



Biotech Daily

Monday July 2, 2018

Daily news on ASX-listed biotechnology companies

- * JUNE BDI-40 UP 1%, ASX200 3%, BIG CAPS 4% NBI 1%
- * YTD BDI-40 UP 18%, ASX200 8%, BIG CAPS 38% NBI 7%
- * YTD: VOLPARA UP 303%, ONCOSIL 206%; AIRXPANDERS DOWN 86%, REVA 75%
- * TODAY: ASX DOWN, BIOTECH UP: IMPEDIMED UP 9%; NEUREN DOWN 5%
- * MESOBLAST NOVAQUEST \$54m LOAN, \$14m SHARES FINANCE
- * ORTHOCELL BEGINS SOUTH AFRICA CELGRO SHOULDER STUDY
- * OPTHEA: PHASE IIb OPT-302 FOR WET AMD TRIAL HALF-WAY
- * CYNATA, RCSI PARTNER FOR STEM CELLS FOR SEPSIS
- * IMMUTEP FILES IMP-321 TACTI-002 IND TO FDA
- * BOTANIX BTX1801 SKIN INFECTION, BTX1308 PSORIASIS TRIALS
- * PROBIOTEC BUYS NEXT-DOOR FACILITY FOR \$3.6m
- * SUDA TO PAY HC BERLIN \$2.6m; RIGHTS OFFER FOR \$6m
- * GENERA REQUESTS 'CONVERTIBLE NOTES CAPITAL RAISING' HALT
- * DIMERIX: FURTHER US PATENT FOR DMX-200
- * PHARMAUST: EPICHEM WINS NATA ACCREDITATION
- * RACE 10m 'PERFORMANCE' SHARES FOR CHAIR, CSO, UPDATE PHARMA
- * DR JOHN MCBAIN TAKES 6.5% OF RHINOMED
- * BOTANIX TO RELEASE 156m SHARES, 13m OPTIONS FROM ASX ESCROW
- * CRESO TO SELL CANNAQIX IN NEW ZEALAND
- * MMJ INVESTS \$5m IN MEDIPHARM LABS
- * ELLEX APPOINTS MIKE SOUTHARD, MIKE MANGANO DIRECTORS
- * OBJ APPOINTS CAMERON REYNOLDS DIRECTOR
- * IDT APPOINTS INTERIM CEO DR DAVID SPARLING CEO ON \$348k
- * PHYLOGICA CEO DR ROHAN HOCKINGS STARTS ON \$395k
- * IMMURON LOSES JOINT CO SEC PETER VAUGHAN
- * STEVEN WOOD REPLACES G MEDICAL CO SEC STEPHEN BUCKLEY

MARKET REPORT

The Australian stock market fell 0.27 percent on Monday July 2, 2018 with the ASX200 down 16.8 points to 6,177.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and five were untraded.

Impedimed was the best, up 3.5 cents or 8.9 percent to 43 cents with 1.4 million shares traded. Oncosil climbed 6.5 percent; Dimerix was up 5.3 percent; Bionomics, Mesoblast and Prescient improved more than four percent; Pharmaxis and Telix were up three percent or more; Actinogen, Admedus, Avita and Factor Therapeutics rose more than two percent; Airxanders and Opthea were up more than one percent; with Cochlear, CSL, Cynata and Starpharma up by less than one percent.

Neuren led the falls, down 14 cents or 4.7 percent to \$2.83, with 59,861 shares traded. Compumedics, Immutep, Imugene and Uscom lost more than three percent; Reva shed 2.2 percent; Polynovo fell 1.9 percent; with Clinuvel, Medical Developments, Nanosonics, Pro Medicus and Resmed down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

While the ASX200 was up 3.0 percent in the month of June, with the Biotech Daily Top 40 Index (BDI-40) up 1.0 percent, for the financial year the BDI-40 doubled the benchmark index.

This month's data has been complicated by the \$502 million departure of Viralytics, with the raw or unadjusted BDI-40 up 1.0 percent for the month and 26.4 percent for the year to June 30, 2018, while the adjusted index was up 0.7 percent for the month and 17.9 percent for the year.

The raw data compares the current 40 companies' cumulative market capitalizations against those companies' previous values one month and one year ago. The adjusted index compensates for the departure of companies over time, as do the S&P indices.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) improved 3.6 percent for the month and 38.4 percent for the year to record highs, with CSL up 3.6 percent and 39.1 percent, respectively, to \$87,141; Resmed up 4.3 percent and 41.4 percent, respectively, to \$20,124 million; and Cochlear up 2.0 and 29.0 percent respectively to \$11,519 million.

The Nasdaq Biotechnology Index (NBI) was up 1.35 percent in June and 6.5 percent for the year (see charts below).

The month of June saw modest to significant falls, with just 11 BDI-40 companies up, 25 down and four unchanged, saved by Nanosonics up \$150 million, Pro Medicus up \$64 million and Sirtex rising \$114 million.

The best in June were Avita, up 66.0 percent to \$88 million, followed by Oncosil (21.0%), Nanosonics (18.8%), Opthea (16.5%), Cynata (9.2%) and Pro Medicus (8.4%).

The worst were led by Impedimed down 25.0 percent to \$150 million, ITL (23.8%), Compumedics (22.7%), Admedus (20.7%), Prescient (20.7%), Reva (18.4%) and Immutep (16.1%).

For the 12 months to June 30, 13 companies were up more than 50 percent, led by Volpara up 302.9 percent; Oncosil (206.4%), Polynovo (198.3%), Imugene (167.7%), Neuren (145.1%), Cynata (136.4%), Prescient (109.1%), Sirtex (87.0%), Avita (79.6%) and Immutep (62.1%).

Curiously, the deepest falls were dominated by US-based companies, led by Airxpanders shedding 86.0 percent of its market capitalization from \$186 million to \$26 million, followed by Reva (74.8%), ITL (68.0%), Osprey (50.5%), Impedimed (47.0%), Ellex (31.8%), Opthea (29.3%) and Mesoblast (21.1%).

Outside the BDI-40 and generally from very low bases, The Three Hundred Club – companies up 300 percent in 12 months – included Paradigm, Bard1 and Bioxyne.

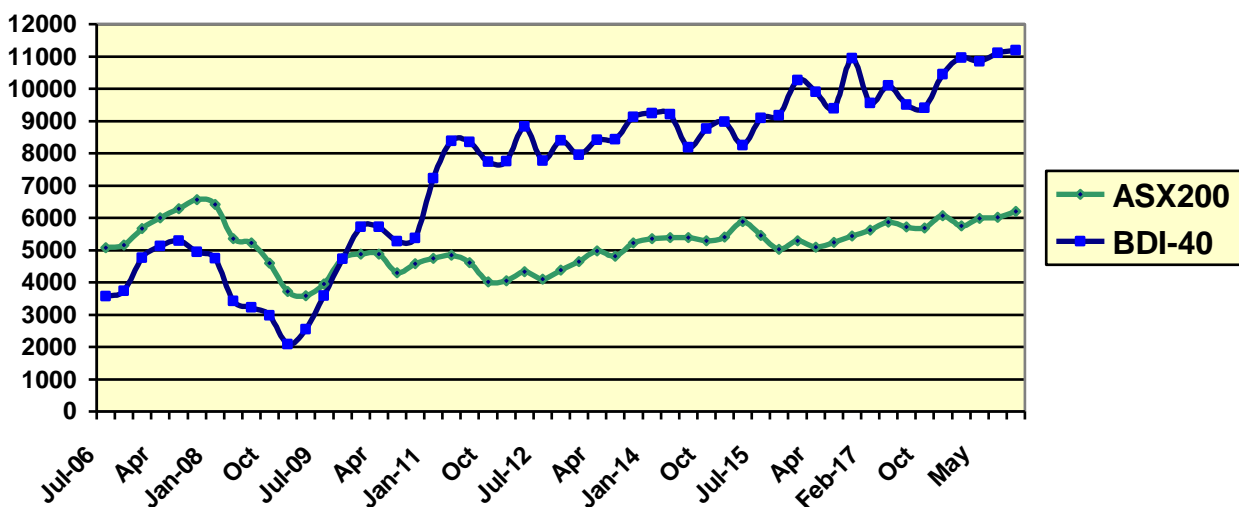
But the best by far was Dr Greg Collier’s Invion with a 4,575 percent improvement from \$4 million to \$187 million, followed by former Chemgenex team-mate Dr James Campbell’s Patrys up 1,425 percent from \$4 million to \$61 million.

I don’t know what they put in the water in Geelong, but it’s worthy of investigation.

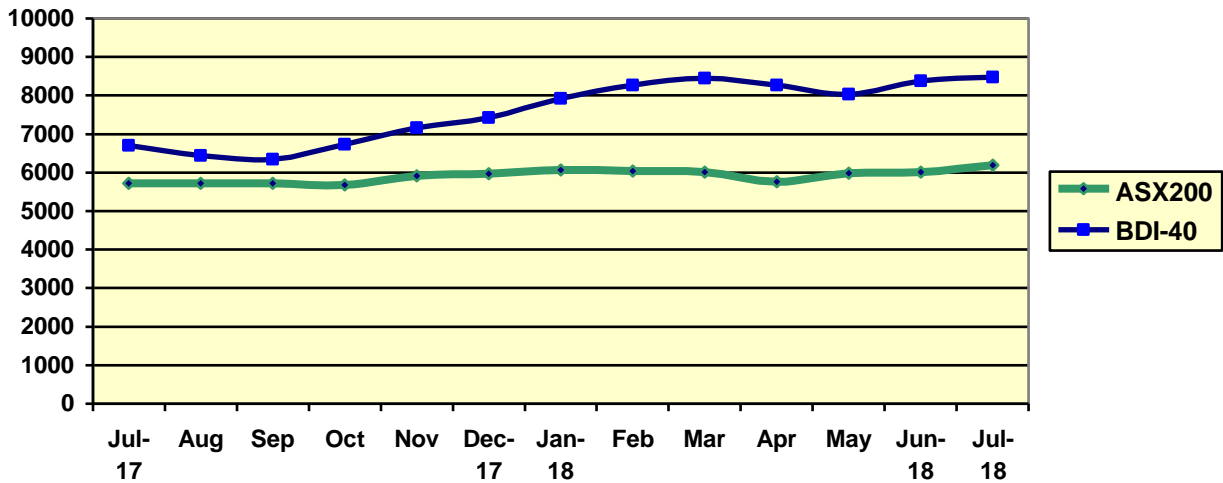
Other not-so-shabby performances were recorded by Invitrocue (833.3%), Cann Group (695.7%), Botanix (288.2%), Noxopharm (228.6%), Medadvisor (209.5%), Probiotec (208.7%) and Painchek (200.0%).

The 16 companies in Cannabis Corner fell 5.1 percent in June but were up a notional 212.5 percent for the year, with several listing during the 12-month period and not having a market capitalization 12 months ago.

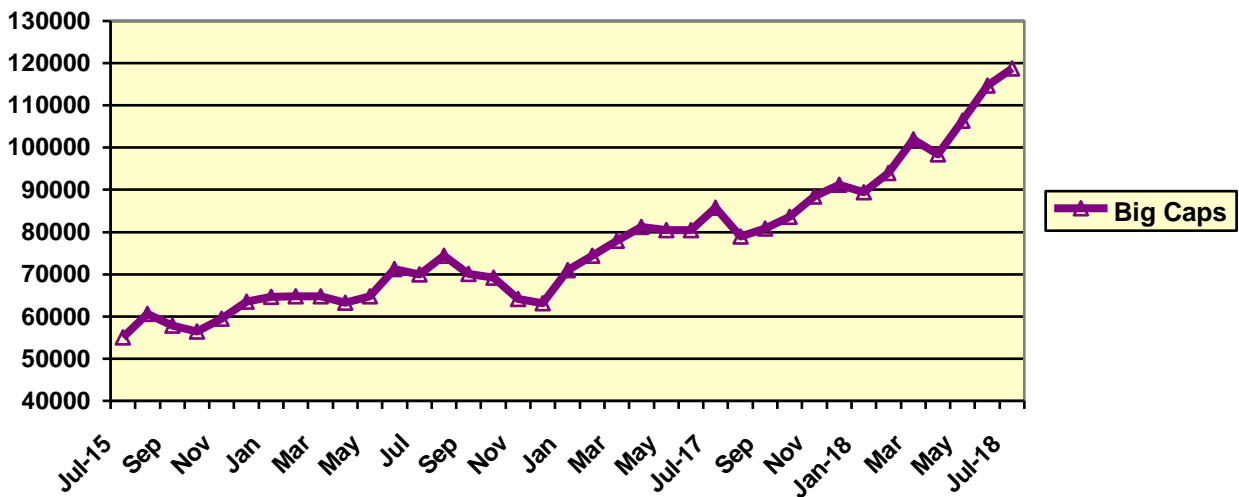
BDI-40 v ASX200 Jun 30, 2006 to Jun 30, 2018- Adjusted



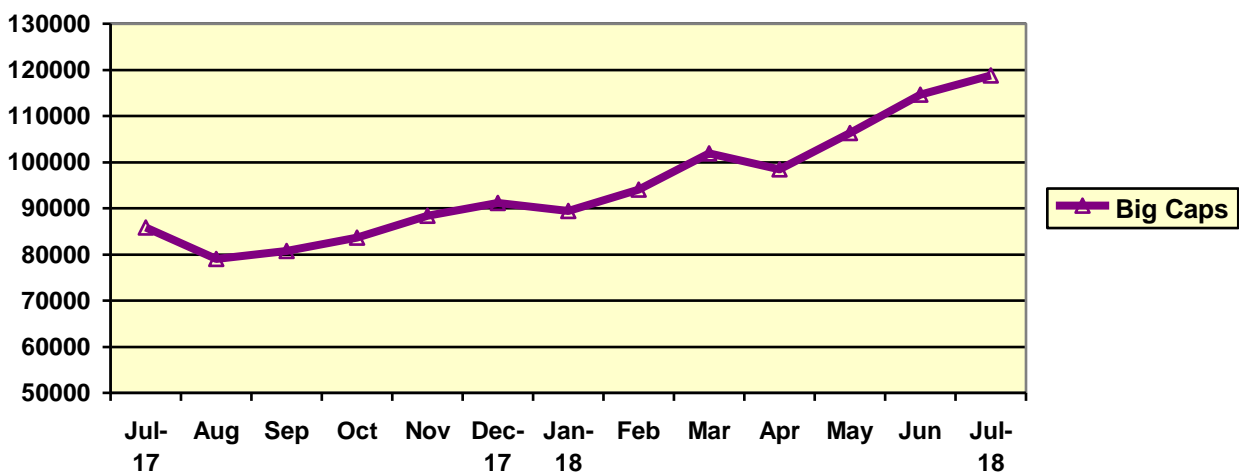
BDI-40 (\$m) v S&P ASX 200 – Jun 30, 2017 - Jun 30, 2018 (current, raw data)



Big Caps \$m (Cochlear, CSL, Resmed) Jun 30, 2015 – Jun 30, 2018



Big Caps \$m (Cochlear, CSL, Resmed) Jun 30, 2017 – Jun 30, 2018



MESOBLAST

Mesoblast says it has a \$US50 million (\$A67.7 million) financing deal with Novaquest Capital Management for remestemcel-L for paediatric graft versus host disease. Mesoblast said the Raleigh, North Carolina-based Novaquest would provide a non-dilutive \$US40 million (\$A54.2 million) loan at 15 percent interest over eight years, with an interest-only period of four years.

The company said that prior to the July 2026 maturity, the loan was “only repayable from net sales of remestemcel-L”, or MSC-100-IV, for paediatric graft versus host disease in all regions except Asia.

Mesoblast said Novaquest would buy \$US10 million (\$13.55 million) of its shares, at a five percent premium to the 10-day volume weighted average price to the agreement date.

The company said it would issue the shares and draw \$US30 million on closing, with the remaining \$US10 million to be drawn when the US Food and Drug Administration approved remestemcel-L for steroid refractory acute graft versus host disease.

Mesoblast was up six cents or 4.05 percent to \$1.54 with 685,071 shares traded.

ORTHOCELL

Orthocell says it has begun a 30-patient efficacy study of its Celgro collagen scaffold for arthroscopic repair of rotator cuff tendon in South Africa.

Orthocell said the study would be conducted on patients with symptomatic full-thickness tears of the two shoulder and back muscles, the supra-spinatus and infra-spinatus, greater than two centimetres, at the Durban, South Africa Busamed Gateway Private Hospital.

Orthocell said that the study’s main aim was to examine Celgro’s performance in augmenting arthroscopic repair of rotator cuff tears within the shoulder, with results for the first two patients expected by December 2018.

Last month, the company said interim results of the first 10 patients from its study of Celgro for tendon regeneration showed it had the ability to guide tendon healing in the shoulder, with patients showing a reduction in pain and an improvement in function and quality of life observed at six and 12 months post-treatment, with no tendon re-tears requiring surgery following the treatment (BD: Jun 6, 2018).

The company said rotator cuff tears were a common source of debilitating shoulder pain and that more than 500,000 rotator cuff surgeries were conducted in the US each year, with data showing up to 57 percent of large rotator cuff repairs tearing again.

Orthocell was unchanged at 32 cents.

OPTHEA

Opthea says it is has recruitment 176 of 351 patients for its phase IIb trial of OPT-302 for wet age-related macular degeneration and was on track to report in 2020.

Opthea said the study was designed to determine if OPT-302, a vascular endothelial growth factor (VEGF) C and D inhibitor, improved visual acuity and anatomical parameters such as retinal fluid and thickness in patients receiving standard of care anti-VEGF therapy for wet age-related macular degeneration (AMD).

Last year, Opthea said its phase I/IIa trial of OPT-302 for wet AMD met its safety and efficacy endpoints, including biological activity at the 0.3mg low dose (BD: Apr 3, 2017).

Today, Opthea chief executive officer Dr Megan Baldwin said “the rate of patient participation in the study is testament to the need for new combination therapies that may offer additional clinical benefit to patients over and above standard of care”.

Opthea was up one cent or 1.9 percent to 53.5 cents.

CYNATA THERAPEUTICS

Cynata says it has a partnership with the Royal College of Surgeons in Ireland to study its Cymerus mesenchymal stem cells in preclinical models of sepsis.

Cynata said the study, titled 'Improved Phagocytosis with Advanced Cell Therapy', was co-funded through the Dublin-based Royal College of Surgeons in Ireland's (RCSI) strategic industry partnership seed fund and would be led by RCSI chair of the department anaesthesia and critical care Prof Gerard Curley, a consultant in intensive care medicine at Dublin's Beaumont Hospital.

Prof Curley said that mesenchymal stem cells "direct the body's immune cells to engulf and kill bacteria during sepsis and reduce damaging inflammation".

"[Mesenchymal stem cells] offer significant hope for the treatment of sepsis, and early research findings are promising," Prof Curley said.

Cynata product development head Dr Kilian Kelly "new and innovative treatments are needed to put an end to the often-tragic consequences of sepsis, which can affect people suddenly and at any stage of life," Dr Kelly said.

"The potential for our Cymerus [mesenchymal stem cells] is enormous, and this partnership has also added an additional indication our growing portfolio of targeted diseases," Dr Kelly said.

Cynata was up one cent or 0.7 percent to \$1.38.

IMMUTEP

Immutep says it has filed its investigational new drug application to the US Food and Drug Administration for a 120-patient combination trial of IMP-321 and Keytruda for cancer. Immutep said the phase II trial of two active immunotherapies, the Tacti-002 trial, would investigate IMP-321, or eftilagimod alpha, in combination with the Merck & Co drug Keytruda, or pembrolizumab, for non-small cell lung cancer and head and neck cancer (BD: Mar 12, 2018).

The company said that if the application was granted, would allow it to ship IMP-321 to US investigators for the trial.

Immutep said it would continue to prepare for the Tacti-002 trial in the US, Europe and Australia, which was expected to begin by the end of 2018, with the first data in 2019.

Immutep fell 0.1 cents or 3.2 percent to three cents with 3.9 million shares traded.

PROBIOTEC

Probiotec says it has completed the purchase of 85 Cherry Lane, Laverton North in Melbourne's west for \$3.6 million.

Probiotec said the property adjacent to its pharmaceutical production facility would cut costs through the reduction in freight and overheads related to off-site warehousing and operational efficiencies and also provide the company with significant expansion capacity to meet the growing needs of the business.

The company said it was currently exploring sale and leaseback proposals for the combined properties.

Probiotec was up three cents or 2.6 percent to \$1.18.

BOTANIX PHARMACEUTICALS

Botanix says it hopes to begin a phase Ib trial of synthetic cannabidiol BTX1801 for skin infections by the end of 2018 and a trial of BTX1308 for psoriasis by October, 2018.

Botanix executive director Matt Callahan said that BTX1801 had “the potential to address the significant global public health issue of antimicrobial resistance”.

The company said that BTX1801 was a new antimicrobial and that data from pre-clinical testing indicated that its Permetrex delivery system “significantly improves the antimicrobial killing power of cannabidiol, achieving close to 100 percent bacterial killing effect at low concentrations of antibiotic resistant strains of the most common skin infection bacteria methicillin-resistant Staphylococcus aureus” or golden staph.

Botanix said it was conducting a market review to identify the ideal skin infection to target, with the intention to execute a rapid development pathway.

The company said it had completed its BTX1308 psoriasis pre-clinical formulation and testing work which supported the mechanism of action for the drug in addressing inflammation, bacterial infection and immune system modulation.

Mr Callahan said that BTX1308 had “the potential to provide a new topical solution to sufferers of psoriasis which is safe and effective”.

The company said it planned to start a study of a number of formulations of BTX1308 for psoriasis in Europe by October.

Botanix was unchanged at 11 cents or 3.6 million shares traded.

SUDA PHARMACEUTICALS

Suda says it will pay HC Berlin Pharma liabilities and legal costs up to EUR1,620,000 (\$A2,559,080) and hopes to raise \$6.12 million in a rights issue.

Suda said the liabilities were capped at EUR1.4 million with legal costs of EUR220,000 and would be paid in five instalments over three and a half years.

In March, Suda said that a German court had dismissed its appeal against the judgement in its case against HC Berlin Pharma and in May said it would meet with HC Berlin Pharma’s receiver to resolve the dispute (BD: Mar 29, May 1, 2018).

The company said it hoped to raise \$6.12 million through a rights issue at 0.5 cents a share, a 45 percent discount to the one-month volume weighted average price, with one free attaching listed option for every two new shares issued.

Suda said the funds would go towards the first instalment of the settlement money, with the rest to be paid from its Federal R&D Tax Incentive.

The company said it had commitments for up to \$2.14 million of the shortfall and the directors would take up their entitlements.

Suda said that the record date was July 9, the offer would open on July 11 and close on July 26, 2018.

The company said that CPS Capital Group was the lead manager to the rights issue. Suda fell 0.2 cents or 25 percent to 0.6 cents with nine million shares traded.

GENERA BIOSYSTEMS

Genera has requested a trading halt “pending an announcement ... regarding a proposed capital raising”.

Separately, Genera said the capital raising was to re-finance its series B convertible notes.

Trading will resume on July 4, 2018 or on an earlier announcement.

Genera last traded at 16 cents.

DIMERIX

Dimerix says the US Patent and Trade Mark Office has allowed a further patent relating to DMX-200 for focal segmental glomerulosclerosis and diabetic kidney disease.

Dimerix said the patent application, titled 'Combination therapy', would provide protection until 2032 and was part of the same family as the method of use patent issued in 2016, and provided coverage for claims to "a pharmaceutical composition comprising a broad range of angiotensin receptor blockers and chemokine 2 receptor antagonists" (BD: Feb 19, 2016).

The company said DMX-200 would be studied in two additional simultaneous phase II trials for focal segmental glomerulosclerosis and diabetic kidney disease, with patients receiving the angiotensin receptor blocker irbesartan along with the trial drug propagermanium, a chemokine 2 receptor antagonist.

Dimerix chief executive officer Kathy Harrison said the additional US patent "further substantiates Dimerix's broad claims over the use of a [chemokine 2 receptor] antagonist with the standard of care angiotensin receptor blocker for treatment of kidney disease".

"It is further validation of the strength of the Dimerix intellectual property portfolio in a therapeutic approach with growing activity levels," Ms Harrison said.

Dimerix was up half a cent or 5.3 percent to 10 cents.

PHARMAUST

Pharmaust says its subsidiary Epichem has ISO17034:2016 accreditation from the Rhodes, New South Wales' National Association of Testing Authorities, Australia.

Pharmaust said ISO17034 was a benchmark for producers of reference material and an internationally recognized standard to check the quality of products to validate analytical measurement methods, or for the calibration of instruments, and provided quality assurance for the production and supply of reference materials.

The company said Epichem was "one of the first companies in Australia to achieve this internationally regarded standard of quality assurance for reference material production to support pharmaceutical drug manufacturing".

Pharmaust said that Epichem already held ISO 9001:2015, a standard for management systems for manufacturing and service organizations that provided a framework for system development.

Pharmaust was up 0.1 cents or 2.4 percent to 4.2 cents.

RACE ONCOLOGY

Race says that milestones for the two tranches of performance shares have been met and are to be converted into shares at the election of holder Update Pharma.

Race said each tranche was worth five million shares, but did not disclose the milestones.

According to the Bloomberg website, the Lebanon, New Jersey-based Update Pharma's founder and chairman was Race chairman Dr William Garner, who is credited with inventing the company's Bisantrone for acute myeloid leukaemia.

Bloomberg said that Update Pharma's chief executive officer was Race chief scientific officer Dr John Rothman.

Race was up half a cent or 2.4 percent to 21.5 cents.

[RHINOMED](#)

Melbourne-based Dr John McBain says he has increased his substantial shareholding in Rhinomed from 6,450,667 shares (5.48%) to 7,664,667 shares (6.51%).

The substantial shareholder notice, in the name of Thirty-Fifth Celebration, said that between March 28 and June 28, 2018 it bought 1,214,000 shares at various prices, with the largest single purchase of 214,000 shares on June 21 for \$29,960 or 14 cents a share. Rhinomed fell half a cent or 2.9 percent to 17 cents.

[BOTANIX PHARMACEUTICALS](#)

Botanix says it will release 156,476,642 shares and 13,000,000 unlisted options from ASX escrow on July 15, 2018.

According to Botanix most recent Appendix 3B new share issue announcement, following the release the company would have 757,424,658 shares available for trading.

The company said the options were exercisable at three cents each by June 30, 2019.

[CRESO PHARMA](#)

Creso says it has a commercial agreement with CB Distributors to sell its cannabidiol (CBD) Cannaqix 50 lozenge for chronic pain in New Zealand.

Creso said the launch followed the launch of Cannaqix 10 in Switzerland and Lichtenstein, with further launches planned in the UK and the Netherlands.

Creso chief executive officer Dr Miri Halperin Wernli said New Zealand was important as it was part of the Asia-Pacific region expected to have 23 percent of the worldwide spend on cannabidiol products by 2022.

Creso was up 2.5 cents or four percent to 65 cents.

[MMJ PHYTOTECH](#)

MMJ says it has invested \$C5 million (\$A5.15 million) for a 6.9 percent shareholding in the privately-held Medipharm Labs.

MMJ said the Barrie, Ontario-based Medipharm owned Canada's largest medical cannabis oil production facility that would support 100,000kg of annual dry cannabis processing, was licenced to produce medical marijuana, and expected to receive a sales licence later this year, and owned a majority share in the Wonthaggi, Victoria Medipharm Labs Australia, which had lodged a cannabis manufacturing licence application.

MMJ fell one cent or three percent to 32.5 cents.

[ELLEX MEDICAL LASERS](#)

Ellex says it has appointed Mike Southard and Mike Mangano as directors, to be ratified by resolution at the company's next annual general meeting.

Ellex said Mr Southard worked at the Fort Worth, Texas-based Alcon Laboratories as head of the surgical business for 25 years, prior to which he was an executive with Beecham Laboratories and Copper-Vision, and held a Bachelor of Science from Oregon State University and a Master of Business Administration from Stanford University.

Ellex said Mr Mangano had more than 23 years of experience in the medical device industry, most recently as the chief executive officer of the San Clemente, California-based Reshape Medical and prior to that worked for Sirtex Medical and Boston Scientific.

Ellex was unchanged at 61 cents.

OBJ

OBJ says it has appointed Cameron Reynolds as a non-executive director, effective from July 2, 2018.

OBJ was up 0.3 cents or 10.7 percent to 3.1 cents with 3.8 million shares traded.

IDT AUSTRALIA

IDT says that interim chief executive officer Dr David Sparling has been confirmed as chief executive officer on a base salary of \$347,500 (excluding superannuation).

IDT fell 0.1 cents or one percent to 9.5 cents.

PHYLOGICA

Phylogica says chief executive officer Dr Rohan Hockings will be paid a base salary of \$395,000 a year, with performance-based bonuses of up to \$198,000.

In April, Phylogica said Dr Hockings had been appointed as chief executive officer, replacing executive chair Stephanie Unwin and told Biotech Daily that Dr Rohan Hockings was the son of director and major investor Dr Bernard Hockings (BD: Apr 11, 2018).

Today, the company said that Dr Rohan Hockings would be entitled to 10,000,000 options exercisable at 50 percent above the ASX closing price on June 29, 2018, vesting in two tranches in 12 and 24 months and subject to shareholder approval.

Phylogica said Dr Hockings had worked in medicine and law including Freehills' equity capital markets division and for four years at McKinsey & Company.

The company said that Dr Hockings held a Bachelor of Medicine and a Bachelor of Surgery from the University of Western Australia and a Juris Doctorate from the University of Melbourne.

Phylogica was up 0.1 cents or 3.85 percent to 2.7 cents.

IMMURON

Immuron says its joint company secretary Peter Vaughan has resigned, effective from July 1, 2018 having "accepted a new executive appointment".

Immuron said that Phillip Hains would continue as the company secretary.

Immuron fell 1.5 cents or 4.4 percent to 32.5 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical says Steven Wood will replace Stephen Buckley as company secretary, effective from June 30, 2018.

G Medical said that Mr Wood was a chartered accountant and an employee of Grange Consulting Group, which provided corporate and financial services.

G Medical was unchanged at 23.5 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JUNE 30, 2018

Company \$Am	Jul-17	Jun-18	Jul-18
Cochlear	8,927	11,288	11,519
CSL	62,639	84,079	87,141
Resmed	14,235	19,296	20,124
BDI-20			
Bionomics	193	282	256
Clinuvel	333	580	527
Compumedics	112	128	99
Cyclopharm	56	69	68
Ellex	129	82	88
Impedimed	283	200	150
LBT Innovations	36	23	23
Medical Developments	292	346	343
Mesoblast	890	725	702
Nanosonics	756	796	946
Neuren	122	307	299
Opthea	150	91	106
Pharmaxis	80	99	99
Polynovo	118	401	352
Immutep	58	112	94
Pro Medicus	546	765	829
Reva	369	114	93
Sirtex	938	1,640	1,754
Telix	21	136	129
Volpara	35	140	141
Second 20			
Actinogen	38	46	45
Admedus	68	82	65
Airxpanders	186	24	26
Avita	49	53	88
Benitec	26	36	35
Cynata	55	119	130
Dimerix	18	14	15
Factor Therapeutics	45	41	39
Genetic Signatures	40	41	38
Imugene	31	86	83
ITL Health	50	21	16
Oncosil	47	119	144
Optiscan	37	28	28
Orthocell	27	30	27
Osprey	103	53	51
Prescient	11	29	23
Prana	27	25	23
Starpharma	269	437	432
Universal Biosensors	73	41	41
Uscom	21	24	23

* Biotech Daily editor, David Langsam, owns shares in Acrux, Benitec, Innate, Mesoblast, Nanosonics, Patrys, Polynovo, Prana, Telix, Volpara and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in a range of other biotechnology companies: <http://www.australianethical.com.au/who-we-invest-in>. These holdings are liable to change.

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