



# Biotech Daily

Thursday December 1, 2011

*Daily news on ASX-listed biotechnology companies*

- \* NOVEMBER BDI-40 DOWN 9.7%, ASX200 DOWN 4.1%
- \* TODAY: ASX, BIOTECH UP: SUNSHINE HEART UP 18%, PHOSPHAGENICS DOWN 6%
- \* CELLMID JAPAN STUDY CONFIRMS MIDKINE-ELISA ACCURACY
- \* GENETIC TECHNOLOGIES' LICENCE FOR AUTOIMMUN DIAGNOSTIKA
- \* AUSTRALIAN PATENT FOR VIRALYTICS PICORNAVIRUS METHOD
- \* HEALTHLINX ADDS 4 TRADEMARK JURISDICTIONS
- \* AUSTRALIAN ETHICAL DUMPS TISSUE THERAPIES
- \* AVITA JV FOR ITALIAN SALES
- \* SUNSHINE HEART WAIVERS A STEP CLOSER TO NASDAQ
- \* VICTORIA APPOINTS BIOTECHNOLOGY ADVISORY COUNCIL
- \* 10% OF PSIVIDA OPPOSE DIRECTOR OPTIONS
- \* ACUVAX OPTION FOR OTC RENAISSANCE
- \* ANTEO PLEADS SCHULTZ TO ASX 26% QUERY
- \* PATRYS TAKES CAPITAL RAISING HALT TO SUSPENSION

## MARKET REPORT

The Australian stock market rebounded 2.64 percent on Thursday December 1, 2011 with the S&P ASX 200 up 108.8 points to 4228.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, six traded unchanged and six were untraded.

Sunshine Heart was the best, up 0.6 cents or 17.65 percent to four cents with 1.1 million shares traded, followed by Allied Health up 15.8 percent to 4.4 cents with 2.9 million shares traded. Genetic Technologies and Heartware climbed more than eight percent; Avita, Nanosonics and Uscom were up five percent or more; Acrux, Cochlear, Mesoblast and QRX were up more than three percent; Clinuvel rose 2.1 percent; with Anteo, Bionomics, CSL, Reva, Sirtex, Starpharma and Tissue Therapies up one percent or more.

Phosphagenics led the falls, down one cent or 6.1 percent to 15.5 cents, with 2.6 million shares traded. Living Cell and Phylogica lost more than five percent; Neuren fell 4.35 percent; Antisense and Biota were down more than three percent; with Alchemia, Circadian, Impedimed and Viralytics down more than one percent.

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

Most of the Biotech Daily Top 20 Index (BDI-20) companies fell in the month of November, but it might have been a different story if we used tonight's data rather than last night's end of the month reference point – but that's statistics for you.

The exceptions were Alchemia and Bionomics, both recovering from earlier falls, Starpharma with a new major investor and Nanosonics looked good by not falling.

The Biotech Daily Top 40 Index (BDI-40) fell 9.7 percent in November with the S&P ASX200 down 4.1 percent for the month. While the ASX began to close the chasm over 12 months, the BDI-40 (which does not include the Big Caps of Cochlear, CSL and Resmed) remained well ahead of the benchmark index for the year to November 30, 2011, up 9.25 percent compared to the ASX200 falling 10.1 percent (see chart below).

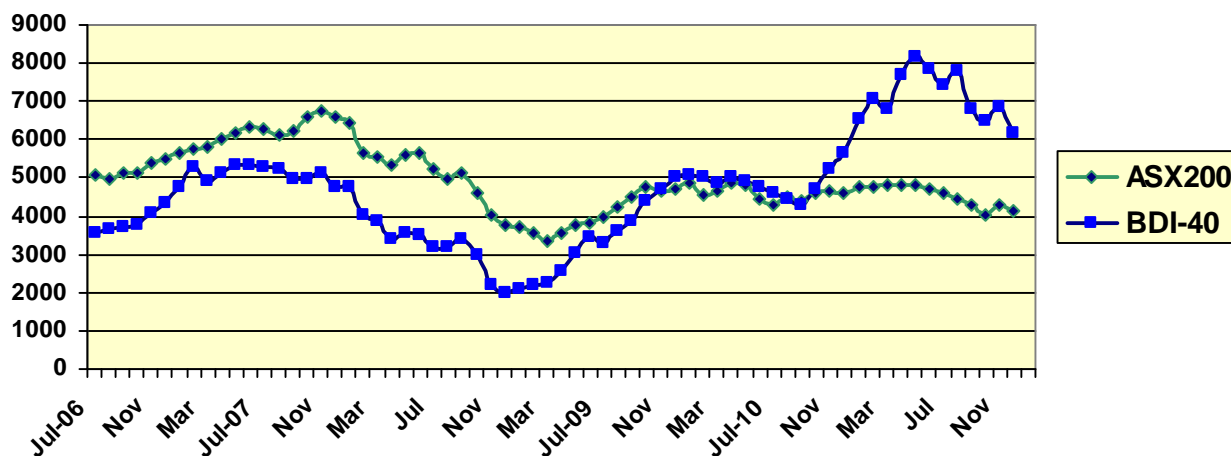
A total of 29 companies fell in November with nine up and two unchanged.

Antisense was the clear winner, up 180 percent to a market capitalization of \$28 million, as the day-traders ramped the expectation of impending trial results for its growth hormone receptor-targeting drug ATL1103 by the end of this year. Bionomics was up 23.1 percent to \$176 million, followed by Anteo (21.3%), Alchemia (18.5%), Optiscan (10%), Compumedics (7.7%), Reva (3.4%) and Nanosonics (0.8%).

Mesoblast's 16.8 percent or \$386 million fall – at the hands of an incorrect but widely disseminated Macquarie Bank report - wiped 6.2 percent from the BDI-40. The biggest percentage fall was Psivida's 68.2 percent drop to \$27 million, triggered by an FDA refusal for its Iluvien drug delivery device. From a low base, Uscom lost 37.5 percent to \$5 million and Tissue Therapies' not-quite-a-licence wounded the company 30 percent to \$70 million, followed by Patrys (28.6%), Benitec (26.3%), Genera (20.0%), Living Cell (18.2%), Mesoblast (16.8%), Acrux (16.3%) and Genetic Technologies (15.9%).

CSL climbed 8.1 percent to \$16,377 million pushing the three Big Caps up a collective 3.6 percent, despite Cochlear and Resmed both falling more than five percent in November, but for the year, the Big Caps were down 18.0 percent.

BDI-40 v ASX200 Jun 30, 2006 To Nov 30, 2011



## CELLMID

Cellmid says a study in Kumamoto, Japan, measuring the blood midkine levels of 233 healthy volunteers confirms the normal reference range for regulatory submissions.

Cellmid said that previous research showed that 95 percent of the individuals tested had midkine levels below 500 picogram/mL and 90 percent were below 350 picogram/mL.

The company said that the study was designed to assess the normal reference range for midkine levels for regulatory submissions, and was an essential component of its diagnostic programs and filings.

Cellmid said the study intended to determine levels of midkine in healthy individuals on the basis of criteria such as smoking and drinking habits and biomarkers including C-reactive protein, low density lipoprotein, blood urea nitrogen and albumin in the blood.

Cellmid said that the study evaluated the use of the MK-enzyme-linked immunosorbent assay (ELISA) test by independent researchers and it "performed very well with 100 percent of the tests passing quality control criteria".

The company said that "dilution linearity", used for assessing ELISA tests, was strong, confirming that the MK-ELISA was "the gold standard in measuring midkine levels in blood".

Cellmid was unchanged at 1.6 cents with 2.5 million shares traded.

## GENETIC TECHNOLOGIES

Genetic Technologies says it has executed a settlement and licence agreement with Autoimmun Diagnostika GmbH of Strassberg, Germany.

Genetic Technologies said Autoimmun Diagnostika had been granted non-exclusive rights to a number of patents relating to its non-coding DNA technology.

The company said that as with other similar agreements, the precise commercial terms of the agreement were confidential and could not be disclosed.

Genetic Technologies said Autoimmun Diagnostika was not a counterparty to either of the two current patent infringement suits it had filed in the US.

Genetic Technologies said discussions with Autoimmun Diagnostika regarding the use of the non-coding technology resulted in non-exclusive access to the technology for Autoimmun Diagnostika products and services as well as normalization of historical sales. Genetic Technologies was up one cent or 8.7 percent to 12.5 cents.

## VIRALYTICS

Viralytics says the Australian Patent Office has granted a patent covering a method for treating or preventing blood cancer with a picornavirus.

Viralytics said its lead anti-cancer virus formulations, Cavatak and Evatak were both members of the picornavirus, or small RNA virus, family, which consisted of more than 250 individual viruses

The company said the patent covered "a method for treating and/or preventing haematologic cancer in a subject by administering a therapeutically effective amount of a picornavirus, such that at least some cells of the cancer undergo viral cell lysis".

Viralytics said the scope of the accepted claims covered the administration of picornaviruses by intravenous, intratumoral, intraperitoneal and intramuscular routes.

The company said the claims covered the use of picornaviruses in purging malignant cells within auto grafts prior to autologous stem cell transplantation or by ex-vivo purging of malignant cells within auto grafts prior to transplantation.

Viralytics fell half a cent or 1.2 percent to 41.5 cents.

## HEALTHLINX

Healthlinx says that registering the ovarian cancer diagnostic Ovplex trademark in six jurisdictions has strengthened its intellectual property position.

Healthlinx said that it had been granted trade marks in the US, South Korea, Malaysia and Israel in addition to the previously announced registration in China and Singapore.

The company said all six jurisdictions either distributed Ovplex or were targets for distribution.

Healthlinx managing director Nick Gatsios said the company's trademark portfolio had been strengthened with China and the US "of particular significance considering their market potential and the steps the company is taking to obtain regulatory approvals and ultimately distribute Ovplex in these jurisdictions."

Healthlinx was up 0.1 cents or 10 percent to 1.1 cents.

## TISSUE THERAPIES

Australian Ethical's Smaller Companies trust has ceased its substantial holding in Tissue Therapies, selling all 11,148,450 shares (6.61%) for \$4,312,565 or 38.7 cents a share.

The previous substantial shareholder notice said Australian Ethical sold 1,882,400 shares for \$2,914,968 or an average price of 51.3 cents a share (BD: Nov 14, 2011).

Tissue Therapies acquired 5,829,935 shares for \$2,914,968 or an average price of 50 cents a share in a rights issue and placement (BD: May 25, 2011) and previously acquired shares at 20 cents and 14 cents a share.

In today's notice Australian Ethical said it sold more than 10 million shares yesterday for about 37 cents a share.

On Monday, Tissue Therapies said it had a European distribution deal with Quintiles and previously had said it expected to sign a licencing deal (BD: Nov 28, 2011).

Tissue Therapies chief executive officer Dr Steven Mercer said the company would earn more from the Quintiles agreement than a licencing deal and was still free to pursue a licencing deal.

Australian Ethical portfolio manager Andy Gracey told Biotech Daily that he felt it was time to exit Tissue Therapies.

"We've had a net very profitable investment in Tissue Therapies," Mr Gracey said.

"We were a little disappointed with the partnering deal," he said.

Tissue Therapies was up half a cent or 1.2 percent to 42 cents.

## AVITA MEDICAL

Avita says it has a joint venture partnership with the Milan-based DS Medigroup Srl for sales and marketing of the Recell Spray-On Skin throughout Italy.

Avita said that Italy had about 63 million people and was the fourth-largest population in the European Union.

The company said the joint venture would be registered in Italy as Avita Medical Italy.

Avita said DS Medigroup was established in 1979 and designed, distributed and marketed medical devices to more than 45,000 doctors throughout Italy specializing in dermatology, oncology, vascular diseases, and corrective and aesthetic medicine.

Avita said the company had a network of qualified product specialists supporting the different product lines, operating from offices in Milan, Rome, Naples and Palermo.

The company said the commercial launch was expected to be in January 2012 in Rome.

Avita was up half a cent or five percent to 10.5 cents.

## SUNSHINE HEART

Sunshine Heart says the Australian Securities Exchange has granted waivers from certain listing rules relating to the reporting obligations and the rotation of its directors.

Sunshine Heart said the waivers not to lodge Appendix 4D Half Year Reports, Appendix 4E Preliminary Final Reports and Appendix 4C Quarterly Reports were conditional on filing the equivalent US Securities Exchange Commission reports.

The company said the ASX waivers were granted on the condition that the terms were announced to the market and the company listed on the Nasdaq Capital Market and registered its shares of common stock under the Securities Exchange Act.

Sunshine Heart was up 0.6 cents or 17.65 percent to four cents with 1.1 million shares traded.

## VICTORIA GOVERNMENT

Victoria's Minister for Technology Gordon Rich-Phillips says the inaugural Biotechnology Advisory Council will be chaired by Prof Ian Gust.

A Department of Business and Innovation media release said the Council would provide advice on current and emerging opportunities and threats to the sector, as well as contributing to the implementation of Government policy.

"The Council will assist the Coalition Government in providing a long term and co-ordinated approach to fostering innovation and promoting growth in Victoria's biotechnology industry," Mr Rich-Phillips said. "The Council brings together expertise gained through experience in small, medium and large companies in a range of sub-sectors, including in international firms, all the way along the industry value chain, from research and development, through commercialization and production, to market."

The Council is composed of Prof Gust, Dr Leigh Farrell, Dr Simon Green, Robert Klupacs, Peter Lewis, Sue MacLeman, Dr Ian Nisbet, Dr Esra Ogru, Dr Paul Savage, Prof Richard Strugnell, Prof Andrew Wilks, Michelle Gallaher, Dr Anna Lavelle.

The Department said the Council members were appointed for two years, would report to Mr Rich-Phillips and would meet several times a year, with the first meeting this month.

The Department said Prof Gust was a board member of several biotechnology companies and research institutes, was chair of the Bio21 Cluster, the founder of the Burnet Institute in the 1980s and CSL research and development director in the 1990s.

## PSIVIDA

All Psivida annual general meeting resolutions were passed but there was significant opposition to director options.

Resolutions to approve the issue of options to chairman Dr David Mazzo and directors Paul Hopper, Michael Rogers and Peter Savas, were passed with more than 4.2 million proxy votes in favor, but with more than two million proxy votes against.

The closest vote was the issue of options to Mr Savas with 4,228,227 proxy votes (67.23%) in favor and 2,061,589 proxy votes (32.77%) against.

The issue of options for chief executive officer Dr Paul Ashton was passed with 5.4 million proxy votes in favor and 1.3 million proxy votes against, while directors Dr Mazzo, Dr Ashton, Paul Hopper, Mr Rogers and Mr Savas were reelected without opposition.

Psivida's most recent Appendix 3B share issue announcement said there were 20,802,592 shares on issue, meaning that the strongest opposition came from 10.3 percent of all shares on issue, sufficient to requisition extraordinary general meetings.

Psivida was untraded at \$1.275.

## ACUVAX

Acuvax says it has an option for a controlling interest in the unlisted 'complementary medicine' company Biohealth Pty Ltd, subject to due diligence and regulatory approvals. Acuvax said it would assist Biohealth with revenue growth, market penetration and new product development of its present platform formulation.

The company said Biohealth sold "illness-specific medicines comprised of natural non-toxic ingredients".

Acuvax said the first Biohealth product, Provent, has been approved and listed by the Australian Therapeutic Goods as a complementary medicine with the claim: 'Helps Maintain Health Respiratory Function'.

The company said Biohealth had been selling the product in a limited capacity over the past two years and had reached the point of moving beyond breakeven and into sustained profitability.

Acuvax said Biohealth was used synonymously in reference to the biopharmaceutical complementary and alternative medicine industry and value was seen in the company's name, trademark and domain name [www.biohealthlimited.com](http://www.biohealthlimited.com) for future expansion opportunities.

Acuvax said it would pay an initial \$10,000 option fee allowing a 60-day due diligence period and subject to a satisfactory outcome a further \$178,000 would be paid to hold 51 percent of the debt-free company.

The option to take a further 10 percent for a further \$100,000 in mid-2012 and a further option of taking 19 percent for \$200,000 during the 2.5 years following completion of the initial 51 percent transaction had been negotiated, to a total stake of 80 percent.

In February, Acuvax changed its ownership, board and management with the resignation of chief executive officer Dr William Ardrey (BD: Feb 9, 2011).

Following the Merck Sharp and Dohme acquisition of the biotechnology assets of the Acuvax 26 percent subsidiary Hawaii Biotech (BD: Jul 23, 2010) and failure of the cancer drug RP101 (BD: Oct 6, 2009), the company saw the departure of majority shareholder Dr Richard Opara (BD: Nov 16, 2010) and the introduction of new shareholders.

Dr Opara held up to 86 percent of Acuvax.

Acuvax was formerly known as Avantogen and before that Australian Cancer Technology with Katherine Woodthorpe, Dr Roger Aston and Paul Hopper as directors.

Dr Opara invested in the company and eventually became a director and chairman.

Acuvax was unchanged at 0.1 cents with 6.8 million shares traded.

## ANTEO DIAGNOSTICS

Anteo has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 6.2 cents on November 28, 2011 to 7.8 cents on November 30, 2011, a 25.8 percent increase and noted an increase in trading volume.

Anteo was up 0.1 cents or 1.3 percent to 7.6 cents with 8.25 million shares traded.

## PATRYS

Patrys has requested a voluntary suspension to follow the trading halt it requested on November 29, 2011, pending "an announcement ... in respect of a capital raising" (BD: Nov 29, 2011).

Patrys last traded at four cents.

## BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

<b>Company \$Am</b>	<b>Dec-10</b>	<b>Nov-11</b>	<b>Dec-11</b>
Cochlear	4,434	3,333	3,158
CSL	19,130	15,151	16,377
Resmed	5,125	4,217	3,984
<b>BDI-20</b>			
Acrux	552	563	471
Alchemia	120	54	64
Bionomics	105	143	176
Biota	179	145	131
Clinuvel	51	46	43
Genetic Technologies	13	63	53
Heartware	1,287	922	876
Impedimed	111	93	84
Living Cell	43	22	18
Mesoblast	547	2,299	1,913
Nanosonics	191	128	129
Pharmaxis	610	298	289
Phylogica	14	25	24
Prima	82	192	168
QRX Pharma	128	231	195
Sirtex	308	262	229
Starpharma	184	278	314
Sunshine Heart	17	48	41
Tissue Therapies	63	100	70
Universal Biosensors	238	143	127
<b>Second 20</b>			
Allied	5	26	24
Anteo	35	47	57
Antisense	5	10	28
Avita	12	24	24
Benitec	12	19	14
Bioniche	134	80	79
Cathrx	37	20	17
Cellmid	14	7	6
Circadian	29	23	22
Compumedics	17	13	14
Genera	25	10	8
Neuren	7	32	27
Optiscan	5	10	11
Patrys	23	14	10
Phosphagenics	78	178	160
Prana	34	43	43
Psivida	101	85	27
Reva	366	177	183
Uscom	17	8	5
Viralytics	19	27	25

\* Biotech Daily editor, David Langsam, owns shares in Alchemia, Allied Health, Biota, Neuren, Optiscan, Pharmaxis, Sunshine Heart and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in Atcor, Circadian, Pharmaxis and QRX. These holdings are liable to change.

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