Biotech Daily

Tuesday October 2, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: FACTOR UP 12.5%; BIONOMICS DOWN 66%**

*** BIONOMICS FALLS 69% AS 'BNC210 FAILS PTSD PRIMARY ENDPOINTS'**

*** QUE Q-122 PHASE II POST-BREAST CANCER HOT FLUSH TRIAL**

*** RESAPP SLEEP APNOEA STUDY RESULTS 'WITHIN A WEEK'**

*** VISIONEERING APPOINTS AUSTRALIA, NEW ZEALAND DISTRIBUTORS**

*** NEUROTECH SUBMITS US FDA MENTE AUTISM APPLICATION**

*** AUSCANN ONLINE MEDICAL MARIJUANA COURSES**

*** LIFESPOT ACQUIRES SENG VITAL CANNABIS VAPORIZER**

*** G MEDICAL HIRES UNNAMED UNDERWRITER FOR NASDAQ OFFER**

*** RICHARD CASHIN TAKES 23% OF GI DYNAMICS**

*** AUSTRALIAN ETHICAL BELOW 5% OF IMMUTEP**

*** NEVILLE BASSETT REPLACES PHARMAUST DIRECTOR DR WAYNE BEST**

MARKET REPORT

The Australian stock market fell 0.75 percent on Tuesday October 2, 2018 with the ASX200 down 46.1 points to 6,126.2 points. Ten of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Factor Therapeutics was the best, up 0.9 cents or 12.5 percent to 8.1 cents with 3.3 million shares traded. Compumedics and Reva climbed six percent or more; ITL was up 5.9 percent; Universal Biosensors improved 4.35 percent; Impedimed, Medical Developments and Opthea rose more than two percent; with Clinuvel and Paradigm up by less than one percent.

Bionomics led the falls, closing down 33 cents or 66 percent to 17 cents, with 38.2 million shares traded. Mesoblast lost 14.5 percent; Orthocell fell 11.9 percent; Dimerix was down 6.7 percent; Benitec and Pro Medicus were down more than five percent; Avita and Starpharma fell four percent or more; Genetic Signatures and Polynovo were down more than three percent; Actinogen, CSL, Cynata, Neuren and Oncosil shed two percent or more; Immutep, Optiscan, Osprey, Pharmaxis, Prescient and Resmed were down by one percent or more; with Cochlear, Nanosonics and Volpara down by less than one percent.

BIONOMICS

Bionomics fell 69 percent when its 193-patient, phase II trial of anti-anxiety drug BNC210 in adults with post-traumatic stress disorder (PTSD), failed to meet its primary endpoint.

Bionomics said the trial "did not meet [the] primary endpoint of decrease in PTSD symptoms as measured by CAPS-5 at 12 weeks" (BD: Jun 30, 2016).

The company said the primary endpoint was the clinician-administered PTSD scale for the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5), or CAPS-5.

Bionomics said that "evidence of anti-depressant effects and anti-anxiety activity [was] observed in the CAPS-5 symptom clusters [and] BNC210 treatment was safe and well-tolerated".

Bionomics chief executive officer Dr Deborah Rathjen told a teleconference that the trial produced "positive clinical trial data" and BNC210 was active after a single dose.

Dr Rathjen said that all work on BNC210 would cease, except the current trial for agitation, with results expected by April 2019.

In May, Bionomics said it had recruited the first of up-to 40 patients for its randomized, double-blind phase II trial of BN210 for geriatric agitation (BD: May 23, 2018).

"Unfortunately, we haven't been able to deliver the results we hoped for … and we are deeply disappointed," Dr Rathjen told the teleconference.

Dr Rathjen said the detailed results showed evidence of anti-anxiety effects and a positive safety profile, but the company would stop all other work on BNC210.

Bionomics chief medical officer Prof Paul Rolan said the trial compared three doses of BNC210 (150mg, 300mg, 600mg and placebo) taken twice daily for 12 weeks, with no significant difference between groups except for some trends in the highest dose group.

University of California San Diego psychiatry professor Prof Murray Stein told the teleconference that "although the results were negative for PTSD, BNC210 may have potential for some of the symptoms of PTSD".

In June 2009, Bionomics said it had begun a 28-patient, phase I trial of anti-anxiety drug BNC210 at the Royal Adelaide Hospital evaluating the safety, tolerability and the pharmacokinetics of BNC210 and in October reported BNC210 was safe, well-tolerated and had "no clinically significant adverse events" (BD: Jun 25, Oct 27, 2009).

Bionomics said at that time that the preclinical profile of BNC210 indicated it was fast-acting and lacked the side-effects seen with current anxiety treatments with the same or greater therapeutic benefit.

In 2011, the company said that two phase Ib trials of BNC210 demonstrated efficacy with reduced sedation and intellectual impairment (BD: Mar 30, 2011).

In 2012, Bionomics said it had licenced BNC210 to the Cambridge, Massachusetts-based Ironwood Pharmaceuticals in a potential $US345 million deal, with a $US3 million (then $A2.9 million) upfront fee but potentially $US345 million in upfront and milestone payments and research funding, as well as royalties on sales of products incorporating BNC210 and other related compounds, with Ironwood responsible for development and commercialization of all products incorporating BNC210 or other licenced compounds, including clinical trials (BD: Jan 22, 2012).

In 2014, Bionomics said it had taken back anti-anxiety drug BNC210 from Ironwood saying the two companies "mutually agreed to terminate this arrangement" but Ironwood would retain a royalty interest in BNC210 (BD: Nov 11, 2014).

Last night on the US OTC market, Bionomics was up 58.4 percent to 61 US cents (84.5 Australian cents), with 227,832 shares traded.

On the ASX today, Bionomics fell as much as 34.5 cents or 69.0 percent to 15.5 cents before closing down 33 cents or 66 percent to 17 cents with 38.2 million shares traded.

QUE ONCOLOGY

Que says it will recruit 130 women for a phase II trial of its non-hormonal Q-122 for women with breast cancer suffering hot flushes and night sweats.

Last year, Que said it had raised $21.4 million from Uniseed and Brandon Capital's Medical Research Commercialisation Fund for the studies (BD: Jun 6, 2017).

The Melbourne-based Que said the placebo-controlled, double-blind trial to be conducted at six Australian sites followed four phase I trials, with US hospitals expected to participate in the study, which would take up-to eight months.

The company said that following a diagnosis of breast cancer, women were routinely prescribed drugs such as tamoxifen or aromatase inhibitors, known as endocrine therapy, which reduced or blocked the action of oestrogen, a hormone known to stimulate the growth of breast cancer.

Que said that one side-effect of reducing oestrogen was an increased likelihood of moderate to severe hot flushes and night sweats.

The company said that the symptoms could "severely impact a women's general well-being and often cause women to stop taking their breast cancer treatment" and it hoped to develop a therapy to address the symptoms.

Que said that previous trials showed that Q-122 had "an excellent safety profile" in more than 60 patients and healthy volunteers.

The company said that in a phase Ib trial in women undergoing oestrogen reduction therapy for breast cancer, 14 of 16 women in the trial (87.5%) showed a reduction in both the frequency and severity of their hot flushes.

Que chief executive officer Dr Rob Crombie said that "up to 75 percent of women undergoing long-term preventative breast cancer treatment suffer hot flushes and night sweats, with some facing more than 20 events in one day".

"We expect through our phase II trials to replicate the data that we have already seen in this patient group as we develop a treatment to substantially improve the quality of life for women on long-term endocrine therapy," Dr Crombie said.

Que said that Melbourne's Monash University endocrinologist and chair of women's health Prof Susan Davis would be the trials lead clinical investigator.

"Many people don't understand the full impact of hot flushes and night sweats," Prof Davis said. "They can be debilitating and negatively affect overall quality of life."

"There is a desperate need for clinical trials of treatments for hot flushes experienced by women undergoing breast cancer therapy," Prof Davis said.

Que said its compounds had "the potential to expand into related conditions, such as hot flushes associated with menopause and hot flushes experienced by men undergoing prostate cancer treatment".

Que is a private company.

RESAPP HEALTH

Resapp says it has completed recruitment of the 600 patients for its prospective, double-blind, sleep apnoea clinical study in Perth, Western Australia.

Resapp said it previously announced its 731-patient proof-of-concept study showed that its sound-based smartphone algorithm for moderate and severe obstructive sleep apnoea showed 86 percent sensitivity and 83 percent specificity compared to simultaneous laboratory poly-somnography (BD: Apr 10, 2018).

Today, the company said the current study was looking to confirm the findings.

Resapp said that top-line results "should be available within a week".

Resapp fell half a cent or 2.2 percent to 22 cents with 4.7 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has appointed Corneal Lens Corp and Contact Lens Centre Australia to distribute its Naturalvue contact lenses in Australia and New Zealand.
Visioneering said that the Christchurch, New Zealand-based Corneal Lens Corp and its associated company Contact Lens Centre Australia would distribute the lenses.
The company said that Corneal Lens Corp was a manufacturer and distributor of contact lens and vison care products in Australasia, South Africa and Hong Kong.
Visioneering said that Contact Lens Centre Australia was a distributor of eye care products and contact lenses in Australia, with a distribution facility in Melbourne.
Visioneering was unchanged at 16.5 cents.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has submitted its application for the Mente Autism program to the US Food and Drug Administration.
Neurotech said it expected the de-novo application approval process to take nine to 12 months.
Neurotech chief executive officer Wolfgang Storf said the filing was “another important milestone for the company”.
Neurotech was unchanged at 13.5 cents.

AUSCANN GROUP

Auscann says it has released “a series of online courses for Australian health professionals, as a part of its medical outreach program”.
Auscann said the program would “support Australian medical practitioners and health professionals with the necessary information to confidently make decisions regarding use of cannabinoid medicines”.
In 2017, the company said it had appointed Canada’s Dr Danial Schecter as its chief medical advisor and subsequently appointed three medical liaison managers to provide guidance and information to the medical community (BD: Jun 15, 2017).
Auscann chairman Dr Mal Washer said that it was “essential that Australian doctors are informed about the endo-cannabinoid system and cannabinoid therapeutics so that they can make informed decisions regarding treatment possibilities”.
“Until it becomes part of the medical syllabus, there is a need to provide accessible, referenced, objective information about cannabinoid medicines that doctors and other health professionals can draw upon to inform their thinking,” Dr Washer said.
Auscann fell 1.5 cents or 1.5 percent to 97 cents.

LIFESPOT HEALTH

Lifespot says it has acquired the remaining 50 percent of Seng Vital to take control of the company and its smart cannabis vaporizer assets (BD: Sep 18, 2018).
Lifespot said the Seng-Vital Cannamed Bluetooth cannabis vaporizer provided “a straightforward, secure and self-controlled method to deliver medicines”.
The company said that the global recreational and medical marijuana vapor market was estimated at $US11.43 billion in 2016 and was expected to be more than $US86.43 billion by 2025.
Lifespot was untraded at 8.1 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical says it has engaged an unnamed New York underwriter to assist in a US public offer through the Nasdaq Exchange.
G Medical said it would remain listed on the ASX and hoped to list on the Nasdaq “within the next four to five months”, pending regulatory and shareholder approvals.
Late last year, founder Dr Yacov Geva said that he owned 57.51 percent of the company (BD: Nov 22, 2017).
G Medical fell half a cent or 1.4 percent to 34.5 cents.

IMMUTEP

Australian Ethical Investment says it has reduced its substantial shareholding in Immutep from 153,530,938 shares (5.07%) to below the 5.0 percent substantial level.
Australian Ethical said that on September 27 and 28 sold 4,028,213 shares for $186,343 or 4.6 cents a share.
Immutep fell 0.1 cents or 1.8 percent to 5.5 cents with 13.4 million shares traded.

GI DYNAMICS

The New York-based Richard Cashin says he has become a substantial shareholder in GI Dynamics with 175,545, 263 shares (22.90%).
Mr Cashin said that on September 21, 2018 he acquired 150,000,000 Chess depository instruments (CDIs) for $3 million or two cents a share.
Last month, GI Dynamics said it had commitments for a $6,944,445 placement at 2.0 cents per CDI (BD: Sep 20, 2018).
GI Dynamics fell 0.2 cents or 8.7 percent to 2.1 cents.

PHARMAUST

Pharmaust says that Neville Bassett has been appointed as a non-executive director replacing subsidiary Epichem chairman Dr Wayne Best, effective today.
Pharmaust said that Mr Bassett was an accountant specializing in corporate, financial and management advisory services and had been involved with public company listings and capital raisings.
The company said that Mr Bassett was currently the chairman of Westar Capital and a director or company secretary of public and private companies.
Pharmaust said that in 1991 Mr Bassett was appointed a director of the Royal Flying Doctor Service in Western Australia and had been chairman of its western operations since 2009.
Pharmaust said that Dr Best would retire as a non-executive director of Pharmaust and continues as Epichem chairman.
Pharmaust was up 0.1 cents or 2.9 percent to 3.5 cents.