Biotech Daily

Wednesday September 14, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ORTHOCELL UP 8%, PRO MEDICUS DOWN 6%**

*** ONCOSIL: 'US TRIAL, CE MARK, DR CHRIS ROBERTS FOR CHAIRMAN'**

*** TGA CANCELS GI DYNAMICS ENDOBARRIER APPROVAL**

*** UNIQUEST'S INFLAZOME RAISES $22m**

*** MEDIBIO, MONASH SLEEP AND MENTAL HEALTH COLLABORATION**

*** STUDY: 'IMPEDIMED L-DEX CUTS BREAST CANCER LYMPHOEDEMA'**

*** FACTOR APPOINTS DR ROBERT RYAN DIRECTOR**

*** BIO-MELBOURNE BREAKFASTS ON INDIA**

*** ACTINOGEN: 'UNDERSTANDING ALZHEIMER'S SYMPOSIUM'**

MARKET REPORT

The Australian stock market was up 0.38 percent on Wednesday September 14, 2016 with the ASX200 up 19.9 points to 5,227.7 points. Eighteen of the Biotech Daily Top 40 companies were up, 15 fell, five traded unchanged and two were untraded.

Orthocell was the best on a positive Perth brokers report, up three cents or 7.9 percent to 41 cents with 439,957 shares traded, followed by Cellmid up 7.1 percent to three cents with 1.3 million shares traded.

Dimerix climbed 6.25 percent; Neuren rose 5.4 percent; Atcor and Prana improved more than four percent; Clinuvel, Impedimed, Living Cell and Starpharma were up more than three percent; Factor Therapeutics, IDT, Mesoblast and Nanosonics rose more than two percent; Admedus and Bionomics were up more than one percent; with Airxpanders, CSL and Cyclopharm up by less than one percent.

Pro Medicus led the falls, down 32 cents or 5.6 percent to $5.42 with 84,105 shares traded.

Benitec and Oncosil fell more than four percent; Acrux, Actinogen and Universal Biosensors were down more than three percent; Anteo, Compumedics, Medical Developments, Osprey, Pharmaxis, Polynovo, Reva and Sirtex were down more than one percent; with Cochlear, Resmed and Viralytics down by less than one percent.

ONCOSIL MEDICAL

Oncosil says Johns Hopkins and MD Anderson are the first two US hospitals to join its trial of its Brachysil treatment for pancreatic cancer.

Oncosil chief executive officer Dr Daniel Kenny and chief medical officer Dr Ashish Soman were in Melbourne today as part of “a non-deal investor update” which has been held in Sydney and will take them to Singapore, Hong Kong and possibly London.

Dr Kenny said the company had changed significantly in the past 18 months with the Conformité Européenne (CE) mark application filed in May and the US Food and Drug Administration approval of the investigational device exemption (IDE) trial granted in July, along with the appointment of former Cochlear chief executive officer Dr Chris Roberts as a director (BD: Jan 25, Jun 30, Aug 2, 2016).

On Monday, Oncosil said that director Martin Rogers would retire at the conclusion of the annual general meeting on October 18, 2016 (BD: Sep 12, 2016).

Today, Oncosil and investment advisory firm Hawkesbury Partners described Dr Roberts as “chairman-elect” but Dr Kenny said that Dr Roger Aston was the chairman and the handover was expected to take place later in the year or early next year.

Dr Kenny said that the company expected to appoint two new directors in the near future.

Dr Kenny said that the investor meetings were “to share the success of the IDE, the details of the trial protocol design, update on the CE mark approval, along with the increase of the number of directors to enhance and complement the board’s skill set”.

Dr Kenny said that the 300-patient trial would be conducted at 20 centres in the US along with Australia, the UK and other potential locations, with the first patient expected to be enrolled by March 2017.

Dr Kenny said that he expected the CE mark to be granted “in the near term”.

Oncosil previously said that the multi-centre, randomized, open-label ‘Oncopac-1’ safety and efficacy trial would be conducted in patients with locally advanced, unresectable pancreatic adeno-carcinoma.

The company said the first stage of the study would enrol 20 patients who would be subject to an FDA safety review, which would be followed by randomization to either Oncosil’s bio-silicon radiation treatment with standard chemotherapy; or standard chemotherapy treatment of gemcitabine alone; or gemcitabine and nab-paclitaxel alone.

Oncosil said that its phosphorous-32 radioactive micro-particles would be implanted intra-tumorally using endoscopic ultrasonography and the primary efficacy endpoint was local progression free survival, with secondary endpoints including progression free survival, overall survival, pain scores, body weight, safety and tolerability and performance status.

Oncosil fell half a cent or 4.2 percent to 11.5 cents.

GI DYNAMICS

GI Dynamics says the Australian Therapeutic Goods Administration will not permit sale of its Endobarrier for obesity and type 2 diabetes from October 12, 2016.

GI Dynamics said it had received notification that the Endobarrier’s inclusion in the Australian Register of Therapeutic Goods would be cancelled with effect from October 12, 2016 and the company would not be permitted to supply the device in Australia.

The company said that it had “the right to request a reconsideration of this decision and is currently considering whether to pursue this course of action”.

The Endobarrier has faced regulatory issues in Europe and the US including an association with liver abscesses (BD: Oct 6, 7, Dec 1, 2014; Jul 30, 31, 2015).

GI Dynamics was up 0.2 cents or 11.8 percent to 1.9 cents with 3.6 million shares traded.

UNIQUEST, INFLAZOME

Uniquest says that Inflazome has raised EUR15 million (A$22 million) in a series A financing round.

Uniquest said that Inflazome was founded on molecules and intellectual property discovered at the University of Queensland and Trinity College, Dublin and licenced from Uniquest, the commercialization arm of the University of Queensland.

The company said that the investment was co-led by Novartis Venture Fund and Fountain Healthcare Partners and was “one of the largest biotech series A investments for intellectual property originating from an Australian university”.

Uniquest said that Inflazome was headquartered in Dublin, Ireland and was developing first-in-class treatments for inflammatory diseases, developing inhibitors of the inflammasome, a key biological target that regulated the innate immune response, associated with a wide variety of diseases driven by chronic inflammation some with limited treatment options.

Uniquest said that the intellectual property was based on the research of the University of Queensland Institute for Molecular Bioscience’s Prof Matt Cooper, Dr Kate Schroder, Dr Rebecca Coll and Dr Avril Robertson in collaboration with Trinity College’s Prof Luke O’Neill and the jointly owned intellectual property had been licenced to Inflazome.

The company said that the investment would allow Inflazome to further develop inflammasome inhibitors, with the initial tranche of investment helping to advance the compounds towards the clinic for the lead indications.

Uniquest chief executive officer Dr Dean Moss said the deal “signalled global market confidence in Uniquest and the quality of research at [the University of Queensland]”.

“This deal is an endorsement of the quality of the research at the University of Queensland and the world leading life science research institute, the Institute for Molecular Bioscience,” Dr Moss said.

Fountain Healthcare Partners co-founder and managing partner Dr Manus Rogan and Inflazome chair said the “considering the breadth and depth of possible applications, the commercial potential for a successful small molecule inhibitor of this key target is clearly in the billions of dollars range”.

Novartis Venture Fund managing director Florent Gros said his company had “searched extensively for inhibitors of the inflammasome”.

“We are very excited by the prospects for Inflazome.” Mr Gros said.

“The company has outstanding assets, expertize and capabilities,” Mr Gros said

Inflazome is a private company.

MEDIBIO

Medibio says it has a partnership with the Monash Institute of Cognitive and Clinical Neurosciences “to improve sleep and mental health outcomes”.

Medibio said the collaboration would “translate cutting-edge science into next-generation mental health solutions” and funding the first 12 months was covered in its budget.

The company said the Monash Institute of Cognitive and Clinical Sciences was the largest institute of its type in the Asia-Pacific region, uniting more than 200 world-class researchers with research infrastructure.

Medibio said the partnership would focus on the further development of Medibio’s early detection and monitoring products and the Institute’s research and treatment approaches for sleep and circadian disorders and the partnership opened opportunities for access to data from sleep disorder and other groups of patients through the Monash Sleep Network.

Medibio was up half a cent or 1.25 percent to 40.5 cents.

IMPEDIMED

Impedimed says a research study shows that use of its L-Dex lymphoedema test resulted in a reduction of persistent, clinical lymphoedema by more than 90 percent.

Impedimed said that the retrospective study conducted by Texas surgical oncologists Dr Alison Laidley and Dr Beth Anglin followed 326 patients at-risk, for breast cancer related lymphoedema, with a median follow-up time of 21.7 months.

The company said that the patients had undergone either an axillary lymph node dissection or a sentinel lymph node biopsy and all patients had a pre-operative baseline measure and at least two postoperative follow-up visits.

Impedimed said that L-Dex bio-impedance spectroscopy measurements were taken on patients as part of their routine post-operative follow-up.

Impedimed said that the cumulative incidence of sub-clinical lymphoedema was 4.3 percent for the sentinel lymph node biopsy patients and 26.7 percent for axillary lymph node dissection patients.

The company said that the L-Dex allowed for early intervention for these patients resulting in a reduction of persistent, clinical lymphoedema by 99.5 percent and 91.4 percent, respectively.

The article, entitled 'The Impact of L-Dex Measurements in Assessing Breast Cancer-Related Lymphedema as Part of Routine Clinical Practice' was published in Frontiers in Oncology and is at: http://journal.frontiersin.org/article/10.3389/fonc.2016.00192/full.

The study concluded that the study demonstrated "that L-Dex assessments can be incorporated into routine breast cancer programs as part of follow-up".

"This is critically important given the recent changes in the [US national Comprehensive Cancer Network] survivorship guidelines for post-treatment follow-up care for breast cancer patients establishing that health-care providers 'educate, monitor, and refer for lymphedema management'," the study concluded.

Impedimed was up five cents or 3.45 percent to $1.50 with 1.9 million shares traded.

FACTOR THERAPEUTICS

Factor Therapeutics says it has appointed Dr Robert Ryan as a non-executive director, effective from September 13, 2016.

Factor said that Dr Ryan was most recently Scioderm Inc co-founder, president and chief executive officer taking the topical SD-101 treatment for epidermolysis bullosa from pre-investigational new drug application to phase III in less than two years and a capital outlay of less than $US25 million.

The company said it hoped to start a 168-patient, phase II, US trial of VF-001 for venous leg ulcers by October 2016, with results by October 2017 (BD: Jul 22, 2016).

Today, Factor said that epidermolysis bullosa led to fragile skin that blistered and tore from minor friction or trauma and Scioderm was the first company to receive Breakthrough designation from the US Food and Drug Administration and was later acquired by Amicus Therapeutics in September 2015 for $US957 million.

The company said that prior to Scioderm, Dr Ryan held executive positions at Celtic Therapeutics and Schwarz Pharma, held regulatory positions at contract research organizations including Quintiles chief regulatory officer and his "product development experience … resulted in the approval of [more than] 20 drug candidates".

Factor said that Dr Ryan held a Doctorate of Philosophy in toxicology from the University of North Carolina.

Factor was up 0.1 cents or 2.2 percent to 4.7 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its September 20, 2016 Bio-Breakfast discuss research and development and commercial opportunities in India.

The Network said that India was undertaking healthcare system transformation and the healthcare industry was “experiencing tremendous growth, particularly in response to the demand for digital healthcare solutions”.

The Bio-Melbourne Network said that the overall Indian healthcare market was worth $US100 billion and was expected to grow to $US280 billion by 2020, rising alongside economic prosperity and increased consumer demand for innovation and new healthcare products.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that “this is creating opportunities for collaboration, licencing deals, market entry and investment opportunities for Melbourne-based partners, broadly across biotech, pharmaceuticals, medical devices and digital health”.

The Network said that the Bio-Breakfast will address the barriers and opportunities, and emerging trends in changing healthcare in India.

The Network said that speakers included the Australia-India Business Advisory Group’s managing partner Kumar Vaidyanathan, Global Patient Portal co-founder and chief technology officer Hayden Cooke and the Multicultural Ministerial Business Advisory Council’s Rohini Kappadath who was the 2015 Telstra Business Woman of the Year.

The Bio-Briefing will be held at the Cube, Australian Centre for the Moving Image, Federation Square, Melbourne on September 20, 2016 with registration from 7:15am, a networking breakfast until 8am and then presentations until 9am.

To register go to: http://bit.do/biobreakfastindia.

ACTINOGEN MEDICAL

Actinogen says it will sponsor a public symposium, entitled ’Understanding Alzheimer’s: The Brains Behind Saving Yours’ in Melbourne, next week.

Actinogen said it was undertaking a phase II trial of Xanamem in mild Alzheimer’s disease and Xanamem inhibited the production of cortisol in the brain, which had been associated with the development of Alzheimer’s disease.

The company said that the symposium was “in recognition of dementia awareness month and world Alzheimer’s day”.

Actinogen chief executive officer Dr Bill Ketelbey said that “the symposium will guide guests on a journey through Alzheimer’s disease, from understanding what the disease is and what causes it, treating and managing it with the latest research and future therapies, through to the impact of the disease on carers and society”.

The company said that speakers would include the Perth, Western Australia-based McCusker Alzheimer’s Research Foundation’s Prof Ralph Martins, the Melbourne-based Florey Institute’s Prof Colin Masters, Alzheimer’s Australia Victoria carer advocate Anne Fairhall and Dr Ketelbey.

The symposium will be held on September 21, 2016, from 5:30pm to 7:30pm, at the Novotel Melbourne, 270 Collins Street, Melbourne.

To register, go to: http://bit.ly/ACWeventbrite.

Actinogen fell 0.2 cents or 3.3 percent to 5.8 cents.