



Biotech Daily

Wednesday November 1, 2023

Daily news on ASX-listed biotechnology companies

- * **BLACK OCTOBER, AGAIN: BDI-40 DOWN 12%; ASX200 4%, BIG CAPS 8%**
- * **TODAY: ASX UP, BIOTECH EVEN: NEXT SCIENCE UP 18%; PARADIGM DOWN 33%**
- * **POLYACTIVA PA5108 IMPLANT 'REDUCES INTRAOCULAR PRESSURE'**
- * **RMIT DEVELOPS 'COMPACT, LIGHTWEIGHT' ECG HEART MONITOR**
- * **ALCIDION RAISES \$5m; SHARE PLAN FOR \$1m MORE**
- * **MGC 'BINDING COMMITMENTS' FOR \$12.5m PLACEMENT**
- * **IDT: 5 CONSECUTIVE QUARTERS OF RISING REVENUE**
- * **INVEX \$14m CAPITAL RETURN**
- * **AUSBIOTECH 2023 BRISBANE CONFERENCE OPENS**
- * **AUSBIOTECH: 'R&D TAX INCENTIVE GENERATES \$3.13 FOR EVERY \$1.00'**
- * **EMYRIA EGM FACES 17.5% PLACEMENT OPPOSITION**
- * **ANATARA REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **SERVATUS APPOINTS MARK WILLIAMS CEO**
- * **4D MEDICAL LOSES DIRECTOR EVONNE COLLIER**

MARKET REPORT

The Australian stock market was up 0.85 percent on Wednesday November 1, 2023, with the ASX200 up 57.6 points to 6,838.3 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Next Science was the best, up 3.5 cents or 17.5 percent to 23.5 cents, with 808,755 shares traded. Compumedics climbed 6.7 percent; 4D Medical, Cyclopharm, Mesoblast and Pro Medicus were up more than five percent; Atomo and Resmed improved more than four percent; Avita, Nanosonics, Polynovo and Starpharma were up more than three percent; Neuren rose 2.05 percent; Cochlear, CSL, Telix and Volpara were up more than one percent; with Clinuvel up by 0.1 percent.

Paradigm led the falls, down 20 cents or 32.5 percent to 41.5 cents, with 8.8 million shares traded. Alcidion lost 27.8 percent; Kazia fell 12.9 percent; Impedimed and Nova Eye were down more than eight percent; Cynata was down 7.4 percent; Genetic Signatures shed six percent; Resonance and Universal Biosensors fell more than five percent; Antisense and Prescient were down more than three percent; Dimerix and Imugene shed more than two percent; Orthocell was down 1.4 percent; with Emvision and Proteomics down by less than one percent.

[BIOTECH DAILY TOP 40 INDEX \(BDI-40\)](#)

All indices fell in October and all – apart from the Biotech Daily Top 40 Index (BDI-40) - were down for the 12 months to October 31, 2023.

The BDI-40 climbed 2.3 percent for the 12-month period, but fell 11.5 percent in October to a collective market capitalization of \$18,437 million.

The benchmark ASX200 fell 3.8 percent in October, down 1.2 percent for the year to October 31.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell a further 7.6 percent in October and were down 19.3 percent for the year, with all three losing ground. The group has fallen to its lowest level in four years.

Cochlear, again, fell the least, down 5.8 percent to \$15,783 million, followed by Resmed down 7.7 percent to \$32,050 million, and the CSL Magic Pudding has gone cold, falling \$9.5 billion or 7.8 percent to \$112,240 million. (See charts below.)

The Nasdaq Biotechnology Index (NBI) lost 6.6 percent in October, down 10.0 percent for the year.

Just eight of the Biotech Daily Top 40 Index (BDI-40) companies were up, four by more than 10 percent; but 29 fell, with 16 down by more than 10 percent.

Dimerix was the best, on its Advanz Pharma licence (BD: Oct 5, 13, 2023), up 216.7 percent from \$24 million to \$76 million. Patrys climbed 14.3 percent to \$16 million, followed by Immutep (12.65%), Micro-X (10.8%), Cynata (4.3%), 4D Medical (3.2%), SDI (2.1%) and Volpara (1.6%). Amplia, Opthea and Prescient looked good by standing still.

Kazia led the falls as it prepares for the “better valuations of the Nasdaq” down \$22 million or 56.4 percent to \$17 million.

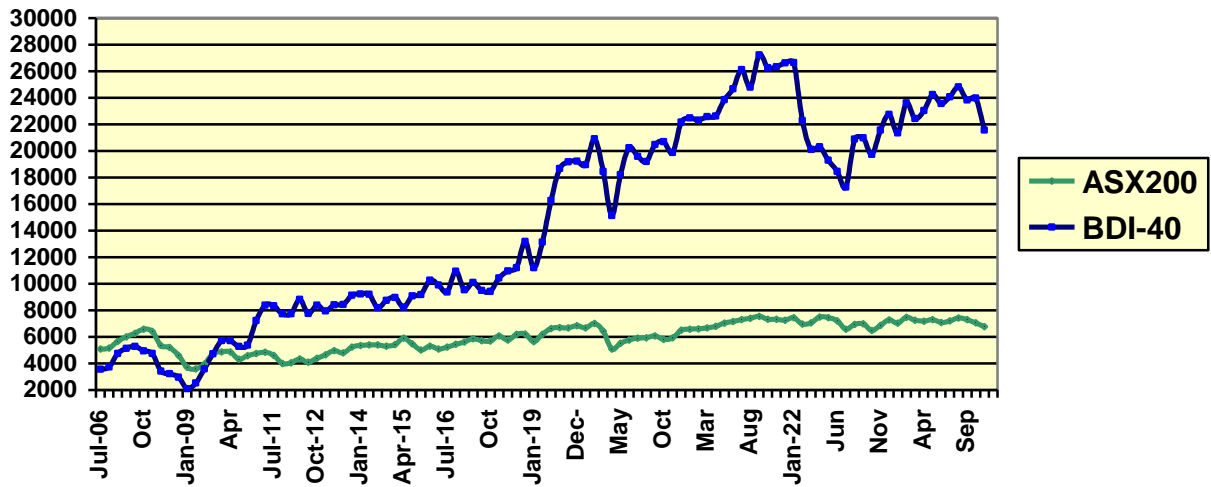
Next Science lost \$63 million or 54.3 percent to \$53 million, followed by Avita (36.8%), Impedimed (34.3%), Cyclopharm (30.45%), Atomo and Telix (23.5%), Resonance (22.2%), Antisense (19.7%), Starpharma (19.1%), Compumedics (18.2%), Proteomics (14.0%), Actinogen (13.6%), Polynovo (12.5%), Alcidion (12.1%) and Nanosonics (10.25%).

Outside the BDI-40, Biotron was up 47.6 percent for the month to \$90 million, Imricor improved 29.6 percent to \$105 million and Painchek was up 8.6 percent to \$63 million, with Optiscan looking stable at \$67 million.

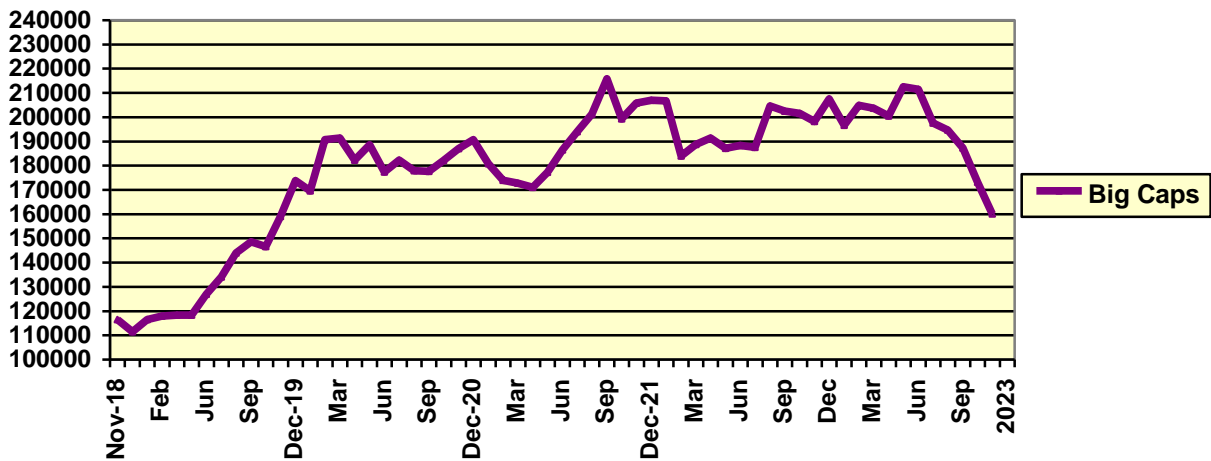
The 11 companies in Cannabis Corner slipped a further 1.4 percent in October and were down 47.6 percent for the year to October 31, 2023.

Seven of the 11 marijuana companies fell, three were unchanged and only Botanix was up. We had hoped to replace Melodiol (Creso) with Little Green Pharma, but the company has been unresponsive.

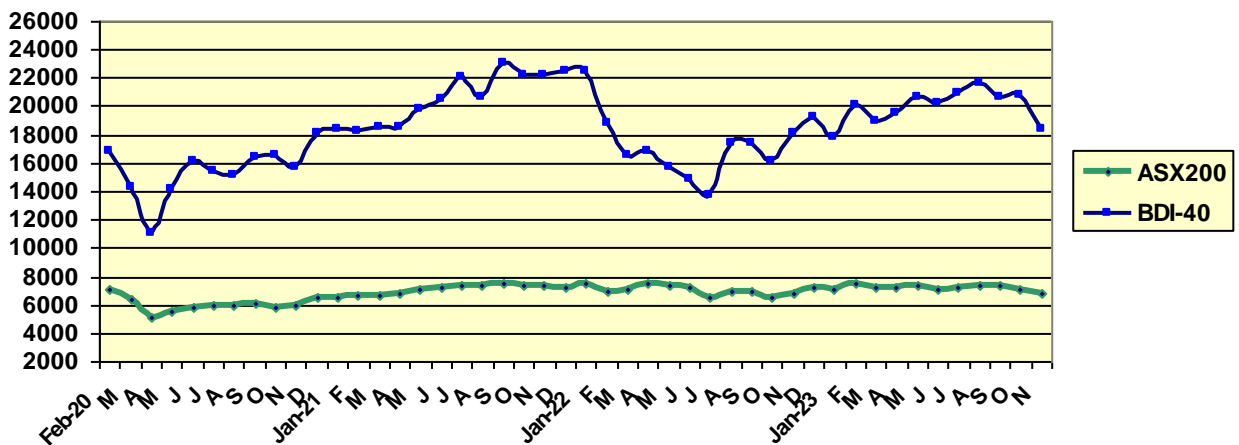
BDI-40 v ASX200 Jun 30, 2006 to Oct 31, 2023- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Oct 31, 2018 – Oct 31, 2023



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Oct 31, 2023 (pre-Covid to date)



POLYACTIVA

Polyactiva says its 37-patient, open-label, phase IIa clinical study of its PA5108 ocular implant for glaucoma shows it reduces intraocular pressure by more than 20 percent. Melbourne's Polyactiva said the primary objectives of the dose-escalation study of its biodegradable implant of latanoprost, or Xalatan, were to show the minimum effective dose of implant to achieve a more than or equal to 20 percent reduction in intraocular pressure at 12 weeks and to assess the safety and tolerability of the implant.

The company said the dose-escalation study enrolled three cohorts, a 10-patient low dose cohort, a 10-patient mid-dose cohort and a 17-patient repeat dose cohort, and that a high dose cohort was not recruited after efficacy targets were achieved with the low and mid dose implants.

Polyactiva said all patients were required to wash-out their intraocular pressure lowering medication prior to receiving their implant and those in the repeat dose cohort received their first low dose implant on day zero of the study and the second within seven days of their week-21 assessment.

Polyactiva said the PA5108 implant was designed to deliver six months of latanoprost and to biodegrade, allowing for repeat dosing, and that the initial cohort showed a more than 20 percent reduction in intraocular pressure at 12 weeks and 26 weeks.

The company said that in a further cohort, the implant's rapid biodegradation profile allowed for eight patients so far to receive a second implant at 21 weeks, providing ongoing, uninterrupted therapy, with no product-related adverse effects.

Polyactiva said patients were monitored until their implant biodegraded and their intraocular pressure returned to levels requiring further medication.

In 2018, Polyactiva said Melbourne's Brandon Capital and Perth's Yuuwa Capital had provided \$16 million to develop its glaucoma implant PA5108, with a seven-patient phase I trial underway (BD: Sep 4, 2018).

At that time, the company said it had used its proprietary polymer pro-drug technology to develop ocular implants that, when placed in the eye, provided sustained treatment over a six-month period, compared to current glaucoma treatment where patients often need to administer four eye drops daily.

Polyactiva said the implant would provide a constant daily therapeutic dose of latanoprost free acid, the active ingredient of common glaucoma treatment Xalatan, for at least 26 weeks.

Polyactiva said the implant had been designed to biodegrade within 90 days after the treatment period and was capable of being administered in an ophthalmologist's office using a custom-designed administration device.

Today, the company said treating glaucoma with daily eye drops had been a mainstay of glaucoma therapy, however between 41 percent to 90 percent of patients did not correctly administer the drops after one year, with ineffective treatment accelerating loss of sight.

Polyactiva said it would present its interim phase II data at Eyecelerator Ophthalmic Innovation Conference in San Francisco on November 2, 2023 and planned to begin its phase IIb trial in the US, Australia, and New Zealand in 2024.

Polyactiva chief executive officer Vanessa Waddell said the results indicated the company would be able to meet its goal of replacing daily eye drops for glaucoma with ocular implants. "Sustained drug delivery via an implant could reduce the reliance on daily eye drops and ensure that the correct amount of medicine is delivered consistently, every day," Ms Waddell said. "The implants received by these trial participants were present for 26 weeks before they biodegraded, which gives us confidence that our technology will be able to deliver a long-term treatment option for glaucoma patients."

Polyactiva is a private company.

ROYAL MELBOURNE INSTITUTE OF TECHNOLOGY

RMIT says it has developed a compact, lightweight electro-cardiogram (ECG) sensor providing “more comfort and less skin irritation” compared to existing devices.

RMIT said the ECG sensors helped manage cardiovascular disease - which killed more than 100 Australians every day - by alerting users to seek medical care.

The Institute said a team of researchers had made the 10-gram wearable device that could be used to prevent heart attacks for people with cardiovascular disease, including in remote healthcare and ambulatory care settings, and compared to most wearable monitors that weighed “a few hundred grams”.

RMIT said the miniaturized three-electrode device’s sensing performance was compared with 12-electrode wearable monitor on the market, showing a comparable level of precision in capturing the heart’s electrical activity.

The Institute said existing devices used wet electrodes containing a conductive gel to increase signals, but its device had three ‘dry’ electrodes, that were “almost invisibly thin, can sense even the slightest signals of a heart in distress” and could be recycled.

The Institute said the team discovered that a hexagonal design was the “winning formula” as it suits the curvy nature of skin and active lifestyles and more accurately captured electro-cardiogram signals, compared with wearable devices on the market.

RMIT said the research, titled ‘Dry electrode geometry optimization for wearable ECG devices’ was published in AIP Applied Physics Reviews and was at: <https://bit.ly/47bTlJc>.

The Institution said the research was performed in part at its Micro Nano Research Facility in the Victorian Node of the Australian National Fabrication Facility with funding from the Cooperative Research Centres Projects and Australian Research Council Research Hub for Connected Sensors for Health.

RMIT said it had filed a patent application to protect the electrocardiogram device.

Lead author and RMIT researcher Peter Elango said heart attacks often occurred with little or no warning, as signals were difficult to spot without continuous monitoring.

“RMIT is exploring ways to translate the work into a commercial product, and we are in discussions with partners regarding potential licensing opportunities,” Mr Elango said.

“Dry electrodes prioritize user comfort, remain durable over time and reduce the likelihood of skin irritation,” Mr Elango said.

“The electrodes are also hydrophobic, meaning they don’t get wet, and so a user can wear the device while they do activities in the water such as swimming and showering, unlike other ECG monitors,” Mr Elango said.

“The device can capture ECG signals even when it is fitted behind a person’s neck - ideal for patients in the aged care sector, including for someone with dementia who may remove it from their chest,” Dr Elango said. “The dry electrodes, which are less than one tenth the width of a human hair, are highly sensitive to the cardiac signals of the user.”

ALCIDION GROUP

Alcidion says it has raised \$5 million in a placement and hopes to raise a further \$1 million in a non-underwritten share purchase plan, at 7.5 cents a share.

Alcidion said the offer price was a 24.7 percent discount to the 10-day volume weighted average price of 10 cents.

The company said the funds would be used “to provide additional balance sheet strength” and it had appointed Henslow Pty Ltd as lead manager to the raise.

Alcidion said the share plan had a record date of October 31, would open on November 10 and close November 24, 2023.

Alcidion fell 2.7 cents or 27.8 percent to seven cents with 21.3 million shares traded.

MGC PHARMACEUTICALS

MGC says it has “binding commitments” to raise \$US7.9 million (\$A12.5 million) in a placement at a post-consolidation price of 25.5 US cents, or 40 Australian cents a share. Last week, MGC said investors supported its 1,000-to-one consolidation, and the issue of 31,000,000 post-consolidation shares, with its 4,427,968,187 shares becoming 4,427,969 shares and 0.02 cents closing price to become 20 cents a share (BD: Oct 26, 2023).

Today, the company said the issue price was equal to the seven-day post-consolidation volume weighted average price.

MGC said it would provide one option for every two shares bought, exercisable at 32 US cents, or 50 Australian cents, each, on a post-consolidation basis within five years.

The company said it would use \$US2.6 million for its phase II Cannepil clinical trial and \$US2.4 million for its phase IIb Cimetra dose finding study as well as investigational new drug applications for both products with the US Food and Drug Administration.

MGC said it would use \$US1.2 million for marketing and pharmaceutical conference costs, \$US1.3 million for working capital and \$US400,000 for the costs of the capital raise.

MGC fell 29.5 post-consolidation cents or 29.5 percent to 70.5 post-consolidation cents.

IDT AUSTRALIA

IDT says its unaudited revenue for the three months to September 30, 2023 was up for the fifth consecutive period to \$3.0 million.

IDT said the revenue for the period was the “highest level in nearly two years and the momentum has accelerated into the current quarter”.

The company said the increased revenue came from its active pharmaceutical ingredient business, which had a 10-fold increase to \$1.2 million compared to the prior period.

IDT said it had built an “integrated value chain” which was the main reason for the increase in demand for its services, allowing it to optimize its processes and enhance efficiency, while it had \$11.3 million in proposals in the three months to September 30.

IDT chief executive officer Paul McDonald said the company’s strategic vision focused on “addressing global drug shortages and playing an instrumental part in supporting sovereign manufacturing capabilities, while serving the clinical trial landscape with novel medicines to assist in the translation of novel medicines in clinical trials”.

“IDT is also well placed to serve our community in developing and manufacturing new treatments for cancer and mental health... we are excited to have successfully capitalized on some of the emerging opportunities, and we believe there are multiple significant avenues of growth for IDT over the medium and longer term,” Mr McDonald said.

IDT was up one cent or 16.7 percent to seven cents with 1.6 million shares traded.

INVEX THERAPEUTICS

Invex says it intends to return \$14.0 million to shareholders following the closure of its phase III ‘Evolve’ trial of Presendin for idiopathic intracranial pressure.

In August, Invex said it closed the trial due to limited market opportunity and costs and the uptake of GLP-1 receptor antagonists for obesity (BD: Jun 28, Aug 21, 2023).

Today, the company said the return would be about 19 cents a share, pending shareholder approval, and it had \$21.2 million in cash at September 30, 2023.

Invex said its programs in traumatic brain injury and glaucoma were “at a much earlier stage of development and require significantly less investment”.

The company said that in 2020 it raised about \$26 million for the trial.

Invex was up 3.5 cents or 17.95 percent to 23 cents.

AUSBIOTECH

Ausbiotech says its 2023 conference began in Brisbane today with “more than 1,200 registered delegates representing the global life science community”.

Ausbiotech said the three-day event had more than 170 speakers at 50 sessions “developed to inform, educate, celebrate and inspire the life science community”.

The industry organization said it was Australia’s “largest life science conference” and that it provided an opportunity for industry professionals “to connect and develop meaningful connections with the aim of advancing [biotechnology]”.

Ausbiotech said Queensland Deputy Premier Dr Steven Miles would join its chief executive officer Lorraine Chiroiu to open the conference, and Queensland Treasurer and Minister for Trade and Investment Cameron Dick would speak at the conference dinner.

Ms Chiroiu said that “Ausbiotech 2023 aims to lift the profile of Australia’s biotechnology industry, share new and ground-breaking knowledge, connect companies, and facilitate access to greater funding sources for companies to develop world-class science into therapies, diagnostics and medical devices”.

“This year’s record-breaking turn-out highlights the growing relevance and importance of the biotechnology industry in Australia,” Ms Chiroiu said.

AUSBIOTECH

Ausbiotech says it has released its ‘Economic impact of the Research & Development Tax Incentive for the biotech industry’ as part of its Brisbane 2023 conference.

Ausbiotech said the report showed the Federal Research and Development Tax Incentive program generated a return of \$3.14 for each dollar of forgone tax revenue spent on research and development in 2021.

The industry organization said the report was developed with Deloitte Access Economics and estimated that between 2011 and 2021 the tax incentive increased Australian gross domestic product by about \$9.1 billion.

Ausbiotech said that the economic impact of the program had increased over time, with an increase of “more than five times over the period 2011 to 2021, from \$308 million in 2011 to more than \$1.6 billion in 2021”.

Ausbiotech said the increased impact of the program reflected “a substantial expansion in company numbers and compounding productivity gains, with the growing [research and development] base of the industry adding to Australia’s stock of knowledge”.

The industry organization said for each dollar of forgone tax revenue, the research and development tax incentive had generated “an average return of \$2.18 for the economy”.

“Similar to the [gross domestic product] and employment impacts, the return to the economy increases substantially over time, from an estimated \$1.32 in 2013 to \$3.14 in 2021,” Ausbiotech said.

Ausbiotech said “most of the sector is made up of small and medium-sized companies, with over 80 percent of companies within this category, and the majority of these being in the pre-revenue and pre-market stage”.

“This report noted that these relatively small companies have high research and development intensity – for small companies, the average ratio of [research and development] expenditure to revenue in 2022 was around 43 percent,” Ausbiotech said.

Ausbiotech chief executive officer Lorraine Chiroiu said the report showed “the value of sustained investment in the sector over time”.

Ausbiotech said the report was at: <https://www.ausbiotech.org/documents/item/789>.

EMYRIA

Emyria says its extraordinary general meeting passed all resolutions but voted more than 17.49 percent against the approval of issue of lead manager options.

Emyria said the resolution to issue the options to the placement lead managers was opposed by 24,253,719 votes (17.49%), with 114,395,115 votes (82.51%) in favor.

In May, the company said it raised \$2.5 million in a placement at 15 cents a share, with Sixty Two Capital and Taylor Collison acting as joint lead managers and entitled to a six percent capital raising fee on the funds raised, each (BD: May 1, 2023).

Today, Emyria said the resolution to ratify the issue of placement shares was opposed by 23,850,244 votes (16.74%).

The company said the remaining resolutions to approve the issue of placement options, approve the issue of lead manager placement securities, ratify the issue of Stocks Digital shares and approve the issue of Stocks Digital options faced 0.31 percent opposition or less.

According to its most recent notice, Emyria had 359,295,244 shares on issue, meaning the opposition to the lead manager options amounted to 6.75 percent of the company, sufficient to requisition extraordinary general meetings.

Emyria was up 0.2 cents or 2.9 percent to 7.2 cents.

ANATARA LIFE SCIENCES

Anatara says it has requested a trading halt “in relation to a proposed capital raising”.

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

Anatara last traded at three cents.

SERVATUS LTD

Servatus says it has appointed executive Mark Williams as chief executive officer, replacing Dr Wayne Finlayson.

Servatus said Mr Williams was appointed as a non-executive director in February 2018, and as chief financial officer in July 2018, and had previously spent two decades working in senior roles at Macquarie Bank.

Last month, the company said that its executive director and chief executive officer Dr Wayne Finlayson had died (BD: Sep 29, 2023).

Today, Servatus said Mr Williams was “deeply honored to step into the chief executive officer role ... and build upon the legacy of Dr Wayne Finlayson”.

Mr Williams said “Wayne was a visionary, and I am proud to build upon his ground-breaking work in microbiome-based therapeutics”.

Servatus is a public unlisted company.

4D MEDICAL

4D Medical says that its non-executive director Evonne Collier has resigned, effective from today.

4D Medical chair Bruce Rathie thanked Ms Collier for her “significant contribution” and wished her the best in her future endeavors.

4D Medical was up 2.5 cents or 5.4 percent to 49 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT OCTOBER 31, 2023

| Company \$Am | Nov-22 | Oct-23 | Nov-23 |
|----------------------|---------------|---------------|---------------|
| Cochlear | 13,137 | 16,747 | 15,783 |
| CSL | 135,252 | 121,752 | 112,240 |
| Resmed | 49,869 | 34,711 | 32,050 |
| BDI-20 | | | |
| Avita | 192 | 582 | 368 |
| Clinuvel | 966 | 736 | 726 |
| Compumedics | 41 | 33 | 27 |
| Cyclopharm | 126 | 266 | 185 |
| Cynata | 45 | 23 | 24 |
| Genetic Signatures | 100 | 73 | 72 |
| Immutep | 255 | 332 | 374 |
| Kazia | 20 | 39 | 17 |
| Medical Developments | 136 | 74 | 69 |
| Mesoblast | 682 | 309 | 289 |
| Nanosonics | 1,241 | 1,258 | 1,129 |
| Neuren | 923 | 1,415 | 1,357 |
| Nova Eye | 39 | 37 | 35 |
| Opthea | 451 | 219 | 219 |
| Pharmaxis | 40 | 24 | 23 |
| Polynovo | 1,323 | 911 | 797 |
| Pro Medicus | 5,829 | 8,479 | 7,786 |
| Starpharma | 219 | 68 | 55 |
| Telix | 2,170 | 3,696 | 2,829 |
| Volpara | 170 | 184 | 187 |
| Second 20 | | | |
| 4D Medical | 190 | 156 | 161 |
| Actinogen | 233 | 44 | 38 |
| Alcidion | 184 | 140 | 123 |
| Amplia | 19 | 16 | 16 |
| Antisense | 54 | 61 | 53 |
| Atomo | 34 | 17 | 13 |
| Dimerix | 51 | 24 | 76 |
| Emvision | 112 | 133 | 125 |
| Impedimed | 159 | 353 | 232 |
| Imugene | 1,102 | 329 | 308 |
| Micro-X | 63 | 65 | 72 |
| Next Science | 154 | 116 | 53 |
| Orthocell | 83 | 74 | 72 |
| Paradigm | 401 | 172 | 168 |
| Patrys | 39 | 14 | 16 |
| Prescient | 115 | 46 | 46 |
| Proteomics | 105 | 136 | 117 |
| Resonance | 31 | 36 | 28 |
| SDI | 97 | 95 | 97 |
| Universal Biosensors | 59 | 57 | 55 |

* 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, 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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