Biotech Daily

Thursday July 27, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AIRXPANDERS UP 9%, ATCOR DOWN 14%**

*** WEHI $405m+ CANADA DEAL FOR VENETOCLAX FOR CANCER**

*** G MEDICAL $84m SMARTPHONE VITAL SIGNS CHINA DEAL**

*** FDA CLEARS COGSTATE COGNIGRAM**

*** BIOTRON PHASE II BIT225 COMBINATION HIV TRIAL RECRUITED**

*** ANTISENSE RESPONDS TO FDA ATL1102 FOR MS 'MODIFICATIONS'**

*** MEMPHASYS SETTLES WITH PULAU MANUKAN, LABUAN, PRIME**

*** CRESO TO BUY MERNOVA MARIJUANA FACILITY FOR $10m**

*** IQ3 REVENUE UP 191.5% TO $5m**

*** CORMORANT INCREASES, DILUTED IN VIRALYTICS, $2.6m PROFIT**

MARKET REPORT

The Australian stock market was up 0.15 percent on Thursday July 27, 2017 with the ASX200 up 8.4 points to 5,785.0 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Airxpanders was best for the second day in a row, up a further 6.5 cents or 9.4 percent to 75.5 cents, with 282,064 shares traded. Actinogen climbed 5.3 percent; Clinuvel, Ellex, and Genetic Signatures improved more than four percent; Cellmid, Nanosonics, Neuren, Oncosil and Opthea were up more than three percent; Polynovo and Universal Biosensors rose more than two percent; Acrux, Compumedics, Cyclopharm, Impedimed and Medical Developments were up more than one percent; with Pro Medicus up 0.6 percent.

Atcor led the falls, down 0.7 cents or 14.3 percent to 4.2 cents with 129,925 shares traded. Psivida lost 11.5 percent; Admedus fell 5.6 percent; Prima fell 4.2 percent; Avita, Living Cell, Orthocell, Prana and Viralytics were down more than three percent; Bionomics, Cochlear, Pharmaxis, Resmed and Reva shed more than one percent; with CSL, Mesoblast and Sirtex down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute has signed a $US325 million ($A404.5 million) deal with the Canada Pension Plan Investment Board for part of its royalties to venetoclax.

WEHI said its researchers co-discovered venetoclax in a collaboration with Abbvie and Roche's Genentech, retaining royalty rights and today said an undisclosed portion of the royalty rights had been sold to the Canada Pension Plan Investment Board.

The Institute said there was potential for sales revenue royalties beyond the headline amount, which comprised $US250 million up-front and $US75 million in milestones.

WEHI said that venetoclax targeted the BCL-2 protein and was currently in a phase III trial for advanced chronic lymphocytic leukaemia, with potential for other cancers.

In 2016, WEHI published a 116-patient, phase I, dose-escalation Melbourne trial which showed that 92 patients (79%) had "promising responses to the drug, with 20 percent of those involved going into complete remission" (BD: Jan 28, 2016).

In May 2016, a 107-patient, single-arm, phase II trial of venetoclax for chronic lymphocytic leukaemia, published in Lancet Oncology, confirmed those results with a 79.4 percent overall response rate, and in January this year, Lancet Oncology published a 49-patient, phase Ib combination trial of venetoclax with rituximab which achieved an 86 percent overall response rate and 51 percent complete remission rate.

According to www.clinicaltrials.gov, a 389-patient, phase III trial of venetoclax with rituximab compared to bendamustine with rituximab for relapsed or refractory chronic lymphocytic leukaemia has been recruited.

The drug is approved by the US Food and Drug Administration, the European Medicines Agency and the Australian Therapeutic Goods Administration (BD: Jan 22, 2017).

Federal Health Minister Greg Hunt said the deal was "one of the great moments in Australian medical science".

Mr Hunt and Victoria Health Minister Jill Hennessy acknowledged each other's contribution to funding the Institute over many years, resulting in discoveries that benefitted people across the globe.

WEHI director Prof Doug Hilton said the discovery by then doctoral student, now Prof, David Vaux at 5.30pm on July 28, 1987 was "simple".

"Genes tell cells when to die, and if they don't, it's cancer," Prof Hilton said.

Prof Hilton said that he saluted all 400 researchers who had worked on the project, singling out the clinical researchers as those who worked full-time in their hospitals and full-time in the Institute and said venetoclax was in more than 40 trials worldwide.

Prof Hilton said the sale of partial royalties to Canada was "a landmark commercial deal" following a change of culture towards commercialization and paid tribute to the business development team led by Julian Clark and Carmela Monger.

Prof Hilton thanked "the vision and steadfast support" from the State and Federal Governments, acknowledged the previous Steve Bracks and John Brumby Governments and said the Australian Synchrotron at Clayton was "essential" for the project.

Prof Hilton said that part of the revenue would go to the Institute's endowment fund for future research projects as well as to a 100-place early childhood education centre being built on the WEHI campus to provide places for the children of working parents.

Ms Hennessy said that "we are so good at research and translation and need to improve commercialization … [but] the reason you all do this and why we support you is giving people a better life".

Ms Hennessey said she had met patients who had been told to go home and prepare to die but following venetoclax "some of those patients are alive five years later".

WEHI said MTS Health Partners was its financial advisor with Covington & Burling LLP as special counsel for the royalty sale and Norton Rose Fulbright as Australian legal adviser.

G (GEVA) MEDICAL INNOVATIONS

G Medical says the Shandong Boletong Information S&T Co will distribute a minimum of $US67,500,000 ($A83.96 million) of its products and services in China.
G Medical said that the Shandong province-based Boletong agreed to purchase a minimum quantity of units within the first year of the G Medical Smartphone Prizma and to provide associated support services for a minimum of 60 months.
The company's website said the Prizma, also described as a "smartphone jacket", had sensors to measure vital signs and biometric parameters and could continuously collect, consolidate and analyze medical data to detect trends over time.
G Medical said that the Prizma sent configurable, automatic alerts, notifications and reminders and enabled patients to instantly share data with predefined third parties, and the data could be stored in the internet 'cloud' subject to privacy policies.
The company said that Boletong's obligation to acquire units would begin on the granting of the China Food and Drug Administration certification, currently in process and Boletong it would establish a call centre providing support services from about 60 nurses and five doctors, with Boletong responsible for recruitment and the establishment of the call centre.
G Medical said that Boletong and its associations were subject to a five year non-competition restraint.
G Medical chief executive officer Dr Yacov Geva said that it was "another significant relationship for G Medical within the ever-growing and lucrative Chinese territory".
"To have further increased our purchase commitment for our G Medical Smartphone Prizma devices, over and above our existing agreements, is an exceptional outcome with a key partner in Boletong," Dr Geva said.
G Medical said that Boletong operated in more than 16 provinces and worked with the national public health care system as a distributor of medical services for the government.
G Medical rose three cents or 17.1 percent to 20.5 cents with 20.15 million shares traded.

COGSTATE

Cogstate says the US Food and Drug Administration has approved its Cognigram cognitive assessment system as a class II exempt medical device.
Cogstate said that the Cognigram system was a digital cognitive assessment tool with self-administered assessment that could be completed both in the clinic and at home.
The company said the Cognigram system was for prescription use, intended to aid healthcare professionals with an objective measurement of cognition for use in individuals aged from six years to 99 years and could be used to assess cognition on a single occasion or cognitive change over periodic assessments, with performance unaffected by language, education, cultural background, or practice.
Cogstate healthcare head Frank Cheng said that "after more than 15 years of intense efforts in supporting academic research and pharmaceutical clinical trials around the world Cogstate is excited to enter the US market for cognitive assessment on the front lines of clinical practice".
Cogstate chief executive officer Brad O'Connor said that many general practitioners and primary care physicians lacked the tools and training to conduct rapid, objective cognitive assessments.
"The launch of the Cognigram system will provide doctors with a rapid, scalable, standardized tool for detection of cognitive impairment and decline," Mr O'Connor said.
Cogstate said it expected to begin commercialization of the system in the US by the end of this year
Cogstate was up two cents or 1.9 percent to $1.07.

BIOTRON

Biotron says its 36-patient, phase II trial of BIT225 in combination with anti-retroviral therapy for HIV is fully-recruited with results expected in October 2017.
Earlier this year, Biotron chief executive officer Dr Michelle Miller said that if the results from the Bangkok, Thailand-based trial were positive, the company would expect to licence the drug to a major pharmaceutical company (BD: Feb 13, Mar 23, 2017).
Biotron was up 0.1 cents or 5.6 percent to 1.9 cents.

ANTISENSE THERAPEUTICS

Antisense says the US Food and Drug Administration requires “modifications to the proposed clinical trial” of ATL1102 for multiple sclerosis
Antisense said it had been in discussions with the FDA over the phase IIb investigational new drug application and the regulator “provided a high-level description of the necessary modifications and will provide actionable details in a formal written response … by late August 2017”.
The company said that during the clinical hold and after receipt of the FDA’s written response it would submit updates to the regulator which would have 30 calendar days to review and potentially clear the application.
Antisense said it was progressing its grant application with the US National Institute of Neurological Disorders and Stroke, where the study synopsis had passed through two levels of feasibility assessment.
The company said it would modify the proposed study design to align with both the expected FDA requirements and feedback from Institute interactions.
Antisense said it would file a submission to the Institute’s extramural science committee for review and potential approval to lodge the grant application.
The company said that its application to conduct a trial of ATL1102 in patients with Duchenne muscular dystrophy at the Royal Children’s Hospital in Melbourne was ongoing and it was addressing questions in-line with the hospital’s approval process.
Antisense was unchanged at 3.9 cents.

MEMPHASYS

Memphasys says it has reached a settlement on all disputes following mediation with Pulau Manukan Ventures Labuan Ltd and Prime Biologics Pte Ltd.
Memphasys said it had consented to Manukan’s full rights and ownership over the preference B Shares in Prime which were subject of a call option deed and Prime and Manukan would no longer pursue any claim against Memphasys in relation to the $S4.8 million debt associated with equipment at the Prime facility in Singapore, believed to be the GF100 blood separator (BD: Feb 17, 2017).
The company said that Prime had agreed to make or discharge Memphasys’ payment obligations to third parties to an agreed amount.
Memphasys said that Prime had agreed to ship certain machinery to the Memphasys Sydney premises and to pay outstanding obligations on the machinery.
The company said that by concluding the long-standing litigation it was “positioned to progress its business plan and, in particular, continue with the commercialization of its lead program, Felix, for human in-vitro fertilization”.
Memphasys rose 0.15 cents or 100 percent to 0.3 cents with 64.1 million shares traded.

CRESO PHARMA

Creso says it will acquire the Nova Scotia, Canada-based Mernova Medicinal for $C10.1 million ($A10.1 million) in cash and equity.
Creso said it would become “the only Australian cannabis company with direct exposure to the world’s largest legal medical cannabis market”.
The first marijuana company to list on the ASX, MMJ Phytotech, said it had operations in Canada and Switzerland (BD: Jan 22, Mar 24, 2015; Aug 3, 2016).
Creso said that the acquisition enabled it to integrate its supply and production chain by building its own growing and extraction facilities.
The company said that Mernova was a private company, with land suited for a medical cannabis growing facility and construction of a 20,000 square feet (1,858 square metres) facility due to begin in the coming months, and had applied for a Health Canada medical cannabis cultivation licence.
Creso was up two cents or 3.6 percent to 57 cents with 1.8 million shares traded.

IQ3 CORP

IQ3 says that customer receipts for the 12 months to June 30, 2017 were up 191.5 percent to $4,860,000.
IQ3 said it had “continued increasing business activity in specialist life science corporate advisory work with clients addressing the Australian, Chinese and United States markets”.
IQ3 was unchanged at 30 cents.

VIRALYTICS

Cormorant Healthcare says it has increased and been diluted in Viralytics from16,420,361 shares (8.9%) to 18,091,987 shares (7.49%)
In 2014, the Boston, Massachusetts-based Cormorant Global Healthcare Master Fund acquired the first parcel of 16,420,361 shares in Viralytics in a $27 million placement at 28 cents a share (BD: Mar 13, 2014).
Today, Cormorant said it bought shares from December 15, 2015 to October 20, 2016 and on July 14, 2017 sold 3,864,605 shares for $3,710,321 or 96 cents a share, which Biotech Daily calculates is a pre-tax profit of $2,628,232.
Viralytics fell three cents or 3.3 percent to 87 cents.