



Biotech Daily

Thursday October 19, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ATOMO UP 9%; PATRYS DOWN 12.5%**
- * **AVITA \$143m ORBIMED LOAN, SORB PLUS 8%**
- * **TELIX 9-MONTH REVENUE UP 527% TO \$326m**
- * **TELIX TLX591 'MEANINGFUL PSA REDUCTION' IN PROSTATE CANCER**
- * **PATRYS PAT-DX1, PAT-DX3 'INHIBIT GLIOMA, IN MICE'**
- * **CORRECTION: TESSELLATE BIO**
- * **RHINOMED TERMINATES SURESCREEN DEAL; REVIEW**
- * **VITURA BUYS DOCTORS ON DEMAND FOR \$25m**
- * **MICROBA BUYS INVIVO FOR \$14m; \$20m RIGHTS OFFER**
- * **BIOXYNE, BREATHE LIFE IMPORT 200kg, \$3.2m MARIJUANA**
- * **VOLPARA: ASX LIFTS QUARTERLY REPORTING REQUIREMENT**
- * **AMPLIA RECEIVES \$2.4m FEDERAL R&D TAX INCENTIVE**
- * **PHARMAXIS COMPLETES MANNITOL SALE TO ARNA PHARMA**
- * **IMRICOR REQUESTS 'CAPITAL RAISING' HALT**
- * **EMYRIA SECURES CANADA MDMA FOR PTSD TRIALS**
- * **INCANNEX: 50% OF INVESTORS, SO FAR, BACK US REDOMICILE**
- * **ECHO IQ 5m DIRECTOR OPTIONS AGM**
- * **EXOPHARM: 20m DIRECTOR OPTIONS AGM**
- * **CARDIEX LOSES LESA MUSATTO; US, AUSTRALIAN DIRECTORS WANTED**
- * **NEUROSCIENTIFIC APPOINTS DR LINDA FRIEDLAND DIRECTOR**

MARKET REPORT

The Australian stock market fell 1.36 percent on Thursday October 19, 2023, with the ASX200 down 96.0 points to 6,981.6 points.

Five of the Biotech Daily Top 40 stocks were up, 25 fell, eight traded unchanged and two were untraded.

Atomo was the best, up 0.2 cents or 9.1 percent to 2.4 cents, with 31,937 shares traded. Universal Biosensors climbed 5.7 percent; Mesoblast improved 4.2 percent; Micro-X was up 3.85 percent; with Antisense and Resmed up by more than one percent.

Patrys continued its ASX-yo-yo and led the falls, down 0.1 cents or 12.5 percent to 0.7 cents, with 1.5 million shares traded; followed by Telix, down \$1.03 or 10.1 percent to \$9.20, with 5.8 million shares traded.

Dimerix lost 6.9 percent; Actinogen and Pharmaxis were down more than five percent; 4D Medical, Alcidion, Cyclopharm, Emvision and Genetic Signatures fell more than four percent; Impedimed, Kazia and Resonance were down more than three percent; Avita, Imugene, Orthocell and Polynovo shed more than two percent; Amplia, Cochlear, CSL, Nanosonics, Proteomics and Volpara were down more than one percent; with Clinuvel, Neuren, Paradigm and Pro Medicus down by less than one percent.

AVITA MEDICAL

Avita says it has a five-year loan for \$US90 million (\$A142.8 million) from the New York-based healthcare investment firm Orbimed.

According to Avita's US Securities and Exchange Commission filing, the interest rate was the greater of the Secured Overnight Financing Rate – currently 5.31 percent - and 4.00 percent "plus, in either case, 8.00 percent" implying a current rate of 13.31 percent.

The company said that "all obligations under the credit agreement will be guaranteed by all of the company's wholly owned subsidiaries, subject to certain exceptions, and secured by substantially all of the company's and each guarantor's assets".

"If, for any quarter until the maturity date of the loan facility, the company's net revenue does not equal or exceed the applicable trailing 12-month amount as set forth in the credit agreement, then the company shall repay in equal quarterly instalments equal to 5.0 percent of the outstanding principal amount of the loan facility on the date the net revenue amount was not satisfied, together with a repayment premium and other fees," Avita said. The company said it would pay an upfront fee, an unused fee on the undrawn portion of the loan, an administration fee, a repayment premium and an exit fee, as well as certain other fees and expenses of the lender.

Avita said it had borrowed \$US40 million, with an additional \$US50 million available in two tranches at its option, based on the achievement of revenue thresholds, and had issued Orbimed a warrant to buy 409,661 shares, exercisable at \$10.9847 a share.

Avita said the loan provided "financial flexibility to support portfolio expansion, global initiatives, and the further development and commercialization of approved indications".

Avita chief executive officer Jim Corbett said the loan "provides us with sufficient capital to meet our goals without the near-term need of equity financing and positions us to reach profitability during 2025".

Avita fell seven cents or 2.1 percent to \$3.24.

TELIX PHARMACEUTICALS

Telix says receipts from customers for the nine months to September 30, 2023 rose 528.6 percent to \$326,038,000, compared to \$51,868,000 in the prior period.

Telix said receipts from customers, primarily from sales of its Illuccix prostate imaging kits, for the three months to September 30, 2023 were up 193.6 percent to \$130,708,000 compared to \$44,525,000 last year.

The company said “increased product manufacturing and related costs reflect higher volume of sales activity and preparation for future product launches”.

Telix chief executive officer Dr Christian Behrenbruch said “the achievement of a fourth consecutive quarter of positive operating cash flow is a major milestone that reflects the company’s maturation as it delivers on its commercial goals and progresses the development of its industry-leading pipeline”.

“We have posted another quarter of double-digit revenue growth for Illuccix in the U.S. with average daily demand for doses continuing to grow month-on-month,” Dr Behrenbruch said.

The company said it had a positive cash flow of \$21,361,000 for the three months to September 30, 2023, with cash and cash equivalents of \$137,444,000 compared to \$117,117,000 in the previous corresponding period.

Telix fell \$1.03 or 10.1 percent to \$9.20 with 5.8 million shares traded.

TELIX PHARMACEUTICALS

Telix says early data from 28 prostate cancer patients in its phase I trial of TLX591 shows that 18 patients (64.3%) had a reduction in prostate specific antigen.

Last year, Telix said it had dosed the first of up to 50 patients in its phase I trial of TLX591 lutetium-177-labelled antibodies for prostate cancer (BD: Jan 27, 2022).

Today, the company said the purpose of the trial was to evaluate the use of prostate specific membrane antigen (PSMA) imaging to select patients for radio-antibody drug conjugate-based PSMA therapy and to confirm the bio-distribution of the radio-antibody investigational therapy.

Telix said the trial met its primary objective of determining whole body distribution and organ radiation and assessing the safety and tolerability of TLX591, when administered in combination with standard-of-care in second-line metastatic castration-resistant prostate cancer.

Telix said 27 percent of the 28 evaluable patients (7.6 patients) had a 30 percent reduction in prostate specific antigen, with 18 percent (five patients) showing a 50 percent reduction.

The company said other results included “consistent lesion delineation”, “excellent uptake and retention in tumour and metastases up-to 14-days post-injection”, radiation exposure to key organs remaining within prescribed safety limits and the highest absorbed dose being in the liver with minimal uptake in the salivary glands.

Telix said the development of TLX591 was continuing with a phase II external-beam radiation therapy combination study and an about 400-patient, phase III standard-of-care combination study open for enrolment in Australia, and in the US in 2024.

Telix chief medical officer Dr Colin Hayward said TLX591 was “being designed to integrate with current standard-of-care, demonstrative of Telix’s continued innovation in prostate cancer treatment”.

“The ... study provides further validation of the potential of TLX591, a first-in-class RADC therapy and the use of PSMA imaging with small molecules to select patients for antibody-based PSMA therapy,” Dr Hayward said.

PATRYS

Patrys says its PAT-DX1 and PAT-DX3 inhibit the brain cancer glioma, and PAT-DX1 with a therapeutic dose of radiation improves survival, in mice.

Patrys said it would present study data in a poster, titled 'A novel lupus-associated antibody that inhibits the growth of aggressive high-grade glioma orthotopic xenografts and enhances radiotherapy via a unique mechanism' at the American Association for Cancer Research brain cancer conference in Minneapolis on October 21, 2023.

Patrys said the Perth-based Telethon Kids Cancer Centre researcher Prof Terrance Johns would present the poster and describe research "confirming the single agent activity of both PAT-DX1 and PAT-DX3... as well as the significant survival benefits from combining PAT-DX1 with a therapeutic dose of radiation".

Last year, the company said the study showed that 10 mice treated with 25mg/kg dose of PAT-DX1 in combination with radiation therapy had increased median survival of 12 days ($p < 0.0002$) compared to 10 mice receiving radiation alone (BD: Aug 10, 2022).

Today, Prof Johns said the study "demonstrated both antibodies reach and inhibit the growth of intracranial brain cancers in rodent models".

"Significantly, we have shown that PAT-DX1 dramatically enhances the activity of radiotherapy, which is the standard-of-care for many forms of brain cancer," he said.

Patrys fell 0.1 cents or 12.5 percent to 0.7 cents with 1.5 million shares traded.

CORRECTION: TESSELATE BIO BV CHILDREN'S MEDICAL RESEARCH INSTITUTE

Yesterday's edition reported that Tessellate Bio BV was developing 'Parp' inhibitors to target DNA damage in the treatment of cancers.

In fact, the Amsterdam-based Tessellate is developing inhibitors of 'alternate lengthening of telomeres' (ALT) designed to target DNA repair pathways to kill cancer cells.

The error was made by the new Wednesday sub-editor who was overwhelmed by the number of articles yesterday and the complexity of the Tessellate information.

They have been dismissed.

Tessellate is a private company.

RHINOMED

Rhinomed says it has ended its exclusive supply deal with Surescreen due to not completing any orders and will conduct an "operational review" due to delayed revenue.

Last year, Rhinomed said it would supply more than 10 million Rhinoswabs to Sydney's Surescreen Australia for its respiratory tests in Australia, New Zealand, Singapore and the South Pacific; and a month later, said it received its first purchase order for 250,000 Rhinoswab Junior Covid-19 swabs (BD: Jul 18, Aug 17, 2022).

Today, the company said that it had a two-year agreement with Surescreen from June 2022 and despite receiving regulatory clearance from the Australian Therapeutic Goods Administration, Surescreen had "not completed any orders with Rhinomed".

Rhinomed said it had terminated the agreement and was in discussions with a rapid antigen test kit company to develop a Covid-19, influenza A and influenza B test kit that would include its Rhinoswab Junior in Australia.

The company said it hoped to distribute these kits to Australian families through its existing retail pharmacy network, and "given the delays in Rhinoswab revenues, the company is completing an operational review".

Rhinomed was unchanged at 3.2 cents.

VITURA HEALTH

Vitura says it has binding agreements to acquire the Brisbane-based Doctors on Demand Pty Ltd for \$25 million in cash and equity.

Vitura said Doctors on Demand operated a digital platform for patients to access telehealth, healthcare and related services with Australian registered healthcare practitioners through video-conferencing technology.

The company said the acquisition would bring “a significant number of prescribers and patients” and diversify its operations and revenues beyond medical cannabis, which it expected to complete by about October 26, 2023.

Vitura said the widespread adoption of telehealth was partly driven by cost-of-living pressures, availability of doctors and pressure on clinics from payroll tax for contracted doctors, all of which it considered “likely to continue into the future”.

Vitura said it would pay \$12.5 million up-front in cash to Doctors on Demand shareholders and \$6.25 million in cash one year from the date of completion as well as it \$6.25 million to shareholder Regal Funds Management through the issue of 17,380,423 Vitura shares at 35.96 cents a share.

The company said the cash component would be funded from a combination of cash reserves and a new debt facility of \$6.25 million from ANZ Bank.

Vitura chief executive officer Rodney Cocks said “just like the merger between Cronos Australia and CDA Health to form Vitura was a game changer, we see this transaction to acquire Doctors on Demand as having the same significant impact”.

“This not only embeds Vitura as a diversified digital health company as we bolt on more services, products and verticals beyond medicinal cannabis, but also supports and assists our sustainable growth and profitability... the transaction also brings with it hundreds of thousands of patients and more than 120 skilled and dedicated doctors who treat patients on the Doctors on Demand platform,” Mr Cocks said.

The company said that Doctors on Demand chief executive officer Kirsty Garrett would be appointed as Vitura’s chief operating officer.

Vitura was up 1.5 cents or 4.3 percent to 36.5 cents.

MICROBA LIFE SCIENCES

Microba says it will buy the Gloucestershire, England-based Invivo Clinical for \$12.5 million and up-to \$8.7 million in earn-out, with a \$20 million rights offer to fund it.

Microba said it had a share purchase plan to acquire 100 percent of Invivo, a microbiome testing business with products including vaginal, oral and urinary testing, and a reported revenue of \$8.9 million for the year to June 30, 2023.

The company said the UK was a “key market” for its move into international markets and the Invivo purchase, with its Sonic Healthcare partnership, gave it access to “the entire UK healthcare market spanning private practice and ... [the National Health Service]”.

Microba said it hoped to raise up-to \$20 million in a one-for-four, non-renounceable rights offer at 23.0 cents a share, a 28.1 percent discount to the close on October 18, 2023.

The company said that an institutional component would be conducted today, October 19, and the retail offer would have a record date of October 23, open on October 26 and close on November 16, 2023.

Microba said its major shareholder Sonic Healthcare has indicated a commitment of 100 percent of its pro rata entitlement, or about \$4 million, which could result in it obtaining a maximum interest in Microba of about 22.4 percent on completion of the offer.

The company said Bell Potter Securities and Morgans Corporate were lead managers.

Microba requested a trading halt and last traded at 32 cents.

BIOXYNE

Bioxyne says its subsidiary Breathe Life Sciences has imported and irradiated 200kg of cannabis flower, worth \$3.2 million, from the United Kingdom.

Bioxyne said Breathe Life had confirmed a future good-manufacturing-practice inspection, audit and certification with the Australian Therapeutic Goods Administration in November for its Brisbane pharmaceutical manufacturing facility, which would allow it to scale production capabilities significantly.

The company said the marijuana was four strains of “premium high [tetrahydrocannabinol] cannabis flower”, would be packed into its Dr Watson brand and sold via special access pathways and supplied as bulk product to compounding pharmacies and licenced manufacturers.

Bioxyne was untraded at 1.1 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says the ASX has lifted the requirement to lodge quarterly cash flow and activities reports due to its positive net operating cash flow for the past 12 months.

Volpara said it would lodge preliminary reports and half yearly reports within two months of the end of the relevant reporting period, with the next report to be the half-year report for the six months to September 30, 2023.

Volpara fell one cent or 1.3 percent to 74 cents.

AMPLIA THERAPEUTICS

Amplia says it has received \$2,408,458 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.

Amplia said the rebate primarily related to expenditure on its phase Ib/IIa clinical trial of AMP945 in advanced pancreatic cancer patients for the year to June 30, 2023.

The company said it would use the funds to repay its Victorian Government R&D Cash Flow Initiative loan of \$2,100,000, with the remaining funds to be used to further progress its AMP945 clinical trials.

Amplia fell 0.1 cents or 1.2 percent to 8.2 cents.

PHARMAXIS

Pharmaxis says it has sold its mannitol respiratory business to Sydney’s Arna Pharma which has taken over day-to-day operations, effective from today.

Earlier this month, Pharmaxis said Arna Pharma would buy its mannitol business, chair Malcolm McComas and director Dr Neil Graham would resign and it would change its name to Syntara (BD: Oct 3, 2023).

Today, the company said that it would be reimbursed by Arna Pharma for the majority of the residual expenses it will incur through the transition period ending in May 2024.

Pharmaxis fell 0.2 cents or 5.9 percent to 3.2 cents.

IMRICOR MEDICAL SYSTEMS

Imricor has requested a trading halt, pending an announcement “in relation to an update in connection with a proposed capital raising”.

Trading will resume on October 23, 2023 or on an earlier announcement.

Imricor was untraded at 45 cents.

EMYRIA

Emyria says Health Canada has approved the export of 3,4-methylene-dioxy-methamphetamine (MDMA) to Australia for its post-traumatic stress disorder (PTSD) trial.

In February, Emyria said it had secured a supply of clinical-grade MDMA from the Vancouver, British Columbia-based Pharmala Biotech (BD: Feb 13, 2023).

In July, Emyria said it had recruited the first of up-to 70 patients in its phase IIb trial of MDMA for post-traumatic stress disorder (BD: Jul 10, 2023).

Today, the company said it would start dosing its MDMA-assisted therapy program. Emyria was unchanged at 6.3 cents with 1.1 million shares traded.

INCANNEX HEALTHCARE

Incannex says 49.7 percent of investors, so far, have voted in favor of its scheme to redomicile to the US, with the scheme meeting to be held November 8, 2023.

Earlier this month, Incannex said Incannex Healthcare Inc would acquire its shares and become the new parent entity of Incannex group (BD: Oct 5, 2023).

Today, the company said 788,532,913 votes (99.64%) cast at October 18, 2023 were in favor with 2,409,285 votes (0.30%) against.

According to its most recent notice, Incannex had 1,587,011,823 shares on offer.

Incannex was up half a cent or 9.1 percent to six cents with 2.0 million shares traded.

ECHO IQ

Echo IQ says its annual general meeting will vote to issue 5,000,000 incentive options to non-executive director Simon Tolhurst, separate from his \$66,000 annual pay.

Echo IQ said the Mr Tolhurst's options would be exercisable at 25 cents each within three years.

The company said the meeting would vote to adopt the remuneration report, elect directors Andrew Grover and Mr Tolhurst, approve its 10 percent placement capacity, allow the issue of equity under its employee equity incentive plan, modify its constitution and appoint an auditor.

The meeting will be held at Suite 404, Level 4, 309 George Street, Sydney on November 21, 2023 at 12pm (AEDT).

Echo IQ fell 0.5 cents or 2.4 percent to 20 cents with 1.3 million shares traded.

EXOPHARM

Exopharm says its annual general meeting will vote to issue 10,000,000 options each to directors Clarke Barlow and Mark Davies.

Exopharm said the options would vest in three tranches, the first tranche of 5,000,000 options exercisable at 1.5 cents, the second tranche of 2,500,000 options exercisable at two cents and the remaining options at three cents each, with all options expiring two years after their date of issue.

The company said Mr Barlow and Mr Davies' options were on-top of their \$48,000 and \$60,000 annual salaries.

Exopharm said investors would vote to adopt the remuneration report, elect directors Mr Barlow and Mr Davies, and approve the additional 10 percent placement capacity.

The meeting will be held online and in-person at Level 5, 126 Phillip Street, Sydney on November 23, 2023 at 12pm (AEDT).

Exopharm was in a suspension at 1.1 cents.

CARDIEX

Cardiex says that non-executive director Lesa Musatto has resigned, effective from October 18, 2023 and it is looking for an Australian and a US-based director.

Cardiex said that it was looking for independent directors “with experience in consumer health technologies, global healthcare, and corporate governance”.

“Commensurate with the above strategy, the company advises that Ms Lesa Musatto has tendered her resignation ... due to her other business commitments,” the company said. Cardiex was in a suspension and last traded at 13.5 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has appointed Dr Linda Friedland as an independent, non-executive director, effective from today, and issue 2,000,000 performance rights.

Neuroscientific said Dr Friedland had more than 25 years of experience in clinical medicine and was currently the deputy chair of the Neurological Council of Western Australia, a consultant to Targimmune Therapeutics, co-founder and director of FFD Capital LLC and Asia- Pacific partner for Camelot Biocapital.

According to LinkedIn, Dr Friedland held a Bachelor of Surgery and a Bachelor of Medicine from Johannesburg’s University of Witwatersrand.

The company said the performance rights would vest in two equal tranches at 12 months and 24 months.

Neuroscientific was untraded at six cents.