Biotech Daily

Monday November 25, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: KAZIA UP 66%; IMUGENE DOWN 8%**

*** KAZIA: GCD-0084 GLIOBLASTOMA EARLY DATA: 'CLINICAL BENEFIT'**

*** NOVITA PLACEMENT RAISES $6.2m; TOTAL $8m**

*** RECCE REQUESTS 'TEST RESULTS' TRADING HALT**

*** MICRO-X INSTALLS 1st MINI X-RAY AT ALFRED HOSPITAL**

*** AVITA, GATES CENTER: SPRAY-ON G-M SKIN FOR EB**

*** IMUGENE COMPLETES CF33 GMP BATCHES**

*** CYNATA APPLIES FOR UK CYP-002 CRITICAL LIMB TRIAL**

*** OPTISCAN TO MEET FDA FOR ORAL CAVITY IMAGING**

*** DIMERIX: FDA PHASE III DMX-200 FSGS MEETING 'PROVIDES CLARITY'**

*** UP TO 13% DISSENT AT ADHERIUM AGM, 2nd SPILL AVOIDED**

*** CORRECTION: PHARMAXIS**

*** CE MARK APPROVAL FOR SIMAVITA'S SMARTZ NAPPY; UP 480%**

*** HERAMED HERABEAT for INDIA'S CLOUDNINE HOSPITAL GROUP**

*** AUSCANN, ASPEN 3-YEAR PACKAGING AGREEMENT**

*** US DEA 'DE-SCHEDULES' BOTANIX SYNTHETIC MARIJUANA**

*** SELECTOR TAKES 5% OF NANOSONICS**

*** SIENNA CEO CARL STUBBINGS STARTS ON $327k**

*** RESPIRI: MARJAN MIKEL CEO, DIRECTOR; MARIO GATTINO GOES**

MARKET REPORT

The Australian stock market was up 0.32 percent on Monday November 25, 2019, with the ASX200 up 21.6 points to 6,731.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and three were untraded.

Kazia was the best, up 29 cents or 65.9 percent to 73 cents with 3.7 million shares traded. Resonance climbed 9.4 percent; Opthea, Optiscan and Osprey were up five percent or more; Pharmaxis improved 4.4 percent; Paradigm was up 3.7 percent; Avita, Ellex, LBT and Oncosil rose more than two percent; CSL, Proteomics and Starpharma were up more than one percent; with Mesoblast and Neuren up by less than one percent.

Imugene led the falls, down 0.5 cents or 8.8 percent to 5.2 cents with 82.1 million shares traded. Patrys lost 8.3 percent; Polynovo shed six percent; Antisense, Immutep and Pro Medicus lost more than five percent; Medical Developments and Next Science fell more than four percent; Clinuvel was down 3.2 percent; Cyclopharm, Cynata and Volpara shed more than two percent; Genetic Signatures, Nanosonics, Orthocell and Telix were down more than one percent; with Cochlear and Resmed down by less than one percent.

KAZIA THERAPEUTICS

Kazia says data from the first nine of 29 patients in its phase II, US study of GCD-0084 for glioblastoma shows the drug “may provide clinical benefit”.
Kazia said that the data was presented as a poster at the Society of Neuro-Oncology meeting in Phoenix, Arizona between November 20 and 24, 2019.
The company said that median progression-free survival was calculated at 8.4 months, compared with 5.3 months for the existing standard-of-care, temozolomide, which implied “that GDC-0084 may delay progression of glioblastoma”.
Kazia said that cross-study comparisons “must always be treated with caution” and the median overall survival “could not be calculated due to insufficient death events”, with six out of eight evaluable patients alive at analysis cut-off date.
In May, the company said the first dose escalation stage of the 9-patient phase II study established 60mg as the maximum tolerated dose of GDC-0084 (BD: May 6, 2019).
Today, Kazia said that the second stage of the study was enrolling 20 patients at seven US sites and would treat all patients at the maximum tolerated dose, which was “designed to elicit confirmatory signals of clinical efficacy”.
The company said that GDC-0084 safety was consistent with prior experience, with hyperglycaemia or raised blood sugar, and oral mucositis, or mouth ulcers, and rashes among the most common drug-related toxicities, with hyperglycaemia and oral mucositis observed at 75mg.
Kazia chief executive officer Dr James Garner said that the preliminary data was “around a third of the total patients to be enrolled, but it has already exceeded our expectations”.
“We see a clear signal that GDC-0084 is providing clinical benefit in this group of patients,” Dr Garner said.
“Although it has not yet been possible to calculate overall survival, the fact that the majority of patients in the first stage of the study remain alive more than a year after diagnosis suggests that a meaningful [overall survival] benefit may emerge as the study matures,” Dr Garner said.
Kazia climbed 29 cents or 65.9 percent to 73 cents with 3.7 million shares traded.

NOVITA HEALTHCARE

Novita says it has raised $6.2 million in a placement of shares at 6.2 cents each to institutions and new investors, taking the total raised to $8,055,797.
In September, Novita said it had raised $1,855,797 in a five-for-11 entitlement offer and shortfall placement at one cent a share (BD: Sep 19, 2019).
Today, the company said the placement price was a 10 percent discount to the last closing price and a 24.5 percent discount to the 15-day volume weighted average price.
Novita said the funds would be used to investigate neurological uses of its Tali technology beyond attention deficits in children, provide working capital, accelerate US marketing and sales, and support commercial activities in Australia, Europe and UK.
The company said that PAC Partners Securities was the placement’s lead manager.
Novita was unchanged at 6.9 cents with 45.3 million shares traded.

RECCE PHARMACEUTICALS

Recce has requested a trading halt “pending the release of an announcement relating to test results of the Company’s product, Recce 327”.
Trading will resume on November 27, 2019 or on an earlier announcement.
Recce last traded at 26 cents.

MICRO-X

Micro-X says it has installed its DRX Revolution Nano miniature x-ray system for mobile medical x-ray at Melbourne's Alfred Hospital.

Micro-X said the Alfred Hospital was the first centre in Australia to use the Nano in clinical diagnostic imaging.

The company said the Alfred Hospital would conduct three months of operational assessment of the x-ray in the emergency and trauma centre and the intensive care unit before confirming a purchase.

Micro-X said that the installation followed "a long collaboration between the Alfred's Radiology Department and … Micro-X from the earliest stages of the Nano's design and development".

Micro-X managing-director Peter Rowland said the DRX Revolution Nano was operational in 10 countries and Australia would be the eleventh.

"We are all very proud to have our revolutionary X-ray product now operating in an Australian hospital and being used to help Australian patients," Mr Rowland said.

"We have received expressions of interest to procure the Nano from a number of Australian hospitals and we are working with Carestream's newly appointed Australian distributor Quantum Health Group to ramp local sales of the Nano in the near term," Mr Rowlands said.

Micro-X was up half a cent or 2.1 percent to 24 cents.

AVITA MEDICAL

Avita says it will work with the Gates Center for Regenerative Medicine to develop a spray-on treatment of genetically modified cells for patients with epidermolysis bullosa.

Avita said the Gates Centre at the Aurora-based University of Colorado School of Medicine had developed therapeutic approaches for genetic skin diseases.

The company said epidermolysis bullosa was "a group of rare and incurable skin disorders caused by mutations in genes encoding structural proteins resulting in skin fragility and blistering, leading to chronic wounds and, in some sub-types, an increased risk of squamous cell carcinoma or death".

Avita said the partnership would combine its Recell spray-on skin cell technology with the Gates Center's combined reprogramming and gene editing technology.

The company said it would have the option to exclusively licence technologies emerging from the partnership for further development and commercialization.

Avita said the Gates Centre was financially supported by New York's Epidermolysis Bullosa (EB) Research Partnership, the Los Angeles EB Medical Research Foundation, London's Cure EB Charity and government grants "in a collaborative effort to rapidly develop and translate this technology to the clinic for meaningful impact on patient lives".

Avita chief executive officer Dr Mike Perry said that Gates researchers had "developed a powerful new approach for treating genetic skin disorders and improving the lives of patients with epidermolysis bullosa".

"This agreement marks an important milestone in Avita's mission to harness the potential of regenerative medicine to address unmet medical needs across a broad range of dermatological indications, including genetic disorders of the skin," Dr Perry said.

Co-principal investigator of the collaboration Prof Ganna Bilousova said that the combination of Avita's spray-on skin cell technology and the Gates Center's reprogramming and gene editing technology "could reduce time to treatment, lower manufacturing complexity, reduce costs and improve patient outcomes".

Avita was up 1.5 cents or 2.7 percent to 57.5 cents with 21.9 million shares traded.

IMUGENE

Imugene says the Los Angeles-based City of Hope has completed clinical grade good manufacturing practice batches for both constructs of its CF33 oncolytic virus.
Imugene said CF33 was developed in two constructs: Checkvacc, a version armed with an immune checkpoint inhibitor inserted in the virus; and Vaxinia, an unarmed construct.
The company said it planned to trial both constructs in separate phase I studies in 2020.
Imugene chief executive officer Leslie Chong said the Good Manufacturing Practice batch completion was “a significant milestone met in our preparation for commencing our planned CF33 oncolytic virus phase I clinical trials in 2020”.
Imugene fell half a cent or 8.8 percent to 5.2 cents with 82.1 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has applied to start a 90-patient, phase II trial of its Cymerus mesenchymal stem cell product CYP-002 for critical limb ischaemia.
In March, Cynata said the UK Medicines and Healthcare Products Regulatory Agency (MHRA) said the trial design was “generally acceptable” and provided “favorable advice” on manufacturing and quality control (BD: Mar 12, 2019).
Today, the company said it had filed a clinical trial authorization application with the MHRA and expected a response within 60 days, and hoped to begin the study in the UK and Australia “early in the coming year”.
Cynata fell three cents or 2.5 percent to $1.155.

OPTISCAN IMAGING

Optiscan says it will meet with the US Food and Drug Administration to discuss its 510(k) submission for its in-vivo, confocal, laser scanning system for oral cavity imaging.
Optiscan said it would meet with the FDA’s centre for devices and radiological health for feedback on the submission in “late January 2020”.
Optiscan was up 0.2 cents or 5.1 percent to 4.1 cents.

DIMERIX

Dimerix says the US Food and Drug Administration has “provided clarity” on the development of DMX-200 for focal segmental glomerulosclerosis (FSGS).
Dimerix said the pre-investigational new drug meeting with the FDA reviewed its dossier for its proposed phase III clinical program for focal segmental glomerulosclerosis, as well as supporting non-clinical study data, manufacturing and process controls, and existing phase I and II clinical data.
The company said focal segmental glomerulosclerosis was a disease affecting both adults and children which attacked the kidney’s filtering units, scarring tissues and causing kidney damage and kidney failure.
Previously, Dimerix said that DMX-200 had been granted EU and US orphan status for focal segmental glomerulosclerosis (BD: Nov 21, 2018; Dec 14, 2015).
Today, the company said the FDA confirmed that the proposed non-clinical package and proposed specifications for the manufacturing of its pharmaceutical-grade drug were “appropriate for registration of DMX-200”.
Dimerix chief executive officer Dr Nina Webster said the company expected to file the investigational new drug application after the readout of its phase II studies in mid-2020.
Dimerix was unchanged at 11 cents.

ADHERIUM

Adherium's annual general meeting passed all resolutions, but with up to 13.3 percent opposition to the remuneration report.

Adherium said that 10,487,912 votes (13.27%) opposed the adoption of the remuneration report, with 68,520,147 votes (86.73%) in favor.

Last year, the company said its remuneration report resolution was opposed by 33.2 percent of votes, providing the first trigger for a potential board spill at this year's meeting (BD: Nov 20, 2018).

Today, proxy votes overwhelmingly opposed the conditional spill resolution, which was not required following the 86.7 percent vote in favour, but the election of directors Thomas Lynch, Dr William Hunter and Matthew McNamara were opposed by similar margins to the remuneration report, with all other resolutions passing easily.

Adherium's most recent Appendix 3B said it had 174,031,986 shares on issue meaning that the opposition to the remuneration report amounted to 6.03 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.

Adherium was untraded at 4.1 cents.

PHARMAXIS

Friday's edition reported that all resolutions were passed at its Pharmaxis annual general meeting except for the re-election of non-executive director William Delaat.

The sentence should have said that all resolutions were passed *easily* at the Pharmaxis meeting except for the re-election of non-executive director William Delaat, which faced 14 percent dissent.

The headline and the second sentence with the detail of the vote were correct.

Biotech Daily apologizes unreservedly to Pharmaxis and Mr Delaat.

The mistake was made by the former Friday sub-editor who instead of simply editing the sentence to length made a mess of it and changed the entire meaning with the omission of one word.

Pharmaxis was up one cent or 4.4 percent to 23.5 cents.

SIMAVITA

Simavita says it has Conformité Européenne (CE) mark for its Smartz wearable and disposable nappy technology for adults and infants.

Simavita said that the Smartz nappy provided alerts through smartphone applications to carers and parents.

Simavita executive chairman Michael Spooner said that "achieving CE mark enables Simavita to commercialize our disruptive technology for adults and infants across the European economic area as well as in other regions that recognize CE mark".

Simavita was up 2.4 cents or 480 percent to 2.9 cents with 46.2 million shares traded.

HERAMED

Heramed says its Indian distributor Consultus India will supply its Herabeat foetal heartrate monitor to Cloudnine Hospital Group for patients to rent for at-home use.

Heramed said that Herabeat was marketed as Her Healthcare at Home, or H-Cube, in India, and Cloudnine had 20 maternity hospitals across seven states, with two hospitals in Bangalore and one near New Delhi chosen for the initial rollout.

Heramed fell three cents or 13.95 percent to 18.5 cents with 4.1 million shares traded.

AUSCANN GROUP HOLDINGS

Auscann says it has a three-year agreement with Sydney's Aspen Pharmacare Australia to package its medicinal marijuana pharmaceutical products.
Auscann said that Aspen would provide packaging services for its hard-shell capsules for chronic pain, manufactured by the Philadelphia, Pennsylvania-based PCI Pharma.
Auscann chief executive officer Ido Kanyon said that Auscann was on track to "getting its first capsules to market," with the solid hard-shell capsules expected to be released for clinical trials towards the end of 2019.
Auscann was up half a cent or 2.3 percent to 22.5 cents.

BOTANIX PHARMACEUTICALS

Botanix says that the US Drug Enforcement Administration has removed its synthetic marijuana products from Schedule 1 of the US Controlled Substances Act.
Botanix said that the de-scheduling would "significantly" decrease cost overheads around manufacturing, storing, shipping and running studies for Botanix products.
The company said its synthetic cannabidiol produced by partner the Athens, Georgia–based Purisys had been removed from schedule one, as well as all degradants, metabolites and analytical reference standards related to synthetic cannabidiol (CBD).
Executive chairman Vince Ippolito said the "change in the regulation of synthetic CBD in the US will make a major difference to the speed of developing Botanix products and greatly reduces the risks and costs of clinical development".
"The ability to manufacture at one site and distribute nationally and internationally means our supply chain is significantly simplified and our ability to recruit the best clinical sites, regardless of DEA licence status, is greatly enhanced," Mr Ippolito said.
Botanix was up half a cent or 4.8 percent to 11 cents with 1.2 million shares traded.

NANOSONICS

Sydney's Selector Funds Management says it has become substantial in Nanosonics with the acquisition of 15,020,747 shares or 5.00 percent.
Selector said it bought the shares between March 1, 2018 and November 22, 2019 but failed to disclose the prices paid as required under the Corporations Act 2001.
The company said that it held the shares "in its capacity as [an] investment manager" with holders including BNP Paribas Nominees, National Nominees, Invia Custodian, State Street Bank and Trust, AET Executor Trustees and RBC Investor Services.
Nanosonics fell 12 cents or 1.7 percent to $6.80 with 1.1 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says that recently-appointed chief executive officer and managing director Carl Stubbings will receive a base salary of $326,705 a year.
Last month, Sienna said it had appointed Mr Stubbings to replace Matthew Hoskin as chief executive officer (BD: Oct 16, 2019).
Today, the company said Mr Stubbings could receive a short-term incentive of up 20 percent of his base salary, or $65,341, subject to the achievement of corporate goals.
Sienna said Mr Stubbings had a long-term incentive of 2,900,000 options exercisable at 5.3 cents, a 25 percent premium to the 30-day volume weight average price, vesting in three equal tranches after execution of the employment contract and expiring in five years.
Sienna fell half a cent or 13.9 percent to 3.1 cents.

RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri says it has appointed Marjan Mikel as chief executive officer and a director replacing Mario Gattino with a further director to be appointed “shortly”.

Respiri’s most recent upheaval began last month with the announcement that Mr Gattino would “leave the company” and it had begun a search for a new chief executive officer (BD: Oct 9, 2019).

The company said at that time that “the deliverables” relating to its Wheezo asthma detection device were “not impacted by Mario’s departure and the company remains fully committed to delivering on the Board's strategy and meeting key milestones on time”.

Later that month the company said that remaining directors Ross Blair-Holt and Prof Bruce Thompson opposed the reelection of Mr Gattino as a director at its annual general meeting (BD: Oct 25, 2019)

That announcement was followed by the news that dissident shareholders requested a meeting to appoint Nicholas Smedley as a director replacing Ross Blair-Holt and Mario Gattino (BD: Oct 30, 2019)

In three separate announcements, on October 30, the company said it received the meeting request, Mr Smedley had been appointed a director, company secretary Alastair Beard would replace former chief executive officer Mr Gattino as interim chief executive officer, with Mr Gattino continuing as a director

Earlier this month, Respiri said Mr Smedley had replaced Mr Blair-Holt as chairman, Mr Blair-Holt and Mr Beard had resigned as directors, with Mr Beard continuing as company secretary and the board spill call had been rescinded (BD: Nov 15, 2019).

Today, along with its annual general meeting materials, Respiri said it had appointed Mr Mikel as chief executive officer and a director, effective from December 2, 2019.

The company said that Mr Mikel was an “experienced managing director and board member” and had worked in Australia, Europe and Japan.

Respiri said that Mr Mikel had founded and sold Healthy Sleep Solutions, with Resmed as a joint venture and shareholder partner.

The company said that Mr Mikel was currently a director of Memphasys and commercial advisor to software as a service company Portt.

Respiri said that Mr Mikel held a Bachelor of Science from the University of Sydney and a Master of Commerce from the University of New South Wales.

Respiri has been attempting to commercialize its wheeze test for asthma since 2006, saying it would be available in Europe and the US in February 2007 (BD: Nov 24, 2006).

In 2015, the then Isonea lost its fourth chief executive officer in a year and later said one issue with the diagnostic was it did not detect breath sounds (BD: Jan 23, Aug 6, 2015).

In 2018, the company said it had appointed Mark Ziirsen and Brendan Mason as directors, replacing Leon L’Huillier and John Ribot-de-Bresac, with Mr Ziirsen later appointed chairman (BD: Jun 14, 2018).

In October 2018, Respiri said it had appointed Dr Thomas Duthy as a director and in November, replaced Mr Ziirsen, Mr Mason and Dr Duthy with Mr Blair-Holt and Prof Bruce Thompson (BD: Oct 24, Nov 27, 2018).

Respiri was up 0.3 cents or 3.4 percent to 9.1 cents.