Biotech Daily

Friday July 2, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ALTERITY UP 30%; PATRYS DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: ARGENICA THERAPEUTICS**

*** FDA APPROVES IMUGENE CF33 'CHECKVACC' BREAST CANCER TRIAL**

*** CYCLOPHARM H1 REVENUE UP 45% TO $8.1m**

*** BTC RAISES $2.5m FOR PHARMAXIS BRONCHITOL, ARIDOL ACQUISITION**

*** ELLUME, AZOVA, ALASKA AIRLINES SARS-COV-2 TEST PARTNERSHIP**

*** US PATENT FOR ALTERITY EXCESS IRON REDISTRIBUTION**

*** CRESO: 'H1 MARIJUANA REVENUE UP 113% TO $3.1m'**

*** PROTEOMICS EXTENDS 'PRESENTATION' SUSPENSION**

*** ESENSE ASX-DELISTING AGM**

*** ALLIANZ TAKES 9% OF STARPHARMA**

*** GINA RINEHART, HANCOCK TAKE 11.5% OF LITTLE GREEN**

*** PERENNIAL TAKES 7.6% OF ATOMO**

*** VISIONEERING APPOINTS DR DWIGHT AKERMAN DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.59 percent on Friday July 2, 2021, with the ASX200 up 43.0 points to 7,308.6 points. Twenty of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and one was untraded.

Alterity was the best, up 0.9 cents or 30 percent to 3.9 cents, with 241.95 million shares traded. Genetic Signatures climbed 8.6 percent; Oncosil and Osprey were up more than seven percent; Universal Biosensors was up 6.1 percent; Actinogen, Antisense, Imugene and Next Science improved four percent or more; Mesoblast was up 3.3 percent; Cyclopharm, Cynata, LBT, Optiscan and Volpara rose more than two percent; Avita, Immutep and Pharmaxis were up more than one percent; with CSL, Medical Developments, Neuren and Resmed up by less than one percent.

Patrys led the falls, down 0.4 cents or 7.3 percent to 5.1 cents, with 28.97 million shares traded. Amplia lost 6.25 percent; Nova Eye was down 3.1 percent or more; Nanosonics, Orthocell, Polynovo and Starpharma shed more than two percent; Telix was down 1.7 percent; with Clinuvel, Cochlear, Opthea, Paradigm and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: ARGENICA THERAPEUTICS

By TIM BOREHAM

ASX code: AGN

Share price: 21.5 cents

Market cap: $15.7 million

Shares on issue: 73,172,250 (27,275,752 in ASX escrow)

Chief executive: Dr Liz Dallimore

Board: Geoff Pocock (chair), Dr Samantha South, Liddy McCall, Terry Budge

Finances (December 2020 first half): revenue nil, other income $296,147, net profit $65,243, cash of about $7 million (post IPO)

Identifiable major holders: Oofy Prosser (Drones Family) 5.98%, University of Western Australia 5.4%, Perron Institute 4.7%, Shane Michael Colley (Fiery King Investments) 2.73%, Shane Hoecock Wee (Wee Family Account) 2.45%

We've all heard the maxim that 'time is money', but in the case of stroke victims 'time is brain'.

From the moment of the dreaded incident, the clock is ticking on getting the patient to a suitably equipped hospital ASAP because millions of brain cells around the clot or rupture will be dying every minute.

According to one scary stat, the patient's brain ages 3.6 years for every hour of delayed treatment.

While 15 million people suffer a stroke annually, five million of them fatally, there's no effective treatment for front-line responders (usually paramedics) to administer.

Victims of the most common ischaemic strokes are usually delivered anti-clotting medication, but this can only be administered up to four hours after the event. And the medicos need to be sure that the stroke is ischaemic (a clot) rather than haemorrhagic, or else the treatment could expedite blood loss resulting from the latter.

Fresh from its ASX listing on June 11, Argenica is seeking to rectify this gaping treatment void with an easily-administered drug to prevent cell death in the first instance.

"Currently there are NO marketed, safe early intervention therapies capable of protecting the brain from damage following stroke," the company says (with the company's emphasis).

Argenica chief executive Liz Dallimore says if a stroke drug is delivered by first responders, it's crucial the agent doesn't exacerbate bleeding in haemorrhagic stroke victims (85 percent of strokes are ischaemic).

"Also, clot drugs can only be delivered about four hours post-stroke so we envisage our drug will increase that therapeutic window for those drugs as well."

Don't cry for me, Argenica

Argenica is based on research carried out by the University of Western Australia (UWA) and the Perron Neuroscience Institute. This effort was headed up by the UWA's Prof Bruno Meloni and Prof Neville Knuckey, head of stroke research at Perron.

Argenica listed on June 11 after raising $7 million at 20 cents per share.

Argenica's lead (ok, only) candidate is ARG-007, a cationic arginine-rich peptide (CARP).

Not to be confused with those the British fought on the Falkland Islands, arginines are amino acids derived from one's diet and essential for producing proteins.

We won't CARP on about it, but the lab-based research examined a number of arginine peptides as neuroprotective agents, with in-vitro trials establishing that ARG-007 (then R18) hit the sweet spot.

"They took R18 through a number of preclinical studies, looking at both [toxicity] in-vitro and then using stroke models [of the middle cerebral artery]," Dr Dallimore says.

The key message was that R18 reduced brain tissue death by 30 percent within the first 24 hours and held these gains 28 days later.

Dr Dallimore started out in stroke research at the Australian Neuromuscular Research Institute, now the Perron Institute.

After completing a Ph D in neuroplasticity jointly at the UWA and at Oxford, Dr Dallimore picked up an MBA from the Australian Graduate School of Management. She has held senior management consulting with gigs at Pricewaterhousecoopers, KPMG and Ernst & Young.

"I have a good combination of understanding the neuroscience as well as having the commercial background," she says.

Thank heaven for ARG-007

Dr Dallimore says when a vessel is blocked, the reduction in the blood flow affects the neurons around the vessels - with all kinds of nasty flow-on effects.

One is where there's an influx of calcium into the cell, which activates cell death pathways.

"You see a cascade of things happening within those neurons," she says.

"We are able to block oxidative stress and calcium influx and ... reduce inflammation.

"It [ARG-007] works in a number of ways down the cell death pathways, which is really important for neuroprotection."

ARG-007 also appears to overcome the blood-brain-barrier, the body's natural defence against foreign agents.

Having done in-vitro modelling and primate studies, the company is finalizing the toxicology and pharmacokinetic data needed for a phase I trial.

The company aims to recruit 40 healthy volunteers by the end of 2021. The study will be carried out by Perth's Linear Clinical Research.

The company is also seeking ethics approval for a phase II study, divided into two parts.

Part A will be based on patients diagnosed with large vessel occlusions, having been admitted (quickly) to hospital in a metropolitan area.

Part B will focus on first responder delivery and the company is mulling how to establish that trial.

An obvious issue is that patients are not exactly in a position to give consent and may not even be conscious.

While consent rules vary from state to state, the next of kin can usually give the nod and ultimately the paramedic can administer the drug without consent if the situation is dire enough (which it usually is).

Argenica's rivals at home...

Argenica IS the only pure-play ASX biotech looking at stroke neuroprotection, but others are nibbling away at the periphery.

Nyrada Inc is focused on cholesterol-lowering drugs but has a clear interest in traumatic brain injury and strokes. The company claims to have the "first ever treatment to prevent brain damage following stroke and head trauma" with its so-called PCSK9 inhibitor.

We've regularly covered the success story Clinuvel, which has regulatory approval for its drug afamelanotide for rare skin orders.

But the company is also evaluating the effect of the drug in a six-patient, phase II stroke study.

The first patient was recently enrolled, having suffered an acute arterial ischaemic stroke.

The immediate aim is to “bring back the patient’s neurological and muscular functions by improving the blood flow to the affected part of the brain”.

Argenica also shares some DNA with Emvision (EMV) which is working on an early stroke detection device for use in ambulances.

Not accidently, WA businessman Geoff Pocock is chair of Argenica and a director of Emvision.

He is also an executive director of bio-resorbable implant mob Osteopore and founded the listed Hazer, which has nothing to do with college frat house rituals but is developing hydrogen technologies.

Emma Waldron is chief financial officer and company secretary for both Emvision and Argenica.

Another interesting name on the Argenica board by the way is Terry Budge, the former chief executive of Bankwest (now owned by the Commonwealth Bank).

Meanwhile, ASX listed compatriot Micro-X is developing a portable stroke scanner, among other things.

And away ...

Globally, a number of other drug developers are pursuing the neuroprotective path, but not with Argenica’s 'plurifunctional’ approach.

Argenica is following the lead of the more advanced private Canadian outfit Nono, which has another arginine peptide called NA-1.

Dr Dallimore says being a fast follower is not such a bad thing, as Argenica can observe Nono’s phase III trial protocol with first responders.

“We have managed to see how they have navigated ethics and patient consent issues,” she says.

“Interestingly, a couple of members of our clinical advisory committee are running those trials in Australia for that company, so we have quite a bit of inside knowledge about how they are setting up those trials.”

She views NA-1 as the closest drug to Argenica’s, as it’s also a peptide (albeit more complex).

Others are pursing treatments based on anti-oxidants and stem cell therapies.

Finances and performance

Argenica shares enjoyed a solid debut ending the first day at 26 cents (a 30 percent premium) but have since drifted back to the listing price.

The 35 million shares issued in the initial public offer (IPO) took total shares on issue to a tad over 73 million, ascribing a $14.6 million market capitalization. Of these shares, 31 percent are escrowed for 12 months with a further six percent locked up for 12 months.

These shares are in the hands of pre-IPO investors who bought-in at either eight cents or 12.5 cents and presumably might want to cash in when the restriction is lifted.

Most of the funds raised will be earmarked for pre-clinical work.

“We have money put aside to look at other indications such as traumatic brain injury and perinatal hypoxia ischaemia,” Dr Dallimore says.

Perinatal hypoxia ischaemia is when the brain does not receive enough oxygen before or after childbirth, with profound effects on mother and child.

Dr Boreham’s diagnosis:

Argenica has been in discussions with its well-credentialed medical advisory committee on the potential safety of ARG-007 for migraines and epilepsy.

The stroke market alone is expected to be worth some $US180 billion a year by 2030, even with the paucity of current treatments.

Another scary stat is that there’s a 25 percent chance of adults over the age of 26 years having a stroke.

At the risk of being Captain Obvious, your columnist opines: Argenica has a long way to go on its quest, which is why it’s valued at a mere enterprise value (market cap less cash) of a mere $7 million or so.

“We have seven years of data supporting this particular arginine, we are pretty confident it will at least be safe,” Dr Dallimore says.

Safe is a good start, but establishing efficacy in humans will entail a ‘boring but important’ stage in which not much will happen from an investor perspective.

Dr Dallimore insists the Argenica story has legs and - as is often the case - it’s the patient investors who are likely to benefit.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. By stroke of good fortune, he remains gainfully employed, nonetheless.

IMUGENE

Imugene says the US Food and Drug Administration has approved its investigational new drug application for a phase I trial of CF33 for triple-negative breast cancer.
Imugene said the study would evaluate the safety and initial evidence of efficacy of intra-tumoral administration of CF33 combined with a human sodium-iodide symporter (hNIS) and an anti-programmed death-ligand 1 (CF33-hNIS-anti PDL1) antibody, which it calls Checkvacc for metastatic triple-negative breast cancer.
The company said the approval off the investigational new drug application (IND) allowed the Los Angeles-based City of Hope to start patient recruitment and dosing.
Imugene said the trial would involve dose escalation followed by the expansion to 12 patients at the final dose and would be led by Dr Yuan Yuan as principal investigator.
The company said its oncolytic virus CF33-HNIS-anti PDL1 was “an immune checkpoint inhibitor armed chimeric vaccinia poxvirus” and oncolytic viruses were designed to selectively kill tumor cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival.
Imugene was up 1.5 cents or 4.3 percent to 36.5 cents with 38.0 million shares traded.

CYCLOPHARM

Cyclopharm says it expects unaudited revenue for the six months to June 30, 2021 to be up about 45 percent to about $8.1 million compared to the previous period.
Cyclopharm said it expected revenue from the patient administration sets would be 20 percent higher than the previous period and Technegas generator revenues were expected to be “almost double” compared to the prior period.
Cyclopharm managing-director James McBrayer said that “strong revenue growth across all our product and service lines in our established markets is driving the business to significantly outperform the results in the first halves of 2020 and 2019”.
“It is encouraging to see the growth strategies we are executing in our established markets are driving improved returns with overall growth well ahead of pre-Covid-19 levels,” Mr McBrayer said.
“Given our momentum we are very confident of continued robust growth in [patient administration sets] revenue in the coming periods,” Mr McBrayer said.
“The generator sales we made this year will lead to ongoing repeat [patient administration sets] orders through the life of these assets,” Mr McBrayer said.
Cyclopharm was up 4.5 cents or 2.7 percent to $1.695.

BTC HEALTH

BTC says it has “firm commitments” to raise $2.5 million at seven cents a share to acquire the distribution rights for Pharmaxis’ Bronchitol and Aridol.
Yesterday, BTC said it would pay Pharmaxis $2 million for a 10-year exclusive distribution deal for Bronchitol and Aridol and requested a capital raising halt (BD: Jul 1, 2021).
Today, the company said the placement was strongly supported by its existing institutional and professional investors.
BTC said the issue price was at a 5.4 percent discount to its last closing price on June 30, 2021 and Taylor Collison acted as the lead manager to the placement.
BTC was up 0.4 cents or 5.4 percent to 7.8 cents.

ELLUME

Ellume says it has partnered with Alaska Airlines to provide severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) testing for travellers.

Ellume chief executive officer Dr Sean Parsons told Biotech Daily that the US Food and Drug Administration emergency use authorization for the company's at-home, 15-minute, rapid Sars-Cov-2 antigen test was accepted for inbound travellers to the US, with requirements varying for outbound travellers depending on the country.

Ellume said the Alaska airlines partnership was through the Frederick, Maryland based Azova Inc, which described itself as a "digital health network for Covid-19 testing".

The company said the service would "make it easy for travellers returning to the US to take … [an] antigen test with video observation for verification that meets US Centers for Disease Control requirements for re-entry into the US".

Ellume said its test was available through Azova for $US50 ($A66.96) with video observation appointments to be made at least one week in advance, and when results were confirmed, Azova would send a Covid Credentials Health Pass via text or email to view and share test and vaccination results via QR code, Credential ID, or PDF.

Biotech Daily has been told of Australians visiting New Zealand being charged $150 per test per family member to be able to enter the Australian airport of departure.

Ellume is a public unlisted company.

ALTERITY THERAPEUTICS

Alterity says the US Patent and Trademark Office has granted a patent covering its iron chaperone technology for redistributing excess iron in the central nervous system.

Alterity said that the patent, titled 'Imidazo [1,5-A] pyridine compounds and their Use', would protect its intellectual property until March 15, 2040.

The company said the patent covered more than 150 novel pharmaceutical compositions designed to redistribute the labile iron implicated in neurodegenerative conditions such as Alzheimer's disease and Parkinson's disease.

Alterity was up 0.9 cents or 30 percent to 3.9 cents with 241.95 million shares traded.

CRESO PHARMA

Creso says its revenue from marijuana products for the six months to June 30, 2021 was up 113.3 percent to $3,100,933 compared to the previous corresponding period.

Creso said that for the three months to June 30, 2021 revenue from the sale of animal and veterinary marijuana products was up 23.9 percent to $1,715,933 compared to the three months to March 31, 2021.

Creso was unchanged at 13.5 cents with 27.25 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested an extension to its voluntary suspension, pending a presentation to the American Diabetes Association.

On Tuesday, Proteomics requested a suspension to follow last week's trading halt requested "pending the release of the presentation" (BD: Jun 25, 29, 2021).

Last week, Proteomics claimed its Promarkerd prognostic blood test for diabetic kidney disease could save US payers $US384 billion ($A505.7 billion) over 10 years and Today, Proteomics said it hoped to lodge an announcement by July 6, 2021.

Proteomics last traded at 92.5 cents.

ESENSE-LAB

Esense says its annual general meeting will vote to delist from the ASX, along with a raft of share issue and loan note ratification resolutions.

Last week, Esense said it proposed to be removed from the official list of the ASX “in the best interest of security holders” (BD: Jun 25, 2021).

The company said at that time that it had been suspended from trading on the ASX since July 27, 2020 following an ASX query and it required funding for its operational and working capital requirements, which since the suspension had been increasingly difficult and it had not benefited from being a listed entity.

Today, Esense said it was considering a listing on the TSX Venture Exchange or the Canadian Securities Exchange following the de-listing “where it considers the company will have greater access to capital, and shareholders will have the benefit of increased liquidity”.

The company said that at the date of the notice of meeting, no listing application had been made to the TSX Venture Exchange or the Canadian Securities Exchange and the proposed terms of any such listing, including a potential timeline, had not been determined.

Esense was attempting to commercialize marijuana “terpenes”.

The company said that shareholders would vote on a list of resolutions to issue stock to noteholders and ratify prior share and option issues, including to Anglo Menda Pty Ltd a company controlled by chair Adam Blumenthal and Azalea Consulting, a company controlled by director Winton Willesee.

Esense said that the meeting would vote to elect directors Mr Willesee, James Ellingford and Peter Hatfull, as well as external directors Deborah Gilmour and Maayan Bar.

The company said that shareholders would vote to approve the appointment and pay for chief executive officer Yoav Elishoov and indemnify directors and officers.

The meeting will be held at Quest South Perth Foreshore, 22 Harper Terrace, South Perth, Western Australia on August 6, 2021 at 1:30pm (AWST).

Esense was in a suspension and last traded at 1.8 cents.

STARPHARMA HOLDINGS

Allianz SE says it has increased its substantial shareholding in Starpharma from 32,746,474 shares (8.06%) to 36,910,063 shares (9.09%).

The Munich, Germany-based Allianz said it bought and sold shares between February 12 and June 29, 2021 at prices ranging from $1.45 to $2.45 a share.

Starpharma fell 3.5 cents or 2.3 percent to $1.495.

LITTLE GREEN PHARMA

Georgina Hope (Gina) Rinehart and Hancock Prospecting says they have become substantial shareholders in Little Green with 26,739,029 shares or 11.50 percent.

The West Perth-based Ms Rhinehart and Hancock Prospecting said they bought shares between March 22 and June 29, 2021, with the single largest purchase 25,000,000 shares for $15,000,000 or 60 cents a share.

Last week, Little Green said it had commitments to raise $27.2 million in a placement at 60 cents a share to buy a Denmark marijuana production facility (BD: Jun 22, 2021).

Little Green fell 1.5 cents or 1.6 percent to 91.5 cents with 1.9 million shares traded.

ATOMO DIAGNOSTICS

Perennial Value Management says it has increased its substantial shareholding in Atomo from 35,628,951 shares (6.35%) to 42,962,957 shares (7.56%).

The Sydney-based Perennial said between August 26, 2020 and June 29, 2021 it bought and sold shares, with the single largest purchase 5,698,640 shares for $1,776,836 or 31.18 cents a share.

Atomo was up one cent or 5.3 percent to 20 cents with 2.8 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has appointed Dr Dwight Akerman as a directors and chair of the science and technology committee.

Visioneering said optometrist Dr Akerman had 41 years of experience in eye care, product development, clinical and regulatory affairs, academic and professional affairs, business development and licensing, and executive management.

The company said Dr Akerman was currently the chief medical editor of the Review of Myopia Management and was most recently Alcon's head of professional affairs and business development, and previously worked for Ciba Vision and Novartis Ophthalmics.

Visioneering said that Dr Akerman held a Doctor of Optometry from Chicago's Illinois College of Optometry and a Master of Business administration from the University of Texas at Tyler.

Visioneering was up three cents or 2.2 percent to $1.38.