Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: ANTISENSE UP 24%, PORTLAND DOWN 14%**

*** STARPHARMA BIOGUIDE: MUCH MORE THAN VIVAGEL**

*** AVEXA, TARGETDRUG DEVELOP HEPATITIS C DRUG**

*** SECOND EUROPEAN PATENT FOR STEM CELL'S NANOG GENE**

*** AVITA TO BREATHE LIFE INTO CLINICAL CELL**

*** ATCOR WINS $1.15m SPHYGMOCOR CONTRACTS WITH EXISTING CLIENT**

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*** HEARTWARE EGM ON SHARE ISSUES**

*** NANOSONICS APPOINTS DAVID RADFORD CEO**

*** ANZ'S OPES PRIME SOLAGRAN SHARES DILUTED BY SHARE CONVERSION**

*** ANZ REDUCES 1% IN BIOPROSPECT TO 14%**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Wednesday June 4, 2008 with the All Ordinaries down 4.8 points to 5,698.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, seven were unchanged and four were untraded.

Antisense was best, up 1.3 cents or 23.64 percent to 6.8 cents on modest volumes, followed by Avexa up 8.93 percent to 30.5 cents and Bionomics up 7.25 percent to 37 cents. Optiscan climbed 6.67 percent; Pharmaxis was up 5.61 percent; Peplin climbed 3.7 percent; Acrux and Circadian rose more than two percent; with Arana and Ventracor up more than one percent.

Portland led the falls, down 0.5 cents or 14.29 percent to 3.0 cents, followed by Psivida down eight percent to 11.5 cents. Agenix and Starpharma lost more than seven percent; Clinuvel, Living Cell and Novogen fell more than six percent; Cathrx fell five percent; Phosphagenics was down 4.35 percent; Proteome fell 3.85 percent; Biota and Heartware shed more than two percent; with Alchemia, Cellestis, Cochlear, Prana and Universal Biosensors down more than one percent.

MARC SINATRA'S BIOGUIDE: STARPHARMA

Overview: Dr Jackie Fairley is a very talented person, as David Langsam's May 7, 2008 interview with the Starpharma CEO made clear. In the last year, under her leadership, Starpharma has inked deals with the US Department of Defense, Unilever, two condom companies (including the makers of Durex) and dermatological pharmaceutical company Stiefel Laboratories.

These and other deals have transformed Starpharma from a one trick pony with their vaginal microbicide, Vivagel, to a true, revenue-generating, platform technology company with a very strong intellectual property portfolio in the area of dendrimers.

With so much going on at Starpharma, what will drive their share price?

Financials: Market cap: $58 million; cash: $8.9 million; last quarter cash burn: $1.2 million.

Directors: Non-executive chairman, Peter Bartels; non-executive deputy chairman, Dr John Raff; CEO, Dr Jackie Fairley; non-executive directors, Ross Dobinson, Richard Hazleton and Dr Peter Jenkins.

Starpharma's board could be improved by the inclusion of senior people with skills in finance, marketing and regulation especially one with international device and pharmaceutical development experience.

Marketed Products:
Starpharma's subsidiary company Dendritic Nanotechnologies provides IP or dendrimers for the following products:
1) Stratus CS: Dade Behring's cardiac analyser uses Starpharma dendrimers to anchor antibodies in the correct orientation;
2) Superfect: Transfection kit sold by Qiagen that uses Starpharma dendrimers to carry nucleic acids into cells;
3) Priostar: New lower cost generation of dendrimer building blocks reputed to have improved thermal and hydrolytic properties;
4) Priofect: EMD Biosciences-Merck KGaA's Nanojuice transfection kit uses Priostar dendrimers as per Superfect; and
5) Starburst: Older style polyamidoamine based dendrimers.

Products in Development:
1) Vivagel vaginal microbicide: product for the prevention of sexually transmitted infections, including HIV, herpes (HSV-2) and human papillomavirus (HPV). It prevents viruses entering cells by binding to them. Vivagel has FDA fast track status for HIV. Data indicates Vivagel may also be spermicidal. Animal studies support efficacy for HIV and HSV-2. Three phase I trials (two in women, one in men) have shown Vivagel to be safe. A further phase I study in sexually active women is ongoing and a phase III study has been designed. Starpharma expects to launch Vivagel in 2010.
2) Vivagel condom coating: added protection product being developed in conjunction with two condom manufacturers. Expected to take the easier FDA 510(k) device route to market.

3) Drug delivery: Starpharma has several early stage projects aimed at improving drug delivery through improved pharmacokinetics, solubilization, targeting and drug loading.
4) Magnetic resonance imaging: projects involve concentrating imaging agents on dendrimers with or without a targeting agent to improve diagnosis of pathology.
5) Food imaging: co-development project with Unilever to develop a research tool to analyze the microscopic structure of foods.

Significant Product Markets: According to UNAIDS, there were 33.2 million people in the world with HIV in 2007, with 1.3 million sufferers in the US. HSV-2 affects 40-60 million Americans and is a major contributing factor to HIV infection. Other microbicides are in late stage development, but none are being developed for such broad applications as Vivagel. The most independent estimate of the market size for a vaginal microbicide is $US900 million by 2011 from the Rockefeller Foundation, although the broad applicability of Vivagel may substantially increase this market.

Vivagel has clear advantages over nonoxynol-9 as a condom coating. Worldwide and US condom sales in 2005 were $US3.2 billion and $US398 million, respectively. It is unclear what percentage of sales was for nonoxynol-9 coated condoms.

Although Starpharma is in the early stages of its drug delivery program, it is worth noting that in 2007, consulting firm Cientifica believes that nanotechnology-based drug delivery will rise to $US26 billion by 2012 from its current $US3.4 billion.

Opinion: The evolution of Starpharma over the last few years has been impressive and it looks like a much more robust company now. The main danger it faces is that, with so many projects, it could lose focus and end up doing none of them well. With the current management team in place, however, I think this is highly unlikely.

Starpharma's share price will be driven primarily by Vivagel in the nearer term, with three risk factors that investors need to consider. The first is that we don't have feedback regarding the acceptability of Vivagel during actual sexual encounters. The second is that participants in its phase III trial will be advised to use condoms as well, making it more difficult to demonstrate any protective effect of Vivagel. Finally, getting Vivagel registered in a significant market by the end of 2010 will require Starpharma's best efforts since similar phase III trials have taken three years. Unexpected changes in these areas will impact significantly on Starpharma's share price

Due to their diversified lower risk nature, Starpharma's other projects will reduce volatility and ultimately set a floor for its share price as they progress. Two projects in particular standout. The Vivagel condom coating projects appear to be absolute no brainers. The Stiefel Laboratories drug delivery project is important because it is the first significant drug delivery deal for Starpharma's dendrimers and it starts to validate the theoretical advantages of dendrimers for drug delivery.

Given the complex nature of Starpharma's projects, I have valued it by comparing it to 12 other similar (at least, in part) ASX-listed life science companies and then adjusting for current market sentiment. In doing so, I arrived at a value of 54 cents a share. Starpharma fell 2.5 cents or 7.14 percent to 32.5 cents.

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AVEXA

Avexa will collaborate with Shanghai Targetdrug Co to develop novel lead inhibitors of hepatitis C virus replication.

Avexa said the collaboration “comes after the successful nomination of lead compounds from both the HIV-integrase and the antibiotic programs for progression into investigational new drug application-enabling studies.

Avexa chief executive officer Dr Julian Chick said the development of new hepatitis C virus treatments was “an opportunity to put Avexa’s proven experience in pure drug discovery into play”.

He said hepatitis C affected 180 million people globally, with only half of patients benefitting from current therapies.

Avexa said Datamonitor estimated the hepatitis C virus market would increase to $4.4 billion in 2010 and $8.8 billion in 2015.

Hepatitis C is an infectious disease that is a leading cause of chronic liver disease resulting in liver inflammation, cirrhosis and liver cancer.

The blood-borne disease is a virus that spreads in its host by replicating its RNA and using this to make the components that form new viruses.

Avexa said it intended to target this replication process to identify inhibitors.

Avexa will focus resources previously assigned to the CCR5 program to the hepatitis C virus program.

The CCR5 program was a collaboration with Targetdrug for HIV at the developmental and preclinical stage.

Avexa said the first component of recruitment for the Apricitabine phase III clinical trial would be completed in the third quarter of this year.

The company said it had initiated 45 sites in North America, Europe, Israel, Australia and South America, with 20 more sites due to be initiated in the coming weeks.

Avexa said it was preparing additional countries and sites for the second of the phase III trials.

Avexa was up 2.5 cents or 8.93 percent to 30.5 cents.

STEM CELL SCIENCES

Stem Cell Sciences has been granted a second European patent for Nanog, a key gene enabling the production of disease specific assays.

Stem Cell said the patent covers mouse Nanog complementing the company’s existing patent, covering human Nanog.

The company said Nanog was “a key factor used to convert adult stem cells back into a pluripotent state” and the technology could be used to reprogram adult cells to behave like embryonic stem cells, “avoiding the controversy associated with using embryos”.

Stem Cell Sciences chief scientific officer Dr Tim Allsopp said Nanog was “like a master control switch” and was a protein that could bind to the DNA encoding many other genes regulating their pattern of activity”.

“In effect, we can use the Nanog gene to turn back the developmental clock in cells and induce an embryonic status in which the cells have the hallmark features of indefinite growth and pluripotency in culture,” Dr Allsopp said.

The two patents “cover manipulating expression of human and mouse Nanog, cells containing introduced human and mouse Nanog genes, reprogramming methods using human and mouse Nanog and related culture media products” Stem Cell Sciences said.

Stem Cell was unchanged at 36 cents.

CLINICAL CELL

Clinical Cell is preparing for its renaissance with its management team meeting investors and media in preparation for tomorrow's extraordinary general meeting.

Clinical Cell's chief executive officer Dr Bill Dolphin and chief financial officer Andrew Cannon were in Melbourne today for a series of briefings and told Biotech Daily that with $8.7 million in the bank and revenue of $2 million a year from the Breathatec acquisiton, the entity reborn from the Clinical Cell merger with Visiomed had great potential as a medical device company.

Dr Dolphin has extensive US Food and Drug Administration experience and will be based in Boston, while Mr Cannon will run the European operation from Cambridge UK.

General manager Lorraine Glover will be in charge of Australian operations.

Dr Dolphin said tomorrow's meeting would vote on a name change to Avita and a 10 for one share consolidation.

He said the company was dealing with a range of issues primarily related to the Recell wound treatment.

"The FDA trials have not gone well," Dr Dolphin said and despite two years of European registration sales had been "small".

Mr Cannon and Dr Dolphin said distribution was the primary problem and direct sales staff and clinical specialists were needed to take Recell to surgeons and demonstrate its effectiveness.

The major would care technologies of Cellspray and Cellspray XP were "on the shelf" and the company would not proceed with them.

With cash in the bank Dr Dolphin said acquisitions would be considered but there was "nothing immediate" planned.

He said the company had four tasks. It needed to sell Recell in Europe, submit a revised protocol in its application to the FDA, improve sales of its Funhaler paediatric incentive asthma spacer device and generate applications for Recell beyond burns treatment to dermatological and cosmetic applications.

Dr Dolphin said there were "a whole slew of applications" for Recell that had not previously been considered including use for scarring, vitiligo and facial repair.

Clinical Cell climbed 0.1 cents or 6.67 percent to 1.6 cents.

ATCOR

Atcor has signed $1.15 million contracts for Sphygmocor systems and clinical trial support services with an undisclosed company for pharmaceutical clinical trials.

Atcor said a significant portion of the $1.15 million would be revenue in the current financial year.

The company said more than 70 percent of the transactions for trials in the US and Europe were repeat business following successful use of Sphygmocor in earlier trials by the same company.

Atcor chief executive officer Duncan Ross said the pharmaceutical trials business was increasing with the evidence that central blood pressures were a more sensitive measure of cardiovascular risk than pressures measured in the arm.

The Sphygmocor system measures the effects of reflected blood pressure in the central aortic pressure wave, which cannot be detected with standard brachial blood pressure monitoring.

Atcor climbed 1.1 cents or 12.36 percent to 10 cents.

EXCELLENCE IN RESEARCH

The Federal Minister for Innovation, Industry, Science and Research, Senator Kim Carr, has called for input to develop the Excellence in Research for Australia initiative.

A media release from Senator Carr said a consultation paper on the Excellence in Research for Australia (ERA) initiative was released today.

Senator Carr said that "only by involving from the outset those affected by ERA could the Government expect to build stakeholder confidence in, and ownership of, the important new evaluation framework".

The release said the consultation process was foreshadowed in February when the initiative was announced, "as part of a transparent and robust development process for the new scheme".

"ERA will inform government, industry, business and others in our community about the quality of research in Australia's higher education institutions, and guide future investment in research," Senator Carr said.

"It is vital that ERA has the confidence of the sector it will assess," Senator Carr said.

"I encourage anyone who is involved in research in Australia to respond to the consultation paper and take up the opportunity to contribute to the development of a first class evaluation framework," he said.

The Excellence in Research for Australia consultation paper seeks feedback on a range of issues, including the attribution of publications and other indicators of research, which will be crucial to the initiative's shape and utility.

The media release said the initiative was being developed by the Australian Research Council and reflected the Government's commitment to a transparent, streamlined, metrics-based approach for evaluating research excellence in Australia's universities.

Senator Carr said he anticipated that, following the general consultation process, the Australian Research Council would establish a metrics working group and begin targeted consultation on the first clusters to be evaluated: the physical, chemical and earth sciences and the humanities and creative arts.

The new framework will aim to identify excellence across the full spectrum of research activity; compare Australia's research effort against international benchmarks; create incentives to improve the quality of research; and identify emerging research areas and opportunities for further development.

The consultation paper was prepared by the Australian Research Council with input from the National Health and Medical Research Council and advice from the Department of Innovation, Industry, Science and Research.

The closing date for responses is June 30, 2008.

For more information, including the consultation paper, go to www.arc.gov.au/era.

PRIMA

All resolutions to the Prima Biomed extraordinary general meeting have been passed but there was significant opposition to the issue of options to directors.

Resolutions approving options to chairman Ata Gokyildirim and chief executive officer Martin Rogers were passed with 25,607,488 proxy votes in favor and 4,933,269 proxy votes against.

A resolution to issue options to Richard Hammel was passed by 23,602,488 proxy votes in favor and 6,938,269 votes against.

All other resolutions including the issue of shares and ratification of previous shares and options were passed overwhelmingly.

Prima was up 0.1 cents or 7.69 percent to 1.4 cents.

SAFETY MEDICAL

Safety Medical has raised $775,000 through a convertible note capital raising and has offered a share purchase plan to existing shareholders.
Shareholders will be able to buy up to $5,000 in shares at 10 cents a share and receive one attaching option for every two shares bought.
The offer will raise up to $1.475 million.
The record date is June 18, 2008 the offer opens on June 25 and closes on July 9, 2008.
The funds will be used to expedite the expansion of the company's Securetouch products and general working capital as well as construct an additional assembly machine, expanding the range of its retractable syringe sizes to 2ml, 3ml and 5ml.
Safety Medical fell one cent or 8.7 percent to 10.5 cents.

HEARTWARE

Heartware shareholders will vote on a series of resolutions relating to a $35 million placement (see Biotech Daily May 23, 2008).
The resolutions include the approval of the allotment of 70,000,000 shares at 50 cents each to investors in Australia and the US; the approval of directors and related parties to participate in the placement; and the grant of 200,000 options to director Tim Barberich.
The meeting will be held at Grant Thornton, Level 17, 383 Kent Street, Sydney on July 11, 2008 at 10am.
Heartware was down one cent or 2.04 percent to 48 cents.

NANOSONICS

Nanosonics has appointed David Radford as chief executive officer and a director, effective from June 16, 2008.
Nanosonics said Mr Radford had more than 20 years experience in the medical device and health care industries.
He holds an honors degree in Applied Biological Science from Bristol Polytechnic, specializing in microbiology and a Masters of Business Administration from the Australian Graduate School of Management.
The company said Mr Radford held senior roles in GE Healthcare, Recall Corp which is a division of Brambles Industries and Cobe Laboratories.
He has worked in business development, operations and regulatory functions and "has driven global expansion into China, India and Japan and was responsible for the acquisition and integration of four businesses in the Asian region" Nanosonics said.
Chief financial officer Chris Grundy has been acting CEO and continues on as CFO.
Nanosonics climbed 1.5 cents or 8.11 percent to 20 cents.

SOLAGRAN

The ANZ Bank has reduced its substantial shareholding in Solagran shares acquired from the Opes Prime Stockbroking collapse following the conversion of unlisted options and contributing shares.
The ANZ said it held 56,283,662 ordinary Solagran shares or 28.518 percent of the company and 9,803,258 contributing shares with a voting power of 3.725 percent.
The ANZ previously held 55,822,662 ordianry shares (42.3%) and 9,828,258 contributing shares.
Solagran fell 2.5 cents or 6.76 percent to 34.5 cents.

BIOPROSPECT

The ANZ Bank has reduced its substantial shareholding in Bioprospect shares acquired from the Opes Prime Stockbroking collapse from 75,575,086 shares (15.52%) to 70,242,343 shares (14.42%).

Bioprospect was up 0.1 cents or 5.0 percent to 2.1 cents.