Biotech Daily

Thursday May 26, 2022

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: CYNATA UP 11%; COMPUMEDICS DOWN 15%**

*** VOLPARA REVENUE UP 32% TO $24m, LOSS DOWN 6.4% TO $15m**

*** PACIFIC EDGE REVENUE UP 49% TO $10.5m; LOSS UP 39% TO $18m**

*** CYNATA: FDA OKAYS CYP-001 FOR GvHD TRIAL**

*** REDHILL: 'DATA BACKS TALICIA FOR H PYLORI IN DIABETICS'**

*** ANTERIS STARTS 2nd DURAVR AORTIC VALVE REPLACEMENT COHORT**

*** ANALYTICA RECEIVES ISO13485:2016 FOR PERICOACH**

*** MICROBA: MIDNIGHT HEALTH TO DISTRIBUTE VIDALITY IN AUSTRALIA**

*** RACE REQUESTS TRIAL RESULTS TRADING HALT**

*** VISIONEERING LACKS QUORUM; ADJOURNS AGM**

*** OSPREY LOSES 2 DIRECTORS; AGM ON HOLD**

*** YARRA FUNDS TAKES 5% OF NANOSONICS**

*** CLARITY APPOINTS DR NEAL SHORE ADVISER**

MARKET REPORT

The Australian stock market fell 0.69 percent on Thursday May 26, 2022, with the ASX200 down 49.3 points to 7,105.9 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and one was untraded.

Cynata was the best, up four cents or 11.0 percent to 40.5 cents, with 666,734 shares traded. Paradigm climbed 8.3 percent; both Micro-X and Prescient were up 6.1 percent; Emvision improved 5.7 percent; Oncosil and Opthea were up more than three percent; Kazia, Medical Developments, Pro Medicus, Proteomics, Starpharma and Volpara rose two percent or more; Resmed and Resonance were up more than one percent; with Cochlear, Clinuvel, Polynovo, Mesoblast and Telix up by less than one percent.

Yesterday's 21.2 percent best, Compumedics, led the falls, down three cents or 15 percent to 17 cents, with 36,718 shares traded. Universal Biosensors lost 10.6 percent; Impedimed was down 7.8 percent; Nanosonics was down 5.7 percent; Patrys fell 4.35 percent; Antisense and Cyclopharm were down three percent or more; Genetic Signatures, Imugene, Nova Eye shed more than two percent; with Actinogen, Atomo, Avita, CSL, Mesoblast and Pharmaxis down by more than one percent.

VOLPARA HEALTH TECHNOLOGIES

Volpara says revenue for the year to March 31, 2022 was up 32.2 percent to $NZ26,113,000 ($A23,863,000), with net loss after tax down 6.4 percent to $NZ16,441,000 ($A15,024,000).

Volpara said revenue grew despite an 11 percent increase in operating costs from $NZ39.0 million to $NZ43.2 million "predominantly attributable to a full year of CRA costs being incurred totalling [about] $NZ3.8 million".

Last year, the company said it bought Boston's CRA Health LLC for $US18.0 million ($A23.5 million) with a further $US4 million ($A5.25 million) in milestone payments.

Today, Volpara said revenue came from the sales of it breast mammography density and quality control software, with annual recurring revenue of $NZ31.8 million, an increase of 19.35 percent on the previous year as a result of subscription revenues.

The company said its diluted loss per share was constant at 7.0 NZ cents for the year to March 31, 2022, with net tangible assets per share fell 54.5 percent to 5.0 NZ cents, and it had cash and cash equivalents of $NZ18,145,000 at March 31, 2022 compared to $NZ32,230,000 at March 31, 2021.

Volpara was up two cents or 2.7 percent to 75.5 cents.

PACIFIC EDGE

Pacific Edge says revenue for the year to March 31, 2022 was up 48.62 percent to $NZ11,445,000 ($A10,459,000), with net loss after tax up 39.13 percent to $NZ19,788,000 ($A18,083,000).

Pacific Edge said revenue came from sales of its Cxbladder non-invasive urine tests for bladder cancer, with a 62 percent increase in sales in the US following a distribution agreement with Kaiser Permanente.

The company said its diluted loss per share was up 30.0 percent to 2.6 NZ cents for the year to March 31, 2022, with net tangible asset per share up 291.2 percent to 13.3 NZ cents, and it had cash and cash equivalents of $NZ35,412,000 at March 31, 2022 compared to $NZ4,129,000 at March 31, 2021.

Pacific Edge was untraded at 68.5 cents.

CYNATA THERAPEUTICS

Cynata says the US Food and Drug Administration has cleared its investigative new drug application for a 60-patient, phase II trial of CYP-001 for acute graft versus host disease.

Cynata said the phase II trial, was titled 'A Multicenter, Randomized, Double-blind, Placebo-Controlled Phase II Study to Investigate the Efficacy and Safety of CYP-001 in Combination with Corticosteroids vs Corticosteroids Alone for the Treatment of High-Risk Acute Graft Versus Host Disease'.

The company said the trial would seek to recruit about 60 patients with high-risk acute graft versus host disease (GvHD) at clinical centres in the US and Australia.

Cynata said participants would be randomiZed to receive either CYP-001 or placebo, in addition to corticosteroids, with the primary objective to assess efficacy of CYP-001 by overall response rate 28 days after dosing.

Cynata chief operating officer Dr Kilian Kelly said the FDA clearance of the IND confirmed the US regulator was "satisfied with both the clinical and pre-clinical data as well as the manufacturing and quality control data … [and was] a hugely important milestone".

The company said it expected to begin enrolment this year, with first results in early 2024.

Cynata was up four cents or 11.0 percent to 40.5 cents.

REDHILL BIOPHARMA

Redhill says its Sydney-invented Talicia (RHB-105) Helicobacter pylori showed safety and efficacy in diabetes patients prone to higher rates of infection and treatment failure.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

In 2019, Redhill said that the US Food and Drug Administration had approved the Giaconda-based Talicia amoxicillin, rifabutin and omeprazole combination delayed-release capsules, for Helicobacter pylori infection (BD: Nov 5, 2019).

Today, the company said that data presented at Digestive Diseases Week showed that in a 293 patient-analyzable modified intent to treat population who received Talicia had pooled eradication rates of 91.7 percent (n=44) and 84.1% (n=206) in patients with and without diabetes mellitus, respectively (p = 0.17).

The presentation of the data, titled 'Low-Dose Rifabutin Triple Therapy (RHB-105) Maintains High Helicobacter pylori (H. pylori) Eradication Rates and Shows Favorable Safety and Efficacy in Subjects with Diabetes Mellitu' and is available at: https://www.redhillus.com/ddw/2022/RHB-105DM/Howden.

Redhill said that no resistance was seen to rifabutin in patients with or without diabetes, but observed resistance rates of four percent and seven percent for amoxicillin, 45 percent and 43 percent metronidazole, and 21 percent and 17 percent resistance to clarithromycin in patients with and without diabetes, respectively.

The company said that "with the exception of an observed higher rate of diarrhea in patients without diabetes versus those with (13.8% versus 6%), the presence of diabetes did not alter the safety or tolerability of Talicia and generally matched the safety profile of the total patient population".

Redhill said that diabetes was associated with higher rates of Helicobacter pylori infection and higher rates of treatment failure with clarithromycin-based therapies, and clarithromycin interacted with some common diabetes medications potentially leading to hypoglycaemia.

The company said that a second, physiologically-based, pharmaco-kinetic study, used modeling to compare Talicia's low-dose rifabutin formulation's (rifabutin 50mg every 8 hours) sustained intragastric antibiotic exposure, a critical component of successful Helicobacter pylori eradication, to exposure rates seen with the generic formulation of rifabutin (150mg taken once daily).

University of Tennessee Health Science Center Prof Colin Howden co-authored the second poster, titled 'Low-Dose Rifabutin Triple Therapy (RHB-105) Demonstrates High Helicobacter pylori (H. pylori) Eradication Rates' which was available at: https://www.redhillus.com/ddw/2022/RHB-105PBPK/Howden.

Prof Howden said that "maintaining high intragastric antibiotic concentrations is necessary for successful Helicobacter pylori eradication".

"The differences in intragastric exposure seen in this study may potentially explain the lower and less consistent eradication rates seen with generic rifabutin, about 70 percent eradication, than seen in the Talicia clinical trial program, about 84 to 90 percent eradication," Prof Howden said.

"Given the need to aim for the most effective empiric first-line eradication therapy, it is important to utilize a therapy with the highest likelihood of Helicobacter pylori eradication success, such as Talicia," Prof Howden said.

Redhill chief medical officer Dr June Almenoff said the data enhanced "the body of evidence supporting the use of Talicia as a first line therapy for Helicobacter pylori".

On the Nasdaq, Redhill was up 0.8 US cents or 0.85 percent to 95.8 US cents ($A1.355) with 193,767 shares traded.

ANTERIS TECHNOLOGIES

Anteris says it has begun implanting the second cohort of its 10-patient, first-in-human trial of its Duravr transcatheter aortic valve replacement system.
Last year, Anteris said it had implanted five of 10 patients with its Duravr transcatheter heart valve for severe aortic stenosis, in its Tbilisi, Georgia study (BD: Nov 22, 2021).
Anteris was up $2.80 or 16.5 percent to $19.80.

ANALYTICA

Analytica says the International Organisation for Standardization has certified the design, development, production, sale and distribution of its pelvic floor aides.
Analytica said the Organization had certified its Pericoach pelvic floor aide with ISO 13485:2016, the international standard of quality systems for medical device manufacturers.
Analytica chief executive officer Geoff Daly said the certification was “a major achievement for Analytica and acquiring this certification allows us to bring Pericoach manufacturing in-house for global manufacture, giving us better control of the production process”.
“The rapid acquisition of this certification is in no small part due to the excellent system developed by Analytica’s quality and regulatory team”, Mr Daly said.
Analytica was untraded at 0.1 cents.

MICROBA LIFE SCIENCES

Microba says the Nib Health Funds-backed Midnight Health will distribute its Vidality subscription health service in Australia.
Microba said that under the three-year agreement, Midnight Health would promote, market and sell Vidality to its network of pharmacists to allow the formulation of personalized supplements for each customer, based on their microbiome test results.
Microba chief executive office Dr Luke Reid said that consumers were “seeking personalized, evidence-based solutions to support their gut health”.
“Together with Midnight Health, we are excited to bring the Vidality product to consumers, a truly personalized solution powered by our technology”.
Microba fell half a cent or two percent to 24.5 cents.

RACE ONCOLOGY

Race has requested a trading halt pending an announcement in relation to the “release of clinical results for the dose escalation phase of the Ib/II Zantrene AML trial in Israel.”
Trading will resume on May 30, 2022, or on an earlier announcement.
Race was up 1.5 cents or 0.9 percent to $1.735.

VISIONEERING TECHNOLOGIES

Visioneering says it has adjourned its annual general meeting, scheduled for 8am (AEST) today, due to the lack of a quorum.
Visioneering said that the virtual meeting had been postponed to June 3, 2022 at 8am (AEST), and would be available at: http://meetnow.global/MWUJJCP.
Visioneering fell one cent or 2.6 percent to 37 cents.

OSPREY MEDICAL

Osprey says that non-executive directors Sandra Lesenfants and Neville Mitchell have resigned.

Osprey said Mr Mitchell had been a director since July 2012 and Ms Lesenfants since June 2017.

Earlier this month, Osprey said it had requested an extension to its voluntary suspension "as it considers its strategic and funding options" (BD: May 10, 2022).

Today, the company said it had postponed its annual general meeting, scheduled for June 2, 2022, until further notice, "while it continues to assess its strategic options".

Osprey last traded at 20 cents.

NANOSONICS

Yarra Funds Management says it has become substantial in Nanosonics with 15,142,937 shares, or 5.0170 percent of the company.

The Melbourne-based Yarra said that between January 21 and May 23, 2022, it bought 950,554 shares for $3,641,992, or $3.83 a share.

Nanosonics fell 22 cents or 5.7 percent to $3.65 with 831,825 shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Dr Neal Shore to its clinical advisory board.

Clarity said Dr Shore was currently the Fort Myers, Florida-based Genesiscare urology and surgical oncology chief medical officer, and the Myrtle Beach, South Caroline-based Carolina Urologic Research Centre medical director.

Clarity fell one cent or 2.2 percent to 45 cents.