



Biotech Daily

Tuesday August 13, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: PATRYS UP 11%, NEUREN DOWN 9%**
- * **PATRYS: '2 OF 6 PHASE I MULTIPLE MYELOMA PATIENTS RESPOND'**
- * **WEHI, CSL, LUDWIG 'INTERLEUKIN-11 A POTENTIAL CANCER TARGET'**
- * **MEDICAL DEVELOPMENTS POSITIVE CARDIAC SAFETY TRIAL**
- * **SUNSHINE HEART HIRES MINNETRONIX FOR C-PULSE POWER SYSTEM**
- * **REGENEUS IPO OPENED TODAY**
- * **HUNTER HALL HAS 18% OF SIRTEX**
- * **MEDTRONIC, J&J, POLARIS, DOMAIN, ADVANCED DILUTED IN GI DYNAMICS**
- * **ANU REDUCES TO 5% OF BIONOMICS**
- * **CHAIRMAN WILLIAM MOBBS TAKES 35% OF ITL**

MARKET REPORT

The Australian stock market climbed 0.96 percent on Tuesday August 13, 2013 with the S&P ASX 200 up 49.0 points to 5,157.7 points.

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

Patrys was the best, up 0.4 cents or 11.1 percent to four cents with 14.0 million shares traded, followed by Living Cell up 10.2 percent to 5.4 cents with 100,000 shares traded and Bionomics up 9.5 percent to 63.5 cents with 1.8 million shares traded.

Prana climbed eight percent; Compumedics was up 7.4 percent; Alchemia and CSL were up four percent or more; Allied Health, Ellex, GI Dynamics, Medical Developments and QRX were up more than three percent; with Acrux, Anteo, Cochlear, Mesoblast and Viralytics up more than one percent.

Neuren led the falls, down one cent or 8.7 percent to 10.5 cents with 2.9 million shares traded. Clinuvel lost 7.2 percent; Tissue Therapies was down 6.9 percent; Prima fell 5.2 percent; Heartware was down 4.4 percent; Atcor, Cellmid and Pharmaxis were down more than three percent; Genetic Technologies, Nanosonics and Universal Biosensors were down more than one percent; with Sirtex down 0.3 percent.

PATRYS

Patrys says two of six multiple myeloma patients treated with PAT-SM6 in its phase I/IIa trial experienced stable disease and none of the six reported serious adverse events. Patrys said the six patients were involved in the second and third cohorts and the positive clinical outcomes supported the trial progressing to its fourth and final patient cohort. The company said that the six patients had end-stage, multi-resistant multiple myeloma and on average had received five prior lines of therapy including autologous stem cell transplantation and other novel marketed compounds including Velcade and Revlimid. Patrys said that therapeutic options for such patients were usually limited to clinical trials and their median overall survival was about nine months.

The company said that each patient in the second cohort received four doses of PAT-SM6 at 1mg/kg given intravenously over a two week period, patients in the third cohort received four doses at 3mg/kg and all patients were then followed-up for 36 days.

Patrys said all six patients tolerated PAT-SM6 very well with no drug-related serious adverse events and no dose-limiting toxicities.

Patrys said that one of the two patients showing stable disease was a 73 year-old man in the second cohort who had previously received six lines of therapy including a stem cell transplant and at the time of entry into the trial he was resistant to all-available therapies and had rapidly advancing disease.

The company said that at day 36 post-treatment with four doses of PAT-SM6, the patients showed evidence of stable disease according to the International Myeloma Working Group criteria.

Patrys said that the second responder was a 75 year-old man from the third cohort who had previously received four lines of therapy and showed significant progression of his disease, but like the first responder, he showed evidence of stable disease after treatment with PAT-SM6 and at day 82 post-treatment his disease was stable and he had not gone on to receive any other treatment.

The company said that after inclusion in the trial, five of the six patients went on to receive additional chemotherapy due to advancing disease and two of the five patients responded positively to drugs to which that previously had been resistant.

Patrys said "this suggests that PAT-SM6 is having a positive influence on the cancer cells by converting them from resistant to sensitive".

The company said the median time to next therapy of 42 days was considered clinically significant.

Patrys said that patient immune systems were closely monitored and natural killer T-cells were significantly increased, suggesting that these cells played a role in the control of tumor growth.

The company said the trial at the University Hospital of Würzburg was led by investigator Dr Leo Rasche and supported by the Department of Medicine director Prof Hermann Einsele.

Patrys chief executive officer Dr Marie Roskrow said the PAT-SM6 trial was "producing some very exciting data".

"It is particularly encouraging to see two patients, with end-stage multiple myeloma, respond so positively to treatment with this novel antibody," Dr Roskrow said.

"All of the patients being recruited into this trial are resistant to the currently marketed drugs and PAT-SM6 is inducing strong and sustained immunological responses," Dr Roskrow said

"As we move into the final cohort of this trial, Patrys is beginning to attract the attention of potential new investors and commercial partners," Dr Roskrow said.

Patrys was up 0.4 cents or 11.1 percent to four cents with 14.0 million shares traded.

[THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH, CSL](#)
[THE LUDWIG INSTITUTE FOR CANCER RESEARCH](#)

The Walter and Eliza Hall Institute says that with CSL its researchers have identified interleukin-11 as a potential new target for anti-cancer therapies.

The Institute said that the importance of interleukin-11 in cancer development had been underestimated, but the researchers found that interleukin-11 was “one of the most important cytokines that stimulate the growth and spread of cancers”.

WEHI said that the discovery suggested that blocking interleukin-11 signaling could provide a new approach to the treatment of bowel and stomach cancer.

The Institute said that when a tumor developed, the normal non-cancerous tissues around it could become inflamed and produce many different molecules, including the two related proteins interleukin-11 and interleukin-6.

The Institute said the hormone-like signaling molecules, called cytokines, were thought to promote the growth and spread of cancer cells, but interleukin-11 was thought to have only a minor, if any, role during cancer development.

WEHI said that Prof Matthias Ernst and Dr Tracy Putoczki had shown that interleukin-11 was “one of the most important cytokines that stimulate the growth and spread of cancers”.

The Institute said that, with CSL scientists, they discovered that blocking interleukin-11 in models of stomach and bowel cancer stopped tumor growth and could lead to tumor shrinkage, making the cytokine a promising potential new target for treating many types of solid cancers.

WEHI said that Prof Ernst and Dr Putoczki made most of their discoveries while working at the Melbourne branch of the Ludwig Institute for Cancer Research of which Prof Ernst was a member.

The findings, in an article entitled ‘Interleukin-11 Is the Dominant IL-6 Family Cytokine during Gastrointestinal Tumorigenesis and Can Be Targeted Therapeutically’, was published today in the journal Cancer Cell and an abstract is available at:

<http://www.cell.com/cancer-cell/abstract/S1535-6108%2813%2900316-4>.

Dr Putoczki said the team was stunned to discover that interleukin-11 was much more potent in promoting cancer development than interleukin-6.

“When considering which cytokines drive cancer development, interleukin-6 has always been in the spotlight,” Dr Putoczki said. “Despite being very similar to interleukin-6, interleukin-11 has often been overlooked by cancer researchers.”

“Our new research now shows that it might in fact be very important,” Dr Putoczki said.

Prof Ernst said the team had begun to explore how the discovery could be applied to potential new anti-cancer therapies.

“Treating cancers with agents that block cytokine signaling is an exciting new approach that potentially has advantages over current treatment strategies,” Prof Ernst said.

“Drugs that block the action of cytokines have previously been developed for both inflammatory disease and cancer and, in the case of interleukin-11, our work does not suggest the likelihood of undesirable side-effects,” Prof Ernst said.

“Moreover, agents that inhibit interleukin-6 signaling are already in clinical trials for ovarian, kidney, prostate and breast cancer,” Prof Ernst said.

“Our discovery paves the way for trials of agents that stifle interleukin-11,” Prof Ernst said.

CSL research senior vice-resident Dr Andrew Nash said that the research had identified a potentially important role for interleukin-11 in stomach and bowel cancer.

“We have developed a number of potential drug candidates that target the interleukin-11 receptor and this data provides preclinical evidence supporting progression into clinical studies,” Dr Nash said.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its cardiac safety QT/QTc trial of its methoxyflurane analgesic has met its primary objective all secondary objectives with no safety concerns.

Medical Developments said the supra-therapeutic single 12mg dose of methoxyflurane showed no evidence of any effect on heart rate, other cardiac measures including P-wave to R-wave interval or QRS duration, or electro-cardiogram morphology, with no safety concerns assessed by clinical laboratory tests, including kidney and liver function tests, and vital signs.

The company said 42 subjects were recruited and 39 completed the Australian phase I, three-way cross-over trial using four times the normal dose of methoxyflurane, the active ingredient in the company's Pentrox inhaler and the trial was completed on-time and on-budget.

Medical Developments said the phase I cardiac safety study was "a very significant milestone ... [providing] further clinical evidence as to the safety of Pentrox and is a critical component of our regulatory strategy to introduce Pentrox into new markets internationally, and Western Europe in particular".

The company said it expected to submit its marketing authorization application for selected countries in Europe by the end of September 2013, as well as update countries considering the registration of Pentrox.

Medical Developments was up six cents or 3.85 percent to \$1.62.

SUNSHINE HEART

Sunshine Heart says the St Paul, Minnesota-based Minnetronix will supply the transcutaneous energy transfer system to power its fully-implantable C-Pulse aorta cuff. Sunshine Heart said that Minnetronix was a medical device engineering company, providing design and manufacturing support.

The company said that a transcutaneous energy transfer system enabled power transfer across the skin without direct electrical connectivity using time-varying magnetic fields.

Sunshine Heart said that transcutaneous energy transfer was used to power implanted devices, such as heart assist devices, artificial hearts and electrical stimulators.

The company said that the agreement used Minnetronix's existing technology and included milestone payments due to Minnetronix prior to US regulatory approval for the fully-implantable C-Pulse system.

Sunshine Heart chief executive officer Dave Rosa said it was the second partnership with Minnetronix, which supplied the second generation C-Pulse driver.

Minnetronix chief executive officer Rich Nazarian said that Sunshine Heart's technology was "the next generation in chronic circulatory support devices and holds great promise for less invasive and more effective treatment of congestive heart failure".

Last night on the Nasdaq, Sunshine Heart fell 31 US cents (33.9 Australian cents) or 3.5 percent to \$US8.52 (\$A9.33) with 227,803 shares traded, equivalent to 3.7 cents before the company left the ASX.

REGENEUS

Regeneus says its initial public offer to raise up to \$12 million at 25 cents a share to commercialize fat stem cells for musculoskeletal disease opened today (BD: Aug 8, 2013).

Regeneus said the offer was being jointly managed by Peloton Capital and BBY and was scheduled to close at 5pm on August 30, 2013.

SIRTEX

Hunter Hall Global Value says it has ceased its substantial holding in Sirtex reducing from 3,027,386 shares (5.43%) to 2,771,400 shares (4.94%).

Hunter Hall said it bought shares from May 8, 2007 until March 3, 2009, sold two parcels in 2010, bought three parcels of shares in 2012 and sold shares between December 2012 and August 6, 2013, with the single largest trade, the sale of 750,000 shares for \$3,600,000 or \$4.80 a share on May 26, 2010.

In its previous substantial shareholder notice for Sirtex, in 2007, Hunter Hall Global Value and associated companies said they became substantial with 3,027,386 shares (5.43%), when the company was trading at \$3.66 (BD: Apr 26, 2007).

Today's substantial shareholder notice said that Hunter Hall Investment Management had "the power to control the exercise of the right to vote attached to the shares and the power to exercise control over the disposal of shares as responsible entity of the Hunter Hall Value Growth Trust (7,313,806 shares), Australian Value Trust (120,000 shares), Hunter Hall Global Deep Green Trust (63,000 shares) and as Investment Manager of Hunter Hall Global Value Limited (2,771,400 shares)" a total of 10,268,206 shares or 18.3 percent. Sirtex fell four cents or 0.3 percent to \$12.96 with 241,686 shares traded.

GI DYNAMICS

GI Dynamics has filed substantial shareholder notices for several institutions following last month's \$60 million capital raising at 53 cents a share (BD: Jul 3, 2013).

GI Dynamics said that Polaris Venture Partners reduced its holding from 25,075,763 Chess depositary interests (CDIs) or 8.83 percent to 18,826,038 CDIs and was also diluted to 4.70 percent.

GI Dynamics said in 2011 that Medtronic held 12.76 percent of the company when it listed on the ASX at \$1.10 and today said that Medtronic held 39,115,442 CDIs or 9.77 percent of the company. (BD: Sep 7, 12, 2011).

The company said that Johnson & Johnson Development Corporation continued to hold 30,130,115 CDIs but was diluted from 10.49 percent to 7.53 percent.

GI Dynamics said that Domain Partners V and DP V Associates reduced and were diluted from 29,746,375 CDIs (10.47%) to 26,746,375 CDIs (6.68%).

The company said that Advanced Technology Ventures continued to hold 33,638,773 CDIs but was diluted from 11.84 percent to 8.40 percent.

GI Dynamics was up two cents or 3.2 percent to 65 cents.

BIONOMICS

The Australian National University has reduced its holding in Bionomics from 23,238,079 shares (6.73%) to 21,642,425 shares (5.26%).

The University said it primarily sold shares between September 18, 2012 and August 5, 2013, but on March 26, 2013 bought 2,782,492 shares for \$1,001,697 or 36 cents a share. In April, Bionomics said it had raised \$12,152,757 at 36 cents a share in its underwritten one-for-eight rights issue (BD: Apr 8, 2013).

Last year the University increased its holding in Bionomics from 19,613,188 shares to 23,238,079 shares but was diluted from 7.73 percent to 6.73 percent (BD: Sep 18, 2013).

The University said at that time that it was allotted 4,829,891 shares for \$1,159,174 or 24 cents a share in September 2009 and sold shares from then until September 14, 2012 at a range of prices.

Bionomics was up 5.5 cents or 9.5 percent to 63.5 cents with 1.8 million shares traded.

ITL LIMITED

ITL executive chairman William Mobbs has increased his substantial shareholding 28,650,117 shares (32.75%) to 30,683,307 shares (34.90%).

The Canberra-based Mr Mobbs said he acquired 2,033,190 shares for \$473,733 or 23.3 cents a share in the ITL executive share plan.

ITL has been conducting a share buyback program.

ITL was untraded at 28.5 cents.