



# Biotech Daily

Monday October 1, 2012

*Daily news on ASX-listed biotechnology companies*

- \* **SEPTEMBER BDI-40 UP 6%, ASX200 UP 1.6%, BIG CAPS UP 4%**  
- **PATRYS UP 70%, UNIVERSAL BIO UP 54%, BIONICHE DOWN 48%**
- \* **TODAY: ASX, BIOTECH FLAT: ELLEX UP 9%, VIRALYTICS DOWN 6%**
- \* **FLOREY, SERVIER COLLABORATE ON ALZHEIMER'S DISEASE**
- \* **CLINUVEL ANSWERS EMA SCENESSE APPROVAL QUESTIONS**
- \* **SUNSHINE HEART REQUESTS REGULATORY TRADING HALT**
- \* **PRANA REQUESTS CAPITAL RAISING TRADING HALT**
- \* **CHINA PATENT FOR BONE ACCESS IV**
- \* **ALCHEMIA APPOINTS 3 AUDEO DIRECTORS**
- \* **PROBIOTEC APPOINTS ROBIN TEDDER DIRECTOR**

## MARKET REPORT

With most States on holidays, the Australian stock market edged up 0.04 percent on Monday October 1, 2012 with the S&P ASX 200 up 1.6 points to 4,388.6 points.

Nine of the Biotech Daily Top 40 stocks were up, nine fell, 10 traded unchanged and 12 were untraded.

Ellex was the best, up 1.5 cents or 8.8 percent to 18.5 cents with 10,000 shares traded, followed by Neuren up 7.4 percent to 2.9 cents with 8.5 million shares traded.

Cellmid climbed 6.7 percent; Impedimed and Psivida were up five percent or more; Genetic Technologies was up 4.55 percent; Living Cell rose 3.9 percent; Cochlear, Resmed and Sirtex were up more than one percent; with Biota up 0.7 percent.

Viralytics led the falls, down 1.5 cents or 5.7 percent to 25 cents with 10,000 shares traded.

Bionomics fell four percent; Avita was down 3.7 percent; Alchemia and Prima shed more than two percent; Universal Biosensors was down 1.2 percent; with Acrux, Clinuvel, CSL, and Pharmaxis down by less than one percent.

### BIOTECH DAILY TOP 40 INDEX (BDI-40)

Spring has sprung for listed life sciences, with the Biotech Daily Top 40 Index (BDI-40) outperforming the S&P ASX200 for the month and year to September 30, 2012.

Sirtex has more than doubled its market capitalization in 12 months, the three Big Caps of Cochlear, CSL and Resmed, which are not included in the BDI-40, are up a collective 45 percent for the 12 months and Cochlear has recovered from its product recall. As British Prime Minister Margaret Thatcher once said: "Rejoice, rejoice!"

The BDI-40 climbed 6.0 percent in September compared to the ASX200 up 1.6 percent. For the year to September 30, the BDI-40 was up 10.1 percent compared to the ASX200 up 9.4 percent (see chart below).

The Big Caps were up 45.1 percent for the year, with CSL up 49.2 percent, and Cochlear returning to its pre-product recall market capitalization up 45.7 percent to \$3,846 million, since the September 2011 tumble. Resmed was up 31.0 percent for the 12 months.

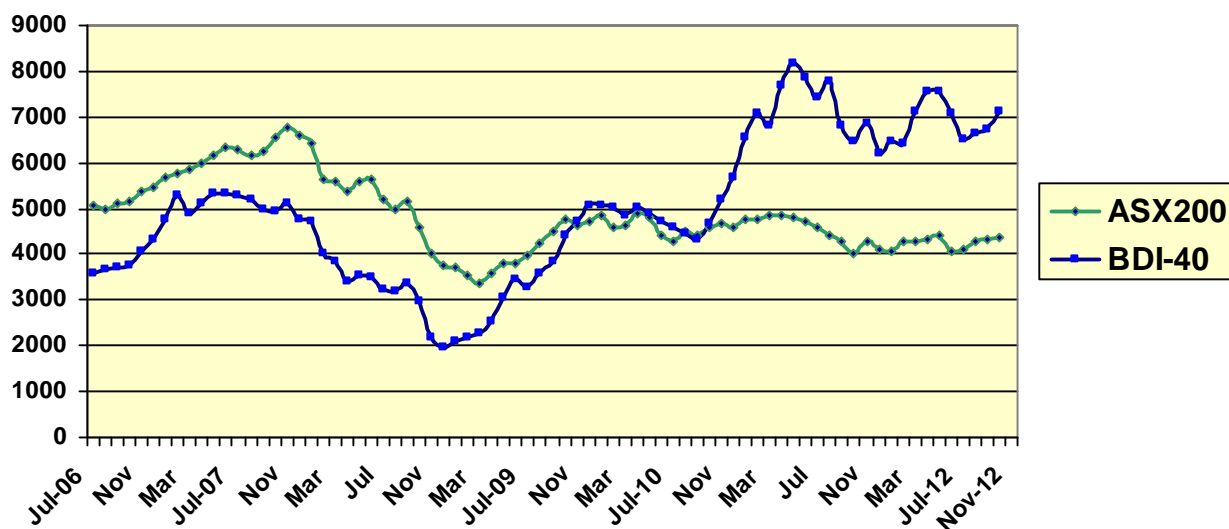
The BDI-40 gained \$401 million in September, with 22 companies up, 15 down and three unchanged. Despite a scathing Macquarie Bank analyst's note, repeating earlier inaccuracies, Mesoblast added the most value, \$113 million, to the total, climbing to \$1,934 million, followed by Sirtex up \$101 million to \$530 million, Heartware up \$62 million to \$1,297, Universal Biosensors up \$50 million and Reva up \$40 million.

By percentage, Patrys was the best, up 70 percent to \$17 million, followed by Universal Biosensors up 54.3 percent to \$142 million, Bionomics (37.3%), Prima (36.8%), Antisense (26.1%), Sirtex (23.5%) and Reva (22.0%).

Bioniche led the falls, down 47.5 percent to \$41 million, followed by Compumedics (35.3%), Genera (21.4%), Benitec (17.6%), Impedimed (15.15%), Allied Health (13.6%) and Ellex (12.5%).

Biota has delayed its delisting shareholder meeting, so there are no changes this month.

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



## FLOREY INSTITUTE OF NEUROSCIENCE, LES LABORATOIRES SERVIER

Servier Laboratories, Melbourne's Florey Institute, St Vincent's Institute and Monash University will collaborate on the role of insulin-regulated amino-peptidase in neurodegenerative disorders such as Alzheimer's disease.

A joint Servier and Florey media release said that insulin-regulated amino-peptidase (IRAP), produced in brain, fat and muscle cells, was a novel target for the therapeutic treatment of neurodegenerative disorders.

The media release said that the role of insulin-regulated amino-peptidase in memory was originally identified at the Florey Institute by Dr Siew Yeen Chai, now at Monash University, while a collaboration with St Vincent's Institute of Medical Research's Prof Michael Parker had shown that inhibitors of insulin-regulated amino-peptidase could have disease modifying effects in Alzheimer's disease.

The media release said that the Australian teams committed significant resources for in-vivo proof-of-concept for insulin-regulated amino-peptidase in mouse models of Alzheimer's disease and had generated valuable know-how and intellectual property.

The Servier and Florey media release said that the collaboration, facilitated by life sciences commercialization company Bio-Link Australia, chose Servier to advance the program to gain access to its expertise in drug discovery and development of central nervous system therapeutic agents.

Servier and the Florey said that the collaboration would focus on further understanding the therapeutic potential of insulin-regulated amino-peptidase in models of neurodegenerative disorders and for the development of a high-throughput assay for the identification of novel drug candidates that inhibit its activity.

The media release said that the research would involve laboratories at Monash University and St Vincent's Institute of Medical Research as well as Servier's Neuroscience Research Unit located within the Institut de Recherche Servier.

The media release said that Servier would provide the Florey and its partners annual support for research activities undertaken as part of the collaboration and support for researchers to work on the insulin-regulated amino-peptidase project and Servier would receive an exclusive option to licence the insulin-regulated amino-peptidase program once agreed research milestones have been met.

Florey Institute director Prof Geoff Donnan said his research institute was "delighted that a groundbreaking piece of work from our scientists and collaborators has the opportunity to be partnered with Servier with the promise of new medicines being developed to treat Alzheimer's disease".

Servier's head of research and development Dr Emmanuel Canet said Servier was dedicated to the research and development of novel therapeutic for the treatment of neurodegenerative and psychiatric diseases.

"This collaboration between Servier and the Florey, Monash University and St Vincent's Institute brings together unique expertise in neurological and psychiatric disorders and drug discovery," Dr Canet said. "This partnership reinforces our quest to find innovative drugs for neurodegenerative diseases such as Alzheimer's disease."

Institut de Recherche Servier general manager Dr Bernard Marchand said the Florey and its partners "performed tremendous efforts in understanding the role of IRAP in the pathology of Alzheimer's disease".

"We consider that IRAP may have potential as a target of therapeutic importance in the development of neurodegenerative diseases and it is the task of this collaboration to validate this belief and provide a platform for the identification of novel therapeutic agents acting on IRAP," Dr Marchand said.

### CLINUVEL

Clinuvel says that it is a question and answer period with the European Medicines Agency for marketing approval for Scenesse for erythropoietic protoporphyria (EPP).

Clinuvel said it filed its marketing application in February 2012 for Scenesse and it was being evaluated by the Agency under the centralized procedure.

Clinuvel's acting chief scientific officer Dr Dennis Wright said the Agency had completed an initial review of the dossier and issued the first formal questions.

Dr Wright said that the Agency's agreed with Clinuvel's assessment that the drug had a good safety profile in all the patients for whom data has been submitted.

Clinuvel said its responses to European Medicine Agency questions were being finalized.

The company said that before a recommendation on the clinical use of Scenesse was made by the Agency's Committee for Medicinal Products for Human Use (CHMP) two further question periods could be imposed.

Clinuvel chief executive officer Dr Philippe Wolgen said the company had restructured the regulatory team in recent months "and despite the tragic loss of Dr Agersborg we have a robust team to follow in his footsteps" (BD: Sep 28, 2012).

"We are on track to obtain registration for Scenesse for EPP patients," Dr Wolgen said.

"The next few weeks we will learn whether more questions remain to be answered as part of the CHMP's final review or whether Clinuvel has satisfied all regulatory requirements," Dr Wolgen said.

Clinuvel fell one cent or 0.6 percent to \$1.56.

### SUNSHINE HEART

Sunshine Heart has requested a trading halt pending "an announcement to the market concerning the regulatory development".

Trading will resume on October 3, 2012 or on an earlier announcement.

Sunshine Heart last traded at four cents.

### PRANA BIOTECHNOLOGY

Prana has requested a trading halt pending "an announcement to the market in relation to a proposed capital raising".

Trading will resume on October 3, 2012 or on an earlier announcement.

Prana last traded at 22.5 cents.

### BONE MEDICAL

Bone says China has approved the grant of a patent for its Axxess IV oral peptide formulation technology.

Bone chairman and chief scientific officer, and inventor of the Axxess technology, Dr Roger New said that China patent was "a significant milestone".

"Although challenging, it is also one of the most rapidly developing pharmaceutical markets and an increasingly competitive place to source of primary manufacturing for active drug substance for global supply," Dr New said.

"This makes it a fertile environment to strike new strategic partnerships," Dr New said.

Bone said that Axxess IV was the patent family that covered its Capthymone product, an oral capsule form of injectable parathyroid hormone, an important treatment for osteoporosis, currently available only as a daily injection.

Bone was up 0.1 cents or 33.3 percent to 0.4 cents with 1.1 million shares traded.

## ALCHEMIA

Alchemia says it has appointed Leigh Bonney, Dr Susan Kelley and Dr David U'Prichard as directors of wholly-owned subsidiary, Audeo Oncology ahead of the planned demerger. Alchemia is in the process of demerge its oncology and its sugar-based versatile assembly of stable templates (VAST) drug discovery assets into Audeo Oncology and Audeo Discovery and list Audeo Oncology on both the ASX and Nasdaq, later this year (BD: Jul 9, Aug 24, 2012).

Alchemia said Ms Bonney held senior positions in strategy and finance in the healthcare industry, including 15 years at Pfizer before retiring in 2011.

The company said that Ms Bonney was formerly chief financial officer of Pfizer Global Research and Development and prior to Pfizer, Ms Bonney worked for McKinsey and Co consulting to industries including healthcare and pharmaceuticals.

Alchemia said Ms Bonney was currently the chief financial officer of the Leona M and Harry B Helmsley Charitable Trust.

The company said that Ms Bonney held a Bachelor of Arts from Yale University, a Master of Arts from Stanford University and a Master of Business Administration from Harvard University.

Alchemia said that Dr Kelley was a medical oncologist with fellowships at the Dana-Farber Cancer Institute, Harvard Medical School and Yale School of Medicine.

The company said that Dr Kelley previously held senior positions in the pharmaceutical industry including the head of strategic drug development, oncology and metabolics with Bayer-Schering Pharmaceuticals and was the head of oncology with Bayer Pharmaceuticals.

Alchemia said that Dr David U'Prichard had "an extensive career in the management of drug discovery and development" and advised life sciences companies as president of Druid Consulting LLC and was previously chief executive officer of 3-Dimensional Pharmaceuticals and held the positions of president and chairman of research and development for SmithKline Beecham Pharmaceuticals and was research director and a board member of Zeneca Pharmaceuticals.

Audeo chairman Stephen Hill said that the appointments "will bring comprehensive expertise across finance, corporate strategy, oncology, drug discovery and clinical development".

Alchemia said the appointments bring the number of non-executive directors to five including Alchemia co-founder Dr Tracie Ramsdale.

The company said that each director had been granted 30,000 pre-initial public offer options over common stock in Audeo.

In July, Alchemia chief executive officer Dr Pete Smith said the US and Australian initial public offer would raise less than \$60 million to complete the existing phase III Hyact trial as well as cover the cost of two sets of regulatory regimes and the company hoped to submit its new drug application to the US Food and Drug Administration by April 2014. Alchemia fell 1.5 cents or 2.9 percent to 50.5 cents.

## PROBIOTEC

Probiotec has appointed Robin Tedder as a director.

Probiotec said that Mr Tedder had more than 35 years experience in business and finance and was currently the chairman of Vintage capital.

The company said that Mr Tedder would fill a casual vacancy until he stands for election at the annual general meeting on November 26, 2102.

Probiotec was untraded at 34.5 cents.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

<b>Company \$Am</b>	<b>Oct-11</b>	<b>Sep-12</b>	<b>Oct-12</b>
Cochlear	2,639	3,874	3,846
CSL	15,582	22,286	23,243
Resmed	4,575	5,634	5,992
<b>BDI-20</b>			
Acrux	533	566	533
Alchemia	69	149	147
Benitec	19	17	14
Bionomics	165	102	140
Biota	146	125	126
Clinuvel	46	54	54
Genetic Technologies	74	56	51
Heartware	893	1,235	1,297
Impedimed	70	33	28
Mesoblast	2,269	1,821	1,934
Nanosonics	120	130	128
Neuren	17	27	32
Pharmaxis	166	336	339
Prima	166	144	197
Reva	197	182	222
Sirtex	240	429	530
Starpharma	265	421	422
Sunshine Heart	57	67	72
Tissue Therapies	78	74	68
Universal Biosensors	147	92	142
<b>Second 20</b>			
Allied Health	18	22	19
Anteo	45	42	44
Antisense	9	23	29
Avita	23	33	34
Bioniche	80	64	41
Cellmid	8	9	9
Circadian	22	18	19
Compumedics	12	17	11
Ellex	9	16	14
Genera	9	14	11
Living Cell	19	17	19
Optiscan	12	13	15
Patrys	13	10	17
Phosphagenics	124	133	128
Phylogica	23	12	13
Prana	43	54	64
Psivida	91	38	37
QRX Pharma	170	100	95
Uscom	8	9	10
Viralytics	29	20	20

\* 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.

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