Biotech Daily

Monday July 18, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: COMPUMEDICS UP 7.5%; BIONOMICS DOWN 6%**

*** GREG HUNT INNOVATION MINISTER, SUSAN LEY RETAINS HEALTH**

*** IMPEDIMED, VANDERBILT PARTNER FOR BIS CARDIAC TEST**

*** PSIVIDA TO CLOSE UK RESEARCH SAVING $1.2m A YEAR**

*** FDA ACCEPTS CLINUVEL SCENESSE DATA PACKAGE FOR EPP**

*** MEDLAB TO RAISE $5m FOR CANNABIS PAIN TRIAL**

*** IMMURON TO REPAY $1m SEA OTTER NOTE**

*** COMPUMEDICS EXPECTS $37m REVENUE, LOW COST MANUFACTURING**

*** PAUL RUGGIERO, 'LIKE-MINDED INVESTORS' TAKE 16% OF CELLMID**

*** VICTORIA, BIO-MELBOURNE US TRADE MISSION**

*** MTP CONNECT 10-YEAR PLAN ROADSHOW**

MARKET REPORT

The Australian stock market was up 0.53 percent on Monday July 18, 2016 with the ASX200 up 28.9 points to 5,458.5 points. Twenty of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and one was untraded.

Compumedics was the best, up three cents or 7.5 percent to 43 cents with 165,452 shares traded.

Antisense climbed 6.25 percent; Factor Therapeutics was up five percent; Admedus, Airxpanders, Benitec, Mesoblast and Oncosil were up three percent or more; Clinuvel and Starpharma rose two percent or more; Impedimed, Pharmaxis, Sirtex and Universal Biosensors were up more than one percent; with CSL, Ellex, Nanosonics, Opthea, Pro Medicus, Resmed and Viralytics up by less than one percent.

Bionomics led the falls, down two cents or 6.25 percent to 30 cents, with 243,086 shares traded. Actinogen and Orthocell lost more than five percent; Living Cell fell four percent; Atcor was down 3.6 percent; Anteo shed 2.4 percent; Avita, IDT, Neuren and Uscom were down more than one percent; with Cochlear and Medical Developments down by less than one percent.

FEDERAL GOVERNMENT

Prime Minister Malcolm Turnbull has appointed former Environment Minister Greg Hunt the Minister of Industry Innovation and Science.
Former Innovation Minister Chris Pyne was appointed Minister for Defence Industry and Health Minister Susan Ley has retained her previous portfolios including responsibility for the proposed $20 billion Medical Research Future Fund.

IMPEDIMED

Impedimed says it will partner with the Nashville, Tennessee-based Vanderbilt University to test its next generation technology platform for “patient and clinician human factors”.
Impedimed did not describe the bio-impedance spectroscopy (BIS) technology or its proposed indications but said the testing and was expected to conclude by October 2016.
In a research note, Cannacord Genuity analyst Dr Matthijs Smith said the new Impedimed device did not require electrodes and had four points of contact, both hands and both feet, allowing segmental analysis and “the first commercial application of this device will be for at-home monitoring to detect fluid build-up in heart failure patients”.
Last year, Impedimed acquired “key assets and intellectual property from Intersection Medical” for its bio-impedance spectroscopy for chronic heart failure and signed an agreement with the Harvard Clinical Research Institute to investigate bio-impedance spectroscopy in chronic heart failure patients. (BD: Oct 26, Nov 3, 2015).
In February, Cannacord raised $75 million to fund sales of Impedimed’s L-Dex lymphoedema test and develop a congestive heart failure test (BD: Feb 9, 2016).
Today, Impedimed said that Vanderbilt School of Nursing principal investigator Prof Sheila Ridner would lead the testing of the hardware design and software user interfaces of the bio-impedance spectroscopy technology platform for patients and clinicians, with researchers observing product use in laboratories and in one-to-one interviews.
“As a long-time user of BIS technology in my research, I am excited about the potential of this next generation device to empower not only clinicians, but also patients, to more easily monitor their health status,” Prof Ridner said.
Impedimed was up two cents or 1.7 percent to $1.18 with 1.7 million shares traded.

PSIVIDA CORP

Psivida says it will consolidate all research and product development in a single location to support its product development program, saving $1.2 million a year.
Psivida said that subject to a UK-required employee consultation process it would to close its Malvern, Worcestershire research facility and locate all research and product development at its “state-of-the-art” facility in Watertown, near Boston, Massachusetts.
Psivida chief executive officer Dr Paul Ashton said that Durasert and Tethadur research and development work would be done in a single location, which would “focus our [research and development] efforts and facilitate product development while reducing operating expenses”.
Psivida said it expected the site consolidation would reduce pre-tax operating expenses by about $US900,000 ($A1,187,459) a year, and it would record about $US680,000 of charges associated with the plan, of which $US550,000 would be cash expenditures, pending currency exchange ratios and the outcome of the consultation process.
Psivida said most charges were expected in the three months to September 30, 2016, with the consolidation expected to be completed substantially by then.
Psivida was unchanged at $4.40.

CLINUVEL PHARMACEUTICALS

Clinuvel says the US Food and Drug Administration has concluded an initial review of, and accepted, its clinical data package for Scenesse for erythropoietic protoporphyria.
Clinuvel said that the FDA deemed its Scenesse (afamelanotide 16mg) clinical data package satisfactory for submitting a new drug application, including clinical datasets on 352 patients from trials conducted between 2006 and 2013, so that the FDA could understand the severity of erythropoietic protoporphyria (EPP) symptoms and clinical effectiveness of Scenesse.
The company said it would organize a pre-new drug application with the FDA and request a rolling review of its dossier under its fast track designation.
Clinuvel said it would request an FDA priority review to shorten the review time from 10 months to six months and the FDA had initiated a workshop on October 24 to learn more about the disease and the effectiveness and safety of the proposed treatment.
The company said that the FDA granted Scenesse orphan drug designation in 2008, so the FDA would waive all Prescription Drug User Fee Act (PDUFA) user fees usually required during the submission process.
Clinuvel regulatory affairs director Dr Nicoletta Muner said the FDA outcome was “a direct result of a decade of our team’s consistency, dedication and transparency in negotiating the best pathway with the Agency”.
“I am very much looking forward to achieving the milestone of presenting the FDA with a quality dossier,” Dr Muner said.
Clinuvel chair, Stan McLiesh said the NDA filing would be “the next significant step towards making Scenesse available in North America, where patients have been vocal in requesting the drug for some time”.
Clinuvel was up 10 cents or two percent to $5.09.

MEDLAB CLINICAL

Medlab says it expects to raise $5,361,150 in a fully underwritten renounceable one-for-nine pro rata rights offer at 30 cents a share.
Medlab said that the principal use of funds would be to accelerate its research and development program and begin human trials using its cannabis-based pain management therapy.
The company said that the offer to shareholders at the record date of July 21, would open on July 25 and close on August 9, 2016.
Medlab said that its leading non-management shareholder Farjoy Pty Ltd had underwritten the issue of about 17,870,500 new fully paid ordinary shares, with Farjoy requesting that chief executive officer Sean Hall and chairman Michael Hall agreeing to limit their participation to $900,000 in shares to increase the company’s liquidity.
The company said that the balance would be handled by lead manager Shaw and Partners.
Medlab said that since listing on the ASX in July 2015 it had expanded its range of food additives to 20 products, developed Nanocelle for tiny particle mouth delivery of medications and advanced its bacteria-based cell culture studies for obesity and its phase I depression trials, with these projects ahead of schedule.
The company said that its pain management trial involved a therapy combining two cannabis compounds, cannabidiol and tetrahydrocannabinol, to be administered through the Nanocelle oral delivery mechanism.
Medlab was unchanged at 42 cents.

IMMURON

Immuron says that following its rights issue raising $5.33 million it will be able to repay its Sea Otter convertible note in cash, rather than through new shares.
Immuron said it took a convertible note facility in February for up to $1.7 million from the New York-based Sea Otter while finalizing its capital raising (BD: Feb 17, Jul 5, 2015).
The company said that convertible note liability was $1,130,000 repayable in equal amounts over the next 15 months.
Immuron said that repaying the note in cash attracted a 2.5 percent repayment premium, but the alternative was to repay in tranches with shares issued at a 10 percent discount to the volume-weighted average price of the lowest five trading days in the prior month; and repaying the note in cash would be non-dilutive.
Immuron was up one cent or 4.35 percent to 24 cents.

COMPUMEDICS

Compumedics says it expects revenue for the 12 months to June 30, 2016 of $37 million in line with previous guidance.
Compumedics said that it expected net profit after tax to be in the range of $2.8 million to $3.2million, with audited full-year results to be released about August 25, 2016.
The company said the results reflected its process of renewing growth, as well as relocating key manufacturing activities to lower-cost economies.
Compumedics was up three cents or 7.5 percent to 43 cents.

CELLMID

Paul Ruggiero says that the “association of like-minded investors” has increased its holding in Cellmid from 102,043,846 shares (11.0%) to 145,221,267 shares (15.6%).
In June and early July, the Gladesville, Sydney-based Mr Ruggiero said he was the Association’s “group coordinator” and named about 20 shareholders who were part of his group (BD: Jun 29, 30, Jul 4, 5, 2016).
Today, Mr Ruggiero’s list of like-minded investors added Harold Gottlieb and the Gottlieb family trust with 12,448,028 shares as well as Trevor Gottlieb with 14,510,000 shares and Tz Holdings and Tz Holdings No 2 with 8,045,493 shares.
Cellmid was up 0.1 cents or 3.2 percent to 3.2 cents with 2.4 million shares traded.

BIO-MELBOURNE NETWORK, VICTORIA GOVERNMENT

The Bio-Melbourne Network says it proposes to lead a medical technologies trade mission to the US on behalf of the State Government of Victoria
The Network said that the mission would take place from October 13 to 21, 2016 and include attendance at Advamed 2016, the largest annual medical technology conference on the US calendar.
Bio-Melbourne Network chief executive officer Dr Krystal Evans said that “the proposed mission aims to support high-growth potential medical technology companies to make new [business-to-business] connections, engage with US [medical technologies] industry leaders, grow market and investor readiness and gain traction in this key export market”.
The Network said it would run a mission information session on July 27, 2016 at the Victorian Government Investment Centre, Level 46, 55 Collins St, Melbourne.
Registration is from 3:45pm with the presentation from 4pm to 5.30pm and to register go to: http://biomelbourne.org/event/us-advamed-trade-delegation-eoi-session/.

MEDICAL TECHNOLOGIES & PHARMACEUTICALS GROWTH CENTRE

The Medical Technologies and Pharmaceuticals Growth Centre, or MTP Connect, says it will tour Australia in July and August to describe its work and a 10-year plan.

MTP Connect was established under the Federal Government's National Innovation and Science Agenda "to promote and accelerate innovation and entrepreneurship, to identify and remove barriers to success and to deliver sectoral competitiveness, collaboration and productivity" and appointed Sue MacLeman as chief executive officer effective from April 2016 (BD: Dec 7, 8, 2015; Feb 26, 2016).

Today, MTP Connect said the draft 10-year sector competitiveness plan intended to boost the innovation, productivity and competitiveness of Australia's medical technology, biotechnology, and pharmaceutical sector.

MTP Connect said that the events would be a "networking opportunity, bringing businesses, industry organisations and the science and research sector together to build links, unlock commercial opportunities and drive innovation".

The meetings will be held in Melbourne on July 25, Adelaide July 26, Sydney August 3, Brisbane August 22, with events planned for Perth and Canberra.

To register, go to: http://www.mtpconnect.org.au/content/sector-competitiveness-plan.