

Biotech Daily

Wednesday February 24, 2021

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: GENETIC SIGNATURES UP 8%; NANOSONICS DOWN 8%
- * MAYNE H1 REVENUE DOWN 8% TO \$209m, LOSS UP 842% TO \$182m
- * NANOSONICS H1 REVENUE DOWN 11% TO \$43m, PROFIT DOWN 74% TO \$1.5m
- * COMPUMEDICS H1 REVENUE DOWN 1% TO \$18m, PROFIT UP 717% TO \$1.3m
- * CLINUVEL H1 REVENUE UP 58% TO \$16m, PROFIT UP 420% TO \$6m
- * LITTLE GREEN H1 REVENUE UP 427% TO \$3.8m, LOSS TO \$484k PROFIT
- * MEDLAB H1 REVENUE DOWN 9% TO \$2.5m, LOSS UP 89% TO \$7.1m
- * USCOM H1 REVENUE UP 232% TO \$2.3m, LOSS DOWN 82% TO \$270k
- * IQ3 H1 REVENUE DOWN 48% TO \$2.2m, LOSS UP 130% TO \$2.2m
- * ALLEGRA H1 REVENUE DOWN 1.6% TO \$2.3m, LOSS DOWN 86% TO \$188k
- * RHINOMED H1 REVENUE UP 17% TO \$1.9m, LOSS UP 3.5% TO \$5.5m
- * UNIVERSAL BIO REVENUE DOWN 54% TO \$3.2m, LOSS UP 58% TO \$7.6m
- * EMYRIA H1 REVENUE UP 165% TO \$1.15m, LOSS DOWN 3% TO \$2.1m
- * OSPREY OPTIONS RAISE \$14.5m; \$1.4m US GOVERNMENT LOAN
- * US 'FORGIVES' \$1.44m IMPEDIMED COVID-19 LOAN
- * FOUNDERS SUE BARD1 FOR PERFORMANCE SHARES
- * OPTHEA: 1,980-PATIENT PHASE III OPT-302 WET AMD TRIALS
- * RESONANCE ADDS CE MARK TO HEPAFAT-AI AUSTRALIAN, US APPROVALS
- * ADALTA: FDA IPF ORPHAN STATUS FOR AD-214
- * MALAYSIAN PATENT FOR AZURE TOCOTRIENOLS
- * RECCE TO LIST ON FRANKFURT EXCHANGE
- * SELECTOR FUNDS BELOW 5% IN NANOSONICS
- * DIRECTOR, CSO DR DANIEL TILLETT INCREASES, DILUTED TO 7% OF RACE
- * CELL CARE REDUCES TO 17% OF CRYOSITE
- * NOXOPHARM DR GRAHAM KELLY REDUCES TO 11% FOR OPTIONS
- * APEIRON, CHRISTIAN ANGERMAYER TAKE PROFIT TO 10% OF BIONOMICS

MARKET REPORT

The Australian stock market fell 0.9 percent on Wednesday February 24, 2021, with the ASX200 down 61.4 points to 6,777.8 points.

Just six of the Biotech Daily Top 40 stocks were up, 30 fell and four traded unchanged.

Genetic Signatures was the best, up 13 cents or 7.7 percent to \$1.81, with 83,201 shares traded. Paradigm climbed 4.4 percent; Uscom improved three percent; Neuren rose 2.7 percent; with Next Science and Nova Eye up by more than one percent.

Nanosonics led the falls, down 49 cents or 8.1 percent to \$5.56, with 8.7 million shares traded.

Impedimed, Kazia and Proteomics lost more than seven percent; Alterity, Antisense, Immutep, Opthea and Osprey fell five percent or more; Imugene, Prescient and Universal Biosensors retreated more than four percent; Cochlear, Mesoblast, Pharmaxis and Starpharma were down more than three percent; Cyclopharm, LBT, Optiscan and Telix shed two percent or more; Amplia, Avita, Clinuvel, Compumedics, Dimerix, Orthocell, Pro Medicus and Resmed were down more than one percent; with Cynata, Medical Developments, Polynovo and Volpara down by less than one percent.

MAYNE PHARMA GROUP

Mayne says revenue for the six months to December 31, 2020 was down 8.1 percent to \$208,842,000 with net loss after tax up 842.3 percent \$181,679,000.

Mayne said revenue included \$160,538,000 from sales of its generic drugs, \$47,871,000 from services, \$212,000 in licence fees and \$221,000 in royalties.

Mayne chief executive officer Scott Richards said that "at the bottom line, the net loss after tax was impacted by a non-cash intangible asset impairment of the generic portfolio".

The company said that diluted loss per share was up 866.7 percent to 11.6 cents, with net tangible asset backing per share up 41.9 percent to 4.4 cents.

Mayne said it had cash and cash equivalents of \$131,535,000 at December 31, 2020 compared to \$98,529,000 at December 31, 2019.

Mayne Pharma fell 1.5 cents or 4.8 percent to 29.5 cents with 5.95 million shares traded.

NANOSONICS

Nanosonics says revenue for the six months to December 31, 2020 fell 11.1 percent to \$43,148,000 with net profit after tax down 74.4 percent to \$1,464,000.

Nanosonics said revenue came from sales of its Trophon ultrasound probe cleaning systems and related products.

The company said diluted earnings per share fell 74.5 percent to 0.48 cents with net tangible asset backing per share up 11.7 percent to 38.73 cents.

Nanosonics said it had cash and cash equivalents of \$87,895,000 at December 31, 2020 compared to \$81,965,000 at December 31, 2019.

Nanosonics fell 49 cents or 8.1 percent to \$5.56 with 8.7 million shares traded.

COMPUMEDICS

Compumedics says revenue for the six months to December 31, 2020 was down 1.4 percent to \$18,048,000 with net profit after tax up 717.4 percent to \$1,316,000.

Compumedics said revenue came from sales of its brain monitoring equipment, ultrasonic blood-flow systems and related services, with profit increased due to \$800,000 received from the Federal Government's Jobkeeper initiative.

Compumedics said diluted earnings per share rose 600.0 percent to 0.7 cents with net tangible assets per share up 13.5 percent to 10.1 cents.

The company said it had cash and cash equivalents of \$5,557,000 at December 31, 2020 compared to \$3,349,000 at December 31, 2019.

Compumedics fell half a cent or 1.1 percent to 45 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the six months to December 31, 2020 was up 57.9 percent to \$15743,215 with net profit after tax up 420.0 percent to \$6,046,980.

Clinuvel said revenue came primarily from sales and reimbursements for Scenesse, or 16mg afamelanotide, for erythropoietic protoporphyria, which had increase due to regulatory approvals in the US and Australia (BD: Oct 9, 2019; Oct 27, 2020).

The company said diluted earnings per share rose 958.3 percent to 12.7 cents, with net tangible asset backing per share up 9.6 percent to \$1.481.

Clinuvel said it had cash and cash equivalents of \$72,918,097 at December 31, 2020 compared to \$57,431,850 at December 31, 2019.

Clinuvel fell 24 cents or 1.2 percent to \$19.80 with 210,555 shares traded.

LITTLE GREEN PHARMA

Little Green says revenue for the six months to December 31, 2020 was up 426.6 percent to \$3,771,231 with last year's loss tax turned to a net profit of \$484,329.

Last year, Little Green said it listed on the ASX at 45 cents a share to grow marijuana and sell medical marijuana products (BD: Feb 24, 2020).

Today, the company said it had diluted earnings per share of 0.32 cents compared to a diluted loss per share of 7.71 cents in the previous corresponding period, with net tangible asset backing per share of 10.3 cents compared to negative 8.5 cents.

Little Green said it had cash and cash equivalents of \$4,448,696 at December 31, 2020 compared to \$2,236,748 at December 31, 2019.

Little Green fell half a cent or 0.7 percent to 68.5 cents with 1.6 million shares traded.

MEDLAB CLINICAL

Medlab says revenue for the six months to December 31, 2020 fell 9.0 percent to \$2,481,737 with net loss after tax down 25.3 percent to \$5,331,906.

Medlab said the revenue was from its Nanabis blend of cannabidiol (CBD) and tetrahydrocannabinol (THC), its CBD-formulation Nanocbd, and its over-the-counter food additives, including NRGbiotic.

The company said that diluted loss per share was down 42.1 percent to 1.90 cents with net tangible assets per share down 50.0 percent to 2.1 cents.

Medlab said it had cash and cash equivalents of \$6,876,276 at December 31, 2020 compared to \$9,689,136 at December 31, 2019.

Medlab fell one cent or 2.9 percent to 33.5 cents.

USCOM

Uscom says revenue for the six months to December 31, 2020 rose 231.9 percent to \$2,269,744 with net loss after tax down 82.0 percent to \$269,661.

Uscom said revenue came from sales of its Uscom1A ultra-sonic cardiac output monitor, Uscom BP+ blood pressure monitor, Spirosonic pulmonary function test and Ventitest ultrasonic ventilator calibration devices.

The company said that sales had increased due to the establishment of its Beijing-based subsidiary, Uscom China, as well as a rise in demand for its Spirosonic pulmonary function test in Europe due to Covid-19.

Uscom said diluted loss per share was down 81.8 percent to 0.2 cents with net tangible asset backing per share up 100 percent to one cent.

The company said it had cash and cash equivalents of \$2,278,159 at December 31, 2020 compared to \$1,480,811 at December 31, 2019.

Uscom was up half a cent or three percent to 17 cents.

IQ3 CORP

IQ3 says revenue for the six months to December 31, 2020 was down 47.5 percent to \$2,247,845 with net loss after tax up 129.6 percent to \$2,181,068.

IQ3 said revenue came from the "provision of capital raising and corporate advisory services to listed and unlisted companies in the life sciences industry".

The company said it had invested in new projects and collaborations with US business partners and expected "a stronger second half".

IQ3 said diluted loss per share was up 130.8 percent to 2.10 cents with net tangible assets per share was down from negative 0.03 cents a share to negative 3.35 cents a share, and it had cash and cash equivalents of \$652,160 at December 31, 2020 compared to \$453,488 at December 31, 2019.

IQ3 was untraded at 16.5 cents.

ALLEGRA ORTHOPAEDICS

Allegra says revenue for the six months to December 31, 2020 fell 1.6 percent to \$2,271,987 with net loss after tax down 85.5 percent to \$118,425.

Allegra said revenue came from sales of its orthopaedic medical devices.

The company said diluted loss per share was down 86.6 percent to 0.11 cents, net tangible asset backing fell 13.45 percent to 3.94 cents, with cash and equivalents of \$273,767 at December 31, 2020 compared to \$287,878 at December 31, 2019. Allegra was up two cents or 6.45 percent to 33 cents.

RHINOMED

Rhinomed says revenue for the six months to December 31, 2020, was up 16.7 percent to \$1,945,537 with net loss after tax up 3.5 percent to \$5,486,116.

Rhinomed said its revenue came from sales its Mute nasal dilators for snoring and sleep apnoea and Pronto for nasal decongestion.

The company said that net tangible assets per share fell 35.1 percent to 2.05 cents, with diluted loss per share down 36.1 percent to 2.16 cents.

Rhinomed said that cash and cash equivalents of \$5,439,401 at December 31, 2020 compared to \$3,513,221 at December 31, 2019.

Rhinomed fell two cents or 16.7 percent to 10 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says revenue for the year to December 31, 2020 was down 53.5 percent to \$3,202,609 with net loss after tax up 57.6 percent to \$7,638,024.

Universal Biosensors said revenue included \$2,565,747 from sales of its Xprecia Stride coagulation test strip and \$568,528 from its testing services.

The company said that diluted loss per share rose 33.3 percent to four cents with net tangible assets per share down 23.5 percent to 13 cents.

Universal Biosensors it had cash and cash equivalents of \$23,561,807 at December 31, 2020 compared to \$30,229,530 at December 31, 2019.

Universal Biosensors fell two cents or 4.65 percent to 41 cents.

EMYRIA (FORMERLY EMERALD CLINICS)

Emyria says revenue for the six months to December 31, 2020 rose 164.9 percent to \$1,146,731 with net loss after tax down 3.2 percent to \$2,073,216.

Emyria said revenue came from patient monitoring data deals with Canopy and Zelira and the treatment of patients at its clinics.

The company said diluted loss per share was down 39.0 percent to 1.0 cent with net tangible asset backing up to 2.27 cents from negative 1.08 cents in the previous corresponding period, and it had cash and equivalents of \$4,869,635 at December 31, 2020 compared to \$1,162,052 at December 31, 2019.

Emyria fell 1.5 cents or seven percent to 20 cents with 1.9 million shares traded.

OSPREY MEDICAL

Osprey says it has raised \$14,522,874 through the exercise of attaching options issued in last year's rights issue, exercisable at 1.4 cents each by February 15, 2021.

Last year, Osprey raised \$12.8 million in a three-for-one rights offer at 1.2 cents per Chess depositary interest (CDI) with each new CDI having an attaching unquoted option (BD: Apr 29, Jun 9, 2020).

Today, Osprey chief executive officer Mike McCormick told Biotech Daily that the options were exercised by investors and the underwriters.

In a media release the company said that the underwriters included funds related to the Brandon Capital-managed Medical Research Commercialisation Fund, Statewide Superannuation, and Hostplus Superannuation, and would not be paid any fee in connection with the underwriting.

Osprey said it had received a loan of \$US1,080,743 (\$A1,363,071) as part of the second draw under the US Federal Government's Paycheck Protection Program, a Covid-19 relief program providing loans to US-based small businesses for the purposes of paying for payroll, rent and utilities, and it expected "a significant portion of this loan will be forgiven" with the balance subject to a 1.0 percent interest rate and payable within five years. Osprey fell 0.1 cents or 5.3 percent to 1.8 cents with 17.75 million shares traded.

IMPEDIMED

Impedimed says a US Federal Government loan of US\$1,140,202 (\$A1,440,857) has been "forgiven".

Impedimed said the loan was under the Paycheck Protection Program of the US Coronavirus Aid, Relief, and Economic Security Act, with all obligations satisfied in full. Impedimed fell one cent or 7.7 percent to 12 cents with 1.5 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says founders Dr Irmgard Irminger-Finger and Tony Walker have begun legal proceedings in the Supreme Court of Victoria, over performance shares.

In 2016, Bard1 was acquired by the Perth, Western Australia mining company Eurogold to develop a "a simple blood test for screening and diagnosing lung cancer at early stages of disease progression" (BD: Feb 24, Jun 20, 2016).

Eurogold said at that time that Bard1 AG was founded in 2011 by the University Hospital of Geneva's head of molecular gynaecology and obstetrics laboratory Dr Irmgard Irminger-Finger.

In 2016, Dr Irminger-Finger held 19.6 percent of the company with the Geneva based Mr Walker holding 16.03 percent of the company.

In 2017, the company said it needed to do further work to improve the accuracy of its lung cancer test, with a 638-sample study showing 72.5 percent accuracy and later that year, announced the publication of an original study that showed up to 86 percent accuracy (BD: May 15, Aug 8, 2017).

Bard1 published similar accuracy for its ovarian cancer test, rising to 99 percent accuracy when used with the standard CA-125 test (BD: Jan 21, Mar 6, Sep 6, 2018).

In 2019, Merchant Funds and Kidder Williams principal David Williams became substantial in Bard1 and the following year, the company merged with Sienna diagnostics, which was developing and commercializing a telomerase-based adjunct test for bladder cancer (BD: Jun 20, 2019' Apr 9, Jul 20, 29, 2020).

In January, Bard1 said that director Dr Irminger-Finger had resigned from the board but would continue to provide scientific expertise to the company (BD: Jan 17, 2021).

Earlier this month, Bard1 announced 100 percent sensitivity and specificity for a blood test for ovarian cancer and 95 sensitivity and 100 percent specificity for a blood test for breast cancer, using newly-acquired SubB2M technology, and the share price rose as much as 761.5 percent from 65 cents to \$5.60 on February 16 (BD: February 11, 15, 2021). Today, Bard1 said that Dr Irminger-Finger's consultancy agreement was recently

terminated.

The company said that the plaintiffs were the original founders and major shareholders of Bard1AG SA (Bard1AG), a fully owned subsidiary of the company, acquired from the

plaintiffs in 2016.
Bard1 said the proceedings related to performance shares issued to the plaintiffs as part

consideration under the acquisition agreements.

The company said that following the December 30-for-one share consolidation, Dr

Irminger-Finger held 3,608,414 performance shares and Mr Walker held 2,950,055 performance shares, with the conversion of performance shares into ordinary shares subject to the achievement of certain milestones related to the lung cancer test before the expiry date, of June 9, 2021.

Bard1 said that the statement of claim alleges among other things that the company was "subject to obligations to do all things as were reasonably necessary to seek to have the test satisfy the milestones by the expiry date and not to deprive the plaintiffs of the opportunity to have each of their performance shares convert into one ordinary share in the company".

The company said that the statement of claim further alleges that in breach of those obligations the plaintiffs have been deprived of that opportunity and the proceedings seek damages, costs, interest and such further or other orders as the Court considers just. Bard1 said it was reviewing the writ and statement of claim and would defend the proceedings and intends in due course to file a comprehensive defence. Bard1 fell 46 cents or 14.5 percent to \$2.71 with 3.2 million shares traded.

OPTHEA

Opthea says two concurrent phase II trials of about 990 patients each, for OPT-302 for wet age-related macular degeneration are on track to begin by April 2021.

Last year, Opthea said that the US Food and Drug Administration and European Medicines Agency (EMA) agreed on key aspects of the proposed phase III trial designs of OPT-302 in combination with a vascular endothelial growth factor-A inhibitor for wet agerelated macular degeneration (wet AMD) (BD: Aug 21, 2020).

Today, the company said the trials would compare the clinical efficacy of 2.0mg dose of OPT-302 administered in combination with either 0.5mg of ranibizumab, marketed as Lucentis, or 2.0mg of aflibercept, marketed as Eylea, on an every four-week or every eight-week dosing regimen, to understand the durability of OPT-302 treatment effect with less frequent dosing.

Opthea said the primary endpoint for both trials was the mean change in best corrected visual acuity from baseline to week-52 for OPT-302 combination therapy compared to anti-vascular endothelial growth factor-A (VEGF-A, namely ranibizumab or aflibercept) monotherapy.

The company said that each patient would be treated for a further year to evaluate extended safety and tolerability over a two-year period.

Opthea said it had appointed Prof Timothy Jackson as chief investigator of the trial combining OPT-302 with ranibizumab and Dr Charles Wykoff as chief investigator of trial in combination with aflibercept.

Opthea chief executive officer Dr Megan Baldwin said that "the design of the OPT-302 phase III program has the potential to generate compelling and persuasive clinical data capable of satisfying regulatory requirements".

Opthea fell nine cents or 5.3 percent to \$1.60 with 1.2 million shares traded.

RESONANCE HEALTH

Resonance says it has received Conformité Européenne (CE) mark for Hepafat-Artificial Intelligence automated liver fat assessment device.

Resonance said the US Food and Drug Administration cleared the Hepafat-AI in December followed by Australian Therapeutic Goods Administration approval last week (BD: Dec 9, 2020; Feb 18, 2021).

The company said Hepafat-AI "automatically analyses magnetic resonance imaging datasets to assess liver fat in patients, providing doctors with a comprehensive, multimetric solution for use in the assessment of individuals with confirmed or suspected fatty liver disease".

Resonance was unchanged at 21.5 cents with 1.1 million shares traded.

ADALTA

Adalta says the US Food and Drug Administration has granted orphan drug designation for its AD-214 for idiopathic pulmonary fibrosis (IPF).

Adalta said the FDA established the Orphan Drug Act "to encourage and provide special incentives to biopharmaceutical companies that undertake the development of promising potential treatments for diseases ... that affect fewer than 200,000 people in the US". Adalta said it orphan drug designation entitled it to benefits including seven years of market exclusivity following approval, additional protocol assistance, reduced review times and waiver of certain marketing authorization application fees.

Adalta fell half a cent or 2.9 percent to 17 cents with 10.05 million shares traded.

AZURE HEALTH TECHNOLOGY

Azure says that the Intellectual Property Corporation of Malaysia has approved a patent application titled 'Transmucosal delivery of tocotrienol'.

Azure said that when granted the patent would protect its intellectual property until 2033. The company said the patent application was directed to compositions formulated for transmucosal delivery of tocotrienols for promoting the treatment or prevention of post exercise muscle soreness, delayed onset muscle soreness, and improving exercise endurance and performance.

Azure said the claims were also directed at reducing inflammation, cardiac fibrosis and treatment of cancer amongst other claims.

Azure is a public unlisted company.

RECCE PHARMACEUTICALS

Recce says it has applied to list on the Frankfurt Stock Exchange to broaden its investor base and enable access to additional capital markets.

Recce said there would not be a related capital raising.

The company said that Frankfurt was the third largest in Europe and tenth largest in the world.

Recce said that it had appointed Deutsche Gesellschaft Für Wertpapieranalyse GMBH as its investor and corporate relations advisor in Europe to "facilitate engagement with prospective investors in ... Germany, Austria and Switzerland, while driving awareness of Recce's novel synthetic anti-infective compounds".

Recce fell one cent or 0.95 percent to \$1.04.

NANOSONICS

Sydney's Selector Funds Management says it has ceased it substantial shareholding in Nanosonics.

Selector said it that between November 26, 2019 and February 22, 2021 it bought, sold and transferred shares, but did not disclose the prices of the transactions as required under the Corporations Act.

RACE ONCOLOGY

Race chief scientist officer and director Dr Daniel Tillett says he has increased and been diluted in Race from 8,758,421 shares (8.02%) to 9,200,000 shares (6.95%).

The Sydney-based Dr Tillett said that between October 21, 2019 and February 28, 2020 he bought 441,579 shares for \$68,121 or an average of 15.4 cents a share.

Dr Tillet said that between March 12, 2020 and February 19, 2021 he was diluted by capital raisings, share cancellations and the exercise of options (BD: Mar 6, 2020). Race was up seven cents or 2.3 percent to \$3.15 with 743,779 shares traded.

CRYOSITE

Cell Care Australia says it has reduced its substantial shareholding in Cryosite from 8,695,000 shares (18.55%) to 8,172,607 shares (17.44).

The Melbourne-based Cell Care said that between February 16 and 23, 2021 it sold shares at prices ranging from 21.21 cents to 27.83 cents.

Cryosite fell one cent or 4.4 percent to 21.5 cents.

NOXOPHARM

Noxopharm founder Dr Graham Kelly says he has reduced his holding from 37,002,294 shares (14.43%) to 28,162,294 shares (10.57%) to exercise IPO options.

The Noxopharm chief executive officer said that through Milligene Pty Ltd for the GE and PR Kelly Family Trust, he sold 8,840,000 shares for \$5,746,000 or 65 cents a share In a separate announcement Noxopharm said that Dr Kelly sold the shares to overseas institutional investors, primarily to fund the exercise of pre-initial public offer investor options due to expire on February 28, 2021.

The company said that Dr Kelly would remain the largest shareholder.

According to the company's most recent Appendix 2A application for quotation announcement, there were 12,325,000 unlisted options exercisable at 30 cents each by February 28, 2021.

Noxopharm fell five cents or 6.85 percent to 68 cents with 5.5 million shares traded.

BIONOMICS

Apeiron Investment Group and Christian Angermayer say they have reduced their Bionomics holding from 81,500,000 shares (13.015%) to 75,833,000 shares (10.31%). Malta's Apeiron and London's Mr Angermayer said that on October 22, 2020 they bought 2,333,000 shares at four cents each in a proposed \$22 million capital raising, including \$5,433,320 from a two-tranche agreement with Apeiron (BD: Jun 2, 2020). They said that they sold 8,000,000 shares on February 24 at 39.7 cents and share. Bionomics fell 5.5 cents or 14.9 percent to 31.5 cents with 2.8 million shares traded.