Biotech Daily

Wednesday September 5, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: REVA UP 12.5%; ONCOSIL DOWN 12%**

*** INVION SPINS-OUT INV102, INV104, DR MITCH GLASS TO CHRONIC AIRWAY**

*** STARPHARMA DEP-IRINOTECAN BEATS IRINOTECAN IN MICE, AGAIN**

*** IMMURON: TRAVELAN PROTECTS 6 OF 8 PRIMATES FROM DYSENTRY**

*** OPTHEA: DSMB BACKS OPT-302 WET AMD TRIAL**

*** REDHILL: 2nd PHASE III TALICIA (RHB-105) HELICOBACTER TRIAL ENROLED**

*** GOODBYE INNATE, HELLO AMPLIA**

*** CLINUVEL: FDA REQUESTS SCENESSE MANUFACTURING INFORMATION**

*** NOXOPHARM DOUBLES PROSTATE CANCER TRIAL COHORT TO 32**

*** NUHEARA US DISTRIBUTION DEAL WITH ADCO MEDICAL**

*** SYDNEY OPTOMETRIST 1st VISIONEERING NON-US SALE**

*** FIL DECREASES TO 5.45% IN CLINUVEL**

*** CVC BELOW 5% IN IDT**

*** DR CHRIS HART OVENTUS CEO, NEIL ANDERSON CTO; ADVISORS**

MARKET REPORT

The Australian stock market fell 1.0 percent on Wednesday September 5, 2018 with the ASX200 down 62.7 points to 6,230.4 points. Nine of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and three were untraded. All three Big Caps fell.

Reva was the best, up three cents or 12.5 percent to 27 cents with 40,008 shares traded. Bionomics climbed 10.5 percent; Impedimed and Starpharma improved more than four percent; Pharmaxis was up 3.2 percent; with Cyclopharm, Nanosonics, Opthea and Sirtex up by less than one percent.

Oncosil led the falls, down 2.5 cents or 11.6 percent to 19 cents, with 1.8 million shares traded. Compumedics lost 9.3 percent; Prescient fell 8.6 percent; Clinuvel and Uscom shed more than six percent; Immutep and Volpara were down more than five percent; Airxpanders fell 4.35 percent; Pro Medicus and Telix were down more than three percent; Benitec, Cynata, Ellex, Factor and Mesoblast shed two percent or more; Actinogen, CSL and Neuren were down more than one percent; with Cochlear, Medical Developments and Resmed down by less than one percent.

INVION

Invion says it will demerge its respiratory assets into Chronic Airway Therapeutics with inventor Dr Mitchell Glass leaving Invion to be Chronic Airway Therapeutics director.

Invion said that chief medical officer and executive director Dr Glass would be Chronic Airways executive director and lead the development of nadolol (INV102) and zafirlukast (INV104), to expedite phase III clinical trials in China.

Invion said that the Chronic Airway would be a public unlisted company and the board would include Invion chair Thian Chew as the spin-out company chair and Invion managing-director Dr Greg Collier as a non-executive director.

The company said that, pending approvals, the demerger would be through an equal capital reduction through an in-specie distribution of shares in Chronic Airway and was expected to be finalized "in late October 2018".

Invion said its existing shareholders would retain their Invion shares and if the demerger was approved and implemented, eligible Invion shareholders would be entitled to one Chronic Airway share for each Invion share held on the record date.

Dr Collier told Biotech Daily that fewer than one percent of shareholders were ineligible and they would not receive Chronic Airway shares.

The company said that the shares that would have been distributed to ineligible shareholders be transferred to a nominee and sold on a best endeavors basis, with the shareholders to receive the sale proceeds, if any, less costs and taxes.

Invion said that the demerger was intended to maximize potential value, by providing a separate structure for each entity to fund and advance its clinical development programs, establish stand-alone teams to focus on the development of its respective assets and benefit from the upside gained as each company delivers on milestones related to clinical development and regulatory clearance.

The company said it completed feasibility, pre-clinical and clinical studies on INV102 and INV104 over three years to the end of 2015, and had been seeking to out-licence or sell the assets to a partner without success (BD: Jul 27, Oct 5, 2015; Apr 4, 2016).

Invion said that Chronic Airway had been established to develop the two assets for China with intentions to file an investigational new drug application with the Chinese Food and Drug Administration within 12 months.

The company said that 68.16 percent Invion owner, Hong Kong's Cho Group would lend no less than $200,000 for the initial overhead and operating costs of Chronic Airway to establish a pathway with the CFDA and appoint key service providers including a clinical research organization.

Invion said that through its research and development services agreement, the Cho Group also provided non-dilutive funding to Invion for the clinical trials and related development of the Photosoft cancer treatment product suite.

"This is a positive development for Invion's shareholders," Dr Collier said.

"Invion has a promising asset for the treatment of various cancers which we expect will enter into clinical trials in 2019, and uniquely, our licence partner the Cho Group will fund the global research and development costs for these programs," Dr Collier said.

Dr Collier said the demerger would allow Invion to focus on Photosoft and provide the development and potential regulatory approval of the respiratory assets in China.

"The demerger also provides a separate structure to fund and develop the respiratory assets which we believe have great promise and could deliver value to shareholders in their own right," Dr Collier said. "[Chronic Airway] has a clear strategy for development in China where chronic respiratory disease, including [chronic obstructive pulmonary disease] is a major healthcare issue," Dr Collier said.

Invion fell 0.3 cents or 8.1 percent to 3.4 cents with 12.0 million shares traded.

STARPHARMA

Starpharma says a study of its dendrimer enhanced-irinotecan for pancreatic cancer shows “complete tumor regression and 100 percent survival” in mice after 57 days.
Starpharma said mice were dosed on days one, eight and 15 of the study in four cohorts receiving saline solution, the maximum tolerated dose of the dendrimer enhanced product (DEP) irinotecan, 40mg/kg of irinotecan, or 40mg/kg irinotecan with 50mg/kg of the cancer drug Fluorouracil (5-FU).
The company said that standard irinotecan and irinotecan in combination with 5-FU inhibited tumors, but with no regression and that both showed “no appreciable overall survival benefit compared to saline”, while the DEP version of irinotecan demonstrated “significant anti-cancer efficacy with complete tumor regression” ($p < 0.0001$).
Starpharma said the DEP-irinotecan cohort had 100 percent survival at 57 days, compared to a median 43-day survival for irinotecan and irinotecan in combination with Fluorouracil.
In 2017, the company said DEP-irinotecan tested in primary colorectal cancer showed “significantly better anti-tumor activity and increased survival compared with irinotecan” in mice (BD: Jun 6, 2017).
Starpharma was up six cents or 4.8 percent to $1.30 with 1.1 million shares traded.

IMMURON

Immuron says six of eight non-human primates tested in a US Department of Defense study of Travelan for bacillary dysentery were symptom-free after 11-days.
Immuron said the study, conducted by the Bangkok, Thailand-based US Armed Forces Research Institute of Medical Sciences, tested Travelan for Shigella flexneri, a diarrhoea-causing bacteria, with eight primates treated with Travelan and four primates as a control group, receiving the drug or a placebo twice a day for six consecutive days.
The company said one primate from the Travelan-treated cohort developed dysentery symptoms within 24 hours to 36 hours of exposure to Shigella flexneri, while another developed symptoms after treatment was completed, while all four control animals developed acute dysentery symptoms in the 24 hour to 36 hour period..
Immuron said the study was one of several commissioned by the US Department of Defense to determine Travelan’s potential as a preventative treatment for US military personnel and civilians overseas where gastrointestinal bacterial infections would be debilitating, and was done in collaboration with the Washington DC-based Department of Enteric Diseases and the Department of Veterinary Medicine.
The Department’s head of enteric vaccines Dr Robert Kaminski said the results “go some way in confirming that Travelan is effective across all strains and species of enteropathogenic bacteria tested”.
“The current study demonstrates that the Travelan product is functionally cross-reactive and prophylactically effective and confirms that Travelan has a substantially broader spectrum of antimicrobial action that previously reported,” Dr Kaminski said.
Immuron chief executive officer Dr Jerry Kanellos said the research showed that in a non-human primate challenge model of shigellosis, or bacillary dysentery, Travelan protected 75 percent of the animals from dysentery.
“All the placebo-treated animals displayed classic dysentery symptoms after challenge with a virulent strain of Shigella … [and] it is also very interesting to note the second case of dysentery in the Travelan cohort developed once the treatment terminated,” Dr Kanellos said.
Immuron was up 1.5 cents or 4.5 percent to 35 cents.

OPTHEA

Opthea says its data and safety monitoring board (DSMB) recommends its phase IIb trial of OPT-302 for wet age-related macular degeneration continue unchanged.
Opthea said the recommendation from the board was the first pre-planned safety review of the trial and had been agreed unanimously.
The company said the board planned to meet every six months until all study participants had completed the trial.
Opthea chief executive officer Dr Megan Baldwin said the “outcomes of this first DSMB interim review of the ongoing phase IIb study are consistent with the favorable safety and tolerability profile observed in our phase I/IIa clinical trial with OPT-302 in 51 wet [age-related macular degeneration] patients” (BD: Apr 3, 2017).
In July, the company said it had recruited 176 of 351 patients for the phase IIb trial of OPT-302 for wet age-related macular degeneration and today said it was “on-track to report primary data from the study in early 2020” (BD: Jul 2, 2018).
Opthea was up half a cent or 0.8 percent to 62.5 cents.

REDHILL BIOPHARMA

Redhill says it has enrolled all 455 patients in its randomized, double-blind, confirmatory, phase III study of Talicia (RHB-105) for helicobacter pylori.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Today, Redhill said the two-arm study compared Talicia against a dual therapy of amoxicillin and omeprazole at equivalent doses.
The company said the study had enrolled non-investigated dyspepsia patients with confirmed helicobacter pylori infections in 55 clinical sites in the US, with patients randomized in a one-to-one ratio to receive four capsules three times a day of either Talicia or the comparator for 14 days.
Redhill said the first phase III study had met its primary endpoint, with a helicobacter pylori eradication rate of 89.4 percent compared to the historical standard-of-care eradication of 70 percent ($p < 0.001$).
The company said it expected results from the second study before the end of 2018, and, if successful, it would complete the package required to file a new drug application with the US Food and Drug Administration in early 2019, subject to additional regulatory feedback.
On the Nasdaq, Redhill was up 12.0 US cents or 1.6 percent to $US7.6 ($A10.58) with 89,873 shares traded.

INNATE IMMUNOTHERAPEUTICS, AMPLIA THERAPEUTICS

Innate says its name has formally changed to Amplia Therapeutics and the ASX stock code will change to ATX.
Amplia chairman Dr Warwick Tong told Biotech Daily that although the name had formally changed, the ASX code was expected to change to ATX later this week or early next week.
Earlier this year, the Melbourne-based Amplia back-doored into Innate for cancer treatments (BD: Mar 23, Apr 6, 2018).
Amplia fell 2.5 cents or 6.85 percent to 34 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says the US Food and Drug Administration has requested further documentation to support the new drug application for Scenesse for erythropoietic protoporphyria.
Clinuvel said the additional information covered product manufacturing information and details from the European post-authorization use of Scenesse (afamelanotide 16mg).
The company said it was seeking regulatory approval for the same treatment dose and regimen in the US as had been approved in the European Union, where Scenesse was available through prescription at specialized treatment centres.
In 2016, Clinuvel said it would submit a rolling “modular dossier” on Scenesse for the rare metabolic disorder erythropoietic protoporphyria (EPP) during the first half of 2017, after meeting the FDA’s Division of Dermatology and Dental Products to discuss the content and format of a new drug application for Scenesse (BD: Nov 9, 2016).
Earlier this year, the company said it had completed its US regulatory submission for Scenesse, after having been in “regular and frequent communication with the [FDA] to discuss the development program in Scenesse as a preventative treatment for adult EPP patients” since 2005 (BD: Jun 25, 2018).
Today, Clinuvel chief scientific officer Dr Dennis Wright said it was “apparent during our interactions that in launching a first-in-class pharmaceutical and novel medicinal product, the agency is focusing on further technical information supporting Scenesse, as well as real world evidence in EPP patients currently coming on in Europe”.
“I am confident the FDA will analyze [the] data as a final step before it takes a stance on priority review,” Dr Wright said.
“Since we are in frequent contact with the agency I believe that both parties are working towards the desired clinical outcome for US erythropoietic protoporphyria patients, although at this stage further timelines have not been provided by the FDA,” Dr Wright said.
Clinuvel fell $1.02 or 6.8 percent to $14.00 with 113,527 shares traded.

NOXOPHARM

Noxopharm says it has been approved to increase the number of patients in its phase I trial of Veyonda, or NOX66, for late-stage prostate cancer.
Noxopharm said it would treat up to 32 patients with metastatic castrate-resistant prostate cancer and no remaining treatment options at Sydney’s St Vincent’s Hospital and they would receive a combination of Lu-PSMA, or 177-lutetium-prostate-specific membrane antigen-617, and Veyonda (NOX66) with safety and prostate-specific antigen responses the main end-points of the study.
The company said the first cohort of eight men, three of which had completed their course of treatment and the remaining five nearing the end of treatment, would receive 400mg of Veyonda, while the second cohort of eight men, six of whom had begun treatment, would receive 800mg.
Noxopharm said both regimens had been well tolerated and that, in the absence of serious safety issues, the study’s investigators had sought permission to increase the number of patients, in order to provide a larger study size capable of delivering meaningful safety and efficacy endpoints.
The company said that the additional 16 patients would be recruited in the coming six months.
In April, Noxopharm said it had been approved to enrol the second cohort of the trial of Veyonda with 177-lutetium radiotherapy (BD: Apr 17, 2018).
Noxopharm fell 3.5 cents or 5.5 percent to 60 cents.

NUHEARA

Nuheara says the Englewood, Colorado-based Adco Medical Suppliers will sell its Iqbuds Boost hearing devices in the US.

Nuheara said Adco was a wholesale supplier of hearing aid equipment, supplies and assistive devices and had a contract with the US Government to supply audiological equipment, as well as being a certified hearing assistance device supplier to the US Department of Veterans Affairs, which supplied about 25 percent of all hearing devices sold in the US and was the biggest employer of audiologists with more than 1,100 staff.

Nuheara chief executive officer Justin Miller said that “by developing strong relationships with quality partners like Adco, that are also the supplier to the US Department of Veterans Affairs, we are confident that we can expand our reach to service more customers across multiple channels”.

Nuheara was up 0.7 cents or 7.95 percent to 9.5 cents with 11.9 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has made its first multi-focal contact lenses outside the US, to Sydney-based optometrist Oliver Woo.

Visioneering said that Mr Woo specialized in the management of paediatric myopia and was “the first ortho-keratologist in Australia to obtain a fellowship from the International Academy of Orthokeratology”.

Mr Woo said the Visioneering lenses had been shown “to slow myopia progression in children and to provide excellent near and distance vision in presbyopic adults”.

Visioneering said that a study published in the journal Eye & Contact Lens said its Naturalvue multi-focal (MF) lens reduced myopia progression in children by about 96 percent with 98.4 percent of the children in the study showing a decrease in the rate of worsening of their myopia.

In January, Visioneering said that 91-patient retrospective data showed that the lenses decreased paediatric myopia by 91 percent (BD: Jan 29, 2018).

Visioneering chief executive officer Dr Stephen Snowdy said that following Conformité Européenne (CE) mark approval the company had been “putting in place the logistics to market our products outside the United States”.

Visioneering was unchanged at 18 cents.

CLINUVEL PHARMACEUTICALS

FIL Limited says it has reduced its substantial holding in Clinuvel from 3,087,276 shares (6.46%) to 2,604,320 shares (5.45%).

The Hong Kong-based FIL said that it sold the 482,956 shares from July 16 to August 31, 2018, at prices ranging between $10.23 and $14.19.

IDT AUSTRALIA

CVC says it has ceased its substantial shareholding in IDT, selling 3,850,000 shares on August 29, 2018 for $498,448, or 12.95 cents a share.

The Sydney-based CVC said it also bought 7,897 shares between June 22 and July 25, 2018 for a total of $603 or 7.6 cents a share.

Biotech Daily calculates that CVC has 11,477,999 IDT shares or 4.68 percent.

IDT was unchanged at 15 cents.

OVENTUS MEDICAL

Oventus chief executive officer Dr Chris Hart told Biotech Daily that he replaced Neil Anderson, last week, with Mr Anderson continuing as chief technology officer.

Dr Hart said that the change was announced in the directors' report section of the full year accounts and Appendix 4E preliminary final report.

On page seven of the 53-page document, Oventus said that it had "decided to clarify the executive roles" with Dr Hart becoming the chief executive officer and Mr Anderson the chief technology officer.

The ASX Guidance Notes 8, 14 and 20 relate to announcements that contain market sensitive information and headlines that clearly convey the fact.

"Market sensitive announcements should be made on a stand-alone basis and not embedded in other announcements that may not be market sensitive," the ASX guidance says.

Biotech Daily did not see the reference to the change of chief executive officer in reviewing the company's accounts and discovered the change in today's announcement of the appointment of a medical technology advisory board.

Today, Oventus said the medical technology advisory board would be composed of "international sleep experts to help guide the development and commercialization of [its] sleep treatment platform".

Oventus said the board would be a US-based consultative advisory body that would report to Dr Hart and provide input and guidance into the company's clinical, developmental and commercial strategy, and introducing products to the US.

The company said that members of the board would be appointed for three-year terms, renewable by mutual agreement.

Oventus said that the medical technology advisory board comprised Dr Lee Surkin, Dr Richard Bogan, Dr Jerry Kram, Dr Mark Hickey, Dr Mark Rasmus, Daniel Brown and Myra Brown.

Dr Hart said "the formation of this board will help drive forward the clear potential of our sleep treatment platform".

Oventus was up one cent or 3.7 cents to 28 cents.