Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: STARPHARMA UP 33%, BENITEC DOWN 13%**

*** CUTLER INNOVATION REVIEW PUBLISHED**

*** STARPHARMA UP 60% on $100m DUREX-VIVAGEL DEAL**

*** PEPLIN BEGINS PHASE III CLINICAL TRIAL FOR PEP005 GEL IN AK**

*** BIOTRON'S BIT225 SYNERGISTIC WITH RNA-BASED HEP C DRUGS**

*** VIRALYTICS' CAVATAK ACTIVE IN VITRO AGAINST GLIOBLASTOMAS**

*** CANADA APPROVES NANOSONICS ULTRASOUND PROBE DISINFECTOR**

*** SOLBEC TURNS FROM CANCER RESEARCH TO LASER EYE SURGERY**

*** SUCCESS SCUPPERS GENERA OPTION PLAN**

MARKET REPORT

The Australian stock market fell 1.6 percent on Tuesday September 9, 2008 with the All Ordinaries down 84.4 points to 5,041.9 points.

Seven of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and 10 were untraded.

Starpharma was best, climbing 60.4 percent to 38.5 cents before closing up eight cents or 33.33 percent at 32 cents with 1.2 million shares traded, followed by Polartechnics up two cents or 18.18 percent to 13 cents and Impedimed up 10 cents or 14.29 percent to 80 cents.

Cochlear, Prana, Ventracor and Resmed were up more than two percent; with Arana and Mesoblast up more than one percent.

Benitec led the falls, down 0.9 cents or 13.04 percent to six cents on small volumes, followed by Cytopia down two cents or 9.09 percent to 20 cents.

Novogen and Peplin lost more than eight percent; Antisense was down 7.58 percent; Cathrx shed 5.06 percent; Pharmaxis and Progen fell more than four percent; Acrux, Cellestis and Clinuvel were down more than three percent; with Alchemia, Bionomics, CSL and Sirtex down more than one percent.

CUTLER REVIEW OF THE NATIONAL INNOVATION SYSTEM

The 206 page review of Australia's innovation system by Dr Terry Cutler has been released by the Minister for Innovation Industry Science and Research Senator Kim Carr.

The report is entitled 'Venturous Australia – building strength in innovation' and chapter headings include: Stalling not sprinting; The case for a public role in innovation; Building excellence in national research; Tax and innovation; and Innovation in Government.

"The report is a working blueprint to reposition Australia's innovation system," Dr Cutler said.

The report shows a general decline in Australian Government expenditure on science and innovation from 1996.

While biotechnology is only mentioned four times in the entire document and not until page 92 does it receive its first mention, the review acknowledges that "many start-up firms too large to qualify for the tax offset endure tax losses for the best part of a decade, particularly in sectors like biotechnology.

"Waiting this long to access the concession hugely degrades its commercial value, particularly for firms engaging in high risk research. And of course many start-ups are unsuccessful and so never access the concession."

The review describes biotechnology as a key industry and says the panel recommends "a dramatic lift in the threshold for refundable credits" and that the incentive should apply to "any research activity in Australia regardless of firm ownership"

The report says a tax based entitlement scheme is poorly suited to large joint or collaborative projects and the Cooperative Research Centre and Australian Research Council Linkage programs be maintained.

The 72 specific recommendations include replacing the existing research and development tax concessions with a tax credit.

All research and development undertaken in Australia which meet relevant definitions be eligible for the tax credit.

A competitive innovation grants program should be introduced to assist innovative firms with limited access to capital in the high-risk proof-of-concept and development stages. Successful firms would be required to repay grants from the royalties or earning streams accruing from commercial success.

The program would seek to assist 200 innovative firms a year at a cost of $150 million a year.

The shadow minister for innovation Senator Eric Abetz said the recommendation "almost perfectly replicates the former Howard Government's Commercial Ready program … worth $200 million a year [and] axed in the May budget as a savings measure".

The report's Recommendation 9.6 says the Government should consider strategies to attract international venture capital funds to Australia as the base for investment in the Asia Pacific region with the short term objectives of attracting a major US venture capital firm to Australia and strengthening Australian links into US capital markets.

The Innovation Investment Fund program should be maintained with 10 new funds to be established over five years at a cost of $300 million over 15 years.

A large number of recommendations relate to reviewing and monitoring the innovation system and Government initiatives.

A National Innovation Council would replace the Science Engineering and Innovation Council incorporating a Research Coordination Council replacing the Australian Research Council and the National Health and Medical Research Council.

The report is available from the Department of Innovation, Industry, Science and Research's web site at www.innovation.gov.au/innovationreview.

STARPHARMA

Starpharma says a full licence agreement worth up to $100 million has been signed with SSL International relating to Vivagel-coated condoms.

SSL manufactures and sells Durex condoms, the worldwide market-leading condom brand.

In a media release to the ASX, Starpharma said that SSL had secured marketing rights to the Vivagel-coated condom in most of the world, including Europe and the US.

Starpharma's vice-president of business development Dr Paul Barrett said SSL would assist Starpharma through the US Food and Drug Administration regulatory process.

"There's an opportunity for a different regulatory pathway for condom coatings compared to Vivagel by itself," Dr Barrett said.

Starpharma said it estimated its receipts under the agreement would exceed $100 million which would comprise royalties on SSL sales, further milestone payments and development support.

Starpharma's chief executive officer Dr Jackie Fairly said with the potential for near term revenue, brand development and the size of the opportunity, her company saw "the Vivagel coated condom as a key element in our corporate strategy".

"We are particularly pleased to be working with a company such as SSL, which has the capabilities and marketing strength to rapidly move the product through registration and into the market," Dr Fairley said.

Dr Fairley said the agreement would undoubtedly be Starpharma's most important commercial milestone to date.

Starpharma said SSL was the world's leading marketer of condoms, with a 30 percent share of the global market for branded condom sales, selling into more than 100 countries around the world.

SSL's website says the company is the result of mergers between Seeton Healthcare and Scholl plc (footware) in 1998 and the London International Group (formerly the London Rubber Company) in 1999.

Global condom retail sales had been estimated at approximately $3.2 billion, with the top four companies representing as much as 70 percent of the market.

SSL's head of innovation, Leigh Taylor, said Vivagel offered "leading edge technology with the potential to enhance our Durex business".

"We are very pleased to have reached agreement with Starpharma and look forward to working with them to bring the product to market," Mr Taylor said.

In addition to the Vivagel coated condom, Starpharma said it continued to develop Vivagel as an applicator-delivered vaginal product for use by women to protect themselves from HIV and herpes simplex virus 2 (HSV-2 or genital herpes).

Starpharma's chief financial officer Ben Rogers told Biotech Daily that the Durex deal would not affect a separate 2007 agreement with another unnamed major condom producer.

The agreement with the unnamed company was announced in July last year (see Biotech Daily; July 18, 2007) and the company was described as the market-leader in its region which is "in the developed world, and ranks within the top five globally, measured by GDP".

The only country that is not in Europe or the US and meets that criteria appears to be Japan.

Vivagel is being evaluated by and developed with the unnamed company unaffected by the Durex deal.

Starpharma climbed as much as 60.4 percent to 38.5 cents before closing up eight cents or 33.33 percent at 32 cents with 1.2 million shares traded.

PEPLIN

Peplin has dosed the first patient in its phase III safety and efficacy trial of PEP005 gel for actinic keratoses on non-head locations, including the trunk and extremities.

Peplin said actinic keratosis (AK) was a common pre-cancerous skin lesion.

Dermatologist and investigator Dr Robert Rosen said that PEP005 gel (ingenol mebutate) had the potential to offer an effective and convenient treatment.

“The greater number of AKs a person has, the greater chance they have of developing the form of skin cancer known as squamous cell carcinoma,” Dr Rosen said.

“Having a treatment that can treat a large region of skin, with potentially just two applications, rather than older forms of therapy which can be painful or involve long-term treatment schedules, should be well received by the medical community,” Dr Rosen said.

Peplin said the phase III trial, Region-I (formerly referred to as PEP005-014), would involve sites in Australia and the US and was designed to replicate PEP005 gel’s efficacy and safety in actinic keratoses in previous studies.

Peplin said the trial was being conducted under a special protocol assessment with the US Food and Drug Administration.

Peplin said the assessment represented “the FDA’s agreement that the design, clinical endpoints and planned statistical analyses of Peplin’s phase III trial protocol [were] adequate to form a basis for approval of a new drug application”.

Peplin’s chief executive officer Tom Wiggans said the phase III trial was “a major milestone”.

“Based on the data we have generated up to this point we believe PEP005 Gel represents a significant advance in the treatment of a common skin condition that reaches its highest worldwide prevalence in Australia, where approximately half of adults have at least one AK lesion,” Mr Wiggans said.

Peplin said Region-I was a randomized, double-blind, vehicle-controlled clinical trial that would be conducted at multiple sites in the US and Australia to confirm the efficacy and safety of PEP005 Gel, when compared to vehicle gel in patients with actinic keratosis lesions on non-head locations.

Peplin said it expected to enroll 250 patients who would apply the study medication or vehicle gel to a 25 square centimeter treatment area containing four to eight lesions.

The gel would be applied at home once a day for two consecutive days.

Peplin said the primary efficacy endpoint for the trial would be the complete clearance rate of lesions and the secondary efficacy endpoint would be the partial clearance rate of lesions within the treatment area.

The company said the endpoints would be evaluated on the 57th day after the start of treatment,

Peplin said Region-I was one of at least two planned phase III trials for PEP005 gel for actinic keratoses.

The company said that pending supporting data from its recently-enrolled PEP005-015, a dose-ranging phase IIb clinical trial in patients with actinic keratosis lesions on the head, and assuming a successful end-of-phase II meeting with the FDA, it planned to initiate a subsequent phase III clinical trial in patients with actinic keratosis lesions on the head in 2009.

Peplin said it believed its current cash, together with the net cash expected on the closing of its private placement and acquisition of Neosil (see Biotech Daily; June 10, 2008), subject to shareholder approval, would be sufficient to fund phase III testing of PEP005 Gel for actinic keratoses on both the head and non-head locations.

Peplin said it owned worldwide commercialization rights of PEP005 for actinic keratoses.

Peplin fell four cents or 8.89 percent to 41 cents.

BIOTRON

Biotron says its lead antiviral drug, BIT225, “has demonstrated enhanced activity when combined with a new class of hepatitis C virus antiviral agents”.

The independent study was conducted by the Maryland-based Southern Research Institute using a surrogate cell culture system and demonstrated that Biotron's BIT225 was “synergistic when combined with a particular class of antiviral drug”.

Biotron said the antiviral drugs inhibited the RNA-dependent RNA polymerase of hepatitis C, known as NS5B.

The company said NS5B inhibitors were the focus of several research and development programs with a number in early clinical development.

“The finding is significant as there is a recognized need to develop antiviral drugs that work in combination to attack [hepatitis C virus],” Biotron said.

Biotron said that BIT225 worked in combination with NS5B inhibitors “to enhance the virus killing ability of both BIT225 and the NS5B inhibitors” improving the standing of BIT225.

Biotron said the results extended the previously reported finding that BIT225 was synergistic with the current standard of care treatment for hepatitis C virus (HCV) of interferon and ribavirin (see Biotech Daily August 7, 2007).

The company said the research demonstrated higher levels of virus death could be effected using significantly lower levels of both drugs than if either was used alone.

“The major practical benefit of synergism between two anti-viral drugs is that, for therapeutic purposes, each drug would remain effective at lower plasma concentrations than if the combined effect was merely additive,” Biotron said.

“This has the potential to decrease the risk of adverse drug side effects and the potential for generation of drug resistant virus strains, as drug levels in the plasma fall below effective concentrations, is reduced,” Biotron said.

Biotron said it recently started a phase Ib/IIa clinical trial of BIT225 as a monotherapy in patients with chronic HCV infection (see Biotech Daily; August 7, 2008).

This trial followed on from a successful phase I clinical trial of BIT225 in healthy volunteers.

Biotron said the trial was due for completion in late 2008.

Biotron was up two cents or 14.29 percent to 16 cents.

VIRALYTICS

University of Newcastle and Viralytics researchers will present a poster on oncolytic activity of Cavatak in laboratory cultures of glioblastomas

Viralytics said the presentation on pre-clinical in vitro activity of Cavatak in human brain cancer cells at the Hunter Medical Research Institute conference on Translational Cancer Research to be held September 10-12, 2008 in Newcastle.

Viralytics said the poster would be presented by Viralytics senior research scientist its Dr Gough Au and covers the potential oncolytic activity of Cavatak in laboratory cultures of glioblastoma human brain cancers.

The company said that results to date, addressing Cavatak-mediated killing of test tube cultures of a number of human glioblastoma cell lines was encouraging.

Viralytics said the research had progressed to animal studies using mice bearing human glioblastoma tumors.

The research is being conducted in collaboration with the professor of neurosurgery at the University of Toronto Dr Abhijit Guha.

The presentation will be available at www.viralytics.com on September 12, 2008.

Viralytics was unchanged at 5.4 cents.

NANOSONICS

Nanosonics says Health Canada has given full approval to market and sell its Ultrasound Probe Disinfector.

Nanosonics said the immediate approval was a “key milestone” in the commercialization of its Disinfector and was “achieved significantly earlier than previously advised”.

“Canadian market entry provides an excellent stepping stone and validation for the lucrative US market,” Nanosonics said.

The ultrasound probe disinfector is scheduled for release in Canada in early 2009, through an already identified dealer partner.

Nanosonics said the 510K regulatory submission for the US Food and Drug Administration was on schedule for submission by the end of 2008, with approval expected after June 2009.

The company said Australian regulatory approval through the Therapeutic Goods Administration was “on track, with the submission of independently audited microbiology results confirming the outstanding performance of the product”.

Nanosonics said the targeted launch and commercialization in Australia was on schedule, with market feedback “indicating a strong support for the technology”.

It is expected that a dealer partnership for Australia and New Zealand would be executed by the end of this year, with commercial sales early in 2009.

Nanosonics said dealer partners had been identified in the major healthcare markets in Europe, with partnership agreements targeted for execution in the second half of 2008, and subsequent revenues anticipated by mid 2009.

Sales training is planned for several European sales teams.

Nanosonics climbed 2.5 cents or 11.63 percent to 24 cents.

SOLBEC PHARMACEUTICALS

Solbec Pharmaceuticals says it has executed an option agreement to acquire Vista, a profitable multicenter Southeast Asian eye surgery business based in Malaysia.

The deal is pending due diligence as well as regulatory and shareholder approval.

An option fee will be payable to Vista.

Solbec’s managing director Dr David Sparling told Biotech Daily that Solbec was looking for a partner to continue the research on its anti-cancer compounds for large tumors.

Dr Sparling said the company was changing direction fro biotechnology research to laser eye surgery.

Solbec will propose to its annual general meeting that the eye care business unit trade under the brand name Freedom Vision Australasia.

Solbec’s chairman Dr William Ardrey who is also Avantogen’s chief executive officer said the Vista acquisition was “in keeping with Solbec’s ethical mission of offering the latest and most relevant treatments to patients”.

“At the same time, the transition offers the additional commercial benefits to shareholders of integrating a cash generating business which can be aggressively expanded into a best-practices eye surgery powerhouse for the Australasian region,” Dr Ardrey said.

Vista chief executive officer Boon Siong Lim will join Solbec’s board on completion of the transaction.

Solbec was up 0.1 cent or 5.56 percent to 1.9 cents.

GENERA BIOSYSTEMS

Genera Biosystems says it will not proceed with the issue of entitlement options proposed in the company's initial public offer prospectus.

Genera said that it had been the board's intention to offer one entitlement option for every two ordinary shares held, with a record date 12 weeks after the Genera Biosystems.

The options were to be issued for one cent, with an exercise price of 50 cents and an expiry date of March 31, 2009.

Genera chairman Fernando Careri said that the company's near-term commercial potential had played a key role in the company's decision not to proceed with the entitlement options.

"Commercial deals for the supply of Paptype that have been progressed with Sonic Healthcare, Gribbles Pathology and Polartechnics [see Biotech Daily; September 5, 2008] together with other supply arrangements that are at an earlier stage of negotiation, have the potential to see Genera Biosystems generate significant operational cashflows within the next two years," Mr Careri said.

"As a consequence, the company's future capital requirement and the timing of that requirement, is likely to be significantly different from what was envisaged prior to the IPO," he said.

Mr Careri said Genera would assess the most appropriate capital program and any raising would seek additional institutional and strategic shareholders.

Genera fell half a cent or 2.56 percent to 19 cents.