Biotech Daily

Monday April 24, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ITL UP 9%; SIRTEX DOWN 13%**

*** SIRTEX SIR-SPHERES FAIL SARAH TRIAL, SOME BENEFITS**

*** REVA RAISING UP TO $53m**

*** SPEEDX, THERMO FISHER PLAN US MYCOPLASMA GENITALIUM TEST**

*** GENETIC SIGNATURES ACCURATELY, QUICKLY DETECTS DENGUE**

*** IMPEDIMED: VANDERBILT NURSING TRIALS SOZO AT HOME**

*** ANTISENSE PREPARES PHASE IIb ATL1102 FOR MS IND**

*** OSPREY 3.3m 'IN THE MONEY' DIRECTORS OPTIONS AGM**

*** BPH SURVIVES MEC RESOURCES SPILL VOTES**

*** HUNTER HALL BELOW 5% OF SIRTEX**

*** UNION LUXEMBOURG BELOW 5% IN OPTHEA**

*** ANALYTICA CHAIRMAN DR MICHAEL MONSOUR TAKES 22%**

*** PETER CORR, INOV8 TAKE 13% OF ANALYTICA**

*** OBJ TAKES '2nd TECHNOLOGY LICENCE' HALT TO A SUSPENSION**

MARKET REPORT

The Australian stock market was up 0.3 percent on Monday April 24, 2017 with the ASX200 up 17.7 points to 5,871.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and four were untraded. All three Big Caps were up.

ITL was the best, up 4.5 cents or 8.6 percent to 57 cents with 395,626 shares traded. Genetic Signatures climbed 7.5 percent; Oncosil improved 4.2 percent; Admedus and Cellmid were up more than three percent; Bionomics, Mesoblast and Polynovo rose more than two percent; Compumedics, Osprey, Pharmaxis and Resmed were up more than one percent; with Cochlear, CSL, Ellex, Medical Developments, Nanosonics and Viralytics up by less than one percent.

Sirtex led the falls, down $2.20 or 12.9 percent to $14.80 with 2.96 million shares traded. IDT lost 6.9 percent; Actinogen fell 5.1 percent; Starpharma and Universal Biosensors were down more than three percent; Airxpanders, Impedimed, Orthocell and Reva shed more than two percent; Acrux and Clinuvel were down more than one percent; with Pro Medicus down 0.7 percent.

SIRTEX MEDICAL

The Sirtex head-to-head 459-patient SIR-Spheres versus sorafenib 800mg daily, liver cancer trial has failed to meet its primary endpoint of overall survival.

Sirtex chief medical officer Dr David Cade told a 9am teleconference, called at 8.56am today, that safety, tolerability and quality-of- life were significantly better for the SIR-Spheres group than sorafenib patients and in the smaller per protocol groups which completed the trial, SIRT and sorafenib had equal overall survival of 9.9 months.

In a presentation to the European Association for the Study of the Liver meeting in Amsterdam on April 22, 2017, lead investigator Dr Valérie Vilgrain reported median overall survival of 8.0 months for the SIR-Spheres group and 9.9 months for sorafenib group.

The 'Sarah: a randomized, controlled trial comparing efficacy and safety of selective internal radiation therapy (with yttrium-90 microspheres) and sorafenib in patients with locally advanced hepatocellular carcinoma' study was the first to compare, selective internal radiation therapy (SIRT) with SIR-Spheres against a chemotherapy agent, sorafenib, as monotherapies.

The study concluded that "[overall survival] did not differ between sorafenib and SIRT".

"The liver-targeted treatment (SIRT) was more effective than the sorafenib systemic treatment in controlling tumor progression in the liver," the abstract concluded.

The abstract is at: https://events.easl.eu/EventProgramme/ILC2017.aspx - enter 'Sarah' in the search term, select April 22, select General session III, and view abstract GS-012.

Sirtex completed recruitment for the French sorafenib versus radio-embolization in advanced hepatocellular carcinoma (Sarah) trial in 2015 and last year, the company said it would combine the data with a similar Singapore-based study and present the combined 800 patient data this year (BD: Mar 5, 2015; Oct 7, 2016).

In 2015, Sirtex fell 62 percent to $14.80 on news that SIR-Spheres with chemotherapy "does not result in a statistically significant improvement in the overall progression-free survival" (BD: Mar 17, 2015).

Sirtex said that the 530-patient trial compared SIR-Spheres with the standard-of-care, oxaliplatin, leucovorin and 5- fluorouracil (Folfox) - to standard-of-care alone for non-resectable metastatic colorectal cancer and later said that despite the Sirflox trial missing its primary endpoint of progression-free survival at any site, SIR-Spheres significantly increased liver tumor progression-free survival, with a statistically significant difference of 7.9 months benefit for progression-free survival in the liver (Jun 1, 2015).

Over the weekend, the Sarah trial abstract said that patients with untreated advanced hepatocellular carcinoma had a poor prognosis and Sorafenib, had a high level of toxicity.

The abstract said that patients with locally advanced or recurrent hepatocellular carcinoma, not amenable to other treatments or after two failed rounds of chemo-embolization, were randomised equally to selective internal radiation therapy (SIRT) with Y-90 resin microspheres or oral sorafenib 800 mg daily.

"In the intention-to-treat analysis, median OS was 8.0 months and 9.9 months in the SIRT and sorafenib groups, respectively (p = 0.179)," the abstract said.

"Median [progression-free survival] was 4.1 months and 3.7 months in the SIRT and sorafenib groups, respectively (p = 0.727)," the abstract said.

"Cumulative incidence of radiological progression at any site did not differ … (p = 0.255) [and] cumulative incidence of radiological progression in the liver as first event was significantly lower in the SIRT than in the sorafenib group (p = 0.015)," the abstract said.

The presentation said the SIRT response rate was significantly higher than the sorafenib group (19.0% v 11.6%, p = 0.042), with a lower rate of treatment-related serious adverse events in the SIRT group (11.7%) compared to the sorafenib group (16.5%).

Sirtex fell $2.20 or 12.9 percent to $14.80 with 2.96 million shares traded.

REVA MEDICAL

Reva says it expects to raise $US40 million ($A52.9 million) through the issue of convertible notes.

Reva said it had agreements with several institutional and one corporate investor for the convertible notes and options and $US32.5 million would be received from the committed investors on the issue of the convertible notes, with the ability to issue a further $US7.5 million of notes, with the second stage requiring shareholder approval.

Reva said the first stage would issue $US33.8 million of notes to repurchase 1,732,260 US shares for $US12.5 million ($A16,528,600, or 95.4 cents per Chess depository instrument) from one participant, leaving net proceeds of $US21.3 million.

The company said that the second stage would place $US18.7 million of convertible notes and it would issue up to 2,362,500 options over US shares, if the entire $US40 million note capacity was subscribed, exercisable at $US5.00 each and to be adjusted upward to a maximum of $US7.212 after a US initial public offer or future financing.

Reva said the convertible notes would have a five-year term, at 8.0 percent a year interest, and allow for cash redemption at 30 months, at maturity, on a change of control, or following an event of default, with interest compounding annually, but only payable on redemption, but note-holders could convert the convertible notes into shares at $US8.655 per US share or $1.144 per CDI.

The company said that Perella Weinberg Partners was its financial advisor.

Reva fell three cents or 2.8 percent to $1.05.

SPEEDX PTY LTD

The Sydney-based Speedx says Thermo Fisher Scientific will support its Mycoplasma genitalium test application to the US Food and Drug Administration.

Speedx said that the Waltham Massachusetts-based Thermo Fisher Scientific would supply its Applied Biosystems 7500 Fast Dx Real-Time PCR System platform for the Resistanceplus MG diagnostic.

The company said that there was no FDA-cleared molecular diagnostic test available for the Mycoplasma genitalium sexually transmitted infection.

Speedx said it would submit the test to the FDA on successful validation for use with the Thermo Fisher 7500 Fast Dx system to detect Mycoplasma genitalium.

The company said that the Resistanceplus MG test was designed to identify both mutations of the bacteria shown to confer resistance to azithromycin, a commonly prescribed macrolide-based antibiotic.

Speedx said the test had Conformité Européenne (CE) mark, Australian Therapeutic Goods Administration approval and was sold in Europe, Australia and New Zealand.

Speedx chief executive officer Colin Denver said that the test was developed “to answer the immediate need for detection and resistance screening for this difficult to manage [sexually transmitted infection]”.

The company said that Mycoplasma genitalium could cause symptoms including as urethritis, cervicitis, endometritis and pelvic inflammatory disease and had been found to have a higher prevalence than Gonorrhoea.

Speedx said that macrolide antibiotics like azithromycin were the first-line treatment for Mycoplasma genitalium infections, but resistance had increased by 40 percent in several countries, leading to the European guideline on Mycoplasma genitalium infections to recommend complementing the molecular detection with an assay capable of detecting macrolide resistance-associated mutations.

Speedx is a private company.

GENETIC SIGNATURES

Genetic Signatures says its Flavivirus detection kit accurately and quickly detected dengue haemorrhagic fever in a 2016 outbreak in Vanuatu.

Genetic Signatures chief scientific officer Dr Doug Millar presented data at the European Congress of Clinical Microbiology and Infectious Diseases in Vienna overnight showing that the company's diagnostic was as accurate as commercially available tests, but produced results in four hours, rather than the two to four weeks required by other tests which had to be sent to New Zealand for analysis.

"In a 187-patient cohort, our new screening kit detected 123 cases of dengue, of which 116 were confirmed to be serotype 2," Dr Millar said.

"Furthermore our real-time [polymerase chain reaction] assay was able to deliver faster results with a high degree of accuracy," Dr Millar said.

"This provides a high degree of confidence in the results obtained, much quicker patient outcomes and valuable population infection data for future location-based planning and mitigation," Dr Millar said.

Genetic Signatures said that dengue haemorrhagic fever had a more than a 20 percent mortality rate if left untreated and diagnosis was difficult and time consuming as most samples had to be sent to New Zealand for detection analysis.

The company said the trial was conducted with Vanuatu's Port Vila Central Hospital used patient samples after the 2016 dengue outbreak and demonstrated the potential of the kit.

Genetic Signatures said the test was in "advanced stages of development, in helping prevent the spread of serious infectious diseases such as Zika and West Nile virus".

The company said that Flaviviridae were viruses found in ticks and mosquitoes and could infect humans, causing morbidity and mortality, with mosquito spread infections including Yellow fever, Dengue fever, Japanese encephalitis, West Nile viruses, and Zika virus, while tick transmission included encephalitis and haemorrhagic diseases

Genetic Signatures said that using existing compatible nucleic acid extraction equipment, hospital and pathology laboratories would be able to test for 15 of the most common variants of the Flaviviruses and Alphaviruses, including all four dengue serotypes, in a single real-time polymerase chain reaction (PCR) primer test.

The company said that once the virus family type was determined, a second regional test had been designed for Australia, Asia, Africa, Latin America, America or Europe to then determine the specific viral infection.

Genetic Signatures was up three cents or 7.5 percent to 43 cents.

IMPEDIMED

Impedimed says it has shipped a Sozo body density system to the Vanderbilt University School of Nursing for an at-home lymphoedema study.

Impedimed said that principal investigator Prof Sheila Ridner at the Nashville, Tennessee-based Vanderbilt University School of Nursing would use the Sozo to monitor fluid levels for early detection of sub-clinical lymphoedema in cancer survivors.

The company said the studies would help Prof Ridner and her team evaluate best practices for at-home lymphoedema monitoring and the data would be used for future marketing of Sozo for the early detection and monitoring of lymphoedema.

Impedimed chief executive officer Richard Carreon said that "one of the advantages of Sozo over our existing device is its ability to establish at-home monitoring programs, which will help cancer survivors manage their lymphoedema risk and improve their well-being and quality of life".

Impedimed fell 1.5 cents or two percent to 72 cents.

ANTISENSE THERAPEUTICS

Antisense says it has begun the submission process for a US investigational new drug application for a phase IIb trial of ATL1102 for multiple sclerosis.
Antisense said that documentation had been provided to its US regulatory agent who would submit the application to the US Food and Drug Administration on its behalf.
The company said that the submission process was expected to be completed in May, to be followed by a 30-day FDA review period.
Antisense said that the application was for a 195-patient trial of ATL-1102 for both remitting relapsing multiple sclerosis and secondary progressive multiple sclerosis.
The company said it was seeking non-dilutive funding for the phase IIb trial from an unnamed US federal agency, had submitted its study synopsis to the agency and was awaiting approval to lodge the full award grant application, with investigational new drug application clearance required for the grant funding.
Antisense was untraded at 3.3 cents.

OSPREY MEDICAL

Osprey's annual general meeting will vote to issue directors 3,340,000 options over Chess depository instruments (CDIs) "in the money".
Osprey said it proposed to issue chairman John Erb 220,000 options, director Neville Mitchell 100,000 options and chief executive officer Mike McCormick 3,020,000 options, exercisable at the price on the day of grant, with 25 percent vesting on August 26, 2017 and in equal monthly instalments over 36 months, and within 10 years.
The company said that shareholders would also vote to re-elect directors Mr Erb and Mr Mitchell and approve the 10 percent placement capacity.
The meeting will be held at Johnson Winter & Slattery, Level 34, 55 Collins Street, Melbourne on May 18, 2017 at 9am (AEST).
Osprey was up half a cent or 1.2 percent to 43.5 cents.

BPH ENERGY

BPH says it has survived a board spill at a requisitioned meeting with 87 percent of votes supporting chairman David Breeze and the existing directors.
BPH said that resolutions to remove Mr Breeze, Dr Bruce Whan, Thomas Fontaine and Greg Gilbert and appoint Dr Peter King, Barry Nicholson and Lun-Man Cheung were opposed by more than 219,568,971 votes and supported by more than 37,793,098 votes.
Last week, BPH said that MEC resources requisitioned the meeting, but the nominated directors were ineligible and the first meeting was invalid (BD: Feb 9, Apr 18, 2017).
Also last week, the Federal Government Takeovers Panel "declined to conduct proceedings … from Grandbridge, Trandcorp Pty Ltd and Mr David Breeze in relation to the affairs of MEC Resources".
The Takeovers Panel said that the application concerned, among other things, the potential effect on control, including a potential dilution of the applicants' voting power, resulting from MEC Resources one-for-two non-renounceable rights issue.
The Panel said that MEC Resources announced on April 20, 2017 that it would allocate shortfall applications pro rata to its shareholders, excluding any related party of MEC Resources, including its directors and their associates, before it allocated any shortfall at its discretion and in light of the announcement, it concluded there was no reasonable prospect that it would make a declaration of unacceptable circumstances.
BPH was untraded at 0.4 cents.

SIRTEX MEDICAL

Hunter Hall Investment Management says it has reduced its substantial holding in Sirtex from 3,152,884 shares (5.46%) to 2,838,081 shares (4.92%).

Hunter Hall said it sold shares between March 31 and April 20, 2017, with the single largest sale 86,953 shares for $1,370,572 or $15.76 a share

OPTHEA

Union Investments Luxembourg SA says it has fallen below the five percent substantial shareholder mark in Opthea.

In 2015, Union Investments became substantial in Opthea with 8,850,000 shares or 5.98 percent, acquiring 2,850,000 shares at 35 cents a share.

Today, Union Investments said it ceased its substantial holding due to a "change in outstanding shares per Appendix 3B announcement dated April 12, 2017" implying that it was diluted below five percent in the recent $45 million capital raising at 93 cents a share (BD: Apr 3, 2017)

Opthea was unchanged at 93 cents.

ANALYTICA

Analytica chairman Dr Michael Monsour has increased his shareholding in the company from 499,576,664 shares (21.08%) to 564,491,918 shares (22.1%).

Dr Monsour said that he bought 64,915,254 shares for $383,000 or 0.59 cents a share.

Analytica fell 0.05 cents or 8.3 percent to 0.55 cents with 3.6 million shares traded.

ANALYTICA

Inov8 LLC and Peter Corr have increased their substantial holding in Analytica from 273,753,209 shares (12.24%) to 320,702,362 shares (12.58%).

In a substantial shareholder notice signed by owner and director Peter B Corr, the St Thomas, US Virgin Islands-based Inov8 said the 46,949,153 shares were bought on April 24, 2017 for $277,000 or 0.59 cents a share.

OBJ

OBJ has requested a voluntary suspension, to follow the April 20 trading halt for "an announcement … in relation to the licencing of a second technology" (BD: Apr 20, 2017).

OBJ last traded at 6.7 cents.