



Biotech Daily

Friday August 9, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: NEUREN UP 10%, PATRYS DOWN 10%**

- * **MAYNE SIGNS TWO SUBACAP DISTRIBUTORS FOR EUROPE**

- * **HEARTWARE H1 REVENUE UP 81% TO \$110m, LOSS DOWN 38% TO \$28m**

- * **GENESIS DIRECTORS: PHI SAN LAM, FRANKIE CHEN, SHARON KWAN**

MARKET REPORT

The Australian stock market slipped 0.19 percent on Friday August 9, 2013 with the S&P ASX 200 down 9.6 points to 5,055.2 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and five were untraded.

Neuren was the best, up one cent or 10 percent to 11 cents with 9.6 million shares traded.

Antisense climbed 7.7 percent; Clinuvel was up 4.35 percent; Atcor and Tissue Therapies were up more than three percent; with Nanosonics, Prima and Resmed up more than one percent.

Patrys led the falls, down 0.4 cents or 10 percent to 3.6 cents with 1.15 million shares traded.

Heartware lost 9.3 percent; GI Dynamics and Phylogica fell more than five percent; QRX lost 4.8 percent; Allied Health, Avita, Bionomics, Pharmaxis and Psivida were down more than three percent; Acrux, Medical Developments and Prana shed more than two percent; Alchemia, Benitec, Cochlear, CSL, Starpharma and Viralytics were down one percent or more; with Mesoblast and Sirtex down by less than one percent.

MAYNE PHARMA GROUP

Mayne Pharma says it has signed two marketing and distribution agreements for Subacap for fungal infections for four European pharmaceutical markets.

Mayne Pharma investor relations manager Lisa Pendlebury told Biotech Daily that Subacap, formerly known as Suba-itraconazole, had been approved in Europe with the UK as the lead reference country along with Germany, Spain and Sweden, under the decentralized regulatory process.

Ms Pendlebury said that distributors had been appointed for the UK, Spain, Italy and Portugal and that Mayne was pursuing further regulatory approvals and distributors in Europe.

Mayne Pharma applied for Australian Therapeutic Goods Administration approval in March and is pursuing US Food and Drug Administration, Japanese and Korean approval (BD: Jun 17, 2013).

Ms Pendlebury said that Mayne expected to receive 35 to 40 percent of the revenue from sales of Subacap.

In a media release Mayne Pharma chief executive officer Scott Richards said that the UK, Spain, Italy and Portugal had \$US40 million a year of itraconazole sales; which was more than half the European itraconazole market and eight percent of the global itraconazole market of \$US490 million.

Mayne said that the Barcelona, Spain-based dermatology company Isdin would market the product in Spain, Italy and Portugal, while the Mumbai, India-based pharmaceutical company Glenmark would market the product in the UK.

Mayne said it would receive upfront payments, milestone payments on meeting market launch hurdles and a percentage of net sales in each country.

The company said it would manufacture the product for both distributors at its manufacturing facility in South Australia, with the product launch expected by the end of 2013 in the UK, early 2014 for Spain and by the end of 2014 for Italy and Portugal, following a 'repeat use' procedure to extend the existing marketing authorization into those additional countries.

Mr Richards said the company was "very pleased to announce the pending commercialization of Subacap in these key Western European pharmaceutical markets".

"Both distribution partners have established sales forces which call on a range of specialists that prescribe itraconazole including dermatologists, gynaecologists as well as [general practitioners], Mr Richards said.

"This is a very important milestone for the company and is the result of a great deal of work by many people," Mr Richards said.

"The conventional formulation of oral itraconazole suffers from poor and unpredictable bioavailability resulting in significant inter and intra-patient variability, which is a frustration to prescribers," Mr Richards said.

"The unique formulation of Subacap capsules, which have approximately twice the bioavailability and significantly reduced variability to existing products, represents a significant innovation," Mr Richards said.

"When launched, Subacap will adopt localized brand names, including Lozanoc, to maximize product recall with prescribers, pharmacists and patients," Mr Richards said.

"The company is continuing to progress the commercialization of Subacap in other markets, including the two key markets of Japan and United States, which represent 41 percent of the global itraconazole market value," Mr Richards said.

"The company is also in late stage discussions with a partner in Korea, the fourth largest itraconazole market globally".

Mayne was up half a cent or 0.9 percent to 58 cents with 1.85 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says that revenue for the six months to June 30, 2013, was up 80.6 percent to \$US100,075,000 (\$A109,848,500), with the net loss after tax down 37.8 percent to \$US25,893,000 (\$A28,421,700).

Heartware said its diluted loss per share was down 43.5 percent from \$US2.94 at June 30, 2012 to \$US1.66 at June 30, 2013 and the company had cash and cash equivalents of \$US190,024,000 at June 30, 2013 compared to \$US85,921,000 at December 31, 2012. Heartware fell 27 cents or 9.3 percent to \$2.62.

GENESIS RESEARCH AND DEVELOPMENT CORP

Genesis says it has appointed Phi San Lam, Frankie Chen and Sharon Kwan as directors. Genesis said that Mr Lam and Mr Chen were New Zealand citizens with business interests in New Zealand and Asia and Ms Kwan was an Australian citizen. Genesis was untraded at 1.9 cents.