



Biotech Daily

Friday July 20, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH FLAT: CELLMID UP 7%, ANTISENSE DOWN 10.5%**
- * **FDA APPROVES PHASE III PSIVIDA MEDIDUR-MICRO UVEITIS TRIAL**
- * **DR STEPHEN WOODFORD TAKES 5% OF USCOM**
- * **AFANDIN FAILS TO FUND ANTISENSE ATL1101 FOR CANCER**
- * **CSL LOSES EXECUTIVE DIRECTOR, 45-YEAR VETERAN PETER TURNER**
- * **ACUVAX EX-CEO DR WILLIAM ARDREY FRAUD CASE - BAIL TO OCTOBER**

MARKET REPORT

The Australian stock market slipped 0.18 percent on Friday July 20, 2012 with the S&P ASX 200 down 7.6 points to 4,199.1 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and six were untraded.

Cellmid was the best, up 0.1 cents or 6.7 percent to 1.6 cents, with 173,824 shares traded.

Uscom climbed 5.3 percent; Pharmaxis, Prima and Sunshine Heart were up more than four percent; Mesoblast rose 2.3 percent; Biota, Nanosonics, Optiscan, Reva and Universal Biosensors were up more than one percent; with Cochlear, Heartware and Sirtex up by less than one percent.

Antisense led the falls, down 0.2 cents or 10.5 percent to 1.7 cents with 31.6 million shares traded.

Patrys lost 8.3 percent; Phylogica fell 7.7 percent; Prana was down 6.25 percent; Genetic Technologies fell 4.35 percent; Bionomics, Phosphagenics and Viralytics were down more than three percent; Impedimed, QRX, Resmed and Starpharma were down more than one percent; with Acrux down 0.7 percent.

PSIVIDA

Psivida says the US Food and Drug Administration has cleared its investigational new drug application for a 300-patient trial of its Medidur micro-insert for posterior uveitis. Last month, Psivida said the first patient had been treated in a small procedure study ahead of the planned phase III trial of the Medidur injectable, sustained-release device (BD: Jun 29, 2012).

Today, Psivida said it had been permitted to conduct two phase III trials to treat patients with posterior uveitis.

Psivida chief executive officer Dr Paul Ashton said the company was "very pleased" to be able to begin phase III trials without the necessity of phase I or phase II trials.

"Importantly, the FDA has agreed that the primary end point in these trials will be recurrence of uveitis within 12 months and that we can reference much of the data, including the clinical safety data, from the clinical trials for Iluvien for diabetic macular oedema conducted by our collaborative partner Alimera Sciences," Dr Ashton said. Dr Ashton said the company had input from the FDA about the design of the trials "and believe these design features will be advantageous in terms of cost and time".

"Because the micro-insert delivers the same drug as our approved Retisert product for posterior uveitis, we expect to these trials will show efficacy," Dr Ashton said.

"Further, as the same micro-insert was used in the Iluvien trials, we expect to observe a comparable side-effect profile in uveitis patients as was seen in [diabetic macular oedema] patients," Dr Ashton said.

"As a result, we are optimistic that our micro-insert will be efficacious for posterior uveitis with a favorable risk/benefit profile and fewer side effects than Retisert," Dr Ashton said. Psivida said that posterior uveitis was an inflammatory disease of one of the layers of the eye, affecting about 175,000 people in the US and was responsible for about 30,000 cases of blindness, making it the third largest cause of blindness.

Psivida said the Medidur micro-insert was a tube about the size of an eyelash, releasing the steroid fluocinolone acetonide at a consistent rate over a period of about 36 months. The company said the micro-insert was injected into the back of the eye during an office visit through the use of a fine gauge needle.

Psivida said the same micro-insert had received marketing authorization, as Alimera's Iluvien, for chronic diabetic macular oedema considered insufficiently responsive to available therapies in the UK, Austria, France and Portugal.

The company said that Alimera expected Iluvien to be the first sustained release pharmaceutical in the EU to treat diabetic macular oedema.

Psivida was untraded at \$2.10.

USCOM

Uscom says Dr Stephen Woodford has acquired 2,721,475 shares or 5.03 percent of the company.

Uscom said Dr Woodford was a private anaesthetist and research physiologist working at the Brisbane Waters Private Hospital and the Australian School of Advanced Medicine at Macquarie University.

The company said that Dr Woodford bought his first Uscom diagnostic device last year and would present the results of cardiovascular research at the American Society of Anesthesiology meeting in Washington in October, 2012.

Uscom was up half a cent or 5.3 percent to 10 cents.

ANTISENSE THERAPEUTICS

Antisense says it is taking back ATL1101 from Afandin following the expiry of an extension for Afandin to secure suitable funding for the development of ATL1101 for cancer. Antisense said it would “resume responsibility for the continued development and commercialization of ATL1101 and will assess alternative development paths and partnering options for the drug”.

Antisense said that in working with Afandin, it had “gained substantial insight with respect to the cancer development opportunities for ATL1101 ... [and] this has provided a valuable contribution towards optimizing the ATL1101 development strategy”.

Antisense said it expected to maintain an ongoing relationship with Afandin and might draw on its development expertise in cancer therapeutics for the product development plans for ATL1101.

The company said that ATL1101 targeted the insulin-like growth factor I receptor and had been shown in animal studies to suppress human prostate tumor growth and had potential applications in various other cancers as well as indications in certain eye diseases where second generation antisense drugs had shown clinical benefits.

Antisense chief executive officer Mark Diamond said that “recent advancements in antisense technology together with the pre-clinical work that we have already conducted on ATL1101 gives us encouragement that further development of the drug is definitely warranted”.

“In addition, we have had interactions with other parties interested in our technology giving us confidence that we are well placed to find a suitable development partner or licensee for ATL1101,” Mr Diamond said.

“There has been a resurgence of interest in the antisense technology platform as evidenced by the number of licencing transactions that have been executed by our technology partner Isis Pharmaceuticals who is also preparing for approval and launch of the world’s first systemically administered antisense drug,” Mr Diamond said.

Mr Diamond said that Antisense had active partnering and development interest in its antisense programs including ATL1103 and ATL1102.

“Accordingly we are enthusiastic about the prospects for the further development of ATL1101,” Mr Diamond said.

Antisense fell 0.2 cents or 10.5 percent to 1.7 cents with 31.6 million shares traded.

CSL

CSL says executive director Peter Turner will leave the company as of October 17, 2012.

CSL said that Mr Turner had been a director since December 2009 and had a long and distinguished career with the company SL for more than 45 years.

CSL’s head of investor relations Mark Dehring told Biotech Daily that Mr Turner was formerly the head of CSL Behring and, most recently, the head of special projects.

CSL chairman Prof John Shine said: “Peter has made an invaluable contribution to CSL over many years as an executive, particularly in his very successful leadership of CSL Behring, and more recently as a director”.

CSL was unchanged at \$41.00 with 1.8 million shares traded.

ACUVAX

Former Acuvax chief executive officer Dr William Ardrey has been remanded to reappear at the Perth Magistrates Court on October 4, 2012, on undisclosed bail conditions.

Dr Ardrey has been charged with 22 counts of gaining benefit through fraudulent means (BD: Feb 28, Apr 20, 2012).

Western Australia Police previously told Biotech Daily that Dr Ardrey had appeared at the Perth Magistrates Court today for a committal hearing and bail conditions had been set but were undisclosed.

Western Australia Police said the complainant in the matter was Phoenix Eagle a company described as a small biotechnology company involved in therapeutic cosmetics. In 2006, Dr Ardrey was appointed chief executive officer of Avantogen, which later became Acuvax, and prior to that was the chief executive officer of Regenera, which later became Advanced Ocular (BD: Aug 29, 2006).

In January, with new investors and new management, the company said it would acquire an Israeli diagnostic company (BD: Jan 25, 2012).

In May, Acuvax said it had a controlling stake in Biohealth Pty Ltd, which was focused complementary medicines comprising natural non-toxic ingredients and its first product Provent had been listed by the Australian Therapeutic Goods Administration on the Register of Therapeutic Goods as a complementary medicine with the claim: 'Helps Maintain Healthy Respiratory Function' (BD: May 18, 2012).

Acuvax was untraded at 0.1 cents.