Biotech Daily

Monday June 1, 2015

Daily news on ASX-listed biotechnology companies

*** SOLID GAINS PUSH BDI-40 UP 13%; ASX200 DOWN 1%, BIG CAPS UP 0.3%**

- PRIMA UP 488%, PHARMAXIS 56%; ANALYTICA DOWN 47%

*** TODAY: ASX, BIOTECH DOWN: PRANA UP 39%, TISSUE THERA DOWN 26%**

*** SIRTEX: 'SIR-SPHERES WITH CHEMO REDUCES LIVER TUMORS'**

*** TISSUE THERAPIES: 'UP TO 2 YEARS TO EU VITROGRO APPROVAL'**

*** EMA ORPHAN STATUS FOR PRANA'S PBT2 FOR HUNTINGTON'S**

*** GENETIC TECHNOLOGIES: 'NEJM BACKS TESTS LIKE BREVAGENPLUS'**

*** US FDA EXPANDS DORSAVI VIMOVE LABEL**

*** SUN EGM FOR DIMERIX BACKDOOR LISTING FOR KIDNEY DISEASE**

*** SANDON CAPITAL TAKES 13% OF ALCHEMIA**

*** IM MEDICAL TO RAISE UP TO $750k**

*** CRAIG CHAPMAN, ADAM GALLAGHER REPLACE AGENIX NICK WESTON**

MARKET REPORT

The Australian stock market fell 0.72 percent on Monday June 1, 2015 with the S&P ASX 200 down 41.8 points to 5,735.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and four were untraded.

Prana was the best, up seven cents or 38.9 percent to 25 cents with 2.7 million shares traded, followed by Sirtex up 14.4 percent to $30.52, Oncosil up 14.3 percent to 12 cents, and Viralytics up 12.7 percent to 62 cents. Both GI Dynamics and IDT climbed 11.1 percent; Avita rose 5.3 percent; Universal Biosensors was up 3.2 percent; Acrux climbed 2.25 percent; with Admedus and Benitec up more than one percent.

Tissue Therapies led the falls, down 1.7 cents or 26.15 percent to 4.8 cents with 4.7 million shares traded, followed by Genetic Technologies down 16.3 percent to 3.6 cents and Optiscan down 12.1 percent to 5.1 cents. Analytica lost 9.1 percent; Patrys fell 8.3 percent; Prima shed 6.7 percent; Antisense, Cellmid and Impedimed fell more than four percent; Mesoblast and Neuren shed more than two percent; with Bionomics, Clinuvel, Cochlear and Starpharma down more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Due to technical issues at data provider Iress, May's Biotech Daily Top-40 Index (BDI-40) closed on Thursday May 28, rather than the last trading day of the month. We hope Iress is able to repair its system before we report the 10-year data at the end of June.

That said, May was good to the BDI-40 which rose a further 12.8 percent, while the S&P ASX200 eased 1.3 percent and the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) edged up a collective 0.3 percent. Cochlear rose 4.6 percent to $4,995 million, CSL climbed 1.4 percent to $43,171 million, but Resmed lost 5.8 percent to $10,677 million.

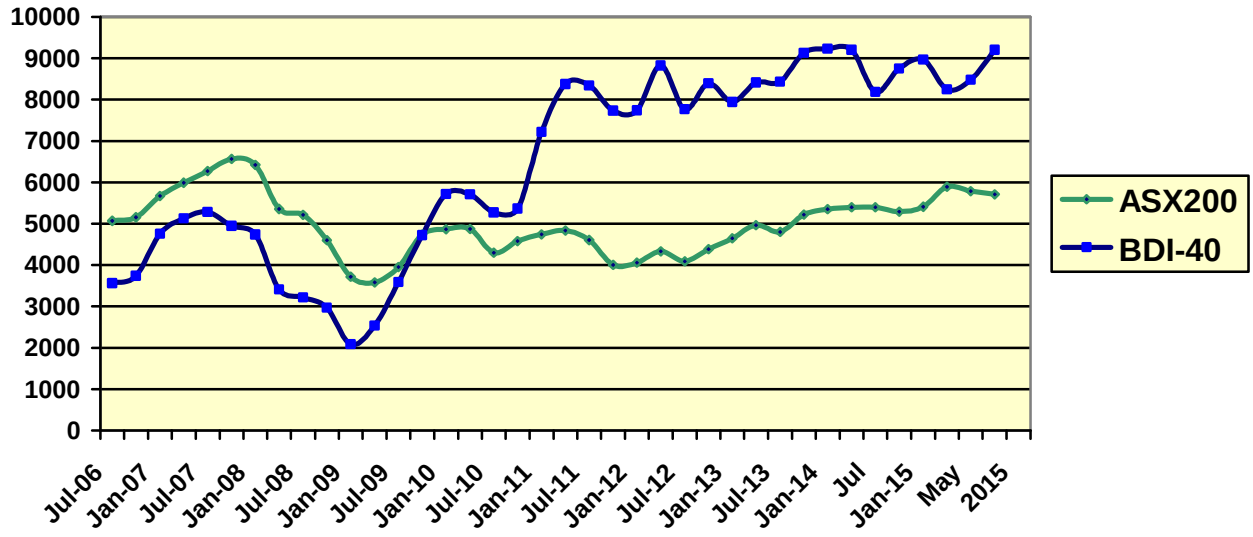
The BDI-40 saw some very strong gains with six companies up by more than 20 percent, 10 by more than 10 percent and only five companies falling more than 10 percent. Sirtex, Prima and Mesoblast added $565 million of the $726 million increase in the BDI-40.

Prima was outstanding on the back of a raft of announcements, including the Ridgeback $15 million placement, up 487.5 percent from $32 million to $188 million, followed by Pharmaxis up 56.25 percent to $75 million, Starpharma (34.6%), Viralytics (26.25%), Sirtex (25.6.1%), Medical Developments (23.9%), Optiscan (18.2%), Compumedics (15.8%), Universal Biosensors (15.2%) and Prana (14.9%).

Analytica had the deepest fall, down $9 million or 47.4 percent to $10 million, followed by Tissue Therapies (33.3%), IDT (20.0%), Anteo (12.5%) and Neuren (12.3%).

Outside the BDI-40, Novogen continued to strengthen on pre-clinical data up 11 percent for the month to $111 million and 326.9 percent above its market capitalization 12 months ago. At $63 million Cynata was 293.75 percent above May 31, 2014 with Cyclopharm up 200 percent for the year and Pro Medicus up 169.4 for the 12 months to $229 million. On the Nasdaq, the three former Australian companies were virtually unchanged, with Biota at $101 million, Heartware up $11 million to $1,663 million and Sunshine Heart up $3 million to $105 million.

BDI-40 v ASX200 Jun 30, 2006 to May 28, 2015 - Adjusted



SIRTEX MEDICAL

Sirtex says that despite its 530-patient Sirflox trial missing its primary endpoint, the trial shows that SIR-Spheres significantly increased liver tumor progression-free survival.

In a teleconference following a presentation overnight at the American Society of Clinical Oncology meeting in Chicago, Illinois, Sirtex restated the previously released data that SIR-Spheres with the oxaliplatin, leucovorin and 5- fluorouracil (Folfox) regime did not show any significant difference for the primary endpoint of progression-free survival at any site, but did show a statistically significant difference of 7.9 months benefit for progression-free survival in the liver.

In a telephone call after the teleconference, Sirtex chief medical officer Dr David Cade told Biotech Daily that the data showed that selective internal radiation therapy (SIRT) and chemotherapy had “a profound capacity to control the hepatic disease”.

“While we haven’t confirmed this yet, but because the majority of patients dying of metastatic colorectal cancer die because of liver failure, if we can control that disease in the liver for substantially longer, we logically should have a positive impact on patients’ survival duration,” Dr Cade said.

“We eagerly anticipate the overall survival data due in 2017,” Dr Cade said.

In the teleconference, Dr Cade summarized the ASCO presentation by co-principal investigator and Royal Melbourne Hospital oncologist Prof Peter Gibbs as well as the subsequent discussion and comments by key opinion leaders.

Dr Cade said that liver damage related to SIR-Spheres was expected and acceptable and could be managed by physicians.

Dr Cade said that patients with metastatic colorectal cancer often died from liver failure and the data showed the SIR-Spheres increased progression-free survival in the liver from a median of 12.6 months for the chemotherapy-alone arm to a median of 20.5 months for patients receiving the Folfox chemotherapy with SIR-Spheres ($p = 0.002$).

Asked why the company had not released the top-line data from the 60 percent of patients with only liver metastases, which could provide greater definition, Dr Cade said that data would be in a publication by the end of 2015 and would be presented to one of the professional body meetings.

Dr Cade said that the definitive evidence of overall survival data would not be compiled until two continuing trials, Foxfire and Foxfire Global, were completed, providing a data set of 1,103 patients and expected in mid-2017.

In a media release with the teleconference Sirtex said it expected increased use of SIR-Sphere in the first-line setting would “gain momentum over time”.

The company said that the Sirflox study was the first to provide “level one” evidence to show a liver-directed therapy in combination with systemic chemotherapy and a biologic agent produced a clinically meaningful and significant effect in the liver and consequently, “incorporation into clinical practice beyond the current salvage setting in [metastatic colorectal cancer] is now a realistic possibility with continued education of the results to the medical oncology community”.

Prof Gibbs said that the finding was important “because the liver is almost invariably the organ where colorectal cancer spreads to first”.

“While half the patients initially diagnosed with colorectal cancer survive thanks to surgical removal of the primary tumor before the disease has spread elsewhere in the body, liver metastases eventually cause the death of the majority of the remaining hundreds of thousands of patients each year whose tumors spread but are inoperable,” Prof Gibbs said.

Sirtex climbed $3.84 or 14.4 percent to $30.52 with 813,166 shares traded.

TISSUE THERAPIES

Tissue Therapies says it will need to conduct new pre-clinical and clinical trials of its Vitrogro ECM wound treatment for European approval.

Tissue Therapies said that the European Medicines Agency's scientific advice working party (SAWP) accepted its revised plan for Vitrogro ECM.

The company said that there would be "further delay, cost and clinical risk, given the company will need to conduct an additional clinical trial" and greater detail on the planned studies would be posted on its website: www.tissuetherapies.com.

Tissue Therapies acting chief executive officer Nigel Johnson said the company could not satisfy the UK Committee for Medicinal Products for Human Use remaining two major objections with respect to safety and the utility of the Insulin-like Growth Factor-1 (IGF-1) component with the existing evidence and trial data.

"The proposed plan is an efficient and cost effective approach that balances risk and speed in addressing the regulatory requirements," Mr Johnson said.

Tissue Therapies said that the EMA advised that as the previous open-label study revealed no severe safety concerns, the additional data from the proposed double-blind, randomized, controlled trial, should be acceptable under the Medical Device Directive in conjunction with planned post marketing surveillance.

The company said that if the trial was positive it would apply to the EMA through the notified body again and proceed through the 210 day consultation process, and the studies would support a US Food and Drug Administration application.

The company said the pre-clinical work would take about five months, to be followed by a clinical trial, primarily in Europe, expected to take 12 to 18 months, subject to patient recruitment and interim analysis.

Tissue Therapies said it had restructured its operational arrangements to conserve working capital and focus its activities on achieving approval in Europe, but "further funds will be required to fully execute the aforementioned activities necessary for approval".

The company said that "given the regulatory demands and being mindful of the need to minimize dilution, [it] is considering strategic options including partnering or other arrangements".

Tissue Therapies fell 1.7 cents or 26.15 percent to 4.8 cents with 4.7 million shares traded.

PRANA BIOTECHNOLOGY

Prana says the European Medicines Agency has approved orphan designation of PBT2 for Huntington's disease (BD: Apr 28, 2015.

Last year, Prana said that PBT2 had met its primary end point of safety and tolerability, and a secondary endpoint of improved measures of cognitive performance in its 109-patient phase II trial in Huntington's disease and the US Food and Drug Administration had granted PBT2 orphan drug status for the indication (BD: Feb 18, Sep 5, 2014).

Prana climbed seven cents or 38.9 percent to 25 cents with 2.7 million shares traded.

ALCHEMIA

The Sydney-based Sandon Capital says it has increased its substantial holding in Alchemia from 32,632,484 shares (10.0%) to 42,932,484 shares (13.2%).

Sandon said it bought the 10,300,000 shares on-market, on May 29, 2015 for $408,961 or an average price of 3.97 cents a share.

Alchemia was unchanged at four cents with 9.1 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says that a May 27, 2015 New England Journal of Medicine special report backs tests like its Brevagenplus diagnostic for breast cancer.
Genetic Technologies said the report, entitled 'Gene-Panel Sequencing and the Prediction of Breast Cancer Risk' distinguished between single nucleotide polymorphisms (SNPs) and gene-panel tests conducted through sequencing'.
The article is at: http://www.nejm.org/doi/pdf/10.1056/NEJMsr1501341.
The company said that its Brevagenplus was a clinically validated, genetically-based predictive risk test for sporadic, or non-hereditary, breast cancer.
Genetic Technologies scientific director Dr Richard Allman said that "while the Brevagenplus test does not evaluate gene-panel sequencing or hereditary cancer testing, we welcome the findings of the authors which reinforce the message that adequate validation is required for cancer risk assessment tests".
The company said that Brevagenplus evaluated a panel of SNPs known to be associated with sporadic breast cancer combined with an established risk prediction algorithm to provide a more accurate risk assessment.
Genetic Technologies said that the value of using SNPs as genetic markers for risk was "receiving increasing attention in the medical literature and the value of adding SNPs to a risk prediction algorithm has been independently confirmed".
Genetic Technologies fell 0.7 cents or 16.3 percent to 3.6 cents with 5.7 million shares traded.

DORSAVI

Dorsavi says the US Food and Drug Administration has provided an expanded 510(k) clearance for its Vimove wearable sensor diagnostic system.
Dorsavi said that the expanded functionality and labeling was "significant because for the first time in the US it permits the use of Vimove to display lower back and pelvic range of motion from healthy patients [or] normative data".
The company said that clinicians and patients would be able to compare how their movements tracked against a normal population based on their age group and help guide therapy decisions and rehabilitation accordingly.
Dorsavi said that the expanded labeling permitted it to record, assess and report on additional static postures including natural standing posture and various sitting postures.
The company said that the inclusion of the pelvic movement data allowed clinicians to independently isolate lumbar spine and pelvic movements.
Dorsavi fell half a cent or 1.8 percent to 27 cents.

DIMERIX BIOSCIENCE, SUN BIOMEDICAL

Sun Biomedical says shareholders will vote on the acquisition of Dimerix Bioscience.
In May, Sun said it would acquire Dimerix for 750,000,041 Sun shares and had placed 160,000,000 shares at one cent each to raise $1.6 million to clients of Forrest Capital, part subject to approvals (BD: May 13, 2015).
The Melbourne-based Dimerix currently has a phase II study of its combination therapy DMX200 for chronic kidney disease (BD: Jun 4, Sep 29, Nov 25, 2014).
Sun proposed a raft of nine resolutions relating to the acquisition.
The meeting will be held at Level 2, 1 Walker Avenue, West Perth, Western Australia on June 30, 2015 at 10.30am (AWST).
Sun was unchanged at 1.0 cents. Dimerix a public unlisted company

IM MEDICAL

IM Medical says Patersons Securities has underwritten a share purchase plan at 0.05 cents a share to raise $550,000 and will separately place shares to raise up to $200,000.
Last month IM Medical said its attempt to acquire data centre service provider Syncom Australia through a reverse takeover failed (BD: Jan 18, May 22, 2015).
Today, the company said that the proceeds would be used to repay December 2014 convertible loans entered into for investment acquisition opportunities and for working capital.
IM Medical said that the share plan and placement were subject to shareholder approval, and would be undertaken through a prospectus and it intended to seek shareholder approval for a one-for-two share consolidation.
The company said the record date was May 29, 2015, and the share plan would close on July 15, 2015.
IM Medical said that share plan investors would receive on free attaching option for every four shares acquired, exercisable at 0.1 cents a share by March 31, 2019.
IM was unchanged at 0.1 cents.

AGENIX

Agenix says that Nicholas Weston has resigned as executive chairman and as a director effective from today.
Mr Weston joined Agenix in August 2008, became chairman in September 2008 and executive chairman in January 2010.
In 2008, Agenix had failed to commercialize its Thromboview pulmonary embolism and deep vein thrombosis diagnostic technology, had entered into a complicated arrangement with a Chinese company to develop a hepatitis B drug and its former chief executive officer Neil Leggett was facing charges of having stolen about $4 million from the company and was subsequently gaoled (BD: Jun 13, 2008; Feb 18, 2010).
In 2010, under the chairmanship of Mr Weston, a commercial and intellectual property lawyer, Agenix recovered more than $900,000 from Mr Leggett's legacy assets, in 2014 Agenix sold AGX-1009 for hepatitis B for $2,056,729 and in March the company resolved the OKS dispute over Thromboview (BD: Sep 20, 2010; Aug 11, 2014; Mar 13, 2015).
Today, the company said that Mr Weston would remain a director of the group's wholly-owned China subsidiary, Agenix Biopharmaceutical (Shanghai) Co to complete the repatriation of funds from China.
The company said the board thanked Mr Weston "for his tireless efforts and dedication in is his role as executive chair".
Agenix said that Mr Weston would continue to assist the company "as a trusted and respected legal advisor".
The company said that Craig Chapman had been appointed as a non-executive chairman and Adam Gallagher had been appointed as a non-executive director.
Agenix said that Mr Gallagher was a director of Scintilla Strategic Investments a major shareholder of the company and was a director and company secretary of Pacific Environment.
The company said that Mr Gallagher held a Masters of Commerce from the University of Queensland and a Bachelor of Economics degree.
Agenix was unchanged at 1.5 cents with two shares traded.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION AT MAY 28, 2015

Company $Am	Jun-14	May 15	Jun-15
Cochlear	3,428	4,774	4,995
CSL	33,888	42,553	43,161
Resmed	7,548	11,329	10,677
BDI-20			
Acrux	145	148	148
Admedus	134	140	127
Benitec	138	90	95
Bionomics	169	171	167
Biotron	21	32	32
Circadian	11	23	22
Clinuvel	65	125	141
GI Dynamics	237	71	69
Impedimed	48	248	279
Mesoblast	1,544	1,223	1,325
Nanosonics	203	461	499
Neuren	107	163	143
Osprey	62	106	102
Pharmaxis	20	48	75
Prima	69	32	188
Psivida	114	147	147
Sirtex	960	1,201	1,508
Tissue Therapies	76	30	20
Universal Biosensors	38	46	53
Viralytics	55	80	101
Second 20			
Actinogen	4	49	48
Analytica	34	19	10
Anteo	204	80	70
Antisense	21	23	22
Atcor	17	41	39
Avita	34	32	33
Cellmid	17	20	18
Compumedics	18	38	44
Ellex	34	37	36
Genetic Technologies	24	65	63
IDT	18	55	44
Living Cell	20	23	25
Medical Developments	72	109	135
Oncosil	39	37	39
Optiscan	6	11	13
Patrys	24	8	8
Prana	108	74	85
Reva	50	175	170
Starpharma	188	185	249
Uscom	21	17	17

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Admedus, Benitec, Biota, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in a range of other biotechnology companies: **http://www.australianethical.com.au/who-we-invest-in**. These holdings are liable to change.

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