Biotech Daily

Tuesday March 21, 2017

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: GENETIC SIGS UP 22%, DIMERIX DOWN 8%**

*** MIPS: 'INHALED OXYTOCIN EQUALS IM FOR POST-BIRTH BLEEDING'**

*** DIMERIX RECEIVES $422k FEDERAL R&D TAX INCENTIVE**

*** MEDICAL DEVELOPMENTS OPENS MANUFACTURING FACILITY**

*** PROTEOMICS TO ADVANCE PROMARKERD KIDNEY TEST IN ASIA**

*** ADALTA EXPANDS ALFRED AD-114 FOR IPF COLLABORATION**

*** ZELDA PAYS CAZIWELL $300k NOW TO SAVE $200k LATER**

*** NICHOLAS MCDONALD REDUCES TO 5% IN BIOTECH CAPITAL**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Tuesday March 21, 2017, with the ASX200 down 4.3 points to 5,774.6 points.

Nineteen of the Biotech Daily Top 40 stocks were up, seven fell, 10 traded unchanged and four were untraded.

Genetic Signatures was the best, up eight cents or 21.6 percent to 45 cents with 51,000 shares traded, followed by Mesoblast up 12.7 percent to $2.39 with 1.5 million shares traded.

Actinogen climbed 5.2 percent; Factor Therapeutics and Living Cell improved more than four percent; IDT, Orthocell, Prima and Reva were up more than three percent; Cyclopharm, Nanosonics and Pro Medicus rose more than two percent; Acrux, Bionomics, Cochlear, Osprey, Pharmaxis, Resmed, Sirtex and Viralytics were up more than one percent; with Medical Developments up 0.2 percent.

Dimerix led the falls, down 0.05 cents or 7.7 percent to 0.6 cents with 100,000 shares traded.

Airxpanders and Cellmid were down more than three percent; Uscom shed 2.6 percent; with Clinuvel, CSL, Ellex and Starpharma down by less than one percent.

MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

Monash Institute of Pharmaceutical Sciences says that 400 micrograms of inhaled oxytocin is equal to 17 micrograms injected for post-partum haemorrhage.

MIPS project leader Prof Michelle McIntosh told Biotech Daily that post-partum haemorrhage occurred when contractions stopped early after birth, not completing the process of contracting blood vessels.

Prof McIntosh said that oxytocin stimulated contractions to continue.

In a media release the Institute said that the first-in-human study compared intra-muscular injection of oxytocin to an inhaled version developed with Glaxosmithkline.

The Institute said that more than 300,000 women in low and low-middle income countries died during pregnancy and childbirth, with post-partum haemorrhage the single largest cause of the deaths.

MIPS said that oxytocin was widely used in wealthy countries, but as an injection, it required refrigeration and a medical professional to administer it safely.

The Institute said that to address the unmet need, its collaborated with Glaxosmithkline in London to develop an inhalable, dry-powder oxytocin.

MIPS said that Glaxosmithkline sponsored the study and the results were presented at the Royal College of Obstetricians and Gynaecologists meeting in Cape Town, South Africa.

The poster, entitled 'Increasing access to oxytocin for the prevention of post-partum haemorrhage in resource-limited settings: phase I data for a heat-stable, dry-powder formulation of inhaled oxytocin in healthy, non-pregnant volunteers' was published by the British Journal of Obstetrics and Gynaecology as poster number JP238 and is available at: http://onlinelibrary.wiley.com/doi/10.1111/1471-0528.9_14572/full.

MIPS said that the study demonstrated that 15 of 16 women completed the study and in the cohort of non-pregnant female volunteers, the effects of inhaled oxytocin were not meaningfully different from the injected counterpart.

The Institute said the results gave "confidence" that inhaled oxytocin would deliver similar effects in prevention of post-partum haemorrhage when given to mothers immediately after giving birth.

Prof McIntosh said the data offered "hope to the many women in resource-constrained settings who do not currently have access to this essential medicine".

"These results show that oxytocin can be delivered similarly via inhalation or injection and therefore we are less likely to be required to conduct the extensive and costly trials needed for an entirely new drug," Prof McIntosh said.

"Instead, we should be able to move forward with trials on a much smaller scale, featuring patients numbering in the hundreds rather than tens of thousands, potentially making the medicine available much sooner," Prof McIntosh said.

MIPS said it had begun recruiting patients for a phase Ib/IIa trial evaluating inhaled oxytocin when given to women immediately after birth, the time at which oxytocin was routinely administered for prevention of post-partum haemorrhage.

DIMERIX THERAPEUTICS

Dimerix says it has received $421,549 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Dimerix said that Federal R&D Tax Incentive refund related to expenditure in the year to June 30, 2016 for its receptor-HIT platform technology development program evaluating new therapeutic treatments targeting G-protein coupled receptors.

Dimerix fell 0.05 cents or 7.7 percent to 0.6 cents.

MEDICAL DEVELOPMENTS

Medical Developments has opened its new manufacturing facility in Scoresby in Melbourne's Eastern suburbs.
Medical Developments chief executive officer John Sharman told Biotech Daily that the new facility would have the capacity to produce 25,000,000 doses of methoxyflurane 3mg a year compared to existing 2,000,000 doses a year.
Mr Sharman said the company moved to the new facility in November 2016, construction was completed in February 2017 with a Australian Therapeutic Goods Administration inspection scheduled for April.
Mr Sharman said the company expected to have good manufacturing practice certification by October with full production expected by the end of the year.
He said that as part of the regulatory process the company would begin manufacture for validation about the middle of the year.
Mr Sharman said that the facility had space to manufacture the rebreathing equipment and regulators that made up the Komassaroff Bags used by ambulance services and had offices for administration and management staff as well as three separate research and development laboratories.
He said that the building could host up to 45 research, manufacturing and administration staff.
Medical Developments was up one cent or 0.2 percent to $5.21.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it will advance deals with partners in Singapore and China to bring its Promarkerd test for kidney disease to Asia.
Proteomics managing-director Dr Richard Lipscombe said that "novel biomarker research is likely to transform the future of obesity and diabetes management".
The company said that kidney disease was one of the major complications of diabetes, affecting about one-third of adult diabetics and keeping people on dialysis cost more than $100,000 per person each year, with the global cost of diabetes $US673 billion in 2015.
Dr Lipscombe said early detection was the key to saving lives and money.
"Promarkerd means we can accurately predict if someone will get the disease in the next four years so they can take life-stye and medication action immediately to cut their risks," Dr Lipscombe said.
Proteomics was up two cents or 11.4 percent to 19.5 cents.

ADALTA

Adalta says it has expanded its collaboration on idiopathic pulmonary fibrosis with Melbourne's Alfred Hospital's Dr Glen Westall and his team.
Adalta said the collaboration was working to validate further its lead candidate AD-114's role in the treatment of idiopathic pulmonary fibrosis and would run for an additional six months and be funded by a Federal Government Innovation Connection grant as well as from the company's research, development and clinical budget.
Adalta chief executive officer Sam Cobb said the company's collaborations and strategic alliances "further enhance the potential for the success of our new treatments for fibrosis".
Dr Westall said he was "excited to continue working with Adalta to further understand this complex fibrotic disease and how the company's novel I-body [technology] may play a role in the treatment of [idiopathic pulmonary fibrosis], for which there is currently no cure".
Adalta climbed four cents or 20 percent to 24 cents.

ZELDA THERAPEUTICS

Zelda says it has a new licence agreement with Caziwell Inc and the payment of $300,000 to Caziwell would extinguish a future $500,000 payment.

Zelda executive chairman Harry Karelis told Biotech Daily that the San Francisco California-based Caziwell was the parent company of the not-for-profit Aunt Zelda's.

In a media release Zelda said that the agreement meant it would maintain exclusive access to patient data, cannabis formulations and protocols for use in its current research activities, with the immediate $200,000 saving and a permanent reduction in future royalty and sub-licence fees.

The company said the new agreement would increase its flexibility to expand its clinical trial program.

Zelda said the original agreement provided exclusive access to patient data concerning the medicinal properties of cannabis formulations and protocols for its use in pre-clinical and human clinical trials and related activities.

The company said the new agreement maintained its exclusive access to patient data, formulations and protocols for use in its pre-clinical research activities in cancer and clinical research activities in sleep disorder and dermatology conditions, but increases the "flexibility to pursue other clinical stage opportunities".

Zelda said that future royalties were reduced from 10 percent to five percent, with sub-licence fees reduced from 25 percent to 10 percent.

The company said that the $300,000 payment eliminated future milestone payments for sleep and dermatology-related clinical trials and allow it to in-licence third party programs with no further financial obligations to Caziwell, saving $200,000 this year, given obligations to pay two clinical trial milestone fees for its proposed sleep disorder and dermatology clinical trials.

Mr Karelis said the restructured agreement moved the company "closer to industry standards".

"We have a full pipeline of opportunities ahead of us and reducing future expenses helps extend our financial capacity to progress these projects," Mr Karelis said.

Zelda was up half a cent or 6.4 percent to 8.3 cents with 25.4 million shares traded.

BIOTECH CAPITAL

Nicholas McDonald says he has reduced his holding in Biotech Capital from 7,755,209 shares (6.87%) to 6,685,453 shares (5.26%).

The substantial shareholder notice said the shares were held by the Sydney-based Mr McDonald directly and as a director of Pritdown Pty Ltd but did not specify the consideration.

Earlier this month, Biotech Capital raised $595,000 through a share plan at 11 cents a share following an oversubscribed placement at the same price, which raised $1,791,864 (BD: Feb 14, Mar 8, 2017).

Biotech Capital fell one cent or 7.1 percent to 13 cents.