



Biotech Daily

Thursday July 30, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ELLEX UP 16%, CELLMID, POLYNOVO DOWN 10%**
- * **GI DYNAMICS TERMINATES US ENDOBARRIER TRIAL**
- * **SYDNEY UNI TO TEST CYNATA STEM CELLS FOR CARDIAC IN-VIVO**
- * **ELLEX EXPECTS RECORD REVENUE OF \$62.5m**
- * **CELLMID RAISES \$4m FOR ADVANGEN HAIR GROWTH SALES**
- * **UNILIFE \$96m FACILITIES, IMPERIUM INSULIN PATCH PUMP LAUNCH**
- * **NOVOGEN REVIEWS PROGRAMS**
- * **SIMAVITA NEW BUSINESS MODEL, CANADA DISTRIBUTORS**
- * **ANALYTICA: 'ONLINE ARTICLE INACCURATE'**
- * **ELLERSTON (PACKER FAMILY) BELOW 5% OF ACRUX**
- * **RETROPHIN BELOW 5% OF CLINUVEL**
- * **KEVIN WYLD, AVANTEOS REDUCES TO 5% OF LBT**
- * **REGENEUS HAS LESS THAN TWO QUARTERS CASH, \$3m R&D CREDIT**
- * **BLUECHIIP HAS ONE QUARTER CASH, \$500k R&D Tax CREDIT**

MARKET REPORT

The Australian stock market was up 0.81 percent on Thursday July 30, 2015 with the ASX200 up 45.3 points to 5,669.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and three were untraded.

Ellex was the best, up 4.5 cents or 15.5 percent to 33.5 cents with 1.4 million shares traded. Oncosil climbed 13.0 percent; Neuren and Universal Biosensors were up more than 10 percent; Clinuvel was up 9.3 percent; Optiscan rose 7.1 percent; Atcor was up 5.3 percent; Anteo, Antisense and Prana were up more than four percent; Actinogen was up 3.4 percent; with Admedus and Psivida up more than one percent.

Both Cellmid and Polynovo led the falls, down 10 percent to 3.6 cents and 9.9 cents, respectively, with 9.5 million shares and 530,000 shares traded, respectively. Tissue Therapies lost 7.7 percent; Prima shed 5.4 percent; Avita fell 4.4 percent; Genetic Technologies was down 3.3 percent; Bionomics and Starpharma shed more than two percent; with Acrux, Benitec, CSL, Mesoblast, Resmed and Sirtex down more than one percent.

GI DYNAMICS

GI Dynamics says it has closed its planned 500-patient US Endobarrier trial, which it previously hoped to restart in this month.

In May, GI Dynamics chief executive officer Mike Dale said that a fifth patient of the 325 enrolled in the 500-patient trial had developed a bacterial liver infection, the cause of the FDA halt to the trial in March (BD: Mar 6, May 6, 2015).

Today, GI Dynamics said the decision followed discussions with the US Food and Drug Administration, but despite collaborative efforts by both parties were unable to yield a feasible path forward for the mitigation of a higher than anticipated incidence of hepatic abscess, a bacterial infection of the liver.

GI Dynamics last traded at 13.5 cents.

CYNATA THERAPEUTICS

Cynata says the University of Sydney will test its Cymerus mesenchymal stem cells in animal models of myocardial infarction and associated heart rhythm abnormalities.

Cynata said the studies would be led by cardiologist and University of Sydney lecturer Dr James Chong.

The company said that Dr Chong had experience in stem cell therapy for heart disease and had several publications, including one that demonstrated regeneration of non-human primate hearts, published in Nature in 2014.

Dr Chong said that cardiovascular diseases were “the greatest non-communicable cause of mortality worldwide”.

“I believe the use of cellular therapies to stimulate regeneration of the failing heart has the potential to significantly change this field,” Dr Chong said.

Dr Chong said that mesenchymal stem cells from other sources had been shown to improve cardiac function after injury and were being tested in clinical trials.

Cynata was up half a cent or 0.7 percent to 69 cents.

ELLEX MEDICAL LASERS

Ellex says it expects to report record revenue of \$62.5 million for the year to June 30, 2015, resulting in an expected net profit before tax of about \$2.5 million.

Ellex said the results were “preliminary and unaudited” with full year results expected by the end of August 2015.

The company said that its “strong operating result was driven by global sales of its treatment laser portfolio, including early-adopter sales of the proprietary 2RT laser, indicated for early age-related macular degeneration and clinically significant macular oedema” along sales of the Integre Pro retinal laser and the full year sales impact of the Itrack glaucoma surgical device, acquired on January 1, 2014, combined with the lower Australian dollar relative to the US dollar.

Ellex chief executive officer Tom Spurling said that sales grew by 15 percent compared with the year to June 30, 2014.

“This marks the third consecutive year of revenue and [net profit before tax] growth for our business,” Mr Spurling said.

“Ellex operates across the four major areas of the eye disease treatment market; glaucoma, diabetic retinopathy, cataracts and [age-related macular degeneration],” Mr Spurling said.

“We have significant growth potential in this market with our devices,” Mr Spurling said.

Ellex climbed 4.5 cents or 15.5 percent to 33.5 cents with 1.4 million shares traded.

CELLMID

Cellmid says it has raised \$4.0 million in a placement to institutional and sophisticated investors at three cents a share.

Cellmid said that KTM Capital acted as manager for the placement and the funds would be used to leverage sales of its Advangen FGF5 inhibitor hair growth products.

Cellmid fell 0.4 cents or 10 percent to 3.6 cents with 9.5 million shares traded.

UNILIFE CORPORATION

Unilife says it has signed a \$US45 million (\$A61.5 million) equity draw-down facility, a separate \$US25 million facility and launched the Imperium insulin patch pump.

Unilife said that the equity draw-down facility with the Chicago-based Lincoln Park Capital Fund provides \$US5 million in initial proceeds and the option to take up to a further \$US40 million, at the company's discretion over 24 months.

The company said that it had a \$US25 million at-the-market facility with Cantor Fitzgerald. Separately, Unilife said that it had introduced the Imperium platform of instant patch pumps for insulin.

The company said that Imperium was a prefilled, disposable, multi-day wearable insulin pump that did not require filling or assembly by the patient.

Unilife said that because it was prefilled and pre-assembled like an insulin pen, "only three intuitive steps [were] required to commence continuous subcutaneous insulin infusion, with on-demand bolus delivery available to the user via the simple push of a button".

Unilife was up 15.5 cents or 35.6 percent to 59 cents with 2.8 million shares traded.

NOVOGEN

Novogen acting chief executive officer Iain Ross says the company will review its pipeline and "may have to re-prioritize some of the programs".

Novogen said it had "an extensive program of activities underway including the lead pre-clinical programs, discovery programs and academic partnerships and initiatives" and the review was expected to report to shareholders by September 1, 2015.

"We remain committed to exploiting and creating value from all our technology platforms in order to build a sustainable, international, biotech company," Mr Ross said.

"Whilst we do not rule out securing third party collaborations and partnerships to further validate and fund our programs, I can confirm there are no [merger and acquisition] plans," Mr Ross said.

"Notwithstanding, it is clear that we cannot realistically undertake and fully resource all our research and development programs in parallel all the way through to market approval and launch," Mr Ross said.

"These are new ground-breaking and first in class technologies and it is critical that we understand which indications, stage of disease and combinations with other oncology agents will deliver the best outcome for patients and value for shareholders," Mr Ross said.

"One outcome from this process will be to focus our valuable resources; set clear, realistic, scientific and commercial priorities in order that we can execute and manage the business effectively and report our on-going progress to our shareholders against the priorities we have established," Mr Ross said.

Mr Ross said the company had begun a search for a chief executive officer, chief medical officer, as well as project and manufacturing management support.

Novogen was unchanged at 20 cents with 1.9 million shares traded.

SIMAVITA

Simavita says it has adopted a “software as a service” business model providing 12-month service contracts for its smart incontinence management (SIM) system.

The company said that the business model would provide a contracted and predictable revenue stream.

Simavita said it had executed agreements with its first US and Canadian customers under the new business model.

The company said that it had binding terms sheets with two Canadian distribution partners the Oakville, Ontario-based Medline Canada Corp and Mississauga, Ontario-based Medprodirect Inc.

Simavita said that the distributors had been granted non-exclusive rights to sell and distribute the smart incontinence management in Canada.

Simavita was up 1.5 cents or 2.6 percent to 59 cents.

ANALYTICA

Analytica says an online article with “statements attributed to the company about its financial position, operational plans, prospects and value ... is inaccurate”.

Analytica said its policy was not to respond to media speculation but as it was seeking to raise capital under a current pro-rata entitlement offer, it was appropriate to respond to the article first published on July 27, 2015.

The company did not name the online publication but said the article was “inaccurate and that it did not authorize its publication or the making of any of the statements contained in it”.

Analytica said it had requested that the article be withdrawn.

The company said that the only statements it authorized were those contained in its market disclosures and current rights issue prospectus.

The Medify website refers to today’s Analytica announcement with a link to a report published on July 27, 2015.

Analytica was unchanged at 0.8 cents.

ACRUX

Ellerston Capital says it has reduced its shareholding in Acrux from 16,630,037 shares (9.99%) to below the five percent substantial threshold.

Ellerston said that it bought and sold shares from February 18, 2013 until March 30, 2015 and this week sold 8,021,770 shares for \$6,062,112 or an average price of 75.6 cents a share.

Ellerston became a substantial shareholder in May, 2012, saying the shares were held by HSBC Custody Nominees, Cogent Nominees, JPM Nominees and National Nominees (BD: May 23, 2012).

In August, Ellerston provided a detailed list of “passive substantial holders” related body corporates of the principal person, including Arctic Asia, Australian Financial Times, Congress (Hong Kong, Malaysia, Cayman, Christchurch, Finance, Holdings, International Finance) and Consolidated Press Property, a raft of Ellerston companies, as well as Hoyts Cinemas (America, Argentina, Chile, Germany, Polska), Park Street Partners Cayman and Perisher Village Developments, among others (BD: Aug 8, 2012).

Ellerston’s website said that it was a subsidiary of Consolidated Press Holdings, a private company of the Packer media and gambling family.

Acrux fell one cent or 1.4 percent to 68.5 cents.

CLINUVEL PHARMACEUTICALS

The New York-based Retrophin says it has ceased its substantial holding in former takeover target Clinuvel.

Last year Retrophin bought shares in an extraordinary large number of very small trades, some as small as single shares, with prices escalating from \$2.10 on August 1 to \$3.10 on September 10, 2014 to 3,309,356 shares (7.79%) (BD: Sep 12, 2014).

In August 2014, Clinuvel rejected Retrophin's bid of about \$95 million saying the proposal "materially undervalues" the company (BD: Jul 28, Aug 8, 2014).

Today, Retrophin said that on July 28, 2015 it sold 2,627,162 shares at \$2.40 a share. Clinuvel was up 25 cents or 9.3 percent to \$2.95.

LBT INNOVATIONS

The Sydney-based Kevin Wyld through Avanteos Investments says he has reduced his substantial holding in LBT from 8,043,637 shares (7.01%) to 5,754,694 shares (5.01%).

Mr Wyld told Biotech daily that the self-managed superannuation fund was held by Avanteos Investments, which in turn was owned by the Commonwealth Bank subsidiary Colonial First State.

The substantial shareholder notice said that Mr Wyld sold the shares on-market between September 26, 2014 and June 22, 2015, with the single largest sale 300,000 shares for \$18,150 or 6.05 cents a share

LBT was up half a cent or 7.1 percent to 7.5 cents.

REGENEUS

Regeneus says its net operating cash burn for the three months to June 30, 2015 was \$1,904,000 with cash at the end of the quarter of \$3,013,000.

Regeneus said it expected to receive a Federal Government Research and Development Tax Incentive of about \$3 million by the end of 2015.

Regeneus fell half a cent or 3.3 percent to 14.5 cents.

BLUECHIIP

Bluechiip says its net operating cash burn for the three months to June 30, 2015 was \$589,000 with cash at the end of the quarter of \$742,000.

Bluechiip said it expected sales, licencing and royalty receipts from customers over the coming months, a Federal Government Research and Development Tax Incentive of more than \$500,000 by October 2015 and was assessing alternatives for capital raising.

The company said it received \$3,000 in receipts from customers in the three months to June 30, 2015 and \$56,000 for the 12 months to June 30, 2015

Bluechiip fell half a cent or 12.5 percent to 3.5 cents.