



Biotech Daily

Tuesday May 26, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: OSPREY UP 33%; PATRYS DOWN 7%**
- * **PRESCIENT LICENCES U-PENN, OXFORD UNI TECH FOR OMNICAR**
- * **CYCLOPHARM: 1st TECHNEGAS SALES IN RUSSIA**
- * **IMAGION: 'MAGSENSE MANUFACTURE ON-TIME DESPITE COVID-19'**
- * **ONCOSIL RIGHTS, SHORTFALL RAISE \$5m; TOTAL \$19m**
- * **ELIXINOL RIGHTS RAISE \$5.6m; TOTAL \$10.9m**
- * **BIOSCIENCE MANAGERS RAISE \$5m FOR ADHERIUM**
- * **LBT DRAWS DOWN FINAL SOUTH AUSTRALIA GOVERNMENT \$1.5m**
- * **TASMANIAN ALKALOIDS MANUFACTURES ZELIRA MARIJUANA PRODUCTS**
- * **MGC: ISRAEL PHASE IIb CANNEPIL EPILEPSY TRIAL**
- * **PALLA TERMINATES UK CODEINE CUSTOMER ACQUISITION; OWED \$3.5m**
- * **CANN GROUP, IDT SUPPLY MARIJUANA PRODUCTS TO ASTRAL, IUVO**
- * **SHUNHO TERMINATES ELIXINOL HEMP FOODS ACQUISITION**
- * **IMPRESSION NAME CHANGE, 7.5m SHARES, 205m OPTIONS, 32m RIGHTS EGM**
- * **GI DYNAMICS 'ASX DELISTING' TRADING HALT**
- * **ALLIANZ TAKES 5% OF STARPHARMA**
- * **LAZARD TAKES 5% OF MAYNE**
- * **MEDICAL DEVELOPMENTS APPOINTS CHRISTINE EMMANUEL DIRECTOR**

MARKET REPORT

The Australian stock market climbed 2.93 percent on Tuesday May 26, 2020, with the ASX200 up 164.4 points to 5,780.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell and eight traded unchanged. All three Big Caps were up.

Osprey was the best on no news, up 0.4 cents or 33.3 percent to 1.6 cents, with 18.6 million shares traded. Impedimed and Prescient climbed more than with eight percent; Antisense was up 7.25 percent; Alterity, Oncosil, Proteomics and Resonance improved five percent or more; CSL, Cyclopharm, LBT and Paradigm were up more than three percent; Mesoblast rose 2.45 percent; Cochlear, Nanosonics, Opthea and Pro Medicus were up more than one percent; with Resmed up 0.6 percent.

Patrys led the falls, down 0.1 cents or 7.1 percent to 1.3 cents, with eight million shares traded. Dimerix and Pharmaxis fell more than five percent; Uscom lost 4.4 percent; Compumedics, Genetic Signatures, Medical Developments and Telix shed two percent or more; Clinuvel, Kazia, Neuren, Next Science, Orthocell and Polynovo were down more than one percent; with Cynata, Starpharma and Volpara down by less than one percent.

PRESCIENT THERAPEUTICS

Prescient says it has licenced an immune receptor platform from the University of Pennsylvania and a related molecular binding system Oxford University.

Prescient said the immune receptor and molecular binding technologies would be combined to develop a chimeric antigen receptor (CAR) cell therapy platform named Omnicar, which would enable T-cell activity control and multi-antigen targeting with a universal cell product.

The company said it would pay an undisclosed upfront fee to the Philadelphia-based University of Pennsylvania and the UK's Oxford University, as well as milestone payments for clinical development and regulatory approval and royalties on future commercial sales. Prescient said that the initial pre-clinical development program for Omnicar would be conducted within its current budget.

According to Prescient's most recent Appendix 4C, the company had cash and cash equivalents of \$8,153,000 at March 31, 2020.

The company said that engineered cell therapies genetically modified a patient's cells to recognize and kill cancer cells that were otherwise hidden from the patient's immune system.

Prescient said that many current cell therapies "also face considerable challenges, including manufacturing, safety and adaptability, that can limit their broader use".

The company said that clinicians had no control over conventional cell therapy products after they were infused into a patient which caused significant safety concerns if toxicities were observed, and many conventional cell therapies could only be directed to target a single cancer antigen, which limited effectiveness when the cancer mutated or expressed different antigens.

Prescient said the Omnicar program hoped to improve the safety and efficacy of current chimeric antigen receptor therapies.

The company said the Omnicar platform formed modular chimeric immune receptor cells that separated antigen recognition from downstream signalling, a process involved in cell growth regulation, cell proliferation, cell differentiation, and apoptosis.

Prescient said that cells expressing a portion of the chimeric immune receptor and the targeting ligand, or binder, could be administered separately, allowing a post-infusion molecular bind to form a fully armed cell therapy product.

The company said that this process used the Oxford University's Spytag or Spycatcher molecular binding system, which acted as a "molecular Velcro".

Prescient said the Omnicar platform would give clinicians control over cell therapy expression in-vivo, by allowing them to tune cell therapy activity either up or down post-infusion and enable them to "switch off" cell therapy activity altogether by ceasing administration of the binders.

The company said Omnicar could reduce the cost of cell therapy by reducing the amount of manufacturing required for each patient due to its compatibility with other products, including T-cells, natural killer cells, macrophages, or phagocytic cells, and stem cells.

Prescient chief executive officer Steven Yatomi-Clarke said there were "significant medical and commercial benefits for companies that can develop improved cell therapy products".

"It is particularly exciting ... for us to progress this revolutionary technology for attacking solid tumors, as well as liquid cancers," Mr Yatomi-Clarke said.

"The licence agreements with [the University of Pennsylvania and Oxford University] align perfectly with [Prescient's] objective of developing personalized cell therapy medicines and complements our targeted therapy pipeline," Mr Yatomi-Clarke said. "We are already working on leveraging our targeted therapy expertise in other cell therapy applications."

Prescient was up 0.4 cents or 8.9 percent to 4.9 cents with 20.8 million shares traded.

CYCLOPHARM

Cyclopharm says it has Russian regulatory approval for its Technegas products for pulmonary embolism detection and has appointed Hascca to distribute the products. Cyclopharm said the Moscow-based Hascca would manage the distribution of Technegas products throughout Russia and had secured the first order of a Technegas generator and the associated patient administration sets.

The company said Hascca would provide technical, sales and educational support in the region to clinicians.

Cyclopharm said Russia was the sixtieth country to approve Technegas, which further supported its efforts to expand the use of Technegas to diagnose and treat other respiratory conditions including chronic obstructive pulmonary disease, asthma and coronavirus related illnesses.

Cyclopharm managing-director James McBrayer said that “after several years of careful planning and positive engagement with the Russian Federal Health Service, it is pleasing to commence sales in Russia”.

“Gaining access to the Russian market clearly demonstrates our ability to continue to drive organic growth in our core business whilst simultaneously focusing on the vitally important [US Food and Drug Administration] approval process and expanding indications beyond [pulmonary embolism]”.

Cyclopharm was up 4.5 cents or 3.3 percent to \$1.42.

IMAGION BIOSYSTEMS

Imagion says the manufacturing of its Magsense human epidermal growth factor receptor-2 (HER-2) nanoparticle is on schedule, uninterrupted by Covid-19.

Imagion said the first phase of manufacturing the cancer-detecting nanoparticles was completed on time and the second phase was expected to continue on schedule as the company prepared for its first human study.

Imagion executive chairman Bob Proulx said the company “took great care in [the] preparations before commencing manufacturing and that has paid off”.

“The first step of the production process is the trickiest, so completing this step on schedule is encouraging,” Mr Proulx said.

The company said it was monitoring the potential impact of the pandemic, as possible delays could arise if intended study sites were unable to start new studies.

Imagion said that it was likely that its planned clinical sites would be available when the nanoparticle production is complete “later this year”.

Imagion fell 0.1 cents or 3.45 percent to 2.8 cents with 32.3 million shares traded.

ONCOSIL

Oncosil says its fully underwritten one-for-11 non-renounceable, pro-rata rights offer at nine cents a share has raised \$5 million, taking the total raised to \$19 million.

Earlier this month, Oncosil said it had commitments to raise \$14 million in a placement at nine cents a share, a 19.3 percent discount to the 5-day volume weighted average price to April 28, 2020 (BD: May 4, 2020).

Today, the company said shareholder applications raised \$3.1 million, with the remaining \$1.9 million shortfall to be placed by lead manager, Bell Potter Securities.

Oncosil was up half a cent or five percent to 10.5 cents with 3.5 million shares traded.

ELIXINOL GLOBAL

Elixinol says its partially underwritten, one-for- 2.51 retails rights offer at 20 cents a share has raised \$5.6 million, taking the total raised to \$10.9 million.

Earlier this month, Elixinol said it had raised \$5.3 million through the institutional component of its rights offer at 20 cents a share, a 48.1 percent discount to the last closing price on May 5, 2020 (BD: May 5, 6, 2020).

Today, the company said it had applications for \$3.1 million, the offer was partially underwritten to \$2.8 million, with the shortfall to be placed to sub-underwriters by lead manager, Bell Potter Securities.

Elixinol was up five cents or 20.8 percent to 29 cents with 6.6 million shares traded.

ADHERIUM

Adherium says it has commitments from the Bioscience Managers Translation Fund-1 to raise \$5 million at three cents a share, with the option for a further \$5 million.

Adherium said it would issue Melbourne's Bioscience Managers \$3.1 million in shares with the balance and the 18-month option to raise the further \$5 million at six cents a share, subject to shareholder approval.

Adherium said the funds would be used for the development of its asthma sensor and chronic obstructive pulmonary disease sensor and software platform, including developing the capacity to measure and report physiological data such as respiratory flow data.

Adherium was up 0.3 cents or 12 percent to 2.8 cents with 3.6 million shares traded.

LBT INNOVATIONS

LBT says it has drawn down the third \$1.5 million under the \$4 million loan facility from the South Australian Government

In 2018, LBT said it would receive \$4 million, with a \$1 million instalment received in May 2019, a \$1.5 million instalment received in June 2019, and the final instalment initially to be received by December 31, 2019, with the deadline later extended to December 31, 2020 (BD: Aug 28, 2018, May 9, Jun 27, 2019, May 8, 2020).

Today, the company said the first two instalments totalling \$2.5 million had been converted to a standard principal and interest loan in February 2020 and were being repaid through fixed quarterly repayments of \$160,000 until February 2024.

LBT said the final \$1.5 million instalment would convert to a separate principal and interest loan, paid in fixed instalments of \$260,000 until February 2024, to fund the development of artificial intelligence, clinical science, and software engineering for its APAS automated plate assessment system analysis and testing technology.

LBT was up half a cent or 3.2 percent to 16 cents.

ZELIRA THERAPEUTICS, TASMANIAN ALKALOIDS

Zelira says it has appointed Tasmanian Alkaloids to manufacture its medical marijuana-based ZTL-101 formula for insomnia and Hope for autism products.

Zelira said the four-year supply agreement gave Tasmanian Alkaloids the exclusive manufacturing rights for one year, "semi-exclusive" rights for the remaining three years, and it expected to launch its insomnia and autism products by October 2020.

Tasmanian Alkaloids is a private company.

Zelira was up 0.3 cents or 6.7 percent to 4.8 cents with 3.9 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has ethics approval for its 103-patient, phase IIb trial of Cannepil for drug resistant epilepsy at Israel's Schneider Children's Medical Center.

MGC said the trial would be a randomized, double-blind, placebo-controlled, parallel design phase IIb study of the safety and efficacy of Cannepil as an "add-on" treatment in children and adolescents with refractory epilepsy, or drug resistant epilepsies.

The company said patients would be aged between one and 18 years of age and receive 12 weeks of treatment, with the first patient treated in September 2020 and the final patient to be treated in October 2021.

MGC managing-director Roby Zomer said that "receiving ethics committee approval for the phase IIb clinical trial of Cannepil is another important milestone for the company".

"Cannepil is one of the company's lead cannabinoid medicine products with a very significant global market opportunity," Mr Zomer said.

"Israel is recognized for its world leading researchers and institutions in relation to cannabis products and we look forward to updating the market as this trial progresses," Mr Zomer said.

MGC was unchanged at 2.5 cents with 7.6 million shares traded.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRIES)

Palla Pharma says it ceased negotiations for the acquisition of unnamed "major" UK customer which owes it \$3.5 million for codeine phosphate supplies.

Last month, Palla said the option to acquire the UK customer's business expired on March 31, 2020, but negotiations were continuing (BD: Apr 1, 2020).

Today, the company said it would seek payment for outstanding invoices for codeine phosphate supply totalling GBP1.9 million (\$A3.5 million) to be repaid by the customer, which did not have its relevant licence reinstated.

Palla said that marketing authorizations acquired from the customer were valid and its finished dosage formulation supply would not be interrupted.

The company said it was transferring manufacturing to its Norway site, and expects Norwegian manufacturing approval by October 2020.

Palla said it expected its earnings for the six months to June 30, 2020 to be "significantly stronger" than the earnings for the six months to December 31, 2019.

Palla was up nine cents or 12.7 percent to 18.5 cents with 7.6 million shares traded.

ELIXINOL GLOBAL

Elixinol says Shanghai Shunho New Materials Technology Co has terminated the \$500,000 purchase of subsidiary Hemp Foods Australia due to the impact of Covid-19.

In February, Elixinol said it would sell Hemp Foods to China's Shanghai Shunho, through subsidiary Yunnan Biological Pharmaceutical Co by April 2020, conditional on a three-year licencing deal appointing Shunho as manufacturer and distributor of Elixinol branded cannabidiol products in China, Hong Kong, Taiwan and Macau (BD: Feb 3, 2020).

Yesterday, the company said Shanghai Shunho had terminated the purchase on May 25, 2020 "due to non-satisfaction of a condition precedent ... citing Covid-19 impacts".

Elixinol said it would continue to operate Hemp Foods "pending an evaluation of all opportunities to capitalize on [its] strong position".

CANN GROUP, IDT AUSTRALIA

Cann Group says it will supply medical marijuana products manufactured by IDT Australia to Astral Health and Iuvo Therapeutics for distribution in the UK and Europe.

Cann said it had a multi-year agreement with the London-based Astral for the supply of a range of IDT's formulated oils, including high tetrahydrocannabinol (THC), high cannabidiol (CBD) and a balanced formulation, with the possibility of additional products to be developed and supplied to Astral over time.

The company said it had a separate three-year agreement with the Neuss, North Rhine-Westphalia, Germany-based Iuvo Therapeutics GmbH to supply IDT's medical marijuana oil formulations and dried marijuana flower material for sale in Germany and other European countries.

The company said it would begin supplying the products under both agreements following regulatory approvals from Australian, UK and European authorities.

Cann Group chief executive officer Peter Crock said the company had shown "an ability to supply a broad range of products from specific medicinal cannabis cultivars to unique finished product formulations that meet our customers' specific end-market requirements". "Our manufacturing arrangements with IDT Australia ensure we can meet the high [good manufacturing practice] standards that reputable distributors in overseas markets such as the UK and Europe require," Mr Crock said.

In a separate announcement, IDT chief executive officer Dr David Sparling said that the export agreements were "great news for IDT".

"Expanded export channels allow us to scale-up our manufacturing and supply operations even further and the parties can leverage off IDT's experience exporting [current good manufacturing practice] pharmaceutical products to Europe and our dealings with the European regulators," Dr Sparling said.

Cann Group was up 18 cents or 17.3 percent to \$1.22 with three million shares traded. IDT was up one cent or 5.7 percent to 18.5 cents with 3.1 million shares traded.

IMPRESSION HEALTHCARE

Impression says shareholders will vote to issue about 7,500,000 shares, 204,500,000 options to executives and change the company's name to Incannex healthcare.

Impression said it proposed to issue 1,750,000 shares and 2,250,000 options to chief executive officer Joel Latham under his remuneration package for the year to June 30, 2020 and 1,750,000 shares times 0.082208 divided by the 15-day volume-weighted average price, and 2,250,000 options for the year to June 30, 2021.

The company said Mr Latham's options would vest in three equal tranches, exercisable at the 15-day volume weighted average price to the issue date.

Impression said it proposed to issue chief medical officer Dr Sud Agarwal 4,000,000 shares, 200,000,000 options and 32,303,593 "performance" rights.

The company said Dr Agarwal's options were exercisable at 20 cents, and would vest following five consecutive days of a closing share price of 20 cents, expiring on September 30, 2021.

Impression said shareholders would vote on the ratification of shares and options in the \$5 million October 2019 placement.

The meeting will be held at Meeting Room 4, Level 1, 757 Bourke St, Docklands, Victoria on June 26, 2020 at 10:30am (AEST).

Impression was up 0.3 cents or 5.7 percent to 5.6 cents with 1.7 million shares traded.

GI DYNAMICS

GI Dynamics has requested a trading halt pending an announcement regarding its “proposed delisting from the ... ASX and the filing of a formal delisting application”. Earlier this month, GI Dynamics said that as part of its ongoing financing efforts, it had “been considering the possibility of delisting from the official list of the ASX and [had] ... applied to the ASX for in-principle advice in this regard” (BD: May 4, 2020). Trading will resume on May 28, 2020 or on an earlier announcement
GI Dynamics last traded at 0.2 cents.

STARPHARMA HOLDINGS

The Munich, Germany-based Allianz SE says it has become a substantial shareholder in Starpharma with 18,648,131 shares or 5.01% of the company. Allianz said it bought shares between January 23 and May 21, 2020, at prices ranging from 67 cents to \$1.22 a share. Starpharma fell one cent or 0.9 percent to \$1.125.

MAYNE PHARMA

Lazard Asset Management Pacific Co says it has become a substantial shareholder in Mayne Pharma with 84,379,755 shares or 5.03 percent of the company. The Sydney-based Lazard said that it bought the shares between February 28 and May 21, 2020 with the single largest purchase on May 6 of 2,743,001 shares for \$1,118,194 or 40.8 cents a share. Mayne fell one cent or 2.2 percent to 44 cents with 8.5 million shares traded.

MEDICAL DEVELOPMENTS

Medical Developments says it has appointed Christine Emmanuel as a non-executive director, effective immediately.

Medical Developments said Ms Emmanuel had more than 30 years' experience in local and international business, and patent and trademark law, was the Commonwealth Scientific Industrial Research Organisation's head of business development and commercial affairs and a director of the Institute of Patent and Trade Mark Attorneys of Australia.

The company said Ms Emmanuel was previously Unilever UK's intellectual property advisory and a patent and trademark attorney for Wilson Gunn UK, Davies Collison Cave and Griffith Hack.

Medical Developments said Ms Emmanuel held a Bachelor of Science and Economics from Melbourne's Monash University, and a Masters of Enterprise from Melbourne University.

Medical Developments fell 21 cents or 2.5 percent to \$8.25 with 303,378 shares traded.