Biotech Daily

Wednesday May 29, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 12.5%; LBT DOWN 12.5%**

*** RESAPP HIRES UNNAMED UK GROUP FOR NEW PRODUCTS**

*** ACTINOGEN HIGHER DOSE XANAHES TRIAL PASSES SAFETY REVIEW**

*** BIONOMICS COMPLETES STRATEGIC REVIEW**

*** NEUROTECH PLEADS SCHULTZ TO ASX 55% QUERY**

*** MGC, RMIT WIN AUSTRALIAN MARIJUANA RESEARCH LICENCE**

*** EMPERY, RYAN LANE BELOW 5% IN IMMURON**

*** CARDIEX APPOINTS RHONDA WELCH HEAD OF MARKETING**

*** REDHILL APPOINTS PROF JUNE ALMENOFF CSO**

MARKET REPORT

The Australian stock market fell 0.69 percent on Wednesday May 29, 2019, with the ASX200 down 44.8 points to 6,440.0 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and six were untraded. All three Big Caps fell.

Oncosil was the best, up 0.8 cents or 12.5 percent to 7.2 cents with 1.9 million shares traded.

Actinogen and Patrys climbed eight percent or more; Proteomics improved 5.1 percent; Neuren and Starpharma were up more than three percent; Antisense, Medical Developments, Optiscan, Prescient and Telix rose two percent or more; Avita was up 1.1 percent; with Polynovo up by 0.8 percent.

LBT led the falls, down 2.5 cents or 12.5 percent to 17.5 cents, with 6.8 million shares traded.

Impedimed lost 11.8 percent; Alterity (Prana) fell 8.1 percent; Opthea shed seven percent; Imugene was down 5.6 percent; Benitec, Kazia and Osprey fell four percent or more; Clinuvel, Ellex, Mesoblast and Volpara shed two percent or more; CSL, Pharmaxis and Resmed were down more than one percent; with Cochlear, Nanosonics and Pro Medicus down by less than one percent.

RESAPP HEALTH

Resapp says it will pay up to $2.3 million to an unnamed UK medical device consultancy to design hardware and wearable devices for its respiratory diagnostics.

Resapp said the consultancy would work with UK medical device manufacturer, OSI Electronics to design, test and finalize two Conformité Européenne (CE) marked devices: a low-cost, handheld device and a small, wearable breathing monitor.

The company said it had negotiated a fixed-price and milestone-based contract and for each device it would pay GBP75,000 ($A137,157) in cash and $250,000 in shares, calculated at the 30-day volume-weighted average price to the start date.

The company said the project had three milestones: the delivery of functional prototypes, delivery of the final designs and CE mark approval.

Resapp said it would pay $500,000 for every milestone, payable in cash or shares at the company's election, with the number of shares at the higher of 80 percent of the 30-days volume weighted average price to the milestone or 10 cents.

Last year, the company said it was "very pleased" with the 1,251-patient, Smartcough-C-2 results, despite missing the first primary endpoint of the diagnosis or exclusion of pneumonia (BD: Oct 30, 31, 2018).

Resapp said at that time it had between 71 percent and 86 percent sensitivity and specificity for lower respiratory tract disease, asthma/reactive airway disease in children over two years of age, and primary upper respiratory tract disease.

In March, the company said that further data from the Smartcough-C-2 trial showed its diagnostic was more accurate than clinicians for the diagnosis of croup and primary upper respiratory tract disease (BD: Mar 18, 2019).

Last month, Resapp said that its 979-patient Australian Breathe Easy study had 86 percent agreement with clinical diagnosis for lower respiratory tract disease and pneumonia (BD: Apr 23, 2019)

Today, the company said the planned Android-based device would be "a low cost option" for its mobile telephone software respiratory diagnostic.

Resapp said that functional prototypes were expected within nine months with CE mark approval targeted in 2020.

The company said the wearable monitor would provide "an easily worn, unobtrusive platform for monitoring patients with chronic disease, [24 hours a day, seven days a week] over extended periods".

Resapp chief executive officer Dr Keating said "a decision on our CE mark application for our mobile software diagnostic [application] is expected shortly and if approved will allow European commercialization for running on off-the-shelf smartphones and also, once development is complete, this new handheld device".

"Being able to offer this option to customers will provide an additional selling point to our already strong value proposition for in-person care," Dr Keating said.

"Furthermore, a wearable monitor will allow us to commercialize new products aimed at assessing and predicting respiratory disease progression," Dr Keating said.

"By outsourcing hardware development, we retain our focus on delivering clinical-quality algorithms for use on smartphones in tele-health and in-person settings, while increasing our addressable market by having additional, specialised platforms on which we can deliver our algorithms," Dr Keating said.

"Having a milestone-based payment structure, where we can choose to pay milestones either in cash or shares, reduces our financial risk and helps optimize our cash flow," Dr Keating said.

The company said it had the right to terminate the contract if milestones were not met.

Resapp fell two cents or 11.4 percent to 15.5 cents with 2.6 million shares traded.

ACTINOGEN MEDICAL

Actinogen says its dose-escalation committee has recommended it continue its phase I Xanahes trial of Xanamem in healthy patients, with some protocol enhancements.
In 2015, Actinogen said a phase I dose-ranging trial showed that Xanamem was safe and well-tolerated from 10mg to 35mg (BD: May 12, 2015).
Earlier this month, the company said its 186-patient, phase II Xanadu trial of Xanamem for Alzheimer's disease "did not achieve statistical significance" (BD: May 7, 2019).
Actinogen said it would study the effects of 20mg and 30mg doses of Xanamem on cortisol production in the brain and expected initial results from its Xanahes higher dose safety studies by the end of June 2019.
Today, the company said the dose escalation committee reviewed safety data from the 34 healthy elderly patients randomized into the first 20mg cohort at May 1, 2019.
Actinogen said the Xanahes trial would randomize 42 patients into a cohort of 20mg of Xanamem or placebo for 12 weeks and following the review, a second cohort of 42 patients with 30mg of Xanamem or placebo daily.
The company said the Xanahes trial would evaluate safety of higher doses of Xanamem and use cognitive efficacy tests to assess how 20mg of Xanamem enhanced cognition following 12 weeks of treatment.
Actinogen chief executive officer Dr Bill Ketelbey said, "the recommendation to continue Xanahes, with refinements to the protocol, is a validation of the Xanahes dose escalation trial and its design".
Actinogen was up 0.1 cents or 8.3 percent to 1.3 cents with 26.5 million shares traded.

BIONOMICS

Bionomics says an independent review by Greenhill & Co has been completed and it continues to identify licencing opportunities and potential merger candidates.
Last year, Bionomics fell 69 percent when its 193-patient, phase II trial of BNC210 did not meet its post-traumatic stress disorder primary endpoint (BD: Oct 2, 2018).
In February, the company said that a drug exposure-response analysis of the trial showed a significant BNC210 blood response (BD: Feb 18, 2019).
Today, Bionomics said it had completed enrolment of its BNC210 clinical trial for agitation in elderly patients and expected top line data by July 2019.
The company said it had submitted a type C meeting request with the US Food and Drug Administration for the design of a potential second phase IIb trial of BNC210 for post-traumatic stress disorder.
Bionomics said it "no longer anticipated" its next Merck & Co Inc collaboration inflection point by July 2019 and was "unable to provide further information at this time", but said Merck & Co continued to conduct clinical development to evaluate the asset.
Bionomics said it had reduced costs and would conduct a capital and debt structure review to determine funding of future clinical trials.
Bionomics executive chairman Dr Errol De Souza said the company "did not identify a compelling alternative to continuing development and partnering discussions to those assets by Bionomics".
"We anticipate reporting the top line data of our exploratory BNC210 clinical trial for the treatment of agitation in elderly patients by the end of June 2019 and will define the strategy for BNC210 for the treatment of [post-traumatic stress disorder] and other anxiety-related disorders following receipt of guidance from the FDA towards the end of [September] 2019," Dr De Souza said.
Bionomics fell 1.5 cents or 10.7 percent to 12.5 cents with 3.7 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech 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 rose 0.6 cents or 54.5 percent from 1.1 cents yesterday to 1.7 cents, today, and noted a "significant increase" in the trading volume.
The Malta-based Neurotech said it had "recently underwent a board renewal and indicated a targeted focus on best possible outcomes for shareholders".
Neurotech was up 0.2 cents or 18.2 percent to 1.3 cents with 27.9 million shares traded.

MGC PHARMACEUTICALS

MGC says the Australian Office of Drug Control has approved a marijuana research licence in collaboration with the Royal Melbourne Institute of Technology.
MGC said the licence would enable it to cultivate marijuana for research at its Melbourne-based research facility.
The company said its botanical and pre-clinical research would focus on optimizing breeding and cultivation processes and "extracting material to assess the efficacy on prostate, melanoma and other cancer cells".
MGC said it would fund the research and own the resulting intellectual property.
MGC was up 0.3 cents or 5.7 percent to 5.6 cents with 9.3 million shares traded.

IMMURON

Empery Asset Management says it has reduced its holding in Immuron from 8,799,105 shares (6.15%) to below the 5.0 percent substantial level.
The New York-based Empery said it disposed of 10,521,610 shares on May 24, 2019, and again failed to disclose the prices paid.
In its most recent previous substantial shareholder notice in April, Empery said it held 8,799,105 shares (6.15%) (BD: Apr 12, 2019).
Today, Ryan Lane as managing member of Empery AM GP LLC, did not explain the increase of 1,722,505 shares or 1.2 percent of the company.
In the substantial shareholder notice, Empery said the listed holders of shares included Ryan Lane, Marin Hoe, Empery Asset Management, Empery AM GP, Empery Asset Master, Empery Tax Efficient LP and Empery Tax Efficient II LP.
Immuron fell 1.5 cents or 9.4 percent to 14.5 cents.

CARDIEX

Cardiex said it has appointed Rhonda Welch as its head of marketing, effective from May 28, 2019.
Cardiex said Ms Welch would lead its marketing initiatives for its wearable devices, medical devices, telehealth and patient and clinical education.
The company said that Ms Welch had 20 years of experience in the US healthcare industry working for Johnson & Johnson and Baxter Healthcare.
Cardiex said Ms Welch was the founder of Welch Healthcare Consulting and was appointed to its advisory board last year (BD: Jul 3, 2018)
The company said Ms Welch held a Master of Economics from the University of Notre Dame in Indiana.
Cardiex fell 0.1 cents or 2.9 percent to 3.4 cents with 1.4 million shares traded.

REDHILL BIOPHARMA

Redhill says it has appointed Prof June Almenoff as its chief scientific officer.

Redhill said that Prof Almenoff was a pharmaceutical executive with gastroenterology and infectious diseases expertise and would lead the commercial strategy for medical and scientific matters, including for Talicia (RHB-105) for Helicobacter pylori infection in preparation for a potential US launch by the end of 2019.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Today, Redhill said that Prof Almenoff would oversee the clinical development of RHB-204 for pulmonary non-tuberculous mycobacteria infections and the pivotal phase III study planned for the second half of 2019.

The company said that Prof Almenoff was currently an adjunct professor at the Durham, North Carolina-based Duke University School of Medicine and previously was Furiex Pharmaceuticals chief medical officer and prior to that worked for Glaxosmithkline.

Redhill said that Prof Almenoff held a Bachelor of Arts from the Northampton, Massachusetts-based Smith College and a Doctor of Medicine-Doctor of Philosophy from New York's Mt Sinai School of Medicine.

On the Nasdaq, Redhill fell 41.11 US cents or 5.3 percent to $US7.40 ($A10.69) with 75,397 shares traded.