Biotech Daily

Thursday March 5, 2015

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: GENETIC TECH UP 16%, ACRUX DOWN 9%**

*** NANOSONICS PLACES $25m, PLAN FOR $3m MORE**

*** TISSUE THERAPIES OFFER RAISES $3.7m, PLACES $570k, TOTAL $8.27m**

*** SIRTEX COMPLETES FRENCH TRIAL RECRUITMENT**

*** MD ANDERSON JOINS IMPEDIMED POST-APPROVAL L-DEX STUDY**

*** LIVING CELL CHANGES DIABECELL TRIAL FOCUS TO US**

*** PHARMAUST 2nd CANCER PATIENT TOLERATES PPL-1, STABLE DISEASE**

*** ANTISENSE READY FOR HIGH-DOSE ATL1103 ACROMEGALY TRIAL**

*** GI DYNAMICS REQUESTS 'BUSINESS' TRADING HALT**

*** CHAIRMAN ANDREW KROGER TAKES 25.6% OF CRYOSITE**

*** CEO WAYNE STRINGER TAKES 18% OF PROBIOTEC**

MARKET REPORT

The Australian stock market edged up 0.04 percent on Thursday March 5, 2015 with the S&P ASX 200 up 2.6 points to 5,904.2 points. Ten of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and four were untraded.

Genetic Technologies was the best, up 0.7 cents or 16.3 percent to five cents with 9.9 million shares traded. Admedus climbed 5.9 percent with 6.5 million shares traded; Compumedics and Oncosil were up more than four percent; Living Cell was up 3.6 percent; Tissue Therapies and Viralytics rose more than two percent; Impedimed, Medical Developments, Resmed and Starpharma up one percent or more.

Acrux led the falls, down 8.5 cents or 9.4 percent to 81.5 cents with 3.8 million shares traded. Patrys lost 8.3 percent; IDT fell 6.7 percent; Circadian was down 5.9 percent; Atcor and Neuren fell more than four percent; Biotron, Clinuvel, Nanosonics, Pharmaxis, Prana and Universal Biosensors were down more than three percent; Anteo shed 2.1 percent; Alchemia, Antisense, Benitec, Bionomics, Ellex and Phosphagenics were down one percent or more; with Cochlear, CSL, Mesoblast and Sirtex down by less than one percent.

NANOSONICS

Nanosonics says a placement at $1.65 a share has raised $25.0 million and it hopes to raise a further $3 million through a share plan.

Nanosonics said that the funds would be used to strengthen its balance sheet for expanded sales of its Trophon EPR ultra-sound probe cleaning system and accelerate product development.

The company said that shareholders at the record date of March 4 would be able to subscribe for up to $15,000 in shares on a first-come, first-served basis.

Nanosonics said that the share plan was expected to open on March 13 and close on March 30, 2015, unless fully subscribed earlier.

Nanosonics chief executive officer Michael Kavanagh said the funds would provide “a powerful balance sheet ensuring working capital strength and flexibility to support our strategic objectives driven by our new direct sales operations in North America as well as expansion globally”.

“Nanosonics is also accelerating its product development pipeline incorporating the next generation Trophon device and a broadening of its proprietary decontamination product portfolio,” Mr Kavanagh said.

“There are now in excess of 4,000 units installed in North America across 1,500 hospitals, including 44 of the top 50 hospitals, with an addressable market opportunity of over 40,000 units across all hospitals and relevant departments in this market alone,” Mr Kavanagh said.

Nanosonics said that its direct sales operation in North America alongside distribution partner GE Healthcare would drive and support both broader and deeper penetration across the total market.

The company said it has expanded its operations in Europe and was planning to enter new markets in Asia, including Japan where regulatory approval had been granted.

Nanosonics said that Canaccord Genuity (Australia) was the sole lead manager to the placement.

Nanosonics fell seven cents or 3.9 percent to $1.71 with 1.3 million shares traded.

TISSUE THERAPIES

Tissue Therapies says its one-for-15, fully underwritten, non-renounceable entitlement offer at 21 cents a share was fully-subscribed raising the maximum $3.7 million.

In February, the company placed $4.0 million at the same price (BD: Feb 4, 2015).

Tissue Therapies chief executive officer Dr Steven Mercer said at that time that the European regulatory approval process had “exceeded the internal timelines and expectations”.

“It has become apparent that the appropriate risk mitigation strategy is to uncouple FDA approvals and sales for a diabetic ulcer trial in the rest of the world from the CE mark process ... and the capital raising will support this objective,” Dr Mercer said in February.

Today, Tissue Therapies said that demand was greater than the 17,557,218 shares available under the entitlement offer and it had completed a $570,000 placement to an existing institutional investor “to partially satisfy the strong demand and reduce the amount of scale-back required for the entitlement offer top-up facility and to two long term off-shore investors who were unable to participate in the recent entitlement offer”.

The company said that Morgans Corporate and Baillieu Holst were the joint lead managers and underwriters to the capital raising.

Tissue Therapies was up half a cent or 2.1 percent to 24 cents.

SIRTEX MEDICAL

Sirtex says that recruitment has been completed in the more than 400-patient French trial directly comparing SIR-Spheres against sorafenib for liver cancer.

Sirtex said that the phase III sorafenib versus radio-embolization in advanced hepatocellular carcinoma (Sarah) trial for non-resectable advanced hepatocellular carcinoma was a randomized, controlled clinical study directly comparing SIR-Spheres yttrium-90 resin microspheres against the standard-of-care, systemic therapy of sorafenib (Nexavar), with results expected “in late 2016”.

The company said that the trial had enrolled patients with liver cancer, with or without portal vein thrombosis, and no extra-hepatic spread, or whose disease has progressed or recurred after previous therapies and were ineligible for surgical resection, ablation or liver transplantation.

Sirtex said that the primary endpoint was to assess whether SIR-Spheres provided an increased overall survival benefit compared to sorafenib, with secondary endpoints including safety and tolerability, progression-free survival, tumor response rates, quality of life scores and overall healthcare costs between the two arms of the study.

Sirtex chief executive officer Gilman Wong said the trial had recruited more than 400 patients in more than 25 centres across France in “a very rapid time frame”.

“If the results from the Sarah study are positive it could elevate the use of SIR-Spheres microspheres to a standard treatment for patients with advanced primary liver cancer,” Mr Wong said

Interventional radiologist at the Paris, France-based Hôpital Beaujon and lead investigator Prof Valérie Vilgrain said the study was “the largest randomized study ever to compare selective internal radiation therapy, or any liver-directed therapy, against the standard-of-care systemic therapy in the treatment of primary liver cancer”.

“Target enrolment was reached in around three years, which is remarkable for a single-country trial of this size in a hard-to-treat cancer with few proven therapeutic choices,” Prof Vilgrain said.

Sirtex said it was the second major study of SIR-Spheres for non-resectable liver cancer to complete patient recruitment this year, following the Foxfire study (BD: Jan 18, 2015).

Sirtex slipped two cents or 0.06 percent to $34.90 with 388,232 shares traded.

IMPEDIMED

Impedimed says the University of Texas MD Anderson Cancer Center has joined its post-approval clinical trial of its L-Dex lymphoedema diagnostic.

Last year, Impedimed began the year 1100-patient, five year, international, post-approval clinical study to objectively establish the clinical utility of its L-Dex device for the early detection of lymphoedema, post breast cancer (BD: Jun 26, 2014).

Today, Impedimed said that the Houston, Texas-based MD Anderson Centre surgical oncologist Dr Sarah DeSnyder had been appointed the principal investigator for the trial site.

Dr DeSnyder said that she was “pleased to participate in this important trial evaluating the significance of identifying subclinical lymphoedema with the potential to improve lymphoedema care and our patients’ quality of life”.

Impedimed chief executive officer Richard Carreon said that the MD Anderson Centre joined “a list of prestigious sites involved in the post-approval clinical trial of the efficacy of L-Dex for improved patient outcomes”.

Impedimed was up one cent or 1.3 percent to 80 cents with 1.3 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says that its Diatranz Otsuka joint venture with Japan's Otsuka Pharmaceutical Factory will develop and launch of Diabecell for type 1 diabetes in the US.

Describing the move as "a new development strategy" for the encapsulated porcine islets of Langerhans, Living Cell said that the joint venture held a royalty-free right to commercialize Diabecell outside the US and Japan.

The company said that Diatranz Otsuka' funding requirements had been reduced as a result of the new development strategy and the Otsuka Pharmaceutical Factory loan facility has been amended to provide funding of up to $NZ28 million ($A27 million).

Last year, Living Cell said that Otsuka Pharmaceutical Factory would lend the joint venture $NZ42 million (BD: Oct 10, 2014)

Today the company said that the new strategy would mean that the joint venture and Otsuka would "focus on developing a Diabecell product that will meet FDA regulatory requirements" and approval by the FDA would facilitate approval for the product across the rest of the world.

In 2012, Living Cell said that an interim analysis of its eight patient Argentinian phase I/IIa trial of Diabecell for unstable type 1 diabetes showed significant efficacy and a 20-patient phase IIb trial had begun in Argentina (BD: Nov 22, 2012).

The following year the company published detailed results and said that Diabecell reduced unaware hypoglycaemic events and average daily insulin doses (BD: Nov 1, 2013).

Biotech Daily has been unable to find further information on the 20-patient trial

Living Cell was up 0.2 cents or 3.6 percent to 5.8 cents.

PHARMAUST

Pharmaust says the second patient in its trial of PPL-1 for cancer has completed the 28-day treatment at the lowest dose without material adverse events and with stable disease.

Pharmaust said that the Royal Adelaide Hospital patient had bowel cancer and the drug was "well-tolerated, without material adverse events and the patient ... had stable disease on completion of the treatment" as determined by computed tomography scan.

The company said that subject to the third patient in the low-dose group completing the treatment schedule by mid-March, the trial would move to higher doses.

Pharmaust said that in parallel to monitoring patients who had completed the full 28-day trial period, it was monitoring levels of the biomarker P70S6K in all patients who received PPL-1 and had stayed on therapy for at least three days.

The company said that a number of patients had to be withdrawn due to reasons unrelated to the study drug.

Pharmaust said that PPL-1 appeared to define "a new and unexpected mechanism of action representing a potentially new class of anti-cancer drug".

The company said that PPL-1 influenced the mammalian target of rapamycin (mTOR) pathway, but, unlike other mTOR drugs, like Novartis' Afinitor, or everolimus, and Pfizer's Sirolimus or rapamycin, it appeared to have very low toxicity.

Pharmaust said that PPL-1 had not shown an adverse event profile commonly associated with conventional anti-cancer drugs, the lowest dose of PPL-1 had shown meaningful reductions in the cancer marker P70S6K and PPL-1 targetted a biochemical pathway that affected a range of regulatory mediators, without the side effect profile of other mTOR drugs currently on the market.

Pharmaust was unchanged at 0.8 cents with 4.8 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has approvals to begin enrolment in its four-patient dose ATL1103 study in patients with the growth disorder acromegaly.
Antisense said that the open-label study would examine the safety, tolerability, pharmacokinetics and efficacy, measured by the effect on serum insulin like growth factor I (sIGF-I) of ATL1103 in adult patients with acromegaly dosed twice weekly with ATL1103 at 300mg for 13 weeks, or 600mg per week, with two months of follow up.
In September, Antisense said it found significant dose-related efficacy for ATL1103 in its 26 patient phase II acromegaly trial, and in an investor briefing said that a higher dose for a longer period should be safe and produce greater efficacy (BD: Sep 3, Oct 20, 2014).
In December, the company said that it planned to increase the subcutaneous dose of ATL1103 to 600mg/week compared to the earlier trial's 200mg/week and 400mg/week week doses (BD: Dec 9, 2014).
Today, Antisense said that the four-patient follow-on study would support its use in dose escalation in patients with more active disease during a phase III clinical trial.
The company said that the study was being conducted in parallel with its partnering process, to add further value to ATL1103 ahead of phase III registration trials.
Antisense said that some patients might need to washout current medication for up to four months, before dosing with ATL1103 could begin and it expected enrolment and dosing would be completed by the end of 2015 with primary efficacy results soon after.
Antisense fell 0.1 cents or one percent to 9.6 cents.

GI DYNAMICS

GI Dynamics has requested a trading halt "pending the release of a material announcement regarding [its] business".
Trading will resume on March 9, 2015 or on an earlier announcement.
GI Dynamics last traded at 30 cents.

CRYOSITE

Cryosite chairman Andrew Kroger says he has increased his substantial shareholding in his company from 11,706,943 shares (24.98%) to 11,975,816 shares (25.56%).
The substantial shareholder notice said the 268,873 shares were acquired on March 2, 2015 at an average price of 40.6 cents a share by SHR Pty Ltd and Colfax Bay Pty Ltd as trustee for the Andrew Kroger Family Superannuation Fund.
Cryosite was untraded at 40 cents.

PROBIOTEC

Probiotec founder and executive director Wayne Stringer has increased his substantial shareholding from 8,675,786 shares (16.4%) to 9,637,690 shares (18.2%).
The substantial shareholder said that 644,794 shares were acquired by Mr Stringer's Inston Pty Ltd on February 27, 2015 at 17.73 cents a share and March 2, 2015 at 18.0 cents a share, but did not disclose prices for the balance of 317,110 acquired shares.
Probiotec was up half a cent or 2.9 percent to 18 cents.