

Biotech Daily

Friday August 28, 2009

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: PSIVIDA UP 11.5%, CATHRX DOWN 12%
- * UK REQUIRES FURTHER HALCYGEN ANTI-FUNGAL DRUG TRIAL
- * SIRTEX PROFIT UP 1406% TO \$18.2m; REVENUE UP 87.6% TO \$73.9m
- * RESONANCE POSTS MAIDEN FULL YEAR \$617k PROFIT
- * IMUGENE POSTS MAIDEN FULL YEAR \$650k PROFIT
- * STIRLING INVESTS IN SHEIMAN DRUG DELIVERY SYSTEM
- * USCOM REVENUE UP 53% TO \$2m; LOSS DOWN 50%
- * BIOPROSPECT APPOINTS SOLAGRAN'S KAMRAN SHAMSI DIRECTOR

MARKET REPORT

The Australian stock market climbed 0.87 percent on Friday August 28, 2009 with the S&P ASX 200 up 38.8 points to 4489.6 points.

Ten of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and three were untraded.

Psivida was best, up 30 cents or 11.5 percent to \$2.90 with 5,600 shares traded, followed by Sirtex up 33 cents or 7.7 percent to \$4.64 with 88,175 shares traded.

Acrux and Cytopia climbed more than five percent; Cellestis, Phosphagenics and Universal Biosensors were up four percent or more; Peplin climbed 3.45 percent; Prana was up 2.2 percent; Progen rose 1.7 percent; with CSL and Resmed up less than one percent.

Cathrx led the falls, down 3.5 cents or 11.7 percent to 26.5 cents with 84,660 shares traded, followed by Sunshine Heart down 10 percent to 4.5 cents.

Compumedics lost 9.5 percent; Alchemia and Tissue Therapies fell more than six percent; Tyrian fell five percent; Bionomics fell 4.2 percent; Impedimed, Mesoblast and Nanosonics were down three percent or more; Antisense, Novogen and Starpharma shed more than two percent; Biota, Clinuvel and Cochlear were down more than one percent; with Genera and Heartware down by less than one percent.

HALCYGEN

Halcygen says the UK regulator has required a further pharmacokinetic study to show that SUBA-itraconazole performs as well against European Sporanox as US Sporanox Halcygen chairman and chief executive officer Dr Roger Aston told Biotech Daily that final agreement was made with the UK Medicines and Healthcare Products Regulatory Agency on Wednesday, August 26, 2009 and the additional trial was expected to be completed by the end of this year.

The company said that its SUBA-itraconazole was an improved generic formulation of the anti-fungal drug Sporanox or itraconazole.

Halcygen said that following the Agency's review of its pharmacokinetic studies, it "guided Halcygen to undertake a single pharmacokinetic study in the European Union to demonstrate that SUBA-itraconazole performs in a similar manner against EU registered Sporanox as it does with US-derived Sporanox.

The company said the advice concurred with Swedish regulatory agency guidance (BD: June 22, 2009) and gave it "the opportunity to file for registration in the EU next year".

Halcygen said that following the completion of the study and with its US data pack, Voisin Consulting would help prepare a marketing authorization application in 2010.

Halcygen said its SUBA-itraconazole formulation was potentially safer as patients administered a 50 percent dose of the drug compared with Sporanox.

The company said SUBA-itraconazole showed lower inter-patient variability as compared to Sporanox resulting in more predictable blood levels and it could be taken on an empty stomach, unlike Sporanox which must be taken after a full meal.

Halcygen said the trial program enabled it to seek approval in the US through the Food and Drug Administration and in Europe via Sweden or the UK as the reference state. In Halcygen's media release Dr Aston said marketing and distribution partners for the EU were being appointed with discussions underway with several pharmaceutical companies. "Once launched SUBA-itraconazole will be competing in the European itraconazole market which is currently over \$US120 million per year," Dr Aston said.

Halcygen said one of the advantages of achieving early EU registration was that the approved dossier could be used for faster approval in Asian territories as well and annual sales in Japan and Korea were more than \$US200 million.

Halcygen was up 4.5 cents or 23.7 percent to 23.5 cents.

<u>SIRTEX</u>

Sirtex says its net profit after tax for the year ending June 30, 2009 increased by 1,406.5 percent to \$18,229,000 on revenue up 87.6 percent to \$73,887,000.

The company said its profit after tax compared to last year's \$1,210,000.

Sirtex said its diluted earnings per share was 32.7 cents up from the previous year's 2.2 cents but no dividend would be paid.

The Sirtex said its product revenue, primarily the sales of its SIR-Spheres liver cancer treatment was \$65,559,000, a 72 percent increase on last year's \$38,125,000.

The company said a 42 percent increase in SIR-Spheres microspheres doses and the deprecation of the Australian dollar were the key factors in the result.

Sirtex said all regional sales of their SIR-Spheres microspheres doses were up with US increasing 28 percent, Europe up 117 percent and Asia Pacific increasing 17 percent. Sirtex chief executive officer Gilman Wong said collaborations with major universities and research institutes were expected to produce developments which "will move into human clinical studies in the coming year".

Sirtex was up 33 cents or 7.7 percent to \$4.64.

RESONANCE HEALTH

Resonance has posted a maiden net profit after tax of \$617,051 for the year to June 30, 2009 compared to a loss of \$41,392 in the previous year.

Resonance reported revenue of \$2,390,961 up 27 percent year compared with \$1,882,611 in the year ended June 30, 2008.

Net tangible assets per share increased from 0.7 cents to 0.9 cents.

Basic earnings per share was 0.2 cents compared 0.0 cents in the previous year. Resonance was unchanged at 1.6 cents.

IMUGENE

Imugene recorded a maiden net profit after tax of \$650,286 for the year ended June 30, 2009 compared to a loss of \$1,911,000 for the previous year.

Total income was \$3,248,438 compared to \$407,844 for the year ended June 30, 2008 with cash inflow from operations of \$881,768.

Imugene reported revenue from sales was \$3,024,028 for the year compared with \$92,000 for the year ended June 30, 2008.

Diluted earnings per share for the year ended June 30, 2009 was 0.04 cents compared to a loss of 1.4 cents the year ended June 30, 2008.

Imugene said revenue increased because of a strategic alliance agreement with Merial Limited. The company said it received payments from Merial of \$2.9 million for research costs and licencing fees for its porcine reproductive and respiratory syndrome vaccine. Imugene was untraded at 10 cents.

STIRLING PRODUCTS

Stirling and Zodiac Capital will acquire majority rights to Sheiman Ultrasonic Research Foundation's aerosol generation drug delivery device.

Stirling said the high density aerosol (HDA) technology prototypes proved efficient and effective in delivering drugs via inhalation.

The company said the HDA device promised to increase drug safety with fewer side effects than oral administration because less drug content was needed.

Stirling said the HDA technology used "focused ultrasonic energy to form a fountain of liquid to be nebulized that produces an aerosol from the walls of the jet that self-propels at several meters per second up a chimney like intake tube".

The company said atomization of the liquid occurred at the base of the jet inside the intake tube and the micro-particle aerosol was transported to the user "by positive dynamic pressure derived intrinsically from the kinetic energy of the jet".

Stirling said the HDA device does not use compressed gas or fan-driven airflow to transport aerosol to the user, reducing the drug loss associated with aerosol condensation inside the nebulization chamber.

Stirling chief executive officer Peter Boonen told Biotech Daily that his company and its associate Zodiac would each provide \$250,000 in shares to Sheiman.

Mr Boonen said the deal was conditional on the raising of \$5-6 million within 12 months for research and development.

He said Sheiman would retain a 35 percent interest in the device, a 35 percent interest in off-patent drugs used in the device and five percent in any products adapted from the technology.

Mr Boonen said Stirling and Zodiac would share equally in the balance. Stirling was untraded at 1.3 cents.

<u>USCOM</u>

Uscom says it increased revenue by 53.04 percent to \$1,921,452 with its net loss down 49.42 percent to \$1,099,889 for the year ending June 30, 2009.

Uscom said the revenue was primarily from sales of its ultra-sonic cardiac output monitor and equipment.

The company said its partnership with Spacelabs Healthcare had provided "critical and rapid access to unexploited global markets" which meant Uscom "achieved cash flow neutrality from normal operations in the final quarter, and was approaching profitability". Uscom's net tangible asset per ordinary share fell from 0.08 cents at June 30, 2008 to 0.06 cents at June 30, 2009.

Uscom was untraded at 76 cents.

BIOPROSPECT, SOLAGRAN

Bioprospect has appointed Solagran employee Kamran Shamsi as a non-executive director effectively immediately.

Mr Shamsi has a degree in Pharmacy and a Master of Administration in marketing.

Bioprospect said that under a development contract Solagran had the right to appoint two nominees to the Bioprospect board.

Bioprospect was unchanged at 2.3 cents.

Solagran was up half a cent or 3.45 percent to 15 cents.