Biotech Daily

Monday July 9, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BENITEC UP 110%; ONCOSIL DOWN 6%**

*** BENITEC UP 124% ON UP-TO $892m AXOVANT GENE THERAPY DEAL**

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*** GI DYNAMICS: RISK-BENEFIT STUDY 'ENDOBARRIER SAFE'**

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*** HYDROPONICS EXTENDS ENDOCA MARIJUANA DEAL**

*** PARADIGM PLEADS SCHULTZ, GOOD NEWS TO ASX 24% QUERY**

*** INVICTUS APPOINTS LOU PANACCIO, RICHARD ESTALELLA DIRECTORS**

MARKET REPORT

The Australian stock market was up 0.22 percent on Monday July 9, 2018 with the ASX200 up 13.7 points to 6,286.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

Benitec was the best, climbing as much as 18 cents or 124.1 percent to 33.5 cents, before closing up 16 cents or 110.3 percent at 30.5 cents with 28.2 million shares traded. LBT climbed 4.55 percent; Osprey and Prana were up more than three percent; Clinuvel, Dimerix, Factor Therapeutics, Mesoblast and Nanosonics rose two percent or more; Compumedics, Ellex, Neuren, Opthea, Pharmaxis and Starpharma were up one percent or more; with Pro Medicus and Sirtex up by less than one percent.

Oncosil led the falls, down 1.5 cents or six percent to 23.5 cents with 4.5 million shares traded. Volpara fell 4.4 percent; Airxpanders, Optiscan, Prescient and Universal Biosensors lost three percent or more; Avita shed 2.9 percent; Bionomics, Impedimed and Polynovo were down one percent or more; with Cochlear, CSL, Cynata, Medical Developments and Resmed down by less than one percent.

BENITEC BIOPHARMA

Benitec climbed as much as 124.1 percent on an up-to $US665 million ($A891.65m) deal with the London and Bermuda based Axovant Sciences for its gene therapy programs.

Benitec said it would receive an upfront cash payment of $US10 million with additional cash payments totalling $US17.5 million for near-term milestones for BB-301 for oculo-pharyngeal muscular dystrophy (OPMD), renamed AXO-AAV-OPMD.

The company said it would be eligible for $US187.5 million in milestone payments, including the $US17.5 million, and would retain 30 percent of the net profits on the worldwide sales of AXO-AAV-OPMD.

Benitec said it would partner with Axovant on five additional gene therapy programs for neurological disorders, receive full research funding for each program and be eligible for $US93.5 million in development, regulatory and commercial milestones, for each program.

Benitec executive chairman Dr Jerel Banks said that “today marks a milestone for Benitec as we believe this transaction to be transformative for our company”.

“In addition to bolstering our opportunity to drive broad-based, clinically meaningful patient benefit across several areas of clinical medicine with true unmet need, this partnership significantly enhances the financial, intellectual, and clinical development resources available to facilitate our efforts to build Benitec into a diversified biopharmaceutical company,” Dr Banks said.

“The non-dilutive capital expected over the near term will allow Benitec to continue to invest in … programs across a range of indications,” Dr Banks said.

“Our management team is focused exclusively on expanding the research, development, and commercial opportunities for the core silence-and-replace platform with the dual goals of enhancing patient benefit and generating shareholder value,” Dr Banks said.

Benitec said that oculo-pharyngeal muscular dystrophy was “a rare progressive, and often fatal, muscle-wasting disease caused by mutation in the poly(A)-binding protein nuclear 1 (PABPN1) gene, that is characterized by eyelid drooping, swallowing difficulties and proximal limb weakness”.

The company said AXO-AAV-OPMD was a single vector, gene-therapy construct system that used a silence-and-replace method employing DNA-directed RNA-interference (ddRNAi) to silence expression of the mutant gene associated with OPMD, while simultaneously expressing a copy of the normal, healthy version of the same gene to restore the function of that gene.

Benitec said that Axovant planned to begin a placebo-controlled clinical study in 2019 in which a single intra-muscular administration of AXO-AAV-OPMD would be given to patients to treat the dysphagia associated with OPMD.

Axovant chief executive officer Dr Pavan Cheruvu said that “the silence-and-replace platform is a targeted approach which directly addresses the underlying genetic cause of diseases arising from expression of dysfunctional proteins, including those caused by nucleotide repeat expansion”.

“I am excited about the potential of this platform for patients suffering from OPMD, many of whom have limited treatment options today,” Dr Cheruvu said.

Benitec said that the first of the five additional programs would focus on developing a single vector silence-and-replace gene therapy product targeting the c9orf72 gene, which was associated with amyotrophic lateral sclerosis and fronto-temporal dementia.

Benitec said that in addition to funding for development of the new research programs, each program target was eligible for milestones totalling $US93.5 million and tiered royalties on global sales.

Benitec closed up 16 cents or 110.3 percent to 30.5 cents with 28.2 million shares traded.

ADMEDUS

Admedus says it has appointed the Bologna, Italy-based Medical Instruments SpA as the exclusive distributor for its Adapt bovine tissue patches in Italy.
Admedus said that initially Medical Instruments would distribute its flagship Adapt bio-scaffold Cardiocel for congenital and structural heart defects and disease.
Admedus chief operating officer David St Denis said the company was “delighted to partner with Medical Instruments to distribute our … technology to the patients and surgeons of Italy”.
Admedus was unchanged at 24 cents.

GI DYNAMICS

GI Dynamics says a report from the Association of British Clinical Diabetologists “indicates that Endobarrier is safe and effective” for diabetes and obesity.
GI Dynamics said the Knowle, Solihull, England-based Association of British Clinical Diabetologists (ABCD) worldwide Endobarrier registry conducted a study with more than 400 patients in 13 centres in four countries, titled ‘First Risk-Benefit Data from the Worldwide Endobarrier Registry’, that showed a mean reduction of 1.5 percent absolute glycated haemoglobin, HbA1C or blood glucose, in 195 patients, and an average 11.2 percent or 14kg weight loss in 256 patients, as well as an associated reduction of 9mmHg of systolic blood pressure in 149 patients from 139mmHg to 130mmHg, between Endobarrier baseline and explant.
The company said the registry showed a serious adverse event rate of 5.7 percent, the majority 3.7 percent gastrointestinal bleeds, but said that all patients suffering a serious adverse event made a full recovery, with many experiencing “considerable benefit despite complications during treatment”.
Sandwell and West Birmingham Hospitals’ Dr Robert Ryder presented the results at the American Diabetes Association meeting in Orlando, Florida from June 22 to 26, 2018 and said the data suggested “the benefits of Endobarrier treatment far outweigh the risks”.
“Our patients are enthusiastic about what Endobarrier has done for them…many of those who face complications still experienced health benefits,” Dr Ryder said.
GI Dynamics was untraded at 3.5 cents.

BIONOMICS

Bionomics says that all 193-patients in its phase II trial of BNC210 for post-traumatic stress disorder have completed treatment, with results expected by April 2019.
In April, Bionomics said that its 192-patient ‘Restore’ phase II safety and efficacy trial of BNC210 for post-traumatic stress disorder was fully recruited, with results expected this year (BD: Apr 11, 2018).
Today the company said the randomized, double-blind, placebo-controlled trial at sites in the US and Australia had a primary endpoint of a decrease in post-traumatic stress disorder (PTSD) symptoms as measured by the clinician-administered PTSD scale (CAPS-5), with secondary endpoints including a decrease in symptoms of anxiety and depression.
Bionomics chief executive officer Dr Deborah Rathjen said that BNC210 had “the potential to be an innovative treatment for patients with PTSD with a solid foundation of clinical data supportive of development not only in PTSD but also in anxiety disorders and conditions where there is co-morbid anxiety and depression”.
Bionomics fell half a cent or 0.95 percent to 52 cents.

STARPHARMA

Starpharma says that a US Food and Drug Administration filing review of the Vivagel BV new drug application found no issues and confirmed its progress to the next stage.
Starpharma said the confirmation of its new drug application filing for Vivagel for bacterial vaginosis (BV) was “a significant regulatory milestone”.
The company said the acceptance “reflects the completeness of the Vivagel BV data package and is expected to positively impact on licencing for the North American region, which is in the advanced stages of negotiation”.
Starpharma said that the FDA confirmed that the application would be the subject of a priority review, which had a target review period of about six months from acceptance.
Starpharma chief executive officer Dr Jackie Fairley said the company was “extremely pleased to have achieved FDA’s acceptance and confirmation that the substantive review is now in progress”.
“This is an important achievement for Starpharma and creates significant commercial value,” Dr Fairley said.
“It’s timely from a licencing perspective as this milestone will positively impact the advanced negotiations currently underway for the North American region and we look forward to making an announcement shortly,” Dr Fairley said.
Starpharma was up 1.5 cents or 1.3 percent to $1.135.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says results from a 34-patient US trial of its Mente Autism neurofeedback device show a “positive impact”.
Neurotech said that research at the Cape Canaveral, Florida-based Carrick Institute concluded that a “short 12-week course of [neurofeedback] using the Mente Autism device can lead to significant changes in brain activity (qEEG), sensorimotor behavior (posturography) and behavior (standardized questionnaires) in [autism spectrum disorder] children”.
The research article, titled ‘The Treatment of Autism Spectrum Disorder With Auditory Neurofeedback: A Randomized Placebo Controlled Trial Using the Mente Autism Device’ was published in Frontiers In Neurology and the full article is available at: https://www.frontiersin.org/articles/10.3389/fneur.2018.00537/full.
Last year, the company said the Mente Autism neurofeedback device was a head band that measured a child’s brain waves and changed sounds to match the needs of the child, with treatment given for 40 minutes each morning of the 12-week trial (BD: Sep 27, 2017)
Today, Neurotech said the study investigated its Mente Autism device, with 17 active treatment patients and 17 control patients.
Carrick Institute founder, principle investigator for the study and lead author of the journal article Prof Frederik Carrick said the Institute was “excited that the study has yielded statistically significant results which show improvements across a wide range of functional areas in the active group, and not in the control group”.
“All of these support the positive feedback and gratitude we have received from parents in the active group, who have noticed improvements in communication and social skills in their child,” Prof Carrick said.
“This study has shown that Mente Autism has a real potential to be considered as a complementary therapy for autistic children,” Prof Carrick said.
Neurotech said the positive results would allow it to progress toward a US Food and Drug Administration submission for Mente Autism, which it aimed to have by October, 2018.
Neurotech fell one cent or 6.25 percent to 15 cents with 2.8 million shares traded.

NOXOPHARM

Noxopharm says patients from its now 24-patient phase Ib study of NOX66 for late-stage prostate cancer have reported dry mouth, mucositis oral and fatigue.
Noxopharm said the nine patients from its direct and abscopal response to radiotherapy (DARRT) study reported the three grade 1, or mild adverse events "possibly related" to NOX66 therapy, with eight of the patients from cohorts one and two, which had NOX66 dosages of 400mg and 800mg respectively and one patient from cohort three, which was dosed at 1200mg.
The company said the data suggested a treatment comprised of seven days of radiotherapy at 20 Gray units and 15 days of NOX66 therapy, with doses of 400 and 800 mg, could be free from the risk of enhanced radiation sickness.
In April, Noxopharm said it had been approved to enrol the second cohort of its combination trial of NOX66 with 177-lutetium radiotherapy for prostate cancer, with enrolment expected to be completed by August 2018 (BD: Apr 17, 2018).
Noxopharm fell 3.5 cents or 5.5 percent to 60 cents.

THE HYDROPONICS COMPANY

Hydroponics says it has extended its deal with Endoca to develop and produce pharmaceutical-grade marijuana products from European and Australian facilities.
Last year, Hydroponics said it would distribute the Hoofddorp, Netherlands-based Endoca BV's medical cannabis products in Australia, through its wholly-owned subsidiary Canndeo (BD: Nov 15, 2017).
Today, the company said it would work with Endoca to supply to multiple international markets. the two companies would have access to each other's cannabis strains and processing methods formulations and it would potentially develop pharmaceutical marijuana products at Hydroponics' Southport, Queensland facility.
Hydroponics was unchanged at 57 cents.

PARADIGM BIOPHARMA

Paradigm 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 17.5 cents or 24.1 percent from 72.5 cents to 90 cents on July 6, 2018 and noted "elevated volumes" of securities traded.
According to ASX data provided by Commsec, Paradigm closed on Friday July 6 at 83 cents with 827,057 shares traded.
Paradigm said that a series of announcements in June and July, as well as news coverage including Biotech Daily data published on line by Stockhead could have been factors in the recent trading.
On July 2, Biotech Daily noted that Paradigm's market capitalization had increased 300 percent in the 12 months to June 30, 2018.
Paradigm fell two cents or 2.4 percent to 81 cents.

INVICTUS BIOTECHNOLOGY

Invictus says it will appoint Lou Panaccio as an independent non-executive director and on June 29, 2018 appointed Richard Estalella as an executive director.

Invictus said that Mr Panaccio was currently a non-executive director of Sonic Healthcare, Avita Medical and Genera Biosystems and previously was an executive and/or director of Melbourne Pathology Group and Monash IVF Group.

The company said it was in the process of restructuring to a public unlisted company which would conduct an initial public offer and list on the ASX by the end of 2018, with Mr Panaccio's appointment effective as of the date of incorporation.

Invictus said that Mr Estalella, previously was appointed as an advisor and was currently the chief executive officer-designate of its US subsidiary, which was in the process of being established.

The company said that Mr Estalella previously was the president of Musclepharm Corp, a US sports nutrition product company.

Invictus is a private company.