Biotech Daily

Tuesday September 12, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: REVA UP 7%, DIMERIX DOWN 10%**

*** AVITA: 'SURGEONS SAY RECELL REDUCES SKIN HARVESTED'**

*** PSIVIDA REVENUE UP 365% TO $9m, LOSS DOWN 14% TO $23m**

*** ANTISENSE ATL1102 DYSTROPHY TRIAL, FUNDS DEPEND ON FDA**

*** EURO PATENT FOR PHARMAUST MONEPANTEL FOR CANCER**

*** RACE PRODUCES 1st BISANTRENE FOR AML BATCH**

*** NOXOPHARM: NOX66 FOR CANCER 'WELL-TOLERATED'**

*** RESPIRI (ISONEA), GREY WORK ON NEW AIRSONEA WHEEZE METER**

*** CONSONANCE TAKES 7% OF SIRTEX**

*** FMR TAKES 6% OF NANOSONICS**

MARKET REPORT

The Australian stock market was up 0.58 percent on Tuesday September 12, 2017 with the ASX200 up 33.3 points to 5,746.4 points.

Ten of the Biotech Daily Top 40 stocks were up, 15 fell, 13 traded unchanged and two were untraded.

Reva was the best, up five cents or 6.8 percent to 79 cents with 51,428 shares traded.

Bionomics, Impedimed, Opthea, Osprey, Psivida and Sirtex climbed more than two percent; Resmed rose 1.6 percent; with Airxpanders, CSL, Nanosonics and Pro Medicus up by less than one percent.

Dimerix led the falls, down 0.1 cents or 10 percent to 0.9 cents with 6.7 million shares traded.

Actinogen, Cellmid and LBT fell four percent or more; Atcor, Mesoblast and Polynovo lost more than three percent; Acrux shed 2.6 percent; Admedus, Cyclopharm, Medical Developments, Neuren, Pharmaxis, Starpharma and Viralytics were down more than one percent; with Cochlear down by 0.2 percent.

AVITA MEDICAL

Avita says that presentations at the European Burns Association meeting in Barcelona confirm that its Recell spray-on skin device reduces the amount of skin harvested.

Avita said the presentations by US, German and British surgeons at the meeting, from September 6 to 8, 2017, confirmed the original rationale for the Recell device and its predecessors the Cellspray and Cellspray XP (BD: Jun 4, 2008).

The company said that the Memphis, Tennessee-based Firefighters Regional Burn Centre's Dr William Hickerson reported on the largest prospective study of the Recell device in treatment of second-degree burn injuries, reviewing outcomes from 101 patients and showing a 97.5 percent reduction in donor skin harvested for treatment of second-degree burn injuries, which yielded a 4.4 times greater likelihood of donor site healing after one week.

Avita said that the Winston-Salem, North Carolina-based Wake Forest Baptist Medical Centre's Dr James Holmes said the device met the co-primary endpoints in the US Food and Drug Administration premarket approval confirmatory trial.

The company said that Dr Holmes reported on the treatment of 30 patients in a randomized, controlled trial who sustained third-degree burn injuries and concluded that relative to conventional skin grafting treatment, use of the Recell device achieved comparable short-term healing and long-term scar and satisfaction outcomes using less donor skin, with no safety concerns.

Avita said that Dr Holmes reported a 32 percent reduction in use of donor skin.

The company said that Dr Holmes presented a clinical case conducted under compassionate use, and said that autograft-sparing with Recell "translates into life-saving treatment of an extensive burn injury".

Avita chief commercial officer Erin Liberto said that "presentations of positive outcomes for treatment of burn injuries of both second- and third-degree, ranging from the face to massive total body surface area injuries, validates the broad implications for [the] application of Recell in elevating the standard of care in burns".

"We eagerly anticipate the opportunity to launch the Recell device in the US," Ms Liberto said.

Avita was unchanged at 6.4 cents with 1.5 million shares traded.

PSIVIDA

Psivida says revenue for the year to June 30, 2017, climbed 365.4 percent to $US7,539,000 ($A9,405,000) with net loss after tax down 14.2 percent to $US18,485,000 ($A23,060,500).

Psivida said that "the year-over-year increase was primarily attributable to the $US5.6 million of revenue recognized in the fiscal second quarter upon termination of the Pfizer agreement" (BD: Feb 8, 2017).

The company said it was focussed on filing its new drug application to the US Food and Drug Administration for its Durasert three-year treatment for posterior segment uveitis.

Psivida said that research and development expenses increased by 3.5 percent to $US14,880,000.

The company said that net loss per share fell 23.5 percent to 52 US cents and it had $US16,898,000 in cash and cash equivalents at June 30, 2017, compared to $US28,992,000 at June 30, 2016.

Psivida was up four cents or 2.5 percent to $1.65.

ANTISENSE THERAPEUTICS

Antisense says it has responded to US Food and Drug Administration questions on its ATL1102 for multiple sclerosis phase IIb investigational new drug application.
Antisense said that the FDA raised specific points in regard to lifting its clinical hold letter (BD: Apr 24, Jul 27, 2017).
The company said that the FDA had 30 days to review and potentially clear the application with a response expected on or before September 30, 2017.
Antisense said that in parallel with the FDA process, its proposed trial of ATL1102 for Duchenne muscular dystrophy at Melbourne's Royal Children's Hospital had resolved all issues, but the ethics committee would require FDA clearance of ATL1102 for the multiple sclerosis application to approve the Duchenne muscular dystrophy trial.
The company said that Australian Ethical Investment participation in a proposed capital raising had been agreed with the issue of shares conditional on receiving approval by September 30, 2017 for the Duchenne muscular dystrophy trial (BD: Jun 26, 2017).
Antisense fell 0.1 cents or 2.6 percent to 3.7 cents.

PHARMAUST

Pharmaust says it has been issued a core European patent covering the use of its lead drug monepantel as a cancer therapy.
Pharmaust said that the patent, entitled 'Kinase Inhibitors for the Treatment of Cancer' would provide intellectual property protection until 2033.
The company said that the patent claimed the use amino-acetonitrile derivatives as potent kinase inhibitors for the treatment of cancer.
Pharmaust said that amino-acetonitrile derivatives included the Elanco compound, monepantel that Pharmaust patented for cancer and was testing in clinical trials.
Pharmaust chief executive officer Dr Richard Hopkins said that "allowance of the method of use patent secures Pharmaust's core intellectual property in another key world market".
Pharmaust fell 0.1 cents or 1.7 percent to 5.8 cents with 1.1 million shares traded.

RACE ONCOLOGY

Race says it has produced the first batch of Bisantrene sufficient to treat up to 60 acute myeloid leukaemia patients.
Race chief executive officer Peter Molloy said that the on-schedule, good manufacturing practice production was "one of the most important milestones in the path to commercialization of a new drug".
The company said that when the drug was released for sale it would be available under a named patient program for acute myeloid leukaemia, starting with France and to be followed by Italy, Turkey and South Korea.
Race said the first batch would provide Bisantrene for up to 60 patients, with further batches to be completed this month, providing enough drug for several hundred patients.
The company said that the San Diego, California-based Irisys LLC completed the formulation and process development and produced the Bisantrene, which would undergo quality control checks over the next four weeks before being released.
The company said that the Bisantrene was manufactured in 10mL vials containing 250mg of the drug as a lyophilised powder, which was then reconstituted as a solution and injected into an intravenous bag for administration to a cancer patient.
Race said that a typical adult patient could require 14 vials for a seven day treatment.
Race was up two cents or 5.9 percent to 36 cents.

NOXOPHARM

Noxopharm says it has recruited 15 of the planned 16 patients in its Tbilisi, Georgia-based phase Ia/Ib studies of NOX66 for cancer (BD: Jan 31, 2017).
Noxopharm said the study involved patients with a range of late-stage cancers who had failed standard treatments with cohort 1 receiving 400mg of NOX66 daily and cohort 2 receiving 800mg of NOX66 daily.
The company said that after two weeks of NOX66 treatment, the patients would be treated with carboplatin over six monthly cycles and so far NOX66 had been well-tolerated at both doses, with one patient with lung cancer showing progressive disease, four patients with lung and breast cancer showed stable disease.
Noxopharm chief executive officer Dr Graham Kelly said the data was “encouraging”.
Noxopharm was up two cents or six percent to 35.5 cents.

RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri says it has contracted Grey Innovation to produce its “next generation breath sensor with a new creative design and superior ergonomics”.
Previous iterations of the Airsonea asthma wheeze detection units failed to detect breath sounds (BD: Aug 6, 2015).
In April, Respiri said its next generation Airsonea at-home monitoring device had been granted class IIa Conformité Européenne (CE) mark approval (BD: Apr 12, 2017).
Today, Respiri said that working with Grey Innovation “evolved from broad ranging partnership discussions on the best pathways to commercialise Airsonea in China, Europe and other major international markets”.
The company said that “Grey’s constructive working relationship with Respiri and intimate knowledge of the technology ensures the fastest completion and lowest execution risk for the upgrade of the breath sensor” and enabled discussions on commercialization options.
Respiri was up 0.4 cents or 13.8 percent to 3.3 cents.

SIRTEX MEDICAL

Consonance Capital Management says it has increased its substantial holding in Sirtex from 3,554,728 shares (6.20%) to 4,089,728 shares (7.31%).
The New York-based Consonance said that Goldman Sachs was a registered holder of the shares with Mitchell Blutt, Kevin Livingston and Benny Soffer as associated holders.
Consonance said it bought shares between September 6 and 11, 2017 with the single largest acquisition 326,700 shares for $5,096,417 or $15.60 a share.
Sirtex was up 14 cents or 2.65 percent to $15.91 with 389,215 shares traded.

NANOSONICS

Fidelity Management & Research (FMR) says it has increased its shareholding in Nanosonics from 14,975,885 shares (5.03%) to 17,974,691 shares (6.04%).
FMR said it acquired the 2,998,806 shares between August 30 and September 7, 2017, at prices from $2.43 to $2.65.
Nanosonics was up two cents or 0.7 percent to $2.72 with 1.3 million shares traded.