Biotech Daily

Thursday April 23, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BIOTRON UP 8%, CELLMID DOWN 8%**

*** MELBOURNE UNIVERSITY: 'CANCER DRUG FOR MALARIA RESISTANCE'**

*** PROTEOMICS A2 MILK CONTRACT**

*** IQ3 IPO TO RAISE $4m FOR BIOTECH ADVISORY**

*** REVA ENROLS EUROPEAN PATIENTS IN FANTOM II STENT TRIAL**

*** TISSUE THERAPIES, EMA TO DISCUSS FURTHER VITROGRO TRIALS**

*** ONE FUNDS (EX-OCTA PHILLIP) TAKES 10% OF AVITA**

*** CSL CFO GORDON NAYLOR TO LEAD INFLUENZA VACCINE BUSINESS**

MARKET REPORT

The Australian stock market was up 0.13 percent on Thursday April 23, 2015 with the S&P ASX 200 up 7.3 points to 5,844.8 points.

Nine of the Biotech Daily Top 40 stocks were up, 14 fell, 12 traded unchanged and five were untraded. All three Big Caps were up.

Biotron was the best, up one cent or 8.3 percent to 13 cents with 611,293 shares traded.

Universal Biosensors climbed 7.4 percent; Oncosil was up 4.1 percent; Admedus, Medical Developments and Pharmaxis rose more than two percent; Benitec, CSL and Nanosonics were up more than one percent; with Cochlear, Resmed and Sirtex up by less than one percent.

Cellmid led the falls, down 0.2 cents or 7.7 percent to 2.4 cents with 315,000 shares traded.

GI Dynamics lost 6.25 percent; IDT fell 5.45 percent; Antisense, Atcor, Optiscan and Prima fell four percent or more; Anteo, Impedimed and Prana were down more than three percent; Viralytics shed 2.3 percent; with Acrux, Mesoblast and Starpharma down by less than one percent.

THE UNIVERSITY OF MELBOURNE

The University of Melbourne says its staff have discovered how the malaria parasite protects itself from anti-malarial drugs and that cancer drugs might defeat the resistance.
The University of Melbourne said that its researchers working with collaborators from Australian National University, Thailand, Singapore and the US found that the effectiveness of anti-malarial drugs known as artemisinins could be increased by combining them with a very low dose of an anti-cancer drug, the proteasome inhibitors carfilzomib and bortezomib.
The article, entitled 'Targeting the Cell Stress Response of Plasmodium falciparum to Overcome Artemisinin Resistance' was published by the Public Library of Science and is available at: http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002132.
The University of Melbourne said that the malaria parasite's resistance to ART drugs was jeopardizing global malaria control.
University of Melbourne Department of Biochemistry and Molecular Biology deputy head and lead author Prof Leann Tilley said that "by disabling the malaria parasite's increased defence system, the anti-malarial medications can work more effectively on patients".
The University said that targeting the parasite's defence system was inspired by anti-cancer drugs used for the blood disorder myeloma which disabled the cell's ability to repair damaged proteins.
"We wanted to find out if combining ARTs with anti-cancer drugs would overcome resistance, so we first developed a mathematical model to understand how resistant parasites respond to ARTs in patients," Prof Tilley said.
"Encouraged by promising predictions from the mathematical model, we completed a detailed laboratory study using parasites from Cambodia where drug-resistance is emerging," Prof Tilley said. "We found that while resistant parasites are much better at surviving ART treatment than sensitive parasites, extending the ART treatment or adding a very low concentration of an anticancer drug is enough to completely reverse the resistance mechanism."
"Malaria continues to kill more than half a million children every year and its treatment relies heavily on a single drug class," Prof Tilley said.
"We need to ensure that these drugs keep working by outsmarting the resistance mechanism," Prof Tilley said.
"ART resistance is currently spreading from its site of origin in Cambodia and has reached six South-East Asian countries," Prof Tilley said. "If it spreads to Africa, where most of the malaria cases occur, this is a major problem."
"It is hoped that the work will translate to much needed new strategies to combat resistant malaria parasites," Prof Tilley said.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has a "major analytical services contract" with A2 Milk to provide protein analysis of its products to validate protein composition and quality control.
Proteomics said it would specifically test for the presence of beta casein variant proteins in A2 Milk's products on a daily basis.
A spokesman for Proteomics told Biotech Daily that the value of the 12 month contract was confidential.
Proteomics said that A2 Milk manufactured branded dairy products and had a significant market presence in Australia and New Zealand and had established operations in China and the UK and had recently launched in the US.
Proteomics was unchanged at 20.5 cents.

IQ3 CORP

Corporate finance and advisory firm IQ3 says it hopes to raise up to $4.4 million in an initial public offer at 30 cents a share and list on the ASX.

IQ3 said the minimum raising would be $4,090,000 and extended the closing date from April 17 to May 1, 2015

In a difficult-to-read prospectus in faint print, IQ3 said it was founded in September 2012 and was “a corporate finance and advisory firm that provides capital raising and corporate advisory services to listed and unlisted companies in the life science sector”.

The IQ3 prospectus said that along with the offer shares, a further 7,150,000 shares would be issued to convertible note-holders and 80,000,000 shares were held by existing shareholders, giving an indicative market capitalization of $30,545,000.

IQ3 said that the funds raised would be used “to develop and advance its corporate advisory, capital raising and distribution capabilities, build the brand and increase the share of voice in the Australian life science industry, identify and evaluate potential strategic growth opportunities aimed at complementing the company’s service offering; [and] increase operational capital to provide for cash flow sustainability to support the demands of growth”.

IQ3 said that if it did not generate sufficient revenue within the first 24 months from contracts with contract sales organization Farmaforce Pty Ltd and clinical research organization Clinical Research Corporation Pty Ltd, it may need to raise further capital.

The prospectus said the board comprised chairman Peter Coolentianos, executive director Spiro Sakiris and non-executive directors Kosmas Dimitriou and Akira Yoshida.

The prospectus said that current shareholders included companies associated with Dr George Syrmalis, Derivative Investments Pty Ltd and Life Science Investements Pty Ltd, holding 20,461,112 shares, expected to be about 20 percent of the company at completion; companies associated with Mr Sakiris, Active Immunity Investments Pty Ltd and Oceana Horizon Investments Pty Ltd with 20,750,000 shares, expected to be about 20.5 percent of the company; companies associated with Con Tsigounis, Zeolite Holdings Pty Ltd and Babi Holdings Pty Ltd, holding 12,800,000 shares, expected to be about 12.5 percent of the company; and Biodynamic Investments with 8,888,888 shares expected to be about nine percent of the company at completion.

IQ3 said that the scientific advisory committee included medical practitioner and Pharmaxis co-founder Dr Brett Charlton; Dr Tim Williamson who holds a Bachelor of Science and Doctorate of Philosophy from the University of Melbourne; registered nurse Helen Teale who has a post-graduate diploma in clinical research; registered nurse Gail Grant; and Masters of Business Administration graduates former Pharmaxis investor relations head and former Biotech Daily deputy editor Jane Sugden and Nicole Bechaz.

The prospectus is available at: http://www.iq3corp.com/iq3corp-prospectus.

REVA MEDICAL

Reva says its up to 110-patient Fantom II clinical trial of its bioresorbable cardiac stent has begun enrolling patients in Europe.

Reva said that the Fantom sirolimus-eluting scaffold was designed to allow the restoration of blood flow in patients being treated for coronary artery disease, then resorb from the body over time.

The company said that the trial began last month in Brazil (BD: Mar 16, 2015).

Reva said that the Fantom II trial was enrolling patients to support a European Conformité Européenne (CE) mark application, which was expected to occur by mid-2016.

Reva was unchanged at 52 cents.

TISSUE THERAPIES

Tissue Therapies says it will meet the European Medicines Agency scientific advisory working party in May 2015 to discuss further Vitrogro wound repair trials.

Tissue Therapies has faced repeated delays in the European regulatory process for Vitrogro, culminating in the resignation earlier this month of long-serving chief executive officer Dr Steven Mercer and chairman Roger Clarke (BD: Apr 7, 2015).

Today, Tissue Therapies said it had reviewed the European regulatory process and the company had addressed more than 30 matters raised by EMA assessors throughout the regulatory process resolving “the vast majority of these issues”.

The company said that the Vitrogro ECM protein comprised two components, vitronectin, which was responsible for the physical action and insulin-like growth factor-1 (IGF-1), which was responsible for the medicinal activity.

Tissue Therapies said that the EMA asked it to address two key issues, relating to the safety and utility of the IGF-1 component.

The company said that EMA requested more preclinical work to assess the utility or additional benefit of the IGF-1 medicinal component in a therapeutic setting and said that the previously conducted clinical study design did not permit an adequate and reliable interpretation of the clinical benefit risk profile of the incorporation of the IGF-1 ancillary substance into the device.

Tissue Therapies said that during the conformity assessment to the Medical Devices Directive, which occurred prior to the EMA’s involvement, the notified body, the British Standards Institute, accepted the clinical study and there was no signal of any problem with the quality, safety or usefulness of the IGF-1 component.

The company said that following the completion of the oral explanation with the UK Committee for Medicinal Products for Human Use, two key objections remained which required it to provide additional data.

Tissue Therapies said it intended to continue to pursue CE marking but would withdraw its application for a scientific opinion from EMA so the objections could be resolved.

The company said that on referring the matter to the EMA once the product was required to be classified, the notified body the BSI reported that the usefulness of the IGF-1 component was demonstrated and from its perspective there was no reason to change the development plan or obtain advice from the EMA Scientific Advisory Working Party.

Tissue Therapies acting chief executive officer Nigel Johnson said the company had “a lot of compelling data that supports an effect of the Vitrogro protein and the IGF-1 component”.

“I genuinely believe in Vitrogro and now that we are changing our development plan, we have an opportunity to take advice from SAWP,” Mr Johnson said. “The issues that CHMP have raised are legitimate and we will address the remaining issues.”

Tissue Therapies interim chairman Dr Cherrell Hirst said the company had “taken measures to conserve the company’s cash position by reducing all non-essential spending”.

“Our highly experienced internal team is working closely with external consultants who have significant experience as US and EU regulators to prepare for a comprehensive discussion with SAWP at the forthcoming meeting in May 2015,” Dr Hirst said.

“Until we know the outcome of that meeting, which may not be definitive, we cannot finalize our future plans,” Dr Hirst said.

“I would like to highlight that Tissue Therapies’ application to the notified body for CE marking in Europe remains viable, and every effort is being made to ensure the Vitrogro ECM’s potential to improve wound management and healing is recognized,” Dr Hirst said.

Tissue Therapies was unchanged at 10.5 cents.

AVITA MEDICAL

One Funds Management for the Asia-Pac Healthcare Fund II says it has increased its holding in Avita from 25,000,000 shares (8.66%) to 41,129,032 shares (10.11%).
The Hunter Street, Sydney-based One Funds said it acquired 16,129,032 shares for $1,000,000 or 6.2 cents in the recent placement which raised $5,042,280 and was followed by a share plan which raised a further $1,135,500 (BD: Mar 12, Apr 16, 2015).
In 2013, the Melbourne-based Octa Phillip Asset Management, acting for the Asia-Pac Healthcare 2 Account, said it had become a substantial shareholder in Avita with the acquisition of 25,000,000 shares (8.66%) (BD: Jun 6, 2013).
The 2013 substantial shareholder notice said that Octa Phillip acquired 9,681,836 shares for $1,161,820 or 12 cents a share in a placement.
The Melbourne-based Bioscience Managers (formerly IB Managers) website said that the Asia Pacific Healthcare Fund II was a 10-year Australian unit trust equity style fund of $55 million.
Bioscience Managers investment manager Dr Amanda Gillon told Biotech Daily that One Funds was the Bioscience Managers trustee and Bioscience Managers was a part of the Phillip Capital group.
Avita was untraded at 7.8 cents.

CSL

CSL says that chief financial officer Gordon Naylor will lead its influenza vaccine business, which is planned for launch at the start of 2016.
CSL said that Mr Naylor has held executive management responsibility for its existing vaccines and pharmaceutical subsidiary, Bio-CSL, since 2012.
The company said it was in the process of acquire the Novartis influenza vaccine business for $US275 million and intended to combine it with Bio-CSL, with completion planned for December 31, 2015, subject to regulatory approvals (BD: Oct 27, 2014).
CSL said that the combined businesses was expected to create the world's second largest influenza vaccine manufacturing company with plants in the US, UK, Germany and Australia, a diversified product portfolio and pandemic capabilities in its major centres of operation and would continue to manufacture, in-licence and distribute a range of vaccines and specialty pharmaceuticals in Australia and New Zealand.
CSL said that Mr Naylor joined the company in 1987, had held operations and general management positions and was appointed chief financial officer in 2010.
The company said that Mr Naylor had "played important leadership roles in CSL's internationalization, most notably in the successive integration of CSL Plasma and Aventis Behring" and the transformation of CSL Plasma.
The company said that Mr Naylor would continue as chief financial officer and a search would begin for a successor.
CSL said that Mr Naylor held a Bachelor of Engineering and a Graduate Diploma in Computing Studies from the University of Melbourne and a Masters in Business Administration from the Melbourne Business School.
CSL was up $1.22 or 1.3 percent to $93.82 with 1.55 million shares traded.