Biotech Daily

Wednesday March 15, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NEUREN UP 19%; PROTEOMICS DOWN 13%**

*** ZELIRA RAISES $1.8m**

*** DORSAVI TO RAISE $750k**

*** QBIOTICS CLOSES MELANOMA TRIAL; LOSES NICHOLAS MOORE**

*** SYMBIO MELBOURNE 'LARGEST TESTING LAB IN STHN HEMISPHERE'**

*** PROTEOMIC: MSAC DENIES PROMARKERD APPLICATION**

*** INCANNEX: DSMB OKAYS PSYLOCIBIN ANXIETY TRIAL**

*** ANALYTICA TELLS ASX: H1 REPORT COMPLIES, GOING CONCERN**

*** NEUROTECH REQUESTS 'MARIJUANA AUTISM DATA' TRADING HALT**

*** PINNACLE TAKES 5.2% OF NANOSONICS**

*** HEALTHCARE 2030, BERGEN, TABLIS REDUCE TO 6% OF NUHEARA**

*** NUHEARA APPOINTS LEROY LIU DIRECTOR**

MARKET REPORT

The Australian stock market rose 0.86 percent on Wednesday March 15, 2023, with the ASX200 up 60.0 points to 7,068.9 points. Twenty-one of the Biotech Daily Top 40 stocks climbed, nine fell, eight traded unchanged, two were untraded. All three Big Caps were up.

Neuren was the best, up $1.93 or 19.6 percent to $11.90, with 3.3 million shares traded, following a report on trofinetide pricing. Prescient climbed 14.3 percent; Micro-X, Patrys and Pharmaxis improved more than four percent; Avita and Clinuvel were up more than three percent; Atomo, Mesoblast, Nova Eye, Orthocell, Pro Medicus, Starpharma and Volpara rose more than two percent; Cochlear, CSL, Emvision, Impedimed, Next Science, Polynovo, Resmed and Telix were up more than one percent; with Nanosonics and Opthea up by less than one percent.

Proteomics led the falls, down 12 cents or 13.2 percent to 79 cents, with 505,426 shares traded. Oncosil lost 6.1 percent; Actinogen and Imugene fell four percent or more; Kazia was down 3.6 percent; Antisense, Medical Developments and Universal Biosensors shed two percent or more; with Genetic Signatures down by 0.6 percent.

ZELIRA THERAPEUTICS

Zelira says it has raised $1.77 million from US investors in a placement at $1.00 a share, a three percent discount to the 15-day volume weighted average price to March 10, 2023.
Zelira said the funds would provide “additional working capital for Zelira to further progress its ongoing strategies of 'multiple shots on goal' for its proprietary formulations, such as Hope 1, through formal [US Food and Drug Administration] clinical trials”.
Zelira chief executive officer Dr Oludare Odumosu said the placement “reflects ongoing confidence by investors in our various strategies and the progression of our efforts to build meaningful long-term value for our investors, shareholders and patients”.
Last year, Zelira conducted a 175-to-one consolidation (BD: Apr 12, 2022).
Zelira was up two cents or two percent to $1.02.

DORSAVI

Dorsavi says it has commitments to raise $750,000 in a placement at 1.10 cents a share, a 7.7 percent discount to the 10-day volume weight average price to March 10, 2023.
Dorsavi said the funds would be used to “further develop the sales pipeline for both the workplace and clinical markets, and for general working capital purposes including to help fast track sales cycles”.
Dorsavi chief executive officer Dr Andrew Ronchi said the funds would “shore-up our financial position as we look to accelerate our revenue growth, win new contracts, and deliver greater operating leverage”.
The company said that Sixty Two Capital Pty Ltd was the lead manager to the placement.
Dorsavi was unchanged at 1.2 cents.

SYMBIO LABORATORIES

The Brisbane based Symbio says that tomorrow it will open “the largest testing laboratory in the Southern Hemisphere” in Ravenhall in Melbourne’s Western suburbs.
Symbio said the 8,600sqm, (2.1 acres, 92,570 square feet) three-level laboratory will offer on-site internship and traineeship programs for students for pharmaceutical, food, agriculture and environmental testing.
Symbio managing-director Bruce Chen said the company was “committed to investing in the future of the industry by providing quality education and training opportunities in a facility leading the world in scientific testing”.
“The new facility in Ravenhall is not just about providing cutting-edge analytical services, it's also about nurturing the next generation of scientists,” Mr Chen said.
The company said the laboratory would create 200 jobs over three years “and make Melbourne’s west the epicentre of world-leading scientific research and development”.
Symbio said it provided rapid turnaround, analytical testing of pharmaceuticals, food, agriculture, cosmetics, water and environmental samples, with about 8,000 Australian clients, conducting 35,000 tests on more than 11,000 samples each week.
The company said that about 40 percent of the Ravenhall laboratory would be dedicated to research and development, including plans to genetically map human illnesses for the development of rapid tests to detect viruses before they can evolve and become resistant to specific drug treatments, as well as tests providing early diagnosis of cancers, such as breast and ovarian cancers and chronic myeloid leukaemia.
Symbio said the laboratory would develop genome sequencing and polymerase chain reaction (PCR) based tests.
Symbio is a private company.

QBIOTICS GROUP

In an announcement on its website dated February 14, 2023, Qbiotics says it has closed its melanoma trials and non-executive director Nicholas Moore has resigned.

In 2021, Qbiotics said it had dosed the first of up-to 25 patients in a phase Ib/IIa study of oncology molecule tigilanol tiglate, or EBC-46, with Keytruda from the Kenilworth, New Jersey-based Merck and Co for unresectable melanoma and completed a $22.5 million placement (BD: Aug 13, 2020; Jun 3, 2021).

On its website, the company said that following the announcement of the closure of its clinical trial in melanoma at the Melanoma Institute of Australia on December 11, 2022, Qbiotics "completed a full review of its human clinical oncology program … [and] as a result, the company has resolved to discontinue development in melanoma with tigilanol tiglate, and thus close both melanoma clinical trials at all sites.

Today, Qbiotics managing-director Dr Victoria Gordon told Biotech Daily that the decision to close the trial "was a business decision rather than a decision about development of the drug".

"As such we did not consider it to be of overall impact," Dr Gordon said.

"We just could not recruit patients into our two melanoma trials," Dr Gordon said.

"Melanoma is the focus indication in the oncology world at the moment and Australia is where the patients are; as such the competition is fierce," she said.

"While not being able to recruit patients we were still paying the contract research organization a significant amount while the sites were open," Dr Gordon said.

"The costs of keeping trial sites open for the melanoma trials without recruiting patients were eroding budget provisions with no tangible benefits delivered," Dr Gordon said.

"[It was] effectively dollars running out the door without any value being created," Dr Gordon said.

"We believed that it was in the best interest of the company to refocus resources on our head and neck cancer phase II trial in the UK and Australia … and our soft tissue sarcoma phase II trial in the US," Dr Gordon said.

On the company website Dr Gordon said that "competition for recruiting patients with melanoma for clinical trials in Australia is very high and is unlikely to improve in the short to medium term".

"In closing the melanoma trials, we are able to prudently refocus our resources on other solid tumor indications, with greater potential to meet major milestones in a more timely and cost effective manner," Dr Gordon said.

Qbiotics said it had identified head and neck cancer and soft tissue sarcoma as the primary preferred indications for demonstrating clinical efficacy of tigilanol tiglate.

In 2020, Qbiotics said it had dosed the first Australian and fifth patient in its up-to 40-patient, phase I/II trial evaluating the dose and safety of tigilanol tiglate for head and neck squamous cell carcinoma, with four patients treated in India (BD: Jul 22, 2020).

In February, Qbiotics said the melanoma program comprised two clinical trials: the tigilanol tiglate monotherapy study QB46C-H04, and the tigilanol tiglate pembrolizumab combination study QB46C-H06 and both would be discontinued.

The company said it would "refocus resources on the head and neck cancer phase II trial … in the UK and Australia, and which is now open for recruitment, and the soft tissue sarcoma phase II trial … in the US and due to open by July 2023".

Qbiotics said it was "in discussions relating to a clinical trial of tigilanol tiglate in combination with the immune check point inhibitor drug pembrolizumab for the treatment of head and neck cancer".

Qbiotics is a public unlisted company.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says Australia's Medical Services Advisory Committee (MSAC) has denied its application for Promarkerd to be included on the Medicare Benefits Schedule.
Proteomics said the Committee was "primarily concerned about the cost of the test and the lack of sufficient data on how use of Promarkerd would change clinical practice, which the company will now work to address".
The company said MSAC acknowledged that the Promarkerd predictive test for diabetic kidney disease (DKD) could save the healthcare system money in the long term.
Proteomics said the UK's National Institute for Health and Care Excellence (NICE) had published a briefing supporting Promarkerd's effectiveness and the American Medical Association had issued Promarkerd a dedicated current procedural terminology code.
Proteomics said its separate regulatory approval application lodged to the Australian Therapeutic Goods Administration was "ongoing".
The company said peer-reviewed studies showed Promarkerd was effective and if available would help clinicians manage diabetes patients.
Proteomics said that the Committee identified a potential wide uptake of the test, and that "in the long term, the use of Promarkerd was predicted to lead to lower … costs due to the prevention or delay of onset of DKD, primarily through the avoidance of procedures such as dialysis and kidney transplants along with associated medication costs".
Proteomics managing director Dr Richard Lipscombe said that the "home grown innovation has traction in both the US and UK, and whilst Australia is not a major market for us in terms of size, we do not want to see the Australian public forced to either pay for Promarkerd out of their own pockets or miss out on the potentially life-saving test".
Dr Lipscombe said the company looked forward to re-engaging with the MSAC to address concerns and clarify any misunderstandings.
Proteomics fell 12 cents or 13.2 percent to 79 cents.

INCANNEX HEALTHCARE

Incannex says the data safety monitoring board review of 37 of patients in its phase II trial of psilocybin for generalized anxiety disorder recommends no changes.
Incannex said that taking data from the first 29 of the up-to 72 patients in its placebo-controlled trial of psilocybin for anxiety, the data analysis showed a "greater than 85 percent chance" that the study would attain the 95 percent statistically significant marker.
The company said an independent study by the DSMB of the 37 enrolled patients identified no safety concerns and recommended the trial continue without change.
Incannex chief executive officer and managing director Joel Latham said the results provided encouragement that "psilocybin-assisted psychotherapy treatment protocol has the potential to transform the lives of people suffering from anxiety".
"Even though the results must remain blinded until the conclusion of the trial, the confidential review has given us the confidence to commence manufacture of our own psilocybin drug product", Mr Latham said.
Mr Latham said the results also gave Incannex confidence to progress its pivotal trials and begin drafting a US Food and Drug Administration investigational new drug application for psilocybin for generalized anxiety disorder.
"The clinical psychedelic lab at Monash University has overseen training of 14 psychotherapists to work on the phase II trial, demonstrating that this transformational treatment is scalable to many therapists and patients throughout the world," Mr Latham said.
Incannex fell one cent or 6.9 percent to 13.5 cents with 10.6 million shares traded.

ANALYTICA

Analytica has told the ASX that it has sufficient cash to continue as a going concern and its half year report complies with accounting standards.
Earlier this month, the ASX said Analytica had been suspended from quotation due to failure to lodge their relevant periodic reports by the due date (BD: Mar 1, 2023).
Today, Analytica told the ASX it had forecast cash until February 2024 based on existing loan facilities, a planned capital raise and revenue from agreements in the US for the sale and distribution of its intra-vaginal Pericoach sensor system for pelvic floor strengthening.
The company said in its annual corporate governance statement from September 21, 2022 it said its board took on the role associated with an audit committee which included overseeing its risk management framework.
Analytica said its half year report auditor was not satisfied with the evidence given for why it continued to be a going concern due to the “absence of signed agreements and confirmed orders”.
Analytica said it had received chief executive officer and chief financial officer declarations and assurances that financial records had been maintained in accordance the Corporations Act and complied with accounting standards.
Analytica was in a suspension at 0.1 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has requested a trading halt “pending the release of the final 54-week safety and efficacy data from its phase I/II trial in autism spectrum disorder”.
Last year, Neurotech said that the 20-week data from its 14-patient, phase I/II trial of its medical marijuana NTI164 showed “statistically significant efficacy” in children with autism (BD: Oct 26, 2022).
Trading will resume March 17, 2023, or on an earlier announcement.
Neurotech last traded at 5.8 cents.

NANOSONICS

Pinnacle Investment Management Group says it has become substantial in Nanosonics, with 15,552,871 shares (5.15 percent).
The Sydney-based Pinnacle said that between November 14, 2022 and March 9, 2023 it bought and sold shares in Nanosonics in 22 transactions, with the single largest purchase on February 9, 2023 of 940,671 shares for $4,338,187 or $4.61 a share.
Nanosonics was up four cents or 0.8 percent to $4.90 with 1.6 million shares traded.

NUHEARA

Healthcare 2030 and associates say they have reduced theirs substantial holding in Nuheara from 12,192,555 shares (7.92%) to 10,415,000 shares (6.07%).
The Boca Raton, Florida-based Healthcare 2030, Bergen Global Opportunity Fund and Eugene Tablis said that from January 13 to March 14, 2023 they sold 1,777,555 shares for $345,538, or 19.4 cents a share.
Nuheara was unchanged at 17 cents.

NUHEARA

Nuheara says it has appointed Leroy (Yean-Shao) Liu as a non-executive director, effective from March 15, 2023.

Nuheara said Mr Liu was currently chief strategy officer at Realtek Semiconductor Corp and previously was Asia Pacific general manager at Dialog Semiconductor.

The company said Mr Liu held Bachelor oof Science and a Master of Science from National Taiwan University.