Biotech Daily

Monday April 4, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PRO MEDICUS, MEDICAL DEVELOP UP 10.5%**
- ONCOSIL, UNIVERSAL BIOSENSORS DOWN 6%

*** MERCY HEALTH SIGNS $21m, 7-YEAR PRO MEDICUS VISAGE 7 DEAL**

*** BIONOMICS STARTS PHASE I BNC101 CANCER STEM CELL TRIAL**

*** STARPHARMA: 'DEP-CABAZITAXEL BREAST CANCER EFFICACY IN MICE'**

*** MEDICAL DEVELOPMENTS APPOINTS MIDDLE EAST DISTRIBUTOR**

*** BIOTECH CAPITAL ACQUIRES BIOINTELECT FOR 10m SHARES**

*** INVION: 'FDA BACKS INV102 PHASE III SMOKING CESSATION PLANS'**

*** LIVING CELL SHARE PLAN RAISES $483k, TOTAL $3.3m**

*** SIMAVITA, POINTCLICKCARE TO INTEGRATE SYSTEMS**

*** ADHERIUM EUROPE OFFICE, APPOINTS JOHN TARPLEE**

*** CELLMID 4th MIDKINE SYMPOSIUM IN BUDAPEST**

MARKET REPORT

The Australian stock market slipped 0.08 percent on Monday April 4, 2016 with the ASX200 down 4.1 points to 4,995.3 points. Fifteen of the Biotech Daily Top 40 were up, eight fell, 10 traded unchanged and seven were untraded. All three Big Caps were up.

Pro Medicus was the best, up 36 cents or 10.53 percent to $3.78 with 473,322 shares traded, followed by Medical Developments up 10.48 percent to $5.80 with 133,322 shares traded. Genetic Technologies and Starpharma climbed more than five percent; Admedus was up 3.1 percent; Acrux, Mesoblast and Prima rose more than two percent; Clinuvel, Compumedics, Nanosonics, Orthocell, Pharmaxis, Resmed and Sirtex were up one percent or more; with Cochlear, CSL and Ellex up by less than one percent.

Oncosil and Universal Biosensors led the falls, both down 5.88 percent to 16 cents and 32 cents, respectively, with 712,906 shares and 8,609 shares traded, respectively. Actinogen and Cellmid lost more than five percent; Neuren fell 4.35 percent; Antisense shed 2.5 percent; with Biotron and IDT down more than one percent.

PRO MEDICUS

Pro Medicus says US subsidiary Visage Imaging has signed a $21 million, seven-year contract with Mercy Health System.

Pro Medicus said the Mercy was “the seventh largest Catholic health care system in the US” and the contract would see its Visage 7 imaging technology implemented across Mercy’s 46 acute care and specialty hospitals, supporting more than 2,000 physicians and 40,000 employees in Missouri, Arkansas, Oklahoma and Kansas.

The company said that when fully implemented Visage 7 would be a key component of Mercy’s image viewing platform and would be used for primary diagnoses, clinical distribution and access to radiology images through Mercy’s electronic health record system.

Pro Medicus said that Mercy was the founder and major shareholder of health care supply-chain organization Resource Optimization & Innovation (ROI) and as part of this deal Visage Imaging has entered into a master purchasing agreement with ROI, with the Mercy the first under the ROI agreement, paving the way for all ROI members to benefit from the group-wide purchasing agreement.

The company said that project planning would begin by July 2016, with the first phase of the implementation to begin by October 2016 and take up to 16 months to complete.

Pro Medicus said the deal was the fourth significant enterprise imaging deal in the past 12 months, following similar deals with the $9.5 million University of Florida Health in April 2015, $11 million Allegheny Health Network in September 2015 and a $3 million deal with an unnamed German government-run hospital in November 2015.

Pro Medicus chief executive officer Dr Sam Hupert said the Mercy agreement “significantly [adds] to our growing footprint in the enterprise hospital space … [and] further endorses our belief that we have unique technology that is ideally suited to address the needs of the large and diverse North American market”.

“By using Visage 7, Mercy will be able to transform its use of medical imaging across its large and distributed health enterprise, paving the way for other ROI members to do the same,” Dr Hupert said.

Pro Medicus climbed 36 cents or 10.5 percent to $3.78 with 473,322 shares traded.

BIONOMICS

Bionomics says it has begun an up-to-60 patient, dose-escalation, phase I trial of anti-cancer stem cell drug candidate BNC101 for metastatic colorectal cancer

Bionomics said the US Food and Drug Administration approved its investigational new drug application last year and pre-clinical studies supporting the application showed that BNC101 was well tolerated with no adverse dose identified (BD: Aug 31, 2015).

Bionomics chief executive officer Dr Deborah Rathjen said the trial start was “an important milestone”.

Last year, the company said it hoped to begin the trial by the end of 2015.

Bionomics said that the open label, multi-centre, Australian trial would aim to demonstrate that BNC101 was safe and well-tolerated and that it was able to delay disease relapse in treated patients.

The company said that the two part trial would study BNC101 alone and in combination with standard of care chemotherapy.

Bionomics said that the principal investigator was Royal Melbourne Hospital oncologist Dr Jayesh Desai.

Bionomics was unchanged at 32 cents.

STARPHARMA

Starpharma says its dendrimer enhanced cabazitaxel has shown efficacy in a human breast cancer model in mice.

Starpharma said that the dendrimer enhanced or DEP-cabazitaxel was a water-soluble version of cancer drug cabazitaxel marketed by SanofiAventis as Jevtana which had 2015 sales of about $US430 million, was registered for advanced prostate cancer and was under development for other cancers, including breast cancer.

The company said that like the docetaxel cancer drug, cabazitaxel was formulated with the detergent polysorbate 80 due to its poor solubility and could be associated with anaphylaxis and neutropenia, but DEP-cabazitaxel was detergent free.

Starpharma said the xenograft mouse trial showed that the DEP-cabazitaxel significantly outperformed cabazitaxel with respect to both level and duration of tumor regression, or anticancer activity and within four weeks of dosing, 100 percent of mice treated with DEP-cabazitaxel were tumor-free and remained so for the duration of the extended study of 150 days, while the Jevtana-treated group exhibited significant tumor regrowth from day-60 onwards.

The company said that tumor growth in both drug treated groups was significantly inhibited compared with the vehicle group ($p < 0.0001$).

Starpharma said that DEP-cabazitaxel-treated animals showed 100 percent survival to the end of the experiment and survival was significantly prolonged compared to Jevtana, which also had a better survival outcome compared to controls ($p < 0.0001$).

Starpharma chief executive officer Dr Jackie Fairley said the company was “very encouraged by these results for DEP-cabazitaxel, our latest development candidate”.

“The growing body of evidence of both efficacy-enhancement and survival benefits with DEP formulations is very positive and illustrates the utility and platform nature of Starpharma’s DEP technology,” Dr Fairley said.

“Early indications for DEP-cabazitaxel are that it also demonstrates similar safety benefits to what we have seen with DEP-docetaxel and other DEP conjugates in terms of reduced bone marrow toxicity,” Dr Fairley said.

Starpharma was up four cents or 5.7 percent to 74 cents with 1.1 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has appointed Pharma Solutions LLC to sell and and market Penthrox in the United Arab Emirates, Jordan, Iraq, Oman and Bahrain.

Medical Developments said that the Dubai, United Arab Emirates-based Pharma Solutions would take over the registration activities for the Penthrox methoxyflurane analgesic inhaler in those countries.

Medical Developments chief executive officer John Sharman said there was “a significant need for a non-narcotic trauma analgesic in the Middle East”.

“Pharma Solutions are forecasting strong growth for Penthrox sales in the UAE and have placed an initial order for Penthrox worth $240,000,” Mr Sharman said.

“This is an exciting deal for Penthrox in the Middle East and adds to our existing distribution agreements in Qatar where we are already making sales and in Saudi Arabia and Israel, where our partners have filed drug registration applications,” Mr Sharman said.

Medical Developments chairman David Williams said the agreement was “another small step in the globalization of Penthrox and hopefully we will add other countries as the year progresses”.

Medical Developments climbed 55 cents or 10.5 percent to $5.80 with 133,322 shares traded.

BIOTECH CAPITAL

Biotech Capital says it has acquired the Sydney-based advisory firm Biointelect for 10,000,000 shares, worth $1.3 million.

Biotech Capital said that Biointelect was profitable, expected strong growth and the acquisition was consistent with its strategy of investing in life science businesses with strong growth potential, which would benefit from greater access to capital".

The company said the transaction has been approved by Innovation Australia's board under the Pooled Development Fund Act 1992.

Pooled development funds have tax benefits including tax-free dividends as well as being capital gains tax exempt, but capital losses cannot be claimed.

Biotech Capital said that Biointelect provided development and commercialization services for the biotechnology, medical device and pharmaceutical industry, including clinical, regulatory, market evaluation, reimbursement strategies and partnering advice.

The company said Biointelect was established in 2011 by Jennifer Herz, with Karl Herz later joining the company and both had experience across the life sciences sector, and employed consultants and was expanding its client base, network and services.

Biotech Capital chairman Dr Richard Treagus said the acquisition of Biointelect was "a very important step in our longer-term growth plans".

"By combining our resources, it significantly strengthens our ability to further invest and build a group of complimentary life science businesses," Dr Treagus said.

Biotech Capital said it had issued 10,000,000 shares to a related party of Ms Herz.

Biotech Capital's share price has been increasing since 2014 when Neuren chairman Dr Treagus and his wife Karen Treagus acquired 2,000,000 shares at five cents a share and later the Lang Walker-related Auckland Trust Co acquired 12,860,583 shares at eight cents a share, with Lang Walker investments director Bruce Hancox appointed a non-executive director (BD: Oct 13, 2014; Sep 1, 2015).

The company said that Ms Herz would be appointed a Biotech Capital director and lead Biointelect, with both Ms and Mr Herz signing contracts, including options over 1,000,000 shares each in Biotech Capital, exercisable at 15.9 cents each, in four tranches.

Biotech Capital was up one cent or 7.7 percent to 14 cents.

INVION

Invion says the US regulator supports its plans for INV102 for chronic respiratory disease patients who can't quit smoking due to increased cough and sputum.

Invion said that it met with the US Food and Drug Administration to discuss phase III plans for INV102, or oral nadolol, for patients with chronic obstructive pulmonary disease who cannot quit cigarette smoking and the FDA supported manufacturing plans for the trial and confirmed that the animal toxicology package was complete.

Invion said its staff explained the role that airway healing could play in enabling patients to quit smoking by reducing cough and phlegm and were able to place the smoking cessation program in the context of treating chronic obstructive pulmonary disease.

Invion head of research and development and chief medical officer Dr Mitchell Glass said "the FDA has confirmed our plans for INV102 as a treatment for patients with established chronic bronchitis who cannot quit smoking due to increased cough and sputum production".

Biotech Daily has repeatedly asked Invion for evidence that smokers fail to give up cigarettes due to increased cough and sputum production, as compared to other reasons such as personal will-power, but without response.

Invion was up 0.1 cents or 20 percent to 0.6 cents.

LIVING CELL TECHNOLOGIES

Living Cell says its share purchase plan has raised $482,607 through the issue of 9,532,034 shares at 5.063 cents a share.

In February, Living Cell said that it raised $2,764,621 through a placement at the same price and the total $3,247,228 would fund the implants in the phase IIb clinical trial of NTCell for Parkinson's disease which began last month (BD: Feb 17, Mar 24, 2016).

Living Cell was unchanged at 5.2 cents.

SIMAVITA

Simavita says it will work with Pointclickcare to integrate its Smart Incontinence Management system with Pointclickcare's electronic health record platform.

Simavita said that the Mississauga, Ontario-based Pointclickcare was "the leading cloud-based software platform for the senior care continuum" and the agreement would ensure system interoperability between the Smart Incontinence Management (SIM) system and the electronic health record platform and the two companies would work together to deploy the integrated products and respective technologies to the aged care sector in North America.

The company said that integration would enable long-term care organizations using the Pointclickcare platform to use 72-hour continence assessment information collected by the SIM technology into their overall healthcare system, while SIM would be able to draw on data held in the Pointclickcare system and provide time efficiencies for carers, eliminate double handling of records, remove the risk of inaccuracies and result in a streamlined customer experience.

Simavita said that the use of electronic health records by senior care providers was mandated in the US.

Simavita chief executive officer Philippa Lewis said the Pointclickcare platform was "known for its design interoperability allowing integration of unique third party solution providers such as Simavita's SIM".

"This integration with Pointclickcare will not only open the way for us to further access the burgeoning North American market, but will also allow Pointclickcare to extend the benefits of SIM to its existing, and future customers," Ms Lewis said.

Simavita was up 0.8 cents or 17.8 percent to 5.3 cents.

ADHERIUM

Adherium says it has established Adherium Europe, based in Guildford, England and appointed John Tarplee as senior vice-president of business development.

Adherium said that Mr Tarplee would lead market development and partnering for European for the company's digital health products to pharmaceutical, remote patient monitoring and clinical trials companies.

The company said that Its Smartinhaler platform and products were Conformité Européenne (CE) mark approved and comprised a range of medication sensors attached to prescription inhalers, along with software integrating data from the Smartinhalers into a usable form.

Adherium said that Mr Tarplee was previously an executive with Danish speciality allergy immunotherapy company ALK-Abello and before that Mr Tarplee spent 10 years at Sanofi-Aventis as UK business unit director, and had worked for Abbott Laboratories and in Fisons Pharmaceuticals.

Adherium was unchanged at 50 cents with 1.2 million shares traded.

CELLMID

Cellmid says it will hold its fourth midkine symposium in Budapest, Hungary, from April 28 to 30, 2016.

Cellmid said that the symposium would be a meeting of key opinion leaders, clinicians and scientists involved in midkine research with experts from 11 countries representing a number of therapeutic and diagnostic fields.

The company said it previously held midkine scientific meetings in Sydney, Istanbul and Kyoto, resulted in collaborations, including the most recent preclinical agreement with Complutense University in Madrid, where researchers were assessing its midkine antibodies in a glioblastoma model in conjunction with cannabinoid treatment, amongst other studies.

Cellmid said that the even would be hosted by partner Pharmahungary and the Hungarian Institute of Foreign Affairs and Trade.

The company said that the agenda included presentations on unpublished and patentable research, so the meeting and lectures would not be recorded.

Cellmid fell 0.1 cents or 5.6 percent to 1.7 cents.