Biotech Daily

Tuesday July 15, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: ACRUX UP 6.6%, AGENIX DOWN 8%**

*** PROTEOME HALTS PROSTATE CANCER DIAGNOSTIC**

*** FMR, FIDELITY TAKE 9% OF HEARTWARE; DEEPHAVEN TAKES 7%**

*** PORTLAND CFO JAMES WYNNE GOES MID-RIGHTS ISSUE**

*** CIRCADIAN TAKES 100% OF VEGENICS**

*** CONOCOPHILLIPS TO EVALUATE BIOSIGNAL'S ANTI-MICROBIAL**

*** UNILIFE SALES BEGIN; APPOINTS DISTRIBUTOR; ANSWERS FDA**

*** BIO-MELBOURNE BREAKFASTS ON INSURANCE**

*** BRAINZ RELEASES 24m SHARES FROM ESCROW**

MARKET REPORT

The Australian All Ordinaries Index fell below 4,900 points on Tuesday July 15, 2008 closing down 97.8 points or 2.0 percent at 4,910.1 points.

Six of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and nine were untraded.

Acrux was best, up seven cents or 6.6 percent to $1.13 on modest volumes; followed by Clinuvel up two cents or 6.45 percent to 33 cents; with Cellestis, Living Cell and Pharmaxis all up by more than two percent.

Agenix led the falls, down 0.3 cents or 7.69 percent to 3.6 cents, followed by Resmed down 24 cents or 6.22 percent to $3.62 with 1.7 million shares traded.

Arana and Biota lost more than five percent; Polartechnics, Progen and Sirtex fell more than four percent; Alchemia, Avexa, Chemgenex, Starpharma and Viralytics were down three percent or more; Phosphagenics and Ventracor shed more than two percent; with Bionomics, Circadian and Peplin down more than one percent.

PROTEOME

Proteome has ceased development of a diagnostic test for prostate cancer.
Proteome chief executive officer Dr Jenny Harry told Biotech Daily the review of the company's operations and the decision to halt the development was "a positive" and would concentrate the development of more productive diagnostic tests.
"While the assay worked it was not optimal," Dr Harry said.
She said it could be developed but the cost to get it to market would be too expensive.
In a media release to the ASX the company said the decision was based on the results of a proof-of-concept study that demonstrated the project did not satisfy internal assessment hurdles.
Proteome said that following validation of data generated by Egenix Inc, which demonstrated increased expression of human carcinoma antigen (HCA) in cancerous versus non-cancerous prostate tissues, the proof-of-concept study evaluated the merits of HCA as a semen-based diagnostic marker for prostate cancer.
Proteome identified a protein that provided prostate-specific detection of HCA in semen, and developed an assay for detection of HCA in clinical samples.
The company said commercialization of the assay would require significant resources along with an extended development timeline.
Proteome chief executive officer Dr Jenny Harry said the company was committed to projects with near-term revenue potential, "as well as leveraging existing intellectual property in the fields of respiratory and infectious diseases".
"In particular, we are exploring opportunities to expand the development of products using our Diagnostiq platform," Dr Harry said.
"For instance, earlier this month we announced an agreement with Bayer Cropscience AG to develop and commercialize diagnostic products for crop management," Dr Harry said.
"There are no liabilities resulting for the termination of the project," Dr Harry told Biotech Daily.
Proteome was untraded at 11 cents.

HEARTWARE

The US based FMR Corp and Fidelity Investments have become substantial in Heartware with 22,636,983 shares or 9.12 percent of the company.
FMR and Fidelity increased their non-substantial holding in Heartware at the recent $31 million placement (see Biotech Daily; May 23, 2008).
FMR and Fidelity recently sold four percent of Cochlear's total share issue (see Biotech Daily; July 2, 2008) having increased in both Cochlear and CSL over the past two years.
Separately the Minnetonka Minnesota-based Deephaven Capital Management has become substantial in Heartware with 20,515,180 shares or 6.61 percent of the company.
Heartware was unchanged at 45 cents.

PORTLAND ORTHOPAEDICS

Portland Orthopaedics says company secretary and chief financial officer James Wynn has resigned "effective immediately"
Portland is involved in a rights issue which is not expected to close until July 25, 2008.
Portland said Richard Gregson had been appointed company secretary in an interim capacity until a new company secretary is appointed.
The company said it would shortly announce a replacement for the chief financial officer.
Portland fell 0.1 cents or 4.76 percent to two cents.

CIRCADIAN

Circadian will acquire 100 percent ownership of Vegenics furthering its move from a biotechnology company incubator to a biologics drug development company.
Circadian owns 67 percent of Vegenics and will acquire the remaining 33 percent from the Ludwig Institute for Cancer Research and the University of Helsinki's Licentia.
Circadian will have total control of Vegenics' vascular endothelial growth factor (VEGF) technologies including VEGF-C, VEGF-D and VEGFR-3 for cancer and other indications.
Circadian said vascular endothelial growth factor proteins C and D help regulate the growth of new blood vessels. Blocking these proteins around tumors may inhibit the growth of existing tumors and prevent the spread of new cancer cells.
The acquisition will be settled in two tranches with an initial issue of 2,589,635 Circadian shares to the Ludwig Institute and 2,527,795 shares to Licentia and a cash payment of $650,000 to Licentia.
The initial issue will equate to a combined interest of 11.3 percent after the issue, with 50 percent of the shares escrowed for 12 months and 50 percent escrowed for 24 months.
The second tranche will see the issue of 532,455 shares to the Ludwig Insititute and 622,545 shares to Licentia, on the earlier of development milestones or the second anniversary of Circadian's acquisition of the Ludwig Institute and Licentia's interests in Vegenics, subject to shareholder approval, if required.
Ludwig Institute for Cancer Research president Ed McDermott Jr said his company was "very excited to further cement our relationship with Circadian now that it will be focused on exploiting the VEGF technology, much of which was originally developed by scientists from the Ludwig Institute for Cancer Research and the University of Helsinki".
The Ludwig Institute and Licentia together will also be entitled to nominate one director to join the board of Circadian.
The transaction is expected to close at the end of July, 2008.
Circadian fell 1.5 cents or 1.67 percent to 88.5 cents.

BIOSIGNAL

Major oil producer Conocophillips will evaluate Biosignal's treatment for microbiologically influenced corrosion in oil and gas infrastructure.
Biosignal said Conocophillips was the third largest integrated energy company in the US, and would fund the evaluation, primarily at Conocophillips's Bartlesville Technology Centre in Oklahoma.
Biosignal said it would supply active compound for the evaluation and conduct some trials at its own facilities in cooperation with Conocophillips.
The company said the evaluation would be conducted over the next six months with results expected early in 2009.
Biosignal will be provided with a detailed report on the work conducted.
Biosignal chief executive officer Prof Peter Steinberg said there was "a great deal of interest from the oil and gas industry in alternative approaches to control of bacteria".
"The current methods rely on toxic chemicals that can have significant environmental impact," Prof Steinberg said.
The interest from Conocophillips followed support from Santos and BHP Billiton and interest from existing chemical suppliers to the industry.
Biosignal said microbiologically influenced corrosion and associated loss of production, costs the oil and gas industry more than $US2 billion a year.
Biosignal was unchanged at 8.5 cents.

UNILIFE MEDICAL SOLUTIONS

Unilife has begun commercial sales of its Unitract 1.0 mL safety syringes and appointed Shanghai's Kindly Enterprise Development Group as a distribution partner.

Unilife says it has received and processed initial sales orders from Kindly Enterprise Development Group (KDL) for its 1.0 mL Safe Syringe and 1mL Insulin Syringe.

Unilife has granted KDL exclusive rights to distribute the syringes in China, the Middle East, Africa, Central and South America and Eastern Europe.

Unilife has also granted KDL the right to distribute the syringes on a non-exclusive basis in Germany and Austria.

KDL may be appointed as a distribution partner for other countries as part of the continued global rollout of these products.

KDL will be responsible for regulatory approval of the Unitract 1mL syringes in those countries that do not automatically accept the product certifications Unilife has previously secured from regulatory agencies within Europe, Australia and Canada.

Unitratc said that as well as being the second largest medical device manufacturer in China, KDL had established "a significant national distribution network covering most Chinese provinces as well as more than 50 other countries around the world".

Within China, KDL has established a national distribution network of more than 20 regional offices which supply medical products to the majority of major hospitals, emergency centres, pharmacies and the China Centre for Disease Control and Prevention. This distribution network is particularly strong within east-coast cities in China such as Shanghai that have high rates of disposable income and world-class healthcare facilities.

Unilife submitted its 510(k) application to the Food and Drug Administration (FDA) for US regulatory approval of its 1mL Unitract Insulin syringes in April this year.

The FDA website says a 510(k) application "requires demonstration of substantial equivalence" to another US legally marketed device

Unilife said the FDA reviewed its application and subsequently requested additional information.

The company said the request was a typical process within the formal FDA review and it would help in their determination of substantial equivalence to an approved predicate device.

The additional information is supplementary evidence to show compliance to the FDA recognized consensus standards for biocompatibility, as well as further data relating to latex content, ageing and sterilization.

Unilife expects the review will be handled promptly and approval "will support scheduled US market launch activities".

This does not interfere with the commercial release of the products in other international regions such as Europe.

Unilife chief executive officer Alan Shortall said the commercial sale of the Unitract range of 1mL safety syringes was "a significant and eagerly anticipated milestone".

"The commercial sale of our 1.0 mL Unitract safety syringes enables Unilife to process initial sales orders, commence product evaluation activities and finalize discussions with a number of other potential distribution partners," Mr Shortall said.

"Whilst we will continue to concentrate our energies towards the industrialisation of the Unilife Prefilled Syringe, we remain committed to the global rollout of our other products," he said.

Mr Shortall said the KDL partnership helped Unilife maintain its focus on the primary commercial opportunities.

Unilife fell 1.5 cents or 4.84 percent to 29.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network's August 5, 2008 breakfast discusses insurance programs, with specialist perspectives from a broker and an underwriter.

The Bio-Melbourne Network says the insurance industry "offers a multitude of options to life science companies" including insuring clinical trials and against intellectual property litigation, but says the questions are how to determine which is best suited to an individual business and what are the characteristics of a well constructed insurance program?

Avatar Corporation chief executive officer, Konrad Aerin, will present on the fundamental elements of a quality insurance program.

Selecting the right broker and insurers, as well as managing those relationships effectively, plays a major role in protecting a business.

Mr Aerin will talk about overseas insurance issues and the key trends in directors' and officers' liability, as well as intellectual property litigation insurance.

Chubb Insurance Company of Australia's regional practice leader for life sciences Travis McIntosh, will discuss how underwriters assess a client's risk profile and the impact that this has on policy coverage and price, with a specific focus on clinical trial insurance. Mr McIntosh will address the issue of lead times, multiple trial programs, multiple jurisdictions and other key factors in determining coverage limits.

The Bio-Breakfast will be in the Supper Room at the Melbourne Town Hall, Swanston St, Melbourne.

Registration begins at 7.15am with a buffet breakfast and presentations at 8am.

For more information contact Nicole Pitcher by email at: npitcher@biomelbourne.org or telephone +613 9650 8800 or visit www.biomelbourne.org.

BRAINZ INSTRUMENTS

Brainz Instruments has applied for the release of 24,418,020 shares from escrow.

The total number of Brainz shares following the release from escrow is 60,000,000 shares.

Brainz was untraded at 2.7 cents.