Biotech Daily

Monday May 18, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NOVOGEN UP 22%, OPTISCAN DOWN 17%**

*** PEPLIN PHASE III NON-HEAD TRIAL CLEARS 67% OF LESIONS**

*** PROGEN, NORTH AMERICAN PARTNER FOR PI-88**

*** BIOGUIDE BRIEF: VERVA, SMALL HOLDERS AND THE UNLISTED SPACE**

*** ETHICS APPROVAL FOR CATHRX IN-HUMAN TRIAL**

*** CEPHALON JUST 2.36% FROM TAKING ARANA**

*** ST VINCENT'S FORUM: WILL BIOSCIENCE LEAD ECONOMIC UPSWING?**

*** EASTLAND REQUESTS 50% RIGHTS ISSUE TRADING HALT**

*** KARMELSONIX LAUNCHES PERSONAL WHEEZOMETER**

MARKET REPORT

The Australian stock market fell 1.0 percent on Monday May 18, 2009 with the S&P ASX 200 down 37.6 points to 3,735.6 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and eight were untraded. All three Big Caps were up.

Novogen was best, up 10.5 cents or 21.88 percent to 58.5 cents with 60,551 shares traded, followed by Labtech up 1.5 cents or 11.5 percent to 14.5 cents.

Acrux, Clinuvel and Polartechnics climbed four percent or more; Genetic Technologies, Resmed and Starpharma were up more than three percent; Alchemia, Biota and Nanosonics rose more than two percent; with CSL, Cochlear, Impedimed and Peplin were up more than one percent.

Optiscan led the falls, down one cent or 16.95 percent to 4.9 cents with 432,301 shares traded, followed by Universal Biosensors down 15.25 percent to $1.00.

Living Cell fell 7.14 percent; Phosphagenics and Phylogica lost more than six percent; Benitec, Cellestis, Circadian, Heartware, Tyrian and Viralytics shed more than two percent, Sirtex fell 1.85 percent; with Arana and Pharmaxis down less than one percent.

PEPLIN

Peplin says its 250-patient Australia and US phase III trial of PEP005 Gel has shown a 67% median clearance rate for solar keratoses.

Peplin's general manager for Australia and chief scientific officer Dr Peter Welburn told Biotech Daily that the 0.05% concentration of PEP005 Gel applied once a day for two days resulted in a median percentage reduction in the number of lesions of 66.7 percent compared to a zero rate for vehicle or placebo (p-value <0.0001).

Dr Welburn said the total clearance rate across all anatomical non-head sites, including the extremely difficult-to-treat back-of-hand and arm locations was equal to 27.4 percent compared to five percent for vehicle (p-value <0.0001) and a partial clearance rate of 44.4 percent compared to eight percent for vehicle (p-value <0.0001).

Dr Welburn said that there was "no other topical take home treatment approved for difficult to treat areas such as back of hand, arm chest".

In its media release to the ASX, Peplin said the phase III trial of PEP005 (ingenol mebutate) for actinic or solar keratosis lesions was on non-head locations, including the trunk and extremities.

Peplin said actinic keratosis was "a common pre-cancerous skin condition caused by sun exposure, which can develop into skin cancers if left untreated".

Peplin's chief executive officer Tom Wiggans said his company's team had "done an excellent job of obtaining great clinical results while completing our first phase III trial within the expected timeframe".

"These strong results achieve an important step towards commercialization," Mr Wiggans said.

"In addition, they confirm efficacy signals with prior trials and market need, since no currently marketed product has proven efficacy for this range of locations for non-head lesions, especially with a two-day course of therapy," he said.

Mr Wiggans said PEP005 Gel provided patients "the potential for a compelling alternative".

Peplin said statistical significance was established in back-of-hand, arm and chest locations.

The company said that it had expected that the inclusion of treatment sites for all non-head lesions would contribute to the lower clearance rates when compared to previous trials, but the total clearance rates ranged from 16 percent to 89 percent by anatomical location with chest, back-of-hand and arms achieving statistical significance.

The other areas did not show statistical significance due to the low number of patients that enrolled with these types of lesions, the company said.

Peplin scientific advisor and Sydney dermatologist Dr Robert Rosen said that current treatment options for solar keratosis had a number of shortfalls, including pain, persisting skin irritation and redness during prolonged treatment periods.

"As a result, patients are often unwilling to use their medications," Dr Rosen said.

"A topical agent like PEP005 Gel, which can effectively and conveniently treat lesions in two days, will be of significant benefit to doctors and their patients," Dr Rosen said.

Peplin said that in line with previous non-head trials, the local skin responses peaked at Day 8 and returned to baseline by Day 29, with no significant adverse effects reported.

Peplin said its would have an end-of-phase II meeting for lesions on the face and scalp with the US Food and Drug Administration on June 3, 2009, a delay caused by "internal scheduling conflicts at the FDA".

Peplin will begin the phase III program for patients with actinic keratosis lesions on the head, an estimated 70 percent of the actinic keratosis market by July 2009.

Peplin was up one cent or 1.52 percent to 67 cents.

PROGEN

Progen has “a binding terms sheet for an exclusive licence agreement” with an unnamed North American company for its lead anti-cancer product PI-88.

Progen halted its phase III trial of PI-88 in July last year, precipitating the long-running sage of bids for Progen’s cash reserves of $70 million (BD: Jul 23, Nov 10, Dec 1, 22, 2008; Jan 28, Mar 9, 27, 2009)

Progen discontinued the phase III study of PI-88 in the adjuvant treatment of hepatocellular carcinoma or primary liver cancer despite phase II trial data indicating safety and some efficacy. Progen said in July 2008 that it had to make a commercial decision in the absence of a partner, the emergence of a competitor and slow patient recruitment.

Progen said at that time that it was difficult to convince a major pharmaceutical company to partner for a drug targeted more at Asian markets that US or European ones.

Today Progen said the terms sheet maintains an option to commercialize PI-88 in Australia and to participate directly in a co-development structure with the clinical development, registration and commercialization of PI-88 in Taiwan while Progen’s partner pursues the development and commercialization of PI-88 elsewhere independently.

Progen said the agreement was be binding on its key commercial terms with finalization subject to the completion of negotiations of the licencing agreement, incorporating the key terms in the terms sheet.

Progen chief executive officer Justus Homburg said the signing was a significant step forward in the development of PI-88 and further broadened its commercial opportunities.

“This partnership should provide cost effective access to global markets for PI-88 that we could not achieve on our own,” Mr Homburg said.

“Our partner is based in North America with strong ties into Asia, the latter being a primary target for PI-88, providing significant value to this partnership,” Mr Homburg said.

“The arrangement has the potential to expand the market opportunity beyond what we could do on our own or with other potential partners whom we have been in discussions with,” Mr Homburg said.

“The arrangement is expected to reduce the costs involved in developing and then marketing our product and provides us with greater financial opportunity,” he said.

“The milestone and royalty payments which can be provided through the partnering arrangement will help fund the progression of our broader product pipeline, including the 500 series, the epigenetics technologies and the cell proliferation compounds,” Mr Homburg said.

Progen said it had completed several phase II clinical trials for PI-88, with strong signs of efficacy in delaying the recurrence of hepatocellular carcinoma, following surgery to remove liver cancer tumors.

Progen said it was also undertaking a phase II clinical trial in Australia and the US to assess the efficacy of PI-88 in combination with dacarbazine to treat patients with advanced melanoma.

Mr Homburg said the commercial benefits afforded by the partnership combined with the strength of the PI-88 technology proved Progen was well positioned to deliver long-term, sustainable growth.

“We have had challenges during the past year. Despite these challenges, however, our focus has continued to be on advancing our portfolio of anti-cancer drugs,” Mr Homburg said. “This partnership demonstrates our unwavering commitment to developing lifesaving products and delivering value to our shareholders.”

Progen was unchanged at 83 cents.

MARC SINATRA'S BIOGUIDE BRIEF: VERVA, CHEMGENEX

In late 2007, Chemgenex spun out its diabetes program and merged it with Adipogen Pharmaceuticals to form Verva Pharmaceuticals.

Chemgenex shareholders received one share in Verva for every five they held in Chemgenex, with each Verva share carrying a notional value 33.4 cents.

The plan had been to list Verva quickly, but due to deterioration in the capital markets, the directors decided against it.

This is where the problems started for small investors.

The major advantage small investors have over large investors is that they can get in and out of a stock at the press of a button. In the unlisted space that advantage is lost because buying or selling is a much more difficult and costly exercise.

After initially raising $2.75 million via a convertible note in late 2007, Verva found it difficult to raise further capital. It recently had to settle for $2.0 million in exchange for shares at 4.7 cents. Obviously, this is a long way from the 33.4 cents a share valuation at the time of the demerger.

Unfortunately, the pain doesn't stop there. The new shares to be issued aren't ordinary shares, but so-called cass A shares that come with anti-dilution protection and preferential rights in certain circumstances.

To get some idea of how-valuable anti-dilution clauses can be, you need to look no further than Verva's anti-dilution clause for the $2.75 million convertible note raising.

What would have delivered note holders 8.2 million Verva shares (at 33.4 cents), will now give them 58.5 million Verva shares (at 4.7 cents), excluding shares issued in exchange for interest on the notes.

The net result is that the ordinary Verva shares Chemgenex investors received back in 2007 are worth a fair bit less than the 4.7 cents per share indicated by the Class A share capital raising.

In short, the unlisted game is not one that the small investor really wants to play for a variety of reasons, but primarily because it takes away the one advantage they have over bigger investors; the ability to get in and out of the market easily.

While the current raising is highly dilutive, it is probably in the best interests of Verva shareholders. What would have been in the best interests of small shareholders, however, is if they had listed Verva immediately after its formation.

Marc Sinatra

Biotech Daily analyst Marc Sinatra and editor David Langsam both inherited Verva shares through their Chemgenex holdings.
Chemgenex was unchanged at 47 cents.

CATHRX

Cathrx has ethics committee approval to begin human trials for its first therapeutic ablation catheter.
Cathrx said the catheter was designed to treat both atrial flutter and atrial fibrillation, which affect about seven million people worldwide.
The company said the first in-humans trial would involve 15 patients with atrial flutter and will take place at Monash Medical Centre in Victoria.
Cathrx said the trial data would be used for approval of a multi-centre trial, expected to begin by the end of 2009.
Cathrx chief executive officer Neil Anderson said beginning the trial was "another milestone achieved on time by the company in the execution of its marketing program".
"The ablation catheter will be our first therapeutic device to commence human trials," Mr Anderson said.
Cathrx was untraded at 62 percent.

ARANA

Cephalon International Holdings increased its substantial shareholding in Arana from 94,790,080 shares (41.64%) to 108,690,522 shares (47.74%).
The change was through an increase in takeover acceptances (BD: Feb 27, Mar 2, May 14, 2009).
The offer is conditional on reaching 50.1 percent of acceptances by June 1, 2009.
Arana fell one cent or 0.74 percent to $1.35.

ST VINCENT'S INSTITUTE

The 2009 St Vincent's Institute forum next week will discuss the question: "Will biosciences lead the next economic upswing?"
The forum meeting will be chaired by Sir Gustav Nossal with speakers including Deutsche Bank's John Macfarlane, the Australian Synchrotron's Dr Daniel Hausermann, the University of Wollongong's Prof Gordon Wallace and the Department of Primary Industry's biosciences research director Dr Ben Cocks.
The forum will be held on May 26, 2009 at the Michael Chamberlin Lecture Theatre, Aikenhead Wing, St Vincent's Hospital, 27 Victoria Parade, Fitzroy, Victoria at 5.30pm.
For further inquiries about the forum call Kathryn O'Connell on +613 9288 2746 or email: koconnell@svi.edu.au.

EASTLAND MEDICAL SYSTEMS

Eastland has requested a trading halt pending an announcement in relation to a funding arrangement for a rights issue.
Eastland said the rights issue which could lead toa 50 percnet increase of its issued capital.
Trading will resume on May 21, 2009 or on an earlier announcement.
Eastland closed up 0.2 cents or 3.85 percent to 5.4 cents.

KARMELSONIX

Karmelsonix says it has launched its Personal Wheezometer at the American Thoracic Society conference in San Diego, California.

Karmelsonix said the response to the company's flagship product was "overwhelmingly positive".

Karmelsonix climbed 0.6 cents or 13.0 percent to 5.2 cents with 1.2 million shares traded.