# Biotech Daily

Tuesday October 29, 2019

*Daily news on ASX-listed biotechnology companies*

*** ASX FLAT, BIOTECH DOWN: LBT UP 13%; OSPREY DOWN 16%**

*** KIRA RAISES $20m FOR KB312 FOR IMMUNE DISORDERS**

*** IMAGION RIGHTS OFFER FOR $6.5m**

*** IP GROUP BACKS UNIQUEST'S JETRA IL-22 FOR FATTY LIVER DISEASE**

*** ADALTA COMPLETES AD-214 PRIMATE STUDY**

*** MEDICAL DEVELOPMENTS, CSIRO WORK ON DRUG MANUFACTURE**

*** ONCOSIL SUBMITS UPDATED CE MARK REPORT**

*** INVION 4C: 'CHO GROUP TO FUND ALL COSTS'**

*** PROTEOMICS RECEIVES $1.1m TAX INCENTIVE**

*** NUHEARA: 'R&D TAX INCENTIVE MAKES TWO QUARTERS CASH'**

*** TELIX TO RELEASE 67.6m ESCROW SHARES**

*** ONCOSIL WITHDRAWS 5m CEO DANIEL KENNY LOAN SHARES**

*** SHAREROOT: OPYL NAME CHANGE, 100-TO-1 CONSOLIDATION AGM**

*** GREG PLUMMER, JETAN TAKE 5% OF USCOM**

*** MERCHANT TAKES 11% OF BARD1**

*** THORNEY, TIGA TAKE 21% OF PALLA PHARMA**

## MARKET REPORT

The Australian stock market edged up 0.07 percent on Tuesday October 29, 2019, with the ASX200 up 4.7 points to 6,745.4 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and two were untraded.

LBT was the best, up two cents or 12.9 percent to 17.5 cents, with 3.3 million shares traded. Kazia was up 5.6 percent; Oncosil and Telix were up more than four percent; Impedimed improved three percent; Medical Developments and Mesoblast rose more than two percent; Antisense and Pro Medicus were up more than one percent; with CSL, Genetic Signatures and Resmed up by less than one percent.

Osprey led the falls, down 0.8 cents or 16 percent to 4.2 cents, with 2.4 million shares traded. Neuren, Orthocell and Patrys lost more than nine percent; Cyclopharm, Pharmaxis and Starpharma fell more than four percent; Avita, Paradigm, Prescient and Resonance were down more than three percent; Actinogen and Polynovo shed more than two percent; Clinuvel, Cynata, Nanosonics, Next Science and Opthea were down by more than one percent; with Cochlear and Compumedics down by less than one percent.

## KIRA BIOTECH

Kira Biotech says it has raised $20 million from Oneventures, IP Group and the Queensland Government to develop KB312 for difficult-to-treat immune disorders.

Kira said in a media release that the series A funding was led by Oneventures, with significant investment from the London and Melbourne-based IP Group and support from the Advance Queensland Business Development Fund.

Kira chief executive officer Dr Dan Baker told Biotech Daily that the company's lead candidate KB312 was first developed by the late Prof Derek Hart and Prof Georgina Clark at Brisbane's Mater Medical Research Institute, and later at the University of Sydney's Anzac Research Institute.

The Philadelphia, Pennsylvania-based Dr Baker said that the company had completed initial testing of KB312 in mice for graft versus host disease and would continue pre-clinical work in mice and cynomolgus monkeys for indications including solid organ transplant, collagen induced arthritis, which was a mouse model for rheumatoid arthritis.

Dr Baker said there was considerable work to be done for manufacturing and he hoped the compound would be in the clinic "by the end of 2021".

In its media release, Kira said that 12 percent of the population would be affected by an autoimmune disease in their lifetime and the economic impact of autoimmune diseases in Australia was $30 billion each year and twice that of cancer.

Dr Baker said that the company's research focused on "immune tolerance and targets cells and pathways that are key activators of the immune response in patients with autoimmune diseases, such as rheumatoid arthritis, systemic lupus erythematosus and type 1 diabetes".

"We're also keen to look at how KB312 might address transplant complications seen in graft-versus-host disease and rejection associated with heart and kidney transplants," Dr Baker said.

Kira said that KB312 was a monoclonal antibody "with a novel target that is common to many immune system disorders and is key to restoration or induction of immune tolerance".

"Unlike existing treatments which broadly target immune cells, Kira's antibody targets a specific activated dendritic cell with CD-83 molecules on its surface, which direct the immune response," Dr Baker said. "In doing so, KB312 limits the negative impacts of broad immunosuppression and preserves beneficial immune cells that protect patients against infections and malignancies."

Kira is a public unlisted company.

## IMAGION BIOSYSTEMS

Imagion says it hopes to raise up to $6.5 million in a one-for-one, pro-rata, renounceable rights offer at two cents a share.

Imagion said the offer price was a 40.6 percent discount to the 10-day volume weighted average price to the date of October 28, 2019.

The company said the record date for the rights offer would be November 1, with the offer opening on November 6, and closing on November 15, 2019.

Imagion said that shareholders would receive one free attaching option for every two shares purchased, exercisable at five cents each within two years.

Imagion said the funds would be used for manufacturing its Magsense Her2 test nanoparticle material along with research and development support, regulatory and clinical costs to undertake a first-in-human study.

Imagion fell half a cent or 17.9 percent to 2.3 cents with 3.2 million shares traded.

## UNIQUEST, JETRA THERAPEUTICS PTY LTD

Uniquest says that University of Queensland spin-out Jetra Therapeutics will develop a therapy for obesity-related liver disease.

Uniquest said in a media release that Jetra was backed by an initial investment from the Melbourne and London-based IP Group.

The commercialization arm of the University of Queensland said Jetra's targeted biologic was engineered by Mater Research Institute researchers to reduce stress in liver cells.

Uniquest said that the discoveries were led by inflammation expert Prof Mike McGuckin, clinical endocrinologist Prof John Prins and immuno-pathologist Dr Sumaira Hasnain.

Dr Hasnain said obesity often led to chronic disease and underpinned liver diseases such as non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH).

"NAFLD is typically characterized by excessive fat accumulation in the cells of the liver and can act as a precursor to more serious inflammatory diseases, such as NASH or the end-stage liver disease, cirrhosis," Dr Hasnain said.

"NASH is predicted to overtake hepatitis C viral infection as the leading cause of liver transplantation in advanced economies, yet there are currently no approved therapies specifically for this disease," Dr Hasnain said.

Dr Hasnain said that pre-clinical studies showed that targeting the liver with an engineered cell-signalling peptide called IL-22 led to a decrease of fat accumulation.

"We now want to further optimize and assess the safety of the therapy, and subsequently undertake clinical trials," Dr Hasnain said.

IP Group Australia managing-director Michael Molinari said that Jetra was his company's first investment with the University of Queensland.

Uniquest chief executive officer Dr Dean Moss said the company was "thrilled the IL-22 biologic program would be further developed as a novel, targeted therapy".

"Obesity-related liver disorders like NASH are clearly an area of considerable unmet clinical need and a growing area of interest for big pharma," Dr Moss said.

Jetra is a private company.

## ADALTA

Adalta says it has completed its four-week, non-human primate safety, toxicology and pharmacology study of AD-214 for idiopathic pulmonary fibrosis.

Adalta said the study showed AD-214 was safe, "well-tolerated" with no study mortalities or adverse events when dosed intravenously up to a dose level of 100mg/kg.

The company said it had completed three non-human primate studies of AD-214, evaluating safety and pharmacology.

Adalta said the first study saw a single dose of AD-214 administered and the other two studies examined three doses, 10mg/kg, 30mg/kg and 100mg/kg administered multiple times over four weeks.

The company said the manufacture of a large amount of AD-214 for a phase I, human clinical trial had been completed, and the trial was expected to begin by April 2020.

Adalta chief executive officer Dr Tim Oldham said the company was "pleased to reach both the toxicology and [good manufacturing practice] … manufacturing milestones on schedule and with expected results, enabling us to progress AD-214 into safety studies in humans as an important next step in bringing a much-needed new therapeutic option to fibrosis patients and in demonstrating the safety of the i-body as a platform".

"We also look forward to additional pharmaco-kinetic and pharmaco-dynamic information from this study in the near future," Dr Oldham said.

Adalta was up two cents or 16.7 percent to 14 cents.

## MEDICAL DEVELOPMENTS INTERNATIONAL, CSIRO

Medical Developments says it will extend its agreement with the Commonwealth Scientific and Industrial Research Organisation on small molecule manufacturing technologies.
Medical Developments said the agreement extended the 2017 partnership to develop new manufacturing technologies (BD: Jun 5, 2017).
The company said the ambition was to develop the next generation of manufacturing technologies to make “small molecule” pharmaceutical products at a significantly lower cost and improved quality, compared to traditional processes.
Medical Developments said it would invest $5 million over five years in the project, with the company potentially paying up to 60 percent of the fee through shares with 40 percent of the fee being reinvested into Medical Development by CSIRO through the purchase of options, which could “only be exercised [or] vested when a developed technology has been proven to be commercially viable” and would be issued at a 10 percent discount to the 7-day volume-weighted average price at the date of invoice.
Medical Developments chief executive officer John Sharman said there had been “good progress in the development of multiple continuous flow technologies” with lidocaine in the final stages of development and “several other technologies in various stages of completion [and] this extension will underwrite [Medical Developments] as a world leader in continuous flow technology”.
CSIRO Biomedical Manufacturing science director Dr Paul Savage said the Organisation was “delighted to extend our partnership with Medical Developments International to develop this new technology.”
“By introducing transformative processing technologies, CSIRO aims to further assist the global competitiveness and growth of the Australian pharmaceutical manufacturing industry,” Dr Savage said.
Medical Developments was up 17 cents or three percent to $5.90.

## ONCOSIL MEDICAL

Oncosil says it has submitted an updated clinical evaluation report to the notified body, British Standards Institute, for its Conformité Européene (CE) mark application.
Earlier this month, Oncosil said the British Standards Institute and the Clinical Oversight Committee had requested a clinical evaluation report including study data for its CE mark application. (BD: Oct 11, 2019).
In March, the company’s share price fell as much as 86.9 percent on news that the Committee found “insufficient clinical benefit” to approve its pancreatic cancer radiotherapy (BD: Mar 25, 2019).
Oncosil said the updated report compared the results of the 50-patient ‘Panco’ study with a systematic literature review of a range of clinical studies of chemotherapy and induction chemotherapy plus consolidated chemo-radiotherapy.
The company said the report showed local disease control rate at 16 weeks of 82 percent in the intention to treat cohort and 91 percent in the per protocol population, there was a prolonged median overall survival of 15.5 months in the intention to treat cohort and 16 months in the per protocol population, with a “clinically relevant” 20 percent reduction in the risk of death compared to chemotherapy alone.
The company said there was an “encouraging” rate of surgical resection with curative intent of 23.8 percent, with about one-in-four Panco patients being converted from an initially inoperable to surgically resectable state with an Oncosil device and chemotherapy, potentially improving patient five-year survival of five percent to 20 percent.
Oncosil was up half a cent or 4.35 percent to 12 cents with 11.6 million shares traded.

## PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has received $1,134,662 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Proteomics said the rebate related to expenditure for the year to June 30, 2019.
Proteomics was untraded at 32.5 cents.

## INVION

Invion says that although its Appendix 4C quarterly report appears to show less than two quarters cash, it is fully funded by the Cho Group.
Invion said that it had a cash burn for the three months to September 30 of $205,000, with cash and cash equivalents of $558,000 at September 30, 2019, and an expected spend of $1,090,000 for the three months to December 31, 2019.
In January, Invion company secretary Melanie Farris told Biotech Daily that all of the company's costs would be on its Photosoft cancer technology and would be funded by the Hong Kong-based Cho Group. (BD: Jan 29, 2019).
Invion was unchanged at 1.3 cents with 3.8 million shares traded.

## NUHEARA

Nuheara says it had customer receipts for the three months to September 30 of $452,000, cash of $4,325,000 and expected to spend $3,970,000 to December 31, 2019.
Nuheara said its cash burn for the three months to September 30 was $1,400,000 and the Appendix 4C quarterly report included a graph showing a reduction in negative operating cashflows from $2.5 million in September 2018 to $1.5 million in September 2019.
Nuheara chief executive officer Justin Miller told Biotech Daily that apart from increasing revenue and decreasing costs the company also expected a Federal Government R&D Tax Incentive "in line with last year's payment".
In 2018, the company said it had received $1,940,741 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program for the year to June 30, 2018 (BD: Oct 23, 2019).
Nuheara was unchanged at 3.8 cents with 2.3 million shares traded.

## TELIX PHARMACEUTICALS

Telix says that 67,556,748 shares and 2,310,165 options, exercisable at 85 cents each by October 14, 2021, will be released from ASX escrow on November 15, 2019.
According to the company's most recent Appendix 3B new issue announcement, following the release it would have 253,279,999 shares available for trading, with no more shares held in escrow.
Telix was up 7.5 cents or 4.8 percent to $1.625.

## ONCOSIL MEDICAL

Oncosil says all annual general meeting resolutions were passed easily, but withdrew a proposal to issue 4,850,000 loan shares to chief executive officer Daniel Kenny.
Last month, Oncosil said the meeting would vote to issue the shares (BD: Sep 27, 2019).
Today, the company said the remuneration report faced 3.96 percent opposition with directors Dr Martin Cross and Michael Basset elected overwhelmingly.

## SHAREROOT

Shareroot says shareholders will vote to change its name to Opyl, hold a 100-to-one consolidation and issue directors 6,000,000 pre-consolidation options.
Shareroot said the annual general meeting would vote on the issue of 2,000,000 unlisted pre-consolidation 'incentive' options each to chairman Dr Julian Chick and directors Marat Basyrov, Damon Rasheed, exercisable at 0.3 cents each within five year of issue.
The company said the current share price was 0.2 cents a share.
Biotech Daily calculates that post-consolidation each director would receive 20,000 options exercisable at 30 cents each, compared to a current price of 20 cents.
Shareroot said the meeting would vote on the ratification of the prior issue of 425,268,959 shares and 44,000,000 unlisted options, approve the issue of 235,000,000 unlisted investor options, 25,000,000 unlisted Sanlam Private Wealth options, approve the 10 percent placement capacity and adopt the long-term incentive plan.
The company said shareholders would vote on the remuneration report and the election of directors Dr Chick, Mr Rasheed and Mr Basyrov.
The meeting will be held at Engine House, 105 Wellington Street, St Kilda, Victoria on November 27, 2019 at 10am (AEST).
Shareroot was unchanged at 0.2 cents with five million shares traded.

## USCOM

Greg Plummer and Jetan says they have become substantial shareholders in Uscom with 7,365,939 shares or 5.37 percent.
The Sydney-based Jetan said it acquired shares between September 27 and October 28, 2019 with the single largest purchase 3,500,000 shares for $350,000 or 10 cents a share.
Uscom was unchanged at 11.5 cents.

## BARD1 LIFESCIENCES

The Perth-based Merchant Funds Management says it has increased its substantial shareholding in Bard1 from 95,440,211 shares (7.68%) to 155,266,958 shares (11.36%).
Merchant said that between July 12 and August 13, it bought and sold shares and on October 28 it acquired 51,682,725 shares for $1,029,428 or 1.99 cents a share.
Merchant managing-director Andrew Chapman told Biotech Daily that the change related to the realignment and amalgamation of two funds.
Bard1 was unchanged at 4.9 cents with 1.9 million shares traded.

## PALLA PHARMA

Thorney Opportunities and Tiga Trading says they have increased their substantial holding in Palla from 13,795,629 shares (17.01%) to 22,466,299 shares (20.80%).
The Melbourne-based Thorney and Thorney Investment Group Australia (Tiga) said they acquired shares between August 26 and October 24, 2019 with most of the shares bought at 70 cents a share through the recent placement and an institutional entitlement offer to raise $31.1 million (BD: Oct 17, 2019).
Palla Pharma was unchanged at 88 cents.