Biotech Daily

Monday June 2, 2014

Daily news on ASX-listed biotechnology companies

*** MAY BDI-40 UP 1%, ASX200 UP 0.1%, BIG CAPS UP 2%**
- PRIMA UP 57%, ANALYTICA UP 42%, UNIVERSAL BIO DOWN 42%

*** TODAY: ASX, BIOTECH UP: CELLMID UP 13%, PRIMA DOWN 11%**

*** COCHLEAR'S RECALLED CI-512 RETURNS AS 'THINNEST IMPLANT'**

*** ATCOR WINS 1st CHINA SPHYGMOCOR ORDER**

*** PHASE I DATA BACKS CIRCADIAN VGX-100 FOR SOLID TUMORS**

*** ANTISENSE TAKES $1m MACQUARIE BRIDGING LOAN**

*** COGSTATE, MERCK CANADA CHANGE COGNIGRAM CONDITIONS**

*** ALLAN GRAY TAKES 14.5% OF STARPHARMA**

*** BENITEC O-T-C TRADES APPROVED IN US**

MARKET REPORT

The Australian stock market was up 0.47 percent on Monday June 2, 2014 with the S&P ASX 200 up 26.0 points to 5,518.5 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and five were untraded. All three Big Caps were up.

Cellmid was the best, up 0.3 cents or 13.0 percent to 2.6 cents with 4.8 million shares traded.

Analytica climbed 9.5 percent; Antisense was up 6.9 percent; Admedus, Circadian and Oncosil were up more than four percent; Clinuvel, Mesoblast and Patrys climbed more than three percent; Cochlear, Nanosonics, Phosphagenics, Prana and Starpharma rose more than one percent; with CSL, GI Dynamics and Resmed up by less than one percent.

Prima led the falls, down 0.6 cents or 11.1 percent to 4.8 cents with 41.4 million shares traded.

Living Cell and Universal Biosensors lost more than nine percent; Optiscan was down 8.6 percent; Avita fell 4.35 percent; Benitec and Bionomics fell more than three percent; Anteo and Neuren shed more than two percent; Alchemia, Medical Developments and Pharmaxis were down more than one percent; with Sirtex down 0.1 percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top-40 Index (BDI-40) improved slightly in May, with a recovery by Prima and improvements by Sirtex, Mesoblast and Analytica compensating for an almost inexplicable fall by Universal Biosensors (BD: May 12, 2014).

Fourteen BDI-40 companies were up, 19 fell and seven were unchanged in May, with the BDI-40 up 1.1 percent compared to the S&P ASX200 up 0.07 percent.

The three Big Caps (which are not included in the BDI-40) were up a cumulative 2.2 percent in May and up 8.3 percent for the year to May 31, 2014, with CSL up 3.0 percent in May to $33,888 million, Cochlear up 2.4 percent to $3,428 million, while Resmed retreated 1.6 percent to $7,548 million.

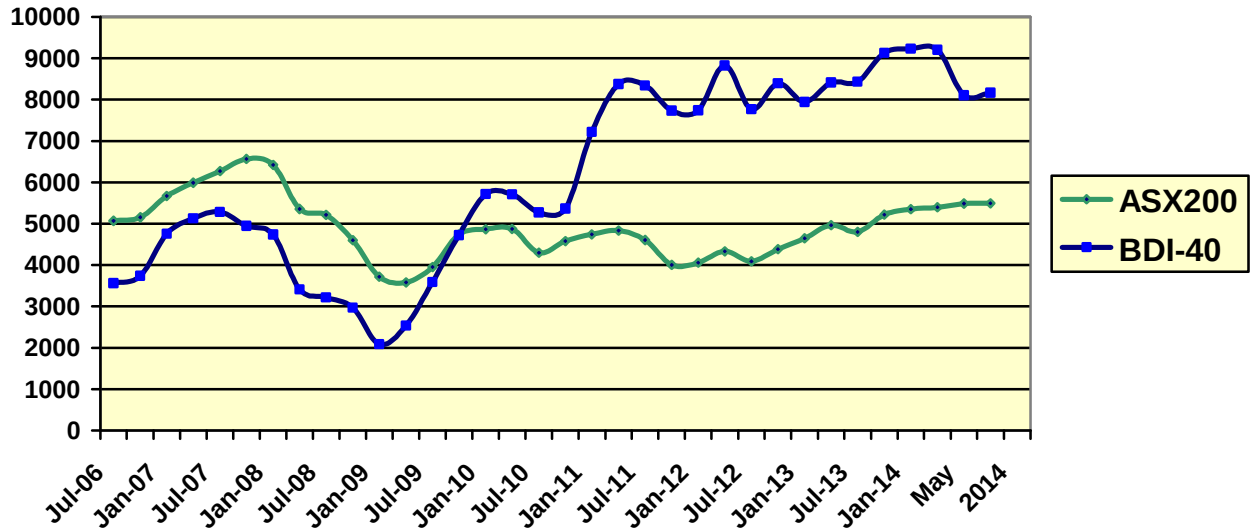
For the year to May 31, the ASX200 was up 11.5 percent, but the BDI-40 was down 25.2 percent, with the deepest falls including Acrux down $478 million or 76.7 percent to $145 million, Universal Biosensors down 68.3 percent to $38 million, Genetic Technologies down 52 percent to $24 million and Mesoblast down $427 million to $1,544 million.

In the month to May 31, Psivida was the best, recovering 56.8 percent to $69 million. Analytica was up 41.7 percent to $34 million, followed by Circadian rising 22.2 percent from a low base to $11 million, Anteo and Prana both up 20 percent to $204 million and $108 million, respectively, Benitec (16.9%), Clinuvel (16.1%) and GI Dynamics (11.8%).

Universal Biosensors had the deepest fall, down 42.4 percent to $38 million, followed by Genetic Technologies down 29.4 percent, Optiscan (25.0%), Neuren (20.1%), Cellmid (19.0%), Pharmaxis (16.7%), Acrux (15.7%), Admedus (14.6%) and Bionomics (13.8%).

Outside the BDI-40, LBT and Resonance are making a slow but consistent recovery, along with renewed performances by Suda and Nusep. On the Nasdaq, Biota fell a further 27.3 percent to $101 million, Heartware climbed 6.1 percent to $1,646 million and Sunshine Heart lost 6.7 percent to $98 million.

BDI-40 v ASX200 Jun 30, 2006 to May 31, 2014 - Adjusted



COCHLEAR

Cochlear says its Nucleus Profile with the previously recalled CI-512 electrode will be launched in Europe this month.

Cochlear said the Nucleus Profile implant with the Contour Advance electrode (CI-512) was the first in the Profile series, which had "the thinnest implant body on the market" and would be the platform for the company's next generation of implants.

The company said that the Profile with Contour Advance electrode was based on the Cochlear Implant (CI) 500 series of implants and had been approved by the European notified body TÜV Rheinland following extensive work to relocate and build a new production process at its Macquarie University facility in Sydney.

In 2011, the CI-512 was the subject of a recall with Cochlear provisioning $138.8 million for the recall and identifying the cause as a loss of hermeticity from unexpected variations in the brazing process during manufacturing (BD: Sep 12, 2011; Jan 22, Feb 7, 2012).

Cochlear said that the launch would expand "the industry's largest cochlear implant portfolio and supports a wider range of surgical techniques among implanting surgeons, giving them and their patients the greatest possible choice".

The company said that other electrodes would be introduced to the series.

Cochlear chief executive officer Dr Chris Roberts told Biotech Daily that the CI-512 was the first in the Nucleus Profile and Contour Advance range and had already been approved in China, Singapore and Thailand.

Dr Roberts said that the company would launch the new range at three European meetings including the European Society of Pediatric Otorhinolaryngology congress in Dublin, Ireland from May 31 to June 3, 2014 and the Conference on Cochlear Implants and Other Implantable Auditory Technologies, in Munich, Germany, June 18-21, 2014.

Dr Roberts said the company was currently involved in the US Food and Drug Administration re-approval process for the CI-512 and approval for the Profile and Contour Advance range.

Cochlear said that the Profile with Contour Advance electrode would be launched in other jurisdictions as regulatory approvals were received.

Cochlear climbed $1.63 or 2.7 percent to $61.50 with 420,150 shares traded.

ATCOR MEDICAL

Atcor says it has received its first order for its non-invasive Sphygmocor XCel central blood pressure measure from its Chinese distributor, Angy (China) Medical.

Atcor said that the initial order for 11 Sphygmocor systems, followed the launch at the China International Medical Equipment Fair in Shenzhen in April 2014.

The company said that the conference was the second largest medical equipment conference in the world, attended by more than 20,000 delegates and 2,800 exhibitors

Atcro chief executive officer Duncan Ross said the company was "delighted that Angy Medical has capitalized on the introduction of Sphygmocor XCel to China with this sale, which follows closely the product's clearance through the Chinese regulatory process".

"It establishes a beachhead for Atcor in the Chinese market where awareness of hypertension is growing," Mr Ross said.

Atcor said that clinical evidence that central blood pressure measurement, as measured by the Sphygmocor system, was a stronger predictor of cardiovascular events had been established and Sphygmocor XCel helped detect cardiovascular diseases earlier, optimized medication for patients with hypertension and provided the most sophisticated software for central blood pressure management.

Atcor was unchanged at 11.5 cents with 2.1 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian says a presentation on its phase I safety and clinical activity data shows an encouraging clinical profile for VGX-100 in patients with advanced solid tumors

The presentation, entitled 'A phase Ib study of combined angiogenesis blockade with nesvacumab, a selective monoclonal antibody (MAb) to angiopoietin-2 (Ang2) and ziv-aflibercept in patients with advanced solid malignancies' was presented over the weekend at the American Society of Clinical Oncology meeting in Chicago and concluded that "VGX-100 alone and in combination with bevacizumab was well tolerated".

The presentation concluded that pharmoco-kinetic data supported weekly dosing and "further clinical evaluation of VGX-100 in combination with chemotherapy and other targeted agents is warranted".

The abstract is at: http://abstracts.asco.org/144/AbstView_144_131977.html.

Circadian said that the 43-patient, phase Ia/Ib dose-escalation study of VGX-100 alone or in combination with bevacizimab (Avastin) was conducted under a US Food and Drug Administration investigational new drug application at the University of Texas MD Anderson Cancer Center in Houston and the University of California, Los Angeles haematology and oncology centre in Santa Monica.

Circadian said that VGX-100 targetted vascular endothelial growth factor C (VEGF-C).

The company said that MD Anderson Cancer Center professor and one of the principal investigators Prof Gerald Falchook presented the data which demonstrated that weekly intravenous administration of VGX-100 was well tolerated at all of the doses studied alone or in combination with bevacizumab.

Circadian said the study provided the first evidence of anti-tumor activity in patients with refractory or recurrent advanced late stage solid tumors without available therapeutic options.

The company said that a best response of stable disease was seen in 14 of 39 evaluable subjects (36%) of which five patients (13%) showed durable stable disease for a period of 16 weeks or more, in colon, ovarian, cervical tumors and renal cell carcinoma.

Circadian said that a patient with triple negative breast cancer had a 16 percent decrease in tumor disease at all sites (bone, lung, lymph nodes and skin) after eight weeks, or two treatment cycles, with weekly VGX-100 at a dose of 2.5mg/kg with 10mg/kg bevacizumab given every two weeks, before discontinuing the study in cycle 3.

The company said that the most common side effects observed were fatigue, rash, nausea and hypertension which were manageable.

Circadian said that the only dose limiting toxicity was a transient grade 3 hypertension observed in one subject at the lowest dose combination.

Prof Falchook said that resistance and tumor escape to currently available anti-cancer drugs such as bevacizumab was "a major challenge in the treatment of cancer patients".

"These results with the investigational drug VGX-100 which targets VEGF-C are encouraging, with early evidence of anti-tumor activity in patients who failed to respond to standard treatment," Prof Falchook said.

"In addition, the observed safety profile of VGX-100 alone or in combination with bevacizumab is promising and warrants further clinical evaluation," Prof Falchook said.

Circadian said Avastin was approved for a number of solid tumor indications and had sales of more than $US6 billion a year but was limited by tumor escape and relapse, possibly caused by up-regulation of alternate pro-angiogenic factors including vascular endothelial growth factor C and VGX-100 was a fully human monoclonal antibody that selectively inhibited VEGF-C, part of the VEGF family of secreted growth factors that were mediators of tumor related angiogenesis, lymphangiogenesis and vascular permeability.

Circadian was up one cent or 4.55 percent to 23 cents.

ANTISENSE THERAPEUTICS

Antisense says it has $1 million funding facility with Macquarie Bank to access capital ahead of its expected $1.2 million Federal Government R&D Tax incentive payment.
Antisense said that the non-dilutive secured facility was repayable by November 30, 2014 and the company expected to have sufficient capital for its operations into 2015.
The company said it expected to receive the Federal Government R&D Tax incentive payment before the repayment time.
Antisense said it expected to report results from both its phase II clinical trial of ATL1103 and its stem cell mobilization proof of concept study of ATL1102 and the facility would be used to help fund activities associated with the proposed pre-investigational new drug application meeting with the US Food and Drug Administration to assess the design of a phase IIb multiple sclerosis trial of ATL1102 and to continue its partnering plans for both ATL1102 and ATL1103.
Antisense was up one cent or 6.9 percent to 15.5 cents.

COGSTATE

Cogstate says it contract with Merck Canada Inc has been amended returning “full rights of promotion of Cognigram in Canada, including direct liaison with physicians”.
Cogstate said that Merck Canada would continue to provide support for electronic marketing and reimbursement efforts for Cognigram in Canada until March 1, 2015 and Cogstate would retain 100 percent of the revenue from any test sold and also take on all costs associated with the marketing and sales of the product.
Last year, Cogstate said that Merck Canada had exclusive rights to market and promote Cognigram in Canada and was responsible for marketing and promoting Cognigram to physicians and providing information for patients and described the deal as “a momentous event for Cogstate” (BD: Mar 6, 2014)
Today. Cogstate said that Cognigram was scientifically validated computerized tool used by doctors to detect early stages of cognitive decline associated with neurodegenerative diseases such as Alzheimer’s disease.
Cogstate chief executive officer Brad O’Connor said the revised agreement “allows us the opportunity to evolve the Cognigram business model in Canada”.
Cogstate was untraded at 24 cents.

STARPHARMA

Allan Gray Australia has increased its holding in Starpharma from 38,225,289 shares (13.43%) to 41,319,032 shares (14.50%).
Allan Gray said that it bought the 3,093,743 shares between February 19 and May 28, 2014 for $2,127,984 or an average price of 68.8 cents a share.
Starpharma was up 1.5 cents or 2.5 percent to 61.5 cents.

BENITEC BIOPHARMA

Benitec says its level 1 American depositary receipt (ADR) facility, trading over-the-counter in the US under the ticker code of BTEBY was approved on May 30, 2014.
Benitec said the Bank of New York Mellon was the authorized representative and depositary bank for the facility and existing US holders of the previous BNIKF shares could transition to the sponsored program without issuance fees for a limited period.
Benitec fell four cents or 3.3 percent to $1.16.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company $Am	Jun-13	May-14	Jun-14
Cochlear	3,762	3,349	3,428
CSL	29,690	32,892	33,888
Resmed	7,984	7,674	7,548
BDI-20			
Acrux	623	172	145
Alchemia	117	172	162
Admedus	41	157	134
Benitec	17	118	138
Bionomics	162	196	169
Biotron	23	22	21
Clinuvel	75	56	65
GI Dynamics	184	212	237
Impedimed	14	44	48
Mesoblast	1,971	1,497	1,544
Nanosonics	135	214	203
Neuren	68	134	107
Osprey	40	62	62
Pharmaxis	56	24	20
Prima	80	44	69
Psivida	79	117	114
Sirtex	600	883	960
Tissue Therapies	27	78	76
Universal Biosensors	120	66	38
Viralytics	24	53	55
Second 20			
Analytica	12	24	34
Anteo	46	170	204
Antisense	14	19	21
Atcor	11	18	17
Avita	34	39	34
Cellmid	18	21	17
Circadian	15	9	11
Compumedics	7	18	18
Ellex	17	34	34
Genetic Technologies	50	34	24
IDT	12	20	18
Living Cell	16	20	20
Medical Developments	67	72	72
Oncosil	8	35	39
Optiscan	12	8	6
Patrys	13	24	24
Phosphagenics	138	94	93
Prana	88	90	108
Starpharma	244	202	188
Uscom	13	21	21

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