Biotech Daily

Tuesday December 10, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PATRYS UP 9.5%; ONCOSIL DOWN 18%**

*** 4DX PRE-IPO ISSUE RAISES $15m**

*** STARPHARMA 'RESULTS TAKE DEP-CABAZITAXEL TRIAL TO PHASE II'**

*** QBIOTICS: 'EBC-46 SOLID TUMOR SAFETY, EFFICACY'**

*** HERAMED PLACEMENT RAISES $1.4m**

*** GENETIC TECHNOLOGIES: BREAST CANCER GENETYPE READY**

*** RESPIRI'S WHEEZO WINS CE MARK, TGA REGISTRATION**

*** CSL APPOINTS CAROLYN HEWSON DIRECTOR**

*** COCHLEAR APPOINTS MICHAEL DANIELL DIRECTOR**

*** PALLA $4m EURO CODEINE DEAL**

*** CANN GLOBAL OLIVIA NEWTON-JOHN MARIJUANA FORMULA RIGHTS**

MARKET REPORT

The Australian stock market fell 0.34 percent on Tuesday December 10, 2019, with the ASX200 down 23.1 points to 6,706.9 points. Seven of the Biotech Daily Top 40 stocks were up, 23 fell, seven traded unchanged and three were untraded.

Patrys was the best, up 0.2 cents or 9.5 percent to 2.3 cents, with 891,629 shares traded. Starpharma climbed 5.7 percent; Mesoblast and Pharmaxis rose two percent or more; Clinuvel, Orthocell and Polynovo were up more than one percent; with CSL up 0.1 percent.

Oncosil led the falls, down three cents or 17.65 percent to 14 cents, with 5.2 million shares traded. Antisense lost 8.05 percent; Next Science, Osprey, Paradigm and Prescient were down more than five percent; Actinogen, Avita and Resonance fell more than four percent; Genetic Signatures, Impedimed, Kazia, Medical Developments, Opthea, Telix and Volpara were down more than three percent; Imugene, LBT and Universal Biosensors shed more than two percent; Cochlear, Nanosonics, Proteomics and Resmed were down more than one percent; with Cynata and Pro Medicus down by less than one percent.

4DX

4DX says it has raised $15 million through the issue of unsecured convertible notes in a “heavily oversubscribed” pre-initial public offering.
4DX said the funds would be used to expand US sales and distribution capability, increase its ‘software as a service’ sales platform, as well as continued product research and development.
The company said it had three respiratory diagnostic software products currently under development, with the first under US Food and Drug Administration review.
4DX executive chairman Andreas Fouras said the demand for convertible notes “shows the market is starting to recognize the significant opportunity presented by our unique four-dimensional lung imaging technology and our well-defined commercial strategy”.
4DX said it expected to launch an initial public offering within the next 12 months.
4DX is a public unlisted company.

STARPHARMA

Starpharma says that six of nine evaluable patients in its 14-patient phase I trial of dendrimer enhanced-cabazitaxel for solid tumors have shown efficacy signals.
Starpharma said the trial met its objectives of evaluating safety, tolerability and preliminary efficacy and could progress to phase II immediately.
The company said the phase I trial identified a recommended dose of 20mg/m2, which meant the trial would transition into phase II.
Starpharma said efficacy signals were observed in six of nine evaluable patients, including “prolonged stable disease, greater than 47 weeks and significant reductions in specific tumor biomarkers such as prostate specific antigen”.
The company said efficacy signals were present in a range of tumor types, including prostate, ovarian, cholangio-carcinoma and pancreatic cancer.
Starpharma said efficacy signals in prostate cancer were observed with doses of dendrimer enhanced product (DEP) cabazitaxel which were up to 40 percent lower than standard cabazitaxel, marketed as Jevtana.
The company said Jevtana was approved for the treatment of prostate cancer, but not for ovarian, pancreatic, and cholangio-carcinoma.
Starpharma said the efficacy signals were “encouraging”, considering that all patients in the study were pre-treated and their cancer had either progressed or had stopped responding to other anti-cancer therapies.
The company said that DEP-cabazitaxel trial participants experienced significantly fewer side effects, such as bone marrow toxicity, including neutropenia, anaemia, and thrombocytopenia, anorexia and vomiting, than are typically seen with Jevtana.
Starpharma said patients did not require anti-nausea, antihistamine or cortisone pre-treatments, as was standard for Jevtana and there were no cases of hypersensitivity or anaphylaxis.
Starpharma chief executive officer Dr Jackie Fairley said the company was “pleased to advance our second dendrimer enhanced product (DEP) product to phase II, and are very excited to see the promising efficacy signals observed in such a resistant patient cohort, and the remarkably low incidence of adverse events, including bone-marrow toxicity/neutropenia, with DEP cabazitaxel.
“We look forward to sharing these results with commercial partners,” Dr Fairley said.
Starpharma was up seven cents or 5.7 percent to $1.295.

QBIOTICS GROUP

Qbiotics says four of 22 patients in its phase I trial of tigilanol tiglate, or EBC-46, for solid tumors have shown a complete response, with no maximum dose reached.

Qbiotics said the open-label, single-arm, non-randomized, dose-escalation study was conducted at four hospitals in Australia, with tigilanol tiglate administered once by intra-tumoral injection.

Last year, the company said that the trial had achieved a complete response in two patients (BD: Nov 13, 2018).

Today, the company said that tigilanol tiglate was “generally well tolerated and doses escalated from 0.06mg/m2 to 3.60mg/m2, without reaching a maximum tolerated dose”.

Qbiotics said that six patients responded to the treatment, with full tumor destruction in four patients with varying solid tumor types.

The company said that the trial recruited patients with a range of tumor types including squamous cell carcinoma, basal cell carcinoma, melanoma, breast adeno-carcinoma, atypical fibro-xanthoma, atypical myxoid fibro-sarcoma, metastatic colorectal adeno-carcinoma, adenoid cystic carcinoma and angio-sarcoma.

Qbiotics said signs of clinical activity were observed in all nine tumor types, even at the lowest doses.

The company said that 96 percent of adverse events were mild to moderate, with the most commonly reported event injection site reactions.

Qbiotic said that adverse events were “generally managed with symptomatic therapy”.

The research was published in an article, titled ‘Phase I dose-escalation study to determine the safety, tolerability, preliminary efficacy and pharmacokinetics of an intratumoral injection of tigilanol tiglate (EBC-46)’ in E Bio Medicine, which is available at: https://www.ebiomedicine.com/article/S2352-3964(19)30786-8/fulltext.

Qbiotics chief executive officer Dr Victoria Gordon said that “two patients with melanoma demonstrated an anenestic, or abscopal, response, where non-injected tumors at different locations in the body also reduced in size”.

“Given the very good safety profile, and positive anti-tumor responses observed, this study supports further development of tigilanol tiglate as a potential treatment of solid tumors,” Dr Gordon said.

The company said that it had begun a phase I/II trial of tigilanol tiglate in patients with head and neck squamous cell carcinoma.

Qbiotics is a public unlisted company.

HERAMED

Heramed says it has “binding commitments” to raise $1,423,531 in a placement at 15.5 cents a share to sophisticated and institutional investors.

Heramed said it would use the funds for business development, strategic planning for its “imminent US market entry”, progress US trials for its Heracare digital monitoring platform Herabeat foetal heartrate monitor.

The company said it would use the funds to continue development of its intellectual property and new technologies as well as support the roll-out of products in Germany, India, and Brazil.

Heramed said Twenty1 Corporate was lead manager and book runner for the placement, with Etchell Capital was its corporate advisor.

The company said it would issue 2.25 million unlisted options, exercisable at 25 cents each for two years, to Twenty1 and Etchell as a placement fee.

Heramed was unchanged at 17 cents with 1.3 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has commissioned its Australian laboratory to supply Genetype for Breast Cancer test, and expects sales to begin by April 2020.
Genetic Technologies said that Genetype was “the world first Genomic test to accurately predict risk of disease by combining the information contained in your DNA with family history and mammography data”.
The company said the tests could identify low-risk individuals as well as high-risk women.
Genetic Technologies said it hoped to market the tests through 12 clinics in Victoria and New South Wales where test kits could be purchased and the tests performed.
The company said that Genetype could reduce mortality “by as much as 20 percent with minimal costs, side effects and drug interactions of a traditional anti-cancer therapy”.
Genetic Technologies was up 0.1 cents or 22.2 percent to 0.55 cents with 38.2 million shares traded.

RESPIRI (PREVIOUSLY ISONEA, KARMELSONIX)

Respiri says it has Conformité Européene (CE) mark approval and Australian Therapeutic Goods Administration registration for its Wheezo asthma diagnostic.
Respiri said that Wheezo was the “world’s first digital wheeze monitoring [product] … to help people with respiratory disease, such as asthma, better manage their condition”.
The company said that Wheezo would be cleared for sale in the European Union and would be listed on the Australian Register of Therapeutic Goods.
Respiri said there were more than 40 million people affected by asthma in the European Union, as well as almost three million people in Australia, “who today cannot effectively monitor their condition on a daily basis”.
The company said that Wheezo would “provide them with an effective ambulatory tool to help better manage their condition every day”.
Respiri chairman Nicholas Smedley said “the CE Mark and TGA clearance is a major accomplishment for Respiri as the submission required rigorous regulatory review against high clinical and safety standards”.
“With this regulatory step completed, we are now at the point of commercialization, with focus on our go to market strategy to make this innovative monitoring solution available to people with asthma as soon as possible,” Mr Smedley said.
Respiri said it was finalizing a manufacturing partnership with a Malaysian company and expected to have a 500 unit polit batch ready in January 2020.
The company said it had a clinical study agreement with Melbourne’s Swinburne University to examine “the measurement of wheeze to determine small airway function” and correlate wheeze rates against standard asthma measures such as forced oscillation technique and multiple breath washout, expected to be completed by April 2020.
Respiri chief executive officer Marjan Mikel said the clinical trial data would allow the company “to approach potential big pharma partners to help us introduce Wheezo to physicians who can then recommend Wheezo to their patients”.
The company said it expected to commercialize Wheezo by the end of 2020.
Respiri, and previously Isonea and Karmelsonix, has been attempting to commercialize its wheeze test for asthma since 2006, saying it would be available in Europe and the US in February 2007 (BD: Nov 24, 2006).
Mr Smedley was appointed a non-executive director of Respiri in October and was appointed chairman in November, with Mr Mikel appointed chief executive officer effective from December 2, 2019 (BD: Oct 30, Nov 15, 25, 2019).
Respiri fell 0.2 cents or 2.5 percent to 7.8 cents with 3.5 million shares traded.

PALLA PHARMA

Palla says it has a supply agreement with an unnamed European tablet producer for a minimum of 10 tonnes of codeine phosphate until the end of 2020.
Palla said the agreement had a total value of $US3 million ($A4.4 million) and could increase from a 10 tonne minimum to up to 15 tonnes of codeine phosphate.
The company said that it had the option to extend the agreement beyond 2020.
Palla said the agreement show the company's "ability to supply the volumes our customers need at competitive pricing" and it had met its target of increasing codeine phosphate production in Norway from 50 tonnes to 70 tonnes a year.
Palla said it expected demand in 2020 to "exceed its current 70 tonne capacity".
Palla was up 1.5 cents or 1.8 percent to 85.8 cents.

CANN GLOBAL

Cann Global says it has an exclusive agreement for the rights to a medicinal marijuana formulation used by Olivia Newton-John in her "holistic approach" to breast cancer.
Cann Global said the products were developed by Ms Newton-John's husband John Easterling, a Cann director and were known as XO-27-XP, ONJ-18-XP and ONJ-XO.
Ms Newton-John said the formula helped with "sleep, stress, mood, and … pain", and reported increased mobility and "increased healthy blood count numbers".
Cann Global said the deal was "cash-free" and based on a "stock-for-stock exchange agreement" between Cann Global and Mr Easterling's company, Plant Matrix Research.
The company said it intended to distribute the formulations under its label.
Cann Global was up 0.1 cents or 6.7 percent to 1.6 cents with 25.8 million shares traded.

CSL

CSL says it has appointed Carolyn Hewson has a non-executive director, effective immediately.
CSL said Ms Hewson has more than 35 years' experience in the finance sector and was most recently a director of BHP.
The company said Ms Hewson was previously a director of Schroders Australia, Stockland Group, BT Investment Management, Westpac Bank, AGL Energy, the Australian Gas Light Company, CSR, AMP, South Australian Water and the Economic Development Board of South Australia.
CSL was up 39 cents or 0.1 percent to $278.34 with 521,767 shares traded.

COCHLEAR

Cochlear says it has appointed Michael Daniell as a non-executive director, effective from January 1, 2020.
Cochlear said Mr Daniell had 40 years' experience in the medical device industry and was a director of Fisher & Paykel Healthcare and the Brandon Capital-managed Medical Research Commercialization Fund and was the managing-director and chief executive officer of Fisher & Paykel Healthcare Corp for 15 years.
Cochlear fell $3.19 or 1.4 percent to $227.42 with 109,885 shares traded.