Biotech Daily

Tuesday December 19, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: UNIVERSAL BIOSENSORS UP 16%; NOVA EYE DOWN 12%**

*** ENLITIC OPENS UP 6% ON $21m IMAGING SOFTWARE IPO**

*** SYNTARA RAISES $10m; PLAN FOR $2m MORE**

*** CARDIEX $4m PLACEMENT 'COMMITMENTS'; $4m RIGHTS OFFER**

*** ANATARA RIGHTS RAISES $1.05m**

*** TELIX FILES TLX250-CDX FDA BIOLOGICS APPLICATION**

*** DORSAVI SIGNS 2 US RESEARCH DEALS WORTH $168k**

*** AZURA: AZR-MD-001 ALLOWS '3-HOUR MEIBOMIAN CONTACT LENS WEAR'**

*** STARPHARMA: DEP-DOCETAXEL 'CONTROLS' PRIOR-TREATED CANCERS**

*** NEUROTECH RECRUITS NTI164 PHASE II/III AUTISM TRIAL**

*** ADALTA I-BODY 'BINDS TO MALARIA PARASITE PROTEIN', IN-VITRO**

*** CLARITY RECRUITS PHASE II CU-64-SARTATE TRIAL EARLY**

*** HERAMED: WINGWOMEN 90-DAY US HERACARE TEST-RUN**

*** CHIMERIC MANUFACTURES PHASE Ib AML TRIAL CHM0201**

*** GENETIC SIGNATURES $7m FEDERAL RDTI; 'CAPITAL RAISING' HALT**

*** TISSUE REPAIR WINS US PATENT FOR GLUCOPRIME**

*** RHYTHM: CEO SEARCH, COST CUTS, COLOSTAT CHANGE, RE-DO RDTI**

*** CERULEA APPOINTS MICHELLE GALLAHER CEO**

MARKET REPORT

The Australian stock market was up 0.84 percent on Tuesday December 19, 2023, with the ASX200 up 62.7 points to 7,489.1 points. Twenty of the Biotech Daily Top 40 stocks were up, 13 fell, five traded unchanged and two were untraded. All three Big Caps were up.

Universal Biosensors was the best, up three cents or 15.8 percent to 22 cents, with 145,100 shares traded, followed by Starpharma up 15.6 percent to 18.5 cents, with 4.3 million shares traded. Resonance rose 8.8 percent; Curvebeam, Impedimed and Neuren climbed more than seven percent; Imugene improved 5.3 percent; Actinogen, Amplia and Clarity were up four percent or more; Orthocell was up 3.7 percent; Telix rose 2.4 percent; Avita, Emvision, Nanosonics, Next Science, Paradigm, Polynovo and Pro Medicus were up more than one percent; with Clinuvel, Cochlear, CSL and Resmed up by less than one percent.

Nova Eye led the falls, down 1.5 cents or 11.5 percent to 11.5 cents, with 747,946 shares traded, followed by Syntara (Pharmaxis) down 11.1 percent to 2.4 cents, with 2.6 million shares traded. Dimerix lost 5.4 percent; 4D Medical, Atomo, Mesoblast and SDI fell more than four percent; Opthea and Proteomics were down more than three percent; Alcidion, Cyclopharm and Medical Developments shed two percent or more; with Prescient down by 1.5 percent.

ENLITIC INC

Enlitic opened up 6.0 percent at 88 cents, having raised $21 million at 83 cents to list under the code ‘ENL’ to commercialize its Endex and Encog imaging software.
Enlitic said the funds were for licencing its medical imaging data management software products, which used “artificial intelligence and data [to empower] … evidence-based decision-making, enhancing research and transforming healthcare delivery”.
The company said it had two products, Endex, which standardized medical image descriptions to a consistent naming convention, and Encog, which removed personal information from clinical data for its use in research.
Enlitic said that improved data quality led “to better decision-making and analysis” with positive benefits to other healthcare departments and staff; and its products were licenced on a subscription-based revenue model that delivered annual recurring revenue.
According to the company’s website, its chair was Lawrence Gozlan, with chief executive officer former Opthea director Michael Sistenich, chief technology officer former Mach7 head of engineering Daniel Kozimor, and its chief operating officer former Mach 7 head of sales John Marshall.
Enlitic climbed as much as 8.4 percent to 90 cents before closing up two cents or 2.4 percent at 85 cents with 284,729 shares traded.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says it has raised about $10 million in a placement at 2.2 cents a share, and hopes to raise a further $2 million in a share purchase plan.
Syntara said the issue price was a 15 percent discount to the five-day volume weighted average price and that the share plan would be at the same price.
The company said the share plan had a record date of December 18 and was expected to open on December 29, 2023 and close on January 30, 2024.
The company said the funds would be used for its phase II study of SNT-5505 for myelofibrosis with standard-of-care, a further phase II study in scarring and Parkinson’s disease and additional general working capital purposes and raising costs.
Syntara said Bell Potter Securities and Canaccord Genuity were joint lead managers and bookrunners to the placement.
Syntara fell 0.3 cents or 11.1 percent to 2.4 cents with 2.6 million shares traded.

CARDIEX

Cardiex says it has “firm commitments” to raise $4.0 million in a placement and hopes to raise $4.0 million more in a one-for-2.87 entitlement offer, at eight cents a share.
Cardiex said that for every three shares issued, investors would receive one option, exercisable at 20 cents each by November 30, 2025.
The company said the entitlement offer had a record date of December 22, would open on December 29, 2023, and close on January 29, 2024.
Cardiex said directors Niall Cairns and Craig Cooper had subscribed for about $790,000 of the placement; with MST Financial Services the lead manager to the offer.
Cardiex said the funds would be used for operations including product development, commercialization, marketing, capital raising costs and general working capital.
Cardiex said subject to the placement and entitlement offer raising a total of $5 million, about 3,620,000 convertible notes equivalent to about 45.25 million shares would convert to shares at the offer price.
Cardiex was in a suspension and last traded at 13.5 cents.

ANATARA LIFESCIENCES

Anatara says its rights offer at 2.2 cents a share has raised $1,055,344.
In November, Anatara said it hoped to raise about $1.055 million in a two-for-five, non-renounceable entitlement offer at 2.2 cents a share (BD: Nov 3, 2023).
Earlier this month, the company said its rights offer raised $657,914, with the $397,422 shortfall partially underwritten to $297,723 (BD: Dec 7, 2023).
Anatara was unchanged at 2.2 cents.

TELIX PHARMACEUTICALS

Telix says it has filed a biologics licence application for TLX250-CDx for clear cell renal cell carcinoma imaging to the US Food and Drug Administration.
Telix said it had been granted a 'breakthrough therapy' rolling review process for TLX250-CDx, or Zircaix, that allowed it to submit material and review required modules on a schedule agreed with the FDA.
The company said it had requested priority review, which if granted would expedite the review time.
Telix said the submission was based on its recent 300-patient, 'Zircon', phase III trial which met its primary and secondary endpoints, with 86 percent sensitivity and 87 percent specificity (BD: Nov 7, 2022).
The company said it had an expanded access program in the US and dosed the first patient earlier this month, as well as a named patient program in Europe that would allow access to TLX250-CDx outside clinical trials to patients with no comparable or satisfactory alternate options (BD: Dec 12, 2023).
Telix chief executive officer Dr Christian Behrenbruch said the filing was "a major milestone and achievement for Telix, which paves the way for a commercial availability for patients in the US in 2024, subject to regulatory review and approval".
Telix chief development officer James Stonecypher said "if approved by the FDA, TLX250-CDx will be the first targeted radio-pharmaceutical imaging agent for kidney cancer to be commercially available to patients in the US".
Telix was up 23 cents or 2.4 percent to $9.79 with 1.2 million shares traded.

DORSAVI

Dorsavi says it has research deals with Norton Healthcare and Georgia Southern University worth a total of $US113,000 ($A168,225).
Dorsavi said with the Louisville, Kentucky-based Norton Healthcare it would research spinal motion and patterns of movement using its wearable sensor technology and algorithms with $99,900 in sponsored research support.
The company said with the Statesboro-based Georgia Southern University it would research running biomechanics using its wearable sensors, generating about $68,600 in funding from the US Department of Defence for a two-year period.
Dorsavi said the signing of the two multi-year agreements built on the momentum of its $100,000, one-year deal with the University of Rochester in April (BD: Apr 18, 2023).
The company said it would receive "greater insights into patterns of human movement from both projects, potentially enhancing outcomes for patients dealing with spinal conditions and stress fractures related to running".
Dorsavi was up 0.3 cents or 27.3 percent to 1.4 cents.

AZURA OPHTHALMICS LTD

Azura says a 67-patient, phase II study of AZR-MD-001 shows that meibomian gland dysfunction patients can wear their lenses comfortably for “at least three hours”.

The Tel Aviv and Melbourne-based Azura said the phase II trial evaluated the safety and efficacy of 0.5 percent AZR-MD-001 in patients who could not comfortably wear their contact lenses and had signs of meibomian gland dysfunction.

The company said meibomian gland dysfunction caused the glands in the eyelids to become blocked, impacting the quality and quantity of meibum secretions and leading to symptoms such as dryness, pain, irritation, poor vision and contact lens discomfort.

Azura said the study met its primary endpoint of a clinically meaningful improvement in meibomian glands yielding liquid secretion scores, with dosed patients having 5.0 glands opened compared to 1.6 glands in control patients at three months ($p < 0.0001$).

The company said 58.2 percent of patients treated with AZR-MD-001 had at least five more glands opened, as measured by meibomian glands yielding liquid secretion responder rate, compared to 6.1 percent of the untreated group ($p < 0001$).

Azura said patients in the study self-administered AZR-MD-001 or inert vehicle to the lower eyelid at bedtime twice weekly for three months.

Azura said the study met its secondary endpoints, including significant improvements in meibum quality, tear stability, ocular surface staining and contact lens wear time.

The company said comfortable contact lens wear time increased by 192 minutes for AZR-MD-001 treated patients compared to 0.65 minutes for controls ($p < 0.0001$), 97.1 percent of AZR-MD-001 patients had their meibum quality return to normal levels compared to 33.6 percent in of untreated patients ($p < 0.0001$).

The company said AZR-MD-001 was an ophthalmic ointment preparation of selenium sulphide applied directly to the meibomian glands in the lower eyelid and was thought to have "a multi-modal mechanism of action that treats the pathophysiology of meibomian gland dysfunction along with the resulting ocular surface symptoms”.

Azura said the treatment broke down the bonds between abnormal keratin proteins to soften blockages, slowed down the production of keratin to prevent future blockages and increased the quality and quantity of meibum produced by the glands.

The company said the study showed AZR-MD-001 was safe and well tolerated, with all adverse events mild-to-moderate in severity and none leading to patient discontinuation.

Azura said the study was the second phase II study of AZR-MD-001 to show statistically significant improvements across multiple endpoints for meibomian gland dysfunction.

The company said the trial was funded by a Medical Research Future Fund grant from Cureator, a biotechnology incubator run by Brandon Capital, whose founder and managing-director Dr Chris Nave was a director of Azura.

Azura chief executive officer Marc Gleeson said meibomian gland dysfunction was “the root cause of many downstream ocular surface conditions that impact quality of life and vision for patients, including contact lens discomfort”.

“By opening up blocked glands and improving the quality of the tear film, we believe many of these ocular surface conditions can be resolved,” said Mr Gleeson.

“In addition to meeting its primary [meibomian glands yielding liquid secretion scores] endpoint, we are especially encouraged that AZD-MD-001 allowed patients who had given up using contacts to wear their contacts again, safely and comfortably, for an additional three hours every day over their normal wear time,” Mr Gleeson said. “We now have two studies showing AZR-MD-001 can improve the signs and symptoms of [meibomian glands dysfunction] and we look forward to discussing these results with the [US Food and Drug Administration] as we advance our phase III development program.”

Azura is a private company.

STARPHARMA HOLDINGS

Starpharma says its 80-patient, phase II trial dendrimer enhanced product (DEP)-docetaxel achieved a “disease control rate” of 28.6 percent to 80.0 percent.
Starpharma said that “disease control rate” was a combination of “stable disease” and “partial responses”.
The company said that the 28.6 percent disease control rate was for DEP-docetaxel monotherapy in patients with advanced gastro-oesophageal cancer, for up to 28 weeks in evaluable patients.
Starpharma said the 80.0 percent rate was in advanced, metastatic non-small cell lung cancer (NSCLC) patient, for up to 24 weeks, with DEP-docetaxel combined with nintedanib.
The company said that patients had up-to nine prior lines of therapy and up-to 37 cycles of previous anti-cancer treatment, as well as those who had exhausted all available treatment options.
Starpharma said DEP-docetaxel in combination with gemcitabine in advanced pancreatic cancer patients showed a 75.0 percent control rate for up-to 23 weeks, and a 33.3 percent control rate and up-to 55.6 percent reduction in tumor lesions when administered as a monotherapy.
The company said DEP-docetaxel in combination with gemcitabine also showed disease control in other advanced cancers, including intrahepatic cholangiocarcinoma and uterine sarcoma, with durable responses for up-to 30 weeks, as well as “encouraging efficacy responses” for advanced cancers including melanoma of the eye and ameloblastoma, with disease control for up-to 46 weeks.
Starpharma said DEP-docetaxel achieved a “favorable safety and tolerability profile compared with conventional docetaxel”, with fewer adverse events and 90 percent of related adverse events being mild.
The company said DEP-docetaxel effectively targeted human tumors, with biopsies showing tumor tissue with levels of docetaxel up-to 60 times higher than blood.
Starpharma chief executive officer Dr Jackie Fairley said that DEP-docetaxel had shown “encouraging results in multiple difficult-to-treat cancers, both as a monotherapy and in combination with gemcitabine or nintedanib”.
“DEP-docetaxel also demonstrated lower rates of key adverse events, including severe neutropenia, hypersensitivity, fluid retention and hair loss, all of which are problematic side effects for patients treated with conventional docetaxel,” Dr Fairley said.
“In the trial, DEP-docetaxel achieved clinically meaningful disease control in multiple patients with advanced metastatic cancer who had no other treatment options available,” Dr Fairley said.
Starpharma was up 2.5 cents or 15.6 percent to 18.5 cents with 4.3 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has completed recruitment for the 56-patient, phase II/III trial of its marijuana-based NTI164 for children with autism spectrum disorder.
Neurotech said it expected trial results by April 2024.
Earlier this month, Neurotech said it had ethics approval to extend its up-to 54-patient, randomized, double-blind, placebo-controlled trial of NTI164 for autism spectrum disorder to adult patients (BD: Dec 4, 2023).
Neurotech was unchanged at 5.5 cents.

ADALTA

Adalta says its i-body has the potential to bind to malaria parasite proteins and inhibit invasion, according to an in-vitro study performed with La Trobe University.

Adalta previously said that i-bodies were named from the “intermediate” of four groups of immunoglobulin or immunoglobulin-like domains (BD: Jan 25, 2023).

Today, the company said it had developed an i-body treatment capable of “high potency inhibition” of the malaria parasite’s invasion of red blood cells and liver cells by multiple parasite strains, and that it could potentially break the malaria lifecycle at multiple stages.

Adalta said its treatment targeted AMA1, a malaria protein critical to enabling invasion of malaria parasites into red blood cells and, at a different stage of their lifecycle, liver cells, but that AMA1 had a high degree of variability from strain to strain and that to date no AMA1 antibody could recognize all strains of the parasite while acting as a strong inhibitor of invasion.

The company said its i-body bound with “high affinity” to a region of AMA1 found in all malaria parasite strains, with the parasite binding “equally or more tightly” to the i-body treatment than the natural receptor of AMA1.

The company said it had filed a patent and that it was looking at grant funding opportunities with La Trobe University.

Adalta founding chief scientist and La Trobe University’s Prof Mick Foley said: “We believe we have delivered a world first here.”

“Until now, no antibody-like molecule has combined the ability to bind strongly to multiple strains of malaria parasite with high potency killing,” Prof Foley said.

“This variability between strains has plagued all previous attempts to produce a single antibody that can inhibit parasite invasion,” Prof Foley said.

“When combined with protecting cells from invasion at two different life cycle stages of the parasite, the new i-body confers the real possibility we may be able to bring forward a new approach to treating malaria,” Prof Foley said.

Adalta was up 0.1 cents or 4.2 percent to 2.5 cents with 5.5 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has recruited its phase II ‘Disco’ imaging trial of copper-64-sartate for neuroendocrine tumors early, with 45 patients instead of 63 patients as planned.

Clarity said the original patient number was based on expected differences between imaging with copper-64-sartate and the current standard-of-care 68-gallium-dotatatate, but that “pre-planned assessment of the images” generated sufficient evidence to plan for a phase III trial.

In 2021, Clarity said it had dosed the first ‘Disco’ trial patient, which used positron emission tomography on patients with known or suspected gastro-entero-pancreatic neuro-endocrine tumors, to assess the potential of copper-64-sartate to diagnose those tumors (BD: Apr 15, 2021).

Today, Clarity said the trial aimed to build on earlier work with sartate-2 which showed that imaging at later time points, enabled by the longer half-life of copper-64 in comparison to 68-gallium, could lead to better identification of disease.

Clarity chair Dr Alan Taylor said that while the main focus for copper-64-sartate was “neuroblastoma in children, for both therapy and diagnosis, which includes two rare paediatric disease designations and two orphan drug designations in this indication, the initial imaging data looks highly encouraging in [neuroendocrine tumors]”.

Clarity was up 7.5 cents or 4.55 percent to $1.725.

HERAMED

Heramed says Wingwomen Inc will use its Heracare fetal monitor for up-to 12 pregnant women at risk of gestational diabetes, pre-eclampsia and gestational hypertension.
Heramed said Boston's Wingwomen would monitor the women for blood pressure, fetal heart rate, weight and mood during a 90-day period beginning in January 2024.
The company said the evaluation was to "assess hyper-intensive related high-risk pregnancies" and define a care model using Heracare to manage these pregnancies.
Heramed said it expected results in 2024, and the parties "signing a commercial agreement" on successful completion of the evaluation which could lead to Wingwomen to use Heracare for 10-to-20 pregnancies a month, expanding to other clinics.
Heramed was unchanged at 2.6 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has manufactured its CHM0201 natural killer cells for its phase Ib trial in up-to 20 patients with acute myeloid leukaemia.
Chimeric said the cells were in transit to the University of Texas MD Anderson Cancer Center for the trial, where they would be studied in combination with the standard-of-care therapies azacitidine and venetoclax.
Chimeric was up 0.1 cents or 3.7 percent to 2.8 cents with 1.1 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has received $6,877,061 from the Federal Research and Development Tax Incentive program and requested a capital raising trading halt.
Genetic Signatures said the rebate related to research and development expenditure for the year to June 30, 2023.
The company requested a trading halt regarding a "capital raising comprising an institutional placement and pro-rata, non-renounceable entitlement offer".
Trading will resume on December 21, 2023, or on an earlier announcement.
Genetic Signatures last traded at 44 cents.

TISSUE REPAIR

Tissue Repair says the US Patent and Trademark Office has allowed a patent relating to the use of its Glucoprime compound and molecule for all applications.
Tissue Repair said the patent, titled 'Biological Polysaccharide Compound' would provide intellectual property protection until June 21, 2042.
The company said Glucoprime and its variants were the underlying technology platform behind its lead drug candidate TR987 for venous leg ulcers and its TR Pro+ cosmetic.
Tissue Repair said the technology had broad applications in animal and human wounds, when applied topically and/or within the body.
Tissue Repair executive director Tony Charara said "the patent protection across the three allowed patents now in force is robust."
"We have delivered on our prospectus objectives of securing solid [intellectual property] protection at a critical point as we explore the next stage of commercialization for TR Pro-Plus and the planned phase III clinical trial commencement for our lead drug candidate TR987," Mr Charara said. "There are no known alternative processes from which to produce the company's proprietary biological polysaccharide molecule."
Tissue Repair was up three cents or 14.3 percent to 24 cents.

RHYTHM BIOSCIENCES

Rhythm says it will appoint a chief executive officer, de-commercialize Colostat, outsource Colostat to a US contractor, reduce costs and re-lodge an RDTI claim.

Rhythm said the changes were part of a strategic review undertaken after several executive management changes and European regulatory changes.

The company said it would realign its operations and resources to help it adopt the "new stringent [in-vitro diagnostic medical device regulation] requirements for all products in development".

Rhythm said it would appoint a chief executive officer to support the transition to the changed in-vitro diagnostic medical device regulations, and that following a handover period executive chair Otto Buttula would relinquish his executive duties.

Last week, the company said it had received a requisition for an extraordinary general meeting to remove Mr Buttula as a director (BD: Dec 15, 2023).

The company said it would produce its Colostat kits for research use only rather than commercial sales and said future revenue from the kits would be dependent on completing the regulatory transition work and then obtaining approval for Colostat.

Rhythm said it would continue to evaluate options for Colostat "in the US market given the [US Food and Drug Administration] regulatory uncertainty".

The company said it would engage a US-based contract manufacturing organization to undertake all future development work on Colostat.

Rhythm said it had already begun the cost reduction process, and that it would apply the work it does to transition to in-vitro diagnostic medical device regulation compliance to its pipeline of breast, lung and gastric cancer products.

The company said it would re-lodge its Federal Research and Development Tax Incentive claim to include overseas expenditure given the current kits could be used for research and development, but that the rebate would be "materially lower than previously announced".

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

CERULEA

Cerulea says it has appointed Michelle Gallaher as its first chief executive officer.

Cerulea said it was a clinical trial centre at Melbourne's Royal Victorian Eye and Ear Hospital, a subsidiary of the Centre for Eye Research Australia, and would be open in 2024 with $10 million of Victorian Government funding.

The clinical trial centre said Ms Gallaher was formerly a Victorian Telstra businesswoman and entrepreneur of the year, had launched four start-ups and was most recently founding chief executive officer at Opyl Ltd.

According to her Linkedin page, Ms Gallaher was previously the Bio-Melbourne Network's chief executive officer and held a Diploma of Applied Science from Melbourne's La Trobe University and a Master of Business Administration from Melbourne's Monash University.