Biotech Daily

Monday December 3, 2012

Daily news on ASX-listed biotechnology companies

*** NOVEMBER BDI-40 DOWN 5%, ASX200 FLAT, BIG CAPS UP 7%**
- PATRYS UP 27%, GENETIC TECHNOLOGIES DOWN 38%

*** TODAY: ASX, BIOTECH UP: ALCHEMIA UP 8%, ALLIED HEALTH DOWN 4%**

*** PSIVIDA: UK NICE REFUSES ILUVIEN REBATE; APPEAL AVAILABLE**

*** BENITEC COMPOUND SILENCES 90% OPMD GENE EXPRESSION**

*** PHOSPHAGENICS BROADENS OPIOID PATCH TO PLATFORM**

*** M&G GROUP TAKES 13% OF GI DYNAMICS**

*** ALCHEMIA EXPECTS $9m OFFSHORE R&D TAX REFUND**

*** BONE CAPTHYMONE DOSE TRIAL**

*** DAVID KENLEY TAKES 6% OF CALZADA**

MARKET REPORT

The Australian stock market was up 0.57 percent on Monday December 3, 2012 with the S&P ASX 200 up 25.5 points to 4,531.5 points.

Fourteen of the Biotech Daily Top 40 stocks were up, nine fell, 12 traded unchanged and five were untraded.

Alchemia was the best, up four cents or 7.8 percent to 55 cents with 239,542 shares traded, followed by Benitec up 7.7 percent to 1.4 cents with 8.1 million shares traded.

Cellmid and Reva climbed more than six percent; Genetic Technologies was up 4.2 percent; Phosphagenics and Tissue Therapies were up more than three percent; CSL, Patrys and Sirtex rose more than two percent; Anteo, Heartware and QRX were up more than one percent; with Acrux and Clinuvel up by less than one percent.

Allied Health led the falls, down 0.1 cents or 4.35 percent to 2.2 cents with 750,000 shares traded, followed by Prima down 4.2 percent to 11.5 cents with 1.6 million shares traded.

Psivida fell 3.4 percent; Optiscan and Pharmaxis shed more than two percent; GI Dynamics, Mesoblast and Viralytics were down more than one percent; with Cochlear, Starpharma and Resmed down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Biotech Daily called the life sciences Spring too early on October 1 after a 6.0 percent rise, and November has seen across the board falls as well as two own-goals. The Biotech Daily Top 40 index (BDI-40) lost a further 5.1 percent in November, with 24 companies falling, 12 climbing and four unchanged.

Starpharma had the deepest value fall, down $135 million or 29.3 percent following the failure of Vivagel to meet its phase III bacterial vaginosis trial endpoint; Acrux lost $88 million with investors weak-kneed over Axiron testosterone replacement royalty income; and Heartware lost $121 million on increasing revenue and an FDA approval – go figure!

The long term chart below indicates that the BDI-40 has been not only a lead indicator for the broader market, but with much greater amplitude. Whether this continues to be the case will be interesting to watch.

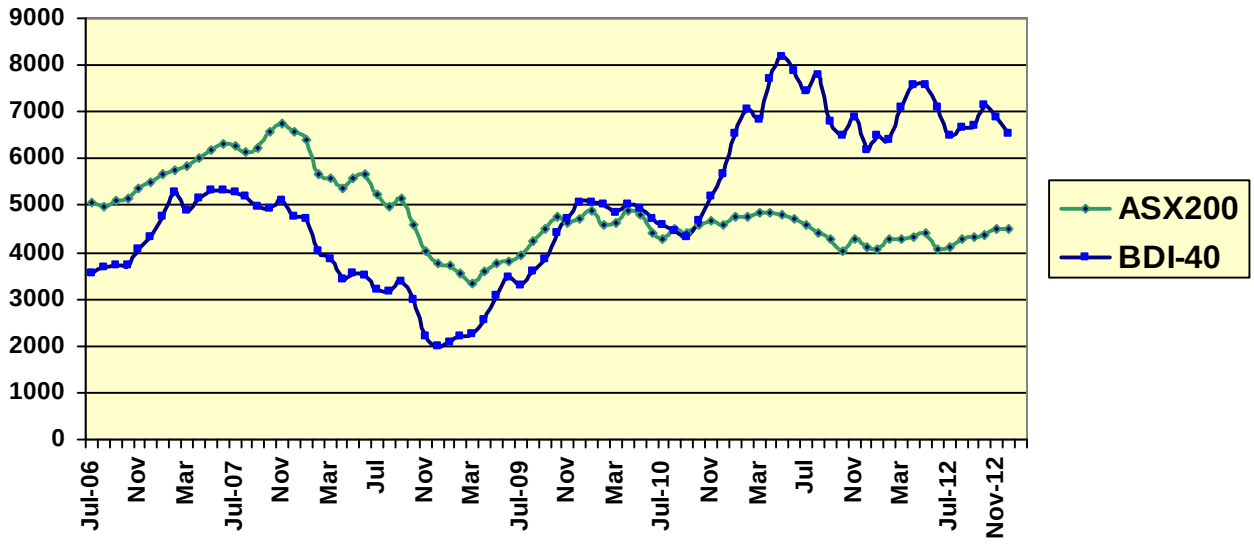
The good news is that the three Big Caps of Cochlear, CSL and Resmed, (which are not included in the BDI-40) were up a collective 7.2 percent in November and 54.8 percent for the year to November 30. All three climbed in November and for the 12 months, with Cochlear up 5.4 percent and 35.4 percent, respectively, CSL up 8.7 percent and 58.5 percent; and Resmed up 2.3 percent and 54.7 percent.

Patrys was the best of the BDI-40 few, climbing $4 million or 26.7 percent to $19 million; followed by Uscom up 22.2 percent from a low base to $11 million; Avita (15.4%); Clinuvel (8.9%); GI Dynamics (8.1%); Sirtex (6.4%); and Universal Biosensors (6.2%).

Along with its second board, Genetic Technologies (BD: Nov 27, 28) lost 38.2 percent from its market capitalization to $34 million; followed by Starpharma (29.3%); Impedimed (25.9%); Bioniche (25.5%); Tissue Therapies (20.3%); Acrux (16.3%) and Prana (16.3%).

Despite its November fall, Prana has returned to a strong news flow and will replace Genetic Technologies in the Top 20. The Top 40 will be reviewed at the end of the year.

BDI-40 v ASX200 June 30, 2006 To November 30, 2012



PSIVIDA

Psivida says the UK National Institute for Health and Clinical Excellence (NICE) has not recommended Iluvien for chronic diabetic macular oedema.
Psivida said the Institute issued final draft guidance concluding that the evidence provided did not show that the benefits Iluvien provided to patients justify the proposed price.
The Institute's chief executive Andrew Dillon said the independent appraisal committee was "aware of the significant impact that chronic diabetic macular oedema can have on those with the condition and their carers".
"However, when NICE recommends any drug or treatment, we have to be sure that it is both clinically and cost effective, because money has to be diverted from elsewhere in the health service to pay for it," Mr Dillon said.
"The Committee concluded that the evidence provided did not show that the benefits fluocinolone intravitreal implantprovides to patients justify the price the [National Health Service] is being asked to pay," Mr Dillon said
The Institute said that it had not issued final guidance to the NHS and registered stakeholders had the opportunity to appeal against the draft recommendations.
Earlier this year Iluvien was approved in the UK, Portugal, France and Germany but the approvals do not include reimbursement cover (BD: May, 8; Jun 6; Jul 19, 27, 2012).
The company said that licensee Alimera Sciences reported that in response to the final draft guidance, it had begun to develop a patient access scheme to address the Institute's cost concerns and if the scheme was accepted, it would make Iluvien available to all patients in the UK considered insufficiently responsive to available therapies.
The company said that there were more than three million people living with diabetes in the UK, nearly 200,000 of whom had vision loss from diabetic macular oedema.
Psivida fell 4.5 cents or 3.4 percent to $1.275.

BENITEC BIOPHARMA

Benitec says that in-vitro delivery of its multi-shRNA cassette, Pabparna, reduces the oculopharyngeal muscular dystrophy target gene expression by 90 percent.
Benitec said that with researchers at the Royal Holloway University London and the Institut de Myologie, Paris the oculopharyngeal muscular dystrophy program was targeting the silencing of the PABPN1, the mutant form of which caused the muscle disease.
Benitec said the research team would proceed to develop a vector for combined silencing of the mutant gene by ddRNAi and replacement with the normal gene.
The company said that delivery of the multi-short hairpin RNA (shRNA) cassette Pabparna to cells expressing the target gene was highly effective at silencing the target gene in those cells, reducing the expression levels to about 10 percent and if achieved in vivo, this level of silencing was likely to result in significant improvement of the currently untreatable muscle disease.
Benitec said that the research team expected that the optimal therapeutic would be based on both suppression of the target mutant gene with DNA-directed RNA interference (ddRNAi) and replacement with the normal or healthy gene and a normal gene had been successfully engineered to be expressed in the ddRNAi-treated cells in-vitro.
Benitec chief executive officer Dr Peter French said that the early data gave the company "confidence to commit to the next step of developing a therapeutic … for in vivo testing".
Dr French said that the Institut de Myologie was the French National Reference Centre for muscle diseases and as such is readily able to recruit patients with into a clinical trial.
Benitec was up 0.1 cents or 7.7 percent to 1.4 cents with 8.1 million shares traded.

PHOSPHAGENICS

Phosphagenics says that work done for its transdermal oxycodone patch can be used as a platform for other transdermal opioid products.

Phosphagenics said that with its German development partner Labtec GmbH it had resolved its oxycodone patch crystallization issues and improved the formulation (BD: May 23, Jun 5, 2012).

The company said that a multi-dose study of the “first-in-class” oxycodone patch was expected to begin in 2013 and following the six week trial an investigational new drug would be submitted to the US Food and Drug Administration for a phase III program.

Phosphagenics said that during the delay in the patch program, it had prepared a strategic, clinical and commercial development plan for the oxycodone patch.

The company said it was working with US advisers, Neura Therapeutik, as well as regulatory and clinical advisers INC Research to develop a detailed target product profile to form part of the final product label and a clinical development plan had been prepared.

Phosphagenics said that the preparation work would provide a platform for the development and commercialization of other opioid pain patches incorporating its tocopheryl phosphate mixture or TPM technology.

Phosphagenics said it had been evaluating several other opioids that had the potential to be included in a comprehensive transdermal pain patch product portfolio and the first selected for further development work was oxymorphone, a semi-synthetic opioid molecule very similar to oxycodone.

The company said that oxymorphone was approved by the FDA to treat moderate to severe chronic pain and had global sales of about $1 billion a year.

Phosphagenics said that oral oxymorphone was three-and-a-half times more potent than oxycodone, it has very low bioavailability, making it “an ideal candidate for transdermal delivery”.

The company said that following a successful pre-clinical program it would begin a single-dose clinical trial of an oxymorphone patch early in 2013.

Phosphagenics chief executive officer Dr Esra Ogru said the company had made a substantial investment in its oxycodone program and planned “to aggressively leverage this technology to produce multiple products in the pain space to maximize shareholder benefit”.

“The prospect of having two major opioid projects entering the clinic simultaneously represents a significant increase in the value of the program,” Dr Ogru said.

“We remain focused and committed to commercialising our first-in-class pain patch technology,” Dr Ogru said.

Neura Therapeutik chief executive officer John LaLota said that the addition of oxymorphone to the transdermal delivery strategy “provides a valuable extension to Phosphagenics’ pain portfolio”.

Phosphagenics was up 0.5 cents or 3.45 percent to 15 cents with two million shares traded.

GI DYNAMICS

M&G Investment Funds says it has increased its substantial holding in GI Dynamics from 34,450,520 Chess depositary interests (12.01%) to 37,523,174 CDIs (13.08%).

The London-based M&G group said it acquired the shares between October 31 and November 29, 2012, with the single largest, and most recent, acquisition 485,440 shares for $316,167 or 65.1 cents a share.

GI Dynamics fell one cent or 1.5 percent to 64 cents.

ALCHEMIA

Alchemia says Alchemia Oncology expects to receive a Federal Government research and development tax incentive of more than $3 million for expenditure in 2011-2012.
Alchemia said that the Audeo Oncology subsidiary Alchemia Oncology would receive $2 million of the payment relating to refundable tax credits from its non-Australian expenditure and followed a successful finding from Ausindustry.
Alchemia said that about $1 million was expected from Australian research and development.
The company said that the overseas finding applied to both Alchemia Oncology's overseas phase III trial activities in 2011-'12 and these activities for the 2012-'13 and 2013-'14 financial years, in which it expected to invest more than $20 million.
Alchemia said that Alchemia Oncology expected to receive a 45 percent refundable tax credit of more than $9 million across the three years, including the $2m for the financial year 2012.
The company said that Alchemia Oncology had applied to Ausindustry for a refund of its Australian research and development expenditure for the year ending June 30, 2012, worth more than $1 million, which was expected within the next few weeks.
Alchemia was up four cents or 7.8 percent to 55 cents.

BONE MEDICAL

Bone says that with Brisbane's Q-Pharm it has begun dosing patients with oral Capthymone to be compared with injectable parathyroid hormone.
Bone chief executive officer Peter Young said that Capthymone was the lead program and the trial of two doses against injectable parathyroid hormone was "to further reinforce that profile and partnering interest".
Mr Young said the study data might be available in the first few months of 2013.
Bone said that injectable parathyroid hormone was an important therapeutic alternative for the treatment of osteoporosis that sold nearly $US1 billion in 2011, even though it was only available as a daily injection.
The company said that a successful oral formulation had the potential to expand the role of parathyroid hormone significantly in osteoporosis in the millions of patients who suffer from osteoporosis and Capthymone was an attractive partnering candidate.
Bone said that parathyroid hormone was the only approved osteoporosis treatment that had an anabolic bone-building effect.
Bone was unchanged at 0.2 cents with 5.8 million shares traded.

CALZADA

Former Calzada director David Kenley has increased his substantial shareholding in Calzada from 20,388,598 shares (5.88%) to 23,941,734 shares (6.91%).
The substantial shareholder notice said Mr Kenley held the shares directly and indirectly through Lateral Innovations and his wife Suzanne Kenley.
Mr Kenley was a founder of the original Metabolic which became Calzada and is the chief executive officer of Calzada's wholly-owned subsidiary Metabolic.
Mr Kenley said he acquired shares between June 27, 2011 and November 30, 2012, with the single largest acquisition 661,041 shares for $29,553 or 4.47 cents a share.
Calzada was unchanged at 4.5 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company $Am	Dec-11	Nov-12	Dec-12
Cochlear	3,158	4,056	4,277
CSL	16,377	23,883	25,959
Resmed	3,984	6,023	6,163
BDI-20			
Acrux	471	539	451
Alchemia	64	152	149
Benitec	14	15	15
Bionomics	176	115	113
Clinuvel	43	56	61
Heartware	876	1,146	1,025
Impedimed	84	27	20
Mesoblast	1,913	1,641	1,717
Nanosonics	129	137	128
Neuren	27	50	45
Pharmaxis	289	397	361
Prana	43	92	77
Prima	168	133	128
Psivida	27	33	31
Reva	197	194	182
Sirtex	229	613	652
Starpharma	314	461	326
Sunshine Heart	41	59	59
Tissue Therapies	70	64	51
Universal Biosensors	127	146	155
Second 20			
Allied Health	24	20	18
Anteo	57	46	47
Antisense	28	20	17
Avita	24	39	45
Bioniche	79	47	35
Cellmid	6	9	8
Circadian	22	17	18
Compumedics	14	10	9
Ellex	11	16	17
Genera	8	12	11
Genetic Technologies	53	55	34
GI Dynamics	252	172	186
Living Cell	18	18	18
Optiscan	11	17	15
Patrys	10	15	19
Phosphagenics	160	158	148
Phylogica	24	11	11
QRX Pharma	195	104	110
Uscom	5	9	11
Viralytics	25	34	24

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