Biotech Daily

Tuesday October 1, 2013

Daily news on ASX-listed biotechnology companies

*** SEPTEMBER BDI-40 UP 3.9%, ASX200 UP 1.6%; BIG CAPS DOWN 3.7%**
- ATCOR UP 71%; PRIMA DOWN 55%

*** TODAY - ASX DOWN, BIOTECH UP: VIRALYTICS UP 7%, PHARMAXIS DOWN 8%**

*** NEUREN NNZ-2591 FRAGILE X EFFICACY IN MICE**

*** UK NICE BACKS PSIVIDA ILUVIEN FOR POST-SURGERY DME**

*** TIANJIN FAILS TO FUND ANTISENSE ATL1102, AGREEMENT ENDS**

*** PHARMAUST SHORTFALL RAISES $815K**

*** GENETIC TECHNOLOGIES BREVAGEN TESTS UP 52%**

*** GERMAN, SWISS CODES FOR GI DYNAMICS ENDOBARRIER**

*** SIRTEX 12c FINAL DIVIDEND**

*** TISIA, TOM HENDERSON DILUTED BELOW 5% IN ONCOSIL**

MARKET REPORT

The Australian stock market fell 0.23 percent on Tuesday October 1, 2013 with the S&P ASX 200 down 12.1 points to 5,206.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and four were untraded.

Viralytics was the best, up 2.5 cents or 6.7 percent to 40 cents, with 75,000 shares traded.

Genetic Technologies and Prima were up more than five percent; Living Cell, Neuren and Phosphagenics were up more than four percent; Anteo, Circadian and Nanosonics were up more than three percent; Benitec, Osprey and Prana rose more than one percent; with Alchemia, Clinuvel, CSL and Psivida up by less than one percent.

Pharmaxis led the falls, down one cent or 7.7 percent to 12 cents with 4.3 million shares traded.

Bionomics lost 6.7 percent; Allied Health and Sirtex fell more than five percent; QRX and Reva fell more than four percent; Patrys was down 3.45 percent; both IDT and Impedimed shed 2.8 percent; Acrux, Cochlear, Mesoblast and Starpharma lost more than one percent; with Resmed and Universal Biosensors down less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top-40 Index (BDI-40) climbed 3.9 percent in September compared to the S&P ASX200 up 1.6 percent.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell a collective 3.7 percent in the month, primarily due to CSL retreating 4.5 percent to $31,179 million, with Resmed also falling 4.5 percent to $8,026 million and Cochlear up 6.6 percent to $3,450 million.

For the 12 months to September 30, including the now departed Heartware, the raw data shows an 11.1 percent fall in the BDI-40, but removing the $1.3 billion Heartware gives a BDI-40 up 7.7 percent for the year, compared to the ASX200 up 19.0 percent for the year and the Big Caps up 28.9 percent.

The five year data (see graphs below) shows the ASX200 up just 13.4 percent compared to the BDI-40 up 113.3 percent - not adjusted for the departure of Heartware, Biota and Sunshine Heart, nor the acquisitions of Arana ($329 million), Cellestis ($365 million), Chemgenex ($225 million) and Peplin ($348 million).

The mathematical exercise of including the value of the three departed companies and the sale price of the four acquisitions shows the adjusted BDI-40 would be up 210.8 percent over five years.

Atcor was September's best, up 70.6 percent to $29 million for the month and 222.2 percent for the year, following its maiden profit, Mexican approval and backing of its Sphygmocor system by the Menzies Research Institute.

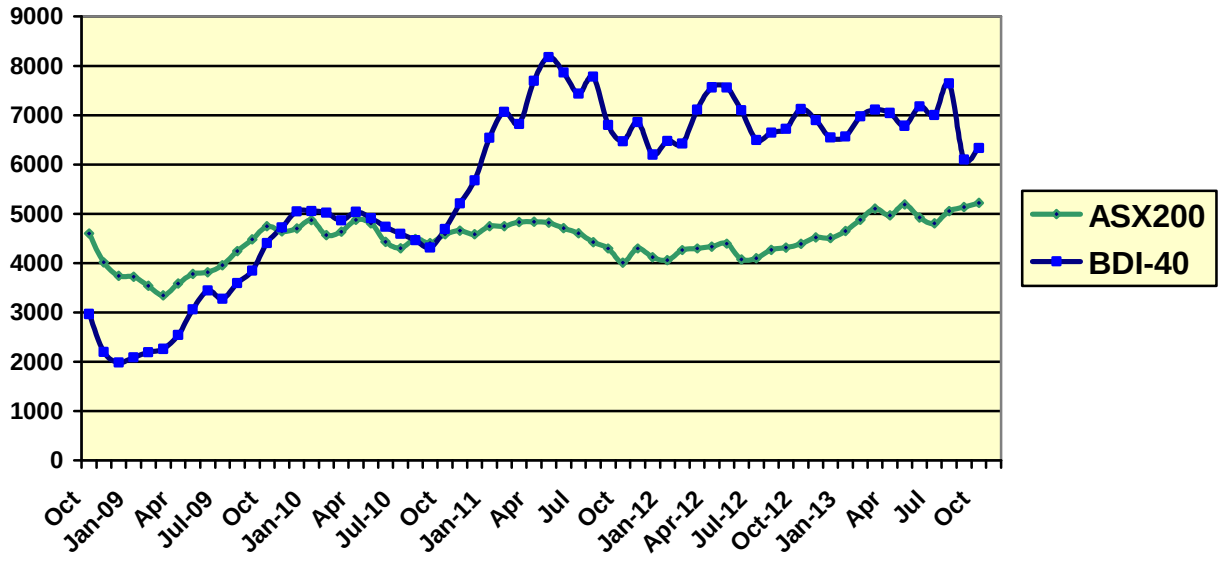
Living Cell was up 63.2 percent to $31 million with its first NTCell implant, followed by Alchemia (45.6%), Bionomics (32.5%), Benitec (29.2%), Impedimed (17.9%) and GI Dynamics (12.3%).

Prima led the falls, down 55.1 percent to $48 million on non-significant phase II CVac efficacy data, followed by Patrys (16.7%), Phosphagenics (13.1%), Medical Developments (11.6%), Tissue Therapies (11.0%) and Prana (10.8%).

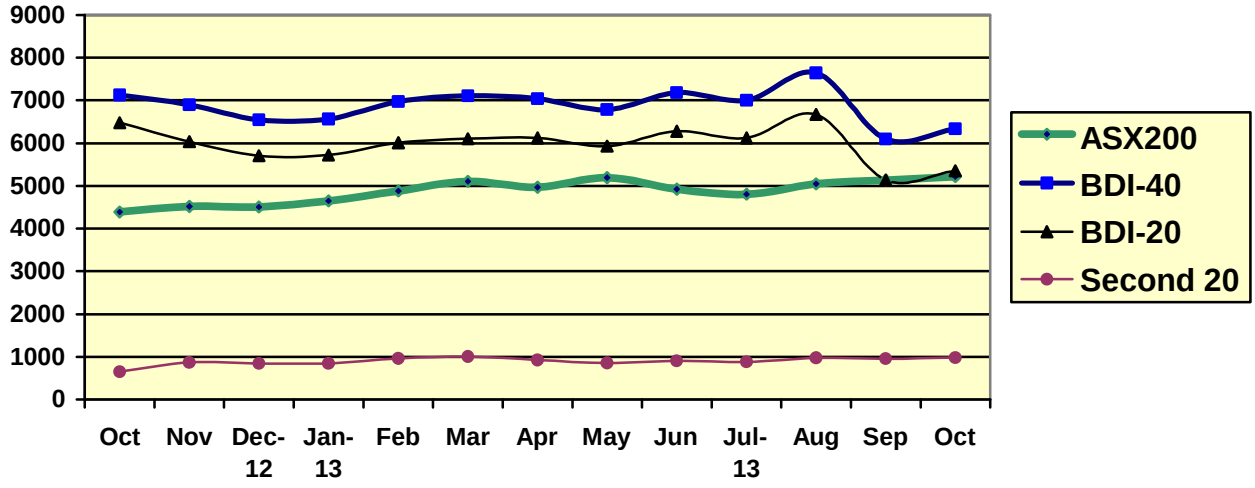
Outside the BDI-40, two companies associated with gambling machine magnate Bruce Mathieson continued their stellar rise, with Mayne Pharma up 18.2 percent to $363 million and Isonea up 14.8 percent to $194 million, or 560 percent and 2,325 percent, respectively, for the year to September 30, 2013.

On the Nasdaq, Biota fell 7.3 percent to $127 million, Heartware lost 11.4 percent to $1,291 million and Sunshine Heart was up 35.9 percent to $208 million.

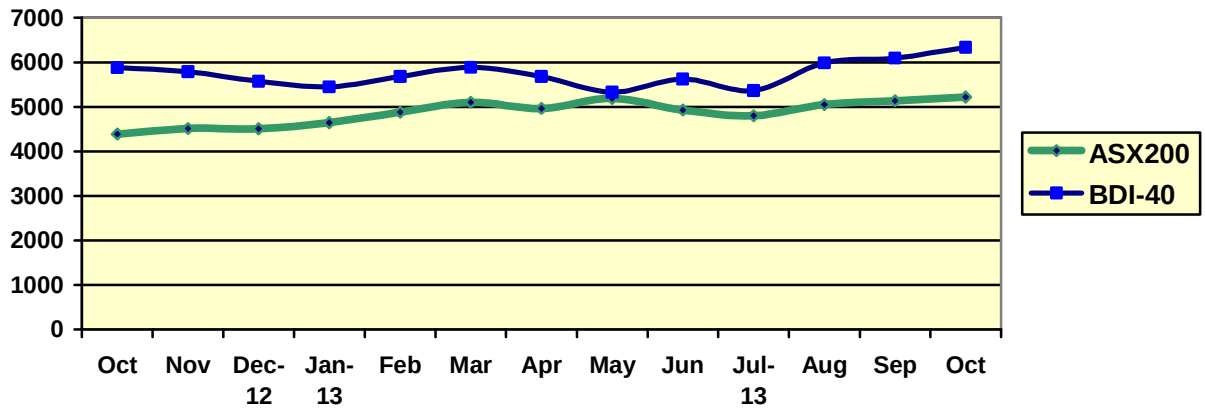
BDI-40 v ASX200 Sep 30, 2008 to Sep 30, 2013 (Five Year Data)



BDI-40 ($m) v S&P ASX 200 – Sep 30, 2012- Sep 30, 2013



BDI-40 ($m) v S&P ASX 200 – Sep 30, 2012- Sep 30, 2013 (Adjusted for Heartware)



NEUREN PHARMACEUTICALS

Neuren says that a mouse model study of NNZ-2591 shows it may have efficacy for Fragile X syndrome

Neuren said that a poster on NNZ-2591 and a presentation on NNZ-2566 were being presented at the Fragile X Research Foundation Investigators Meeting in Southbridge, Massachusetts on September 30 and 1 October 2013.

Neuren said that NNZ-2566 and NNZ-2591 were each shown to reverse the differences between normal or wild-type mice and 'fmr1 knockout mice', normalizing known Fragile X behavioral, anatomic and biochemical characteristics.

The company said that the studies were conducted by the Fragile X Research Foundation Drug Validation Initiative led by Dr Patricia Cogram.

The poster, entitled 'The Impact of NNZ-2591 on the fmr1 Knockout Mouse Model of Fragile X Syndrome' was co-written by Neuren chief science officer Larry Glass and concluded that NNZ-2591 treatment for 28 days "appears to normalize the phenotype of fmr1 KO mice".

"The efficacy of the drug was observed not only in behavioral studies but also in studies of dendrite morphology and ERK/Akt activation," the poster concluded.

"Taken together, these data suggest that the novel small molecule, NNZ-2591, may represent a potentially important treatment for Fragile X syndrome," the poster concluded.

"As we move toward initiation of the phase II clinical trial of NNZ-2566 in Fragile X syndrome later this year, the expanding scientific foundation continues to reinforce our confidence in the strategy," Mr Glass said.

"The positive results with NNZ-2591, also an analogue of a naturally occurring growth factor, are encouraging as well, providing further options for therapy development," Mr Glass said.

Neuren was up 0.4 cents or 4.2 percent to 9.9 cents.

PSIVIDA CORP

Psivida says the UK National Institute for Health and Care Excellence has recommended Iluvien for chronic diabetic macular oedema (DME) post-cataract surgery.

Psivida said the Institute had issued "final draft guidance recommending Iluvien as an option for the treatment of chronic diabetic macular edema that is insufficiently responsive to available therapies in pseudophakic eyes, those that have already undergone cataract surgery".

The company said the recommendation reversed the final draft guidance previously issued by the Institute for this subgroup of chronic diabetic macular oedema patients.

Psivida said that the Institute's final guidance recommending Iluvien to the National Health Service was expected to be published in November 2013, which would result in NHS reimbursement in England and Wales under the patient access scheme submitted by licencee Alimera Sciences.

Psivida chief executive officer Dr Paul Ashton said the company expected Iluvien would be available to treat a significant subgroup of chronic diabetic macular oedema patients.

"We are encouraged that Alimera plans to continue to work with NICE in an effort to broaden access to Iluvien to include all chronic DME patients who could benefit from the treatment," Dr Ashton said.

Psivida said that Iluvien was a sustained release intravitreal micro-insert, with marketing authorization in the UK, Austria, Portugal, Germany, France and Spain, and pending in Italy and it was commercially available in the UK and Germany.

Psivida was up three cents or 0.7 percent to $4.35.

ANTISENSE THERAPEUTICS

Antisense says that Tianjin International Joint Academy of Biotechnology and Medicine has failed to meet its ATL1102 joint venture obligations and the agreement has lapsed.
Last year, Antisense said it would proceed with its joint venture with Tianjin International Joint Academy of Biotechnology and Medicine to develop ATL1102 initially for multiple sclerosis as well as stem cell mobilization and asthma (BD: Feb 29, Jul 18, 2012).
The company said the Academy had advised it only had funding for a primate study in the stem cell mobilization application of ATL1102, was keen to continue the collaboration on that basis, but was unable to meet the conditions for the joint venture.
Antisense said that no further extension would be offered to the Academy and it would have full control of the development and commercialization of ATL1102 in all applications.
The company said that it was running a primate chronic toxicology study of ATL1102 with results due by April 2014 to support a potential phase IIb trial in multiple sclerosis patients.
Antisense said it was keen to progress the clinical development of ATL1102 for stem cell mobilization and existing supplies of ATL1102 drug product had been assessed as being of suitable quality and sufficient quantity for use in a human proof-of-concept study.
Antisense said expected to submit a clinical trial application for a human study before the end of this year and have the study completed with results by the middle of 2014.
Antisense said it estimated the cost of the study to be about $400,000 to be covered by an expected Federal Government 45 percent research and development tax credit and the money to be raised from the loyalty option issue (BD: Sep 27, 2013).
Antisense managing director Mark Diamond said the company was “very pleased to be able to move directly into a human study to confirm the potential of ATL1102 in the [stem cell mobilization] application and we are excited about having results potentially as soon as the middle of next year”.
“The development of the drug for the [stem cell mobilization] application will be a relatively inexpensive and quick development program, given it is an acute treatment of one week administration,” Mr Diamond said. “As we believe we have sufficient safety experience on the drug to support the program all the way through to registration studies, associated development costs are expected to be much lower.”
Antisense was unchanged at 1.4 cents with 2.7 million shares traded.

PHARMAUST

Pharmaust says Peloton Capital has placed the 81,500,000 one cent shortfall shares and attaching options raising a further $815,000.
The company raised $2.5 million in a placement and $185,000 in the share plan for the Pitney Pharmaceuticals acquisition (BD: Aug 12, 21; Sep 16, 2013).
Pharmaust was unchanged at 1.1 cents with 4.1 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it received 914 Brevagen breast cancer test samples in the three months to September 30, 2013, 52 percent more than the previous three months.
Genetic Technologies said that the rises over 15 months had been achieved “with only a modest increase in the number of sales representatives” and the increase was a result of a focus on key geographic regions, breast centres and medical practitioners.
In 2012, then chief executive officer Dr Paul MacLeman said the test price was $US945 and the company received an undisclosed percentage of that fee (BD: May 22, 2012).
Genetic Technologies was up 0.4 cents or 5.1 percent to 8.3 cents.

GI DYNAMICS

GI DYNAMICS says the German and Swiss authorities have provided tracking codes as steps towards reimbursement of its Endobarrier for obesity and type 2 diabetes.
GI Dynamics said that the German Institute of Medical Documentation and Information designated preliminary Operationen and Prozedurenschlussel codes for the Endobarrier duodenal liner and the Swiss Federal Office for Statistics had published a unique Schweizerische Operationsklassifikation code for the implantation of the Endobarrier.
The company said that the designation and implementation of thee codes allowed authorities to track costs and align reimbursement codes for the Endobarrier therapy.
GI Dynamics said that once data on a sufficient number of Endobarrier procedures had been accumulated, it would be evaluated and the company expected the codes would be mapped to procedure codes and costs.
GI Dynamics chief executive officer Stuart Randle said the designations were “the next, vital step to achieving appropriate reimbursement at the national level”.
“Endobarrier Therapy continues to gain interest and traction among physicians, patients, health insurers and government agencies, as demonstrated by this recent action by the German and Swiss health authorities,” Mr Randle said.
GI Dynamics was unchanged at 82 cents.

SIRTEX MEDICAL

Sirtex says it will pay a final fully franked dividend of 12 cents a share for holders on the record date of October 11, 2013 with payment on October 25, 2013.
Sirtex chief executive officer Gilman Wong said the dividend was a 20 percent increase on the previous year’s dividend and demonstrated “the board’s confidence in the strength of the business”.
“At the same time as paying a higher dividend, Sirtex continues to re-invest heavily back into the business in order to realize our 2020Vision strategy,” Mr Wong said.
“Our flagship Sirflox clinical study is fully recruited and is now in the data maturation stage,” Mr Wong said.
“We expect that initial results should be available in 12 months’ time, with detailed results to be presented at a major North American scientific conference in January 2015,” Mr Wong said.
“Positive results from this study would be expected to result in significantly increased demand for our SIR-Spheres microspheres,” Mr Wong said.
“Our re-investment back into the business is to ensure that Sirtex is in an optimal position to be able to take advantage of this increased demand and deliver sustainable long-term growth,” Mr Wong said.
“In the period preceding the release of the results of our Sirflox study Sirtex will continue to grow, although as in the past there will be some fluctuation in the percentage growth rate of dose sales quarter on quarter,” Mr Wong said.
Sirtex fell 79 cents or 5.8 percent to $12.82 with 487,338 shares traded.

ONCOSIL MEDICAL

The Perth, Western Australia-based Tisia Nominees says its 15,000,000 share holding has been diluted from 6.46 percent to 4.96 percent.
Tisia Nominees director Tom Henderson said the dilution was caused by the recent $7.8 million placement at 13 cents a share (BD: Sep 13, 2013).
Oncosil was unchanged at 13 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company $Am	**Oct-12**	**Sep-13**	**Oct-13**
Cochlear	3,846	3,237	3,450
CSL	23,243	32,645	31,179
Resmed	5,992	8,404	8,026
BDI-20			
Acrux	533	553	550
Alchemia	147	136	198
Allied Health	19	91	93
Benitec	14	24	31
Bionomics	140	255	338
Clinuvel	54	67	61
Impedimed	28	28	33
Mesoblast	1,934	1,725	1,809
Nanosonics	128	232	216
Neuren	32	117	119
Osprey	33	67	73
Pharmaxis	339	40	40
Prana	64	203	181
Prima	197	107	48
Psivida	37	107	116
Reva	222	197	199
Sirtex	530	720	764
Starpharma	422	278	292
Tissue Therapies	68	73	65
Universal Biosensors	142	119	127
Second 20			
Anteo	44	45	47
Antisense	29	20	20
Atcor	9	17	29
Avita	34	41	39
Cellmid	9	20	18
Circadian	19	13	14
Compumedics	11	15	14
Ellex	14	26	26
Genetic Technologies	51	43	41
GI Dynamics	182	292	328
IDT	10	19	19
Living Cell	19	19	31
Medical Dev	67	86	76
Optiscan	15	10	10
Patrys	17	18	15
Phosphagenics	128	99	86
Phylogica	13	7	8
QRX Pharma	95	122	113
Uscom	10	12	14
Viralytics	20	32	33

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

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