



Biotech Daily

Tuesday June 24, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: BIONOMICS UP 22%, BENITEC DOWN 6%**
- * **BIONOMICS, MERCK \$537m DEAL FOR BNC375 COGNITION DRUG**
- * **SIEMENS ORDERS 1st UNIVERSAL BIOSENSORS PT-INR TEST STRIPS**
- * **ITALIAN APPROVAL FOR PSIVIDA, ALIMERA ILUVIEN**
- * **ANATARA DEVELOPS INCITIVE'S PINEAPPLE STEMS FOR DIARRHOEA**
- * **COGSTATE SIGNS \$2m IN CONTRACTS**
- * **ACUVAX DROPS CANCER FOR ACTIVISTIC FUNDS COLLECTION**
- * **RA CAPITAL TAKES SMALL PROFIT TO 11% OF BENITEC**
- * **QUEENSLAND, CANADA INDUSTRY ORGANIZATIONS COLLABORATE**
- * **BRAIN RESOURCE LOSES DIRECTOR RUSSELL JAMISON**

MARKET REPORT

The Australian stock market fell 0.38 percent on Tuesday June 24, 2014 with the S&P ASX 200 down 20.5 points to 5,432.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, 13 traded unchanged and one was untraded.

Bionomics was the best, up 9.5 cents or 21.8 percent to 53 cents with 2.1 million shares traded, followed by Universal Biosensors up 17.95 percent to 23 cents with 1.4 million shares traded.

Avita climbed 4.55 percent; Admedus, Antisense, Ellex, Osprey and Pharmaxis were up more than three percent; Optiscan and Prima rose more than two percent; GI Dynamics, Mesoblast and Nanosonics climbed more than one percent; with Starpharma up 0.9 percent.

Benitec led the falls, down seven cents or 5.9 percent to \$1.12 with 204,856 shares traded, followed by IDT down five percent to 19 cents with 15,000 shares traded.

Analytica, Circadian and Oncosil fell more than four percent; Acrux, Cellmid, Clinuvel lost three percent or more; Medical Developments, Neuren and Tissue Therapies shed more than one percent; with Cochlear, CSL and Sirtex down by less than one percent.

BIONOMICS

Bionomics says it will be paid an upfront payment of \$US20 million (\$A21.2 million) for signing a collaboration with Merck & Co for its BNC375 cognitive dysfunction program. Bionomics said that the BNC375 program was targeting Alzheimer's disease and other central nervous system conditions and the collaboration could be worth up to \$US506 million (\$A536.8 million) including milestones, but not including royalties on product sales. In 2012, following validation in preclinical models of memory deficit Bionomics nominated BNC375 as its drug candidate for Alzheimer's disease and said it was preparing for both clinical trials and strategic partnering of BNC375 (BD: Dec 14, 2012).

The company said at that time that BNC375 was a positive allosteric modulator of the alpha-7 nicotinic acetylcholine receptor (alpha-7 nAChR), a target for the improvement of memory and learning deficits in illnesses like Alzheimer's disease.

In October 2012, Bionomics presented two posters showing the alpha-7 compounds outperformed benchmark compounds including Pfizer's donepezil, marketed as Aricept, that reported \$US2.5 billion in sales in 2011 (BD: Oct 16, 2012).

Today, Bionomics said that under the exclusive research collaboration and licence agreement, Merck (known as Merck Sharp and Dohme outside the US and Canada) would fund all research and development, including clinical development, and would be responsible for worldwide commercialization of any products from the collaboration.

Bionomics chief executive officer Dr Deborah Rathjen told a teleconference that BNC375 had not been trialled in humans, but it had shown pre-clinical safety and efficacy.

Dr Rathjen said that BNC375 also had potential for other diseases that exhibited memory loss and cognitive impairment including Parkinson's disease, schizophrenia and attention deficit hyperactivity disorder (ADHD).

In a media release Dr Rathjen said Bionomics was "very excited to work with Merck to progress new therapies for cognitive impairment in conditions such as Alzheimer's disease".

"We believe that the combination of Bionomics' innovative approach and technologies, within its lonx platform, has the potential to rapidly advance new treatments," Dr Rathjen said.

"This significant agreement, our second with Merck, further validates our drug discovery platforms," Dr Rathjen said.

In July 2013, Bionomics announced an option and licence agreement with Merck worth up to \$US172 million to discover and develop novel small molecule candidates for the treatment of chronic pain, including neuropathic pain (BD: Jul 31, 2013).

Merck Research Laboratories head of early development and discovery sciences said Dr Rupert Vessey said that "Bionomics' capabilities and overall expertise in discovery and characterization of small molecules for this neuroscience target class is impressive".

Bionomics said that BNC375 was "a key compound" from its research program and BNC375 and its related compounds displayed potent efficacy in animal cognitive impairment models.

The company said that Alzheimer's was the most common type of dementia and thought to be caused by damage to nerve cells in the brain.

Bionomics said that symptoms were characterized by a decline in memory or other thinking skills, affecting everyday activities and was fatal, with one in nine Americans older than 65 years having Alzheimer's disease and the sixth leading cause of death in the US.

The company said that by 2025 the number of Americans aged 65 and older with Alzheimer's was forecast to rise to 7.1 million.

Bionomics said that more than 332,000 Australians had Alzheimer's disease.

Bionomics climbed 9.5 cents or 21.8 percent to 53 cents with 2.1 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has received its first commercial order from Siemens Healthcare Diagnostics for the production and supply of blood coagulation test strips.

Universal Biosensors chief financial officer Saleshe Balak told Biotech Daily that the value of the initial modest order for the prothrombin time international normalized ratio (PT-INR) test strips was confidential and could not be disclosed.

The company said the first commercial order was “an important event in the development of the first point-of-care coagulation testing product under Universal Biosensors’ collaboration with Siemens”.

Universal Biosensors said the global point-of-care coagulation test market was estimated to be worth more than \$US1 billion a year, with about 65 percent PT-INR testing.

The company said that the Siemens test, to monitor warfarin anti-coagulant therapy was expected to be launch by October 2014.

Universal Biosensors said it was working with Siemens to finalize the product, but Siemens was responsible for regulatory approvals and the launch.

The company said that Universal Biosensors would manufacture the PT-INR strips at the plant in Rowville, Victoria.

Universal Biosensors said that the PT-INR test was the first of three in development with Siemens to deliver laboratory-quality results at the point-of-care in response to growing demand for near-patient testing, including time-critical coagulation data.

Universal Biosensors chief executive officer Paul Wright said the first commercial order was “a major step forward in our program with Siemens towards our shared vision for bringing a range of new products to the point-of-care coagulation testing market”.

“Universal Biosensors will leverage its existing infrastructure to provide world-class manufacturing support to Siemens with a view to generating a new and diversified earnings stream for our business,” Mr Wright said.

Universal Biosensors climbed 3.5 cents or 17.95 percent to 23 cents with 1.4 million shares traded.

PSIVIDA

Psivida says the Agenzia Italiana del Farmaco (Italian Medicines Agency) has approved Iluvien for vision impairment associated with chronic diabetic macular oedema.

Psivida said the approval was for patients considered insufficiently responsive to available therapies.

The company said that the Italian marketing authorization notice for Iluvien was published on June 18, 2014 in the Gazzetta Ufficiale della Repubblica Italiana, the official journal of record of the Italian government.

Psivida said that Iluvien was designated as a C class product in Italy and initially would be available to private paying patients, with licensee, Alimera Sciences pursuing H class designation to expand patient access to the product.

The company said that Italian authorization was the seventh national approval in the European Union (EU) along with Austria, the UK, Portugal, France, Germany and Spain.

Psivida said that Alimera was seeking approval from another 10 EU countries and was awaiting a decision from the US Food and Drug Administration on the refiled new drug application, with a Prescription Drug User Fee Act (PDUFA) date of September 26, 2014.

Psivida chief executive officer Dr Paul Ashton said the company was “very pleased that Iluvien has been granted marketing authorization in all seven EU countries where initial applications have been submitted”.

Psivida was unchanged at \$4.15.

ANATARA LIFESCIENCES

Anatara says it will seek distribution and development partners for its pineapple stem-based diarrhoea treatment at BIO2014 in San Diego, California June 23 to 26, 2104.

Anatara said that lead product Detach was a non-antibiotic treatment for diarrhoea developed by chief science officer Dr Tracey Mynott and worked against bacteria, viruses and other causes of diarrhoea.

“Detach acts by stopping bacteria from attaching to the lining of the intestine, as well as blocking the action of their toxins, the underlying cause of diarrhoea,” Dr Mynott said.

“It works differently to antibiotics in that it doesn’t try to kill bacteria and instead lets them pass through the intestine harmlessly,” Dr Mynott said.

Anatara said it raised \$1.75 million earlier this year and was commercializing Detach for pigs ahead of expanding it to other livestock and then developing it for humans.

Anatara chief executive officer Dr David Venables said that Detach was “a proven, natural treatment for diarrhoea in piglets and is an effective alternative to antibiotics”.

“The World Health Organization has warned that anti-microbial resistance is a significant looming threat to human health and authorities are now moving to tackle the issue by limiting the use of antibiotics in animal agriculture,” Dr Venables said.

Anatara chairman Dr Mel Bridges said that growing demand for antibiotic-free food would make Detach an attractive product for livestock farmers.

Incitive listed on the ASX in May 2006 with Don Home as chief executive officer and Dr Mynott as chief scientific officer to develop the pineapple-stem derivative bromelain for inflammatory disease including cancer, but in 2009 dropped bromelain for a cardiac monitoring system before delisting (BD: Mar 22, 2006; Jun 22, 2009; Apr 12, 2010).

In 2007, Dr Bridges was appointed chairman and Alchemia founder Dr Tracie Ramsdale was appointed as a director (BD: Oct 11, Nov 22, 2007).

Anatara is an unlisted public company.

COGSTATE

Cogstate says it has signed more than \$2 million of sales, including a first contract for Precision Recruitment as well as other smaller contracts in the past two weeks.

Cogstate said that the amount of contracted revenue expected to be recognized in the year to June 30, 2015 was \$5.4 million.

Earlier this month, Cogstate said it expected revenue for the year to June 30, 2014 to be “in the range of \$11.4 - \$12.0 million ... [with] net loss before tax in the range of \$4.5 - \$5 million” compared to revenue for the 12 months to June 30, 2013 of \$12,600,530 and a loss after tax of \$1,957,233 (BD: Aug 21, 2013; Jun 6, 2014).

Cogstate was untraded at 30 cents.

BENITEC

RA Capital Management has reduced its substantial shareholding in Benitec from 14,018,691 (12.20%) to 12,804,078 shares (11.14%).

The Sydney-based RA Capital said the shares were held by RA Capital Healthcare Fund and Blackwell Partners, gave Citigroup as its address, and said the two entities sold 1,214,613 shares on-market for \$1,485,922 or \$1.22 a share.

In April, RA Capital said it acquired 7,009,346 shares for \$7,500,000 or \$1.07 a share and in February became a substantial shareholder in the \$31.5 million placement at \$1.07 a share (BD: Feb 24, Apr 17, 2014).

Benitec fell seven cents or 5.9 percent to \$1.12.

ACUVAX

Acuvax says it has signed a binding heads of agreement to acquire Activistic Pty Ltd and its funds collection system (BD: Jun 23, 2014).

Acuvax said that collections for fund raising activities were often cumbersome and cost prohibitive for charities and other not-for-profit organizations and Activistic had developed a cost efficient system enabling regular payments or contributions using a mobile telephone network.

Acuvax said it would complete an initial placement of about 15 percent of its issued capital (\$170,000) at 0.05 cents a share to seek re-quotations on the ASX and to make the first exclusive option fee payment to Activistic and subject to shareholder approval, it would raise up to \$430,000 at 0.05 cents a share and hold a 320-to-one consolidation.

In 2013, Perth's GBU Capital tried to back-door list Biolife Science and its Her-Vaxx technology into Acuvax, returning Dr Roger Aston and Paul Hopper to their cancer company but failed to raise the minimum \$4 million (BD: Dec 20, 2012; Jul 4, 2013). Biolife was later acquired by Imugene (BD: Oct 23, 2013).

Acuvax was in a suspension and last traded at 0.1 cents.

LIFE SCIENCES QUEENSLAND

Life Sciences Queensland says it will work closely with Bioindustrial Innovation Canada to accelerate the commercialization of advanced technologies.

The Queensland industry group said it had a memorandum of understanding with Bioindustrial Innovation Canada to collaborate on composites, chemicals from sugars and lignin-based materials.

Life Sciences Queensland said the collaboration would contribute to building enablers for scientific community development, sharing of knowledge and best practices, organizing seminars and scientific conferences, attracting and developing young talent, development of joint educational programs in the field of novel bio-based processes and products and wide communication of scientific results.

Life Sciences Queensland chief executive officer Mario Pennisi said that northern Australia's tropical climate lent itself to the development of high productivity biomass crops and "along with our strategic location in Indo-Pacific region, makes us an ideal partner for technology developers in Canada who wish to engage this region".

"This agreement provides us with a platform to actively investigate opportunities for collaboration in order to achieve outcomes, delivering value to our respective stakeholders," Mr Pennisi said.

Bioindustrial Innovation Canada executive director Dr Murray McLaughlin said the agreement "recognizes the key elements of the innovation strategies of the Canadian and Australian institutions, specifically in the development of sustainable chemistry technology platforms"

Life Sciences Queensland said that relationships between industrial, academic or governmental organizations would be established to initiate joint projects in research, development, demonstration or commercial partnering.

The industry organization said that Bioindustrial Innovation Canada was that country's "pre-eminent accelerator for the commercialization of large-scale industrial biotechnology and related sustainable chemistry, was funded through a combination of revenues and investments from the private sector and governments, including \$15 million from the Government of Canada's Centres of Excellence for Commercialisation and Research program.

BRAIN RESOURCE

Brain resource says that Russell Jamison has resigned as a non-executive director “for personal reasons” after 11 years with the company.

Brain Resource said that Mr Jamison’s resignation altered the balance of the board to equal numbers of executive and non-executive directors and this would be addressed with the next appointment.

The company said that the structure of the board would be reviewed to reflect the company’s US focus and it would seek a replacement who was well-positioned to contribute to the ongoing growth in the US market.

Brain Resource said that there were “a number of candidates under review”.

Brain Resource was untraded at 25.5 cents.