORIA, OSAKA TO COLLABORATE ON MEDICAL RESEARCH**

*** UBS AG BUYS, SELLS, BORROWS, RETURNS SIRTEX SHARES BELOW 5%**

*** INVION FOUNDER DR WILLIAM GARNER DOWN TO 6%**

*** PERPETUAL REDUCES TO 7% OF PRO MEDICUS**

*** PHYLOGICA APPOINTS NATASHA FORDE JOINT COMPANY SECRETARY**

MARKET REPORT

The Australian stock market climbed 0.69 percent on Friday March 27, 2015 with the S&P ASX 200 up 40.8 points to 5,919.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and one was untraded. All three Big Caps were up.

IDT was the best, up 2.5 cents or 13.9 percent to 20.5 cents with 644,827 shares traded.

Acrux and Ellex climbed more then six percent; Alchemia and Atcor were up more than five percent; Biotron, Circadian, GI Dynamics and Osprey were up more than three percent; Benitec, Medical Developments, Mesoblast and Starpharma rose two percent or more; Admedus, Resmed and Universal Biosensors were up more than one percent; with Cochlear, CSL and Sirtex up by less than one percent.

Phosphagenics led the falls, down 0.4 cents or 8.9 percent to 4.1 cents with 1.3 million shares traded.

Bionomics, Nanosonics and Tissue Therapies fell more than four percent; Prana and Prima lost more than three percent; Antisense, Genetic Technologies and Impedimed shed more than two percent; with Avita, Clinuvel, Neuren, Oncosil and Optiscan down more than one percent.

PSIVIDA

Psivida says it has completed enrolment of the 120 patients in its pivotal phase III trial of Medidur for the treatment of the blinding eye disease posterior uveitis.

Psivida said it would allow 10 additional patients seeking entry into the trial who met the entry criteria, which was expected to report top line data by the end of 2016, and based on the results, to file for regulatory approval in late 2016 or early 2017.

The company said that the trial was a double-blind study comparing injections of Medidur to sham injections randomized on a two-to-one basis, with a primary end point of the recurrence of posterior uveitis within one year.

Psivida said it would seek approval based on the safety and efficacy data from the single phase III trial together with short term data from a utilization study of its proprietary inserter and the US Food and Drug Administration had confirmed that it could reference much of the data from the phase III clinical trials of Iluvien for diabetic macular oedema.

The company said the Massachusetts Eye Research & Surgical Institute had enrolled the most patients in the study and its chief executive officer Dr C Stephen Foster said the trial was “a major advance in the treatment of uveitis ... with the delivery of medication into the vitreous cavity without the need for travel to an operating room and with effective provision of corticosteroid for a sustained three years”.

Psivida said that Medidur was an injectable micro-insert delivering the steroid flucinolone acetonide on a sustained basis for 36 months and used the same micro-insert as the US and European approved Iluvien for diabetic macular oedema which it also developed.

The company said that posterior uveitis was a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, producing swelling and destroying eye tissues, which could lead to severe vision loss and blindness, with about 175,000 people in the US affected, resulting in about 30,000 cases of blindness making it the third leading cause of blindness.

The company said that patients with posterior uveitis were typically treated with systemic steroids but frequently developed side effects limiting dosing and patients progressed to immune suppressants or biologics, with severe side effects including an increased risk of cancer.

Psivida chief executive officer Dr Paul Ashton said that “based on results of a phase II study and prior experience with this implant, we believe that Medidur will provide improved outcomes compared to standard-of-care but with a significant reduction in side effects”.

“Medidur should also lower treatment costs and offer the reduced invasiveness of an injection every three years compared with the frequent administration of existing therapies,” Dr Ashton said.

Psivida was unchanged at $5.10.

DORSAVI

Dorsavi says it has had its first sales into the UK public health system in England and Northern Ireland.

Dorsavi said that the Royal Preston Hospital, part of the Lancashire Teaching Hospitals National Health Service Trust would use its Vimove live assessment and monitoring applications to capture objective data on a patient’s movement before and after pharmaceutical intervention.

The company said that the Northern Ireland Western Health and Social Care’s Altnagalvin Hospital Rheumatology Department would use Vimove in a research program to measure movement in patients with ankylosing spondylitis, an arthritis of spinal joints.

Dorsavi was up half a cent or 1.7 percent to 30.5 cents.

MESOBLAST

Mesoblast says it has been allowed a Japanese patent covering its adult mesenchymal precursor cells for the formation and repair of blood vessels in ischemic tissues.
Mesoblast said the patent, entitled 'Perivascular Mesenchymal Precursor Cell Induced Blood Vessel Formation', covered the use of these cells derived from bone marrow, adipose tissue and dental pulp and provided commercial rights in Japan to March 29, 2024, with potential for an extension of up to five years based on duration of clinical development.
The company said that the allowed claims covered the use of its allogeneic or off-the-shelf mesenchymal precursor cells for cardiovascular conditions including congestive heart failure, ischemic heart disease, coronary artery disease, acute myocardial infarction and angina, as well as for certain neurological conditions such as cerebrovascular ischemia or stroke, renal ischemia and limb ischemia, or peripheral arterial disease.
Mesoblast said it had been previously granted a European patent from the same patent family, which provided exclusive commercial rights in Europe to at least March 29, 2024, with similar patent claims pending in the US.
The company said the patent extended and broadened its intellectual property position in Japan with respect to the treatment of cardiac and vascular diseases beyond a previously allowed patent covering allogeneic culture-expanded mesenchymal stem cell product candidates for treating damaged heart muscle to improve heart function and would strengthen its commercial strategy in Japan under the Pharmaceuticals, Medical Devices and Other Therapeutic Products Act, which established a framework for expedited approval in Japan for regenerative medical products.
Mesoblast said it had about 67 patent families, including more than 625 patents or patent applications, that provided substantial competitive advantages for the commercial development of regenerative medicine products based on mesenchymal lineage cells.
Mesoblast was up seven cents or two percent to $3.65 with 1.5 million shares traded.

SUDA

Suda says it has raised $5.3 million in a "heavily over-subscribed" placement of 146.5 million shares at 3.6 cents a share.
Suda said the funds would be used to add value to two of its oral sprays SUD-001 sumatriptan spray for migraine headache and SUD-003 sildenafil, or Duromist oral spray for treatment of erectile dysfunction, working capital and support development activities.
The company said that in parallel to its partnering discussions with pharmaceutical companies, it would begin scale-up manufacturing and further clinical studies to confirm the advantages of the two oral sprays compared to the standard-of-care tablets;
Suda said that discussions were ongoing with more than 80 pharmaceutical companies spanning Zolpimist for insomnia, Artimist for paediatric malaria, as well as SUD-001, SUD-002 for nausea and vomiting, SUD-003 and SUD-005 for anxiety, as well as oral sprays for product line or franchise extensions.
Suda chief executive officer Stephen Carter said that following the placement, "Suda will be in an exceptionally strong financial position".
"We will have the capital to continue to build value in our portfolio of first-in-class oral sprays and to accelerate the commercialization process for a number of our key products," Mr Carter said. "Our objectives over the next 12 months include some key value inflection points based on licensing or outright sales of our lead projects."
Suda said that Hartleys acted as lead manager to the placement.
Suda fell 0.1 cents or 2.4 percent to four cents with 3.8 million shares traded.

VICTORIA GOVERNMENT

The Victoria Government says that Biomedical Research Victoria and Osaka University's Graduate School of Medicine will collaborate on medical research.

Victoria Minister for Innovation Adem Somyurek said the two organizations had signed a memorandum of understanding to facilitate joint medical research and provide a framework for Victorian researchers and organizations to engage with Osaka University in health and medical research.

A media release from Mr Somyurek said the agreement would "pave the way for the exchange of selected life science experts to attend forthcoming events in Melbourne and Osaka including Ausmedtech 2015 in April, Ausbiotech 2015 and Australia Biotech Invest in October and the Medical Japan exhibition next year.

SIRTEX MEDICAL

The Singapore-based UBS AG and related bodies corporate says they have ceased their substantial shareholding in Sirtex.

Last week, UBS AG became substantial in Sirtex with 3,028,395 shares or 5.36 percent (BD: Mar 20, 2015).

UBS AG said that between March 18 and March 24, 2015, in more than 100 separate trades, it bought, sold, borrowed and returned shares held for various custodians with the "power to control disposal over shares pursuant to stock borrowing and lending activities".

Sirtex was up 15 cents or 0.75 percent to $20.17 with 813,557 shares traded.

INVION

Invion founder Dr William Garner has again reduced his substantial holding, this time from 54,805,774 shares (9.59%) to 33,296,310 shares (5.828%).

Dr Garner said that on March 23 and 24, 2015 he sold 23,509,469 shares for $850,608 or an average price of 3.62 cents a share.

Last year, Dr Garner reduced his holding to 11.24 percent selling at 7.57 cents a share and in 2013, Dr Garner was replaced as chief executive officer by Dr Greg Collier and was described at the time as Invion's largest shareholder (BD: May 6, 2013; Mar 26, 28, 2014).

Invion was unchanged at 3.3 cents with 6.1 million shares traded.

PRO MEDICUS

Perpetual and its subsidiaries have reduced their holding in Pro Medicus from 7,794,273 shares (7.77%) to 6,768,586 shares (6.85%) selling shares between October 14, 2014 and March 25, 2015 at prices ranging from 84 cents or $1.60.

Pro Medicus was unchanged at $1.60.

PHYLOGICA

Phylogica says it has appointed Natasha Forde as a joint company secretary, effective from March 26, 2015.

Phylogica was up 0.2 cents or 8.3 percent to 2.6 cents.