Biotech Daily

Friday November 1, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MICRO-X UP 16%; AMPLIA DOWN 15%**

*** OCTOBER BDI-40 NEW RECORD HIGH – UP 2%, ASX200 DOWN 1%**

- MAJOR CHANGES: PRO MEDICUS TO BIG CAPS; CLARITY, EBR PROMOTED

*** AMPLIA PLACEMENT, RIGHTS RAISE $9.9m; $3.1m TO GO**

*** ANTERIS: $25m OBSIDIAN DRAW-DOWN FACILITY 'FOR US IPO'**

*** ARGENICA ARG-007 STROKE TRIAL CONTINUES UNCHANGED**

*** DIMERIX: MICHIGAN UNI FOR FSGS DMX-200 PATIENT RECRUITMENT**

*** PYC DOSES 1st PYC-001 ADOA TRIAL PATIENT**

*** CARDIEX HAS 20k US CONNEQT PULSE MONITOR PRE-ORDERS**

*** FIREBRICK MEXICO NASODINE PATENT**

*** AUDEARA RECEIVES $688k FEDERAL R&D TAX INCENTIVE**

*** GENETIC TECHNOLOGIES 2nd SUSPENSION EXTENSION**

MARKET REPORT

The Australian stock market fell 0.5 percent on Friday November 1, 2024, with the ASX200 down 41.2 points to 8,118.8 points. Fourteen of the Biotech Daily Top 40 companies were up, 21 fell and five traded unchanged.

Micro-X was the best, up one cent or 15.9 percent to 7.3 cents, with 372,919 shares traded. Medadvisor climbed 6.4 percent; Genetic Signatures was up 5.2 percent; Actinogen, Imugene and Universal Biosensors were up more than four percent; Cyclopharm, SDI and Starpharma were up more than three percent; Cynata, Medical Developments, Syntara and Telix rose more than two percent; with 4D Medical, Cochlear, Pro Medicus and Resmed up by less than one percent.

Amplia led the falls, down two cents or 14.8 percent to 11.5 cents, with 3.9 million shares traded. Avita lost five percent; Atomo and Opthea fell more than four percent; Clinuvel and Immutep were down more than three percent; Aroa, Curvebeam, Dimerix, Nova Eye, Paradigm, Percheron and Resonance shed more than two percent; Alcidion, Clarity, CSL, EBR, Orthocell and Polynovo were down one percent or more; with Emvision, Mesoblast and Neuren down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Today is pivotal for the Biotech Daily Top 40 Index (BDI-40), with the promotion of Pro Medicus to form the four Big Caps – the first change to the Big Caps in our 19 years.

In the course of October 2024, Pro Medicus overtook Cochlear's market capitalization – demanding its promotion from the BDI-20 into the Big Caps.

The consequential vacancy has been filled by Clarity, joining Telix in the multi-billion-dollar, radio-therapy club in the BDI-20.

A further consequential is the promotion of EBR Systems into the Second 20, just ahead of strong competition from Botanix and Optiscan. The latter have some revenue, while EBR is awaiting FDA approval for its cardiac pacing device.

Other contenders for promotion through the lists include 4D Medical, Arovella, Echo IQ, LTR Pharma, Lumos, Mach7, Pacific Edge and Painchek.

With the removal of the $20,360 million Pro Medicus, and promotion of the $384 million EBR, the raw data for the BDI-40 falls 49.4 percent to $20,475 million, a considerable drop, but nevertheless 11.05 percent higher than 12 months ago on October 31, 2023.

The BDI-40 (including Pro Medicus) was up 2.3 percent for the month of October and 119.4 percent for the year to October 31, compared to the benchmark ASX200 down 1.3 percent for the month and up 20.3 percent for the year.

The Nasdaq Biotechnology Index (NBI) fell 2.5 percent in October, but was up 25.9 percent for the year. Cannabis Corner fell a further 0.7 percent in October.

The collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) rose 1.9 percent to $211,671 million. Resmed led the charge, up 5.6 percent to $54,190 million, followed by CSL up 0.6 percent to $138,943 million and Cochlear up 0.5 percent to $18,538 million. From today, there will be four Big Caps.

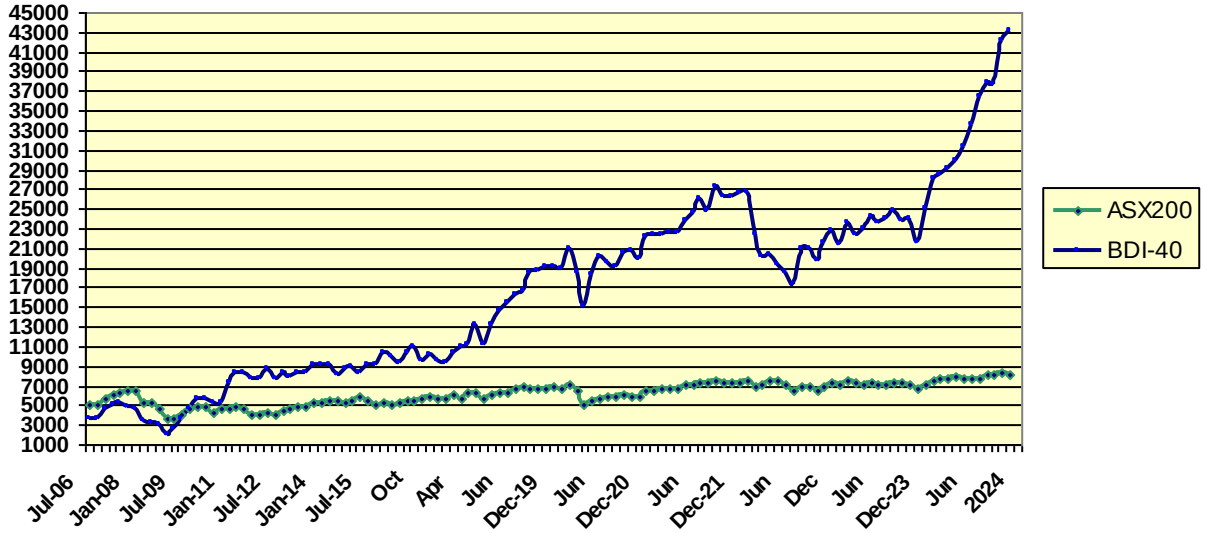
In the month of October, 16 of the BDI-40 companies were up, three by more than 10 percent; 22 fell, with 14 down by more than 10 percent; and two were unchanged.

Orthocell was the best, up $59 million or 66.3 percent to $148 million, followed by Mesoblast (17.3%), Pro Medicus (11.9%), Aroa (8.7%), Opthea (7.1%), Dimerix (6.7%), Proteomics (6.7%) and Telix (2.4%). EBR climbed 21.1 percent to $384 million.

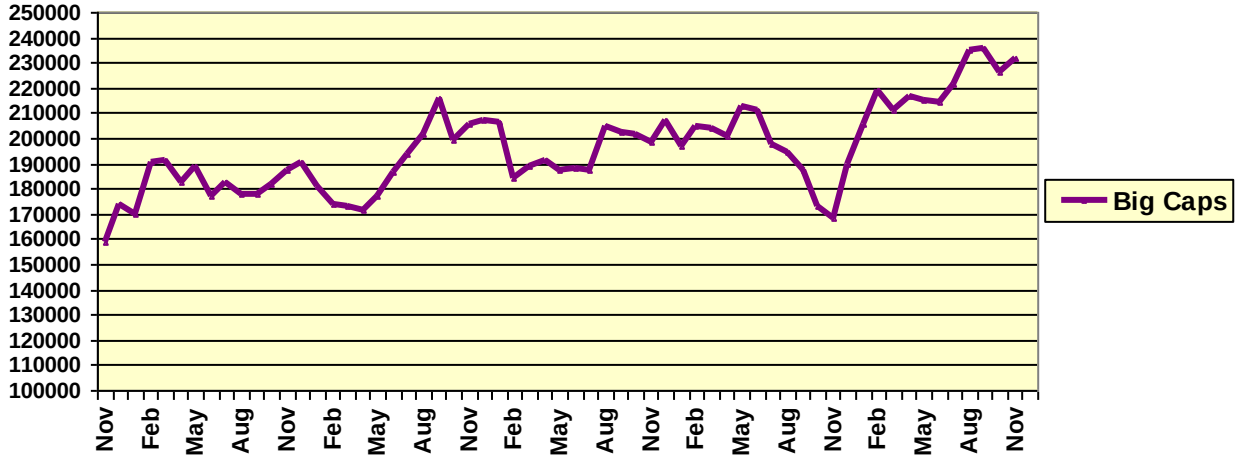
Medadvisor led the falls, on increased receipts, down $104 million or 44.4 percent to $130 million, followed by Curvebeam (37.9%), Resonance (22.2%), Polynovo (21.9%), 4D Medical (21.3%), Clarity (20.0%), Universal Biosensors (20.0%), Neuren (19.1%), Amplia (18.2%), Immutep (16.0%), Nanosonics (14.1%), Alcidion (12.05%), Percheron (11.6%) and Imugene (10.4%).

The 12 companies that comprise Cannabis Corner slipped 0.7 percent in October to $277 million, with most (six) unchanged, three up and three down.

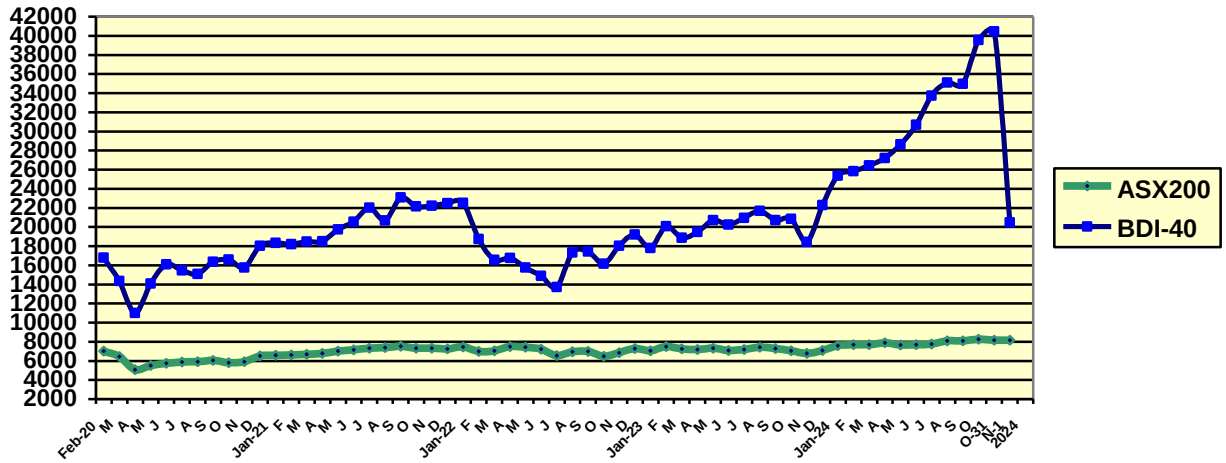
BDI-40 v ASX200 Jun 30, 2006 to Oct 31, 2024- Adjusted



Big Caps $m (COH, CSL, PME, RMD) Oct 31, 2019 – Oct 31, 2024



BDI-40 ($m) v S&P ASX 200 – Jan 31, 2020 – Oct 31, 2024 (Pre-Covid to date)



AMPLIA THERAPEUTICS

Amplia says it has raised $8.1 million in a placement and $1.8 million in an institutional rights offer at 11.5 cents a share, with a $3.1 million retail right offer to follow.

On Wednesday, Amplia said it hoped to raise up-to $13.0 million at 11.5 cents a share, a 22.3 percent discount to the 10-day volume weighted average price, in an $8.1 million placement and a $4.9 million, one-for-6.45 rights offer (BD: Oct 30, 2024).

Today, the company said that its placement raised $7.8 million, with a further $300,000 raised from its directors, subject to shareholder approval, and $1.8 million from an institutional entitlement offer.

Amplia managing-director Dr Chris Burns, said “the success of this capital raise is very significant in terms of Amplia achieving its stated goals in pancreatic cancer of completing the Accent trial with the company’s lead compound narmafotinib, and initiating a trial of narmafotinib in the US in combination with Folfirinox.”

The company said the retail component of the rights offer had a record of November 1, would open on November 6 and close on November 22, 2024.

Amplia said any shortfall under the retail offer would be subscribed for by the underwriters, Bell Potter and Taylor Collison.

Amplia fell two cents or 14.8 percent to 11.5 cents with 3.9 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says it has a $25 million draw-down equity facility with New York’s Obsidian Global Partners to support its initial public offer and re-domicile to the US.

Earlier this year, Anteris said it intended to redomicile to the US, list on the Nasdaq via the Delaware-based Anteris Technologies Global Corp and remain on the ASX through Chess depository interests (BD: Aug 13, 2024).

At that time, the company said the US holding company Anteris Technologies Global Corp expected to raise between about $US75 million ($A114 million) and $US100 million ($167 million) in an initial public offer of shares, which was expected to be underwritten, to list on the Nasdaq.

Last month, Anteris said it had delayed its planned re-domicile to the US, its Nasdaq listing, scheme meetings and its extraordinary general meeting (BD: Sep 30, 2024).

Today, the company said it had drawn-down an initial $7.5 million, with additional draw-downs to be made in increments of $5.0 million.

Anteris said that for each draw-down it would pay Obsidian a fee of three percent, and that each convertible note had a face value of $US1.15 ($A1.75).

The company said in addition to each draw-down it would issue Obsidian options with a total value equal to 25 percent of the amount drawn-down, exercisable at $25.00 each within three years from the issue date,

Anteris said the issue of the first tranche of options following its initial $7.5 million draw-down was subject to shareholder approval, and if not approved, would incur a $300,000 payment to Obsidian.

The company said it was permitted to repay the convertible notes in cash at any time, at no premium to the face value of the notes prior to January 15, 2025, a five percent premium to the face value of the notes between January 16 and June 30, 2025 or a 10 percent premium after July 1, 2025.

Anteris said the conversion price of the convertible notes would be the lesser of $20.00 and 90 percent of the seven-day volume weighted average price during the 20 days prior to Obsidian converting the notes.

Anteris fell 55 cents or 5.1 percent to $10.20.

ARGENICA THERAPEUTICS

Argenica says a data safety board review of the first 46 patients in its 92-patient, phase II trial of ARG-007 for stroke recommends the study continue “with no modifications”.
Earlier this year, Argenica said it had dosed the first cohort in the study of ARG-007 for acute ischaemic stroke, with no adverse events reported; and later, said following five-patient safety data it had been approved to continue the trial (BD: Apr 10, 29, 2024).
In July, the company said it had opened eight of 10 trial sites and dosed 20 of up-to 92 patients in its single-dose, placebo-controlled, phase II trial of ARG-007 for acute ischaemic stroke (BD: Jul 24, 2024).
Last month, Argenica said it had dosed 43 of 92 patients in the trial with no adverse events and all 10 sites administering doses (BD: Sep 6, 2024).
Today, the company said the independent data safety monitoring board recommended that the phase II trial “continues with no modifications to the study protocol”.
Argenica said that 58 patients had been dosed to date, with seven of the 10 activated hospitals having dosed patients.
The company said one patient had two non-serious adverse events that were reported “as possibly related to the administration of ARG-007” including bradycardia and hypotension, more than eight hours after dosing in the trial.
Argenica said the trial was double-blinded, so it was “not known if this patient received placebo or ARG-007” but under the study protocol, such events must be reported.
The company said the next safety review would follow the dosing of 69 patients and it expected all 92 patients to be dosed by July 2025, with topline data to be provided “within weeks of the final 90-day follow up of last patient dosed”.
Argenica fell 1.5 cents or 1.9 percent to 77 cents.

DIMERIX

Dimerix says it has partnered with the Ann Arbor-based University of Michigan to identify patients for its up-to 286-patient, phase III trial of DMX-200 for kidney disease.
In 2022, Dimerix said it had US Food and Drug Administration approval for its phase III trial of DMX- 200 for focal segmental glomerulo-sclerosis (FSGS) kidney disease and later said it had dosed the first patient (BD: Oct 21, 2021; Feb 1, May 9, 31, 2022).
Earlier this year, the company said an interim trial analysis showed that DMX-200 reduced proteinuria more than placebo (BD: Mar 11, 2024).
Today, Dimerix said it would use the University of Michigan’s ‘Nephrotic Syndrome Study Network of Rare Kidney Diseases’ (Neptune) to “assist with biomarker profiling and prospectively identifying patients with FSGS most likely to benefit”.
The company said the University had enrolled more than 1,100 participants from 32 sites in the last 16 years to collect “comprehensive, long-term clinical and molecular data into a resource for better understanding nephrotic syndrome complexities, including FSGS”.
Dimerix said the partnership would help identify US patients who met the criteria, might benefit from DMX-200 and refer those patients to the closest clinical trial site.
The company said an interim analysis was planned after the first 144 patients reached 35-week treatment “expected around mid-2025”.
Dimerix chief medical officer Dr David Fuller said the deal was “an extremely important collaboration … as Neptune is the recognized global leader in rare kidney disease”.
“The Neptune match program has a track record of … assisting recruitment into trials and should boost our recruitment rate … while the biomarker work will provide … invaluable insights into the mechanism-of-action and response to DMX-200,” Dr Fuller said.
Dimerix fell one cent or 2.5 percent to 39 cents with 1.4 million shares traded.

PYC THERAPEUTICS

PYC says it has dosed the first of up-to three patients in the first cohort of its single ascending dose study of PYC-001 for autosomal dominant optic atrophy (ADOA).
Earlier this year, PYC said it had ethics approval for a nine-patient, single-ascending dose study of PYC-001 for the blinding-eye disease ADOA (BD: Aug 15, 2024).
Today, the company said the first patient received a 3 microgram (µg) intra-vitreal dose of PYC-001 in one eye.
PYC said two more patients would be enrolled in the initial dose cohort, and were "expected to receive their first dose of PYC-001 soon".
The company said the study was scheduled to last about 18 months and would provide safety, tolerability and efficacy data for PYC-001 in 2025.
PYC said the study would be used to inform a multiple ascending dose study, which it expected to begin by July 2025 as well as the design of a registrational trial, expected in 2026, for approval of the drug with a new drug application planned for 2028.
The company said it was the second drug development program to use its RNA conjugate platform to have advanced into human trials.
PYC said the first program had provided positive safety and efficacy signals in patients with the blinding eye disease retinitis pigmentosa type-11 (BD: 5, 12, Aug, 2024).
PYC was up half a cent or 2.7 percent to 19 cents with 1.1 million shares traded.

CARDIEX

Cardiex says it has had more than 20,000 pre-orders of its arterial health assessment for the Conneqt Pulse vascular biometric monitor in the US.
Cardiex said the "key milestone marks the first phase of the company's transition to delivering transformative cardiovascular solutions, based on our industry-leading vascular biomarker technology, across a broader range of healthcare markets".
The company said it had conducted a "very successful waitlist campaign for Pulse" which included a six-part 'nurturing campaign', and that exclusive invitations for pre-orders of the product had commenced.
Cardiex said Conneqt Pulse was designed to "meet the rising demand for comprehensive cardiovascular health monitoring solutions that go beyond traditional blood pressure measurement".
The company said the device was focused on accessible, personalized health insights and was "set to become a valuable tool for individuals seeking pro-active cardio-vascular health management and for clinicians looking to enhance patient care with advanced vascular health metrics".
Cardiex said it would continue to roll-out "additional waves of exclusive pre-order invitations to wait-list members over the coming weeks … to ensure an efficient pre-order experience, optimize customer support and prepare for the device's broader market launch".
Cardiex managing-director Craig Cooper said it was "a pivotal moment for the company as we launch the Conneqt Pulse, bringing our vascular health technology directly to US consumers for the first time".
"This phased. pre-order roll-out allows us to ensure a smooth customer experience while efficiently managing demand and conversions," Mr Cooper said.
"Reaching this milestone reaffirms the strength of our strategy, and we expect the positive momentum to support revenue growth and accelerate our entry into broader healthcare markets," Mr Cooper said.
Cardiex was up 0.3 cents or 3.8 percent to 8.2 cents.

FIREBRICK PHARMA

Firebrick says the Mexican Institute of Industrial Property has granted a patent protecting its Nasodine nasal spray for Covid-19.

Firebrick managing-director Dr Peter Molloy told Biotech Daily that the patent, titled 'Prevention of Infection by Highly Pathogenic Viruses using Topical Application of Povidone-Iodine on Mucous Membranes' would protect the company's intellectual property until 2041.

The company said the patent "protected the use of Nasodine nasal spray and any other intra-nasal povidone-iodine preparations as a method of reducing the viral load of Sars-Cov-2 in the nose".

Firebrick said the patent was supported by published clinical trial results which showed that in Covid-19 subjects "with early symptoms, the frequent use of Nasodine over three days resulted in a 100 percent clearance of the virus from the nasal passages".

Last year, the company said its 39-patient, phase II trial showed Nasodine reduced severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) viral load 100 percent compared to 48 percent for placebo ($p = 0.028$) (BD: Aug 7, 2023).

Today, Firebrick said granted claims covered pre-exposure prophylaxis, or preventative use prior to exposure, against Sars-Cov-2, notably in the case of healthcare workers.

The company said the Nasodine patent had been granted in the US, Australia and South Africa, with applications in other countries pending.

Dr Molloy said the "patent and the clinical trial are very relevant to the use of Nasodine as a nasal antiseptic."

"The elimination of viruses from the nose and especially pandemic viruses, is a key benefit of Nasodine," Dr Molloy said.

Firebrick was up 0.1 cents or 1.8 percent to 5.7 cents.

AUDEARA

Audeara says it has received $688,307 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive Program.

Audeara said the incentive related to expenditure on the development of its "headphones and innovative personal sound amplification solutions" for the year to June 30, 2024.

Audeara managing-director Dr James Fielding said the Australian Government program "greatly assists Australian companies to advance their innovative solutions".

"This offset is especially important for Audeara as it continues to progress its healthy listening solutions, which have the benefit of assisting those with hearing difficulties," Dr Fielding said.

Audeara was untraded at 4.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it "requires additional time to … secure funding to finalize its entitlement offer and secure a strategic distribution partnership".

Last week, Genetic Technologies requested a suspension following a trading halt for its "operational review and progress on its fund raising" which it initially expected to announce on October 21, 2024 (BD: Jul 26; Oct 17, 21, 2024).

Later, the company said it had extended the suspension (BD: Oct 24, 2024).

Today, Genetic Technologies said it expected trading to resume on December 2, 2024, or on an earlier announcement.

Genetic Technologies last traded at 3.9 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT OCT 31, 2024

Company $Am	Oct 31, 2023	Sep 30, 2024	Oct 31, 2024
Cochlear	15,783	18,431	18,538
CSL	112,240	138,047	138,943
Pro Medicus	7,786	18,187	20,360
Resmed	32,050	51,317	54,190
BDI-20			
Avita	368	396	418
Clarity	275	2,734	2,187
Clinuvel	726	716	711
Compumedics	27	55	56
Cyclopharm	185	169	156
Cynata	24	39	42
Genetic Signatures	72	151	152
Immutep	374	494	415
Impedimed	232	113	111
Medical Developments	69	50	52
Mesoblast	289	1,285	1,507
Nanosonics	1,129	1,130	971
Neuren	1,357	1,952	1,579
Nova Eye	35	42	39
Opthea	219	960	1,028
Polynovo	797	1,823	1,423
SDI	97	111	117
Starpharma	55	42	39
Syntara	23	59	56
Telix	2,829	6,841	7,005
Second 20			
4D Medical	161	277	218
Actinogen	38	71	71
Alcidion	123	83	73
Amplia	16	44	36
Aroa	266	195	212
Atomo	13	13	14
Curvebeam	104	58	36
Dimerix	76	209	223
EBR Systems	202	317	384
Emvision	125	174	167
Imugene	308	357	320
Medadvisor	104	234	130
Micro-X	72	39	37
Orthocell	72	89	148
Paradigm	168	68	73
Percheron	53	95	84
Prescient	46	33	33
Proteomics	117	89	95
Resonance	28	27	21
Universal Biosensors	55	45	36

* Biotech Daily editor, David Langsam, owns shares in 4D Medical, Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, Clarity, Cochlear, Control Bionics, Cynata, Nanosonics, Neuren, Patrys, Polynovo, Syntara and Telix as well as non-biotech stocks. Through Australian Ethical Superannuation he has an indirect interest in other companies: **https://www.australianethical.com.au/personal/ethical-investing/companies-we-invest-in/**. These holdings are liable to change.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au; www.biotechdaily.com.au