Biotech Daily

Thursday February 14, 2019

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: CYCLOPHARM UP 11%; BENITEC DOWN 14%**

*** MINOMIC APPOINTS CIRRUS DX FOR MICHECK PROSTATE CANCER TEST**

*** NOMINATIONS OPEN FOR VICTORIA MANUFACTURING HALL OF FAME**

*** FEDERAL $26m FOR HEARTKIDS, CHILDHOOD HEART DISEASE**

*** PARADIGM PLANS PHASE II/III MPS TRIAL**

*** GI DYNAMICS READY FOR US PIVOTAL ENDOBARRIER TRIAL**

*** COLLEGES BACK ALTHEA MEDICAL MARIJUANA EDUCATION**

*** MEDLAB EXPANDS NRGBIOTIC DEPRESSION TRIAL RECRUITMENT**

*** CRESO, HEMPMATE COLLABORATE ON MARIJUANA FOR EUROPE**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Thursday February 14, 2019, with the ASX200 down 4.2 points to 6,059.4 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and four were untraded. All three Big Caps were up.

Cyclopharm was the best, up 11 cents or 11 percent to $1.11 with 851 shares traded.

Airxpanders and Antisense climbed more than eight percent; Compumedics and Oncosil were up more than six percent; Prana and Prescient improved more than five percent; Genetic Signatures and Medical Developments rose more than two percent; Actinogen, Cochlear, Resmed and Telix were up more than one percent; with CSL, Ellex, Mesoblast, Nanosonics and Pro Medicus up by less than one percent.

Yesterday's 38.1 percent best, Benitec, led the falls, down two cents or 13.8 percent to 12.5 cents, with 599,877 shares traded.

Patrys lost 7.7 percent; Orthocell shed 6.1 percent; Cynata and Imugene were down more than five percent; Impedimed fell four percent; Proteomics lost 3.6 percent; Paradigm shed 2.9 percent; Clinuvel and Volpara were down more than one percent; with Opthea down 0.3 percent.

MINOMIC INTERNATIONAL

Sydney's Minomic says Cirrus Dx will distribute its prostate cancer blood test providing US clinicians and patients early access to the diagnostic.

Minomic said that the Rockville Maryland-based Cirrus Dx was a certified high complexity laboratory, which would use Micheck as a laboratory developed test (LDT), once internal validation was completed.

The company said that the agreement "completes an important step in commercializing Micheck in the world's largest healthcare market".

Minomic chief executive officer Dr Brad Walsh told Biotech Daily the size of the contract was confidential but the company had targeted the sale of 40,000 tests, at $US600 a test in its first year, initially through urology clinics.

Dr Walsh said that a competitor commercial prostate cancer diagnostic was marketed at $US1,000 per test.

"There are other commercially available tests, but we believe we perform better compared to the published data on those tests," Dr Walsh said.

Dr Walsh said that Micheck had blood markers other than the standard prostate specific antigen (PSA) test that "give an indication of how aggressive the cancer is".

Dr Walsh said that men with a raised PSA go on to a biopsy but only half had cancer.

He said that a 300-patient prospective trial showed the Micheck was superior to the standard PSA test, the Prostate Health Index Test and the Free-PSA test.

Dr Walsh said that with all tests set at 95 percent sensitivity for the minimum number of false positives, Micheck outperformed the specificity, or false negatives, of the other tests scoring 46 percent, compared to 27 percent, 23 percent and 16 percent, respectively.

In a media release, Dr Walsh said that "being able to offer Micheck as [a laboratory developed test] through our partnership with Cirrus Dx will provide the company with three important outcomes: real world data which can be used in subsequent FDA approval submissions, validation of Micheck and its clinical utility and finally, royalty revenues".

Cirrus Dx president Dr William Nelson said "the ability of Micheck to improve the diagnosis of prostate cancer and, in particular, reduce the number of unnecessary biopsies being performed is a game-changer and we look forward to working with Minomic to bring this vital improvement into the US market".

Minomic said it expected the internal validation studies to be completed by April, 2019.

The company said that a suitable reimbursement code had been identified and both companies believed that appropriate reimbursement would be available.

Minomic said that it was developing diagnostics for solid tumors, including prostate, bladder and pancreas.

Minomic is a public unlisted company.

VICTORIA GOVERNMENT

The Victoria Government say that nominations have opened for the 2019 Victorian Manufacturing Hall of Fame Awards for "outstanding businesses and individuals".

A media release from Victoria's Minister for Jobs, Innovation and Trade Martin Pakula said the awards "highlight the importance and strength of the local industry and the bright future of manufacturing in Victoria".

The State Government said the theme of this year's awards was 'Industrial Evolution', recognizing exceptional leadership and innovation.

The Government said that nominations would close on March 11 and the winner announced on May 14, 2019.

To nominate, got to: www.vic.gov.au/halloffame.

FEDERAL GOVERNMENT

The Federal Government says it will establish the Heartkids Project with $26 million for childhood heart disease, which affects more than 65,000 Australians.
A media release from Federal Health Minister Greg Hunt said that today was “international day for congenital heart disease” and $20 million would go to medical research into congenital heart disease from the Medical Research Future Fund, with $6 million to support Heartkids with $1 million per year over six years.
The Government said that the funding was “for an open grant round aimed at better understanding the disease’s genetic causes and prevention and treatment options”.
Mr Hunt said that unlike other cardiovascular problems, which commonly present in adults over 45 years, congenital heart disease had its greatest impact on the young.
“Congenital heart disease is the leading cause of deaths for Australian infants and the second leading cause of death for children,” Mr Hunt said.
“Sadly, eight babies are born with congenital heart disease every day, with four passing away each week [and] there is currently no known cure,” Mr Hunt said.
The media release said that of the 300,000 Australian births each year, up to 3,000 babies were born with a form of congenital heart disease.
“For the first time, there are now more adults than children living with congenital heart disease and this large and growing population requires lifelong and highly specialized medical care,” Mr Hunt said.
Mr Hunt said that the National Strategic Action Plan for Childhood Heart Disease would guide improvements for the care of thousands of patients, save lives, coordinate policy action for tackling the disease and drive collaboration in management, care and support, research and community awareness.
Mr Hunt said that the Plan targetted three priority populations that were disproportionally affected by childhood heart disease: Aboriginal and Torres Strait Islander people; adolescents and young adults who are moving from paediatric to adult cardiac health services; and people living in remote, or rural and regional locations.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it is planning a phase II/III trial of injectable pentosane polysulfate sodium for muco-poly-saccharidosis.
Paradigm said the randomized, double-blind, placebo-controlled, multi-centre trial would target patients in Australia, the US, the UK and Germany.
The company said it would use its pentosane polysulfate sodium (PPS) as an adjunct therapy, alongside enzyme replacement therapy or bone marrow transplantation, for muco-poly-saccharidoses (MPS) a family of disorders caused by inherited defects in the catabolism of sulfated components of connective tissue known as glycosaminoglycans.
Paradigm said that the cumulative rate for all types of MPS was about 3.5 cases in 100,000 live births and generally the patients presented with: a dysmorphic syndrome often with early onset middle ear disease, deafness, or upper airways obstruction; learning difficulties, behavioral disturbance and dementia and mild somatic abnormalities; and as a severe bone dysplasia.
The company said it had acquired 24-week phase IIa clinical trial data of its PPS treatment, which showed improved pain and physical function (BD: Nov 22, 2018).
The company said it would submit an investigational new drug application to the US Food and Drug Administration by July 2019.
Paradigm fell 3.5 cents or 2.9 percent to $1.16.

GI DYNAMICS

GI Dynamics says it has institutional review board approval for a pivotal up-to 240-patient, US trial of Endobarrier for obesity and type two diabetes.

In 2015, GI Dynamics closed a 500-patient US trial after five of the 325 enrolled patients developing bacterial liver infections (BD: Mar 6, May 6, Jul 30, 2015).

In 2016, the Australian Therapeutic Goods Administration cancelled its approval and in 2017 the European Union followed (BD: Sep 14, Oct 24, 2016; May 18, Nov 13, 2017).

Today, GI Dynamics said it had approval for the two-part trial, beginning with 50 patients receiving Endobarrier and 17 control patients and then up to 240 patients, with 180 receiving Endobarrier and 60 control patients.

The company said that each of the trial arms included “lifestyle therapy” and diabetes medication.

GI Dynamics chief executive officer Scott Schorer said that US Food and Drug Administration approval of the investigational device exemption for the pivotal trial was conditional on institutional review board (IRB) approval (BD: Aug 13, 2018).

“This IRB approval now satisfies that condition,” Mr Schorer said. “We continue to push forward with the clinical study sites that will be part of the …study, and we anticipate being in a position to announce these clinical sites shortly.”

GI Dynamics was untraded at 1.8 cents.

ALTHEA GROUP

Althea says it has the support of two Australian medical bodies for its medical marijuana education program for doctors.

Althea said its learning portal had been accredited by the Royal Australian College of General Practitioners and the Australian College of Rural and Remote Medicine for the first module of its program, to launch today, February 14, 2019.

The company said that the modules were specifically at general practitioners and the content offered would allow Australian doctors to learn more about medicinal cannabis, without incurring cost.

Althea said that the initial module focused on the endocannabinoid system and the appropriate use of medicinal cannabis in patients with symptoms related to chronic non-cancer pain.

The company said that a further four accredited educational modules were planned for release on the portal, with each course completed earning the relevant continuing professional development points for the respective Colleges.

Althea listed on the ASX in September 2018 and in January 2019 said it was supplying 300 patients in Australia with medical cannabis.

Today, Althea chief executive officer Josh Fegan told Biotech Daily that by registering on its website, patients could find doctors and pharmacists who could prescribe and supply medical marijuana, through the Australian Therapeutic Goods Administration special access scheme.

Mr Fegan said that one of the company’s products, Rideau, contained 20mg/ml cannabidiol and 1mg/ml tetrahydrocannabidiol and cost $300 for a one-month supply.

Mr Fegan said that until marijuana products were approved by the TGA and listed on the Pharmaceutical Benefits Scheme, the only reimbursement would be through private health insurance coverage.

Mr Fegan said that there were about 100 doctors and 350 pharmacies in Melbourne, Sydney and Brisbane registered with the company’s program.

Althea fell 2.5 cents or 6.25 percent to 37.5 cents.

MEDLAB CLINICAL

Medlab says it has begun the second round of recruitment for its 150-patient, phase IIa combination trial of its probiotic NRGBiotic with anti-depressants for depression.
Medlab said it was hoping to make standard anti-depressants more effective by using NRGBiotic to improve gut health.
The company said the trial would be led by Brisbane-based Queensland University of Technology and it had recruited 32 patients.
Medlab said that a European 2,000 patient study showed that “certain strains of bacteria in the gut are depleted in people with depression”.
Medlab chief executive officer Dr Sean Hall said that NRGBiotic was available from pharmacies and there was “substantial anecdotal evidence of its positive effects but we’re taking the clinical trial route to provide scientific validation and a drug pathway”.
Medlab fell two cents or 4.9 percent to 38.5 cents.

CRESO PHARMA

Creso says it has a collaboration with the Zurich, Switzerland-based Hempmate AG for the development and commercialization of its hemp products in Europe.
Creso said the agreement covered a number of co-development initiatives, addressing Europe’s unmet needs for cannbidiol hemp products to alleviate anxiety, stress, chronic pain and help with sleep.
The company said its first products had already been developed and would be launched in Germany, the UK, France, Italy and Spain by July 2019.
Creso was up half a cent or 1.3 percent to 39 cents.