Biotech Daily

Thursday June 16, 2016

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: CELLMID UP 10%; AVITA DOWN 13%**

*** USCOM SIGNS $65m 5-YEAR CHINA DEAL**

*** QBID PLACES FIRST IMMURON TRAVELAN, PROTECTYN ORDERS**

*** ORTHOCELL: 'EARLY CELGRO SHOULDER SAFETY, TOLERABILITY'**

*** VICTORIA $365k FOR $2.5m MEDICAL DEVELOPMENTS PLANT**

*** PRESCIENT READY FOR PTX-200 COMBINATION AML TRIAL**

*** PHARMAUST'S EPICHEM WINS $250k LEISHMANIASIS GRANT**

*** ANATARA DETACH PIG TRIALS, LATROBE ANA0019 FOR HUMANS STUDY**

*** AVITA 2-FOR-9 RIGHTS ISSUE FOR $11.5m**

*** OVENTUS $12m IPO OPENS**

*** ALCHEMIA STILL SELLING HYACT, PANTHER GONE, SUSPENSION LIFTED**

*** GSK EXTENDS MEDADVISOR RESPIRATORY DRUG MESSAGES**

*** BIONOMICS APPOINTS DAVID WILSON, PETER TURNER DIRECTORS**

MARKET REPORT

The Australian stock market slipped 0.02 percent on Thursday June 16, 2016 with the ASX200 down just 1.1 points to 5,146.0 points. Nine of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and two were untraded. All three Big Caps fell.

Cellmid was the best, up 0.3 cents or 10 percent to 3.3 cents with 18.6 million shares traded. Orthocell climbed 7.9 percent; Acrux was up 6.5 percent; Medical Developments and Viralytics were up more than three percent; Benitec and Compumedics rose more than two percent; with Actinogen and Living Cell up more than one percent.

Avita led the falls, down 1.5 cents or 13.0 percent to 10 cents with 2.1 million shares traded. Mesoblast lost 8.8 percent; Genetic Technologies fell 5.3 percent; Atcor and Clinuvel were down more than three percent; Antisense, Ellex, Factor, Impedimed, Nanosonics, Osprey, Sirtex and Starpharma shed more than two percent; IDT, Neuren, Pharmaxis, Polynovo, Pro Medicus and Resmed were down more than one percent; with Airxpanders, Cochlear, CSL and Reva down by less than one percent.

USCOM

Uscom says it has an agreement with China International Intellectech Corp targeting sales worth $US48.2 million ($A65.2 million) in China over the next five years.

Uscom said that the Beijing-based China International Intellectech Corp (CIIC) Shanghai division imported medical devices and would assist with registration and distribution of the Uscom BP+ and Spirosonic devices, accelerating the path to market, along with the establishment of an Uscom office in Shanghai.

The company said that the contracted sales targets were dependent on China Food and Drug Administration approval, with first revenues expected by October 2016.

Uscom said that total revenue for the year to June 30, 2015 was $2.0 million with unaudited figures showing revenue for the nine months to March 31, 2016 of $1.87 million.

The company said that CIIC was a state-owned enterprise managed by the Chinese Central Government generating annual revenue of $10.5 billion, with126 subsidiaries and branches focusing on international cooperation in the fields of economy, technology and talent in China and 76 countries.

Uscom said that the Shanghai CIIC was the most profitable of the subsidiaries contributing about 65 percent of revenues and previously partnered with Medtronic, Philips, Zoll and Covidean for medical device distribution in China.

Shanghai CIIC Science and Technology Development general-manager Wenan Zhu said his company was “the leaders in medical device distribution in China and are rapidly growing, while cardiovascular disease, asthma and [chronic obstructive pulmonary disease] are becoming increasingly common health care challenges”.

“Our focus is on distributing practice leading technologies to improve medical care of these diseases in China and the Uscom products fit our needs and growth strategy well,” Mr Zhu said.

Uscom executive chairman Prof Rob Phillips said the agreement was “transformational for Uscom and is a platform from which we can deliver profitability and reliable revenue growth to investors for the coming decade”.

“A relationship with a Chinese Government owned distributor with scale and credibility will ensure we achieve the market penetration and revenues our products deserve,” Prof Phillips said.

Uscom climbed as much as three cents or 12 percent to 28 cents, before closing unchanged at 25cents, with 1.5 million shares traded.

IMMURON

Immuron says that QBID has placed its first orders for both Travelan and Protectyn to ensure they have stock of both products for sale in China from the JD.com website.

In May, Immuron said it had a distribution agreement with the Melbourne-based Quality Brands International Direct (QBID) for its Travelan for travellers diarrhoea and Protectyn for gastro-intestinal health (BD: May 10, 2016).

The company said at that time that QBID had partnerships with JD.com and other Chinese electronic commerce platforms.

Today, Immuron chief executive officer Thomas Liquard said that the company had been working with QBID to meet launch timelines.

“Given the recent high demand from China for Australian and New Zealand products, ensuring that our products were available for purchase by Chinese consumers was critical for the company,” Mr Liquard said.

The company did not state the value of the orders.

Immuron was up one cent or 4.1 percent to 25.5 cents.

ORTHOCELL

Orthocell says it has “positive initial safety and tolerability results” for its Celgro collagen-based scaffold for full thickness tears of shoulder rotator cuff tendons.

Last year, Orthocell said the 30-patient trial of its Celgro SMRT Graft collagen scaffold for surgical repair of shoulder rotator cuff tendons was being conducted at the Perth, Western Australia-based St John of God Hospital (BD: Dec 16, 2015).

Today, Orthocell said that an interim review of the first three patients at 42 days post operation showed no complications and demonstrated the scaffold was safe and well tolerated with no inflammatory reactions or complications.

Orthocell managing-director Paul Anderson said the initial assessment was “very positive and represents an important step forward in the development of Celgro”.

“Finding a cell and tissue-friendly scaffold that is also capable of load sharing to support tissue regeneration has been a challenge that has not been adequately addressed by other scaffolds currently available,” Mr Anderson said.

Orthocell said that more than 370,000 rotator cuff surgeries were carried out in the US every year and that up to 57 percent of large rotator cuff repairs regularly tore again.

The company said the Celgro SMRT Graft scaffold aimed to reduce the re-tear rate by providing a more cell-friendly environment to improve tissue healing and quality, and integration and stabilization of the repair.

The company said Celgro was “a breakthrough in regenerative medicine … developed and manufactured in Australia … to significantly improve tissue in-growth and repair”.

Orthocell said that the product was in development for applications within the general surgical and uro-gynecological specialities, among others.

Orthocell was up 2.5 cents or 7.9 percent to 34 cents.

MEDICAL DEVELOPMENTS

Medical Developments says it has received a Victoria Government $365,000 Future Industries Manufacturing grant for its $3 million Penthrox manufacturing plant.

Medical Developments said the Future Industries grants were for Victorian companies implementing new manufacturing technologies and processes.

In March, the Government announced three funds: the $200 million Future Industries Fund with grants up to $100,000 for scoping, planning and feasibility, with up to $1 million for approved projects, as well as the $508 million Premier’s Jobs and Investment Fund and the $500 million Regional Jobs and Infrastructure Fund (BD: March 17, 2016).

Today, Medical Developments chief executive officer John Sharman said the grant would assist the construction of a new manufacturing plant for the Penthrox inhaled methoxyflurane analgesic, at its Scoresby premises in Melbourne’s Eastern suburbs.

The company said that the facility was designed to support the expansion of Penthrox and demand for up to 25 million units a year, incorporated technology developed in partnership with the CSIRO to satisfy medium term demand, with the ability to expand.

Medical Developments said that plant was expected to be finished by March 2017.

Medical Developments said that Victoria Minister for Industry and Employment Wade Noonan formally announced the grant and a Victoria Government media release said the facility would create 15 new jobs and boost exports by $50 million.

“The Andrews Labor Government is helping manufacturers like Medical Developments International to create jobs and target new growth opportunities,” Mr Noonan said. “Our Future Industries Manufacturing Program is about giving local companies the support they need to transition towards an advanced manufacturing economy.”

Medical Developments climbed 20 cents or 3.45 percent to $6.00.

PRESCIENT THERAPEUTICS

Prescient says it expects to begin a phase Ib/II trial of the Akt inhibitor PTX-200 plus cytarabine in refractory or relapsed acute myeloid leukaemia.

Prescient previously announced a 17-patient phase I/II trial of PTX-200, or triciribine phosphate monohydrate acquired from Aktivate Therapeutics for breast cancer, a 30-patient trial of PTX-200 for metastatic ovarian cancer and a potential phase Ib trial of PTX-100, or GGTI-2418 acquired from Pathway Oncology, for metastatic breast cancer (BD: May 30, Dec 11, 2014; Jun 10, 23, 29, 2015; Feb 17, 2016).

The company said PTX-200 targeted the protein kinase B, or Akt, tumor survival pathway.

In February, Prescient said the seventeenth and final patient had been dosed in the escalation stage of its phase Ib metastatic breast cancer trial at the New York Montefiore Cancer Centre and the recommended phase II dose would be 35mg/m2 PTX-200, with chemotherapy (BD: Feb 17, 2016).

Last year, the company said the 30-patient phase Ib/II trial of PTX200 in combination with cisplatin was underway at the Tampa, Florida-based Moffitt Cancer Centre, initially funded by the US Department of Defense (BD: Jun 29, 2015).

Today, Prescient executive director Paul Hopper told Biotech Daily that the company was proceeding with the PTX-200 trials, with the US Food and Drug Administration reactivated investigational new drug application for PTX-100 for a phase Ib trial for metastatic breast cancer and multiple myeloma on hold for the time being.

Yesterday, Prescient said that the New Haven, Connecticut-based Yale Cancer Centre would join the proposed phase Ib/II trial for acute myeloid leukaemia, which was expected to recruit its first patient at the Moffitt Cancer Centre “shortly”.

The company said that Yale’s Dr Thomas Prebet would lead the 18-patient, phase Ib stage of the trial of PTX-200 with cytarabine for refractory or relapsed acute leukaemia.

“[Acute myeloid leukaemia] remains a very challenging disease, especially in the relapse and refractory setting and there is a need for new, targeted therapies,” Dr Prebet said.

Dr Prebet said that earlier phase I haematology clinical trials suggested the drug might have significant activity in acute myeloid leukaemia.

Prescient said that the Moffitt Cancer Centre trial was led by Prof Jeffrey Lancet.

Prescient was up 0.1 cents or 1.1 percent to nine cents.

PHARMAUST

Pharmaust says that subsidiary Epichem has won a $250,000 Federal Government grant to help develop compounds to treat leishmaniasis in humans and animals.

Pharmaust said the grant through the Trade and Investment Ministry Australian Tropical Medicine Commercialization Grants Program was for a project entitled ‘Novel compounds for the treatment of leishmaniasis in humans and animals’ to be led by Epichem in partnership with the Swiss-based Drugs for Neglected Disease Initiative.

The company said that leishmaniasis was a potentially fatal parasitic disease spread by various species of sand fly and was a human health issue in 98 countries, with 350 million people at risk of infection, most notably poor populations living in remote areas.

Pharmaust said that leishmaniasis was also a significant disease in a number of animals, especially dogs in many parts of Europe and North America.

The company said the grant would fund Epichem to provide the synthetic and medicinal chemistry for the program to develop new treatments for leishmaniasis with the DNDI.

Pharmaust said that any human drugs resulting from the project would be for the benefit of DNDI, but Epichem had the right to commercialize treatments for leishmaniasis in animals.

Pharmaust fell 0.1 cents or 1.1 percent to 8.8 cents.

ANATARA

Anatara says it has begun two trials to support its application to register Detach with the Australian Pesticides and Veterinary Medicines Authority and overseas.

Anatara said that approval for the pineapple stem bromelain-derived based Detach for diarrhoea in Australia would open the opportunity to register it for sale in Asia.

The company said that the first new trial, and its third farm trial, would be a pig farm efficacy study in un-weaned piglets, or suckers, and the second trial would be a good laboratory practice target animal safety, also in suckers.

Anatara said it also had begun a research and development collaboration with Melbourne's La Trobe University exploring Detach product extensions and opportunities for the core active components of Detach.

The company said that the objective of the placebo-controlled, parallel group, randomized, blinded pig farm efficacy trial was to expand the dosing instructions for the final registration label, with results from the 450 two-day old sucker piglet trial expected by October 2016.

Anatara said the farm had a history of problems with pre-weaning scour, or diarrhoea, current approaches such as antibiotics failed to control the problem and the trial would investigate the ability of Detach to reduce mortality, the incidence, severity and duration of scour compared to placebo.

The company said that the objective of the target animal safety study was to provide detailed safety data on Detach when administered orally to piglets at dose rates higher than the recommended single dose, beginning at two days of age, and examining the effect of re-dosing piglets after three-to-four day intervals over a three week period.

Anatara said that the study would be conducted in accordance with VICH1, a trilateral European Union, Japan and US program aimed at harmonizing technical requirements for veterinary product registration and would support the rollout of Detach.

The company said that Detach had been shown to be safe, but a formal safety assessment was a requirement for registration of new active ingredients and new veterinary formulations in Australia, Europe and the US.

Anatara chairman Dr Mel Bridges said the studies would complete the clinical trial requirements for the Australian dossier.

"Anatara still expects approval and product launch in Australia in 2017," Dr Bridges said.

The company said that the La Trobe University collaboration would develop active components within Detach for the treatment of inflammatory diseases in humans and in companion animals.

Anatara said the agreement was for the production, validation and pre-clinical evaluation of the active component ANA0019 isolated from the active ingredient in Detach and earlier work had shown that ANA0019 had anti-inflammatory activity by blocking MAP kinase pathways and the production of pro-inflammatory cytokines, validated targets for anti-inflammatory drugs.

Anatara chief scientific officer Dr Tracey Mynott said the program would generate a data package demonstrating the efficacy, potency, stability and pre-clinical safety of ANA0019.

"This pre-clinical [research and development] program will provide the data package Anatara needs to pursue ANA0019's development and partnering activities in both animals and humans," Dr Mynott said.

"Since listing in October 2014 Anatara continues to execute on its business plan and deliver on its key milestones," Dr Bridges said.

"Anatara expects Detach to be on sale in Australia in 2017, with launch into a number of Asian markets also targeted shortly after the Australian launch," Dr Bridges said.

Anatara climbed six cents or 5.3 percent to $1.19.

AVITA MEDICAL

Avita says it is offering a partly-underwritten, two-for-nine rights issue at nine cents a share to raise up to $11,455,040 for its US launch and product commercialization.
Avita said that the non-renounceable rights issue was underwritten to $5 million by Morgans Corporate with a record date of June 21, and would open on June 23 and close of July 4, 2016.
The company said the funds would be used for clinical and commercial initiatives, as well as supporting operational work to achieve specific upcoming milestones.
Avita fell 1.5 cents or 13.0 percent to 10 cents with 2.1 million shares traded.

OVENTUS MEDICAL

Oventus says its initial public offer to raise up to $12 million at 50 cents a share to list on the ASX to commercialize its O2vent anti-snoring mouth guard device has opened.
Last week, Oventus said the offer was fully-underwritten by Bell Potter Securities, the offer would open on June 16 and close on June 30, 2016 (BD: Jun 8, 2016).
The prospectus is available at: www.oventusmedicalinvestors.com.

ALCHEMIA

Alchemia says that the ASX has ruled that it is in compliance with the activities Chapter 12 of the Listing Rules and the suspension has been lifted.
The ASX suspended Alchemia from the close on June 14, 2016 as it “did not have sufficient operations to warrant the continued quotation” and yesterday the company said it had “provided a submission to the ASX to demonstrate its on-going compliance with Chapter 12 and specifically 12.1 of the Listing Rules” (BD: Jun 15, 2016).
Today the company said it maintained activities “with a continued goal of realizing value by selling or licencing its proprietary intellectual property in carbohydrate therapeutics”.
In 2015, Alchemia said Panther Biotechnology would buy its oncology assets including the Hyact platform for cash and stock worth more than $US16 million ($A20.7 million), but that deal was reported as being delayed (BD: Jul 1, Aug 3, 2015).
At the time of publication yesterday, the status of the Panther acquisition was unknown, with no one available at Alchemia.
Today, Alchemia said it was “focussed on seeking a licencing partner for its Hyact [intellectual property] platform or the sale of our Alchemia Oncology subsidiary”.
“Discussions have been held with several parties in recent months and … continues to review new opportunities within the life sciences sector and may consider reviewing opportunities in other sectors in the future,” Alchemia said.
The company said it continued to maintain its patent portfolio, finalize the phase III trial, complete study reports for two additional trials using the Hyact technology, carry out cost-cutting measures and prepare its 2015-’16 Research and Development Incentive Grant application.
Alchemia said it had “numerous discussions with other participants in related fields to discuss possible mergers, acquisitions, in-licencing and joint-ventures”.
The company said that it had about $2.25 million in cash and it expected a Research and Development Tax Incentive of up to $400,000 later this year.
Alchemia climbed 0.2 cents or 25 percent to one cent.

MEDADVISOR

Medadvisor says that Glaxosmithkline Australia has extended its respiratory medication services agreement for a further 12 months.
Medadvisor said Glaxosmithkline provided messages to patients prescribed respiratory drugs to support and improve the effective and safe use of the medicines.
The company said that Glaxosmithkline had been using its platform since February 2015 and it received patient engagement program revenue from Glaxosmithkline for the use of the platform.
Medadvisor was up 0.2 cents or 4.55 percent to 4.6 cents with 4.1 million shares traded.

BIONOMICS

Bionomics says it has appointed David Wilson and Peter Turner as non-executive directors.
In March, the Sydney-based substantial shareholder CVC called for an extraordinary general meeting to remove Bionomics chairman Graeme Kaufman and director Trevor Tappenden (BD: Mar 16, 2016).
An earlier Bionomics general meeting voted 188.4 million votes (64.1%) against resolutions to approve 16,082,988 warrants to four investment groups, with 105.3 million votes (35.9%) in favour (BD: Mar 3, 2016).
In April, Bionomics announced a shareholder working group to assist and advise on board recruitment and invited 7.8 percent shareholder Laurence Freedman and 5.1 percent shareholder CVC's Sandy Beard to join the working group, but to date they had declined the invitation (BD: Apr 14, 2016).
Today, Bionomics said that the appointment of Mr Wilson and Mr Turner followed a shareholder consultation process and a review of the board structure to strengthen the areas of finance related to investment banking and in life science drug development, manufacturing and commercialisation.
The company said that Mr Wilson was currently life sciences corporate advisory he executive chairman of London-based WG Partners with more than 30 years' experience in investment banking, financing and mergers and acquisitions.
Bionomics said that previously Mr Wilson worked for Piper Jaffray as head of European investment banking and as Piper Jaffray Ltd chief executive officer.
The company said that Mr Wilson held a Bachelor of Arts from Cambridge University.
The company said that Mr Turner was previously CSL Behring Group president and CSL chief operating officer.
Bionomics said that Mr Turner held a Bachelor of Science from the University of Melbourne and a Masters of Business Administration from the Royal Melbourne Institute of Technology.
Bionomics chairman Graeme Kaufman said the appointments would "enhance the expanded board's skills base in investment, finance and drug development".
Bionomics seven member board comprises Mr Kaufman, chief executive officer Dr Deborah Rathjen, Trevor Tappenden, Dr Errol De Souza, Dr Alan Dunton, Mr Wilson and Mr Turner.
Bionomics was unchanged at 29.5 cents.