

Biotech Daily

Tuesday December 8, 2020

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: ONCOSIL UP 8%; AMPLIA DOWN 6.25%
- * CONTROL BIONICS \$15m IPO OPENS UP 87%
- * ANATARA DEVELOPS 3FDC FOR MOOD; GARP IBS TRIAL DELAYED
- * INCANNEX PLANS PSILOCYBIN FOR ANXIETY TRIAL
- * REDHILL INCREASES TALICIA FOR HELICOBACTER PYLORI COVERAGE
- * NUHEARA: 'RECORD MONTHLY DIRECT-TO-CUSTOMER UNIT SALES'
- * ALTHEA: 'NOVEMBER RECORD REVENUE OF \$847k'
- * TALI \$9.4m DEAL WITH TIMES, BRAND CAPITAL FOR INDIA
- * ANTISENSE RECEIVES \$651k FEDERAL R&D TAX INCENTIVE
- * RECCE DIIS APPROVES FURTHER \$4.2m OFFSHORE RDTI
- * RESONANCE REQUESTS 'REGULATORY CLEARANCE' TRADING HALT
- * ELEANORE GOODRIDGE REDUCES TO 8.3% IN NYRADA
- * GEOFF HOLLIS REPLACES IMAGION CO SEC JOVANKA NAUMOSKA

MARKET REPORT

The Australian stock market was up 0.19 percent on Tuesday December 8, 2020, with the ASX200 up 12.7 points to 6,687.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell and eight traded unchanged. All three Big Caps were up.

Oncosil was the best, up one cent or eight percent to 13.5 cents, with 3.4 million shares traded. Antisense climbed five percent; LBT and Polynovo improved four percent or more; Compumedics, Neuren and Paradigm were up more than three percent; Cynata and Universal Biosensors rose more than two percent; Clinuvel, Cochlear, Medical Developments, Pro Medicus, Proteomics and Starpharma were up one percent or more; with CSL, Genetic Signatures, Kazia and Resmed up by less than one percent.

Amplia led the falls, down 1.5 cents or 6.25 percent to 22.5 cents, with 254,067 shares traded. Nova Eye lost 5.6 percent; Actinogen, Imugene and Osprey fell four percent or more; Resonance and Uscom retreated more than three percent; Dimerix, Pharmaxis, Prescient and Telix shed two percent or more; Immutep, Next Science and Opthea were down more than one percent; with Nanosonics and Volpara down less than one percent.

CONTROL BIONICS

Control Bionics yesterday opened at \$1.12, 86.7 percent above its initial public offer of 60 cents, to commercialize its technology to convert thoughts to computerized actions. Under the ASX code of CBL, the company reached a high of \$1.24 before closing the day up 96.7 percent at \$1.18 with 4.9 million shares traded.

In November, Control Bionics said its \$15 million initial public offer at 60 cents a share has closed oversubscribed ahead of the proposed ASX listing (BD: Nov 27, 2020).

Control Bionics chief executive officer Rob Wong told Biotech Daily the company's Neuronode Trilogy was able to convert thoughts to computerized actions including telephone conversations and had US Food and Drug Administration, Therapeutic Goods Administration approval and Conformité Européenne (CE) marking.

Control Bionics fell 13 cents or 11.0 percent to \$1.05 with 2.1 million shares traded.

ANATARA LIFESCIENCES

Anatara says it is planning a study of components of its gastro-intestinal re-programming for psychological functioning in adults with moderate depression, anxiety or stress. Anatara said it had developed a "colon-targeted formulation", 3FDC, as a subset of its pineapple stem, bromelain-based "gastro-intestinal re-programming" compounds which contained "ingredients that are known to have broad-ranging effects in the gastrointestinal tract and systemically, including modulation of gut-brain axis".

Anatara chief executive officer Steve Lydeamore told Biotech Daily that the company's bromelain-based gastro-intestinal re-programming (Garp) included bromelain and other components which were safe and had been shown to have efficacy for gut health. The company said the study would evaluate whether 3FDC delivered to the colon,

effected psychological functioning, "specifically assessing for potential improvement in symptoms of anxiety, depression and stress".

Anatara said it had been awarded an undisclosed Federal Innovation Connections Grant, funding to be provided to the Commonwealth Scientific and Industrial Research Organisation and the planned study would take place at the CSIRO Nutrition and Health Research Clinic in Adelaide.

The company said gastro-intestinal re-programming (Garp) was developed to address irritable bowel syndrome and inflammatory bowel disease and it expected to begin a randomized, controlled trial for irritable bowel syndrome in early 2021.

Mr Lydeamore said the revised timeline for a Garp partnering deal was by July 2021, with preliminary results of the irritable bowel syndrome trial expected in June 2021.

In June, the company said it hoped to begin a trial of Garp for irritable bowel syndrome by December 31, 2020. (BD: Jun 23, 2020).

Anatara was up 1.5 cents or 8.8 percent to 18.5 cents.

INCANNEX HEALTHCARE

Incannex says it will conduct a 72-patient, phase II trial of psilocybin-assisted psychotherapy for generalized anxiety disorder, with Melbourne's Monash University. Incannex said the randomized, double-blind, active-placebo-controlled trial to assess the safety and efficacy of the psychotherapy, would be led by Monash researcher Dr Paul Liknaitzky and was expected to be the largest psychedelic research program in Australia. The company said it would hold a pre-investigational new drug application meeting with the US Food and Drug Administration "as soon as practicable".

Incannex was up three cents or 20.7 percent to 17.5 cents with 46.6 million shares traded.

REDHILL BIOPHARMA

Redhill says it has increased its US coverage for Talicia, formerly Heliconda or RHB-105, for Helicobacter pylori infections to more than 40 million additional Americans. In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010). Last year, Redhill said the US Food and Drug Administration has approved the Talicia delayed-release capsules for Helicobacter pylori infection (BD: Nov 5, 2019) Today, Redhill said that coverage for Talicia, comprising omeprazole magnesium, amoxicillin and rifabutin had increased to more than 167 million Americans. The company said it previously had announced listings of Talicia as a preferred brand on the national formularies of Prime Therapeutics, Envisionrx, and Express Scripts. Redhill chief commercial officer Rick Scruggs said that with the addition of unrestricted coverage Talicia was available to "more than 70 percent of commercial lives". "The unrestricted commercial coverage achieved for Talicia to date far exceeds our expectations at such an early stage following the product's launch," Mr Scruggs said. "Antibiotic resistance is a major issue in the treatment of H pylori infections and yet, despite current guideline recommendations from the American College of Gastroenterology calling for use of the most effective first-line treatment, physicians are still prescribing treatment regimens containing antibiotics such as clarithromycin that face high levels of bacterial resistance," Mr Scruggs said.

"This growth in unrestricted commercial access helps change that dynamic by increasing access to Talicia to more than 167 million Americans," Mr Scruggs said.

Redhill said that about 35 percent of Americans were affected by Helicobacter pylori infection, which was a group 1 carcinogen and the strongest risk factor for gastric cancer. The company said that eradication of Helicobacter pylori had been shown to reduce the risk of gastric cancer by up to 75 percent.

Redhill fell 16 US cents or 1.81 percent to \$US8.66 (\$A11.67) with 132,151 shares traded.

<u>NUHEARA</u>

Nuheara says it had its highest monthly direct-to-customer sales in November of 1,949 Iqbuds2 Max units.

Nuheara said that in the two months of October and November it had sold 2,891 Max hearing and sound filtering units for augmenting hearing.

The company said its Max average price was \$430 and return on advertising spend was 2.45 times exceeding the previous quarter of 1.74 times.

Nuheara chief executive officer Justin Miller said the company had been "significantly assisted with Iqbuds2 Max being placed on the cover of Time magazine and named as one of the world's best inventions of 2020".

Nuheara fell 0.3 cents or 5.8 percent to 4.9 cents with 16.1 million shares traded.

ALTHEA GROUP HOLDINGS

Althea says it has recorded its highest monthly unaudited revenue of \$847,499 in November 2020, along with an increase in new patients and health care professionals. Althea said the average number of new patients for its medical marijuana and health care professionals in Australia per business day was 41.71 and 2.24, respectively, and it was "seeing a strong rebound in sales in Victoria following a long Covid-19 lockdown". Althea said it had a 48 percent increase in UK sales to \$110,378 in November. Althea fell one cent or 1.8 percent to 53.5 cents with 16.1 million shares traded.

TALI DIGITAL

Tali says it has investment and advertising agreements of up-to \$US7 million (\$A9.4 million) with Brand Capital International for its Detect and Train programs in India. Tali said that Brand was the strategic investment arm of Bennett, Coleman and Co which was part of the Times Group, publishers of the Times of India.

The company said Brand would invest \$US2 million for 81.8 million shares at 3.3 cents a share under the investment agreement, with additional investments up to \$US5 million. Tali said that under the advertising agreement the Times Group would be its partner for marketing and sales for its cognitive performance tools for children with attention and learning difficulties in India.

Tali managing-director Glenn Smith said the company would leverage the investment "to expand in India through the Times Group's 360-degree media assets, which includes popular print, television, radio and digital channels in India".

"The commercial agreement validates the opportunity for Tali [intellectual property] and product platform and highlights how Tali can work with various channel partners to facilitate the rollout of our product globally," Mr Smith said.

Tali was up 1.7 cents or 45.95 percent to 5.4 cents with 143.0 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has received \$650,603 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Antisense said the rebate related to research and development expenditure for the year to June 30, 2020.

Antisense was up half a cent or five percent to 10.5 cents with 3.2 million shares traded.

RECCE PHARMACEUTICALS

Recce says the Federal Department of Industry Innovation and Science has approved a further \$9,637,500 in off-shore Research and Development Tax Incentive claims. In November, Recce said the Department's advanced overseas finding related to expenditure of \$17,150,000 for its synthetic antibiotics program for the three years to June 30, 2022, which Biotech Daily calculated to translate to a cash incentive of \$7,460,250 (BD: Nov 26, 2020).

Today, the company said it was eligible for \$9,637,500 for its synthetic anti-viral research and development program taking the total to \$26,787,500, making the company eligible for a further Incentive of \$4,192,313, taking the total Incentive to \$11,652,563. Recce was unchanged at \$1.21.

RESONANCE HEALTH

Resonance has requested a trading halt "pending the release ... of a further ASX announcement in relation to a regulatory clearance".

Trading will resume on December 10, 2020 or on an earlier announcement.

Resonance last traded down half a cent or 3.1 percent to 15.5 cents.

<u>NYRADA</u>

Nyrada says Eleanore Goodridge's substantial holding has been reduced from 10,474,832 Chess depository instruments (CDIs) (9.58%) to 9,134,832 CDIs (8.34%). Nyrada and Ms Goodridge did not disclose the sales price of the shares. Nyrada fell 1.5 cents or 6.1 percent to 23 cents.

IMAGION BIOSYSTEMS

Imagion says it has appointed Geoff Hollis as company secretary, replacing Jovanka Naumoska, effective from today

In October, Imagion said Mr Hollis had been appointed chief financial officer to replace Brian Conn effective from December 1, 2020 (BD: October 19, 2020).

The company said Ms Naumoska would continue as a non-executive director.

Imagion fell one cent or 7.1 percent to 13 cents with 8.5 million shares traded.