Biotech Daily

Tuesday September 17, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: TELIX UP 9%; COMPUMEDICS DOWN 5%**

*** BENITEC: 3 DOG STUDIES FOR FDA BB-301 PHASE I OPMD TRIAL**

*** IQ ACQUIRES TEX CORE FOR SOLID TUMORS FROM UNIVERSITY OF TEXAS**

*** ANTISENSE REQUESTS 'ATL1102 DMD RESULTS' HALT**

*** ALCIDION $895k, 3-YEAR HEALTHSCOPE PARTNERSHIP**

*** AVITA US RECELL TRIAL FOR SKIN INJURIES**

*** LIVING CELL TELLS ASX 32% FALL QUERY: 'NEWSLETTER NOT NEWS'**

*** ASX SUSPENDS G MEDICAL FOR FAILURE TO RESPOND TO QUERY**

*** NOVITA: TALI TRAIN SUPPLY AGREEMENT WITH UK'S EDTECH IMPACT**

*** PROTEOMICS PROMARKERD: 'VALIDATED'**

*** HERAMED, MAYO COLLABORATION FOR PREGNANCY MONITOR**

*** JAPANESE PATENT FOR IMMUTEP LAG525 ANTIBODY**

*** US PATENT FOR DIMERIX DMX200 COMBINATION THERAPY**

*** PINNACLE REDUCES BELOW 5% IN COCHLEAR**

*** MACQUARIE BELOW 5% IN IMPEDIMED**

*** JIMMY THOMAS, IVY PONNIAH TAKE 6% OF GENETIC TECHNOLOGIES**

*** INVITROCUE CEO DR STEVEN FANG REPLIES TO SPILL CLAIMS**

*** RACE APPOINTS DR DANIEL TILLETT DIRECTOR**

*** SOMNOMED APPOINTS MATTHEW CONLON FOR NORTH AMERICA SALES**

MARKET REPORT

The Australian stock market was up 0.33 percent on Tuesday September 17, 2019, with the ASX200 up 21.8 points to 6,695.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and six were untraded. All three Big Caps rose.

Telix was the best, up 12.5 cents or nine percent to $1.51, with 3.0 million shares traded. Kazia climbed 8.05 percent; Genetic Signatures and Opthea rose more than six percent; Clinuvel and Polynovo improved more than four percent; both Impedimed and Neuren were up three percent; Next Science, Osprey, Pro Medicus and Universal Biosensors rose more than two percent; Avita, CSL, Nanosonics and Oncosil were up one percent or more; with Cochlear, Medical Developments and Resmed up by less than one percent.

Compumedics led the falls, down three cents or 4.8 percent to 60 cents, with 373,559 shares traded, with Immutep, Imugene and Volpara down more than four percent. LBT and Paradigm lost more than three percent; Mesoblast, Orthocell and Proteomics were down more than one percent; with Ellex down 0.9 percent.

BENITEC BIOPHARMA

Benitec says it plans to conduct three dog studies for an application to the US Food and Drug Administration for a BB-301 phase I oculo-pharyngeal muscular dystrophy trial.

At 3.59pm yesterday, Benitec said it would conduct the three pre-clinical studies to "facilitate the filing of an investigational new drug application" and the formal initiation of a phase I trial for oculo-pharyngeal muscular dystrophy (OPMD).

In June, the company said that its up-to $US665 million ($A953.6 million) deal with Axovant Sciences for BB-301 for oculo-pharyngeal muscular dystrophy had been terminated (BD: Jun 7, 2019).

In 2018, Benitec said it would partner with Axovant on five additional gene therapy programs for neurological disorders, receive full research funding for each program and be eligible for $US93.5 million in milestones for each program (BD: Jul 9, 2018).

Benitec executive chairman Dr Jerel Banks described the deal at that time as "a milestone for Benitec as we believe this transaction to be transformative for our company".

In June, Benitec said the deal would be terminated, effective from September 3, 2019 and it would conduct several exploratory analyses prior to a clinical study of BB-301 for oculo-pharyngeal muscular dystrophy.

Benitec executive director Megan Boston told Biotech Daily at that time that the company would work on further optimization of the compound in preparation for human clinical trials.

The company said that pre-clinical mouse data showed that biological efficacy could be improved by optimizing the delivery method to dose key target tissues that underlie morbidity and mortality associated with oculo-pharyngeal muscular dystrophy.

Benitec said the initial biological efficacy profile from a mouse model of BB-301 for oculo-pharyngeal muscular dystrophy remained unchanged.

The company said completion of the experimental work delayed the BB-301 study beyond the Axovant licence and collaboration agreement timelines.

In 2017 and 2018, the company said it had European and US orphan drug designation, for BB-301 for oculo-pharyngeal muscular dystrophy (BD: Jan 22, 2017; Jan 21, 2018).

Today, Benitec said that the three dog studies would "support the optimization of the methods of administration, confirm the efficiency of vector transduction in the key tissue compartments underlying the disease phenotype, confirm the optimal drug doses in advance of initiation of human clinical studies and finalize experiments designed to characterize any toxicological datapoints that would underlie future regulatory filings and clinical study designs".

Dr Banks said that the company had "an unprecedented opportunity to develop a novel genetic medicine that could facilitate clinically meaningful patient benefit in a potentially fatal disorder for which profound unmet medical need exists".

In 2016, Benitec said its first-in-human phase I/IIa trial of the DNA-directed interference (ddRNAi) TT-034 for hepatitis C failed to show any efficacy (BD: Sep 16, 2016)

Benitec said the trial met its primary safety endpoint, TT-034 was well tolerated but "there was no significant decrease in viral load in treated patients", a secondary endpoint.

The trial was expected to begin by the end of 2013, but the first patient was not dosed until May 2014, followed by recruitment delays (BD: Mar 22, Dec 9, 2013; May 29, 2014).

In 2015, Benitec hoped to raise $95 million to list on the Nasdaq, eventually settling for $19 million, chief executive officer Dr Peter French resigned in December as the trial was approaching its conclusion and in February, Benitec's share price tumbled on the termination of the trial (BD: Aug 19, Dec 9, 2015; Feb 26, 2016).

Benitec fell half a cent or 10 percent to 4.5 cents with 3.6 million shares traded.

THE IQ GROUP GLOBAL

The IQ Group says it has acquired Tex Core from the University of Texas, to develop cancer therapeutics for drug-sensitive and drug-resistant solid tumors.

In an emailed media release, not released on the ASX platform at the time of publication, the IQ Group said it was “shaking up the local biotech industry with its acquisition of [the] novel anticancer drug platform from leading US medical research giant the University of Texas”, but did not disclose the payment terms.

The company said the drug platform had “the ability to develop a range of well-tolerated, [magnetic resonance imaging]-detectable cancer therapeutics that target drug-sensitive and drug-resistant solid tumors.

IQ Group said the first cancer therapeutic to be commercialized from the platform was Oxalitex, a platinum-based chemotherapeutic that targetted only tumor cells, activated within the tumor and overcame drug-resistance mechanisms with minimal side effects.

The company said that pre-clinical research at the University of Texas and MD Anderson Cancer Center showed that Oxalitex localized to ovarian, lung and colon tumors and was superior to traditional platinum-based chemotherapy drugs.

IQ executive chairman Dr George Syrmalis said that Tex Core was “a landmark development in oncology that will significantly improve the efficacy of platinum-based cancer therapeutics”.

The company said that 50 percent of all chemotherapy patients were treated with platinum-based chemotherapy and despite their wide use, the platinum compounds were known for extreme side effects, which meant doses must be limited, and patients often presented with platinum resistance, making treatment ineffective.

IQ said that its lead Oxalitex indication was ovarian cancer, the number one cause of gynaecological cancer deaths globally, with more than 239,000 women diagnosed with ovarian cancer every year, and only 45 percent surviving beyond five years.

“Oxalitex provides new hope for ovarian cancer patients who are not responding to standard-of-care therapies, as it has the ability to kill cancer cells even when tumors are advanced and platinum-resistant, which is unfortunately the case with most ovarian cancer diagnoses,” Dr. Syrmalis said.

The IQ Group said it would work with the Oxalitex researchers and inventors at the University of Texas and MD Anderson Cancer Center to start clinical trials in the next 12 months and it planned to develop Oxalitex through an orphan drug designation in ovarian cancer, using an expedited approval pathway.

IQ was untraded at 28.5 cents.

ANTISENSE THERAPEUTICS

Antisense has requested a trading halt pending “an announcement in relation to the preliminary results of the company’s ATL1102 for DMD phase II clinical trial”.

In May, Antisense said that it had completed enrolment of the nine patients in the trial of ATL1102 for Duchenne muscular dystrophy (BD: May 24, 2019).

Earlier this month, Antisense said it expected to meet regulators in October and November to discuss the design and conduct of the next trial of ATL1102 for Duchenne muscular dystrophy (BD: Sep 2, 2019).

Antisense said that based on pre-clinical and clinical data generated for ATL1102, it could seek approval for a phase IIb trial in Europe, in parallel with the current phase II study at Melbourne’s Royal Children’s Hospital (BD: Jul 16, 2018, Jul 24, 2019).

Trading will resume on September 19, 2019 or on an earlier announcement.

Antisense last traded at 4.7 cents.

ALCIDION

Alcidion says it has a $895,000, three-year partnership with Melbourne's Healthscope to provide data and analytics services to improve healthcare.

Alcidion said it would develop dashboards to support predictive analytics and long-range planning for Healthscope services to "drive transformation in the way healthcare is managed and delivered".

Alcidion managing director Kate Quirke said the company was "excited to establish this relationship with Healthscope to augment their data and analytics capabilities across the organization".

"This is Alcidion's first implementation of our data analytics capabilities into a private hospital group," Ms Quirke said. "It demonstrates how important data is becoming across the healthcare sector."

"We look forward to sharing our extensive capabilities around health care data management to assist Healthscope to drive better outcomes," Ms Quirke said.

Alcidion was up three cents or 14.6 percent to 23.5 cents with 10.0 million shares traded.

AVITA MEDICAL

Avita says it has US Food and Drug Administration investigational device exemption for a pivotal trial of Recell for soft tissue skin healing.

Avita company said it expected the 52-week prospective, multi-center, randomized controlled safety and efficacy study to begin "within the next six months" but did not disclose the expected number of patients.

The company said that the Recell 'spray-on-skin' autologous cell harvesting device used a small amount of a patient's own skin, reducing the amount of donor skin required.

In 2018, Avita said the FDA had approved US sales of its Recell system to treat second and third-degree burns (BD: Sep 21, 2018).

Today, the company said the study would compare the clinical performance of conventional skin grafting with and without the use of the Recell system in combination with meshed auto-grafting on acute full-thickness skin defects, including de-gloving, in which the skin is ripped from the underlying tissue, crush wounds in which there is a break in the skin surface, abrasions, lacerations and surgical wounds.

The company said each patient would have a control wound treated with conventional skin grafting and a wound treated with expanded skin grafting in combination with Recell.

Avita said study's primary efficacy endpoints were the "incidence of healing by eight weeks post treatment [and] donor skin sparing, evaluated by comparing the ratios of donor skin required to treat the wounds".

The company said that long-term safety and effectiveness data would include blinded evaluation of scar outcomes and patient treatment preference.

Avita chief technology officer Andy Quick said that "based on the compelling safety and effectiveness of the Recell system in treating burn wounds, we believe our innovative technology is ideally positioned to be evaluated as a treatment to heal trauma-and surgery-related wounds".

Avita chief executive officer Dr Michael Perry said that "many burn specialists who have experience treating burn patients with the Recell system also treat patients with trauma injuries in their clinics."

"The treatment protocols for burns and trauma are well-aligned and as such, we anticipate a positive transfer of clinical experience to benefit this patient population during the clinical trial," Dr Perry said.

Avita was up half a cent or one percent to 52 cents with 13.8 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell has told an ASX 'aware' query that despite a 32.0 percent fall in its share price, information in a shareholder newsletter was neither new nor material.

The ASX said that following publication of its 'Living Insights Newsletter September 2019' on September 9 2019 "disclosing the negative future prospects for NTCell" the company's share price fell 32.0 percent from 2.5 cents to a low of 1.7 cents shortly after trading opened on September 10, 2019.

The ASX asked whether Living Cell considered the information "to be information that a reasonable person would expect to have a material effect on the price or value of its securities" and if not, then to advise the basis for that view.

Living Cell said that the information was not material because "it was already known to the market" through earlier disclosures.

In July, Living Cell interim chairman Prof Bernie Tuch said the company would plan a phase III trial as "larger patient numbers are needed to convince regulatory authorities" (BD: Jul 24, 2019).

Last week, Living Cell said it received a call to replace directors Dr Ken Taylor, Robert Willcocks and Laurie Hunter with Dr Andrew Kelly and Dr Roland Toder, from unnamed members with 5.26 percent of the company, but gave no reasons (BD: Sep 10, 2019).

Today, Living Cell told the ASX said that information provided for the first time by with New Zealand's regulatory agency Medsafe in their letter of May 9 "could not be considered as price sensitive because it was not clear that an application would not be successful notwithstanding the apparent regulatory position".

The company said that further analysis was required and confirmed the position, following which the announcement of July 23, 2019 was made.

Living Cell said the letter's intent was to help it decide on the next steps in the development of NTCell as a treatment for Parkinson's disease and raised issues including which section of the New Zealand Medicines Act guides Medsafe's recommendation to approval a xeno-transplant product and in assessing efficacy data the agency could comment but would have to seek input from an external agency with expertise and in following up with Medsafe, its comment was "it is complicated" and it was seeking internal legal advice and would await input from their selected external agency on efficacy.

"Each of the inputs including Medsafe's management's opinion if released alone could be misleading as the board's work in progress remains to decide whether to submit a new drug application to Medsafe, undertake a further study to increase patient numbers or neither," the company said.

The company said it "still has to decide if it will proceed with a regulatory submission to Medsafe or not, and as communicated is investigating the feasibility of another clinical trial".

Living Cell was unchanged at 1.8 cents with one million shares traded.

G MEDICAL INNOVATIONS

The ASX says it has suspended G Medical for failure to respond to an ASX query.

Last week, G Medical requested a voluntary suspension to follow the trading halt requested on September 6, pending "a response to an ASX query" (BD: Sep 6, 10, 2019).

Last year, the company answered ASX questions regarding missed milestones for its mobile telephone electronic health devices (BD: Mar 28, 2018).

The ASX said the suspension under Listing Rule 17.3 would continue until the G Medical provided a satisfactory response to the query.

G Medical last traded at 8.1 cents.

NOTIVA HEALTHCARE

Novita says it has a supply agreement with Edtech Impact for its Tali Train mobile software for attention training in children between the ages of three and eight years.
Novita said that the Chester, UK-based Edtech was a school-led online marketplace that maps user feedback around educational outcomes, enabling teachers to filter products based on their impact in different school environments.
The company said Edtech would include Tali Train to its platform, which reached more than 180,000 teachers in more than 90 percent of schools in the UK.
Novita said the partnership would involve “specific school leader only events” and collect data which related to the use and the social, economic and education impact of Tali Train in the UK school system.
The company said this would provide a base for potential expansion of the Tali technology into the UK National Health Scheme and provide a base for expansion into Europe, following the recent Conformité Européene (CE) mark approval (BD Aug 30, 2019).
Novita was up 0.2 cents or 18.2 percent to 1.3 cents with 33.8 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its Promarkerd immunoassay in-vitro diagnostic test for diabetic kidney disease has been validated through a 100-patient cross-platform study.
Proteomics said the validation would allow the Promarkerd test to be manufactured “as either an immunoassay kit or … configured to run on automated machine platform, allowing the analysis of hundreds of blood samples at a time”.
The company said the immunoassay validation followed a cross-platform study to demonstrate data equivalence in 100 patient samples analyzed against the mass spectrometry version of Promarkerd.
Proteomics said that both Promarkerd technology platforms exhibited high correlation (r = 0.97), where r = 1.0 represents perfect correlation.
The company said that the immunoassay was designed using the Adelaide-based TGR Biosciences' advanced Captsure technology platform and TGR would complete stability studies on the Promarkerd immunoassay in-vitro diagnostic test as well as start production of test packs of reagents for evaluation by potential licence partners.
Proteomics managing director Dr Richard Lipscombe said that the new Promarkerd in-vitro tests complemented the mass spectrometry version of Promarkerd which meant that “laboratories can use the test system that best suits the equipment of the laboratory and the specialist experience of their laboratory staff”.
“This … will increase the attractiveness of Promarkerd in the diagnostics community which should accelerate the commercialization of our ground breaking test,” Dr Lipscombe said.
The company said the validation study results were presented at the Human Proteome Organization World Congress in Adelaide between September 15 to 18, 2019.
Proteomics fell half a cent or 1.4 percent to 36 cents.

HERAMED

Heramed says it will partner with the Rochester Minnesota Mayo Clinic for a platform to improve at-home pregnancy care, based on the Mayo’s OB Nest project.
Heramed said the project would use “[artificial intelligence] powered algorithm and a combination of a digital platform and smart connected devices to assist expecting mothers as well as healthcare professionals in better managing pregnancy care”.
Heramed was unchanged at 16.5 cents.

IMMUTEP

Immutep says the Japan Patent Office has granted a patent for its LAG525 humanized form of its IMP701 antibody for the treatment of cancer and infectious disease.
Immutep said the patent, titled 'Antibody molecules to LAG-3 and uses thereof', would protect its intellectual property until March 13, 2035.
The company said patent was co-owned by the Basel, Switzerland-based Novartis AG and Immutep's wholly owned subsidiary, Immutep SAS.
Immutep was up 0.1 cents or 4.55 percent to 2.1 cents with 24.3 million shares traded.

DIMERIX

Dimerix says the US Patent and Trademark Office has allowed a patent covering the use of DMX200 with any angiotensin receptor blocker for kidney disease.
Dimerix said the patent, titled 'Combination Therapy' claimed the use of any chemokine receptor 2 (CCR2) antagonist, such as DMX200, in kidney disease patients receiving any angiotensin receptor blocker, "wherein the CCR2 antagonist and the angiotensin receptor blocker may be administered either together or separately".
The company said the patent would protect the intellectual property until at least 2032.
Dimerix was untraded at 9.3 cents.

COCHLEAR

Pinnacle Investment Management Group says it has reduced below five percent in Cochlear.
In March, Pinnacle said it had become a substantial shareholder in Cochlear with 2,955,885 shares or 5.12 percent of the company (BD: Mar 6, 2019).
Today, the Brisbane-based Pinnacle said that it bought and sold shares in more than 480 trades between March 20 and September 13, 2019, with the single largest sale on August 14 of 28,699 shares for $5,836,515 or $203.37 a share.
Cochlear was up $1.86 or 0.9 percent to $209.30 with 140,969 shares traded.

IMPEDIMED

The Sydney-based Macquarie Group says it has reduced its holding in Impedimed to below the five percent substantial shareholder level.
In July, Macquarie said it had become a substantial shareholder in Impedimed with 24,768,177 shares or 5.28 percent (BD: Jul 29, 2019).
Today, Macquarie said that in more than 400 trades between August 16 and September 11, 2019 it bought, sold and transferred shares at prices from 13 cents to 17 cents.
Impedimed was up half a cent or three percent to 17 cents.

GENETIC TECHNOLOGIES

Jimmy Thomas and Ivy Ruth Ponniah say they have increased their holding in Genetic Technologies from 141,941,607 shares (5.2%) to 177,744,013 shares (6.05%).
The Brisbane-based Mr Thomas and Ms Ponniah said that between July 26 and September 12, 2019 they bought 35,802,406 shares, with the single largest purchase on August 16, 2019 of 13,000,000 shares for $65,000 or 0.5 cents each.
Genetic Technologies fell 0.05 cents or 9.1 percent to 0.5 cents with one million shares traded.

INVITROCUE

Invitrocue chief executive officer Dr Steven Fang has replied to a series of allegations made by “disaffected directors” who have called for his removal from the board

Earlier this month, Invitrocue filed two board spill motions, one from Prof Hanry Yu, Ee Ting Ng and Kit Wei Lui to remove chief executive officer Dr Steven (Boon Sing) Fang as a director and one from Dr Fang and directors Gary Pace and Andreas Lindner to remove Prof Yu and Mr Lui as directors (BD: Sep 9, 2019).

Last week Wednesday, Invitrocue said Prof Yu, Mr Lui and Ms Ng called a meeting to remove Dr Steven Fang, citing an array of allegations, and later called a meeting to remove recently-appointed director Geoffrey Thomas (BD: Sep 10, 11, 13, 2019).

Today, Dr Fang said that the company’s direction had been “carefully and strategically planned by gathering key market intelligence, as well as feedback from oncologists, clinical partners and investors”.

“The company established an implementation plan with one year, three years and five years comprehensive financial modelling and forecasts,” Dr Fang said.

He said that “early success met with industry-specific headwinds, the revenue base in 2017 was built up by the same team that leads the company today [and] the initial success was from contract research services and came from two major clients”.

Dr Fang said that the generic contract research service business was highly competitive and low margin, “which started declining in contract value as clients sought after more competitively priced service providers”.

“In 2018, management presented a strategy to the board on personalized oncology and use of an in-vitro, or laboratory-based, cancer cell-based model for clinical services and drug testing work would be possible,” Dr Fang said. “It was proposed that such a strategy would not only allow Invitrocue to continue offering its contract research services but also allow it to build on that capability for a higher margin oncology business.”

He said the diversification plan was tabled, discussed and approved by the board, “the move towards personalized oncology was very well received and we continue to attract key investors and partners today”.

Dr Fang said that travel costs “went up as a direct result of market and business development efforts to drive Onco-PDO cancer testing services” and the board and management had been compliant in its disclosures, reporting and filings; all board agenda items were clearly presented along with supporting information.

Dr Fang said that the “disaffected directors create a dysfunctional board [and] given the board disagreement, many items resulted in a hung decision”.

“[They voted] against almost all board items, causing delay and disruption to funding but offering no viable alternative funding,” Dr Fang said.

Dr Fang said that the disaffected directors frustrated and delayed the completion of statutory filings such as the Appendix 4E preliminary final report, “causing the initial suspension of trade by not agreeing to sign the confirmation of IVQ’s authorized person for announcements as requested by ASX, and disrupting the provision of continuous disclosure to the market”.

Dr Fang said that the casting vote was used to appoint Mr Thomas “because of the disaffected directors’ opposition would be a loss to Invitrocue and its shareholders”.

He said that Mr Thomas was a fellow of the Australian Institute of Directors and was “highly regarded in Australia’s business community with extensive experience in Australian public companies”.

Dr Fang urged shareholders “to endorse our proposal and reject the alternative resolution”.

Invitrocue was in a suspension and last traded at six cents.

RACE ONCOLOGY

Race says it had appointed substantial shareholder and “prominent biotechnology investor” Dr Daniel Tillett to the board of directors.

Last month, Race said Dr Tillett was expected to join the Race board after buying 8.5 million shares for $561,000 in the company’s $1.45 million capital raising, taking his holding to 8,758,421 shares or 8.69 percent of the company (BD: Aug 20, 2019).

Today, the company said Dr Tillett was the founder and chief executive officer of Sydney’s Nucleics, which specialized in DNA sequencing and genomics.

Race was unchanged at 11.5 cents.

SOMNOMED

Somnomed says it had appointed Matthew Conlon as North American head of sales and marketing, effective October 1, 2019.

Somnomed said Mr Conlon had experience in the medical devices industry and medical technologies sector, and had previously worked for AM Surgical, Cantel Medical and Respironics.

Somnomed was up five cents or 2.4 percent to $2.15.