Biotech Daily

Monday November 2, 2015

Daily news on ASX-listed biotechnology companies

*** OCTOBER BDI-40 UP 14%, ASX200 UP 4%, BIG CAPS UP 5%**
- AVITA UP 60%, LIVING CELL 38%, PRO MEDICUS 37%; OSPREY DOWN 62%

*** TODAY: ASX, BIOTECH DOWN: ONCOSIL UP 6%, ATCOR DOWN 27%**

*** MESOBLAST PLANS US IPO**

*** US PRICES ATCOR SPHYGMOCOR AT $25 PER TEST**

*** CORRECTION: CIRCADIAN**

*** INVION COMPLETES INV102 MILD ASTHMA TRIAL ENROLMENT**

*** HUNTER HALL REDUCES BELOW 5% OF SIRTEX**

*** OBJ PLAN RAISES $484k, TOTAL $6.7m**

*** UNNAMED US COMPANY REGENEUS CRYOSHOT CANINE PRE-OPTION**

*** ALLAN GRAY INCREASES, DILUTED TO 12% OF PHOSPHAGENICS**

*** CRAIG CHAPMAN, NAMPAC INCREASE, DILUTED TO 18% OF AGENIX**

MARKET REPORT

The Australian stock market fell 1.4 percent on Monday November 2, 2015 with the ASX200 down 73.6 points to 5,165.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and four were untraded.

Oncosil was the best, up one cent or 5.7 percent to 18.5 cents with 3.9 million shares traded, followed Genetic Technologies up 5.6 percent to 1.9 cents with 3.8 million shares traded and Clinuvel up 5.3 percent to $3.00 with 73,929 shares traded. Polynovo climbed 3.7 percent; IDT, Nanosonics, Optiscan, Pharmaxis and Tissue Therapies rose more than two percent; Acrux, Anteo and Ellex were up one percent or more; with Medical Developments and Resmed up by less than one percent.

Atcor led the falls, down eight cents or 26.7 percent to 22 cents with 3.2 million shares traded followed by Prima down 10.5 percent to 5.1 cents with 19.7 million shares traded. Viralytics lost 5.2 percent; Avita, Compumedics and Living Cell fell four percent or more; Actinogen and Cellmid were down more than three percent; Bionomics, Impedimed, Pro Medicus, Reva and Starpharma shed more than two percent; Benitec, CSL, and Orthocell lost more than one percent; with Cochlear and Sirtex by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The month formerly known in financial astrology as 'Black October' was excellent for Australian biotechnology companies with 27 of the Biotech Daily Top 40 (BDI-40) climbing, including 10 up by more than 20 percent and just nine falling.

The BDI-40 sailed through the cumulative $7,000 million market capitalization mark for the first time since August 2013, when falls by Mesoblast and the departing Heartware coincided with the election of the Abbott-Hockey Government, which cut innovation programs, as well as a run of organic company set-backs, ironically starting with the Lucy Turnbull-chaired Prima closing its CVac program, and more bad news through 2014.

The BDI-40 was up 14.4 percent in October to $7,300 compared to the S&P ASX200 up 4.3 percent for the month. For the year to October 31, the BDI-40 was up 30.2 percent while the ASX200 fell 5.2 percent.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed a cumulative 5.3 percent for the month and were up 19.0 percent for the year. Cochlear rose 5.6 percent to $5,041 million, CSL was up 4.2 percent to $43,221 million with Resmed up 9.4 percent to $11,177 million.

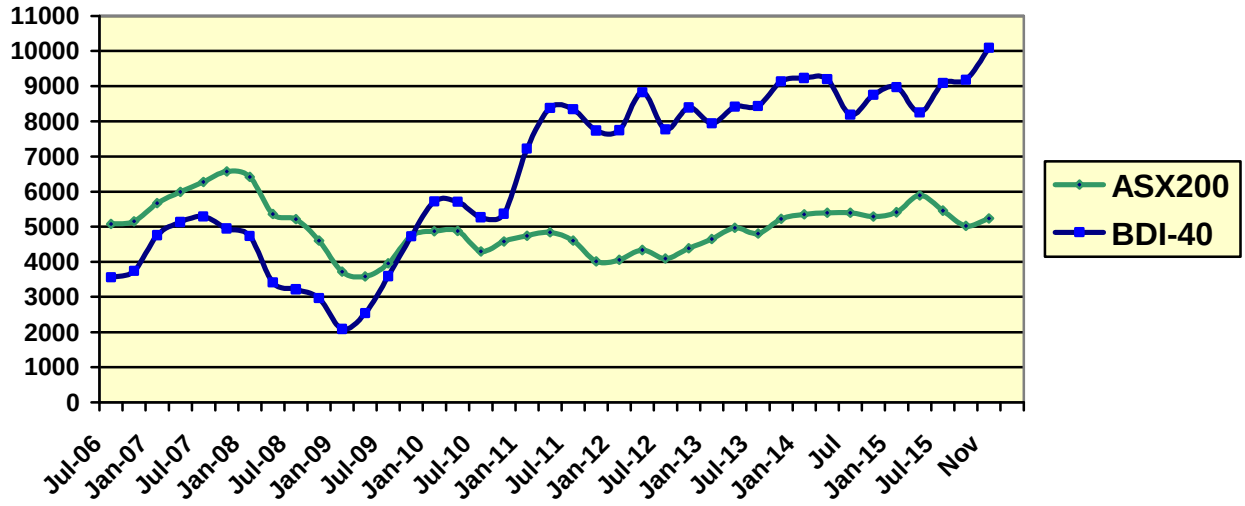
Sirtex contributed $272 million to the nearly $1 billion improvement in the BDI-40, with Mesoblast, Nanosonics and Pro Medicus each adding more than $80 million.

Avita was the best, up 60.0 percent to $56 million on a run of good news, followed by Living Cell (37.5%), Pro Medicus (36.7%), Ellex (32.6%), Acrux (31.6%), Uscom (30.8%), Circadian (27.6%), Atcor (25.5%), Compumedics (21.7%) and Nanosonics (21.4%).

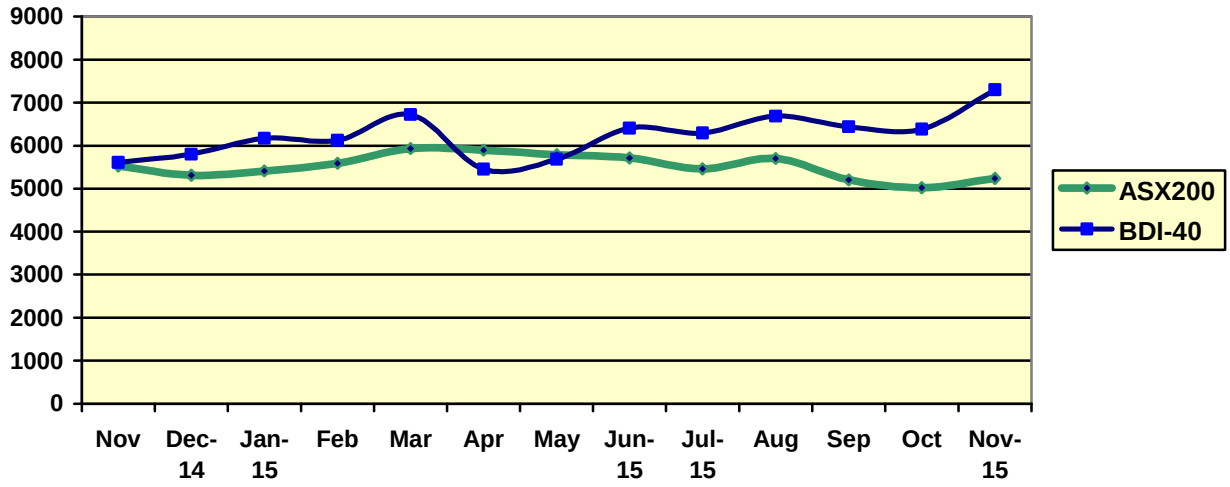
Osprey led the falls on missing a US trial endpoint, down $63 million or 62.3 percent to $43 million, followed by Optiscan (18.2%) and Starpharma (13.9%).

On the Nasdaq, Heartware fell 19.0 percent to $1,047 million, half its August 31 value, with Biota down 4.6 percent million and Sunshine Heart recovering 12.1 percent.

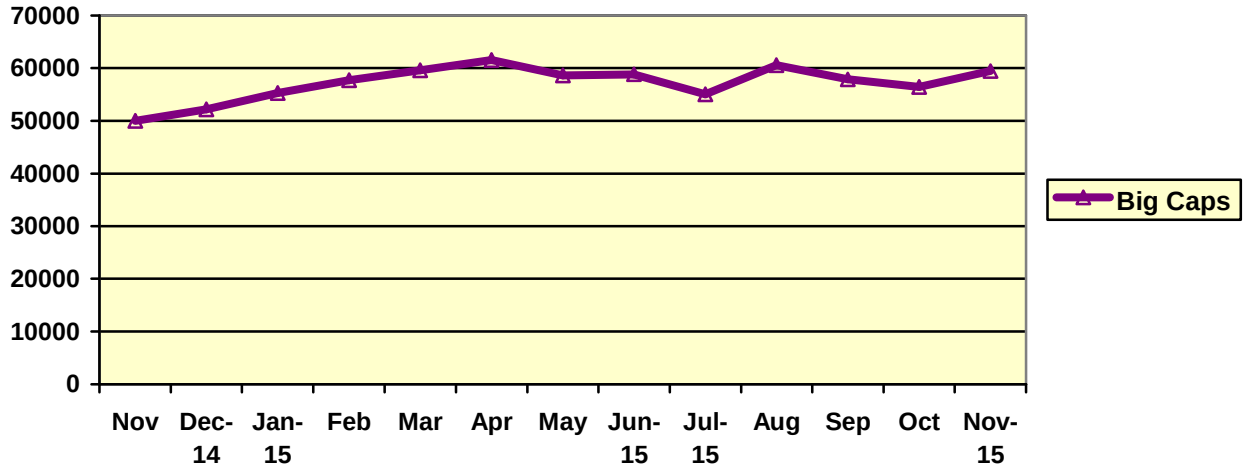
BDI-40 v ASX200 Jun 30, 2006 to Oct 31, 2015 – Adjusted



BDI-40 v ASX200 Oct 31, 2014 to Oct 31, 2015



Big Caps (Cochlear, CSL, Resmed) Oct 31, 2014 – Oct 31, 2015)



MESOBLAST

Mesoblast says it plans “to conduct a registered initial public offering” in the US.
Last week, Mesoblast requested a two-week voluntary suspension for a capital raising (BD: Oct 30, 2015).
Today, the company said it previously had submitted a draft registration statement to the Securities and Exchange Commission and it intended “to publicly file its registration statement with the SEC and commence the offering next week”.
Mesoblast last traded at $3.41.

ATCOR MEDICAL

Atcor says the US has set reimbursement for each Sphygmocor central blood pressure test at $US17.91 ($A25.07) and published a detailed code description.

In March, Atcor said the American Medical Association recommended the change from category III to category I (BD: Mar 10, 2015).

Today, Atcor said that for US reimbursement, the Centres for Medicare and Medicaid Services assigned a national average payment of $US17.91 for the test, in line with other reimbursed procedures requiring similar nursing and physician time and effort.

The company said that the American Medical Association-designated current procedural terminology (CPT) code supported Sphygmocor medical tests for “arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive”.

The company said that the reimbursement CPT category I code 93050 would take effect from January 1, 2016, replacing CPT category 3 code 0311T, providing “physicians and hospitals with a direct and simpler path to seek reimbursement for the Sphygmocor procedure”.

Atcor said that, as a national average, most major metropolitan markets would reimburse at a higher level and the reimbursed amount was in addition to the reimbursement the doctor or hospital received for a patient's visit.

The company said that Sphygmocor required no consumable expenditure and the reimbursed amount was a net contribution to the practice or hospital.

Atcor said that about 30 percent of US adults, or 70 million people, had hypertension and 30 million of these were covered under Medicare, the US government health plan for the retiree population.

The company said the annual US total economic cost of treating hypertension and related disorders such as stroke, heart failure and kidney disease was more than $US700 billion and these diseases were the largest contributor to US healthcare costs.

Atcor chief executive officer Duncan Ross said the procedure code and valuation “provide certainty for doctors that the Sphygmocor test can be reimbursed”.

“Confirmation of the valuation for the category I code covering the Sphygmocor test is a major milestone for Atcor and a crucial step that supports full commercialization of the Sphygmocor technology,” Mr Ross said.

Atcor fell eight cents or 26.7 percent to 22 cents with 3.2 million shares traded.

CORRECTION: CIRCADIAN

Friday’s edition incorrectly said that Circadian’s annual general meeting would include the renewal of the 10 percent placement capacity.

The November 30, 2015 meeting will vote on the change of name to Opthea, the re-election of chair Dominique Fisher and the adoption of the remuneration report.

The mistake was made by the Friday sub-editor who had read far too many Appendix 4C Quarterly Reports and mistakenly believed that all companies need to refresh their placement capacities.

Circadian made no mention of refreshing its 10 percent placement capacity.

Biotech Daily apologizes unreservedly for the mistake.

The sub-editor has taken up a new post correcting weights and ages for tomorrow’s three-minute horse race Victoria State public holiday’s form guide.

Circadian was untraded at 24.5 cents.

INVION

Invion says it has completed enrolment in its 66-patient, phase II trial of INV102 (nadolol) for mild asthma.

Invion said that US National Institutes of Health-funded nadolol in mild asthma (Nima) trial would administer the last dose by the end of April 2016, followed by reporting of safety and efficacy, which would be assessed by impact on non-specific airway hyper-responsiveness after six months therapy.

The company said that randomized, double-blind, placebo-controlled trial was designed to confirm improvements in on non-specific airway hyper-responsiveness previously reported by the Houston, Texas-based Baylor College of Medicine's Dr Nicola Hanania in two open-label trials of INV102.

Invion said that the trial at Baylor, the Durham, North Carolina-based Duke University and Washington University St Louis would analyze and report on biomarker and bronchoscopy samples, while Invion was responsible for management of drug supply, management and compliance with the investigational new drug application and regulatory communications.

Invion chief medical officer Dr Mitchell Glass said that completion of randomization was "a critical step in planning for study completion, statistical analysis and reporting".

"Nima has already provided important results concerning the safety of Invion's proprietary titration scheme and of six months of nadolol treatment even in mild asthma patients with baseline [on non-specific airway hyper-responsiveness] who are not on inhaled corticosteroids," Dr Glass said.

"While mild asthma is not ultimately a commercial target in Invion's development plan, the demonstration of safety in these vulnerable patients strongly supports our goal of reversing the contraindication of nadolol and thereby the introduction of nadolol to treat a wide range of airway diseases," Dr Glass said.

Dr Glass said that the company had initiated dialogue with the National Institutes of Health to follow the trial with a study in moderate to severe asthma patients.

Invion was up 0.1 cents or 9.1 percent to 1.2 cents.

SIRTEX MEDICAL

Hunter Hall Investment Management has reduced its substantial holding in Sirtex below the five percent substantial level.

Last week Hunter Hall reduced to 2,913,221 shares (5.10%) (BD: Oct 29, 2015).

Today, the company said it further reduced in Sirtex, selling 70,607 shares for $2,643,453 or $37.44 a share and it held 2,842,614 shares or 4.97 percent of Sirtex.

In March, following the failure of the Sirflox trial to meet its primary endpoint, the Sirtex share price fell as much as 55 percent and Hunter Hall bought 1,251,375 shares at $17.44 a share, the first time Hunter Hall had bought Sirtex shares since May 2013 when it reached an internal maximum and as the Sirtex price increases, Hunter Hall is required to sell down to remain under the limit (BD: Mar 17, 19, 2015).

Sirtex fell 20 cents or 0.5 percent to $37.85 with 325,514 shares traded.

OBJ

OBJ says its share plan raised $484,000 of the hoped for $1.75 million and the shortfall could be placed at its discretion.

In September, OBJ said it had raised $6.25 million in a placement at 5.7 cents a share (BD" Sep 24, 2015).

OBJ was unchanged at 5.6 cents with 1.7 million shares traded.

REGENEUS

Regeneus says that “one of the world’s top five animal health companies” has taken an option to partner the development and commercialization of Cryoshot Canine.
Regeneus said that Cryoshot was its off-the-shelf allogeneic stem cell therapy for dogs with osteoarthritis and other musculoskeletal conditions.
The company said that the unnamed US animal health company would jointly fund a pre-pivotal study assessing Cryoshot as a treatment for canine osteoarthritis for “an exclusive option to develop and commercialise Cryoshot Canine”.
Regeneus said University of Pennsylvania School of Veterinary Medicine’s Prof Dorothy Brown would be the principal investigator on the study, which began today, would assess pain and dysfunction in 80 arthritic, client-owned dogs.
The company said that dogs would be given a Cryoshot Canine intra-articular injection, or a control, and would be assessed by questionnaires and force-plate analysis.
Regeneus said that the results were expected by October 2016 and would be used to finalize the design of a pivotal US Food and Drug Administration trial with good manufacturing practice grade product.
The company said that on completion of the study, the unnamed animal health partner had “a period in which to exercise its option to enter into an exclusive licence over the Cryoshot technology”.
Regeneus said that it would receive an upfront licence fee and would be entitled to other development milestone payments and royalties, to be agreed at the time.
The company said that the unnamed partner would be responsible for funding the pivotal study and manufacture of Cryoshot and would have “exclusive global rights for sales and marketing for canine applications”.
Regeneus head of animal health Dr Duncan Thomson said the company wanted Cryoshot to be “one of the first allogeneic off-the-shelf stem cell therapies available for the treatment of canine osteoarthritis”.
Regeneus fell half a cent or 3.7 percent to 13 cents.

PHOSPHAGENICS

Allan Gray says it has increased its holding in Phosphagenics from 133,609,911 shares to 152,341,550 shares but has been diluted from 13.13 percent to 12.07 percent.
Allan Gray, previously known as Orbis Investment Management, bought and sold shares between March 21, 2012 and October 29, 2015 with the single largest purchase 2,923,356 shares for $232,245 or 7.9 cents a share.
Last year, Phosphagenics raised $16.3 million in a placement at eight cents a share and a further $3 million through a share plan (BD: Jul 11, Aug 5, 2014).
Phosphagenics was unchanged at 1.4 cents with 3.2 million shares traded.

AGENIX

Agenix director Craig Graeme Chapman has increased his holding from 24,911,464 shares to 28,083,877 but has been diluted from 18.35 percent to 17.85 percent.
The substantial shareholder notice said that the Kenmore, Queensland-based Mr Chapman held the shares as trustee for Nampac Discretionary Account and acquired 3,172,413 shares for $46,000 or 1.45 cents each “pursuant to resolutions approved at meeting of shareholders on October 27, 2014”.
The meeting agreed to pay Mr Chapman his directors fees in shares in lieu of cash.
Agenix fell 0.1 cents or 7.1 percent to 1.3 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION AT OCT 31, 2015

Company $Am	**Nov-14**	**Oct-15**	**Nov-15**
Cochlear	4,157	4,772	5,041
CSL	37,561	41,472	43,221
Resmed	8,236	10,213	11,177
BDI-20			
Acrux	181	95	125
Admedus	188	116	123
Benitec	66	64	65
Bionomics	225	199	233
Biotron	24	20	17
Circadian	9	29	37
Clinuvel	153	124	125
Impedimed	107	260	293
Medical Developments	75	190	190
Mesoblast	1,335	1,066	1,150
Nanosonics	256	374	454
Neuren	129	138	151
Osprey	70	106	43
Pharmaxis	16	73	75
Prima	49	115	115
Psivida	133	147	156
Reva	97	270	320
Sirtex	1,446	1,871	2,143
Universal Biosensors	30	61	73
Viralytics	57	109	104
Second 20			
Actinogen	11	36	36
Anteo	112	81	79
Antisense	17	15	14
Atcor	15	47	59
Avita	32	35	56
Cellmid	19	27	29
Compumedics	18	46	56
Ellex	30	43	57
Genetic Technologies	13	29	29
IDT	17	69	75
Living Cell	26	16	22
Oncosil	37	52	59
Optiscan	6	11	9
Orthocell	19	37	34
Polynovo	38	56	59
Prana	103	69	59
Pro Medicus	88	241	329
Starpharma	198	251	216
Tissue Therapies	83	13	14
Uscom	20	13	17

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

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