Biotech Daily

Tuesday July 26, 2016

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: OPTHEA UP 10%; LIVING CELL DOWN 14%**

*** OPTHEA PHASE I OPT-302 AMD 'SAFETY, ACTIVITY'**

*** CELLMID SALES REVENUE UP 147% TO $4m**

*** RACE HIRES CAMARGO FOR BISANTRENE US REGULATORY PATHWAY**

*** OVENTUS STARTS TITRATABLE O2VENT-T TRIAL**

*** PHARMAXIS CEO GARY PHILLIPS EARNS 827k PERFORMANCE SHARES**

*** STEPHEN TINDALL, K ONE W ONE DILUTED TO 6.6% OF ADHERIUM**

*** NUHEARA TO LAUNCH IQBUDS IN LAS VEGAS IN JANUARY 2017**

*** TYRIAN, CONTAGNO ASSET MANAGEMENT BACK-DOOR AGM**

MARKET REPORT

The Australian stock market edged up 0.07 percent on Tuesday July 26, 2016 with the ASX200 up 3.9 points to 5,537.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and two were untraded.

Opthea was best, up 5.5 cents or 10.4 percent to 58.5 cents, with 661,641 shares traded.

Cellmid climbed 9.4 percent; Pharmaxis and Genetic Technologies rose more than five percent; Acrux was up 3.75 percent; Airxpanders and Prana rose more than one percent; with Cochlear, Impedimed and Viralytics up by less than one percent.

Living Cell led the falls, down 1.4 cents or 14.1 percent to 8.5 cents, with 2.5 million shares traded.

Benitec and Biotron lost more than seven percent; Admedus, Universal Biosensors and Uscom fell more than four percent; Osprey was down 3.4 percent; Ellex, Factor Therapeutics, Nanosonics, Prima and Sirtex shed more than two percent; CSL, Neuren, Orthocell and Resmed were down more than one percent; with Clinuvel, Medical Developments, Mesoblast, Pro Medicus, Reva and Starpharma down by less than one percent.

OPTHEA

Opthea says its first-in-human, 20-patient, phase I, dose-escalation trial of OPT-302 for wet age-related macular degeneration has demonstrated safety and clinical activity.

Opthea said the OPT-302 for wet age-related macular degeneration trial achieved the primary objective of safety and tolerability, both as a monotherapy and in combination with the standard-of-care Lucentis, as well as meeting the secondary endpoint of changes in visual acuity and anatomic improvements.

The company said that following the three-month multiple dosing period OPT-302 showed clinical activity in both naïve patients and prior-treated patients and the results suggested that combined inhibition of vascular endothelial growth factor (VEGF) C and D (OPT-302) with VEGF-A might lead to improved outcomes over the anti-VEGF-A Lucentis alone.

Opthea said the study was run under a US investigational new drug program at 14 sites and it would proceed to a 30-patient, phase IIa, randomized, dose-expansion study in naïve patients or those who had a sub-optimal response to prior anti-VEGF-A therapy.

The company said the trial enrolled 20 patients with a mean age of 74.8 years into three OPT-302 dose levels of 0.3mg, 1.0mg or 2.0mg, in combination with 0.5mg Lucentis, and a 2.0mg OPT-302 monotherapy group, with patients receiving three intra-vitreal injections at four week intervals, with a week-12 follow-up visit one month after the third dose.

Opthea said that for the monotherapy patients, Lucentis rescue therapy was provided at investigator discretion or if patients had a five letter decrease in vision or greater and no reduction in central subfield thickness of at least 10 percent with presence of fluid.

The company said that all cohorts enrolled two naïve patients and three patients who had received prior anti-VEGF-A therapy, except for cohort 2 (1.0mg OPT-302 with Lucentis), which enrolled five previously-treated patients.

Opthea said that OPT-302 demonstrated “encouraging clinical activity” as measured by the secondary endpoints of changes from baseline in best corrected visual acuity and anatomic measures for both treatment naïve patients and those who showed a sub-optimal response to prior anti-VEGFA therapy.

Opthea said that 16 of 19 evaluable patients at week-12 maintained or gained vision compared to baseline and the other three patients that all received combination OPT-302 with Lucentis did not lose more than three letters.

The company said that the mean gain in visual acuity from baseline at week 12 in four treatment naïve patients who received either 0.3mg or 2.0mg OPT-302 with Lucentis was 16.5 letters and 9.5 letters in the two who received 2.0mg OPT-302 with Lucentis.

Opthea said that the mean visual acuity gain from baseline at week-12 in 10 patients who showed a sub-optimal response to prior anti-VEGF-A therapy was four letters with combination OPT-302 with Lucentis.

The company said that the mean central subfield thickness, measuring the average central retina thickness, decreased in all combination treatment groups at week-12, with a mean reduction from baseline of 42.7 percent in four treatment-naïve patients and 10.8 percent in 10 patients with a sub-optimal response to anti-VEGF-A therapy.

In the monotherapy cohort, three of five patients, including one naïve and two prior treated, did not require rescue with anti-VEGF-A therapy, with a mean visual acuity gain of 3.3 letters from baseline.

Opthea chief executive officer Dr Megan Baldwin said she was “delighted that we have achieved the outcomes and expectations of this … study and demonstrated the potential of OPT-302 to improve clinical outcomes for wet AMD patients”.

The company said it was recruiting patients into the phase IIa dose expansion cohorts and planning for a randomized, controlled, phase IIb study in 2017.

Opthea was up 5.5 cents or 10.4 percent to 58.5 cents.

CELLMID

Cellmid says that receipts from customers for the 12 months to June 30, 2016 was up 146.5 percent to $3,883,000.

Cellmid chief executive officer Maria Halasz told Biotech Daily that most of the income came from sales of the Advangen Évolis hair growth products with a further $160,000 received as royalty payments from Pacific Edge from sales of the Cxbladder bladder cancer diagnostic products.

Cellmid was up 0.3 cents or 9.4 percent to 3.5 cents.

RACE ONCOLOGY

Race Oncology says Camargo Pharmaceutical Services will prepare its Bisantrene pre-investigational new drug (IND) package for the US Food and Drug Administration.

Race said that the Cincinnati, Ohio-based Camargo was “a leader in 505(b)(2) drug development in the US”.

Camargo’s website said that the 505(b)(2) pathway was designed, “in part, to help avoid unnecessary duplication of studies already performed on a previously approved … drug; the section gives the FDA express permission to rely on data not developed by the [new drug application] NDA applicant”.

“A 505(b)(2) NDA contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant,” Camargo said.

Race chief executive officer Peter Molloy told Biotech Daily that the pre-IND meeting would allow the FDA to decide whether to approve the NDA pathway, but the company also intended to take Bisantrene to a phase III study for US approval.

Mr Molloy previously told Biotech Daily that Bisantrene was a phase II/III drug trialled in 44 clinical studies and on more than 2,000 patients, which showed it did not have the cardiac toxicities of other anthracycline drugs used as chemotherapy agents for cancer (BD: Aug 27, 2015).

Mr Molloy said at that time, that Bisantrene had been approved in France for acute myeloid leukaemia (AML) having demonstrated a 48 percent complete response rate, but was never launched, because it was effectively “lost” in a string of pharmaceutical company mergers and the company.

Mr Molloy said that Race intended to start a named patient program in France which could generate up to $50 million in revenues over five years and a phase II AML bridging study in the US would enable the patient safety database and all historical data to support Bisantrene for a phase III FDA study.

Today, Race said that Camargo would assemble a technical dossier on Bisantrene, prepare and submit a pre-IND meeting request with the FDA, complete and submit a pre-IND package to the FDA and attend the meeting with the FDA, with Race Oncology.

The company said that the purpose of the pre-IND meeting was “to gain FDA concurrence on the use of the 505(b)(2) pathway for Bisantrene, guidance on the proposed clinical trial to be conducted under the IND, and guidance on the on-going development process for Bisantrene”.

Race said that the project was expected to take about six months and once the pre-IND meeting was concluded, the IND could be completed and submitted.

Race fell one cent 3.85 percent to 25 cents.

OVENTUS MEDICAL

Oventus says it has recruited the first of 40 obstructive sleep apnoea patients to assess the comfort, safety and efficacy of its titratable O2Vent-T mouth guard.
Oventus said that Brisbane trial would investigate the comfort and efficacy of the inclusion of an airway into an oral appliance and was expected to be completed by April 2017.
Oventus clinical director Dr Chris Hart told Biotech Daily that the trial would be randomized one-to-one into one arm with a blocked airway in the O2Vent-T compared to an open airway to measure efficacy.
Dr Hart said that the titratable O2Vent-T allowed the patient to adjust their lower jaw position under dentist supervision.
In a media release, Oventus said the airway was designed to deliver air to the back of the mouth, by-passing obstructions from the nose, soft palate and tongue.
Dr Hart said the first clinical trial of the O2Vent Mono “showed the benefit of the inclusion of the airway, especially for [obstructive sleep apnoea] patients with nasal obstructions”.
Dr Hart said that trial of the titratable O2Vent-T would “provide more qualitative and quantitative data on the benefits of the inclusion of the airway for people with and without nasal obstructions”.
“This trial is the first of numerous clinical trials planned over the coming year,” Dr Hart said. “The additional clinical evidence will help us to implement our world-wide market rollout plans.”
Oventus said that the O2Vent-T was registered with the Australian Therapeutic Goods Administration and a 510k application had been lodged with the US Food and Drug Administration.
Oventus was up 6.5 cents or eight percent to 88 cents.

PHARMAXIS

Pharmaxis says chief executive officer Gary Phillips will be issued 827,000 performance shares at no cost, vesting in two tranches on June 30, 2018 and 2019.
Pharmaxis said that the issue was subject to shareholder approval.
At today’s closing price of 30.5 cents the shares were worth $252,235.
Pharmaxis was up 1.5 cents or 5.2 percent to 30.5 cents with 1.1 million shares traded.

ADHERIUM

The Auckland New Zealand-based K One W One Ltd says its 10,990,860 shareholding in Adherium has been diluted from 7.85 percent to 6.57 percent of the company.
The substantial shareholder notice, signed by director Stephen Tindall.
Last year, the becoming substantial shareholder notice was signed by director Brian Mayo-Smith and said that the 10,990,860 shares were acquired under a share swap agreement (BD: Aug 28, 2015) .
Adherium was unchanged at 50 cents.

NUHEARA

Nuheara says it will formally launch its Iqbuds sound filtering and device ear buds at the Consumer Electronics Show in Las Vegas, Nevada, from January 5, 2017.
Nuheara said the show was “the world’s largest and high profiled consumer electronics trade fair”.
Nuheara fell 0.2 cents or 2.9 percent to 6.7 cents with 1.8 million shares traded.

TYRIAN DIAGNOSTICS, CONTANGO MICROCAP

Tyrian says investors will vote on 16 resolutions for the back-door listing of the management buy-out of CSM Holdings, known as Contango Asset Management.

In June, Tyrian chairman Roger Amos told Biotech Daily that he would remain the chairman of the new entity, which would no longer have any direct involvement in biotechnology (BD: Jun 24, 2016).

Today, Tyrian proposed to consolidate its shares on a one-for-300 basis and raise $17,185,980 through a prospectus share offer at 60 cents a share, or 0.2 cents a share on a pre-consolidation basis, in an offer fully-underwritten by Taylor Collison.

The resolutions include a name change to Contango Asset Management as well as the election of new directors and the issue of shares to the new directors.

The meeting will be held K&L Gates, Level 31, 1 O'Connell Street, Sydney on August 25, 2016 at 9am (AEST).

Tyrian was suspended at 0.1 cents.