Biotech Daily

Tuesday August 30, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: GENETIC TECHNO UP 21%, OSPREY DOWN 14%**

*** CSL FILES FDA CSL830 FOR HEREDITARY ANGIOEDEMA APPLICATION**

*** IMMURON, US NAVY CAMPYLOBACTER, ETEC COLLABORATION**

*** MEDLAB TAKES NRGBIOTIC FOR DEPRESSION TO PHASE IIa TRIAL**

*** ATCOR REVENUE DOWN 19% TO $5.6m, LOSS UP 130% TO $5m**

*** ALLEGRA REVENUE DOWN 32% to $5m, LOSS UP 138% TO $2m**

*** GENETIC SIGNATURES REVENUE UP 64% TO $3m, LOSS UP 14% TO $3m**

*** ANATARA POSTS 1st REVENUE OF $2.8m, LOSS DOWN 60% TO $724k**

*** RESONANCE REVENUE DOWN 3% to $2.6m, PROFIT TO $382k LOSS**

*** ALCHEMIA REVENUE UP 112% TO $25m, LOSS TO $21m**

*** PSIVIDA ADDS 13 PATENTS, APPLICATIONS THIS YEAR**

*** TIGA TAKES 5% OF ANATARA**

*** MEMPHASYS APPOINTS JOHN PEREIRA DIRECTOR**

MARKET REPORT

The Australian stock market edged up 0.17 percent on Tuesday August 30, 2016 with the ASX200 up 9.1 points to 5,478.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, 10 were unchanged and one was untraded.

Yesterday's worst, Genetic Technologies, was the best, up 0.3 cents or 21.4 percent to 1.7 cents with two million shares traded. IDT and Neuren climbed more than four percent; Universal Biosensors was up 3.7 percent; Clinuvel and Impedimed rose more than two percent; Admedus, Avita, CSL and Reva were up more than one percent; with Airxpanders, Ellex and Psivida up by less than one percent.

Yesterday's best, Osprey, led the falls, down 5.5 cents or 13.75 percent to 34.5 cents with 920,926 shares traded. Acrux lost 11.5 percent; Benitec and Mesoblast fell more than seven percent; Bionomics shed 4.1 percent; Actinogen and Cellmid were down more than three percent; Starpharma fell two percent; Biotron, Factor Therapeutics, Nanosonics, Oncosil and Resmed were down one percent or more; with Cochlear, Medical Developments, Opthea, Pro Medicus, Sirtex and Viralytics down by less than one percent.

CSL

CSL says the US Food and Drug Administration has accepted its biologics licence application for its C1-esterase inhibitor CSL830 for hereditary angioedema.

CSL said that the application through CSL Behring for the low-volume subcutaneous C1-esterase inhibitor human replacement therapy was as a prophylaxis to prevent hereditary angioedema attacks.

The company said that hereditary angioedema was a rare genetic disorder caused by a deficiency of C1-esterase inhibitor (C1-INH), one of the proteins that work with the immune system to control inflammation.

CSL said that symptoms included episodes of swelling in the face, abdomen, larynx and extremities and could be fatal if untreated.

CSL chief scientific officer and research and development director Dr Andrew Cuthbertson said that the FDA review of the application was “another step towards providing advanced prophylactic treatment options to people living with [hereditary angioedema]”.

“Since CSL Behring first reported the possibility of C1-INH replacement therapy for [hereditary angioedema] over 40 years ago, we have remained committed to innovative research and providing advanced treatment options to people living with [hereditary angioedema],” Dr Cuthbertson said

“Subcutaneous prophylaxis is the next important step in helping [hereditary angioedema] patients to prevent [hereditary angioedema] attacks,” Dr Cuthbertson said.

CSL said that hereditary angioedema occurred in about one in 10,000 to 50,000 people and was caused by lack of or malfunctioning C1-INH, leading fluid to build up in body tissues, causing considerable swelling episodes referred to as angioedema.

The company said that patients who had abdominal attacks of hereditary angioedema could experience episodes of extreme pain, diarrhoea, nausea and vomiting caused by swelling of the intestinal wall and attacks that involved the face or throat could result in airway closure, asphyxiation and, if untreated, death.

CSL was up $1.47 or 1.35 percent to $110.14 with 916,590 shares traded.

IMMURON

Immuron says it has a collaboration agreement with the Naval Medical Research Center to test Travelan in Campylobacter and entero-toxigenic Escherichia coli.

Immuron said that Campylobacter and entero-toxigenic Escherichia coli (ETEC) were gram-negative bacteria and were major causes of traveller’s diarrhoea.

The company said that a study of American military personnel in Thailand showed that more than half of those with diarrhoea were infected with Campylobacter species.

Immuron said that in most people who became ill with campylobacteriosis, symptoms developed within five days and illness typically lasted seven days, with a dozen species of Campylobacter implicated in human disease and Campylobacter jejuni the most common.

The company said that entero-toxigenic Escherichia coli caused about 157,000 deaths a year, mostly in children, with no vaccines available.

Immuron said that US Food and Drug Administration approved clinical trials “would open the door for the potential approval of campylobacter and ETEC vaccine-based products that meet the needs of both military personnel and civilian populations”.

Immuron said the testing of its cow colostrum based products by the US Army and the US Navy might lead to the development of a vaccine-based hyper-immune colostrum product that contained all three sets of antibodies, providing a broad spectrum prescription product for both military and civilian use.

Immuron fell two cents or 6.7 percent to 28 cents.

MEDLAB CLINICAL

Medlab says it will begin a double-blind, placebo-controlled, phase IIa trial of its bacteria-based NRGBiotic anti-depression therapy that targets the gut–brain axis.

Medlab said that the phase II trial would dose patients for eight weeks and was due to begin in October 2016, pending ethics approval.

The company said that in the phase I trial, 36 patients who had been prescribed anti-depressants for an average 2.5 years were administered NRGBiotic to assess whether it could improve depression symptoms and clinical outcomes.

Medlab said that the phase I trial at the Royal Brisbane Hospital showed significant improvement on a validated questionnaire in about 80 percent of the trial cohort, with the second trial showing improvement in more than 90 percent of the trial cohort.

Medlab said that the supervisor of the phase I and phase IIa trials was University of Queensland's clinical psychologist Dr Matthew Bambling.

The company said the US National Institute of Health Human Microbiome Project intended to broaden understanding of the role of bacteria living in and on humans.

Medlab said that NRGBiotic was a bacteria-based medicine that targeted the gut–brain axis on the expectation that this intervention would provide a benefit to patients diagnosed with treatment-resistant depression.

Medlab managing-director Sean Hall said that the phase I trial was positive for the underlying hypothesis and the application of NRGBiotic.

"The results are encouraging from a scientific point of view as well as from the perspective of patients since we have discovered some positive effects in relation to depression when existing medicines have been ineffective," Mr Hall said.

Medlab was unchanged at 37.5 cents.

ATCOR MEDICAL

Atcor says revenue for the 12 months to June 30, 2016 fell 19.2 percent to $5,596,830, with net loss after tax up 129.8 percent to $4,845,539.

Atcor said that sales were down 8.3 percent to $5,023,068, but "following a difficult first half, sales increased in the second half to $3.3 million, up 29 percent compared to the [previous corresponding period]".

The company said that it had focussed on clinical unit placements since the introduction of the US CPT1 reimbursement code which covered the Sphygmocor test and they had increased significantly in the six months to June 30, 2016 with clinical sales up more than 120 percent compared to the six months to December 31, 2015.

Atcor said that the three months to June 30, 2016 was the first full quarter year of sales after reimbursement was confirmed, with 25 Sphygmocor units sold or leased to clinical practices, more than double the sales of the previous corresponding period and in line with expectations.

Atcor chief executive officer Duncan Ross said the company was "pleased by the strong rebound in the second half".

"This includes initial clinical unit sales growth which followed confirmation of reimbursement by [US] Medicare in February and March this year," Mr Ross said.

"We have increased our specialist sales team to scale-up for a targeted roll-out focused on four US metropolitan areas to accelerate sales," Mr Ross said.

Atcor said that net tangible asset backing per share fell 33.3 percent to 1.6 cents, diluted loss per share increased 166.7 percent to 2.4 cents and the company had cash and equivalents of $1,773,950 at June 30, 2016 compared to $3,449,943 at June 30, 2015.

Atcor was unchanged at 12.5 cents.

ALLEGRA ORTHOPAEDICS

Allegra says revenue for the year to June 30, 2016, fell 31.5 percent to $5,018,556 with net loss after tax up 138.1 percent to $2,035,788.
Allegra said that revenue was from the sale of orthopaedic goods and “the decrease directly related to key surgeons participating in a multi-centre total knee study with a separate orthopaedic company … [and it was] still experiencing the adverse effects of the acquisition of Small Bone Innovations by Stryker in the previous financial year.
The company said that diluted loss per share increased 114.8 percent to 3.20 cents at June 30, 2016, net tangible assets per share fell 49.7 percent to 3.13 cents and it had $1,154,590 in cash and cash equivalents at June 30, 2016.
Allegra was untraded at 14 cents.

GENETIC SIGNATURES

Genetic Signatures says that revenue for the year to June 30, 2016, was up 63.5 percent to $3,357,566 with net loss after tax up 13.8 percent to $3,026,598.
Genetic Signatures said that it had record sales revenue of its Easyscreen enteric and respiratory virus detection kits up 74.9 percent to $1,825,018, with most of the balance of revenue a Federal Government R&D Tax Incentive.
The company said that net tangible asset backing per share fell 40.7 percent to 6.4 cents, with diluted loss per share down 19.2 percent to 4.2 cents and cash and cash equivalents of $2,564,254 at June 30, 2016 compared to $5,461,686 at June 30, 2015.
Genetic Signatures fell two cents or 3.8 percent to 51 cents.

ANATARA

Anatara says it has earned its first revenue for the year to June 30, 2016 of $2,800,485, with net loss after tax down 59.7 percent to $723,934.
Anatara said the revenue was primarily $2,283,000 from its licence option with the Florham Park, New Jersey-based Zoetis for its Detach non-antibiotic treatment for diarrhoea in farm animals (BD: Jan 27, Jul 22, 2016), with interest of $352,144 and $165,246 from a Federal Government Research and Development Tax Incentive.
The company said that its net tangible asset backing per share was up 80.0 percent from 0.15 cents at June 30, 2015 to 0.27 cents at June 30, 2016, with diluted loss per share down 80.0 percent to 0.01 cents.
Anatara said that it had cash and cash equivalents of $6,387,041 at June 30, 2016 compared to $1,497,539 at June 30, 2015.
Anatara was up 6.5 cents or 6.0 percent to $1.15.

RESONANCE HEALTH

Resonance says revenue for the year to June 30, 2016 fell 3.0 percent to $2,596,624 turning last year’s net profit after tax of $463,234 to a loss of $384,366.
Resonance said that sales and Ferriscan radiology services increased 4.3 percent to $2,547,685, but other income decreased compared to the prior year.
The company said that basic loss per share was 0.10 cents at June 30, 2016, compared to basic earnings per share of 0.12 cents at June 30, 2015, tangible assets per share fell 18.6 percent to 0.57 cents at June 30, 2016 and it had $2,512,441 in cash and cash equivalents at June 30, 2016, compared to $2,797,203 at June 30, 2015.
Resonance fell 0.1 cents or 3.2 percent to 3.0 cents.

ALCHEMIA

Alchemia says that revenue for the 12 months to June 30, 2016 was up 112.1 percent to $25,298,976, turning the previous loss to a net profit after tax of $21,425,996.
Alchemia said that revenue was primarily from the sale of its generic fondaparinux to former partner Dr Reddy's Laboratories (BD: Sep 25, Nov 18, 2015).
The company said diluted earnings per share at June 30, 2016 was 6.6 cents, compared to a diluted loss per share of 4.9 cents at June 30, 2015, net tangible assets per share was down 76.3 percent to 0.84 cents and it had cash and equivalents of $1,873,917 at June 30, 2016 compared to $5,020,970 at June 30, 2015.
Alchemia was unchanged at one cent.

PSIVIDA CORP

Psivida says it has been granted or allowed 13 patents and applications since the start of 2016.
Psivida said it had a total of 42 US issued patents and allowed applications with a further 191 in non-US jurisdictions, with an additional 108 applications pending.
Psivida chief executive officer Dr Paul Ashton said that protection of intellectual property "continues to be extremely important to us".
Psivida said the 13 patents issued and applications allowed included two in the US for Tethadur, eight in foreign jurisdictions including five for Tethadur in Japan, China and Australia, one for the Medidur injector in Japan and Hong Kong and one for Medidur in Japan as well as three design patents for the new smaller needle injector.
Psivida was up two cents or 0.4 percent to $5.12.

ANATARA LIFE SCIENCES

The Melbourne-based Tiga Trading says it has become a substantial shareholder in Anatara with 2,507,773 shares (5.08%).
The Tiga notice, signed by secretary Avee Waislitz, said the holders were Thorney Investment Group Australia and Jamahjo Pty Ltd, with 198,211 shares acquired at "market prices" between May 18 and August 29, 2016, but failed to disclose the cost of the shares as required under the Corporations Act.

MEMPHASYS (FORMERLY NUSEP)

Memphasys says it has appointed John Pereira as an independent, non-executive director, effective from today.
Memphasys said that Mr Pereira established Norbury Pereira, formed a partnership with Cornwall Stodart and was Burdett Buckeridge Young's head of corporate advisory.
Memphasys said that Mr Pereira formed Alchemy Corporate Advisors with Burdett Buckeridge Young, established Tristar Corporate Advisors, was the founder of India Equities Fund and Olympus Funds Management.
Memphasys said that Mr Pereira held a Bachelor of Laws and a Bachelor of Jurisprudence from the Gold Coast, Queensland-based Bond University.
Memphasys was untraded at 0.6 cents.