Biotech Daily

Wednesday October 1, 2014

Daily news on ASX-listed biotechnology companies

*** SEPTEMBER BDI-40 DOWN 4%, ASX200 DOWN 6%, BIG CAPS DOWN 0.75%**
- LIVING CELL UP 32%, CLINUVEL UP 31%, BIOTRON DOWN 26%

*** TODAY: ASX UP, BIOTECH DOWN:**
- TISSUE THERAPIES UP 8%, PATRYS DOWN 10%

*** EUROPEAN GUIDELINES RECOMMEND SIRTEX SIR-SPHERES**

*** WEHI: 'JAK INHIBITORS CAN TREAT 80% OF BOWEL CANCERS'**

*** MESOBLAST PARTNER JCR FILES FOR JR-031 GVHD JAPAN APPROVAL**

*** NOVOGEN TAKES FDA ADVICE ON CANTRIXIL FOR OVARIAN CANCER**

*** GENETIC TECHNOLOGIES LAUNCHES BREVAGENPLUS IN THE US**

*** ALLAN GRAY TAKES 16% OF STARPHARMA**

*** ANALYTICA TAKES CAPITAL RAISING TRADING HALT TO SUSPENSION**

MARKET REPORT

The Australian stock market was up 0.78 percent on Wednesday October 1, 2014 with the S&P ASX 200 up 41.3 points to 5,334.1 points. Ten of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and six were untraded.

Tissue Therapies was the best, up 2.5 cents or 8.3 percent to 32.5 cents with 204,097 shares traded.

Impedimed and Neuren climbed more than seven percent; Acrux was up 4.9 percent; Nanosonics, Optiscan and Prana rose more than two percent; Sirtex and Starpharma were up more than one percent; with CSL, Medical Developments and Resmed up by less than one percent.

Patrys led the falls, down 0.2 cents or 9.5 percent to 1.9 cents with 974,242 shares traded.

Viralytics lost 6.25 percent; Antisense, Genetic Technologies and Oncosil all fell 4.35 percent; Admedus, Anteo, Pharmaxis and Phosphagenics lost more than three percent; Biotron, Clinuvel and Psivida shed two percent or more; Alchemia and Living Cell fell more than one percent; with Bionomics, Cochlear and Mesoblast down less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The September Biotech Daily Top-40 Index (BDI-40) wilted 4.4 percent from its August 11.1 percent gains, with the S&P ASX200 down a further 5.9 percent.

A plethora of small falls and a couple of major haemorrhages were somewhat offset by several minor improvements. The deepest falls in market capitalization were Mesoblast losing $218 million and Acrux down $73 million, with Sirtex adding $33 million to the total.

Just 12 of the BDI-40 companies were up, with 25 down and three unchanged.

Living Cell was September's best by percentage, up $6 million or 31.6 percent to $25 million, followed by Clinuvel up 30.8 percent to $140 million, Impedimed (26.2%), Viralytics (18.0%), Compumedics (11.1%), Analytica (10.3%), Nanosonics (8.3%), Alchemia (7.5%), Prana (6.5%) and Sirtex (2.7%).

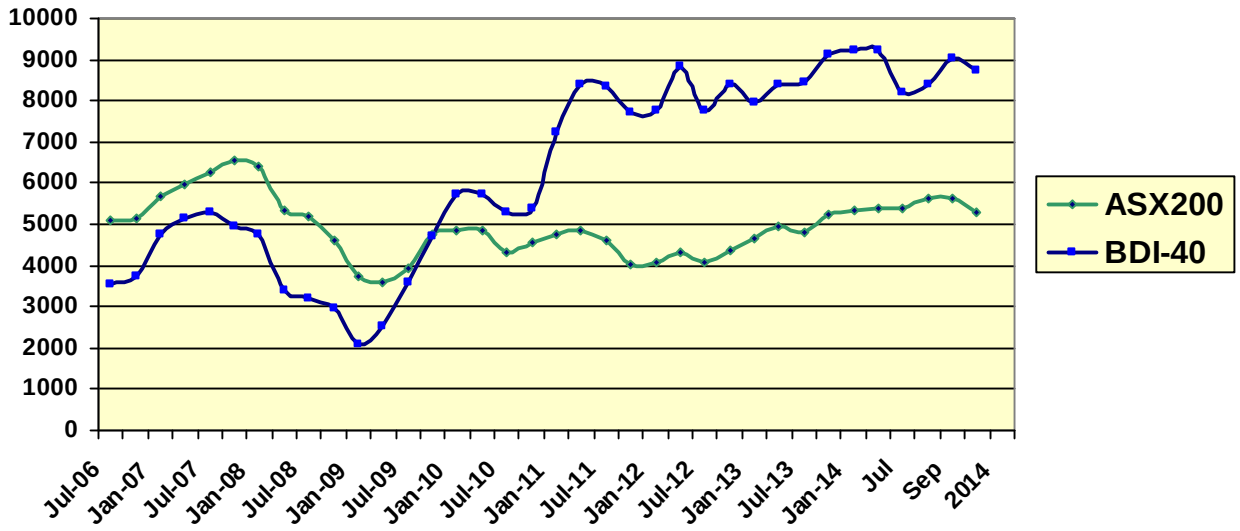
Biotron had the deepest fall, down 25.8 percent to $23 million, followed by Antisense and IDT, both down 22.7 percent to $17 million; Acrux (22.2%), Neuren (20.4%), Universal Biosensors (18.75%), Uscom (18.2%), Tissue Therapies (17.7%), Genetic Technologies (16.7%), Mesoblast (13.6%) and Patrys (11.8%).

The three Big Caps (which are not included in the BDI-40) fell a cumulative 0.75 percent in September, with Resmed up 0.2 percent to $7,969 million, while Cochlear fell 3.7 percent and CSL slipped 0.6 percent. For the year to September 30, 2014, the Big Caps climbed 10.5 percent, the BDI-40 fell 5.9 percent and the ASX200 was up 1.4 percent.

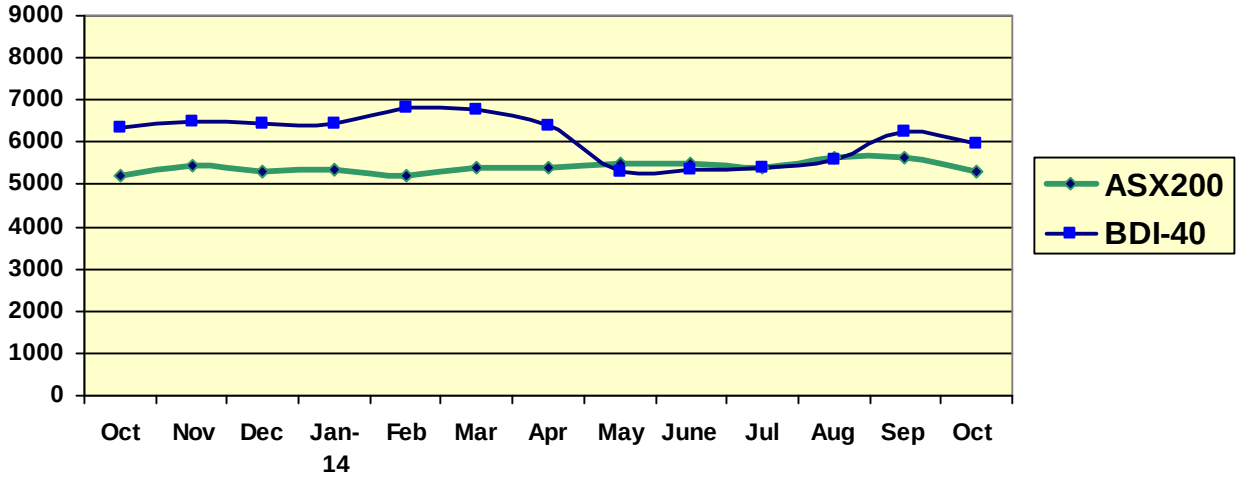
Outside the BDI-40, Isonea fell 51.0 percent in September to $24 million, 87.6 percent below its peak of $194 million at September 30, 2013. Reva climbed 66.7 percent to $90 million on a $50 million capital raising, but remained 54.8 percent down for the year.

On the Nasdaq, Biota was up 15.1 percent, Heartware climbed 2.2 percent, Sunshine Heart was up 7.9 percent, while the Canadian Bioniche jumped 30 percent to $39 million.

BDI-40 v ASX200 Jun 30, 2006 to Sep 30, 2014 - Adjusted



BDI-40 v ASX200 Sep 30, 2013 to Sep 30, 2014



SIRTEX MEDICAL

Sirtex says that the European Society of Medical Oncology has included its SIR-Spheres yttrium-90 microspheres in clinical guidelines for metastatic colorectal cancer.

The clinical practice guidelines were published in an article entitled 'Metastatic colorectal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up' in the journal Annals of Oncology.

The article is at http://annonc.oxfordjournals.org/content/25/suppl_3/iii1.full.pdf+html.

"In patients with liver-limited metastases failing the available chemotherapeutic options, radio-embolisation with yttrium-90 resin microspheres can also prolong the time to tumor progression," the journal article said.

Sirtex said that the guidelines endorsed SIR-Spheres as a proven technology to "prolong time to liver tumor progression" in metastatic colorectal cancer patients who had failed to respond to available chemotherapy options.

The company said its SIR-Spheres were the only product used for radio-embolisation or selective internal radiation therapy recommended in the guidelines.

Sirtex Medical Europe GmbH chief executive officer Nigel Lange said the company was "very pleased that the authors of major international clinical guidelines in the treatment of [metastatic colorectal cancer] have singled out radio-embolisation, and particularly our unique product, SIR-Spheres Y-90 resin microspheres, as an appropriate treatment for patients with colorectal liver metastases that have failed to respond to chemotherapy".

"We believe the new ... clinical guidelines will have an immediate effect on improving patient access to SIR-Spheres [yttrium-90] resin microspheres across Europe," Mr Lange said.

Sirtex said that as clinical evidence for the European Society of Medical Oncology recommendation, the authors cited a multi-centre, randomized controlled study conducted by Prof Alain Hendlisz and colleagues entitled 'Phase III trial comparing intravenous fluorouracil infusion with yttrium-90 resin microspheres for liver-limited metastatic colorectal cancer refractory to standard chemotherapy'.

The company said that it completed recruitment of patients for its 500-patient, randomized, Sirflox study comparing SIR-Spheres in combination with standard chemotherapy to standard chemotherapy alone in patients diagnosed with inoperable metastatic colorectal cancer, with data expected in 2015 (BD: Feb 25, 2014).

Sirtex climbed 33 cents or 1.5 percent to $22.30 with 258,152 shares traded.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

the Walter and Eliza Hall Institute says its scientists have shown that more than 80 percent of bowel cancers could be treated with existing drugs.

WEHI said that the study found that Janus kinase, or Jak, inhibitors halted tumor growth in bowel cancers with a genetic mutation that was present in more than 80 percent of bowel cancers.

The Institute said that multiple Jak inhibitors were currently used, or were in clinical trials, for diseases including rheumatoid arthritis, psoriasis, blood cancers and myelo-proliferative disorders.

WEHI said that bowel cancer was the second-most common cancer in Australia with nearly 17,000 people diagnosed every year, accounting for about 10 percent of cancer-related deaths.

The Institute said that Prof Matthias Ernst, Dr Toby Phesse, Dr Michael Buchert and colleagues, in collaboration with Australian and international researchers, began the study while at the Parkville branch of the Ludwig Institute for Cancer Research and continued at the Institute.

The study, entitled 'Partial inhibition of gp130-Jak-Stat3 signaling prevents Wnt–Beta-catenin–mediated intestinal tumor growth and regeneration' was published in Science Signaling, with an abstract at: http://stke.sciencemag.org/content/7/345/ra92.abstract.

Dr Phesse said more than 80 percent of bowel cancers were driven by a defect in the Wnt (Wingless-related integration) signaling pathway.

"This genetic defect triggers a high level of signaling in the pathway, leading to uncontrolled cell growth and therefore cancer," Dr Phesse said.

"Targeting Wnt signaling directly as a treatment for bowel cancer presents several challenges as normal cells in the intestine rely on low levels of Wnt signaling to renew and keep the gut healthy," Dr Phesse said.

"Blocking Wnt might prevent tumor growth but it could also cause significant damage to the intestines," Dr Phesse said.

WEHI said that tumor cell growth could be stimulated by another signaling pathway, involving Janus kinase proteins.

The Institute said that the research team examined whether targeting this parallel pathway could limit tumor growth without affecting the normal cells of the intestine.

"Our research showed that blocking Jak proteins could inhibit tumor growth in preclinical models of bowel cancer and human bowel cancer cells that have high levels of Wnt signaling," Dr Phesse said.

"Importantly, we didn't see any side effects in our preclinical models as Wnt signaling could still function in the normal cells of the intestine, as JAK inhibitors only block cell growth in cells with very high Wnt signaling, such as those found in the tumors," Dr Phesse said.

"This makes it a very attractive therapy for bowel cancer," Dr Phesse said.

Dr Buchert said the results were significant, as several Jak inhibitors had been approved for clinical use for other diseases.

"Clinical trials have already shown that Jak inhibitors are safe for human use," Dr Buchert said. "We hope that this will enable our research to rapidly reach clinical trials for bowel cancer patients and deliver benefits in the near future."

In 2010, Cytopia and its Jak inhibitor CYT387 were acquired by YM Biosciences, which in turn was bought by Gilead in 2012, taking the drug, renamed momelotinib, to an on-going phase III trial for myelofibrosis (BD: Feb 1, 2010; Dec 13, 2012).

MESOBLAST

Mesoblast says that Japanese partner JCR Pharmaceuticals has filed an application for JR-031 for the treatment of acute graft versus host disease.

Mesoblast said that filing of the mesenchymal stem cell product for approval for manufacturing, marketing, and product registration with the Japanese Pharmaceuticals and Medical Devices Agency for acute graft versus host disease in children and adults would be subject to a priority review as JR-031 had orphan drug status.

The company said that if the application was successful, JR-031 would be the first allogeneic cell-based product approved in Japan.

Mesoblast said it was entitled to milestone payments on JR-031 product regulatory filings, approvals, royalties and other payments at pre-defined thresholds of cumulative net sales.

The company said it had global rights to develop JR-031 for all clinical indications, other than for haematologic malignancies in Japan, and JCR had a right of first negotiation to commercialize other mesenchymal stem cell-based orphan designations in Japan.

Mesoblast chief executive Prof Silviu Itescu said the application was an “important milestone”.

“We look forward to a positive outcome which will provide a treatment for children and adults with acute graft versus host disease, a life-threatening condition,” Prof Itescu said.

Mesoblast said it planned a product registration filing with the US Food and Drug Administration for its allogeneic mesenchymal stem cells product in children with steroid-refractory acute graft versus host disease in 2016 and was on track to launch its allogeneic mesenchymal stem cells product in Canada and New Zealand in 2016 in children with graft versus host disease.

Mesoblast fell four cents or 0.9 percent to $4.28 with 346,249 shares traded.

NOVOGEN

Novogen says the US Food and Drug Administration has provided guidance on the process to take Cantrixil to US clinical trials for late-stage ovarian cancer.

Novogen said that the guidance related to the drug manufacturing scale-up process, the pre-clinical animal testing program and the general design of the phase I study for an investigational new drug (IND) application for a first-in-man study in the US.

Novogen executive chairman Dr Graham Kelly said that the company was “familiar with the IND application process and this guidance would not normally be of any great significance, except for the fact that Cantrixil is a first-in-class product, being developed as an intra-cavity anti-cancer product” designed to be delivered directly into cavities such as the peritoneal cavity, or abdomen, and the pleural cavity, or thorax.

“That first-in-class status had the potential to have raised issues by the regulator,” Dr Kelly said. “Fortunately, no such issues were flagged.”

Novogen said the phase I trial would be conducted in women with late stage ovarian cancer, with Cantrixil injected directly into the peritoneal cavity.

The company said that the rationale was that by injecting Cantrixil directly into the peritoneal cavity, the cancer stem cells and their daughter cells were exposed to much higher levels of the drug candidate than would be achieved by intravenous injection.

“While this particular IND process is directed at the use of Cantrixil to treat late-stage ovarian cancer, the product has been designed to treat any form of disseminated cancer within the abdomen,” Dr Kelly said. “This condition is known as peritoneal carcinomatosis and is a late-stage condition associated mostly with cancers that arise in the abdominal cavity, such as colorectal cancer, ovarian cancer and primary peritoneal cancer.”

Novogen was up half a cent or 3.7 percent to 14 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has launched its Brevagenplus in the US, expanding the breast cancer diagnostic to African-American and Hispanic women.

Genetic Technologies said that the test for women at risk of developing sporadic, or non-hereditary, breast cancer was an enhancement of the first generation Brevagen.

The company said that the Brevagenplus assessed clinical risk factors and genetic markers known to be associated with sporadic, or non-hereditary, breast cancer to determine a woman's five-year and lifetime risk of developing the disease.

Genetic Technologies scientific director Dr Richard Allman said that in 2007, “the identification of a number of single nucleotide polymorphisms, each with a small relative risk, led to the development of the first commercially available genetic risk test for sporadic breast cancer, Brevagen, which was launched in 2011”.

“The intervening three years have seen rapid progress in both technology and the rate of genetic discoveries, such that the number of [single nucleotide polymorphisms] which have now been associated with breast cancer has increased 10-fold,” Dr Allman said.

“Brevagenplus incorporates these latest discoveries to provide an improved polygenic risk test,” Dr Allman said.

Genetic Technologies said that the results from Brevagenplus provided physicians with information to assist in developing a patient-specific breast cancer risk reduction and screening plan based on professional medical society guidelines, such as the American Cancer Society and the National Comprehensive Cancer Network.

The company said that the test used a non-invasive cheek swab and combined information from the patient's genetic markers known to be associated with sporadic breast cancer, with a risk score which included factors such as age, age at menarche, age at live first birth, race and ethnicity to calculate risk of developing sporadic breast cancer.

Genetic Technologies said the test provided five-year and lifetime predictive risk assessments to more accurately determine the patient’s risk of developing breast cancer.

The company said that US subsidiary Phenogen Sciences would market Brevagenplus to healthcare providers in women's health.

Genetic Technologies said chief executive officer Alison Mew said the company was “proud to be able to bring a better understanding of individual breast cancer risk to many more women ... [which was] another important step in executing our strategy to become a dedicated molecular diagnostics company”.

Genetic Technologies fell 0.1 cents or 4.35 percent to 2.2 cents.

STARPHARMA

Allan Gray Australia has increased its holding in Starpharma from 41,319,032 shares (14.50%) to 49,848,435 shares (15.91%).

Allan Gray said that it bought the 8,529,403 shares between May 30 and September 22, 2014 for $5,392,383 or an average price of 63.2 cents a share with the majority acquired in last week’s placement at 65 cents a share (BD: Sep 22, 2014).

Starpharma was up one cent or 1.5 percent to 66 cents.

ANALYTICA

Analytica has requested a voluntary suspension to follow the trading halt requested on September 29, pending “an announcement to the market in relation to the capital raising” (BD: Sep 29, 2014).

Analytica last traded at 3.9 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company $Am	**Oct-13**	**Sep-14**	**Oct-14**
Cochlear	3,450	4,118	3,966
CSL	31,179	35,414	35,197
Resmed	8,026	7,955	7,969
BDI-20			
Acrux	550	329	256
Alchemia	198	201	216
Admedus	93	223	216
Benitec	31	119	116
Bionomics	338	269	261
Biotron	19	31	23
Clinuvel	61	107	140
GI Dynamics	328	227	228
Impedimed	33	84	106
Mesoblast	1,809	1,608	1,390
Nanosonics	216	242	262
Neuren	119	157	125
Osprey	73	70	71
Pharmaxis	40	17	16
Prima	48	48	47
Psivida	116	147	147
Sirtex	764	1,209	1,242
Tissue Therapies	65	96	79
Universal Biosensors	127	32	26
Viralytics	33	50	59
Second 20			
Analytica	10	29	32
Anteo	47	125	121
Antisense	20	22	17
Atcor	29	15	14
Avita	39	34	33
Cellmid	18	22	21
Circadian	14	9	9
Compumedics	14	18	20
Ellex	26	38	36
Genetic Technologies	41	18	15
IDT	19	22	17
Living Cell	31	19	25
Medical Developments	76	66	61
Oncosil	39	43	41
Optiscan	10	7	7
Patrys	15	17	15
Phosphagenics	86	124	112
Prana	181	108	115
Starpharma	292	210	204
Uscom	14	22	18

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Admedus, Benitec, Biota, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Alchemia, Atcor, Avita, Circadian, Cochlear, Ellex, IDT, Impedimed, Innate Immunotherapeutics, Pharmaxis, Prana, Resmed and Sirtex. These holdings are liable to change.

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