Biotech Daily

Tuesday October 30, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MEDICAL DEVELOPMENTS UP 9%; OSPREY DOWN 14%**

*** RESAPP MISSES 1st PRIMARY ENDPOINT, MIXED US TRIAL RESULTS**

*** ALLAN GRAY INVESTS $10m IN OSPREY; $10.5m RIGHTS ISSUE**

*** MEDLAB: FROM PHASE I NANABIS CANCER PAIN TRIAL TO PHASE II**

*** CELLMID RECEIVES $808k FEDERAL R&D TAX INCENTIVE**

*** IMAGION HAS ONE QUARTER CASH, 'MORE COMING'**

*** MEDIGARD LICENCES KUNOVUS KT009 FOR DISC DEGENERATION**

*** BIOTRON TELLS ASX: HIV TRIAL DATA 'CURRENTLY CONFIDENTIAL'**

*** OPTISCAN AGM FOR 1.94m DIRECTOR 'RIGHTS', 12.8m OPTIONS**

*** RECCE 250k DIRECTOR DR JOHN PRENDERGAST SHARES AGM**

*** INVITROCUE AGM FOR 6m DIRECTOR OPTIONS**

*** ZELDA AGM FOR 25m CEO DR RICHARD HOPKINS OPTIONS**

*** TIM ROBERTSON, FARJOY TAKE 11.5% OF MEDLAB**

*** MGC EPILEPSY ACTION ONLINE INFORMATION, ACCESS PORTAL**

*** CRESO EDIBLE MARIJUANA R&D CENTRE OF EXCELLENCE**

MARKET REPORT

The Australian Stock Market was up 1.34 percent on Tuesday October 30, 2018 with the ASX200 up 76.9 points to 5,805.1 points. Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and four were untraded.

Medical Developments was the best on a positive trading update, up 41 cents or 9.3 percent to $4.81 with 63,659 shares traded. Neuren climbed 8.2 percent; Bionomics was up 6.7 percent; Cynata, Mesoblast and Oncosil improved more than five percent; Clinuvel and Universal Biosensors were up more than four percent; Starpharma was up 3.15 percent; CSL, Orthocell and Polynovo rose more than two percent; Cochlear, Factor, Impedimed and Paradigm were up more than one percent; with Ellex, Genetic Signatures, Nanosonics and Telix up by less than one percent.

Osprey led the falls, down 2.5 cents or 14.3 percent to 15 cents, with 457,188 shares traded. Immutep lost 6.8 percent; Optiscan shed 5.2 percent; Dimerix, Imugene and Volpara fell more than four percent; Compumedics, Prana and Prescient shed more than two percent; with Airxpanders and Avita down more than one percent.

RESAPP HEALTH

Resapp fell as much as 61.4 percent on mixed results for its pivotal, US, 1251-patient respiratory disease diagnostic trial, including missing its first primary endpoint.

Resapp ended an extended suspension for the second trial of the Resappdx diagnostic saying it had a 73 percent to 78 percent positive percent agreement (sensitivity) and a 71 percent to 86 percent negative percent agreement (specificity) for lower respiratory tract disease, asthma/reactive airway disease in children over two years of age, and primary upper respiratory tract disease.

The company said results for pneumonia and bronchiolitis were below 70 percent accuracy "and submission for these diseases will occur in a second phase" and it had a "technical issue" with croup results.

Resapp said that it had 67 percent sensitivity and 64 percent specificity for pneumonia.

Resapp's listing on www.clinicaltrials.gov nominated the diagnosis or exclusion of pneumonia as the first primary endpoint, with "other childhood respiratory diseases" the second primary endpoint, but did not specify a level of positive or negative agreement as a benchmark for the primary outcomes.

Resapp said it intended to submit a de novo premarket submission to the US Food and Drug Administration for the first three indications.

The company said the Smartcough-C-2 trial of its cough-based smart-phone application was a double-blind, prospective study to evaluate the efficacy of the Resappdx diagnostic for the diagnosis of childhood acute respiratory diseases.

Last year, Resapp fell as much as 82.3 percent to 5.5 cents on news that its 1,245-patient Smartcough-C trial failed to meet its endpoints (BD: Aug 9, 2017).

Resapp said at that time that "contrary to instructions and training, a high number of patients were treated before clinical research staff recorded their cough sounds [and] a high number of recordings were also found to contain a second person's cough sounds or an unacceptable amount of background noise and interference".

Today, the company said that 1,470 patients were recruited into the study with 1,251 patients aged from 29 days to 12 years completing the study and analyzable.

Resapp said its diagnostic was compared to clinical diagnoses by an independent, clinical adjudication committee using all available data, including radiology and microbiology.

The company said that in 429 cases (34.3%) two adjudicators did not agree and a third adjudicator was required to reach a majority consensus, "which highlights the scale of the challenge faced when diagnosing respiratory illnesses".

Resapp's results show that for all indications, lower respiratory tract disease, asthma/reactive airway disease, asthma/reactive airway disease in children under two years, primary upper respiratory tract disease, pneumonia (focal), pneumonia and bronchiolitis in children over two years of age, the best sensitivity was 77 percent for primary upper respiratory tract disease falling to 63 percent for pneumonia.

The company said that overall sensitivity ranged from 60 percent to 86 percent.

Resapp chief executive officer Dr Tony Keating said the results for lower respiratory tract disease, asthma/reactive airways disease, for children over two years of age, and primary upper respiratory tract disease "demonstrate that our algorithms effectively aid clinicians in making important clinical diagnostic decisions".

"Our diagnoses are especially useful in settings such as telehealth, where a stethoscope and additional diagnostic tests such as a chest x-ray or blood tests are not available," Dr Keating said.

Dr Keating said the company would pursue FDA submissions for thee three diseases in parallel to European and Australian submissions for six diseases.

Resapp closed down 12 cents or 54.6 percent at 10 cents with 50.1 million shares traded.

OSPREY MEDICAL

Osprey says Allan Gray has invested $10.0 million in a placement at 15.5 cents a share and it hopes to raise a further $10.5 million in a one-for-five rights offer.
Osprey said that 26.9 percent shareholder Brandon Capital Partners intended to take up its pro rate entitlement in the non-renounceable offer.
The company said that the record date for the rights issue was November 2, the offer would open on November 7 and close on November 16, 2018.
Osprey said the proceeds would be used for its “group purchasing organizations” marketing program, expand the US sales team and resources, support post-approval market trials, registry studies and physician sponsored trials for specific presentations and publications, accelerate pilot sales programs in Western Europe and continued research and development of the product portfolio.
Osprey fell 2.5 cents or 14.3 percent to 15 cents.

MEDLAB CLINICAL

Medlab says the five-patient trial of Nanbis marijuana extract for cancer pain has shown the compound to be safe and it will proceed to the 25-patient phase IIa trial.
Medlab said that Sydney;s Royal North Shore Hospital independent data safety monitoring board had approved the move to phase IIa.
In July, Medlab said recruitment was underway at the Hospital and managing-director Dr Sean Hall told Biotech Daily that the phase I trial would recruit five patients and the phase IIa trial would have 25 patients (BD: Jul 4, 2018).
In May, Medlab said the trial would test the safety, efficacy and dose tolerance of cancer patients with both managed and unmanaged pain (BD: May 15, 2018).
Today, the company said that the second stage of the trial would focus on further safety but also tolerance and dose escalation, in cancer patients with unmanaged pain.
Medlab said the phase I study showed that Nanabis was safe, effective for up to nine hours following a single dose administered, with levels detected at first blood draw at 30 minutes and reaching maximum concentration in blood the plasma in 1.25 hours.
The company said that “early indications confirm that Nanabis helps with pain reduction”.
“Although pain measurement was not a key part of stage 1, the early results of pain reduction while being administered Nanabis was very encouraging,” Dr Hall said.
Medlab was up one cent or 2.9 percent to 36 cents.

IMAGION BIOSYSTEMS

Imagion says its net operating cash burn for the three months to September 30, 2018 was $1,563,000 with cash at the end of the quarter of $1,986,000.
Imagion said that it had $54,000 in receipts from customers with an expected cash burn for the three months to December 31, 2018 of $1,926,000.
The company said it had held a rights issue to raise $4.3 million but last week said it had raised $410,924 and hoped to place the $3,874,980 shortfall to sophisticated and professional investors within three months (BD: Oct 22, 2018).
Today, Imagion chief executive officer Robert Proulx told Biotech Daily “we are optimistic we will place the majority of the shortfall within the allotted time”.
Imagion was untraded at 4.3 cents.

CELLMID

Cellmid says it has received $807,972 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cellmid said the rebate related to expenditure on its midkine and FGF5 inhibitor programs for the year to June 30, 2018.
Cellmid fell one cent or 2.9 percent to 34 cents.

MEDIGARD

Medigard says it has licenced the Kunovus owned injectable KT009 for intervertebral disc degeneration, degenerative disk disease and chronic lower back pain.
Medigard said it would pay the Sydney-based Kunovus Pty Ltd initial upfront fees of $35,000 over 60 days, payments of defined fees based on clinical trial milestones, a royalty on net sales, an annual licence maintenance fee of $25,000, capped reimbursement of past intellectual property costs and a share of sublicence fees.
The company said it had an option to purchase the KT009 intellectual property from the licensor and reduce certain fees otherwise payable.
Medigard executive director Dr Ian Dixon told Biotech Daily that KT009 was an injectable biologic, currently at pre-clinical testing and intended to treat disc degeneration.
In a media release, the company said that KT009 had “demonstrated reversal of disc tissue destruction in sheep and in rabbits [and] has also shown pain relief in a rat model”.
Medigard said it would make clinical grade recombinant KT009 (GDF6), conduct preclinical testing and then run a small human trial in Australia with patents suffering intervertebral disc degeneration or degenerative disc disease.
The company said that lower back pain was among the top three causes of disability, ranking above diabetes and mental health as a contributor to years lost to disability, and the costs of back pain treatment, absenteeism and disablement exceed all other musculoskeletal conditions, estimated at $US100 billion in the US.
Medigard said it would have “the worldwide exclusive rights to commercialize two granted US patents and associated patent applications” which had been demonstrated in an animal study presented in May 2018 by the University of California San Diego team led by Prof Koichi Masuda describing the use of an injection recombinant endogenous human protein, that is a biologic drug KT009, to treat disc degeneration and resultant chronic lower back pain.
“As an alternative to surgery or implants, the KT009 treatment seeks to harness the natural biological activity of an endogenous protein to regenerate the [intervertebral disc] tissue,” the company said.
Dr Dixon said that “an injectable KT009 product could transform the lives of millions of people suffering intervertebral disc degeneration and degenerative disk disease and become a big-selling drug,” Dr Dixon said.
One of three inventors named on the Kunovus patents, Sydney-based spinal and orthopaedic surgeon Dr Ashish Diwan said that “translating medical scientific discoveries into a drug used to treat millions of people is something that every medical doctor dreams”.
“The collaboration with Medigard is the next phase in solving the problems in my patients that I see every day,” Dr Diwan said.
“Once we demonstrate that KT009 can be made, is safe, and patients benefit from its injection, we anticipate that a pharmaceutical company may partner with us to take KT009 through phase III clinical trials, registration and marketing,” Dr Dixon said.
Medigard was up 0.3 cents or 12 percent to 2.8 cents.

BIOTRON

Biotron has told the ASX that it properly published the results of its 27-patient, phase II, combination trial of BIT225 with anti-retro-viral drugs for HIV-infected patients.

The ASX asked a series of 15 questions including multiple sub-questions about the announcement of the results, relating to determining significance, stating endpoints and compliance with the ASX Listing Rules.

In September, Biotron said the trial showed "significant immunological benefits" but did not state the data was statistically significant nor provide the data and the "p" value which indicates the probability that it occurred by chance (BD: Sep 28, 2018).

But in response to questions, Biotron chief executive officer Dr Michelle Miller told Biotech Daily the difference between the active and control groups in the BIT225-009 trial was "statistically significant".

The ASX noted the 105 percent increase in the company's share price from 2.0 cents on September 27 to 4.1 cents on September 28, 2018 and the "significant increase" in trading volumes, as reported in Biotech Daily on that day.

Today, in a six-page response, Biotron said that it had conducted the trial properly, described the trial, its endpoints and the data analysis and said that some of the key data was confidential.

"The data, detailed analyses and graphs from the [primary biomarker] sCD163 and the flow cytometric analyses have not been released to the market, as they remain trade secrets and subject to strict confidentiality, and hence within Listing Rule 3.1A.1, until presented at upcoming scientific conference(s) in the US in late 2018 [or] 2019," Biotron said.

"Details of the date, time and location of presentation(s) will be released to the market when they are available, and the presentation(s) will be released to the market immediately after being presented," Biotron said.

Biotron was up half a cent or three percent to 17 cents with 41.8 million shares traded.

OPTISCAN

Optiscan's annual general meeting will vote to grant three directors 1,940,000 free "performance rights" and 12,800,000 options.

Optiscan said that the annual general meeting would vote to approve the grant of 1,100,000 performance rights and 8,000,000 options to chairman Darren Lurie, 660,000 rights and 4,800,000 options for Dr Philip Currie and 180,000 rights for Graeme Mutton.

The company said that the performance rights would vest on December 1, 2018 conditional on the directors being with the company at that time.

Optiscan said that options would vest in four tranches over 30 months with an eight cent price hurdle for the first three tranches and a 10 cents price hurdle for the last tranche.

The company said that the first two tranches were exercisable at five cents, the third tranche at 6.5 cents and the final tranche at eight cents, by May 31 and November 30, 2022 and May 31 and November 30, 2023.

The company's notice of meeting said shareholders would vote on the remuneration report, a change of auditors, the 10 percent placement facility and the re-election of director Dr Currie.

The meeting will be held at Chartered Accountants Australia and New Zealand, Level 18, Bourke Place, 600 Bourke Street, Melbourne, on November 30, 2018 at 10am (AEDT).

Optiscan fell 0.3 cents or 5.2 percent to 5.5 cents.

RECCE PHARMACEUTICAL

Recce will vote to grant director Dr John Prendergast 250,0000 shares in addition to his $50,000 a year cash fee.
Recce said that shareholders would vote on the remuneration report, the prior issue of shares and options, the employee incentive plan, the 10 percent placement capacity, and the election of directors James Graham and Dr Prendergast.
The meeting will be held at the Automic Group, Level 5, 126 Phillip Street, Sydney, on November 29, 2018 at 12pm (AEDT).
Recce fell half a cent or 2.8 percent to 17.5 cents.

INVITROCUE

Invitrocue will vote to issue chief executive officer Dr Steve Fang and five directors 6,000,000 options, exercisable at five cents each within 15 years.
Invitrocue said the meeting would vote to issue Dr Steven Fang Boon Sing 1,250,000 options, Jamie Khoo Gee Choo 1,250,000 options, with1,000,000 options each to Prof Hanry Yu, Dr Andreas Lindner and Chow Yee Koh, and 500,000 options to Ee Ting Ng.
The company said it proposed to issue $12,500 in shares to Dr Lindner, comprising half his director's remuneration.
Invitrocue's notice of meeting said that shareholders would vote on the remuneration report, the prior issue of shares, 10 percent placement capacity and to re-elect directors Prof Yu, Ms Khoo, Dr Lindner and Dr Gary Pace.
The meeting will be held at Deloitte Private, Level 9, Grosvenor Place, 225 George Street, Sydney on November 29, 2018 at 11am (AEST).
Invitrocue was untraded at 9.2 cents.

ZELDA THERAPEUTICS

Zelda will vote to grant 25,000,000 options to chief executive officer Dr Richard Hopkins, exercisable in five tranches from 10 cents to 30 cents, within three years.
The company announced the issue earlier this month (BD: Oct 12, 2018)
Zelda said that shareholders would vote on the remuneration report, renewing the 10 percent placement capacity and the re-election of directors Dr Stewart Washer and Mara Gordon.
The meeting will be held at Blackwall Legal Boardroom, Level 26, 140 George Street, Perth, on November 30, 2018 at 9am (AWST).
Zelda was unchanged at 5.9 cents with 1.1 million shares traded.

MEDLAB CLINICAL

The Sydney-based Farjoy Pty Ltd says it has increased its substantial shareholder in Medlab from 21,855,556 shares (10.51%) to 23,979,322 shares (11.53%).
The substantial shareholder notice, signed by managing-director Timothy Robertson, of Weston Woodley Robertson, said that Farjoy bought shares between August 17, and October 29, 2018 at prices ranging from 34 cents to 43 cents.
Medlab was up one cent or 2.9 percent to 36 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has partnered with Epilepsy Action Australia to establish an online platform to provide information and education on medicinal cannabis and epilepsy.
MGC said the website was designed as an educational tool to provide easily packaged, accessible, user-friendly information about epilepsy and medicinal cannabis.
The company said the platform was intended for healthcare practitioners and patients with epilepsy and would provide information through its 'Get Educated" and 'Get Access' portals, which would consist of news, research breakthroughs and information on how to access medicinal cannabis treatments and clinical trials.
MGC was up 0.2 cents or 3.7 percent to 5.6 cents with 3.6 million shares traded.

CRESO PHARMA

Creso says it has established "the first dedicated research and development centre for medical and nutritional edible cannabis at its Mernova Medicinal Site in Nova Scotia".
Creso said the centre would focus on edible formulations using engineered marijuana extracts and non-cannabis ingredients to "deliver an enhanced experience".
The University of Zürich's former director of the Institute for Prevention and Public Health and Creso advisor Prof Felix Gutzwiller said that "for the first time, we see a company bringing together international knowledge in the field of medicinal and nutritional cannabis".
"It's a fascinating initiative," Prof Gutzwiller said.
Creso chief executive officer Dr Miri Halperin Wernli said the research centre would "create high-quality, purposefully designed and lab-tested products which will cater for specific applications such as sleep, pain or anxiety".
"The products will be enriched with appealing terpene profiles enhancing their health and wellness benefits," Dr Miri Halperin Wernli said.
"Like with fine wine and craft beer, premium cannabis consumers want enhanced experiences that fit their lifestyle and from premium products of the highest quality," Dr Halperin Wernli said.
Creso fell three cents or seven percent to 40 cents.