Biotech Daily

Wednesday September 19, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CELLMID UP 13%, OPTISCAN DOWN 10.5%**

*** FEDERAL GOVERNMENT FREEZES ALL GRANTS**

*** AUSBIOTECH STATEMENT, BIOTECH DAILY COMMENT**

*** NSW GOVERNMENT LAUNCHES $5m MEDICAL DEVICES FUND**

*** AVEXA IN-VITRO SUCCESS CLAIMED WITH HIV INTEGRASE INHIBITORS**

*** SUNSHINE HEART CHAIR-ELECT JON ERB STARTS ON $100k, OPTIONS**

*** IMMURON CLOSTRIDIUM DIFFICILE CANDIDATE '100% MOUSE EFFICACY'**

*** PERPETUAL TAKES MORE PROFITS IN SIRTEX DOWN TO 6.6%**

*** EASTLAND PREPARING ARTIMIST MANUFACTURING**

*** CELLMID APPOINTS MARTIN ROGERS DIRECTOR**

MARKET REPORT

The Australian stock market climbed 0.54 percent on Wednesday September 19, 2012 with the S&P ASX 200 up 23.7 points to 4,418.4 points.

Fourteen of the Biotech Daily Top 40 stocks were up, six fell, 13 traded unchanged and seven were untraded. All three Big Caps were up.

Cellmid was the best, up 0.2 cents or 13.3 percent to 1.7 cents with 2.4 million shares traded.

Viralytics climbed 6.25 percent; Acrux and Prima were up more than five percent; Prana and Sirtex and were up more than four percent; Clinuvel, Psivida and Uscom were up more than three percent; Heartware rose 2.0 percent; Alchemia, Bionomics, Cochlear, CSL, Mesoblast and Resmed were up one percent or more; with Pharmaxis up 0.5 percent.

Optiscan led the falls, down one cent or 10.5 percent to 8.5 cents with 26,612 shares traded.

Genetic Technologies lost 8.7 percent; Benitec was down 6.25 percent; Patrys and Universal Biosensors fell more than four percent; with Neuren down 3.85 percent.

FEDERAL GOVERNMENT

A spokesperson for Federal Industry and Innovation Minister Greg Combet has confirmed to Biotech Daily that innovation grants programs have been suspended.

The spokesperson said the Federal Government was "collecting additional information on how grants programs are being rolled out and examining every dollar of spending to make sure taxpayers are getting value for money".

"This is a normal part of the Budget process and is exactly what fiscally responsible governments do," the spokesperson said. "While this process is underway there will be a brief pause in the granting of funds."

"However, all the background work such as the preparation of guidelines and assessment of applications is continuing in the normal way," the Government spokesperson said.

Yesterday, Greens' Member for Melbourne Adam Bandt asked Treasurer Wayne Swan: "Can you rule out any deferral, freezing or pausing of ARC, NHMRC or other science grants in an attempt to get the budget to surplus?" but received no meaningful reply.

AUSBIOTECH

Ausbiotech has called on the Federal Government "to provide some certainty to the innovation sector as support programs are frozen, including Commercialisation Australia, the Clean Technology Investment Fund and payments under the R&D Tax Incentive".

In a media release, the industry organization said that concern was mounting as the Federal Government was "unable to advise when programs will resume".

Ausbiotech chief executive officer Dr Anna Lavelle said the response was "a very concerning development on so many levels".

"This interruption to support for a burgeoning industry has the potential to wind back our hard-won momentum in biotechnology," Dr Lavelle said.

"Members are extremely and justifiably anxious about what this means about if and when the programs will resume normal functioning - especially with the disastrous and swift axing of the Commercial Ready program fresh in their memories," Dr Lavelle said.

"On behalf of the industry I call on the Government to give a clear timeline for resumption and an assurance that these programs are not at risk - after years of policy planning, inquiries, reviews and funds have been invested in their implementation," Dr Lavelle said.

BIOTECH DAILY EDITORIAL

Biotech Daily has followed Australian politics closely and has never heard of whole-of-Government grants being suspended indefinitely while under review.

The paltry funding to Commercialisation Australia is insignificant compared to investments by the UK, US and Israel and the 45 percent research and development tax credit is only helpful if companies are first able to raise the funds to do the research and development.

To threaten these programs is the single most bizarre action of the Labor Federal Government since boasting of the demise of the Commercial Ready program.

That National Health and Medical Research Council grants are also threatened, leaves Biotech Daily only able to conclude that the Labor Federal Government appears to have no strategic overview and little inter-Ministerial communication.

It is hard to understand what the Federal Government intends, other than to run a razor through every Department to find funds for its more recent policy promises, and while they may or may not be laudable promises, to disrupt the innovation grants process without replacing them with something 10-fold larger and better-targeted is simply madness.

If Prime Minister Julia Gillard wants to attack State Premiers for taking the axe to necessary programs, it would be a good idea to not be doing the same.

David Langsam, Editor

NEW SOUTH WALES GOVERNMENT

The New South Wales Government has created a $5 million a year Medical Devices Fund.

The New South Wales Minister for Medical Research, Jillian Skinner called for applications to support the development and commercialization of medical devices in the State.

“The establishment of the Medical Devices Fund was a key election commitment for the NSW Government and reflects our support for medical research in this state,” Ms Skinner said.

“The NSW Government has committed $5 million annually for a new Medical Devices seeding fund to support the development of medical devices to further better treatment options and patient outcomes,” Ms Skinner said.

“The NSW Government has boosted the funds available in its inaugural year, 2012-2013 to make $8 million available,” Ms Skinner said.

“This fund will foster the design and development of medical devices while also promoting their potential uses and benefits,” Ms Skinner said.

“Investment in quality medical research, including the development of medical devices and technology, supports innovative clinical outcomes as well as contemporary methods of care for patients,” Ms Skinner said,

Ms Skinner said she had seen the profound effect that innovative medical devices had on the lives of patients and their families and had with families when their child’s cochlear implants were turned on for the first time.

“It’s impossible not to be moved to see a mother’s face when her child hears her voice for the first time,” Ms Skinner said.

“It’s these kinds of life-changing innovations that we want to see created, developed and supported through the Medical Devices Fund,” Ms Skinner said.

The New South Wales Government media release said the Medical Devices Fund would support individuals, public and private hospitals, medical research institutes, universities, other public sector research organizations and the medical devices industry to take local innovations to a worldwide market.

Ms Skinner said project applications for the Medical Devices Fund opened in September and preliminary applications would close on October 10, 2012.

Ms Skinner said the Government had appointed an expert group to assess projects, chaired by the State’s chief scientist and engineer Prof Mary O’Kane.

Prof O’Kane said the $5 million a year program would build on the economic and social benefits that Resmed and Cochlear had already forged.

“I anticipate that this fund will be a pivotal contributor to building future medical technology commercial success in NSW”, Prof O’Kane said.

The New South Wales Government media release said the expert group would include Cochlear chief financial officer Neville Mitchell, Resmed’s head of innovation Dr Bob Frater, North Sydney Local Health District director Michael Still and ABC Radio and Television presenter Adam Spencer.

Further details regarding the Medical Devices Fund, including the expert group and application kit are available at www.health.nsw.gov.au/ohmr/.

AVEXA

Avexa says test results from an independent US laboratory confirm in-vitro activity of its new generation HIV integrase inhibitors against resistant human immunodeficiency virus.
Avexa interim chief executive officer Dr Jonathan Coates told Biotech Daily that the in-vitro preclinical research was undertaken on two compounds from the company's series of 40 HIV integrase inhibitors.
In a media release Avexa said the research showed that its novel compounds had potent activity against not only the sensitive strains of virus found in untreated persons, but also against resistant HIV strains, which could contain mutations which reduced the activity of the current marketed HIV integrase inhibitors.
Avexa said the HIV integrase enzyme was essential to the replication of the virus and was the target for the currently marketed drugs raltegravir and elvitegravir, but treatment with these first generation HIV integrase inhibitors could give rise to resistance owing to mutations in the HIV integrase gene, which reduced the effectiveness of these drugs.
The company said that current inhibitors required either twice-daily dosing or use of a pharmacological boosting agent to achieve sufficient levels of drug.
Avexa said its HIV integrase program was developing a new generation of HIV integrase inhibitor which retained activity against resistant HIV and could be given once a day.
The company said that a successful optimization program resulted in a series of compounds from which two leads had been selected for further pre-clinical development with equal potency against wild type HIV as the current market leader raltegravir; significantly more potent against highly resistant HIV; and a pharmacokinetic profile indicative of once daily dosing without pharmacological boosting
"These novel compounds have advantages over the currently marketed drugs and show great promise as improved, new generation integrase inhibitors," Dr Coates said.
"Integrase inhibitors have proven to be an effective and well prescribed class of HIV drugs, despite the limitations of resistance and dosing issues," Dr Coates said.
"Avexa's compounds overcome these limitations and could prove very valuable second generation drugs," Dr Coates said.
Avexa was up 0.3 cents or 16.7 percent to 2.1 cents with 11.0 million shares traded.

SUNSHINE HEART

Sunshine Heart says Jon Erb will be paid $50,000 a year as a director, increasing to $100,000 on October 1, 2012 when he becomes the chairman.
In a posting to the ASX entitled 'Overseas Filing' Sunshine Heart said Mr Erb had been granted an option to purchase 54,000 shares of common stock at an exercise price of $US8.27, exercisable within 10 years, valuing the options at $US446,580.
Last night on the Nasdaq, Sunshine Heart closed at $US8.89.
The company said the option was subject to stockholder approval and other conditions and would vest in one forty-eighth portions on the 12th day of each month from October 12, 2012 until the option were fully exercisable.
Sunshine Heart said that it had entered into a consulting agreement, effective from January 1, 2013, with former chairman Nicholas Callinan who retires as a director at the end of 2012 (BD: Sep 13, 2012).
The company said that Mr Callinan would provide advisory services and receive $2,083 a month from January 1, to March 31, 2013 and from April 1, 2013, hourly compensation "at an hourly rate to be determined by our chief executive officer", with the agreement expiring on March 31, 2015.
Sunshine Heart was untraded at four cents.

IMMURON

Immuron says it has “very encouraging results” from the first of several animal studies using a novel approach to treat Clostridium difficile infections.
Immuron said the mouse study results were generated ahead of schedule under a government-supported collaboration with Monash University (BD: Jan 31, 2012).
The company said the Clostridium difficile product was based on its hyperimmune cow colostrum production and technology platform and was expected to exhibit the proven high safety profile that characterizes Travelan, its product for travelers diarrhoea.
Immuron said that the high safety profile and the clear market need for an effective treatment for Clostridium difficile infections was expected to accelerate development.
Immuron said the study mice were infected with a lethal dose of Clostridium difficile and all mice that received active treatment survived infection and showed an overall increase in weight, as opposed to no survival for the control group that received a placebo treatment.
The company said that both the infectious cycle and the type of disease seen in mice was similar to that in humans, with Clostridium difficile toxins causing the same effects.
Immuron said the mouse study was being repeated to validate the first results.
The company said that optimization of the proprietary vaccination given to the cows to produce hyperimmune colostrum was underway to further enhance the product in preparation for human clinical trials expected in 2013.
Immuron said that Clostridium difficile was a bacterium that caused diarrhoea and serious, potentially life threatening intestinal conditions including colonic perforation and toxic megacolon and the major trigger for the development of Clostridium difficile infection was the use of broad-spectrum antibiotics.
Immuron said the annual global Clostridium difficile product market was estimated to be $314 million in 2011 and forecast to grow to more than $500 million by 2019.
Immuron chief executive officer Joe Baini said that “since the mouse model is an appropriate human disease model, we expect that the results generated to date should also be seen in humans”.
Monash University lead investigator Prof Dena Lyras said the results to date were “very promising, and we hope to provide further data validating these initial results over the coming months”.
“Furthermore, it is our intention to develop a product that not only prevents symptoms, but also prevents transmission of this debilitating and life-threatening disease,” Prof Lyras said.
Immuron was unchanged at 1.7 cents.

SIRTEX MEDICAL

Perpetual and its subsidiaries have further reduced their substantial shareholding in Sirtex from 4,398,070 shares (7.89%) to 3,684,869 shares (6.61%).
Last week, Perpetual and its subsidiaries reduced their shareholding in Sirtex by 560,389 shares (7.89%) (BD: Sep 12, 2012).
Last year, Perpetual and its subsidiaries increased their holding from 2,850,000 shares (5.11%) to 4,958,459 shares (8.89%) and said at that time that shares were acquired by a range of nominee companies including JP Morgan Chase, Citicorp, National, Cogent, UBS and RBC Dexia and were acquired from May 17, 2011 to October 12, 2011 at prices from $4.21 to $5.25 (BD: Oct 14, 2011)
Today, Perpetual said it sold shares between September 11 and 17, 2012 at prices ranging from $7.70 to $8.40.
Sirtex was up 41 cents or 4.8 percent to $8.90, with 162,161 shares traded.

EASTLAND MEDICAL SERVICES

Eastland says E-Z-EM Canada Inc division Therapex will manufacture the registration and validation batches of Artimist.
Eastland said the agreement was a fee for service agreement and is not a manufacturing licence or a joint venture agreement.
The company said that Therapex had progressed the manufacturing process substantially over the past four months and were on track to produce registration batches in December 2012.
Eastland said that scale-up testing had been completed and the analytical and technical development programs were well advanced.
The company said that it expected to fill 20,000 units of Artimist in the first registration batches scheduled for December 2012.
Eastland was up 0.1 cents or 2.9 percent to 3.5 cents with 2.5 million shares traded.

CELLMID

Cellmid has appointed Martin Rogers as a non-executive director.
Cellmid said that Mr Rogers was the former chief executive officer of Prima Biomed and continues as a non-executive director.
Mr Rogers was recently appointed a director and deputy chair of Consegna Group (BD: Sep 3, 2012).
Cellmid said that Mr Rogers held degrees in chemical engineering and science and had “a depth of experience in incubating companies and publicly listed organizations”.
The company said that Mr Rogers had experience in all aspects of financial, strategic and operational management and had raised more than $100 million in equity.
Cellmid was up 0.2 cents or 13.3 percent to 1.7 cents with 2.4 million shares traded.