



Biotech Daily

Monday September 10, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: IMPEDIMED UP 27%; REVA DOWN 15%**
- * **BLUECHIIP RAISES \$5.5m, SHARE PLAN**
- * **SIRTEX VOTERS 99.7% BACK \$1.9b CDH BID; 92.6% DON'T VOTE**
- * **PHOSPHAGENICS QUESTIONS MYLAN GENERIC DAPTOMYCIN SALES**
- * **CORRECTION: BOTANIX PHARMACEUTICALS**
- * **PAINCHEK LICENCES APPLICATION TO ALLITY AGED CARE**
- * **US OKAYS NOVITA TALI TRAIN FOR ADHD**
- * **PHARMAUST: CANCERS SENSITIVE TO MONEPANTEL IN-VITRO**
- * **IMAGION OPTIMIZES HER2 BREAST CANCER TEST NANOPARTICLES**
- * **AUSTRALIAN PATENT FOR INVION PHOTOSOFT CANCER THERAPY**
- * **MEDADVISOR TO USE PATIENT DATABASE FOR TRIAL RECRUITMENT**
- * **SUDA WINS FEDERAL HOME AFFAIRS 'TRUSTED TRADER' STATUS**
- * **TELIX REQUESTS 'ACQUISITION' TRADING HALT**
- * **ANTEO'S 'SHORT TERM' CEO CHRISTOPHER PARKER CONTINUES**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Monday September 10, 2018 with the ASX200 down 2.1 points to 6,141.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and three were untraded. All three Big Caps rose.

Impedimed was the best on no news, up 10.5 cents or 26.9 percent to 49.5 cents with 491,138 shares traded. Clinuvel climbed 19.25 percent; Optiscan improved 17.8 percent; Prescient was up 7.2 percent; Factor and Universal Biosensors were up more than six percent; Medical Developments and Pro Medicus climbed more than three percent; Osprey and Starpharma rose more than two percent; Bionomics was up 1.9 percent; with Cochlear, CSL, Resmed and Sirtex up by less than one percent.

Reva led the falls, down 3.5 cents or 14.6 percent to 20.5 cents, with 10,957 shares traded. Uscom lost 6.7 percent; ITL retreated 5.4 percent; Airxpanders, Ellex, Immutep, Imugene, LBT and Neuren fell four percent or more; Actinogen and Orthocell were down more than three percent; Benitec and Cynata shed more than two percent; Nanosonics was down 1.8 percent; with Opthea and Mesoblast down by less than one percent.

BLUECHIIP

Bluechiip says it has raised \$5.5 million in an oversubscribed placement at 5.9 cents a share to sophisticated and professional investors.

Bluechiip chief executive officer Andrew McLellan said the funds would “provide a foundation for Bluechiip to finalize its product portfolio through to validation and release of our chips, readers and software”.

“It also enables us to fully support our ... partners’ product release and to fund working capital to meet our growing orders,” Mr McLellan said.

Bluechiip said that shareholders at the record date of September 7 could subscribe for up to \$15,000 in new shares at the placement price of 5.9 cents a share, with the offer opening on September 14 and closing on September 28, 2018.

Bluechiip said that Melbourne’s CCZ Statton Equities was the lead manager to the placement.

Bluechiip fell 0.7 cents or 10.0 percent to 6.3 cents with 2.5 million shares traded.

SIRTEX MEDICAL

Sirtex says that 99.7 percent of voting shareholders approved the CDH Genetech and China Grand Pharmaceutical and Healthcare \$1.9 billion bid for the company.

Sirtex said that 26,311,219 votes from 1,203 holders (99.69%) supported the acquisition at \$33.60 a share, with 80,922 votes from 34 holders (0.31%) opposed.

The company’s most recent Appendix 3B new issue announcement said it had 55,789,512 shares on offer, meaning that 52.7 percent of Sirtex shares were not voted in the meeting.

According to the Sirtex 2017 annual report, the company had 16,656 individual shareholders, implying that only 7.4 percent of shareholders bothered to vote with 92.6 percent not voting for the offer.

The company said it had applied to the Federal Court of Australia to approve the scheme of arrangement for the acquisition at a hearing scheduled at 10:15am on September 12, 2018.

Sirtex was up 10 cents or 0.3 percent to \$32.90 with 669,311 shares traded.

PHOSPHAGENICS

Phosphagenics says the Mylan on-line product catalogue has been updated to include a generic daptomycin injectable product with a list of wholesalers.

Phosphagenics said that Mylan Laboratories received US Food and Drug Administration approval to market a generic daptomycin injectable on June 6, 2018 and on July 27, 2018 Mylan’s label was published on the US National Library of Medicine website identifying that the generic daptomycin product would be sold under a Mylan label.

The company said that under the licencing agreement of October 26, 2012, which was originally signed with Agila Specialties Private which was subsequently acquired by Mylan, its tocopheryl phosphate mixture (TPM) technology was licenced exclusively for the development and commercialization of a TPM-daptomycin injectable product.

Phosphagenics said it was not aware of whether any sales of the daptomycin product had occurred, but any sales by Mylan or any related Mylan party “would be restrained under the terms of the licencing agreement ... [and it had] reserved its rights”.

The company said that this was “again an issue related to the licencing agreement with Mylan ... a matter entirely separate to the Singapore arbitration completed in November 2017 on which both parties presently await a decision”.

Phosphagenics fell 0.3 cents or 12.0 percent to 2.2 cents with 7.1 million shares traded.

CORRECTION: BOTANIX PHARMACEUTICALS

Friday's edition referred to the co-founder of Botanix Dr Bosch but incorrectly gave his name as Robert instead of the correct name of William (Bill) Bosch.

Biotech Daily apologizes unreservedly for the error, which was made by the former Friday sub-editor who has found alternative employment with Spark Plugs and Washing Machines Weekly.

Botanix fell 0.1 cents or 1.0 percent to 9.6 cents with 1.1 million shares traded.

PAINCHEK (FORMERLY EPAT TECHNOLOGIES)

Painchek says it has licenced its smartphone pain assessment system to the Sydney-based residential age care provider Allity Aged Care.

Painchek said the one-year agreement made the application available to Allity's nursing and care staff, who could use it to assess residents' clinical pain levels at two of New South Wales residential aged care homes, covering 239 residents.

The company said the software used facial recognition to assess pain through micro-facial expressions in residents unable to communicate with staff, analyzing three-second videos and calculating a pain severity score.

Painchek said the agreement allowed Allity to extend the licence to their 45 residential aged care facilities, with revenue from the agreement consistent with standard Painchek annual subscription licence agreements, which averaged \$5 a month for each licenced bed and \$10 a month for each active resident.

The company said It would begin Allity staff training and the technology roll-out from November 2018.

Painchek fell half a cent or 9.1 percent to five cents.

NOVITA HEALTHCARE

Novita says the US Food and Drug Administration has approved its Tali Train paediatric attention difficulty assessment and training system.

Novita said that Tali Train had received classification as a "computerized cognitive assessment aid, exempt" class 2 medical device from the FDA and could be sold in the US without further clinical trials or submission of an FDA 510k application.

The company said that Tali Train was an adaptive game-based system designed for children aged three to eight years with attention difficulties, including autism spectrum disorder or attention deficit hyperactivity disorder (ADHD), as an early intervention.

Novita managing-director Glenn Smith said the classification was "a major milestone" and the company would advance discussions with potential partners to support a US launch.

"Attention disorders and difficulties among children are a major issue across the world and the US is no exception," Mr Smith said.

"Given early intervention therapies have demonstrated value in treating children and improving attention, concentration and learning outcomes, we believe there is a significant market opportunity in the US for a validated treatment like Tali Train," Mr Smith said.

Novita said that 6.1 million US children had been diagnosed with ADHD and 69 percent aged between six and eight years of age were taking ADHD medication including psycho-stimulants including methylphenidate, or Ritalin.

"While psycho-stimulants are a popular treatment for attention difficulties, the majority of evidence suggests drugs can only treat the symptoms and not the core underlying causes," Novita said.

Novita was up 0.3 cents or 9.1 percent to 3.6 cents with 11.9 million shares traded.

PHARMAUST

Pharmaust says Olivia Newton-John Cancer Research Institute staff have confirmed sensitivity of cancer cell lines to monepantel.

Pharmaust said that in-vitro studies by the Institute showed that human brain, breast, ovarian and prostate cancer cell lines were sensitive to monepantel.

The company said the researchers showed sensitivity of previously untested human melanoma cancer cell lines, widening the possible reach of the drug's anti-cancer targets. Pharmaust said that two non-cancerous ovarian cell lines were relatively insensitive to monepantel, consistent with its specificity for cancer cells.

The company said the data corroborated internal research that had identified 28 independent cancer cell lines that were sensitive, in culture, to treatment with monepantel, whereas three non-cancer cell lines were relatively insensitive.

Pharmaust said that the longer cancer cell lines were exposed to monepantel, the greater the anti-cancer activity, and for most of the cancer cell lines tested, significant and progressive increases in the effects were observed over one to five days.

The company said that research into the molecular cascade activated by monepantel to exert anti-cancer activity was being extended.

Pharmaust said that the work conducted by the Olivia Newton-John Institute was partly supported by a Federal Government \$50,000 Innovation Connections grant.

Pharmaust chief scientific officer Dr Richard Mollard said that independent confirmation of monepantel's anti-cancer activity in specific cancer cell lines was "a great milestone".

"This work enables Pharmaust to progress through its [research and development] program with greater certainty and expand its intellectual property portfolio on the mechanisms underpinning [monepantel's] mode of action," Dr Mollard said.

Pharmaust was unchanged at 3.5 cents.

IMAGION BIOSYSTEMS

Imagion says it has optimized the nanoparticle formulation for a diagnostic for HER2 breast cancer cells in the lymph nodes.

Imagion said the optimization was "a key milestone in its drive to first-in-human testing" for its first intended clinical product and it would take it to clinical development.

The company said its manufacturing partner would proceed with manufacturing of the first batch of the human epidermal growth factor receptor 2 (HER2) nanoparticle test reagent which would be used in a toxicology study, a prerequisite to the planned first-in-human study expected in early 2019.

Last year, Imagion said it had hired the Oss, Netherlands-based Chemconnection to produce and supply clinical grade Magsense nanoparticle formulations for its HER2 breast cancer trials (BD: Oct, 2017).

Today, Imagion executive chairman Bob Proulx said the optimization was "a pivotal achievement and represents a significant technical advance in our development plan".

"Optimizing our nanoparticle formulation is a key step in moving us closer to a first-in-human clinical study," Mr Proulx said. "The manufacturing of this initial batch of the formulation allows us to conduct our toxicology study and keeps us on track to commence the first-inhuman study early next year."

Imagion said that during 2018 and prior to the first-in-human study the company expected to have the nanoparticles tested for safety and toxicity, begin production of a second batch of material for the initial human research study and seek regulatory and institutional approval for the human research study.

Imagion fell 0.8 cents or 9.1 percent to eight cents.

INVION

Invion says IP [intellectual property] Australia has granted it a patent for the use of its photo-dynamic therapy Photosoft, or chlorin e4 sodium, against a range of cancers. Invion said the patent, titled 'Chlorin derivative useful in photodynamic therapy and diagnosis', protected Photosoft intellectual property until 2033.

The company said that the patent supported its program to manufacture topical and intravenous formulations for the treatment of all cancers, including lung, prostate, ovarian and skin cancer.

The company said Photosoft was a photo-sensitizing agent used in photo-dynamic therapy, which used non-toxic photo-sensitizers and visible light in combination with oxygen to produce cytotoxic-reactive oxygen to kill malignant cells, shut down tumors and stimulate the immune system, in contrast to surgery, radiotherapy and chemotherapy which mostly suppress the immune system.

Invion chief executive officer Dr Greg Collier said the technology "uses its patented photo-sensitizer combined with a laser light activation in the near-infra-red peaks of absorption to achieve a deeper tissue penetration that targets increased treatment efficacy".

"The new topical and intravenous Photosoft formulations are being designed to address the limitations of prior [photo-dynamic therapies] and also providing a positive whole-body immune response treatment for patients," Dr Collier said.

Invion was unchanged at 3.5 cents with 3.1 million shares traded.

MEDADVISOR

Medadvisor says it will expand its revenue streams by adding clinical trial recruitment to its patient medication advisory system.

Medadvisor said that patient recruitment for clinical trials was "a \$2 billion industry with significant challenges in finding the most eligible patients in a cost effective and timely manner".

The company said that 80 percent of trials were delayed due to issues recruiting the required number of patients.

Medadvisor said it could use its existing manufacturer relationships and its patient database of more than one million users to assist patient recruitment for trials, by identifying patients who met certain inclusion criteria such as those on certain medications, location proximity to trial sites, age and other demographic attributes.

The company said that its database, formed by partnering with pharmacies to provide notification of prescription renewals had "proven to be an effective channel at identifying eligible patients, generating patient interest and initial screening ... [and had] already completed four small-scale clinical trial recruitment programs".

Medadvisor said that for the four trials the recruitment process was open for less than two weeks before milestones were achieved.

The company said it could target efforts geographically or by trial site availability to smooth the workload for trial administrators, with revenue charged on a set-up and per eligible patient fee basis.

Medadvisor chief executive officer Robert Read said the strategy was "a win for patients and a win for innovative pharmaceutical and biotech companies who globally have struggled to find efficient methods of clinical trial recruitment".

"Given a patent life is fixed, the cost of each week of delay is one week at full global sales for that product before the patent ends, not to mention one week longer before patients can access therapy," Mr Read said.

Medadvisor was unchanged at 3.9 cents.

SUDA PHARMACEUTICALS

Suda says it has been accredited as an Australian Trusted Traded, through a trade initiative by the Department of Home Affairs.

Suda said the accreditation was delivered by the Australian Border Force and recognized businesses with a secure supply chain and compliant trade practices.

The company said the accreditation rewarded businesses with a range of trade facilitation benefits and reduced regulatory burden both in Australia and overseas, through mutual recognition arrangements.

Suda was unchanged at 0.4 cents.

TELEX PHARMACEUTICALS

Telex has requested a trading halt “pending an announcement regarding a material acquisition”.

Trading will resume on September 12, 2018 or on an earlier announcement.

Telex last traded at 87 cents.

ANTEO DIAGNOSTICS

Anteo says Christopher Parker will continue as chief executive officer until June 30, 2019 “to provide continuity” as it progresses its battery and diagnostics sectors.

In April, Anteo said that Mr Parker replaced three-month chief executive officer Dr Stefan Enderling who had resigned “for family reasons” (BD: Apr 9, 2018).

The company said at that time that Mr Parker was appointed on a short-term contract while it conducted a search for a permanent chief executive officer.

In 2015, Anteo said it would buy the Belgium-based Diasource Immunoassays for up to \$34 million in cash and scrip, and last year said it would sell Diasource for \$23.8 million in cash (BD: Aug 26, 2015; Jan 25, 2016; Sep 1, 2017).

In October 2017, the company said it would use its nano-coating technology, previously used for molecular testing for lithium-ion batteries (BD: Oct 18, 2017).

Today, Anteo said its focus was on the growth potential of lithium-ion batteries using its Antecoat technology, extending the value chain of point-of-care medical diagnostics and the quantitative lateral flow point-of-care diagnostics.

Anteo was up 0.1 cents or 7.7 percent to 1.4 cents.