



Biotech Daily

Wednesday November 14, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: OPTISCAN UP 10%; FACTOR DOWN 96%**
- * **FACTOR FALLS 97% ON VF001 VENOUS LEG ULCER FAIL**
- * **VICTORIA \$100k FOR COMPUMEDICS, DEAKIN SLEEP DIABETES STUDY**
- * **EXOPHARM \$7m IPO FOR EXOSOME REGENERATIVE MEDICINE**
- * **BIONOMICS 2nd PLACEMENT RAISES \$2m OF \$4m; TOTAL \$9.8m**
- * **BIONOMICS 37% REMUNERATION 1ST STRIKE**
- * **OPTHEA RECRUITS PHASE IIb OPT-302 AMD TRIAL**
- * **PAINCHEK LAUNCHES ON-LINE TRAINING COURSE**
- * **RESAPP 'ISO COMPLIANT' FOR CE MARK, TGA**
- * **RHINOMED AGM FOR 9m DIRECTOR OPTIONS**
- * **KINETIC, AUST SUPER INCREASE; BRANDON, CM DILUTED IN OSPREY**
- * **PROTEOMICS: ADELAIDE EQUITY, SCINTILLA CORPORATE ADVISORS**
- * **ANATARA APPOINTS STEVEN LYDEAMORE CEO ON \$395k**

MARKET REPORT

The Australian stock market lost 1.74 percent on Wednesday November 14, 2018 with the ASX200 down 101.4 points to 5,732.8 points. Ten of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and six were untraded. All three Big Caps fell.

Optiscan was the best, up 0.6 cents or 10 percent to 6.6 cents, with 339,283 shares traded. Neuren climbed 5.3 cents; Actinogen, Avita, Ellex and Prana improved more than four percent; Compumedics and Osprey were up more than three percent; Medical Developments rose 2.8 percent; with Prescient up 1.2 percent.

Factor led the falls, down 97.3 percent to 0.2 cents before closing down 7.0 cents or 95.9 percent at 0.3 cents with 333.5 million shares traded. Bionomics lost 16.1 percent; Dimerix, Impedimed and Oncosil fell five percent or more; Cochlear, Paradigm, Pro Medicus and Universal Biosensors were down more than four percent; Cynata, Mesoblast, Nanosonics and Telix were down more than three percent; Clinuvel, CSL, Immutep, Orthocell and Volpara shed more than two percent; with Resmed down 1.8 percent.

FACTOR THERAPEUTICS (FORMERLY TISSUE THERAPIES)

Factor Therapeutics fell as much as 97.3 percent to 0.2 cents on news that its 157-patient, phase II trial of VF001 for venous leg ulcers “failed to meet all endpoints”.

Factor said that the results analysis “demonstrated no clinically meaningful or statistically significant difference in measures of wound healing, compared with placebo, ongoing development of VF001 for all indications [had been] halted, [it would] limit further activity to maintaining existing intellectual property portfolio” and as part of an overall downsizing, chief executive officer Dr Rosalind Wilson would resign pending suitable transition arrangements.

In April 2017, the company began recruitment for the randomized, double-blinded, placebo-controlled, US Food and Drug Administration-directed, phase II trial of VF001 for venous leg ulcers (BD: Apr 7, 2017).

In 2008, the then Tissue Therapies, began European approval-directed trials in Perth and Toronto of the original wound treatment, then called Vitrogro (BD: Jul 9, 2008).

In 2011, the company said that Vitrogro had demonstrated wound healing in 22 of 24 venous leg ulcers, but in 2013 European regulators changed Vitrogro’s classification from device to medicine (BD: Jul 14, 2011; Mar 18, 2013).

From 2015, Tissue Therapies appointed Dr Christian Behrenbruch as an executive director, changed its name to Factor Therapeutics, appointed Dr Wilson as chief executive officer and began the current FDA-directed trial of VF-001 for venous leg ulcers (BD: Oct 12, 2015; Mar 24, Apr 29, 2016; May 22, 2017).

Today, Factor Therapeutics said that “across all three measures of healing evaluated in the study, reduction in wound size, the proportion of patients whose ulcers fully healed and the time to achieve full healing, treatment with VF001 did not provide any additional benefit when compared with placebo plus standard care”.

Results charts provided by the company showed near identical reduction in mean and median wound area reduction for placebo, low dose and high dose VF001.

The company said that although low dose VF001 patients had a 40.0 percent rate of complete ulcer healing, compared with 35.8 percent for both the high dose and placebo it was not statistically significant ($p = 0.689$).

Factor said that in terms of time to complete ulcer healing, the low dose showed the greatest benefit above placebo and the high dose VF001, but it was marginal and without statistical significance ($p = 0.386$).

Dr Wilson said the company “undertook this trial with the goal of determining whether VF001 could improve healing for patients with venous leg ulcers and we have answered that question; unfortunately, the results clearly demonstrate that it does not”.

“Although the trial was well designed and executed, the outcome is that there is no clinical justification to progress further with the development of this asset, for this indication,” Dr Wilson said.

Factor Therapeutics chair Dr Cherrell Hirst said the “disappointing news means that we will cease development of VF001 in all indications and, in the immediate term, limit our activity to maintaining the company’s existing intellectual property portfolio”.

“The Australian directors have indicated their willingness to remain in place, without remuneration,” Dr Hirst said.

“In addition to maintenance of the intellectual property portfolio, the board will proceed to review all options available to, and in the best interests of, the company and its shareholders,” Dr Hirst said.

Dr Hirst thanked the company’s shareholders for their support as well as the staff, investigators, trial staff, partners and patients.

Factor closed down 7.0 cents or 95.9 percent at 0.3 cents with 333.5 million shares traded.

[COMPUMEDICS, VICTORIA GOVERNMENT](#)

Compumedics says the Victoria Government has provided a grant for its Somfit diabetes collaboration with Deakin University and Diabetes Australia.

of Deakin Rural Health research deputy director Dr Kevin McNamara told Biotech Daily that the Victoria Government would provide a matching grant of \$100,000 to Compumedics \$100,000 along with the provision of equipment and services.

Compumedics said that the grant was from the Victorian Department of Health and Human Services Acceleration Fund “to help deliver clinical-grade, consumer-accessible blood-glucose and sleep monitoring”

The company said its Somfit Health Management Platform was “the first of its kind to enable a patient-central point-of-care for continuous blood-glucose [HbA1c] measurements coupled with a ... wearable sensor with mobile sleep-management capabilities.

Compumedics said that Deakin Rural Health was a research and training-focused group at Deakin University’s School of Medicine, with the aim “to improve access for rural and remote communities to appropriate health services”.

The company said the grant would support research into the risks associated with problem sleep and diabetes and the Somfit Sleep Diabetes Health Study was designed to incorporate a community-wide, continuous blood-glucose and consumer-level polysomnography sleep assessment.

Compumedics said that between 50 percent and 90 percent of people with diabetes had obstructive sleep apnoea and 77 percent had insomnia; and insulin resistance, or the ability for the body to generate insulin naturally, had been shown to be adversely impacted by poor sleep quality while meta-analysis suggests that poor sleep health was associated with significantly increased HbA1c, a biomarker of diabetes control.

The company said the study would develop and test the efficacy of the Somfit platform’s sleep health intervention for people with diabetes, establishing a feasible sleep health intervention for primary care and would test the intervention effects on key health and wellbeing outcomes for patients with diabetes and whether there was a reduced diabetes risk in those patients with pre-diabetes.

Compumedics executive chairman Dr David Burton said the project “brings together the best-of-class consumer electronics, proven and professional grade [internet] cloud analytics and, most importantly, some of the region’s most distinguished researchers, to tackle sleep and diabetes risk, one of our greatest health problems”.

“Deakin Rural Health is well-versed in bringing valuable and meaningful health solutions to rural communities [and] Diabetes Australia is the third longest established diabetes association in the world and has over one million registered diabetics in Australia alone,” Dr Burton said.

Dr McNamara said the proposal “supports the translation of cutting-edge diagnostic research into clinical care”.

“If our hypothesis that improved sleep management will slow diabetes progression is correct, it may lead to reduced rates of diabetes complications and hospitalizations, and reduced healthcare costs,” Dr McNamara said. “Potential benefits include health and wellbeing outcomes, especially given that sleep quality is a pillar of health that has been overlooked and which increasingly appears linked to blood glucose control in diabetes.”

“Effective population-level interventions are paramount to reducing the impact of the diabetes epidemic and Somfit improves healthcare access,” Dr McNamara said. “This is potentially of particular benefit for communities with poor access to sleep healthcare, such as those patients from rural and remote areas and those on low incomes.”

Compumedics was up 1.5 cents or 3.9 percent to 40 cents.

EXOPHARM

Exopharm says it hopes to raise up to \$7 million in an initial public offer at 20 cents a share to list on the ASX and develop exosomes as regenerative medicines.

The Melbourne-based Exopharm said that exosomes were “key messengers” and it hoped to develop and commercialize therapeutic agents, “initially a product called Plexaris and later as a product called Exomeres.

Exopharm said that exosomes were able “to exert powerful effects on the actions and behavior of cells ... [and were] potent, broad acting, have effects that are both long-term and short-term and play key roles in many important mechanisms involved in ageing, diseases and degeneration/regeneration”.

The company said exosome therapies were challenged of an efficient exosome extraction and purification process but its Leap technology provided “a key step” in the process to isolate and purify exosomes from adult stem cells and other sources.

Exopharm said its chair was Melbourne lawyer Jason Watson with directors Alto Capital’s David Parker and Noxopharm and Medigard director Dr Ian Dixon.

Exopharm told Biotech Daily the raising was “a broker firm offer” for customers of the Perth-based Alto Capital and not available to the public or other brokers.

He said the company was hoping to secure the ASX code of EX1, but the timing of the listing would depend on the raising and regulatory requirements.

The prospectus is available at <https://exopharm.com/download-prospectus>.

BIONOMICS

Bionomics says its second placement at 16.37 cents a share has raised \$1,976,281 of a hoped for \$3,984,183.

On Monday, Bionomics said it raised \$7,873,505 from BVF and expected to raise a further \$3,984,183 from BVF and other investors for a total of \$11,857,688, taking BVF’s holding to 19.9 percent and it would offer a share plan at 15.5 cents a share (BD: Nov 12, 2018).

Today, Bionomics chair Dr Errol De Souza said that “based on feedback from the brokers of insufficient demand from institutions along with difficult market conditions over the last two days, the board has made the decision not to proceed with the offer” and the placement would consist “solely of shares placed to BVF”.

Bionomics said that placement proceeds totaled \$9,849,786 and the final pricing and terms for the share plan would be announced on November 22, 2018.

The company said Shaw Stockbroking and Bell Potter were the joint lead managers.

Bionomics fell 2.5 cents or 16.1 percent to 13 cents with 4.5 million shares traded.

BIONOMICS

Bionomics says it has a remuneration report first strike, with 46,479,971 votes (37.2%) against and 78,523,572 votes (62.8%) in favor providing a board spill first trigger.

The Corporations Act (Section 250U) provides for a ‘two strikes and re-election’ process if a company’s remuneration report is opposed by more than 25 percent of votes at two consecutive annual meetings, taking the company to a vote on a board spill motion.

The company’s most recent Appendix 3B new issue announcement said that Bionomics had 482,903,192 shares on issue, prior to this week’s capital raising, meaning that the votes against the remuneration report amounted to 9.6 percent of the company, sufficient to requisition extraordinary general meetings.

Bionomics said that director David Wilson was re-elected with 163.7 million votes in favor and 12.9 million votes against.

OPTHEA

Opthea says it has completed randomization of 351 treatment-naïve patients in its phase IIb trial of OPT-302 for wet age-related macular degeneration (AMD).

Opthea said that since December last year it had recruited the patients at 113 clinical sites in the US, Europe and Israel and was “ahead of the projected timelines”.

The company said that as a result, the reporting of the primary data from the study was expected by the end of 2019.

Opthea chief executive officer Dr Megan Baldwin said “it is a pleasure to report the completion of recruitment in the OPT-302 phase IIb wet AMD study ahead of schedule and this milestone represents a very significant achievement”.

Opthea was unchanged 57 cents.

PAINCHEK

Painchek says it has launched an on-line training course to support broader market adoption in collaboration with Dementia Training Australia.

Painchek said the course provided “a hands-on guide to support the effective use of Painchek by professional carers” and a Family Carer version was in development for patients at home.

Painchek chief executive officer Philip Daffas said the online course was “an important step in supporting professional carers as Painchek’s clinical usage expands”.

The company said the course was freely available from the Dementia Training Australia website at: www.dta.com.au/dta_courses/painchek-elearning/ or via the www.PainChek.com website.

Painchek was up 0.2 cents or 4.35 percent to 4.8 cents.

RESAPP HEALTH

Resapp says the British Standards Institution has approved its quality management system as International Organization of Standardization (ISO) 13485:2016 compliant.

Resapp said the approval followed a BSI audit and expected a formal certificate within two weeks.

The company said that ISO 13485 was an essential step for Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval for its products.

Resapp was up one cent or 10 percent to 11 cents with 8.5 million shares traded.

RHINOMED

Rhinomed says its annual general meeting will vote to issue directors 9,000,000 options.

Rhinomed said the options would be exercisable at a 145 percent premium to the 5-day volume-weighted average price to the meeting date, and within three years.

The company said it proposed to issue 3,000,000 options each to chair Ron Dewhurst and chief executive officer Michael Johnson, with 1,500,000 each to directors Eric Knight and Brent Scrimshaw.

Rhinomed said the shareholders would vote to approve the remuneration report, the 10 percent placement capacity, the prior issue of shares and related party participation in a placement and re-elect director Mr Scrimshaw.

The meeting will be held at Executive Suite 79/80, Level 3, Melbourne Cricket Ground, Brunton Avenue, Jolimont, Melbourne, on December 14, 2018 at 10am (AEDT).

Rhinomed fell half a cent or 2.2 percent to 22.5 cents.

OSPREY MEDICAL

Kinetic Investments and Australian Super say they have increased their holdings in Osprey, but have been diluted in the recent \$20.5 million capital raising. Last month, Osprey said Allan Gray had invested \$10.0 million in a placement at 15.5 cents a share and it hoped to raise \$10.5 million in a rights offer (BD: Oct 30, 2018). Today, Kinetic said it had increased and was diluted from 18,418,742 shares (7.25%) to 23,764,199 shares (5.88%); Australian Super said it had increased and was diluted from 23,644,059 shares (6.96%) to 24,983,344 shares (5.29%) ; Brandon Capital said its 91,413,524 share-holding in Osprey had been diluted from 26.9 percent to 22.6 percent; and CM Capital said its 34,040,899 share-holding had been diluted from 10.4 percent to 8.4 percent of Osprey. Osprey was up half a cent or 3.45 percent to 15 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has appointed South Australia's Adelaide Equity Partners to work with the Gold Coast Queensland-based Scintilla Capital as its corporate advisors. Proteomics said that Adelaide and Scintilla would "work together to provide investor relations support and corporate advisory services ... to unlock investor value and establish the foundation for further corporate growth". The company said that Adelaide would be issued 1,250,000 options on it achieving a 20-day volume-weighted average price of 45 cents, exercisable at 50 cents each within three years and 500,000 options to Scintilla on the same terms. Proteomics fell three cents or 8.7 percent to 31.5 cents.

ANATARA LIFESCIENCES

Anatara says it has appointed Bionomics chief financial officer Steven Lydeamore as its chief executive officer on \$395,000 a year, effective from December 3, 2018. Anatara chair Sue MacLeman said that Mr Lydeamore's appointment was "a key step in the company's development and transition to its focus on human health". The company said that Mr Lydeamore would be entitled to short-term incentives up to 40 percent of his base salary subject to performance indicators, and a long-term incentive of 600,000 options. Anatara said that Mr Lydeamore had experience in sales and marketing, research and development, business development, mergers and acquisitions, manufacturing and finance in the Asia Pacific, Europe, Latin America and North America. The company said that previously, Mr Lydeamore worked for the Toronto-based Apotex, including as the head of business development, chief business officer and managing director, and before that was with FH Faulding & Co in Australia and Mayne Pharma US. Anatara said Mr Lydeamore held a Bachelor of Business from Deakin University and a Master of Business Administration from the Royal Melbourne Institute of Technology. Anatara said that interim chief executive officer Dr Tracie Ramsdale would revert to her previous role as a non-executive director. Anatara was unchanged at 49 cents.