Biotech Daily

Wednesday August 22, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 27%; PRESCIENT DOWN 8%**

*** 'EXPERT PANELS' BACK GLOBAL KINETICS PKG FOR PARKINSON'S**

*** ST VINCENT'S BUYS 1st LBT APAS INDEPENDENCE**

*** VICTORIA $3m FOR 30 RESEARCH PROJECTS**

*** IDT REVENUE UP 39% TO $13m, LOSS UP 2097% TO $17m, IMPAIRMENT**

*** USCOM REVENUE DOWN 18% TO $2.8m, LOSS UP 9% TO $2m**

*** IMMUTEP POSTS $2.6m REVENUE, LOSS UP 36% TO $12.8m**

*** SOMNOMED REVENUE UP 29% TO $64m, LOSS UP 158% TO $8.6m**

*** ACADIA PAYS NEUREN $13.6m FOR TROFINETIDE LICENCE**

*** IMMUTEP RECEIVES $1.9m FRENCH TAX REBATE**

*** ACTINOGEN: DSMB BACKS XANADU PHASE II TRIAL, AGAIN**

*** SUDA WINS SUD-003, SUD004 SOUTH AFRICA PATENT**

*** REGAL TAKES 13.4% OF VISIONEERING**

*** KINETIC TAKES 6.7% OF VISIONEERING**

*** ADALTA RELEASES 24m SHARES FROM ASX ESCROW**

*** MICRO-X LOSES DIRECTORS JIM MCDOWELL, DAVID SYMONS**

*** ZELDA: PROF DAVID CASARETT, DR DUSTIN SULAK ADVISORS**

MARKET REPORT

The Australian stock market fell 0.29 percent on Wednesday August 22, 2018 with the ASX200 down 18.4 points to 6,266.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and two were untraded.

Impedimed was the best on no news, up 7.5 cents or 27.3 percent to 35 cents with 1.7 million shares traded. LBT climbed 17.4 percent; Neuren was up 12.95 percent; ITL rose 11.8 percent; Osprey improved 5.95 percent; Actinogen, Avita and Medical Developments were up more than three percent; Mesoblast and Pro Medicus rose more than two percent; with Nanosonics and Pharmaxis up more than one percent.

Prescient led the falls, down 0.7 cents or 7.95 percent to 8.1 cents with 482,303 shares traded. Reva lost 6.25 percent; Compumedics and Dimerix fell more than four percent; Airxpanders, Genetic Signatures and Opthea were down more than three percent; Bionomics, Immutep, Oncosil, Prana and Universal Bio shed more than two percent; with Clinuvel, CSL, Cynata, Optiscan, Orthocell and Polynovo down one percent or more.

GLOBAL KINETICS CORP

Global Kinetics says that “two separate expert panels” have recommended its Personal Kinetigraph (PKG) wearable monitors to manage Parkinson’s disease.

Global Kinetics said the two panels examined “the ideal objective measurement tool and clinical utility of the PKG in routine assessment and care of Parkinson’s patients”.

The company said that the first publication, authored by the Sweden-based Lund University’s Prof Per Odin and the King’s College London’s Prof Kallol Ray Chaudhuri and titled ‘Viewpoint and practical recommendations from a movement disorder specialist panel on objective measurement in the clinical management of Parkinson's disease’ was published online in Nature Parkinson’s Disease.

The article is available at: https://www.nature.com/articles/s41531-018-0051-7.

Global Kinetics said the second publication, authored by the Kansas City-based University of Kansas Medical Centre’s Dr Rajesh Pahwa titled ‘Role of the Personal KinetiGraph in the routine clinical assessment of Parkinson’s disease: recommendations from an expert panel’ was published online in Expert Review of Neurotherapeutics, with an abstract available at: https://www.tandfonline.com/doi/full/10.1080/14737175.2018.1503948.

Both publications acknowledged funding assistance from Global Kinetics.

The company said the two publications concluded that the Personal Kinetigraph provided “a continuous objective measure of patient symptoms, including bradykinesia, which is both treatment responsive and the clearest indicator of underlying pathological degeneration”.

Global Kinetics said that bradykinesia referred to slowness of movement, which was related to the loss of dopamine responsiveness in brain cells and unlike more obvious and commonly associated symptoms such as dyskinesia, which was a response to standard treatments for Parkinson’s, and tremor, bradykinesia was often difficult for a patient to identify and for a doctor to assess.

The company said the publication reported that “no other clinical or research grade technology can provide passive measures of bradykinesia, establishing the [Personal Kinetigraph] as an essential objective measure of bradykinesia in clinical decision-making”.

Global Kinetics said the Personal Kinetigraph was approved for clinical use in 17 countries, including US Food and Drug Administration and Conformité Européenne (CE) mark approvals.

The company said that early clinical experience and expert opinion suggested that use of “continuous objective measurement technologies such as the PKG have the potential to improve medical care in people with Parkinson’s disease”.

Global Kinetics said the publications follow the American Medical Association issue of new category III current procedural terminology (CPT) codes effective from January 1, 2019.

The company said that Parkinson’s disease was one of the few chronic diseases treated through subjective observation of symptomology, but its Personal Kinetigraph was used by clinicians to provide clinically validated continuous, objective measures of the distinguishing movement symptoms of Parkinson’s.

Global Kinetics chief executive officer John Schellhorn said that there was “much interest and dialogue about wearable technologies in Parkinson’s [and] two international panels of experts have recognized the value of the PKG in routine care”.

“These studies, combined with the CPT III codes which will become effective [on] January 1, 2019, position the PKG as a viable tool to objectively measure key Parkinson’s symptoms,” Mr Schellhorn said.

Global Kinetics is a public unlisted company.

LBT INNOVATIONS

LBT says Melbourne's St Vincent's Hospital has bought its first Automated Plate Assessment System (APAS) Independence.

LBT has previously said that each system, used for the automated imaging, analysis and interpretation of bacterial culture plates following incubation, would cost about $US300,000 ($A400,000).

Today, the company said the first purchase was "significant" for it and its 50 percent owned joint venture company Clever Culture Systems.

LBT said that the APAS Independence was "the only stand-alone, automated plate reader using artificial intelligence available commercially anywhere in the world".

The company said that St Vincent's Hospital was the first installation site for the APAS Independence and completed a six-week independent evaluation using a pre-production instrument at the end of 2017.

LBT said it was the distributor for Australia and New Zealand, Clever Culture Systems was the manufacturer and supplier of the instrument and LBT would generate revenue directly as the Australian distributor of the instrument, as well as revenue generated by Clever Culture Systems.

The company said that the future development of additional analysis modules would extend the clinical application and addressable market for APAS Independence, with Clever Culture Systems responsible for managing the regulatory pathway.

LBT chief executive officer Brent Barnes said the company was "proud to deliver the first sale of an APAS Independence instrument globally in our launch market of Australia".

"We have been working for the past five years to deliver this important milestone," Mr Barnes said.

"The decision by St Vincent's Hospital to purchase an instrument provides validation for our APAS technology and we look forward to continuing to collaborate with St Vincent's Hospital in the development of future analysis modules and as a centre of excellence," Mr Barnes said.

LBT was up two cents or 17.4 percent to 13.5 cents with 1.1 million shares traded.

VICTORIA GOVERNMENT

The Victoria Government says it will provide $3 million from the Victorian Medical Research Acceleration Fund for 30 research projects.

A media release from the Minister for Health Jill Hennessy said the Fund was part of the Government's $20 million plan to invest in health and medical research.

The Government said the grants were for projects including the accuracy of artificial intelligence to diagnose skin cancer, artificial intelligence and smartphones to help young people with mental health, a technology to detect drug resistant superbugs, and brain implants that allow people with motor neuron disease to control a robotic limb through direct thought.

Ms Hennessy said the Government "started the fund to ensure projects that have the potential to save lives across the world don't get held up because they couldn't attract early funding".

The Victoria Government said that a full list of second round projects was available at: www.health.vic.gov.au/victorian-medical-research-acceleration-fund.

The Government said that submissions for the third round of funding would open later this month and close at the end of October.

IDT AUSTRALIA

IDT says revenue for the 12 months to June 30, 2018 was up 39.4 percent to $13,300,000, with net loss after tax up 2,096.5 percent to $16,979,000.
IDT said its revenue was mainly derived from consulting research and development and the manufacture of active pharmaceutical ingredients for customers.
IDT chief financial officer Joanna Johnson told Biotech Daily the loss included a $14,144,000 impairment charge relating to the 2014 purchase of 23 generic drugs from Sandoz and the sale of most of them in April (BD: Nov, 3, Dec 18, 2014; Apr 4, 2018).
Ms Johnson said that the underlying loss for the year to June 30, 2018 fell 58.8 percent to $2,835,000, but for the six months to June 30, 2018, the company made an underlying profit of $223,000.
The company said that its diluted loss per share rose 22.0 percent to 6.9 cents and it had cash and cash equivalents of $14,027,000 at June 30, 2018 compared to $8,417,000 at June 30, 2017.
IDT was up 2.5 cents or 27.8 percent to 11.5 cents.

USCOM

Uscom says that revenue for the year to June 30, 2018, was down 18.2 percent to $2,861,708 with net loss after tax up 8.9 percent to $1,960,923.
Uscom said the decrease in revenue was related to the interruption of manufacturing during relocation, expansion and re-approval of its manufacturing facility, as well as that the implementation of its new China business strategy disturbing its sales in China.
The company said that research and development spending increased 38.4 percent to $850,000.
Uscom said that net tangible asset per share rose 22.7 percent to 0.027 cents, with diluted loss per share the same as last year at 1.6 cents.
The company said that it had cash and cash equivalents of $2,493,575 at June 30, 2018 compared to $1,663,565 at June 30, 2017.
Uscom was unchanged at 16.5 cents.

IMMUTEP (FORMERLY PRIMA BIOMED)

Immutep says its revenue for the year to June 30, 2018 was $2,630,484, with net loss after tax up 36.1 percent to $12,746,020.
Immutep said its revenue was due to milestone payments received from its partners.
Earlier this year, the company said it received payments from Novartis for IMP701, EOC for a trial approval and $1.3 million from the French Government (BD: Feb 23, Jul 31, 2018).
Today, Immutep said it received $1,008,678 in miscellaneous income relating to the sale of LAG-3 research material, along with $3,214,441 in grant income, $322,518 in “other income” and $177,186 in interest.
The company said that research and development spending increased 33.3 percent to $10.0 million, due to expenses related to patient recruitment for two IMP321 clinical trials, as well as the development of a new drug candidate IMP761.
Immutep said that net tangible asset per share rose 38.9 percent to 0.50 cents, with diluted loss per share up 19.5 percent to 0.49 cents.
The company said that it had cash and cash equivalents of $23,475,521 at June 30, 2018 compared to $12,236,974 at June 30, 2017.
Immutep fell 0.1 cents or 2.9 percent to 3.4 cents with 2.7 million shares traded.

SOMNOMED

Somnomed says revenue for the 12 months to June 30, 2018 was up 29.0 percent to $63,806,011 with last year's net loss after tax up 157.8 percent to $8,619,551.
Somnomed said revenue from its core mouth guard anti-snoring device business was up 600.0 percent from last year to $11.2 million, but the business' annual loss was $10.4 million, with the "direct to patient model … [proving] more complex than was previously anticipated" after results were below expectations.
The company said that net tangible asset backing per share rose 3.2 percent to 37.2 cents for the year to June 30, 2018, diluted loss per share increased 148.8 percent to 15.5 cents and it had cash and cash equivalents of $13,383,389 at June 30, 2018 compared to $14,210,321 at June 30, 2017.
Somnomed fell eight cents or 3.9 percent to $1.97.

NEUREN PHARMACEUTICALS

Neuren says Acadia Pharmaceuticals has paid the $US10 million ($A13.6 million) upfront fee for its North American licence agreement for trofinetide.
Earlier this month, Neuren said the San Diego, California-based Acadia Pharmaceuticals would pay $630 million in upfront fees, milestones and royalties for a licence to trofinetide for Rett syndrome, Fragile X and other indications for North America, alone.
Today, Neuren said Acadia would pay it "double-digit percentage royalties" on net sales of trofinetide for all disease indications in North America.
Neuren climbed 14.5 cents or 12.95 percent to $1.265 with 1.4 million shares traded.

IMMUTEP (FORMERLY PRIMA BIOMED)

Immutep says it has received an EUR1,221,906 ($A1,910,010) cash rebate from the French Government under its Crédit d'Impôt Recherche scheme.
Immutep said the Crédit d'Impôt Recherche scheme, or "research tax credit", was a tax incentive by which French companies conducting research and development activities in Europe could be reimbursed 30 percent of their eligible expenditure.
The company said it qualified for the tax incentive through its subsidiary Immutep SAS, which conducted research and development at its Châtenay-Malabry, Paris laboratory.
Immutep said the funds would go towards the clinical development of IMP321 and the preclinical development of IMP761.

ACTINOGEN MEDICAL

Actinogen says the Xanadu data safety monitoring board has reaffirmed its recommendation that the phase II trial should continue without modification.
Earlier this year, Actinogen said it had approval from the board to continue its phase II trial of Xanamem for Alzheimer's disease (BD: May 23, 2018).
Today, the company said the periodic review looked at safety data from 125 patients, and was conducted as part of the company's responsibility to oversee the safety of the trial, with a third, and likely final, review to be held before the end of 2018.
Actinogen said that 136 of the planned 174 patients had been enrolled in the trial, with top-line results expected by July, 2019.
Actinogen was up 0.2 cents or 3.45 percent to six cents.

SUDA PHARMACEUTICALS

Suda says the South African Intellectual Property Office has granted the first patent for its sildenafil-based products SUD-003 and SUD-004.
Suda said the patent, titled 'Oral Spray Formulations and Methods for Administration of Sildenafil', covered the administration of sildenafil, the active drug in Viagra and Revatio, by oral spray for the treatment of sexual dysfunction induced by selective serotonin reuptake inhibitor anti-depressants, as well as the treatment of pulmonary arterial hypertension, until December 2032.
The company said SUD-003 was for erectile dysfunction, while SUD-004 was for the treatment of pulmonary arterial hypertension.
Suda said it had similar patents granted in the US, Japan, Russia, Australia, New Zealand, Canada and Singapore, with patent applications pending in other jurisdictions.
Suda executive chairman Stephen Carter said the patent "reinforces our proprietary position covering the oral spray delivery of sildenafil for erectile dysfunction and pulmonary arterial hypertension".
Suda fell 0.1 cents or 16.7 percent to 0.5 cents with 7.0 million shares traded.

VISIONEERING TECHNOLOGIES

Regal Funds Management says it has increased its substantial shareholding in Visioneering from 23,560,856 shares (11.96%) to 33,106,832 shares (13.44%).
The Sydney-based Regal said that between December 7, 2017 and August 21, 2018 it bought and sold shares, with the single largest sale of 500,000 shares for $215,000, or 43 cents a share on March 8, and the single largest purchase of 11,111,111 shares for $2,000,000, or 18 cents a share on August 21.
Visioneering was up one cent or 5.7 percent to 18.5 cents.

VISIONEERING TECHNOLOGIES

Kinetic Investment Partners says it has become a substantial shareholder in Visioneering with 16,458,894 shares or 6.68 percent of the company.
The Melbourne-based Kinetic said it acquired 7,044,445 for $1,286,060, or 18.3 cents a share between April 20 and August 20, 2018.
The substantial shareholder notice said the registered holders of the shares included JP Morgan Nominees, National Nominees, Cogent Nominees, Northern Trust and Citigroup Nominees.

ADALTA

Adalta says it has released 24,047,138 shares from ASX escrow, taking the number of shares available for trading to 116,493,662 shares.
Adalta said the shares were in escrow for two years from listing and were held by major shareholder Yuuwa Capital with 22,082,027 shares, chairman Dr Paul MacLeman, with 439,636 shares, director Dr John Chiplin with 610,883 shares and chief executive officer Sam Cobb with 914,592 shares.
The company said that 588,411 shares remained subject to ASX escrow.
Adalta was untraded at 29.5 cents.

MICRO-X

Micro-X says non-executive directors Jim McDowell and David Symons will resign in the coming months due to “imminent career changes”.
Micro-X said Mr McDowell’s resignation would be effective from August 31, 2018, as he had accepted an offer to become the chief executive of the South Australian State Government’s Department of Premier and Cabinet, which required his retirement from commercial appointments and external directorships.
The company said Mr Symons would retire from the board at the annual general meeting in November.
Micro-X fell two cents or 6.1 percent to 31 cents.

ZELDA THERAPEUTICS

Zelda says it has appointed “medicinal cannabis experts” Prof David Casarett and Dr Dustin Sulak to its scientific and medical advisory board.
Zelda managing-director Dr Richard Hopkins said that Prof Casarett and Dr Sulak had “extensive expertise in the use of medicinal cannabis that will inform our clinical programs for indications including autism, insomnia and cancer”.
“Their ability to access US-based patient groups will also support our strategy to bring Zelda-branded products to market,” Dr Hopkins said.
Zelda said that Prof Casarett was a palliative care physician and health services researcher whose work focuses on improving systems of care for people with serious life-threatening illnesses.
The company said that Prof Casarett was a professor of medicine at the Durham, North-Carolina-based Duke University School of Medicine and Duke Health chief of palliative care.
Zelda said that Prof Casarett’s research and clinical interests included evaluating the use of cannabis to treat neuropathic pain and nausea.
The company said that Prof Casarett was the author of more than 100 journal articles and the author of three non-fiction books including ‘Stoned: A Doctor’s Case for Medical Marijuana’.
Zelda said that Dr Sulak’s clinical practice treated refractory conditions in adults and children.
The company said that Dr Sulak held undergraduate degrees in nutrition science and biology from Indiana University and a Doctorate of Osteopathy from the Arizona College of Osteopathic Medicine.
Zelda said that Prof Casarett and Dr Sulak would be issued 1,500,000 options each, with all options exercisable at 12.5 cents each by August 22, 2021, with 1,000,000 options vesting immediately and the second tranche of 2,000,000 options, vesting on August 22, 2020.
Zelda fell 0.2 cents or 2.8 percent to seven cents with 1.5 million shares traded.