



Biotech Daily

Monday September 16, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: ACTINOGEN UP 14%; IMPEDIMED DOWN 15%**
- * **LBT: APAS WINS CE MARK, MEETS GOLDEN STAPH STANDARDS**
- * **ADALTA, GE HEALTHCARE: DEAL FOR I-BODY DIAGNOSTIC IMAGING**
- * **BOTANIX BTX1702 PAPULO-PUSTULAR ROSACEA TRIAL**
- * **NOVITA SHORTFALL RAISES \$30k; TOTAL \$1.86m**
- * **CORRECTION: IMAGION, TELIX**
- * **CYNATA REQUESTS 'FUJIFILM OPTION' TRADING HALT**
- * **PROTEOMICS 'PROMARKERD ASSAY DEVELOPMENT' TRADING HALT**
- * **CRESO 'PHARMACIELO ACQUISITION' TRADING HALT**
- * **CRESO CANADA MARIJUANA FACILITY LICENCE**
- * **ALCHEMIA TO BE AUSTRALIAN PRIMARY HEMP; CONSOLIDATION**
- * **ED GRAUBART REPLACES POLYNOVO US SALES HEAD KEVIN WHITELEY**
- * **JEREMY GREEN, REDMILE REDUCE TO 12.4% OF AVITA**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Monday September 16, 2019, with the ASX200 up 4.3 points to 6,673.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and four were untraded. All three Big Caps fell.

Actinogen was the best, up 0.1 cents or 14.3 percent to 0.8 cents, with 8.3 million shares traded. Kazia, Next Science and Uscom climbed more than eight percent; Paradigm was up seven percent; Orthocell was up 5.3 percent; LBT, Mesoblast and Resonance were up four percent or more; Telix and Universal Biosensors rose more than two percent; with Clinuvel and Medical Developments up by less than one percent.

Impedimed led the falls, down three cents or 15.4 percent to 16.5 cents, with 1.3 million shares traded. Antisense lost six percent; Cyclopharm was down 5.2 percent; both Immutep and Osprey fell 4.35 percent; Alterity was down 3.45 percent; Cochlear, Dimerix, Neuren and Opthea shed two percent or more; Nanosonics, Neuren, Oncosil and Polynovo, Prescient, Pro Medicus, Resmed and Volpara were down more than one percent; with Avita, CSL, Genetic Signatures and Starpharma down less than one percent.

LBT INNOVATIONS

LBT says its automated plate assessment system (APAS) has met methicillin-resistant Staphylococcus aureus standards and has won Conformité Européene mark approval.

LBT said its APAS Independence completed its methicillin-resistant Staphylococcus aureus (MRSA), or golden staph, trial at Melbourne's St Vincent's Hospital.

In April, the company said it began the blinded study to validate APAS Independence to analyze MRSA and develop the final stage of its analysis modules (BD: Apr 2, 2019).

Today, LBT said the trial met the sensitivity and specificity requirements which providing the clinical validation required for regulatory clearance and the MRSA analysis module would be made available for sale following finalization of the APAS Independence CE mark registration, expected "at the end of September 2019".

LBT said the MRSA analysis module was important for the launch of the APAS Independence in the Europe, as testing for MRSA, combined with urine testing, accounted for "50 to 70 percent of the specimens processed in the majority of laboratories," due to greater requirements for infection control screening.

The company said the MRSA analysis module would be available in Australia through its existing Therapeutic Goods Administration registration, and in the US after US Food and Drug Administration clearance with 510(k) submission, expected by April 2020.

LBT was up half a cent or four percent to 13 cents with 1.9 million shares traded.

ADALTA

Adalta says it has a commercial agreement with the Chicago-based GE Healthcare for its i-body platform to develop diagnostic imaging.

Adalta said its i-body technology was "a new class of human protein therapeutic", named from the "intermediate" of four groups of immunoglobulin or immunoglobulin-like domains, based on the shape of the shark single domain antibody and one tenth the size of traditional antibodies (BD: Jul 7, 2016).

Today, the company said that with GE Healthcare it would develop i-bodies for diagnostic imaging to identify molecular markers of activated T-cells and help in the selection and monitoring of patients receiving immunotherapy, with the initial work focussing on granzyme B, a serine protease commonly secreted by immune cells in cancer.

Adalta executive chairman Dr Paul MacLeman said that "the small size and flexibility of the i-body makes it ideal as an imaging agent".

GE Healthcare head of molecular imaging oncology Sanka Thiru said GE was "partnering with companies like Adalta to build a portfolio of molecular imaging agents for those disease biomarkers that will help accelerate the development of the next generation of immuno-oncology treatments".

Adalta did not disclose the financial terms for the agreement.

Adalta was up 1.5 cents or 13.0 percent to 13 cents with 1.5 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it will begin a 36-patient, randomized, controlled, phase Ib trial of synthetic cannabidiol drug BTX1702 for papulo-pustular rosacea by the end of 2019.

Botanix said papulo-pustular rosacea was a chronic inflammatory skin disease characterized by intensely inflamed skin and acne-like breakouts across the face.

The company said the phase Ib study would be funded by the company's recent \$40 million capital raising (BD: Aug 9, 2019).

Botanix was up half a cent or two percent to 25.5 cents with 5.2 million shares traded.

NOVITA HEALTHCARE

Novita says it has raised a further \$30,000 and has issued 91,000,000 shortfall shares, at one cent each, taking the total raised to \$1,855,796.

In August, Novita said it hoped to raise \$2 million in a five-for-11 rights issue at one cent a share and issue up to 204,230,285 shares (BD: Aug 7, 2019).

On August 27 and 30, the company said it had raised \$485,796, with a further shortfall placement raising \$1.09 million (BD: Aug 27, 30, 2019).

In September, Novita said it raised a further \$250,000 in a shortfall placement, taking the total raised to \$1,825,000 (BD: Sep 5, 2019).

Today, Novita said it had issued 91,000,000 shortfall shares, but chief executive officer Glenn Smith told Biotech Daily that the company had raised \$1,855,796 so far and it would “update the market in relation to the completion of the offer in the coming days”. Novita was unchanged at 1.1 cents.

CORRECTION: IMAGION BIOSYSTEMS; TELIX PHARMACEUTICALS

Friday’s article on Imagination mentioned by comparison that Telix had a market capitalisation of about \$280 million. The market capitalization of Telix is about \$345 million.

The error was made by relying on trading screens receiving the Morningstar ASX feed, which, for reasons we do not know, can’t calculate shares held in ASX escrow or offshore. No reporters, copy-takers, sub-editors, check sub-editors, editors or publishers were hurt in making this correction.

Imagination was up 0.3 cents or 7.9 percent to 4.1 cents.

Telix was up 3.5 cents or 2.6 percent to \$1.385 with 1.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has requested a trading halt “pending an announcement in relation to the licence option agreement between the company and Fujifilm corporation”.

In August, Cynata said that discussions with Fujifilm to exercise a licence option for its mesenchymal stem cell product CYP-001 for graft-versus-host disease were progressing and Fujifilm had until September 19, 2019 for the option to expire.

Trading will resume on September 18, 2019 or on an earlier announcement.

Cynata last traded at \$1.42.

PROTEOMICS

Proteomics says it has requested a trading halt “pending the release of an announcement regarding the Promarkerd assay development and validation”.

Trading will resume on September 18, 2019 or on an earlier announcement.

Proteomics last traded at 36.5 cents.

CRESO PHARMA

Creso says it has requested a trading halt “pending an announcement regarding the proposed acquisition of the company by Pharmacielo”.

In June, Creso said it would be bought by Pharmacielo for \$122 million through a scheme of arrangement (BD: Jun 7, 2019).

Trading will resume on September 18, 2019 or on an earlier announcement.

Creso last traded at 38.25 cents.

CRESO PHARMA

Creso says its Halifax, Nova Scotia-based Mernova facility has a processing licence to extract, produce and distribute its marijuana-based products.

Creso said the licence expanded its operations beyond the cultivation and sale of dried flower and to include marijuana-based oils, concentrates and other cannabis derived products in Canada and abroad.

The company said the facility could produce up to 4.0 tonnes of dry marijuana flowers and 1.5 tonnes of “trim” for oil and extracts.

ALCHEMIA

Alchemia says its annual general meeting has voted for the company to become Australian Primary Hemp and reduce the shares on offer by 20-to-one.

In 2014, Alchemia’s share price fell as much as 86.1 percent to 8.6 cents on news that its 415-patient, phase III trial of HA-irinotecan for metastatic colorectal cancer failed to meet its phase III primary endpoint (BD: Oct 27, 2014).

In 2015, the company’s share price fell a further 51.8 percent to four cents on lower than expected revenue for its generic fondaparinux and a dispute with distribution partner Dr Reddy’s (BD: May 29, 2015).

In June, Alchemia said it would acquire the Geelong-based Australian Primary Hemp to become a marijuana-growing company (BD: Jun 21, 2019).

Today, Alchemia said that all resolutions were passed overwhelmingly including to change the company’s name to Australian Primary Hemp, change the nature and scale of activities, replace its constitution, hold a 20-for-one consolidation, along with resolutions relating to the proposed changes and funding measures.

The company said the greatest dissent was on the issue of shares to a corporate advisor, which passed with 99,107,483 votes (92.6%) in favor and 7,972,439 votes (7.4%) against.

The company’s most recent Appendix 3B new issue announcement said Alchemia had 324,723,671 shares on issue meaning the votes against the corporate advisor shares was 2.5 percent of the company, not sufficient to requisition extraordinary general meetings.

Alchemia said the consolidation would reduce the number of shares on offer from 324,723,621 shares to 16,236,181 shares, effective on September 18, 2019.

Alchemia was in a suspension at 1.1 cents.

POLYNOVO

Polynovo says it has appointed Ed Graubart as Polynovo North America LLC senior vice president, replacing the recently-appointed Kevin Whiteley.

In April, Polynovo said it had appointed Mr Whiteley as head of US sales and said he would receive 1,000,000 options vesting over four years and exercisable at 75 cents each by 2025 (BD: Apr 26, 2019).

Today, the company said that Mr Whiteley had stepped down within his three-month probationary period, forfeiting his 1,000,000 options.

Polynovo said Mr Gaubart’s appointment would allow the company to scale up its American sales and marketing.

The company said Mr Graubart had more than 29 years’ experience in the orthopaedic medical industry, working for Titan Spine LLC and Nuvasive Inc.

Polynovo said Mr Graubart would receive 1,000,000 share options exercisable at \$1.55 a share, with 250,000 vesting annually from August 13, 2021.

Polynovo fell three cents or 1.4 percent to \$2.07 with 3.55 million shares traded.

AVITA MEDICAL

Jeremy Green and the Redmile Group LLC say they have decreased their holding in Avita from 250,000,000 shares (13.41%) to 232,590,853 shares (12.42%).

The San Francisco-based Redmile and Mr Green said that between May 24 and September 13, 2019 they sold and transferred share, with sale prices ranging between 47.2 and 51.7 cents a share, and transfer prices of 52 cents a share.

Avita fell half a cent or 0.96 percent to 51.5 cents, with 9.9 million shares traded.