Biotech Daily

Friday March 12, 2010

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: LIVING CELL UP 12%; VIRALYTICS DOWN 4%**

*** STARPHARMA'S VIVAGEL 'COMPARABLE' SAFETY TO PLACEBO**

*** INTERSUISSE LAUNCHES NEW $200m ASIA-PACIFIC FUND**

*** BIOMD PASSES ALL BIO-COMPATIBILITY TESTS**

*** BENITEC'S GRAHAM PATENT GRANTED IN JAPAN**

*** INCITIVE EGM TO BECOME HAWKLEY OIL AND GAS**

*** SOLAGRAN CLAIMS $38,914 RUSSIAN SALES IN 10 DAYS**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Friday March 12, 2010 with the S&P ASX 200 up 3.9 points to 4818.1 points.

Twenty-three of the Biotech Daily Top 40 stocks were up, eight fell, four traded unchanged and five were untraded.

Living Cell was best, up two cents or 11.8 percent to 19 cents with 314,749 shares traded, followed by Avexa up 8.3 percent to 13 cents with 9.2 million shares traded.

Alchemia, Clinuvel and Tissue Therapies climbed more than four percent; Novogen, Pharmaxis, Phylogica and Prana were up more than three percent; Acrux, Antisense, Genetic Technologies, Optiscan, Phosphagenics, QRX, Starpharma and Sunshine Heart rose more than two percent; with Biota, Circadian and Nanosonics up more than one percent.

Viralytics led the falls, down 0.2 cents or 3.6 percent to 5.3 cents with 693,000 shares traded, followed by Cellmid down 3.45 percent to 2.8 cents with 2.3 million shares traded and Prima down 3.3 percent to 14.5 cents with 2.5 million shares traded.

Benitec lost 2.1 percent; with Cellestis, Psivida, Sirtex and Universal Biosensors down more than one percent.

STARPHARMA

Starpharma says a 61-patient trial shows its vaginal microbicide Vivagel (3% SPL7013 gel) has comparable safety and tolerability to two placebo gels in sexually active women.

Starpharma said 22 women vaginally applied Vivagel twice daily for 14 days, 21 had a matched placebo gel without the SPL7013 active ingredient and 18 women were supplied an alternative experimental placebo based on hydroxyethyl cellulose (HEC).

The company said all three groups were comparable for the percentage of women with one or more abnormal genital findings related to the study gels observed by the investigators during a pelvic examination.

Starpharma said there was no statistically significant difference in the proportion of women who had one or more sign and/or symptom of genital irritation considered to be possibly, probably or definitely related to administration of gels between the Vivagel, matched placebo and HEC treatment groups.

The percentage of women with one or more adverse events considered to be possibly, probably or definitely related to product use during clinic pelvic examination was 18.2% in Vivagel, 28.6% in matched placebo and 22.2% in HEC placebo gel groups.

Starpharma said that overall, there was no statistically significant difference in the proportion of women who had one or more abnormal genital signs reported on observation by the investigator or symptoms as reported by the participant considered to be possibly, probably or definitely related to administration of gels between the Vivagel (63.6%), matched placebo gel (52.4%), and HEC gel (38.9%) treatment groups (p=0.30).

The incidence of investigator reported signs and patient reported symptoms expressed per 100 person-years of participation in the study was 0.197 with Vivagel, 0.133 in matched placebo gel, and 0.083 with HEC placebo gel (p=0.06).

Signs and symptoms were defined as: pelvic pain; vaginal and vulvar pain; tenderness; vulvar itching, oedema, erythema, lesions, abrasions or rash; vaginal itching, oedema, erythema, dryness or lesions; cervical oedema, erythema, discharge or lesions; dysuria; vulvovaginitis; cervicitis or dyspareunia.

There were no grade 3 or higher laboratory values for haematology, liver function, creatinine level and coagulation.

The percentage of women who had at least one adverse event considered possibly, probably or definitely related to product use was 77.3% in Vivagel, 66.7% in matched placebo gel, and 50.0% in HEC placebo gel groups.

Non-genital adverse events were low in number and included diarrhoea and headache.

The incidence of genital signs and symptoms reported with Vivagel in this study is in line with previous Vivagel safety studies and other topical vaginal products, the company said.

Starpharma chief executive officer Dr Jackie Fairley said her company was “pleased to report positive findings from this study, our first in sexually-active women”.

“These data provide further evidence of the safety and tolerability of the Vivagel active ingredient SPL7013 and will support its development as both a stand-alone gel [for] bacterial vaginosis, genital herpes and HIV and as a condom coating,” Dr Fairley said.

Starpharma said that adverse events were mainly mild, self-limiting, and resolved spontaneously.

The company said there were no severe (grade 3) or serious (grade 4) adverse events reported and participant adherence to the required regimens was 95-100 percent, indicating the products were well tolerated by the participants.

Blood tests showed no evidence of any treatment-related effects in study participants.

Starpharma said that some further analysis of secondary assessments for the study was ongoing and a phase II efficacy study in bacterial vaginosis was planned for this year.

Starpharma was up 1.5 cents or 2.1 percent to 71.5 cents.

INTERSUISSE BIOSCIENCES

Intersuisse Biosciences' Australian Bioscience Fund is launching a $200 million Asia Pacific healthcare fund.

Intersuisse Biosciences (IB) said the launch followed "the success of its high-performing IB Bioscience Fund I".

The company said the new fund would be called the IB Asia Pacific Healthcare Fund II and would focus on healthcare and medical science companies in the Asia-Pacific including Australia, New Zealand, China, India and Japan.

IB fund manager Matt McNamara said the fund was managed by an Australian-led global team and would be a closed-end fund with a five year investment period, targeting mid to later-stage healthcare and medical science companies in Australasia and the Asia-Pacific.

"It will target outstanding technologies in clinical trial and commercialization stage with strong prospects for international commercial transactions," Mr McNamara said.

"We believe it will offer a superior investment return at reduced risk," Mr McNamara said.

Intersuisse said the IB Australian Bioscience Fund I had a "stellar performance" returning 83 percent in the 19 months since it opened July 2008, compared to the S&P ASX200 absolute return loss of five percent.

Intersuisse said the IB Fund I made three successful exits and made distributions to investors from year one and was also returning capital.

Mr McNamara said the IB Asia Pacific Healthcare Fund II investment strategy would focus on private equity style investments in mid to later stage companies rather than early stage venture capital.

"This is an area where we believe there is a skills and funding gap in the market," he said.

"This strategy reduces risk and shortens the time to exit compared to early stage venture investments. Companies in this mid-later stage also face dramatically different challenges to early stage companies," Mr McNamara said.

He said the Asia-Pacific medical and healthcare market had experienced double digit growth over the past four years as a result of the ageing population, increasing affluence and government commitments to expanding healthcare services.

This growth was projected to continue for the next five years, with the healthcare market projected to grow at a compound annual growth of around 14 percent to at least 2012.

BIOMD

Biomd says that its Cardiocel and Gynecel products for cardiac and pelvic floor repair have passed all bio-compatibility tests.

Biomd said medical device contract research organization North American Science Associates (Namsa) conducted the tests and its products passed all 13 tests, with two tests passed "at the lowest level".

The company said the Namsa reports provided a comparative evaluation of the biological responses to test and control materials.

Biomd said test periods were chosen to ascertain that a steady state had been reached with respect to biological response.

The company said the results would give the necessary biocompatibility certification for Cardiocel and Gynecel and would form an integral part of the regulatory submissions to the Australian Therapeutic Goods Administration and the US Food and Drug Administration late in 2010.

Biomd said further biocompatibility reports from Namsa on long term biological testing were expected by August 2010.

Biomd was untraded at 5.3 cents.

BENITEC

Benitec says that a patent entitled 'Control of Gene Expression' and part of the Graham patent family of RNA interference patents has been granted in Japan.

Benitec said the patent was in the foundational Graham RNAi patent family and was related to the patent under reexamination at the US Patent and Trademark Office.

Benitec chief executive officer Sue MacLeman said she was delighted the Japanese patent office has recognized the importance of the claims and accepted the patent which had "broad coverage and leverage in the field of RNAi therapeutics".

Benitec said the granted claims included a genetic construct for expressing a ribonucleic acid (RNA) to silence a target gene in a eukaryotic cell.

"The granting of this patent is an important step for licencing and collaborations in Japan," Ms MacLeman said.

Ms MacLeman said her company assigned the patent family to the Commonwealth Scientific and Industrial Research Organisation in 2006 but retained "a worldwide non-revocable right to the human field".

Benitec fell 0.1 cents or 2.1 percent to 4.6 cents with 1.8 million shares traded.

INCITIVE

Incitive will hold an extraordinary general meeting on April 12, 2010 to change direction from bromelain research and development for cancer to oil and gas exploration.

Resolutions include authorization to change the nature and scale of its activities; a name change to Hawkley Oil and Gas; a series of share issue approvals; the election of directors; and a 26.67-to-one share and option consolidation (BD: Oct 13, 2009).

The meeting will be held on April 12, 2010 at Level 1, 2 Ross Place, South Melbourne, Victoria at 10am .

Incitive was up 0.1 cents or 16.7 percent to 0.7 cents with 13.5 million shares traded.

SOLAGRAN

Solagran says that in the 10 days since its Ropren over-the-counter, herbal, cure-all launch in Russia it sold 31 courses worth $US1,150 each.

Solagran said 383 courses of Ropren were sent to pharmacies and private clinics with the inaugural sale occurring on 18 February 2010 and by the end of February 2010, the equivalent of 31 courses of Ropren were sold at $US1,150 per course.

"In many instances individual bottles of Ropren are being sold by pharmacies (a full course of Ropren is six bottles)," Solagran said.

Solagran said it was "confident of achieving the forecast previously provided of selling in excess of 13,000 courses of Ropren by December 2010".

Replying to an ASX Appendix 4C quarterly cash statement query earlier this year, Solagran said it expected revenue of $US15 million by December 2010 (BD: Feb 5, 2010).

Last year Solagran cut the expected sale price of Ropren from $US3,500 to $US6,000 a course to "between $US1,100 and $US1,250" with one course equal to six grams of Bioffective R substance (BD: Oct 23, 2009).

Solagran fell one cent or 4.4 percent to 21.5 cents with 1.1 million shares traded.