Biotech Daily

Thursday July 30, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: USCOM UP 5%; ANTISENSE DOWN 19%**

*** MARK SULLIVAN WINS CLUNIES ROSS ENTREPRENEUR AWARD**

*** CYNATA CYP-001 2-YEAR GvHD FOLLOW-UP: 60% SURVIVAL RATE**

*** OSPREY: GE HEALTHCARE TO DISTRIBUTE DYEVERT**

*** PARADIGM 10 US ACCESS PPS OA PATIENTS REPORT REDUCED PAIN**

*** STARPHARMA STARTS DEP DOCETAXEL COMBINATION STUDY**

*** ANTISENSE PLANS EURO, US TRIALS OF ATL1102 FOR DMD**

*** AROA: MYRIAD CE MARK; SYMPHONY FDA APPROVAL**

*** ORTHOCELL FILES CELGRO NERVE REPAIR TO TGA**

*** TALI SUPPLIES DETECT TO 1,6k PRIMARY SCHOOL CHILDREN**

*** MESOBLAST RECEIPTS DOWN 18% TO $35m**

*** HYDRIX RECEIPTS UP 29% TO $16m**

*** STARPHARMA RECEIPTS UP 158% TO $7.2m**

*** IQ3 RECEIPTS UP 29% TO $7.2m**

*** ELIXINOL H1 RECEIPTS DOWN 57% TO $7m**

*** MEDLAB RECEIPTS UP 11% TO $6.5m**

*** CARDIEX RECEIPTS $5.1m**

*** BIONOMICS RECEIPTS DOWN 59% TO $3.6m**

*** DORSAVI RECEIPTS DOWN 36% TO $2.4m**

*** AMPLIA RETAIL RIGHTS RAISE $1.83m; TOTAL $4m**

*** ZELIRA: 1 QUARTER CASH; CAPITAL RAISING TRADING HALT**

*** HEMIDEINA WINS FEDERAL $660k FOR HERA COCHLEAR IMPLANT**

*** ELIXINOL AGM: 19% OPPOSE DUFF, ELLERY RIGHTS**

*** NEUREN APPOINTS LAUREN FRAZER CFO, CO SEC**

*** NEUROSCIENTIFIC APPOINTS PROF DAO-YI YU ADVISOR**

MARKET REPORT

The Australian stock market was up 0.74 percent on Thursday July 30, 2020, with the ASX200 up 44.7 points to 6,051.1 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and one was untraded. All three Big Caps were up.

Uscom was the best, up one cent or 5.4 percent to 19.5 cents, with 175,841 shares traded, followed by Next Science up 5.1 percent to $1.44 with 113,071 shares traded.

Clinuvel, Mesoblast and Orthocell climbed more than four percent; Dimerix, Nanosonics and Resonance were up more than three percent; Cochlear, CSL, Impedimed, Nova, Pro Medicus and Prescient improved more than one percent; with Cynata, Medical Developments, Polynovo and Resmed up by less than one percent.

Antisense led the falls, down 1.9 cents or 19.0 percent to 8.1 cents, with 10.4 million shares traded.

Immutep lost five percent; Oncosil fell 4.2 percent; Amplia, Avita, Opthea and Proteomics were down more than three percent; Neuren, Osprey and Pharmaxis shed more than two percent; Compumedics, Genetic Signatures, Imugene, Paradigm, Universal Biosensors and Volpara were down more than one percent; with Starpharma and Telix down by less than one percent.

ACADEMY OF TECHNOLOGY AND ENGINEERING
MEDICINES DEVELOPMENT FOR GLOBAL HEALTH

The Academy of Technology and Engineering says Medicines Development for Global Health founder Mark Sullivan has won the Clunies Ross Entrepreneur Award.
The Academy said that Mr Sullivan won the Award for Entrepreneur of the Year “for his new approach to a tropical disease that is a leading cause of blindness”.
In 2018, the US Food and Drug Administration approved the Medicines Development for Global Health oral moxidectin 8mg for river blindness or onchocerciasis in patients aged 12 years and older, awarding it a priority review voucher (BD: Jun14, 2018).
Last year, Copenhagen’s Novo Nordisk bought the priority review voucher, but did not disclose the price (BD: Aug 13, 2019).
The website www.priorityreviewvoucher.org, maintained by voucher co-developer David Ridley, said that vouchers had been sold at prices ranging from $US68 million to $US350 million with the most recent recorded sale for $US105 million.
Today, the Academy of Technology and Engineering said that Mr Sullivan recognized the importance of re-purposing a veterinary medicine to treat and help eliminate river blindness, the world’s second-most common cause of blindness.
The Academy said
due to infection and Mr Sullivan raised the capital required to re-establish manufacturing, undertake pre-clinical and clinical trials, assembled the regulatory submission and won the approval for human use of moxidectin.
“In doing so, Mr Sullivan’s company became the first not-for-profit company in history to win solo US FDA approval for a new medicine,” the Academy said.
A media release from the Academy said that Medicines Development for Global Health had begun the process of introducing moxidectin into Africa and would begin development for four other tropical diseases affecting disadvantaged communities.

CYNATA THERAPEUTICS

Cynata says a two-year follow-up of its 15-patient phase I trial of CYP-001 for acute graft-versus-host disease (GvHD) has shown a 60 percent overall survival rate.

In 2018, Cynata said that at day-100 of the trial, 13 of 15 patients with steroid-resistant GvHD showed an improvement by at least one grade compared to baseline and eight of 15 patients' symptoms were completely resolved, with no treatment-related serious adverse events or safety concerns (BD: Dec 18, 2018).

Today, the company said that nine of 15 patients had survived two years following the initial dose, which compared "favourably with previously published outcomes".

Cynata said that comparable studies had shown 16.6 percent to 40 percent survival rates, which showed the "significant potential of CYP-001 as a new treatment option for GvHD".

The company said its GvHD licence partner, Fujifilm, was planning a phase II trial.

Cynata chief operating officer Dr Kilian Kelly said that the follow-up results "suggest that the high initial treatment response rates observed with CYP-001 100 days after treatment may result in a longer-term benefit".

"Overall, our phase I study results are very positive compared to published results with other methods of treatment," Dr Kelly said.

Cynata was up half a cent or 0.8 percent to 63 cents.

OSPREY MEDICAL

Osprey says that GE Healthcare will be its exclusive distributor in Europe, Russia, the Middle East, Africa, Central Asia and Turkey.

Osprey said that its Dyevert cardiac dye minimization devices were complemented by GE Healthcare's range of iodinated x-ray contrast media and together they provided a platform to address the rising problem of acute kidney injury (AKI) following interventional coronary angiograms in patients with chronic kidney disease.

The company did not disclose the commercial terms of the four-year agreement.

GE Healthcare head of pharmaceutical diagnostics Kevin O'Neill said the two companies "share a similar goal rooted in improving patient outcomes".

"Both our product portfolios and educational efforts, which are aligned with cardiology guidelines for AKI minimization, offer interventional cardiologists the opportunity to safely image patients by reducing the risk of AKI," Mr O'Neill said.

Osprey said that if it developed new products GE Healthcare would have the first right of refusal to distribute and promote them in the region.

Osprey fell 0.1 cents or 2.2 percent to 4.4 cents with 175.9 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says that 10 osteo-arthritis patients in its US injected pentosan polysulfate sodium expanded access program have reported reduced pain at 12 weeks.

Paradigm said that patients reported a 65 percent mean reduction in pain scores from baseline, following sub-cutaneous injection of pentosan polysulfate sodium, or Zilosul, twice weekly for six weeks, which was well-tolerated and with no serious adverse events.

The company said that oral non-steroidal anti-inflammatory drugs (NSAIDS) and opioids had been reported to reduce pain by about 30 percent.

Paradigm said that of the 10-patient results were replicated in a confirmatory phase III trial it would "provide a compelling product alternative to the use of current treatments of moderate to severe [osteo-arthritis] pain".

Paradigm fell four cents or 1.2 percent to $3.20 with 4.8 million shares traded.

AROA BIOSURGERY

Aroa says it has Conformité Européenne (CE) mark for its Myriad for tissue growth and US Food and Drug Administration approval of its Symphony for wound closure.
Aroa said both products used its Endooform technology, an extracellular matrix biomaterial derived from ovine, or sheep, forestomach.
The company that Myriad was a highly perforated, thick, multi-layered Endoform graft designed for dermal soft tissue reconstruction of complex wounds, tissue resections and injuries from trauma, and would launch in Europe in 2021.
Aroa said that its Symphony was cell and tissue-based skin substitute which used Endoform and hyaluronic acid to support healing during the proliferative phase to reduce the time of wound closure, particularly in patients with severely impaired or compromised healing due to disease, and was planned to launch in the US in 2021.
Aroa was up 12 cents or 8.45 percent to $1.54 with 8.8 million shares traded.

STARPHARMA

Starpharma says it has started its 10 to 12-patient dendrimer enhanced product (DEP) docetaxel and gemcitabine combination study for advanced cancers.
Starpharma said it had begun recruiting patients with advanced cancers, including pancreatic cancer, at the Manchester, UK-based Christie Hospital, and expected to expand to two additional sites “in the coming weeks”.
Starpharma fell half a cent or 0.45 percent to $1.10.

ANTISENSE THERAPEUTICS

Antisense says the European regulator has accepted plans for a phase IIb trial of ATL1102 for Duchenne muscular dystrophy, with further information for a higher dose.
Antisense said that the European Medicines Agency feedback reflected “the prior scientific advice received from the three European Union national authorities on the appropriateness of the key trial design parameters of dose duration, safety monitoring plan, endpoints, and potential pivotal status for the planned phase IIb study of ATL1102 in non-ambulant boys with Duchenne muscular dystrophy”.
The company said it was considering a 25mg per week arm into the trial and the EMA said it required “a further rationale … for the selection of the proposed higher dose levels up to 100mg per week and for consideration to be given to the use of intermediate doses and an increase to the sample size to around 35 patients per arm”.
Antisense said that the submission to the EMA was made before the analysis of the complete phase II trial data and confirmation of ATL1102 efficacy at 25mg per week dose (BD Dec 17, 2019; May 22, 2020).
Antisense managing-director Mark Diamond told Biotech Daily that in the phase II trial of ATL1102 for multiple sclerosis a 400mg per week dose was found to be safe and well-tolerated.
The company said the EMA encouraged it to submit its paediatric investigational plan to the EMA Paediatric Committee.
Antisense said it had begun activities for the manufacture of clinical trial supplies of ATL1102 and made pre-payments to the contract manufacturer.
The company said it was involved in discussions with US key opinion leaders, advocacy groups, and regulatory consultants on the clinical path for ATL1102 for in Duchenne muscular dystrophy in the US.
Antisense fell 1.9 cents or 19.0 percent to 8.1 cents with 10.4 million shares traded.

ORTHOCELL

Orthocell says it has filed an Australia Therapeutic Goods Administration regulatory application for its Celgro for peripheral nerve repair.

Orthocell said the application included recent results which showed the restoration of voluntary muscle movement in 96 percent of nerve repairs at 12-months following Celgro surgery, as well as 86 percent of patients able to significantly reduce or stop their medication.

Orthocell managing-director Paul Anderson said the application was “a very important milestone”.

“Our research to date indicates that Celgro is a superior product for facilitating complex nerve regeneration, when compared to current alternatives, and we are optimistic in achieving regulatory clearance to enable Australian patients to access its life-changing impact,” Mr Anderson said. “We have seen incredible results so far … [including] one of our quadriplegic patients progressed from having no strength in his arm and no movement in his fingers and thumb, to playing wheelchair rugby.”

Orthocell was up 1.5 cents or 4.4 percent to 35.5 cents with 1.2 million shares traded.

TALI DIGITAL

Tali says it had supplied its Tali Detect psychometric attention assessment tool to 1,613 students aged between four and eight years across 30 Australian schools.

Tali said the Tali Detect was supplied to students through the Schools Early Release Program, which had initially aimed to recruit 1,000 students.

The company said of the 1,613 students tested, 416 had completed the five-week Tali Train digital attention deficit learning and training program.

Tali managing-director Glenn Smith said the Program “helped to provide critical insights into the use and benefits of Tali’s technology platform, as our team prepares to ramp up sales efforts … with a primary goal of improving attention skills in early childhood”.

Mr Smith said some schools “recognized the benefits of assessing a child’s strengths and weaknesses in the major domains of attention, particularly when many classrooms have moved to remote and online learning models”.

Tali fell 0.7 cents or 20.6 percent to 2.7 cents with 27.4 million shares traded.

MESOBLAST

Mesoblast says customer receipts including milestone payments and royalties for the year to June 30, 2020 were down 18.2 percent $US25,176,000 ($A35,053,850).

Mesoblast said the receipts included upfront and milestone payments from Grünenthal of $US17,500,000 and royalty receipts of $US7,676,000 from JCR Pharmaceuticals for sales of Temcell for acute graft versus host disease in Japan.

Mesoblast chief executive Prof Silviu Itescu said the company had imminent milestones including an interim analysis of the phase III trial of remestemcel-L for Covid-19, the US Food and Drug Administration advisory committee review for potential approval of remestemcel-L in children with steroid-refractory acute graft versus host disease and phase III read-outs in chronic heart failure and back pain.

“These key milestones will take the company into the most significant period in its history,” Prof Itescu said.

The company said it had cash and cash equivalents at June 30, 2020 of $129,328,000 compared to $50,426,000 at June 30, 2019.

Mesoblast was up 18 cents or 4.9 percent to $3.83 with 10.4 million shares traded.

HYDRIX

Hydrix says receipts from customers for the 12 months to June 30, 2020 were up 29.0 percent to $16,020,000 compared to the previous corresponding period.
Hydrix said that sales of products, including its Angel Medical Guardian System implantable heart-attack warning device, had increased despite the impact of Covid-19.
The company said it had cash and cash equivalents of $1,690,000 at June 30, 2020 compared to $235,000 at June 30, 2019.
Hydrix said it had raised $2 million in a rights offer at 7.5 cents a share in July and expected to receive $1 million raising through a placement in September, shareholder approval (BD: Jul 6, 27, 2020).
Hydrix fell 0.8 cents or 8.7 percent to 8.4 cents with 1.5 million shares traded.

STARPHARMA

Starpharma says that receipts from customers for the year to June 30, 2019 were up 157.5 percent to $7,229,000, including milestone payments.
In February, Starpharma said it received a $US3 million milestone from Astrazeneca following the dosing of the first patient in its phase I ASD0466 trial (BD: Feb 11, 2020).
Today, the company said it cash and cash equivalents of $30,054,000 at June 30, 2020 compared to $51,319,000 at June 30, 2019.

IQ3 CORP

IQ3 says its receipts from customer for the 12 months to June 30, 2020 were up 29.0 percent to $7,209,000 compared to the previous corresponding period.
IQ3 said receipts from sales of life sciences consultancy services for the three months to June 30, 2020 were up 64.6 percent to $1,605,000, and it had cash and equivalents of $227,000 at June 30, 2020, compared to $265,000 in cash at June 30, 2019.
IQ3 was untraded at 24 cents.

ELIXINOL GLOBAL

Elixinol says its receipts from customer for the six months to June 30, 2020 were down 57.3 percent to $7,023,000 compared to the previous corresponding period.
The company said sales of its hemp and cannabidiol-based food additives fell due to the Covid-19 pandemic and it had shifted its distribution to online retail to enable future sales.
Elixinol said it had cash and cash equivalents of $16,768,000 at June 30, 2020, compared to $48,141,000 at June 30, 2019.
Elixinol fell one cent or 5.1 percent to 18.5 cents with 1.3 million shares traded.

MEDLAB CLINICAL

Medlab says it receipts from customers for the year to June 30, 2020 were up 11.2 percent to $6,484,000 compared to the previous corresponding period.
Medlab said customer receipts from sales food additives and medical marijuana-based products for cancer pain and nausea for the three months to June 30 were down 44.9 percent to $1,426,000 due to “reduced retail foot traffic resulting from Covid-19”.
The company said it had cash and cash equivalents of $9,063,000 at June 30, 2020 compared to $11,442,000 at June 30, 2019.
Medlab was up half a cent or 3.7 percent to 14 cents.

CARDIEX

Cardiex says its customer receipts for the year to June 30, 2020 were $5,112,000, with receipts for the three months to June 30 of $1,540,000.
Last year in its preliminary final report, Cardiex reported revenue of $3,907,093, for the 12 months to June 30, 2019.
Today, the company said it had been required by the ASX to begin filing Appendix 4C quarterly reports from June 30, 2020.
Cardiex said the increase in receipts was “largely attributed to … winning pharma study contracts … with Bayer and other major pharmaceutical companies”.
Cardiex said it had cash and equivalents of $2,062,000 at June 20, 2020 compared to $4,980,826 at June 30, 2019.
Cardiex was up 0.1 cents or three percent to 3.4 cents with 4.8 million shares traded.

BIONOMICS

Bionomics says its receipts from customers for the year to June 30, 2020 were down 58.3 percent to $3,637,000 compared to the previous corresponding period.
In March, Bionomics said it had completed the sale of its French subsidiaries, Neurofit and Prestwick Chemical, to Domain Therapeutics for EUR1,790,029 ($A3,043,357), which had been sold to repay the debt owed to the subsidiaries for scientific research on its drug candidates (BD: Mar 3, 2020; Dec 11, 2019).
Last year, the company said it had customer receipts of $8,725,000, primarily from the two French subsidiaries (BD: Jul 31, 2019).
Bionomics said it had cash and cash equivalents of $4,578,000 at June 30, 2020, compared to of $13,986,000 at June 30, 2019.
Bionomics was up 0.1 cents or 1.4 percent to 7.2 cents with 1.2 million shares traded.

DORSAVI

Dorsavi says its customer receipts for the year to June 30, 2020 were down 36.4 percent to $2,365,000 compared to the previous corresponding period.
Dorsavi said customer receipts for the three months to June 30 from sales of its wearable motion analysis devices fell 53.8 percent to $548,000.
The company said sales were down due to the impact of the Covid-19 pandemic on the physical therapy industry, with an up-to 70 percent reduction of patient volumes in the US.
Dorsavi said it had cash and cash equivalents of $1,685,000 at June 30, 2020, compared to $2,767,000 at June 30, 2019.
Dorsavi fell 0.3 cents or 11.5 percent to 2.3 cents with 1.5 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it had applications for $1.83 million in its fully-underwritten retail rights offer at 10 cents and will raise a total of $4 million.
Amplia said that $170,000 shortfall would be placed by the underwriter Taylor Collison.
The company said the $2 million institutional offer was supported by its largest shareholder Platinum Investment Management with Blueflag Holdings becoming a substantial shareholder (BD: Jul 1, 2020).
Amplia fell half a cent or three percent to 16 cents.

ZELIRA THERAPEUTICS

Zelira says it has three months of funds and has requested a trading halt pending an announcement “in relation to a capital raising”.
In its Appendix 4C quarterly report, Zelira said it had cash and cash equivalents at June 30, 2020 of $1,697,000, compared to $3,080,000 at June 30, 2019, but said it was “confident the capital raising will provide sufficient cash to fund its operation”.
Trading will resume on August 3, 2020 or on an earlier announcement.
Zelira last traded at 5.9 cents.

HEMIDEINA

Hemideina says it has won a $660,000 Biomedtech Horizons grant for its Hera miniature wireless power and data transfer system for implantable hearing devices.
Melbourne’s Hemideina said the funds would assist development of its mechanical sound processing technology “and result in hearing implant products that improve clinical outcomes … for people who are profoundly deaf”.
Last year, the company said it raised $4 million in series A funding to commercialize the Hera wireless implant, the second round of equity financing and followed the validation of its core mechanical signal processing technology (BD: Nov 19, 2020).
Today, Hemideina said the Biomedtech funds, from the Federal Medical Research Future Fund and delivered by MTP Connect, would cover collaboration with other researchers on wireless power and data transmission and “fast track demonstration of a miniature wireless power and data transfer system for implantable medical devices”.
Hemideina chief executive officer Dr Elizabeth Williams said the Hera implant would “significantly disrupt the global hearing implant market by redefining the cochlear implant”.
The company said that the technology was inspired by insect hearing systems to “transform hearing implants and the quality of life for the profoundly deaf”.
Hemideina is a private company.

ELIXINOL GLOBAL

Elixinol says its annual general meeting as carried all resolutions, but with 19.45 percent dissent against leaving entitlements for Andrew Duff and Greg Ellery.
In April, Elixinol said that founder and director Paul Benhaim would replace chairman Mr Duff, and Oliver Horn would replace director Mr Ellery, with immediate effect, with both Mr Duff and Mr Ellery resigning from the board (BD: Apr 6, 2020).
Today, the company said that the leaving entitlements of $127,800 for Mr Duff and $85,000 for Mr Ellery were opposed by 12.04 million votes (19.45%), with 49.85 million votes (88.55%) in favor.
Elixinol’s most recent Appendix 2A new share issue announcement said the company had 192,837,064 shares on issue meaning that the opposition to the leave entitlements was 6.2 percent of the shares on issue, sufficient to requisition extraordinary general meetings.

NEUREN PHARMACEUTICALS

Neuren says it has appointed Lauren Frazer as chief financial officer and company secretary, effective from August 1, 2020.
Neuren chief executive officer Jon Pilcher said that Ms Frazer had “already made a strong contribution during her short time at Neuren”.
Neuren fell three cents or 2.3 percent to $1.285.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has appointed Prof Dao-Yi Yu to its scientific advisory board.
Neuroscientific said that Prof Yu was the head of physiology and pharmacology research at Perth's Lions Eye Institute.
The company said that Prof Yu had published about 300 peer-reviewed publications in and would assist in advancing its glaucoma program into clinical studies.
Neuroscientific was up 1.5 cents or seven percent to 23 cents.