Biotech Daily

Tuesday September 19, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 7%, ACRUX DOWN 6%**

*** CYCLOPHARM, ANSTO, CYCLOTECH, MACQUARIE IMAGING AGREEMENT**

*** PARADIGM READY FOR PHASE IIb PPS OSTEOARTHRITIS TRIAL**

*** CLINUVEL PREPARING SUBMISSION; FDA EPP WORKSHOP**

*** ADALTA AD-114 SAFE IN MONKEYS**

*** SIMAVITA TAKES $695k R&D TAX INCENTIVE LOAN**

*** ADHERIUM: TIMOTHY MARCOTTE CFO, ROB TURNBULL VP FINANCE**

*** VOLPARA APPOINTS RADIOLOGIST DR MONICA SAINI CONSULTANT**

*** G MEDICAL APPOINTS ASHLEY KRONGOLD DIRECTOR**

*** MTP CONNECT, LIFE SCIENCES QUEENSLAND COLLABORATION**

*** RHINOMED SELLS 425 UNMARKETABLE PARCELS, 436k SHARES**

MARKET REPORT

The Australian stock market slipped 0.12 percent on Tuesday September 19, 2017 with the ASX200 down 7.0 points to 5,713.6 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and three were untraded.

Prana was the best, up 0.4 cents or 7.3 percent to 5.9 cents with 69,386 shares traded.

Medical Developments climbed 4.3 percent; Atcor, Living Cell and Oncosil improved more than three percent; Cyclopharm rose 2.7 percent; Admedus, Airxpanders, Bionomics, Neuren, Polynovo and Viralytics were up more than one percent; with Resmed up 0.9 percent.

Acrux led the falls, down one cent or 5.9 percent to 16 cents with 960,637 shares traded, followed by Compumedics down 5.1 percent to 37 cents with 93,933 shares traded.

Cellmid and ITL fell four percent or more; Osprey lost 3.5 percent; Clinuvel shed 2.5 percent; Avita, Cochlear, Factor Therapeutics, Mesoblast and Opthea were down more than one percent; with CSL, Ellex, Impedimed, Nanosonics, Pro Medicus, Reva, Sirtex and Starpharma down by less than one percent.

CYCLOPHARM

Cyclopharm says it has a term sheet with Cyclotek, Pettech and Macquarie University to establish a new molecular imaging sector.

In a joint media release, Cyclopharm said that Cyclotek (Aust) Pty Ltd's new wholly-owned subsidiary Cyclotek NSW Pty Ltd would be supported by the Australian Nuclear Science and Technology Organisation subsidiary Pettech Solutions Pty Ltd and Macquarie University in the venture, which would allow the use of assets including Cyclopharm's cyclotron at Macquarie University to manufacture positron emission tomography (PET) radiopharmaceuticals including fluorodeoxyglucose (FDG) and other investigational products for imaging.

The company said that Cyclotek NSW "strengthens the existing FDG marketplace while increasing the research and development capability for new PET diagnostic agents and novel isotopes".

The joint media release said that Pettech would sell its existing FDG business operations and allow full use of the ANSTO cyclotron facility at Lucas Heights to the new company.

Cyclopharm said it would provide Cyclotek NSW operational control of its cyclotron facility at Macquarie University Hospital and the collaboration would be used to manufacture new PET diagnostics not otherwise produced in New South Wales.

The media release said that Cyclotek executives would lead and support the business together with providing access to its licensed PET diagnostic technologies from its strong international partnerships and Macquarie University would support the venture through collaborations for research and development of new PET diagnostic tracers, clinical trials, as well as on the development of training opportunities for the industry.

The media release said that Pettech would supply FDG to customers in New South Wales, with Cyclotek branding occurring at a later date.

Cyclopharm was up two cents or 2.7 percent to 75 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has ethics approval for a 100-patient, phase IIb trial of pentosan polysulfate sodium for knee osteoarthritis and bone marrow oedema lesions.

Paradigm said that the randomized, double-blind, placebo-controlled trial was expected start "in the coming weeks" with results by April 2019.

The company said the trial would be held at four sites: Quuensland's Griffith University clinical trials unit, Sportsmed Hospital in Stepney, South Australia, Emeritus Research in Malvern East, Victoria and Linear Clinical Research in Nedlands, Western Australia.

Paradigm said patients with knee osteoarthritis and sub-chondral bone marrow lesions would be evaluated for safety, tolerability, pain levels and effects on disease symptoms.

The company said that the trial would be run by its clinical research partner Emeritus Research with its Prof Andrew Ostor as principal investigator.

Paradigm chief executive officer Paul Rennie said the trial was important because injectable PPS could be a promising, safe and effective treatment for bone marrow oedema lesions in people with knee osteoarthritis, a condition with significant need.

"Most current treatments do not effectively address the disease and can have destructive effects on joint structure or adverse side effects," Mr Rennie said.

"We hope PPS can … significantly reduce [osteoarthritis] pain and stop or slow the structural destruction of the joint," Mr Rennie said.

"Additionally, we hope PPS may offer an alternative to the use of opioids for treating [osteoarthritis] pain," Mr Rennie said.

Paradigm was up 2.5 cents or 6.2 percent to 43 cents.

CLINUVEL

Clinuvel says that the US Food and Drug Administration will hold a public workshop on erythropoietic protoporphyria on October 24, 2017.

Clinuvel said that Scenesse, or 16mg afamelanotide, was granted marketing authorisation for adult erythropoietic protoporphyria, or EPP, patients in Europe in December 2014 and prior to the proposed therapy there were no medicinal remedies for EPP patients.

The company said that the FDA had recognised that afamelanotide met an unmet clinical need and treated a severe genetic condition for patients who are life-long deprived of light.

Clinuvel said that Scenesse was granted orphan drug designation for EPP by the FDA in 2008 and fast track designation in 2016, allowing for a rolling review of the new drug application.

The company said that rolling review allowed the FDA to start the review of the scientific dossier when all modules had been submitted and passed formal validation, a two-month process after submission of the final application module.

Clinuvel said it had a positive FDA answer on acceptance of the current safety data, as the FDA issued a carcinogenicity waiver in 2017 and it had applied for a priority review which would secure a maximum review period of six months, compared to the standard 10 months.

The company said it expected the FDA would answer the priority review request at the start of the review period.

Clinuvel said that the Scenesse safety profile had been positive to date and no safety concerns had been detected from the European distribution thus far and safety data generated under the European post-authorisation safety study would form part of the submission, with the data due in December 2017.

The company said it was “unlikely” that the FDA would require a risk evaluation and mitigation strategy for Scenesse and instead, it had been given the choice to design a pharmacovigilance program like the current European program using one or two EPP disease registries.

In a link provided by Clinuvel, the FDA said that the public workshop on EPP was “intended to discuss how best to facilitate and expedite the development of safe and effective drug therapies to treat signs and symptoms related to EPP”.

“FDA will provide information for and gain perspective from patients and patient advocacy organizations, health care providers, academic experts and industry on disease symptoms and its impact on daily life, experience with current treatment regimens for EPP and various aspects of clinical development of products intended to treat EPP,” the US regulator said.

“The input from this public workshop will help in developing topics for further discussion,” the FDA said.

Clinuvel acting chief scientific officer Dr Dennis Wright said that “given the novelty of afamelanotide as a systemic photoprotectant, our objective is to provide the FDA with a quality dossier in order to maximise the chances of regulatory approval”.

“Paramount to success is our ability to demonstrate to the FDA that Scenesse, as an innovative and first-in-class treatment, is safe,” Dr Wright said.

“A pivotal part of our NDA will be the inclusion of 12-month data analyses from European EPP patients,” Dr Wright said.

“We keep working towards the best possible dossier to obtain marketing authorisation,” Dr Wright said.

Clinuvel fell 17 cents or 2.5 percent to $6.61.

ADALTA

Adalta says a safety study of AD-114 in non-human primates shows it is well-tolerated with no study mortalities or adverse effects relating to AD-114.

Adalta said that the third pre-clinical trial was an ascending, repeat-dose study of the safety and pharmacokinetic activity of AD-114, delivered daily for seven days through subcutaneous and intravenous routes at multiple dose levels.

The company said the data would support the package of preclinical information required by potential pharmaceutical partners.

Adalta managing-director Sam Cobb said the company was “very pleased with the way that AD-114 performed in our third non-human primate study”.

“It appears to be safe and well-tolerated and the fact that no off-target effects were observed helps to build the case for AD-114 as a potential therapy for fibrosis,” Ms Cobb said.

“We are now preparing to run the four week non-human primate toxicology study in the first half of 2018, with this being the last hurdle before AD-114 enters human clinical trials in 2018,” Ms Cobb said.

Adalta was untraded at 22.5 cents.

SIMAVITA

Simavita says it has a loan of $695,039 from an undisclosed lender, secured against its expected 2016-’17 Federal Government Research and Development Tax Incentive.

Simavita said it “bought (sic) forward receipt of these funds in order to rapidly progress its discussions with a number of international manufacturing companies regarding its new transformational platform technology Alertplus”.

The company is commercializing smart incontinence monitoring.

Simavita did not disclose the name of the lender or provide details about the loan interest rate or fees.

Simavita was untraded at 2.3 cents

ADHERIUM

Adherium says it has appointed Timothy Marcotte as its chief financial officer, replacing Rob Turnbull who has been appointed head of finance and business services.

Adherium said that Mr Marcotte will join the leadership team based in San Mateo, California.

Adherium chief executive officer Arik Anderson said that Mr Marcotte’s “experience in overseeing product rollouts into new markets will be invaluable and contribute significantly to our future strategy in the US”.

The company said that Mr Marcotte had more than 35 years of experience working at public and private medical device companies as chief executive officer, chief financial officer and chief operating officer.

Adherium said that Mr Marcotte previously worked at medical device companies, including Zonare Medical Systems, VNUS Medical Technologies, and Repeater Technologies.

The company said that Mr Marcotte held a Masters of Business Administration from the University of Michigan.

Adherium said that former chief financial officer Mr Turnbull had been appointed as vice-president of finance and business services and would have additional operational responsibilities.

Adherium was up 0.4 cents or 4.4 percent to 9.5 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has appointed breast imaging physician Dr Monica Saini as its consultant diagnostic radiologist.
Volpara said that Dr Saini was the Santa Fe, New Mexico-based Santa Fe Imaging's chief of breast imaging for eight years before she was appointed GE Healthcare's consultant medical director of automated breast ultrasound systems.
The company said that Dr Saini would also work as a radiologist at the Wellington, New Zealand-based Hutt Hospital in Wellington.
Volpara chief executive officer Dr Ralph Highnam said Dr Saini had "a deep understanding of breast imaging diagnostics" with experience in surgery and oncology.
The company said that Dr Saini held a Bachelor of Science in Nursing from the University of Wisconsin-Madison, a Masters of Science from the Chicago, Illinois-based Rosalind Franklin University, a Doctors of Medicine from the Chicago, Illinois-based Rush University, a Diagnostic Radiology Residency from University of Wisconsin-Madison and a Fellowship in Women's Imaging from the University of Washington.
Volpara was unchanged at 56 cents.

G MEDICAL INNOVATIONS

G Medical says it has appointed Ashley Krongold as a non-executive director.
G Medical said that Mr Krongold was the chief executive officer of the Melbourne-based Krongold Group, a third-generation, family-run group of companies, with businesses spanning various industries.
The company said that prior to the Krongold Group, Mr Krongold worked for 15 years in the investment banking and accounting industries and was a founding member of Investec Bank Australia, worked at William Buck Chartered Accountants, ANZ Corporate Finance (London) and ANZ Private Bank (Australia).
G Medical said that Mr Krongold was currently a director of Weebit Nano and Dotz Nano and was a founding partner of global equity crowd-funding platform, Ourcrowd.
G Medical was unchanged at 38.5 cents.

MTP CONNECT, LIFE SCIENCES QUEENSLAND

MTP Connect and Life Sciences Queensland say they have signed an agreement to further their relationship and boost the Queensland life sciences sector.
MTP Connect said that Queensland had "Australia's most advanced and competitive life sciences industry sector, and is quite possibly the healthiest life sciences industry in the Asia-Pacific region".
The Federal government-funded MTP Connect said that Life Sciences Queensland had 170 member organizations.
The organization said that "biotechnology and the industries it will enable in the future are a key part of Queensland's economic prosperity and the [memorandum of understanding] indicates a positive step in cross-sector collaboration to build the profile, capacity and capability of the sector to ensure long-term economic, social and environmental benefits to Queensland, and ultimately Australia".
MTP Connect chief executive officer Sue MacLeman said that Life Sciences Queensland was "vital in providing strategic direction and support to Queensland's life science sector, and our formal partnership will enhance and compliment the advocacy work of both of our organisations, giving greater voice to our associates in the sector and increasing our positive impact".

RHINOMED

Rhinomed says it has completed the sale of 425 unmarketable share parcels totalling 436,120 shares.

Rhinomed said that the shares were sold on-market at 18.0 cents each.

The company said that 108 shareholders continued to have unmarketable holdings, with a total of 104,993 shares or 0.11 percent of its issued capital.

Rhinomed was unchanged at 18 cents.