Biotech Daily

Wednesday July 22, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BONE UP 50%, CYTOPIA DOWN 5%**

*** BIOGUIDE BRIEF: PRIMA'S $25.5m CONVERTIBLE NOTE**

*** CSL BEGINS SWINE FLU VACCINE TRIAL**

*** VIRAX DRUG 'A NEW MECHANISM SUPPRESSING HIV REPLICATION'**

*** LIVING CELL PREPARES NZ TYPE 1 DIABETES TRIAL; WRITES TO NHMRC**

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*** CE MARK FOR FERMISCAN BREAST CANCER TEST**

*** EUROPEAN SALES APPROVAL FOR KARMELSONIX COUGH-COUNTER**

*** GREGORY WORTH TAKES 11% OF MEDICAL THERAPIES**

MARKET REPORT

The Australian stock market was up 0.44 percent on Wednesday July 22, 2009 with the S&P ASX 200 up 17.8 points to 4,068.5 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and five were untraded.

Bone was best, up six cents or 50 percent to 18 cents with 4,000 shares traded followed by Living Cell up 15.15 percent to 19 cents and Mesoblast up 12.1 percent to 97 cents.

Both Acrux and Cathrx climbed 9.1 percent; Clinuvel and Tissue Therapies were up more than eight percent; Progen rose 5.6 percent; Avexa was up 4.55 percent; Compumedics and Novogen were up more that three percent; Alchemia and Nanosonics rose more than two percent; with Cellestis and Resmed up more than one percent.

Cytopia led the falls, down 0.4 cents or 5.33 percent to 7.1 cents with 10,000 shares traded followed by Optiscan down 4.8 percent to four cents.

Prana and Universal Biosensors lost more than three percent; Genera, Labtech and Psivida shed more than two percent; Cochlear was down 1.9 percent; with Biota, Chemgenex, CSL, Peplin and Sirtex down by less than one percent.

MARC SINATRA'S BIOGUIDE BRIEF NOTE: PRIMA BIOMED

Convertible notes can be dressed up to look like just about anything.

In their nastiest form, the note holder can use them as part of a profitable short selling strategy and/or to capture a greater slice of the company. In a more appropriate form, they can be used by biotech companies to obtain significant amounts of working capital where the level of risk makes finding equity investment difficult.

On the surface, the $25.5 million convertible note funding announced by Prima Biomed yesterday sounds great.

There are no interest payments, the cash comes in on a monthly basis, Prima can opt to repay in cash rather than shares and Prima can terminate the agreement if the share price falls below an unspecified level – along with other rights the company holds.

The equation for converting the notes into shares, however, hands most of the upside to the note-holder, while minimizing any downside.

As noted by a Biotech Daily reader, however, the note-holder, Springtree Special Opportunities Fund, has only raised $US1.15 million so far, meaning that many of the shares issued to Springtree may well be put straight on the market.

Based on what is currently known, Springtree's decision to enter into the note with Prima appears to be based more on a finance thesis than an investment thesis. Consequently, I don't believe the deal should be seen as a huge endorsement of Prima's technology.

Although the Prima's management has the company up and running again, any selling by Springtree of its shares is likely to cap Prima's share price around its current level and investors seeking quick gains may do better to look elsewhere in the near term.

Prima fell 0.6 cents or 8.45 percent to 6.5 cents with 12.7 million shares traded.

Marc Sinatra
Analyst

CSL

CSL has begun its Adelaide trial of Panvax H1N1 A/California candidate vaccine against the H1N1 'swine influenza.
CSL said the trial is in partnership with clinical research organization CMAX and the Royal Adelaide Hospital in South Australia.
CSL's public affairs director Dr Rachel David told Biotech Daily that the drug was being given to 240 healthy volunteers in two arms, one with a 15 microgram dose and one with a 30 micrograms dose, receiving two injections of the vaccine, three weeks apart.
Dr David said the first patients were dosed today and trial data was expected by September with the vaccine available as early as October 2009.
In a media release CSL said the trial participants CSL said the trial was being conducted "with view to fulfilling a commitment to the Australian Department of Health and Ageing to supply up to 10 million people with a vaccine against H1N1 'swine influenza'.
CSL fell 15 cents or 0.5 percent to $29.86 with 3.8 million shares traded.

VIRAX

Virax says its VIR201 HIV vaccine “clearly demonstrates an immune response confirming the results of viral load suppression from the phase I/IIa clinical trial” in Australia.

Virax said the data was presented by a group of Virax collaborators led by the Royal Perth Hospital’s Prof Martyn French at the International AIDS Society conference in Cape Town, South Africa.

The company said the presentation detailed the immune system’s antibody response to the VIR201 vaccine and was the outcome of additional immunological testing of clinical samples from the Australian trials of VIR201.

Virax chief executive officer Dr Larry Ward said the presentation was “an extremely significant milestone for the development of VIR201”.

“The Australian trials of VIR201 demonstrated that the vaccine suppressed the levels of HIV virus in infected individuals,” Dr Ward said.

“The paper documents clinical data of an immune readout potentiated by VIR201 that correlates with the viral load suppression,” he said.

“This data fills a gap in the results from the Australian trials,” Dr Ward said.

“In order to further build on this data we will be using the antibody isotyping assays as major immune read-out in our ongoing trial in South Africa,” Dr Ward said.

The company said the data demonstrated that VIR201 vaccination induced an IgG2 antibody response against the p24 antigen encoded in the vaccine and such an antibody response was not observed in those participants receiving a placebo injection.

Virax said the data was statistically significant (p=0.014).

In addition VIR201 induced an IgG1 immune response against p24 relative to placebo (p=0.018) and also an IgG1 response against gp41 (p=0.066), an antigen not encoded in VIR201.

A VIR201 induced IgG2 response against gp41 was not observed.

Importantly vaccine-induced IgG2 antibodies to a vaccine-encoded antigen (p24) were associated with lower HIV replication and could provide the mechanism as to how VIR201 suppressed viral load in the Australian trials, the company said.

Prof French and co-workers said that because of recent high profile failures in the preventative vaccine arena it was important that new strategies for producing immune responses other than the purely T-cell-based HIV vaccines approaches were pursued.

The company said the mechanism of action of antibody isotype switching (IgG1 to IgG2) was such a novel mechanism of action.

Virax said further details of the paper would be available on its website.

The company said the data enhanced its approach to developing VIR201 as a product that potentially defers the introduction to anti-retroviral therapies for patients.

Virax said the key benefits included the reduction of adverse side effects, increased patient compliance, particularly in the developing world, and a health economic benefit given the annual cost of anti-retroviral treatments of about $US15,000 per patient.

The company said the market for HIV medications was large and growing and projected to increase from $US9.3 billion in 2007 to $US15.1 billion in 2017.

Virax said VIR201 uses its Co-X-Gene technology and had been tested in two Australian phase I/IIa trials where it was shown to be safe and well tolerated and possessed the ability to suppress viral load in patients undergoing antiretroviral treatment in the context of a treatment interruption.

VIR201 is in a phase I/IIa trial in South Africa.

Virax was up 1.6 cents or 45.7 percent to 5.1 cents with 1.4 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says its type 1 diabetes xenotransplant trial is ready to begin with all regulatory approvals completed.

Living Cell said the phase I/IIa trial of encapsulated pig islets of Langerhans Diabecell has been authorized by the New Zealand Minister of Health and the regional ethics committee and information on the study was available on the US National Institutes of Health registry website www.ClinicalTrials.gov.

Living Cell chief executive officer Dr Paul Tan told Biotech Daily that the formal enrolment process could begin and the first patient was expected to receive the first implant by the end of September or early October 2009.

Dr Tan said it was the Western world's first xenotransplant trial in 10 years. He said the last trial was also conducted by Living Cell founder and medical director Prof Bob Elliott in New Zealand and the patient had been reported with continued benefit from the porcine islets of Langerhans still producing insulin.

Dr Tan said he has written to Australia's National Health and Medical Research Council to begin the regulatory process for similar trials in Australia.

Living Cell was up 2.5 cents 15.15 percent to 19 cents.

IDT

IDT has written a five page response to an ASX query confirming its compliance with all corporate governance issues relating to Listing Rule 4.10.3.

IDT received the ASX query on July 15, 2009 saying the Exchange had reviewed the company's corporate governance practices from the June 2008 annual report and gave the company one week to respond under threat of suspension from trading.

The company confirmed it had whistleblower and quality policies on its updated website.

In the letter to IDT, ASX Markets Supervision said it had "reviewed the corporate governance disclosures in the annual reports of all entities".

"Upon our review of the company's annual report, ASXMS could not identify a statement in the annual report confirming whether the company had followed or not followed the following recommendations of the council: Recommendations 3.1, 3.3 and 10.1.

"ASXMS attaches particular importance to encouraging a consistently high standard of listed entities' disclosures about the council's corporate governance recommendations," the ASX letter said.

IDT said it took the view "that its corporate governance practices and policies work to ensure that the rights of all key stakeholders and its obligations to them are met".

"The board and management have an overriding obligation to act with care and diligence in accordance with the law in serving the interests of IDT's shareholders, employees, customers and the community," the company said.

"The company is in the process of reviewing IDT's corporate governance statement for the 2009 annual report to ensure that it meets the requirements of the updated corporate governance council principles and recommendations issued in August 2007," IDT said.

Earlier this year, the ASX began a crack down on companies failing to lodge director's interest statements on time (BD: June 25, 2009).

The crackdown followed the April 2008 Opes Prime collapse which revealed directors failing to declare that they had given away shares in margin lending arrangements.

Among the companies questioned was one that was one day late in filing with a previous history of 20 years of compliance and another whose company secretary was unable to fill in the form because he had died.

IDT was up 2.5 cents or 1.57 percent to $1.62.

FERMISCAN

Fermiscan says its x-ray diffraction breast cancer test has received Conformitée Européenne (CE) mark authorizing sale in the European Union.
Fermiscan said it had satisfied the relevant requirements in the EU's Medical and Healthcare Products Regulatory Agency directives that its product conforms and that it is fit for its intended purpose.
Fermiscan said it had begun to establish the necessary infrastructure in Europe for a commercial roll out of the test.
Fermiscan fell 1.7 cents or 21.25 percent to 6.3 cents.

KARMELSONIX

Karmelsonix says it has been granted Conformitée Européenne (CE) mark for the Pulmotrack 3010 Coughcount device.
Karmelsonix said the certification allowed the sale and use of Karmelsonix' cough detection module in the European Union.
The company said the Pulmotrack-CC facilitated detection, counting and documentation of coughs and had been submitted for US Food and Drug Administration approval and would be submitted for Australian Therapeutic Goods Administration approval.
Karmelsonix said the machine used "elaborate algorithms to identify coughs and differentiate between true coughs and other signals such as speech, crying and snoring".
Karmelsonix fell 0.1 cents or 2.5 percent to 3.9 cents.

MEDICAL THERAPIES

Gregory Glen Worth has increased his substantial shareholding in Medical Therapies from 13,637,809 shares (7.27%) to 22,885,320 shares (10.77%).
Most of the shares were bought at 2.2 cents a share on July 7, 2009.
Medical Therapies was untraded at 2.9 cents.