



Biotech Daily

Tuesday October 1, 2024

Daily news on ASX-listed biotechnology companies

- * SEPTEMBER BDI-40 RECORD HIGH - UP 13%; ASX UP 2%; BIG CAPS DOWN 6%
- * TODAY: ASX DOWN, BIOTECH UP: CYNATA UP 9%; 4D MEDICAL DOWN 11%
- * CARTHERICS RAISES \$15m FOR OVARIAN CANCER THERAPY
- * MTP CONNECT OPENS \$28.5m HEART DISEASE, DIABETES GRANTS
- * BIONICS \$4.8m HELMSLEY GRANT FOR CROHN'S DISEASE DEVICE
- * MICRO-X RECEIVES FINAL \$1.5m VAREX X-RAY TUBE MILESTONE
- * CMRI, TESSELATE, OMICO ALT CANCER RESEARCH DEAL
- * CLINUVEL FILES SCENESSE FOR EPP IN CANADA
- * NYRADA: 'NYR-BIO3 BEATS STANDARD FOR HEART DAMAGE, IN RATS'
- * TRIVARX TAKES \$500k KASHCADE RDTI LOAN
- * ISLAND REQUESTS 'CAPITAL RAISE' TRADING HALT
- * ASX SUSPENDS BLUECHIIP, CHIMERIC ON LATE REPORTS
- * TRYPTAMINE 55m M-D, CHAIR, DIRECTOR OPTIONS AGM
- * USCOM 10m M-D PROF ROB PHILLIPS RIGHTS AGM
- * IMAGION PLEADS 'SCHULTZ' TO ASX 100% PRICE QUERY
- * HISHENK TAKES 5% OF TISSUE REPAIR

MARKET REPORT

The Australian stock market fell 0.74 percent on Tuesday October 1, 2024, with the ASX200 down 60.9 points to 8,208.9 points. Nineteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and two were untraded. All three Big Caps rose.

Cynata was the best, up two cents or 9.3 percent to 23.5 cents, with 291,937 shares traded. Actinogen climbed 8.3 percent; Opthea was up 7.1 percent; Impedimed improved 5.4 percent; Clarity and Micro-X were up more than four percent; Clinuvel, Cochlear, Immutep and Mesoblast climbed more than three percent; Emvision, Imugene, Medadvisor, Proteomics and Syntara rose two percent or more; Avita, Polynovo, Pro Medicus, Resmed, Resonance and Telix were up by more than one percent; with CSL up by 0.7 percent.

4D Medical led the falls, down 7.5 cents or 11.1 percent to 60 cents, with 3.05 million shares traded. Amplia lost 6.25 percent; Percheron and Prescient fell more than four percent; Alcidion was down 3.2 percent; Aroa, Dimerix, Genetic Signatures and Orthocell shed more than two percent; SDI was down 1.1 percent; with Neuren down 0.07 percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The September Biotech Daily Top 40 Index (BDI-40) returned to a new all-time record high in the first month of Melbourne Spring, up 13.1 percent to a collective market capitalization of \$39,549 million.

The BDI-40 was up 89.8 percent for the year to September 30, compared to the benchmark ASX200 up 2.2 percent for the month and 17.3 percent for the 12 months.

The Nasdaq Biotechnology Index (NBI) fell 2.3 percent in September but was up 20.6 percent for the year to September 30, 2024. Cannabis Corner recovered 5.3 percent in September.

The collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell 5.9 percent from the previous record high to \$207,795 million.

CSL lost \$10,761 million or 7.2 percent to \$138,047 million, Cochlear fell 5.1 percent to \$18,431 million, with Resmed down 2.2 percent to \$51,317 million – all three slightly below their record highs.

Pro Medicus again contributed the most to the BDI-40 – up a further \$2,811 million in September to \$18,187 million. It is most probable that next month, Pro Medicus will be promoted into the Big Caps.

In September, 22 of the BDI-40 companies were up, 15 by more than 10 percent; 16 fell, with 10 down by more than 10 percent; and two were unchanged.

4D Medical was the percentage best, up \$96 million or 53.0 percent to \$277 million, followed by Syntara (34.1%), Amplia (33.3%), Opthea (33.3%), Percheron (21.8%), Clarity (19.9%), Nanosonics (19.6%), Mesoblast (18.4%), Pro Medicus (18.3%), Impedimed (16.5%), Avita (15.5%), Cynata (11.4%), Polynovo (11.4%), Telix (10.6%) and Cyclopharm (10.5%).

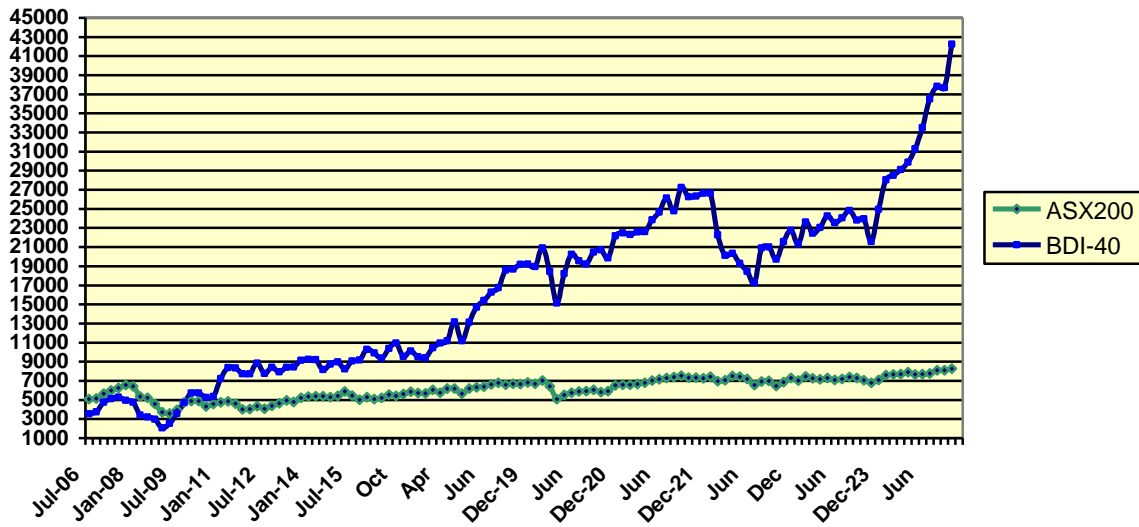
Actinogen led the August falls, down \$51 million or 41.8 percent to \$71 million, followed by Paradigm (20.9%), Imugene (17.7%), Proteomics (17.6%), Immutep (16.0%), Dimerix (15.7%), Alcidion (14.4%), Curvebeam (13.4%), Nova Eye (12.5%) and Genetic Signatures (11.2%).

The 12 companies that comprise Cannabis Corner recovered a collective 5.3 percent in September to \$279 million, with most of the gain by Cann group up \$26 million or 136.8 percent to \$45 million (see yesterday's ASX price query). Bioxyne rose 17.4 percent to \$27 million and Avecho fell 40 percent to \$6 million.

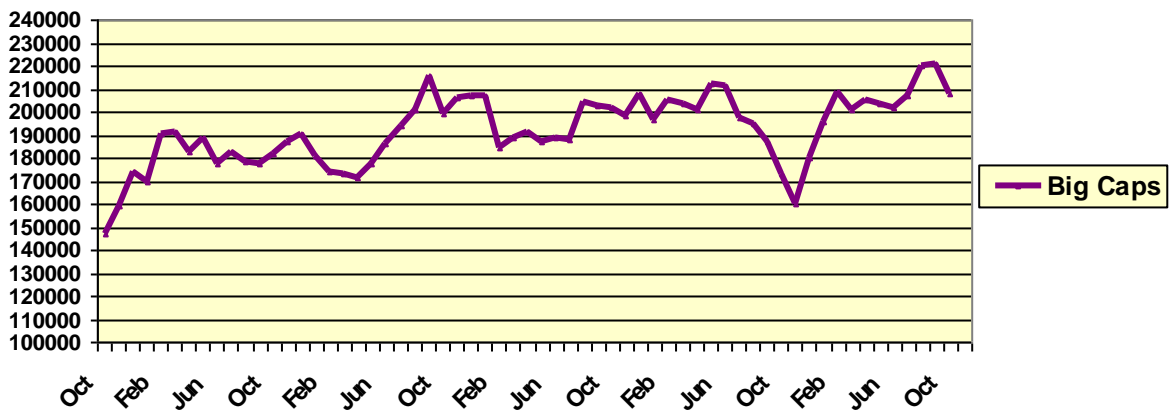
On the Nasdaq, with its "better valuations than the ASX" Bionomics lost a further \$5 million or 38.5 percent to \$8 million. Eyepoint (formerly Psivida) fell 12.7 percent to \$618 million.

Kazia recovered a further 10.5 percent to \$21 million, Queensland's Protagonist was up 2.5 percent to \$3,830 million and Incannex improved 2.0 percent to \$51 million.

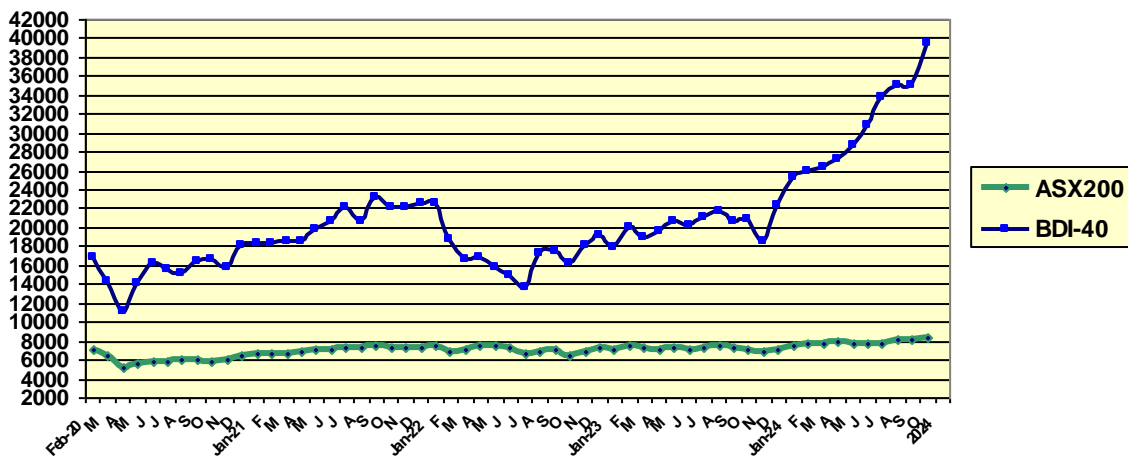
BDI-40 v ASX200 Jun 30, 2006 to Sep 30, 2024- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Sep 30, 2019 – Sep 30, 2024



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Sep 30, 2024 (Pre-Covid to date)



CARTHERICS PTY LTD

Cartherics says it has raised “well over its target \$15 million” in an oversubscribed financing round to unnamed “existing investors and new private investors”.

Cartherics said the funds would be used to progress clinical trials of its chimeric antigen receptor natural-killer cell therapy product CTH-401 in ovarian cancer and expand its pipeline to additional indications.

Cartherics chief executive officer Prof Alan Trounson said the “successful capital raising, in times of scant investment support in biotechnology, is welcome and further supports confidence in the company for the delivery of effective therapies in ovarian cancer and other difficult diseases.”

Cartherics chair Bob Moses said the company was “eager to initiate the clinical trial for CTH-401, building on the promising results from our pre-clinical studies”.

“This important milestone underscores our commitment to delivering innovative treatments for ovarian cancer and highlights the confidence our investors have in our vision to enhance patient outcomes and drive growth,” Mr Moses said.

Cartherics is a private company.

MTP CONNECT

MTP Connect says it has opened expressions of interest for its \$28.5 million accelerator program for companies developing drugs or devices for heart disease and diabetes.

Last month, MTP said it would provide \$28.5 million for drugs and devices for cardiovascular disease and the complications of type 1 and type 2 diabetes (BD: Sep 2, 2024).

At that time, the industry organization said funds were from the Federal Government Medical Research Future Fund (MRFF) with co-operation from industry partners CSL and Roche Diagnostics through the Targeted Translation Research Accelerator (TTRA).

Today, MTP Connect said companies could apply for up-to \$1.5 million in funding, starting with an initial expression of interest, with applications closing on November 4, 2024.

MTP Connect chief executive officer Stuart Dignam said the funding was “critical to backing Australian innovations to tackle these significant chronic health problems and move Australia up the global innovation league table”.

“Access to funding remains the biggest challenge for start-ups and innovators,” Mr Dignam said. “The capital markets, especially when you’re at an early stage with your innovation, are particularly tough.”

“While Australia is recognized as a global research leader, ranking in the top 10 of the Global Innovation Index, we slip down to thirtieth for outputs from that research,” he said.

“Our new TTRA initiative, covering both drugs and devices, is designed to nurture these health and medical innovations to reach commercial proof-of-concept with the potential to attract further capital and support,” Mr Dignam said.

“We are asking applicants to provide a cash co-contribution for ‘skin-in-the-game’ and to maximize the MRFF investment,” Mr Dignam said. “Successful applicants will receive ongoing acceleration support through mentoring and access to specialist advice.”

“They’ll also be connected with our impact partners, CSL and Roche Diagnostics, so they can tap into the best of global industry expertise and support,” Mr Dignam said.

Mr Dignam said the accelerator model had shown that pairing non-dilutive funding with access to industry knowledge, mentoring, market expertise and commercialisation skills was “a powerful multiplier for start-ups and [small to medium enterprises]”.

The organization said an information seminar would be held online on October 8, 2024 at 12.30pm (AEDT), with registration available at: <https://bit.ly/3XPUK5b>.

For more information and to apply, go to: <https://bit.ly/3BpFT9P>.

[BIONICS INSTITUTE](#)

The Bionics Institute says it has a \$US3.2 million (\$A4.8 million) grant from New York's Leona and Harry Helmsley Charitable Trust for its Crohn's disease device.

The Bionics Institute said it would receive the funding over three years, to upgrade its vagus nerve stimulation device which was currently in clinical trials for Crohn's disease. Last year, a media release from Austin Health said its clinicians had implanted the first Florey Institute and Bionics Institute-developed electrical nerve stimulation device in a Crohn's disease patient (BD: Dec 14, 2023).

At that time, Austin Health said the device had been developed to prevent inflammation recurring after bowel surgery by the Florey and Bionics institutes in collaboration with the University of Melbourne.

Today, the Bionics Institute said the research would be led by Prof James Fallon and Prof Sophie Payne and would upgrade the device "into an intelligent device that monitors inflammation and adjusts therapeutic stimulation in real time".

Prof Fallon said the current device was "programmed to give three hours of electrical stimulation per day with the intention of keeping patients with Crohn's disease in remission".

"We aim to design a new version of the device that stimulates the nerve only when inflammation is detected, essentially delivering personalized therapy," Prof Fallon said.

The Bionics Institute chair John Stanhope said the Institute was "delighted to partner with the Helmsley Charitable Trust" for the treatment of Crohn's disease.

[MICRO-X](#)

Micro-X says it has transferred the high-voltage, multi-beam x-ray tubes to Varex Imaging and received the final milestone payment of \$US1.0 million (\$A1.5 million).

In 2022, Micro-X said it had a \$15 million collaboration with the Salt Lake City, Utah-based Varex Imaging Corporation to licence its Nex multi-beam x-ray tubes, and take a 9.9 percent holding in Micro-X for \$7,454,223 (BD: Sep 19, 2022).

At the time, the company said it would licence its Nex x-ray tubes to Varex Imaging exclusively for \$US5 million, payable in five equal milestones over 12 months.

Last year, Micro-X said it had received \$US2 million from Varex Imaging in milestone payments, bringing the total received to \$US3.0 million (BD: Mar 17, 2023).

Today, the company said Varex could repeatably manufacture the Nex-based, multi-beam x-ray tubes.

Micro-X said the Nex technology took about eight years to complete and the "transfer took nearly two years due to the inherent complexity of the Nex manufacturing process and infrastructure required to repeatably and reliably manufacture this technology".

The company said the Nex technology remained its intellectual property.

Micro-X said Varex had "already ordered \$100,000 of Micro-X high power generators to support their high-voltage multi-beam x-ray tubes, with discussions advanced for additional orders by Varex of Micro-X high power generators, by the end of 2024".

Micro-X chief executive officer Kingsley Hall said completing the collaboration was "a testament to both technical teams and our excellent relationship with Varex, a major player and technology leader in global x-ray imaging".

"Moving forward, Varex's multi-beam x-ray tubes will use high-voltage Nex technology, with performance enhanced by Micro-X high-voltage generators," Mr Hall said.

"This creates a pathway of continued collaboration and revenues for us from the sale of Micro-X generators," Mr Hall said.

Micro-X was up 0.3 cents or 4.5 percent to seven cents.

[CHILDREN'S MEDICAL RESEARCH INSTITUTE, TESSELLATE BIO BV, OMICO](#)

CMRI says with Tessellate Bio BV and Omico it is researching alternative lengthening of telomeres (ALT) as a therapeutic target in multiple cancerous tumor types.

The Children's Medical Research Institute (CMRI) said the research would "advance the understanding of the prevalence of alternative lengthening of telomeres across tumor types and the genetic factors involved, and thereby accelerate the development of precision medicine tools and new cancer therapies".

The Institute said alternative lengthening of telomeres was a mechanism that some cancer cells used "to maintain the integrity of their telomeres during cell division, and is essential for their unlimited replicative potential".

Last year, Amsterdam's Tessellate said it had EUR8 million (\$A13.3 million) to develop 'ALT' inhibitors, to target DNA damage in the treatment of cancers (BD: Oct 18, 2023).

At that time, Tessellate said it was founded by CMRI's Prof Hilda Pickett and the Lisbon-based Instituto de Medicina Molecular's Prof Claus Azzalin and that alternative lengthening of telomeres were discovered at CMRI in 1995.

Today, the Institute said the large genomically-characterized patient sample cohort was collected by Omico, or the Australian Genomic Cancer Medicine Centre, as part of the Cancer Molecular Screening and Therapeutics program.

CMRI said it had allowed the partners to explore alternative lengthening of telomeres (ALT) prevalence in primary tissue samples utilizing the C-Circle assay, which was the expected "gold-standard for establishing alternative lengthening of telomeres ALT status".

The Institute said that while ALTs had been detected in 10 percent to 15 percent of all cancers, it had primarily been studied in cancers with alternative lengthening of telomeres prevalence exceeding 50 percent, for example soft tissue sarcomas and osteo-sarcomas. CMRI said initial results were showing "the presence of ALT in cancers that were previously not associated with this mechanism of telomere maintenance".

CMRI chief executive officer Prof Roger Reddel said synthetic lethality had "huge potential for the development of new cancer therapies but has so far been directed to only a small proportion of cancer types by targeting of homologous recombination deficiency (HRD)". Tessellate is a private company.

[CLINUVEL PHARMACEUTICALS](#)

Clinuvel says it has filed a new drug submission to Health Canada for Scenesse, or afamelanotide, to treat erythropoietic protoporphyria (EPP) in adult patients.

Last year, Clinuvel said it dosed its first Canadian EPP patient after Health Canada approved the drug under a special access program (BD: May 1, 2023).

Today, the company said the review process involved an assessment of the safety and efficacy of Scenesse for the proposed indication as well as the drug's quality and that Health Canada "may complete the review of a new drug candidate within 300 days".

Clinuvel said there were about 280 erythropoietic protoporphyria patients in Canada and that if approved Scenesse would be the first treatment available in the territory.

Clinuvel chief scientific officer Dr Dennis Wright said the special access program had "provided an important bridge for Canadian patients to access treatment and helped us understand the Canadian therapeutic landscape." "A formal authorization will enable more Canadian patients to receive Scenesse and is a logical next step."

"The dossier submitted contains both data which led to the [US Food and Drug Administration's] approval, as well as long-term data collected during the follow up of EPP patients worldwide," Dr Wright said.

Clinuvel was up 50 cents or 3.6 percent to \$14.52 with 240,425 shares traded.

[NYRADA](#)

Nyrada says its NYR-BI03 led to “superior” cardio-protection compared to standard-of-care Captopril after myocardial infarction, in rats ($p < 0.001$).

Nyrada said NYR-BI03 showed “strong efficacy in limiting cardiovascular damage following acute myocardial ischemic-reperfusion injury” when compared to vehicle and a US Food and Drug Administration-approved Captopril.

The company said ischemic-reperfusion injury was “a leading cause of tissue damage following the restoration of blood flow to the heart post-injury”.

Nyrada said a group of eight rats dosed with NYR-BI03 showed reduced cardiac tissue damage by 86 percent ($p < 0.001$).

The company said it had commissioned the study of NYR-BI03 in rat models of acute myocardial ischemia-reperfusion injury.

Nyrada said the study found NYR-BI03 showed “strong cardio-protection that was superior to Captopril”, a drug commonly administered following ischemic events.

Nyrada chief executive officer James Bonnar said the results were “an exciting development for Nyrada, presenting additional therapeutic and commercial options for our lead drug candidate NYR-BI03”.

Earlier this year, Nyrada said it began “good laboratory practice” pre-clinical studies of NYR-BI03 for brain injury, in rats and dogs (BD: Mar 28, 2024).

Nyrada was up four cents or 61.5 percent to 10.5 cents with 17.4 million shares traded.

[TRIVARX \(FORMERLY MEDIBIO\)](#)

Trivarx says it has a \$500,000 loan from Kashcade RD1 Pty Ltd at 1.38 percent a month interest against its Federal Government Research and Development Tax Incentive.

Trivarx said the loan from the Sydney-based Kashcade had an establishment fee of 2.0 percent and was repayable from the proceeds of its tax incentive for the year to June 30, 2024 by November 30, 2024, which could be extended for 30 days.

The company said the funds would be used for working capital purposes.

Trivarx was up 0.1 cents or 5.3 percent to two cents.

[ISLAND PHARMACEUTICALS](#)

Island has requested a trading halt “pending an announcement ... in relation to a proposed capital raise”.

Trading will resume on October 3, 2024, or on an earlier announcement.

Island last traded at eight cents.

[BLUECHIIP, CHIMERIC THERAPEUTICS](#)

The ASX says it has suspended Bluechiip and Chimeric under Listing Rule 17.5 for “not lodging the relevant period report by the due date” effective from today.

Bluechiip said it was “currently engaged in discussions with a number of international companies” and that it would not lodge its audited financial statements for the year ended June 30, 2024 until the strategic review and associated capital raising were substantially completed.

In June, Bluechiip said it had a \$300,000 loan from an unnamed shareholder and was conducting a strategic review for the “possible sale of the business” (BD: Jun 13, 2024).

Bluechiip last traded at 0.3 cents.

Chimeric last traded at 1.4 cents.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says its annual general meeting will vote to issue its managing-director, chair and directors up-to a total of 55,000,000 options.

Tryptamine said shareholders would vote to approve 20,250,000 options for managing-director Jason Carroll; 9,000,000 options for chair Mark Davies; 15,750,000 options for director Chris Ntoumenopoulos; with directors Peter Molloy and Clarke Barlow to receive 4,500,000 options, each; and 1,000,000 options for director Gage Jull.

The company said the options would be issued pending performance hurdles.

Tryptamine said the first tranche of options were exercisable at three cents each by December 31, 2027, the second tranche at four cents each by December 31, 2029 and the third tranche were exercisable at five cents each by December 31, 2030.

The company said the meeting would vote to adopt the remuneration report, elect Mr Davies, Mr Barlow, Mr Carroll, Mr Molloy, Mr Jull and Mr Ntoumenopoulos as directors and approve the future issue of securities.

The meeting will be held at the Celtic Club, 48 Ord Street, West Perth on November 8, 2024 at 2pm (AWST).

Tryptamine was unchanged at 1.8 cents with 1.3 million shares traded.

USCOM

Uscom says its annual general meeting will vote to issue managing-director and chair Prof Rob Phillips 9,670,117 share rights.

Uscom said the rights were valued at \$250,000 based on a 2.18 cent a share volume weighted average price for the year to June 30, 2024; and would vest on July 1, 2025, pending performance milestones, in addition to Prof Phillips' \$250,000 a year salary.

Uscom said the meeting would vote to adopt the remuneration report, re-elect director Christian Bernecker and ratify the issue of shares.

The meeting will be held at Suite 2, Level 8, 66 Clarence Street, Sydney on October 25, 2024 at 11.30am (AEDT).

Uscom was untraded at 1.4 cents.

IMAGION BIOSYSTEMS

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

The ASX said the company's share price rose 100.0 percent from a low of 2.5 cents at the close of trade on September 27 to 5.0 cents on September 30, 2024 and noted a "significant increase" in the volume of shares traded.

Imagion said its share price had "traded down significantly in recent months for no apparent reasons following implementation of a business and board restructure, to a very low market capitalization for the core technology and intellectual property of the business".

Imagion was up 1.4 cents or 35 percent to 5.4 cents with 2.2 million shares traded.

TISSUE REPAIR

Sydney's Hishenk Pty Ltd says it has become a substantial shareholder in Tissue Repair with 3,100,000 shares, or 5.1 percent.

Hishenk and its director Michael Abolakian did not disclose the cost of shares as required under the Corporations Act 2001.

Tissue Repair fell half a cent or 1.4 percent to 35 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT SEP 30, 2024

Company \$Am	Sep 30, 2023	Aug 31, 2024	Sep 30, 2024
Cochlear	16,747	19,419	18,431
CSL	121,752	148,808	138,047
Resmed	34,711	52,484	51,317
BDI-20			
Avita	582	343	396
Clinuvel	736	772	716
Compumedics	33	57	55
Cyclopharm	266	153	169
Cynata	23	35	39
Genetic Signatures	73	170	151
Immutep	332	588	494
Impedimed	353	97	113
Medical Developments	74	46	50
Mesoblast	309	1,085	1,285
Nanosonics	1,258	945	1,130
Neuren	1,415	1,944	1,952
Nova Eye	37	48	42
Opthea	219	720	960
Polynovo	911	1,637	1,823
Pro Medicus	8,479	15,376	18,187
SDI	95	111	111
Starpharma	68	41	42
Syntara	24	44	59
Telix	3,696	6,184	6,841
Second 20			
4D Medical	156	181	277
Actinogen	44	122	71
Alcidion	140	97	83
Amplia	16	33	44
Aroa	270	188	195
Atomo	17	13	13
Clarity	306	2,280	2,734
Curvebeam	133	67	58
Dimerix	24	248	209
Emvision	133	185	174
Imugene	329	434	357
Medadvisor	126	245	234
Micro-X	65	35	39
Orthocell	74	80	89
Paradigm	172	86	68
Percheron	61	78	95
Prescient	46	35	33
Proteomics	136	108	89
Resonance	36	29	27
Universal Biosensors	57	43	45

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