



# Biotech Daily

Monday December 9, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: ANTISENSE UP 6%, ANTEO DOWN 12%**
- \* **BENITEC FILES US IND FOR 'SINGLE-SHOT' TT-034 FOR HEPATITIS C**
- \* **PRANA COMPLETES PHASE II PBT2 IMAGINE ALZHEIMER'S DOSING**
- \* **WELL-FUNDED SUDA PAUSES BERGEN DRAW-DOWN EQUITY FACILITY**
- \* **MEDICAL DEVELOPMENTS H1 PROFIT FALL; GSK ENDS CONTRACT**
- \* **ALLAN GRAY TAKES 9% OF ACRUX**
- \* **HUNTER HALL REDUCES TO 4% OF BIOTA**
- \* **PERSISTENCY REDUCES TO 6% OF LIVING CELL**
- \* **CELLMID REQUESTS CAPITAL RAISING TRADING HALT**
- \* **AVITA REQUESTS 'COMPANY CHANGES' TRADING HALT**

## MARKET REPORT

The Australian stock market fell 0.80 percent on Monday December 9, 2013 with the S&P ASX 200 down 41.6 points to 5,144.4 points. Eight of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and seven were untraded.

Antisense was the best, up one cent or 6.25 percent to 17 cents, with 438,939 shares traded.

Benitec and GI Dynamics climbed more than five percent; both Neuren and Pharmaxis were up 4.8 percent; Impedimed rose two percent; Resmed was up 1.4 percent; with Alchemia or QRX up by less than one percent.

Anteo led the falls for the second trading day in a row, down two cents or 12.1 percent to 14.5 cents with 8.5 million shares traded, followed by Phylogica down 11.1 percent to 1.6 cents with 1.3 million shares traded.

Admedus lost 6.7 percent; Bionomics, Medical Developments and Patrys fell five percent or more; Prima and Starpharma fell more than four percent; Prana was down 3.85 percent; Acrux, Mesoblast, Sirtex and Viralytics shed more than two percent; IDT lost 1.2 percent; with Clinuvel, Cochlear, CSL and Nanosonics down by less than one percent.

### BENITEC BIOPHARMA

Benitec says it has filed its US investigational new drug application for a first-in-man phase I/IIa trial of its DNA-directed RNA interference drug TT-034 for hepatitis C. Benitec said it filed the application to the US Food and Drug Administration on December 6, 2013 and the 14-patient trial could begin 30 days after filing "unless the FDA has questions that cannot be answered within that time".

Benitec chief executive officer Dr Peter French said the company was "delighted to have achieved this major milestone in Benitec's transition to a clinical stage company".

"The IND is the culmination of years of work by Benitec's subsidiary, Tacere Therapeutics," Dr French said.

"TT-034, as a single shot treatment for patients with hard to treat active hepatitis C infection, will be seen as a disruptive technology in this field if, as we expect, it demonstrates clinical safety and efficacy," Dr French said.

Benitec was up 2.5 cents or 5.2 percent to 50.5 cents.

### PRANA BIOTECHNOLOGY

Prana says it has completed the treatment phase of its 42-patient, phase II, imaging trial of PBT2 for Alzheimer's disease.

Prana said that the 42 patients with prodromal or mild Alzheimer's disease had been enrolled in the double-blind, placebo-controlled clinical trial with 40 patients completing the planned 12 months of treatment with PBT2 or placebo.

The company said that the Imagine trial primary outcome was the effect of 12 months of treatment with a daily oral dose of 250mg of PBT2 on beta amyloid deposits in the brain. Prana said that other outcomes included the effects of PBT2 on increasing brain activity, brain volume and cognition.

The company said that patients were screened by positron emission tomography brain scans to confirm a level of beta amyloid deposit consistent with prodromal or early disease.

Prana said that two patients withdrew during the trial, a retention rate of 95 percent, and an independent data safety advisory board met five times during the course of the trial and on no occasion made any recommendations to vary the original trial protocol.

The company said that data compilation and statistical analysis would begin shortly after the last few patients complete their follow up visit, with results expected in March 2014.

Prana said that all available treatments for Alzheimer's disease were approved to provide some degree of symptomatic relief, but none changed the course of the disease and the eventual decline in patient's cognition and health.

The company said that its Imagine study design aimed to demonstrate PBT2's potential as an effective disease modifying treatment available to patients.

Prana said that the trial received funding from the New York based Alzheimer's Drug Discovery Foundation.

Foundation executive director Dr Howard Fillit said that at the time of initiating the trial, "we noted that PBT2 stood out as one of the few remaining orally available agents with clinical trial evidence of cognitive benefit for Alzheimer's patients".

"Since then the relevance of this trial and its design has only increased, in light of the changing competitive and regulatory landscape for Alzheimer's drugs in development," Dr Fillit said. "The ADDF is proud to have supported this PBT2 trial design that reflects the US Food and Drug Administration's new guidelines encouraging companies to look at treating patients earlier in the disease process," Dr Fillit said.

Prana fell 2.5 cents or 3.85 percent to 62.5 cents.

## SUDA

Suda says that following its \$5.6 million placement it has paused its funding agreement with the New York-based Bergen Global Opportunity Fund, with mutual consent.

Suda said it signed the Bergen agreement in December 2012 and had drawn down \$2.2 million for working capital and to fund the phase III trial of Artimist for paediatric malaria.

The company said that the balance of funds available was \$3.6 million and it and Bergen had postponed further scheduled funding for a six-month period without penalty.

Suda executive chairman Stephen Carter the company "used the funding provided by Bergen over the past 12 months to raise the requisite capital".

"During that time, our share price appreciated from a low of 2.8 cents in December 2012 to the 6 to 7 cent range in November [and] December 2013," Mr Carter said.

"The funding offered us the flexibility to raise capital in a highly efficient and cost effective manner, thus maximizing value for our shareholders and enabled us to conclude the Novadel acquisition," Mr Carter said. "We are extremely grateful to Bergen, who has been an excellent corporate citizen and supportive shareholder over this period."

Suda fell 0.2 cents or 3.1 percent to 6.3 cents with 3.7 million shares traded.

## MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it expects profit for the six months to December 31, 2013 to fall about 65.4 percent to \$500,000 with the loss of a Glaxosmithkline spacer contract.

Medical Developments said that its Pentrox analgesic inhaler and other medical device and veterinary business sales were "on-budget" for the first five months of 2013-'14.

The company said that it expected profit after tax for the six months ending December 31, 2013 would be about \$500,000, including a one-off tax adjustment of \$360,000.

In February, Medical Developments reported revenue for the six months to December 31, 2012 of \$6,482,000 with net profit after tax of \$1,444,000 and said that spacer sales were \$2,856,000, Pentrox analgesic inhaler sales were \$3,450,000, with veterinary product sales of \$176,000 (BD: Feb 22, 2013)..

The company said spacer sales in New Zealand had been "impacted by an unusually mild winter"; a merger between the New Zealand-based Ebos Group and Symbion delayed sales until the beginning of 2014; and Glaxosmithkline had cancelled its spacer supply contract as a result of two products being approved for sale by the Australian Pharmaceutical Benefits Scheme that competed against its market leading Seretide.

In December 2012, Medical Developments said it had an agreement with Glaxosmithkline to supply 130,000 asthma space chambers a year for two years (BD: Jan 20, 2013).

Today, the company said that Glaxosmithkline "advised us the cancellation has nothing to do with [the] performance or the quality of our product, rather the change represents a shift in its Seretide marketing strategy as a result of the changing competitive landscape".

Medical Developments said it had initiatives and strategies in place to win back the lost volumes, the issues were "all timing problems and there has been no negative impact on the size of the market for our products or our prospects".

The company said that spacer sales for December were excellent and it was confident volumes would return to forecast levels during the six months to June 30, 2014.

Medical Developments said that the European business was growing and the US Food and Drug Administration 510(k) pre-market approval in November meant the company could sell the Space Chamber Plus range in the world's largest respiratory devices market, where more than 20,000,000 space chambers were sold each year.

The company said it expected to have a US partner by June 30, 2014.

Medical Developments fell six cents or five percent to \$1.15.

### ACRUX

Allan Gray Australia has increased its substantial holding in Acrux from 13,059,434 shares (7.84%) to 14,980,243 shares (9.00%).

Allan Gray said that between November 19 and December 4, 2013 it bought 1,920,809 shares for \$4,743,492 or an average price of \$2.47 a share.

Acrux fell five cents or 2.1 percent to \$2.30 with 2.1 million shares traded.

### BIOTA PHARMACEUTICALS

Biota says Hunter Hall Investment Management has reduced its holding in Biota to 1,008,939 shares or 3.56 percent of the company.

In a filing to the US Securities and Exchange Commission, Biota did not state the value of the sale, but the company has been trading around \$US4.00.

In July, Hunter Hall Investment Management reduced its holding in Biota to 2,080,839 shares or 7.32 percent of the company (BD: Jul 29, 2013).

In its last ASX statement on Biota in 2011, Hunter Hall said it held 24,781,543 shares or 13.66 percent of the company, equivalent to 3,097,693 US shares following the merger with Nabi Pharmaceuticals (BD: Aug 10, 2011; Apr 23, Oct 23, 2012).

In 2010, when Biota was trading at 98 cents, Hunter Hall held 14.14 percent of the company (BD: Dec 16, 2010).

On the Nasdaq on Friday, Biota fell 16 US cents or 3.87 percent to \$US3.97 (\$A4.35, equivalent to 54 cents pre-merger) with 37,490 shares traded.

### LIVING CELL TECHNOLOGIES

Persistency Private Equity has reduced its substantial holding in Living Cell from 25,610,891 shares (7.17%) to 22,037,675 shares (6.17%).

The Gibraltar-based Persistency said it sold 130,000 shares for 9.9 cents a share on December 5, 2013 and between January 15, 2009 and December 5, 2103 it sold 3,573,216 at "various price levels".

Living Cell was unchanged at 10 cents.

### CELLMID

Cellmid has requested a trading halt pending "in relation to a proposed capital raising that is material to the company's business".

Trading will resume on December 11, 2013 or on an earlier announcement.

Cellmid last traded at 3.3 cents.

### AVITA MEDICAL

Avita has requested a trading halt pending "changes to the company".

Avita said it was "in the process of finalizing changes to the company and the trading halt is requested until an announcement is made to the market".

Trading will resume on December 11, 2013 or on an earlier announcement.

Avita last traded at 9.3 cents.