Biotech Daily

Monday August 1, 2011

Daily news on ASX-listed biotechnology companies

*** JULY BDI-40 UP 4.5%; ASX200 DOWN 4.0%**
- YEAR TO JULY 31: BDI-40 UP 74.2%; ASX DOWN 1.5%

*** TODAY: ASX, BIOTECH UP:**
- PHARMAXIS UP 14%; PHOSPHAGENICS DOWN 8%

*** BIODIEM REGAINS 'FLU VACCINE RIGHTS, EXPANDS LICENCES**

*** CBIO MISSES PHASE IIa XTOLL RHEUMATOID ARTHRITIS ENDPOINT**

*** AVITA UNAUDITED REVENUE UP 19% TO $4.5m**

*** KARMELSONIX HAS ONE QUARTER CASH; FUNDS COMING**

*** BIONOMICS BNC105 CANCER TRIAL RESULTS TRADING HALT**

*** M&G GROUP TAKES 9% OF MESOBLAST**

MARKET REPORT

The Australian stock market rebounded 1.65 percent on Monday August 1, 2011 with the S&P ASX 200 up 73.2 points to 4497.8 points.

Sixteen of the Biotech Daily Top 40 stocks were up, six fell, 10 traded unchanged and eight were untraded. All three Big Caps were up.

Pharmaxis was the best, up 15 cents or 13.6 percent to $1.25 with 961,579 shares traded, followed by Living Cell up 8.3 percent to 6.5 cents with 85,000 shares traded.

Benitec climbed 7.4 percent; Prana was up 6.1 percent; Cellmid and Mesoblast were up more than four percent; Prima was up 3.85 percent; Anteo and Sunshine Heart rose more than two percent; with Acrux, Biota, Cochlear, CSL, Phylogica, QRX, Starpharma and Tissue Therapies up more than one percent.

Phosphagenics led the falls, down one cent or 7.7 percent to 12 cents, with 589,686 shares traded.

Optiscan lost five percent; Impedimed was down 3.1 percent; Genetic Technologies shed 2.7 percent; with Alchemia and Heartware down more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Expecting July to be a bad month for biotechnology, following the global trend, it was a surprise to see that the first six companies of the Biotech Daily Top 20 Index (BDI-20) were up.

Thirteen of the BDI-20 improved in July and seven fell, while the Second 20 saw seven rise and seven fall, giving the robust BDI-40 a total of 20 companies up, 14 down and six unchanged.

The Biotech Daily Top 40 Index (BDI-40) was up 4.5 percent for July compared to the S&P ASX200 down 4.0 percent (see charts below). The BDI-40 was up 74.2 percent for the year to July 31, 2011, compared to the ASX200 down 1.5 percent.

The deepest BDI-20 fall of $102 million by Heartware was compensated by Mesoblast's $129 million (5.3%) increase, but overall the BDI-20 was up $340 million or 5.2 percent.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) all fell, with CSL the worst, dragging the collective Big Cap total down 5.9 percent for the month and 12.2 percent for the year.

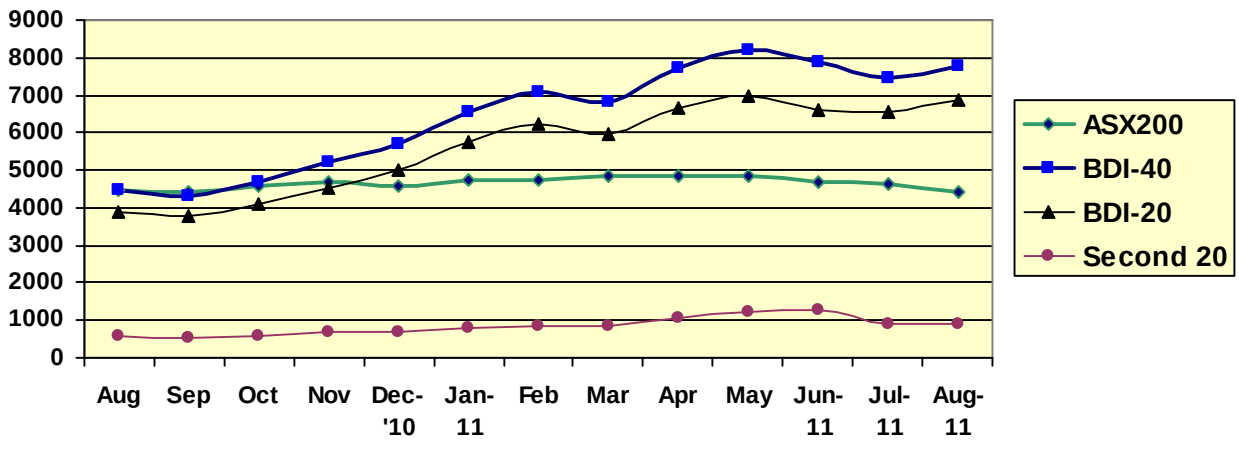
Optiscan was best from a low base, up 62.5 percent to $13 million, followed by the recovering Cathrx up 40 percent to $21 million, Pharmaxis up 30.7 percent to $251 million, Acrux continuing upward by 21.1 percent to $683 million, Bionomics (15.7%), Impedimed (14.6%) and Alchemia (9.95%).

Advanced Surgical led the falls, down 25 percent to $6 million, followed by Sunshine Heart down 23.5 percent to $39 million, Viralytics down 16.3 percent to $36 million, Prana (15.1%) and Heartware (10.3%).

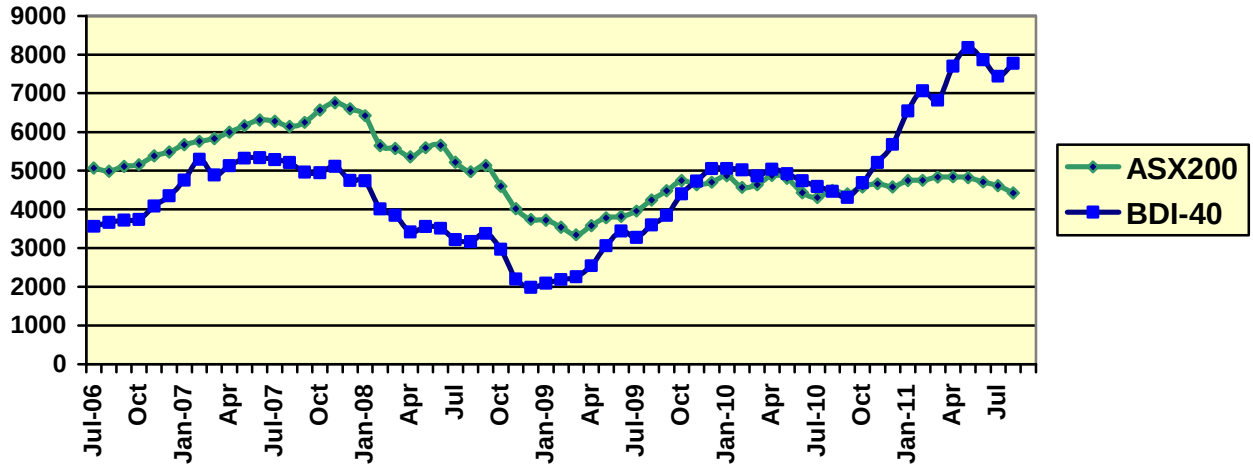
Outside the BDI-40, the post-merger Alllied Health was up 209.1 percent to $34 million, Neuren was up 66.7 percent to $15 million, while Reva fell 22 percent to $238 million.

Biotechs raised $24.4 million in July.

BDI-40 v ASX200 Jul 31, 2010 to Jul 31, 2011



BDI-40 v ASX200 Jun 30, 2006 to Jul 31, 2011



BIODIEM

Biodiem says regaining rights to its live attenuated influenza vaccine candidate has led to expanded licences with Serum Institute of India and the World Health Organisation.

Biodiem said that Nobilon International BV originally held the licence and was part of the Merck Sharp and Dohme group, which had returned the rights to the live attenuated influenza vaccine (LAIV) technology as part if its pipeline prioritization.

Biodiem said it would receive technical and clinical dossiers on the development of the vaccine from Nobilon, including data from the European phase I and II trials in seasonal influenza, and technical data relating to the cell-based manufacturing of the LAIV.

The company said it had regained world-wide licencing rights, excluding Russia and the Confederation of Independent States, for the LAIV vaccine vector project, a platform technology for vaccine design for infectious disease and cancer indications.

Biodiem chief executive officer Julie Phillips said the control provided “immediate significant advantages in terms of future out-licencing arrangements”.

Biodiem said that following the re-acquisition from Nobilon the licence arrangement with Serum Institute of India had been expanded and the Serum Institute would pay advance royalties of $US1 million, of which $US248,000 had been received.

Biodiem said the Serum Institute launched Nasovac last year in India and held an exclusive licence to the egg-based LAIV technology for the private market in India and a non-exclusive licence for the private markets in Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan and Sri Lanka.

Biodiem says it has licenced the influenza vaccine to the World Health Organization, contributing to the Global Pandemic Influenza Action Plan by supporting the transfer of production technology to developing country manufacturers.

The company said the agreement replaced the licence granted to the World Health Organisation by Nobilon in 2009.

Biodiem said the non-exclusive licence was designed to support wider distribution of the live attenuated influenza vaccine in developing countries.

Whereas public sector use was royalty-free, royalties would flow to Biodiem directly from private sector sales.

Ms Phillips said that Biodiem and its partner, the Institute of Experimental Medicine in Russia had further improved its relationship with the World Health Organisation.

Biodiem was up two cents or 25 percent to 10 cents.

CBIO

CBio says its 155-patient phase IIa safety and efficacy trial of XToll failed to meet its primary endpoint, but met secondary endpoints.

CBio said the trial of XToll or recombinant chaperonin 10 (Cpn10), a modified version of the naturally occurring protein chaperonin 10, in patients with moderate to severe rheumatoid arthritis despite treatment with methotrexate, was intended to be a proof-of-concept, rather than a dose-ranging, trial and the 75mg dose was 'sub-optimal'.

The company said the trial compared 25mg and 75 mg subcutaneous doses against placebo, with efficacy and safety assessed by the American College of Rheumatology (ACR) measure rheumatoid arthritis signs and symptoms improvement.

CBio said the primary endpoint was measured by the percentage of patients achieving an ACR20 response at week 12, that is, a 20 percent improvement in signs and symptoms.

The company said that the secondary endpoints included ACR50, ACR70 and ACR-N responses, swollen joint count, tender joint count, disease activity score and health assessment questionnaire measures at a range of time points.

CBio said that ACR20 mean values across the trial population were not statistically different between XToll and placebo patient groups, with mean values for the ACR20 at the end of week-12, 42 percent in patients receiving 75mg, 35 percent in patients receiving 25mg, and 30 percent for placebo.

CBio said the trial showed statistically significant or clinically meaningful improvement in secondary endpoints including the XToll 75mg patient group showing statistically significant improvement in ACR-N scores at weeks 8, 10 and 12 compared to placebo.

The company said that both XToll groups had a statistically significant decrease in swollen joint count at week-12 compared to placebo and the trial showed a statistically significant and clinically meaningful improvement in disease activity at week 12 in the 75mg patient group.

The company said tender joint counts and swollen joint counts were statistically significantly reduced at the week 12 primary endpoint.

CBio said that one distinct subset of patients, those with disease activity duration of more than 14 years, showed a statistically significant difference between 75mg XToll and placebo in ACR20 values at week 12.

The company said that the "findings indicate that XToll delivered subcutaneously demonstrates signs of clinical effect in patients with rheumatoid arthritis".

CBio said that patients who continued to receive XToll in the extension protocol continued to show signs of clinical response for up to 52 weeks.

The company said that patients on 75mg XToll had improved health assessment questionnaire scores and XToll demonstrated a strong safety profile:

CBio said that "overall XToll was safe and well-tolerated. Injection site reactions tended to be more common in the XToll patient groups compared to placebo" and the majority of injection site reactions were mild in intensity and did not require treatment.

The company said that the 75mg dose was sub-optimal and not equivalent to that achieved in the earlier intra-venous and the trial supported the need to use higher doses in a dose-ranging study in order to determine the optimal doses of drug.

Cbio executive chairman Stephen Jones said the results "indicate that we are seeing a real clinical effect".

"The signals at this time continue to point to a good safety profile," Mr Jones said. "It is the view of the board these results warrant the continued investigation of XToll".

Cbio managing director Jason Yeates said the next step was "a clinical trial to determine the optimal dose of XToll with subcutaneous administration".

CBio fell 39.5 cents or 58.1 percent to 28.5 cents with 3.6 million shares traded.

AVITA MEDICAL

Avita says its unaudited revenue for the year to June 30, 2011 is $4,472,194, 19 percent higher than the previous corresponding period.

Avita said that revenue from sales of its Recell spray-on skin wound treatment was up 61 percent compared to the previous year.

The company said that the Recell treatment, invented by Western Australia burns surgeon Dr Fiona Wood, continued to increase as a proportion of the company's income.

Avita chief executive officer Dr William Dolphin said that Recell sales "were very strong, not only year-to-year and quarter-over-quarter but also in consecutive quarters".

"Recell is a simple-to-use bedside kit that is now available to clinicians in Australia, Belgium, France, Germany, Italy, Portugal, Russia, the Middle East, the Netherlands and the United Kingdom," Dr Dolphin said.

"We are very proud of our financial results for fiscal 2011, but we strongly believe that we can do even better in fiscal 2012, continuing to grow the top line and improve the bottom line as we establish Avita and Recell as a market leader in the field of regenerative medicine," Dr Dolphin said.

Avita said that Recell had been used to treat more than 3,500 patients for burns, hypo- and hyper- pigmentation, such as vitiligo, acne scar revisions and aesthetic skin rejuvenation procedures such as wrinkle removal.

Avita was up one cent or eight percent to 13.5 cents.

KARMELSONIX

Karmelsonix says its net operating cash burn for the three months to June 30, 2011 was $1,284,000 with cash at the end of the quarter of $1,318,000.

Karmelsonix Asia Pacific managing director Paul Eisen told Biotech Daily that the company's extraordinary general meeting on August 10 would vote on the placement of 500 million shares at about 1.5 cents to raise about $7.5 million and the company was considering raising a further $3 million in the US (BD: Jul 13, 2011).

Karmelsonix was unchanged at 1.1 cents with 3.4 million shares traded.

BIONOMICS

Bionomics has requested a trading halt "pending the announcement of results from its BNC105 clinical trials".

Bionomics began trials of BNC105 for renal cell carcinoma and mesothelioma last year (BD: Jan 27, Mar 26, 2010; Jun 23, 2011).

Trading will resume on August 3, 2011 or on an earlier announcement.

Bionomics last traded at 64 cents.

MESOBLAST

M&G Investment Funds have increased their substantial holding in Mesoblast from 22,494,385 shares (8.04%) to 25,409,156 shares (9.06%).

Mesoblast was up 41 cents or 4.5 percent to $9.50.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Big Caps $Am	**Aug-10**	**Jul-11**	**Aug-11**
Cochlear	3,996	4,086	4,022
CSL	18,217	17,454	16,203
Resmed	5,594	4,436	4,220
BDI-20			
Acrux	313	564	683
Alchemia	103	117	136
Bionomics	102	191	221
Biota	177	173	175
Cellestis	267	306	362
Clinuvel	71	50	52
Genera	29	13	11
Heartware	976	994	892
Impedimed	86	89	102
Living Cell	65	22	20
Mesoblast	299	2,420	2,549
Nanosonics	133	176	177
Pharmaxis	497	192	251
Phylogica	18	29	28
Prima	68	262	261
Sirtex	280	273	284
Starpharma	127	372	383
Sunshine Heart	17	51	39
Tissue Therapies	26	97	95
Universal Biosensors	231	162	172
Second 20			
Advanced Surgical	18	8	6
Anteo	28	53	56
Antisense	10	8	8
Benitec	12	26	25
Bioniche	95	101	96
Cathrx	32	15	21
Cellmid	7	9	9
Circadian	27	26	27
Compumedics	19	13	13
Genetic Technologies	14	85	86
LBT Innovations	7	4	4
Optiscan	6	8	13
Patrys	19	22	21
Phosphagenics	70	103	107
Prana	33	53	45
Psivida	66	83	88
QRX Pharma	96	210	207
Uscom	14	11	11
Viralytics	18	43	36
Virax	12	4	4

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

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