Biotech Daily

Wednesday September 6, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: STARPHARMA UP 8%, ACRUX DOWN 28%**

*** FDA, GENERICS KILL ACRUX, ELI LILLY $1b AXIRON**

*** PHARMAXIS, SYNAIRGEN READY FOR LOXL2 FIBROSIS TRIAL**

*** ORTHOCELL: 'EARLY DATA BACKS CELGRO SAFETY, TOLERABILITY'**

*** G MEDICAL AWARDS DIRECTORS 70m 'PERFORMANCE' RIGHTS**

*** PRUDENTIAL (M&G) INCREASES TO 14% OF MESOBLAST**

*** BRANDON, MRCF, AUSTRALIAN SUPER TAKE 27% OF OSPREY**

*** LUSIA GUTHRIE DINES ON ENTREPRENEURSHIP, AI WITH RACI**

MARKET REPORT

The Australian stock market fell 0.29 percent on Wednesday September 6, 2017 with the ASX200 down 16.5 points to 5,689.7 points.

Thirteen of the Biotech Daily Top 40 stocks were up, nine fell, 16 traded unchanged and two were untraded.

Starpharma was the best, up eight cents or 7.9 percent to $1.09 with 1.15 million shares traded.

Opthea climbed 5.9 percent; Orthocell improved 4.9 percent; Admedus, Atcor and Viralytics were up more than three percent; CSL, ITL, Medical Developments, Nanosonics, Pharmaxis, Sirtex and Universal Biosensors rose one percent or more; with Cochlear and Mesoblast up by less than one percent.

Acrux led the falls, closing down 7.5 cents or 28.3 percent to 19 cents with 7.2 million shares traded.

Prima lost 8.7 percent; Genetic Signatures fell five percent; Prana was down 3.6 percent; Reva shed 2.5 percent; Compumedics, Ellex and Resmed were down more than one percent; with Clinuvel and Oncosil down by less than one percent.

ACRUX

Acrux says that it and Eli Lilly and Co have agreed to terminate their licencing agreement for its Axiron testosterone replacement, ending US sales.

Biotech Daily calculates that Eli Lilly has received revenue of more than $US810.8 million ($A975.5 million) from Axiron sales (see below).

Acrux chief executive officer Michael Kotsanis told Biotech Daily that a US Food and Drug Administration-required trial would have cost “hundreds of millions of dollars” and sales had fallen since July 5, 2017, when generic versions of Axiron appeared on the market.

Mr Kotsanis said that Acrux would continue its patent appeal and if the company won it would pursue Perrigo for damages.

In a media release Acrux said that termination of the US licence was effective immediately and termination of the licence outside the US would be effective in 90 days.

The company said it would have global rights to Axiron.

Acrux said that following an advisory committee meeting in 2014, the FDA required holders of new drug applications for approved testosterone products to conduct a post-marketing requirement clinical trial to address the question of whether an increased risk of heart attack or stroke existed among users of testosterone products.

The company said the trial would need to be conducted independently or through a consortium of new drug application NDA holders, with a submission of the final trial protocol required by September 5, 2017.

Acrux said that in the absence of a commitment to the protocol, the FDA could take regulatory action against an application holder.

The company said that a hearing on the Axiron formulation and axilla application patents granted by the US Patent and Trademark Office is scheduled to be heard in the Court of Appeals for the Federal Circuit in Washington, DC on October 5, 2017, with a decision expected within six months.

Acrux said that generic versions of Axiron were launched in the US by Perrigo and Teva in July and August 2017, respectively, along with an authorized generic marketed by Prasco.

The company said that “with the commercial uncertainty related to the impact of generics, the continued decline in the testosterone market and the uncertain apportioned costs to participate in the [clinical trial] consortium of testosterone NDA holders, a request will be submitted to FDA to withdraw the NDA from the US market”.

Acrux said it believed the Axiron axilla application patent was valid and enforceable, it was committed to asserting its intellectual property rights for Axiron and with Eli Lilly it continued to stand by the safety and efficacy of Axiron when used as indicated.

In July, Acrux said Eli Lilly’s Axiron revenue fell 4.2 percent to $US143.0 million ($A180.4 million) for the year to June 30, 2017, compared to June 30, 2015 (BD: Jul 26, 2017).

Biotech Daily calculates that since Axiron sales began in April 2011, Eli Lilly has earned $US810.8 million ($A975.5 million) from the product with Acrux receiving $127.7 million in milestone payments and more than $145 million in royalty revenue, with an additional $US25 million ($A28.4 million) milestone payment in 2014 for exceeding $US100 million in annual Axiron sales (BD: Jan 31, 2014).

Biotech Daily believes the total revenue to Acrux from Eli Lilly for Axiron amounts to $301.4 million.

Mr Kotsanis said the company had $39.6 million in cash and receivables at June 30, 2017 with a cash burn of $12 million to $13 million expected for the year to June 30, 2018

Mr Kotsanis said that Acrux had a pipeline of products with three expected to be the subject of an FDA approval application in 2018.

Acrux fell as much as 30.2 percent to 18 cents, before closing down 7.5 cents or 28.3 percent to 19 cents with 7.2 million shares traded.

PHARMAXIS

Pharmaxis says it has completed preclinical work on the anti-fibrotic lysyl oxidase type 2 inhibitor program for fibrosis and will start a human trial this year.

In 2015, Pharmaxis announced the collaboration with the Southampton, England-based Synairgen Plc to develop a selective inhibitor to the lysyl oxidase type 2 (LOXL2) enzyme to treat the lung disease idiopathic pulmonary fibrosis (BD: Aug 5, 2015).

Pharmaxis said at that time that that idiopathic pulmonary fibrosis was a potentially fatal disease that affected about 100,000 people in the US and the LOXL2 enzyme was being targeted because it was known to promote scar tissue which hardened and irreparably damaged the lungs of idiopathic pulmonary fibrosis patients.

The company said it was hoped that the inhibition of LOXL2 would slow the build-up of scar tissue and improve survival rates that were worse than for many cancers.

Today, Pharmaxis said its small molecule LOXL2 inhibitor had proven efficacy in multiple pre-clinical models of fibrosis and was ready for phase I trials by the end of this year.

The company said that its drug discovery group had developed a number of selective small molecule inhibitors to the LOXL2 enzyme using the same amine oxidase platform that delivered PXS-4728A, an anti-inflammatory drug that was acquired by Boehringer Ingelheim in 2015 (BD: May 18, 2015).

Pharmaxis said that the LOXL2 enzyme was fundamental to the fibrotic cascade that follows chronic inflammation in the liver disease non-alcoholic steato-hepatitis (NASH), cardiac fibrosis, kidney fibrosis and idiopathic pulmonary fibrosis (IPF), and it also plays a role in some cancers.

Pharmaxis chief executive officer Gary Phillips said the extensive pre-clinical program "has confirmed that they have all the characteristics of a successful once a day, oral drug".

"They have shown excellent efficacy in several different in vivo fibrosis models including fibrosis of the liver, lung, kidney and heart," Mr Phillips said.

"These findings have been the subject of presentations at a number of international scientific conferences and more data will be presented at similar upcoming events as the phase I studies proceed," Mr Phillips said. "In regulatory toxicity studies, our compounds have been well-tolerated and shown a good safety profile."

Pharmaxis was up half a cent or 1.85 percent to 27.5 cents.

ORTHOCELL

Orthocell says it has initial positive safety and tolerability for the first three of 25 patients in a study of Celgro for hip joint full thickness cartilage defects.

Orthocell said that the primary objective of the study at Melbourne's St Vincent's Hospital was to demonstrate the safety and performance of the Celgro collagen membrane when used to augment treatment of hip cartilage defects.

The company said that Celgro was being used to enhance the 'micro-fracture' technique in which small holes were made in the bone surface to encourage cartilage to reform.

Orthocell said that Celgro was placed over the cartilage defect to stabilise the clot formed from the micro-fracture and provide infrastructure to guide tissue repair and regeneration.

Orthocell managing-director Paul Anderson said the early data was "further validation of Celgro's safety and performance profile and its applicability across a range of clinical applications".

The company said that it was undertaking other clinical studies using Celgro to augment repair of the rotator cuff tendon within the shoulder, to guide jaw bone regeneration and to assist in the re-joining of severed or damaged peripheral nerves.

Orthocell was up 1.5 cents or 4.9 percent to 32 cents.

G (GEVA) MEDICAL INNOVATION

G Medical has awarded 70,000,000 ‘performance’ shares to founder Dr Yacov Geva and directors Louis Antoniou, Kenneth Melani and Brendan de Kauwe.
In May, G Medical raised $12 million at 20 cents a share to list on the ASX and commercialize its mobile telephone health devices (BD: May 10, 2017).
A change in substantial notice Dr Geva said he had increased his holding by 58,469,154 shares to 63.43 percent of the company, of which 58,036,154 shares were from the exercise of performance rights.
In directors’ interest statements, Mr Antonio said he exercised 1,199,337 performance rights to shares, Mr Melani said he exercised 799,558 performance rights to shares and Mr de Kauwe he exercised 795,455 performance rights to shares.
The company’s May replacement prospectus said that the 70,000,000 class A performance rights would vest and convert on US Food and Drug Administration approval for its mobile telephone jacket within 12 months of listing on the ASX.
The performance milestone for a further 60,000,000 class B performance rights was for revenue of $US30 million “during any continuous period of 12 months within 24 months from admission” with 60,000,000 class C performance rights when the cumulative earnings before interest, tax, depreciation and amortization reaches $US25 million with 36 months of listing on the ASX (BD: Sep 4, 2017).
G Medical was unchanged at 39 cents with 2.3 million shares traded.

MESOBLAST

Prudential PLC says with its subsidiaries it has increased its holding in Mesoblast from equivalent to 53,658,040 shares (12.35%) to 65,452,353 shares (14.19%).
The London-based Prudential said that M&G Investment Management and Eastspring Investment were wholly-owned subsidiaries.
The company said it sold shares between July 13 and September 1, 2017, selling 91,335 shares at $1.99 each in July and acquiring 10,639,192 shares in the Mesoblast placement for $14,894,867 or $1.40 a share (BD: Aug 25, 2017).
Mesoblast was up one cent or 0.7 percent to $1.51 with 1.05 million shares traded.

OSPREY MEDICAL

Brandon Capital says it has increased its holding in Osprey from 60,505,552 shares (23.8%) to 91,413,524 shares (26.9%).
The substantial shareholder notice, signed by director Dr Chris Nave said the shares were acquired in the recent $32.5 million placement and rights issue at 40 cents a share (BD: Aug 4, 30, 2017).
Dr Nave said that the shares were held by Brandon Capital, the Medical Research and Commercialization Fund Pty Ltd for the MRCF Trust, BBF1 Trustco Pty Ltd for the Brandon Biosciences Fund No 1 Trust, BBF1 IIF Partnership LP, Australian Super Pty Ltd for Australian Super, and three MRCF Services entities.
Osprey was unchanged at 41.5 cents.

ROYAL AUSTRALIAN CHEMICAL INSTITUTE, LBT INNOVATIONS

The Royal Australian Chemical Institute says LBT co-founder Lusia Guthrie will discuss entrepreneurship and artificial intelligence next week.

RACI said that Ms Guthrie would share insights from her 35 years in Australia's biotechnology sector as the keynote speaker at the Institute's Bioactive Discovery and Development group dinner on September 12, 2017.

The Institute said that Ms Guthrie's talk, entitled 'Entrepreneurship, opening doors, seizing the opportunities', would provide an opportunity to hear how to succeed in the biotechnology sector.

RACI said that Ms Guthrie would describe her experiences co-founding LBT, listing the company on the ASX, achieving the first US Food and Drug Administration approval for an artificial intelligence (AI) technology for microbiology and launching LBT's products.

The Institute said that Ms Guthrie was currently chairperson of Clever Culture Systems AG an LBT joint venture based in Zurich.

RACI said that Ms Guthrie was runner-up for Biotech Daily's 2016 CEO of the Year Award year for winning FDA approval for her company's second technology.

RACI Bioactive Discovery and Development group chair Dr Danny Gelman said that "to hear from a person with as much experience in the biotech sector as Lusia is a fantastic opportunity and one we are grateful to share".

Dr Gelman said that the group dinners provided networking opportunities for scientists and professionals involved in all stages of the discovery and development of bioactives.

The dinner will be held on Tuesday, September 12, 2017, at the Pumphouse Hotel, 128 Nicholson St, Fitzroy, Melbourne, at 7pm.

To register, go to https://www.ivvy.com.au/event/VBG735.