Biotech Daily

Tuesday January 29, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ALCHEMIA UP 6%, PATRYS DOWN 10%**

*** FDA CONCERNS ON PHARMAXIS TRIAL DESIGN; TRADING HALT**

*** TISSUE THERAPIES HAS ONE QUARTER CASH; CONSIDERING OPTIONS**

*** ALCHEMIA LOSES CEO DR PETE SMITH**

*** UNIQUEST LOSES M-D DAVID HENDERSON**

*** MEDICAL DEVELOPMENTS CEO JOHN SHARMAN EARNS BONUS**

MARKET REPORT

The Australian stock market climbed 1.11 percent on Tuesday January 29, 2013, with the S&P ASX 200 up 53.8 points to 4,889.0 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and five were untraded.

Alchemia was the best, first falling 8.8 percent to 28.5 cents, but closing up two cents or 6.45 percent to 33 cents with 1.15 million shares traded.

Avita, Phylogica and Sirtex climbed four percent or more; CSL, Neuren and Sunshine Heart were up more than three percent; Clinuvel rose 2.8 percent; GI Dynamics, QRX and Starpharma were up more than one percent; with Acrux, Cochlear and Nanosonics up by less than one percent.

Patrys led the falls, down 0.4 cents or 10.3 percent to 3.5 cents with 337,846 shares traded.

Genetic Technologies lost 7.9 percent; Benitec and Living Cell were down six percent or more; Allied Health, Cellmid, Optiscan and Reva fell four percent or more; Medical Developments and Universal Biosensors shed more that two percent; Viralytics was down 1.6 percent; with Mesoblast and Resmed down by less than one percent.

PHARMAXIS

Pharmaxis has requested a trading halt pending “the outcome, of the review of Bronchitol for … cystic fibrosis by the [US FDA] Pulmonary-Allergy Drug Advisory Committee”.

Pharmaxis said the Pulmonary-Allergy Drug Advisory Committee (PADAC) was an independent expert advisory panel to the US Food and Drug Administration which would discuss its application on January 30, 2013 (US time).

The FDA Committee briefing package included questions relating to trial design and data analysis, raising issues including post-hoc analyses and drop-out rates.

“The most significant is the treatment-related early discontinuations that occurred disproportionally more often in the [Bronchitol] DPM-treated groups than the control groups,” The FDA said. “This resulted in the post hoc creation by Pharmaxis of a ‘modified’ intent to treat population (MITT) that included only ITT patients who attended the week-6 study visit. As a result, patients who dropped out before week-6 of either study are entirely excluded from efficacy analyses.”

The FDA said that the effect of early drop-outs was more pronounced for study 301 and resulted in only 88 percent of DPM patients being included in the MITT analysis compared to 95 percent of control patients, while for study 302, 96 percent of DPM patients and 99 percent of control patients were included in the MITT population.

Another factor that contributed to the problem regarding differential missing data is the fact that throughout the conduct of the studies there was additional missing data as a result of differential drop-out at week-14 and week-26 when efficacy assessments (FEV1 determinations) were made, the FDA said.

The FDA said that “another analysis issue was that for study 302 the control group’s screening FEV1 value was higher by 60 mL (2016 mL vs 1956 mL) than the baseline value”, which was discussed at the pre-NDA meeting, at which time Pharmaxis proposed to adjust the baseline value for FEV1 by averaging the screening and baseline FEV1 values to arrive at a new ‘adjusted’ baseline.

“As the screening and baseline values for all other groups for both trials … were very similar, the functional effect of this proposal would be that the difference between treatment groups in the change from baseline in FEV1 would be larger if the baseline was ‘adjusted’ to try to account for the difference between the baseline and screening values,” the FDA said. “The Agency mentioned that such post hoc manipulations were generally not acceptable and stated that the discrepancy between the screening and baseline FEV1 for control group versus treatment group in DPM-CF-302 (study 302) creates a significant problem, and raises a question about the study conduct (ie, problem with blinding).”

The FDA said the potential conduct issue “created a large regulatory obstacle to overcome”.

“In summary, given the difference in results when data for missing patients are included in the analyses along with the patients with observed data, from a statistical perspective, a replicated statistically significant effect of DPM on the primary efficacy endpoint has not been demonstrated and, as such, the overall effect of DPM in CF patients in terms of the change from baseline in FEV1 in the ITT population cannot be confirmed,” the FDA said.

“The appropriateness and difference in study results based on the use of different analysis study populations will be a significant topic of discussion,” the FDA said.

The website said the Committee would vote on questions relating to the safety and efficacy of 400 mg Bronchitol twice daily.

Pharmaxis said it was “not in a position to comment on the briefing materials until the meeting process has been concluded”.

Trading will resume on January 31, 2013 or on an earlier announcement.

Pharmaxis last traded at $1.25.

TISSUE THERAPIES

Tissue Therapies says its net operating cash burn for the three months to December 31, 2012 was $1,752,900 with cash at the end of the quarter of $1,973,000.
Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that the company was “considering all options available including capital raisings”.
Previously, the company had expected its Vitrogro wound treatment to be approved in Europe by the end of 2012 but regulatory delays meant that sales were unlikely before August 2013 (BD: Oct 30, 2012).
Tissue Therapies was unchanged at 29 cents.

ALCHEMIA

Alchemia says that chief executive officer Dr Peter Smith has resigned “by mutual agreement” and a search is underway for a replacement.
Executive chairman Dr Mel Bridges said that Dr Smith had made a significant contribution to the company and was “a key driver in the efforts to strategically reposition Alchemia’s oncology assets” now held in the Audeo subsidiary and along with the approval of fondaparinux in the US, were key milestones for the company.
Alchemia said it would move quickly to appoint a replacement chief executive officer.
Dr Bridges said that given the failure of the US initial public offer for Audeo Oncology in December 2012, the board was “in advanced planning on how best to maximize shareholder value for the oncology division” (BD: Dec 21, 2012).
Alchemia said fondaparinux was an injectable anticoagulant approved in the US for the prevention and treatment of deep vein thrombosis after knee or hip surgery and its approval and launch was a major achievement for the company and its partner Dr Reddy’s.
“There are very few drug development companies in Australia that are firstly launching an approved drug in the US market, and also have a very advanced pipeline of oncology … assets,” Dr Bridges said.
Dr Smith was appointed Alchemia’s director of commercialization in 2006 and promoted to chief executive officer in 2007 (BD: May 18, 2006; Apr 26, 2007).
Alchemia fell as much as 8.8 percent to 28.5 cents but closed up two cents or 6.45 percent to 33 cents with 1.15 million shares traded.

UNIQUEST

Uniquest says that managing director David Henderson will retire in February 2013 to develop directorship interests and pursue innovation in the internet space.
Mr Henderson said he was “very proud of what we have accomplished at Uniquest and it has been an absolute privilege to work with the Uniquest team”.
Uniquest is the commercialization arm of the University of Queensland.
Uniquest chairman Dr Carrie Hillyard said that Mr Henderson’s contribution over the past 16 years, to Uniquest and the research commercialization sector in Australia, had been significant.
“Under David’s leadership, the company has grown to be regarded as Australia’s leading university technology transfer organization, with an enviable reputation overseas,” Dr Hillyard said.
Uniquest said it would appoint an acting chief executive officer from February 15 and engage an executive search company to help recruit a new managing director.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that chief executive officer John Sharman has become entitled to the third and final tranche of his long-term incentive plan.

Medical Developments said that the after tax bonus amount had been applied by the company in satisfying the issue of shares at $1.46 a share, to be held in escrow for 12 months.

In 2011, Medical Developments set share price and market capitalization thresholds to be achieved for each tranche, allowing Mr Sharman to acquire up to three percent of the company's shares, with the third milestone a market capitalization of $75 million with a share price of $1.46 for more than three months (BD: Sep 9, 2011).

The company said that after acquiring his third tranche of shares Mr Sharman owned 1,474,928 shares.

Medical Developments fell five cents or 2.4 percent to $2.00.