Biotech Daily

Thursday June 30, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ONCOSIL UP 12%; NEUREN DOWN 7%**

*** FEDERAL ELECTION 2016: PROMISES, EVIDENCE AND CREDIBILITY**

*** MAYNE RAISES $634m OF $888m TARGET, RETAIL OFFER OPENS JULY 5**

*** IDT RAISES $6m FOR GENERICS MANUFACTURE**

*** BIONOMICS BEGINS PHASE II BNC210 PTSD STUDY**

*** CANADA LICENCES MMJ MARIJUANA PLANT, PERFORMANCE SHARES**

*** CYNATA CONSIDERING REGIENCE $400k OFFER**

*** ALLEGRA BORROWS $1m FROM 35% ROBINWOOD**

*** ONCOSIL HOPES FOR CE, FDA APPROVALS 'IN THE NEAR TERM'**

*** ACRUX 'SEVEN PROJECTS BY JULY 2017', PATENT HEARING**

*** RESAPP NEGOTIATING PAEDIATRIC STUDY WITH 2 US HOSPITALS**

*** PHOSPHAGENICS: 'TPM NO BENEFIT IN OLDER PIGLETS'**

*** PAUL RUGGIERO, 'LIKE-MINDED INVESTORS' TAKE 10% OF CELLMID**

*** WARD FERRY TAKES 6% OF SIMAVITA**

*** UNIVERSAL BIOSENSORS APPOINTS CRAIG COLEMAN DIRECTOR**

MARKET REPORT

The Australian stock market was up 1.77 percent on Thursday June 30, 2016, with the ASX200 up 91.0 points to 5,233.4 points. Twenty-six of the Biotech Daily Top 40 stocks were up, nine fell, four traded unchanged and one was untraded. All three Big Caps rose.

Oncosil was best, up 1.5 cents or 12 percent to 14 cents with 1.5 million shares traded. Reva climbed 8.9 percent; Benitec and Polynovo rose more than seven percent; Admedus and Universal Biosensors were up more than six percent; Genetic Technologies and Mesoblast were up more than five percent; Atcor, Living Cell, Osprey and Uscom were up four percent or more; Airxpanders, Antisense, Cellmid, CSL and Opthea were up more than three percent; Impedimed rose 2.7 percent; Acrux, Bionomics, Biotron, Clinuvel, Cochlear, Medical Developments, Nanosonics, Orthocell, Resmed and Viralytics were up more than one percent; with Starpharma up 0.8 percent.

Neuren led the falls, down 0.4 cents or 6.8 percent to 5.5 cents with 1.1 million shares traded. Compumedics lost 6.4 percent; Actinogen, IDT and Prana fell four percent or more; Anteo and Factor shed more than two percent; with Ellex down one percent.

FEDERAL ELECTION 2016 EDITORIAL

Saturday's question boils down to: "Which political party is best for innovation in general and biotechnology in particular?" Voters need to weigh promises against performance.

The Liberal-National Coalition came to office promising no cuts to science research and development, but that was a broken promise, justified by a phantom 'Budget emergency'.

The 2014 and 2015 Budgets axed the Innovation Investment Fund, cut CSIRO and CRC funding and used the promise of a $20 billion Medical Research Future Fund to justify cuts to Medicare and Health, but without a commercialization component to market inventions and return revenue. For the 'party of business' to forget rewarding investment is bizarre.

Labor and the Greens blocked the Coalition's 1.5 percent cut to the popular 45 percent Research and Development Tax Incentive, and that cut remains before the Senate.

The Greens promise to increase R&D spending to 3.0 percent of GDP by 2025 and 4.0 percent of GDP by 2030. Labor's target is 3.0 percent of GDP by 2030.

Both the Greens and Labor will retain the 45 percent R&D Tax Incentive, reinstate the Innovation Investment Fund and continue funding co-operative research centres. Labor says it will reverse cuts, introduce new programs and it has specific investment policies.

The Greens say the MRFF should have funding from successful ventures and both the Greens and Labor oppose funding the MRFF by cuts to Health or Medicare. Labor has been silent on commercialization and a funding feed-back loop.

But each of the contenders has serious negatives:

The Liberal-National Coalition promises simply cannot be believed. Apart from then Opposition Leader Tony Abbott's litany of broken promises, Prime Minister Malcolm Turnbull's innovation promises resulted in media releases on Adelaide ship building, the car industry and 'landing pads' in California. Nothing has come from the MRFF.

Mr Abbott appointed Dr Larry Marshall, who cut CSIRO's climate change unit and Prof Anne Kelso who wasted $3.3 million of the NHMRC's funds on sleep studies for climate deniers. Had Mr Turnbull reversed those decisions he might have more credibility.

Labor earns points for the R&D Tax Incentive, but Senator Carr thinking the $80 million a year Commercialisation Australia was a good idea is a worry. It was underfunded by about $920 million a year, compared to competitor countries.

The Greens have the best 'big picture' policies, but there is an absence of detail.

Despite the 'hung Parliament chaos' rhetoric, innovation benefitted from the Gillard ALP-Greens-Independents Government. Biotech Daily would like to see the Greens retain the balance of power to vet the Labor or Liberal-National Coalition promises. A Labor-Greens Government previously served our sector well and there is little evidence that conservatives support innovation - it is counter to their culture.

David Langsam, Editor

MAYNE PHARMA

Mayne says its placement at $1.50 a share has raised $287 million and its institutional rights offer at $1.28 a share raised $347 million.
Earlier this week, Mayne said it would raise $888 million to cover the $881 million cost of buying 37 approved and five US Food and Drug Administration-filed products from Israel's Teva Pharmaceutical Industries (BD: Jun 28, 2016).
Today, Mayne said that the placement book-build was covered "multiple times".
The company said that the underwritten one-for-1.725 non-renounceable entitlement offer was taken up by about 99.9 percent of eligible institutional shareholders.
Mayne said the retail component for shareholders at the record date of today, June 30, would open on July 5 and close on July 15, 2016.
Mayne was up 42 cents or 28.3 percent to $1.905 with 72.4 million shares traded.

IDT AUSTRALIA

IDT says it has raised $6,100,006 in a private placement to institutional and sophisticated investors at 22 cents a share.
IDT said that the funds would be used to manufacture launch stock of temozolomide in preparation for the US launch, following the earlier than expected US Food and Drug Administration's approval of the product and to accelerate the re-commercialization of other priority drugs in the portfolio (BD: Dec 18, 2014; Sep 24, 2015; April 13, 2016).
The company said that some of the funds would be used to accelerate the outsourced manufacturing of several of the US generic portfolio drugs acquired in 2014.
IDT managing-director Dr Paul MacLeman said the early approval of the company's first proprietary generic product temozolomide was "very pleasing … [and was] the first of a larger generic portfolio that will over time transform IDT and its prospects, moving IDT from a service provider to an integrated specialist generics company".
IDT fell one cent or 4.3 percent to 22.5 cents with 1.1 million shares traded.

BIONOMICS

Bionomics says it has begun a 160-patient, phase II trial of BNC210 in adults with post-traumatic stress disorder (PTSD) in Australia and New Zealand.
Bionomics said that the study's primary objective was to determine whether BNC210 causes a decrease in symptoms of PTSD as measured by the US National centre for PTSD Clinician-Administered PTSD Scale (CAPS).
The company said that secondary objectives included the determination of the effects of BNC210 on anxiety, depression, quality of life, and safety.
Bionomics said that the study was a randomized, double-blind, placebo-controlled design with subjects to be treated over 12 weeks with BNC210 or placebo with the Melbourne-based Monash Alfred Psychiatry Research Centre's Prof Jayashri Kulkarni as principal investigator.
The company said that PTSD was "very common and its societal and economic burden extremely heavy" with five to 10 percent of the population having PTSD at some point in their lives and only two drugs, the anti-depressants paroxetine and sertraline, approved to treat PTSD.
Bionomics said that the anti-depressant had "not been shown to ameliorate the full range of PTSD symptoms" and complete remission of symptoms was rare.
Bionomics was up half a cent or 1.8 percent to 28.5 cents.

MMJ PHYTOTECH

MMJ says that Health Canada has approved its subsidiary United Greeneries Duncan, British Columbia facility to grow marijuana for medical cannabis.
MMJ said it was the first Australian company to receive a Canadian medical cannabis cultivation licence and "one of a select group of companies globally with the capacity to commercially cultivate medicinal grade cannabis in a federally regulated system".
The company said that the hydroponic marijuana growing operation had about 10,000 square feet, or about 930m^2 of cultivation area and it had spent about $C8 million on the facility, which included a narcotics vault and a biochemical and analytical laboratory.
MMJ managing-director Andreas Gedeon said the licence was "a significant milestone for MMJ, as it underpins the evolution of our 'farm-to-pharma' strategy".
MMJ said that the licence satisfied the first of two milestones under the July 2015 merger terms, providing for the issue of 8,500,000 shares to the vendors of MMJ Bioscience Inc.
The company said that performance milestones attaching to 1,000,000 class D rights had been satisfied and could vest at the election of the performance right holder.
MMJ was up 6.5 cents or 36.1 percent to 24.5 cents with 12.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says it is considering an offer from Japan's Regience KK to invest $400,000 in its stem cell development and commercialization alliance.
In March, Cynata said it had a preliminary agreement for the Regience KK alliance for Japan and certain other Asian countries (BD: Dec 3, 2015; Mar 3, 2016).
Cynata said in March that the agreement provided 60-days for Regience to make an initial investment of $250,000 for new Cynata shares, at a 25 percent premium to the 10-day volume weighted average price and subject to a 12-month escrow.
The company extended the agreement value and for a further 60 days in April and today, said that the $400,000 investment would be on the same terms.
Cynata climbed 4.5 cents or 17.0 percent to 31 cents.

ALLEGRA ORTHOPAEDICS (ADVANCED SURGICAL DESIGN & MANUFACTURE)

Allegra says it has a $1 million loan from 35.4 percent shareholder Robinwood Investments to progress its bone substitute project.
Earlier this month Allegra said its collaboration with the University of Sydney had developed a ceramic scaffold to assist regenerate bone tissue and degrade as it was replaced by natural bone (BD: jun 8, 2016).
Today Allegra said that the loan was "secured by a fixed and floating charge over all the assets and undertakings of Allegra".
The company said that the loan was on normal commercial terms negotiated on an arm's length basis from Robinwood Investments Pty Ltd.
Allegra said that the loan might constitute the disposal of a substantial asset to a related party or substantial holder for the purposes of ASX Listing Rule 10.1 which relates to transactions with persons in a position of influence and it had obtained a conditional waiver from the ASX.
In 2014, the Bowral, New South Wales-based Hartnell family, through Robinwood Investments, increased its substantial holding in the then Advanced Surgical to 22,557,364 shares or 35.383 percent of the company, acquiring shares in a rights issue at five cents a share (BD: Oct 24, Nov 20, 2014).
Allegra was untraded at 15 cents.

ONCOSIL

Oncosil says that its Conformité Européenne (CE) mark and US Food and Drug Administration phase III trial approvals “could be in the near term”.

Oncosil filed its US investigational device exemption application with the US Food and Drug Administration for its localized radiation treatment for pancreatic cancer late last year in parallel with its CE mark application (BD: Dec 14, 2015).

In March, the company said that its timeline for CE mark approval might be delayed beyond March 2016 and it had filed a further 1,700 pages of protocols, trial results and data to the FDA (BD: Mar 1, 2016).

Today the company said since further material to its European notified body, the British Standards Institute, there had been no additional follow-up questions.

Oncosil said that the “near term” CE mark approval would allow commercial sales of its Brachysil radiation treatment for pancreatic cancer in the European Union and application for commercialization in the Asia-Pacific.

The company said that following interactions with the FDA it had filed an investigational device exemption amendment, today.

Oncosil said that were “no guarantees, [but] the company remains confident of a successful outcome with the FDA which it believes could be in the near term”.

The company said the investigational device exemption (IDE) approval and the collection of study data would be used to support a pre-market approval application to the FDA and enable the company to commercialize the technology in the US.

Oncosil chief executive officer Daniel Kenny said that the company had hoped the process would be completed by July 2016, but “we believe a positive outcome is still achievable in the near term”.

Mr Kenny said that 72 percent of FDA IDE submissions were approved within two question and answer cycles and Oncosil was concluding the first cycle.

Oncosil was up 1.5 cents or 12 percent to 14 cents with 1.5 million shares traded.

ACRUX

Acrux says it is progressing work on its topical and transdermal generic products and expects to have up to seven projects in active development by July 2017.

Acrux has said that it was working on its onychomycosis development project for nail bed fungal infections but provided no further detail on its pipeline.

The company said that the “key difference with our new generic program is that we are not developing new formulations to create new intellectual property”.

“Our expertise is being used to recreate formulations of proven actives that have an existing market position and an attractive commercial profile,” Acrux said.

“Our goal is to develop a portfolio of topical and transdermal generics and develop these into a strong, sustainable revenue stream for Acrux,” the company said.

Acrux said that Axiron had attracted the interest of generic companies in the US and of Axiron has net US sales of more than $US145 million in 2015.

The company said that with Eli Lilly it had filed lawsuits against a number of companies that had filed an application for a generic version of Axiron for infringement of specified issued US patents.

Acrux said that litigation began in June in the US District Court for the Southern District of Indiana against the generic companies.

The company said that the relevant patents included claims relating to the formulation application of testosterone to the axilla and to the applicator used to apply Axiron.

Acrux was up one cent or 1.4 percent to 72 cents.

RESAPP HEALTH

Resapp says that negotiations with two US hospitals for its paediatric respiratory diagnostic study are expected to conclude in July and the trial to begin shortly after.
Resapp said that both hospitals were among the top 10 in the US, with more than 60,000 patients a year at their emergency departments and they would allow “fast enrolment of large numbers of patients and provide the highest quality clinical results”.
Resapp said that it would file a de novo premarket submission to the FDA on completing the studies which was expected by October this year (BD: Mar 14, 2016).
The company said that the FDA de novo process had a 120-day review cycle.
Resapp fell two cents or 5.1 percent to 37 cents with 5.2 million shares traded.

PHOSPHAGENICS

Phosphagenics says that adding tocopheryl phosphate mixture (TPM) to feed for older pigs showed no significant benefit in feed conversion rate (BD: Dec 3, 2015).
Phosphagenics said the proof-of-concept study in the grower finisher pigs, assessed the potential for additional performance benefits of TPM as a feed additive and was the second of two independent studies assessing the commercial value of TPM as a feed additive in the pig production market.
The company said that the second study results showed that older pigs treated with TPM at doses of 5ppm to 30ppm “did not demonstrate significant improvements in performance, as assessed by [feed conversion rate] and carcass yields”.
Phosphagenics said in January that the first study reported that TPM treatment statistically improved performance in newly weaned pigs in the first 14 days, but not in the second period from day 15 to day 34.
The company said at that time that “unforeseen health issues in the pigs during this second phase resulted in significant suppression of performance across the board for all treatment groups, compromising [feed conversion rate] assessments”.
Phosphagenics said the results suggested that treating “immature or newly weaned pigs may be more beneficial than initiating TPM treatment when the pigs are older”.
Phosphagenics was unchanged at 1.2 cents with 1.6 million shares traded.

CELLMID

Paul Ruggiero says that the “association of like-minded holders” have increased their holding in Cellmid from 65,100,000 shares (7.0%) to 93,950,381 shares (10.1%).
The Gladesville, Sydney based Mr Ruggiero said he was the Association’s “group coordinator”, which included himself and Lorissa Ruggiero and their superannuation fund with 12,750,940 shares, Darin and Tania Anjoul and the Tan Group superannuation fund with 20,750,000 shares, Rebecca Deragopian with 10,792,779 shares, Ivan Staresnic with 9,000,000 shares, J20 Investments with 9,299,880 shares the Bance Family superannuation fund with 4,019,482 shares, Bejjani Runia with 2,500,000 shares, Cherrington Trust with 4,000,000 shares, Jihad Aoun with 3,000,000 shares, DK Services with 3,620,000 shares, Divya Zaveri with 2,818,700 shares, Vivek Zaveri with 1,752,600 shares, Allan Raad with 3,892,000 shares, Raphael Hirschhorn with 1,415,000 shares, Joe and Rhonda Khoury with 2,000,000 shares, Susan Kizana with 1,200,000 shares and Doris Lavranos with 1,139,000 shares .
The substantial shareholder notice did not disclose the cost of the shares as required by the Corporations Act.
Cellmid was up 0.1 cents or 3.1 percent to 3.3 cents with 2.3 million shares traded.

SIMAVITA

The Ward Ferry Asian Reconnaissance Fund has increased its holding in Simavita from 7,102,222 Chess depository instruments (CDIs) (7.7%) to 24,402,222 CDIs (9.7%).
The Hong Kong-based Ward Ferry said that the registered holder of the shares was HSBC Nominees Australia and they were acquired in the recent placement at five cents a share (BD: Jun 29, 2016).
Simavita was unchanged at five cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has appointed 14 percent holder Viburnum executive chairman Craig Coleman as a non-executive director.
Universal Biosensors said that Mr Coleman's career of 30 years has spanned banking and finance, corporate advisory and funds management and he was formerly the Home Building Society's managing-director.
The company said that Mr Coleman was previously an executive with the ANZ Banking Group and was currently the executive chairman of Viburnum Funds which held about 14 percent of Universal Biosensors.
Universal Biosensors said that Mr Coleman was currently a director of Bell Financial Group, Pulse Health and Rubik Financial.
The company said that Mr Coleman held a Bachelor of Commerce from the University of Western Australia.
Universal Biosensors was up two cents or 6.7 percent to 32 cents.