Biotech Daily

Tuesday April 24, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: GENERA UP 20%, NANOSONICS DOWN 6.5%**

*** GENERA UNVEILS SIROCCO AUTOMATED DIAGNOSTICS PLATFORM**

*** HEARTWARE PREPARES FOR FDA EXPERT PANEL MEETING**

*** STARPHARMA PLEADS SCHULTZ TO ASX 8% QUERY**

*** MEDICAL DEVELOPMENTS EXPECTS $2.2m NET PROFIT**

*** CATHRX HAS LESS THAN ONE QUARTER CASH, FUNDING 'SOON'**

*** CORRECTION: CYCLOPHARM**

*** BIO-MELBOURNE NETWORK WORKSHOPS SOCIAL NETWORKS**

*** ASIC PROSECUTES ACTINOGEN'S DAVID ZOHAR**

MARKET REPORT

The Australian stock market closed up 0.18 percent on Tuesday April 24, 2012 with the S&P ASX 200 up eight points to 4,360.4 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and three were untraded.

Genera was the best, up four cents or 20.0 percent to 24 cents with 133,235 shares traded.

Heartware, Impedimed and Psivida climbed more than seven percent; Sunshine Heart was up 6.9 percent; Benitec, Circadian and Ellex were up five percent or more; Phylogica was up 4.2 percent; Neuren was up 3.85 percent; Acrux and Genetic Technologies rose two percent or more; with Alchemia and Cochlear were up one percent or more.

Nanosonics led the falls, down 3.5 cents or 6.5 percent to 50.5 cents with 48,160 shares traded.

Antisense and Biota lost more than five percent; Pharmaxis fell 4.4 percent; Allied Health, Optiscan and Prana were down more than three percent; Avita, Living Cell, Phosphagenics, Prima and Sirtex shed two percent or more; with QRX, Starpharma and Tissue Therapies down more than one percent.

GENERA BIOSYSTEMS

Genera has unveiled its Sirocco multiplexed automated diagnostics machine, using the company's Ampasand silica bead diagnostics platform.

Genera first used the Ampasand platform for its Paptype human papillomavirus diagnostic and later extended its use for its RTIplex multiplexed respiratory pathogen diagnostic.

Genera executive chairman Lou Panaccio told Biotech Daily that Sirocco could run "any kind of Ampasand type test".

"It can run a number of tests at one time, from one sample and can be used for a whole range of molecular diagnostic tests including sexually-transmitted infections, food pathogens and respiratory illnesses," Mr Panaccio said.

Mr Panaccio said that infections often were the result of multiple pathogens and Ampasand tests run on the Sirocco instrument using Genera's QPlots software would automatically detect and report all identified pathogens.

Genera said the first Sirocco prototype was completed in December 2011 and had been in operation at it Scoresby laboratory since then and its operational capability had been enhanced with a modified version of the company's proprietary QPlots software.

Genera said the short-term strategic focus was to place Sirocco instruments in a range of diagnostic laboratories across a number of jurisdictions and corporate groups and for these laboratories to run Genera-developed molecular diagnostic tests.

The company said it would build "significant long term value by expanding the menu of proprietary tests capable of running on the Sirocco" and the molecular diagnostic market was worth more than $4 billion a year.

Genera said the first two placements of Sirocco units would validate the platform and tests by independent high volume diagnostic pathology laboratories, with long-term partner Healthscope Pathology the first Sirocco recipient, in the next two weeks.

The company said the second unit was likely to be placed in a high volume diagnostic laboratory located overseas and it was in discussion with laboratories in both North and South America.

Genera's chief scientific officer Dr Karl Poetter said that automation was "the key to the use of our tests in diagnostic laboratories".

Dr Poetter said the Sirocco prototype was user friendly, easy to run, the data generated was accurate and the instrument was robust.

"We have tested the system to the point of failure for the past three months and have found that all the components of Sirocco are able to perform under very severe conditions," Dr Poetter said.

Genera said its Paptype test had been modified for the Sirocco platform and previous trial samples were being retested to validate the Paptype Sirocco platform (SP) model.

Genera said that during the next nine months it expected to validate the first two Sirocco units, conclude commercial agreements for the supply of the units and diagnostic tests, as well as complete Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark registration of Paptype SP and RTIplex, and begin commercial volume production of Paptype SP and RTIplex.

Mr Panaccio said that the development of the Sirocco prototype enabled engagement with prospective development partners as well as diagnostic laboratories.

"We have shown that we can construct an automated testing platform in a capital-efficient manner [and] … have the skills to develop world leading [molecular diagnostic] tests," Mr Panaccio said.

Mr Panaccio said that the Sirocco platform was best explained by watching a video at: http://generabiosystems.corporateit.com.au/display.aspx?Id=40.

Genera climbed four cents or 20 percent to 24 cents.

HEARTWARE INTERNATIONAL

The US Food and Drug Administration's Circulatory System Devices Panel will vote on the approval of Heartware's left ventricular assist device for bridge-to-transplant, tomorrow.
The Panel's meeting with Heartware in Gaithersburg Maryland is one of the final steps in the approval process and will consider the company's pivotal trial data as well as request answers to specified safety and efficacy questions.
If the Panel votes in favor, the FDA process takes a further two to five months to provide market approval.
In 2010 Heartware reported that its bridge-to-transplantation heart pump study showed that 92 percent (126 patients) of the 137 investigational device patients met the primary endpoint of being alive on the originally implanted device, transplanted or explanted for recovery at 180 days (BD: Nov 15, 2010).
Heartware said at that time that the clinical study showed that 94 percent of the investigational device patients achieved a survival endpoint at 180 days and the study projected one-year survival of 91 percent.
Heartware said that results for the comparator arm of the study, derived from 499 contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support had 90 percent success of the primary endpoint at 180 days, as well as Kaplan-Meier survival at 180 days of 90 percent and 86 percent at 360 days.
The company said that based on these results, non-inferiority of the investigational device was established [$p < 0.001$].
In documents posted on the FDA's Advisory Committees website the Panel was given three voting questions for tomorrow's meeting:
1. Is there reasonable assurance that the Heartware system is safe for use in patients who meet the criteria specified in the proposed indication?
2. Is there reasonable assurance that the Heartware system is effective for use in patients who meet the criteria specified in the proposed indication?
3. Do the benefits of the Heartware system for use in patients who meet the criteria specified in the proposed indication outweigh the risks for use in patients who meet the criteria specified in the proposed indication?

The documents on the FDA website pose safety and efficacy data questions for the Panel to consider including the rate of neurological events, pump failure and exchange rates, treatment and control comparability, endpoint assessment and a range of other issues.
Heartware was up 14 cents or 7.65 percent to $1.97.

STARPHARMA

Starpharma has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose from $1.70 on April 20, 2012 to $1.83 on April 23, 2012, a 7.6 percent increase and noted an increase in trading volume.
Starpharma fell two cents or 1.1 percent to $1.80.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it expects its net profit after tax for the year to June 30, 2012 to be about $2.2 million an 26.4 percent increase over the previous year's $1.74 million.
Medical Developments said it supplied emergency medicine products including Penthrox for acute pain as well as Asthma medication delivery devices.
Medical Developments fell two cents or 2.8 percent to 70 cents.

CATHRX

Cathrx says its net operating cash burn for the three months to March 31, 2012 was $1,712,000 with cash at the end of the quarter of $1,623,000.
Cathrx did not disclose whether it had any other funding sources available.
In March Cathrx announced a new strategy and said it would reduce its cash burn by 50 percent, expected “a significant tax rebate” for the 2011-’12 year and said additional capital would be required (BD: Mar 8, 2012).
Cathrx executive chairman Denis Hanley told Biotech Daily today that the proposed capital raising was proceeding well and he hoped it would be concluded soon.
Cathrx was untraded at four cents.

CORRECTION: CYCLOPHARM

Last night’s edition had an incorrect headline saying that Cyclopharm’s annual general meeting would vote on 13 million director options and an incentive plan.
The article on Cyclopharm was correct that shareholders would vote to issue managing director James McBrayer 6,707,383 shares, provide financial assistance of $603,664 to buy the shares and elect a director.
The mistake was made by the former sub-editor.
Cyclopharm was unchanged at 4.2 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will run workshops on social media for life sciences on April 30 and May 3, 2012.
The Network said that Australia had three million Linkedin users of 150 million worldwide, more than 10 million Facebook users and two million Twitter users and social media as a communication channel was “becoming difficult to ignore”.
The Network said that large corporations including Westpac, NAB and Telstra used Facebook, Twitter and Youtube as do all the major pharmaceutical companies and major research institutions.
Bio-Melbourne Network chief executive officer Michelle Gallaher said the question was the value proposition and how to justify the resources.
The Network said the April 30 workshop was an educational networking opportunity to learn about the social media channels and how to obtain the most out of them.
The Network said participants would gain an understanding of the threats and opportunities of each channel to their business and how to incorporate different social media channels into their overall marketing communication strategy.
The Network said that sessions involving hands-on demonstrations would be provided.
The Bio-Melbourne Network said the May 3 workshop was for users of social media with presenters providing expertise on the legal liability and risk of using social media. The Network said that compliance issues around ASX and regulatory reporting and communicating to more diverse audiences would be covered, using company case studies to manage emerging issues and monitor the company’s brand as well as competitor, partners and stakeholders.
Both workshops will be held at the Bio-Melbourne Network, 25 Flinders Lane, Melbourne.
Registration is from 8:45am, with workshops finishing at 12:30pm.
For more information and to book, go to: http://www.biomelbourne.org/events/latest.

ACTINOGEN

Actinogen says that the Australian Securities and Investments Commission alleges executive director David Zohar issued false or misleading information when he was a director of a different company.

Actinogen said that Mr Zohar received a prosecution notice from the Magistrates Court of Western Australia and would defend the matter.

The company said the notice was issued by ASIC alleging three breaches of subsection 1309(2) of the Corporations Act and that on August 27, 2008, September 4, 2008 and October 10, 2008 Mr Zohar as a director of Aluminex, permitted the giving of information which related to the affairs of Aluminex which was false or misleading.

Actinogen's company description on the ASX said it was focused on the detection and isolation of soil actinomycetes found in Western Australia and the semi-purification and screening of bioactive compounds produced by actinomycetes, including a project on antibiotic and anti-fungals from soil and water isolates.

Most recently the company has said it would pursue bio-fuel interests.

Actinogen was untraded at 2.9 cents.