Biotech Daily

Thursday May 29, 2014

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: PRIMA UP 12%, AVITA DOWN 12.5%**

*** BENITEC TREATS FIRST HEPATITIS C PATIENT**

*** ANALYTICA STARTS PERICOACH PRODUCTION**

*** FDA REGISTERS SIENNA SCD-7 TELOMERASE CANCER DIAGNOSTIC**

*** TGA APPROVES RESONANCE HEPAFAT-SCAN FOR REGISTER**

*** ORTHOCELL HOPES TO RAISE $8m IN IPO**

*** MEDICAL DEVELOPMENTS CLOSER TO UK PENTHROX APPROVAL**

*** SMARTSTENT WINS 1st VICTORIA MEDTECH'S GOT TALENT**

*** BIODIEM, GRIFFITH UNIVERSITY COLLABORATE ON BDM-I**

*** CALZADA EGM FOR 10m CHAIRMAN DAVID WILLIAMS OPTIONS**

*** FISHER FUNDS BELOW 5% IN UNIVERSAL BIOSENSORS**

*** EX-CEO GARY DAVEY REDUCES, DILUTED TO 7.4% OF USCOM**

*** GENETIC TECHNOLOGIES APPOINTS EUTILLIO BUCCILLI CFO**

MARKET REPORT

The Australian stock market was up 0.14 percent on Thursday May 29, 2014 with the S&P ASX 200 up 7.7 points to 5,519.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and four were untraded.

Prima was the best, up 0.6 cents or 12 percent to 5.6 cents with 49.5 million shares traded, followed by Anteo up 11.4 percent to 24.5 cents with 9.3 million shares traded. Circadian climbed 9.5 percent; Benitec was up 7.1 percent; Viralytics was up 5.3 percent; Oncosil and Universal Biosensors were up more than four percent; Clinuvel and Medical Developments were up more than three percent; Analytica rose 2.4 percent; with Ellex and Starpharma up more than one percent.

Avita led the falls, down 1.5 cents or 12.5 percent to 10.5 cents with 20,554 shares traded. Followed by Optiscan down 10.3 percent to 3.5 cents with 75,628 shares traded. Genetic Technologies lost 6.8 percent; Tissue Therapies fell 3.3 percent; Acrux, Impedimed and Patrys shed more than two percent; with Alchemia, Bionomics, Nanosonics, Neuren and Pharmaxis down more than one percent.

BENITEC BIOPHARMA

Benitec says it has dosed the first patient in its first-in-man, single infusion, phase I/IIa trial of TT-034 for hepatitis C.

Benitec chief executive officer Dr Peter French said the start of the trial was “a landmark in the company’s history”.

The company said that the trial was the first time Benitec’s gene silencing technology, DNA-directed RNA interference (ddRNAi) had been used systemically in patients.

Dr French said the primary objective of the first trial was to demonstrate that TT-034 could be used safely in patients with hepatitis C.

“Pre-clinical work in non-human primates demonstrated very low toxicity results at therapeutically relevant doses and we’re hopeful that we will see the same favorable tolerability in humansm,” Dr French said.

“In addition, we will be able to assess the impact of TT-034 treatment on ... viral load in these patients and this important efficacy marker constitutes one of the secondary endpoints of this study,” Dr French said.

Benitec said that the TT-034 phase I/IIa clinical trial was an open label, dose escalation study in 14 patients chronically infected with hepatitis C genotype 1.

The company said that initial patient cohorts would be treated with a sub-therapeutic dose of TT-034 to ensure that there were no unexpected safety concerns, before proceeding to higher, potentially therapeutic doses.

Benitec said that the data safety monitoring board would assess the data from each patient after the first patient in each cohort and between cohorts and would determine the timing of each subsequent dosing.

Benitec was up eight cents or 7.1 percent to $1.20.

ANALYTICA

Analytica says it has begun production of its intra-vaginal Pericoach sensor devices for pelvic floor strengthening, with “first domestic sales expected in the next few weeks”.

Analytica said the first units would be shipped to trained Pericoach accredited pelvic floor exercise clinics and specialists.

The company said that patients could buy the Pericoach device and subscription during a consultation with an accredited health professional using its point-of-sale hardware.

Analytica said that a Federal Government program was available to reimburse the cost of associated health professionals treating chronic urinary stress incontinence, a factor likely to encourage patients to seek help from their clinicians.

The company said it had 7,400 units on order to be delivered over the next few months and sales at $298 a unit could provide $2.1 million in revenue.

Analytica said the production system could be quickly and inexpensively scalable with capacity increases funded from sales.

The company said that its production partner had the capacity for about 125,000 units a year and doubling the capacity would incur a $60,000 cost in duplicate tools which could be online in eight weeks.

Analytica said that increasing production capacity to millions of units a year could be achieved at our existing production partners for less than $1 million with Analytica maintaining ownership of the tools and intellectual property.

Analytica chief executive officer Geoff Daly said the company was “in a very strong position ... [with] no debt, cash in the bank thanks to the recent capital raising, and a unique product that treats a massive and unmet medical need”.

Analytica was up 0.1 cents or 2.4 percent to 4.2 cents.

SIENNA CANCER DIAGNOSTICS

Sienna has registered its lead product the anti-human telomerase reverse transcriptase (hTERT) antibody SCD-A7 with the US Food and Drug Administration.
Sienna said that under the FDA registration, US-based pathology laboratories could develop their own diagnostic tests for cancer, using its SCD-A7 reagent which was an antibody against telomerase, an established biomarker for cancer.
The company said that telomerase was an enzyme that elongated chromosome ends, or telomeres, and could be found in up to 90 percent of human carcinomas.
Sienna said that given the established power of the telomerase biomarker in correlating with malignancy, global pathology labs are interested in accessing this new reagent to develop their own diagnostic tests.
The company said it was in advanced discussions with major US pathology companies, with first sales expected by the end of 2014.
Sienna managing director Dr Kerry Hegarty said that US pathology labs would “soon be the first in the world to be able to offer patients a urine test for bladder cancer developed using our product”.
“Data from Sienna’s in-house clinical studies indicated potential benefits of SCD-A7 over other current testing procedures,” Dr Hegarty said.
“Those results, combined with the non-invasive nature of the test, represent an important innovation, both for clinicians and patients,” Dr Hegarty said.
Sienna said that cystoscopy was the industry standard for the diagnosis and monitoring of bladder cancer and could cost up to $US2,000 per procedure, whereas its non-invasive urine tests using the reagent might assist in the early, cost effective detection of cancer, with an expected cost of less than $US150 per test.
“Registration of this product with the FDA and imminent first sales mark major milestones for Sienna,” Dr Hegarty said.
Sienna said that bladder cancer was the fifth most common cancer in the US, with more than 72,000 cases diagnosed in 2013 expected to rise to more than 74,500 in 2014.
The company said that it was in commercial and clinical discussions in Australia and Europe, with distribution plans for South East Asia, Canada and South America.
Sienna is a public unlisted company

RESONANCE HEALTH

Resonance says it has Therapeutic Goods Administration approval to list its Hepafat-Scan product on the Australian Register of Therapeutic Goods.
Resonance said that the Hepafat-Scan was a software medical device that enabled the non-invasive measurement of fatty liver using magnetic resonance imaging and Register listing was an important milestone as the company prepared to launch the product.
Resonance said the listing enabled it to supply Hepafat-Scan in Australia and to apply the Conformité Européenne (CE) mark, enabling the product to be sold in Europe.
The company said that the US Food and Drug Administration cleared the Hepafat-Scan in 2013.
The company said that fatty liver disease could be asymptomatic and was often undiagnosed and the gold standard for diagnosis was a liver biopsy with a visual estimate of fat by a pathologist.
Resonance said that the Hepafat-Scan provided a non-invasive solution to researchers and clinicians that needed to measure the liver fat content of their patients and the Hepafat-Scan reported the percentage of the liver that was fat.
Resonance was up 0.8 cents or 17.0 percent to 5.5 cents with 7.8 million shares traded.

ORTHOCELL

Orthocell says it hopes to raise $8 million through an initial public offer of 20 million shares at 40 cents a share and list on the ASX.

Orthocell said it was developing treatments for tendon, cartilage and soft tissue injuries using its Ortho-ATI autologous tenocyte implantation, using a patient's own stem cells to repair damaged tendons, and its collagen-based scaffold Celgro to provide mechanical strength to facilitate tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications was in late stage development (BD: Apr 16, 2014).

The company said that the public offer was being led by the Sydney-based KTM Capital and the Perth-based Azure Capital with Shaw Stockbroking as co-manager.

Orthocell said that the funds would be used to finalize the development of Celgro and apply for Australian regulatory approval; maintain regulatory approvals for Ortho-ATI and Ortho-ACI cartilage repair product in Australia; increase marketing of Ortho-ATI in Australia; and prepare for regulatory approvals of Ortho-ATI.

Orthocell chief executive officer Paul Anderson said that musculo-skeletal conditions were "the most common reason to access health care services and costs Australia more than $4 billion each year".

"Regenerative medicine aims to address these conditions by repairing and regenerating damaged tissue using the body's own building blocks in a more effective manner than ever before," Mr Anderson said.

"To date, clinic trial data has demonstrated the long term effectiveness of Ortho-ATI in its ability to regenerate tendon structure, offering patients both ongoing pain relief and restoration of function," Mr Anderson said.

Orthocell chairman Dr Stewart Washer said Orthocell was "a revenue generating company whose line of products have wide ranging applicability in repairing tendon, cartilage and soft tissue which has been damaged by disease, injury and the ageing process".

Orthocell said it had Australian Therapeutic Goods Administration approval to manufacture and sell Ortho-ATI in Australia, New Zealand and affiliated countries.

The company said that the prospectus was available at: www.orthocell.com.au.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it expects to file its responses to the UK Medicines and Healthcare Products Regulatory Agency for its Penthrox analgesic inhaler, next week.

Medical Developments said that it submitted its regulatory dossier and marketing authorization application in November 2013, received its first round of questions, the responses had been completed, with the review expected to be completed in six months.

Medical Developments said that if successful, the Penthrox inhaler would be approved for sale in the UK, France, Belgium and Ireland before the end of 2014.

The company said it had signed binding terms sheets and final documentation with distribution companies in Mexico and Singapore, had unsigned offers from potential representatives in the UK, France, Belgium, Ireland, Spain and Hungary, with some agreements including upfront licence payments and was discussing distribution partnerships with companies in Israel, Taiwan and Canada.

The company said that along with US approval for its Space Chamber Plus range of respiratory devices, it had added respiratory masks to the products and the combination mask and spacer products were expected to be on sale in the US in the next two months.

Medical Developments said it expected its Commonwealth Scientific and Industrial Research Organisation project to reduce manufacturing costs to be completed this year.

Medical Developments was up four cents or 3.3 percent to $1.25.

VICTORIA GOVERNMENT, SMALL TECHNOLOGIES CLUSTER

Victoria Minister for Technology Gordon Rich-Phillips says Smartstent has won the inaugural Medtech's Got Talent challenge.

A Victoria Government media release said the competition was run by the Small Technologies Cluster with support from the Victorian Government and recognized "the achievements of the state's brightest medical technology entrepreneurs".

The media release said that Smartstent was developed by Melbourne-based clinicians, Dr Thomas Oxley, Dr Nicholas Opie and Dr Rahul Sharma, who identified the need for new technology to assist patients in their care.

Mr Rich-Phillips said Smartstent's brain-machine interface gathered and decoded brain signals to control devices such as prosthetic limbs and had the potential to transform the lives of people living with paralysis as a result of disease or injury.

"Through its participation in the Medtech's Got Talent challenge, Smartstent and its fellow finalists have attracted greater attention in the marketplace, while also undertaking an accelerated technology development program including intensive mentoring and a range of business workshops," Mr Rich-Phillips said.

The media release said that Smartstent was seeking $3 million in further investment.

The Victorian Government said it had supported the Medtech's Got Talent program with $278,000 in funding through its Enabling Technologies Skills Strategy – Small Technologies program.

The media release said that Medtech's Got Talent assisted promising entrepreneurs to develop business concept pitching skills, technology roadmaps and launch commercialization activities, and the program was open to students, recent graduates or post-doctoral students employed by a Victorian-based institution or company.

BIODIEM

Biodiem says it will collaborate with Griffith University to screen candidate proteins that potentially interact with BDM-I and explore predicted binding interactions.

Biodiem said that Griffith University's Institute of Glycomics would identify possible candidates which were structurally related to BDM-I from the protein database bank.

The company said that the database contained all known structures between protein targets and their ligands and BDM-I would be verified against the identified targets and the results fed into an information package about how BDM-I worked as an antimicrobial.

The company said that the work would be co-funded by Griffith University's Industry Fund and Biodiem and the project would be led by Prof Yaoqi Zhou and Dr Joe Tiralongo.

Biodiem is a public unlisted company.

CALZADA

Calzada will vote to grant chairman David Williams 10,000,000 options with 7,500,000 exercisable at nine cents each and 2,500,000 exercisable at 20 cents each.

Calzada said the company was trading below nine cents share when Mr Williams was appointed to the board earlier this year (BD: Feb 28, Mar 13, 2014).

The company said that the options would be granted within one month of approval at the meeting and were exercisable within three years.

In its most recent Appendix 3B notice, Calzada had 418,509,426 shares on issue.

The meeting will be held at Unit 2, 320 Lorimer Street, Port Melbourne on July 1 9, 2014 at 9am (AEST).

Calzada fell 0.7 cents or 6.7 percent to 9.8 cents with one million shares traded.

UNIVERSAL BIOSENSORS

New Zealand's Fisher Funds says it has ceased its substantial shareholder in Universal Biosensors reducing from 9,189,077 shares (5.23%) to 8,515,380 shares (4.86%).
Fisher Funds said it sold 673,697 shares for $136,012 or 20.2 cents a share.
Yesterday, Fisher Funds reduced its holding from 11,014,077 shares (6.27%) to 9,189,077 shares (5.23%) selling 1,825,000 shares for $332,208 or an average price of 18.2 cents a share.
Last week, Fisher Funds said that it acquired shares from August 22, until September 24, 2013 and sold shares between May 13 and May 19, 2014, the day of the largest sales of 874,097 shares for $146,261 or 16.7 cents a share.
In a previous substantial shareholder notice Fisher Funds acquired 3,066,457 shares for $2,356,049 or an average price of 76.8 cents a share (BD: Jun 26, 2013).
Fisher Funds began selling, following a presentation which included details of a Johnson & Johnson lump sum service fee option to acquire the rights to the Universal Biosensors blood glucose test strips, believed to have triggered selling that led to a 39.4 percent share price fall (BD: May 12, 2014).
Universal Biosensors was up one cent or 4.9 percent to 21.5 cents with 3.9 million shares traded.

USCOM

Former Uscom deputy chairman and chief executive officer Gary Davey has reduced his substantial holding in Uscom and been diluted through a placement.
The Munich, Germany and Sydney-based Mr Davey said that he had reduced and been diluted from 6,284,609 shares (15.03%) to 6,039,000 shares (7.4%).
Uscom was unchanged at 26 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed Eutillio Buccilli as its chief financial officer, effective from June 2, 2014.
Genetic Technologies said that Mr Buccilli had more than 35 years of senior management experience in the financial services, contracting and recruitment, property and retail industries.
The company said that Mr Buccilli had held senior management positions with General Electric, Computer Science Corporation, Coles Myer and Challenger.
Genetic Technologies fell 0.3 cents or 6.8 percent to 4.1 cents.