



Biotech Daily

Friday September 12, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: CLINUVEL UP 12%, PRANA DOWN 5%**
- * **WEHI DISCOVERS CARTILAGE ROLE IN RHEUMATOID ARTHRITIS**
- * **PRIME MINISTER ABBOTT OPENS DOHERTY INSTITUTE**
- * **OCTOBER FOR ALCHEMIA PHASE III HA-IRINOTECAN CANCER RESULTS**
- * **RETROPHIN TAKES 8% OF TARGET CLINUVEL IN TINY TRADES**
- * **CSL \$3m CEO OPTIONS, RIGHTS; 20% DIRECTORS FEES HIKE AGM**
- * **COCHLEAR \$1.6m DR CHRIS ROBERTS STOCK, \$500k PROF BYRNE AGM**
- * **CB CO, CURRAN SUPER FUND REDUCES TO 13% OF ATCOR**
- * **SIMAVITA LOSES CHAIRMAN PETER COOK**
- * **ACTINOGEN APPOINTS VINCENT RUFFLES CLINICAL RESEARCH HEAD**

MARKET REPORT

The Australian stock market fell 0.27 percent on Friday September 12, 2014 with the S&P ASX 200 down 15.0 points to 5,531.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and seven were untraded.

Clinuvel was the best, up 39 cents or 11.8 percent to \$3.69 with 201,729 shares traded.

Bionomics, Circadian and Universal Biosensors climbed more than five percent; Biotron was up 4.55 percent; Atcor and Nanosonics were up more than three percent; Benitec, Prima and Tissue Therapies rose more than two percent; Neuren and Resmed were up more than one percent; with Mesoblast up 0.8 percent.

Prana led the falls, down 1.5 cents or 5.45 percent to 26 cents with 828,636 shares traded.

Admedus, Anteo, Antisense, GI Dynamics, Impedimed, Oncosil and Phosphagenics lost more than three percent; Acrux, Analytica and Psivida shed more than two percent; Alchemia and Cochlear fell more than one percent; with CSL and Sirtex down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that cartilage plays an active role in the destruction and remodelling of joints seen in rheumatoid arthritis.

The Institute said that rather than being an 'innocent bystander' as previously thought, Dr Tommy Liu, Prof Ian Wicks, Dr Kate Lawler, Dr Ben Croker and their colleagues made the discovery that "cartilage participates in the production of inflammation-signalling chemicals and contributes to its own destruction" while investigating the role of the protein SOCS3 in controlling inflammation during rheumatoid arthritis.

The study, entitled 'Key Role of Suppressor of Cytokine Signaling 3 in Regulating gp130 Cytokine-Induced Signaling and Limiting Chondrocyte Responses During Murine Inflammatory Arthritis' was published in the journal *Arthritis and Rheumatology* and an abstract is at <http://onlinelibrary.wiley.com/doi/10.1002/art.38701/abstract>.

The Institute said that over time, rheumatoid arthritis could destroy the cartilage that lubricates and cushions the joints, while bones can be remodelled, leading to disfigurement, pain and reduced mobility.

Dr Liu said cartilage was previously thought to be a victim of an over-zealous immune system rather than playing an active role in rheumatoid arthritis.

"Autoimmune diseases such as rheumatoid arthritis are the result of the immune system wrongly attacking normal, healthy tissue," Dr Liu said.

"Our study has shown for the first time that cartilage participates in the production of inflammation-signalling chemicals and contributes to its own destruction," Dr Liu said.

WEHI said that the study investigated how the suppressors of cytokine signalling (SOCS) molecules that controlled the flow of chemical messages within and between cells regulated inflammation in rheumatoid arthritis.

The Institute said that when the researchers created a model that lacked SOCS3 molecules in the cartilage, they found that tissue degradation increased.

"Without SOCS3, cartilage cells produced enzymes that drove tissue degradation and increased inflammation by releasing signalling molecules that triggered an increased autoimmune response," Dr Liu said. "We also found that cartilage could produce a protein called RANKL that triggers bone remodeling."

"These results show that cartilage is not an innocent bystander that gets damaged as a result of rheumatoid arthritis, but instead plays an active role in disease progression," Dr Liu said. "Targeting the action of these inflammatory chemical messages could boost the efficacy of current treatments."

THE DOHERTY INSTITUTE

Prime Minister Tony Abbott formally opened Melbourne's Doherty Institute in the Parkville biomedical precinct today (BD: Feb 11, 2014).

A media release from the University of Melbourne said the Institute was named for Nobel Laureate Prof Peter Doherty and was a \$210 million partnership between the University and the Royal Melbourne Hospital and funded by the Federal and Victoria Governments.

The media release said that 10-storey, state-of-the-art building would house more than 700 health professionals "developing new ways to track, diagnose, treat and prevent the world's most significant infectious diseases".

The University said the Doherty Institute would focus on diseases that posed public health threats such as HIV, viral hepatitis, influenza, tuberculosis and drug-resistant bacteria.

Institute director Prof Sharon Lewin said the establishment of the Doherty Institute was "a bold and ambitious move that will transform infectious diseases research, training and care in the Australian, regional and global health communities".

ALCHEMIA

Alchemia says it is finalizing the database for the pivotal phase III trial of HA-irinotecan in metastatic colorectal cancer and it expects to report top-line results in October 2014.

Alchemia said that data query resolution and data verification were almost complete which would enable the locking of the database and the initiation of data analysis.

The company said that the timing of regulatory submissions to the US Food and Drug Administration and the European Medicines Agency for approval of HA-irinotecan were unchanged and expected by July 2015.

Alchemia chief executive officer Thomas Liquard said the company was “on the verge of performing the primary endpoint analysis ... [and] while we had expected to be in a position to report our results by the end of September, this will take slightly longer than expected”.

Alchemia chief scientific officer Dr Tracey Brown said that highest priority was “the careful execution of this process to support the preparation of a regulatory dossier that will maximize the chances of obtaining a timely drug approval”.

Alchemia said the 415-patient phase III trial of HA-irinotecan for metastatic colorectal cancer randomized its first patient in December 2011 and recruited the last patient in February 2013 and had completed four safety reviews by the data safety monitoring board.

Alchemia fell one cent or 1.6 percent to 62 cents.

CLINUVEL PHARMACEUTICALS

The New York-based Retrophin has increased its substantial holding in potential takeover target Clinuvel from 2,839,033 shares (6.70%) to 3,309,356 shares (7.79%).

Retrophin said it bought the 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.

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

In July, Retrophin offered up to \$95 million “through a share swap worth about \$2.14 a share or \$2.17 in cash per share.

On the day Clinuvel made the announcement of the July 17 offer, the company climbed 49.5 cents or 29.4 percent from \$1.685 to \$2.18 with 313,734 shares traded.

At that time, Clinuvel said that the offer was unsolicited and advised shareholders “to take no action” while it evaluated the proposal which was subject to numerous conditions and later said the “proposal materially undervalues Clinuvel”.

Clinuvel was up 39 cents or 11.8 percent to \$3.69.

ATCOR MEDICAL

CB Co Pty Ltd for the Curran Superannuation Fund has reduced its substantial shareholding in Atcor from 22,332,347 shares (14.18%) to 20,632,347 shares (12.97%).

The substantial shareholder notice said that the 1,700,000 shares were sold off-market for \$153,000 or 9.0 cents a share.

In March, CB Co said it acquired 3,332,347 shares off-market for \$448,817 or 13.5 cents a share (BD: Mar 10, 2014).

The Sydney-based CB Co said that it acted for the Curran Superannuation Fund, which was associated with Capital Investment director Charles Paul Curran.

Atcor was up 0.3 cents or 3.3 percent to 9.3 cents.

CSL

CSL will vote to grant chief executive officer Paul Perreault up to \$US2,932,500 (\$A3,226,044) in performance stock and increase directors fees to \$3,000,000.

CSL's notice of annual general meeting said it would seek shareholder approval to grant Mr Perreault up to \$US1,020,000 in performance options, exercisable at the five-day volume weighted average price to September 30, 2014 by September 30, 2019 and up to \$US1,912,500 in "performance rights" exercisable at no cost by September 30, 2019, with both pending specified performance hurdles.

The company said it proposed to increase the total remuneration pool for directors by 20 percent from \$2,500,000 to \$3,000,000.

CSL said shareholders would vote on the re-election of directors Prof John Shine, Christine O'Reilly and Bruce Brook.

The meeting will be held at the National Tennis Centre, Melbourne Park, Batman Avenue, Melbourne on October 15, 2014 at 10am (AEDT).

CSL fell 44 cents or 0.6 percent to \$73.36 with 937,233 shares traded.

COCHLEAR

Cochlear will vote to grant chief executive officer Dr Chris Roberts up to \$1,625,509 in performance rights and options and pay Prof Edward Byrne a retirement allowance of up to \$500,000.

Cochlear said that non-executive director Prof Byrne was entitled to \$421,719 in retirement allowance at June 30, 2014, but the final total would depend on the date Prof Byrne retired and interest accrued.

Cochlear chief financial officer Neville Mitchell told Biotech Daily that a resolution requesting a temporary \$500,000 increase in directors' remuneration was to cover Prof Byrne's retirement allowance.

Cochlear detailed a combination of long term and short term options and performance rights for Dr Roberts, pending specified performance hurdles.

The company said shareholders would be asked to vote to approve the issue of up to 11,821 long term incentive performance rights worth \$61.33 each and 60,771 long term options worth \$11.93 each, exercisable at \$68.56 each, with a total value of \$1,450,000

Cochlear said shareholders would be asked to vote to approve the issue of up to 2,781 short term incentive performance rights worth \$63.11 each, being 30 percent of the 2013-'14 short term incentive payment of \$585,055.

Cochlear's notice of meeting said shareholders would vote on the re-election of directors Roderic Holliday-Smith and Andrew Denver.

The meeting will be held at the ASX, Exchange Square Auditorium, 20 Bridge Street, Sydney on October 14, 2014 at 10am (AEDT).

Cochlear fell \$1.10 or 1.5 percent to \$66.99 with 493,769 shares traded.

SIMAVITA

Simavita says that chairman Peter Cook has resigned as a director effective immediately, with Ari Bergman appointed as acting chairman.

Simavita said that Mr Cook was appointed a director on November 20, 2013 and chairman on January 31, 2014.

The company said it would appoint a suitable replacement as part of a process of recruitment of additional non-executive directors.

Simavita fell two cents or 3.6 percent to 54 cents.

ACTINOGEN

Actinogen says it has appointed Vincent Ruffles clinical research vice-president, responsible for strategy, scientific and regulatory oversight of UE2343 clinical programs. In August, Actinogen said it will acquire the Edinburgh, Scotland-based Corticrine to develop its UE2343 for Alzheimer's disease (BD: Aug 27, 2014).

Today Actinogen said that Mr Ruffles had nearly 20 years of experience in the pharmaceutical and biotechnology industries working across all phases of the drug development cycle, beginning in the UK at Hoechst-Roussel, now Sanofi, and later in Geneva, Switzerland for Serono, now Merck Serono, followed by Procter & Gamble and Amgen.

The company said that Mr Ruffles had "worked across several blockbuster drugs taking them through clinical development" and had extensive experience in Alzheimer's disease and related therapeutic areas.

Actinogen said that as part of his remuneration package Mr Ruffles would be issued 2,000,000 loan plan shares at an issue price of two cents each, to vest in three years from the date of commencement of employment, subject to shareholder approval.

Actinogen fell 0.1 cents or 2.1 percent to 4.7 cents.