Biotech Daily

Tuesday August 2, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 14%, BENITEC DOWN 7%**

*** PSIVIDA, NY HOSPITAL FOR SPECIAL SURGERY OSTEOARTHRITIS TRIAL**

*** FDA APPROVES 300-PATIENT ONCOSIL PANCREATIC CANCER TRIAL**

*** REDHILL COMPLETES PHASE IIa RHB-104 FOR MS FOLLOW-UP**

*** MACH7 SIGNS $1m 5-YEAR US MEDICAL CENTRE IMAGING DEAL**

*** OSPREY REQUESTS CAPITAL RAISING TRADING HALT**

*** MELROSES CONVERT 5m RECCE PERFORMANCE SHARES, TAKE 38.5%**

MARKET REPORT

The Australian stock market fell 0.84 percent on Tuesday August 2, 2016 with the ASX200 down 46.9 points to 5,540.5 points.

Eight of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and four were untraded.

Oncosil was the best, up two cents or 13.8 percent to 16.5 cents with 20.3 million shares traded.

Airxpanders climbed 7.8 percent; Pharmaxis was up 5.3 percent; Psivida rose 4.55 percent; Prana was up 3.1 percent; IDT rose 2.2 percent; Clinuvel was up 1.4 percent; with CSL, Resmed and Sirtex up by less than one percent.

Benitec led the falls, down one cent or 7.4 percent to 12.5 cents with 158,800 shares traded.

Biotron lost 6.25 percent; Bionomics fell 5.2 percent; Acrux, Cellmid, Compumedics, Starpharma and Universal Biosensors were down more than three percent; Living Cell, Medical Developments and Prima shed more than two percent; Admedus, Avita, Mesoblast, Neuren, Opthea and Polynovo were down more than one percent; with Cochlear, Impedimed, Nanosonics and Viralytics down by less than one percent.

PSIVIDA

Psivida says New York's Hospital for Special Surgery will begin a six-patient study of a sustained-release implant for severe knee osteoarthritis.

Psivida said that investigator-sponsored, open-label, single dose, safety and tolerability study of the screw implant to deliver the cortico-steroid dexamethasone, will assess six patients receiving the implant in one knee.

The company said that change from baseline in weekly mean of pain intensity at rest, during activity and at night would be assessed weekly for 24 weeks.

Psivida said the implant was designed to provide long-term pain relief for severe knee osteoarthritis, which was expected to delay the need for knee replacement surgery.

The company said that the implant would be surgically implanted into the non-articulating area of the knee in an outpatient procedure, with the duration of release following a single treatment expected to extend to one year or more.

Psivida said that the Hospital for Special Surgery's chief of the surgical arthritis Dr Mark Figgie filed the investigational new drug application and would be the principal investigator.

The company said that knee osteoarthritis was a degenerative joint disease that resulted from the breakdown of joint cartilage and underlying bone, with joint pain and stiffness the most common symptoms for the more than 10 million people with the disease.

Psivida said that nearly 50 percent of all people over 85 years developed symptomatic knee osteoarthritis, and two-thirds of obese people developed it in their lifetimes.

The company said that no cure exists, but pain and movement restriction associated with the disease were treated with oral analgesics, non-steroidal anti-inflammatory drugs, corticosteroids taken orally or injected into the knee or hyaluronic acid injected into the knee.

Psivida said that with degeneration, damage and pain from knee osteoarthritis could become severe, making it the leading cause of total knee replacement surgery, with more than 700,000 procedures performed in the US in 2015.

The Hospital for Special Surgery's clinical research medical director Dr Robert Hotchkiss said the Hospital believed the sustained release dexamethasone implant had "the potential to provide long-term pain relief and to contribute to improved joint function for patients with severe osteoarthritis, which can delay knee replacement surgery".

"Implanting a small, secure reservoir that delivers a corticosteroid on a sustained basis directly to the knee could avoid the issues with systemic steroid delivery and repetitive knee injections," Dr Hotchkiss said.

"This implant, the result of the combined insights [of the Hospital for Special Surgery] and the expertise of Psivida, has the potential to create a paradigm shift in a variety of conditions," Dr Hotchkiss said.

Psivida chief executive officer Dr Paul Ashton said that the investigator-led IND was "an important step in Psivida's goal of becoming the leader in sustained-release drug delivery products in ophthalmology and beyond".

"We hope to use our technologies to treat many chronic or debilitating conditions that require sustained, localized delivery of a drug," Dr Ashton said.

In 2005, Psivida voted to acquire the Boston Massachusetts-based Control Delivery Systems in what was effectively a backdoor listing for CDS (BD: Nov 15, 2005).

Psivida's key asset prior to the merger was its bio-silicon delivery system, which was used by the then Epitan, now Clinuvel, for the product Melanotan, also known as EPT1647, CUV1647 and now Scenesse, and is being further developed by Oncosil for the delivery of its anti-cancer radiotherapy.

Psivida climbed 22 cents or 4.55 percent to $5.05.

ONCOSIL MEDICAL

Oncosil says the US Food and Drug Administration has approved an investigational device exemption application for its pivotal 300-patient pancreatic cancer trial.

Oncosil said that the multi-centre, randomized, open-label 'Oncopac-1' safety and efficacy trial would be conducted at up to 30 centres in the US, UK, Europe and Australia in patients with locally advanced, unresectable pancreatic adeno-carcinoma.

The company said that the first stage of the study would enrol 20 patients who would be subject to an FDA safety review, which would be followed by randomization to either Oncosil's bio-silicon radiation treatment with standard chemotherapy; or standard chemotherapy treatment of gemcitabine alone; or gemcitabine and nab-paclitaxel alone.

Oncosil said that its phosphorous-32 radioactive micro-particles would be implanted intra-tumorally using endoscopic ultrasonography.

The company said that the primary efficacy endpoint was local progression free survival, with secondary endpoints including progression free survival, overall survival, pain scores, body weight, safety and tolerability and performance status.

Oncosil said that the first subject was expected to be enrolled "in early 2017" with recruitment expected to take about two years, with each patient to be followed until disease progression and all patients followed for overall survival until death, or until the last enrolled patient completed 52 weeks of overall survival follow-up.

Oncosil chief executive officer Daniel Kenny said the FDA trial approval was "a significant milestone in our regulatory pathway and a validation of our product".

"The IDE approval is beneficial in supporting our on-going CE mark application and we remain confident of obtaining our CE mark in the near term," Mr Kenny said.

Oncosil was up two cents or 13.8 percent to 16.5 cents with 20.3 million shares traded.

REDHILL BIOPHARMA

Redhill says the last of 18 patients has completed the final follow-up in its phase IIa trial of RHB-104 for relapsing-remitting multiple sclerosis.

Redhill said the open label phase IIa 'Cease-MS' study was designed to evaluate safety and potential efficacy of fixed oral dose RHB-104 as an adjunct to interferon beta-1a.

The company said patients received RHB-104 for 24 weeks and were evaluated for a further 24-weeks during which they were treated with interferon beta-1a alone.

RHB-104 was originally developed as Myoconda at Sydney's Giaconda and the asset was sold with Heliconda (RHB-105) and Picoconda (RHB-106) to Redhill (BD: Aug 17, 2010).

Today, Redhill said that the study was being analyzed with top-line final results expected by the end of 2016.

The company said that interim 24-week results announced in March 2016 showed "positive safety and efficacy signals" with an annualized relapse rate at 24 weeks of 0.288 in the modified intent-to-treat population and 0.0 in the per-protocol population, compared with reported studies of interferon beta-1a therapies Avonex (0.67) and Rebif (0.87-0.91).

The company said that 88 percent of the modified intent-to-treat population and 100 percent of the per-protocol population were relapse-free at 24 weeks, compared to data on Rebif (75%) in comparison with Avonex (63%) as stand-alone first-line therapies.

Redhill said that US and worldwide sales of multiple sclerosis therapies were estimated at more than $US12 billion and $US18 billion, respectively

The company said RHB-104 was being evaluated as a treatment for Crohn's disease with a phase III trial underway and an interim analysis expected by the end of 2016.

Last night on the Nasdaq, Redhill climbed $US1.42 or 10.81 percent to $US14.55 ($A19.28) with 232,880 shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has signed a five-year $US800,000 ($A1,059,974) enterprise imaging platform software agreement with an unnamed US university medical centre.
Mach7 said that the majority of the contract value was expected to be recognised as revenue this year, on the software being delivered and installed at the medical centre.
The company said it would earn a guaranteed annual support fee for at least five years, increasing its growing annual support fee revenue stream.
Mach7 said that the medical centre performed more than 20,000 surgeries each year and generated more than $US2 billion in annual revenue.
The company quoted the unnamed customer saying Mach7 was chosen ahead of its competitors because of its technical superiority, extensive flexibility and immediate benefit to the enterprise without the significant investments in custom coding that other solutions would have required.
Mach7 said that the “flexible and robust tool set” was an off-the-shelf product enabling specialized workflows and in addition to basic routing and pre-fetching functionality, the workflows allowed customers to improve clinical operations and patient outcomes, while reducing costs.
Mach7 was up 0.2 cents or 5.6 percent to 3.8 cents with 1.3 million shares traded.

OSPREY

Osprey has requested a trading halt “pending an announcement by Osprey in relation to a proposed capital raising”.
Trading will resume on August 4, 2016 or on an earlier announcement.
Osprey last traded at 34 cents.

RECCE

Recce chairman Dr Graham Melrose and Olga Melrose say they have increased their substantial holding from 24,300,003 shares (35.48% to 29,316,003 shares (38.48%).
The Perth, Western Australia-based Dr Melrose said that he and Ms Melrose acquired the 5,016,000 shares at no cost through the conversion of class A performance shares.
Recce was up two cents or 8.3 percent to 26 cents.