



Biotech Daily

Thursday September 27, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: OPTISCAN UP 16%; UNIVERSAL BIO DOWN 16%**
- * **ATOMO SIGNS MYLAN FOR DEVELOPING WORLD RAPID HIV TEST**
- * **CLINICAL GENOMICS 'CAN'T CONFIRM, DENY' AFR \$40m IPO**
- * **ORTHOCELL: 'SILVER-COATED CELGRO PREVENTS INFECTION' IN-VITRO**
- * **INVION, CHRONIC AIRWAY HIRE R&G FOR CHINA NADOLOL FOR COPD**
- * **AUSTRALIAN ETHICAL REDUCES TO 5% OF IMMUTEP**
- * **BOTANIX BTX1308 PSORIASIS TRIAL APPROVED**
- * **MGC TO SELL MARIJUANA DERMA DIVISION TO CANNAGLOBAL**
- * **MICRO-X REQUESTS 'CAPITAL RAISING' HALT**
- * **ELIXINOL REQUESTS 'CAPITAL RAISING' HALT**
- * **SIMAVITA TAKES 'PLACEMENT' HALT TO SUSPENSION**
- * **SIENNA LOSES DIRECTOR DR JOHN CHIPLIN**
- * **AUSCANN TO LOSE M-D ELAINE DARBY, GAINS DR PAUL MACLEMAN**

MARKET REPORT

The Australian stock market fell 0.18 percent on Thursday September 27, 2018 with the ASX200 down 11.1 points to 6,181.2 points. Twenty of the Biotech Daily Top 40 stocks were up, 12 fell, five traded unchanged and three were untraded.

Optiscan was the best, up 0.8 cents or 16 percent to 5.8 cents with 39,884 shares traded. Genetic Signatures climbed 12 percent; Airxpanders was up 10 percent; Benitec, Prana and Starpharma improved more than six percent; Nanosonics, Oncosil and Orthocell were up more than five percent; Impedimed was up 4.5 percent; Factor and Polynovo were up more than three percent; Osprey and Paradigm rose more than two percent; Compumedics, Cyclopharm, Pharmaxis and Telix were up more than one percent; with Medical Developments, Resmed and Volpara up by less than one percent.

Yesterday's 42.5 percent best, Universal Biosensors, led the falls, down 4.5 cents or 15.8 percent to 24 cents with 2.9 million shares traded. LBT lost 8.7 percent; Prescient and Reva retreated more than three percent; Bionomics, Clinuvel, Immutep and Opthea shed more than two percent; with Cynata and Neuren down more than one percent.

ATOMO DIAGNOSTICS

Sydney's Atomo says it has a strategic partnership with the Canonsburg, Pennsylvania-based Mylan NV to commercialize its HIV test in developing countries.

Atomo said the Rapid HIV tests had Conformité Européenne (CE) mark and were designed for use in low and middle-income countries, allowing people to screen themselves in their own homes with a device "engineered for simplicity and accuracy".

The company said the test, based on its Atomo Rapid technology platform, was designed to detect the presence or absence of HIV antibodies in a single drop of blood obtained from a fingertip, with results delivered in 15 minutes.

Atomo said that Mylan had exclusive rights to commercialize the products in more than 100 countries in Africa, Asia, the Middle East, the Russia-based Commonwealth of Independent States and Latin America.

The company said that Mylan planned to launch the Mylan HIV Self-Test "in early 2019". Atomo chief executive officer John Kelly said that Mylan was "the global health leader in HIV treatment and the largest supplier of [anti-retro-viral drugs]".

"This strategic partnership will mean that the products designed by Atomo can be introduced to more than 100 countries, so that millions of people will have access to award-winning rapid tests," Mr Kelly said.

Atomo said that one-third of the 36.7 million people living with HIV were not aware of their status and while testing rates had improved, many countries faced obstacles in expanding access to testing, such as patients being hard-to-reach or socially isolated due to stigma and discrimination.

The company said that deploying point-of-care self-tests in communities was "vital to increasing the proportion of people who know their HIV status".

Mylan chief executive officer Heather Bresch said the agreement was "another great example of our work to support the HIV/AIDS community, especially those living in low- and middle-income countries".

"Our partnership with Atomo to supply HIV rapid diagnostic tests for self-testing is an important step in our collective goal of preventing HIV infections and expanding treatment," Ms Bresch said.

Atomo is a private company.

CLINICAL GENOMICS

Clinical Genomics has responded to an article in today's Australian Financial Review claiming that it is looking for a \$40 million initial public offer to list on the ASX.

Clinical Genomics chief executive officer Dr Larry LaPointe told Biotech Daily: "We cannot confirm or deny market rumors but we continue to explore a number of capital finance options."

The Financial Review claimed that the Sydney-based Reunion Capital Partners was advising the company on the fund-raising, for late November 2018.

Biotech Daily called Reunion, but had no response at the time of publication.

In June, Clinical Genomics said it had raised \$33 million for its Colvera blood test for recurrent colorectal cancer and for its use in colorectal cancer screening.

The company said at that time that new investors including Sydney's Moelis Australia Asset Management and Regal Funds joined existing shareholders Oneventures and the New Jersey-based Quest Diagnostics and in the funding round.

Clinical Genomics said its test identified the "DNA of tumor cancer cells in circulating blood".

Clinical Genomics is a private company.

ORTHOCELL

Orthocell says that adding a silver nano-particle-coating to its Celgro scaffold has “the potential to prevent infection and enhance [dental] bone regeneration” in-vitro.

Orthocell said that the study showed the combination was “a nano-medicine breakthrough in the control of infection in bone defect repair which is highly desired in clinical practice”.

The company said that the study was conducted by the University of Western Australia’s Centre for Orthopaedic Translational Research, in collaboration with the Royal Melbourne Institute of Technology and the Fremantle, Western Australia University of Norte Dame Fremantle and Lund University Sweden.

Orthocell said that the research article, titled ‘Fabrication of a silver nanoparticle-coated collagen membrane with anti-bacterial and anti-inflammatory activities for guided bone regeneration’ was published in Biomedical Materials Research with an abstract available at: <https://www.ncbi.nlm.nih.gov/pubmed/30213920>.

Orthocell managing-director Paul Anderson said the study results indicated that silver-coated Celgro had the potential to prevent infection and enhance bone regeneration.

The company said dental implants were effective for managing missing teeth but they relied on solid anchorage and integration between the implant and the dental bone.

Orthocell said up to 60 percent of patients did not have sufficient bone volume to secure an implant and required a bone substitute and barrier membrane, such as Celgro, but some procedures were susceptible to infection, which could impede or prevent healing.

The company said the study supported silver-coated Celgro to guide bone regeneration and showed “strong anti-bacterial and anti-inflammatory properties”.

Orthocell said it planned to use silver nanoparticle technology to broaden Celgro applications to include infection prevention in bone and soft tissue repair.

Orthocell was up 1.5 cents or 5.3 percent to 30 cents.

INVION

Invion says that Chronic Airway Therapeutics has hired Beijing’s R&G Pharma Studies Co to support the development of nadolol for chronic obstructive pulmonary disease.

Earlier this month, Invion said it would demerge its nadolol (INV102) and zafirlukast (INV104) respiratory assets into the public unlisted Chronic Airway to expedite phase III trials in China with inventor Dr Mitchell Glass leaving Invion to be Chronic Airway’s executive director (BD: Sep 5, 2018).

The company said it completed feasibility, pre-clinical and clinical studies on INV102 and INV104 over three years to the end of 2015, and had been seeking to out-licence or sell the assets to a partner without success (BD: Jul 27, Oct 5, 2015; Apr 4, 2016).

Today, Invion said that Chronic Airway and R&G were ready to commence the regulatory process and would request a pre-investigational new drug application meeting and end-of-phase II meeting with the China Food and Drug Administration, by the end of 2018.

Invion fell 0.1 cents or 2.8 percent to 3.5 cents with 2.7 million shares traded.

IMMUTEP

Australian Ethical Investment says it has reduced its substantial shareholding in Immutep from 192,199,218 shares (6.35%) to 153,530,938 shares (5.07%).

Australian Ethical said that between September 4 and 26 it sold shares with the single largest sale 9,300,000 shares for \$396,691 or 4.3 cents a share.

Immutep fell 0.1 cents or 2.1 percent to 4.7 cents with 7.1 million shares traded.

[BOTANIX PHARMACEUTICALS](#)

Botanix says it has ethics approval for a 15-patient phase Ib trial of its synthetic cannabidiol BTX1308 for psoriasis.

Botanix said the first patient was expected to be enrolled “in the near term” with the trial to be run by the Hamburg, German-based Bioskin GmbH contract research organization which had a validated psoriasis plaque test.

The company said that the study would assess the safety and efficacy of BTX1308 on psoriasis plaques, with the ability to compare multiple formulations and test products at the same time on the same patient.

Botanix executive director Matt Callahan said that BTX1308 was “the third product to commence a phase Ib patient study in the last 12 months”.

“There is a significant unmet need for a safe and effective product for mild to moderate psoriasis and we look forward to advancing the clinical development of BTX1308, with expected completion of the study in early 2019,” Mr Callahan said.

Botanix said that testing of multiple formulations of BTX1308 showed the superiority of its Permetrex formulation against other, higher dose traditional formulation approaches, in delivering synthetic cannabidiol into the skin.

The company said the study would compare BTX1308 against placebo and an active comparator in 15 patients at a single study site in Australia.

Botanix fell 0.2 cents or two percent to 9.8 cents with 2.8 million shares traded.

[MGC \(MEDICAL GRADE CANNABIS\) PHARMACEUTICALS](#)

MGC says it will sell MGC Derma to Cannaglobal for \$C12.5 million (\$A13.25 million) in equity, a \$C2.5 million loan repayment and a five-year supply agreement.

MGC said that Cannaglobal was a Canadian cannabis investment company.

Biotech Daily was unable to find any information about the company, but MGC executive chairman Brett Mitchell told Biotech Daily that Cannaglobal was a recent start-up.

Earlier this week, MGC said it had issued “a formal contract default notice” to South Korea cosmetics manufacturer Varm Cosmo for its failure to meet obligations relating to a \$40 million a year binding agreement to buy marijuana-based cosmetics from its Ljubljana, Slovenia-based subsidiary MGC Derma (BD: Oct 20, 2017; Sep 25, 2018).

In January 2018, MGC told the ASX it had not received the \$1 million payment expected in November and that the delay in the receipt of the \$1 million payment had been caused by “operational and logistics factors, including damage in transit to some of the bulk sample containers” (BD: Jan 21, 2018).

Today, the company said that to complete the Cannaglobal transaction, which required shareholder approval, it had acquired the remaining 49 percent held by Slovenia-based MGC Derma partner Dr M Burstein Ltd for \$C1.25 million.

MGC said it had an exclusive five-year supply agreement for the provision of cannabidiol, proprietary production intellectual property and cosmetic materials to Cannaglobal.

The company said that the agreement included an upfront \$C1 million order and payment for the initial supply of cannabidiol and materials order, with funds to be received within 10 business days.

MGC said the sale of the Derma division allowed it to focus on developing its “pharmaceutical product pipeline, generate first [pharmaceutical] revenues and construct its ... seed-to-pharma commercial operations in Malta”.

MGC was up 0.4 cents or 8.3 percent to 5.2 cents with 7.7 million shares traded.

MICRO-X

Micro-X has requested a trading halt “pending the release of an announcement to the market in relation to a capital raising”.

Trading will resume on October 1, 2018 or on an earlier announcement.

Micro-X last traded at 39 cents.

ELIXINOL GLOBAL

Elixinol has requested a trading halt “pending the announcement to the market in relation to the outcome of a proposed capital raising”.

Trading will resume on October 1, 2018 or on an earlier announcement.

Elixinol last traded at \$2.15.

SIMAVITA

Simavita has requested a voluntary suspension to follow the trading halt requested on September 25, “regarding a proposed placement to sophisticated and professional investors” (BD: Sep 25, 2015).

Simavita last traded at three cents.

SIENNA CANCER DIAGNOSTICS

Sienna says that director Dr John Chiplin will resign on September 30, 2018.

Sienna said that Dr Chiplin had been a non-executive director since early 2016.

Sienna was unchanged at 8.5 cents.

AUSCANN GROUP

Auscann says that founder and managing-director Elaine Darby will resign from the company, with Dr Paul MacLeman appointed as executive director.

Auscann said it was “transitioning from a start-up company focused on licencing and product development, to a pharmaceutical production and sales business”.

The company said that it had begun a search for a new chief executive officer and Ms Darby would “continue in her role to ensure an orderly transition process”.

Auscann said that Dr MacLeman had more than 25 years’ board and executive experience in life sciences, agricultural and not-for-profit sectors.

The company said that Dr MacLeman was currently the chair of Adalta, Livac Pty Ltd and a non-executive director of Sypharma Pty Ltd and was formerly the chief executive officer of Genetic Technologies, IDT and Hatchtech.

Auscann chairman Dr Mal Washer said Dr MacLeman had “an in-depth understanding of the Auscann business through his existing engagement since October 2017 and his ongoing contribution to the Company’s pharmaceutical development activities, culminating in our patent application for a new final dose form cannabinoid therapeutic”.

Auscann said that Dr MacLeman would receive up to \$25,000 a month equivalent to \$1,250 per half day for 20 days.

Auscann was up half a cent or 0.5 percent to 99.5 cents.