



Biotech Daily

Friday August 29, 2014

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: CLINUVEL UP 10%, ONCOSIL DOWN 12.5%
- * EX-PHOSPHAGENICS CEO DR ESRA OGRU BAIL EXTENDED
- * BENITEC TT-034 HEPATITS C TRIAL: 'MORE DELAYS, MORE TRIAL SITES'
- * ELLEX REVENUE UP 27% TO \$54m, LOSS TO PROFIT OF \$788k
- * ATCOR REVENUE DOWN 44% TO \$5m, PROFIT TURNS TO \$2m LOSS
- * ALCHEMIA FONDAPARINUX SALES UP 2% TO \$10m
- * ALCHEMIA REVENUE DOWN 35% TO \$16m, LOSS DOWN 45% TO \$7m
- * GENETIC TECHNOLOGIES REVENUE DOWN 34% TO \$5m, LOSS UP 9%
- * MEDICAL AUSTRALIA REVENUE UP 30% TO \$12m, LOSS TO \$105k PROFIT
- * LBT REVENUE DOWN 11% TO \$4m, PROFIT DOWN 38% TO \$331k
- * AVITA SALES DOWN, REVENUE DOWN 19% TO \$3m, LOSS DOWN TO \$5m
- * PHYLOGICA REVENUE UP 5% to \$826k, LOSS DOWN 5% TO \$3m
- * CIRCADIAN REVENUE DOWN 24% TO \$878k, LOSS DOWN 16% TO \$4m
- * DORSAVI REVENUE UP 42% TO \$2.6m, LOSS UP 14% TO \$2.5m
- * UNILIFE REVENUE UP 436% to \$16m, LOSS DOWN 8% TO \$62m
- * MICHAEL DALE TO REPLACE GI DYNAMICS CEO STUART RANDLE

MARKET REPORT

The Australian stock market was flat on Friday August 29, 2014 with the S&P ASX 200 up 1.5 points to 5,625.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and four were untraded.

Clinuvel was the best, up 24 cents or 9.6 percent to \$2.75 with 34,683 shares traded. GI Dynamics climbed 8.3 percent; Prana was up 4.55 percent; Acrux was up 3.3 percent; Atcor, Impedimed, Phosphagenics and Universal Biosensors rose more than two percent; with Sirtex, Tissue Therapies and Viralytics up more than one percent.

Oncosil led the falls, down 1.5 cents or 12.5 percent to 10.5 cents with 2.0 million shares traded. Avita and IDT lost more than six percent; Benitec and Pharmaxis fell more than five percent; Medical Developments and Neuren fell four percent or more; Admedus, Anteo, Bionomics and Biotron lost more than three percent; Alchemia and Starpharma shed more than two percent; with CSL and Living Cell down more than one percent.

PHOSPHAGENICS

Former Phosphagenics chief executive officer Dr Esra Ogru is expected to appear for a plea hearing in the Melbourne County Court in September.

Dr Ogru has pleaded guilty to six charges of dishonestly obtaining a financial advantage by deception with the amounts totalling \$6,146,732.06 (BD: Aug 20, 21, 22, 2014).

Four of the charges relate to invoices valued at \$5,600,842.70 and two relate to credit card reimbursements valued at \$545,889.36.

In the County Court today, Counsel for Dr Ogru, Dr Martine Marich told Justice Felicity Hampel that there was no dispute with the Prosecution regarding the first four counts, but regarding the credit card counts "my client suspects there may be legitimate claims and wants to see the bank statements".

Dr Marich said it had taken time to receive the bank statements.

Dr Marich told the court that Baby Z, who was born with the potentially fatal disease molybdenum cofactor deficiency type A, had been in hospital for 10 days of the past three weeks.

Justice Hampel said that she wanted to hear all three pleas before sentencing the two co-accused, unless Dr Marich notified the Court of any delay, prior to September 19.

Justice Hampel extended Dr Ogru's bail until September 26, 2014.

Phosphagenics was up 0.2 cents or 2.0 percent to 10 cents with 1.5 million shares traded.

BENITEC BIOPHARMA

Benitec says it continues to have delays in dosing patients and intends to accelerate enrolment in its phase I/IIa trial of TT-034 for hepatitis C.

Benitec said that second patient dosing was delayed "due to the unexpected failure of two patients being monitored for eligibility at Duke Clinical Research Centre".

The company said that during the 28-day monitoring process, the patients experienced fluctuations in viral load and/or liver enzymes that were outside the clinical protocol inclusion criteria and before any patient could be dosed, their viral load and liver enzyme results must be within acceptable levels.

Benitec said that additional patients at Duke were going through the monitoring process, and a further patient was progressing at the University of California San Diego.

The company said that it would begin recruitment of additional clinical trials sites, examine the enrolment process to identify areas for enhancement, appoint an internal clinical trial specialist to actively manage the trial in conjunction with the company's contract research organization and trial sites.

Benitec fell 5.5 cents or 5.3 percent to 98 cents.

ELLEX MEDICAL LASER

Ellex says revenue for the 12 months to June 30, 2013 fell 9.9 percent to \$42,805,000 taking last year's net loss after tax of \$816,000 to a net profit after tax of \$788,000.

Ellex said that "the improved operating performance is a direct result of improved sales, primarily in the US".

Ellex said that net tangible asset backing per share fell 10.4 percent to 15.5 cents.

The company said that diluted earnings per share was 0.7 cents compared to the previous year's loss of 1.0 cents per share.

Ellex said it had \$1,768,000 in cash and equivalents at June 30, 2014 compared to \$786,000 for the previous corresponding period.

Ellex was unchanged at 35 cents.

ATCOR MEDICAL

Atcor says revenue for the 12 months to June 30, 2014 fell 44.2 percent to \$5,053,284 taking last year's \$2,641,608 net profit after tax to a \$2,559,440 net loss after tax.

Atcor said that sales relating to pharmaceutical company clinical trials fell \$4.3 million from record prior year levels, but European sales rose nine percent, Asia-Pacific sales increased eight percent and US clinical practice sales rose 10 percent.

The company said that US research sales were lower than the prior year, as a large government order did not repeat; but the segment was expected to return to growth in 2014-'15

Atcor said that net tangible asset backing per share fell 34.4 percent to 2.1 cents.

The company said that diluted loss per share was 1.7 cents compared to the previous year's earnings of 1.8 cents.

Atcor said it had \$2,168,156 in cash and equivalents at June 30, 2013 compared to \$2,874,209 for the previous corresponding period.

Atcor was up 0.2 cents or 2.15 percent to 9.5 cents.

ALCHEMIA

Alchemia says total generic fondaparinux profit share for the 12 months to June 30, 2014 was up 2.3 percent to \$US9.19 million (\$A9.82 million).

Alchemia said that total sales for the year to June 30, 2014 by partner Dr Reddys Laboratories was \$37.66 million with its profit share \$9.82 million, of which the company would receive \$8.01 million following agreed deductions

Last year, Alchemia earned \$9.6 million in profit share from partner Dr Reddy's Laboratories sales of fondaparinux for the year to June 30, 2013 (BD: Aug 20, 2013).

Today, Alchemia said that its profit share of generic fondaparinux sales for the three months to June 30, 2014 was \$2.15 million and it would receive \$1.62 million.

Alchemia said that its quarterly contribution of \$530,000 (\$US500,000) towards yield and cost of goods improvement activities would continue until December 31, 2014.

The company said that for the three months to June 30, 2014 Dr Reddy's maintained its total US market share by volume at 32 percent, despite a reduction in overall market volumes.

Alchemia said that pricing pressure "continues to be a factor while the recent channel consolidation in the US, where a number of retailer-wholesaler mergers occurred, has also affected the profit share result".

The company said that Dr Reddy's was continuing to expand the sale of fondaparinux into additional markets following the launch of the drug in Canada during the quarter.

Alchemia fell 1.5 cents or 2.4 percent to 60.5 cents.

ALCHEMIA

Alchemia says that revenue for the year to June 30, 2014 fell 34.9 percent to \$15,811,000 with net loss after tax reduced 45.2 percent to \$6,924,000.

The company said diluted loss per share increased 31.25 percent from 1.6 cents at June 30, 2013 to 2.1 cents at June 30, 2014, net tangible asset backing per share down 22.2 percent from 5.4 cents at June 30, 2013 to 4.2 cents at June 30, 2014.

Alchemia said it had cash and equivalents of \$7,949,000 at June 30, 2014 compared to \$5,064,000 at June 30, 2013.

GENETIC TECHNOLOGIES

Genetic Technologies says revenue for the 12 months to June 30, 2014 fell 33.5 percent to \$5,428,112, with a net loss after tax up 8.9 percent to \$10,125,197.

Genetic Technologies said that the number of Brevagen breast cancer tests fell in the three months to March 31, 2014 due to a combination of "severe winter weather conditions ... and the introduction of the US Affordable Care Act, so-called Obama Care, which created uncertainty in patients' understanding of their out-of-pocket expense liability".

The company said that the following three months saw a return to growth and that total samples for the 12 months to June 30, 2014 was 3,935 "more than double that received in the previous corresponding period".

Genetic Technologies said that revenue from licencing its non-coding DNA patents fell 82 percent from \$4,784,913 to \$863,832.

The company said that diluted loss per share fell 10.7 percent from 1.97 cents at June 30, 2013 to 1.76 at June 30, 2014.

Genetic Technologies said it had cash and equivalents of \$2,831,085 at June 30, 2014 compared to \$1,721,293 million at June 30, 2013.

Genetic Technologies was unchanged at 2.7 cents.

MEDICAL AUSTRALIA

Medical Australia says that revenue for the 12 months to June 30, 2014 was up 30 percent to \$11,874,962 turning last year's loss to a \$105,241 net profit after tax.

Medical Australia said that the increased revenue reflected "the contribution from the Medivet business that was acquired during the year but also from organic sales growth achieved in the human healthcare division".

The company said that net tangible assets per shares was 3.66 cent compared to the previous year's 0.08 cents deficit, with diluted earnings per share 0.14 cents compared to the previous year's loss of 2.90 cents a share.

Medical Australia said it had cash and cash equivalents of \$1,757,258 at June 30, 2014, compared to \$129,134 at June 30, 2013.

Medical Australia was unchanged at 16 cents.

LBT INNOVATIONS

LBT says that revenue for the year to June 30, 2014 fell 11.2 percent to \$3,920,000, with net profit after tax down 37.7 percent to \$331,000.

LBT said that it received \$3.00 million in milestone payments for its Automated Plate Assessment System program with Hettich AG Switzerland along with \$648,000 in royalties from the France-based Biomérieux for its automated plate streaking system.

The company said diluted earnings per share fell 37.7 percent from 0.53 cents at June 30, 2013 to 0.33 cents at June 30, 2014, with net tangible asset backing per share down 35.0 percent from 4.0 cents at June 30, 2013 to 2.6 cents at June 30, 2014.

LBT said it had cash and equivalents of \$1,791,020 at June 30, 2014 compared to \$876,000 at June 30, 2013.

LBT was up half a cent or four percent to 13 cents.

AVITA MEDICAL

Avita says that revenue for the year to June 30, 2014 fell 19.1 percent to \$3,277,714, with net loss after tax reduced 36 percent to \$5,147,391.

Avita says that sales of its Recell wound repair products was down five percent to \$2,683,133.

The company said diluted loss per share fell 41.3 percent from 2.69 cents at June 30, 2013 to 1.58 cents at June 30, 2014, with net tangible asset backing per share down 46.9 percent from 3.2 cents at June 30, 2013 to 1.7 cents at June 30, 2014.

Avita said it had cash and equivalents of \$3,648,390 at June 30, 2014 compared to \$10,616,849 at June 30, 2013.

Avita fell 0.7 cents or 6.7 percent to 9.8 cents.

PHYLOGICA

Phylogica says revenue for the year to June 30, 2014, was up 5.0 percent to \$826,000 reducing net loss after tax by 5.3 percent to \$3,258,000.

Phylogica said commercial income from contracts to fund research was up 15.3 percent to \$692,150 and was based on a mixture of funding full time equivalent research salaries and milestone payments.

The company said that diluted loss per share fell 40.5 percent to 0.44 cents at June 30, 2014 and net tangible assets per share was up 42.3 percent from 0.26 cents to 0.37 cents.

Phylogica said it had \$4,021,588 in cash and cash equivalents at June 30, 2014, compared to \$1,806,905 at June 30, 2013.

Phylogica was up 0.1 cents or 6.7 percent to 1.6 cents with 3.6 million shares traded.

CIRCADIAN

Circadian says that revenue for the year to June 30, 2014 fell 23.9 percent to \$878,083, with net loss after tax reduced 16.0 percent to \$3,996,142.

Circadian said that royalties and licence fees were down 3.1 percent to \$603,152.

The company said diluted loss per share fell 16.0 percent from 9.79 cents at June 30, 2013 to 8.22 cents at June 30, 2014, with net tangible asset backing per share down 21.2 percent from 33 cents at June 30, 2013 to 26 cents at June 30, 2014.

Circadian said it had cash and equivalents of \$7,162,020 at June 30, 2014 compared to \$11,003,941 at June 30, 2013.

Circadian was unchanged at 19 cents.

DORSAVI

Dorsavi says that revenue for the year to June 30, 2014, was up 42.3 percent to \$767,000 with net loss after tax up 114.7 percent to \$3,562,000.

Dorsavi said the majority of revenue was from sales of its spine and movement diagnostic products, up 32.6 percent to \$529,000

The company said that said that its net tangible asset per share was up from a deficit of 1.55 cents at June 30, 2013 to 11.83 cents at June 30, 2014, with diluted loss per share down 82.1 percent to 3.60 cents.

Dorsavi said that it had cash and cash equivalents of \$13,938,000 at June 30, 2014 compared to \$274,000 at June 30, 2013.

Dorsavi was up 1.5 cents or 3.6 percent to 43 cents.

UNILIFE

Unilife says revenue for the year to June 30, 2014, was up 436 percent to \$US14,689,000 (\$A15,712,760) reducing net loss after tax by eight percent to \$US57,899,000 (\$A61,929,750).

Unilife said that the increased revenue was from “development activities for various customers” for its pre-filled syringe business.

The company said that diluted loss per share fell 24.4 percent from 0.78 US cents at June 30, 2013 to 0.59 US cents at June 30, 2014, with net tangible assets per US share down from 25 US cents at June 30, 2013 to a deficit of six US cents per share at June 30, 2014. The company said that net tangible assets per Australian depositary interest (CDI) fell from four cents at June 30, 2013 to a deficit of one cent per CDI at June 30, 2014.

Unilife said it had \$US8,368,000 in cash and cash equivalents at June 30, 2014, compared to \$US5,736,000 at June 30, 2013.

Unilife was up 1.5 cents or 3.4 percent to 46 cents.

GI DYNAMICS

GI Dynamics says Michael Dale has been appointed chief executive officer and a director replacing Stuart Randle, effective from September 18, 2014.

GI Dynamics said that Mr Randle would retire as president and chief executive officer, but would remain on the board and available as a consultant during a transition period.

The company said that Mr Dale’s base annual salary would be \$US450,000 (\$A481,329), with the right to a performance bonus of up to a further 45 percent, pending performance hurdles as well as on the start date Mr Dale would be granted options to acquire stock equal to 5.0 percent of the company at an exercise price equal to the “fair market value restricted stock unit grant”, pending hurdles.

GI Dynamics said that Mr Dale was expected to relocate to the Boston, Massachusetts vicinity within six months of the start date and he would be reimbursed up to \$US100,000 for relocation costs including costs associated with the sale and purchase of residences.

The company said that Mr Dale had more than 25 years executive experience in public and private medical device organizations, including medical device companies in the cardiovascular, neuro-modulation and electrophysiology markets.

The company said that Mr Dale was previously the chairman, president and chief executive officer of ATS Medical until its acquisition in 2010 by Medtronic and most recently he was the president and chief executive officer of Helical Solutions developing of the Tornado system for treatment of atrial fibrillation.

GI Dynamics said that Mr Dale had held executive roles with Endocardial Solutions, Cyberonics, St Jude Medical and Edwards Life Sciences.

The company said that Mr Dale held a Bachelor of Science degree from California Polytechnic State University in San Luis Obispo, California.

GI Dynamics chairman Jack Meyer thanked Mr Randle for his “significant contributions to the company over the last decade”.

“Stu was instrumental in securing the CE mark for Endobarrier, gaining Food and Drug Administration approval for initiating the pivotal clinical study for Endobarrier in the United States and successfully completing critical financings, including the company’s initial public offering on the Australian Securities Exchange,” Mr Meyer said.

GI Dynamics was up four cents or 8.3 percent to 52 cents.