Biotech Daily

Monday August 1, 2016

Daily news on ASX-listed biotechnology companies

*** JULY BDI-40 UP 15%, ASX UP 6%, BIG CAPS UP 6%, NBI UP 14%**
- OSPREY UP 62%, ANTISENSE UP 60%, IMPEDIMED 41%, USCOM 37%

*** TODAY: ASX UP, BIOTECH DOWN: ANTEO UP 12.5%, ANTISENSE DOWN 11%**

*** CYNATA APPLIES FOR PHASE I UK CYP-001 GVHD TRIAL**

*** FDA 'CLEAR PATH' FOR DIMERIX DMX-200 FOR KIDNEY DISEASE**

*** UNILIFE 'NO MATERIAL SHORTALL SHORTFALL, STAFF CHANGES, CUTS'**

*** MESOBLAST 2-YEAR BACK PAIN DATA BACKS LOWER DOSE MPCs**

*** DORSAVI REVENUE UP 122% TO $3m, $1m IN Q4**

*** EURO PATENT FOR REGENEUS FAT STEM CELLS FOR ACNE**

*** BLUECHIIP SELLS 1st SAMPLE TRACKING STARTER KIT TO CHINA**

*** INNATE PLACEMENT, 4.85m DIRECTOR OPTIONS AGM**

*** MEDLAB WELCOMES NSW CANNABIS LAW CHANGE, TRIAL READY**

*** RHINOMED APPOINTS MCKESSON MUTE WHOLESALE DISTRIBUTOR**

*** ADHERIUM CEO GARTH SUTHERLAND INCREASES, DILUTED TO 7%**

MARKET REPORT

The Australian stock market was up 0.45 percent on Monday August 1, 2016 with the ASX200 up 25.0 points to 5,587.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and three were untraded.

Anteo was the best, up 0.5 cents or 12.5 percent to 4.5 cents with 1.6 million shares traded. Benitec climbed eight percent; Oncosil was up 7.4 percent; Oncosil rose 7.4 percent; Acrux was up 5.4 percent; Living Cell and Mesoblast improved more than three percent; Compumedics, Factor Therapeutics, Prima, Reva, Starpharma and Viralytics rose more than two percent; with Resmed up 0.2 percent.

Antisense led the falls, down 0.5 cents or 10.9 percent to 4.1 cents with 716,000 shares traded. Admedus and Ellex lost more than six percent; Cellmid fell 5.7 percent; IDT and Osprey fell more than four percent; Actinogen, Medical Developments and Orthocell shed more than two percent; Avita, Bionomics, Neuren, Prana, Sirtex and Uscom were down more than one percent; with Cochlear, CSL and Pro Medicus down less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

July was good for the S&P ASX200, up 6.3 percent, but it was much better for the Biotech Daily Top 40 Index (BDI-40) which climbed 14.6 percent.

The BDI-40, which does not include the three Big Caps of Cochlear, CSL and Resmed, rose 17.0 percent for the year to July 31, compared to the ASX200 falling 2.4 percent.

The three Big Caps were up an average 6.4 percent for the month to July 31, 2016 to a collective market capitalization of a record $74,372 million, and up 22.8 percent for the 12 months. Resmed was up 10.8 percent to $12,914 million, followed by Cochlear up 9.5 percent to $7,593 million and CSL up 4.95 percent to $53,865 million.

In July, 30 of the BDI-40 companies were up, 20 by more than 10 percent and 12 by more than 20 percent, with just six companies losing ground, the worst by just 8.9 percent.

While Sirtex contributed $350 million to the BDI-40's collective market capitalization, Impedimed and Nanosonics were both up by more than $145 million.

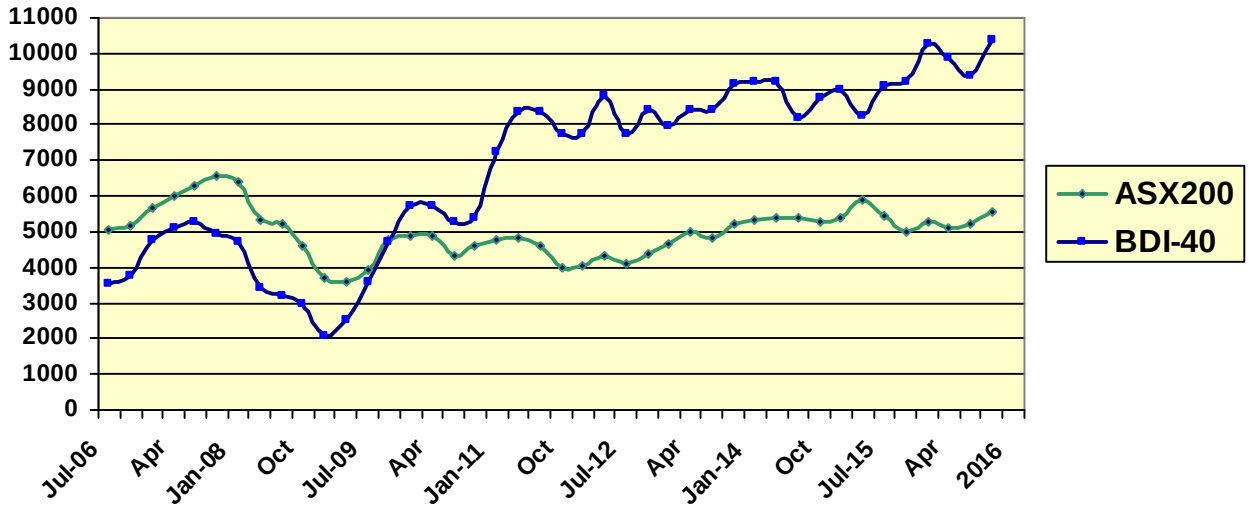
From low bases, Osprey was the best, recovering a further 61.8 percent to $55 million followed by Antisense up 60 percent to $8 million. Impedimed climbed 41.4 percent, followed by Uscom (37.0%), Opthea (31.1%), Benitec (28.6%), Orthocell (26.3%), Nanosonics (25.2%), Avita (24.5%), Sirtex (23.9%) and IDT (20.4%).

Universal Biosensors led the falls, down 8.9 percent to $51 million, followed by Viralytics (8.5%), Genetic Technologies (6.1%), Medical Developments (2.0%) and Prana (1.9%).

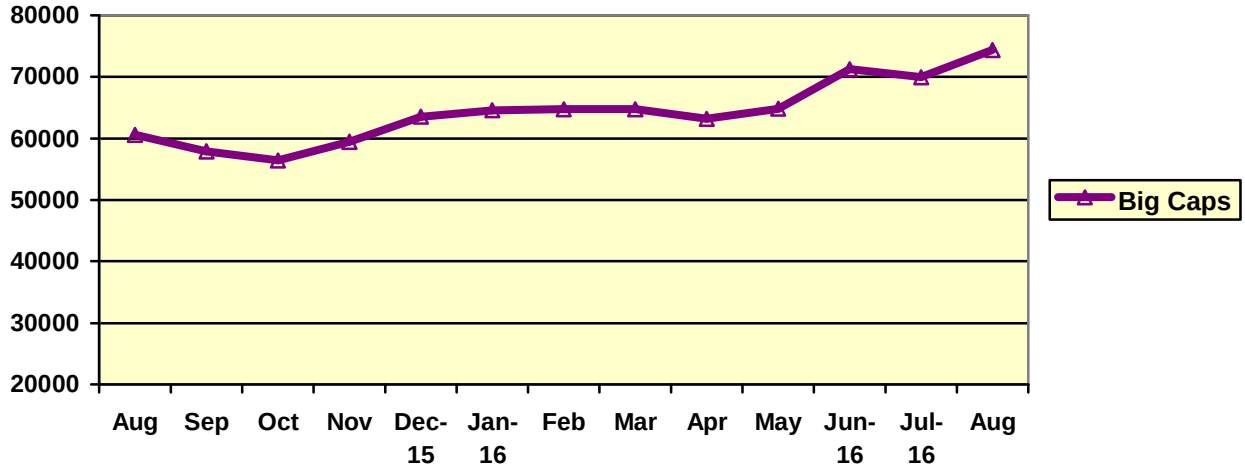
The July Nasdaq Biotech Index rose 14.4 percent, with former Australian companies Heartware down 1.5 percent to $1,338 million, Aviragen (Biota) down 4.1 percent to $70 million and Sunshine Heart rebounding 83.3 percent from a long-term low to $22 million. Israel's Redhill, developing Giaconda's assets, climbed 20.2 percent to $220 million.

Outside the BDI-40, Analytic doubled to $22 million and generics manufacturer Mayne Pharma climbed 93.6 percent to $2,987 million, with Cyclopharm, Innate and Resapp at all-time highs of $84 million, $83 million and $228 million, respectively.

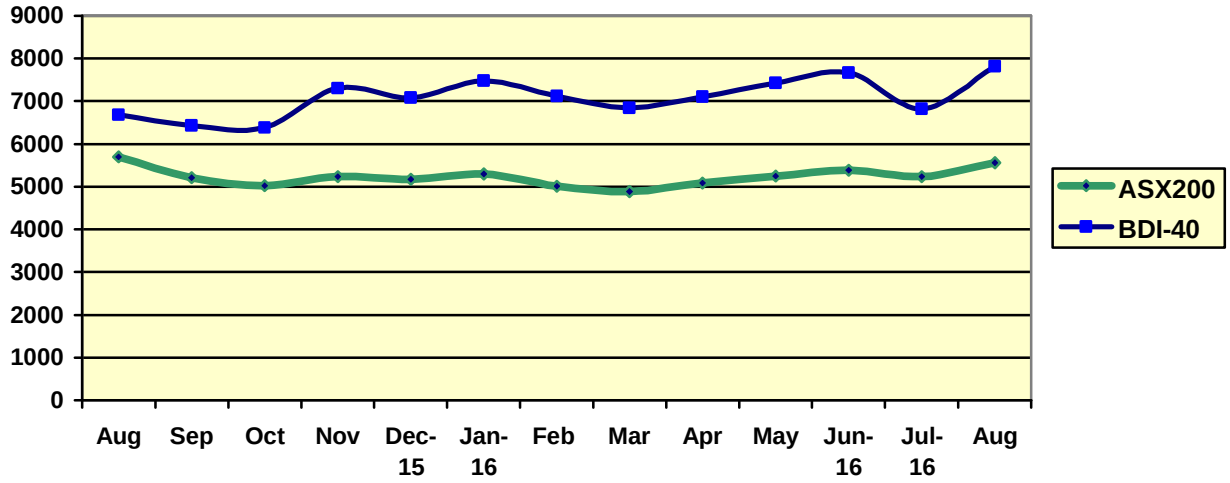
BDI-40 v ASX200 Jun 30, 2006 to Jul 31, 2016 - Adjusted



Big Caps $m (Cochlear, CSL, Resmed) Jul 31, 2015 – Jul 31, 2016



BDI-40 ($m) v S&P ASX 200 – Jul 31, 2015 – Jul 31, 2016



CYNATA THERAPEUTICS

Cynata says it has applied to the UK Medicines and Healthcare products Regulatory Agency for a phase I study of CYP-001 for graft-versus-host disease.

Cynata chief executive officer Dr Ross Macdonald told Biotech Daily that the trial's primary endpoint was safety with a secondary endpoint of a reduction in the severity of symptoms.

The company said that graft-versus-host disease was a potentially fatal disease that often followed a bone marrow transplant and occurred when the immune cells in the donor graft material attacked the recipient's host tissues as foreign.

Cynata said the application to the MHRA followed "a successful scientific advice meeting which took place earlier this year" and the company's head of product development Dr Kilian Kelly said the application was "the culmination of an intensive program of manufacturing process development, safety evaluation and proof-of-concept studies".

"The successful outcomes from our product development activities over the past two-and-a half years have allowed us to move things forward," Dr Kelly said.

"We have been very pleased with the result of our pre-clinical program and are eager to advance to an initial clinical study with our induced pluripotent stem cell-derived [mesenchymal stem cell] therapeutic product, CYP-001," Dr Kelly said.

Cynata was up two cents or 5.6 percent to 38 cents.

DIMERIX

Dimerix says the US Federal Drug Administration has clarified the path to registration for DMX-200 for chronic kidney disease.

Dimerix said that minutes from its pre-investigational new drug application meeting with the FDA specified the orphan indication of focal segmental glomerular sclerosis, for which DMX-200 had orphan designation.

The company said that there were “no apparent roadblocks or extra costs identified” for filing its investigational new drug application for the first US pharmaco-kinetic study and DMX-200 would be treated as an adjunct therapy rather than a combination therapy, resulting in a less expensive, smaller pivotal trial.

Dimerix said that the FDA minutes provided the potential for approval from a single pivotal phase III trial with a single end-point of improvement in proteinuria from baseline, “bringing huge cost benefits over running two phase III trials”.

The company said that the FDA recognized the importance of heterodimer pharmacology, or the combination of two molecules, validating its technology in identifying new treatments.

Dimerix said that DMX-200 was identified using its receptor-heteromer investigation technology, or Receptor-HIT, screening assay combining two existing drugs, the chemokine receptor CCR2 blocker propagermanium used for its anti-inflammatory properties, and the angiotensin II type I receptor blocker irbesartan which was registered in the US for hypertension and treatment of diabetic nephropathy.

The company said that in the FDA meeting, it confirmed that as angiotensin receptor blockers, including irbesartan, were standard-of-care for treatment of chronic kidney diseases, and it was “appropriate that DMX-200 [was] positioned as an adjunct therapy and not a fixed dose combination therapy”.

Dimerix said it planned to package propagermanium as an extended release formulation, reducing dosage from the current three times daily dosing, to be delivered to patients on irbesartan therapy.

The company said that treatment of DMX-200 as an adjunct therapy reduced the complexity of the phase III trial required for registration, compared with those for a fixed dose combination therapy, providing a relatively simple, and inexpensive, path to opening an application for a pharmacokinetic study for the extended release formulation.

Dimerix said that a substantial portion of the meeting was focused on identification of appropriate end points for a pivotal phase III trial in focal segmental glomerular sclerosis (FSGS).

The company said that proteinuria was common in FSGS patients and was broadly accepted as a strong independent risk factor for disease progression.

Dimerix said that the FDA advised that for DMX-200 “a substantial change in proteinuria in patients with marked proteinuria at baseline may be an acceptable endpoint for traditional or accelerated approval”, and provided “vital information to assist in the design of the likely single pivotal phase III trial for registration.

The company said that the FDA provided “valuable feedback” on the Australian phase II trial which would help maximise the supporting value of the trial for the phase III trial.

Dimerix executive chairman Dr James Williams said the FDA was “extremely helpful in providing Dimerix with advice and information to help us succeed in the development of DMX-200 for FSGS”.

“As this rare and severe disease has no current effective treatments, the FDA has shown significant interest in assisting companies to expedite their development path to ensure treatment options are made available to patients as quickly as possible,” Dr Williams said.

Dimerix fell 0.2 cents or 18.2 percent to 0.9 cents with 14.3 million shares traded.

UNILIFE

Unilife says executive violations did not cause material losses, it has less than six months cash and along with board changes it has cut staff by 40 percent.

In a series of announcements, Unilife said that investigations into founder and former executive chairman Alan Shortall and former chairman Jim Bosnjak identified no material financial loss to the company, but Mr Shortall's consultancy had been terminated and company's controller, treasurer and chief accounting officer Dennis Pyers had been appointed as special projects senior advisor.

Unilife said that the internal investigation into violations of company policies and procedures and possible violations of law and regulation by Mr Shortall and Mr Bosnjak had been substantially completed and to date "identified no material financial loss".

The company said it was "continuing to evaluate the impact of these matters, including on financial reporting and internal controls over financial reporting, related to previously-issued financial statements, current interim financial information and management's certifications".

Unilife said it expected to amend US Securities and Exchange Commission financical filings "to correct the immaterial errors identified as a result of the investigation".

The company said there were "material internal control weaknesses, which … [it] continues to evaluate and … has commenced a remediation process with the assistance of a third party internal audit provider".

Unilife said it had reported the matters to the US SEC and Nasdaq and continued to cooperate fully with the SEC with respect to the SEC's ongoing investigation.

The company said it had terminated its consulting agreement with Mr Shortall.

Unilife said it had a cash burn of $US13,914,000 ($A18,326,460) in the three months to June 30, 2016, with $US21,102,000 in cash.

Unilife said it continued to cut costs as it focused on the customer programs, the workforce had been reduced by more than 40 percent to about 140 employees and it had sublet a significant portion of its office space in King of Prussia, Pennsylvania.

The company said that interim chief executive officer John Ryan had been appointed chief executive officer, former Merck Bioventures president Dr Michael Kamarck had been appointed a director, former general-manager Ian Hanson had been appointed chief operating officer and general counsel Stephanie Walters would also take on the role of company secretary.

Unilife said that former general-manager Dr Molly Weaver had been appointed head of quality and regulatory affairs and chief compliance officer, replacing Mark Iampietro, with chief financial officer since 2015 David Hastings appointed chief accounting officer, replacing Dennis Pyers.

Unilife said it would "focus primarily on active and new customer programs in its portfolio of wearable injector systems".

"This primary focus on wearable injectors is expected to enhance operating efficiencies and better position the company to take advantage of commercial opportunities within the fast-growing market for wearable injectors, where Unilife has industry-leading technology and already has a strong customer base," the company said.

"In addition to other previously announced wearable injector programs with Sanofi and Medimmune, the global biologics research and development arm of Astrazeneca, Unilife has commenced wearable injector development programs with Amgen under its previously announced strategic collaboration," Unilife said.

Unilife fell one cent or 11.9 percent to 7.4 cents with 4.6 million shares traded.

MESOBLAST

Mesoblast says that at 24 months its mesenchymal precursor cells were well-tolerated with the lower six million dose more effective in reducing pain.

Mesoblast said that the 24-month results from the 100-patient, four-arm, randomized, placebo-controlled phase II trial of its chronic low back pain product candidate MPC-06-ID were presented at the Spine Intervention Society meeting in New Orleans, July 27 to 30, 2016 by lead investigator Dr Michael DePalma.

The company said that the presentation, entitled 'A Randomized, Controlled Trial Evaluating the Safety and Effectiveness of Immuno-selected, Allogeneic, Mesenchymal Precursor Cells for Treatment of Chronic Low Back Pain' won the 'Best Basic Science Abstract' award at the meeting.

"The long term results from this study indicate that a single injection of Mesoblast's allogeneic mesenchymal precursor cells into the disc of patients with moderate to severe [chronic low back pain] due to degenerative disc disease was well tolerated and provided substantial improvement in pain and function over 24 months compared with control therapies," Dr DePalma said.

In 2014, Mesoblast said that a presentation on its phase II degenerative disc disease trial showed that a single injection of its stem cells resulted in improved pain and function at 12 months (BD: Jan 30, Nov 13, 2014).

Mesoblast said at that time that the trial enrolled 100 patients with moderate to severe low back pain caused by early disc degeneration, who were randomized to receive direct intra-disc injection of saline (n= 20), hyaluronic acid (n=20), six million allogeneic mesenchymal precursor cells (MPCs) in hyaluronic acid carrier (n=30) or 18 million MPCs in hyaluronic acid carrier (n=30) and were being assessed for safety and efficacy over 36 months to evaluate long-term treatment effects.

Today, the company said that the six million dose, used in the on-going phase III trial, resulted in the greatest proportion of patients meeting the phase III primary endpoint of overall treatment success, a composite of both pain and functional responder status.

Mesoblast said that 50.0 percent of subjects who received six million MPCs achieved the pain responder criteria at both 12 and 24 months of a 50 percent pain reduction compared to 12.5 percent for saline controls ($p = 0.020$) with 36.0 percent for the 18 million MPC dose and 23 percent for those receiving hyaluronic acid.

The company said that 46.2 percent of subjects who received six million MPCs achieved the functional responder criteria at both 12 and 24 months compared to 12.5 percent for the saline-treated controls ($p = 0.042$), with 53.9 percent for patients receiving 18 million MPCs ($p = 0.01$ vs saline) and by 29.4 percent for those receiving hyaluronic acid.

Mesoblast said that overall treatment success at 12 months was achieved by 50 percent of patients in the six million MPC group compared with 18.8 percent in the saline group ($p = 0.056$) and 77 percent of MPC-treated patients who achieved overall treatment success at 12 months maintained this at 24 months ($p = 0.09$ vs saline).

The company said that overall treatment success at both 12 and 24 months was achieved by 38.5 percent of the six million MPC group, 34.6 percent of the 18 million MPC group, 17.7 percent of the hyaluronic acid group and 12.5 percent of the saline group.

Dr DePalma said that if the findings from the on-going phase III trial were comparable, "Mesoblast's MPCs could become a valuable treatment for a significant number of people suffering with chronic low back pain who currently have no other viable option".

Mesoblast said its phase III trial was recruiting 360 patients across 30 sites in the US and Australia, randomized two-to-one to receive either six million MPCs or saline control, with interim data expected "in early 2017".

Mesoblast was up four cents or 3.6 percent to $1.16 with 874,314 shares traded.

DORSAVI

Dorsavi says that unaudited customer revenue for the year to June 30, 2016 was up 122.4 percent to $3,020,000 compared to the year to June 30, 2015.
Dorsavi said that it wrote a record $1,008,000 in contracts for the three months to June 30, 2016, up 40.0 percent compared to the three months to March 31, 2016 and up 104.9 percent compared to the three months to June 30, 2015.
Dorsavi chief executive officer Dr Andrew Ronchi said the company had reduced costs, invested in product development and won health and safety and clinical clients.
Dorsavi was up three cents or 9.1 percent to 36 cents.

REGENEUS

Regeneus says the European Patent Office has granted a patent covering the use of its stem cell secretions technology for the topical treatment of acne.
Regeneus said that its first European patent, entitled 'Compositions of adipose tissue-derived secretions for use in the topical treatment or prevention of acne' provided commercial rights in Europe to March 15, 2032.
The company said the European grant followed the Australian grant in October 2014 and the patent was being pursued in other key territories, including the US and Japan.
Regeneus said that its fat-based stem cell technology used the molecules, including cytokines and growth factors, secreted by mesenchymal stem cells and it was exploring partnering options for the development and commercialization of the technology.
Regeneus said that skin conditions and wound healing were among the "most promising and near term areas for cell-based regenerative medicine products".
The company said that there had been few treatment innovations or improvements in the treatment of acne over the last 10 years, the demand for new improved acne treatments was high and the global market for acne-based prescription treatments was more than $US3 billion a year.
Regeneus fell half a cent or 3.85 percent to 12.5 cents.

BLUECHIIP

Bluechiip says it has sold a sample tracking starter kit to China's Centre for Disease, Control and Prevention in Beijing.
Bluechiip said that the Ministry of Health's Centre focused national attention on developing and applying disease prevention and control, environmental health, occupational health and safety, health promotion, prevention and education activities.
The company said that the starter kit had both English and Chinese interfaces and with the reader and 3,000 associated consumables, allowed the Centre to become familiar with its technology and to train staff in its use and was the first step to a full product roll-out.
Bluechiip chief executive officer Andrew McLellan said the sale to the Centre confirmed the value of the technology to partners and customers that needed to effectively control sample integrity through the chain of custody.
"The sale continues Bluechiip's recent momentum of kit sales to partners," Mr McLellan said.
Bluechiip said it had displayed its tracking technology at the European Society of Human Reproductive Embryology trade show in Helsinki, Finland, which had more than 10,000 attendees and hundreds of vendors presenting products and technologies for the in-vitro fertilization market.
Bluechiip was up half a cent or 20 percent to three cents.

INNATE IMMUNOTHERAPEUTICS

Innate investors will vote on nine resolutions relating to prior placements, including director participation, as well as the issue of 4,850,000 director options.
Innate recently raised $6,626,610 in placements at 26 US cents or 34 Australian cents and 36 New Zealand cents as well as at 18 US cents a share and a rights issue at 25 Australian cents a share (BD: Jun 10, Jul 20, 2016).
The company said shareholders would vote to approve the share issues including to chairman Michael Quinn and directors Christopher Collins, Dr Robert Peach, Andrew Sneddon and Elizabeth Hopkins and to re-elect Mr Quinn, Mr Sneddon and Dr Peach.
Innate said it proposed to issue 900,000 options to Mr Quinn, 600,000 options to each of Mr Sneddon and Ms Hopkins, 1,000,000 options to Dr Peach and 1,750,000 options to chief executive officer Simon Wilkinson, with all options to be granted on August 31, 2016 and exercisable at 65 cents each by August 31, 2018.
The meeting will be held at Grant Thornton, Seagrass room, Level 17, 383 Kent Street, Sydney on August 31, 2016 at 11am (AEST).
Innate was unchanged at 40 cents.

MEDLAB CLINICAL

Medlab says that it supports the New South Wales decision to allow doctors to legally prescribe cannabis for patients, which begins today, August 1, 2016.
Medlab said that the legal change allows patients to obtaining cannabis legally.
Medlab managing-director Sean Hall told Biotech Daily that pending regulatory approval the company was preparing to begin human trials of a cannabis based medicine, involving a therapeutic combination of the two cannabis compounds cannabidiol and tetrahydrocannabinol for pain using its Nanocele small particle mouth spray.
In a media release Mr Hall said the State Government's move highlighted the benefits of cannabis as a pain management tool.
Medlab said it was completing a $5.4 million capital raising.
Medlab was unchanged at 40 cents.

RHINOMED

Rhinomed says it has appointed McKesson Corp as a wholesale distributor of the Mute snoring and sleep nasal plugs for the North American pharmacy market.
Rhinomed said that the San Francisco, California-based McKesson was one of the oldest and largest healthcare distribution companies in the world, was the fourth largest pharmacy network in the US and serviced more than 3,000 pharmacies in the US.
Rhinomed fell 0.2 cents or 8.3 percent to 2.2 cents with 1.9 million shares traded.

ADHERIUM

Adherium chief executive officer Garth Sutherland has increased his holding from 11,174,450 shares to 11,347,688 shares but has been diluted to 6.78 percent.
The Auckland, New Zealand-based Mr Sutherland who is also the company's founder and chief technology officer said that the 173,238 shares were acquired through the exercise of options for $13,039 or 7.5 cents each.
Mr Sutherland said the dilution was through the recent placement of $8,023,049 in shares at 50 cents each to Fidelity International (BD: Jul 20, 2016).
Adherium was unchanged at 50 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JULY 31, 2016

Company $Am	**Aug-15**	**Jul-16**	**Aug-16**
Cochlear	5,184	6,936	7,593
CSL	44,787	51,323	53,865
Resmed	10,592	11,651	12,914
BDI-20			
Acrux	114	120	122
Admedus	164	64	74
Bionomics	180	137	142
Clinuvel	131	203	236
Ellex	36	109	129
Impedimed	333	353	499
Medical Developments	158	354	347
Mesoblast	1,314	410	427
Nanosonics	498	648	811
Neuren	161	94	98
Opthea	31	74	97
Pharmaxis	71	81	90
Polynovo	41	156	156
Prima	93	85	85
Pro Medicus	250	482	540
Psivida	165	139	165
Reva	158	470	542
Sirtex	1,735	1,464	1,814
Universal Biosensors	66	56	51
Viralytics	140	235	215
Second 20			
Actinogen	37	44	44
Airxpanders	158	219	227
Anteo	99	42	42
Antisense	18	5	8
Atcor	40	25	26
Avita	37	49	61
Benitec	104	14	18
Biotron	33	19	20
Cellmid	29	31	32
Compumedics	48	61	70
Factor (TIS)	18	25	30
Genetic Technologies	50	33	31
IDT	51	49	59
Living Cell	20	37	38
Oncosil	46	64	63
Orthocell	43	19	24
Osprey	116	34	55
Prana	87	53	52
Starpharma	209	237	242
Uscom	14	27	37

* Biotech Daily editor, David Langsam, owns shares in Acrux, Admedus, Benitec, Mesoblast, Nanosonics, Neuren, 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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