



Biotech Daily

Tuesday September 18, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PRESCIENT UP 6%; GENETIC SIGS DOWN 7%**
- * **CSL: TGA APPROVES HIZENTRA FOR CIDP**
- * **MEMPHASYS WORKS WITH MONASH ON FELIX SPERM SEPARATION**
- * **PHARMAXIS: 30% OPPOSE PLACEMENT; EDWARD RAYNER ELECTED**
- * **ITALY'S VISION GROUP TRIALS NUHEARA IQBUDS BOOST**
- * **LIFESPOT BUYS SENG VITAL FOR MARIJUANA VAPORIZER**
- * **HK JULIAN BIOTECH, WU YANHENG 19% OF ADMEDUS; ZHANG OVERLAP**
- * **RACE CHAIRMAN DR WILLIAM GARNER TRANSFERS, REDUCES TO 18.5%**
- * **ELIXINOL TO TRADE ON US OTCQX**
- * **IMUGENE APPOINTS MAYO'S PROF TANIOS BEKAI-SAAB ADVISOR**

MARKET REPORT

The Australian stock market fell 0.38 percent on Tuesday September 18, 2018 with the ASX200 down 23.5 points to 6,161.5 points.

Eight of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and six were untraded. All three Big Caps fell.

Prescient was the best, up 0.5 cents or 5.6 percent to 9.5 cents with 81,250 shares traded. LBT climbed five percent; Optiscan and Paradigm rose more than two percent; Clinuvel and Starpharma were up more than one percent; with Cynata and Telix up by less than one percent.

Genetic Signatures led the falls, down five cents or 7.25 percent to 64 cents, with 72,725 shares traded.

Compumedics and Neuren lost more than five percent; Avita, Immutep and Imugene fell more than four percent; Nanosonics was down 3.4 percent; Mesoblast, Oncosil and Volpara shed more than two percent; Actinogen, Cochlear, CSL, Orthocell, Pharmaxis and Resmed were down more than one percent; with Ellex, Polynovo and Pro Medicus down by less than one percent.

CSL

CSL says the Australian Therapeutic Goods Administration has approved Hizentra for maintenance therapy to treat chronic inflammatory demyelinating polyneuropathy.

CSL said the approval through its Behring division was based on data from its phase III polyneuropathy and treatment with Hizentra (Path) study, the largest controlled clinical study in chronic inflammatory demyelinating polyneuropathy (CIDP) patients to date.

The company said the multi-centre, double-blind, randomized, placebo-controlled, parallel-group study assessed the safety, efficacy and tolerability of Hizentra

CSL said that CIDP was “a rare auto-immune disorder that affects the peripheral nerves and may cause permanent nerve damage”.

The company said that with CIDP patients, the myelin sheath, or the protective covering of the nerves, was damaged, which might result in numbness or tingling, muscle weakness, fatigue, and other symptoms.

CSL said that the effects of CIDP could worsen over time, leading to significant activity limitations and a decreased quality of life.

The company said that “until now, the only immunoglobulin therapy to treat CIDP was intravenously administered by infusion in a hospital setting”.

“Today’s approval means that many Australian patients who previously had to visit a hospital to receive treatment intravenously will be able to self-administer subcutaneous immunoglobulin therapy at home,” CSL said.

The company said that Hizentra could “resolve the fluctuating side effects encountered by some patients receiving intravenous immunoglobulin”.

CSL chief scientific officer and research and development director Dr Andrew Cuthbertson said that CSL Behring had “dedicated years to studying CIDP to bring patients a more convenient treatment option with proven efficacy and the flexibility and freedom to self-infuse”.

“Along with intravenous immunoglobulins Privigen and Intragam 10, we are proud to offer a portfolio of therapies for CIDP patients in Australia,” Prof Cuthbertson said.

CSL said that TGA approval for Hizentra for CIDP followed approval in the European Union, the US, New Zealand and Switzerland.

CSL fell \$2.94 or 1.4 percent to \$205.29 with 918,492 shares traded.

MEMPHASYS

Memphasys says it has a collaboration with Melbourne-based in-vitro fertilization (IVF) company Monash IVF Group to develop its Felix sperm separation system.

Memphasys said that it would issue Monash IVF \$80,000 in shares for its part of the collaboration and grant a 12-month licence to exploit Felix and market its use in Australia and Malaysia from the later of the date that Felix was ready for commercial use and sale and the date of regulatory approval expected by the end of 2019.

The company said that the shares would be deemed to be the issue price of its next capital raising of more than \$2 million.

Memphasys said it had been working with Monash IVF for six months testing the Felix prototype, which selected the most viable, least DNA-damaged sperm for IVF procedures. The company said that Monash IVF clinicians and researchers would provide advice on the design and operation of the new Felix device to be marketed to clinics.

Monash IVF chief research and development officer Prof Michelle Lane said her group saw “great potential in the Felix device to provide a new treatment paradigm for male infertility and we are keen to assist Memphasys to bring the device to commercial fruition”.

Memphasys was up 0.3 cents or 27.3 percent to 1.4 cents with 1.5 million shares traded.

PHARMAXIS

Pharmaxis says that up to 30 percent of votes cast at its extraordinary general meeting opposed the ratification of its recent \$24.0 million placement.

Pharmaxis said that 18,530,270 votes (30.22%) opposed the first tranche of the placement, with 42,015,079 votes (68.52%) in favor and 773,197 (1.26%) at “the proxy’s discretion”.

The company said that the second tranche was approved by a wider margin and the issue of shares to directors faced about 10 percent opposition.

In August, Pharmaxis said it raised \$24.0 million at 32.5 cents a share which was “a 3.1 percent premium to last closing price” (BD: Aug 6, 2018).

According to the company’s most recent Appendix 3B new share announcement, Pharmaxis had 358,450,576 shares on issue, meaning that the largest number of opposing votes to the resolutions, against the approval of shares to director Dr Kathleen Metters, of 20,103,697 votes, amounted to 5.6 percent of the company, sufficient to call extraordinary general meetings.

The company said the meeting elected Arix Bioscience investment director Edward Rayner as a non-executive director.

In August, Pharmaxis said that Arix invested \$14.2 million in the placement for an 11 percent holding.

Pharmaxis fell half a cent or 1.6 percent to 31 cents.

NUHEARA LIMITED

Nuheara says it will conduct a sales trial of its hearing and sound filtering Iqbuds Boost earbuds in 50 Vision Group shops in Italy.

Nuheara said the Milan-based Vision Group was “the leading optical retailer in Italy with 2,059 outlets which [was] 20 percent of the total Italian optical market”.

The company said the Paris, France-based optical company Acuitis would sell the Iqbuds Boost earbuds, as well as its original Iqbuds device (BD: Feb 23, 2018).

Nuheara chief executive officer Justin Miller said the optical sector was “embracing hearing health retailing with increasing scale and professionalism”.

“In comparison to traditional hearing clinics, the optical retail industry is more advanced and sophisticated in the way it merchandises and markets to its customers,” Mr Miller said. “The stores are large and spacious with contemporary merchandising, professional sales support and are better positioned in viable high traffic areas such as premium shopping centres and strip malls.”

Nuheara was unchanged at 8.4 cents with 1.3 million shares traded.

LIFESPOT HEALTH

Lifespot says it has bought the remaining 50 percent of Seng Vital, for \$50,000 cash and \$225,000 in shares at 8.56 cents a share, for its cannabis vaporizer assets.

Lifespot said that its wholly-owned subsidiary, Bodytel GmbH had developed a system integrated with the Seng Vital vaporizer and demonstrations were “underway to seek commercial arrangements in licencing supply” (BD: May 1, 2017).

Lifespot said the Seng Vital marijuana vaporizer had a digital sign-on, was fingerprint activated for safety and security, had session tracking for adherence and responsible use, with adverse event tracking through doctor monitoring and recorded pain scores by users with other functions available.

Lifespot was up 0.2 cents or 2.5 percent to 8.3 cents.

ADMEDUS

Wu Yanheng and Hong Kong Julian Biotechnology say they have an overlapping percent holding in Admedus with Zhang Lishan, Star Bright Holdings and associates.

Yesterday, the Melbourne-based law firm Norton Rose Fulbright filed a substantial shareholder notice on behalf of Zhang Lishan, Star Bright Holdings, Constellation International Holdings Limited (CIHL), Constellation Immunotherapy Limited (CIL), Carron Services Ltd and Hong Kong Star Bright Management Limited which said they had become substantial shareholders in Admedus with 70,556,169, shares or 19.99 percent of the company (BD: Sep 17, 2018).

Today, Wu Yanheng and Hong Kong Julian Biotechnology said they held 66,049,869 shares or 18.72 percent of Admedus.

The substantial shareholder notice said that Mr Wu and Hong Kong Julian had a relevant interest through Constellation International Holdings Limited (CIHL) and Constellation Immunotherapy Limited (CIL).

Mr Wu gave his address as Guangzhou, Guangdong, China.

Admedus was in an extended suspension for its "recapitalization" and last traded at 13.5 cents.

RACE ONCOLOGY

Race chairman Dr William Garner says he has reduced his holding in the company from 15,100,000 shares (19.95%) to 14,294,218 shares (18.51%).

Dr Garner said that on April 26, 2018 he bought 100,000 shares for \$32,314, or 32.3 cents a share and on August 28 a further 50,000 shares for \$7,185, or 14.4 cents a share.

Dr Garner said that on September 12, 2018 he transferred 955,782 shares off-market "to non-related shareholders of director-related entity" for no cost.

Race was unchanged at nine cents.

ELIXINOL GLOBAL

Elixinol says it will begin trading on the US Over-The-Counter Quality Exchange (OTCQX) under the symbol ELLXF from the open on September 18, 2018.

Elixinol said that trading on the OTCQX would be in parallel to its ASX listing.

The company said that US investors would be able to find information and real-time level 2 quotes for the company on www.otcmarkets.com.

Elixinol chief executive officer Paul Benhaim said the OTCQX would "enable Elixinol Global to provide US investors with timely news and information to help them better analyze, value and trade our securities".

"Trading on [the] OTCQX is part of our broader strategy to significantly increase the awareness of [Elixinol] in the US market, particularly as consumer interest is expanding rapidly across the areas of hemp-derived [cannabidiol] and dietary supplements," Mr Benhaim said.

Elixinol fell 10 cents or 4.9 percent to \$1.94.

IMUGENE

Imugene says it has appointed the Mayo Clinic's Prof Tanios Bekaii-Saab to its scientific advisory board.

Imugene said that Prof Bekaii-Saab was the Rochester Minnesota-based Mayo Clinic Cancer Centre's co-leader of the gastrointestinal cancer program, medical director of the cancer clinical research office and a haematology and oncology consultant at the Mayo Clinic in Phoenix, Arizona.

Imugene chief executive officer Leslie Chong said that Prof Bekaii-Saab was a "leader in gastro-intestinal treatment and research ... [and] the principal investigator on numerous clinical trials focused on new targeted and immune therapies in gastro-intestinal malignancies".

The company said that Prof Bekaii-Saab had authored or co-authored more than 350 peer reviewed publications, abstracts, and book chapters for journals including Lancet Oncology, Journal of Clinical Oncology, the Journal of the American Medical Association, Journal of the National Cancer Institute, Annals of Oncology and Clinical Cancer Research.

Imugene fell 0.1 cents or 4.55 percent to 2.1 cents with 14.1 million shares traded.