Biotech Daily

Thursday July 18, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ELLEX UP 19%, ACRUX DOWN 8.5%**

*** PHARMAXIS 143% REVENUE GROWTH 'DISAPPOINTING', PBS RULES**

*** FUJIKURA PAYS CELLMID $440k FOR MIDKINE TEST LICENCE OPTION**

*** FDA APPROVES ELLEX 2RT FOR MACULAR OEDEMA, AMD NEXT FOCUS**

*** INVION STARTS PHASE II INV103 (XTOLL) LUPUS TRIAL**

*** MESOBLAST EARNS $4.3m R&D TAX REFUND**

*** PHOSPHAGENICS INQUIRY CONTINUES**

*** LINDSAY CARTHEW TAKES 12% OF AGENIX**

*** CATHERINE OFFICER REPLACES VIRALYTICS CO SEC SARAH PRINCE**

*** BIO-MELBOURNE BREAKFASTS ON ALZHEIMER'S**

MARKET REPORT

The Australian stock market was up 0.23 percent on Thursday July 18, 2013 with the S&P ASX 200 up 11.7 points to 4,993.4 points.

Nine of the Biotech Daily Top 40 stocks were up, 14 fell, 12 traded unchanged and five were untraded.

Ellex was the best, up five cents or 19.2 percent to 31 cents with 368,967 shares traded, followed by Cellmid up 16.1 percent to 3.6 cents with 11.9 million shares traded.

GI Dynamics and Universal Biosensors climbed more than six percent; Medical Developments was up 5.8 percent; Starpharma was up 4.3 percent; Avita was up 3.7 percent; Bionomics rose 2.9 percent; with Anteo up 1.7 percent.

Acrux led the falls, down 32 cents or 8.5 percent to $3.46 with 2.3 million shares traded, followed by Pharmaxis down 8.1 percent to 17 cents with 3.4 million shares traded.

Living Cell and Patrys fell more than seven percent; Genetic Technologies lost 5.3 percent; Prima was down 3.3 percent; Alchemia, Heartware, Mesoblast, Nanosonics and Reva shed more than two percent; QRX and Resmed were down more than one percent; with Clinuvel, CSL and Sirtex down by less than one percent.

PHARMAXIS

Pharmaxis says its sales increase of 143.2 percent to $3,237,000 for the year to June 30 2103 is “disappointing” and expects to further improve the rate of increase.

The company said that a change to its Australian Pharmaceutical Benefits Scheme reimbursement guidelines for Bronchitol for cystic fibrosis was expected to lead to increased sales.

In a teleconference, Pharmaxis chief executive officer Gary Phillips said that although the sales of Aridol and Bronchitol had increased significantly, the rate of take up of Bronchitol in the largest market, Germany, was not as good as expected.

Mr Phillips said that the more recent UK listing of Bronchil for cystic fibrosis, in April 2013, had shown that a better-targeted prescribing regime had led to more consistent use and sales, whereas the German clinics appeared to be prescribing Bronchitol to all patients with a consequent cycling on-and-off the drug.

“The product grows steadily, but not as fast as I would like,” Mr Phillips said. “We are still looking at ways of improving it.”

Mr Phillips said that Pharmaxis had introduced physiotherapy support as well as marketing vitamin supplements for cystic fibrosis patients.

Mr Phillips said that Australian sales of Bronchitol had been “disappointingly lower than expected due to restrictive PBS guidelines” but announced that a change in the guidelines had been approved.

In a media release, Pharmaxis said that the Pharmaceutical Benefits Advisory Committee had approved a change the wording of the PBS listing for Bronchitol, removing a requirement for patients to demonstrate a 10 increase in a spirometric measure of lung function in order to secure continued reimbursement.

Pharmaxis said that invoiced sales of Aridol and Bronchitol had increased 157.9 percent to $962,000 for the three months to June 30, 2013 compared to the previous corresponding period and up 143.2 percent for the year to June 30, 2013.

The company’s Appendix 4C recorded a 259.0 percent increase to $1,249,000 for the three months to June 30, 2013 and a 133.8 percent increase to $3,776,000 for the 12 months to June 30, 2013.

Pharmaxis chief financial officer David McGarvey told the teleconference that the unaudited financial statements were the amounts invoiced in the period, whereas the Appendix 4C reported amounts received by the company.

Pharmaxis said that Aridol sales had continued increasing in the US and Europe but were static in Australia, with total sales of about $400,000 for the three months to June 30, 2013, while Bronchitol had increased from negligible sales a year ago to about $600,000 for the three months to June 30, 2013.

Mr McGarvey said that cost reduction program was on-track and the company had $64 million in cash at June 30, 2103.

Mr Phillips said that the company was continuing to pursue licencing and partnership agreements to fund earlier stage programs and that it had a shortlist of potential partners for cystic fibrosis and other respiratory diseases.

Mr Phillips said that drafting the protocols for the additional US trial for US Food and Drug Administration approval was “well-advanced” and the first patient was expected to be enrolled by July 2014, with a paediatric plan to be discussed with the FDA following a review of the adult trial.

Pharmaxis fell 1.5 cents or 8.1 percent to 17 cents with 3.4 million shares traded.

CELLMID

Cellmid says that Fujikura Kasei Co will exercise its licence option for the midkine diagnostic technology and pay the JPY40 million ($A440,000) milestone fee.
Cellmid said that in February it supplied Fujikura its proprietary anti-midkine diagnostic antibodies for validation on Fujikura's latex platform (BD: Feb 11, 2013).
The company said the agreement was conditional on Fujikura reaching accuracy of 500 picogram/ml midkine on its latex diagnostic platform using Cellmid's antibodies.
Cellmid said that a latex-based test with a 500 picogram/ml accuracy could be used to identify individuals with elevated midkine levels and in turn was expected to lead to the development of a number of cancer diagnostic products.
Cellmid said the two companies would proceed to a supply and licence agreement for the development and marketing of multiple cancer diagnostic products using Fujikura's latex assay with Cellmid's midkine antibodies,
Cellmid said that Fujikura would pay royalties on products sold and bear product development and marketing costs, while it would support Fujikura's regulatory and product development programs with its midkine diagnostic expertise.
Cellmid said it had "a highly accurate" midkine enzyme-linked immunosorbent assay (Elisa), but a latex-based assay would be suitable for commercial products, as it was widely used in pathology laboratories and preferred as it could easily be automated.
Cellmid was up 0.5 cents or 16.1 percent to 3.6 cents with 11.9 million shares traded.

ELLEX MEDICAL LASERS

Ellex says it has US Food and Drug Administration FDA 510(k) approval for its 2RT retinal rejuvenation therapy for clinically significant macular oedema.
Ellex said that clinically significant macular oedema was "the most common form of diabetic eye disease" which could result in blindness.
The company received Conformité Européenne (CE) mark approval in 2012 for its 2RT laser treatment for the same indication (BD: Jul 18, 2012).
Ellex said there were treatments for clinically significant macular oedema, including its Integre photocoagulation laser portfolio, but 2RT achieved similar outcomes without the collateral damage to the retina associated with conventional thermal photocoagulation.
Ellex chief executive officer Tom Spurling said that "unlike photocoagulation, 2RT is a pain-free and damage-free treatment option for patients".
The company said that despite its role in the treatment of clinically significant macular oedema, it was the potential of 2RT to treat the early form of age-related macular degeneration which was the principal focus of promising clinical and laboratory studies.
"The 510(k) approval will help us with our efforts to gain more clinical exposure for 2RT in the US," Mr Spurling said.
Ellex said that age-related macular degeneration was the most common cause of blindness and severe vision loss in Australia, with one in seven Australians over the age of 50 years affected by the disease and the early form accounted for up to 80 percent of all cases of age-related macular degeneration.
The company said that no treatment existed to halt the progression of age-related macular degeneration (AMD) to its advanced stage.
"Unlike other treatment options for AMD, which are invasive and target the late-stage complications associated with the disease, 2RT offers the potential to treat AMD in its early stages with a simple in-office treatment," Mr Spurling said. "This means that, for the first time, AMD could be treated before legal blindness occurs or vision is lost."
Ellex climbed five cents or 19.2 percent to 31 cents.

INVION (FORMERLY CBIO)

Invion says it has begun enrolment in its 32-patient phase II clinical trial of INV103 in patients with mild systemic lupus erythematosus.

Invion said the trial of INV103, formerly known as XToll, would be conducted in Pennsylvania and Texas under a US Food and Drug Administration investigational new drug application.

The company said that INV103 was a modified version of the naturally occurring human protein, chaperonin 10 and the study aimed to generate data on the safety, tolerability, and efficacy of INV103 as a therapy for lupus, with four cohorts of eight patients.

Invion said that only one drug had been approved by the FDA for the treatment lupus in the last 50 years and "a large gap currently exists for effective treatment therapies".

The company said that Lupus was a complex disease area with a drug market expected to reach more than $4 billion in the US and five major EU markets by 2020.

Invion chief executive officer Dr Greg Collier said that the beginning of the INV103 phase II lupus trial was "a major milestone for the company".

"The complex lupus treatment market has been clinically underserved, and positive data from this trial would deliver a promising lead on a potential future therapy," Dr Collier said.

"The FDA's acceptance of our IND for lupus means Invion is working under two INDs to develop two drug assets in three phase II clinical programs," Dr Collier said.

"This is a significant achievement by any measure for a company of Invion's size, however made even more so given we are less than 12 months into existence," Dr Collier said.

Invion said that the trial was expected to run for about 12 months, with safety and efficacy data from the first two cohorts available in about six months.

Invion was unchanged at 3.5 cents.

MESOBLAST

Mesoblast says it has received $4.3 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Mesoblast said the rebate related to research and development expenditure in 2011-'12 and the funds would be used to advance development of its mesenchymal precursor cell technology platform and product pipeline.

Mesoblast fell 13 cents or 2.2 percent to $5.67 with 228,606 shares traded.

PHOSPHAGENICS

Phosphagenics says the investigation of material invoicing irregularities is continuing and chief executive officer Dr Esra Ogru remains suspended.

Two weeks ago, Phosphagenics suspended Dr Ogru pending an investigation into "irregular transactions in relation to its invoicing and accounting records" (BD: Jul 1, 2013).

Phosphagenics said at that time that it believed that the amounts involved could be material, but did not affect the current cash balance of $14.1 million.

Biotech Daily has spoken with Phosphagenics founder and chief executive officer Harry Rosen but Mr Rosen has been unable to provide any further details at this stage.

Mr Rosen told Biotech Daily that he was awaiting a report from the investigators to learn the scale of any irregularities.

Biotech Daily understands that an unnamed major accounting firm is conducting the investigation and that Dr Ogru has not returned to work since the first announcement of the trading halt on June 28, 2013.

Phosphagenics was unchanged at 11 cents.

AGENIX

Lindsay Carthew says he has increased his substantial shareholding in Agenix from 8,007,968 shares (9.12%) to 13,043,047 shares (11.60%).
Mr Carthew said that as Trustee for the Lindsay Carthew Family Trust he acquired the 5,035,469 shares in the May capital raising which included a rights issue at three cents a share and a convertible notes issue (BD: Jan 21, Feb 22, May 17, 2013)
Agenix was unchanged at 2.8 cents.

VIRALYTICS

Viralytics says Catherine Officer has replaced Sarah Prince as company secretary, effective immediately.
Viralytics said that both Ms Prince and Ms Officer worked as solicitors for Company Matters Pty Ltd and the change was a continuation of the existing engagement.
Viralytics was unchanged at 24 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its August Bio-Breakfast will discuss the latest developments in the diagnosis and treatment of Alzheimer's disease.
Bio-Melbourne chief executive officer Michelle Gallaher said there was "a huge commercial opportunity in Alzheimer's with many of the products aimed at the disease being discontinued in the last decade and several new drug candidates aimed at late stages of the disease failing in recent phase III clinical trials".
"However, this has not deterred industrious biotech companies and researchers from continuing their work in this area that clearly has great market potential with a large unmet medical need," Ms Gallaher said.
Speakers at the August 6, 2013 Bio-Breakfast include the Florey Institute of Neuroscience and Mental Health director Prof Geoffrey Donnan, the Florey Institute's senior deputy director Prof Graeme Jackson, Prana Biotechnology executive chairman Geoffrey Kempler, the Florey Institute's Dr David Darby and Cogstate chief scientific officer Dr Paul Maruff.
The Bio-Melbourne Network said the August 6 Bio-Breakfast would be held at the Melbourne Brain Centre, Kenneth Myer Building, 30 Royal Parade, on the corner of Genetics Lane, Parkville, Melbourne.
Registration is from 7:15am with presentations from 8am to 9:30am.
For more information and to book go to http://www.biomelbourne.org/events/view/288.