



Biotech Daily

Monday March 13, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: IDT UP 8%, DIMERIX DOWN 8%**
- * **PHARMAXIS: SYNAIRGEN PRE-CLINICAL DATA FOR IPF DRUG**
- * **MMJ JUMPS 58% ON GERMAN O-T-C MEDICAL MARIJUANA APPROVAL**
- * **TBG, MEDIGEN DEVELOP ANTI-THYROID DRUG TEST**
- * **BENITEC ISSUES NANT 29m SHARES, TOTAL \$5.45m, NANT 28.6%**
- * **BOTANIX PLEADS SCHULTZ TO ASX 50% QUERY**
- * **SIRTEX DELAYS \$30m SHARE BUY BACK, AGAIN**
- * **RHINOMED REQUESTS CAPITAL RAISING TRADING HALT**
- * **AUSTRALIAN ETHICAL TAKES 7.6% OF PHARMAXIS**
- * **GI DYNAMICS: MANOEL GALVAO NETO, DAVID CUMMINGS ADVISORS**

MARKET REPORT

The Australian stock market fell 0.32 percent on Monday March 13, 2017, with the ASX200 down 18.25 points to 5,757.3 points. Eight of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and five were untraded. All three Big Caps fell.

IDT was the best, up one cent or eight percent to 13.5 cents with 338,500 shares traded.

Avita climbed five percent; Ellex, Factor Therapeutics and Mesoblast rose more than two percent; with Oncosil, Pharmaxis and Universal Biosensors up by more than one percent.

Dimerix led the falls, down 0.05 cents or 7.7 percent to 0.6 cents with 250,000 shares traded.

Genetic Signatures and Impedimed lost more than six percent; Living Cell, Orthocell and Osprey fell more than four percent; Benitec was down 3.1 percent; Pro Medicus shed 2.3 percent; Actinogen, Airxpanders, Atcor, Compumedics, ITL and Starpharma were down more than one percent; with Cochlear, CSL, Nanosonics, Resmed and Sirtex down by less than one percent.

PHARMAXIS

Pharmaxis says Synairgen PLC has made progress towards a phase I trial of a selective inhibitor to the lysyl oxidase-like 2 enzyme for idiopathic pulmonary fibrosis.

Pharmaxis said that collaborator, the Southampton, England-based Synairgen, had made announced that the lead compound had “inhibited cross-link formation, reduced fibrosis score and improved lung function [or elastance] in a [mouse] model of lung fibrosis”.

Synairgen said it previously reported that using cells from idiopathic pulmonary fibrosis patients, it could reduce cross-linking of collagen fibres in an in-vitro model of idiopathic pulmonary fibrosis and had subsequently shown that this resulted in a reduction in tissue stiffness of about 50 percent.

The company said that oral administration of one of the compounds “significantly inhibited cross-link formation, reduced fibrosis score and improved lung function” in mice.

Synairgen said that together the results suggested that inhibition of lysyl oxidase-like 2 enzyme (LOXL2) using the novel inhibitors had the potential to improve lung function in patients with lung fibrosis by reducing tissue stiffness and completion of toxicology studies would enable phase I clinical trials by the end of the year, as planned.

The company said that idiopathic pulmonary fibrosis was a fatal lung disease, with a median survival of two to three years, and had a worse prognosis than many cancers affecting up to 132,000 people in the US with 50,000 new cases diagnosed each year. Synairgen said that current products for idiopathic pulmonary fibrosis generated more than \$US1 billion in global revenue in 2016.

The company said that the underlying cause of idiopathic pulmonary fibrosis was not fully understood, but it resulted from a build-up of scar tissue which damaged the structure of the lung affecting normal uptake of oxygen into the blood, with the resultant stiffening of the lungs making it increasingly difficult to breathe.

Synairgen said scar tissue was formed largely of collagen and LOXL2 was an enzyme that stiffened scar tissue by forming cross-links between the collagen molecules.

Synairgen said that it was collaborating with Pharmaxis to develop small molecule inhibitors of LOXL2 for the treatment of idiopathic pulmonary fibrosis and other fibrotic conditions including non-alcoholic steato-hepatitis, kidney fibrosis and cardiac fibrosis. Pharmaxis was up half a cent or 1.8 percent to 28.5 cents.

MMJ PHYTOTECH

MMJ says that Switzerland-based subsidiary Satipharm AG's 10mg and 50mg Gelpell-CBD cannabidiol microgel capsules can be sold in pharmacies throughout Germany.

MMJ said that Satipharm had secured German pharmaceutical central number codes for the over-the-counter medical marijuana products.

The company said that its German online distribution partner the Elbingerode-based Bodfeld-Apotheke pharmacy began shipping the cannabidiol extract products to regulated markets globally, enhancing its capacity to scale-up product sales.

MMJ said that Bodfeld accepted all major payment methods, which solved a payment gateway issue due to the Federal US ban on cannabinoids.

The company said that Satipharm had a binding letter of intent with a pharmaceutical distributor and retailer in Denmark for marketing and distribution in Scandinavia.

MMJ managing-director Andreas Gedeon said expansion into Europe was “a key focus”.

“The availability of our Gelpell-CBD microgel capsules over-the-counter throughout all German pharmacies is a key milestone and positions Satipharm as one of the leading CBD suppliers in Europe,” Mr Gedeon said.

MMJ was up 27.5 cents or 57.9 percent to 75 cents with 23.0 million shares traded.

TBG DIAGNOSTICS

TBG says that with Medigen and the National Taiwan University Hospital it would develop and distribute a product to evaluate adverse reactions to anti-thyroid drugs.

TBG said that with 51.8 percent shareholder Taiwan's Medigen Corp the partnership would obtain the worldwide right to develop and distribute an in-vitro diagnostic that could identify and prevent patients with Grave's disease from developing further life-threatening agranulo-cytosis after taking anti-thyroid thionamide drugs.

The company said that a patent entitled 'Method for assessing the risk of adverse drug reaction and device thereof' had been granted in Taiwan and was pending in China and Hong Kong, which would make it the first diagnostic company to distribute patented products in China.

TBG said that Grave's disease is one of the leading causes of hyper-thyroidism and has a prevalence of about 1.6 percent in the general population, which was treated with thionamide, which was known to induce life-threatening agranulo-cytosis in a percentage of treated patients.

The company said that Taiwan University Hospital's Prof Tien-Chun Chang and Prof Pei-Lung Chen identified two human leukocyte antigen (HLA) alleles and obtain patents that are able to predict increased risk of thionamide-induced agranulo-cytosis (TIA).

TBG said that the agreement would allow it, to develop human leukocyte antigen in-vitro diagnostic products or services that could identify individuals at risk for TIA.

Prof Chang said "we have already begun to screen our patients for the associated HLA genes and in doing so, we have already reduced the number of patients of TIA in the past year".

TBG chief operating officer Eugene Cheng said the company had been focused on the development, manufacturing, and global distribution of human leukocyte antigen in-vitro diagnostic products for the use in transplantation, transfusion, tissue banking and autoimmune disease associations.

"Adding drug companion tests to TBG's current portfolio is perfectly in line with our company focus," Mr Cheng said.

TBG was up one cent or 5.9 percent to 18 cents.

BENITEC BIOPHARMA

Benitec says it has issued Nant Capital 29,305,819 shares at 18.59 cents a share in the second tranche placement taking the total to \$5.45 million.

Benitec said the issue meant that the Los Angeles, California-based Nant Capital held 28.57 percent of the company and the funds would be used to develop and fund the BB-401 and BB-501 gene-silencing head and neck cancer and the squamous cell carcinoma programs (BD: Oct 24, Nov 23, Dec 23, 2016; Jan 30, 2017).

Benitec fell half a cent or 3.1 percent to 15.5 cents.

BOTANIX PHARMACEUTICALS

Botanix has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 50 percent from 4.4 cents on March 6 to 6.6 cents on March 13, 2017 and noted a trading volume "significantly above the average".

Botanix said it posted a presentation for the American Academy of Dermatology meeting on March 6, 2017.

Botanix was up 2.2 cents or 44.0 percent to 7.2 cents with 65.3 million shares traded.

SIRTEX MEDICAL

Sirtex has told the ASX it has again delayed the start of its up to \$30 million, 2,000,000 share buy-back on April 17, instead of March 27, 2017

Sirtex told the ASX the change was “to allow sufficient time to respond to a threatened injunction as more fully detailed in the ASX release dated March 2, 2017”.

Earlier this month Sirtex said that it postponed the proposed share buy-back following a threatened injunction from a shareholder (BD: Mar 2, 2017).

Last month, Sirtex said it received a draft statement of claim from Todd Hayward who acquired 340 Sirtex shares for \$9,449 on December 1, 2016 and held them when the company's share price fell following a profit warning by former chief executive officer Gilman Wong, followed by Mr Wong's dismissal (BD: Dec 9, 2016; Feb 1, 13, 2017). Sirtex said the correspondence threatened an injunction to stop the share buyback, “on the basis he alleges that the implementation of the share buyback will materially prejudice Sirtex's ability to satisfy any liability arising in respect of the claims” and it would delay the buy-back from March 9 to March 27, 2017, while it addressed the allegation. Sirtex fell seven cents or 0.4 percent to \$17.48 with 772,171 shares traded.

RHINOMED

Rhinomed has requested a trading halt “pending an announcement in relation to a proposed capital raising”.

Trading will resume on March 15, 2017 or on an earlier announcement.

Rhinomed last traded at 1.7 cents.

PHARMAXIS

Australian Ethical Investment says it has increased its substantial shareholding in Pharmaxis, from 19,297,634 shares (6.05%) to 24,311,470 shares (7.62%).

Australian Ethical said that it bought the shares between February 3 and March 10, 2017 with the single largest acquisition 3,700,000 shares for \$1,019,739 or 27.6 cents a share.

GI DYNAMICS

GI Dynamics says it has appointed Prof Manoel Galvao Neto and Prof David Cummings, to its scientific advisory board.

GI Dynamics said that Prof Galvao was a professor at the Miami, Florida-based Florida International University's Herbert Wertheim College of Medicine and affiliate professor of surgery at the Sao Paulo, Brazil-based ABC College of Medicine in Canto Andrew.

The company said that Prof Cummings was a professor of medicine at the Seattle-based University of Washington, studying the hormonal and neurochemical pathways that regulate appetite, body weight and glucose homeostasis by using experiments ranging from bench science to clinical investigation.

The company said that Prof Cummings held a Doctor of Medicine from Harvard Medical School and the Massachusetts Institute of Technology.

GI Dynamics was up 1.9 cents or 52.8 percent to 5.5 cents with 1.9 million shares traded.