Biotech Daily

Monday February 5, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: SIRTEX UP 0.55%; OPTHEA DOWN 13%**

*** ORTHOCELL RABBIT TRIAL BACKS CELGRO FOR ACL RECONSTRUCTION**

*** CYNATA STEM CELLS ENGINEERED FOR CANCER**

*** BOTANIX RAISES $15m**

*** PROTEOMICS OPTIONS RAISE $111k, $3.3m TO GO**

*** ELLEX H1 SALES UP 12% TO $38m**

*** CLINICAL GENOMICS: 'INSURE FIT MORE ACCURATE'**

*** ANATARA: FDA OKAYS DETACH-TREATED PIGS 'FOR HUMAN FOOD'**

*** G MEDICAL CHINA GREEN CHANNEL TAX BREAKS**

*** TPI COMPLETES PORTUGAL SALE**

*** XIANHUI MENG, SMART TOP OVERSEAS TAKE 17% OF USCOM**

*** MEDLAB DIRECTOR DREW TOWNSEND INCREASES, DILUTED TO 8%**

*** OBJ CHAIRMAN GLYN DENISON RETIRES AFTER 12 YEARS**

*** GENETIC TECHNOLOGIES DR PAUL KASIAN CHAIRMAN; BLOCKCHAIN**

*** REVA APPOINTS DR STEPHEN OESTERLE DIRECTOR**

MARKET REPORT

The Australian stock market fell 1.56 percent on Monday February 5, 2018 with the ASX200 down 95.2 points to 6,026.2 points. Two of the Biotech Daily Top 40 stocks were up, 31 fell, five traded unchanged and two were untraded. All three Big Caps fell.

Sirtex was up 15 cents or 0.55 percent to $27.65 with 1.5 million shares traded, with Ellex up half a cent or 0.53 percent to 95 cents with 335,889 shares traded.

Opthea led the falls, down eight cents or 12.9 percent to 54 cents with 124,428 shares traded. Oncosil lost 9.4 percent; Airxpanders fell 8.5 percent; Compumedics, Cyclopharm and LBT were down seven percent or more; Benitec and Osprey shed more than six percent; Starpharma lost 5.6 percent; Actinogen, Immutep (Prima), Polynovo and Universal Biosensors fell more than four percent; Avita, Impedimed, Mesoblast, Neuren, Pharmaxis and Telix were down three percent or more; Admedus, Bionomics, Factor Therapeutics, Medical Developments, Nanosonics and Viralytics shed two percent or more; Clinuvel, Prana, Resmed, Reva and Volpara were down more than one percent; with Cochlear, CSL, Pro Medicus and Psivida down by less than one percent.

ORTHOCELL

Orthocell says a trial of 72 rabbits shows that its Celgro braided collagen fibre rope can be used for anterior cruciate ligament (ACL) reconstruction.

Orthocell said that in the study 36 rabbits receiving an autograft, of their own tissue, and the other 36 rabbits received Celgro collagen rope for ACL reconstruction.

The company said that the cases were evaluated at multiple time points undergoing either a regeneration assessment or mechanical test to assess the performance of the Celgro collagen rope when compared to autologous tendon graft for anterior cruciate ligament reconstruction.

Orthocell said that more pre-clinical studies would be required before human trials could begin.

The company said that the study showed host ligament stem cells from the anterior cruciate ligament stump were capable of ingrowth into the biomechanically superior Celgro rope, which was “a key breakthrough in the use of collagen scaffolds”.

Orthocell said that its Celgro collagen rope had “the potential to greatly improve ACL reconstruction outcomes and [was] capable of replacing legacy autologous graft for ACL reconstruction”.

Orthocell managing-director Paul Anderson said that an “off-the-shelf biological device that augments ACL reconstruction is highly desired by the orthopaedic industry”.

“Not only does this data support the potential for an off the shelf augment to ACL reconstruction, but it also acts to validate Celgro as a collagen medical device platform technology, for use across multiple indications including bone, tendons and peripheral nerves,” Mr Anderson said.

Orthocell said that the study was led by its chief scientific officer Prof Ming-Hao Zheng in conjunction with the University of Western Australia.

The company said that the study was designed to show that Celgro collagen rope was equal to, or better than the use of an autologous tendon graft, such as hamstring, for ACL reconstruction, which could result in donor site discomfort and other associated complications.

Orthocell said that the top-line data indicated that Celgro rope had superior biomechanical properties and was capable of replacing autologous grafts for anterior cruciate ligament reconstruction, the host ligament stem cells from the ACL stump were capable of ingrowth into the collagen rope for tissue regeneration and it integrated with native bone with a tensile strength similar to that of the natural ligament.

The company said that the anterior cruciate ligament was one of the major stabilizing ligaments of the knee, connecting the femur to the shin bone tibia and once it ruptured, it was incapable of healing.

Orthocell said that the anterior cruciate ligament could be injured in several ways including changing direction rapidly, landing from a jump or direct contact or impact, and was a common injury, usually requiring surgical intervention, with a long period for rehabilitation before returning to pre-injury activities.

The company said there were between 100,000 and 200,000 anterior cruciate ligament ruptures a year in the US alone.

Orthocell said that successful reconstruction surgery tightened the knee and restored stability, helping patients avoid further injury and a return to work and playing sports.

The company said that surgical repair mostly involved reconstructing the anterior cruciate ligament using grafts from the patient’s hamstring tendon, a procedure that removed part of the tendon to take the place of the ruptured ligament.

Orthocell was unchanged at 35 cents.

CYNATA THERAPEUTICS

Cynata says the first stage of a mouse study evaluating the ability to genetically engineer its Cymerus stem cells to treat cancers has had “very promising results”.
Cynata said that its Cymerus mesenchymal stem cells were engineered to express diagnostic and therapeutic proteins and the expression was stable, with the persistence of cells in mice consistent with expectations.
The company said the study at Harvard Medical School was led by Centre for Stem Cell Therapeutics and Imaging director Dr Khalid Shah and investigated the potential utility of genetically-engineered stem cells to express diagnostic and therapeutic proteins with applications in oncology.
Cynata said that the first stage of the study showed that its stem cells could be engineered to express the diagnostic and therapeutic proteins using unique expression promoters developed by Dr Shah’s team and the expression was stable during continued growth of the modified stem cells in the laboratory and the modified stem cells persisted in-vivo “for a sufficient duration to facilitate a therapeutic effect”.
Dr Shah said that the Cynata’s mesenchymal stem cells [MSCs] “have so far shown ideal properties required to progress the cells into different disease models”.
“In particular, the modified Cynata cells behave in a very similar fashion to traditional MSCs,” Dr Shah said.
Cynata product development head Dr Kilian Kelly said that “this type of cellular engineering opens up numerous potential additional applications of our platform manufacturing technology”.
Cynata fell two cents or 2.3 percent to 86 cents with 1.1 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has raised $15 million in an “oversubscribed placement” at 11 cents a share to institutional and sophisticated investors in Australia and Asia.
Botanix said the funds would take BTX1503 to a phase II acne trial, with remaining funds to be used to develop BTX1204 for atopic dermatitis, BTX1308 for psoriasis and further explore the commercial potential of its Permetrex drug delivery system.
Botanix fell 1.5 cents or 10.7 percent to 12.5 cents with 12.8 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has raised $111,250 from the exercise of options and its directors “have indicated that it is also their intention to exercise [their] options”.
Proteomics said that if all PIQO options were exercised at 20 cents each by March 31, 2018, the company would receive a further $3,335,121.
Proteomics fell two cents or 6.7 percent to 28 cents.

ELLEX MEDICAL LASERS

Ellex says that sales for the six months to December 31, 2017 increased 11.7 percent to $38.2 million compared to previous corresponding period.
Ellex said that core lasers and ultrasound sales were up 7.9 percent to $32.8 million, its Itrack for minimally invasive glaucoma surgery sales were up 44.4 percent to $5.2 million, with 2RT for macular degeneration sales constant at $200,000.
The company said that glaucoma therapy device sales comprised half of group revenue.
Ellex was up half a cent or 0.5 percent to 95 cents.

CLINICAL GENOMICS

Clinical Genomics says that a colorectal cancer screening study shows its Insure Fit was "significantly more sensitive" than two competitor faecal occult blood tests.
Clinical Genomics said the study of 1,006 asymptomatic patients, aged between 50 and 75 years, compared its Insure faecal immunochemical test (Fit), sold as Colovantage Home in Australia, against OC Fit-Chek, and Hemoccult II Sensa.
The company said that the article, entitled 'A Comparison of Fecal Immunochemical and High-Sensitivity Guaiac Tests for Colorectal Cancer Screening' was published in the American Journal of Gastroenterology in October 2017, with an abstract available at: https://www.ncbi.nlm.nih.gov/pubmed/29016558.
Clinical Genomics said the study compared the three faecal occult blood tests and patients also received a screening colonoscopy and quoted the authors reporting that "Insure FIT was statistically significantly more sensitive than both the OC Fit-Check and Hemoccult II Sensa".
Clinical Genomics IVD head Mark Boyle said the study provided "important evidence that not all [faecal occult blood tests] are equal and that physicians should consider using highly sensitive and specific [tests], such as Insure Fit, in colorectal cancer screening programs".
The company said that Insure FIT was US Food and Drug Administration cleared to detect human haemoglobin from blood in stools, as an aid in the detection of lower gastrointestinal bleeding.
Clinical Genomics is a private company.

ANATARA LIFESCIENCES

Anatara says that the US Food and Drug Administration has provided "complete" letter for the technical section of its human food safety submission.
Anatara is developing its pineapple stem, bromelain-derived Detach as a non-antibiotic treatment for pig and human diarrhoea.
The company said that the letter "confirms that the US Food and Drug Administration is satisfied that food products from animals treated using Detach will be safe for human consumption".
Anatara said the human food safety submission was "a major component of a new animal drug application (NADA) which is currently underway and is necessary for enabling the marketing of Detach in the US".
The company said that the technical section included an assessment on whether Detach would contribute to antimicrobial resistance.
Anatara executive chairman Dr Mel Bridges said that the safety of edible products from drug-treated, food-producing animals was "a critical part of the US drug approval process, so receipt of the complete letter is a core step for the entry of Detach into world markets".
"The efficacy, overall safety and manufacturing information required for the approval of human and animal drugs is very similar, but the safety of a drug targeted at food-producing animals must undergo an additional level of stringent review to ensure that there are no residual safety issues for the human consumer," Dr Bridges said.
Dr Bridges said that the human food safety section of the registration process could take three to six years to complete and up to 70 percent or $8 million of expenditure for a new drug, so "the fact that Anatara has achieved an outcome within three years of opening our investigational new animal drug application is an outstanding result and speaks to the strong safety profile we've seen for Detach in our trials,".
Anatara was up fell two cents or 1.1 percent to $1.77.

G (GEVA) MEDICAL INNOVATIONS

G Medical says the China Food and Drug Administration has granted acceptance to the 'Green Channel' regulatory approval for its Prizma medical smart telephone sensor case.
G Medical said the Guangdong CFDA approval to subsidiary Guangzhou Yimei Innovative Medical S & T, would reduce local enterprize income tax from 25 percent to 15 percent.
The company said it had passed technical inspection by the CFDA, setting the ground for complete regulatory approval and production infrastructure setup.
G Medical said Prizma was aimed at consumers allowing them to turn their telephones into mobile medical monitors, storing data in the internet cloud to share with third paries.
G Medical fell half a cent or 1.6 percent to 30 cents with 2.4 million shares traded.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says it has completed the sale of its Lisbon, Portugal-based subsidiary located in Lisbon for EUR2.85 million ($A4.5 million) (BD: Nov 6, 2017).
In November and today, TPI did not name its Portugese subsidiary nor the purchaser.
The company said that specialized active pharmaceutical ingredient manufacturing equipment previously stored at the Lisbon facility had been transferred to its recently acquired Norwegian opiate and finished dose facility Vistin Pharma ASA, which would conduct all of its active pharmaceutical ingredient production (BD: Oct 3, 2017).
TPI fell five cents or 2.2 percent to $2.19.

USCOM

Smart Top Overseas says it has increased its substantial holding in Uscom from 18,000,000 shares (13.12%) to 23,158,475 shares (16.88%).
A notice signed by director Xianhui Meng said the British Virgin Islands-based Smart Top bought 5,158,475 shares for $1,134,865 or 22 cents a share on February 1, 2018.
Uscom was unchanged at 20 cents.

MEDLAB CLINICAL

Medlab director Drew Townsend says he has increased his holding in the company but has been diluted from 15,500,000 shares (9.64%) to 16,055,553 shares (7.72%).
Mr Townsend said he bought 555,553 shares for $166,666 or 30 cents each in the 2016 rights issue which raised $5,361,150 at 30 cents a share and was diluted in last month's placement which raised $24 million at 90 cents a share (BD: Aug 15, 2016; Jan 25, 2018).
Medlab fell 10 cents or 11.3 percent to 78.5 cents with 1.8 million shares traded.

OBJ

OBJ says that chairman Glyn Denison formally retired as a director on February 2, 2018.
OBJ said it "greatly acknowledges the contribution made by Mr Denison during his 12 years as a director … particularly his contribution as chairman responsible for assisting with [the] commercialization of OBJ's technologies.
Last year, the company said that Mr Denison would "remain on the board pending the appointment of a suitable director as his replacement" but at the time of publication there had been no further appointments (BD: Aug 31, Oct 6, 2017).
The board comprises Jeffrey Edwards, Dr Christopher Quick and Steven Schapera.
OBJ was unchanged at 3.5 cents with 6.3 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says that Dr Paul Kasian has been appointed as chairman.
Last week, Genetic Technologies said that a board spill was successful with former chairman Dr Malcolm Brandon and director Grahame Leonard resigning ahead of the extraordinary general meeting, chief executive officer Eutillio Buccilli voted from the board, with Samuel Xue Lee, Peter Rubenstein and Jerzy Muchnicki, elected to the board (BD: Jan 31, 2018).
Today, the company said that Dr Kasian had been a director of the company for more than four years and his appointment as chairman "provides continuity in the newly restructured board … as it seeks to build on the genomic assets and expertise developed to date and take advantage of new and developing opportunities".
Dr Kasian said the "new board has fully endorsed the company's existing business and technology and is looking forward to continuing development of its predictive cancer platforms across the exciting area of colon cancer along with existing non-familial breast cancer".
"Embracing new technologies such as blockchain to provide greater efficiencies in how tests are created, stored and passed on to patients, researchers and big Pharma may provide a quantum leap in efficiencies and opportunities for GTG moving forwards," Dr Kasian said.
Genetic Technologies said that Dr Kasian was appointed a director in 2013 and had experience in in business leadership and biotechnology investing (BD: Dec 12, 2013).
The company said that Dr Kasian held a Doctorate of Philosophy in microbiology and a Master of Business Administration from the University of Melbourne.
Genetic Technologies was in a suspension and last traded at 1.55 cents.

REVA MEDICAL

Reva says it has appointed Dr Stephen Oesterle as a director, effective immediately.
Reva said that Dr Oesterle had clinical, medical device and board expertise and was currently a venture partner at New Enterprise Associates, an advisor to Sweden's EQT Partners and Singapore's Temasek Holdings and a director of at Baxter International.
The company said that Dr Oesterle was formerly Medtronic's head of medicine and technology and a member of its executive operating committee for 14 years, overseeing technology investments and corporate investments in emerging private companies, as well as a member of Medtronic's business development and strategy committee which approved all corporate acquisitions.
Reva said that Dr Oesterle held an undergraduate degree from Harvard, a Doctor of Medicine from Yale Medical School and a fellowship in interventional cardiology at Stanford University Hospital.
The company said that Dr Oesterle served on the faculties at Harvard and Stanford medical schools where he directed invasive cardiology services at each hospital.
Reva fell half a cent or one percent to 48.5 cents.