Biotech Daily

Wednesday February 15, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRESCIENT UP 10%; ANTISENSE DOWN 7%**

*** COCHLEAR H1 REVENUE UP 8% TO $885m, PROFIT DOWN 16% TO $142m; BUYBACK**

*** PRO MEDICUS H1 REVENUE UP 28% TO $57m, PROFIT UP 32% TO $27m**

*** HYDRIX: TGA 'NOT GOING TO ACCEPT' GUARDIAN HEART WARNING DEVICE**

*** QUEENSLAND UNI WINS LEDUCQ $8m FOR STREP A mRNA VACCINE**

*** MONASH TRIALS GLYPH LYT-300 FOR ANXIETY, POST-PARTUM DEPRESSION**

*** ANTERIS RAISES $35m, CANCELS $50m DRAW-DOWN EQUITY FACILITY**

*** ZELIRA: CANTHEON $12.4m FOR HOPE MARIJUANA TRIALS**

*** MEDIBIO $1.25m PLACEMENT 'COMMITMENTS', PLAN FOR $1.5m MORE**

*** MAYNE DILTIAZEM, DORYX US LAUNCHES; REVENUE REVISION**

*** LITTLE GREEN APPROVAL FOR PSILOCYBIN DEPRESSION TRIAL**

*** POLYNOVO NOVOSORB SYNPATH FOOT ULCER TRIAL DELAY**

*** PROTEOMICS EXTENDS APACOR BRITAIN PROMARKERD DEAL**

*** CLINUVEL MANUFACTURES 'PRENUMBRA INSTANT' FOR STROKE**

*** BOTANIX DENIES SWEATING PROFIT FORECAST, RETRACTS 'SCENARIOS'**

*** RHYTHM RETAINS ISO13485:2016 FOR COLOSTAT TEST**

*** CRESO REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** CRESO TO RELEASE 134.1m VOLUNTARY ESCROW SHARES**

*** L1 TAKES 11% OF ANTERIS**

*** SERVATUS APPOINTS EILIS QUINN DIRECTOR**

*** ANTEO APPOINTS TSUI MIN LIAN MARKETING HEAD**

MARKET REPORT

The Australian stock market fell 1.06 percent on Wednesday February 15, 2023, with the ASX200 down 78.7 points to 7,352.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell and 10 traded unchanged.

Prescient was the best, up one cent or 10 percent to 11 cents, with 1.1 million shares traded. Nova Eye climbed eight percent; Cochlear improved 7.75 percent; Cyclopharm and Resonance rose more than three percent; Impedimed, Nanosonics and Next Science were up more than two percent; Clinuvel, Emvision, Paradigm, Universal Biosensors and Volpara were up by more than one percent; with Pro Medicus and Resmed up by less than one percent.

Antisense led the falls, down 0.7 cents or seven percent to 9.3 cents, with one million shares traded. Cynata lost 6.15 percent; Dimerix, Genetic Signatures, Patrys and Pharmaxis fell more than three percent; Actinogen, Medical Developments, Oncosil and Telix shed more than two percent; Immutep, Orthocell and Proteomics were down more than one percent; with Avita, CSL, Neuren, Opthea and Polynovo down by less than one percent.

COCHLEAR

Cochlear says that revenue for the six months to December 31, 2022 was up 7.9 percent to $885,200,000 with net profit after tax down 16.4 percent to $141,600,000.
Cochlear said that sales revenue increased nine percent “driven by strong growth in cochlear and acoustic implant revenue” with cochlear implants sales up 12.05 percent to $513.1 million, and service sales, including sound processor upgrades up 0.8 percent to $258.6 million, with the acoustics division including bone conduction and acoustic implants up 19.8 percent to $120.9 million.
Cochlear said Americas revenue was up 14.4 percent to $444.5 million, Europe, Middle East and Africa sales were $286.7 million, with the Asia Pacific up 15.2 percent to $161.4 million.
Cochlear said that an interim dividend of $1.55 a share, franked at 54 cents, for shareholders on the record date of March 22 would be paid on April 14, 2023, compared to an unfranked $1.55 interim dividend a share for the six months to December 31, 2021.
The company said research and development expenditure was up 4.05 percent to $102,600,000 or 11.0 percent of total revenue.
Cochlear said that that it expected net profit for the year to June 30, 2023 to “be weighted to the second half driven by the rollout of the Nucleus 8 Sound Processor,” which launched in October, 2022.
The company said diluted earnings per share fell 16.35 percent to $2.153 with net tangible assets per share down 2.6 percent to $19.869 compared to the previous corresponding period, and it had cash and cash equivalents of $521,700,000 at December 31, 2022 compared to $553,100,000 at December 31, 2021.
The company said that it “intends to buy-back up to $75 million” of its shares under an on-market buy-back starting March 8, 2023 and finishing March 7, 2023.
According to its most recent filing, Cochlear had a total of 65,781,532 shares on offer.
Cochlear climbed $16.20 or 7.75 percent to $225.28 with 245,980 shares traded.

PRO MEDICUS

Pro Medicus says revenue for the six months to December 31, 2022 was up 28.3 percent to $56,887,000 with net profit after tax up 31.5 percent to $27,189,000.
Pro Medicus said that revenue came from sales of its Visage 7 imaging platform, picture archiving communications systems and radiology information systems.
The company said a fully franked interim dividend of 13.0 cents a share for holders at the record date of March 3 would be paid on March 24, 2023, compared to a fully franked interim dividend of 10.0 cents a share in the previous corresponding period.
Pro Medicus chief executive officer Dr Sam Hupert said the company was pleased with its financial metrics and it improved “strongly against a difficult macro-economic backdrop”.
“Completing three large-scale implementations in Novant Health, Allina Health and Inova Health in the first half sets us up for a step change in transaction volumes in the second half as we will get a full six months of transaction revenues from these three sites,” Dr Hupert said.
“The other positive was that whilst North America is our key market and we continued our growth trajectory there, we also saw improvements in Australia and an underlying improvement in Europe, so the improvement was across the board,” Dr Hupert said.
Pro Medicus said diluted earnings per share rose 31.7 percent to 25.96 cents, with net tangible assets per share was up 33.3 percent to 84 cents and cash and equivalents of $65,470,000 at December 31, 2022 compared to $56,952,000 at December 31, 2021.
Pro Medicus was up 42 cents or 0.65 percent to $65.47 with 383,618 shares traded.

HYDRIX

Hydrix says the Australian Therapeutic Goods Administration has told it that its application for its Angel Medical Systems Guardian “is not going to be accepted”.

In 2021, Hydrix said that it had applied to have the Eatontown, New Jersey-based Angel Medical’s Guardian cardiac arrest warning device included on the Australian Register of Therapeutic Goods (BD: Jun 28, Jul 21, 2021).

At that time, the company said it made the application to the Australian Therapeutic Goods Administration following the US Food and Drug Administration pre-market approval for the device and its new upgraded battery, with TGA approval expected “by early 2022”.

Today, Hydrix said it had not yet received “formal notice” of the decision of the TGA and that the outcome would “not impact current revenue and earnings”.

The company said that the TGA advised that Angel Medical’s clinical evidence “did not demonstrate that the patient benefits sufficiently outweighed the risks of an implanted device using a pacemaker lead to monitor the heart signal to detect and alarm a patient of a life-threatening situation”.

Hydrix said that the TGA had granted it until February 27, 2023 to consider its response, and that it would evaluate the matters raised and alternate pathways to seek TGA approval.

Hydrix executive chair Gavin Coote said “the TGA’s view came as a surprise and was not the outcome we were expecting, given FDA approval endorsed the safety and efficacy of the Guardian device, concluding the benefits outweighed the risks, based on the same information provided to the TGA”.

“It is an unfortunate setback for Australian [acute coronary syndrome] patients who would benefit from the device and we will continue to make the case for them as we seek to find an approval pathway with the TGA,” Mr Coote said.

Hydrix said that Australia was one of eight countries where it had exclusive rights to distribute the Guardian device and had begun commercialization in Singapore and Malaysia, where eight successful implants have been completed.

Hydrix fell 0.95 cents or 16.2 percent to 4.9 cents with 3.05 million shares traded.

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says it has $8 million from the Paris-based Leducq Foundation to develop an mRNA vaccine against group A Streptococcus.

The University said there was no vaccines for prevention of group A Streptococcus (strep A) but “efficacy data from the team’s pre-clinical studies was promising”.

The University said that Streptococcus A bacteria caused “strep throat” and scarlet fever, and was a major driver of antibiotic use in children.

The University of Queensland said that repeated infections could lead to rheumatic heart disease which was “the most significant cause of childhood death due to heart failure”.

The University of Queensland’s Prof Mark Walker said “the support from the Leducq Foundation will allow us to build on research already underway … where we have been collaborating with Moderna to develop an mRNA vaccine against Strep A”.

Leducq chief scientific officer Dr David Milan said “Leducq is excited about the potential of a Strep A mRNA vaccine to significantly reduce not only strep throat infections but subsequent rheumatic heart disease, a major source of mortality worldwide, especially in low- and middle-income countries”.

MONASH UNIVERSITY

Monash University says it will begin a 50-volunteer, phase IIa, placebo-controlled, proof-of-concept trial of LYT-300 for social anxiety trial by July 2023.
The University said that with Boston's Puretech Health, it developed the Glyph technology to enable the oral administration of drugs with low oral bioavailability and LYT-300 was the oral form of allopregnanolone, marketed as Zulresso for post-partum depression.
Monash University said it would begin a phase IIa, open-label, proof-of-concept study in women with post-partum depression after June 2023.
The University said that allopregnanolone was the only US Food and Drug Administration-approved medication for post-partum depression and had been shown to be effective for the treatment of depression and potentially other neurological conditions, but its use was "limited by negligible oral bioavailability and it is currently only approved as a 60-hour intravenous infusion" which was likely to limit use.
Monash University said that the LYT-300 trial was "the first clinical validation of the Glyph technology in humans".
The University said the platform was developed by Prof Chris Porter and his team at the Monash Institute of Pharmaceutical Sciences and used lipid absorption pathways, targeting drug absorption to the lymphatic system and away from the liver, providing patients an opportunity to switch from intravenous administration to an oral capsule.

ANTERIS TECHNOLOGIES

Anteris says following its $35 million placement at $24.00 a share, it will not proceed with a $50 million standby equity purchase agreement with Yorkville Advisors Global.
Last week, Anteris said it expected to have a $50 million standby equity purchase agreement with the Mountainside, New Jersey-based Yorkville (BD: Feb 6, 2023).
Anteris fell seven cents or 0.3 percent to $22.03.

ZELIRA THERAPEUTICS

Zelira says Cantheon Capital LLC will provide $US8.6 million ($A12.4 million) for phase II and III trials of its Hope marijuana product for autism.
Last year, the company said "almost 70 percent" of 45-patients in its observational trial of its Hope marijuana for autism spectrum disorder had at least "moderate" therapeutic effects (BD: May 17, 2022).
In November 2020, Zelira said it and Emyria had a real-world data agreement for an up to 150-patient observational trial of Zelira's Hope marijuana for autism (BD: Nov 9, 2020).
Today, Zelira said that the special purpose vehicle, or joint venture subsidiary, with the Dallas, Texas-based Cantheon would see it contribute its Hope product, intellectual property and real-world data for 55 percent equity ownership of the subsidiary.
The company said that "cash investors" would contribute about $36 million to fund the special purpose vehicle in exchange for a cumulative 45 percent equity interest, with Cantheon's initial $US8.6 million interest to be a maximum of 12.93 percent.
Zelira said that it had a mandate with SW4 Advisors to raise the remaining $US26 million required for the trials.
Zelira said that the special purpose vehicle had appointed Ingenu as its contract research organisation.
Ingenu chief executive officer and Cantheon medical advisor Dr Sud Agarwal was previously a director of Incannex (BD: Jun 28, 2022).
Zelira was unchanged at $1.20.

MEDIBIO

Medibio says it has “commitments” for a $1.245 million placement, at 0.15 cents a share, and hopes to raise a further $1.5 million in a partly underwritten share plan.
Medibio said investors would receive one option for every two shares purchased in the placement and plan, exercisable at 0.4 cents by June 15, 2025.
The company said that the share plan, was underwritten by directors David Trimboli and Chris Ntoumenopoulos to $350,000, had a record date of February 14, would open on February 20 and close on April 6, 2023.
Medibio said that CPS Capital Group Pty Ltd was lead manager, broker and corporate advisor to the capital raising.
Medibio was up 0.05 cents or 50 percent to 0.15 cents with 30.4 million shares traded.

MAYNE PHARMA

Mayne says it will launch Diltiazem extended-release capsules and Doryx MPC 60mg in the US and revise dermatology revenue down by $US15 million to $US19 million.
Mayne said that Diltiazem capsules were the generic alternative to Cardizem, a calcium channel blocker used to treat high blood pressure, angina and certain heart arrhythmias.
The company said that Doryx MPC or doxycycline hyclate delayed-release tablets, was a tetracycline-class antimicrobial indicated as adjunctive therapy for severe acne.
Mayne said that 2021-’22 reported net dermatology revenue of $US84 million would be revised down by $US15 million to $US19 million “to reflect an understatement of the co-pay claims provision at June 30, 2022 relating to dermatology inventories in the retail pharmacy customer channel”.
The company said that the adjustment was “related to the timing of revenue recognition and [did] not have an impact on cash in 2021-’22 or 2022-’23”.
Mayne was up three cents or one percent to $2.92 with 414,734 shares traded.

LITTLE GREEN PHARMA

Little Green Pharma says it has ethics approval for a 60-patient, phase II trial of psilocybin with psychotherapy for treatment resistant major depressive disorder.
Little Green said that its wholly-owned subsidiary Reset Mind Sciences would conduct the12-month, single-centre, randomized, open-label, superiority phase II trial examining the efficacy and safety of psilocybin-assisted psychotherapy involving family members compared to standard psilocybin-assisted psychotherapy for adults with treatment resistant major depressive disorder.
The company said the University of Western Australia’s Prof Sean Hood would be the principal investigator, with Edith Cowan University’s Dr Stephen Bright co-investigator.
Little Green said it expected the trial to begin by July 2023 at the Harry Perkins Institute of Medical Research in Perth.
Reset Mind Sciences chief executive officer Shaun Duffy said “we’re focused on testing and refining psychotherapy protocols and developing a network of clinicians with real world experience in the administration of psychedelic assisted psychotherapy”.
“The trial will be one of the first psilocybin assisted therapy trials in Australia and we trust it will contribute meaningfully to the clinical evidence supporting the use of psilocybin and other psychedelics for the treatment of chronic mental illness in Australia,” Mr Duffy said.
Mr Duffy said the company expected the trial evidence to be “highly instructive” for patients under changes announced by the Australian Therapeutic Goods Administration.
Little Green fell 0.5 cents or 2.4 percent to 20 cents.

POLYNOVO

Polynovo says slow enrolments have delayed its 138-patient, randomized, controlled, safety and efficacy trial of Novosorb Synpath for chronic diabetic foot ulcers.
Polynovo said that the trial had enrolled 25 patients and the previous guidance of completing enrolment by April 2023 had been extended to “early 2H CY23” meaning the period from July 1 and December 31, 2023 (BD: Aug 10, 2022).
Polynovo fell one cent or 0.4 percent to $2.26 with 1.2 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has extended its distribution agreement with the Wokingham, England-based Apacor for its Promarkerd test for diabetic kidney disease to Great Britain.
In 2021, Proteomics said it had a two-year exclusive distribution agreement with the Apacor for its Promarkerd diagnostic in Great Britain (BD: Nov 23, 2021).
Today, the company did not disclose the commercial terms of the agreement but said both companies agreed to an additional five-year term, expiring on January 31, 2028.
Proteomics said that with Apacor it would focus on the inclusion of Promarkerd in the National Institute for Health and Care Excellence guidelines and to engage with the National Health Services supply chain tender process for commercial roll-out in the UK.
Proteomics fell 1.5 cents or 1.4 percent to $1.045.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has completed the manufacture of its Prenumbra Instant sub-cutaneous liquid injectable treatment for arterial ischaemic stroke.
Last year, Clinuvel said it intended to develop the Prenumbra Instant (afamelanotide) as a treatment for arterial ischaemic stroke, after five of six stroke patients in a pilot study had improved neurological functions, with no adverse reactions (BD: Mar 15, Jul 28, 2022).
Today, the company said it had completed the current good manufacturing practice standard for Prenumbra Instant and would submit regulatory dossiers in the US and EU.
Clinuvel was up 28 cents or 1.2 percent to $23.88.

BOTANIX PHARMACEUTICALS

Botanix says executive director Matthew Callahan did not say sofpironium bromide for sweating would generate $144 million to $288 million in profit a year.
Botanix said the Seven West media-owned West Australian newspaper reported on its sofpironium bromide for hyperhidrosis or excessive sweating.
The company said the article “incorrectly attributes a forecast for the product’s profits to … Mr Callahan, that the product ‘would generate anywhere between $US100 million to $US200 million in profit a year’.”
“Mr Callahan did not make that forecast at the recent JP Morgan conference, or at all,” Botanix said.
Botanix said the numbers appeared to have been taken from the most recent investor presentation on January 31, 2023 and the slide ‘US market opportunity for hyperhidrosis’ which set out “various scenarios for potential market share and … potential gross sales”.
“To the extent that these scenarios could be considered a financial forecast, Botanix retracts the scenarios and examples sales figures given,” the company said. “Botanix does not have a reasonable basis for making a sales forecast at this stage.”
Botanix was up 0.3 cents or 4.7 percent to 6.7 cents with 11.0 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says the International Organisation for Standardisation has maintained its ISO13485:2016 for its Colostat blood test to detect colorectal cancer.
Rhythm said the British Standards Institution had provided the ISO13485:2016 certification, the international standard of quality systems for medical device manufacturers.
Rhythm was unchanged at 95 cents.

CRESO PHARMA

Creso has requested a trading halt “pending an announcement regarding a capital raising”.
Trading will resume on February 17, 2023 or on an earlier announcement.
Creso last traded at 1.8 cents.

CRESO PHARMA

Creso says it will release 134,105,335 shares from voluntary escrow on February 26, 2023.
According to its most recent filing, Creso said that it had a total of 1,958,847,517 shares on issues, with no shares in ASX escrow and further shares in voluntary escrow, due to be released on August 26, 2023 and January 10, 2024.

ANTERIS TECHNOLOGIES

L1 Capital Pty Ltd says it has increased its substantial share-holding in Anteris from 1,137,029 shares (8.39%) to 1,526,756 shares (10.98%).
Last week, Anteris said it has raised $35 million in a placement at $24.00 a share, “corner-stoned” by its two largest holders, Perceptive Advisors and L1 Capital, subscribing “beyond their existing pro-rata shareholding” (BD: Feb 9, 2023).
Today, the Melbourne-based L1 Capital said that from March 17 to July 20, 2022 it sold shares and on February 10, 2023 bought 427,084 shares for $10,250,016 or $24.00 a share.

SERVATUS

The Coolum Beach Queensland Servatus says it has appointed Eilis Quinn as a non-executive director.
Servatus said that it was developing autoimmune and microbiome therapies and Ms Quinn had more than 25 years’ experience in the healthcare industry in business and commercial strategy.
The company said that Ms Quinn was currently Jazz Pharmaceuticals general manager for Australia and New Zealand and previously worked for Vertex Pharmaceuticals.
Servatus chief executive officer Dr Wayne Finlayson said that Ms Quinn brought “extensive commercial leadership experience within the global biotech and pharmaceutical industries”.
The company said that Ms Quin held a Bachelor of Science from Northern Ireland’s University of Ulster, a Master of Arts from the UK’s University of Sheffield and a Master of Science from London’s University of Westminster.
Servatus is a public unlisted company.

ANTEOTECH

Anteo says it has appointed Tsui Min Lian as its chief marketing officer, effective from March 15, 2023.

Anteo said that Ms Lian was an “experienced sales and marketing leader” and had previously worked for General Electric, Resmed and Toll Group.

The company said that Ms Lian held a Bachelor of Science from the University of London, and a Master of Business Administration from the University of Adelaide.

Anteo was unchanged at 4.8 cents with 1.4 million shares traded.