Biotech Daily

Monday September 30, 2019

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ANTISENSE UP 16%; GENETIC SIGS DOWN 11%**

*** USCOM TO RAISE UP TO $1m IN PRIVATE PLACEMENT**

*** KINOXIS: UP TO $7m US GRANT FOR KNX100 FOR OPIOID WITHDRAWAL**

*** KAZIA: 'CANTRIXIL PARTIAL RESPONSE IN 2 OF 9 PATIENTS'**

*** RESAPP: 'ALGORITHM ACCURATE FOR OBSTRUCTIVE SLEEP APNOEA'**

*** INVION PREPARES FOR 2020 BASAL CELL CARCINOMA LIGHT TRIAL**

*** NOXOPHARM: 'NOX66 BOOSTS 177LU-PSMA FOR PROSTATE CANCER'**

*** INVITROCUE TO OPEN HONG KONG R&D LABORATORY**

*** IMMUTEP: 51m PERFORMANCE RIGHTS, 1-FOR-10 CONSOLIDATION AGM**

*** MESOBLAST TO RELEASE 14.5m VOLUNTARY ESCROW SHARES**

*** PHYLOGICA 'PARTNERSHIP' TRADING HALT**

*** AVITA TO LIST ON NASDAQ**

*** MORGAN STANLEY BELOW 5% IN AVITA**

*** OSTEOPORE: MR LIEW, RAIN MAKER, MR SENG, PROF TEOH, PROF YANG**

*** ADMEDUS REQUESTS 8th FUNDING SUSPENSION EXTENSION**

*** CYCLOPHARM APPOINTS SALES, REGULATORY, SERVICE STAFF**

*** ONCOSIL CFO NICHOLAS FALZON IN, TOM MILICEVIC, DR ASH SOMAN OUT**

MARKET REPORT

The Australian stock market fell 0.4 percent on Monday September 30, with the ASX200 down 27.8 points to 6,688.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and two were untraded.

Antisense was the best, up 1.1 cents or 16.4 percent to 7.8 cents, with 2.4 million shares traded. Paradigm climbed 13.8 percent; Uscom was up 8.7 percent; Mesoblast rose seven percent; Avita and Kazia were up more than six percent; Cyclopharm was up 5.5 percent; Resonance improved 4.35 percent; Compumedics, Optiscan, Orthocell and Volpara rose more than two percent; Cynata, Medical Developments and Oncosil were up more than one percent; with Cochlear and Telix up by less than one percent.

Genetic Signatures led the falls, down 13 cents or 11.2 percent to $1.035, with 59,486 shares traded. Pharmaxis and Prescient lost more than seven percent; Next Science was down six percent; Universal Biosensors fell five percent; LBT fell 4.55 percent; Ellex was down 3.5 percent; Opthea and Osprey shed more than two percent; with Nanosonics and Neuren down more than one percent.

USCOM

Uscom says it hopes to raise up to $1,050,000 through a private placement of shares at 10 cents each to management and major shareholders.
Uscom said the funds raised would be used to build new Uscom 1A, BP+ and Spirosonic devices following record manufacturing in June, support marketing initiatives in China, Europe and the US, and to cover the costs of China and US regulatory approvals.
The company said 4,000,000 shares would be issued to Uscom China director Teresa Guo and “an unrelated current shareholder”.
Uscom said 3,000,000 shares would be issued to executive chairman Prof Rob Phillips, pending shareholder approval.
The company said it would offer up to $350,000 worth of shares to Meng Xianhui, to be acquired by December 31, 2019.
Uscom was up one cent or 8.7 percent to 12.5 cents.

KINOXIS THERAPEUTICS

Kinoxis says it has been awarded a US grant of up to $US4.6 million ($A6.8 million) to fund the pre-clinical and clinical development of KNX100 for opioid withdrawal.
Last year, Kinoxis said it had raised $3.9 million to develop small molecules that mimic oxytocin to treat substance abuse disorders with the University of Sydney and said that Uniseed, a venture fund operating at the Universities of Melbourne, New South Wales, Sydney and Queensland, and the Commonwealth Scientific and Industrial Research Organisation invested $750,000 of the total raised (BD: Feb 15, 2018).
Today, Kinoxis chief executive officer Hugh Alsop told Biotech Daily that the funds would cover the completion of the current toxicology study and other pre-clinical work in rats and dogs for the company’s US Food and Drug Administration investigational new drug application.
Mr Alsop said the company expected to start a human trial in healthy volunteers by the end of 2020.
Kinoxis said the grant was from the US National Institutes of Health (NIH) and the National Institute on Drug Abuse (NIDA) under the National Institutes of Health Helping to End Addiction Long-term (NIH Heal) initiative.
The company said that opioid withdrawal was the rapid onset of severe physical and mental distress following a partial or total reduction of opioid consumption.
Kinoxis said that opioid overdose was “the number one cause of preventable deaths in the US, killing more people than motor vehicle accidents” and that in Australia, opioids caused more than three deaths a day in 2018 and were linked to more than half of the drug-induced deaths.
The company said the NIH Heal initiative was launched in April 2018 to improve prevention and treatment strategies for opioid misuse and addiction and enhance pain management.
Kinoxis said the initiative aimed to improve treatments for chronic pain, curb the rates of opioid use disorder and overdose, and achieve long-term recovery from opioid addiction.
The company said that KNX100 was a small molecule therapeutic drug candidate being developed for a range of substance use disorders, including opioid use disorder.
Kinoxis said that the compound was discovered by researchers at the University of Sydney and had demonstrated potent anti-addictive properties in numerous pre-clinical models.
Kinoxis is a private company.

KAZIA THERAPEUTICS

Kazia says that two of nine patients in its phase I study of Cantrixil for ovarian cancer have had a partial response with tumors “reduced in size by 30 percent or more”.
In 2016, Kazia said it began the trial at five US and Australian sites and in 2018 said that 11 of 14 enrolled patients were well enough to receive treatment at the dose of 5.0mg/kg (BD: Dec 6, 2016; Oct 10, 2018).
In April, the company said one of nine-patients in the dose-escalation part A of the study had a partial response when co-administered with chemotherapy, with five patients achieving “stable disease after two cycles of Cantrixil monotherapy” (BD: Apr 1, 2019).
Today, Kazia said that new data was presented on a poster at a European Society for Medical Oncology meeting in Barcelona, showing that two of nine patients had a partial response, three had “stable disease” and four had “progressive disease”.
The company said the median progression-free survival across all nine patients was 5.5 months, compared to historical data for a similarly advanced population having a median of 3.4 months “suggesting that Cantrixil may help to delay tumor recurrence”.
Kazia said it had completed recruitment for a 12-patient phase Ib efficacy trial in August, and expected “to report data from this component of the study early in … 2020”.
Kazia was up 3.5 cents or 6.5 percent to 57 cents.

RESAPP HEALTH

Resapp says a 308-patient, at-home obstructive sleep apnoea study shows its diagnostic has more than 83 percent sensitivity and specificity from 73 to 90 percent.
Resapp said the prospective, blinded study analyzed breathing and snoring sounds recorded using a mobile telephone on a bedside table.
The company said that 13 patients with incomplete clinical data and 57 who had a partner or pet in the room were excluded, and of the 238 analyzable patients, 37 percent were female, the mean age was 49 years (ranging from 18 to 82 years) with a mean apnoea hypopnoea index (AHI) of 27 per hour, ranging from zero to 119/h.
The company said the endpoints were the algorithms’ performance in identifying three severities of obstructive sleep apnoea from mild (AHI ≥ 5/h), to moderate (AHI ≥ 15/h) and severe (AHI ≥ 30/h) when compared to an American Academy of Sleep Medicine Type II sleep study of full, but unattended poly-somnography in the patient’s home.
Resapp said that for all three AHI thresholds, the area under the curve was greater than 0.91 showing that the algorithms, when used at-home, had “an excellent ability to identify mild, moderate or severe [obstructive sleep apnoea]”.
The company said that for the three AHI thresholds of 5/h, 15/h and 30/h the software had a sensitivity of 85 percent, 83 percent and 83 percent, respectively, and a specificity of 73 percent, 80 percent and 90 percent, respectively with the measure of specificity for 5/h “limited due to the low numbers of study participants with very low AHI”.
Resapp chief executive officer Dr Tony Keating said “we achieved excellent performance previously during our in-laboratory sleep studies and it is great to see the same high levels of performance replicated in our intended use setting, in peoples’ homes”.
“Nearly one billion people suffer from sleep apnoea and 80 percent of those with moderate or severe sleep apnoea remain undiagnosed,” Dr Keating said.
“By delivering a highly scalable, low cost smartphone app for [obstructive sleep apnoea] screening we have a huge opportunity to reduce the health and economic impact of undiagnosed [obstructive sleep apnoea],” Dr Keating said.
Resapp was up 2.5 cents or 11.4 percent to 24.5 cents with 3.3 million shares traded.

INVION

Invion says it is optimizing its Photosoft-based IVX-PDT cancer drug, in preparation for a trial for basal cell carcinoma by July 2020.
Invion said its aim was to generate “a high purity compound which addresses all regulatory and clinical requirements and can be manufactured at large scale, allowing for efficient market supply” and had developed IVX-P03, a higher purity version of IVX-P02.
The company said that further optimization and definition of IVX-PDT would include laboratory studies to ensure that the same drug compound could be used in a variety of forms for various cancer types.
Invion said the first clinical study for basal cell carcinoma was expected to begin by July 2020, with other skin indications such as actinic keratosis to follow.
The company said basal cell carcinoma was a common skin cancer which was typically managed by surgery, which was effective in most cases, but could lead to scarring.
Invion said it was developing the topical IVX-Skin as a treatment for basal cell carcinoma and working with Melbourne’s Formulytica, it had developed a gel formulation which was well-tolerated in animal topical safety studies.
The company said it had hired Brisbane’s Veracity Clinical Research to conduct the trial with Dr Lynda Spelman as principal investigator.
Invion said lasers commissioned from the Guangxi, China-based Guilin Xingda Photoelectric Medical Device Co had been received and were in pre-clinical studies.
Invion said it was investigating the application of an intra-venous formulation in solid cancers, such as mesothelioma and lung cancer.
Invion fell 0.1 cents or 6.25 percent to 1.5 cents with 7.3 million shares traded.

NOXOPHARM

Noxopharm says that combining its Veyonda (NOX66) with 177-lutetium prostate specific membrane antigen (177Lu-PSMA) radiotherapy is superior to 177Lu-PSMA alone.
Noxopharm said that Veyonda “boosts the anticancer effect of the intravenous radiopharmaceutical … 177Lu-PSMA in men with late-stage prostate cancer”.
The company said that one of the aims of its study was to see if Veyonda could boost 177Lu-PSMA so that more men were able to complete the full course of radiation before the cancer progressed and they need to stop treatment (BD: Sep 5, 2018; May 23, 2019).
Today, Noxopharm said that 14 patients receiving 177Lu-PSMA alone were compared to 16 patients receiving the combination therapy, with the latter group starting “with a higher overall prostate specific antigen (PSA) level, suggesting that the cancer was more progressed in this group at the start of treatment”.
The company said that 11 patients in the combination group had a PSA reduction of 69 percent compared to five in the 177Lu-PSMA alone group; progression free survival was 8.4 months for the combination group compared to 2.0 months for the 177LU-PSMA alone group; and 11 patients (69%) in the combination group were able to start the fourth cycle of treatment, compared to three of 14 patients (21%) in 177LU-PSMA alone group.
Noxopharm said the combination therapy was well tolerated.
Noxopharm executive chairman Dr Graham Kelly said the data was “exciting … because anti-cancer drug trials rarely deliver such significant improvements in response rates”.
Noxopharm said that the data came from two separate clinical studies at the same hospital and with the same clinicians, as well as similar patient selection criteria and treatment protocols.
“Hence the validity in comparing the two sets of data,” the company said.
Noxopharm was up 3.5 cents or 9.7 percent to 39.5 cents.

INVITROCUE

Invitrocue says it expects to open a commercial research and development laboratory in Hong Kong by November 2019.
Invitrocue said that the laboratory would provide better contact with users of its Onco-patient-derived organoids (PDO), as well as provide distribution opportunities in China and Macau.
The company said the laboratory was located in the Hong Kong Science and Technology Park, a regional hub for innovation and technology development.
Invitrocue said it had hired staff, including a general manager, a research and development manager and a clinical coordinator, but did not disclose who had filled the roles.
Invitrocue executive chairman Dr Steven Fang said the new laboratory was “an important milestone in the international expansion of our capability to help cancer patients receive the right drug at the right time”.
Invitrocue was in a suspension and last traded at six cents.

IMMUTEP

Immutep will vote to grant 51,000,000 performance rights to chief executive officer Marc Voigt and director Pete Meyers, and approve a one-for-10 share consolidation.
Immutep said that it proposed to issue 36,000,000 free performance rights to Mr Voigt, in addition to his salary, in three equal tranches of 12,000,000 shares each, vesting yearly from October 1 2020 to 2022, expiring one year after the vesting date.
The company said the rights were service-based and would be granted on the condition that Mr Voigt remained with the company.
Immutep said it proposed to grant 15,000,000 performance rights in lieu of the $105,000 yearly director’s fee to Mr Meyers.
The company said the rights would vest in three equal tranches of 5,000,000 shares under the same conditions as Mr Voigt’s performance rights.
Immutep said it proposed to consolidate its share capital through the conversion of every 10 shares into one share in the company.
The company said that if the resolution was passed its current 3,866,243,835 shares would be reduced to 386,624,384 shares.
Immutep said that other resolutions included the adoption of a remuneration report, the re-election of Mr Meyers, approval of an additional 10 percent placement capacity, and the ratification of previous share and warrant issues.
The meeting will be held at Boardroom Pty Ltd, Level 12, 225 George St, Sydney, on November 1, 2019 at 11am (AEDT).
Immutep was unchanged at 2.3 cents with 10.4 million shares traded.

MESOBLAST

Mesoblast says that 14,464,259 shares will be released from voluntary escrow on October 12, 2019.
According to the company’s most recent Appendix 3B, Mesoblast would have 498,659,542 shares available for trading after the release.
Mesoblast was up 0.4 cents or 6.15 percent to 6.9 cents with 3.15 million shares traded.

PHYLOGICA (TRADING AS PYC THERAPEUTICS)

Phylogica has requested a trading halt “pending an announcement to the market regarding a proposed strategic partnership that is material to the company”.
Trading will resume on October 2, 2019 or on an earlier announcement.
Phylogica last traded at 4.4 cents.

AVITA MEDICAL

Avita says it has been approved to list on the Nasdaq on October 1, 2019, under the ticker code RCEL.
In 2012, Avita listed on the Over-The-Counter Quality Exchange (OTCQX) trading American depositary receipts under the code AVMXY (BD: Mar 29, 2012).
Today, the company said that shareholders of with OTCQX listed shares do not need to take any action as the AVMXY shares would automatically move to the Nasdaq and trade under the RCEL ticker symbol.
Avita said its securities on the ASX would continue to trade without interruption.
Avita chief executive officer Dr Michael Perry said that “following the robust uptake and adoption of our Recell system by US burn centers, we view the trading of our American depositary shares on the Nasdaq as a natural extension of our growth plan”.
Avita was up 3.5 cents or 6.3 percent to 59 cents with 13.5 million shares traded.

AVITA MEDICAL

The New York-based Morgan Stanley says it has ceased its substantial holding in Avita.
Morgan Stanley said that in 30 trades on September 25 it bought, sold, returned and borrowed shares, with the single largest sale 71,582 shares for $43,307 or 60.5 cents each.
On Friday, Morgan Stanley said it had become a substantial shareholder in Avita with the equivalent of 139,908,470 shares or 7.47 percent with the single largest purchase 609,441 shares for $267,384 or 43.9 cents a share (BD: Sep 27, 2019).

OSTEOPORE

The Rain Maker Management, Prof Hanry Yang, Marcus Liew, and directors Goh Khoon Seng and Prof Teoh Swee Hin say they are substantial holders in Osteopore.
Last week, Osteopore said it listed on the ASX to develop its three-dimensional printing with bio-resorbable materials for bone regeneration (BD: Sep 23, 2019).
Today, in separate announcements, five Singapore-based holders said they were above the five percent substantial shareholding mark.
The Rain Maker Management for Benny Chua Kok Meng (Benny Cai Guomin) said it held 15,285,927 shares or 15.10 percent of the company.
Invitrocue director Prof Yang said he had 9,084,936 shares or 8.97 percent of Osteopore.
Mr Liew said he had 7,142,785 shares or 7.06 percent of the company.
Osteopore director Prof Teoh said he had 7,030,309 shares or 6.94 percent of the company.
Company director Mr Goh said he had 6,835,617 shares or 6.75 percent of Osteopore.
Osteopore was up 4.5 cents or 4.9 percent to 96 cents with 1.4 million shares traded.

ADMEDUS

Admedus has requested an eighth extension to its voluntary suspension to finalize its re-capitalization plan.
In April, Admedus requested a trading halt “pending an announcement regarding the ... immunotherapies sale transaction” and later requested a voluntary suspension for the sale of Admedus Vaccines, formerly Coridon (BD: Apr 15, 17, 2019).
On April 23, the company responded to an ASX aware query, announced the termination of the Vaccine business sale and requested an extension to the suspension “to finalize the ... recapitalization plan” (BD: Apr 23, 2019).
Between May and September, Admedus requested six more extensions without providing any further information (BD: May 7, 21; Jun 4; Jul 1, Aug 5, Sep 2, 2019).
Today, the company said it expected the suspension to last until October 15, 2019, or the release of an earlier announcement.
Admedus last traded at six cents.

CYCLOPHARM

Cyclopharm says it has appointed Dr Mark Doverty, Niamh McAree, Sally-Ann Cornelius and Chris Quinn to senior management roles.
Cyclopharm said it had appointed Dr Doverty as the head of regulatory compliance and clinical research, Ms McAree as quality and regulatory head, Ms Cornelius as head of sales and Mr Quinn as head of service.
The company said Dr Doverty was previously the manufacturing quality head at the Australian Therapeutic Goods Administration.
Cyclopharm said Ms McAree had extensive international experience in medical device and pharmaceutical manufacturing compliance with both Merck and Terumo.
The company said Ms Cornelius had 20 years’ experience working in nuclear medicine and molecular imaging, and most recently was the head of molecular imaging as Bayer Radiology Australia and New Zealand.
Cyclopharm said Mr Quinn had worked with medical devices since 2005 at Gammasonics, had established a service division at Global Medical Solutions Australia, and worked in Molecular Imaging at Bayer Radiology Australia and New Zealand.
Cyclopharm was up six cents or 5.5 percent to $1.15.

ONCOSIL MEDICAL

Oncosil says Nicholas Falzon will replace Tom Milicevic as chief financial officer and company secretary, and Dr Ash Soman has resigned as chief medical officer.
Oncosil said that Dr Soman had stepped down effective September 20 and Mr Milicevic had resigned effective September 27, 2019.
The company said Mr Falzon was a director at PFK Chartered Accountants and had been associated with Oncosil for almost 10 years.
Oncosil said that “day-to-day management and medical monitoring of the ongoing clinical trial program has been fully outsourced to the clinical research organization already contracted to support this program”.
Oncosil was up 0.1 cents or 1.6 percent to 6.5 cents.