Biotech Daily

Thursday November 29, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PHYLOGICA UP 14%, STARPHARMA DOWN 29%**

*** STARPHARMA: EXTRANEOUS VARIABLES CAUSED TRIAL FAILURE**

*** HATCHTECH DEOVO KILLS LICE BY DISRUPTING METAL COMPOUNDS**

*** VIRALYTICS CLAIMS PHASE I CAVATAK BLADDER CANCER EFFICACY**

*** BIODIEM RAISES $2.2m**

*** PROGEN UNDERWRITTEN 3-FOR-5 RIGHTS ISSUE FOR $3m**

*** BIOXYNE AGM LOSES CHAIRMAN IAN MUTTON, DIRECTOR, SHARE VOTE**

*** STARPHARMA LOSES DIRECTOR ROSS DOBINSON**

MARKET REPORT

The Australian stock market was up 0.68 percent on Thursday November 29, 2012 with the S&P ASX 200 up 30.4 points to 4,477.7 points.

Eleven of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and five were untraded. All three Big Caps were up.

Phylogica was the best, up 0.3 cents or 13.6 percent to 2.5 cents with 674,075 shares traded.

Antisense and Genetic Technologies were both up 9.1 percent; Avita was up 7.7 percent; Mesoblast, Prana and Viralytics climbed more than four percent; Compumedics and Phosphagenics were up more than three percent; CSL rose 2.9 percent; Bionomics and Sirtex were up more than one percent; with Cochlear and Resmed up by less than one percent.

Starpharma led the falls, losing as much as 67 cents or 41.4 percent to 95 cents, before closing down 47 cents or 29.0 percent to $1.15 with 5.5 million shares traded.

Heartware and Patrys lost more than seven percent; Tissue Therapies was down 6.35 percent; Circadian, Ellex, Nanosonics, Neuren and QRX shed two percent or more; Alchemia, Pharmaxis and Universal Biosensors were down more than one percent; with Acrux down 0.4 percent.

STARPHARMA HOLDINGS

Starpharma has included women from lower socio-economic areas among the extraneous variables that could have led to Vivagel's phase III bacterial vaginosis trial failure.

After the market closed last night, Starpharma said that Vivagel failed to meet its phase III trial primary endpoint for clinical cure in the treatment of bacterial vaginosis.

Starpharma said that the two phase III studies of Vivagel "achieved statistically significant clinical cure and resolution of patient-reported symptoms of [bacterial vaginosis] at the end of treatment visit (two to five days post treatment)"

"However, the primary endpoint of clinical cure two to three weeks after the cessation of treatment was not met," Starpharma said.

In a conference call this morning, Starpharma chief executive officer Dr Jackie Fairley said that if two sites with high rates of placebo effect were removed from the data, the primary endpoint of 'test of cure' at two to three weeks "would have given statistical significance".

Dr Fairley said that the two centres were in lower socio-economic areas with a less well-educated community and that along with less or more sexual activity, self-medication and alternative therapies could have been reasons for an increased rate of placebo effect.

"We are both surprised and disappointed by these results … particularly not meeting the endpoints," Dr Fairley said.

She said that the increase in placebo efficacy was "clearly a surprising result".

The US Centers for Disease Control and Prevention said bacterial vaginosis was "a condition in women where the normal balance of bacteria in the vagina is disrupted and replaced by an overgrowth of certain bacteria" [and] "activities or behaviors [that] can upset the normal balance of bacteria in the vagina and put women at increased risk [include]: having a new sex partner or multiple sex partners [and] douching".

Monash University Michael Kirby Centre senior research fellow and a specialist in research with sex workers, Cheryl Overs, told Biotech Daily that the increase in efficacy of the placebo group in the lower socio-economic areas "could indicate that the women are compliant with the protocols".

"And having ceased using deodorant products, their natural vaginal flora have returned, reducing or eradicating the symptoms of bacterial vaginosis," Ms Overs said.

Last year, Starpharma published phase II results showing that Vivagel achieved clinical cure of bacterial vaginosis in 46 percent of 132 patients at two to three weeks after completion of therapy, compared to 12 percent for the placebo ($p = 0.006$), while 74 percent of patients achieved clinical cure at two to five days after completion of therapy compared to 22 percent in the placebo group ($p = 0.0002$) (BD: May 23, Aug 15, 2011).

Last night the company said that each of the phase III studies enrolled about 250 women and 50 percent and 57 percent of women, respectively, achieved clinical cure with Vivagel compared to 17 percent and 21 percent with placebo ($p < 0.001$) at end of treatment.

At the two to three weeks 'test of cure', the clinical cure rates for Vivagel and placebo were 27 percent versus 21 percent, respectively, in trial SPL7013-015 and 28 percent versus 28 percent in trial SPL7013-016.

Dr Fairley said that although the company would not pursue a new drug application with the FDA for treatment, it would consider other label options such as "symptomatic relief" and said other regulators might not insist on the same time point.

Dr Fairley said that the prevention of recurrence trial was fully recruited and was "not negatively impacted in any way by these results" because it had a different design and endpoint and the treatment was every second day for 16 weeks.

Dr Fairley said the trial had "no relevance to anti-viral activity" of Vivagel but the safety data would assist.

Starpharma closed down 47 cents or 29.0 percent to $1.15 with 5.5 million shares traded.

HATCHTECH

Hatchtech says the active ingredient (Ha44) in Deovo for head lice works by fatally disrupting all stages of the life cycle in a model of head lice

Hatchtech said that a study of the model organism Drosophila melanogaster or fruit fly showed that Ha44 was able to chelate heavy metal ions including zinc, iron and copper and thereby disrupt metal dependent targets within the insect that require these ions for normal function.

Hatchtech chief scientific officer Dr Vern Bowles told Biotech Daily that Ha44 “is a metal chelator that interacts with metal ions in the target insect disrupting the normal life cycle of the insect”.

The company said that the research has been published by the Public Library of Science One in an article co-written by Dr Bowles entitled ‘The Ovicidal, Larvacidal and Adulticidal Properties of 5,59-Dimethyl-2,29-Bipyridyl against Drosophila Melanogaster’ and was available through a link at: http://hatchtech.com.au/scientific-background.

Hatchtech said the article described the mechanism of action of Ha44 and its ability to fatally disrupt all stages of the life cycle of Drosophila melanogaster, from eggs to adult flies.

”This research conducted under an Australian Research Council Linkage Grant in conjunction with the University of Melbourne is consistent with the spectrum of activity of Ha44 that we have observed against head lice in the laboratory and in clinical studies,” Dr Bowles said. “It demonstrates all stages from eggs to adults are susceptible to the compound with a single application.”

”Furthermore the results indicate that Ha44 is acting on several targets within the insect which suggests that target site resistance is unlikely to evolve,” Dr Bowles said

The company said it had completed a cardiac electrical trial known as a Thorough QT study, a safety assessment required by US and European regulators for most new molecular entities.

Hatchtech is a private company.

VIRALYTICS

Viralytics says Cavatak binds to the ICAM-1 receptor on the surface of human bladder cancer tissues, with patients’ melanoma lesions appearing to stabilize or reduce in size.

Viralytics said that preliminary data from a phase I in bladder cancer trial showed evidence of possible immune activation in patients with reductions in injected lesions.

The company said the research was conducted in collaboration with England’s University of Surrey head of oncology Prof Hardev Pandha’s research team.

Viralytics said that injected Cavatak virus cleared from circulation within about 48 hours with possible secondary viral replication and the mild virus kept working in patients as it was designed to persist in targeting cancer cells.

Prof Pandha said the findings were “very encouraging in our quest to enter early phase clinical evaluation of Cavatak for the treatment of patients with superficial bladder cancer”.

“Novel therapeutic strategies are urgently needed in the indication as evidenced by the current worldwide shortage of a Bacille Calmette-Guerin, a common treatment for this condition,” Prof Pandha said.

Viralytics said that in the US in 2012 there would be about 70,000 new cases and 15,000 deaths from bladder cancer.

Viralytics said 13 subjects had been dosed in its US phase II melanoma study with three demonstrating immune-related progression-free survival at six months.

Viralytics was up 1.5 cents or 4.9 percent to 32 cents.

BIODIEM

Biodiem says its rights issue has raised $2,239,166 of a hoped for $2.55 million.
Biodiem said that $1,775,310 was raised through entitlement and shortfall applications for 35,506,201 shares at five cents share.
Earlier this month Biodiem issued a replacement prospectus saying that Patersons Securities had reduced the original $2 million underwriting to $463,856 (BD: Nov 2, 2012).
Biodiem said that for every two new shares investors would receive one attaching option exercisable at eight cents by December 31, 2104, for two new shares.
The company said that the underwriting agreement required Patersons to take 9,277,119 shares and 4,638,560 attaching options for $463,856, taking the total raised to more than the $2 million minimum subscription.
Biodiem was unchanged at 4.6 cents.

PROGEN PHARMACEUTICALS

Progen says it expects to raise up to $3 million through a fully underwritten, three-for-five, non-renounceable, rights issue in the first three months of 2013.
Progen said that shareholders would have the opportunity to apply for additional shares through a shortfall facility and the underwriter would take up any under-subscription.
The company said that the rights issue price would be based on a volume-weighted average price over the three months preceding the offer opening date.
Progen said the funds would be used for continued preclinical and clinical development of PG545 for solid tumors and additional working capital.
Progen fell one cent or four percent to 24 cents.

BIOXYNE

Bioxyne says the remuneration report, the election of Dr William Harrison and a placement capacity have been defeated and chairman Ian Mutton has resigned.
Bioxyne said that the annual general meeting overwhelmingly re-elected Patrick Ford as a director but also overwhelmingly defeated a prior share issue.
The company said that newly appointed director Tony Ho would be chairman.
The remuneration report resolution was defeated by 41,124,460 votes (62.91%) to 24,245,147 votes (37.09%) with the other two resolutions defeated by about 55 percent of the votes to 45 percent.
Bioxyne was untraded at three cents.

STARPHARMA HOLDINGS

Starpharma says that non-executive director Ross Dobinson has resigned effective from the close of business, yesterday.
The company said that a proposed resolution to re-elect Mr Dobinson ar tomororw's annual general meeting has been withdrawn.
Starpharma said that Mr Dobinson was a founding director and had "a significant role in the establishment and early development of the company".