



Biotech Daily

Monday March 1, 2010

Daily news on ASX-listed biotechnology companies

- * FEBRUARY BDI-40 FALLS; RETAINS LEAD OVER S&P ASX200
- * TODAY: ASX UP, BIOTECH DOWN: CLINUVEL UP 6%; AVEXA DOWN 15%
- * TIBOTEC DROPS AVEXA HIV INTEGRASE OPTION
- * FEDERAL GOVERNMENT CALLS FOR INNOVATION FUND APPLICATIONS
- * SIRTEX, OXFORD TRIAL SIR-SPHERES FOR BOWEL CANCER
- * CENTRAL, EASTERN EUROPE ETHICS APPROVAL FOR CBIO TRIAL
- * CALZADA INVESTIGATES FAT DRUG CHINA PIRACY CLAIMS
- * MORGAN STANLEY CEASES SUBSTANTIAL IN PRANA
- * STIRLING REQUESTS ACQUISITION TRADING HALT
- * SAFETY MEDICAL SUSPENDED FOR ABSENT ACCOUNTS
- * VIRAX APPOINTS BROKER, INVESTOR TIM COOPER AS DIRECTOR
- * SOLAGRAN SAYS H1 'OWED' SALES TAKES REVENUE UP 242% TO \$1m

MARKET REPORT

The Australian stock market climbed 1.05 percent on Monday March 1, 2010 with the S&P ASX 200 up 48.8 points to 4686.5 points. Eight of the Biotech Daily Top 40 stocks were up, 14 fell, 12 traded unchanged and six were untraded.

Clinuvel was best, up 1.5 cents or 5.8 percent to 27.5 cents with 253,978 shares traded followed by Patrys up half a cent or 3.6 percent to 14.5 cents. Cellestis, Cochlear, Phosphagenics and Starpharma rose more than two percent; with Bionomics, Biota, CSL and Optiscan up more than one percent.

Avexa led the falls, down two cents or 15.4 percent to 11 cents with 12.7 million shares traded, followed by Living Cell down 8.1 percent to 17 cents with 7,500 shares traded. Psivida fell 5.4 percent; LBT, Nanosonics, Sirtex and Viralytics fell more than three percent; Alchemia, Genera and Novogen shed more than two percent; with Acrux and Chemgenex down more than one percent.

[BIOTECH DAILY TOP 40 INDEX](#)

Narrowly retaining its numerical lead over the ASX benchmark, the Biotech Daily Top 40 Index (BDI-40) fell 3.2 percent in February 2010, while the S&P ASX 200 climbed 1.5 percent. The BDI-20 fell 2.4 percent for the month, with the Second 20 down 7.7 percent.

But for the year to February 28, 2010, the BDI-40 was up 115.2 percent, compared to the ASX200 up 38.7 percent. The BDI-20 was up 118.6 percent for the year with the Second 20 up 97.5 percent.

The three Big Caps of Cochlear, CSL and Resmed, which are not included in the BDI-40, collectively gained 9.9 percent for the month – their biggest gain in more than a year - but were 7.2 percent lower than 12 months ago. Cochlear fell 0.03 percent to \$3,607 million, Resmed climbed 10.8 percent to \$4,911 million and CSL had its first significant improvement since October 2009, up 11.7 percent for the month.

Twenty-six biotechnology companies fell with 16 falling more than 10 percent, while nine climbed with five up by more than 10 percent.

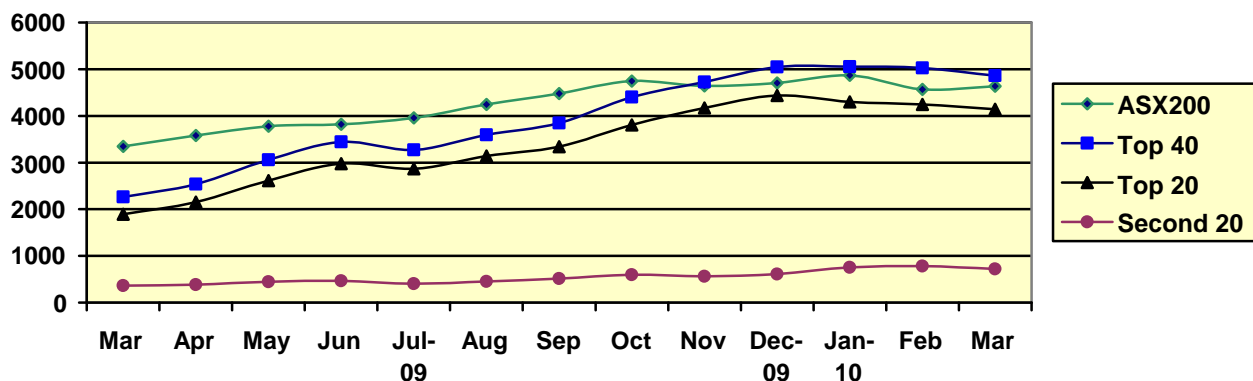
Heartware was the best in February 2010, with a \$71 million capital raising taking it up 34 percent to \$603 million, followed by Clinuvel up 23.1 percent to \$80 million, Tissue Therapies up 19.2 percent to \$31 million, Phosphagenics up 16.3 percent to \$57 million and QRX up 14.0 percent to \$98 million. Virax was the best performer outside the Top 40 climbing 72.7 percent to \$19 million with Anteo up a further 37.5 percent to \$22 million.

Cathrx led the falls, down 47.4 percent to \$20 million, followed by Chemgenex down 27.4 percent to \$193 million, Phylogica (26.9%), Bone (26.3%), Patrys (24.3%), Circadian (21.9%), Avexa (21.4%) and Novogen (21.3%).

Biotechs raised \$80.6 million in February 2010 compared to the \$5,450,000 raised in February 2009 and more than \$580 million in the year to February 28, 2010.

Despite a component problem (BD: Feb 26, 2010) Nanosonics has established itself as a successful innovator with product in the market and will be promoted to the Top 20, swapping with Phosphagenics which appears to be concentrating as much on its cosmetic applications as its transdermal human health applications.

Biotech Daily Top 40 (\$m) v S&P ASX 200 2009-2010



AVEXA

Tibotec will drop its exclusive option on Avexa's early stage HIV integrase program effective from tomorrow March 2, 2010, despite "considerable progress" with the program. Avexa said Johnson & Johnson's Tibotec chose to let the option period expire "due to potential future conflicts with its own internal programs".

Avexa said Tibotec had profiled a number of its compounds, which had shown "a high level of potency and activity against raltegravir resistant enzymes" that validated Avexa's results (BD: May 4, Nov 5, Dec 10, 2009).

Avexa said it retained the intellectual property and data from the program and would continue with Tibotec on a non-exclusive basis and be able to discuss collaborations and licencing of the program with other parties.

Avexa's chief scientific officer Dr Jonathan Coates told Biotech Daily that HIV encoded integrase "which is a protein which integrates the virus into CD4 human host cells".

"Without integrase, HIV can't replicate, so it is the target in this program," Dr Coates said. In the media release to the ASX Dr Coates said his company had "made considerable progress with our HIV integrase program during the option period".

"We now have a number of very exciting and potent leads with activity against HIV resistant to other integrase inhibitors," Dr Coates said.

The company said the HIV integrase program discovered and identified a number of novel compound classes and potential lead assets with low nanomolar potency that have demonstrated significant activity against known integrase-resistant HIV strains.

These compounds are highly potent against raltegravir and elvitegravir-resistant viruses and have shown activity superior to raltegravir against wild type HIV-1.

Avexa said the compound classes also possess properties that may suggest a once-a-day, un-boosted, oral dosing regime was likely.

The company said in vitro studies demonstrated that the compounds were specific for HIV integrase and were integration and integrase specific inhibitors in whole cell assays, confirmed by PCR studies; were highly active against wild type integrase and mutations in integrase that confer cross-resistance to raltegravir, elvitegravir and the diketo acids; and maintained equivalent potency in 50 percent normal human serum.

Avexa fell two cents or 15.4 percent to 11 cents with 12.7 million shares traded.

INNOVATION INVESTMENT FUND

The Minister for Innovation Senator Kim Carr says fund managers should apply for the Federal Government's venture capital support program, the Innovation Investment Fund. A Departmental officer told Biotech Daily the program expected to fund two or three applicants.

A media release from Senator Carr's office said investment in venture capital was "a driver of innovation" and the fund was "an important catalyst for building new innovative businesses, developing fund managers and growing a domestic venture capital market".

"Through the IIF program the Australian Government will provide \$20 million to each successful fund manager to establish new funds of \$40 million or more," Senator Carr said. "The IIF program has generated a total commitment of almost \$500 million to date from government and the private sector to commercialize Australian research. A number of world leading products and services have been developed through the program."

Applications close on May 31, 2010.

The media release said information seminars for potential applicants would be held in Perth, Adelaide, Melbourne, Sydney, Brisbane and Canberra in early March 2010.

For more information go to: www.ausindustry.gov.au or telephone: 13 28 46.

SIRTEX MEDICAL

Sirtex says it will collaborate with the University of Oxford to trial SIR-Spheres in patients with bowel cancer that has spread to the liver.

Sirtex said the Foxfire trial would be led by Gray Institute for Radiation Oncology and Biology's Dr Ricky Sharma and Hammersmith Hospital's Dr Harpreet Wasan.

The company said Dr Sharma and Dr Wasan hoped the randomized, controlled study of 490 patients at 24 hospitals across the UK would show whether Sirtex's SIR-Spheres microspheres combined with chemotherapy could give patients better medical outcomes than chemotherapy alone.

Dr Sharma said that "radiotherapy works well in treating bowel cancer and this new way of administering high-dose radiation therapy [Sir-Spheres] directly into the blood supply of the cancer appears to be effective when we combine it with chemotherapy".

Sirtex said that bowel cancer was the third most common cancer in the UK with 38,000 people diagnosed each year.

About 50 per cent of patients experience spread of the disease to the liver and most patients cannot be cured by surgery, the company said.

Sirtex chief executive officer Gilman Wong said the study was a milestone for the company's clinical program to gather data that demonstrated the efficacy of SIR-Spheres microspheres as an effective therapy to treat liver cancer.

"We expect the results of the study will establish a new standard of care for patients who currently have limited treatment options available," Mr Wong said.

Sirtex said the study was funded in partnership with Cancer Research UK, the Bobby Moore Fund for Cancer Research.

Sirtex said Dr Sharma had conducted a smaller trial which showed a combination of SIR-Spheres microspheres and chemotherapy shrank liver cancer tumors in 90 percent of patients compared to 50 percent of patients treated with chemotherapy.

Sirtex fell 19 cents or 3.4 percent to \$5.45.

CBIO

CBio says it has ethics approvals from all Central and Eastern European clinical trial sites of its XToll drug for rheumatoid arthritis and regulatory approvals for Bosnia and Georgia. CBio managing director Jason Yeates said the approvals were "the first significant operational milestones" for its 150-patient phase II clinical trial.

Rheumatologist and principal investigator Prof Peter Nash said the trial investigators met in Belgrade to discuss the trial and learn more about the science behind XToll.

"The response was extremely positive and we anticipate good commitment from these overseas sites in terms of recruitment and participation in the trial," Prof Nash said.

"The data we have to date is blinded, but it does suggest that XToll appears to be affecting at least three of the most targeted inflammatory pathways associated with rheumatoid arthritis," Prof Nash said.

"Current leading drugs work by blocking a single inflammatory pathway. This blocking action is thought to have a knock-on effect to the healthy functioning of the immune system," Prof Nash said.

"XToll appears to work differently. There is potential here that XToll could effectively treat rheumatoid arthritis and leave the immune system functioning effectively," he said.

Mr Yeates said that in recent months Astrazeneca, Eli Lilly and Bristol Myers Squibb had concluded rheumatoid arthritis deals "with upfront payments starting at \$US85 million plus hundred of millions in development milestones, sales milestones and royalties".

CBio was up two cents or 5.6 percent to 38 cents.

CALZADA

Calzada (formerly Metabolic) says it is investigating claims in today's The Age newspaper that its anti-obesity drug AOD9604 is being manufactured and sold in China.

Metabolic's phase II trial of AOD9604 taken orally showed little or no efficacy in subjects compliant with US Food and Drug Administration rules on diet and exercise (BD: Feb 21, 2007). But the trial showed some efficacy in the non-compliant subjects, who did not complete exercise and dietary targets.

Last year, Phosphagenics signed a collaborative research and option agreement with Metabolic for AOD9604, as a transdermal cosmetic compound (BD: Aug 13, 2009).

In The Age's 'Insider' column David Symons said increasing numbers of body builders were using black market AOD9604, "attracted by its fat-busting capabilities when injected directly into the abdomen".

Mr Symons said the Chinese version "almost certainly breaches Metabolic's patents but is doing brisk trade due to its reputation for moving stubborn belly fat".

"Biochemists are unsurprised that bodybuilders are achieving results where Metabolic's clinical studies failed," Mr Symons said.

"When taken as a tablet the AOD9604 peptide, like all peptides, is prone to being broken down in the stomach and intestine before it can be absorbed into the bloodstream," Mr Symons said in The Age.

Mr Symons is a director of Genera Biosystems.

Calzada said it held the AOD9604 patents in China and other parts of the world including the key United States and European Union markets.

The company is investigating the apparent manufacture of AOD9604 in China and its possible sale into other countries including the US and Australia in contravention of this patent position.

Calzada said the investigation was in its early stages and the company had no reliable information regarding the quantity or quality of the AOD9604 produced; the volume of sales; the number or type of customers and their location or the potential uses of the manufactured product.

The company said it was investigating additional third party claims regarding the product's manufacture and use.

Calzada was up 0.2 cents or 6.1 percent to 3.5 cents with 2.2 million shares traded.

PRANA BIOTECHNOLOGY

Morgan Stanley Australia Securities ceased its substantial shareholding in Prana on February 25, 2010.

Morgan Stanley said that it sold the shares in parcels of 100,000 shares or fewer between 19 cents and 15 cents a share.

Morgan Stanley became substantial in Prana on November 3, 2009 with a holding of 12,078,175 shares or 5.18 percent.

Prana was unchanged at 15 cents.

STIRLING PRODUCTS

Stirling has requested a trading halt pending an announcement "in relation to the settlement and acquisition of a major pharmaceutical manufacturing facility in Canada".

The company said the transaction was "subject to the final approval of the Canadian courts".

Stirling last traded at 1.3 cents.

SAFETY MEDICAL

Safety Medical has been suspended from trading on the ASX following its failure to lodge full year statutory accounts.

The ASX named 13 companies of which Safety Medical was the only biotechnology company listed as failing to provide the full year accounts.

Separately, Safety Medical said negotiating with “a potential significant new ... investor” and as a result it had delayed the release of its Appendix 4D and interim financial report for the half year to December 31, 2009.

The company said the documents would be released in conjunction with the investor announcement on or before the commencement of trading on March 8, 2010.

Safety Medical last traded at 3.7 cents.

VIRAX

Virax has appointed stockbroker Tim Cooper as a non-executive director from today.

Virax said Mr Cooper had a private client base and worked in the family business of, Herbert P Cooper and Son, one of Australia’s oldest and most respected private client advisory stock-broking firms.

Virax said Mr Cooper was appointed his company’s managing director in 1991, the firm merged with Hartley Poynton in 1998 and since 2003, he was with Macquarie Equities.

Virax said Mr Cooper was also a substantial shareholder through Unaval Nominees.

Virax was up half a cent or 3.85 percent to 13.5 cents with 2.6 million shares traded.

SOLAGRAN

In its Appendix 4D half-yearly report to the ASX, Solagran has claimed a 242 percent increase in revenue for the six months to December 31, 2009 of \$1,040,511.

Solagran said its net loss was down 39 percent to \$2,772,113.

The company said its net tangible assets per security was up 29.7 percent to 4.8 cents a share compared to the previous corresponding period.

Solagran has said it was developing conifer green needles as an over-the-counter remedy for ailments ranging from liver cancer and alcoholism to Alzheimer’s disease.

The company says it can synthesize the extracts into the “finished pharmaceutical Ropren” along with a range of “Bioeffectives” for specific indications.

Solagran said in the notes accompanying the Appendix 4D that although it had booked \$1,040,511 in revenue, the cost of sales was \$898,170.

The company said that on December 15, 2009 its 85 percent subsidiary Sibex recorded the sale of 10.5 kg of polyprenols to Galenopharm, for the production of Ropren.

The company said Sibex recorded the sale of \$608,283 of the material in its accounts as ownership had passed.

Solagran said that under the terms of the contract between Sibex and Galenopharm payment was “not due until the finished pharmaceutical is sold by the distributor”.

Solagran said the rights to produce Bioeffective R substance and Ropren were transferred from Galenopharm to Solagran’s wholly owned Russian subsidiary, Solagran Son.

All rights to Ropren are now controlled by Solagran entities with Galenopharm continuing as “toll manufacturer”.

The company said Ropren sales began in the Russian market in February 2010. Two years ago, Solagran said manufacturing partner Galenopharm was free to commence production of Ropren for sale throughout Russia (BD: Mar 19, 2008).

Solagran was up half a cent or 2.4 percent to 21.5 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company \$Am	Mar-10	Feb-10	Jan-10
Cochlear	3,607	3,618	3,892
CSL	20,083	17,978	18,970
Resmed	4,911	4,432	4,492
Top 20			
Acrux	327	324	350
Alchemia	126	142	116
Antisense	29	30	32
Avexa	110	140	131
Bionomics	92	107	119
Biota	390	374	431
Cellestis	303	342	314
Chemgenex	193	266	279
Clinuvel	80	65	82
Genera	44	44	44
Heartware	603	450	483
Impedimed	79	82	85
Living Cell	50	57	60
Mesoblast	257	295	191
Nanosonics	128	140	144
Novogen	48	61	61
Pharmaxis	569	585	596
Sirtex	326	374	421
Starpharma	177	168	165
Universal Biosensors	283	288	291
Second 20			
Benitec	15	16	14
Bone Medical	14	19	13
Cathrx	20	38	44
Cellmid	10	11	11
Circadian	25	32	32
Compumedics	29	32	29
Genetic Tech	15	15	16
Labtech	9	9	12
Optiscan	9	9	11
Patrys	28	37	23
Phosphagenics	57	49	50
Phylogica	19	26	32
Prana	35	36	35
Prima	101	97	96
Psivida	67	76	78
QRX Pharma	98	86	80
Sunshine Heart	19	19	20
Tissue Therapies	31	26	22
Uscom	27	31	29
Viralytics	22	26	13

* Biotech Daily editor, David Langsam, owns shares in Alchemia, Bionomics, Chemgenex, Impedimed, Neuren and Optiscan, as well as non-biotechnology stocks and has an indirect interest through Australian Ethical trusts in Cochlear, Genera, Pharmaxis, QRX, Resmed and Tissue Therapies. These holdings are liable to change at any time.

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