Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: COMPUMEDICS UP 43%, FACTOR DOWN 9%**

*** COMPUMEDICS SIGNS $5m BARROW MEG NEURO-IMAGING CONTRACT**

*** G MEDICAL RECEIVES $7m FOR CHINA MOBILE HEALTH JV**

*** ALL CHANGE AT PHYLOGICA; $5m RAISED**

*** GENETIC SIGNATURES AUSTRALIA, EURO TEST APPROVAL; US PATENT**

*** AVITA CHINA STUDY: 'RECELL IMPROVES DONOR SITE HEALING 31%'**

*** OVENTUS SIGNS MODERN DENTAL FOR SALES; FUNDS TRADING HALT**

*** PARADIGM TO TRY PPS FOR HEART FAILURE**

*** SUDA TO BUY ANAGRELIDE FROM ALUZTRA FOR CANCER**

*** BVF, MARK LAMPERT TAKE 10% OF BIONOMICS**

*** HUNTER HALL, PENGANA BELOW 5% IN MACH7**

*** GI DYNAMICS: DR FRANCESCO RUBINO, DR PHILIP SCHAUER ADVISORS**

*** OSPREY APPOINTS MEDTRONIC'S SANDRA LESENFANTS DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.83 percent on Tuesday June 20, 2017 with the ASX200 down 47.9 points to 5,757.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and three were untraded.

Compumedics was the best (see below), up 16 cents or 43.2 percent to 53 cents with 1.7 million shares traded. Dimerix climbed 12.5 percent; Atcor and Psivida improved more than 10 percent; Actinogen was up 6.7 percent; Benitec, Living Cell and Mesoblast were up four percent or more; Neuren was up 3.45 percent; Acrux, Airxpanders, Clinuvel, LBT, Resmed and Starpharma rose more than two percent; Viralytics was up 1.1 percent; with Cochlear and Pro Medicus up by less than one percent.

Factor Therapeutics led the falls, down 0.6 cents or 9.1 percent to six cents with 1.3 million shares traded. Bionomics and Pharmaxis fell four percent or more; Cellmid, Osprey and Universal Biosensors lost more than three percent; ITL, Opthea, Orthocell and Polynovo shed more than two percent; with Admedus, Oncosil and Sirtex down more than one percent.

COMPUMEDICS

Compumedics says it has signed a $US3.75 million ($A4.93 million) magneto-encephalography contract with the Barrow Neurological Institute.

Compumedics said that it would deliver its first Neuroscan Orion Lifespan magneto-encephalography (MEG) system to the Phoenix, Arizona-based Barrow Institute by July 2018 and the agreement was its "largest system contract".

The company said that the Barrow Neurological Institute was "the world's largest neurological disease treatment and research institution … and home of the Muhammad Ali Parkinson Centre".

Compumedics said that the Barrow Institute was "consistently ranked as one of the best neurosurgical training centres in the world"

Compumedics executive chairman Dr David Burton told Biotech Daily that it was "always our strategy to provide the best equipment to the best institutions for validation".

The company said the contract established a collaboration with the Institute, for US Food and Drug Administration applications and beta-site services such as biomarker test protocols and access to secure patient databases for epilepsy, autism, dementia and Parkinson's disease management services, along with validation and verification studies.

Compumedics said that later collaborative stages would include working on improved and expanded government health reimbursement codes to help enhance brain healthcare.

Dr Burton said the company was "very pleased and honored to announce this strategic … milestone, representing the largest system contract in Compumedics' history".

"In 2016 Compumedics, Neuroscan and [the Korean Research Institute of Standards and Science] united their achievements and ongoing efforts, as part of a comprehensive 20-year exclusive technology transfer and licence agreement to produce the new Orion Lifespan MEG," Dr Burton said.

"This contract marks the commencement of our global MEG leadership in the multi-billion dollar brain imaging market," Dr Burton said.

"This is a unique inflection point in Compumedics' evolution to date, paving the way for a major new multi-billion dollar global market for the company," Dr Burton said.

Compumedics said that its MEG was "a functional neuro-imaging technique for mapping brain activity by recording magnetic fields produced by electrical currents occurring naturally in the brain, using very sensitive magnetometers".

The company said that magneto-encephalography provided up to five orders of magnitude of temporal resolution, or the speed of brain functional or cognitive measures, over other traditional functional magnetic resonance imaging. positron emission tomography or other conventional imaging systems.

Compumedics climbed 16 cents or 43.2 percent to 53 cents with 1.7 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical says it has received $US5 million ($A6.6 million) from the Guangzhou Sino-Israel Bioindustry Investment Fund for its joint venture.

In May, the Cayman Islands-based G Medical said the Guangzhou Fund would invest the funds for a 30 percent interest in the subsidiary and use best efforts to facilitate $US10 million of additional government grant or loan funding(BD: May 22, 2017).

In February, the company said it had a term sheet with the Fund to distribute its mobile telephone electronic health devices, had completed trials of the technology and expected Conformité Européenne (CE) mark approval by July 2017 and US Food and Drug Administration approval by the end of the year (BD: Feb 20, 2017).

G Medical was up one cent or 7.4 percent to 14.5 cents.

PHYLOGICA

Phylogica says it has raised $5 million and has appointed chair Stephanie Unwin chief executive officer and Dr Robert Hayes chief scientific officer.
Phylogica said that Australian Land Pty Ltd invested $5 million at four cents a share which would be used for the pre-clinical development of Phylomer lead candidates.
In its substantial shareholder notice, signed by company secretary Nicholas Clive Wyatt, the Perth -based Australian Land said it held 160,300,000 shares (7.56%) of the company.
Phylogica non-executive chair Stephanie Unwin told Biotech Daily that she needed to complete arrangements with her current employer, the Western Australia Government-owned Synergy power company, but expected to take up the role of chief executive officer within two months.
Ms Unwin said Phylogica would conduct a search for an independent non-executive chair.
Phylogica said that Ms Unwin held senior executive roles at Synergy from 2011 and had experience across operational and commercial responsibilities, as well as experience as a company director.
The company said that Ms Unwin held Bachelor of Laws and a Bachelor of Economics from Perth's Murdoch University,
Phylogica said that Dr Hayes was formerly Amgen's head of biologics and a Janssen Pharmaceuticals vice-president and head of Centyrex, a company developing proteins as therapeutics with transformational properties, which had a collaboration with Phylogica to understand the ability to use Phylomers to deliver therapeutic proteins into cells.
The company said that Dr Hayes had 18 years in research and development and would "lead all aspects of discovery research at Phylogica".
The company said that Dr Hayes held Master of Science from London's University College, a Doctorate of Philosophy from London's Imperial College and completed postdoctoral work at the University of California in Berkeley.
Phylogica said it would hire additional professionals in intracellular drug delivery to its scientific advisory board and renew its "entire intellectual property portfolio with the commencement of composition of matter claims around its lead delivery and cargo candidates".
Separately, the Perth-based director Bernard Hockings said he had reduced his holding in the company from 615,924,185 shares (30.73%) to 582,924,185 shares (27.5%) through the "exercise of a call option" selling 33,000,000 shares for $990,000 or three cents each.
Phylogica fell 0.2 cents or 4.8 percent to four cents with 4.5 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has Australian and European regulatory approval for its enteric viral detection product and has a US patent for its core 3Base technology.
Genetic Signatures said that it had approval for its 3Base polymerase chain reaction assays, for enteric protozoan, enteric bacterial and Clostridium difficile detection and had received Australian Therapeutic Goods Administration and European Medicines Agency approval for its enteric viral detection product.
The company said it had Conformité Européenne (CE) mark approval for its entire Easyscreen enteric pathogen detection kit range.
Genetic Signatures said the US patent was entitled 'Molecular Detection Assay using Direct Treatment with a Bisulphite Reagent' and would provide protection until 2031.
The company said that a similar patent had been issued in Australia, Europe, Japan, New Zealand, Singapore and South Africa and was pending in other jurisdictions.
Genetic Signatures was unchanged at 40 cents.

AVITA MEDICAL

Avita says a 106-patient randomized controlled trial in China shows that Recell can increase the healing rate of skin donor sites by 30.7 percent.

Avita said that spraying a suspension of cells from its Recell spray-on skin device on a skin donor site could accelerate healing “and deliver a superior final outcome” including wound healing and aesthetic appearance.

The research article, entitled ‘Randomized clinical trial of autologous skin cell suspension for accelerating re-epithelialization of split-thickness donor sites’ was published in the British Journal of Surgery and an abstract is at: http://bit.ly/2rPMhh0.

The article concluded that “the use of autologous skin cell suspension with hydrocolloid dressings accelerated epithelialization and improved healing quality of the donor site compared with hydrocolloid dressings alone”.

Avita said the article was based on work by a team of burns and plastic surgeons at the Guangzhou, China-based Sun Yat Sen University Hospital.

The company said the researchers evaluated the time for the epithelial layer of skin to restore on donor sites, with and without Recell, reporting the median time to complete re-epithelialization was 9.0 days in the Recell group, compared with 13.0 days in the control group, a statistically significant 30.7 percent difference ($p < 0.001$).

The authors said patients and independent observers reported the donor sites treated with Recell had better physical attributes and patients were more satisfied with healing quality.

Avita chief executive officer Mike Perry said the data showed that Recell could be used “both to reduce patient trauma and to help patients heal faster”.

“Our pivotal trial in the US, announced last month, showed how Recell allowed doctors to successfully treat burns using about 30 percent less donor skin,” Mr Perry said.

“Now, in China, surgeons have shown that the donor site itself can heal some 30 percent faster when treated with regenerative epithelial suspension made using the Recell device,” Mr Perry said.

“Demonstration of clinical benefit for treatment of burn injuries and treatment of donor sites further substantiates the key, versatile role for Recell in burn care,” Mr Perrry said.

Avita was unchanged at 7.7 cents.

OVENTUS MEDICAL

Oventus says it has signed a global distribution deal with the Hong Kong-based Modern Dental Group for its O2Vent mouth-guard anti-snoring device.

Oventus said the agreement was exclusive for the US and non-exclusive elsewhere.

The company said that Modern Dental was “the world’s largest dental prosthetic device provider” with more than 70 sales and customer services centres in North America, Europe, Australia and China.

Oventus said that Modern Dental had acquired the US-based Microdental which covered about 34,000 dental offices and operated in Europe and in Australia through its subsidiary Modern Dental Pacific.

The company said that the agreement was “a key milestone … as it scales up its global rollout plans”.

Oventus chief executive officer Neil Anderson said “the agreement will accelerate our sales and allow us to continue to commercialize the product range for the sleep clinician channel over the coming year”.

Separately Oventus requested a trading halt pending a capital raising.

Trading will resume on June 22, 2017 or on an earlier announcement.

Oventus last traded at 38 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has licence a patent relating to the use of pentosan polysulfate sodium for heart failure from Norway's University of Oslo.

Last week, Paradigm said its phase IIa pentosan polysulfate sodium (PPS) allergic rhinitis trial did not meet its primary endpoints (BD: Jun 16, 2017).

Today, the company said it would complete its phase II trial of PPS for bone marrow oedema, or bone bruising, and begin its PPS Ross River virus trial, before starting a 24-patient phase II pilot heart failure trial and a phase IIb heart failure trial in 2018.

Paradigm said it had sufficient cash, including an expected Federal Government R&D Tax Incentive expected by October 2017, to progress all the current programs, and begin planning the osteoarthritis and phase II pilot heart failure clinical trials.

The company said it had signed a worldwide exclusive licence for the patent entitled 'Inhibitors of ADAMTS4 or ADAMTS5 for use in preventing or treating cardiac remodelling and chronic heart failure' from the University of Oslo.

Paradigm said that the patent was founded on preclinical data using pentosan polysulfate sodium as the inhibitor of ADAMTS4 versicanase, an enzyme involved in the degenerative process in heart failure.

The company said studies showed that PPS improved systolic function, or the amount of pressure in the arteries during contraction of the heart muscle, in the heart failure model and had the potential to stop or reverse disease progression in heart failure.

Paradigm was up five cents or 15.6 percent to 37 cents.

SUDA

Suda says it expects to acquire the intellectual property to anti-cancer agent Anagrelide and a number of its potentially non-toxic analogues from Aluztra Bio Ltd.

Suda said it had a binding memorandum of understanding with the Southampton, England-based Aluztra, with up to six months to complete due diligence.

The company said that an oro-mucosal spray of Anagrelide could potentially avoid the side-effects associated with the molecule when administered as an oral capsule.

Suda said that Aluztra and its partner Cancer Research UK would be entitled to a low single-digit percentage royalty on direct net sales or a share of income generated from commercialization of an oro-mucosal spray of Anagrelide.

The compan said that Anagrelide was used as an anti-thrombotic agent to reduce elevated levels of platelets, which provided growth factors that nourished cancer cells and enabled them to take hold and develop into tumors.

Suda said that Anagrelide had the potential to be developed as an effective anti-cancer agent, but was limited in its current formulation by cardio-stimulatory side-effects.

The company said that an oro-mucosal spray formulation could minimize the side-effects by avoiding first-pass metabolism of the active drug in the liver.

Suda said that cancer immunotherapies stimulated the patient's own immune system and Anagrelide would be complementary, rendering circulating cancer cells more susceptible to attack by the body's own killer cells.

Suda chief executive officer Stephen Carter said that Anagrelide was "an interesting opportunity for Suda".

"We believe that the use of our proprietary Oromist technology to formulate an oral spray of Anagrelide with efficient oro-mucosal absorption of the active agent could represent a compelling new strategy for the treatment of solid tumors," Mr Carter said.

Suda was unchanged at 1.8 cents.

BIONOMICS

BVF Partners and Mark Lampert say they have increased their holding in Bionomics from 42,911,975 shares (8.91%) to 49,147,193 shares (10.21%).
Last week, San Francisco, California-based BVF Partners, Biotechnology Value Fund and Mr Lampert said they had become substantial shareholders in Bionomics with 42,911,975 shares (8.91%) (BD: Jun 8, 2017).
Today, the group said they bought the shares between June 7 and 16, 2017 with the single largest acquisition 932,980 shares for $373,938 or 40.1 cents a share.
Bionomics fell two cents or 4.9 percent to 39 cents.

MACH7 TECHNOLOGIES

Hunter Hall Investment and Pengana Capital have ceased their substantial shareholding in Mach 7.
Pengana and Hunter Hall said they acquired shares between December 9, 2016 and January 5, 2017 and sold or disposed of shares from January 5 to June 16, 2017, with the single largest sale 5,617,953 shares for $614,082 or 10.9 cents a share.
Mach7 was unchanged at 11 cents.

GI DYNAMICS

GI Dynamics says it has appointed Dr Francesco Rubino and Dr Philip Schauer to its scientific advisory board.
GI Dynamics said that the board would be a resource during its US investigational device exemption trial and would support studies and commercialization in the United Kingdom, Germany, the Middle East and Europe.
GI Dynamics chief executive officer Scott Schorer said that Dr Rubino was “a pioneer in the field and has helped lead the evolution of bariatric surgery towards metabolic surgery, created the thought process regarding [gastro-intestinal] tract involvement in the pathophysiology of type 2 diabetes, and independently developed the animal model proof of the Endobarrier mechanism of action”.
Mr Schorer said that Dr Schauer had “a focus on severe obesity and the pathophysiology of type 2 diabetes, is a leading researcher in the disease state, and has performed over 7,000 procedures for type 2 diabetes and obesity”.
The company said that Dr Rubino held a Doctor of Medicine from the Rome-based Catholic University.
GI Dynamics said that Dr Schauer was the past president of the American Society for Metabolic and Bariatric Surgery and immediate past chair of Obesity Week.
The company said that Dr Schauer held a Doctor of Medicine from the University of Texas at San Antonio.
GI Dynamics said that Dr Schauer had been the principal investigator or co-investigator on numerous research grants and had published numerous papers, abstracts, and book chapters related to gastrointestinal and laparoscopic surgery.
GI Dynamics was up 0.25 cents or 3.9 percent to 6.65 cents with 2.97 million shares traded.

OSPREY MEDICAL

Osprey said it has appointed Sandra Lesenfants as a non-executive director.
Osprey said that Ms Lesenfants was currently the head of Medtronic's cardiac and vascular group endo-venous, or within the vein, business, responsible for the development and marketing of products for chronic venous insufficiency, deep vein disease and embolization.
The company said that Ms Lesenfants led the acquisition of Sapheon and its Venaseal closure system and the integration Covidien's vascular therapy business.
Osprey said that previously Ms Lesenfants worked for Covidien, EV3 and Siemens Healthcare.
The company said that Ms Lesenfants held a biomedical computer engineering degree from the University of Technology of Compiegne in Northern France.
Osprey fell 1.5 cents or 3.85 percent to 37.5 cents.