Biotech Daily

Tuesday February 9, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ALTERITY UP 23%; LBT, OSPREY DOWN 4.55%**

*** PHARMAXIS: 1st US BRONCHITOL FOR CYSTIC FIBROSIS EXPORT; $4m**

*** STARPHARMA: ASTRAZENECA TO TRIAL AZD0466 FOR LEUKAEMIAS**

*** BIONOMICS RAISES $16m FOR 2nd BNC210 PTSD TRIAL**

*** LITTLE GREEN RAISES $22m; PLAN FOR $5m MORE**

*** MICHAEL FOX FOUNDATION GRANTS ALTERITY $641k FOR PARKINSON'S**

*** NOXOPHARM CLAIMS VEYONDA SUCCESS FOR PROSTATE CANCER**

*** CELLMID: FGF5 'APTAMERS' CRITICAL FOR HAIR LOSS**

*** BIOCURATE: DR DAMIEN BATES CEO; DR GLENN BEGLEY ADVISOR**

MARKET REPORT

The Australian stock market fell 0.86 percent on Tuesday February 9, 2021, with the ASX200 down 59.5 points to 6,821.2 points. Nineteen of the Biotech Daily Top 40 stocks were up, 17 fell and four traded unchanged. All three Big Caps fell.

Alterity was the best, up 0.9 cents or 23.1 percent to 4.8 cents, with 245.9 million shares traded. Impedimed improved 7.4 percent; Prescient and Resonance climbed five percent or more; Actinogen and Starpharma were up more than four percent; Pharmaxis, Polynovo, Universal Biosensors and Uscom were up more than three percent; Antisense, Neuren and Proteomics rose more than two percent; Dimerix, Medical Developments, Opthea and Volpara were up more than one percent; with Genetic Signatures and Telix up by less than one percent.

LBT and Osprey led the falls, both down 4.55 percent to 10.5 cents and 2.1 cents, respectively, with 1.4 million shares and 2.2 million shares traded, respectively. Cynata and Oncosil fell more than four percent; Mesoblast, Optiscan, Orthocell, Paradigm and Patrys lost more than three percent; Amplia, CSL, Immutep and Kazia shed more than one percent; with Avita, Clinuvel, Cochlear, Cyclopharm, Nanosonics, Pro Medicus and Resmed down by less than one percent.

PHARMAXIS

Pharmaxis says it has exported the first shipment of Bronchitol for cystic fibrosis to the US, earning a further $US3 million ($A4 million) milestone payment.

Pharmaxis said the locally-developed and manufactured Bronchitol (mannitol) was approved by the US Food and Drug Administration last October as “add-on maintenance therapy … in cystic fibrosis patients 18 years of age and older” (BD: Nov 2, 2020).

The company said at that time that US licencee, the Parma, Italy-based Chiesi Farmaceutici SpA, would pay a $US7 million milestone with a further $US3 million on shipment of commercial launch stock, scheduled by April 2021.

In 2012, then Pharmaxis chief executive officer Dr Alan Robertson hoped Bronchitol would be on sale in the US early the following year (BD: Jan 25, 2012).

In 2013, the FDA refused the application, requiring an additional trial and the company began its third phase III trial, meeting its endpoint with other measures not statistically significant (BD: Mar 19, 2013; Oct 30, 2014; Feb 23, Jun 13, 2017).

In 2019, the FDA’s pulmonary-allergy drugs advisory committee backed Bronchitol but the FDA required a further small trial to demonstrate that clinicians understood revised product packaging and user instructions, with Pharmaxis filing the revised new drug application last year (BD: May 9, Jun 20, 2019; May 5, 2020).

Today, Pharmaxis said it had increased production at its factory in Sydney’s Frenchs Forest and dispatched the first shipment of Bronchitol to Atlanta, Georgia.

The company said the drug had been manufactured and prepared for export at its FDA and Australian Therapeutic Goods Administration-approved facility.

Pharmaxis chief executive officer Gary Phillips said the export announcement was “a proud and very rare achievement for a home-grown pharmaceutical research company”.

“Not only did the team at Pharmaxis design, lead and complete the three large scale international clinical trials which established Bronchitol as a safe and effective medication for [cystic fibrosis] patients, we have now manufactured the drug to be used by adult … patients in the US,” Mr Phillips said.

“Production of drugs for delivery to the lungs is one of the most difficult processes undertaken in medicine manufacturing,” Mr Phillips said.

“Our factory is equipped with the technology to engineer a powder with precise control of the particle size, suitable for delivery via a hand-held inhaler,” Mr Phillips said.

“The powder is put into capsules, and then packaged with all the information required for use by [cystic fibrosis] patients who will take the drug twice a day,” he said.

Pharmaxis said it expected Bronchitol sales in the US “to contribute strongly to the product’s global sales and profit growth, making the Pharmaxis mannitol respiratory business cash flow positive from [this financial year],” Mr Phillips said.

The company said that cystic fibrosis was a debilitating genetic disease-causing progressive damage to the lungs and other organs.

Pharmaxis said that Bronchitol was approved and listed for the treatment of adults and children with cystic fibrosis in Australia and was marketed in Europe, Russia and several other countries.

The company said that the Chiesi Group would be responsible for the commercialization of Bronchitol in the US.

Pharmaxis said that Bronchitol joined its first commercial product the Aridol lung function test in being US FDA-approved.

Pharmaxis was up 0.3 cents or 3.4 percent to 9.1 cents with 2.6 million shares traded.

STARPHARMA

Starpharma says Astrazeneca intends to expand its AZD0466 program to a phase I trial for patients with acute leukaemias.
Starpharma said AZD0466 was a “highly optimized, nanomedicine formulation” of Astrazeneca’s novel dual B-cell lymphoma extra-large (Bcl2/xl) inhibitor which uses Starpharma’s dendrimer enhanced product (DEP) technology.
The company said preclinical data showed the DEP technology delivered a “significant improvement in therapeutic index … which enabled the progression of AZD0466 into the clinic”.
Starpharma said AZD0466 had broad ranging anti-cancer activity which resulted from the dual Bcl2 and Bcl/xl activity, and provided positive pre-clinical data for AZD0466 in haematological cancers, including those resistant to venetoclax.
The company said AZD0466 demonstrated anti-cancer activity in pre-clinical models of haematological cancers, including acute myeloid leukemia, acute lymphoblastic leukemia and non-Hodgkin’s lymphoma.
Starpharma chief executive officer Dr Jackie Fairley said that the “intention is to expedite development of AZD0466 with the objective of obtaining regulatory approval for specific indications of high unmet clinical need”.
The company said Bcl inhibitors had “attracted a lot of interest due to their role in cancer cell death [or apoptosis] and the dual BcL2/xl inhibition by AZD0466 holds significant promise for both haematological and solid cancers”.
Starpharma said that Bcl2 was a clinically validated oncology target with the Bcl2 inhibitor, venetoclax, co-developed by the Walter and Eliza Hall Institute of Medical Research, Abbvie and Roche’s Genentech, and was approved by the US Food and Drug Administration in 2016.
Starpharma was up nine cents or 4.6 percent to $2.04 with 2.8 million shares traded.

BIONOMICS

Bionomics says it has commitments to raise $15,991,634 at 14.5 cents a share for a phase IIb trial of its anti-anxiety drug BNC210 for post-traumatic stress disorder.
In 2015, Bionomics said it raised $16,404,649 at 40.8 cents a share for a phase II trial of BNC210 for post-traumatic stress disorder (PTSD) (BD: Dec 8, 2015).
In 2018, the company fell 69 percent when its 193-patient, phase II trial of BNC210 in adults with PTSD failed to meet its primary endpoint (BD: Oct 2, 2018).
Today, the company said the issue price of 14 5 cents was a 263 percent premium to the capital raise in September 2020 and a 20 percent discount to the 30-day volume weighted average price (VWAP) to February 5, 2021.
Bionomics said it would conduct a rights offer for existing shareholders.
The company said that under the subscription agreement with Apeiron Investment Group owned by Christian Angermeyer, Apeiron said it would underwrite a future placement up to $15 million at a minimum price of six cents a share, and the commitments for the placement meant that obligation had been fulfilled.
Bionomics executive chair Dr Errol De Souza said the placement was “strongly over-subscribed” including support from Apeiron, Biotech Value Fund, Merck, Peter Thiel and Mike Novagratz.
“We remain on track to the completion of our ongoing seven-day dosing pharmacokinetic study of our novel BNC210 tablet formulation [by April 2021] and starting the phase IIb PTSD trial in mid-2021”.
Bionomics was up 1.5 cents or 6.8 percent to 23.5 cents with 4.9 million shares traded.

LITTLE GREEN PHARMA

Little Green says it has “firm commitments” to raise $22 million in a placement at 65 cents a share and plans a non-underwritten share plan of $5 million

Little Green said the funds would assist the company’s “next phase of growth by accelerating sales and marketing efforts in Australia and offshore markets, expanding cultivation and manufacturing capacity and providing general working capital”.

The company said the share plan record date was February 8, it would open on February 15 and close on March 3, 2021.

Little Green said Canaccord Genuity (Australia) would be the lead manager to the placement and had been appointed as corporate advisor.

Little Green fell 15 cents or 16 percent to 78.5 cents with 5.4 million shares traded.

ALTERITY THERAPEUTICS

Alterity says Michael J Fox Foundation has granted $US495,000 ($A641,423) to determine the optimal dose of ATH434 drug for Parkinson’s disease.

Alterity said it was the second funding from the Foundation and would be used to evaluate the pharmacologic profile of ATH434 in a primate model to determine the dose for future Parkinson’s disease clinical trials.

The company said ATH434 targeted alpha-synuclein misfolding and aggregation through the redistribution of excess labile iron.

Alterity chief executive officer Dr David Stamler said that the “potential to expand into other Parkinsonian disorders that implicate alpha-synuclein has always been part of our strategy and this funding allows us to take another step towards realizing a program in Parkinson’s disease”.

The company said that by targeting alpha-synuclein, ATH434 had the potential to modify the course of synucleinopathies such as Parkinson’s disease and multiple system atrophy, for which ATH434 was due to enter a phase II trial this year.

Alterity was up 0.9 cents or 23.1 percent to 4.8 cents with 245.9 million shares traded.

NOXOPHARM

Noxopharm says its phase I/II trial of Veyonda with 177-lutetium-PSMA-617 reports median overall survival outcome of 19.7 months in half of all prostate cancer patients.

In October, Noxopharm said it had treated the last of 56 patients in its phase Ib/IIa trial of Veyonda, or NOX66, with 177-lutetium-prostate specific membrane antigen-617 (177-Lu-PSMA-617) radiation therapy for prostate cancer (BD: Oct 12, 2020).

In February, the company said data from 32 patients treated with the 400mg and 800mg doses showed a median overall survival rate of 17.1 months and 28 of 32 patients had a fall in prostate specific antigen levels (BD: Feb 14, 2020).

Today, the company said the combined drug overall survival of 19.7 months compared to 13.3 months reported in an Australian study of 177-Lu-PSMA -617 on its own.

Noxopharm said that 86 percent of men had a reduction in prostate specific antigen (PSA) levels, “indicating a very high rate of response of the cancer to the treatment”.

The company said that “46 percent of men were able to complete the full six cycles of treatment without cancer progression” and compared to a previous study the combination had added more than “15 months of additional survival to men with end-stage cancer”.

The company said it would add clinical, commercial and transactional strategies in response to the multiple opportunities.

Noxopharm was up 14.5 cents or 21.2 percent to 83 cents with 7.8 million shares traded.

CELLMID

Cellmid says research with three Japanese institutes shows that the composition of its FGF5 inhibitors are critical for use against hair loss.

Cellmid said the University of Hokkaido, Yokohama National University and the Chiba Institute of Technology collaborated on the research into “aptamers”, or oliogonucleotides or peptide molecules, showing that “newly identified aptamer constructs inhibiting FGF5 are highly effective and specific”.

The company said that FGF5 was “a critical regular of hair growth, initiating the transition of hair follicles out of growth and into rest and fall”.

Cellmid said it marketed several brands of FGF5 inhibiting hair growth products.

Cellmid was unchanged at 10 cents.

BIOCURATE

Biocurate says it has appointed Dr Damien Bates as acting chief executive officer replacing Dr Glenn Begley who will continue as an advisor to the company.

Biocurate, a joint venture between the University of Melbourne and Monash University, supported by the Victoria Government said Dr Begley would be “a specialist scientific, commercial and strategic advisor” to the organization.

The company said that Dr Bates was appointed chief scientific officer and head of translational medicine about nearly two years ago.

Biocurate chair John Brumby said the leadership transition “marked a critical next step for the company’s development”.

“We have a well-developed project portfolio, a highly-skilled and committed team and an excellent relationship with our shareholder universities,” Mr Brumby said.

Mr Brumby said that Dr Beglely had “made an outstanding contribution to Biocurate and we thank him for his untiring efforts to deliver our vision”.