



# Biotech Daily

Thursday November 28, 2013

*Daily news on ASX-listed biotechnology companies*

- \* ASX FLAT, BIOTECH DOWN: MEDICAL DEVEL UP 9%, PHYLOGICA DOWN 15%
- \* SAFETY BOARD APPROVES ALCHEMIA PHASE III HA-IRINOTECAN TRIAL
- \* ALCHEMIA FONDAPARINUX PROFIT SHARE UP DESPITE SALES FALL
- \* NEUREN \$2m SHARE PLAN TAKES RAISING TO \$23.5m
- \* INSTITUT CURIE TO USE IMPEDIMED L-DEX IN CANCER TRIAL
- \* ELI LILLY LAUNCHES ACRUX'S AXIRON IN BRAZIL
- \* CYNATA RETURNS TO ASX FROM ECO QUEST TOMORROW
- \* OBJ FILES 3<sup>rd</sup> MAGNETIC TRANSDERMAL PATENT APPLICATION
- \* PERTH'S CORNERSTONE HOPES TO SAVE BONE
- \* PROGEN LOSES REMUNERATION VOTE – 71% AGAINST
- \* PHARMAXIS AGM FACES 16% DISSENT AGAINST REMUNERATION
- \* UP TO 19% OPPOSE AVEXA REMUNERATION REPORT
- \* QUIXOTE, MYER FAMILY, ASIA UNION, DILUTED IN COGSTATE
- \* GENETIC TECHNOLOGIES DIRECTOR BENJAMIN SILLUZIO WITHDRAWS
- \* ADRIAN BOWERS REPLACES RESONANCE CO SEC NAOMI HAYDARI

## MARKET REPORT

The Australian stock market edged up 0.03 percent on Thursday November 28, 2013 with the S&P ASX 200 up 1.4 points to 5,334.3 points. Ten Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and five were untraded. All three Big Caps were up.

Medical Developments was best, up 11.5 cents or 9.35 percent to \$1.345 with 24,491 shares traded. Antisense climbed 6.25 percent; Living Cell was up 4.8 percent; Acrux, Benitec and Cellmid rose more than two percent; with Cochlear and Mesoblast up more than one percent.

Phylogica led the falls, down 0.3 cents or 15.0 percent to 1.7 cents with 2.6 million shares traded. Patrys lost 8.9 percent; Impedimed and Neuren fell more than seven percent; Atcor was down 5.6 percent; Genetic Technologies and Osprey fell more than four percent; Admedus, Anteo and QRX were down more than three percent; Avita and Tissue Therapies shed two percent or more; with Bionomics, Psivida and Viralytics down more than one percent.

## ALCHEMIA

Alchemia says the data safety monitoring board has approved continuing its 415-patient phase III trial of HA-irinotecan for metastatic colorectal cancer.

Alchemia said that following a review of all patients in pivotal trial, who had been randomized to receive either HA-irinotecan or irinotecan, as part of the 5-fluorouracil, leucovorin and irinotecan (FOLFIRI) regimen, the data safety monitoring board recommended the trial continue as planned, given there was no evidence of safety concerns for the patients.

Alchemia chief scientific officer Prof Tracey Brown said the board's "fourth recommendation to continue our phase III clinical trial of HA-irinotecan represents the achievement of another important milestone in the progress of this pivotal trial".

"The independent [data safety monitoring board] reviewed data generated from the administration of over 4,500 chemotherapy treatments and it is reassuring to know that we can continue treating patients safely".

Alchemia said that trial results were expected by July 2014.

Alchemia fell half a cent or 0.8 percent to 59.5 cents.

## ALCHEMIA

Alchemia's profit share for generic fondaparinux sales for the three months to September 30, 2013 was up 70.8 percent to \$2.46 million despite a 19.75 percent fall in net sales.

Alchemia said its profit share of sales was \$A3.0 million (\$US2.75 million) for the period but would receive \$2.46 million (\$US2.25 million) following its contribution of \$540,000 (\$US500,000) towards yield and cost of goods improvement activities.

The company said the contributions to Dr Reddy's would cease at December 31, 2014.

For the three months to September 30, 2012 Alchemia received \$1.44 million on net sales of \$US12 million (BD: Nov 22, 2012).

Today, Alchemia said that net sales fell 19.75 percent to \$US9.63 million.

Alchemia chief executive officer Charles Walker told Biotech Daily that the profit share for the three months to September 30, 2012 was "lower due to the ramp-up of fondaparinux sales, so this time the profit share was up despite a small fall in net sales revenue".

The company said that the September profit share brought the total profit share for the 12 months to September 30, 2013 to \$10.51 million.

Alchemia said "the quarter's gains in market share when compared with those for the last quarter were off-set by adjustments made to provide for anticipated Medicaid rebates, lower average pricing arising from comparatively more products being sold to the non-retail sector during the quarter and some incremental competitive pressure".

The company said the sales revenue performance followed "record results achieved in the June quarter and reflects continued competitiveness and commercial progress in the US market by partner Dr Reddy's".

Alchemia said that Dr Reddy's increased its market share by 6 percent to 13 percent in the institutional sector while maintaining its leadership position with 51 percent in the retail sector, increasing its total market share by volume to 30 percent from 27 percent in the three months to June 30, 2013.

The company said that Dr Reddy's had reduced the costs of manufacture and sales of fondaparinux.

Alchemia said Dr Reddy's expects EU approval for fondaparinux in late 2014 or early 2015, following a planned resubmission of its application.

### NEUREN PHARMACEUTICALS

Neuren says its share plan has raised \$2 million of a hoped for \$3 million through the issue of about 17.6 million shares at 11.5 cents a share.

In October, Neuren said it had raised \$21.5 million in a placement to professional and sophisticated investors at 11.5 cents a share and would offer a shareholder plan capped at \$3 million (BD: Oct 22, 2013).

Neuren fell one cent or 7.4 percent to 12.5 cents with 10.0 million shares traded.

### IMPEDIMED

Impedimed says that the Paris, France-based Institut Curie will use its L-Dex lymphoedema diagnostic in an 800-patient prospective, multi-centre, clinical trial.

Impedimed said that Institut Curie was "one of Europe's leading oncology research centres" and the five-year, randomized, controlled trial would take place at five centres in France to study early detection and treatment of lymphoedema related to breast cancer.

The company said that the study would follow 800 women for two years with L-Dex as the primary measurement criteria, with patients measured before cancer treatment and every four to six months, up to 24 months post-treatment.

Impedimed said that it was "the first major trial in the field of the prevention of lymphoedema following the treatment of breast cancer in France" and a first step in changing clinical practice in France to one of a pre-emptive care model for lymphoedema. The company said the trial results could be expected to have a similar impact around the world.

Impedimed chief executive officer Richard Carreon said the company was "pleased that Institut Curie selected L-Dex for this very important clinical trial".

"This marks a critical step in the expansion of L-Dex into Europe and the continued journey of making L-Dex the standard of care for all cancer patients at risk for lymphoedema," Mr Carreon said.

Impedimed fell two cents or 7.1 percent to 26 cents.

### ACRUX

Acrux says Eli Lilly is distributing its Axiron testosterone replacement therapy in Brazil for men hypogonadism or a deficiency or absence of endogenous testosterone.

Acrux said the product was called Axeron in Brazil.

Acrux executive chairman Ross Dobinson said the company was "pleased that Lilly has achieved another milestone in the international commercialization of Axiron, which is already available to patients in the United States, Australia and Canada and which also recently received approval in Germany".

Acrux was up six cents or 2.45 percent to \$2.51 with 1.3 million shares traded.

### CYNATA THERAPEUTICS (FORMERLY ECO QUEST)

The ASX says that Cynata will be reinstated to official quotation from the start of trading on November 29, 2013, following compliance with the listing rules.

The ASX said that 44,906,701 shares were available for trading under the code CYP and 11,164,701 quoted options exercisable at 20 cents by December 31, 2014 would trade under the code CYPO.

Cynata last traded at a pre-consolidation 2.5 cents.

## OBJ

OBJ says it has lodged an Australian provisional patent application entitled 'Method and Apparatus for Increased Partitioning of Agents into the Stratum Corneum'.

OBJ said the application was lodged by wholly-owned subsidiary, International Scientific Pty Ltd for its third a magnetic-enhanced delivery technology known as 'Enhanced Partitioning and Penetration System' which used synchronized time varying magnetic fields in unison with micro-vibrational energy to increase the rate of ingredient partitioning from a formulation and increased diffusion into the upper skin layers, or the stratum corneum, that were the primary target for cosmetic and skin care products.

OBJ said its E-Skin patent had been lodged internationally as a final specification under the Patent Cooperation Treaty.

OBJ was up 0.3 cents or 12.5 percent to 2.7 cents with 21.4 million shares traded.

## BONE MEDICAL

Perth-based investment and corporate services company Cornerstone Corporate expects to recapitalize Bone Medical and pay off its La Jolla Cove draw-down equity facility.

Bone was attempting to commercialize oral peptides for osteoporosis and arthritis.

Bone said that there would be an internal debt-to-equity restructure with a majority of the company's creditors, settlement and termination of the La Jolla Cove agreement, a \$200,000 bridge-funding through unsecured converting loans provided by investors introduced by Cornerstone, a capital raising through the issue of 8,750,000,000 shares at 0.04 cents a share to raise up to \$3,500,000, the appointment of Cornerstone managing director Robert Towner as chairman and a 50-to-one consolidation at the completion of the consolidation, subject to shareholder approval.

Mr Towner was formerly a director of Biomed which developed the Adept process bovine cardiac patch, now called Cardiocel, which merged with Allied Medical to become Allied Health and now named Admedus.

Bone said that Cornerstone would act as lead manager to the placement.

The company said that existing directors, management and certain service providers had agreed to remove more than \$1.8 million in unpaid fees owed for past services from the balance sheet through debt conversion or waiving payment, with about \$1 million to be written-off.

The company said that about \$500,000 in outstanding debt owed to La Jolla Cove would be waived in exchange for the issue of shares under a settlement and release agreement and the debt would be reduced to \$US219,000 by the issue of shares.

Bone said that La Jolla agreed to provide \$US80,000 in bridge financing, with any amount drawn down repayable from the first funds received under the placement, together with a payment equal to 25 percent of the amount drawn down.

Bone said that co-founder and technology inventor Dr Roger New would step down as chairman on completion of the recapitalization but continue as a director and chief scientific officer.

The company said it planned to seek shareholder approvals for the recapitalization plan in January 2014.

Bone said the company's major shareholders were Dr New's Proxima Concepts Ltd and its subsidiary, Proxima Laboratory and Research Services, which held 20.58 percent of the company and would vote in favor of the arrangement.

Bone was up 0.1 cents or 100 percent to 0.2 cents with 20.1 million shares traded.

## PROGEN PHARMACEUTICALS

Progen's remuneration report was defeated with 22,376,117 votes (71.4%) against, providing the first trigger for a potential board spill at the next annual general meeting. Progen said that 8,942,016 votes (28.6%) supported the remuneration report.

The Corporations Act (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.

The company's most recent Appendix 3B new issue announcement said that Progen had 55,285,315 shares on issue, meaning that the votes against the remuneration report amounted to 40.5 percent of the company, sufficient to requisition extraordinary general meetings.

Yesterday, chairman Stuart James withdrew his bid for re-election as a director and the company did not publish the proxy voting on the withdrawn resolution (BD: Nov 27, 2013). The re-election of director Jitto Arulampalam, the ratification of previous stock issues and the issue of options to directors and employees were all passed overwhelmingly. Progen was up two cents or 10.5 percent to 21 cents.

## PHARMAXIS

Pharmaxis faced modest dissent against its remuneration report with 8,415,789 votes against (16.3%) and 43,085,823 votes in favor (83.7%).

Pharmaxis' most recent Appendix 3B share issue announcement said there were 309,017,869 shares on issue, meaning that the strongest opposition came from 2.7 percent of shares on issue, not sufficient to requisition extraordinary general meetings. Resolutions re-electing chairman Malcolm McComas and granting performance rights to chief executive officer Gary Phillips were supported by more than 90 percent of votes. Pharmaxis was unchanged at 11 cents.

## AVEXA

Avexa faced dissent against its remuneration report with 44,030,284 votes against (19.3%) and 184,379,418 votes in favor (80.7%).

Avexa's most recent Appendix 3B share issue announcement said there were 847,688,779 shares on issue, meaning that the strongest opposition came from 5.2 percent of all shares on issue, sufficient to requisition extraordinary general meetings. A resolution to re-elect director Allan Tan was opposed by 37.1 million votes and supported by 199.1 million votes.

Avexa was unchanged at 1.3 cents.

## COGSTATE

Quixote Investment of Portland Oregon has been diluted in Cogstate from 12,961,831 shares or 17.37 percent to 14.75 percent, following a \$7.55 million capital raising. Earlier this month, Cogstate said it would raise \$3.5 million in a placement and raise a \$4.05 million in a rights issue, all at 37 cents a share (BD: Nov 19, 2013).

In 2011, Cogstate acquired Axon Sports, whose founding partners, Quixote Investment principals Rudy Chapa and Patricia Eiting would retained their positions as Axon directors and Mr Chapa was appointed as a Cogstate director (BD: Aug 22, 2011).

Cogstate was untraded at 36 cents.

### COGSTATE

Melbourne's Myer family has increased its holding in Cogstate from 13,938,868 shares to 15,549,523 shares but has been diluted from 18.68 percent to 17.69 percent.

The substantial shareholder notice said that Myer & Myer Pty Ltd, Myer Investments Pty Ltd, Max Myer, Edwina Myer, Lucy Myer and Martyn Myer bought shares, exercised options and transferred shares between August 24, 2011 and November 20, 2013.

### COGSTATE

Asia Union Investments says it has increased its holding in Cogstate from 6,937,171 shares to 7,472,928 shares but has been diluted from 10.42 percent to 8.50 percent. The Sydney-based Asia Union substantial shareholder notice said that between March 2011 and July 2012 it bought 535,757 shares for \$130,382 or an average price of 24.3 cents a share.

### GENETIC TECHNOLOGIES

Genetic Technologies says director Benjamin Silluzio has withdrawn his re-election nomination from tomorrow's annual general meeting.

Genetic Technologies said that Mr Silluzio withdrew his nomination "due to a number of commitments with other public companies ... [and] he no longer has sufficient time available to continue in his role as a director".

RBS Morgans family office managing partner, Mr Silluzio was appointed a director in December 2012 after a vote against the election of chairman Mel Bridges and director Huw Jones at the 2012 annual general meeting and the subsequent resignation of then chief executive officer Dr Paul MacLeman and the company's head of legal and corporate Dr David Sparling (BD: Nov 27, 28; Dec 10, 2012).

Genetic Technologies fell 0.3 cents or 4.7 percent to 6.1 cents.

### RESONANCE HEALTH

Resonance says that Adrian Bowers has been appointed chief financial officer and company secretary replacing company secretary Naomi Haydari.

Resonance said that Ms Haydari resigned to begin annual leave and parental leave. The company said that Mr Bowers held a Bachelor of Business degree and his appointment was effective immediately.

Resonance was unchanged at 3.1 cents with 7.5 million shares traded.