



Biotech Daily

Monday May 1, 2023

Daily news on ASX-listed biotechnology companies

- * APRIL BDI-40 UP 6%, ASX200 UP 2%, BIG CAPS UP 6%; NBI UP 1.5%
- * TODAY: ASX, BIOTECH UP: USCOM UP 14%; IMPEDIMED DOWN 11%
- * REDHILL REVENUE DOWN 28% TO \$93m; \$108m LOSS; 40:1 CONSOLIDATION
- * 4D MEDICAL: 1st US VETERANS AFFAIRS XV LVAS SCAN
- * EMYRIA RAISES \$2.5m
- * FIREBRICK RAISES \$1m
- * NOVA EYE: 1st US ITRACK ADVANCE SURGERY, SALES
- * POLAND APPROVES TRUSCREEN CERVICAL CANCER TEST
- * CLINUVEL TRIALS SCENESSE FOR VARIEGATE PORPHYRIA
- * GERMANY APPROVES IMMUTEP EFTI, AVELUMAB UROTHELIAL CANCER TRIAL
- * AROVELLA CLOSES PERTH OROMIST R&D PLANT
- * CANN GROUP DRIED MARIJUANA FLOWER ON SALE IN GERMANY
- * PHARMAUST COMPLETES MND DOSING; 'CAPITAL RAISE' HALT
- * POLYNOVO REQUESTS 'REVENUE' TRADING HALT
- * DIMERIX REQUESTS 'CAPITAL RAISING' TRADING HALT
- * ANTERIS 1.5m DIRECTOR OPTIONS AGM
- * RICHMOND HILL TAKES 7.1% OF UNIVERSAL BIOSENSORS
- * GZ FAMILY TAKES 9.1% OF LUMOS
- * GZ FAMILY TAKES 5.1% OF ATOMO
- * ASAHI GLASS REDUCES TO 6.1% IN REGENEUS
- * DIMERIX APPOINTS CLINTON SNOW DIRECTOR
- * CMO DR JOHN FRIEND REPLACES KAZIA'S DR JAMES GARNER, ON \$830k PA
- * TOM MILICEVIC REPLACES ANTEO CFO TIM PRITCHARD; CHARLIE HUANG

MARKET REPORT

The Australian stock market was up 0.35 percent on Monday May 1, 2023, with the ASX200 up 25.4 points to 7,334.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and two were untraded.

Uscom was the best, up 0.5 cents or 14.3 percent to four cents, with 207,161 shares traded. Oncosil was up 9.1 percent; Resmed climbed 6.6 percent; Amplia, Atomo, Imugene, Kazia and Nova Eye improved four percent or more; Actinogen, Emvision and Telix were up more than three percent; Resonance rose 2.3 percent; Clinuvel, Mesoblast, Orthocell and Prescient were up more than one percent; with CSL, Cyclopharm and Opthea up by less than one percent.

Impedimed led the falls, down two cents or 10.8 percent to 16.5 cents, with 7.5 million shares traded. Antisense and Cynata fell five percent or more; Genetic Signatures, Micro-X and Universal Biosensors were down more than three percent; Nanosonics, Neuren and Paradigm shed two percent or more; Immutep, Next Science, Pro Medicus, Proteomics and Volpara were down more than one percent; with Avita and Cochlear down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) climbed 6.2 percent in April to \$20,698 million.

Overall, 16 of the BDI-40 companies were up, with 10 up by 10 percent or more; while 21 fell, with 11 down by more than 10 percent, but it was a tale of two indices.

The heavy lifting was done by the BDI-20, with 12 companies up (seven by more than 10 percent) and eight down, with three down by more than 10 percent.

Just four companies in the less robust Second 20 were up, of which three climbed more than 10 percent in April; while 13 fell, with eight down by more than 10 percent.

Telix contributed the most, up \$1,172 million or 54.0 percent to a record market capitalization of \$3,342 million, but Impedimed was the percentage best, adding \$144 million or 77.0 percent to \$331 million. At 18.5 cents, Impedimed is still a long way from its 2007 initial public offer price of 72 cents and its all-time high of \$1.56 in 2016.

From a low base, Kazia was the third best, recovering \$11 million or 34.4 percent to \$43 million, followed by Pharmaxis (33.3%), Amplia (25.0%), Avita (17.9%), Emvision (16.2%), Cyclopharm (15.2%), Nanosonics (13.5%) and Compumedics (12.0%).

Paradigm led the falls, down \$116 million or 28.9 percent to \$285 million, followed by Cynata (27.5%), Resonance (25.9%), Alcidion (22.6%), Uscom (22.2%), Nova Eye (18.4%), Dimerix (16.2%), Atomo (13.6%), Patrys (12.1%), Medical Developments (10.4%) and Antisense (10.0%).

The ASX200 was up 1.8 percent in April to 7,309 points, a 1.7 percent fall over 12 months, compared to the BDI-40 up 31.4 percent for the year (see charts below). The Nasdaq Biotechnology index was up 1.5 percent in April and was up 11.3 percent for the year.

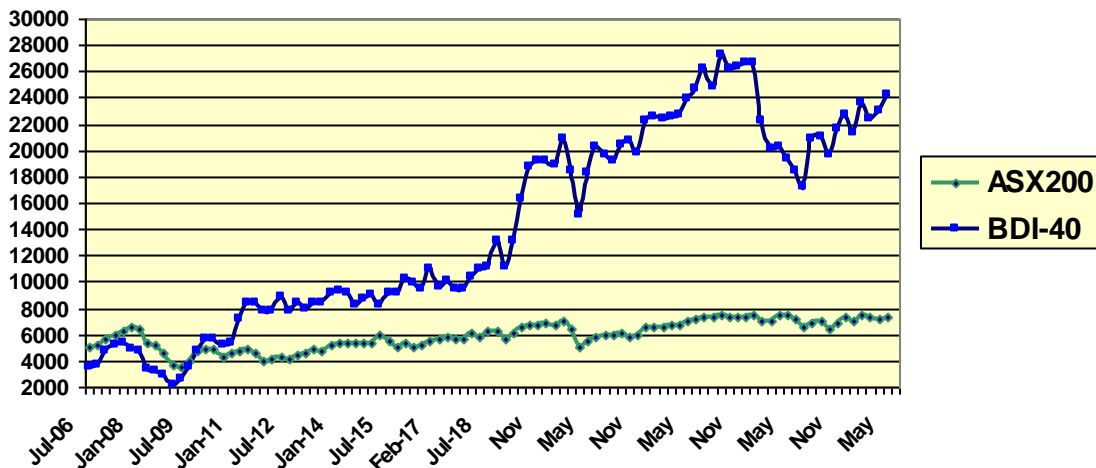
The collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) rose 6.0 percent in April to \$212,563 million, 13.5 percent higher than April 30, 2022, and not far from its record high of \$215,852 at August 30, 2021.

Cochlear climbed 7.9 percent to \$16,395 million CSL was up 6.5 percent to \$146,640 million, with Resmed up 4.6 percent to \$49,528 million.

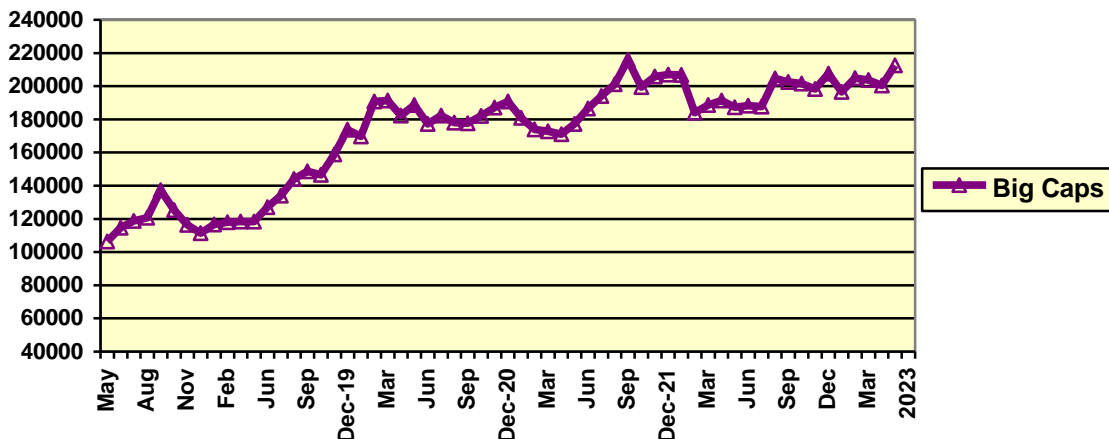
Cannabis Corner continued its downward slide, losing a further 5.7 percent in April to a collective market capitalization of \$699 million, 39.6 percent below last year. Five companies fell, led by Avecho down 35.3 percent to \$11 million, only two were up with Cann Group up 14.3 percent to \$64 million, with four unchanged.

Outside the BDI-40, 4D Medical jumped \$157 million or 167.0 percent to \$251 million on the first commercial sales of its lung imaging system. EBR was up 26.2 percent for the month and 43.7 percent for the year, with pivotal results due later this month, and despite a series of ASX queries, Arovella was up 72.7 percent for the month and 119.2 percent for the year to \$57 million.

BDI-40 v ASX200 Jun 30, 2006 to Apr 30, 2023- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Apr 30, 2018 – Apr 30, 2023



REDHILL BIOPHARAMA

Redhill says that revenue for the 12 months to December 31, 2022 fell 27.9 percent to \$US61,800,000 (\$A93,145,000) with net loss after tax down 26.7 percent to \$US71,669,000 (\$A108,065,000).

Redhill said that prescriptions of Talicia, containing omeprazole magnesium, amoxicillin and rifabutin, increased 57 percent, but didn't ascribe a value to the sales.

The company said that Talicia, formerly RHB-105, was "the most prescribed branded agent by US gastro-enterologists" and was on-track to become the most prescribed branded Helicobacter pylori therapy in the US in 2023.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

On the Nasdaq, Redhill was up 15 US cents or 6.58 percent to \$US2.43 (\$A3.66) with 110,878 shares traded. In March, Redhill conducted a 40-to-one consolidation.

4D MEDICAL

4D Medical says it has completed its first commercial X-ray velocimetry lung ventilation analysis software (XV LVAS) scan with the US Department of Veterans Affairs.

Last month, 4D said it had its first XV LVAS software-as-a-service contract with the University of Miami worth up to \$1.5 million (BD: Apr 5, 13, 2023).

Today, the company said the first commercial scan for the Department of Veterans Affairs was done at the Harry S Truman Memorial Veterans Hospital in Colombia, Missouri.

4D Medical said its technology provided physicians "with the insight only available through a four-dimensional image".

The company said that the scan was its first commercial activity with the Department of Veterans Affairs and although "not immediately material from a revenue perspective" was significant validation of its engagement with the Department.

4D Medical chief executive officer Prof Andreas Fouras said the Harry S Truman Hospital was "within a network that is larger than the entire hospital system across Australia".

"The promise of utilising XV technology to inform treatment for veterans afflicted by respiratory disease has now been demonstrated in a routine ... setting," Prof Fouras said. "Furthermore, 4D Medical's XV LVAS software as a service platform is extremely scalable, providing a proven basis for our ambitions to deliver rich respiratory health insights across the entire veterans affairs," Prof Fouras said. "Pursuing this opportunity with the Veterans Affairs is our highest priority."

4D was up 10.5 cents or 12.35 percent to 95.5 cents with 4.7 million shares traded.

EMYRIA

Emyria says it has "firm commitments" for a \$2.5 million placement at 15 cents a share, an 11.76 percent discount to the last traded price on April 21, 2023.

Emyria said each share would have an attaching option, exercisable at 30 cents within two years, Dr Andrew 'Twiggy' Forrest's Tattarang Tenmile Ventures invested in the placement, with Sixty Two Capital and Taylor Collison joint lead managers entitled to a six percent capital raising fee on the funds raised by each respective manager.

Emyria said the funds would support its 3,4-methylene-dioxy-methamphetamine (MDMA) and psilocybin assisted therapies from July 1, 2023, advance its "ultra-pure cannabinoid" trial, advance pre-clinical screening of its novel MDMA-inspired drug with the University of Western Australia and for working capital.

Emyria fell 1.5 cents or 8.8 percent to 15.5 cents with 2.9 million shares traded.

[FIREBRICK PHARMA](#)

Firebrick Pharma says it has “binding commitments” for a \$1 million placement at 15 cents a share, led by its management team and supported by existing investors.

Firebrick said the shares would be issued in two tranches, with 5,610,000 shares to be issued on May 9, 2023 and the second pending shareholder approval would issue executive chair Dr Peter Molloy and director Dr Stephen Goodall 530,000 shares each on or about June 13, 2023.

The company said the funds would be used to complete the Nasodine phase III trial, to support costs associated with the Administrative Appeals Tribunal regulatory appeal and for working capital (BD: Mar 1, Dec 2, 2022).

Dr Molloy said the placement was designed to top up cash reserves until the company received an expected research and development tax incentive in September and it put the company in “a strong position to deliver on [its] goals”.

Firebrick fell 1.75 cents or 8.75 percent to 18.25 cents.

[NOVA EYE MEDICAL](#)

Nova Eye says it has its first US sales of Itrack Advance, with the first surgery to treat glaucoma performed on April 11, 2023.

The company said feedback on device performance was “very positive” and its sales team would continue to introduce Itrack Advance to existing customers who were familiar with the surgical technique and efficacy of the original Itrack catheter.

Nova Eye managing director Tom Spurling said the support provided by existing customers was pleasing as the company continued commercial roll out.

Nova Eye was up one cent or 4.2 percent to 25 cents.

[TRUSCREEN GROUP](#)

Truscreen says the Polish Ministry of Health has listed its cervical screening device on the Polish Innovation Register.

Truscreen said Poland had an annual total of 3,513 cervical cancer cases due to having no national screening or vaccination program, which contributed to the country’s low early detection rate and higher rate of high-risk infection.

The company said it has been partnering with a private network of medical clinics to roll-out its optical and electrical cervical screening devices.

Truscreen said the regulatory approval would increase awareness of its device.

Truscreen was up 0.4 cents or 19.05 percent to 2.5 cents.

[CLINUVEL PHARMACEUTICALS](#)

Clinuvel says it has begun a six-patient study of Scenesse, or 16mg afamelanotide, for “the rare metabolic disorder” variegate porphyria.

Clinuvel said patients in the trial would be dosed with Scenesse every four weeks for six months, with a one-month follow-up.

The company said the study focused on the frequency and severity of phototoxic and dermatological symptoms, including changes in the severity of skin disease.

Clinuvel said it had dosed its first Canadian erythropoietic protoporphyria (EPP) patient after Health Canada had approved the drug under a special access program, with treatment covered by health insurance.

Clinuvel was up 32 cents or 1.6 percent to \$20.54.

IMMUTEP

Immutep says German has approved a 30-patient, investigator-led, open-label, phase I trial of eftilagimod alpha, or efti, with avelumab for metastatic urothelial carcinoma. Immutep said the trial was jointly funded with the Darmstadt, Germany's Merck KGaA and would evaluate the dual immune-oncology combination of efti, formerly IMP321, and avelumab, or Bavencio, an anti-programmed death-ligand 1 (anti-PD-L1) therapy for patients with metastatic urothelial carcinoma.

The company said it had regulatory approval from the Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines for the trial evaluating the safety and efficacy of efti.

Immutep said urothelial carcinoma was the most common type of bladder cancer, and the trial would use efti in combination with Merck KGaA's Bavencio.

Immutep chief executive officer Marc Voigt said that as well as bringing a new chemotherapy-free treatment to patients with advanced urothelial cancer the trial hoped to "build upon the encouraging clinical data" for efti in combination with avelumab in other cancers.

"Efti's unique activation of antigen-presenting cells to fight cancer has shown a benefit with avelumab, and we believe this dual ... approach has broad potential to drive superior clinical outcomes across a variety of indications, including bladder cancer, where avelumab monotherapy has regulatory approval," Mr Voigt said.

Immutep fell half a cent or 1.9 percent to 26 cents.

AROVELLA THERAPEUTICS (FORMERLY SUDA PHARMACEUTICALS)

Arovella says it has completed the shutdown of its Perth Oromist research and development facility in line with last year's strategic review.

In 2012, the then Suda acquired the Novamist sublingual technology platform to develop spray formulations of existing drugs (BD: Dec 21, 2012).

Last year, Arovella said that a review found that closing the Oromist facility would cost up to \$300,000 and save about \$1.5 million a year, and it would close the site to focus on its invariant natural killer T-cell program (BD: Oct 26, 2022).

Today, the company said it would focus entirely on its invariant natural killer T-cell therapy platform for allogenic cell therapies to target blood cancers and solid tumors.

Arovella chief executive officer Dr Michael Baker thanked "everyone involved for the professionalism demonstrated in completing the orderly shutdown of the research and development facility".

Arovella fell 0.3 cents or four percent to 7.2 cents with 2.1 million shares traded.

CANN GROUP

Cann Group says Germany has approval the sale of its dried marijuana flower product, with the first shipment delivered and released for supply.

Cann Group said the high tetrahydrocannabinol (THC) marijuana flower was developed through its research and development and breeding program and is part of its overseas supplier program.

Cann Group chief executive officer Peter Koetsier said while the short-term priority was supplying Australian customers, the shipment signalled the beginning of plans to "increase sales overseas in countries such as Germany" as production capacity increases.

Cann Group was unchanged at 16.5 cents.

PHARMAUST

Pharmaust says it has dosed all 12 patients in its phase I/II trial of monepantel for motor neurone disease, and has requested a trading halt regarding a capital raising.

Last year, Pharmaust said it has dosed the first patient in its open-label, four-week dose-escalation, trial to assess the safety and tolerability of monepantel in patients with motor neurone disease, also known as Lou Gehrig's disease (BD: Oct 3, 2022).

Today, the company said all 12 patients had elected to continue the treatment and it expected a safety monitoring committee to review the data for safety, pharmaco-kinetics and pharmaco-dynamics, later this month.

Separately, Pharmaust said it had requested a trading halt "pending an announcement of a capital raising".

Trading will resume May 3, 2023, or on an earlier announcement.

Pharmaust was untraded at 10 cents.

POLYNOVO

Polynovo says it has requested a trading halt "in respect of finalizing an announcement on revenue performance".

Trading will resume May 3, 2023, or on an earlier announcement.

Polynovo last traded at \$1.63.

DIMERIX

Dimerix says it has requested a trading halt "for the purposes of considering, planning and executing a capital raising".

Trading will resume May 3, 2023, or on an earlier announcement.

Dimerix last traded at 9.7 cents.

ANTERIS TECHNOLOGIES

Anteris says its annual general meeting will vote to issue 4,167 shares and options to chief executive officer Wayne Paterson and 1,459,167 shares and options to directors. Anteris said shareholders would vote to issue 4,167 shares and options to Mr Paterson in return for a \$100,008 advance with the options exercisable at \$29.00 each within two years.

The company also said shareholders would vote to issue a further 1,000,000 options to Mr Paterson, 225,000 options to chair John Seaberg, 115,000 options to director and company secretary Stephen Denaro and 115,000 options to director Wenyi Gu.

Anteris said the options were exercisable at \$21.19 each, within five years and vesting in three equal annual tranches.

Anteris said the meeting would vote to adopt the remuneration report, re-elect Mr Denaro as a director, approve the 10 percent placement facility and ratify the issue of 1,454,167 shares and options from the February 15, 2023 capital raising.

The company said shareholders would vote to issue 500,000 options to Evolution Capital Pty Ltd for their services in facilitating the capital raising, exercisable at \$29 each by February 15, 2025.

The meeting will be held virtually and at the Hilton Brisbane, 190 Elizabeth Street, Brisbane, on May 29, 2023 at 10am (AEST).

Anteris was up five cents or 0.2 percent to \$22.13.

UNIVERSAL BIOSENSORS

Richmond Hill Capital Pty Ltd says it has increased its holding in Universal Biosensors from 12,903,212 shares (6.08%) to 15,080,709 shares (7.10%).

The Melbourne-based Richmond Hill said between February 8 and April 28, 2023, it bought 2,177,497 Chess depositary interests (CDIs) for \$579,793 or an average of 26.6 cents per CDI.

Universal Biosensors fell one cent or 3.9 percent to 24.5 cents.

LUMOS DIAGNOSTICS

GZ Family Holdings Pty Ltd as trustee for GZ Family Trust says it has increased its holding in Lumos from 20,605,638 shares (8.07%) to 24,930,614 shares (9.12%).

The Sydney-based GZ Family Holdings said that between April 3 and 24, 2023 it bought shares in 22 separate transactions, with the largest purchase 2,000,000 shares for \$40,030, or 2.0 cents a share.

Lumos fell 0.1 cents or 5.6 percent to 1.7 cents.

ATOMO DIAGNOSTICS

GZ Family Holdings Pty Ltd as trustee for GZ Family Trust says it has become a substantial shareholder in Atomo with 29,118,147 shares, or 5.10 percent.

The Sydney-based GZ Family Holdings said that between June 17, 2022 and April 13, 2023 it bought the shares in more than 80 transactions, with the largest purchase 2,000,000 shares on March 17, 2023 for \$90,068, or 4.5 cents a share and 2,000,000 shares on April 5, 2023 for \$78,059 or 3.9 cents a share.

Atomo was up 0.15 cents or 4.4 percent to 3.55 cents.

REGENEUS

AGC Inc, formerly the Asahi Glass Co, says it has reduced its substantial holding in Regeneus from 22,459,393 shares (7.5%) to 18,837,757 shares (6.1%).

The Tokyo-based AGC said that between February 8 and April 26, 2023 it sold 3,621,636 shares in 11 transactions, at prices ranging from 1.0 cents to 1.9 cents.

Regeneus was untraded at 1.2 cents.

DIMERIX

Dimerix says it has appointed Clinton Snow as a non-executive director, effective from May 1, 2023.

Dimerix said Mr Snow had about 20 years of experience in engineering management, risk management, project delivery and assurance including his current role as a non-executive director of Icetana.

The company said Mr Snow held a Bachelor of Chemical Engineering and a Bachelor of Commerce from the University of Melbourne.

KAZIA THERAPEUTICS

Kazia says that its New Jersey-based chief medical officer Dr John Friend has replaced chief executive officer Dr James Garner, effective from today.

Kazia said that Dr Friend had been appointed chief executive officer and would be appointed managing-director “in due course” and would be paid \$US550,000 (\$A830,000) a year, with the opportunity to earn up to 60 percent of that in short-term incentives, with 3,000,000 options to be granted as a long-term incentive.

Kazia chair Iain Ross said that Dr Garner was appointed in February 2016 and was “responsible for the transformation of the legacy Novogen business into the current organization”.

“He drove the in-licencing of paxalisib and EVT801 and managed the deployment of a broad clinical program for both assets, in collaboration with leading cancer centres in the US and Europe,” Mr Ross said.

“He leaves to pursue other opportunities,” Mr Ross said.

“On behalf of the board and on a personal basis, I want to thank James for his enormous contribution to Kazia, and to wish him every success in his future endeavors,” Mr Ross said.

Last year, Kazia said the first stage of the paxalisib arm in the GBM Agile glioblastoma study did not meet pre-defined criteria for continuing in its “primary path-to-market” and the share price fell 52.9 percent to 24 cents and continued falling until December, but has been recovering in recent months (BD: Aug 1, 2022).

The company said that Dr Friend was appointed chief medical officer in November 2021. Kazia said that Dr Friend was “an accomplished physician executive with a more than 25-year career” and a background in establishing and leading business units in small to mid-sized biopharmaceutical companies.

The company said that Dr Friend was previously Collectar Biosciences chief medical officer and had worked for Helsinn Therapeutics, Akros Pharma, Actavis, Alpharma, Hospira and Abbott Laboratories.

Kazia said that Dr Friend held a Bachelor of Arts in chemistry from the Dallas, Texas-based Southern Methodist University and a Doctor of Medicine from the New Brunswick-based Rutgers State University of New Jersey.

Kazia was up 0.75 cents or four percent to 19.5 cents.

ANTEOTECH

Anteo says Tom Milicevic has been appointed acting company secretary and chief financial officer replacing Tim Pritchard, effective from May 27, 2023.

Anteo said Mr Pritchard was pursuing opportunities outside the company and it had begun a search for a replacement.

The company said Mr Milicevic had more than 20 years of experience in finance including IQ Group, Oncosil and Allegra, and had been engaged on a contract basis from May 1, 2023.

Anteo said Dr Charlie Huang had resigned as chief innovation officer effective from today. Anteo managing-director David Radford said the company was moving to a commercially focused entity “and these changes in personnel will enable the company to bring additional skills that are aligned to this vision of profitable international growth”.

Anteo was up 0.1 cents or three percent to 3.4 cents with 1.3 million shares traded.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT APR 30, 2023

Company \$Am	May-22	Apr-23	May-23
Cochlear	15,093	15,199	16,395
CSL	129,502	137,716	146,640
Resmed	42,623	47,587	49,528
BDI-20			
Avita	227	497	586
Clinuvel	794	939	995
Compumedics	46	25	28
Cyclopharm	140	171	197
Cynata	53	40	29
Genetic Signatures	192	109	108
Immutep	295	229	233
Kazia	111	32	43
Medical Developments	250	96	86
Mesoblast	673	704	649
Nanosonics	1,168	1,505	1,708
Neuren	482	1,704	1,810
Nova Eye	35	49	40
Opthea	357	341	332
Pharmaxis	53	33	44
Polynovo	615	1,193	1,149
Pro Medicus	5,099	6,747	6,442
Starpharma	326	188	196
Telix	1,318	2,170	3,342
Volpara	214	193	201
Second 20			
Actinogen	158	124	116
Alcidion	222	159	123
Amplia	24	16	20
Antisense	77	60	54
Atomo	65	22	19
Dimerix	48	37	31
Emvision	150	105	122
Impedimed	213	187	331
Imugene	1,228	803	803
Micro-X	92	54	50
Next Science	186	146	146
Oncosil	46	12	11
Orthocell	81	74	74
Paradigm	280	401	285
Patrys	47	33	29
Prescient	85	74	78
Proteomics	112	116	107
Resonance	55	27	20
Universal Biosensors	117	58	54
Uscom	18	9	7

* Biotech Daily editor, David Langsam, owns shares in Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, Clarity, Cochlear, Control Bionics, Cynata, Nanosonics, Neuren, Patrys, Pharmaxis, Polynovo, Telix, Volpara and 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.

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