Biotech Daily

Monday December 17, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: AIRXPANDERS UP 8%; IMUGENE DOWN 9%**

*** IMUGENE: HER-VAXX FOR GASTRIC CANCER 'SAFETY, RESPONSES'**

*** GENETIC SIGNATURES EASYSCREEN RESPIRATORY KIT CE MARK**

*** FEDERAL GOVERNMENT $3m FOR PAEDIATRIC LEUKODYSTROPHIES**

*** IMAGION, PLANET INNOVATION TO DEVELOP MAGSENSE**

*** NUHEARA, UK SPECSAVERS PARTNER FOR IQBUDS SALES**

*** RACE: TRUEMED SELLS AML NAMED PATIENT BISANTRENE IN ISRAEL**

*** DORSAVI REQUESTS 'RIGHTS ISSUE RESULTS' HALT**

*** TBG BUYS ZHANGYE MEDICAL LAB FOR CHINA TESTING SERVICES**

*** VIRBAC ORDERS $350k CRESO ANIMAL MARIJUANA PRODUCTS**

*** GENERA AGM PASSES ALL RESOLUTIONS**

*** VINVA BELOW 5% IN MAYNE**

*** GREY INNOVATION, TWO BULLS TO TAKE RESPIRI STAKE; CHINA**

*** NEUREN CSO DR LARRY GLASS RETIRES AS DIRECTOR**

*** OVENTUS APPOINTS SHARAD JOSHI DIRECTOR**

MARKET REPORT

The Australian stock market was up 1.0 percent on Monday December 17, 2018, with the ASX200 up 56.3 points to 5,658.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and four were untraded.

Airxpanders was the best, up 0.2 cents or 8.3 percent to 2.6 cents, with 640,420 shares traded. Genetic Signatures climbed 7.7 percent; Immutep, Nanosonics, Pro Medicus and Telix improved more than three percent; Cochlear and CSL rose two percent or more; Neuren and Proteomics were up more than one percent; with Clinuvel, Medical Developments and Mesoblast up by less than one percent.

Imugene led the falls, down 0.2 cents or 9.1 percent to two cents with 24.3 million shares traded. Orthocell lost 6.25 percent; Kazia shed 5.2 percent; Actinogen fell 4.2 percent; Antisense was down 3.3 percent; Avita, Cynata, Ellex, Impedimed, Polynovo, Prescient and Volpara shed two percent or more; Compumedics and Starpharma were down more than one percent; with Opthea and Resmed down by less than one percent.

IMUGENE

Imugene says its 14-patient phase Ib study of its HER-Vaxx gastric cancer vaccine with chemotherapy shows it is safe and increased antibody response in all dose levels.
Imugene said HER-Vaxx was studied at 10 micrograms (µgm), 30 µgm and 50 µgm, with the standard-of-care chemotherapy, cisplatin and fluorouracil or capecitabine.
The company said that all dose levels showed an increased antibody response in patients, no safety issues were reported and HER-Vaxx was found to be well tolerated.
Imugene said the cohort review committee recommended a dose of 50 micrograms for the phase II dose and it expected to dose the first phase II patient in "early 2019".
Imugene said that of the 10 patients evaluable for tumor growth assessment, five patients had a partial response and four showed stable disease.
Imugene chief executive officer Leslie Chong said the company was "cautiously encouraged by meeting all the endpoints of the study and data from the top-line results in a small sample size, in particular the five patients whose best response showed more than 30 percent decrease in their tumor size from baseline scans".
"With these early results from the HER-Vaxx clinical study, Imugene's B-cell active immunotherapy approach is showing positive signs which provides us with further confidence in our B-cell immunotherapy pipeline," Ms Chong said.
Imugene said that HER-Vaxx was designed to produce an antibody response against the HER-2 cancer growth signal receptor protein, which was found on the cell surface in breast and gastric cancers.
The company said that a 68-patient, phase II study would test the efficacy, safety and immune response in gastric cancer patients with metastatic gastric cancer over-expressing the HER-2 protein, randomized to either HER-Vaxx plus standard-of-care chemotherapy or standard-of-care alone.
Imugene said that the primary endpoint was overall survival and the secondary endpoint would be progression-free survival.
Imugene fell 0.2 cents or 9.1 percent to two cents with 24.3 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has Conformité Européenne (CE) mark in-vitro diagnostic (IVD) registration for its Easyscreen respiratory pathogen detection kit.
Genetic Signatures said that rapid identification of viral respiratory infections was "critical in initiating antiviral treatment and limiting the spread of the infection" and its Easyscreen kit identified 14 common respiratory pathogens, including influenza A and B, rhinovirus and Mycoplasma pneumoniae.
The company said the Easyscreen respiratory pathogen detection kit allowed for rapid detection of pathogens in up to 94 specimens per batch in about 4.5 hours with minimal hands-on time for laboratory technicians, allowing a rapid high-throughput workflow.
Genetic Signatures said the respiratory pathogen detection kit was the third Easyscreen product to receive the CE mark approval, following the enteric range for protozoan, viral and bacterial targets and its antibiotic resistant kit, and it expected Australian Therapeutic Goods Administration approval "in the coming months".
Genetic Signatures chief executive officer Dr John Melki said that "registration of our respiratory kit is an important achievement within our European commercialization efforts".
"Our regulatory and product development teams have a proven track record of taking product through the regulatory process with three product ranges achieving full CE-IVD registration in the last 18 months," Dr Melki said.
Genetic Signatures was up six cents or 7.7 percent to 84 cents.

FEDERAL GOVERNMENT

The Federal Government says it will provide $3 million for rare childhood brain disorders known as leukodystrophies.

In a media release, Federal Health Minister Greg Hunt said the research would be led by the Melbourne-based Royal Children's Hospital's Prof Richard Leventer and the University of Queensland's Prof Ernst Wolvetang.

The media release said Prof Leventer was part of the team that discovered Massimo Damiani's rare variant of leukodystrophy.

The Government said that Mr Damiani was diagnosed with the disease in 2009 and died last year.

Mr Hunt said that leukodystrophy is a rare genetic condition characterized by degeneration of the white matter of the brain and the Australian-led research team, pioneered a new "trio whole genome" sequencing approach to establish that Massimo's condition was caused by mutations in a gene not previously associated with the disease.

Mr Hunt said that the $3 million funding would "allow researchers to understand disease mechanisms faster and test potential therapies in potentially life-changing timeframes".

"This research begins with patient recruitment for genomic diagnosis, moving to disease modelling and pre-clinical testing, then full circle back to the patient with the promise of human clinical trials for novel treatments," Mr Hunt said.

The media release said that leukodystrophies affected the central nervous system and caused loss of normal brain function, leading to progressive and severe intellectual and physical disabilities.

The Government said that there were no cures for most leukodystrophies, life expectancy was typically months to several years at best and quality of life could be extremely poor.

The media release said that until recently about half of cases presenting with these debilitating conditions remained unsolved.

The Federal Government said the funding would support research into faster genomic diagnostics for both known and unresolved cases of leukodystrophies and develop adaptable, repeatable and scalable disease modelling and translational capabilities for the clinical treatment of rare childhood brain disorders.

The Government said that the research aimed to reduce the proportion of undiagnosed leukodystrophies to less than 10 percent by 2020 by applying genomic technologies to provide more diagnoses for Australian children with leukodystrophies.

IMAGION BIOSYSTEMS

Imagion says Melbourne-based Planet Innovation will help develop its Magsense cancer imaging technology.

Imagion said the two companies would work on design concepts and the development of prototype systems for its pivotal clinical study.

Imagion Biosystems executive chairman Bob Proulx said the company was "very excited to team up with Planet Innovation to assist us in the next steps towards commercialization of the Magsense technology".

"As we are rapidly approaching our first in human study for the nanoparticle component of our technology, we now need to add focus on the instrument platform," Mr Proulx said.

"Planet Innovation is a world class engineering and design firm that can take our expertise and know-how on the Magsense instrument technology to help us develop our first clinical and commercial product," Mr Proulx said.

Imagion fell 0.1 cents or 2.8 percent to 3.5 cents.

NUHEARA

Nuheara says it will sell its Iqbuds and Iqbuds Boost hearing and sound filtering devices through optical and hearing retailer Specsavers Optical Group.
Nuheara said that the Guernsey-based Specsavers has 1,978 shops in the UK, Guernsey, Jersey, Ireland, Norway, Sweden, Finland, Denmark, the Netherlands, Spain, Australia and New Zealand.
The company said its range of smart hearing buds would be trialed in the Sussex Specsavers shop with a view to increased roll-out over 2019.
Nuheara said that Specsavers had revenues of more than GBP2.6 billion ($A4.6 billion), was the UK's largest optical retailer, with more than 36 million customers and was "one of Europe's pioneers in adopting the cross-over sales approach of optical and audiology products, by entering the hearing market in 2002".
The company said that Specsavers had audiology services in more than 900 optical shops, including Australia, and sold 337,770 hearing aids last financial year.
Nuheara said that its range of smart hearing buds would allow Specsavers shops to participate in the hearing healthcare market, with or without audiologists and the shops with audiological services would be able to recommend and sell its devices to customers not ready to receive a hearing aid but needing support in the mild to moderate hearing loss category.
Nuheara said that it had approval for its hearing devices from the UK National Health Service and Specsavers was "a champion of the NHS" with 60 percent of its 17.3 million UK customers funded by the NHS, and the largest private provider of NHS digital hearing aids.
The company said that Specsavers provided support to regions and towns not able to be serviced by NHS hospital-based audiological services.
Nuheara was up 0.3 cents or 4.35 percent to 7.2 cents with 14.1 million shares traded.

RACE ONCOLOGY

Race says the Netanya, Israel-based Truemed will sell and distribution Bisantrene for acute myeloid leukaemia in Israel under a named patient program.
Race said that Truemed was a pharmaceutical distributor with experience in driving named patient programs in Israel.
Race chief executive officer Peter Molloy said that "Israel could be an important contributor to future global [named patient program] sales of Bisantrene".
The company said that under the three-year agreement, Truemed would take 40 percent of Bisantrene sales turnover and had the exclusive right to sell and distribute Bisantrene in Israel for named patient program use, sourcing Bisantrene exclusively from distribution partner Durbin, in the UK.
Race said that Truemed would be responsible for regulatory approval.
Race fell 0.2 cents or 2.25 percent to 8.7 cents with 1.5 million shares traded.

DORSAVI

Dorsavi has requested a trading halt "pending an announcement … in relation to the one-for-three non-renounceable rights issue … and the placement of the under-subscriptions".
In November, Dorsavi said it hoped to raise up to $3.2 million through the rights offer at 5.8 cents a share (BD: Nov 21, 2018).
Trading will resume on December 19, 2018 or on an earlier announcement.
Dorsavi last traded at 6.2 cents.

TBG DIAGNOSTICS

TBG says it will acquire the Zhangsha Zhangye Medical Laboratory Corp, through its subsidiary TBG Biotechnology Xiamen, with Zhangye taking 42.1 percent of TBG Xiamen.
TBG said that the Zhangsha, Hunan-based Zhangye provided medical laboratory testing services to hospitals and the community.
The company said Dongyuan Huaxin (Beijing) Capital Management was a private equity firm, one of the parties in the agreement and would provide capital for TBG Xiamen.
TBG said Dongyuan would be issued 11.25 percent of TBG Xiamen for RMB10,679,283 ($A2,158,393) in cash and TBG would hold 46.65 percent of TBG Xiamen.
The company said the funds would expand the capabilities of its laboratories. molecular diagnostic kits and associated products; expand its sales capabilities; and distribution.
TBG said the proposed transactions would decrease consolidated assets by $1,917,012, or 13 percent; decrease consolidated equity by $709,060 or five percent; reduce half year revenue by $384,221; and reduce half year loss by $385,500.
TBG was up 0.1 cents or 2.3 percent to 4.5 cents.

CRESO PHARMA

Creso says European distributor Virbac has made its first order for $350,000 of marijuana-based food additive animal health products.
In 2017, Creso said it had a three-year commercialization deal with Virbac Switzerland to distribute marijuana-based food additives for cats and dogs in Switzerland and Lichtenstein. (BD: Aug 7, 2017).
Today, Creso chief executive officer Dr Miri Halperin Wernli said “we have a promising start with our animal health products in Switzerland and Liechtenstein with very encouraging feedback from veterinarians, clinics and pet owners and we are now entering the expansion phase into many countries in Europe and Latin America”.
Creso was up half a cent or 1.4 percent to 36.5 cents.

GENERA BIOSYSTEMS

Genera says all resolutions to its 2018 annual general meeting were passed easily, with the strongest dissent 2.5 percent against a mezzanine loan facility.
Although Genera called the meeting for 11am, the company posted the results after the market closed at 5.52pm on Friday December 14, 2018.
Genera was untraded at 16 cents.

MAYNE PHARMA

The Sydney-based Vinva Investment Management says it has ceased to be a substantial share-holder in Mayne Pharma.
Vinva said that between December 5 and 12, 2018 it bought 103,279 shares for $97,630 or 94.5 cents a share and sold 106,864 shares for $97,125 or 90.9 cents a share.
Earlier this month, Vinva said it bought 99,648,311 shares for $116,410,485 or $1.168 a share, sold 165,726 shares for $192,671 or $1.163 a share and “transferred” 153,481 shares of no cost (BD: Dec 6, 2018).
At that time Vinva said it held 78,822,159 shares or 5.00 percent of Mayne.
Biotech Daily calculates, Vinva continues to hold 78,818,574 shares or 4.98 percent.
Mayne was up 3.5 cents or 3.9 percent to 93 cents with 6.1 million shares traded.

RESPIRI

Respiri says that development partners Grey Innovation and Two Bulls will acquire shares in the current fund raising, with an unnamed Chinese company “interested”.
Last week, Respiri requested a trading halt for a capital raising (BD: Dec 14, 2018).
Today, the company said that Grey Innovation founder and director Jefferson Harcourt and Two Bulls under the leadership of founding partner Evan Davey would “add their significant technical expertize with their appointment as strategic advisors”.
Respiri chief executive officer Mario Gattino said that Grey and Two Bulls had “played an important role in helping Respiri achieve our milestones and get to this exciting next phase, the 2019 launch of the wheeze monitor the world is waiting for”.
Mr Harcourt said “we believe in the technology and we believe in the ability of Respiri to realize its global potential with the strong consumer marketing experience of Mario Gattino and [chief customer experience and communications officer] Wani Wall”.
In a separate announcement, Respiri said it was “well-advanced in negotiations with a major China-based pharmaceutical group to optimize the planning and market entry of Respiri into the Chinese market”.
“This party has expressed interest in extending the partnership to include an equity investment in Respiri,” the company said.
Respiri was untraded at 9.3 cents.

NEUREN PHARMACEUTICALS

Neuren says that chief science officer and former chief executive officer Dr Larry Glass will retire as a director effective from December 31, 2018.
Neuren said that Dr Glass would continue as the chief science officer.
Neuren executive chairman Dr Richard Treagus said the company had “strengthened and refreshed the board through the appointment of three non-executive directors [and] that now enables Larry to retire as a director and focus on his important executive role as we advance the development of NNZ2591 and approach the start of the trofinetide phase III trial”.
Neuren was up two cents or 1.45 percent to $1.40.

OVENTUS MEDICAL

Oventus says it has appointed the Boston-based Sharad Joshi as a non-executive director, effective from December 14, 2018.
Oventus said that Mr Joshi had been involved in the medical technology industry for more than 30 years and held executive positions for the past 10 years.
The company said that most recently Mr Joshi was Microline Surgical’s chief executive officer.
Oventus said that Mr Joshi “had exposure to the sleep market”, experience with intellectual property, management, regulatory approvals, sales and marketing of medical devices including launch, capital raising and investor relations.
Oventus was untraded at 27 cents.