



# Biotech Daily

Tuesday March 16, 2010

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: LIVING CELL UP 33%; USCOM DOWN 13%**
- \* **ELI LILLY'S \$773m+ FOR ACRUX'S AXIRON TESTOSTERONE TREATMENT**
- \* **BIOGUIDE BRIEF: HERE'S TO ACRUX, ITS INVESTORS & AUSSIE BIOTECH**
- \* **CATHRX REVIEW MOOTS CAPITAL RAISING**
- \* **FLUOROTECHNICS FIRST SWISS SALE**
- \* **OBJ APPOINTS DR KEVIN HAMMOND PARTNERING MANAGER**

## MARKET REPORT

The Australian stock market climbed 0.27 percent on Tuesday March 16, 2010 with the S&P ASX 200 up 13.1 points to 4797.2 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and four were untraded. All three Big Caps were up.

Living Cell was best, up 5.5 cents or 33.3 percent to 22 cents with 1.2 million shares traded, followed by Tissue Therapies up 4.65 percent to 22.5 cents with 210,202 shares traded.

Avexa, Biota and Cellmid climbed more than three percent; Acrux, Chemgenex, Heartware and Nanosonics rose two percent or more; Impedimed, Novogen and Psivida were up more than one percent; with Cochlear, CSL and Resmed up by less than one percent.

Uscom led the falls, down eight cents or 13.3 percent to 52 cents with 11,500 shares traded, followed by Cathrx down eight percent to 23 cents with 22,500 shares traded.

Genetic Technologies lost 4.55 percent; Patrys and Starpharma fell more than three percent; Antisense, Phosphagenics and QRX shed two percent or more; with Genera, Mesoblast, Pharmaxis and Viralytics down one percent or more.

## [ACRUX](#)

Acrux's Axiron deal with the Indianapolis-based Eli Lilly is likely to be worth at least \$US670 million (\$A733 million) including upfront fees, milestones and royalties.

Announcing what may be the biggest Australian biotechnology deal Acrux said it was eligible to receive up to \$US335 million in milestone payments, plus royalties on worldwide sales of its Axiron testosterone replacement treatment.

Acrux chief executive officer Dr Richard Treagus told Biotech Daily his company would receive \$US50 million in upfront fees on signing the exclusive, global deal within 15 days.

"It really sets us up with a great partner," Dr Treagus said. "We're delighted."

"We believe it's quite possibly the biggest single deal for an Australian biotech," Dr Treagus said.

Dr Treagus said his company was focused on US Food and Drug Administration approval and Eli Lilly would work with Acrux to gain registration, which he expected early next year.

Last year Acrux said it expected registration "by the end of 2010" (BD: Sep 29, 2009).

He said that he hadn't traded off royalties for milestone payments.

"Royalties will be at least equal to the upfront fees and milestone payments," he said.

Careful not to disclose confidential details, he agreed that Biotech Daily's "double digit royalty" question was "a good guess".

Dr Treagus said that Acrux was forecasting a profit for 2009-'10 of \$44 million to \$48 million and there was an intention to pay a dividend, this year.

He said Eli Lilly had "a vision for men's health" that made it an excellent partner for Acrux's testosterone treatment.

Dr Treagus said sales of Eli Lilly's erectile dysfunction treatment Cialis rivaled Pfizer's Viagra.

In a media release, Acrux said Cialis sales were \$US1.6 billion in 2009.

Acrux said it was "firmly on the path of becoming the first Australian biotech company to introduce a number of therapeutic products into global pharmaceutical markets".

Acrux's chairman Ross Dobinson paid tribute to the confidence that shareholders had shown in Acrux's ability to commercialize its innovative product range.

"The Axiron licencing agreement with Eli Lilly, believed to be the largest licensing deal ever struck by an Australian biotech company, validates the commitment and support shown by Acrux's stakeholders, including our State and Federal Governments, over many years," Mr Dobinson said.

"Acrux was founded as a spin-off from Monash University a decade ago and can now anticipate profitability, dividends and a suite of products in global pharmaceutical markets," Mr Dobinson said.

Acrux said Eli Lilly had considerable commercial strength worldwide, with products distributed in 143 countries.

Acrux has a partnership with Eli Lilly's animal health division, Elanco. A marketing application for the first veterinary product using Acrux's technology was submitted to the FDA in late 2008 and Acrux expects the FDA's review "in the near future".

The deal provides substantial financial returns to Acrux, vindicating the \$23 million investment made by shareholders in 2007 to fund the phase III development of Axiron.

Acrux will receive an up-front payment of \$US50 million, \$US3 million on the transfer of manufacturing assets, \$US87 million on the issue of a marketing authorization by the FDA and up to \$US195 million in potential commercialization milestones, as well as royalty payments on future global sales of Axiron.

Acrux said it expected no deduction of foreign withholding tax from any of the deal payments and that any tax liability on the initial \$US50 million would not be significant, due to the use of past tax losses, but a third-party royalty of \$1.9 million would be payable.

Acrux said its first profit would recover the majority of its accumulated losses since inception.

Acrux said that pending FDA approval of Axiron and the receipt of the associated payment from Eli Lilly, it intended to pay dividends to shareholders from 2011.

Acrux said it was a pooled development fund with a range of tax exemptions.

Dr Treagus told Biotech Daily that Acrux had a number of compounds in development and the upfront fee would provide “an opportunity to evaluate which to advance or accelerate”.

Acrux climbed to \$2.60 but closed up five cents or 2.1 percent at \$2.43 with 2.9 million shares traded.

### [MARC SINATRA'S BIOGUIDE BRIEF: ACRUX](#)

Finally, after the Progen saga, Avexa's phase III apricitabine results, the FDA's analysis of Chemgenex's Omapro data, Novogen pulling its phase III trial of phenoxodial, CBio's disastrous float and a raft of other news that isn't at the front of my mind right now, I finally get to look to at something that is positive for biotech.

Today, Acrux announced a deal with Eli Lilly for Axiron, a treatment for men's testosterone insufficiency, with a headline value of \$US335 million.

The deal includes a \$US50 million upfront fee, \$US3 million on transfer of manufacturing assets, \$US87 million on marketing clearance and up to \$US195 million in further milestone payments.

On top of that, as usual, there will be royalties payable to Acrux on Axiron sales. The royalty rate is confidential, but expect something in the neighborhood of 10-15 percent of sales.

For Australian biotech, the best part of the deal is that it eclipses Cytopia's 2006 JAK3 deal with Novartis which had a headline value of \$US214.5 million, but only a \$US9.5 million upfront fee, given its much earlier stage and, consequently, higher risk.

The best part of the deal for Acrux shareholders is that having completed phase III trials, the Axiron project is low risk, as far as biotechnology is concerned and that the milestone and royalty payments that were largely pie-in-the sky in the Cytopia deal, are highly likely to be received in Acrux's deal.

Acrux's technology is solid, the successful use of testosterone to treat male testosterone insufficiency well-supported in the literature and market, not surprisingly. Axiron clinical trial results have been excellent and the method of application it employs clearly superior to the current crop of very messy and transference-prone products on the market.

This is an excellent day for Acrux, its shareholders and Australian biotechnology.

Now, if only Chemgenex can get a positive recommendation from the FDA's oncologic drugs advisory committee, which is due to discuss Chemgenex's Omapro data on March 22, we could be in for some very good times.

The biotechnology window may open, again, and we will all be thankful for that.

## [CATHRX](#)

Cathrx says its sales shortfall has affected cash flow and “indicated the need to raise additional capital” to execute its new business plan.

The company avoided announcing a capital raising but said “all shareholders [should] be given the opportunity to participate ... to protect themselves from potential dilution”.

In a report to shareholders from chairman Denis Hanley, Cathrx said that in late 2009, with manufacturing scale-up underway, sales growth was permanently falling behind published projections.

The company said distributors were asking for changes to many of the products to help them achieve their sales objectives.

Cathrx said that although the product platform could accommodate the changes, it was not possible to continue producing product in volume while changing product designs.

The company said it decided to undertake a thorough review of its sales strategy and its product offering.

Mr Denis Hanley said the company’s chief financial officer Amanda Wong and all of the research and development operations staff “modeled every alternative sales growth plan together with its cash flow implications”.

That information together with a review of segmental trends in the market place was reviewed and a number of decisions made, the company said.

Cathrx said it would appoint a new chief executive officer with more experience in the industry and with a deeper understanding of the sales and marketing task.

The company said it would focus its “demonstrated skills on the development of new product features and benefits for the growing market for re-processable products and reduce the financial and environmental cost of cardiac catheter procedures”.

Mr Hanley told Biotech Daily that his company’s catheters could be separated into their component parts, cleaned, sterilized and tested before being re-used.

Cathrx said in its media release that it would “seek to form partnerships with organizations who understand the service market for reprocessed product where Cathrx provides the product design and manufacture and where our partner provides the reprocessing service for the market”.

The company said it would continue to work on advanced ablation products for the treatment of atrial fibrillation.

Cathrx said many European hospitals were trying to recycle current single-use products, but there were “obvious limitations to doing this”.

Cathrx said no other company was developing product specifically designed for reprocessing.

In the media release Mr Hanley said the sales shortfall significantly affected the company’s cash flow and indicated the need to raise additional capital to execute the new plan, but all shareholders should be given the opportunity to participate to protect themselves from potential dilution.

“Your board and I share your frustration that this has become necessary,” Mr Hanley said. “As you are no doubt aware your directors have all invested in our company personally,” he said.

“Over \$50 million has been spent on the development of our patented product platform, but, in the scheme of things this is not an unreasonable cost to have achieved what we have achieved,” Mr Hanley said.

“So while it is frustrating that the execution of our first attempt at a sales plan was not successful, the opportunity has not diminished.

Indeed with this new segmentation plan it may have grown.

Cathrx fell two cents or eight percent to 23 cents.

## FLUOROTECHNICS

Fluorotechnics says its Gelcompany has made the first sale of its high performance electrophoresis flat-top tower system into Switzerland.

The buyer is the vice-dean of the faculty of medicine at Switzerland's Geneva University and University Hospital Prof Denis Hochstrasser.

Fluorotechnics said Prof Hochstrasser was one of the world's leading proteomics scientists and also on the board of the Human Proteome Organisation Council.

Prof Hochstrasser said he had been "waiting 20 years for an electrophoresis system like this".

"Never have I seen a system that is so reproducible, robust and easy to use," Prof Hochstrasser said.

"The results are outstanding and will offer new opportunities for the use of [two dimensional] electrophoresis," he said.

Fluorotechnics and Gelcompany chief executive officer James Walker said the Swiss debut with Prof Hochstrasser would help bring more sales.

"This endorsement from Prof Hochstrasser is an enormous boost in marketing the product to other proteomics service providers," Mr Walker said.

Fluorotechnics was untraded at 31 cents.

## OBJ

OBJ has appointed Dr Kevin Hammond as the company's partnering manager.

OBJ said Dr Hammond had more than 30 years experience with leading pharmaceutical and cosmetic companies.

Dr Hammond holds a PhD in physical biochemistry, a BSc in biochemistry and is a member of the editorial board of the International Journal of Cosmetic Science.

OBJ was up half a cent or 8.5 percent to 6.4 cents with 86.5 million shares traded.