



Biotech Daily

Monday December 16, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: SYNTARA UP 12%; MEDADVISOR DOWN 8%**
- * **ANTERIS HOPES FOR \$139m ATGC NASDAQ IPO**
- * **PAINCHEK UNDERWRITTEN RIGHTS RAISE \$5.1m**
- * **NASDAQ TO DELIST GENETIC TECHNOLOGIES; 2nd CREDITORS MEETING**
- * **4D MEDICAL, CHICAGO UNI LUNG IMAGING DEAL**
- * **CONTROL BIONICS NEUROSTRIP FOR US SPORT, JAPAN REHABILITATION**
- * **INOVIQ: 'NK EXOSOMES KILL BREAST CANCER, IN-VITRO'**
- * **INVEX: 'EXENATIDE PROTECTS ALZHEIMER'S BRAIN CELLS, IN-VITRO'**
- * **NEURIZON: 'NUZ-001 REDUCES ALS RISK OF DEATH 78%'**
- * **CHIMERIC OPENS PHASE Ib CHM0201 TO 'NEW AML' PATIENTS**
- * **PYC: 'PHELAN-MCDERMID PYC-002 TRIALS IN 2026'**
- * **TRYPTAMINE: 'TRP-8803 DOSE SAME FOR OBESE, NON-OBESE PATIENTS'**
- * **PROTEOMICS RECEIVES \$2.2m FEDERAL R&D TAX INCENTIVE**
- * **PATRYS RECEIVES \$1.3m FEDERAL R&D TAX INCENTIVE**
- * **CARDIEX REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **PERCHERON REQUESTS 'TRIAL DATA' TRADING HALT**
- * **ARCHER PLEADS 'SCHULTZ, ALPHABET' TO 35% ASX PRICE QUERY**
- * **GREGORY GEORGE, G TO THE FOURTH TAKE 18% OF MESOBLAST**
- * **AUSTRALIAN ETHICAL REDUCES TO 14.5% OF SOMNOMED**
- * **AUSTCO APPOINTS ANN LARKINS DIRECTOR**
- * **INVION APPOINTS PROF ROBERT RAMSAY SCIENTIFIC ADVISOR**

MARKET REPORT

The Australian stock market fell 0.56 percent on Monday December 16, 2024, with the ASX200 down 46.5 points to 8,249.5 points. Twelve of the Biotech Daily Top 40 companies were up, 23 fell, three traded unchanged and two were untraded.

Syntara was the best, up 0.8 cents or 12.1 percent to 7.4 cents, with 23.5 million shares traded. Curvebeam climbed four percent; Alcidion was up 3.4 percent; Cyclopharm, Cynata and Orthocell rose more than two percent; Proteomics and Telix were up more than one percent; with Aroa, Clarity, Clinuvel, Cochlear, Opthea and Pro Medicus up by less than one percent.

Medadvisor led the falls, down 2.5 cents or 8.2 percent to 28 cents, with 349,833 shares traded. Actinogen and EBR lost more than seven percent; Immutep and Paradigm slipped more than six percent; Imugene was down 5.1 percent; Prescient and Starpharma fell more than four percent; Avita and Nova Eye were down more than three percent; Amplia, Compumedics and Dimerix shed two percent or more; 4D Medical, Emvision, Impedimed, Medical Developments, Micro-X and SDI were down more than one percent; with CSL, Genetic Signatures, Mesoblast, Nanosonics, Neuren and Resmed down by less than one percent.

ANTERIS TECHNOLOGIES

Anteris says US holding company ATGC hopes to raise \$US88,800,000 (\$A139,397,000) at \$US6.00 (\$A9.42) a share in an initial public offer to list on the Nasdaq.

Earlier this month, Anteris said it had shareholder and court approval to redomicile to the US and list on the Nasdaq through the Delaware-based Anteris Technologies Global Corp (ATGC) with final ASX trading on December 5 (BD: Nov 13, Dec 3, 5, 2024).

Last week, the company said ATGC had opened an initial public offer of 14,800,000 shares to list on the Nasdaq, but did not state a share price (BD: Dec 10, 2024).

Today, Anteris said the shares were expected to begin trading on the Nasdaq on December 13, with the offer to close on December 16, 2024.

The company said that following the US offer, ATGC intended to list its Chess depositary interests (CDIs) each equal to one US share on the ASX under the symbol 'AVR'.

Anteris has been removed from the official list and last traded at \$10.54.

PAINCHEK

Painchek says it has raised \$5.1 million at 2.5 cents a share in its fully-underwritten, one-for-eight, non-renounceable entitlement offer.

Last month, Painchek said it would raise \$5.1 million at 2.5 cents a share, a 14.4 percent discount to the five-day volume weighted average price (BD: Nov 25, 2024).

Today, the company said it raised \$2.095 million from shareholders, with the remaining \$3.022 million shortfall taken up by the underwriter Canaccord Genuity Australia.

Painchek said the funds would be used for commercialization activities for its pain management applications for adults and infants as well as platform development and working capital.

The company said shareholders would receive one attaching option for every share issued, exercisable at five cents each within 12 months.

Painchek was unchanged at 2.6 cents.

GENETIC TECHNOLOGIES

Genetic Technologies' voluntary administrators say the company will be delisted from the Nasdaq tomorrow, and a second creditors meeting is scheduled for Friday.

Last month, FTI Consulting said its Ross Blakeley and Paul Harlond were appointed as voluntary administrators of Genetic Technologies (BD: Nov 20, 2024).

Today, the company said it received a delisting notice from the Nasdaq on December 6, which "referenced the voluntary administrators' appointment and associated public interest concerns raised by it, concerns regarding the residual equity interest of the existing listed securities holders and concerns about the company's ability to sustain compliance with all requirements for continued listing on Nasdaq".

Genetic Technologies said the compliance requirements included "requiring it to maintain a minimum \$US2.5 million (\$A3.93 million) in net shareholders equity".

Separately, FTI Consulting said it had called a second creditors meeting after it "received multiple non-binding indicative offers for the potential acquisition of the company's assets as a going concern".

The administrators said that "a deed of company arrangement proposal solely for the purpose of acquiring the company's listed shell was also received".

The meeting will be held online on December 20, 2024 at 11am (AEDT).

In December 2006, Genetic Technologies had a market capitalization of \$136 million and was a member of the Second 20 of the Biotech Daily Top 40 Index (BDI-40).

The company was in the BDI-20 in 2011, but by 2015 had been demoted from the BDI-40.

In 2014, Genetic Technologies founder Dr Mervyn Jacobson was sentenced to two years and eight months gaol, with a minimum of 12 months, for conspiracy and market manipulation (BD: Nov 28, 2014).

In the Supreme Court of Victoria, Justice Stephen Kaye said Dr Jacobson was convicted on two charges of conspiring to take part and 33 charges of taking part in transactions which had or were likely to have the effect of creating or maintaining an artificial price of GTG shares contrary to Section 1041A of the Corporations Act, relating to the purchase of shares by the Colorado-based XY Inc, as well as by himself, his daughter Tamara Newing and her husband Geoffrey Newing, between May 16 and November 2, 2006.

Genetic Technologies was in a suspension and last traded at 3.9 cents.

4D MEDICAL

4D Medical says it will supply its computed tomography-based (CT) lung ventilation (LVAS) imaging products to the University of Chicago Medicine.

4D Medical said its imaging technology would allow the University of Chicago to "deliver unparalleled precision in the diagnosis and management of lung conditions, further enhancing its role as a leader in pulmonary care innovation".

The company did not disclose the commercial terms of the agreement.

4D Medical said it had expanded its separate deal with the University of California San Diego (UCSD) to include its Select chest computed tomography screening service for identifying patients suitable for treatment with endobronchial valves.

4D Medical managing-director Prof Andreas Fouras said the University of Chicago deal was "another critical step in our US expansion strategy and underscores the rapidly growing recognition of [our] innovative technology in transforming respiratory care".

"The combination of functional lung imaging derived from CT LVAS and quantitative structural information, sets the standard for pulmonary imaging," Prof Fouras said.

4D Medical fell half a cent or 1.1 percent to 46 cents with 1.1 million shares traded.

CONTROL BIONICS

Control Bionics says its Neurostrip wearable sensors will be used by Neuro Elite Athletics for training US athletes and for rehabilitation by Stroke Lab in Japan.

Control Bionics said it had acquired 20 percent of the Salt Lake City, Utah-based Neuro Elite Athletics for \$US250,000 (\$A392,000).

The company said Neuro Elite Athletics used its Neurostrip electro-myography product in its Neurobounce program, which trained athletes to increase their vertical leap “by five-to-15 cm ... in just eight sessions”.

Control bionics said Neurobounce generated revenue through set-up fees, recurring software-as-a-service subscriptions and per-athlete fees, with each program expected to make about \$US25,000 a year.

The company said it would receive direct revenue from hardware sales, software subscriptions and its share of Neurobounce distributions.

Control Bionics said it held exclusive rights to expand Neurobounce to Australia and Japan.

The company said it had a separate deal with Tokyo’s Stroke Lab rehabilitation facility to use its Neurostrip technology for neurological rehabilitation.

Control Bionics said it expected a joint operating agreement to be signed by April 2025 and that the two agreements were “expected to generate material revenue through new recurring subscription fees and hardware sales”.

Control Bionics chief executive officer Jeremy Steele said the agreements underscored “Control Bionics’ ability to enter and lead high-growth markets”.

“With Neurobounce’s proven success in sports and Stroke Lab’s rehabilitation expertise, we are driving innovation while delivering value for our shareholders,” Mr Steele said.

“By strengthening our relationships with existing customers, it offers us the opportunity to more rapidly scale Control Bionics,” Mr Steele said.

“In addition, delivering on our objective of diversifying into new markets and generating recurring revenue we are building a business that has a very promising future,” Mr Steele said.

Control Bionics was up 0.1 cents or 1.5 percent to 6.6 cents.

INOVIQ

Inoviq says a proof-of-concept study shows engineered natural killer (NK) cells can produce exomes that “specifically target and kill breast cancer cells, in-vitro”.

Inoviq said the target was achieved by incorporating a chimeric antigen receptor (CAR) on the surface of the exosomes and that the receptor recognized and bound to a protein overexpressed by breast cancer cells, “increasing efficacy and reducing off-target effects”.

The company said its Exo-ace technology was used to isolate CAR-exosomes released by NK cells, with the study showing the highest dose of CAR-NK-exosomes “killed over 30 percent of breast cancer cells and showed significantly greater efficacy than exosomes isolated from NK cells as reported in other studies”.

Inoviq said it would “enhance the tumour killing activity of these exosomes by pre-stimulating cells with activators”, with optimal dosing and tumour killing activity to be evaluated in animal models prior to pre-clinical studies.

The company said further milestones included further in-vitro data by July 2025 and in-vivo efficacy data by 2026.

Inoviq was up two cents or 3.8 percent to 54.5 cents.

INVEX THERAPEUTICS

Invex says studies of its Exenatide in a three-dimensional human brain model of Alzheimer's disease shows it is well-tolerated and increases brain cell viability. Invex said the studies showed a low dose of its glucagon-like peptide 1 (GLP-1) agonist Exenatide was well-tolerated and led to no adverse effects on neural cell health in a model of Alzheimer's brain tissue in a three-day incubation period, and that Exenatide increased cell viability by about 24 percent in the presence of a sub-lethal concentration of hydrogen peroxide, which induced oxidative stress, in-vitro.

The company said the study showed Exenatide protected cell membrane integrity in the model of Alzheimer's disease brain micro-tissues when hydrogen peroxide was increased to a normally lethal concentration.

Invex said it would explore the mechanism-of-action of Exenatide in Alzheimer's disease and potential in other neuro-degenerative diseases, including traumatic brain injury.

Invex was untraded at 7.4 cents.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says after eight months, its nine-patient study shows NUZ-001 "significantly reduced the risk of death by 78.1 percent" for amyotrophic lateral sclerosis (ALS).

Earlier this year, the then Pharmaust said it had dosed nine patients in its up-to 12-patient, open-label, phase I, 12-month extension study of the then monepantel for motor neuron disease (MND), or amyotrophic lateral sclerosis (ALS); and later, said it had approval to enrol the final three patients (BD: Feb 14, Apr 10, 2024).

In August, the company said that after four months, five of the nine patients in the 12-month extension study of monepantel for motor neuron disease showed "no functional decline" (BD: Aug 26, 2024).

Today, Neurizon said eight patients continued on treatment following one patient death due to respiratory failure, with a 40.3-month mean time since onset of disease for the cohort and a total accumulative exposure to NUZ-001 of 15.5 years.

The company said NUZ-001 remained well-tolerated and showed "encouraging results in slowing disease progression and increasing the life expectancy of patients with ALS".

Neurizon said compared to untreated, unmatched controls from a historical database the extension study showed NUZ-001 "significantly increased survival ($p = 0.00062$)" and "significantly reduced the risk of death by 78.1 percent ($p = 0.0044$)".

The company said the study showed a mean rate of reduction in disease progression from baseline of 0.77 points per month, with no serious, treatment-related adverse events reported in the 27 months of continuous treatment.

Neurizon fell 1.5 cents or 8.3 percent to 16.5 cents with 1.2 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has opened its 20-patient, phase Ib trial of CHM0201 to enrol 12 patients with newly diagnosed acute myeloid leukaemia (AML).

Earlier this year, Chimeric said it had dosed the first patient in its up-to 20-patient, phase Ib trial of its CHM0201 natural killer (NK)-cells therapy in combination with standard-of-care azacitidine and venetoclax for acute myeloid leukaemia; and in June, said it had dosed the first cohort of three patients (BD: Feb 8, Jun 5, 2024).

In October, the company said it dosed the first eight patients with relapsed or refractory acute myeloid leukaemia, with no dose-limiting toxicities (BD: Oct 24, 2024).

Chimeric was up 0.1 cents or 16.7 percent to 0.7 cents with 11.1 million shares traded.

PYC THERAPEUTICS

PYC says pre-clinical studies show PYC-002 “addresses the underlying cause of Phelan-McDermid syndrome”, in animals, with in-human trials expected in 2026.

PYC said the pre-clinical studies showed PYC-002 increased SHANK3 gene expression in the critical regions of the brain implicated in [Phelan-McDermid syndrome], in animal models”.

The company said the underlying cause of Phelan-McDermid syndrome was “insufficient expression of the Shank3 gene in neurons within the brain”.

PYC said the studies showed PYC-002 restored “Shank3 gene expression in neurons derived from [Phelan-McDermid syndrome] patients back to the levels seen in unaffected individuals”.

The company said it would progress PYC-002 into an investigational new drug-enabling pathway prior to human trials expected to begin by July 2026.

PYC managing-director Dr Rohan Hockings said the “data supporting this milestone show great potential for the first RNA therapy in this indication”.

“The read-through benefits from other clinically-validated drug candidates within this class in different diseases occurring in the same target cell and organ provide a clear path to the patient-impact that we are striving for,” Dr Hockings said.

PYC fell 6.5 cents or 4.3 percent to \$1.435 with 884,681 shares traded.

TRYPTAMINE THERAPEUTICS

Tryptamine says the optimal range of psilocin blood levels after intra-venous infused psilocybin-based TRP-8803 were “highly similar in non-obese and obese individuals”.

Earlier this year, Tryptamine said its 11-healthy volunteer, phase Ib trial showed TRP-8803 was “generally safe and well-tolerated” (BD: Oct 18, 2024).

Last month, the company said the phase Ib study confirmed the required dose for a phase II trial but did not state the specific dose (BD: Nov 19, 2024).

Later, Tryptamine said it dosed all three obese participants in the study, with results expected by the end of the year (BD: Nov 29, 2024).

Today, the company said “obese volunteers infused with TRP-8803 achieved and maintained controlled psilocin blood levels within the putative therapeutic zone”.

Tryptamine chief executive officer Jason Carroll said completing the phase Ib study into an obese subject population was “another important step in the company’s clinical development pathway for TRP-8803”.

“We are confident of the infusion being effective for an obese population without the need for weight-based dosing regimens,” Mr Carroll said.

“The study met the required safety standard, as well as delivery of consistent and accurate psilocin blood levels within the targeted zone when compared to any published results from literature for oral psilocybin dosing regimens,” Mr Carroll said.

Tryptamine fell 0.3 cents or 7.1 percent to 3.9 cents with six million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has received \$2,156,377 from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.

Proteomics said the incentive related to research and development expenditure for the year to June 30, 2024.

Proteomics was up one cent or 1.5 percent to 66.5 cents.

PATRY'S

Patrys says it has received \$1,285,000 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Patrys said the incentive related to expenditure for the year to June 30, 2024.

Patrys fell 0.1 cents or 25.0 percent to 0.3 cents with 5.35 million shares traded.

CARDIEX

Cardiex has requested a trading halt "pending the completion of a proposed capital raising".

Trading will resume on December 18, 2024, or on an earlier announcement.

Cardiex last traded at 9.9 cents.

PERCHERON THERAPEUTICS

Percheron has requested a trading halt pending the announcement of "top line data for the company's phase IIb clinical trial of avicursen in Duchenne muscular dystrophy".

Trading will resume on December 18, 2024, or on an earlier announcement

Percheron last traded at 5.9 cents.

ARCHER MATERIALS

Archer has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.

The ASX said that Archer's share price rose 35.1 percent from a low of 28.5 cents at the close of trading on December 12, 2024, to a high of 38.5 cents today, and noted the "significant increase in the volume" of shares traded.

Archer said that a possible explanation for the recent trading activity could be an announcement from Alphabet, Google's parent entity "in which it unveiled a new generation chip that helped overcome a key challenge in quantum computing".

The company said that following the Alphabet announcement there "was increased investor interest, with US quantum computing stocks and quantum [exchange traded funds] trading up materially".

Archer said it was "the only known quantum computing technology company on the ASX".

Archer was up five cents or 14.5 percent to 39.5 cents with three million shares traded.

MESOBLAST

Gregory George and G to the Fourth Investments says they have increased their Mesoblast holding from 191,314,585 shares (16.76%) to 206,719,319 shares (18.10%).

The Tampa, Florida-based Mr George said the shareholders included James George, Grant George, Citicorp and JP Morgan; and the shares were acquired between October 11 and December 14, 2024, with the single largest purchase 4,156,982 shares on December 10 for \$4,776,875, or \$1.15 a share.

Mesoblast fell one cent or 0.5 percent to \$1.83 with 7.9 million shares traded.

SOMNOMED

Australian Ethical says it has reduced its substantial shareholding in Somnomed from 34,243,860 shares (15.85%) to 31,395,623 shares (14.53%).

The Sydney-based Australian Ethical said that between August 29 and December 12, 2004 it sold 2,848,237 shares for \$1,348,109, or 47.3 cents a share.

Somnomed fell 5.5 cents or 11.5 percent to 42.5 cents.

AUSTCO HEALTHCARE

Austco says it has appointed Ann Larkins as a non-executive director, effective from today.

Austco said Ms Larkins was the executive director and chief information officer at the Australian Red Cross Lifeblood and had been chief information officer and executive director of health information services at Barwon Health and Alfred Health.

The company said Ms Larkins held a Master of Business Technology from Sydney's University of New South Wales.

Austco was up half a cent or two percent to 25 cents.

INVION

Invion says it has appointed Peter MacCallum Cancer Centre's Prof Robert Ramsay as its scientific advisor

Invion said Prof Ramsay was co-head of Peter MacCallum's gastro-intestinal program, had conducted pre-clinical studies of INV043 at Peter MacCallum and was working to bring the results of these studies into an anogenital cancer clinical trial.

The company said Prof Ramsay would provide "critical strategic guidance on Invion's upcoming clinical trials and research programs".

Invion was up 2.5 cents or 9.4 percent to 29 cents.