



Biotech Daily

Monday March 23, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CLINUVEL UP 5%; NEXT SCIENCE DOWN 33%**
- * **IMPEDIMED: UNNAMED 470 US CENTRE SOZO LYMPHOEDEMA DEAL**
- * **PROTEOMICS IDENTIFIES BIOMARKERS FOR ENDOMETRIOSIS**
- * **REGENEUS: US PROGENZA PATENT, 'COVID-19 LINK'**
- * **SUDA: UP-TO \$870k MITSUBISHI TANABE ZOLPIMIST INSOMNIA DEAL**
- * **CLINUVEL: APRIL US SCENESSE FOR EPP LAUNCH**
- * **COGSTATE, EISAI TO LAUNCH NOUKNOW FOR 'BRAIN HEALTH' IN JAPAN**
- * **AUSCANN RECEIVES \$1.2m FEDERAL R&D TAX INCENTIVE**
- * **GI DYNAMICS PROPOSED FUNDING EGM**
- * **IMAGION REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **MGC TAKES MARIJUANA COVID-19 J-V HALT TO SUSPENSION**
- * **ADMEDUS QUOTES \$5m, 435k DIRECTOR OPTIONS**
- * **ALTHEA EXTENDS VOLUNTARY ESCROW OF 10m SHARES**
- * **ANTHONY BARTON TAKES 5% OF PYC, AGAIN**
- * **IQ3: DR SYRMALIS, MS XU IN; MR DIMITRIOU, MR COOLENTIANOS OUT**
- * **IDT APPOINTS DIRECTOR MICHAEL KOTSANIS**

MARKET REPORT

The Australian stock market fell 5.62 percent on Monday March 23, 2020, with the ASX200 down 270.6 points to 4,546.0 points. Just three of the Biotech Daily Top 40 stocks were up, 34 fell, two traded unchanged and one was untraded.

Clinuvel was the best of the three, up 72 cents or 4.9 percent to \$15.37 with 329,175 shares traded. CSL and Impedimed climbed more than four percent; with Cyclopharm up 0.7 percent.

Next Science led the falls, down 49 cents or 32.8 percent to \$1.005 with 499,102 shares traded. Optiscan lost 30.8 percent; Alterity fell 29.4 percent; LBT was down 20 percent; Volpara shed 19.8 percent; Oncosil and Orthocell fell more than 18 percent; Compumedics and Dimerix lost more than 17 percent; Antisense and Resonance were down more than 16 percent; Patrys was down 15.4 percent; Cynata and Polynovo were down more than 14 percent; Kazia and Starpharma fell 13 percent or more; Actinogen, Imugene, Pharmaxis and Proteomics shed more than 11 percent; Opthea and Resmed lost more than nine percent; Amplia and Telix fell eight percent or more; Osprey, Prescient and Pro Medicus fell more than seven percent; Ellex and Medical Developments were down more than six percent; Avita and Nanosonics fell more than five percent; Paradigm was down 3.2 percent; Genetic Signatures, Mesoblast and Uscom shed more than two percent; with Cochlear down 0.28 percent.

IMPEDIMED

Impedimed says it has purchasing agreement with an unnamed US oncology care network for its Sozo bio-impedance spectroscopy for lymphoedema prevention. Impedimed said the agreement allowed 1,200 physicians at 470 cancer treatment locations in the US to access Impedimed's Sozo lymphoedema prevention program to treat more than one million patients a year.

The company said the lymphoedema prevention program used Impedimed's "test trigger, treat protocol" for early detection and intervention of cancer-related lymphoedema. Impedimed chief executive officer Richard Carreon said that with the purchasing agreement the company expected "Sozo sales in this network to begin immediately and to expand throughout the upcoming year".

An Impedimed spokesperson told Biotech Daily that the name of the oncology care network and financial terms were confidential.

Impedimed was up 0.2 cents or 4.2 percent to five cents with 1.5 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has applied to patent protein biomarkers with the "potential to diagnose endometriosis using a simple blood test".

Proteomics managing-director Dr Richard Liscombe told Biotech Daily that endometriosis occurred "when the tissues that line the uterus spread outside of the uterine cavity and surround other organs, including in the peritoneum, ovaries, fallopian tubes, pleura and lungs".

The company said that the endometriosis biomarkers, or "protein fingerprints", were identified in a 54-patient, proof-of-concept study comparing women with endometriosis to two control groups: healthy women and women with symptoms but no clinical diagnosis. Dr Lipscombe said the study "was performed on two independent cohorts, with the protein biomarkers being statistically significant markers for disease in both".

Dr Lipscombe said the next stage was to validate the biomarker panel in a large clinical study and "partner with organizations who have access to a large number of high-quality samples from endometriosis sufferers".

The company said that endometriosis affected one in nine Australian women and on average took seven to 12 years to be diagnosed "due to the lack of a diagnostic tool beyond invasive surgery".

Dr Lipscombe said that if the company could develop "a simple blood test that can be ordered by a [general practitioner], it could save women years of suffering".

The company said that if the development of the test was successful it would be "the world's first non-invasive test for endometriosis".

Proteomics fell 2.5 cents or 11.1 percent to 20 cents.

REGENEUS

Regeneus says the US Patent and Trademark Office has allowed a patent covering its Progenza stem cell technology for inflammatory conditions including respiratory disease. Regeneus said that inflammatory conditions included "acute respiratory distress syndrome, which has been linked to Covid-19".

The company said that the patent, titled 'Therapeutics using adipose cells and cell secretions' covered the treatment of inflammatory conditions with the combination of stem cells and secretions and would provide protection until 2032.

Regeneus was up 1.5 cents or 23.1 percent to eight cents.

SUDA PHARMACEUTICALS

Suda says South Korea's Mitsubishi Tanabe Pharma Korea will pay up-to \$US500,000 (\$A869,600) plus royalties for a 10-year licence to its Zolpimist oral spray for insomnia. In 2018, Suda said it would licence Zolpimist to Mitsubishi Tanabe Pharma Singapore for up to \$US980,000 in Singapore, Malaysia and the Philippines, with a 12-month option on Thailand, Indonesia, Vietnam, Myanmar, Cambodia, Laos and Brunei (BD: Dec 19, 2018). Today, the company said it would receive an upfront fee of \$US100,000, as well as a \$US100,000 milestone payment based on Mitsubishi Tanabe Korea obtaining regulatory approval, and sales target-based milestone payments of up to \$US300,000. Suda said it would receive royalty payments of 12 percent of net sales and a handling fee for supplying Zolpimist and would work with Mitsubishi Tanabe Korea to "coordinate and oversee activities to ensure the success of the product within the territory". Suda fell 0.1 cents or 2.3 percent to 4.2 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will begin a three-phase launch of Scenesse for erythropoietic protoporphyria in the US after April 15, 2020. In October, Clinuvel said the US Food and Drug Administration had approved Scenesse, or afamelanotide, for erythropoietic protoporphyria (EPP) (BD: Oct 9, 2019). Today, the company said that during phase I of the launch, three hospitals and medical centres would provide treatment to EPP patients. Clinuvel said that in phase II, Medicare-Medicaid would "need to complete its review of the Scenesse dossier and provide an opinion on the national and local coverage for the treatment" for Scenesse to be confirmed for Medicare-Medicaid services. The company said that phase III would consist of direct distribution of the drug to a maximum of 30 Medicare-Medicaid centres, trained and accredited by Clinuvel. Clinuvel said that it would establish a US co-payment savings program for EPP patients with commercial or private health insurance. Clinuvel climbed 72 cents or 4.9 percent to \$15.37 with 329,175 shares traded.

COGSTATE

Cogstate says that Tokyo's Eisai will launch the Nouknow "digital brain performance tool ... for self-assessment of brain health" on March 31, 2020. Cogstate said that Nouknow was based on its technology and Eisai would initially target municipalities providing health services to local residents and corporations providing health checks for employees. Last year, the company said it had an agreement with pharmaceutical company Eisai Co Ltd to distribute its technology in Japan (BD: Aug 28, 2019). Today, Cogstate said Eisai would market Cogstate technology as a digital cognitive assessment tool for cognition in Japanese markets, excluding clinical trials, where Cogstate would continue to market its products independently. The company said that Eisai paid an upfront royalty payment of \$US1million, invested about \$US1.9 million in Cogstate shares and was funding necessary product development activities Japanese users, as well as a commercial team in Japan. Cogstate said the two companies would share profits equally, taking into account the associated cost of sales for the product in Japan, for an initial term of 10 years, with performance criteria to maintain exclusivity after five and eight years. Cogstate fell six cents or 17.1 percent to 29 cents.

AUSCANN GROUP HOLDINGS

Auscann says it has received \$1,207,175 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Auscann said the rebate related to research and development expenditure for its cannabinoid-based hard-shell capsules in the year to June 30, 2019.

Auscann fell two cents or 11.8 percent to 15 cents with 1.6 million shares traded.

GI DYNAMICS

GI Dynamics says it has lodged a draft proxy statement and notice of a special meeting with the ASX and US Securities and Exchange Commission for a funding meeting.

GI Dynamics said it had engaged a non-US financial advisor to assist proposed fundraising activities outside the US.

The company said the notice of proposed meeting was in draft form "and may be subject to material change following its review by the ASX and SEC", with a final version to be sent to stockholders for the special meeting expected in early April 2020.

GI Dynamics said it needed additional funding to carry on business and hoped to issue new Chess depository instruments (CDIs) in one or more private placements.

"There is no guarantee, however, that the company will be successful in raising any funds from investors," GI Dynamics said.

The proposed notice of meeting included resolutions to issue up-to 6,342,159,500 CDIs, equal to 126,843,190 US shares to sophisticated and professional investors in one or more private placement transactions.

The company said further resolutions were to approve the issue of warrants for up to 317,107,950 CDIs (equal to 6,342,160 US shares) to the unnamed financial advisor; approve 30,000 options over US shares to non-executive director Dr Praveen Tyle; and approve amendments to the June 15, 2017 agreement with Crystal Amber, along with agreements of August 21, 2019 and January 13, 2020.

GI Dynamics said it proposed to pay the financial advisor a cash commission of five percent of gross proceeds raised under the placements along with five percent of the CDIs issued to non-US investors under the placements introduced by the advisor up to a maximum of 317,107,950 CDIs (6,342,160 US shares), along with a tail fee of five percent of funds raised from investors introduced by the advisor, and options over five percent of CDIs issued to those investors up to 71,071,550 CDIs (or 1,421,431 US shares).

GI Dynamics fell 0.1 cents or 25 percent to 0.3 cents with 2.1 million shares traded.

IMAGION BIOSYSTEMS

Imagion has requested a trading halt "pending the release of an announcement in relation to a capital raising".

Trading will resume on March 25, 2020 or on an earlier announcement

Imagion last traded at 1.6 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested a voluntary suspension to follow the trading halt requested on March 19, pending an announcement on "a material agreement regarding a strategic joint venture with a Swiss company in relation to Covid-19" (BD: Mar 19, 2020).

The company said it expected the suspension to last until March 24, 2020.

MGC last traded at 1.7 cents.

ADMEDUS

Admedus says it has applied for a quotation of 435,000 options exercisable at \$11.20 intended as “long term incentive options for specific directors”.

In February, an Admedus extraordinary general meeting approved a 100-to-one share consolidation (BD: Feb 26, 2020).

Today, the company said the options would vest in three tranches; the first tranche vesting after a director’s 12 months of service with the company and a closing share price of \$16.80 for 10 out of 20 sequential days; the second after 18 months with the company and 10 out of 20 days with a closing share price of \$22.40; and the third tranche vesting after 24 months with the company and a share prices of \$33.60 for 10 out of 20 sequential days.

Admedus said that if the share price hurdles were not met within 36 months, the board could extend the period for up to 12 months.

Admedus fell two cents or 0.6 percent to \$3.48.

ALTHEA GROUP HOLDINGS

Althea says it will extend the voluntary escrow period of the Melbourne-based Mancann Pty Ltd’s 10,000,000 shares from March 23 to September 21, 2020.

Althea said the extension was granted in an agreement between Mancann and the company’s initial public offering lead manager, Sydney’s PAC Partners.

Althea fell two cents or 11.4 percent to 15.5 cents with 1.6 million shares traded.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

The Perth-based Anthony Barton and associates say they have become substantial in PYC with 155,200,314 shares or 5.3 percent of the company.

Last year, Mr Barton and associates said their 145,141,814 shares had been diluted to 4.95 percent, following a share issue (BD: Nov 21; Dec 2, 2019).

Today, a substantial shareholder notice signed by Mr Barton said that shares were acquired through “on market purchases” but did not disclose the date of purchase or the price of shares, as required under the Corporations Act 2001.

PYC fell 0.4 cents or 7.7 percent to 4.8 cents with 5.6 million shares traded.

IQ3 CORP

IQ3 says it has appointed chief executive officer Dr George Syrmalis chair and Lei Xu as acting director, replacing directors Kosmas Dimitriou and Peter Coolentianos.

IQ3 said Dr Syrmalis was the executive chairman of IQ Group Global and IQX.

The company said Ms Xu was acting director of corporate finance and advisory and had worked for the company since 2014.

IQ3 said Ms Xu held a Bachelor of Science from the Zhenjiang, China-based Jiangsu University, a Master of Science from Scotland’s University of Stirling, and a Master of Business Administration from Sydney’s Australian Graduate School of Management.

IQ3 was untraded at 12.5 cents.

IDT AUSTRALIA

IDT says it has appointed Michael Kotsanis as a non-executive director, effective from March 23, 2020.

IDT said Mr Kotsanis had more than 30 years' experience in strategy and operations in the pharmaceutical industry and was currently the chief executive office of Acrux.

The company said Mr Kotsanis was previously an executive at Synthon Holding BV, Hospira, and Mayne Pharma.

IDT fell 1.5 cents or 15 percent to 8.5 cents.