



Biotech Daily

Thursday November 21, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: PRESCIENT UP 28%; VOLPARA DOWN 10%**
- * **CHINA OKAY FOR MEDICAL DEVELOPMENTS PENTHROX TRIAL**
- * **STARPHARMA EU APPROVAL FOR VIVAGEL CONDOMS**
- * **RESONANCE DEVELOPS AUTOMATIC LIVER FAT ASSESSMENT TOOL**
- * **PHYLOGICA RETAIL RIGHTS RAISE \$5.3m, TOTAL \$26.8m**
- * **IMMURON PHASE III IMM-124E TRIAL FOR TRAVELLERS DIARRHOEA**
- * **KAZIA REQUESTS GDC-0084 GLIOBLASTOMA TRIAL TRADING HALT**
- * **PAINCHEK: \$1m MILESTONE, 30m DIRECTOR OPTIONS VEST**
- * **PAINCHEK EXPECTS TO SIGN \$5m FEDERAL GOVERNMENT CONTRACT**
- * **MEMPHASYS WINS \$549k ARC GRANT FOR CELL SORTERS**
- * **MEMPHASYS IDENTIFIES 5 COUNTRIES FOR INITIAL FELIX SALES**
- * **HERAMED, KINDERHELDIN GERMAN HERABEAT MIDWIFE SERVICE**
- * **HEALTH HOUSE TO DISTRIBUTE ZELDA, ILERA HOPE MARIJUANA**
- * **NOVITA REQUESTS CAPITAL RAISING TRADING HALT**
- * **ANTEOTECH TO ASX: 'IMRA CONTRACT LODGED BY NEXT TRADING DAY'**
- * **JEREMY GREEN, REDMILE REDUCE TO 11% OF AVITA**

MARKET REPORT

The Australian stock market fell 0.74 percent on Thursday November 21, 2019, with the ASX200 down 49.5 points to 6,672.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, four traded unchanged and five were untraded.

Prescient was the best on no news, up 1.6 cents or 27.6 percent to 7.4 cents, with 29.7 million shares traded. Imugene climbed 13.2 percent; LBT was up 8.8 percent; Resonance improved 6.9 percent; Patrys rose five percent; Alterity, Compumedics and Medical Developments were up four percent or more; Amplia was up 3.9 percent; Genetic Signatures, Optiscan and Pharmaxis rose more than two percent; Antisense was up 1.2 percent; with Clinuvel, Cochlear and Cynata up by less than one percent.

Volpara led the falls, down 20.5 cents or 10.4 percent to \$1.77, with three million shares traded. Opthea fell 7.7 percent; Paradigm and Polynovo lost six percent or more; Immutep, Impedimed and Uscom lost more than five percent; Avita and Osprey fell more than four percent; Telix was down 3.7 percent; Oncosil and Orthocell shed more than two percent; with CSL and Nanosonics down by more than one percent.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says the Chinese National Medical Product Administration has approved its Pentrox investigative new drug application for trauma and procedural pain. Medical Developments said it had begun work for required bridging studies for its Pentrox inhaled methoxyflurane analgesic both trauma pain and surgical procedural pain, which it expected to complete within 12 months.

The company said it would undertake a bridging pharmaco-kinetic study to support the use of Pentrox in China, which would be submitted to the National Medical Product Association (NMPA) alongside previous clinical data.

Medical Developments chief executive officer John Sharman said the trial approval was “a significant milestone for our company”.

“The NMPA has accepted the safety and efficacy of the global clinical data,” Mr Sharman said. “The clinical program we are undertaking in China comprises small studies designed to support the safety and efficacy of Pentrox in Chinese people.”

“Our partner in China, Daiichi Sankyo, is Japan’s biggest pharmaceutical company, which is expanding aggressively in China,” Mr Sharman said.

“The Chinese market has an unmet need for a strong non-opioid analgesic like Pentrox and the ultimate approval by the NMPA of Pentrox will be very positive for [the company] and Daiichi Sankyo,” Mr Sharman said.

Medical Developments chairman David Williams said the approval by the People’s Republic of China was “a red-letter day” and a very exciting milestone.”

Medical Developments rose 25 cents or 4.2 percent to \$6.26 with 382,681 shares traded.

STARPHARMA HOLDINGS

Starpharma says it has marketing approval for its Vivagel condoms in Europe and partner Lifestyles will launch the product under the name Absolute dual protection.

In 2017, Starpharma said the sale of the Ansell condom business, now Lifestyles, to Chinese company Humanwell Healthcare was “an opportunity” for its Vivagel condom (BD: Sep 5, 2017).

In July, the company said it had \$2,807,000 in receipts from customers for the year to June 30, 2019, including \$800,000 from product supply, royalties and research revenue from partners, related to its Vivagel BV and Vivagel condoms (BD: Jul 16, 2019).

Starpharma was unchanged at \$1.32 with 1.1 million shares traded.

RESONANCE HEALTH

Resonance says it has trained a neural network to automatically assess liver fat using its Hepafat-scan magnetic resonance imaging datasets.

Resonance said the artificial intelligence tool was intended to provide “a fully-automated solution for the assessment of liver fat, and to be integrated directly into existing radiology workflows”.

The company said it was intended as a clinician aid to assess, diagnose and manage liver fat in non-alcoholic fatty liver disease and non-alcoholic steato-hepatitis patients.

Resonance said the as-yet-to-be-named artificial intelligence tool had demonstrated “high diagnostic ability at all clinical thresholds as demonstrated in [a recent] unpublished validation study”.

The company said it had begun preparation of a dossier for regulatory clearances and it hoped to submit an application for regulatory approval by April 2020.

Resonance was up one cent or 6.9 percent to 15.5 cents with 11.1 million shares traded.

PHYLOGICA (TRADING AS PYC THERAPEUTICS)

Phylogica says its fully-underwritten retail rights offer at 5.5 cents a share has raised \$5,262,055, with a \$7,270,134 shortfall, taking the total raised to \$26.8 million. Earlier this month, Phylogica said it had raised \$14.3 million in the institutional offer and expected to raise a further \$12.5 million in the retail offer (BD: Nov 4, 2019). Today, the company said Australian Land would be allocated the shortfall shares. Phylogica was unchanged at 5.7 cents with 1.1 million shares traded.

IMMURON

Immuron says it plans to file an investigational new drug application to the US Food and Drug Administration for a phase III trial of IMM-124E for travellers diarrhoea. Immuron said it would submit the investigational new drug (IND) application for IMM-124E, or Travelan, by July 2020, following guidance and feedback from a recent FDA meeting. The company said Travelan had been marketed and sold as an over-the-counter Therapeutic Goods Administration-listed medicine for travellers diarrhoea in Australia, as a dietary supplement for digestive tract protection in the US and as a natural health product in Canada, for more than a decade (BD: Nov 23, 2009). Immuron was unchanged at 13 cents.

KAZIA THERAPEUTICS

Kazia has requested a trading halt "pending the release of new clinical data from its GDC-0084 phase II trial". In May, Kazia said an eight-patient, phase IIa, safety study of GDC-0084 for glioblastoma established that a 60mg dose was tolerated (BD: May 6, 2019). Trading will resume on November 25, 2019 or on an earlier announcement. Kazia last traded at 44 cents.

PAINCHEK

Painчек says it has reached its \$1 million annualized customer contract recurring revenue milestone, allowing 30,066,051 unvested director options. Painчек said it had contracts covering 280 aged care facilities and 24,170 beds, of which about 12,000 beds related to Federal Government grant pricing. In its notice of meeting, the company said that chief executive officer Philip Daffas would receive 13,666,387 options, John Murray 8,199,832 options, with 4,099,916 options each to Ross Harricks and Adam Davey, all exercisable at two cents each by November 24, 2019. Painчек fell 1.5 cents or 5.2 percent to 27.5 cents with 4.8 million shares traded.

PAINCHEK

Painчек says it expects to sign a Federal Government grant contract for \$5 million "imminently". Painчек said the Federal Government would reimburse the company for residential aged care operators to be provided with a one-year subscription licence to use its mobile phone application to determine pain in elderly patients.

MEMPHASYS

Memphasys says it has been awarded a three-year \$549,452 grant with Newcastle University and the University of New South Wales to develop cell sorters.

Memphasys said it would provide an additional \$60,000 a year to the program to develop cell sorters that would scale production of viable sperm cells and other cell types using electro-phoretic technology.

The company said the Australian Research Council grant project would be led by the co-inventor of the Felix sperm separation technology Prof John Aitken and inventor of Terumo BCT's Quantum cell expansion system, Dr Robert Nordon.

Memphasys was unchanged at 5.9 cents.

MEMPHASYS

Memphasys says it has identified Iran, Japan, India, Canada and New Zealand to target initial commercial sales of its Felix sperm separation device.

Memphasys said it expected first sales in mid to late 2020.

HERAMED

Heramed says it has a two-year deal with Berlin's based Kinderheldin and Duttenhofer Group to add the online midwife service to its foetal heart rate monitor.

Heramed said Kinderheldin's online midwife service would be offered by the company and existing distributor Duttenhofer through individual access codes provided when the Herabeat device is purchased.

The company said the service would be complimentary for those who purchased the device during launch but would transition to a monthly rent and subscription-based payment.

Heramed fell 1.5 cents or 6.1 percent to 23 cents with 6.8 million shares traded.

ZELDA THERAPEUTICS

Zelda says the UK-based Health House Holdings will distribute its Hope medical marijuana products for autism spectrum disorder in Australia and the UK.

Yesterday, Zelda said Ilera Therapeutics, with whom it intended to merge to form Zelira Therapeutics, planned to launch its Hope medical marijuana products in multiple US states and globally from early 2020 (BD: Nov 20, 2019).

Today, the company said the Health House agreement would include its insomnia investigation formulation, which it intended to launch pending a positive outcome from results of its phase II clinical trial, expected by April 2020.

Zelda was unchanged at 6.7 cents.

NOVITA HEALTHCARE

Novita has requested a trading halt "pending an announcement regarding a proposed capital raising".

In September, Novita said it raised \$1,855,797 in a five-for-11 entitlement offer and shortfall placement at one cent a share (BD: Sep 19, 2019).

Trading will resume on November 25, 2019 or on an earlier announcement.

Novita last traded at 6.9 cents.

[ANTEOTECH \(FORMERLY ANTEO DIAGNOSTICS\)](#)

Anteotech has told the ASX that it received the counter-signed IMRA America agreement on Saturday November 16 and published it on Monday November 18, 2019.

On Monday, Anteotech said it has an agreement with the Ann Arbor, Michigan-based IMRA America to produce and market Anteobind-coated IMRA 40 nanometer colloid gold particles for lateral flow assays for point-of-care diagnostics (BD: Nov 18, 2019).

In its November 18 query, the ASX said the announcement entitled 'Anteotech signs commercial contract with IMRA America Inc' was released at 9:40am on November 18, 2019 and asked the company if this was information a reasonable person would expect to have a material effect on the price or value of its securities and if so, when it first became aware of the information.

Anteotech said it believed the information would be material and it first became aware of the signed commercial agreement on November 16, 2019 and lodged the announcement prior to opening of the next trading day.

Anteotech was up 0.1 cents or 5.3 percent to two cents with 7.4 million shares traded.

[AVITA MEDICAL](#)

Jeremy Green and Redmile Group say they have reduced their substantial holding in Avita from 232,590,853 shares (12.42%) to 225,659,260 shares (10.65%).

The San Francisco, California-based Redmile Group and Mr Green said that on November 20, 2019 they acquired 11,864,407 shares in the \$120 million institutional placement at 59 cents a share (BD: Nov 13, 2019).

Redmile Group and Mr Green said that between October 24 and November 5, 2019 they sold 18,786,000 shares on market for between 59.0 and 68.9 cents a share.

Avita fell 2.5 cents or 4.6 percent to 52 cents with 32.7 million shares traded.