

Biotech Daily

Tuesday June 16, 2020

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: PARADIGM UP 16%; PATRYS DOWN 13%
- * RACE: BISANTRENE FOR AML '40% OVERALL RESPONSE'
- * NEUREN: ACADIA RESUMES PHASE III TROFINETIDE RETT TRIAL
- * STARPHARMA: VIVAGEL BV IN CENTRAL, EASTERN EUROPE
- * MEMPHASYS: FELIX SPERM SEPARATOR SALES 'ON-TRACK'
- * RESAPP: PHENIX LICENCES RESAPPDX-EU FOR TELEHEALTH
- * CELLMID: \$1.2m FROM JAPAN TV HAIR LOSS SALES
- * RESPIRI, PHARMACY GUILD ASTHMA MANAGEMENT COURSE
- * G MEDICAL CEO DR YACOV GEVA 10m SHARES, 65m RIGHTS AGM
- * LIFESPOT REQUESTS CAPITAL RAISING TRADING HALT
- * THC REQUESTS CAPITAL RAISING TRADING HALT
- * CYNATA CEO, DIRECTOR SELL SHARES
- * AUSTRALIAN ETHICAL TAKES 11% OF ELLEX
- * INVESTORS MUTUAL BELOW 5% IN ELLEX
- * AUSTRALIAN ETHICAL TAKES 17% OF COGSTATE
- * FIL TAKES 5% OF STARPHARMA
- * PYC: CHAIR ALAN TRIBE AUST LAND 30%, DIRECTOR DR HOCKINGS 9%
- * L1 'BELOW 5%' IN CRESO; HOLDS 6.3%
- * DR DARRYL MAHER REPLACES CYNATA DIRECTOR PETER WEBSE, CO SEC
- * ANCILA DESAI REPLACES IDT CFO, CO-SEC JOANNA JOHNSON
- * SINEAD TEAGUE REPLACES EXOPHARM CO SEC DAVID PARKER

MARKET REPORT

The Australian stock market climbed 3.89 percent on Tuesday June 16, 2020, with the ASX200 up 222.5 points to 5,942.3 points. Thirty-four of the Biotech Daily Top 40 stocks were up, two fell and four traded unchanged. All three Big Caps were up.

Paradigm was the best, up 43 cents or 16.1 percent to \$3.10, with 2.9 million shares traded. Cyclopharm climbed 15.2 percent; Amplia was up 14.3 percent; Starpharma was up 9.3 percent; Actinogen, Avita and Mesoblast were up more than eight percent; Clinuvel and Nanosonics rose more than seven percent; Compumedics, Imugene, LBT, Medical Developments and Polynovo climbed more than six percent; Genetic Signatures, Opthea, Prescient and Volpara were up more than five percent; Impedimed, Kazia, Neuren, Next Science, Orthocell and Telix improved four percent or more; Cochlear, Immutep and Resmed were up more than three percent; Cynata, Dimerix, Optiscan, Pharmaxis, Proteomics, Resonance, Universal Biosensors and Uscom rose more than two percent; CSL was up 1.9 percent; with Ellex up 0.8 percent.

Patrys led the two falls, down 0.2 cents or 13.3 percent to 1.3 cents with 76,000 shares traded and Pro Medicus fell 0.4 percent.

RACE ONCOLOGY

Race says that four patients of 10 patients in its phase II trial of Bisantrene for relapsed or refractory acute myeloid leukaemia had responses to the drug.

Race said that one patient had a complete remission following Bisantrene administration, with three patients having a partial remission.

In March, Race said the trial was expected to recruit 12 adults over 12 months and to report complete responses and a range of secondary endpoints including leukaemia free survival and overall survival (BD: Mar 18, 2020).

Today, the company said the open-label, single arm, investigator-initiated trial was conducted at Israel's Sheba Medical Centre on patients with an average of three prior lines of treatment.

Race said Bisantrene had been shown to be an effective salvage therapy with little or no cardiotoxicity.

The company said it recruited the expected 12 patients but had to end the trial early "given the Covid-19 situation in Israel".

Race said it administered 250 milligrams (mg) per square metre (m2) of Bisantrene via intravenous infusion over two hours once daily for seven days, with an ongoing 24-month follow up period.

The company said the aim of the trial was to assess clinical efficacy for overall survival and leukaemia-free survival, though long-term survival was expected to be unlikely based on the patient cohort.

Race clinical advisory board chairman Prof Borje Andersson said that "while Bisantrene had been demonstrated to be an effective [acute myeloid leukaemia] salvage drug in the 1980s, the data we had were old".

"It is important for us to study it by today's standards using the current formulation, as we sought to confirm whether our strategy of repurposing this drug was sound," Prof Andersson said.

"We also wanted to confirm that Bisantrene could still generate a meaningful response rate in this highly frail patient population with heavily pre-treated [acute myeloid leukaemia]," Prof Andersson said.

The company said that of the 10 patients, one achieved complete remission, three had a partial remission and one patient bridged to allogeneic stem cell transplantation. Race said there was marked activity in four of four patients with difficult to treat extramedullary acute myeloid leukaemia..

The company said Bisantrene was well tolerated with no unexpected serious toxicities and the most frequently reported serious adverse events were thrombo-cyto-paenia, or low blood platelets, and mucositis or mouth ulcers, but both were expected side effects for this class of drug.

Race said that one patient had transient grade one kidney toxicity but no liver toxicities were observed.

The company said next generation DNA sequencing of the responding patient samples had identified a wide array of genetic mutations, including those associated with activated signalling, splicing, chromatin modification and epigenetic modification.

Race executive chairman Dr John Cullity said: "This drug is talking to us".

"As this was an open-label, single-agent trial, we can be confident that it was the Bisantrene exposure which generated the positive results," Dr Cullity said.

The company said data from the study would be submitted to a peer-reviewed journal for publication and a follow-up study, combining Bisantrene with other anti-leukaemia drugs was in advanced planning.

Race was up 16.5 cents or 52.4 percent to 48 cents with 8.3 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says that its US partner Acadia Pharmaceuticals has reinitiated enrolment for its phase III study of trofinetide for Rett syndrome.

Neuren said enrolment was temporarily paused in March 2020 due to restrictions in the US due to the Covid-19 pandemic (BD: Mar 24, 2020).

Neuren was up six cents or four percent to \$1.56.

<u>STARPHARMA</u>

Starpharma says it has launched Vivagel BV for bacterial vaginosis in Central and Eastern European, but did not specify which countries.

Starpharma said Vivagel BV would be available over-the-counter and further launches were planned in additional European countries and in Asia.

Starpharma chief executive officer Dr Jackie Fairley said the company was "excited to see Vivagel BV being rolled-out through Europe".

Starpharma was up nine cents or 9.3 percent to \$1.06.

MEMPHASYS

Memphasys says it is on track for the first commercial sales of its Felix sperm separation device this year, despite delays caused by the Covid-19 pandemic.

Memphasys said that following the recommencement of elective surgeries in Australia, its partner and key opinion leader site Monash IVF had resumed in-vitro fertilization services and testing of the Felix device.

The company said final Felix key opinion leader trial outcomes would be delayed due to Covid-19 restrictions in the US, Canada, Europe, India and Iran.

Memphasys said it expected to complete installation and test runs of equipment for final cartridge manufacturing and cleanroom certification by the end of July 2020.

The company said that due to its "strong financial position" the line of credit with chair Alison Coutts had been terminated (BD: Feb 23, 2018).

Memphasys fell 0.2 cents or 3.4 percent to 5.7 cents.

RESAPP HEALTH

Resapp says it has a two-year licence agreement with Brisbane's Phenix Health to use the Resappdx-EU respiratory diagnostic in Phenix's telehealth smartphone application. Resapp said Phenix would be allowed to use its Resappdx-EU from July 1, 2020 and would pay a per test licence fee of between \$5 and \$10.

Resapp chief executive officer Dr Tony Keating said, "our initial launch, via Phenix's telehealth Iphone operating system application, will see our clinically-validated and regulatory-approved diagnostic test available to Phenix's customers Australia-wide". Resapp was up half a cent or 2.9 percent to 18 cents with 2.7 million shares traded.

CELLMID

Cellmid says it has received \$1.19 million in wholesale revenue of its Jo-Ju branded hair loss products from a sales event on Japan's television shopping channel QVC. Cellmid said the \$1.19 million compared to events leading to \$1.14 million revenue in June 2019 and \$1.13 million in December 2019.

Cellmid fell one cents or 7.7 percent to 12 cents with 2.8 million shares traded.

<u>RESPIRI</u>

Respiri says it has a two-year agreement with the Pharmacy Guild of Australia to develop an asthma management online training course.

Respiri said it expected the continuing professional development training program to enhance and support the capability of pharmacists to help asthma patients, supported by its Wheezo asthma management device.

Respiri was up 0.3 cents or 3.75 percent to 8.3 cents with three million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical says its annual general meeting will vote to issue 10,000,000 shares and 65,000,004 "incentive performance rights" to founder officer Dr Yacov Geva.

G Medical said it would vote to issue 1,200,000 shares and 8,966,666 performance rights to director Dr Brendan de Kauwe, 600,000 shares and 2,400,000 performance rights to director Dr Kenneth Melani and 400,000 shares and 1,600,000 performance rights each to directors Dr Shuki Gleitman, Urs Wettstein and Prof Zeev Rotstein.

The company said it would vote to issue a further up to 7,000,000 shares and 48,833,330 performance rights to certain key management personnel.

G Medical said it would vote to issue 3,415,000 options to Pelaton Capital, 1,000,000 options to Evolution Capital Advisors, 650,000 options to Prosperion Wealth Management and 585,000 options to MacMillan Capital.

The company said it would also vote to ratify a series of placements and share issues, to re-elect Dr Melani, to issue 47,060,527 loan conversion shares to Dr Geva, on a potential placement of up to \$15 million and to approve a 10 percent placement facility.

The meeting will be held at the G Medical Office, 3rd floor, 5 Oppenheimer Street,

Rehovot, Israel on July 16, 2020 at 10am (IDT) or 5pm (AEST).

G Medical was unchanged at 5.3 cents with 3.7 million shares traded.

LIFESPOT HEALTH

Lifespot has requested a trading halt "pending an announcement in relation to a proposed capital raising.

Trading will resume on June 18, 2020 or on an earlier announcement. Lifespot last traded at 3.5 cents.

THC GLOBAL GROUP

THC has requested a trading halt pending an announcement "to consider, plan for and executive a capital raising".

Trading will resume on June 22, 2020 or on an earlier announcement. THC last traded at 38 cents.

CYNATA THERAPEUTICS

Cynata says chief executive officer Dr Ross Macdonald and director Dr Stewart Washer have sold 1,000,000 shares to an unnamed institutional investor.

Cynata said the funds would be used to fund the partial repayment of director loans of \$300,000 each.

Cynata was up 1.5 cents or 2.4 percent to 63 cents.

ELLEX MEDICAL LASERS

Australian Ethical Investment says it has increased its substantial shareholding in Ellex from 13,760,672 shares (9.58%) to 15,878,458 shares (11.06%). The Sydney-based Australian Ethical said that between March 24 and June 11, 2020 it bought 2,117,786 shares for \$1,191,883.66 or an average 56.3 cents a share. Ellex was up half a cent or 0.8 percent to 60 cents.

ELLEX MEDICAL LASERS

Investors Mutual says it has ceased its substantial shareholding in Ellex. In January, the Sydney-based Investors Mutual said it held 8,932,315 shares or 6.22 percent of the company (BD: Jan 19, 2020).

Today, Investors Mutual said that between January 30 and June 12, 2020 it sold 2,782,315 shares for \$1,768,668 or an average of 63.6 cents a share.

Biotech Daily calculates that Investors Mutual continues to hold 6,150,000 shares or 4.28 percent of the company.

COGSTATE

Australian Ethical Investment says it has increased its substantial shareholding in Cogstate from 22,857,143 shares (16.09%) to 29,485,793 shares (17.33%). The Sydney-based Australian Ethical said that between July 31, 2019 and June 12, 2020 it bought 6,628,650 shares for \$1,931,491 or an average of 29.1 cents a share. Cogstate was up three cents or 8.6 percent to 38 cents.

STARPHARMA

Fidelity International Limited (FIL) says it has become a substantial shareholder in Starpharma with 18,632,740 shares or 5.00 percent of the company. Last year, the Sydney, Hong Kong and Bermuda-based FIL said that it had ceased to be a substantial shareholder in Starpharma with 18,511,410 shares or 4.98 percent of the company (BD: May 1, 2019).

Today, FIL said that between May 19 and June 11, 2020 it bought 3,612,310 shares, with the single largest purchase 540,751 shares on May 29, 2020 for \$1.10 a share.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC chair Alan Tribe said his company Australian Land has increased its substantial shareholding from 794,663,760 shares (27.11%) to 882,563,760 shares (30.11%). The Perth-based Mr Tribe and Australian Land said they acquired 87,900,000 shares on June 15, 2020 for \$7,032,000 or 8.0 cents a share.

Separately, PYC director Dr Bernard Hockings said he reduced his holding from 351,559,571 shares (11.98%) to 263,659,571 shares (8.99%).

The Perth-based Dr Hockings said he sold 87,900,000 shares for \$7,032,000 or 8.0 cents a share on June 15, 2020.

PYC was up 0.8 cents or 8.8 percent to 9.9 cents with 6.6 million shares traded.

CRESO PHARMA

L1 Capital Global Opportunities Master Fund says it has ceased to be a substantial shareholder in Creso.

Last week, the Melbourne and Cayman Islands-based L1 said it had become substantial with 17,968,888 shares or 6.44 percent of the company (BD: Jun 9, 2020).

Today, L1 said that on June 11, 2020 it sold 400,000 shares.

Biotech Daily calculates that L1 holds 17,568,888 shares or 6.29 percent of the company. Creso fell 0.1 cents or 2.1 percent to 4.6 cents with 3.9 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has appointed Dr Darryl Maher as an independent non-executive director effective from June 16, 2020, replacing Peter Webse.

Cynata said Dr Maher was a specialist haematologist, had more than 23 years' experience at CSL and was most recently the head of research and development and medical affairs at CSL Behring Australia.

The company said Mr Webse had been a non-executive director since 2012 and would step down effective from June 30, 2020 but remain as company secretary.

IDT AUSTRALIA

IDT says Ancila Desai will replace chief financial officer and joint company secretary Joanna Johnson who has resigned, effective immediately.

IDT said Ms Desai had more than 15 years' finance experience and previously worked for Metcash, Toll and Boost Juice.

Ms Desai's Linkedin page said she held a Bachelor of Commerce from New Delhi's Jesus and Mary College and a Master of Business Systems from Melbourne's Monash University.

IDT thanked Ms Johnson for her contribution to the company since March 2014.

IDT was up half a cent or 3.3 percent to 15.5 cents.

EXOPHARM

Exopharm says it has appointed Sinead Teague as company secretary, replacing David Parker, who will continue as a non-executive director.

Exopharm said Ms Teague had more than 10 years' experience as a company secretary. The company said Mr Parker had been company secretary since 2018.

Exopharm fell half a cent or 2.1 percent to 23 cents.