



# Biotech Daily

Tuesday August 23, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH EVEN: LIVING CELL UP 7%, ACRUX DOWN 43%**
- \* **ACRUX FALLS 45% ON AXIRON PATENT RULING**
- \* **ITL REVENUE UP 10% TO \$31m, PROFIT DOWN 84% TO \$344k**
- \* **OBJ REVENUE UP 0.5% TO \$1.5m, LOSS UP 51% TO \$3.6m**
- \* **INVITROCUE, QIAGEN PARTNER FOR BIOMARKERS, TRANSLATION**
- \* **ADMEDUS 8-YEAR DATA: NO CALCIFICATION, NO REPEAT PROCEDURES**
- \* **MGC READY FOR CANNABINOID PATCH HUMAN SAFETY TRIAL**
- \* **LIVING CELL: DIATRANZ OTSUKA CLOSING INVERCARGILL PIG FACILITY**
- \* **YUUWA HAS 54% OF ADALTA, PLATINUM 8%, CITYCASTLE 5%; ESCROW**
- \* **CRYSTAL AMBER TAKES 14.5% OF GI DYNAMICS**
- \* **DRH, DAVID HANNON TAKE 11% OF NOXOPHARM**
- \* **GERARDO INCOLLINGO REPLACES IQ3 CO SEC KELVIN BOATENG**

## MARKET REPORT

The Australian stock market was up 0.7 percent on Tuesday August 23, 2016 with the ASX200 up 38.7 points to 5,553.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, 11 were unchanged and one was untraded.

Living Cell was the best, up 0.6 cents or 7.4 percent to 8.7 cents with 439,881 shares traded. Pro Medicus climbed 5.7 percent; both Airxpanders and Prana improved 4.55 percent; Osprey was up 3.1 percent; CSL and Neuren rose more than two percent; Anteo, Factor Therapeutics, Impedimed, Pharmaxis and Universal Biosensors were up more than one percent; with Clinuvel, Cochlear, Medical Developments and Sirtex up by less than one percent.

Acrux led the falls, down 30.5 cents or 42.7 percent to 41 cents with 11.9 million shares traded. Actinogen lost 8.5 percent; Benitec and Biotron fell more than seven percent; Cellmid, Compumedics, Mesoblast and Polynovo were down three percent or more; Antisense and Starpharma shed more than two percent; Admedus and Uscom were down more than one percent; with Ellex, Nanosonics and Resmed down less than one percent.

## ACRUX

Acrux fell as much as 44.8 percent to 39.5 cents on the news that a US court ruled its Axiron patents invalidated, allowing generic versions.

Acrux said the US District Court for the Southern District of Indiana ruled the formulation and axilla application patents granted by the US Patent Office for Axiron had been invalidated and therefore would not be infringed by the commercialization of generic versions of Axiron by the generic companies that challenged the patents.

The company said that its applicator patent was valid but not infringed by the majority of parties.

Acrux said that with US partner Eli Lilly it was “disappointed with the US District Court’s ruling that the Axiron formulation and axilla application patents [were] not valid and would not be infringed by generic competitors” and the two companies would review the decision and consider whether to appeal.

Acrux chief executive officer Michael Kotsanis told Biotech Daily that the two companies would need time to consider the ruling but would make a decision on whether to appeal as soon as practicable.

The company said the launch of generic competition to Axiron in the US would cause a material decline in its net sales and the resulting royalties received by Acrux.

Acrux said that with Eli Lilly it had filed lawsuits against Perrigo Israel Pharmaceuticals, Watson Laboratories, known as Actavis, Amneal Pharmaceuticals and Lupin Pharmaceuticals, each of which had filed an abbreviated new drug application for a generic version of Axiron, for infringement of certain issued US patents.

Acrux closed down 30.5 cents or 42.7 percent to 41 cents with 11.9 million shares traded.

## ITL

ITL says revenue for the 12 months to June 30, 2016 was up 9.7 percent to \$31,083,000 with net profit after tax down 83.8 percent to \$344,000.

ITL executive chairman Bill Mobbs said that while “achieving strong underlying sales growth, profits were reduced in 2015-’16 compared to the previous year” primarily due to a loss of \$400,000 in the Myhealthtest start-up which was expected to breakeven in 2018 and contracting margins in its Australian healthcare business, and an air-conditioning breakdown at its Malaysia facility.

Mr Mobbs said Myhealthtest had “a niche in a potentially enormous market place, in particular diabetes”.

“[ITL’s] Healthcare Australia is increasing its sales of intravenous cannula insertion packs and, as a supplier of custom sterile packs, is also progressively growing its market share in [New South Wales] public hospitals,” Mr Mobbs said.

Mr Mobbs said strategies were being implemented “to improve pricing, reduce material purchase costs and decrease labor costs”.

“The board is confident the company’s growth strategy with multiple revenue streams, and the profit improvement plans for the healthcare Australia business, will enable ITL to provide increased returns to shareholders in the future,” Mr Mobbs said.

ITL said that it had cash and cash equivalents of \$611,000 at June 30, 2016 down 44.6 percent to \$611,000 compared to \$1,103,000 at June 30, 2015.

The company said that diluted earnings per share fell 84.8 percent to 0.38 cents compared to the previous year’s 2.50 cents and net tangible asset backing per share fell 18.75 percent from 11.2 cents to 9.1 cents.

ITL said it paid a 0.25 cent dividend in 2015, but there would be no dividend this year.

ITL climbed 1.5 cents or 9.7 percent to 17 cents.

## OBJ

OBJ says that revenue for the year to June 30, 2016 was up 0.5 percent to \$1,515,000, with net loss after tax up 51.1 percent to \$3,555,000.

OBJ said it had taken “strong steps towards sustainable licencing revenues from its first product licences from partnering activities and the potential of first licensing revenues from [its] own internal product development programs”.

The company said that confirmation by Procter & Gamble to licence its technology for a number of products and confirmation of the adoption of the technology by a second P&G brand were “significant milestones”.

OBJ said that its partnering programs and internal product developments made significant progress in the year to June 30, 2016.

The company said that its net tangible assets per share increased 86.4 percent from 0.22 cents at June 30, 2015 to 0.41 cents at June 30, 2016, with diluted loss per share up 33.3 percent to 0.20 cents.

OBJ said that it had cash and cash equivalents of \$7,334,205 at June 30, 2016 compared to \$3,519,337 at June 30, 2015.

OBJ was up half a cent or 5.15 percent to 9.2 cents with 7.8 million shares traded.

## ADMEDUS

Admedus says that eight-year data from its phase II extension study of Cardiocel for paediatric congenital heart defects shows all 14 patients progressing well.

In a media release, not published on its ASX platform and described as “important but not material”, Admedus said that there was “no sign of calcification or need for repeat procedures” in any patients.

Admedus said it had been able to follow-up 14 of the original 30 patients in its 2008 South Africa phase II trial (BD: Oct 9, 2008; Apr 5, 2012).

The company said that the lead patient had been implanted for eight and a half years, another four patients for more than seven years, another six for more than six years and three for greater than five years.

Admedus said that the procedures ranged from ventricular septal defects, or hole in the heart, through to complex reconstructions like the Rastelli procedure, illustrating the broad application of Cardiocel in congenital heart defect repairs and reconstructions.

Admedus executive chairman Wayne Paterson said that the data was “a significant progression in the congenital heart surgery market”.

“It is well known that other tissue patches on the market can calcify within 18 months post-implantation in paediatrics, making the results from our long-term Cardiocel study exciting,” Mr Paterson said.

Admedus said the follow-up was “the longest term reported follow up data from a clinical study in congenital defect paediatric patients”.

The company said that the data “confirms a significant competitive advantage between Cardiocel and other products currently used in in the congenital heart surgery market, and illustrates why Cardiocel is a bio-scaffold of choice for surgeons and patients alike”.

“This is very important data as we continue to roll-out Cardiocel globally and push into the adult cardiac and vascular markets,” Mr Paterson said.

“We are confident that we have a best in class product and this data will assist our on-going global sales push,” Mr Paterson said.

Admedus fell half a cent or 1.5 percent to 33.5 cents.

## INVITROCUE

Invitrocue says it has a three-year agreement with Qiagen Suzhou to accelerate the discovery of biomarkers and translational medicine research in China.

Invitrocue said the agreement between its wholly-owned subsidiary Invitrocue Biomedical Service Suzhou and the Suzhou, Jiangsu-based Qiagen Suzhou Translational Medicine Co would see Invitrocue provide three-dimensional cellulosic scaffolding technology and cell-based assay to build in-vitro screening models for Qiagen Suzhou.

The company said that the first contract under the agreement was for an in-vitro cell-based transfection screening model aimed at validating the most effective small interfering RNA (siRNA) sequences using Qiagen's library and transfection reagents.

Invitrocue executive director Dr Steven Fang said that "a strategic partnership with Qiagen Suzhou is a major endorsement of our unique cell-based technology and will be immediately revenue generating".

"By utilizing our cell-based expertise, we look forward to expanding the range of high quality services we provide Qiagen Suzhou," Dr Fang said.

Qiagen Suzhou business development director Dr Wesley Zhang said that "by collaborating with Invitrocue, we could expand our industry leading services for biomarker discovery and translational medicine research".

"We believe that the strategic partnership is a significant milestone in providing our integrated solution approach of precision medicine in work with pharmaceutical and hospital clients," Dr Zhang said.

Invitrocue fell one cent or 10.5 percent to 8.5 cents.

## LIVING CELL

Living Cell says 50 percent-owned joint venture company Diatranz Otsuka will consult with its employees on closing the Invercargill, South Island of New Zealand pig facility.

Last year, Living Cell said it had completed contracts to resume control of the manufacturing of its encapsulated pig choroid NTCcell from Diatranz Otsuka, which would concentrate its research and development on the Diabecell encapsulated pig islets of Langerhans cells in the US and the Invercargill, Southland, South Island pig facility was "surplus to [Diatranz Otsuka's] requirements" (BD: Aug 18, Dec 2, 2015).

Today the company said that its pig breeding facility was in the North Island and its manufacturing facility at Papatoetoe, south of Auckland on the North Island.

The pigs were originally left isolated on Auckland Island, about 500km south of the South Island and removed for environmental reasons.

In 2006, the then Living Cell Technologies' medical director Prof Bob Elliott said: "Located on the Auckland Islands ... for centuries without human contact, the isolation of the ... pigs has kept them free of infections common in other herds" and since 1999, Living Cell bred the pigs in isolation to meet international regulatory guidelines which specify the cleanliness of pig tissue for treating human disease (BD: Aug 15, 2006).

The company said that Diatranz Otsuka had licenced its other 50 percent shareholder Japan's Otsuka Pharmaceutical Factory to use Diabecell in the US and Japan, Otsuka was developing Diabecell in the US and Diatranz Otsuka retained the right to use it in the rest of the world and was no longer carrying out research and development in New Zealand.

Living Cell was up 0.6 cents or 7.4 percent to 8.7 cents.

## MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it will begin cannabinoid skin patch safety trials on human volunteers in late September 2016, with results due by the end of the year.

MGC said that following positive results it would begin efficacy tests for acne, psoriasis and seborrhoea, or oily skin, with the dermatological skin care product line “on-track to be available for purchase in 2017 ... [and a dermatological product]“allows consumers to easily purchase a [cannabinoid]-based skin care product to assist with their condition without requiring a prescription”.

The company said that microbiology tests in Slovenia demonstrated the safety of its cannabinoid skin care ingredients with no adverse reactions.

MGC said it was applying for European Cosmetics Product Notification approval as a dermatological tested cosmetics label in the European Union.

MGC co-founder and managing director Nativ Segev said that “we are on track towards the release of dermatologically tested product for the suffering of psoriasis, acne and seborrhoea conditions”.

MGC fell 0.1 cents or 2.4 percent to 4.1 cents with 6.7 million shares traded.

## ADALTA

The Perth, Western Australia based Yuuwa Capital says it has become a substantial shareholder in Adalta with 54,059,848 shares (54.06%).

Yuuwa and Adalta director and Dimerix executive chairman Dr James Williams said that Yuuwa acquired 41,659,848 shares for \$4,894,454 or 11.75 cents a share, on August 11, 2016 and acquired a further 12,400,00 shares for \$3,100,000 or 25 cents a share in Adalta’s recent \$10 million initial public offer (BD: Aug 22, 2016).

The Sydney-based Platinum Investment Management said it had become substantial in Adalta with 8,000,000 shares (8.00%) in the initial public offer at 25 cents a share, with HSBC Custody nominees (Australia) the registered holder.

Melbourne-based Citycastle Pty Ltd director Leon Serry said his company held 5,311,856 Adalta shares (5.31%), acquiring 3,334,889 shares for \$400,000 or 12.0 cents a share prior to 2010, a further 976,967 shares for \$100,000 or 10.2 cents a share on February 23, 2016 and 1,000,000 shares for \$250,000 in the initial public offer.

Adalta said 49,928,298 shares or 49.93 percent was in escrow, with 26,354,040 shares in voluntary escrow and 23,574,258 shares in ASX escrow.

The company said that the escrow arrangements related to holdings owned by Yuuwa Capital, Citycastle, 3,041,330 shares held by Melbourne’s La Trobe University, 480,235 shares held by chief executive officer Samantha Cobb, 73,273 shares held by chairman Dr Paul MacLeman’s Dalroar Pty Ltd and 361,756 shares held by director Dr John Chiplin. Adalta fell one cent or 3.6 percent to 27 cents.

## GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 62,359,151 shares (13.11%) to 68,843,661 shares (14.48%).

The London and St Peter Port, Guernsey Island-based Crystal Amber Fund said it acquired 6,484,510 shares for \$226,958 or an average price of 3.5 cents a share.

The company’s website said it was listed on London’s Alternative Investment Market.

The Crystal Amber Fund substantial shareholder notice was signed by Kevin Smith and Danny Felbabel as company secretary.

GI Dynamics fell 0.1 cents or 2.8 percent to 3.5 cents.

### NOXOPHARM

DRH Superannuation and David Hannon say they have increased their holding in Noxopharm from 7,566,429 shares (10.07%) to 8,391,429 shares (11.16%).

The Sydney-based DRH Superannuation substantial shareholder notice said that the registered shareholders included its DRH Superfund No2, RAH (STC) Pty Ltd and Mr Hannon, with the 825,000 shares acquired between August 10 and 19, 2016 for \$139,380 or an average price of 16.9 cents a share.

Noxopharm was up one cent or 6.25 percent to 17 cents.

### IQ3 CORP

IQ3 says that Gerardo Incollingo has been appointed company secretary replacing Kelvin Boateng.

IQ3 was untraded at 31 cents.