Biotech Daily

Wednesday June 26, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMUGENE UP 7%; USCOM DOWN 15%**

*** BIONOMICS BNC210 FAILS AGITATION TRIAL**

*** SUDA 'OVERSUBSCRIBED RIGHTS' RAISE $3.9m**

*** ALCIDION RENEWS $970k WESTERN SUSSEX PATIENTRACK CONTRACT**

*** DIMERIX OPENS WA RECRUITMENT FOR DMX-200 TRIALS**

*** RHYTHM ADDS ALFRED HOSPITAL TO COLOSTAT TRIAL**

*** BANK OF AMERICA SELLS, TRANSFERS SHARES, TAKES 5% OF IDT**

*** JENCAY CAPITAL TAKES 12% OF UNIVERSAL BIOSENSORS**

*** MACQUARIE TAKES 5% OF IMPEDIMED, YET AGAIN**

*** AIRXPANDERS 3rd 'DEBT AGREEMENT' SUSPENSION EXTENSION**

*** SALESH BALAK REPLACES UNIVERSAL BIOSENSORS RICK LEGLEITER**

MARKET REPORT

The Australian stock market fell 0.26 percent on Wednesday June 26, 2019, with the ASX200 down 17.5 points to 6,640.5 points.

Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and two were untraded.

Imugene was the best, up 0.1 cents or 7.1 percent to 1.5 cents, with 1.1 million shares traded. Proteomics climbed 6.15 percent; Polynovo was up 4.1 percent; Opthea improved 3.9 percent; Mesoblast and Optiscan rose more than two percent; Avita was up 1.2 percent; with Cochlear, Compumedics, CSL, Cynata, Ellex and Medical Developments up by less than one percent.

Uscom led the falls, down 2.5 cents or 15.15 percent to 14 cents, with 69,133 shares traded. Kazia lost 11.7 percent; Osprey was down nine percent; Orthocell fell 5.3 percent; Clinuvel, Oncosil and Telix retreated four percent or more; Alterity (Prana) was down 3.3 percent; Antisense, Cyclopharm, Immutep, Prescient and Pro Medicus shed two percent or more; Paradigm and Volpara were down more than one percent; with Nanosonics, Neuren, Resmed and Starpharma down by less than one percent.

BIONOMICS

Bionomics says its 40-patient, phase II trial of BNC210 for agitation “did not differentiate from placebo on the primary and secondary efficacy end points”.

Last year, Bionomics fell as much as 69 percent to 15.5 cents on news that BNC210 failed to meet its primary endpoint in a 193-patient trial for post-traumatic stress disorder (PTSD) (BD: Oct 2, 2018).

Today, the company said the top-line results of the BNC210 exploratory trial for agitation in elderly patients in a hospital setting “indicated that BNC210 treatment did not differentiate from placebo on the primary and secondary efficacy end points”.

Bionomics said that comparison of mean peak daily Pittsburgh agitation scale scores, or observations of aberrant vocalization, motor agitation, aggressiveness and resisting care, “showed a gradual improvement for both BNC210 and placebo over the five-day treatment period, but without evidence of a treatment effect”.

The company said that the phase II study was designed to assess the therapeutic potential of BNC210 to treat agitation in hospitalized elderly patients as a separate indication and to evaluate safety of BNC210 in the elderly patient population.

Bionomics said that the safety of BNC210 was confirmed.

Bionomics consultant chief medical officer Prof Paul Rolan said that the trial results “do not support further development of BNC210 for treatment of agitation, [but] given BNC210’s consistent safety profile and the demonstration by pharmaco-metric exposure-response modelling of its potential to treat post-traumatic stress disorder, we remain confident in pursuing PTSD, provided that we can achieve the blood exposure levels predicted by the modelling analysis“.

The company said that to build the case for BNC210, it would invest $300,000 in a single ascending dose study in healthy volunteers to show that BNC210 blood levels necessary to meet the primary endpoints for effectiveness in treating PTSD in a further trial, were achievable using the solid dose formulation, with results expected about October.

Bionomics executive chairman Dr Errol De Souza said that if the solid dose formulation study confirmed that the required blood levels were achievable, and the US Food and Drug Administration guidance supported a second phase II trial of BNC210 in PTSD, “then Bionomics intends to proceed with the further formulation development and preparation for a second phase II trial”.

“We believe that, a second trial of BNC210 in PTSD will be the best option available to Bionomics to rebuild shareholder value,” Dr De Souza said. “However, it is clear that we will require funding beyond our current resources to do so.”

Dr De Souza said the company had “expressions of interest from third parties to provide funding for the trial” and would engage with shareholders, partners and others.

Bionomics fell as much as 2.2 cents or 39.3 percent to 3.4 cents, before closing down 1.9 cents of 33.9 percent at 3.7 cents with 42.8 million shares traded.

Biotech Daily calculates that Bionomics has a market capitalization of $20.15 million, with $22.1 million in cash at March 31, 2019.

SUDA PHARMACEUTICALS

Suda says it has raised $3,897,650 in a “significantly oversubscribed” rights offer at 0.4 cents a share.

Suda said it raised $3,442,612 from institutional shareholders and new investors in the oversubscribed rights issue and an additional $455,038 in a placement, for a total of $3.9 million.

Suda was unchanged at 0.4 cents with 3.4 million shares traded.

ALCIDION

Alcidion says it has renewed its $970,000 Western Sussex Hospitals National Health Service Trust Patientrack contract for five years.
Alcidion said it was the second renewal by Western Sussex and the Patientrack hospital workflow system was operational in 68 wards across the Trust's three hospitals.
Alcidion was up half a cent or 4.35 percent to 12 cents with 3.4 million shares traded.

DIMERIX

Dimerix says it will open recruitment for its two current phase II trials of DMX-200 at the Perth, Western Australia-based Linear Clinical Research.
Dimerix said it was conducting a 10-patient trial of DMX-200 for focal segmental glomerulosclerosis (FSGS) and a 40-patient trial of DMX-200 for diabetic kidney disease.
The company said the FSGS trial was a 16-week, phase IIa, double-blind, randomized, placebo-controlled, crossover safety and efficacy study.
Dimerix said the diabetic kidney disease trial was a 12-week, phase II, double-blind, randomized, placebo-controlled, crossover safety and efficacy study.
Dimerix chief executive officer Dr Nina Webster said the trials were "close to achieving full recruitment".
"These results are pivotal for the company as they will provide further clinical data to support the company's regulatory and partnering strategy," Dr Webster said.
Dimerix was unchanged at 8.4 cents.

RHYTHM BIOSCIENCES

Rhythm says it has added Melbourne's Alfred Hospital to its 1,000-patient Colostat clinical trial for colorectal cancer, with Prof Gregor Brown as the principal investigator.
The company said the trial was a prospective, cross-sectional, multi-centre study comparing Colostat to faecal immune test, relative to colonoscopy (BD: Feb 20, Mar 18, 2019).
Rhythm said it expected to complete recruitment by the end of this year.
Rhythm was up one cent or 6.1 percent to 17.5 cents.

IDT AUSTRALIA

The Bank of America says it has become a substantial shareholder in IDT with 12,220,000 shares or 5.16 percent.
The Charlotte, North Carolina-based Bank of America said that Merrill Lynch Futures held 6,710,000 shares and Merrill Lynch International held 5,510,000 shares.
The Bank of America said that on March 22, 2019 it sold 6,000,000 shares for $900,000 or 15 cents a share and returned 2,454,080 shares.
The Bank of America said it returned 20,082 shares on March 29 and borrowed 4,020,082 shares on June 20, 2019.
The substantial shareholder notice did not explain how the Bank of America became substantial by selling and transferring out shares, but included an 'International Prime Brokerage Agreement' naming Sydney's Regal Funds Management as trustee of the Atlantic Absolute Return Fund.
IDT was up 1.5 cents or 9.7 percent to 17 cents.

UNIVERSAL BIOSENSORS

Jencay Capital says it has increased its shareholding in Universal Biosensors from 16,775,962 shares (9.47%) to 20,792,320 shares (11.72%).
The Sydney-based Jencay said that between March 27 and June 24, 2019, it acquired 4,016,358 shares for $778,760 or 19.4 cents a share.
Universal Biosensors was unchanged at 19 cents.

IMPEDIMED

The Sydney-based Macquarie Group and related parties say they have become substantial shareholders in Impedimed with 18,993,265 shares or 5.00 percent.
Macquarie Group said that in hundreds of trades between May 23 and June 21, 2019 it bought, sold, borrowed, returned and transferred shares at prices between 11 cents and 19 cents.
In 2017, Macquarie Group said it had become substantial in Impedimed with 20,647,529 shares (5.50%), buying shares at prices ranging from 57 cents to 85 cents, ceasing its substantial holding in July 2017 (BD: Jun 30, Jul 11, 2017).
In 2018, Macquarie Group said it bought Impedimed shares at prices ranging from 35 cents to 46 cents, ceasing its substantial holding in March 2019 (BD: Aug 13, 2018).
Last month, the Group said it became substantial in Impedimed with 19,041,569 shares (5.01%) and on May 27 ceased its substantial holding (BD: May 21, 2019).
Impedimed was untraded at 11.5 cents.

AIRXPANDERS

Airxpanders has requested its third extension for its suspension to “finalize its review of financial and strategic alternatives and provide the market with an accurate update”.
In May, Airxpanders requested two extensions to its voluntary suspension, following its March 29 “debt agreement” trading halt (BD: Mar 29, Apr 2, May 3, May 17, 2019).
The company said it expected the suspension to last until July 31, 2019.
Airxpanders last traded at 3.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says Salesh Balak will replace chief executive officer Rick Legleiter as interim principal executive officer, effective from July 15, 2019
Universal Biosensors said Mr Balak would take over the role until it had more clarity on its strategic direction.