



Biotech Daily

Tuesday March 31, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: GENETIC TECHNO UP 48%, CIRCADIAN DOWN 9%**
- * **DR BILL KETELBEY PAINTS THE ACTINOGEN RENAISSANCE**
- * **GENETIC SIGNATURES OPENS UP 20% AT 48c**
- * **RHINOMED SIGNS EBOS SYMBION FOR MUTE DISTRIBUTION**
- * **ITL EXPANDS MALAYSIAN MANUFACTURING FACILITY**
- * **PHARMAUST GRANTED JAPAN PPL-1 COLLABORATION PATENT**
- * **USCOM: 'AMA CPT CATEGORY 1 CODE APPLIES TO BP+'**
- * **GENETIC TECHNOLOGIES PLEADS NASDAQ, AGAIN, TO ASX 52% QUERY**
- * **MINDEROO (METAL) GROUP FURTHER, DILUTED TO 11% OF ADMEDUS**
- * **GOLDMAN SACHS BUYS, 'BORROWS' TAKES 5% OF NANOSONICS, AGAIN**
- * **CM CAPITAL INCREASES, DILUTED TO 8.6% OF OSPREY**
- * **CELLMID APPOINTS LUCY ROWE COMPANY SECRETARY**

MARKET REPORT

The Australian stock market rose 0.78 percent on Tuesday March 31, 2015 with the S&P ASX 200 up 45.4 points to 5,891.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and two were untraded. All three Big Caps were up.

Genetic Technologies was best, up 1.5 cents or 48.4 percent to 4.6 cents with 57.5 million shares traded, followed by Patrys up 1.1 percent to one cent with 1.25 million shares traded. Biotron climbed 7.1 percent; Benitec and Uscom were up five percent or more; Cellmid rose 4.55 percent; Acrux, Neuren and Prana were up more than three percent; Alchemia, Avita, Oncosil, Resmed and Sirtex were up one percent or more; with Cochlear, CSL, Impedimed, Medical Developments and Mesoblast up by less than one percent.

Circadian led the falls, down 1.5 cents or 8.8 percent to 15.5 cents with 21,500 shares traded, followed by Analytica down 8.3 percent to 2.2 cents with 768,146 shares traded. Osprey lost 5.5 percent; IDT and Tissue Therapies fell more than four percent; Pharmaxis was down 3.85 percent; Admedus, Atcor, Clinuvel and Universal Biosensors shed two percent or more; with Anteo, Bionomics and Ellex down more than one percent.

ACTINOGEN MEDICAL

Actinogen chief executive officer Dr Bill Ketelbey says his company which listed in 2007 to develop actinomycetes “is really only four months old”.

Actinogen attempted to commercialize two actinomycetes, found in Western Australian soil, which produced compounds which showed antibiotic activity against methicillin-resistance staphylococcus aureus and vancomycin resistant enterococci bacteria.

The previous management was unable to make headway and late last year the shell was taken over and the 11-beta-hydroxysteroid dehydrogenase type 1 (11bHSD1)-inhibitor UE2343 was licenced from the University of Edinburgh as a potential treatment for Alzheimer’s disease and renamed Xanamem (BD: Aug 27, 2014).

Dr Ketelbey joined Actinogen following 30 years in the sector, much of it in senior roles with Pfizer, having qualified as a medical doctor at the University of the Witwatersrand, South Africa and earning a Masters of Business Administration at Macquarie University.

At Pfizer he was responsible for leading the development of a range of medicines including for Alzheimer’s disease and was involved in developing monoclonal antibodies directed at amyloid plaques, a hallmark of Alzheimer’s disease.

With a complete change of board and management, relocation to Sydney and the appointment of a new scientific advisory board, the company was effectively reborn.

“[Actinogen] is not well known and we need to explain our asset Xanamem to the finance community and the research community,” Dr Ketelbey said.

Dr Ketelbey said a phase I single dose safety trial had been conducted in Wales and a toxicology program completed in dogs, before Actinogen acquired UE2343.

He said the second phase I trial was being conducted by Linear Clinical Research at the Sir Charles Gairdner Hospital in Perth, Western Australia and the first cohort of eight volunteers had been dosed at 10mg oral Xanamem twice daily for nine days, with the independent dose escalation committee approving the second cohort at 20mg, and the third cohort at 35mg expected to be completed by the end of April, followed by a 12 volunteer trial comparing Xanamem on subjects who had been fed to subjects fasting and concluding with a further four volunteers undergoing lumbar puncture to confirm central nervous system pharmacokinetics and plasma and cerebro-spinal fluid levels.

“All the data is expected to be completed by mid-year to inform the phase II protocol currently under development,” Dr Ketelbey said.

He said that the phase II trial of Xanamem in early Alzheimer’s patients and those with mild cognitive impairment, or prodromal Alzheimer’s disease would begin in early 2016 in Australia, the UK and the US, and be concluded by the end of 2017.

“The advisory board met on March 20 and is about to sign-off with a trial design to optimally inform the safety and efficacy of Xanamem in Alzheimer’s disease and allow for statistical significance,” Dr Ketelbey said.

He said the company had funds for all the phase I and pre-clinical work, but would need to raise capital for the phase II trial.

Dr Ketelbey said that when the stress hormone cortisol was chronically elevated it was associated with cognitive impairment, neural death, amyloid plaquing and hippocampus shrinkage, all hallmarks of Alzheimer's disease.

"If we can lower the cortisol it will benefit the symptoms and the patient, which has been shown through the work in rodents," Dr Ketelbey said.

He said that there was indirect evidence that the broad HSD inhibitor carbenoxolone reversed cognitive impairment in elderly type 2 diabetes patients.

Dr Ketelbey said that by blocking cortisol over-production, Xanamem had potential against cognitive dysfunction in schizophrenia, depression and diabetes, potential in treating obesity and type 2 diabetes, cardiovascular disease, post-traumatic stress disorder and post-myocardial infarction repair, and the company retained its actinomycete assets.

Actinogen fell 0.4 cents or 4.6 percent to 8.3 cents with 634,023 shares traded.

GENETIC SIGNATURES

Genetic Signatures opened on the ASX at 48 cents, 20 percent above its initial public offer 40 cent price, climbing as much as 43.75 percent to 57.5 cents.

Genetic Signatures said the \$7.5 million in funds raised would be used to commercialize its pathogen diagnostic kits (BD: Nov 20, 2014).

Genetic Signatures closed up 8.5 cents or 21.25 percent at 48.5 cents with 2.1 million shares traded.

RHINOMED

Rhinomed says it has signed an Australian wholesale pharmacy distribution with Symbion for its Mute snoring and sleep quality technology.

Rhinomed said that Symbion was part of the EBOS Group, based in New Zealand and Headquartered in Melbourne, and would wholesale the Mute technology into their pharmacy network of more than 1200 pharmacies including the Chemmart, Terry White, Good Price and Blooms the Chemist pharmacy chains, with a recommended retail price of \$19.95 for a starter pack and \$29.95 for the three-pack refill.

The company said that Mute was registered with the Australian Therapeutic Goods Administration, the US Food and Drug Administration and had Conformité Européenne (CE) mark approval and it would expand Mute's franchise in the Australian market with other pharmacy wholesale groups.

Rhinomed chief executive officer Micahel Johnson said the company was "looking forward to bringing silence and a good night's sleep to millions of Australians as we begin the sell in of the Mute technology into these pharmacies".

"The response from pharmacies has been extremely positive with strong early orders in the pipeline [and] we would expect to see revenues from this relationship starting to flow [by July 2015]," Mr Johnson said.

Rhinomed was up 0.1 cents or 4.55 percent to 2.3 cents with 6.2 million shares traded.

ITL

ITL says that its ITL Biomedical division, which provides biological, primarily blood, sampling has opened a new manufacturing and production facility in Bemban, Malaysia. ITL said that the state-of-the-art facility was “a major milestone in [its] history and development”.

The company said that the production area had doubled to 5,000 square metres on a 10,000 square metre site, with the number of clean rooms increased from two to three. ITL said that the “substantially larger facility” solved its expansion needs and the planned transfer of further business from ITL Healthcare Australia was underway, with a consequent “large reduction in costs”.

The company said that ITL Healthcare assembled procedure and medical packs in Melbourne and distributing to more than 200 hospitals in Australia.

ITL said that the previous manufacturing facilities at Lahat in Malaysia were significantly space constrained and the move, expansion and renovation was completed on schedule and on budget in December 2014, with the official opening on March 19, 2015.

ITL executive chairman Bill Mobbs said the facility would be “a stepping stone towards considerable growth for both the Biomedical and Healthcare divisions”.

“The facility will give ITL the ability to cater for our customers increased demands as well as improving quality and efficiency,” Mr Mobbs said.

“In 2014, ITL brought six new products to market, and with the new facility we intend to release 14 in 2015,” Mr Mobbs said.

ITL was untraded at 22.5 cents.

PHARMAUST

Pharmaust says it has been granted a Japanese patent resulting from a collaboration with an unnamed Japanese corporation which began in 2013.

According to the World Intellectual Property Organisation website, the patent, entitled ‘Anticancer Agent Comprising Aminoacetonitrile Compound As Active Ingredient’ was made on an application by Pitney Pharmaceuticals, which was acquired by Pharmaust, and the Tokyo, Japan-based Nihon Nohyaku Co, with Pharmaust executive chairman Dr Roger Aston named as a co-inventor.

Pharmaust said that the patent described an invention on a series of analogues of PPL-1, or monepantel and allowed the company access to about 80 analogues of PPL-1, which had been synthesized by the unnamed Japanese company and tested for anticancer activity by Pharmaust.

The company said that the joint patent application permitted Pharmaust to commercialize the analogues subject to other prevailing intellectual property at the time of commercialization.

Dr Aston said “the commercialization of aminoacetonitriles in cancer, of which PPL-1 is a key approved product for treatment of veterinary diseases, is Pharmaust’s principal activity at the present time”.

“Pharmaust currently has a collaborative research and option agreement with one of the top five major global pharmaceutical companies for the development and commercialization of PPL-1 in veterinary cancers,” Dr Aston said.

“Our recent success in demonstrating meaningful reductions of blood cancer markers in late stage cancer patients who have failed standard of care, gives us further confidence that we are on track with our commercialization pathway,” Dr Aston said.

Pharmaust was unchanged at 1.1 cents with 2.9 million shares traded.

USCOM

Uscom says the American Medical Association recommendation for a new current procedural terminology code for arterial pressure waveforms applies to its BP+ diagnostic. Earlier this month, Atcor jumped 116 percent on the AMA recommendation of a current procedural terminology (CPT) category 1 code for arterial pressure waveforms following an application from the US Renal Physician Association for the addition of the category 1 CPT code 9300X1, and deletion of the existing category III code 0311T for non-invasive calculation and analysis of central arterial pressure waveforms with interpretation and report, which included the Sphygmocor central aortic blood pressure waveform measure (BD: Mar 10, 2015).

Today, Uscom executive chairman Prof Rob Phillips said the AMA editorial panel decision was “an important step in the process of US reimbursement for clinicians measuring and analyzing central arterial pressure waveforms, and is highly important for the US adoption of the Uscom BP+”.

“The BP+ is US patent protected with an innovative approach to the measurement of pulse pressure waveforms and central blood pressure,” Prof Phillips said.

Uscom said that the new category 1 CPT code was expected to be released by the AMA on August 31s 2015, and the Medicare payment rates to be published in November 2015. Uscom was up one cent or five percent to 21 cents.

GENETIC TECHNOLOGIES

Genetic Technologies has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price climbed from 3.1 cents on March 30 to 4.7 cents, a 51.6 percent increase, today March 31, 2015 and noted an increase in trading volumes. In February, the ASX questioned the company regarding a similar move when the share price climbed 51.7 percent from 2.9 cents to 4.4 cents, following a jump of eight percent on the Nasdaq, with 8,563,000 America depository receipts (ADRs), equivalent to 1,280,400,000 Australian shares traded and the company said it had previously announced the addition of six US centres offering its Brevagenplus breast cancer test (BD: Jan 29, Feb 12, 2015).

Last night on the Nasdaq, Genetic Technologies climbed \$US1.24 or 33.51 percent to \$US4.94 with 12,704,189 ADRs traded, equivalent to 1,905,628,350 Australian shares. Today, Genetic Technologies closed up 1.5 cents or 48.4 percent to 4.6 cents with 57.5 million shares traded.

ADMEDUS

Minderoo Group says its substantial holding in Admedus of 173,027,958 shares has been diluted from 12.91 percent to 10.73 percent.

Minderoo, formerly the Metal Group, and associated with Western Australian miner Andrew Forrest, said it had been diluted in the recent placement at 7.0 cents a share which raised \$12 million (BD: Mar 18, 2015).

Admedus fell 0.2 cents or 2.7 percent to 7.2 cents with 12.9 million shares traded.

NANOSONICS

The Delaware-based Goldman Sachs Group says that it has become a substantial shareholder in Nanosonics again this time 14,902,971 shares or 5.33 percent.

Two weeks ago Goldman Sachs said it became substantial in Nanosonics with 14,925,513 shares (5.34%) held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australian, HSBC Custody Nominees Australia and the Bank of New York Mellon, with some of the holdings relating to Goldman Sachs and JP Morgan Chase subject to an "overseas securities lender's agreement", as well as Rothesay Life and Morgan Stanley as parties to a "global master securities lending agreement" (BD: Mar 20, 2015).

Last week, Goldman Sachs ceased its substantial shareholding in Nanosonics, saying that between March 18 and March 23, 2015 it received shares under a counterparty agreement, returned shares, lent and borrowed shares, with the sole paid transaction the sale of 313,483 shares for \$575,241 or \$1.835 a share (BD: Mar 26, 2015).

Today, Goldman Sachs said that is bought and borrowed shares between December 3, 2014 and March 26, 2015, taking its total control of shares to 14,902,971 shares or 5.33 percent.

Nanosonics fell half a cent or 0.3 percent to \$1.90 with 540,959 shares traded.

OSPREY MEDICAL

CM Capital says it has increased its holding in Osprey from 33,271,668 shares to 34,040,899 shares, but has been diluted from 27.6 percent to 22.1 percent.

The Brisbane, Queensland-based CM Capital said that the shares were held by two funds the VT4A fund and VT4B as trustees for CM Capital Venture Trusts 4A and 4B.

Last week, Osprey raised \$16,324,000 in a placement at 53 cents per Chess depository instrument (BD: Mar 23, 2015).

Osprey fell 3.5 cents or 5.5 percent to 60 cents.

CELLMID

Cellmid says it has appointed Lucy Rowe as company secretary replacing joint company secretaries Nicholas Falzon and Jillian McGregor, effective from today.

Cellmid said that Ms Rowe had worked in the financial services industry for the last 15 years and held company secretarial positions with other listed companies.

Cellmid was up 0.1 cents or 4.55 percent to 2.3 cents.