



Biotech Daily

Wednesday September 1, 2021

Daily news on ASX-listed biotechnology companies

- * AUGUST BDI-40 UP 12% TO RECORD \$23b; BIG CAPS UP 7%, ASX200 UP 2%
- * TODAY: ASX, BIOTECH DOWN: PRESCIENT UP 10%; LBT DOWN 8%
- * IMUGENE: HER-VAXX MISSES GASTRIC CANCER SECONDARY ENDPOINT
- * PALLA PHARMA H1 REVENUE DOWN 43% TO \$7m, LOSS UP 267% TO \$33m
- * HYDRIX REVENUE DOWN 50% TO \$7.4m, LOSS UP 204% TO \$9.8m
- * EPSILON H1 REVENUE DOWN 7% TO \$3.2m, LOSS DOWN 26% TO \$4.1m
- * CRESO H1 REVENUE UP 109% TO \$3m, LOSS UP 9% TO \$19m
- * CARDIEX REVENUE UP 14% TO \$5.3m, LOSS UP 67% TO \$5.5m
- * MGC REVENUE UP 43% TO \$3m, LOSS DOWN 28% TO \$14m
- * EMYRIA REVENUE UP 95% TO \$2m, LOSS DOWN 6% TO \$4.9m
- * CANN GLOBAL REVENUE DOWN 17% TO \$1.5m, LOSS DOWN 41% TO \$5m
- * 4D MEDICAL CONTINUES I-MED RADIOLOGY PROGRAM
- * NEUREN: ACADIA TROFINETIDE UNDER-5 RETT TRIAL; ANGELMAN IND
- * RESAPP: INDONESIA APPROVES RESAPPDY
- * MEMPHASYS: HYDRIX TO PAY \$500k, 1m SHARES FOR FELIX FLAW
- * ALTHEA: BOSTON BEER DEAL FOR CANADIAN MARIJUANA DRINKS
- * HEXIMA APPOINTS JAKE NUNN DIRECTOR
- * MEDIBIO M-D CLAUDE SOLITARIO PAY RISE TO \$200k: CO-SEC CHANGE

MARKET REPORT

The Australian stock market slipped 0.1 percent on Wednesday September 1, 2021, with the ASX200 down 7.8 points to 7,527.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 23 fell and three traded unchanged. All Big Caps fell.

Prescient was the best, up two cents or 10.3 percent to 21.5 cents, with 4.6 million shares traded. Osprey climbed 9.1 percent; Compumedics and Nova Eye were up more than eight percent; Immutep and Patrys improved more than seven percent; Pharmaxis was up six percent; Oncosil was up 4.2 percent; Kazia and Neuren rose more than three percent; with Avita and Cynata up one percent or more.

LBT led the falls, down one cent or 7.7 percent to 12 cents, with 39,352 shares traded. Next Science and Uscom lost more than six percent; Mesoblast and Polynovo shed more than five percent; Actinogen, Pro Medicus, Proteomics and Resonance fell more than four percent; Clinuvel, Imugene and Universal Biosensors were down more than three percent; Amplia, Antisense, Dimerix and Paradigm shed two percent or more; with Medical Developments, Orthocell and Resmed down by one percent.

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

Spring sprung in August with the Biotech Daily Top-40 Index (BDI-40) back in record territory – along with the three Big Caps.

The BDI-40 was up 11.7 percent in August to a record \$23,103 million, and up 41.3 percent for the year to August 31, 2021, while the benchmark ASX200 was up 1.9 percent to 7,535 points, and up 24.3 percent for the 12 months to August 31.

The collective three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) were up 7.2 percent in August to a record \$215,852 million and up 21.5 percent for the year.

Cochlear fell a further 5.8 percent to \$15,339 million, but that was easily offset by Resmed putting on 11.4 percent to \$58,540 million and CSL – also known as The Magic Pudding – was up 7.2 percent to \$141,973 million.

While Imugene's \$736 million August increase was the single largest contributor to the index, despite still being in early-stage trials with no revenue, Dimerix had a higher percentage leap (see below).

Mesoblast's \$162 million tumble in August to a market capitalization of \$1,080 million – 65.2 percent below the same time last year – was easily offset by Pro Medicus up \$510 million, Telix up \$408 million, Nanosonics up \$401 million and Clinuvel up \$399 million.

Twenty-three of the BDI-40 companies were up, 15 by more than 10 percent and 10 by more than 25 percent in August. Fourteen companies fell, with seven down by more than 10 percent.

Dimerix was the best (from a low base) up \$39 million or 81.25 percent to \$87 million, followed by Imugene up 49.9 percent to \$2,212 million, Neuren (35.9%), Ellex (32.6%), Pharmaxis (32.6%), Impedimed (31.7%), Clinuvel (27.2%), Telix (27.1%), LBT (26.7%), Nanosonics (25.1%), Genetic Signatures (18.4%), Cynata (11.9%), Kazia (11.6%), Universal Biosensors (10.7%), Immutep (10.5%) and Optiscan (10.3%).

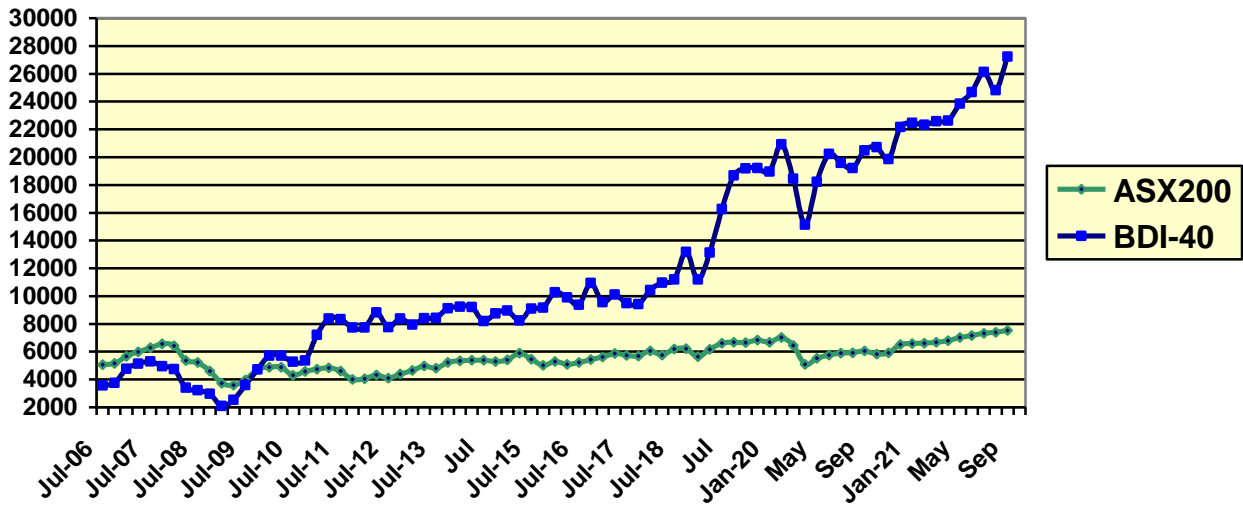
Osprey led the falls, down \$13 million or 31.7 percent to \$28 million, followed by Resonance (30.3%), Patrys (19.8%), Orthocell (13.7%), Mesoblast (13.0%), Starpharma (10.8%) and Paradigm (10.7%).

Outside the BDI-40, Rhinomed put on a further 77.4 percent to \$94 million on the back of its Rhinoswab deal with the New South Wales Government.

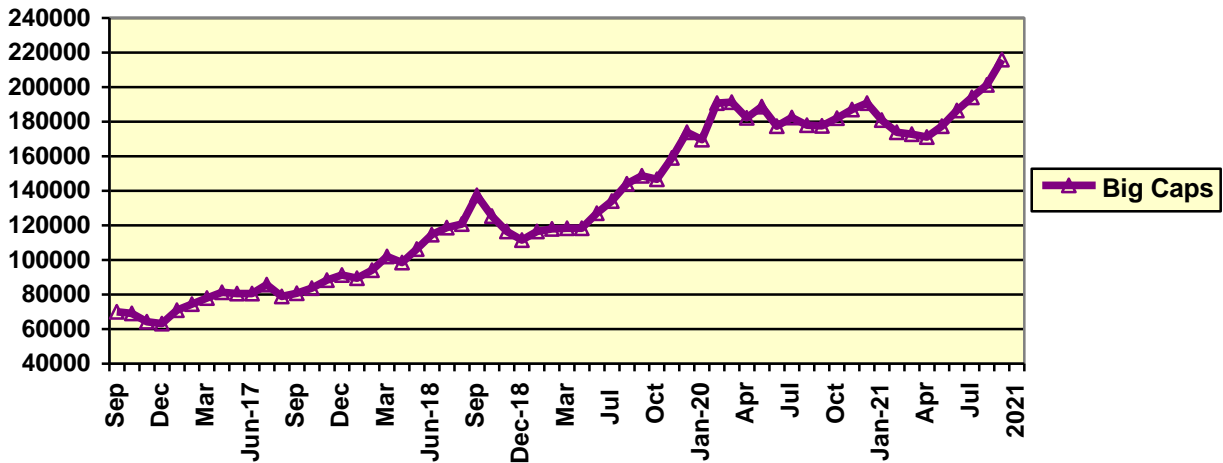
Cannabis Corner was up 10.3 percent to \$1,724 million, with Incannex up \$181 million or 66.3 percent to \$454 million, and we checked it twice to make sure it wasn't a hallucination.

On the Nasdaq, Queensland's Protagonist eased 1.4 percent to \$3,152 billion, Redhill with Australian assets climbed 57.3 percent to \$645 million and Eyepoint (Psvida) improved 33.5 percent to \$430 million. The Nasdaq Biotechnology Index was up 4.1 percent in August to 5,348 points – up 25.5 percent for the year to August 31, 2021.

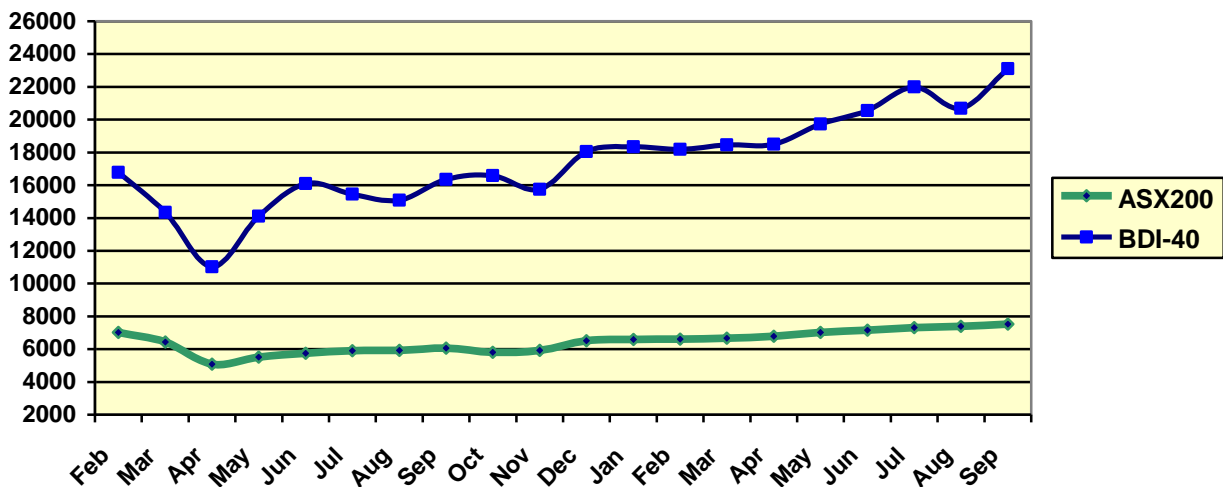
BDI-40 v ASX200 Jun 30, 2006 to Aug 31, 2021- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Aug 31, 2016 – Aug 31, 2021



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Aug 31, 2021 (current, raw data)



IMUGENE

Imugene says its phase II trial of HER-Vaxx for HER-2 positive gastric cancer did not meet statistical significance for the secondary efficacy endpoint of progression-free survival. Imugene said that it used a one-sided false positive probability of 0.10, for the “signal generating study” and the analysis of the data showed a p-value of 0.266, for HER-Vaxx with standard-of-care chemotherapy compared to the standard-of-care chemotherapy alone control arm.

The company said there was “no difference in safety between the two treatment arms, showing HER-Vaxx does not add toxicity to [standard-of-care] chemotherapy”.

Imugene said that the trial was designed to evaluate the efficacy, safety, and immune response in metastatic gastric cancer over-expressing the human epidermal growth factor receptor-2 (HER-2) protein.

In 2019, Imugene said it had dosed the first of 68 patients in its open-label, randomized, multi-centre phase II trial of HER-Vaxx, or IMU-131, for HER-2-positive gastric cancer (BD: Mar 14, 2019).

Today, the company said that the primary endpoint was overall survival with secondary endpoint including progression-free survival.

Imugene said that 36 patients had been enrolled and 24 achieved a progression-free survival event, that is 20 percent growth in tumors or new lesions.

The company said it was “awaiting the events needed for [overall survival] evaluation and will subsequently analyze all data”.

Imugene said that its progression-free survival hazard ratio of 0.719 was comparable to the Genentech and Roche registrational study which had a hazard ratio of 0.71, and also examined the effect of Herceptin plus chemotherapy versus chemotherapy alone in advanced HER-2 positive gastric cancer.

The company said that “based on these results ... [it] plans two further company sponsored phase II studies and one investigator sponsored study with HER-Vaxx in early and late-stage gastric cancer”.

Imugene managing-director Leslie Chong said the company was “encouraged” by the data and planned three new HER-Vaxx trials, in early and late-stage gastric cancer including combination with programmed death-1 (PD-1) and programmed death ligand-1 (PD-L1) checkpoint inhibitors in the US, Australia and South Korea.

Imugene said that HER-Vaxx was a B-cell activating immunotherapy designed to treat tumors that overexpress the HER-2/neu receptor, such as gastric, breast, ovarian, lung and pancreatic cancers.

Imugene fell 1.5 cents or 3.6 percent to 40 cents with 48.4 million shares traded.

PALLA PHARMA

Palla says revenue for the six months to June 30, 2021, was down 42.7 percent to \$7,060,872 with net loss after tax up 267.2 percent to \$33,105,663.

Palla said revenue was from its narcotic raw material, poppy seeds, finished dosage formulations and active pharmaceutical ingredients in Australia and Norway.

The company said revenue was reduced due to the delay in the launch of products and manufacturing inefficiencies with reduced sales due to Covid-19, and a fall in poppy seed sales following reduction in domestic harvest growing area due to climate conditions.

Palla said that diluted loss per share was up 213.1 percent to 22.42 cents, net tangible asset backing per share was down 67.6 percent to 11 cents, and it had cash and cash equivalents of \$897,312 at June 30, 2021 compared to \$1,644,223 at June 30, 2020.

Palla fell 10 cents or 26.3 percent to 28 cents with 1.8 million shares traded.

HYDRIX

Hydrix says revenue for the year to June 30, 2021, was down 50.1 percent to \$7,445,221 with net loss after tax up 203.7 percent to \$9,778,693.

Hydrix said revenue was primarily from its services business, with \$71,620 from sales of Angel Medical's Guardian heart attack alert device.

The company said that diluted loss per share was up 57.2 percent to 6.84 cents, net tangible asset backing per share improved from negative 7.01 cents to 0.44 cents, and it had cash and cash equivalents of \$6,647,225 at June 30, 2021 compared to \$1,690,194 at June 30, 2020.

Hydrix was unchanged at 15 cents.

EPSILON HEALTHCARE (FORMERLY THE HYDROPONICS COMPANY)

Epsilon says revenue for the six months to June 30, 2021, was down 6.7 percent to \$3,248,555 with net loss after tax down 25.7 percent to \$4,143,972.

Epsilon said revenue was primarily from the sales of its medical marijuana products.

The company said that Covid-19 pandemic-related disruptions in supply chains affected inventory acquisition from Asian manufacturers resulting in a decline in hydroponics equipment sales.

The company said diluted loss per share was down 44.9 percent to 2.17 cents, net tangible asset backing per share was down 20 percent to eight cents, and it had cash and cash equivalents of \$3,101,642 at June 30, 2021 compared to \$9,039,348 at June 30, 2020.

Epsilon was up half a cent or 3.6 percent to 14.5 cents.

CRESO PHARMA

Creso says revenue for the six months to June 30, 2021, was up 108.6 percent to \$3,031,753, with net loss after tax up 9.0 percent to \$18,966,748.

Creso said its revenue came from sales of marijuana products, with sales of \$1.7 million from North America, \$1.3 million from sales in Europe and the Middle East, with \$10,461 in sales from the Asia Pacific.

The company said diluted loss per share fell 76.8 percent from 7.97 cents to 1.85 cents, net tangible asset backing per share was up 50 percent to 2.4 cents, with cash and cash equivalents of \$13,654,203 June 30, 2021, compared to \$3,282,130 at June 30, 2020.

Creso was unchanged at 13 cents with 8.6 million shares traded.

CARDIEX

Cardiex says revenue for the year to June 30, 2021, was up 13.9 percent to \$5,257,624 with net loss after tax up 67.0 percent to \$5,545,597.

Cardiex said revenue was from sales of cardiovascular devices and services to hospitals, clinics, research institutions and pharmaceutical companies, with \$4,217,518 from the Americas, \$389,153 from Europe and \$1,949,1122 from the Asia-Pacific.

The company said net tangible asset backing per share was unchanged at 0.8 cents, diluted loss was up 39.1 percent at 0.64 cents a share and it had cash and cash equivalents of \$3,665,259 at June 30, 2021 compared to \$2,061,642 at June 30, 2020.

Cardiex was up 0.2 cents or 3.1 percent to 6.7 cents.

MGC PHARMACEUTICALS

MGC says revenue for the year to June 30, 2021, was up 42.5 percent to \$2,962,897 with net loss after tax down 27.9 percent to \$13,967,106.

MGC said revenue was primarily from sales of marijuana products, with sales of its herbal Artemic for Covid-19 amounting to about \$705,000, with the balance relating to consulting services provided by subsidiaries Medicani and Medicinal Cannabis Clinics.

MGC said that diluted loss per share was down 47.9 percent to 0.73 cents, net tangible asset backing per share was down 60 percent to 0.08 cents, and it had cash and cash equivalents of \$5,443,241 at June 30, 2021 compared to \$1,873,373 at June 30, 2020. MGC was unchanged at 4.8 cents with 4.1 million shares traded.

EMYRIA (FORMERLY EMERALD CLINICS)

Emyria says revenue for the year to June 30, 2021, was up 95.0 percent to \$1,975,909 with net loss after tax down 6.3 percent to \$4,906,234.

Emyria said \$1.2 million of the revenue came from patients visiting its marijuana clinics with \$768,366 for patient monitoring data deals with Canopy and Zelira.

The company said diluted loss per share was down 26.3 percent to 2.24 cents, with net tangible asset backing up 23.3 percent to 2.54 cents, and it had cash and equivalents of \$6,528,926 at June 30, 2021 compared to \$3,686,333 at June 30, 2020.

Emyria fell 1.5 cents or 6.4 percent to 22 cents with 1.2 million shares traded.

CANN GLOBAL

Cann Global says revenue for the year to June 30, 2021, was down 16.5 percent to \$1,488,031 with net loss after tax down 40.7 percent to \$4,770,484.

Cann Global said revenue was from its hemp food products, accounting for \$929,969 of the total revenue and \$427,043 from chia food products.

The company said revenue from Australia in sales of hemp food products was \$849,787, while sales of chia food products was \$156,365 and the sales of hemp food products in the rest of the world was \$80,182 and sales of chia food products was \$270,678.

Cann Global said diluted loss per share was down 60 percent to 0.10 cents, net tangible asset backing per share was down 51.7 percent to 0.169 cents, and it had cash and cash equivalents of \$10,573,053 at June 30, 2021 compared to \$7,417,095 at June 30, 2020.

Cann Global was up 0.05 cents or 11.1 percent to 0.5 cents with 4.5 million shares traded.

4D MEDICAL

4D Medical says it will begin the second phase of its clinical pilot program with Sydney medical imaging provider I-Med Radiology Network.

4D said the first phase of the trial referred patients for an XV lung ventilation analysis software (XV LVAS) scan, which "provided doctors with greater insight into the patients' lung health".

The company said disease indications analyzed using XV LVAS included asthma, chronic obstructive pulmonary disease, bronchiectasis, sarcoidosis, silicosis, and long Covid-19, a term that described persistent symptoms following Covid infection.

4D said it confirmed the compatibility of its XV LVAS system with I-MED's imaging infrastructure and the pilot program would move into the second phase, which would allow additional radiologists to become familiar with the XV LVAS application.

4D Medical fell 6.5 cents or 4.1 percent to \$1.53.

NEUREN PHARMACEUTICALS

Neuren says that Acadia Pharmaceuticals will conduct a 10-patient trial of trofinetide for girls with Rett syndrome, aged two to five years.

Neuren said the 'Daffodil' trial by its US partner Acadia would be a 12-week, multi-center, open-label, safety, tolerability and pharmaco-kinetics study in this younger age group, to be followed by a possible open-label extension for up to an additional 21 months.

The company said that the trial was limited to a small number of female participants in specified weight ranges, to enable measurements of the blood levels of trofinetide.

Last month, Neuren said Acadia had completed enrolment in the 180-patient, phase III 'Lavender' trial of trofinetide in Rett syndrome, with results expected by the end of the year (BD: Aug 5, 2021).

Separately, Neuren said it had filed an investigational new drug application to the US Food and Drug Administration for NNZ-2591 to treat Angelman syndrome.

Neuren said it applied for an ethics approval to conduct the phase II trial at three hospitals in Australia and it was completing investigational new drug applications for NNZ-2591 for Phelan-McDermid syndrome and Pitt Hopkins syndrome.

Neuren chief executive officer Jon Pilcher said filing the investigational new drug application was a "very important milestone in our plan to develop NNZ-2591 for multiple serious neurological conditions".

Neuren was up eight cents or 3.7 percent to \$2.26.

RESAPP HEALTH

Resapp says Indonesia has approved its Resappdx cough-based, smartphone respiratory disease test.

Last month, Resapp said it partnered with Alodokter to launch Resappdx in Indonesia prior to December 1, 2021 (BD: Aug 4, 2021).

Resapp managing-director Dr Tony Keating said that "obtaining regulatory approval in Indonesia is an important step in our partnership with Alodokter".

Resapp was up 0.1 cents or 2.2 percent to 4.6 cents.

MEMPHASYS

Memphasys says Hydrix has agreed to pay \$500,000 and issue 1,000,000 Hydrix shares for the rectification of an "engineering flaw with the Felix device".

In March, Memphasys said the flaw in its Felix sperm separation device was found in the validation process and would delay production and commercial sales (BD: Mar 8, 2021).

Today, the company said the issue had been rectified and Hydrix would pay \$500,000 reimbursement for costs incurred by Memphasys with \$125,000 (plus GST) to be paid per quarter over four quarters and issue Memphasys 1,000,000 Hydrix shares.

Memphasys said it would issue 3,000,000 options to Hydrix, exercisable at 10 cents each within two-years.

Memphasys executive chair Alison Coutts said that "while the engineering issue, which contributed to a substantial delay to initial commercial sales process of Felix, was disappointing, I am pleased we have reached settlement with Hydrix and that both parties remain committed to the partnership in bringing the Felix device into commercialisation".

The company said verification activities on the upgraded Felix device were completed by June 30, 2021, and validation activities were expected to be completed by September 30, 2021, but these had been delayed by Covid-19.

Memphasys was up 1.3 cents or 22.0 percent to 7.2 cents with 1.7 million shares traded.

ALTHEA GROUP HOLDINGS

Althea says subsidiary Peak Processing Solutions and the Boston Beer Company will launch a range of non-alcoholic marijuana -infused beverages in Canada.

Althea said the Boston Beer Company would provide Peak with up to \$US2 million (\$A2.7 million) for capital improvements associated with the project.

The company said that Peak would receive a minimum of \$US285,000 for each year of the five-year term of the agreement, totaling to \$US1,420,000.

Althea said Peak would be the exclusive manufacturer of all cannabis beverages produced or sold in Canada under the Boston Beer Company branding, for the term of the agreement.

The company said Peak had the right of first refusal to act as the Boston Beer Company's exclusive provider to commercialize any of its intellectual property in connection with the development or manufacture of cannabis products outside Canada including the US.

Althea was up five cents or 21.3 percent to 28.5 cents with 3.9 million shares traded.

HEXIMA

Hexima says it has appointed Jake Nunn as a non-executive director, effective from today, September 1, 2021.

Hexima said Menlo Park, California-based Mr Nunn had more than 25 years' experience in the life science industry as an investor, independent director, research analyst and investment banker.

The company said Mr Nunn was currently an advisor to several life science companies and a venture advisor at New Enterprise Associates (NEA), where he founded the public market healthcare investing practice in 2006.

Hexima said that prior to NEA, Mr Nunn was a partner at San Francisco's MPM Capital.

The company said that Mr Nunn was currently a director of Oventus Medical, Regulus Therapeutics, Trevena, and Addex Therapeutics.

Hexima said that Mr Nunn was previously a director of Dermira and Hyperion Therapeutics.

Hexima fell two cents or 6.9 percent to 27 cents.

MEDIBIO

Medibio says managing-director Claude Solitario will be paid \$200,000 pa, with Matthew Watkins appointed company secretary and Melanie Leydin continuing as a director.

The company said Mr Solitario's salary was previously \$150,000 and effective from July 1, 2021, his base salary would be \$200,000 a year, including superannuation.

Medibio said that Mr Solitario would be entitled to a short-term incentive of up-to 30 percent of the salary, pending the achievement of key performance indicators.

The company said that former joint company secretary with Ms Leydin would continue as a non-executive director.

Medibio said that Mr Watkins, would provide company secretarial services through Leydin Freyer Corp Pty Ltd of which Ms Leydin was the principal.

Medibio was unchanged at 0.7 cents with 1.5 million shares traded.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT AUGUST 31, 2021

Company \$Am	Sep-20	Aug-21	Sep-21
Cochlear	12,631	16,281	15,339
CSL	129,960	132,452	141,973
Resmed	35,022	52,557	58,540
BDI-20			
Avita	754	629	672
Clinuvel	1,027	1,468	1,867
Compumedics	69	69	73
Cyclopharm	111	155	155
Cynata	104	67	75
Ellex	45	46	61
Genetic Signatures	325	179	212
Immutep	95	408	451
Medical Developments	389	271	259
Mesoblast	3,106	1,242	1,080
Nanosonics	1,822	1,595	1,996
Neuren	146	184	250
Opthea	703	444	460
Paradigm	641	504	450
Pharmaxis	38	43	57
Polynovo	1,461	1,501	1,475
Pro Medicus	2,697	6,074	6,584
Starpharma	564	548	489
Telix	419	1,504	1,912
Volpara	346	281	294
Second 20			
Actinogen	29	174	183
Alterity	58	82	79
Amplia	15	26	24
Antisense	44	121	109
Dimerix	146	48	87
Impedimed	71	142	187
Imugene	241	1,476	2,212
Kazia	104	164	183
LBT Innovations	36	30	38
Next Science	240	317	291
Oncosil	95	37	38
Optiscan	30	126	139
Orthocell	82	102	88
Osprey	42	41	28
Patrys	17	91	73
Prescient	37	125	125
Proteomics	56	126	116
Resonance	62	76	53
Universal Biosensors	55	140	155
Uscom	26	23	23

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