Biotech Daily

Tuesday September 20, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: ORTHOCELL UP 5%, DIMERIX DOWN 6%**

*** CSIRO $52m OVER 5 YEARS FOR 'FUTURE SCIENCE PLATFORMS'**

*** FEDERAL GOVERNMENT $23m FOR INCUBATOR SUPPORT**

*** ITL WINS $900k BARWON HEALTH SUPPLY CONTRACT**

*** CE MARK APPROVAL FOR SPEEDX RESISTANCEPLUS MG**

*** ALLEGRA EXPANDS SR-HT-GAHNITE BONE SUBSTITUTE TO ALL USES**

*** MEMPHASYS TO RAISE $940k FOR WORKING CAPITAL, LEGAL COSTS**

*** IMUGENE HER-VAXX PASSES PRE-CLINICAL TOXICOLOGY**

MARKET REPORT

The Australian stock market edged up 0.17 percent on Tuesday September 20, 2016, with the ASX200 up 8.8 points to 5,303.6 points.

Fourteen of the Biotech Daily Top 40 companies were up, 13 fell, eight traded unchanged and five were untraded.

Orthocell was the best on an investor road show, up two cents or 5.1 percent to 41 cents with 323,606 shares traded.

Oncosil and Opthea improved four percent or more; Cellmid was up 3.45 percent; Cochlear, Nanosonics and Reva rose more than two percent; Actinogen, Avita, Impedimed, Sirtex and Starpharma were up more than one percent; with CSL, Medical Developments, Pro Medicus and Viralytics up by less than one percent.

Dimerix led the falls, down 0.1 cents or 6.25 percent to 1.5 cents with 4.7 million shares traded.

Clinuvel, Neuren and Prima fell more than five percent; Ellex and Genetic Signatures lost more than four percent; Admedus was down three percent; Living Cell shed 2.25 percent; Compumedics, Mesoblast, Pharmaxis and Resmed were down more than one percent; with Acrux and Airxpanders down by less than one percent.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says it will increase investment in “breakthrough science” through six ‘Future Science Platforms’ to more than $52 million a year by 2020.

The Organisation said the establishment of the Platforms would “underpin innovation in health and biology, resources, agriculture and manufacturing, have the potential to support the reinvention and creation of new industries and new jobs for Australia”.

CSIRO chief executive Dr Larry Marshall said that “investing in challenging and riskier science will ensure research continues to meet the needs of industry, community and the environment in a rapidly changing world”.

“We've freed up resources to enable this initial $17 million investment in 2016-’17 to launch the [Platforms]” increasing to more than $50 million a year by 2020.

“The Platforms fuel deeper collaboration across disciplines as we tackle things that haven't been done before, which is exactly what we need to stay ahead of accelerating global disruption of all kinds from economic to environmental,” Dr Marshall said.

The CSIRO said that the Future Science Platforms would invest in research and the delivery of products and were “an investment in the next crop of researchers”.

The Organisation said that the six Platforms included ‘Synthetic Biology’ which was intended to fund “the design, fabrication and construction of new biological parts, devices, systems and machines, as well as the re-design of existing biological systems for useful purposes”.

“Synthetic biology enables revolutionary advances in cellular factories, designer organisms and biological devices,” CSIRO said.

The Organisation said that ‘Probing Biosystems’ was intended to be “a revolution in healthcare and agriculture through devices and systems to obtain real-time information from living organisms about their health and well-being … [leading] to the ability to provide health and medical interventions that are timely, customized and highly specific.”

Other Platforms included the newly coined term ‘Environomics’, which is also the name of several companies in the US and Australia providing consultancy, accountancy and holistic primary care services, along with ‘Deep Earth Imaging’, ‘Digiscape’ and ‘Active Integrated Matter’.

For more information on the Future Science Platforms, go to: www.csiro.au/FSP.

FEDERAL GOVERNMENT

The Federal Government says the Incubator Support initiative has $23 million for incubators to help start-up companies access advice, capital and connections.

A Federal Government media release said that business incubators would increase innovation capacity by bringing communities of entrepreneurs together to increase the flow of local knowledge and foster collaboration.

The media release said that applications had opened for matching grants between $10,000 and $500,000 for new incubators in regions or business sectors with strong links to international trade, and for existing, incubators to expand their services and incubators could access matching grants of up to $25,000 to engage experts-in-residence.

The media release said that the Incubator Support initiative was a new element of the Entrepreneurs’ Program and part of the National Innovation and Science Agenda.

The Government said that the Incubator Support initiative was originally an $8 million initiative, and it had committed a further $15 million over four years to ensure more innovative businesses, especially those in regional and rural areas, could access the resources and networks needed to grow.

For more information go to: www.business.gov.au/incubator-support.

ITL LIMITED

ITL says its healthcare division has won a new $900,000 one-year contract with the Geelong, Victoria-based Barwon Health, a major provider of regional health services.
ITL said that the contract was to supply customized procedure packs and would enable the healthcare division to provide its two new innovative product ranges, the Airtech range of “light-weight, environmentally responsible surgical fabrics that use the latest manufacturing technologies to provide optimal clinical protection” and its clinically equivalent medical and surgical consumables manufactured in its Malaysian facility.
The company said that Barwon Health provided emergency and acute, mental health, primary care, community services, aged care and sub-acute rehabilitation services.
ITL executive chairman Bill Mobbs said the contract was “yet another that has marked a successful start to the current financial year for ITL healthcare”.
“The Barwon contract follows the recently announced contract wins with Metro South Health in Brisbane and Austin Health in Melbourne, alone worth $2.5 million per annum,” Mr Mobbs said.
ITL was up three cents or 16.7 percent to 21 cents.

SPEEDX PTY LTD

Speedx says it has Conformité Européenne (CE) approval for its Resistanceplus MG assay for Mycoplasma genitalium and resistance-related mutations.
The Sydney-based Speedx said that mutations in the 23S ribosomal RNA gene of the Mycoplasma genitalium bacteria had been shown to confer resistance to azithromycin, a commonly prescribed macrolide-based antibiotic.
Speedx chief executive officer Colin Denver said that company was “excited to receive CE [in-vitro diagnostic] marking for this revolutionary new benchmark for [Mycoplasma] genitalium and antibiotic resistance testing”.
“As with the better known [sexually transmitted disease] gonorrhoea, [Mycoplasma] genitalium has developed serious treatment challenges because of the recent rise of antibiotic resistance,” Mr Denver said.
Speedx has a collaboration with the Melbourne Sexual Health Centre and the Royal Women’s Hospital to investigate the prevalence of Mycoplasma genitalium in men.
Melbourne Sexual Health Centre’s Prof Catriona Bradshaw said that Mycoplasma genitalium was an emerging sexually transmitted infection “with a marked ability to develop resistance to antimicrobials that are commonly used to treat other sexually transmitted infections such as chlamydia”.
“We are facing a crisis where up to 50 percent of individuals attending urban … services such as [the] Melbourne Sexual Health Centre do not respond to current recommended first line treatment,” Prof Bradshaw said.
“For some time, we have needed diagnostic tests for Mycoplasma genitalium that also report antimicrobial resistance in order to individualize patient therapy and optimize cure rates,” Prof Bradshaw said.
Speedx said that it was in discussions with US medical centres to conduct clinical trials of its Resistanceplus MG assay and planned to apply for US Food and Drug Administration pre-market approval in 2017.
The company said that the was no FDA-cleared molecular diagnostic test for Mycoplasma genitalium and it had a material transfer agreement with the US Centers for Disease Control and Prevention to evaluate the performance of the Resistanceplus MG assay.
Speedx is a private company.

ALLEGRA ORTHOPAEDICS

Allegra says it has expanded its Sr-HT-gahnite bone substitute collaboration with the University of Sydney's professor of bio-medical engineering Prof Hala Zreiqat.

In June, Allegra said the collaboration had developed a ceramic scaffold to assist regenerate bone tissue and degrade as it is replaced by natural bone, with Prof Zreiqat and her team using three-dimensional printing technology to developed the ceramic, composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite (a zinc-aluminium-oxide), described as Sr-HT-gahnite (BD: June 8, 2016).

"It actually kick-starts the process of bone regeneration making it a superior material to those bone substitutes currently available," Prof Zreiqat said in June.

Today, Allegra said that the previous agreement was limited to use in veterinary and orthopaedic products and the expansion allowed for Sr-HT-gahnite material to be developed "for all applications and for all fields of use".

The company said that Sr-HT-gahnite was developed as a scaffold on which the body could regenerate new bone, then degrades as it was replaced by natural bone.

Allegra said that the expanded licence covered using the ceramic for applications including, but not limited to, coatings to improve the long-term stability of implantable medical devices, drug delivery and skeletal tissue regeneration.

The company said that six and nine month x-ray results of its animal study showed extensive bone in-growth which was integrated with bone at the defect edge, with complete bridging of the defect observed in some specimens.

Allegra said that the 12 month animal study would be concluded in October 2016 and the 12-month evaluation was expected "to indicate significantly greater bone in-growth and bridging of the defect".

Allegra executive chairman Peter Kazacos said that the expansion "adds enormous scope to the current bone project".

Allegra was untraded at 14 cents.

MEMPHASYS

Memphasys says it has appointed Platinum Road Pty Ltd as its corporate advisor and is raising $940,000 through the issue of secured convertible notes.

Memphasys said that the funding was "a mix of new capital and the conversion of debts owed by the company into convertible notes".

Platinum Road's website said that the principals of the Richmond, Victoria company were Dr David Menzies and Peter Shakespeare.

Memphasys said that Platinum Road's renewable mandate was initially for two months and was for the purposes of raising funds and to give strategic and marketing advice.

The company said it had terminated the mandate of former corporate advisors, Transocean Securities and the consulting services of Dr Robert Gilmour.

Memphasys said that executive chairman Alison Coutts and director Andrew Goodall would each contribute $450,000 and lead product Spermsep inventor, University of Newcastle Prof John Aitken, would contribute $40,000 as conversion of consulting fees.

The company said that convertibility of the notes was subject to shareholder approval.

Memphasys said that the convertible notes had a two year term at 10 percent interest per annum, payable monthly in arrears and converting at 0.6 cents a share.

The company said that the funds would be used for working capital, primarily to assist in the development of the next generation Spermsep device and to fund litigation against Prime and Manukan in Singapore (BD: Sep 12, 2016).

Memphasys was untraded at 0.8 cents.

IMUGENE

Imugene says pre-clinical testing by Charles River Laboratories shows no adverse effects at doses higher than those to be used in the phase Ib trial about to begin.

Imugene said that the Wilmington, Massachusetts-based Charles River Laboratories conducted two studies on its HER-Vaxx immune-therapeutic cancer vaccine for gastric cancer, a repeat dose toxicology study in rats and a cardiovascular and respiratory safety pharmacology study in beagle dogs.

The company said that the final audited preclinical reports on both studies showed that "no adverse effects were noted at doses which are higher than those to be used in the phase Ib trial commencing imminently in 2016".

Imugene said it was important that "very strong cancer fighting antibodies were measured in the sera of both species" - a critical marker for the vaccine working as expected.

Imugene chief operating officer Leslie Chong said the studies were "yet another critical milestone met in our preparation for commencing our phase Ib/II clinical trial in patients with gastric cancer".

Imugene was up 0.1 cents or 12.5 percent to 0.9 cents with 3.2 million shares traded.