



Biotech Daily

Thursday June 29, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: DIMERIX UP 12.5%, NEUREN DOWN 7%**
- * **NEUREN RAISES \$11.5m FOR PHASE III RETT PREPARATIONS**
- * **IMPEDIMED 1st SOZO SALES**
- * **CLARITY RAISES \$4m FOR 'THERANOSTICS'**
- * **DORSAVI VIMOVE MEASURES MOVEMENT IN PFIZER-BACKED STUDY**
- * **INVITROCUE TO RAISE \$685k**
- * **CLARIFICATION: ITL, MYHEALTHTEST**
- * **CORRECTION: CSIRO, DATA61**
- * **MMJ: MARIJUANA LICENCE RENEWED, APPLIES FOR SALES**
- * **ESENSE, 374 COLLABORATE ON CANNABIS TERPENES**
- * **MEMPHASYS AWAITS NEW SPERMSEP, RENAMED FELIX; PRIME CHANGES**
- * **CRYSTAL AMBER TAKES 45% OF GI DYNAMICS**
- * **ROBERT LEDERER TAKES 5% OF ANATARA**
- * **RESONANCE LOSES DR JASON LOVERIDGE TO GERMANY'S 4SC**

MARKET REPORT

The Australian stock market was up 1.08 percent on Thursday June 29, 2017 with the ASX200 up 62.4 points to 5,818.1 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 12 fell, five traded unchanged and one was untraded. All three Big Caps rose.

Dimerix was the best, up 0.1 cents or 12.5 percent to 0.9 cents with 16.1 million shares traded. Prana climbed 8.5 percent; LBT was up 6.7 percent; Actinogen, Compumedics, Oncosil and Polynovo were up more than five percent; Impedimed, Nanosonics and Sirtex rose four percent or more; Mesoblast and Prima were up three percent or more; Avita, Cyclopharm, Orthocell, Pharmaxis and Starpharma rose more than two percent; with CSL, ITL, Medical Developments and Reva up more than one percent.

Neuren led the falls, down 0.5 cents or 6.6 percent to 7.1 cents with 4.7 million shares traded. Psivida fell 4.1 percent; Benitec, Bionomics and Osprey lost more than three percent; Acrux, Atcor and Viralytics shed more than two percent; Factor Therapeutics fell 1.6 percent; with Airxpanders, Ellex and Pro Medicus down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says it has raised \$11.5 million at 6.2 cents a share to prepare for a phase III trial of trofinetide for Rett syndrome.

Neuren said that the London-based Lanstead Capital had invested \$10 million, with the balance from Rettsyndrome.org and the company's directors and management.

The company said that the raising was at 1 3.3 percent premium to the 10-day volume weighted average price to June 26, 2017.

Neuren said it planned to meet with the US Food and Drug Administration neurology division by October 2017 to discuss the remaining development for trofinetide for Rett syndrome, including the phase III trial design.

The company said it would begin manufacturing and non-clinical activities required for a phase III trial including optimization of the commercial drug manufacturing process, stability testing and analytical validation of the liquid drug formulation, a toxicity study in a second species, required for a phase III trial with longer dosing and to support a FDA new drug application.

Neuren executive chairman Dr Richard Treagus said the raising was "a very important financing for Neuren and the Rett syndrome community".

Neuren said it would receive \$3 million in July 2017, with \$1.5 million from Lanstead and \$1.5 million from Rettsyndrome.org and Neuren's directors and management.

The company said the remaining \$8.5 million from Lanstead would be invested in a "sharing agreement" enabling it to secure potential upside from the expected news flow.

Neuren said the sharing agreement meant the funds would be paid in 18 monthly settlements measured against a benchmark price of 8.86 cents a share and if the share price exceeded the benchmark for the month Neuren would receive more than 100 percent of the settlement on a pro-rata basis, with no upper limit, but if the share price fall below 8.86 cents the company would receive less than 100 percent of the settlement on a pro-rata basis.

The company said that a share price fall would not result in an increase in the number of shares received by Lanstead or any other benefit accruing to Lanstead.

Neuren said that Lanstead would be issued 161.3 million shares for the \$10 million commitment with a further 8.1 million shares in consideration for the sharing agreement.

Neuren fell half a cent or 6.6 percent to 7.1 cents with 4.7 million shares traded.

IMPEDIMED

Impedimed says it has begun a "targeted launch" of its Sozo body fluid measurement platform in Europe and Australia, with first commercial sales underway.

Impedimed said that the launch followed the receipt of Conformité Européenne (CE) mark and was focused on converting existing customers to the latest technology and targeting new installations at large, multidisciplinary hospitals (BD: Jun 21, 2017).

The company said that large hospital systems would be the first customers to use the Sozohub software to connect devices for various fluid and body composition indications.

Impedimed chief executive officer Richard Carreon said the company was "very excited to see the first initial sales of Sozo so soon after receiving CE Mark".

"The initial launch of Sozo and our new suite of software products will provide us invaluable clinician and patient feedback, both from single site usage up through large hospital enterprise systems," Mr Carreon said. "The experience gained from this phase will allow us to move to a broader commercial launch in the coming months and ultimately prepare us for the US introduction slated for later this calendar year."

Impedimed was up 3.5 cents or 4.7 percent to 78.5 cents with 1.6 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has raised \$4 million to develop its radio-pharmaceutical pipeline using its “theranostic” technology and expand its presence in Europe and the US.

Clarity executive chairman Dr Alan Taylor told Biotech Daily that theranostics was the combination of therapies and diagnostics in a single agent.

The company said the investment round was supported by current and new investors to provide matching funds for grants awarded in 2016, including a \$2.5 million Cooperative Research Centre grant and a \$1 million Accelerating Commercialisation grant.

Clarity said the money would fund the development of Sartate, a radio-peptide product that helped visualise and kill cancerous cells using copper radio-isotopes.

Dr Taylor said Clarity had completed a phase I/II diagnostic trial for neuro-endocrine tumors in adults in 2016 and was awaiting published results (BD: May 24, 2017).

Dr Taylor said a phase I/II Australia and US trial of Sartate for neuroblastoma in children would begin by September 2017, with an Australian phase II therapeutic trial for neuro-endocrine tumors in adults by end of the year, and a broader diagnostic trial in Europe.

Clarity said the money would fund development of a prostate specific membrane antigen-targeting product for the diagnosis and treatment of prostate cancer and a Bombesin product targeting the gastrin-releasing peptide receptor, which was present in a number of serious cancers including lung, ovarian, prostate, and breast.

Dr Taylor said that Bombesin was a 14-amino acid peptide originally isolated from the skin of the European fire-bellied toad, or *Bombina bombina*.

The company said that both products used its copper-64 and copper-67 theranostic, which had benefits over existing isotopes “including a perfect pairing for diagnosis and therapy, optimization of dose and centralized manufacture and supply”.

Dr Taylor said he was “excited to see how much Clarity has grown in the last few years, which is testament to the capabilities of our team and collaborators, and we are very pleased to receive continuous strong support from our investors”.

“The capital raising puts Clarity in a very strong position, providing matching funds for around \$5 million of grant funding to spend on our programs and enabling us to progress our pipeline and complement it with new and exciting products,” Dr Taylor said.

Clarity is a public unlisted company.

DORSAVI

Dorsavi says a Pfizer supported study is using its Vimove wearable sensors to assess the impact on movement and muscle activity of an unnamed over-the-counter product.

Dorsavi said that prior to Vimove, healthcare companies were reliant on subjective measures and patient-reported outcomes, such as questionnaires.

The company said that insurers and regulatory bodies were seeking objective and functional outcome measures in an attempt to prioritize the funding or approval of evidence based interventions, and Vimove provided “objective data to inform the benefits of certain treatments or interventions”.

Dorsavi chief executive officer Dr Andrew Ronchi said that the importance of using a US Food and Drug Administration-cleared device to capture clinically relevant data was being recognised by both pharmaceutical and medical device companies.

“Apart from the current study, several medical device companies are using Vimove to investigate the functional outcomes their products have on patients,” Dr Ronchi said.

“Vimove is used to measure patients before and after treatments or procedures to objectively track their improvement,” Dr Ronchi said.

Dorsavi was up 1.5 cents or 5.3 percent to 30 cents.

INVITROCUE

Invitrocue says it intends to raise \$685,087 through the placement of 8,563,583 shares at eight cents each and 2,057,563 options exercisable eight cents within one year.

Invitrocue said the placement would fund development of the oncology patient-derived organoid (Onco-PDO) business and for working capital.

The company said the issue was within the 15 percent capacity under ASX Listing Rules.

Invitrocue fell half a cent or 7.7 percent to six cents.

ITL HEALTH GROUP

Last night's edition reported that ITL subsidiary Myhealthtest expected to have tests on the market by the end of 2017 for diabetes, cholesterol, prostate cancer and thyroid cancer.

The company has told Biotech Daily that the prostate test was for the prostate specific antigen (PSA), which was the industry standard blood metric for monitoring the development and progress of a number of prostate issues, including prostate cancer.

ITL said the thyroid test was for the thyroid stimulating hormone (TSH), a standard measure for determining abnormal thyroid activity.

The company said that thyroid dysfunction could arise from a range of underlying conditions, and in consultation with their doctor the TSH test would give patients information that helped them monitor the progress of their condition and the success of their treatment.

ITL was up one cent or 1.9 percent to 53 cents.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Yesterday's edition included an incorrect internet address for Data61's Expert Connect.

The correct address is: <https://expertconnect.data61.csiro.au/>.

The mistake was made by the former sub-editor who has learnt that data is not information, information is not knowledge and knowledge is certainly not wisdom.

MMJ PHYTOTECH

MMJ says that Canada has renewed 60 percent subsidiary Harvest One's marijuana cultivation licence and the company has applied to sell medical cannabis.

MMJ said that the application was through Harvest One wholly-owned subsidiaries United Greeneries and the licence was valid until June 26, 2020.

The company said that Health Canada had permitted United Greeneries to store up to \$C6,250,000 (\$A6,254,880) worth or 625kg of dried cannabis buds at any given time in its level 8 vault and had assigned a value of \$C10,000 per kilogram of dried buds.

MMG said that United greeneries had a "wholesale off-take agreement" with an unnamed licenced producer for the sale of its initial 100kg of cannabis for \$C500,000, subject to the sales amendment, along with a right of first refusal for the unnamed company to buy its further production for a period of 12 months, and United Greeneries planned to continue wholesale distribution with the company while it built a retail platform for the recreational cannabis market over the next few months.

MMJ managing-director Andreas Gedeon said that "our operational activities are unfolding according to our business plan and ... our strategic efforts to build a leading international cannabis company are coming together".

MMJ was up two cents or 6.25 percent to 34 cents with 2.4 million shares traded.

ESENSE-LAB

Esense says it expects to collaborate on marijuana terpene products with the Reno, Nevada-based and Nevada-licensed medical cannabis laboratory 374 Labs.

The company said it had an agreement with 374 Labs for the development, marketing and sales of products to 374 clients, including growers, extraction laboratories, manufacturers and distributors and the two companies would develop products based on its terpenes, with distribution through 374 Labs, including dispensaries, vapor shops in Nevada and California and world-wide online sales.

The company said each party would retain its respective intellectual property, with consideration to share any future jointly developed intellectual property and 374 Labs would be entitled to commission based and revenue sharing incentives.

Esense said that retail cannabis sales in 2016 were about \$US4.5 billion and expected to increase to \$US6.1 billion for 2017.

Esense was up 1.5 cents or 5.2 percent to 30.5 cents.

MEMPHASYS

Memphasys says the first two cartridges of its next generation Spermsep device, to be renamed Felix, are due to be delivered tomorrow June 30, 2017.

Memphasys said that Felix was Latin for "joy" and the system was cost effective, quick and easy to operate and would select the most viable sperm without damaging sperm DNA.

The company said capacity had increased from 0.6ml to 1.8ml and following testing of the cartridges Melbourne engineering company Hydrix would approved to complete the order.

Memphasys said that further validation would be conducted in-house, along with the University of Newcastle's Prof John Aitken, Monash In-Vitro Fertilization (IVF) group,

Westmead IVF and the University of New South Wales IVF group and on completion it would develop the final, disposable cartridges to be validated in "global key opinion leader

studies to start in about six months and be completed by mid-2019.

The company said that it had appointed former director Mark Gell as a consultant.

Memphasys said that the Singapore-based Prime Biologics, a related company with which it had legal issues, had received the resignations of executive chairman Dr Hari Nair and managing director John Manusu (BD: Nov 11, 2016; Feb 15, 17, Mar 2, 2017).

Memphasys was untraded at 0.1 cents.

ANATARA LIFE SCIENCES

The Sydney-based Robert Anthony Lederer says he has become a substantial shareholder in Anantara with 2,472,000 shares or 5.00 percent of the company.

Mr Lederer said the shares were held by RTL Group Investments Pty Ltd and his superannuation fund with 195,000 shares acquired for \$179,993 or cents or 92.3 cents a share, between February 28 and June 27, 2017.

Anantara was unchanged at \$1.00.

GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 246,504,725 shares (44.19%) to 252,504,725 shares (45.26%).

The London and Guernsey Island-based Crystal Amber Fund said that between June 23 and 27, 2017 it bought 6,000,000 shares for \$409,598 or 6.8 cents a share.

GI Dynamics fell half a cent or 7.1 percent to 6.5 cents with 1.7 million shares traded.

RESONANCE HEALTH

Resonance says non-executive director Dr Jason Loveridge will resign, effective from June 30, 2017, following his appointment as chief executive officer Germany's 4SC Resonance said that the Munich, Germany-based 4SC AG was a bio-pharmaceutical company.

The company said that Dr Loveridge had been a director for four years.

Resonance chairman Dr Martin Blake said the board thanked Dr Loveridge "for the contribution he has made to Resonance over the past four years".

"Dr Loveridge will remain available to the company in a corporate advisory role," Dr Blake said.

Resonance was untraded at 2.4 cents.