Biotech Daily

Thursday March 18, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PATRYS UP 21%; ACTINOGEN DOWN 6%**

*** MONASH, ET AL EMBRYO MODELS FOR PREGNANCY STUDIES**

*** VOLPARA DENSITY 'REDUCES BREAST CANCER FALSE POSITIVES'**

*** AMPLIA, GARVAN WORK ON AMP945 FOR PANCREATIC CANCER**

*** ADHERIUM PLACEMENT RAISES $18m**

*** VISIONEERING $1m SHARE PLAN**

*** ITM TO SUPPLY TELIX RADIO-ISOTOPES**

*** CHIMERIC DOSES 1st GLIOBLASTOMA TRIAL PATIENTS**

*** OSPREY: 3 MORE US DISTRIBUTION DEALS**

*** BOD, DRUG SCIENCE STUDY MEDICABILIS FOR 'LONG COVID'**

*** OVENTUS APPOINTS CONNECT DME, CIRCADIAN DISTRIBUTORS**

*** NYRADA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ASIC RESTRICTS TBG CAPITAL RAISING**

*** GOODBYE CANNPAL; AUSCANN EXPANDS, BOARD CHANGES**

MARKET REPORT

The Australian stock market fell 0.73 percent on Thursday March 18, 2021, with the ASX200 down 49.3 points to 6,745.9 points. Nineteen of the Biotech Daily Top 40 stocks were up, 17 fell and four traded unchanged. All three Big Caps were down.

Patrys was the best on no news, up 0.5 cents or 20.8 percent to 2.9 cents, with 17.3 million shares traded. Antisense climbed 11.1 percent; Alterity, Oncosil and Prescient were up five percent or more; Impedimed, Imugene and LBT improved more than four percent; Dimerix and Telix were up more than three percent; Cynata, Paradigm, Resonance and Universal Biosensors rose two percent or more; Amplia, Medical Developments and Orthocell were up more than one percent; with Kazia and Opthea up by less than one percent.

Actinogen led the falls, down 0.2 cents or 5.9 percent to 3.2 cents, with 32.1 million shares traded. Optiscan and Proteomics fell more than four percent; Next Science and Uscom were down more than three percent; Cochlear, Cyclopharm, Mesoblast, Nanosonics, Pharmaxis and Starpharma shed two percent or more; Avita, CSL, Nova and Resmed were down more than one percent; with Clinuvel, Genetic Signatures, Neuren, Polynovo and Pro Medicus down by less than one percent.

MONASH UNIVERSITY

Two research groups have developed human embryo models from either skin cells or human embryonic stem cells for use in early-stage pregnancy research.

Monash University said that a team of scientists led by Prof Jose Polo had reprogrammed fibroblasts, or skin cells, into a three-dimensional cellular structure that is morphologically and molecularly similar to human blastocysts, a fertilized embryo.

The University said artificial blastocysts named Iblastoids, or induced blastoids, could be used to model the biology of early human embryos in the laboratory.

In a study published in Nature, titled 'Modelling human blastocysts by reprogramming fibroblasts into Iblastoids' Monash University's Prof Polo said that given that "Iblastoids with specific genetic loads can be generated, this will allow studies of early developmental diseases and screening for treatments".

"Iblastoids could also serve as an excellent platform for toxicity and viral susceptibility screens, as well as enabling gene therapy techniques," Prof Polo said.

The abstract is at: https://www.nature.com/articles/s41586-021-03372-y.

A separate study published in Nature, titled 'Blastocyst-like structures generated from human pluripotent stem cells' led by the University of Texas Southwestern Medical Centre and China's Kunming Medical Centre, said than an embryo model was developed from human pluripotent stem cells, derived from pre-implantation embryonic stem cells.

The study said that Iblastoids were an "alternative to blastocysts for studying early human development, understanding early pregnancy loss and gaining insights into early developmental defects".

The abstract is at https://www.nature.com/articles/s41586-021-03356-y.

In a Nature article titled 'First completed model of the human embryo', the University of Michigan's Dr Yi Zheng and Prof Jianping Fu outlined the logistical and ethical challenges of fabricating embryos including "strict ethical rules prevent the culturing of human embryos past [the equivalent of 14 days in-vivo], when structures associated with gastrulation begin to appear".

The article is at: https://www.nature.com/articles/d41586-021-00581-3.

VOLPARA HEALTH TECHNOLOGIES

Volpara says its 3,000-patient 'Dense' study of Volpara Density for breast density assessment has reduced its false-positive cancer rate compared to the initial results.

Volpara said the randomized, controlled Dense trial assessed women for 10-years to determine whether breast magnetic resonance imaging (MRI) was cost-effective in reducing interval cancers in women with dense breasts.

In 2019, the company said its 40,000-patient Dense trial showed that the number of interval cancers "drops dramatically" when x-rays, Volpara Density and breast MRI were combined, (BD: Mar 4, 2019).

Today the company said the 2019 results had "a relatively high false-positive result" when screening for internal cancers and a 3,000-participant round of the Dense trial had a false-positive interval cancer detection rate of 26.3 incidents per 1,000 screening examinations compared to 79.8 per 1,000 screening exams in the 40,000-participant round.

Volpara chief executive officer Dr Ralph Highnam said the first Dense trial results showed a dramatic decrease in the number of interval cancers by varying screening based upon Volpara Density [and the] follow-up results demonstrate that as screening programs settle into these new protocols, the number of false positive is significantly reduced and makes the new protocol much more viable".

Volpara was unchanged at $1.295.

AMPLIA THERAPEUTICS

Amplia says it will collaborate with Sydney's Garvan Institute of Medical Research to develop its focal adhesion kinase (FAK) inhibitor AMP945 for pancreatic cancer.
Amplia said the collaboration would combine Garvan's research into FAK biology and its clinical research network with Amplia's FAK inhibitors and drug development capability.
The company said the research would evaluate AMP945's impact on the fibrotic tumor micro-environment, the biological process supporting the growth of pancreatic cancers.
Amplia managing-director Dr John Lambert said that "by leveraging Garvan's deep understanding of the different biological roles that FAK can play, we aim to optimize the design of our planned clinical trials, recruit the right pancreatic cancer patients and treat them in the right way, giving AMP945 the best chance for success".
Amplia said that the terms of the agreement were confidential but did include "future, success-based payments by Amplia to Garvan on AMP945 achieving specified clinical, regulatory and commercial sales milestones".
The company said it had US orphan drug status for pancreatic cancer and the Garvan agreement could expand into other therapeutic areas (BD: Mar 25, 2020).
Amplia was up half a cent or 1.9 percent to 26.5 cents.

ADHERIUM

Adherium says it has "subscription commitments" to raise $18 million in a placement at 1.5 cents a share.
Adherium said the placement was supported by $5 million each from cornerstone investors Trudell Medical and the Bioscience Managers Translation Fund 1.
The company said the funds would be used for development of its Hailie respiratory device monitors, commercial evaluations in North America and partnering agreements.
Adherium said MST Financial was the lead manager of the placement.
Adherium fell 0.2 cents or 9.5 percent to 1.9 cents with 8.8 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it hopes to raise $1,000,000 in a share plan at 1.7 cents per Chess Depository Interest (CDI), following its $22 million placement (BD: Feb 17, 2021).
Visioneering says that investors would receive one free attaching option for every two CDIs purchased, exercisable at 3.0 cents each until February 28, 2024.
The company said the funds would be used for international expansion, product launches, clinical trials, general working capital and to achieve "break-even cash flow".
Visioneering said the share plan record date was February 16, opening on March 18 and closing on April 1, 2021.
Visioneering was unchanged at 1.8 cents with four million shares traded.

TELIX PHARMACEUTICALS

Telix says Isotopen Technologien Munchen AG will supply "no-carrier-added lutetium-177", a therapeutic isotope, for its molecularly targeted radiation products.
Telix said that under the clinical and commercial supply agreement, the Garching, Bavaria-based Isotopen Technologien Munchen AG would supply the lutetium-177 for its investigational programs in prostate and renal cancers, as well as for scale-up and commercialization of the products, subject to approval.
Telix was up 15 cents or 3.6 percent to $4.36 with one million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has dosed the first four-patient cohort in its up-to 36-patient, phase I study of chlorotoxin chimeric antigen receptor T-cells for glioblastoma.
Last year, Chimeric said it raised $35 million in an “over-subscribed” initial public offer at 20 cents to develop the chlorotoxin chimeric antigen receptor (CLTX-Car) T-cell therapy it licenced from California’s City of Hope (BD: Sep 22, Dec 11, 2020).
Today, the company said the first cohort of four patients with glioblastoma in the dose escalation study had received the lowest dose of 44 x 10^6 CLTX-Car-T cells.
Chimeric said it would begin recruitment of glioblastoma patients for the next dose level of 88 x 10^6 CLTX-Car-T cells when the final patient in the first cohort had completed the follow-up period.
Chimeric fell one cent or 3.1 percent to 31.5 cents with 3.1 million shares traded.

OSPREY MEDICAL INC

Osprey says it has agreements with three independent sales agencies to distribute its Dyevert cardiac dye minimization devices in 11 US states.
Osprey said St Patrick’s Distributing Inc would distribute in Colorado, Idaho, Montana Utah and Wyoming; EA Medical would be responsible for Arkansas, Kansas, Missouri and Nebraska, with Wiil Medical distributing Dyevert in Wisconsin and Illinois.
The company said the two-year agreements had escalating quarterly sales targets, and it would pay commissions to the independent sales agencies (ISA) based on total revenues.
Osprey chief executive officer Mike McCormick said that with the additional three agreements the company had “seven ISA agreements covering 21 states”.
Osprey was unchanged at 2.1 cents with 1.7 million shares traded.

BOD AUSTRALIA

Bod says it will collaborate with London’s Drug Science UK to assess the efficacy of its marijuana-based Medicabilis for managing long-term symptoms of Covid-19.
Bod said the long-term effects of Covid-19 included chronic pain, anxiety, sleep disturbances and fatigue.
The company said that one in 10 UK people testing positive for Covid-19 had symptoms for up-to 12 weeks and one in five had long-term symptoms for five weeks or more.
Bod said the Medicabilis study was expected to begin “in the coming months”.
Bod fell two cents or 3.7 percent to 52.5 cents with 2.3 million shares traded.

OVENTUS MEDICAL

Oventus says it has appointed Connect DME and Circadian Australia to distribute its devices for obstructive sleep apnoea in the US and Australia, respectively.
Oventus said the companies would supply its O2Vent Optima and laboratory inside a laboratory or ‘lab in lab’ business model, which used “a scanner to measure the patient’s mouth size for a custom-fit for the O2vent” (BD: Sep 2, 2019).
The company said that under a three-year agreement, Connect DME (durable medical equipment) would offer the O2Vent platform to customers through member health plans.
Oventus said that Circadian Australia would distribute the O2Vent platform to clients in high-risk professions to manage the issues of fatigue in the workplace.
Circadian Australia is not related to Circadian Technologies, now Opthea.
Oventus fell half a cent or 2.5 percent to 19.5 cents.

NYRADA INC

Nyrada has requested a trading halt pending “an announcement relating to an update on the company’s capital structure, including a capital raising program”.
Trading will resume on March 22, 2021.
Nyrada last traded at 31.5 cents.

TBG DIAGNOSTICS

TBG says the Australian Securities and Investments Commission has restricted its ability to raise funds after failing to lodge a financial report, on time.
TBG said it had not filed the financial report for the year to December 31, 2019 by the due date of March 31, 2020, instead filing the report on June 15, 2020 and paying a late lodgment fee.
The company said that ASIC had ruled that it would “not be able to rely on the reduced disclose rules under Section 713 of the Corporations Act 2001 on special prospectuses and instead must issue a full prospectus in order to raise funds from certain investors”.
TBG said the capital raising restrictions would not impact its operations and business.
TBG was in an ASX suspension and last traded at 27 cents (BD: Mar 17, 18,19, 2020).

AUSCANN GROUP HOLDINGS, CANNPAL ANIMAL THERAPEUTICS

Auscann says it has completed its acquisition of Cannpal, implementing the scheme of arrangement and finalizing board changes.
Last year, Auscann said it would acquire Cannpal, with a scheme of arrangement to pay 1.3 Auscann shares for every one Cannpal share, valuing Cannpal, which produced marijuana products for dogs, at $17.5 million (BD: Nov 16, 2020).
Last week, Cannpal said shareholders voted overwhelmingly (99.91%) in favor of the merger, the Supreme Court of Western Australia approved the scheme of arrangement, and it ceased trading on the ASX on March 11 (BD: Mar 8, 10, 11, 2021).
Today, Auscann said Layton Mills assumed the role of chief executive officer, today, replacing Nick Woolf who would continue as an advisor (BD: Jan 17, 2021).
Auscann said that Cannpal directors Geoff Starr, Robert Clifford and Dr Kathryn Adams had been appointed as directors, effective from April 1, 2021.
Auscann said Kidder Williams was the financial advisor for the acquisition, with Minter Ellison acting as its legal advisor.
Auscann fell half a cent or 3.3 percent to 14.5 cents with 3.6 million shares traded.