Biotech Daily

Thursday May 5, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ANTISENSE UP 10%, IDT DOWN 7%**

*** REDHILL ROADSHOW TO DEEPEN AUSTRALIAN CONNECTION**

*** ELIMINATE DENGUE: 'WOLBACHIA REDUCES ZIKA'**

*** STARPHARMA: 'VIVAGEL ACTIVE AGAINST ZIKA VIRUS'**

*** SOMNOMED RAISES $4m, $6.5m TO GO**

*** HEARTWARE Q1 REVENUE DOWN 21% TO $74m**

*** GORDAGEN: US STUDY 'NE1-ELITE MUSCLE RECOVERY EFFICACY'**

*** OPTHEA DOSES FIRST PHASE IIA OPT-302 AMD PATIENT**

*** GOODBYE TISSUE THERAPIES, WELCOME FACTOR THERAPEUTICS**

*** LANG WALKER GROUP TAKES 17% OF MEDICAL AUSTRALIA**

*** PT DWI SATRYA UTAMA TAKES 5% OF MACH7**

*** GI DYNAMICS APPOINTS JIM MURPHY CFO**

MARKET REPORT

The Australian stock market edged up 0.15 percent on Thursday May 5, 2016 with the ASX200 up eight points to 5,279.1 points. Ten of the Biotech Daily Top 40 stocks were up, 15 fell, 12 traded unchanged and three were untraded.

Antisense was best, up 0.4 cents or 10.3 percent to 4.3 cents with 712,000 shares traded. Living Cell and Starpharma climbed six percent or more; Viralytics was up 5.3 percent; Actinogen improved 4.5 percent; Orthocell was up 3.5 percent; Factor Therapeutics (formerly Tissue Therapies) rose 2.7 percent; Pharmaxis was up 1.8 percent; with Airxpanders, Nanosonics and Resmed up by less than one percent.

IDT led the falls, down 2.5 cents or 7.35 percent to 31.5 cents with 110,752 shares traded. Bionomics lost 6.9 percent; Anteo and Atcor fell more than five percent; Admedus, Avita, Impedimed, Oncosil, Osprey and Pro Medicus were down more than three percent; Mesoblast shed 2.3 percent; Cochlear, CSL and Sirtex were down more than one percent; with Acrux down 0.8 percent.

REDHILL BIOPHARMA, GIACONDA

Israel's Redhill Biopharma chief executive officer Dror Ben-Asher says his company wants to strengthen ties with the Australian biotechnology and investor community.

In Melbourne as part of an Australian investor non-deal road show with Redhill product manager and former Giaconda executive Patrick McLean, Mr Ben-Asher says that three of the seven candidates in its oral drug pipeline were acquired from the Sydney-based Giaconda.

Mr Ben-Asher said that Redhill was listed on both the Tel Aviv stock exchange and the Nasdaq under the code RDHL and had a small number of Australian investors.

He said that the company was currently conducting a phase III US Food and Drug Administration-approved trial of RHB-104 for Crohn's disease, developed from Giaconda's Myocondo, in the US and at 18 sites in Australia and New Zealand.

Mr Ben-Asher said that Giaconda founder Prof Thomas Borody was a member of the Redhill scientific advisory board.

In March, Redhill said its 118-patient phase III trial of RHB-105 for Helicobacter infection, developed from Giaconda's Heliconda, had shown safety and superior efficacy for Helicobacter pylori infection over the standard-of-care (BD: Mar 31, 2015.

In August 2010, Giaconda sold its Myoconda, Heliconda and Picoconda patents to Redhill for $US500,000 plus seven percent of net sales that gave Redhill the charge over Giaconda's 78,373,505 shares (BD: Aug 17, 2010).

Today, Mr Ben-Asher said that RHB-106, developed from Giaconda's Picoconda had been licenced to Salix and was in phase I/II trials.

He said that a "legacy" drug Rizaport, or RHB-103, was approved in Europe for migraine and a re-submission had been filed to the FDA for US approval.

Mr Ben-Asher said that all the company's products were orally administered small molecules for gastro-intestinal or oncological indications.

Mr Ben Asher said that Redhill operated as a virtual company with 25 full-time staff, of which about half were administration and management in Tel Aviv, and a further 10 research and development staff in the US and Canada.

He said that the company had a market capitalization of about $US150 million dollars and at March 31, 2016 had $US53 million in cash with a burn rate of about $US5 million per quarter.

Mr Ben-Asher said that Orbimed was one of Redhill's major investors, holding about six percent of the company.

"So far we have never failed a study," Mr Ben-Asher said.

He said that the company had been very selective in which drugs it acquired and the way in which it planned its trials.

Mr Ben-Asher said that with eight drugs in development across 11 indications it was inevitable the perfect track record would eventually be broken.

Apart from the three Australian-initiated drugs, Redhill said it was developing RHB-102 or Bekinda which was in post-phase III registration discussions for "oncology support" as well as in a US phase III study for gastroenteritis and a US phase II study for irritable bowel syndrome, while RP101 was in phase I/II trials for pancreatic cancer.

Mr Ben-Asher said that the mission in Australia was simply to raise awareness of his company and there were "no deals or pitch" other than to meet investors to tell the story of what he considered to be a most unusual and lean company.

"We have genuine links in Australia and want people to know that we exist and what we have," Mr Ben-Asher said.

Last night on the Nasdaq, Redhill was up eight US cents or 0.65 percent to $US12.48 ($A16.63) with 10,673 shares traded.

ELIMINATE DENGUE, MONASH UNIVERSITY

Eliminate Dengue says that Wolbachia bacteria can reduce Zika virus in its primary vector, the Aedes aegypti mosquito, potentially reducing, transmission and disease

In a media release from Melbourne's Monash University-based Eliminate Dengue, lead scientist Prof Scott O'Neill said the findings were the first published report on the effect of the naturally-occurring Wolbachia pipientis on Zika virus.

The media release said that the study was undertaken by researchers at Brazil's Oswaldo Cruz Foundation as part of the Eliminate Dengue international research collaboration.

The article, entitled 'Wolbachia Blocks Currently Circulating Zika Virus Isolates in Brazilian Aedes aegypti Mosquitoes' was published in Cell Host & Microbe and an abstract is at: http://www.cell.com/cell-host-microbe/abstract/S1931-3128(16)30157-3.

Senior author and head of the Brazilian Eliminate Dengue team Dr Luciano Moreira said that the potential of Wolbachia to inhibit transmission of mosquito-borne viruses had been known for some time and was being used as a natural control method for dengue virus.

"Zika and dengue belong in the same family of viruses so with the Zika outbreak in Brazil, the logical idea was to test the mosquitoes carrying Wolbachia by challenging them with the Zika virus," Dr Luciano Moreira said.

The media release said that Dr Moreira's team gave Brazilian field mosquitoes and Wolbachia-infected mosquitoes the Zika virus by feeding them with two recently isolated strains of the virus circulating in Brazil.

Eliminate Dengue said that mosquitoes infected with Wolbachia showed greatly reduced virus in mosquito saliva indicating that Wolbachia would be expected to block Zika transmission in the field.

Eliminate Dengue said it began conducting field trials using mosquitoes with Wolbachia in 2011 and had released them in Brazil, Colombia, Vietnam, Indonesia and Australia to target transmission of dengue.

Prof O'Neill said there had been good progress in the program's smaller trials and that preparations were being finalised for larger scale releases.

"Globally, we're very encouraged by our results," Prof O'Neill said. "Long term monitoring in our international project sites has shown that Wolbachia is sustaining itself at high levels in the majority of these sites up to five years after application".

"In areas where mosquito populations have high levels of Wolbachia, we haven't seen any significant local transmission of dengue," Prof O'Neill said

STARPHARMA HOLDINGS

Starpharma says laboratory studies have shown the its anti-microbial Vivagel, formerly SPL7013, has potent antiviral activity against the Zika virus in-vitro.

Starpharma said that the studies showed near complete antiviral protection at SPL7013, or astodrimer sodium, concentrations significantly below that used in the Vivagel condom.

Starpharma chief executive officer Dr Jackie Fairley told Biotech Daily that the studies were conducted at a US Food and Drug Administration-accredited contract research organization in the US.

Dr Fairley said that the data would assist in adding the Zika virus to the list of viruses allowed on the label for the Ansell Vivagel-coated Dual Protect brand of condoms.

Dr Fairley said that although Zika was a mosquito-borne virus, it had been confirmed to be a sexually transmitted infection.

Dr Fairley said the condoms were approved for claim for protection from HIV, herpes simplex virus and human papillomavirus.

Starpharma climbed 4.5 cents or 6.9 percent to 70 cents with 1.8 million shares traded.

SOMNOMED

Somnomed says its institutional underwritten two-for-25 entitlement offer was oversubscribed and raised $4,034,958 at $2.50 a share.
On Tuesday, Somnomed said it expected to raise $10,502,337, with the institutional offer concluding on May 4 and the retail offer opening on May 10 and closing on May 27, 2016.
Somnomed was up 12.2 cents or 4.4 percent to $2.90.

HEARTWARE INTERNATIONAL

Heartware says that sales revenue for three months to March 31, 2016 fell 21.3 percent to $US55.1 million ($A73.6 million) compared to the same period in 2015.
Heartware chief executive officer Doug Godshall said that sales of its ventricular assist system (HVAD) were “impacted by competitive dynamics in Germany, as well as lower implant volumes in certain other international markets”.
“In the US, the bridge-to-transplant segment of the market for which the HVAD system is approved, showed softness resulting from a slowdown in the volume of patients eligible for bridge-to-transplant procedures at the start of the year and an evolving trend toward destination therapy due to ease of reimbursement,” Mr Godshall said.
Heartware said that in the three months to March 31, 2016, 578 HVAD systems were sold globally, down 19 percent from the first quarter of 2015 and US revenue from the sale of 295 units, was down 21 percent to $US33.3 million, with more than half of the comparative decrease due to the completion of enrolment in the Endurance2 destination therapy trial.
Last night on the Nasdaq, Heartware fell $US5.65 or 16.4 percent to $US28.81 ($A38.49, equivalent to $1.10 before departing the ASX) with 2,143,153 shares traded.

GORDAGEN PHARMACEUTICALS

Gordagen says an independent US study of its NE1-Elite dietary supplement shows efficacy for muscle soreness and function following eccentric exercise.
Gordagen said that the 17-patient University of Mount Union, Ohio study aimed to confirm its existing positive efficacy evidence of its NE1-Elite formulation for exercise performance and muscle recovery post exercise.
The company said that participants were college football players and their weight trained peers undergoing off-season training and the double-blind, placebo-controlled study showed significant enhancements to recovery from exercise-induced muscle soreness, muscle micro-trauma and weakness.
Gordagen said the “top-line results” indicated that participants in the supplement group reported a lack of whole-body muscular pain compared to a control group ($p = 0.02$) 24 hours after a challenging weight training session involving 25 eccentric repetitions at 80 percent of one-repetition maximum in the bench press, squat, and biceps curl, indicating a significant reduction in delayed onset muscle soreness after exercise.
Gordagen said the participants receiving NE1-Elite had a less-pronounced ($p = 0.05$) hanging arm angle, an indicator of swelling and micro-trauma, compared to controls, 24-hours post-eccentric exercise, pointing to enhanced muscle recovery after exercise.
The company said that there was a strong trend ($p = 0.056$) for the active group to perform a Wingate cycle sprint with greater peak power the day after the damaging eccentric exercise compared to the control group, which was indicative of improved muscle power maintenance.
Gordagen said that it intended to launch NE1-Elite in the US by the end of 2016.
Gordagen is a private company.

OPTHEA (FORMERLY CIRCADIAN TECHNOLOGIES)

Opthea says it has dosed the first patient in its phase IIa trial of OPT-302 for wet age-related macular degeneration (AMD).

Opthea said that the phase IIa dose-expansion study would enrol about 30 subjects with wet AMD, randomized into two treatment groups of OPT-302 as monotherapy or in combination with Lucentis administered by intra-vitreal injection on a monthly basis for three months, with primary data analysis expected by the end of 2016.

In April, Opthea said its on-going, 20-patient, phase I, dose escalation trial of OPT-302 for wet age-related macular degeneration met the primary objective of safety, was safe and well tolerated as a mono-therapy and in combination with ranibizumab, with no dose limiting toxicities following 28-day safety review of high dose 2mg OPT-302 mono-therapy and dose escalation cohorts of 0.3mg, 1.0mg or 2mg OPT-302 in combination with 0.5mg ranibizumab, marketed as Lucentis(BD: Apr 21,2016).

The company said at that time that OPT-302 was a novel vascular endothelial growth factor C and vascular endothelial growth factor D 'trap' therapy administered either alone or in combination with ranibizumab on a monthly basis for three months by ocular injection.

Opthea said that the phase I/IIa study was being run under a US Food and Drug Administration investigational new drug program at 14 US sites.

Opthea was unchanged at 48 cents.

FACTOR THERAPEUTICS (FORMERLY TISSUE THERAPIES)

Tissue Therapies says it has completed its formal name change to Factor Therapeutics and is trading under the new ASX code of FTT.

Factor Therapeutics said the objective of the corporate branding strategy was "to improve the clarity, meaning and differentiation of the company as it further builds its presence in the advanced wound care space".

Executive director Dr Christian Behrenbruch said that "considerable internal discussion and planning went into the change of name as part of our restructuring activities over the past nine months or so".

"Key to this objective has been positioning our core technology strength in the use of targeted growth factors for wound healing," Dr Behrenbruch said.

Factor chair Dr Cherrell Hirst said the "new brand [had] been road-tested with clinicians and key opinion leaders and we have received positive feedback".

"Ultimately we feel this re-branding not only helps message our corporate turn-around, but also helps our business partners to better understand our core development focus," Dr Hirst said.

Tissue Therapies began developing its Vitrogro wound treatment more than 10 years ago and following a successful eight-patient Western Australia trial in 2008, began a Canadian trial which was delayed and folded into a 30-patient Australian trial of Vitrogro for chronic venous leg ulcers (BD: Aug 11, 2008; Jan 19, Jul 23, 2009).

The company claimed "exceptional results" for the trial and then faced continuous and on-going delays in the European registration process including questions over its device or drug categorization (BD: Sep 30, 2010; Feb 25, Mar 26, 2015).

Last year, founding chief executive officer Dr Stephen Mercer and chairman Roger Clarke resigned, replaced by Dr Hirst and chief operating officer Nigel Johnson was appointed acting chief executive officer, with Dr Behrenbruch appointed an executive director in October 2015 (BD: Apr 7, Oct 12, 2015).

Factor was up 0.1 cents or 2.7 percent to 3.8 cents with 1.4 million shares traded.

MEDICAL AUSTRALIA

The Lang Walker Group says it has increased its substantial holding in Medical Australia from 22,174,340 shares (16.21%) to 23,641,007 shares (17.29%).
The substantial shareholder notice said that Auckland Trust Co as trustee for the Second Pacific Master Superannuation, and Walker Group acquired 1,466,667 shares for $72,000 or 4.9 cents a share on April 28, 2016.
Medical Australia was up 0.3 cents or six percent to 5.3 cents.

MACH7 TECHNOLOGIES (FORMERLY 3D MEDICAL)

The Jakarta, Indonesia -based PT Dwi Satrya Utama says it has become a substantial shareholder in Mach7 with the acquisition of 47,254,393 shares (5.28%).
The substantial shareholder notice, signed by PT Dwi Satrya Utama director Yerri Goei said the shares were acquired on April 8, 2016 as consideration for the acquisition of Mach7 Technologies Pte Ltd from his company at a deemed price of 10 cents a share.
Mach7 was unchanged at 6.2 cents with 1.2 million shares traded.

GI DYNAMICS

GI Dynamics says it has appointed Jim Murphy as chief financial officer, responsible for finance, accounting and administration, effective immediately.
GI Dynamics said that Mr Murphy would also act as company treasurer and secretary.
The company said that Mr Murphy was previously Oxigene's and Hemasure's chief financial officer and was part of a team at Whatman that consolidated 18 operating locations to nine.
GI Dynamics fell 0.1 cents or 5.9 percent to 1.6 cents.