

Biotech Daily

Thursday November 1, 2012

Daily news on ASX-listed biotechnology companies

- * OCTOBER BDI-40 DOWN 3%, ASX200 UP 3%, BIG CAPS UP 3% VIRALYTICS UP 70%, NEUREN UP 56%, PRIMA DOWN 33%
- * TODAY: ASX, BIOTECH DOWN: PATRYS UP 20%, GENERA DOWN 9%
- * PATRYS EXPANDS PAT-SM6 MULTIPLE MYELOMA TRIAL TO MELBOURNE
- * ELLEX TO SUPPLY SIGNOSTICS ULTRASOUND SUB-ASSEMBLY
- * MAYNE LICENCES INTAS INJECTABLES; RETAIL OFFER RAISES \$25m
- * NO GSK BIOTA RELENZA SALES, NO ROYALTY; INAVIR EARNS \$26k
- * CONSEGNA PASSES ON ASPEN MEDISYS
- * CONSEGNA HAS LESS THAN ONE QUARTER CASH, \$6m FACILITY
- * PHARMAUST HAS ONE QUARTER CASH, \$1m RAISING
- * ANDREW BAKER, STARPHARMA, VAXXAS AUSBIOTECH JANSSEN GONGS
- * CONNOR O'MEARA WINS \$7k AUSBIOTECH-GLAXOSMITHKLINE AWARD
- * AUSBIOTECH ELECTS MICHELLE BURKE DIRECTOR

MARKET REPORT

The Australian stock market fell 1.32 percent on Thursday November 1, 2012 with the S&P ASX 200 down 59.4 points to 4,457.6 points. Five of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and 10 were untraded.

Patrys was the best, up 0.6 cents or 20 percent to 3.6 cents with 1.4 million shares traded. Benitec climbed 7.1 percent; Psivida was up five percent; Phosphagenics was up 3.2 percent; Bionomics was up 1.6 percent; with Cochlear up 0.6 percent.

Genera led the falls, down 1.5 cents or 9.4 percent to 14.5 cents with 10,000 shares traded. Cellmid and Mesoblast fell more than five percent; Avita, Sunshine Heart and Viralytics were down more than three percent; Acrux and Tissue Therapies shed more than two percent; CSL, GI Dynamics, Nanosonics and Resmed were down more than one percent; with Alchemia, Pharmaxis, Sirtex and Starpharma down less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 index (BDI-40) lost 3.2 percent in October, primarily due to falls by Mesoblast and Heartware, while the ASX200 climbed 3.0 percent.

Proving that one crocus does not make a Spring and following the 6.0 percent September rise, modest to strong rises by most of the 40 BDI-40 stocks were more than off-set by a total \$444 million loss by Mesoblast down 15.1 percent or \$293 million to \$1,641 million and Heartware down 11.6 percent or \$151 million to \$1,146 million. (Removing those two falls the BDI-40 would have climbed 3.1 percent for the month.)

In October, 22 companies were up, 17 fell and one was unchanged.

Viralytics was the best from a low base, up \$14 million or 70 percent to a market capitalization of \$34 million; followed by Neuren up 56.25 percent to \$50 million; Prana up 43.75 percent to \$92 million; Pharmaxis (17.1%); Sirtex (15.7%); Avita (14.7%); Bioniche (14.6%); Ellex (14.3%) and Optiscan (13.3%). For the year to October 31, Alchemia was up 181.5 percent, with Sirtex up 134.0 percent.

Prima had the deepest fall, down 32.5 percent to \$133 million; followed by Antisense down 31.0 percent to \$20 million; Sunshine Heart (18.1%); Bionomics (17.8%); Phylogica (15.4%); Mesoblast (15.1%); Reva (12.6%); Patrys (11.8%) and Heartware (11.6%).

The three Big Caps of Cochlear, CSL and Resmed, (which are not included in the BDI-40) were up a collective 2.7 percent in October and 49.6 percent for the year to October 31. In October Cochlear continued its recovery up 5.5 percent, CSL was up 2.75 percent and Resmed was up 0.5 percent.

Outside the BDI-40, Medical Developments was up 53.7 percent for the month and 255.2 percent for the year, with strong improvements by Avexa, Biotron and Cryosite. With Biota's departure to the Nasdaq, Psivida has been promoted to the BDI-20 and GI Dynamics joins the BDI-40.

BDI-40 v ASX200 June 30, 2006 To October 31, 2012



PATRYS

Patrys says that Melbourne's Alfred Hospital ethics committee has approved its PAT-SM6 phase I/IIa multiple myeloma trial to begin by the end of 2012, with results by April 2013. Patrys said it had regulatory approval for the trial at Germany's University Hospital Würzburg and the addition of the Australian site would allow accelerate patient recruitment.

The company said that multiple myeloma was a cancer of the plasma cells in bone marrow with over-production of malignant or cancerous plasma cells leading to bone disease, anaemia, kidney problems, reduced immunity and infections and with a five year survival rate of about 40 percent, multiple myeloma was largely incurable.

The company said that the Australian principle investigator would be the Alfred Hospital's Prof Andrew Spencer, who was involved in translational and early phase research with an interest in mechanisms of drug resistance and the development of new approaches for the treatment of haematological malignancies.

Patrys said the trial would be a 12-patient, open-label, multi-dose escalation trial in relapsed and multi-resistant patients with multiple myeloma and patients would be enrolled in four dosing groups and receive a minimum of two cycles of treatment. Patrys said that if a patient showed a partial response to treatment with PAT-SM6 an additional cycle of treatment would be offered.

Patrys chief executive officer Dr Marie Roskrow said the trial was an open-label multi dose escalation study so the company would be able to release data on an ongoing basis. Patrys said the patients in the phase I/IIa trial, had typically failed all currently marketed drugs and had a very poor prognosis.

The company said that the primary objective was to evaluate the safety and tolerability of escalating doses of PAT-SM6 and the secondary objective was to measure efficacy as determined by a series of laboratory assays.

Patrys was up 0.6 cents or 20 percent to 3.6 cents with 1.4 million shares traded.

ELLEX MEDICAL LASERS

Ellex has a contract with ultrasound developer Signostics to manufacture the critical subassembly of the Signostics ultrasound device, Signos RT (real time).

In 2011 Signostics won the Melbourne Design Awards' best medical and scientific project award for its handheld Signos personal ultrasound system (BD: Mar 17, 2011).

Ellex chief executive officer Tom Spurling said the agreement with Signostics was an important initiative to identify new, complementary revenue streams, leveraging its existing manufacturing and engineering capabilities.

"Whilst we remain committed to maintaining and improving our position as a leader in the global ophthalmic laser and imaging market, this is an important opportunity to ensure the optimal utilization of our highly skilled manufacturing team and to diversify our earnings", Mr Spurling said.

Ellex said it would manufacture the sub-assembly of the Signos RT device in its facility in Adelaide.

Signostics chief executive officer Warren Ortmann said that the partnership with Ellex would allow it to increase production capacity ahead of the global launch of the Signos RT device in key markets, including the United States and Australia.

Mr Spurling said that he expected the agreement with Signostics to be ongoing, with 800 units targeted for production over the coming six months.

Ellex was untraded at 19 cents.

MAYNE PHARMA GROUP

Mayne says it has a licencing and distribution agreement with India's Intas

Pharmaceuticals for a range of injectable products for the Australian market.

Mayne said the profit-share agreement would begin with rights to 11 hospital products with market sales of \$73 million a year and it expected to file applications for the products with the Australian Therapeutic Goods Administration in 2013.

The company said that it had also secured a right of first refusal for the exclusive distribution of another 30 pipeline injectable products across a range of therapeutic areas with current market sales of \$140 million a year.

Mayne said that, so far, there were no generic equivalents to 15 of these products and it expected several would be the first generic versions approved.

The company said that all products would be developed and supplied by Intas from their TGA and US Food and Drug Administration-approved facilities.

Mayne Pharma chief executive officer Scott Richards said the company was "committed to building its domestic business".

"One of the avenues to achieving this goal is by in-licensing attractive niche products with low competitive dynamics while at the same time delivering cost effective medicines to patients," Mr Richards said.

Mayne said that following the completion of the acquisition of Metrics in mid-November, it would seek TGA approval for a number of Metrics' products in Australia (BD: Oct 4, 2012). Mayne said it had also completed the retail part of its fully-underwritten \$65 million equity raising in relation to the Metrics acquisition, raising about \$24.7 million.

Mayne said the offer was oversubscribed and "due to overwhelming demand ... Mayne Pharma will scale back applications for additional new shares under the top-up offer made by eligible retail shareholders, which are in excess of an additional 1.13 times their entitlement".

Mayne Pharma was up 1.5 cents or 5.9 percent to 27 cents with 1.3 million shares traded.

BIOTA

Biota said there were no Glaxosmithkline Relenza sales in the three months to September 30, 2012 and Daiichi Sankyo's \$740,000 Inavir sales would provided a royalty of \$26,000. In July \$2.0 million Glaxosmithkline royalty payment for sales of Relenza in the three months to June 30, 2012, taking the year total to \$4.2 million, with sales of \$3.3 million in the three months to September 30, 2011 (BD: Oct 27, 2011; Jul 26, 2012).

Biota has delisted from the ASX and will list on the Nasdaq on November 9, 2012.

CONSEGNA

Consegna says it won't exercise its option to acquire the anti-cancer nanotechnology assets of Aspen Medisys.

In 2011, Consegna (then Helicon) began due diligence for the anti-tumor technology codeveloped with Aduro Biotech Inc (BD: May 4, 2011; Apr 12, Jul 4, 2012).

Consegna said at that time that more than \$11 million had been spent on development with potential licencing in veterinary and human applications to treat tumors associated with ovarian, lung and pancreatic cancers.

Today, Consegna said that it decided not to proceed "based on the longer than expected development and commercialization timeframe, higher than expected required investment and weaker intellectual property position".

Consegna fell 0.1 cents or 8.3 percent to 0.2 cents with 12.1 million shares traded.

CONSEGNA

Consegna says its net operating cash burn for the three months to September 30, 2012 was \$777,000 with cash at the end of the quarter of \$207,000.

Consegna managing director Fabio Panutti told Biotech Daily that the company was involved in a \$5 million deal and had a \$6 million draw down equity facility with the New York-based Lind Partners.

PHARMAUST

Pharmaust says its net operating cash burn for the three months to September 30, 2012 was \$116,000 with cash at the end of the quarter of \$106,000.

Pharmaust director Sam Wright told Biotech Daily that the company had an underwritten \$1 million raising with Peloton Capital to be approved at the company's annual general meeting on November 7, 2012.

Pharmaust was untraded at 0.8 cents.

AUSBIOTECH, JANSSEN-CILAG

The 2012 Janssen company awards have been won by Starpharma and Vaxxas with the late Dr Andrew Baker honored as the recipient of the Industry Leadership award. sponsored by Johnson & Johnson's Janssen-Cilag the awards were presented in conjunction with the Ausbiotech conference, with Starpharma named Company of the Year and the Brisbane's Vaxxas the Emerging Company of the Year for its nano-patch. Ausbiotech said that Dr Baker was a 28-year veteran of the biotechnology and pharmaceutical industries and helped to found several listed Australian companies.

AUSBIOTECH, GLAXOSMITHKLINE

Queensland University of Technology's Connor O'Meara has won the \$7,000 Ausbiotech Glaxosmithkline Student Excellence Award for a vaccine for chlamydia trachomatis. Ausbiotech and Glaxosmithkline said that Mr O'Meara's vaccine "disarms the bad properties of the disease transforming it into common bacteria" and the grant would allow him to present his research at an international conference.

Ausbiotech and Glaxosmithkline said that there was no vaccine for chlamydia trachomatis and attempts have shown that excessive inflammation following vaccination could contribute to infertility rather than preventing it.

Mr O'Meara said his group's approach was to design vaccines "that elicit tolerance towards disease, despite the presence of an infection".

AUSBIOTECH

Ausbiotech says the appointment of Bristol-Myers Squibb Australia director of external affairs Michelle Burke as a director will bolster late-stage development and industry policy. Ausbiotech said that directors Dr Paul Walton and Dr Peter Isdale had retired at its annual general meeting at its Melbourne conference.

Ausbiotech said the board comprised chair Dr Deborah Rathjen, chief executive officer Dr Anna Lavelle, Dr Mark Harvey, Dr Meera Verma, Ms Michelle Burke, Peter Turvey and Dr Greg Roger.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Nov-11	Oct-12	Nov-12
Cochlear	3,333	3,846	4,056
CSL	15,151	23,243	23,883
Resmed	4,217	5,992	6,023
BDI-20			
Acrux	563	533	539
Alchemia	54	147	152
Benitec	19	14	15
Bionomics	143	140	115
Clinuvel	46	54	56
Genetic Technologies	63	51	55
Heartware	922	1,297	1,146
Impedimed	93	28	27
Mesoblast	2,299	1,934	1,641
Nanosonics	128	128	137
Neuren	32	32	50
Pharmaxis	298	339	397
Prima	192	197	133
Psivida	85	37	33
Reva	190	222	194
Sirtex	262	530	613
Starpharma	278	422	461
Sunshine Heart	48	72	59
Tissue Therapies	100	68	64
Universal Biosensors	143	142	146
Second 20			
Allied Health	26	19	20
Anteo	47	44	46
Antisense	10	29	20
Avita	24	34	39
Bioniche	80	41	47
Cellmid	7	9	9
Circadian	23	19	17
Compumedics	13	11	10
Ellex	11	14	16
Genera	10	11	12
GI Dynamics	260	182	172
Living Cell	22	19	18
Optiscan	10	15	17
Patrys	14	17	15
Phosphagenics	178	128	158
Phylogica	25	13	11
Prana	43	64	92
QRX Pharma	231	95	104
Uscom	8	10	9
Viralytics	27	20	34

^{*} 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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