# Biotech Daily

Thursday April 19, 2012

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: SUNSHINE HEART UP 7%, CELLMID DOWN 21%**

*** PHARMAXIS ON-TRACK FOR BRONCHITOL; ASM8 SCIENTIFIC REVIEW**

*** NASDAQ, US OTC LISTINGS MIXED RESULTS FOR AVITA, PRIMA**

*** AUSTRALIANS IMPLANTED WITH GI DYNAMICS' ENDOBARRIER**

*** HYPERION TAKES 7% OF COCHLEAR**

*** NEUREN PLEADS SCHULTZ TO ASX 35% QUERY**

*** CELLMID OPENS ÉVOLIS HAIR PRODUCT WEBSITE**

*** CONSEGNA: BREATHEASSIST NASAL PLUGS REGULATOR-FREE**

## MARKET REPORT

The Australian stock market climbed 0.32 percent on Thursday April 19, 2012 with the S&P ASX 200 up 14.0 points to 4,362.7 points.

Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and four were untraded.

Sunshine Heart was the best, up 0.2 cents or 7.1 percent to three cents with 909,800 shares traded.

Phosphagenics climbed seven percent; both Antisense and Benitec were up 5.9 percent; Mesoblast and Neuren were up more than three percent; Viralytics rose 2.9 percent; Avita, Clinuvel, Nanosonics, Sirtex and Starpharma were up more than one percent; with Cochlear and CSL up by less than one percent.

Yesterday's 100 percent best, Cellmid, led the falls, down 0.6 cents or 21.4 percent to 2.2 cents with 110.5 million shares traded.

Both Bioniche and Patrys lost 9.1 percent; Prima was down 6.25 percent; Circadian, Heartware and Psivida were down more than five percent; Impedimed and Optiscan fell more than four percent; Pharmaxis was down 3.9 percent; Phylogica and Reva shed more than two percent; Biota, Genetic Technologies and QRX were down more than one percent; with Acrux, Alchemia and Resmed down by less than one percent.

PHARMAXIS

Pharmaxis expects to file its marketing application for Bronchitol for cystic fibrosis to the US Food and Drug Administration within the next 40 days.

Pharmaxis chief executive officer Dr Alan Robertson told a quarterly investor briefing teleconference that with Australian and European approval completed he hoped to file the US application ”next month”.

Dr Robertson said the FDA had a 10-month response period and there would be a public committee meeting to discuss the application prior to the FDA decision, which would probably be by the end of 2012.

Dr Robertson said that Bronchitol had been recommended for reimbursement by the Australian Pharmaceutical Benefits Advisory Committee, but was yet to be listed on the Pharmaceutical Benefits Scheme, providing reimbursement.

Dr Robertson said there were no real barriers to reimbursement in Europe but a process needed to be undertaken with the UK’s National Institute for Health and Clinical Excellence for reimbursement.

He said that in Germany, Bronchitol’s designation as an orphan product exempted it from review by the national pricing and reimbursement body.

Dr Robertson said that Pharmaxis was in transition from a drug development company to an operating business concentrating on sales and distribution.

He said sales teams were ready to go in both the UK and Germany and the challenge for the company was to ensure that Bronchitol was on hospital pharmacy lists and approved in their budgets.

Dr Robertson said the pivotal US and Europe, 485 patient phase III trial of Bronchitol for bronchiectasis was fully recruited and expected to be completed by the end of 2012 with results early in 2013.

He said the primary outcome was a 25 percent reduction in exacerbations related to bronchiectasis.

Dr Robertson told the teleconference that the Aridol asthma test sold 1,540 in its first three months on the US market generating about one third of Aridol’s $300,000 revenue for the company.

Dr Robertson said that the confounding results from the ASM8 phase IIa trial for allergic asthma would be thoroughly investigated by Pharmaxis scientists (BD: Apr 17, 2012), but the trial resulted in “a lot of information from not many patients”.

Dr Robertson said that there was a four to six week wash-out period between doses and ASM8 had a half-life of seven hours.

He said there was no clear explanation why patients treated for 14 days with ASM8, then provided the four to six week wash-out period, before being dosed as controls, had as great an efficacy with 0.9 percent saline as they did with ASM8.

Dr Robertson said that the small number of ASM8-naïve controls in the first treatment group did not have any reduction in their response to their asthma allergens.

He said the apparent long term effect of ASM8 was good for the patients, but difficult for researchers and needed to be better understood.

Dr Robertson said that while the 3mg dose of ASM8 was the right strength he said the dosing regime might not be daily as expected, but further research was required.

Dr Robertson said there were five million people with allergic asthma who do not respond to current drugs

Pharmaxis fell five cents or 3.9 percent to $1.225.

## AVITA MEDICAL, PRIMA BIOMED

Recent US listings by Avita and Prima have had mixed, if not bizarre, results.
Avita upgraded from simple 'pink sheets' under the code AVMXF, effectively selling Australian shares to US buyers, to the much-promoted Over The Counter Quality Exchange (OTCQX) trading American depositary receipts (ADRs) under the code AVMXY (BD: Mar 29, 2012).
Each Avita ADR is equivalent to 20 Australia shares.
Over several days, the allegedly hard-to-trade AVMXF shares have gone up in value while the OTCQX shares have fallen, despite an apparently locked relationship.
Last night, AVMXF shares were up one US cent or 3.7 percent to 28 US cents with 30,677 shares traded, while AVMXY shares fell 12 US cents or 2.14 percent to $US5.50 with 1,685 shares traded.
With roughly equal value, either some investors are "having a bet each way" or something very weird, even for US markets, is going on.
Go figure.
Prima announced its debut on the Nasdaq Global Market (GM) last week (BD: Apr 13, 2012), but after an initial jump from $US13.75 to $US16 on what the Nasdaq appears to be calling no volume, the price fell to $12.04 on April 17, with 2,875 shares traded; and last night dived $US3.74 or 31.06 percent to $US8.30 with 8,195 shares traded.
Prima's US PBMD American depositary receipts are equivalent to 30 Australian shares.
Avita was up half a cent or two percent to 26 cents with 480,974 shares traded.
Prima fell 1.5 cents or 6.25 percent to 22.5 cents with 11.5 million shares traded.

**David Langsam**
**Editor**

## GI DYNAMICS

GI Dynamics says the first group of patients at Melbourne's Epworth Centre for Bariatric Surgery has been implanted with the Endobarrier at the Epworth Hospital.
Despite being located nearby and sharing the name, the Epworth Centre for Bariatric Surgery has previously told Biotech Daily that it was unrelated to the major private hospital, although its theatre facilities were used for procedures.
In a media release GI Dynamics chief executive officer Stuart Randle said that the Centre's director Dr Harry Frydenberg and his team had implanted the first group of patients in Australia with the Endobarrier.
The removable device, which GI Dynamics has compared to Roux en-Y gastric surgery is inserted into the duodenum and anchored to the end of the stomach, preventing absorption in that part of the intestine.
The company said that the Endobarrier had been shown to lower HbA1c of blood glucose levels, achieve weight loss of more than 20 percent and improve metabolic functions including cholesterol, blood sugar and triglycerides within one year.
"We are extremely pleased to have been able to make this innovative therapy available for the first time in Australia," Dr Frydenberg said.
"My expectation is that Endobarrier therapy may be the preferred treatment option for many more overweight diabetic patients in my practice," Dr Frydenberg said.
GI Dynamics said the Australian Diabetes Council estimated that more than 3.5 million, or one in four, Australian adults had either diabetes or pre-diabetes and that type 2 diabetes cost the country about $3 billion a year.
The company said that the International Diabetes Federation estimated that globally 320 million people had type 2 diabetes.
GI Dynamics was up seven cents or 6.7 percent to $1.11.

## COCHLEAR

Hyperion Asset Management has increased its holding in Cochlear from 3,585,878 shares (6.3%) to 4,235,536 shares (7.44%).
The Brisbane-based Hyperion said it bought and sold shares between December 22, 2011 and April 16, 2012 on behalf of a large number of holders including superannuation funds and the University of Queensland, including four major purchases of a total of 482,769 shares for $29,524,896 or an average price of $61.16 share.
Cochlear was up 51 cents or 0.8 percent to $62.50.

## NEUREN PHARMACEUTICALS

Neuren 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 2.3 cents on April 16, 2012 to 3.1 cents on April 19, 2012, a 34.8 percent increase and noted an increase in trading volume.
Neuren was up 0.1 cents or 3.7 percent to 2.8 cents with 81.6 million shares traded.

## CELLMID

Cellmid says it has opened a commercial website for its Évolis hair growth products, to allow pre-release sales as well as customer information and support.
Cellmid said that the Évolis products were Australian Therapeutic Goods Administration approved with claims of "promotes hair growth", "helps prevent hair loss and thinning" and "restores the natural hair growth cycle".
Cellmid said that the Évolis products would be sold mainly as over-the-counter medicines in pharmacies at a recommended retail price of $89 for each 50ml bottle.
The website is at www.evolisproducts.com.au.
Cellmid was down 0.6 cents or 21.4 percent to 2.2 cents with 110.5 million shares traded.

## CONSEGNA GROUP

Consegna says its Breatheassist Sport nasal plugs do not require regulatory approval in the US, Europe or Australia.
Last year Consegna said that a clinical study showed that the nasal dilating plugs enhanced nasal airflow by 37 percent and there were multiple licencing opportunities for the product including drug delivery, snoring cessation, sleep apnoea, the filtration of pollen and other pollutants (BD: Sep 16, Nov 29, 2011).
Today, Consegna said the nasal plugs had "a clear path for sale and distribution" and fell outside the US Food and Drug Administration regulation, The European Union Medical Device Directive and the Australian Therapeutic Goods Acts.
Consegna's managing director Fabio Pannuti said that Breatheassist Sport was "a compelling product for the millions of people who participate in active sports".
Consegna chairman Rod Tomlinson said that "with the London Olympics approaching … this regulatory advice represents an important part of this program".
Consegna was unchanged at three cents with 1.3 million shares traded.