



# Biotech Daily

Friday February 27, 2015

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH FLAT: VIRALYTICS UP 31%, OPTISCAN DOWN 26%**
- \* **PRIMA CANS 10-YEAR CVAC FOR OVARIAN CANCER, IMMUTEP FOCUS**
- \* **BIONOMICS; 'NEW BIOMARKERS BENEFIT BNC105 FOR KIDNEY CANCER'**
- \* **ELLEX H1 REVENUE UP 19% TO \$31m, PROFIT UP 108% TO \$815k**
- \* **PHARMAXIS REVENUE UP 133% TO \$13m, LOSS DOWN 68% TO \$7m**
- \* **MEDICAL AUST H1 REVENUE UP 44% TO \$8m, LOSS TO \$420k PROFIT**
- \* **LBT H1 REVENUE DOWN 32% TO \$1.6m, PROFIT DOWN 34% TO \$511k**
- \* **GI DYNAMICS REVENUE UP 25% TO \$4m, LOSS UP 36% TO \$62m**
- \* **PROGEN H1 REVENUE UP 88% TO \$2.5m, LOSS UP 4% TO \$2m**
- \* **PHARMAUST H1 REVENUE DOWN 8% TO \$1m, LOSS UP 68% TO \$1m**
- \* **SIMAVITA REVENUE UP 238% TO \$581k, LOSS DOWN 23% TO \$4m**
- \* **DORSAVI H1 REVENUE UP 113% TO \$825k, LOSS UP 270% TO \$4m**
- \* **PROBIOTEC H1 REVENUE DOWN 2% TO \$31m, PROFIT TO \$26m LOSS**

## MARKET REPORT

The Australian stock market was up 0.34 percent on Friday February 27, 2015 with the S&P ASX 200 up 20.3 points to 5,928.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and two were untraded.

Viralytics was the best on no news but with an ASX Query, to which it said it knew no reason for the price movement, up 9.5 cents or 31.15 percent to 40 cents with 1.3 million shares traded. IDT climbed 7.4 percent; Anteo, Bionomics, Circadian, Clinuvel, Ellex, Neuren, Pharmaxis and Prana were up more than three percent; Avita, CSL, Oncosil and Sirtex were up one percent or more; with Nanosonics up 0.85 percent.

Optiscan led the falls, down 2.3 cents or 25.6 percent to 6.7 cents with 5.8 million shares traded. Compumedics and Prima lost more than seven percent; Biotron and Universal Biosensors shed more than six percent; Acrux, Admedus, Atcor and Impedimed fell more than four percent; Benitec was down 2.8 percent; with Antisense, Genetic Technologies, GI Dynamics, Mesoblast and Starpharma down one percent or more.

## PRIMA BIOMED

Prima says it will close its 10-year CVac clinical programs instead “prioritizing its highly prospective LAG-3 based immunotherapy products”.

Prima had been developing CVac for ovarian cancer with its first trial results posted in 2006 showing that four of 21 patients at Melbourne’s Austin hospital had longer than expected progression-free survival (BD: May 16, 2006).

The company ran out of funds to further develop the technology until Martin Rogers revived the company with a series of draw down equity facilities and then brought the former Mayor of Sydney Lucy Turnbull to the board (BD: May 14, 2008; Oct 7, 2010). At the time of publication, Ms Turnbull’s husband Malcolm was the Minister for Communications in the Federal Government.

In 2013 Prima fell to 3.8 cents on news that it had suspended its phase II/III CAN-004 ‘Canvas’ Australian, European and US trial of CVac for ovarian cancer saying that top-line analysis of its 63-patient CAN-003 phase II trial had failed to show significant progression-free survival.

The company resumed the trial with the endpoint of overall survival (BD: Apr 28, 2014).

In October, Prima said that the New York-based Bergen Global Opportunity Fund would help fund the acquisition of French immuno-oncology company Immutep SA for its complementary types of cancer immuno-therapies based on its lymphocyte activation gene 3 (LAG-3) technology (BD: Oct 2, 2014).

Today, Prima effectively said it would close its CVac programs to focus on LAG-3.

Prima said it would “consolidate its clinical trial program of CVac and pursue opportunities to monetize its cancer vaccine manufacturing infrastructure”.

“Despite the promising nature of CVac, clinical development of autologous cell therapies such as CVac is considerably more complex and costly to develop and produce than for biologicals such as IMP321,” Prima said.

The company said that the timely sourcing of suitable patients for Prima’s enlarged clinical trial for CVac, CAN-004B, “has proven to be more difficult than anticipated ... due to longer than expected clinical and regulatory approvals and the limited availability of platinum-sensitive second remission ovarian cancer patients, particularly in Eastern Europe”.

Prima said that as a consequence, the timeframe for generating sufficient data in this indication would be considerably longer and more expensive than planned.

Ms Turnbull said the decision to cease recruitment of CVac had not been taken lightly and has been made with the best interests of Prima’s shareholders in mind.

“IMP321 is a highly attractive immunotherapy treatment that has the potential to treat cancer sufferers including ovarian, pancreatic and metastatic breast cancer patients in a shorter timeframe,” Ms Turnbull said.

“After due consideration and consultation, including with Prima’s scientific advisory board chairman and external experts, we are firmly of the view that focusing on the development of LAG-3 related product candidates, especially IMP321, is the right and the most responsible course of action and is in the best interests of Prima’s shareholders and patients,” Ms Turnbull said.

Prima said that the most advanced LAG-3 based product IMP321 generated more than double the expected response rate in HER-2 negative metastatic breast cancer in a phase IIa clinical trial, with a phase IIb study expected to begin by the end of 2015, while partnerships for LAG-3 programs with Glaxosmithkline and Novartis were in ongoing clinical trials or close to starting.

Prima said that final analysis of the CAN-003 overall survival data would take place in mid-2015 and the company would seek to partner the future development of CVac.

Prima fell 0.3 cents or 7.9 percent to 3.5 cents with 17.2 million shares traded.

## BIONOMICS

Bionomics says new data from its trial of BNC105 for metastatic renal cancer identifies ferritin and interleukin-8 as biomarkers correlating with improved progression-free survival. Bionomics said that the ferritin and interleukin-8 (IL-8) were identified as correlating with improved progression-free survival in patients in the trial.

Last year, Bionomics said the 136-patient phase II Disruptor-1 trial failed to meet its primary endpoint with no significant difference between the two arms, comparing BNC105P with everolimus (Afinitor) to everolimus alone, but chief executive officer Dr Deborah Rathjen told Biotech Daily the results were “just the beginning of the data from the trial” which would inform future trials (BD: Mar 19, 2014).

In September, Bionomics said that four biomarkers were associated with patient response to BNC105 in combination with everolimus and 57 percent of patients were positive for the four biomarker signature, with 60 percent of these disease-free at six months, with only five percent of the patients that were negative for the four-biomarker signature disease-free at six months (BD: Sep 29, 2014).

Today, Bionomics said that elevated baseline ferritin and lower baseline IL-8 were associated with improved progression free survival ( $p = 0.0291$  and  $p = 0.0149$ , respectively).

The company said that 89 percent of patients expressing elevated plasma levels of ferritin and lower plasma levels of IL-8 at baseline were disease progression free at six months. Bionomics said that the data would be presented by the City of Hope, California, Comprehensive Cancer Center kidney cancer program co-director Dr Sumanta Pal at the American Society of Clinical Oncology Genitourinary Cancers Symposium in Orlando, Florida, February 26 to 28, 2015.

“The Disruptor-1 trial offered a unique opportunity to assess biomarkers related to the activity of BNC105,” Dr Pal said.

“Interestingly our findings suggest that baseline levels of ferritin and IL-8 may predict an excellent clinical outcome with the combination of Afinitor with BNC105,” Dr Pal said.

“Plans are underway already to validate this finding in a biomarker-driven trial,” Dr Pal said.

Dr Rathjen said that the biomarker data was “a compelling improvement compared to the 34 percent [progression-free survival] observed at six months in the unselected population”.

“These results indicate that moving forward, biomarker-based patient selection has the potential to provide guidance and optimize clinical outcomes in the treatment of renal cancer, presenting a range of new possibilities for BNC105,” Dr Rathjen said.

“We will continue to explore further data and the options for the advancement of the compound,” Dr Rathjen said.

Bionomics said that a prospective biomarker-driven study examining combined Afinitor and BNC105 treatment of renal cancer patients selected by baseline IL-8 and ferritin was in development.

The company said that the four biomarkers previously identified as displaying blood concentration changes following administration of BNC105 and correlated with a better progression-free survival were matrix metalloproteinase 9 (MMP9), stem cell factor (SCF), sex hormone binding globulin (SHBG) and serum amyloid P component (SAP).

Bionomics said that increases in MMP-9 and SCF were associated with improved PFS ( $p = 0.0421$  and  $P = 0.0291$ , respectively), while decreases in SHBG and SAP were associated with improved progression-free survival ( $p = 0.0184$  and  $p = 0.0063$ ).

Bionomics was up 1.5 cents or 3.2 percent to 48.5 cents with 1.4 million shares traded.

### ELLEX MEDICAL LASERS

Ellex says revenue for the six months to December 31, 2014, was up 18.6 percent to \$30,691,000 with net profit after tax up 108.4 percent to \$815,000.

Ellex said that including "exchange differences on translating foreign operations" the total comprehensive income increased by 1,666.7 percent from \$75,000 to \$1,325,000.

The company said that net tangible assets per share fell 15.0 percent to 17 cents and diluted earnings per share was up 74.4 percent to 0.75 cents at December 31, 2014 compared to 0.43 cents for the previous period.

Ellex said that cash and cash equivalents at December 31, 2014 was \$3,899,000 compared to \$1,768,000 at June 30, 2014.

Ellex was up one cent or three percent to 34 cents.

### PHARMAXIS

Pharmaxis says that revenue for the six months to December 31, 2014, was up 133.0 percent to \$12,538,000 reducing net loss after tax 68.2 percent to \$6,572,000.

Pharmaxis said that sale of goods, primarily Bronchitol for cystic fibrosis and Aridol, was up 27.6 percent to \$3,040,000 with other revenue including the Federal Government Research and Development Tax Incentive and interest up 216.6 percent to \$9,498,000.

Pharmaxis said that diluted loss per share fell 97.0 percent from 6.7 cents in the previous year to 0.02 cents for the six months to December 31, 2014, with net tangible assets per share up 200 percent to 3.6 cents.

The company said it had cash and cash equivalents of \$19,814,000 at December 31, 2014, compared to \$34,182,000 at December 31, 2013.

Pharmaxis was up 0.3 cents or 3.4 percent to 9.1 cents.

### MEDICAL AUSTRALIA

Medical Australia says revenue for the six months to December 31, 2014, was up 43.6 percent to \$7,593,618, returning the company to a net profit after tax of \$419,976.

Medical Australia said its human health business improved 19 percent with sales revenue of \$966,380 and its animal health division was up 613.0 percent to \$1,558,680.

Medical Australia said that net tangible assets per share was up 20.6 percent from 3.5 cents to 4.22 cents for the six months to December 31, 2014.

The company said diluted earnings per share was 0.39 cents at December 31, 2014, compared to a loss of 0.26 cents in the previous corresponding period.

Medical Australia said that cash and cash equivalents at December 31, 2014 was \$3,089,711 compared to \$1,757,258 at June 30, 2014.

Medical Australia was unchanged at 9.9 cents.

### LBT INNOVATIONS

LBT says its revenue for the six months to December 31, 2014 fell 32.4 percent to \$1,602,000 taking net profit after tax down 33.8 percent to \$511,000.

LBT said that diluted earnings per share fell 41.6 percent from 0.77 cents in the previous corresponding period to 0.45 cents for the six months to December 31, 2014, with net tangible assets per share falling 8.1 percent to 2.94 cents.

The company said it held cash and cash equivalents of \$1,546,000 at December 31, 2014 compared to \$2,080,000 at June 30, 2014.

LBT was untraded at seven cents.

## GI DYNAMICS

GI Dynamics says that revenue for the year to December 31, 2013, was up 25.4 percent to \$US2,838,000 (\$A3,639,540) with net loss after tax up 35.5 percent to \$US48,205,000 (\$A61,830,240).

GI Dynamics said the increased revenue came from sales of its Endobarrier for obesity and type 2 diabetes despite a European export halt (BD: Oct 7, Dec 1, 2014).

The company said that net tangible assets per Chess depositary interests (CDIs) fell 31.25 percent to 0.11 Australian cents, with diluted loss per common share up one US cent or 1.9 percent to 54 US cents.

GI Dynamics said that it had cash and cash equivalents of \$US51,191,000 at December 31, 2014 compared to \$US58,616,000 at December 31, 2013.

GI Dynamics fell half a cent or 1.7 percent to 28.5 cents.

## PROGEN

Progen says that revenue for the six months to December 31, 2014, was up 88.2 percent to \$2,549,909 with net loss after tax up 4.2 percent to \$2,045,104.

Progen earns revenue through its wholly-owned subsidiary Pharmasynth biopharmaceutical contract manufacturing division.

The company said that diluted loss per share increased 4.2 percent to 3.70 for the six months to December 31, 2013, with net tangible assets per share fell 21.5 percent to 11.02 cents at December 31, 2014 compared to 14.04 cents at December 31, 2013.

Progen said it had cash and cash equivalents of \$3,554,218 at December 31, 2014, compared to \$2,981,215 at June 30, 2014.

Progen was unchanged at 15.5 cents.

## PHARMAUST

Pharmaust says revenue for the six months to December 31, 2014 was down 8.0 percent to \$992,000 with a net loss after tax up 67.7 percent to \$1,073,000.

Pharmaust director Sam Wright said that the majority of its income came from its Epichem division, which provided synthetic and medicinal chemistry services.

Pharmaust said its net tangible assets per share fell 53.7 percent to 0.105 cents at December 31, 2014 compared to 0.227 cents at December 31, 2013, with diluted loss per share increased 40.0 percent from 0.05 cents to 0.07 cents.

The company said it had cash and cash equivalents of \$1,282,374 at December 31, 2014 compared to \$2,304,323 at June 30, 2014

Pharmaust fell 0.1 cents or 11.1 percent to 0.8 cents 3.5 million shares traded.

## SIMAVITA

Simavita says that revenue for the six months to December 31, 2014, was up 238.2 percent to \$580,510 reducing net loss after tax 23.4 percent to \$4,067,524.

Simavita said that revenue came from the sale of its smart incontinence management (SIM) system, including initial US sales.

Simavita said that diluted loss per share fell 83.3 percent from 0.36 cents in the previous year to 0.06 cents for the six months to December 31, 2014, with net tangible assets per share down 14.4 percent to 9.78 cents, with cash and cash equivalents of \$4,932,426 at December 31, 2014, compared to \$6,844,197 at June 30, 2014.

Simavita was unchanged at 46 cents.



## DORSAVI

Dorsavi says that revenue for the six months to December 31, 2014, was up 113 percent to \$824,870 with net loss after tax up 270 percent to \$3,977,597.

The company said that diluted loss per share was up 126.4 percent to 3.26 cents for the six months to December 31, 2014.

Dorsavi said that net tangible assets per share fell 35.7 percent to nine cents at December 31, 2014 compared to 14 cents at December 31, 2013.

The company said it had cash and cash equivalents of \$9,341,000 at December 31, 2014, compared to \$13,938,000 at June 30, 2014.

Dorsavi was untraded at 36.5 cents.

## PROBIOTEC

Probiotec says its revenue for the six months to December 31, 2014 fell 2.3 percent to \$31,451,374 taking the previous \$1,031,650 net profit after tax to a loss of \$26,099,715.

Probiotec said that it included impairment costs of \$24,250,850 in the six months accounts, with \$18.8 million relating to its ADP Protein Plant, \$5.4 million relating to its sports nutrition brands Slimmm, Arthroflex and Biggest Loser, a \$1.1 million loss on the sale of its South Nowra, New South Wales production facility and \$700,000 relating to its Impromy collaboration with the Commonwealth Scientific and Industrial Research Organisation which had "grown significantly with over 290 pharmacies now contracted and providing the program".

Probiotec said that its net tangible assets per share fell 51.2 percent from 76.1 cents at December 31, 2013 to 37.2 cents at December 31, 2014.

The company said that said that diluted loss per share was 47.30 compared to the previous corresponding period's diluted earnings per share of 1.89 cents.

Probiotec said it held cash and cash equivalents of \$225,842 at December 31, 2014 compared to \$1,116,587 at June 30, 2014.

Probiotec fell six cents or 24.5 percent to 18.5 cents.