



Biotech Daily

Friday April 8, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: CELLMID UP 18%; BIOTRON DOWN 6%**
- * **NOMINATIONS FOR \$750k PRIME MINISTER'S SCIENCE PRIZES**
- * **ADMEDUS EXTENDS CORONEO DISTRIBUTION TO AUSTRALIA, NZ**
- * **ORTHOCELL 'DEAL READY, POSITIONED FOR GROWTH' ROADSHOW**
- * **CYCLOPHARM POTENTIAL 2nd STRIKE BOARD SPILL AGM**
- * **CELLMID ESTABLISHES MIDKINE LYRAMID, KINERA SUBSIDIARIES**
- * **3D COMPLETES MACH7 MERGER; NAME CHANGE, ASX CODE COMING**
- * **ONCOSIL RESCHEDULES 24m LOAN SHARES EGM**
- * **FLINDERSFERTILITY BACKS REPRODUCTIVE HEALTH ON FACEBOOK**
- * **OTSUKA DILUTED TO 5% IN LIVING CELL**
- * **BIO-MELBOURNE BREAKFASTS ON SCALE-UP AT CSIRO CLAYTON**

MARKET REPORT

The Australian stock market fell 0.53 percent on Friday April 8, 2016 with the ASX200 down 26.5 points to 4,937.6 points.

Fourteen of the Biotech Daily Top 40 Index companies were up, 14 fell, 10 traded unchanged and two were untraded.

Cellmid was the best, up 0.3 cents or 17.65 percent to two cents with 4.4 million shares traded. Avita climbed 8.3 percent; Prana was up 6.15 percent; Pro Medicus rose 5.7 percent; Prima was up 4.9 percent; Clinuvel climbed 3.3 percent; Nanosonics, Starpharma, Tissue Therapies and Uscom rose more than two percent; Bionomics, Ellex, Living Cell and Polynovo were up more than one percent; with Cochlear up 0.1 percent.

Biotron led the falls, down 0.4 cents or 6.25 percent to six cents with 734,663 shares traded. Airxpanders, Benitec and Orthocell fell more than four percent; Acrux and Viralytics lost more than three percent; Admedus, Atcor and Impedimed shed more than two percent; Anteo, Medical Developments and Universal Biosensors were down more than one percent; with CSL, Resmed, Reva and Sirtex down by less than one percent.

FEDERAL GOVERNMENT, OFFICE OF THE CHIEF SCIENTIST

Australia's chief scientist Dr Alan Finkel has called for nominations for the \$750,000 Prime Minister's Prizes for Science, which close on April 28, 2016.

A media release from the chief scientist's office said that Dr Finkel would chair the selection committee and the prizes have been extended to include a \$250,000 Prime Minister's Prize for Innovation as well as the \$250,000 Prime Minister's Prize for Science, reduced from the previous award of \$300,000, as well as the \$50,000 Prize for New Innovators.

"As chief scientist, I am encouraged every day by the science stories I hear," Dr Finkel said.

"The depth and breadth of our science community is extraordinary, and its contribution to our nation is profound," Dr Finkel said.

"The prizes celebrate the teachers, researchers and entrepreneurs who show us just how exciting our future might be, with the winners receiving substantial prize money," Dr Finkel said.

The awards include four prizes valued at \$50,000 each, the Frank Fenner Prize for Life Scientist of the Year; the Malcolm McIntosh Prize for Physical Scientist of the Year; the Prime Minister's Prize for Excellence in Science Teaching in Primary Schools; and the Prime Minister's Prize for Excellence in Science Teaching in Secondary Schools.

Details on the prizes and the nomination process are available at:

<http://science.gov.au/community/PrimeMinistersPrizesforScience/Pages/default.aspx>.

ADMEDUS

Admedus says it will sell Coroneo's Extra-Aortic Annuloplasty Ring and related products in Australia and New Zealand, extending its UK and German agreements.

In January, Admedus said that the Montréal, Quebec-based Coroneo's extra-aortic ring was complementary to its bio-scaffold Cardiocel for the repair of aortic heart valves and would be managed and sold in the UK and Germany through its existing sales and marketing infrastructure (BD: Jan 27, 2016).

Today, the company said it expected approval for the implant by the end of 2016.

Admedus chief executive officer Lee Rodne said there was "a natural synergy between the Extra-Aortic Ring and our product Cardiocel, and we view this as a beneficial relationship in the lead up to Cardiocel being approved in the Australian market".

Admedus said that the Coroneo Extra-Aortic Ring was the first specially-designed aortic annuloplasty ring on the market used to surgically repair the aortic valve and complemented the use of Cardiocel in heart valve repairs.

The company said that a presentation at the Heart Valve Society meeting in New York, highlighted that Cardiocel "demonstrated the closest profile to native aortic valves, rendering it best suited for aortic valve reconstructions".

"We will continue to look to build revenue across the business, through our existing product portfolio's and through partnerships across our own technologies and complementary technologies from other companies," said Mr Rodne.

Admedus said that in October 2015, it initiated a Cardiocel post-market clinical study to reconstruct aortic valves in 80 patients at four heart centres in the US and Europe.

The company said that the study was designed to illustrate the utility and benefits of Cardiocel in aortic valve reconstruction over valve replacements and patients would be reviewed at six, 12 and 24 months post-surgery to evaluate safety data and primary and secondary endpoints.

Admedus fell one cent or two percent to 48 cents.

ORTHOCELL

Orthocell says it expects Conformité Européenne (CE) mark approval for its natural collagen dental scaffold within three months.

Orthocell chairman chief executive officer Paul Anderson said that with chairman Dr Stewart Washer and chief operating officer Alex McHenry, the company had 17 meetings in Sydney and Melbourne over four days in its 'Deal ready and positioned for growth' road show, reporting progress over the past year.

Mr Anderson told Biotech Daily that with last year's \$4.3 million capital raising and revenue of \$461,000 for the six months to December 31, 2016, an expected \$1 million Federal Government R&D Tax Incentive and a cash burn of \$1.2 million for the three months to December 31, 2015, the company had a two-year runway.

Mr Anderson said the company expected CE mark approval for its Celgro pig-based collagen scaffold by July 2016 and the scaffold had multiple potential uses, with the first use as a support for dental implants, in which the bio-resorbable Celgro scaffold covered the jaw bone graft, acting as a barrier between the soft tissue and the bone.

Last year, Orthocell said that Perth's St John of God Hospital had approved a 30-patient trial of its Celgro SMRT Graft collagen scaffold for surgical repair of shoulder rotator cuff tendons, to reduce the re-tear rate by improving mechanical stabilization and providing a more cell friendly environment to improve healing (BD: Dec 16, 2015).

Mr Anderson said that the Celgro scaffold could also be used for hip cartilage repair and a study was being planned for that indication.

Mr Anderson said that Orthocell was also preparing for its first pre-investigational new drug application meeting with the US Food and Drug Administration for its autologous and homologous tenocyte implants (Ortho-ATI) for tendon repair and autologous and homologous chondocyte implants (Ortho-ACI) for cartilage repair.

He said the company was also involved in partnering discussions for its cell therapies, as well as preparing for European regulatory approvals.

Mr Anderson said that both Ortho-ATI and Ortho-ACI were Australian Therapeutic Goods Administration approved and available in Australia, Hong Kong and Singapore and the data from use in these countries would support regulatory applications in other countries.

He said that Orthocell was also developing growth factors for bone cartilage and tendon repair as well as laboratory produced tendons for ligament and tendon replacement.

Orthocell fell two cents or 4.8 percent to 40 cents.

CYCLOPHARM

Cyclopharm's annual general meeting may vote on a second strike board spill, following last year's narrow first strike against the remuneration report.

In 2015, the meeting 25.8 percent of votes opposed the remuneration report and under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill (BD: May 26, 2015).

If the spill vote is passed by more than 50 percent of votes the directors must stand for reelection, but if it fails, the trigger is reset to no opposition.

Cyclopharm said that the annual general meeting would also vote on the re-election of chairman Vanda Gould and an on-market buy-back of up to 25 percent of its shares.

The meeting will be held at the Russell Bedford NSW, Level 29, Suncorp Place, 259 George Street, Sydney on May 11, 2016 at 11.30am (AEST).

Cyclopharm fell four cents or 6.7 percent to 56 cents.

CELLMID

Cellmid says it has set up subsidiaries, Lyramid and Kinera, to commercialize its midkine antibody and protein assets, respectively.

Cellmid said that Lyramid was likely therapeutic indications in fibrotic diseases and cancer and Kinera had been formed to commercialize midkine protein assets in ischemic diseases, with a focus on chronic heart disease.

The company said that the subsidiaries had a clear therapeutic product development focus, which could be attractive to investors who might want to fund drug development programs in specific diseases.

Cellmid said that the subsidiaries had identifiable cost centres and budgets improving transparency through the group and as unlisted public companies the subsidiaries were able to receive venture capital, government or private investment unlike Cellmid, which was excluded from many of these funding sources by virtue of its shares being listed.

The company said that dedicated funding to the subsidiaries would limit dilution while allowing holders of listed shares to benefit from the upside in the projects.

Cellmid said that it owned 79 patents and patent applications in 20 patent families relating to midkine a strategic review led by the chair of the scientific advisory committee Dr Bryce Vissel had narrowed the key therapeutic opportunities to three areas, fibrosis, cancer and chronic heart disease, which were expected to be best commercialised through the new corporate structure.

"The company has a well-considered research strategy underpinned by international efforts by excellent scientists," Dr Vissel said. "There is strong scientific merit and therapeutic opportunities for Cellmid's midkine asset portfolio."

Cellmid said that a large number of the midkine protein and antibody studies had been conducted and the April Budapest symposium would "round up the scientific work and ... contribute to a sharper focus for our therapeutic programs" (BD: Apr 4, 2016).

The company said that a focused, transparent and user-friendly corporate and operational structure would accelerate the delivery of investor value and prepared the subsidiaries, including the Advangen hair loss business for corporate transactions.

Cellmid was up 0.3 cents or 17.65 percent to two cents with 4.4 million shares traded.

3D MEDICAL

3D says it has completed its merger with Mach7 Technologies Pte and expects to change its name to 'Mach7 Technologies' and its ASX code to M7T, shortly (BD: Oct 26, 2015).

3D said the merger was approved by shareholders at the March 31, 2016 extraordinary general meeting and was subject to formalities including the issue of 459,499,119 shares to the Mach7 vendors for the transaction, as well as a further 300,000,000 performance shares to the vendors, which could convert to ordinary shares subject to specific revenue and share price targets at December 31, 2016 and December 31, 2017.

The company said that following the departure of directors Frank Pertile and Stephen Hewitt-Dutton the board comprised chairman Ken Poutakidis with non-executive directors Damien Lim, Nobuhiko Ito and Dr Nigel Finch, as well as managing director and global chief executive officer Albert Liong, who starts on \$US234,000 (\$A311,517) a year .

3D said that its chief executive officer and chief financial officer Jenni Pilcher would continue as chief executive officer of the Australian operations as well as chief financial officer, with Alyn Tai as company secretary.

Mr Poutakidis said that the merger would "transform the company into a global operation led by a motivated and talented leadership team".

3D was up 0.1 cents or 1.6 percent to 6.2 cents with 1.4 million shares traded.

ONCOSIL MEDICAL

Oncosil has rescheduled its meeting to elect Dr Chris Roberts a director, issue him 10 million loan shares, with 14 million loan shares for chief executive officer Daniel Kenny. The meeting was original planned for March 24, 2016 with the loan share price the market price on the day of issue, but Oncosil postponed the meeting, citing concerns over the share issue price. (BD: Feb 25, Mar 22, 2016)

In February, Oncosil said that shareholders would also vote on extending the vesting period and repayment for a 500,000 share tranche of loan shares for chairman Dr Roger Aston and extend the vesting period and repayment period for a tranche of 5,000,000 loan shares for director Martin Rogers (BD: Mar 21, 2014).

Oncosil said that it had previously issued 5,000,000 shares at 10 cents each to Mr Rogers, 12,000,000 at 13 cents to Mr Kenny and 2,000,000 at 13 cents each to Dr Aston. In March, Oncosil said that the amendments related to the pricing of the shares given the change in the share price since the loan share issues were originally proposed and the notice of the meeting was issued.

Oncosil closed at 14.5 cents on February 25 when the meeting was announced, and at 16 cents on March 22, 2016.

In February Oncosil raised \$10 million in a placement to Regal Funds at 22 cents a share and had been trading as high as 27.5 cents a share in January (BD: Feb 10, 2016).

Today, Oncosil said that the loan shares for Dr Roberts and Mr Kenny would be issued at 22 cents each, the same price as the Regal Funds investment.

The meeting will be held at PKF Sydney, Level 8, 1 O'Connell Street, Sydney on May 9, 2016 at 10am (AEST).

Oncosil was unchanged at 15.5 cents.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says that Flindersfertility has publicized early success of their new Embryocollect pre-implantation genetic screening service on Facebook.

Reproductive Health said that the Adelaide-based Flindersfertility, formerly Flinders Reproductive Medicine Pty Ltd and part of Flinders Medical Service, had reported that the use of its Reproductive Health's Embryocollect service "resulted in a significant improvement in clinical pregnancy rates for the initial small group of [in-vitro fertilization] patients introduced to the service, all of which had previous unsuccessful IVF histories".

In a media release, Flindersfertility chief executive officer Stefan Moro said that the "clinical results and the ease of the cohesive service approach have encouraged our organisation to consider ways to broaden the accessibility and use of [pre-implantation genetic screening]".

Reproductive Health chief executive officer Dr Michelle Fraser said that the "initial very positive clinical feedback demonstrates the clinical performance of Embryocollect and is so rewarding for our company".

"These results provide confidence for the other IVF clinics intending to use Embryocollect and also those considering our [pre-implantation genetic screening] service for the near future," Dr Fraser said.

Reproductive Health said that pre-implantation genetic screening was a selection tool to assist in the identification of embryos with the greatest likelihood of viability, which identified aneuploid embryos, with an abnormal number of chromosomes, prior to transfer, reducing the chances of an unsuccessful transfer.

Reproductive Health was untraded at nine cents.

LIVING CELL TECHNOLOGIES

Japan's Otsuka Pharmaceutical Factory says its 25,000,000 share-holding in joint venture partner Living Cell has been diluted from 6.15 percent to 5.12 percent.

Otsuka said that it had been diluted in Living Cell's recent placement and share plan which raised \$3,247,228 at 5.063 cents a share (BD: Feb 17, Apr 4, 2016).

Living Cell was up 0.1 cents or 1.85 percent to 5.5 cents.

BIO-MELBOURNE NETWORK

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Bio-Melbourne Network says its April Bio-Breakfast will investigate scale-up new technologies from laboratory-based prototype to clinically-ready product.

The Network said that Melbourne had "a rich innovation ecosystem and one of the identified gaps is moving research out of the lab and into commercial product development".

The industry organization said that the Bio-Breakfast, entitled 'Scaling-up for success: Production and manufacturing for commercial product development' would highlight the capabilities and partnerships at the Biomedical Materials Translational Facility, led by Monash University and Commonwealth Scientific and Industrial Research Organisation at their joint Clayton precinct.

The Network said that speakers at the breakfast would be Boron Molecular's Zoran Manev, CSIRO's Mark Bown and Monash Institute of Medical Engineering's Prof Magdalena Plebanski.

The April 14, 2016 Bio-Breakfast will be held at CSIRO, Bayview Terrace, Clayton, with registration from 7.20am, breakfast from 7.30am to 8am and presentations from 8am to 9am.

To register go to: <http://bit.ly/1UMrh7c>.