Biotech Daily

Tuesday April 5, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ATOMO UP 9%; NEUREN DOWN 5%**

*** MICROBA FALLS 28% ON IPO FOR GUT TESTS, THERAPIES**

*** RESONANCE: CARPL TO VALIDATE FERRISMART, HEPAFAT-AI**

*** TRUSCREEN 'SUPERIOR FOR CERVICAL CANCER SCREENING'**

*** PRESCIENT OPENS PTX-100 T-CELL LYMPHOMA EXPANSION COHORT**

*** AVITA: '15 RECELL PRESENTATIONS FOR BURNS TREATMENT'**

*** NEUROTECH: MARIJUANA NTI164 'SAFE, TOLERABLE'**

*** ADALTA INHALED AD-214 PRE-CLINICAL WORK 'ON-TRACK'**

*** INOVIQ HIRES RESEARCHDX TO DEVELOP SUB-B2M CANCER TEST**

*** TOTAL BRAIN TO ISSUE $1.3m CONVERTIBLE NOTES TO ZOLTAN VARGA**

*** BIOTRON RECEIVES $1.6m FEDERAL R&D TAX INCENTIVE**

*** AROVELLA: ANAGRELIDE FOR CANCER US PATENT**

*** VGI: US PATENT FOR TOCOTRIENOL DELIVERY**

*** CLARITY: GREEN CFO, VICKERY CO SEC, DR IAGARU ADVISER**

MARKET REPORT

The Australian stock market was up 0.19 percent on Tuesday April 5, 2022, with the ASX200 up 14.2 points to 7,527.9 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 15 fell and four traded unchanged.

Atomo was the best, up one cent or 8.7 percent to 12.5 cents, with 1.7 million shares traded. Dimerix climbed 6.1 percent; Paradigm was up 5.9 percent; Antisense, Imugene, Polynovo and Resonance rose four percent or more; Clinuvel, Mesoblast, Nanosonics, Nova Eye, Pro Medicus and Prescient were up more than three percent; Avita, Kazia and Opthea improved more than two percent; Cyclopharm, Immutep, Medical Developments, Proteomics and Uscom were up one percent or more; with CSL up 0.3 percent.

Neuren led the falls, down 22 cents or 5.3 percent to $3.98, with 157,168 shares traded. Alcidion, Micro-X, Next Science and Patrys fell four percent or more; Orthocell and Telix lost more than three percent; Emvision, Oncosil and Starpharma shed more than two percent; Compumedics, Cynata, Resmed, Universal Biosensors and Volpara fell more than one percent; with Cochlear and Genetic Signatures down less than one percent.

MICROBA

Microba opened down 2.2 percent at 44 cents, following a successful $30 million at 45 cents a share, falling as much as 27.8 percent to 32.5 cents.

In February, Microba said it hoped to raise the funds to list on the ASX under the code MAP to test gut microbiome and develop therapies for diseases (BD: Feb 22, 2022).

According to the Microba prospectus, its technology measured the human gut microbiome for consumers, clinicians and researchers, which assisted the discovery and development of therapeutics for chronic diseases, including for inflammatory bowel disease.

Microba said it had sold more than 20,000 microbiome test reports to date, had distribution partners in the US, Europe, Middle East, Australia, and New Zealand, and planned to start a phase I trial for inflammatory bowel disease in December 2022.

Microba said that its core technology was developed by Prof Philip Hugenholtz and Prof Gene Tyson, it was formed in 2017 and acquired intellectual property from the University of Queensland that formed the basis of its analysis platform.

The company said that its pre-offer indicative market capitalization was $93 million.

Microba said its chair was Pasquale Rombola, Prof Ian Frazer was its deputy chair, with directors including Prof Tyson, Dr Caroline Popper, Dr Hyungtae Kim and Richard Bund; and its chief executive officer was Dr Luke Reid.

Microba closed down 10 cents or 22.2 percent at 35 cents with 4.3 million shares traded.

RESONANCE HEALTH

Resonance says Carpl will licence its Ferrismart and Hepafat-AI (artificial intelligence) magnetic resonance imaging-based liver imaging systems, validating the technologies.

Resonance said that the agreement with the New Delhi, India-based Carpl, would provide it with a licence to access Ferrismart and Hepafat-AI in the US, Brazil, India, Canada and Australia, allowing healthcare professionals to compare their current imaging diagnosis methods with artificial intelligence-assisted software medical systems.

The company said that its devices would be held in an internet “cloud” environment administered and controlled by it and de-identified data would be exchanged between Carpl and Resonance through secure transfer methodology.

Resonance said that Carpl would be compensated through commissions on sales achieved through its Caring Analytics Platform and that sales proceeds would be collected by Carpl and paid to Resonance each month.

Carpl chief executive officer Dr Vidur Mahajan said that “with the [artificial intelligence] ecosystem, and thereby the number of [artificial intelligence] applications for radiology, growing at an exponential pace, it is nearly impossible for hospitals and imaging centres to have techno-commercial relationships with tens, if not hundreds of developers”.

“Carpl serves as the single integration layer between healthcare providers and [artificial intelligence] developers,” Dr Mahajan said. “Apart from clinical deployment, we also intend to help Resonance Health run validation studies for their algorithms.”

Resonance managing-director Mitchell Wells said the partnership allowed his company to reach markets including India, Brazil, US, Australia and Canada.

“This opportunity also utilizes our new delivery methodology for our [artificial intelligence] services, which sees us moving away from on-premises deployment to controlled cloud-hosting of our devices,” Mr Wells said.

“This enables a singular master version of all our devices to be held in a company-administered and controlled cloud environment … a superior solution and vastly more scalable and cost effective than multiple on-premises deployments” Mr Wells said.

Resonance was up half a cent or four percent to 13 cents.

TRUSCREEN GROUP

Truscreen says a trial comparing its device against two other cervical cancer screening methods has “highlighted the superiority” of its screening method.

Truscreen said the China-based trial of 15,661 women aged 21 and older across 64 teaching hospitals compared human papillomaviruses (HPV) testing and liquid-based cytology (LBC) with Truscreen’s less-invasive electronic and optical system.

The company said that Truscreen’s sensitivity was 87.5 percent compared to cytology’s 66.5 percent, with a “high degree of statistical significance” ($p < 0.001$) and that its specificity was 88.4 percent ($p < 0.001$), higher than both cytology and (86.3%) and high-risk HPV testing (78.3%).

Truscreen said that the trial also used co-testing, carrying out with multiple types of screening tests at the same time, and that the sensitivity of Truscreen with high-risk HPV co-testing was higher than that of LBC with high-risk HPV co-testing at 98.4 percent versus 95.9 percent ($p = 0.006$}.

The Chinese Obstetricians and Gynaecologists Association said the study “highlighted the superiority of Truscreen’s screening method”, Truscreen was “appropriate as a primary screening tool in regions with high morbidity and mortality to cervical cancer … [and] due to resource restrictions, cytology cannot be effective in mass population screening programs in the areas with high morbidity and mortality of cervical cancer … [and] Truscreen minimizes the need for training and facilities and offers a real-time result”.

Truscreen chief executive officer Juliet Hull said that “the validation of our technology … together with the recent national price approval of our Truscreen device have provided opportunities … to further expand distribution of our Truscreen cervical cancer screening technology in China”.

Truscreen was up one cent or 16.7 percent to seven cents.

PRESCIENT THERAPEUTICS

Prescient says it has opened recruitment for up-to 12-patients in the expansion cohort of its phase Ib trial of PTX-100 for T-cell lymphomas.

In 2019, Prescient said it had dosed the first of up-to 24 patients in a trial of PTX-100 for solid and blood cancers and last year said it would develop PTX-100 as a monotherapy for T-cell lymphoma, expanding its phase Ib study, which showed an “excellent” safety profile (BD: Nov 14, 2019; Jul 27, 2021).

Today, the company said the open-label, non-randomized study at Melbourne’s Epworth Hospital, would enrol eight to 12 patients with relapsed and refractory T-cell lymphoma, aiming to complete recruitment by the end of 2022.

Prescient said it would include several patients with cutaneous T-cell lymphoma to provide further insights on drug activity in T-cell lymphomas overall.

Prescient managing-director Steven Yatomi-Clarke said that peripheral T-cell lymphoma was “not a common malignancy, but the nature of the disease and lack of effective treatment options may provide a shorter regulatory path, and the fastest route to market for PTX-100 in a high value area of unmet clinical need”.

“Subject to efficacy observed in this expansion cohort, it may be possible to conduct a subsequent registration study that is smaller and shorter than large phase III studies typically seen in other cancer trials,” Mr Yatomi-Clarke said.

Mr Yatomi-Clarke said he was encouraged by the “excellent” safety profile of PTX-100 and that it was significant because PTX-100 “may have utility in fragile patients that are unable to tolerate other therapies with high toxicities”.

Prescient was up half a cent or 3.3 percent to 15.5 cents with 3.7 million shares traded.

AVITA MEDICAL

Avita says there will be 15 doctor-initiated presentations on its Recell spray-on skin for burns at the American Burn Association meeting in Las Vegas, April 5 to 8, 2022.
Avita said that the presentations would "highlight the clinical and cost-saving benefits of the Recell autologous cell harvesting device" and cover issues such as decreasing preparation time, early post-operative mobilization, impact on length of stay after treatment, partial thickness paediatric burn injuries, timing of applications, catastrophic burn management and comparative analyses.
Avita chief executive officer Dr Mike Perry said that "the depth and breadth of the Recell system data being presented at the …meeting highlights the impact this platform is having on the treatment protocol for burn injuries".
Avita was up five cents or 2.2 percent to $2.37.

NEUROTECH INTERNATIONAL

Neurotech says its ongoing trial of its marijuana-derived NTI164 for paediatric autism spectrum disorder has demonstrated "safety and tolerability".
Neurotech said the open-label study of children between eight and 17 years old with a medical diagnosis of level II and III autism spectrum disorder was evaluating the safety and tolerability of a full-spectrum marijuana product with less than 0.3 percent tetrahydrocannabinol (THC), across the dose regime of 5mg/kg to 20mg/kg in 5mg/kg increments, as well as the efficacy of NTI164 in reducing symptoms such as irritability, hyperactivity, sleep disorders and behavioral crises.
The company said the study had shown safety and tolerability across the dosing regime, no serious adverse events were reported, with positive trends and improvements to patients compared to baseline assessments and improvements in behavioral indicators.
Neurotech said that the trial would be completed by July, with a phase II/III registration directed trial due to begin by October 2022.
Neurotech chair Brian Leedman said that NTI164 "has the potential to introduce to the market a treatment option for paediatric [autism spectrum disorder] which is natural, safe and based on the results to date, offers positive behavioral improvements".
The company said it was in discussions with the Australian Therapeutic Goods Administration to assess product scheduling and classification and it had initiated pre-investigation new drug discussions with the US Food and Drug Administration.
Neurotech fell 0.2 cents or 3.4 percent to 5.7 cents with 4.4 million shares traded.

ADALTA

Adalta says its pre-clinical development work for the inhaled version of AD-214 for fibrotic diseases is "on-track" with results by the end of the year.
Last year, Adalta said it completed its phase I trial of AD-214 at 5mg/kg for idiopathic pulmonary fibrosis and other interstitial lung diseases with no dose limiting issues identified and would progress to efficacy studies of inhaled AD-214 (BD: Jul 19, 2021).
Today, the company said that it aimed to confirm that AD-214 could be delivered to the far airways of the lungs, be retained in fibrotic tissues and modulate the progression of fibrosis.
Adalta said in-vivo and in-vitro studies were underway for AD-214 in an inhaled format, and were due to be completed by October with results expected "across [the] next two quarters".
Adalta was up 0.1 cents or 1.35 percent to 7.5 cents.

INOVIQ (FORMERLY BARD1 LIFE SCIENCES, SIENNA CANCER DIAGNOSTICS)

Inoviq says it has engaged Researchdx to develop and validate its Sub-B2M-based tests for detecting the pan-cancer biomarker Neu5Gc.

In 2020, the then Sienna Diagnostics said it had licenced the B subunit of Subtilase cytotoxin (SubB) from the University of Adelaide which targeted and bound to Neu5Gc, the tumor biomarkers found in multiple human cancers including breast, ovarian, prostate and others (BD: Apr 20, 2020).

Today, Inoviq said that it had an agreement with the Irvine, California-based Researchdx to complete technology transfer, feasibility testing, assay development, analytical and clinical validation of the Sub-B2M-based tests.

The company said that Researchdx would use several variations of the Sub-B2M tests for monitoring breast and ovarian cancer and to detect Neu5Gc concentrations, expected to be completed within six months of the commencement date.

Inoviq said it would pay for the costs of work undertaken and related sample, reagent and consumable expenditure but did not disclose the financial details of the agreement.

Inoviq chief executive officer Dr Leearne Hinch said Researchdx was a contract diagnostic organization with a US-based College of American Pathologists accredited and Clinical Laboratory Improvement Amendments (CLIA) certified laboratory, and was “an ideal partner to help progress the development and commercialization of our Sub-B2M-based tests in the US”.

“This agreement is important as it delivers two milestones-in-one with Researchdx providing accredited [contract research organization] services and being a potential clinical laboratory partner for SubB2M-based lab developed tests in the US,” Dr Hinch said.

Inoviq fell 2.5 cents or 2.9 percent to 83.5 cents.

TOTAL BRAIN

Total Brain says it has entered a convertible note subscription agreement to issue $1,278,485 worth of convertible notes to Zoltan Varga.

Total Brain said the proceeds from the issue would be used to repay the principal and interest of the $US500,000 loan owed to Zoltan Varga and replace the capital repaid to F45 Inc (BD: Mar 30, 2022).

The company said the 1,278,485 notes had a face value of $1.00 each, a conversion price of 13.8 cents a share, which was a 20 percent premium to the closing share price at March 31, 2022, carried an interest rate of 12 percent per annum and a maturity date of 18 months from the issue date.

Total Brain said that assuming the shareholder approval is obtained, the maximum number of shares that the notes might converted to was 10,931,974 shares, leading Zoltan Varga to hold 22.71 percent of the company provided no shares are disposed.

Total Brain fell two cents or 16.7 percent to 10 cents.

BIOTRON

Biotron says it has received $1,558,525 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Biotron said the rebate related to research and development expenditure for the year to December 31, 2021.

Biotron fell 0.1 cents or 1.3 percent to 7.5 cents with 2.6 million shares traded.

AROVELLA THERAPEUTICS

Arovella says the US Patent and Trademark Office has approved its patent for its invariant natural killer T-cell platform for treating blood cancers.
Arovella said the patent, titled 'Use of Anagrelide for Treating Cancer' would protect its intellectual property until December 2035, and would add to granted patents in Europe, Japan and Australia.
Arovella fell 0.1 cents or 2.4 percent to 4.1 cents with 4.5 million shares traded.

VGI HEALTH TECHNOLOGY

VGI says the US Patent and Trademark Office intends to grant it a patent for the transmucosal administration of a tocotrienol for the treatment of muscle soreness.
VGI said that, when granted, the patent, titled 'Transmucosal Delivery of Tocotrienol' would provide commercial rights in the US until November 13, 2032.
The company said that in June 2020, a US patent directed to a method of treating post exercise muscle soreness or delayed onset muscle soreness by transmucosal administration of a tocotrienol was granted.
VGI said that the present divisional patent application extended the coverage to pharmaceutical compositions containing delta tocotrienol which have been formulated for transmucosal delivery and could be used for the treatment or prevention of additional indications such as fibrosis and cancer.
VGI managing-director Dr Glenn Tong said that "the US is one of the highest priority markets for both our drug development program and our nutraceuticals business and we are very pleased with this strengthening of our intellectual property rights coverage internationally".
VGI said that it had corresponding patents in the US, Canada, Japan, the European Union, Australia, New Zealand, Singapore and South Africa.
On the National (formerly Newcastle) Stock Exchange, VGI was untraded at 10 cents.

CLARITY PHARMACEUTICALS

Clarity says it has appointed David Green to replace Robert Vickery as chief financial officer and appointed Dr Andrei Iagaru to its scientific advisory board.
Clarity said that Robert Vickery would continue as company secretary.
The company said that Mr Green had more than 25 years of experience in finance roles, most recently as Ellume's chief financial officer and previously worked for Ernst & Young, Sigma Pharmaceuticals, Chiquita Brands and Alchemia.
Clarity said that Dr Iagaru was a professor of radiology and chief of the nuclear medicine and molecular imaging division at California's Stanford University.
The company said that Dr Iagaru had published more than 200 papers in peer-reviewed journals and other publications.
Clarity was up two cents or 3.2 percent to 65 cents.