



Biotech Daily

Thursday September 17, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: PSIVIDA UP 8%; AVEXA DOWN 4%**
- * **FDA EXPEDITES CSL, OTHER H1N1 'SWINE' FLU VACCINE APPROVALS**
- * **FURTHER \$1.4m FROM US NIH FOR STARPHARMA'S VIVAGEL**
- * **COMPUMEDICS SIGNS \$210k CHINA DEAL**
- * **ACUVAX \$488k PLACEMENT, DIRECTOR DAVID SANDERS RESIGNS**
- * **FERMISCAN APPOINTS IAN CHALMERS, MARK FORDREE DIRECTORS**
- * **PRIMA ISSUES 40m DIRECTOR SHARES**
- * **LIVING CELL MEETING APPROVES 25.5m SHARE ISSUE**

MARKET REPORT

The Australian stock market climbed 1.4 percent on Thursday September 17, 2009 with the S&P ASX 200 up 64.5 points to 4714.9 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and three were untraded.

Genetic Technologies was technically best, up 0.7 cents or 13.7 percent to 5.8 cents with 10 shares traded, followed by Psivida up 7.95 percent to \$4.75 with 13,568 shares traded.

Compumedics, Living Cell and Prana climbed five percent or more; Benitec, Phosphagenics and Sunshine Heart were up four percent or more; Cathrx and Progen were up more than three percent; Tissue Therapies and Universal Biosensors rose more than two percent; with Alchemia, Circadian, Cochlear, CSL and Pharmaxis up less than one percent.

Avexa led the falls, down half a cent or 4.35 percent to 11 cents with 1.3 million shares traded.

Clinuvel and Labtech lost more than three percent; Chemgenex and Sirtex shed more than two percent; with Acrux, Heartware, Mesoblast, Novogen, Peplin, Resmed and Uscom down by more than one percent.

CSL

The US Food and Drug Administration has approved CSL's influenza A (H1N1) 2009 monovalent injectable vaccine.

The FDA said on its website the approval yesterday (September 15 in the US) that it also approved injectable vaccines manufactured by Novartis and Sanofi Pasteur as well as an intranasal vaccine from Medimmune.

CSL's public affairs director Dr Rachel David told Biotech that the first \$US180 million (\$A206 million) shipment of bulk antigen was being prepared for a US Department of Health and Human Services order.

Dr David said the speed of approval from the trials, which began in Adelaide in July (BD: Jul 22, 2009), with results published last week (BD: Sep 11, 2009) was because the FDA treated the vaccine as "a strain change rather than a new drug".

"They are treating it as a booster to the seasonal influenza vaccine and it's relatively simple to evaluate that data," Dr David said.

The FDA said it "approved these vaccines as a strain change to each manufacturer's seasonal influenza vaccine".

"There is considerable experience with seasonal influenza vaccine development and production and influenza vaccines produced by this technology have a long and successful track record of safety and effectiveness in the United States," the FDA said.

"The influenza A (H1N1) 2009 monovalent vaccines will undergo the usual testing and lot release procedures that are in place for seasonal influenza vaccines," the FDA said.

Dr David said CSL was awaiting Australian Therapeutic Goods Administration approval for the Panvax H1N1 A/California vaccine against H1N1 'swine influenza'.

The trial, conducted in partnership with clinical research organization CMAX and the Royal Adelaide Hospital in South Australia, showed that the lower dose 15 microgram dose was as effective as the higher 30 micrograms dose.

In a media release in July, CSL said the trial was conducted "with view to fulfilling a commitment to the Australian Department of Health and Ageing to supply up to 10 million people with a vaccine against H1N1 'swine influenza'".

A TGA spokeswoman told Biotech Daily she did not know when the vaccine might be approved.

CSL was up 24 cents or 0.7 percent to \$34.40 with 3.4 million shares traded.

STARPHARMA

Starpharma says the US National Institutes of Health provided a further \$US1.25 million (\$A1.43 million) for the development of Vivagel and related research.

The company said the NIH funds for the development of the vaginal microbicide for the prevention of sexually transmitted infections including HIV and genital herpes (HSV-2) was in addition to the more than \$US26 million received over the past five years.

Starpharma said the money would be applied to existing programs for the development of Vivagel and related microbicide research including clinical work at Starpharma and through its collaborators.

Starpharma chief executive officer Dr Jackie Fairley said the company had "several new funding programs under consideration".

The company said the US Food and Drug Administration had designated Vivagel "as a fast-track product to accelerate its development".

Starpharma said the market for topical microbicides was worth at least \$US1.5 billion a year.

Starpharma was unchanged at 45 cents.

COMPUMEDICS

Compumedics says its German-based ultrasonic blood flow division DWL Elektronische GmbH has sold EUR 125,000 (\$A210,000) of trans-cranial Doppler systems to China. Compumedics chief financial officer David Lawson told Biotech Daily that the shipment was the company's largest order so far of the trans-cranial Doppler systems for China. Mr Lawson said the trans-cranial Doppler systems measured blood flow through the brain and were primarily used for stroke treatment and prevention.

In a media release to the ASX, Compumedics said China was "a latent market" for its sleep, brain and ultrasonic blood flow monitoring products with sales of \$3 million to \$4 million a year across its product portfolio.

The company said it expected China to be "a much more integral market opportunity for the company over coming years".

Compumedics said the installed base of sleep and brain or neurological monitoring and diagnostic beds in China was very low on a per capita basis, so "the emerging opportunity in these markets is vast, particularly with China's recent emphasis on up-grading its healthcare sector".

Compumedics was up one cent or five percent to 21 cents.

ACUVAX

Acuvax hopes to raise \$488,000 through the placement of 24,400,000 shares to sophisticated investors at two cents a share.

Acuvax chief executive officer Dr William Ardey said the placement would be used "to invest further in immunology, as well as for general working capital".

The company said David Sanders has resigned as a non-executive director but would continue as its general counsel.

Acuvax fell 0.4 cents or 11.4 percent to 3.1 cents.

FERMISCAN

Fermiscan announced the appointment of Ian Chalmers and Mark Fordree as directors. The company said Mr Chalmers was the chief executive of Medicines Australia and was previously chief executive of the Australian Local Government Association and executive director at both Australian Private Hospitals Association and the Australian Lifewriters Association.

Fermiscan said Mr Fordree held partner and director level roles in major investment and stock broking businesses and established EG Capital.

EG Capital Bioequities Fund was wound up on December 22, 2009 amid some controversy following a visit to the company by the Australian Securities and Investments Commission.

Fermiscan said the appointment of Mr Chalmers and Mr Fordree "contributes to the renewal process and strengthens the capabilities and expertise of the board".

Fermiscan was up 0.3 cents or 4.35 percent to 7.2 cents.

PRIMA BIOMED

Prima has issued 40,025,000 shares following the exercise of options.

Prima executive director Martin Rogers told Biotech Daily that the exercised options were shares were primarily director options.

Prima was unchanged at 10.5 cents with 4.2 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says the issue of 25,500,000 shares and 10,200,000 attaching options was approved overwhelmingly by today's general meeting.

The issue follows the placement of the stock in July (BD: Jul 30, 2009).

Living Cell was up one cent or 5.13 percent to 20.5 cents.