Biotech Daily

Monday November 1, 2021

Daily news on ASX-listed biotechnology companies

*** OCTOBER BDI-40 UP 0.3%; ASX200 DOWN 0.1%; BIG CAPS UP 3%**

*** TODAY: ASX, BIOTECH UP: TELIX UP 10%; ANTISENSE DOWN 19%**

*** ANTISENSE PHASE II/III DMD EU OKAY; RAISES $20m, RIGHTS FOR $16.8m**

*** HEXIMA RAISES $10m, SHARE PLAN FOR $1m**

*** PATRYS RAISES $2.5m, RIGHTS OFFER FOR $5.3m**

*** EYE CO: DRY AMD FLUDROCORTISONE ACETATE 'NO ADVERSE EVENTS'**

*** AUSTCO $1.6m SINGAPORE TACERA MAINTENANCE CONTRACT**

*** NEXT SCIENCE, TELA BIO US 'WHITE LABEL' DEAL**

*** BIOTRON STARTS 2 PHASE II BIT225 HIV TRIALS**

*** IMUGENE, EUREKA JOIN ONCOLYTIC VIRUS, T-CELLS FOR TUMORS**

*** RACE APPLIES FOR PHASE II ACUTE MYELOID LEUKAEMIA TRIAL**

*** BIONOMICS: 'FDA OKAYS BNC210 SOCIAL ANXIETY DISORDER TRIAL'**

*** CRESO, INNUANA TO GROW MARIJUANA, SWISS DISTRIBUTION**

*** PARADIGM REQUESTS 'FDA RESPONSE' TRADING HALT**

*** MEDADVISOR REQUESTS 'CUSTOMER AGREEMENT' TRADING HALT**

*** BARD1 NAME CHANGE TO INOVIQ, 2m DIRECTOR OPTIONS AGM**

*** BARD1 FOUNDER DR IRMINGER-FINGER DILUTED BELOW 5%**

*** AUSBIOTECH DRAFT 'DECADAL BLUEPRINT' FOR CONSULTATION**

*** AUSBIOTECH TO LOSE 9-YEAR DIRECTOR, CHAIR MICHELLE BURKE**

MARKET REPORT

The Australian stock market was up 0.64 percent on Monday November 1, 2021, with the ASX200 up 47.1 points to 7,370.8 points. Nineteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and one was untraded.

Telix was the best, up 61 cents or 10.1 percent to $6.64, with 744,294 shares traded. Prescient climbed 7.1 percent; Amplia improved five percent; Imugene, Next Science, Oncosil and Polynovo were up more than four percent; Nanosonics and Pro medicus were up three percent or more; Cochlear, CSL, Immutep, Impedimed, Kazia and Starpharma rose more than two percent; Clinuvel, Compumedics, Medical Developments, Mesoblast and Nova Eye were up more than one percent; with Universal Biosensors up 0.7 percent.

Antisense led the falls, down 5.5 cents or 18.6 percent to 24 cents with 11.8 million shares traded. LBT lost 8.7 percent; Patrys shed 7.1 percent; Resmed fell 4.9 percent; Actinogen and Cyclopharm were down more than three percent; Cynata, Neuren and Opthea shed more than two percent; Avita, Osprey and Proteomics were down more than one percent; with Genetic Signatures down 0.7 percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

October was a month of standing still, with many small falls and rises in the Biotech Daily Top-40 Index (BDI-40) which was up 0.3 percent, compared to the benchmark ASX200 down 0.1 percent, while the Nasdaq Biotechnology Index (NBI) fell 1.9 percent.

The collective market capitalization of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) recovered 3.2 percent in October to $205,773 million – 4.7 percent below its August 31 record high.

The Magic Pudding we call CSL rose 4.5 percent to $136,629 million – 3.8 percent from its August 31 record high - followed by Cochlear up 4.05 percent to $14,987 million, while Resmed eased 0.2 percent to $54,157 million, having posted yet another quarter of record revenue.

For the year to October 31, the BDI-40 climbed 41.0 percent, the ASX200 was up 23.5 percent, the Big Caps rose 10.0 percent and the NBI was up 21.7 percent.

The 22 companies that make up Cannabis Corner were 57.6 percent above October 31, 2020 (see below).

Pro Medicus added the most, up $217 million (4.0%) to $5,705 million, while Imugene added $111 million (4.2%) to $2,733 million.

Seventeen of the BDI-40 companies were up, six by more than 10 percent, while 21 fell, with only two down by more than 10 percent.

Impedimed was the best, recovering $90 million or 48.1 percent to $277 million, followed by Antisense up $51 million or 43.2 percent to a record $169 million, from a low base Osprey was up 25.0 percent, followed by Cyclopharm (19.2%), Resonance (17.1%) and Actinogen (14.0%).

Starpharma led the falls, down $105 million or 19.4 percent to $435 million, followed by Avita (10.7%), Paradigm (9.9%), Compumedics (9.5%) and Neuren (8.8%).

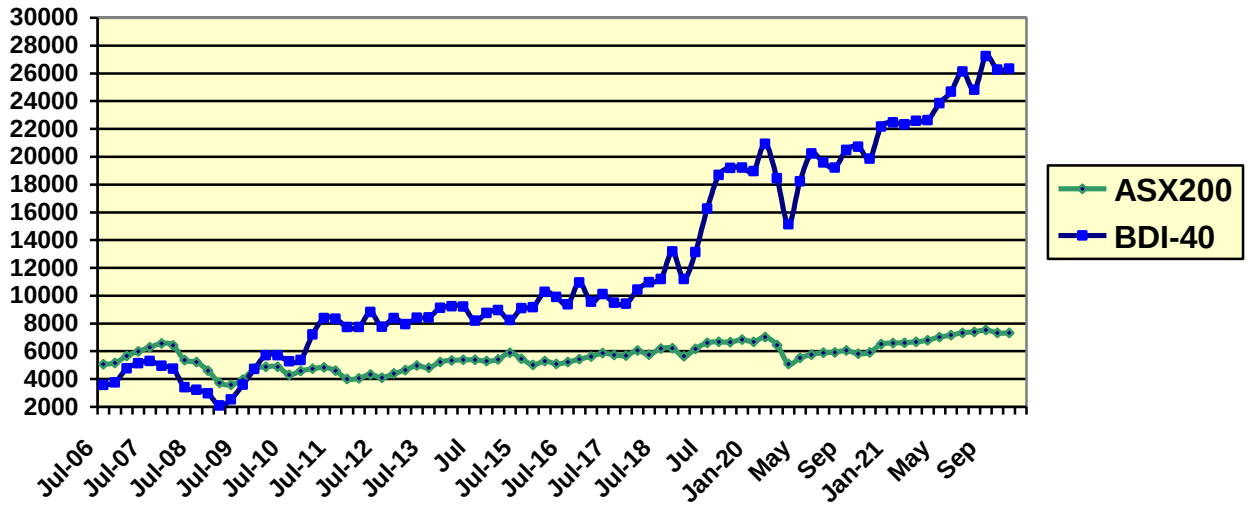
Outside the BDI-40, Cogstate and Rhythm were strong in October, with the latter up 22.0 percent for the month but 717.5 percent for the year to October 31.

The collective market capitalization of the 22 companies in Cannabis Corner was up 3.97 on October to $1,806 million, but up 57.6 percent for the year to October 31, showing the importance of time-points.

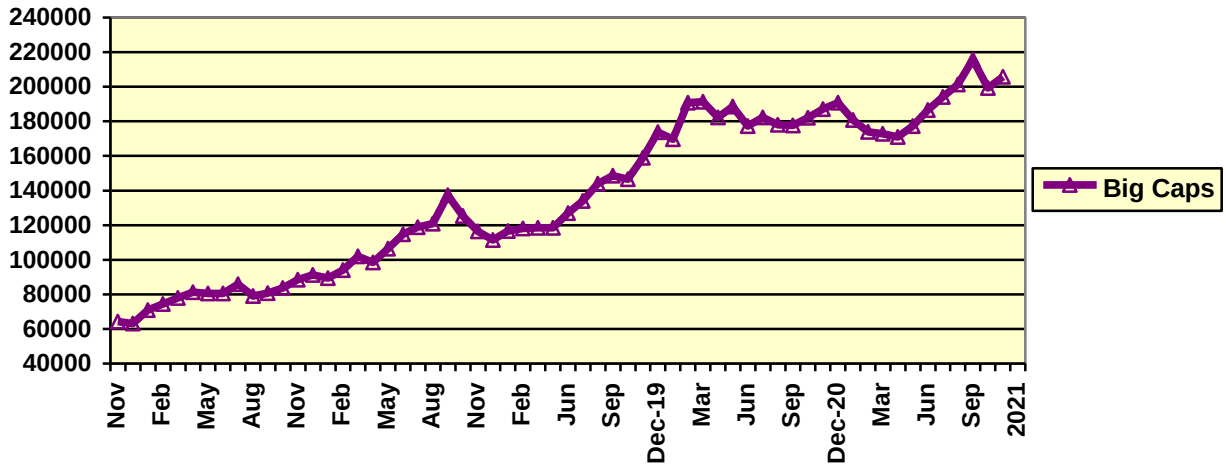
On the Nasdaq, Queensland's Protagonist recovered from its US Food and Drug Administration hold, up 69.0 percent to $1,971 million more than $1 billion below its July 31 record high.

Redhill, with Australian assets, recovered 14.2 percent to $338 million but still 47.6 percent below its August 31 record high of $645 million. Eyepoint (formerly Psivida) was up 5.8 percent to $439 million.

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



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



ANTISENSE THERAPEUTICS

Antisense says a European Medicines Agency committee supports plans for ATL1102 for Duchenne muscular dystrophy and it has raised $20 million at 24 cents a share.
Antisense said that the EMA paediatric committee “adopted a positive final opinion on its [114 patient] paediatric investigation plan for ATL1102 for Duchenne muscular dystrophy, following a meeting on October 15, 2021, with EMA ratification to follow.
The company said that a paediatric investigation plan aimed to ensure that the necessary data was obtained through studies in children and was “required to support the authorization of a medicine for children in the European Union”.
Antisense said that the oversubscribed placement would fund a phase IIb/III trial of ATL1102 in non-ambulant boys in Europe.
The company said the placement at 24 cents a share was an 18.6 percent discount to the closing price on October 27, 2021, and it would hold a one-for-9.4 rights offer for a further $16.8 million, with a record date of November 10, opening on November 15 and closing on November 29, 2021.
The company said that investors would receive one option for every two shares acquired, exercisable at 48 cents each by the earlier of December 20, 2024 or 20 business days after the “acceleration trigger date” or the date of a “futility analysis results”.
Antisense said the joint lead managers to the placement were Morgans Corporate and Wilsons Corporate Finance, with XEC Partners Pty Ltd its corporate adviser.
The company said that the up-to 114-patient, phase IIb/III trial would be a multi-centre, randomized, double-blind, placebo-controlled study to determine the efficacy, safety, and pharmacokinetic profile of ATL1102 at doses of 25mg and 50mg, administered once weekly by sub-cutaneous injection for 52 weeks in non-ambulatory participants with Duchenne muscular dystrophy, as a potentially pivotal regulatory-directed trial with a follow-on, open-label extension trial.
Antisense said that patients would be randomized to either 25mg or 50mg ATL1102, or placebo, stratified by corticosteroid use, with 108 patients expected to complete the trial.
The company said that clinical research organization Parexel would conduct and manage the trial and was finalizing site evaluations to select the more than 30 sites for the trial in about nine European countries, with recruitment to begin once trial application approvals had been received for each jurisdiction.
Antisense said that University College London Biomedical Research Centre program director Prof Thomas Voit would be the co-ordinating principal investigator.
Antisense fell 5.5 cents or 18.6 percent to 24 cents with 11.8 million shares traded.

HEXIMA

Hexima says it has commitment to raise $10 million in a placement at 32 cents a share and hopes to raise up to $1 million in a share plan at the same price.
Hexima said the share price was a 14.6 percent discount to the 15-day volume-weighted average price to October 27, 2021.
The company said the proceeds would be used to begin preparations for phase III trials of topical pezadeftide (formerly HXP124) for onychomycosis, or toe fungus, expected to begin by the end of 2022.
Hexima said that the share plan record date was October 29, the offer would open on November 8, and close on November 22, 2021
The company said that Wilsons Corporate Finance and Canaccord Genuity (Australia) were joint lead managers for the placement.
Hexima was up half a cent or 1.4 percent to 37 cents.

PATRYS

Patrys says it has raised $2.5 million in a placement at 3.5 cents a share through Territory Funds Management and expects to raise up to $5.3 million through a rights offer.
Patrys said the one-for-12 rights offer would be at the same price, which was a 17.8 percent discount to the 10-day volume-weighted average price to October 27, 2021.
The company said the rights offer was fully underwritten by Lazarus Corporate Finance.
Patrys said the record date would be November 4, the offer would open on November 9 and close on November 29, 2021.
The company said the proceeds would help begin a formal development program for PAT-DX3 and research and development into antibody drug conjugates.
Patrys fell 0.3 cents or 7.1 percent to 3.9 cents with 19.1 million shares traded.

EYE CO PTY LTD

Eye Co says its phase Ib study of intravitreal fludrocortisone acetate for dry, age-related macular degeneration found no evidence of any ocular or systemic adverse events.
Eye Co said it was the first time the drug had been used in humans with retinal disease.
The company said that patients were monitored for five months following the injection and there was “no evidence of intra-ocular pressure spikes or cataract development commonly associated with products injected into the eye”.
Eye Co said fludrocortisone acetate was a potential treatment for geographic atrophy, associated with the dry form of age-related macular degeneration for which no treatment was currently available, and the drug had “significant potential in the treatment of other major retinal diseases”.
Eye Co is a private company.

AUSTCO HEALTHCARE

Austco says it has a $1.6 million contract with Singapore’s Ng Teng Fong General Hospital and the Jurong Community Hospital for its Tacera nurse call system.
Austco said the maintenance contract covered the hospital to September 2026.
Austco chief executive officer Clayton Astles said that the work on the Tacera “refresh [were] underway, somewhat delayed due to Covid-19 restrictions, but are due to be completed later this financial year”.
Austco was up half a cent or 3.6 percent to 14.5 cents.

NEXT SCIENCE

Next Science says it has a 10-year contract with Tela Bio for US distribution of a white label version of its Xperience “no rinse” anti-microbial surgical wash.
Next Science said the agreement would provide exclusive distribution rights to the Malvern, Pennsylvania-based Tela Bio across the US plastic and reconstructive surgery market, included an annual licencing fee, a transfer price arrangement and minimum order requirements, but did not specify to value or volume.
The company said that the agreement gave Tela Bio first right of negotiation for a distribution deal with similar terms in the European Union on when Xperience gained Conformité Européenne (CE) mark approval.
Next Science said that Tela Bio would market Xperience under the name Protex plastic surgical solution.
Next Science was up five cents or four percent to $1.30.

BIOTRON

Biotron says it has begun a 27-patient, Thailand phase II trial and a 20-patient, Sydney phase II trial of BIT225 in HIV-1-positive populations.

Biotron said that the two trials were “designed to investigate further the immune changes observed in [a previous] study”.

The company said that, for the first time, BIT225 would be tested in people who hade been taking approved anti-retroviral treatment (ART) for an extended period with well-controlled HIV-1 infection.

Biotron said that previously, BIT225 had been tested in newly infected, anti-retroviral treatment-naïve people commencing treatment for the first time.

The company said that the 27-patient BIT225-010 Thailand trial would “determine the safety, tolerability and efficacy of daily 200mg BIT225 for up to 24 weeks in HIV-1-infected treatment naïve participants starting anti-retroviral therapy with standardised dolutegravir-based treatment with efficacy determined by HIV-1 RNA at two different levels.

Biotron said that the 20-patient, BIT225-011 Sydney trial would be conducted in Sydney and include people who had not achieved “full immune reconstitution despite long term durably suppressive ART”.

The company said that group was estimated to be more than one third of the HIV-treated people was “at an increased risk of clinical progression to AIDS and other morbidities and has higher rates of mortality than HIV-infected patients who have attained full immune reconstitution”.

Biotron said that BIT225 would be added to anti-retroviral treatment for 12 weeks, after which time they will remain on ART as per standard treatment protocols.

Biotron managing-director Dr Michelle Miller said the Sydney trial was “an important step towards demonstrating the clinical benefit that BIT225 could bring to the treatment of HIV-1, especially in a still at-risk group”.

“BIT225’s unique dual action in targeting HIV-1 in cellular reservoirs and improving immune functions has the potential to improve health outcomes in this population,” Dr Miller said.

The company said that the trials were expected to conclude in mid-2022 with data to be available by the end of 2022.

Biotron was up 0.6 cents or 12.5 percent to 5.4 cents with 17.2 million shares traded.

IMUGENE

Imugene says it will work with Eureka Therapeutics to evaluate combining its CD19 oncolytic virus technology with Eureka’s Artemis T-cell therapy in solid tumors.

Imugene said the partnership with the Emeryville, California-based Eureka would aim to establish a “mark and kill” process in which its CD19 oncolytic virous technology would force tumors to express CD19, which could then be targeted by Eureka’s anti-CD19 Artemis T-Cell therapies.

Imugene managing-director Leslie Chong said that T-cell and chimeric antigen receptor-T-cell (Car-T) therapies had “not achieved much success in solid tumors in part because of a lack of tumor-specific targets”.

“By using our proprietary oncolytic technology to force the tumor to express the CD19 target, we now have the ability to address this shortcoming,” Ms Chong said.

“We believe the synergy between our Oncarlytics platform and Eureka’s anti-CD19 Artemis T-cells has the potential to shift the cellular medicine paradigm in treating solid tumors,” Ms Chong said.

Imugene was up two cents or four percent to 51.5 cents with 67.8 million shares traded.

RACE ONCOLOGY

Race Oncology says it has applied ethics approval for a 60-patient, phase II trial of Zantrene for extra-medullary acute myeloid leukemia or myelodysplastic syndromes.
Race said it applied to the New South Wales' Hunter-New England human research ethics committee for the trial to begin by the end of 2022.
The company said the two-stage trial would begin with high dose Zantrene (bisantrene dihydrochloride) over seven days followed by one or more consolidating treatments of Zantrene in combination with cytarabine arabinoside.
Race said that the second stage would trial a low dose of Zantrene in combination with an "oral hypo-methylating agent" for patients unable to tolerate high dose chemotherapy.
The company said that extramedullary acute myeloid leukaemia occurred when leukaemia spread from the bone marrow and formed solid tumors in other organs.
Race said that myelodysplastic syndromes were a group of blood cancers affecting the production of normal blood cells in the bone marrow.
The company said that the primary endpoint would be complete response and complete response with incomplete haematological recovery, with an aim of bridging to an allogeneic haematopoietic stem cell transplant, or safety and tolerability.
Race said that secondary endpoints included safety and tolerability of Zantrene, overall and event-free survival, and fat mass and obesity associated (FTO) protein expression or other biomarkers with response to treatment.
Race said the trial was expected to run for up to 40 months.
Race was up nine cents or 2.7 percent to $3.37 with 353,882 shares traded.

BIONOMICS

Bionomics says it has US Food and Drug Administration approval for a 150-patient, phase II trial of BNC210 for acute social anxiety disorder.
In 2016, Bionomics said its 24-patient phase II trial of BNC210 for generalized anxiety disorder met its primary endpoints of change in cerebral perfusion and task-related brain activity (BD: Sep 21, 2016).
Today, the company said that the study would be a randomized, double-blind, multi-centre trial comparing BNC210 to placebo on the anxiety levels on the Liebowitz social anxiety scale, during an anxiety-producing task.
Bionomics said it expected to begin the trial by the end of this year, and have initial data by the end of 2022.
Bionomics fell half a cent or four percent to 12 cents with 2.9 million shares traded.

CRESO PHARMA

Creso says the Turbenthal, Switzerland-based Innuana AG will grow and market marijuana for the Swiss medicinal cannabis market.
Creso said the two companies signed a letter of intent "following recent amendments to the Swiss Narcotics Act in March 2021" allowing patient access to medicinal cannabis.
The company said that the legislative shifts would enable it to expand its Swiss operations and enter into the Swiss medicinal cannabis market.
In 2017, Creso said with the Lengnau, Switzerland-based Domaco Dr med Aufdermaur AG would supply its cannabinoid food additives (BD: Mar 7, 2017).
Today, Creso said that under the agreement, Innuana would produce medical marijuana to Creso's specifications, which Creso would then distribute in Switzerland.
Creso was up one cent or 8.3 percent to 13 cents with 33.9 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says its annual general meeting will vote to change its name to Inoviq and grant 2,000,000 options to four directors.
Bard1 said the name change would “better reflect” the vision, intellectual property and product portfolio since it acquired Sienna Cancer Diagnostics (BD: Jul 29, 2020).
The company said investors would vote to issue 500,000 options each to directors Dr Geoffrey Cumming, Prof Allan Cripps, Phillip Powell, and Robert (Max) Johnston.
Bard1 said the options would vest in equal tranches, on reaching a 7-day volume-weighted average price of $2.32 and exercisable at $2.32 by September 30, 2023, and the second on a 7-day VWAP of $3.00, exercisable at $3.00 by September 30, 2024.
The company said the meeting would vote on the remuneration report, the election of Mr Johnston, the 10 percent placement facility, the ratification of the issue of placement and share plan shares and options, and the consolidation of its performance shares.
The virtual meeting will be held on November 29, 2021 at 2pm (AEDT).
Bard1 fell two cents or 1.9 percent to $1.03.

PARADIGM BIOPHARMACEUTICALS

Paradigm has requested a trading halt pending its review of “a response from the US Food and Drug Administration”.
In September, Paradigm said the FDA requested modifications to its adrenal screening and mitigation plan for its trial of pentosan polysulfate sodium (BD: Sep 27, 2021).
Trading will resume on November 3, 2021 or on an earlier announcement.
Paradigm last traded at $2.06.

MEDADVISOR

Medadvisor has requested a trading halt “pending the release of an announcement regarding a customer agreement”.
Trading will resume on November 3, 2021 or on an earlier announcement.
Medadvisor last traded at 36 cents.

BARD1 LIFE SCIENCES

Bard1 founder and former director Dr Irmgard Irminger-Finger says she has decreased her holding in Bard1 and been diluted below five percent.
Dr Irminger-Finger said she bought 10,000 shares at $1.85 a share and sold 50,000 shares at $1.82 a share, and was diluted to 4.55 percent through a share issue.
In July, Bard1 said it raised $15 million in a placement at $1.55 a share (BD: Jul 30, 2021).

AUSBIOTECH

Ausbiotech says it has called for consultation on a draft ‘Decadal Biotechnology Blueprint’.
Ausbiotech said the ‘Biotechnology Blueprint: A Decadal Strategy for the Australian Biotechnology Industry’ was available at: www.ausbiotech.org.
To submit feedback, email: admin@ausbiotech.org or to request a Word version for tracking, contact: admin@ausbiotech.org or telephone +613 9828 1400.
Separately Ausbiotech said that chair Michelle Burke would retire at the November 5, 2021 annual general meeting, having been a non-executive director for nine years, the maximum allowed under its constitution.

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

Company $Am	Nov-20	Oct-21	Nov-21
Cochlear	14,326	14,404	14,987
CSL	132,624	130,713	136,629
Resmed	40,140	54,257	54,157
BDI-20			
Avita	637	614	548
Clinuvel	1,058	2,048	1,905
Compumedics	73	74	67
Cyclopharm	163	156	186
Cynata	96	83	88
Ellex	47	57	60
Genetic Signatures	271	207	199
Immutep	128	468	487
Medical Developments	356	369	351
Mesoblast	1,848	1,077	1,031
Nanosonics	1,580	1,864	1,792
Neuren	116	261	238
Opthea	750	474	448
Paradigm	612	493	444
Pharmaxis	35	59	57
Polynovo	1,785	1,253	1,247
Pro Medicus	3,431	5,488	5,705
Starpharma	576	540	435
Telix	425	1,608	1,693
Volpara	334	298	300
Second 20			
Actinogen	23	209	243
Alterity	39	72	70
Amplia	24	26	25
Antisense	54	118	169
Dimerix	51	75	82
Impedimed	90	187	277
Imugene	247	2,622	2,733
Kazia	100	207	192
LBT Innovations	35	35	33
Next Science	221	265	247
Oncosil	116	38	38
Optiscan	58	139	130
Orthocell	65	98	103
Osprey	32	20	25
Patrys	34	79	77
Prescient	37	168	180
Proteomics	47	94	101
Resonance	69	41	48
Universal Biosensors	57	137	132
Uscom	26	21	21

* 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.

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