# Biotech Daily

Tuesday May 21, 2013

*Daily news on ASX-listed biotechnology companies*

*** ASX DOWN, BIOTECH UP: PHARMAXIS UP 48%, ANTISENSE DOWN 10%**

*** FDA CLEARS PHARMAXIS BRONCHITOL FOR CF PATH**

*** FORMER CBIO EXECUTIVE REPAYS INVION 'TERMINATION PAY'**

*** AGENIX APPOINTS CRAIG CHAPMAN DIRECTOR**

## MARKET REPORT

The Australian stock market fell 0.55 percent on Tuesday May 21, 2013, with the S&P ASX 200 down 28.9 points to 5,180.1 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and three were untraded.

Pharmaxis was the best, climbing as much as 7.5 cents or 55.6 percent to 21 cents before closing up 6.5 cents or 48.15 percent at 20 cents with 16.0 million shares traded, followed by Phylogica up 27.8 percent to 2.3 cents with 696,136 shares traded.

Benitec and Universal Biosensors climbed more than seven percent; Clinuvel was up 5.3 percent; Avita, Patrys and Prana rose more than four percent; GI Dynamics was up 3.2 percent; Ellex, Optiscan, Prima and QRX were up more than two percent; Acrux, Atcor, Impedimed and Starpharma were up more than one percent; with Cochlear and Mesoblast up by less than one percent.

Antisense led the falls, down 0.1 cents or 10 percent to 0.9 cents with 4.4 million shares traded.

Both Allied Health and Genetic Technologies lost 6.7 percent; Neuren eased 5.2 percent following yesterday's 13.7 percent rise; Cellmid was down 3.13 percent following yesterday's 14.3 percent climb; Osprey shed 2.4 percent; Bionomics, CSL, Psivida, Sirtex and Viralytics were down more than one percent; with Heartware and Resmed down by less than one percent.

PHARMAXIS

Pharmaxis says the US Food and Drug Administration has agreed to a pivotal 300-patient, phase III trial of Bronchitol for cystic fibrosis in adults aged 18 years and over.

Pharmaxis said it had concluded “a productive end of review meeting with the US Food and Drug Administration which has provided the company with a clear outline of the clinical trial required to gain approval for Bronchitol (mannitol) to treat cystic fibrosis in the United States”.

Pharmaxis chief financial officer David McGarvey told Biotech Daily the company hoped to begin dosing by July 2014 and expected to conclude the trial about mid-2016.

“We have the funds to complete that program,” Mr McGarvey said.

In March the FDA refused the Pharmaxis application for Bronchitol of cystic fibrosis and said it required more data (BD: Mar 19, 2013).

In 2011, the European Medicines Agency overturned its previous refusal to grant marketing authorization of Bronchitol for cystic fibrosis allowing the drug for patients aged over 18 years, but requiring a further trial to allow the drug for patients aged six to 18 years (BD: May 25, Jun 27, Oct 24, 2011).

In 2010, Pharmaxis’ second of two pivotal phase III trials missed its primary efficacy endpoint of demonstrating greater efficacy for Bronchitol (400mg mannitol) compared to control (50mg mannitol) ($p = 0.059$) (BD: Jun 23, 2010).

Today, Pharmaxis said the FDA type A meeting discussed the remaining clinical work required to show substantial evidence of efficacy in patients with cystic fibrosis.

The company said it agreed with the FDA that the clearest and most expeditious regulatory path forward was a further single pivotal trial in adults aged 18 years and over.

Pharmaxis said it was also agreed that the trial should have a very similar design to the two large scale clinical trials already undertaken and would be of six months dosing duration with improvement in lung function as measured by a change in forced expiratory volume in one second (FEV1) as its primary endpoint.

Pharmaxis chief executive officer Gary Phillips said the result of the meeting with the FDA was “very pleasing”.

“With the guidance of the FDA we have been able to quickly remove uncertainty about what is required to gain approval for Bronchitol in the US market where orphan drug status allows us seven years of market exclusivity from approval,” Mr Phillips said.

“Our aim was to identify the fastest way to the US market with the least clinical and regulatory risk,” Mr Phillips said.

“Restricting the trial population to adult cystic fibrosis patients has a number of benefits compared to the wider population studied in the earlier phase III trials,” he said.

“The variability of FEV1 results and the apparent response to the control drug seen in children and adolescents will no longer be an issue,” Mr Phillips said.

“A post hoc analysis of the subgroups of adult patients in [the earlier phase III trials] showed a significant improvement in FEV1 and there was no evidence of a control effect,” he said. “We will therefore use respirable low dose mannitol as the control.”

Pharmaxis said it would use its extensive phase III database to ensure the relevant adult patient group was enrolled, design effective patient retention strategies and accurately power the trial and expected to enroll about 300 patients.

The company said that it would propose a separate development program to the FDA for patients aged six to 17 years after the protocol for the study in adult patients was finalized.

Mr Phillips said the company could complete its business plan based on firm foundations and it would be detailed on May 28, 2013.

Pharmaxis climbed as much as 7.5 cents or 55.6 percent to 21 cents before closing up 6.5 cents or 48.15 percent at 20 cents with 16.0 million shares traded.

## INVION (FORMERLY CBIO)

Invion says one of four former CBio executives subject of legal action to recover about $1.2 million in termination and other payments has agreed to repay his part of the funds.
Invion said that the unnamed defendant gave “no admission as to liability” but would repay the purported termination payment with interest and costs.
In 2011, following the failure of the phase II trial of X-Toll or chaperonin-10 for rheumatoid arthritis investors moved to spill the board and there was an exit from the company of most of the previous management and board (BD: Aug 1, Oct 26, 27, Nov 1, 2011).
In 2012, CBio said it had begun legal proceedings against the former executive chairman, chief executive officer, chief financial officer and company secretary in relation to payments of $736,600 related to the departure of the executives from the company, “an additional $183,333 as performance bonuses relating to the capital raisings undertaken” and $459,000 to SGB Jones Pty Ltd after Stephen Jones resigned as an executive chairman and consultant to the company as well as $100,000 to Mr Jones in relation to a performance bonus relating to the capital raisings undertaken (BD: Jun 25, 2012).
In Queensland Supreme Court documents, former executive chairman Stephen George Burch Jones, former chief executive officer Jason Richard Yates, former chief financial officer James Greig and former company secretary Benjamin Lee Graham were named as the defendants in the matter, with a hearing date set for tomorrow, May 22, 2013.
Late last year, Invion said the former executives lodged a counterclaim for $1,246,666.96 (BD: Oct 23, 2012).
Today, Invion said it would “continue to vigorously pursue its claim against the remaining defendants, which includes interest and costs”.
Invion fell 0.1 cents or 2.2 percent to 4.4 cents.

## AGENIX

Agenix says it has appointed Craig Chapman as a non-executive director effectively immediately.
Agenix said that Mr Chapman had more than “25 years experience across a range of service sectors and has been instrumental in a number of highly successful consolidation plays listed on the ASX including S8, Greencross and G8 Education” and held senior management roles, company secretarial positions and directorships with the companies.
The company said that Mr Chapman held a Bachelor of Commerce degree from the University of Queensland and a Graduate Diploma in Applied Corporate Governance.
Agenix was up 0.1 cents or 4.2 percent to 2.5 cents.