



Biotech Daily

Monday February 15, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: PRIMA UP 11%; CELLESTIS DOWN 8%**
- * **AVEXA'S ATC FOR HIV RESISTANCE-FREE, EFFICACIOUS AT 144 WEEKS**
- * **HIGH COURT ENDS UWA-GRAY (SIRTEX) CASE**
- * **CELLESTIS H1 REVENUE, PROFIT, DIVIDEND UP**
- * **PSIVIDA H1 REVENUE UP, CASH BURN DOWN**
- * **CBIO OPENS DOWN 50%**
- * **TISSUE THERAPIES CHAIRMAN GIVES 1.9m SHARES TO KEY STAFF**
- * **INCITIVE REQUESTS ACQUISITION TRADING HALT**
- * **BIO-MELBOURNE BREAKFASTS ON PROF COWLEY, OBESITY, DIABETES**

MARKET REPORT

The Australian stock market fell 0.36 percent on Monday February 15, 2010 with the S&P ASX 200 down 16.6 points to 4545.5 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and eight were untraded. All three Big Caps were up.

Prima was best, up 1.5 cents or 10.7 percent to 15.5 cents with 3.3 million shares traded, followed by Phosphagenics up 8.9 percent to 9.8 cents with 3.6 million shares traded.

Tissue Therapies climbed 7.3 percent; Impedimed was up 5.1 percent; Antisense was up 3.85 percent; CSL, Genetic Technologies and Starpharma rose more than two percent; with Mesoblast and QRX up more than one percent.

Cellestis led the falls on excellent news (see below), down 29 cents or 8.3 percent to \$3.21 with 78,080 shares traded, followed by Prana down 6.9 percent to 13.5 cents.

Living Cell lost five percent; Benitec and Viralytics were down more than four percent; Sunshine Heart shed 2.9 percent; with Chemgenex and Novogen down one percent or more.

[AVEXA](#)

Avexa says 144-week data from its phase IIb extension study for apricitabine has shown no resistance to the drug and sustained efficacy.

Avexa said that of the 36 patients who successfully completed the full study, "94 percent [34 patients] maintained undetectable viral loads up to week 144".

The company said that in these patients, no resistance to apricitabine (ATC) was detected and no apricitabine-related serious adverse events were observed.

Avexa said that on average, the patients were able to maintain their CD4 cells above 500 cells per microlitre, the level where many current guidelines indicate antiretroviral treatment need not be initiated.

The patients in the extension trial include about 10 who were originally in the 3TC control group and swapped over to apricitabine.

Earlier this month Avexa announced top line data from its phase III trial comparing apricitabine to 3TC in which some of the data showed benefits, but not at statistically significant levels (BD: Feb 4, 5, 2010).

Avexa's chief scientific officer Dr Jonathan Coates said the company was "delighted that ATC continues to provide consistent, positive benefits for patients suffering from HIV".

"These results, along with the initial data from the phase III study announced earlier this month, provide a clear indication of the medical value of ATC," Dr Coates said.

Avexa said that 36 of the 42 patients enrolled in the phase IIb extension study successfully completed the full study of 144 weeks, with apricitabine as part of their optimized background regimen.

The company said that 34 of the 36 patients maintained undetectable viral loads up to week 144.

Of the patients who entered the study with a higher level of pre-existing drug resistance (more than two thymidine associated mutations), more than 90 percent of them achieved undetectable viral loads, indicating that the activity of apricitabine was not compromised by increasing numbers of thymidine associated mutations, a set of mutations that are known to mitigate the activity of other nucleoside reverse transcriptase inhibitors (NRTIs) such as tenofovir, abacavir and zidovudine, the company said.

Avexa said six patients did not complete the study, of which only two (4.7%) failed to maintain control of their viral load below detectable.

Of these, one showed no additional mutations in apricitabine's and other NRTIs' target, the reverse transcriptase gene, and the other showed the presence of a mutation which was frequently related to the use of other antiviral agents in the optimized background regimen.

Two patients were withdrawn from the study due to compliance issues and two for clinical trial eligibility reasons.

Avexa said "the excellent safety and tolerability profile of ATC has now been maintained beyond three years of treatment".

Throughout the 144 weeks of study, no ATC-related serious adverse events were observed and there was no evidence of the associated side effects often seen with other anti-HIV drugs, which often necessitate a change in therapy.

This is further confirmed by ATC's high level of compliance, with more than 95 percent of patients taking their full dose of ATC consistently throughout the 144 week study.

Avexa's chief executive officer Dr Julian Chick told Biotech Daily he expected to see resistance in patients with 3TC and FTC resistance but did not and said apricitabine was active against other resistant strains.

Dr Chick said the full phase III results were expected in March.

Avexa closed unchanged at 13 cents with 6.6 million shares traded.

SIRTEX

The High Court of Australia has rejected a special leave application from the University of Western Australia in its long-running battle against Sirtex founder Dr Bruce Gray. The High Court's manager of public information Jane Mussett told Biotech Daily the special application was rejected on Friday February 12, 2010 and the University was refused costs.

The case has centred primarily on Dr Gray's and Sirtex's right of ownership of the intellectual property which was created at a time when Dr Gray was an employee of the University (BD: Sep 8, Oct 7, 2009).

Sirtex fell five cents or 0.84 percent to \$5.90.

CELLESTIS

Cellestis says its net profit after tax for the six months to December 31, 2009 was up 12 percent to \$3,189,000 on revenue from sales up 26 percent to \$18,207,000.

Cellestis said it spent \$620,000 or 3.4 percent of revenue on research and development up from the \$398,000 spent in the six months to December 31, 2008.

The company said it would pay a fully franked dividend of 1.5 cents a share on March 12, 2010 with a record date of February 26, 2010.

Cellestis said its net tangible assets per security was up from 20.4 cents for the six months to December 31, 2008 to 24.6 cents for the half year to the end of 2009.

Diluted earnings per share for the six months was 3.3 cents.

Cellestis fell 29 cents or 8.3 percent to \$3.21.

PSIVIDA

Psivida's revenue from collaborative research and development and royalties increased 15.3 percent to \$US6,816,000 (\$A7,686,000) in the six months to December 31, 2009.

The revenue primarily came from collaborations with Pfizer and Alimera, with royalty payments of \$US64,000 from Bausch & Lomb.

Psivida said the operational loss fell from \$US3,800,000 for the six months to December 31, 2008 to \$US220,000 for the half year to the end of 2009.

The net loss after income tax for the six months to December 31, 2009 was up 20.4 percent to \$US1,615,000.

Psivida's investor relations vice-president Brian Leedman told Biotech Daily that the "negligible cash burn" and revenues were "expected to continue for the foreseeable future until we receive royalty payments from Bausch & Lomb for Retisert payments later this year.

Mr Leedman said the company "also hope to begin profit share from Alimera for Iluvien in early 2011, after FDA approval hopefully later this year".

Psivida was untraded at \$3.80.

CBIO

CBio opened its first day of trading on the ASX down 50 percent from its initial public offer price of \$1.00 at 50 cents.

Prior to the initial public offer and as recently as October 2009, CBio raised \$10 million through the issue of 20,000,000 shares at 50 cents each (BD: Oct 9, 2009).

The company traded between 38 cents and 50 cents and closed at 39.5 cents with 456,274 shares traded.

TISSUE THERAPIES

Tissue Therapies chairman Roger Clarke has reduced his holding in the company from 7,150,000 shares (5.17%) to 5,258,000 shares (3.80%).

The 1,892,000 shares were exercised from options at 12 cents a share and resulted from the conversion of a convertible note.

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that Mr Clarke "exercised the options and provided the shares to key staff to reward performance".

Tissue Therapies was up 1.5 cents or 7.3 percent to 22 cents.

INCITIVE

Incitive has requested a trading halt pending an announcement on a "proposed acquisition".

Trading will resume on February 17, 2010 or on an earlier announcement.

In 2009, Incitive decided not to proceed with the acquisition of V-Patch Medical Systems (BD: Oct 13, 2009).

Incitive's assets and its former lead compound ICV0019 were derived from bromelain, an extract from pineapple stems.

In 2008, Incitive reviewed its business "including the possibility of exiting the sector" (BD: Oct 17, 2008).

The company said the ICV0019 program had been "very successful and demonstrated that it has the potential to be a significant drug in the treatment of anti-inflammatory and autoimmune diseases".

Incitive last traded at 0.6 cents.

BIO-MELBOURNE NETWORK

Monash Obesity and Diabetes Institute director Prof Michael Cowley will discuss diabetes, heart disease and obesity at the Bio-Melbourne Network's March 2, 2010 Bio-Breakfast. Bio-Melbourne Network chief executive officer Michelle Gallaher said that Prof Cowley's work was "very timely given the rising prevalence of obesity in this country and the significant pressure on the public health system that this condition will have if the numbers keep increasing at the current rate".

Prof Cowley will explain why some people put on more weight than others and how his research work has led to the creation of Orexigen Therapeutics based in the US.

The Bio-Melbourne Network said Orexigen had a number of drug candidates for obesity under development in phase IIb and phase III.

The Network said Prof Cowley would discuss his experiences with setting up Orexigen and why he and his family returned to Australia in 2008 after many years living in the US. Prof Cowley won the 2009 Science Minister's prize for Life Scientist of the year.

The Breakfast will be held the Supper Room, Melbourne Town Hall, Swanston Street, Melbourne with registration from 7.15am and the presentation at 8am.

For more information or to book online go to <http://www.biomelbourne.org/events/view/94> or call Anita Petris on +613 9667 8182.