Biotech Daily

Tuesday July 29, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH FLAT: IMPEDIMED UP 11%, CIRCADIAN DOWN 10%**

*** BURNET, GERMANY'S ARTES COLLABORATE ON MALARIA VACCINE**

*** NANOSONICS 12-MONTH SALES UP 44% TO $21.5m**

*** MAYNE TO DISTRIBUTE IDT'S GENERIC TEMOZOLOMIDE IN THE US**

*** NORWAY APPROVES, PORTUGAL PAYS FOR PSIVIDA ILUVIEN FOR DME**

*** ANTISENSE COMPLETES PHASE II ATL1103 ACROMEGALY DOSING**

*** US PATENT FOR IMUGENE'S HER-VAXX**

MARKET REPORT

The Australian stock market was up 0.2 percent on Tuesday July 29, 2014 with the S&P ASX 200 up 11 points to 5,588.4 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and one was untraded.

Impedimed was the best, up three cents or 11.1 percent to 30 cents with 765,536 shares traded.

Nanosonics climbed 9.3 percent; Antisense was up 7.7 percent; Ellex rose 5.4 percent; Admedus and Avita were up four percent or more; Acrux, Cellmid, IDT and Patrys were up more than three percent; Analytica and Mesoblast rose more than two percent; Benitec and Sirtex were up more than one percent; with CSL and Resmed up by less than one percent.

Circadian led the falls, down two cents or 10 percent to 18 cents with 129,139 shares traded.

Both Optiscan and Osprey lost five percent; Neuren and Prana fell more than four percent; Alchemia, Oncosil, Starpharma and Uscom were down more than three percent; Genetic Technologies shed 2.9 percent; with Bionomics, Cochlear, GI Dynamics, Pharmaxis, Psivida and Tissue Therapies down more than one percent.

THE BURNET INSTITUTE

The Burnet Institute says it will collaborate with the Langenfeld, Germany-based Artes Biotechnology GMBH to develop a malaria vaccine.

The Institute said that the collaboration was funded by the Seattle, Washington-based Program for Appropriate Technology in Health (PATH) through its Malaria Vaccine Initiative.

The Burnet Institute said that the project will use technology developed by Burnet deputy director Prof David Anderson and colleagues.

The Institute said that Artes held the rights to the Metavax chimeric duck hepatitis B virus-like particle platform for vaccine production.

The Burnet said that the project hoped to produce vaccines that could block the transmission of malaria infection from mosquitoes to people.

The Institute said that purified vaccine antigens (Pfs25 and Pfs230) would be produced as virus-like particles for initial testing in laboratory studies.

The Institute said that the virus-like particles would be taken-up by immune cells to prime and prepare the immune system to fight malaria.

The Burnet Institute's centre for biomedical research co-head Prof James Beeson said the challenges in developing an effective malaria vaccine were substantial.

"One of the challenges for malaria is how to best make vaccines in order to stimulate a strong and effective immune response and boost the immune system to fight malaria infections," Prof Beeson said.

Artes managing director Dr Michael Piontek said the collaboration was "a great opportunity for developing new malaria vaccines".

"In this new project, Burnet and Artes will combine their expertise to develop and test a novel approach for producing malaria vaccines," Dr Piontek said.

The Institute said that although malaria was one of the world's leading causes of illness and death there was no vaccine approved for use.

The Burnet said that more than 600,000 people died from malaria each year and it most severely affected young children and pregnant women.

NANOSONICS

Nanosonics says sales of its Trophon EPR ultrasound probe cleaner for the 12 months to June 30, 2014 were up 44.3 percent to $21.5 million compared to the previous year.

In its Appendix 4C Quarterly Report, Nanosonics said that sales for the three months to June 30, 2014 were up 26.3 percent to $6,592,000 compared to the prior quarter and up 5.1 percent compared to the prior corresponding period.

The company said it had $21.23 million in cash at June 30, 2014 with a further $3.04 million received in July relating to sales in the quarter.

Nanosonics chief executive officer Michael Kavanagh said that the "strong results and growth momentum coupled with strengthening market fundamentals provide confidence in our goal of establishing Trophon as a new standard of care".

"All regions demonstrated growth for the year as awareness of imaging related healthcare acquired infections grows and the need for better disinfection solutions becomes more evident," Mr Kavanagh said.

Mr Kavanagh said that a report by the US Joint Commission, responsible for the accreditation and certification of healthcare organizations, "highlighted high level disinfection as one of the top five non-compliance requirements for hospitals, critical access hospitals, ambulatory and office based surgery facilities".

Nanosonics was up seven cents or 9.3 percent to 82 cents.

IDT AUSTRALIA, MAYNE PHARMA GROUP

IDT says that Mayne Pharma's US division will distribute its generic temozolomide for melanoma and glioblastoma multiforme in the US.
IDT said that temozolomide had US sales of about $US340 million in the 12 months to May 31, 2014 and was originally marketed as Temodar by Merck Inc.
The company said that the commercial terms of the deal were confidential, with definitive documents containing full commercial terms to be finalized.
IDT said the agreement provided for an initial term of 10 years, with Mayne Pharma the exclusive US distributor for IDT's temozolomide, subject to minimum orders.
The company said that the agreement provided for upfront payments to IDT on execution of the memorandum of understanding, execution of definitive documents, specified regulatory milestones of IDT's temozolomide abbreviated new drug application including US Food and Drug Administration approval of its temozolomide.
IDT said the agreement contained a transfer-pricing and profit-share arrangement based on Mayne Pharma's US sales of temozolomide.
The company said that the Adelaide-based Mayne Pharma had a generic pharmaceutical business in Greenville, North Carolina that developed, manufactured, marketed and distributed more than 25 products, with a pipeline of products under development.
IDT said that Mayne's US products division serviced retail accounts including Wal-Mart, McKesson, Walgreens, Rite Aid, Cardinal Health and CVS.
The company said that the abbreviated new drug application submission for temozolomide was the first of its generic filings and had been accepted for review by the US Food and Drug Administration and was progressing through the review process. (BD: Nov 18, 2013).
IDT managing director Dr Paul MacLeman said the deal with Mayne Pharma "fits squarely within IDT's strategy is to maximize the value of our globally-accredited drug manufacturing facility and to develop a generic drug portfolio in our own right".
Dr MacLeman said the deal allowed IDT "to extract the maximum value from its existing assets, moving up the value chain as an owner and content provider of high value generic products such as temozolomide, rather than solely as a contract manufacturer".
Mayne Pharma chief executive officer Scott Richards said that the IDT agreement was "a testament to Mayne Pharma's growing product portfolio and scale in the US".
"Temozolomide will be a welcome addition to the US product portfolio and we look forward to launching this product following FDA approval," Mr Richards said.
IDT said that it intended to build on its generic drug portfolio strategy with plans to develop or acquire additional generic drugs over the next 12 to 18 months.
IDT was up one cent or 3.85 percent to 27 cents.
Mayne Pharma was up two cents or 2.3 percent to 89.5 cents.

PSIVIDA

Psivida says that Iluvien has been granted marketing authorization in Norway and approved for reimbursement in Portugal for chronic diabetic macular oedema.
Psivida said that the approval and reimbursement were for "the treatment of vision impairment associated with chronic diabetic macular oedema considered insufficiently responsive to available therapies".
The company said that the Norwegian marketing authorization was the first following the completion of the European Union mutual recognition procedure (BD: Jul 1, 2014).
Psivida said that Iluvien had been approved for reimbursement in Portugal by Infarmed, the marketing authorization body of the Portuguese Ministry of Health and licencee
Psivida fell five cents or 1.1 percent to $4.60.

ANTISENSE THERAPEUTICS

Antisense says it has dosed all 26 patients in its phase II trial of ATL1103 for the growth disorder acromegaly, with no patient withdrawals or reports of any serious adverse events.
Antisense said that the patients would be monitored for two months after their last dose of ATL1103, with primary efficacy results expected by the end of August 2014.
The company said that the primary efficacy endpoint was the percentage reduction from each patient's baseline of serum insulin-like growth factor I (IGF-I) levels to their levels one week after the completion of dosing.
Antisense said that acromegaly patients had elevated serum IGF-I levels compared to the normal population and reducing their serum IGF-I to within a normal range was accepted by clinical authorities as the therapeutic goal for treatment of the disease.
The company said that positive results from an interim analysis in 2013 of the data from the first eight patients provided indicative data on the efficacy of ATL1103 with the serum IGF-I reductions achieved in line with reductions that could be therapeutically effective (BD: Jan 19, 2014).
Antisense said that blood samples collected from all the patients would be shipped from the trial sites in the UK, Central Europe and Australia to a laboratory in Germany for measurement of serum IGF-I, the values would be transferred to the contract research organization in the UK for entry into the trial database and after all checks were completed, the IGF-I data would be statistically analyzed and reported.
The company said it expected primary efficacy results by the end of August 2014.
Antisense managing director Mark Diamond said the phase II trial results would "not only be a significant milestone for the company, but potentially also for patients with this life threatening condition where there is a need for more effective treatment options".
Antisense was up one cent or 7.7 percent to 14 cents.

IMUGENE

Imugene says the US Patent and Trademark Office has allowed its application protecting the HER-Vaxx cancer immunotherapy for gastric cancer until 2030.
Imugene said that the patent, entitled 'Multiepitope Vaccine for HER2/Neu-associated Cancers' protects the method of composition and method of use of the HER-Vaxx for the generation of a therapeutic antibody response against HER-2/neu.
The company said that HER-Vaxx was a therapeutic cancer immunotherapy that stimulated a polyclonal antibody response to HER-2/neu, the same biomarker targeted by the $US6.9 billion a year drug Herceptin.
Imugene said that HER-Vaxx had completed a phase I study in breast cancer and the next stage of development would be a phase II study in gastric cancer.
Imugene executive director Dr Nick Ede said that gaining a key US patent was "the biggest milestone for almost every biotechnology company".
"This adds extra value to HER-Vaxx as this will protect it in the world's largest pharmaceutical market until 2030," Dr Ede said.
Imugene said that gastric, or stomach, cancer was the second most common cause of cancer-related death in the world and the fourth most commonly diagnosed cancer, with more than 1,000,000 new cases diagnosed each year.
Imugene fell 0.2 cents or 12.5 percent to 1.4 cents with 2.2 million shares traded.