



Biotech Daily

Wednesday March 19, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: ANTISENSE UP 12%, BIONOMICS DOWN 30%**
- * **BIONOMICS FALLS ON BNC105P RENAL CELL CARCINOMA DATA**
- * **NOMINATIONS OPEN FOR \$500k PRIME MINISTER'S SCIENCE PRIZES**
- * **AVEXA PLEADS SCHULTZ TO ASX 73% QUERY**
- * **DENNIS PYERS REPLACES UNILIFE CFO RICHARD WIELAND, JOB OFFER**

MARKET REPORT

The Australian stock market climbed 0.21 percent on Wednesday March 19, 2014 with the S&P ASX 200 up 11.0 points to 5,355.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight were unchanged and five were untraded.

Antisense was the best, up two cents or 12.1 percent to 18.5 cents with 1.0 million shares traded.

Genetic Technologies, Pharmaxis and Prima climbed five percent or more; Tissue Therapies was up 4.3 percent; Admedus and Living Cell were up more than three percent; Ellex, Patrys and Sirtex rose more than two percent; Benitec, Resmed and Reva were up more than one percent; with Acrux and Alchemia up by less than one percent.

Bionomics led the falls, down 22.5 cents or 30.4 percent to 51.5 cents with 6.0 million shares traded.

Avita lost 8.3 percent; Anteo fell 7.3 percent; Atcor fell four percent; Optiscan was down 3.85 percent; Neuren and Prana shed more than two percent; Nanosonics, QRX, Universal Biosensors and Viralytics were down more than one percent; with Clinuvel, Cochlear, CSL and Mesoblast down by less than one percent.

BIONOMICS

Bionomics says its 136-patient phase II trial of BNC105P for renal cell carcinoma has failed to meet its primary endpoint with no significant difference between the two arms. Bionomics chief executive officer Dr Deborah Rathjen told Biotech Daily that the results were “just the beginning of the data from the trial” which would inform future trials. Bionomics said the trial’s primary endpoint was improvement in six-month progression-free survival with the addition of BNC105P to everolimus (Afinitor) as compared to everolimus alone (BD: Jan 27, 2010; Jun 3, 2011).

The company said that median progression-free survival for 23 of the 69 patients in the BNC105P arm was 4.7 months (with a 95 percent confidence interval (CI) of 2.4 months to 6.4 months), compared to the 20 of the 67 patients in the everolimus alone arm of 4.1 months (CI = 2.6 months to 6.2 months) and a significance value of $p = 0.6625$.

Bionomics said that in the subset of 30 Fuhrman grade 2 (earlier stage tumor) patients, 14 patients in the everolimus and BNC105P arm had an average 2.3 month increase in progression free survival to 6.4 months, compared with the 16 patients in the everolimus-alone arm.

The Fuhrman grade 2 data showed a much wider 95 percent confidence interval for the patients on everolimus and BNC105P of 1.8 months to 10.5 months compared to everolimus-alone with a 95 percent confidence interval of 2.3 months to 6.8 months.

Bionomics said that in a further subgroup of 26 patients with liver metastases, 13 patients on everolimus with BNC105P had an average progression-free survival of 6.6 months compared to 13 patients on everolimus-alone with an average progression-free survival of 2.8 months.

The company’s data also showed that 12 patients on the combination treatment with prior nephrectomy had an average 3.0 month increase in progression-free survival compared to six patients on everolimus-alone.

Bionomics said that secondary endpoints included determining the progression-free survival with BNC105P alone in patients progressing on everolimus, evaluating the adverse events of the combination and determining the overall survival, up to a maximum of five years from registration.

The company said that biomarker changes correlated with progression-free survival or lack thereof at six months, in a statistically significant manner ($p = 0.0136$ - 0.0348) consistent with previous BNC105 studies and the first time biomarkers that correlated with progression-free survival reported for a vascular disrupting agents in renal cancer.

Dr Rathjen said the trial, entitled Disruptor-1, was “the first of its kind in testing the combination of an mTOR inhibitor with a vascular disrupting agent in renal cancer, with the prospect of adding a new dimension to the renal cancer treatment armamentarium”. “Significant progress has been made in validating BNC105 as an anti-cancer agent,” Dr Rathjen said.

“Through patient subgroup analysis and association of biomarkers to treatment benefit, the data from this trial shows us the best way forward to maximizing the utility of BNC105 for renal cancer patients, as well as how to best employ the drug in other cancer types,” Dr Rathjen said.

“Disruptor-1 has produced a ground-breaking discovery of potential biomarkers that may allow pre-treatment selection of patients most likely to benefit from BNC105,” Dr Rathjen said. “We are exploring partnership opportunities for BNC105 and expect to attract a depth of interest given the compelling data generated from this trial and the recent ovarian cancer trial data.”

Bionomics fell as much as 24 cents or 32.4 percent to 50 cents before closing down 22.5 cents or 30.4 percent at 51.5 cents with 6.0 million shares traded.

FEDERAL GOVERNMENT

The Federal Government says that nominations have opened for the \$500,000 Prime Minister's Prizes for Science.

The Federal Minister for Industry Ian Macfarlane said it was important to recognize the country's best scientists and science teachers and the important work that they do.

"The Prime Minister's Prizes for Science reaffirms our commitment to science research and to educating and inspiring students to study and practice science," Mr Macfarlane said.

A media release from Mr Macfarlane's office said that during the past 13 years the prizes had recognized Australians responsible for many globally significant discoveries, including the bionic ear, the cervical cancer vaccine, technology that underpins fast, reliable wireless computing and evidence of an accelerating universe.

The media release said the \$300,000 Prime Minister's Prize for Science recognized achievement at the very highest level by an Australian scientist; supported by four prizes valued at \$50,000 each, the Frank Fenner Prize for Life Scientist of the Year; the Malcolm McIntosh Prize for Physical Scientist of the Year; the Prime Minister's Prize for Excellence in Science Teaching in Primary Schools; and the Prime Minister's Prize for Excellence in Science Teaching in Secondary Schools.

The media release said that a two-stage nomination process simplified the requirements for submitting nominations for the first stage of the process and short-listed nominees would be invited to submit additional details.

For further details go to: www.industry.gov.au/scienceprizes.

AVEXA

Avexa has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 73.3 percent from 1.5 cents on March 17 to 2.6 cents on March 18, 2014 and noted "a substantial increase in the trading volume".

Avexa fell 0.2 cents or 9.5 percent to 1.9 cents with 2.1 million shares traded.

UNILIFE CORPORATION

Unilife says that controller Dennis Pyers will act as interim chief financial officer replacing executive vice-president Richard Wieland until a permanent chief financial officer is found. Unilife said that Mr Wieland was leaving the company after four years.

The company said that Mr Pyers had been the chief accounting officer, vice-president and controller since July 2010.

Unilife said that Mr Pyers spent more than 25 years with KPMG, including as a partner from 2002 to 2009.

The company said that interested chief financial officer candidates could contact human resources vice-president Cynthia Lighty on +1 717-384-3400 or careers@unilife.com.

Unilife was up 2.5 cents or 2.8 percent to 92 cents.