Biotech Daily

Friday June 19, 2020

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.1 percent on Friday June 19, 2020, with the ASX200 up 6.1 points to 5,942.6 points. Twenty-three of the Biotech Daily Top 40 stocks were up, 10 fell, five traded unchanged and two were untraded. All three Big Caps rose.

Osprey was the best, up 0.2 cents or 22.2 percent to 1.1 cents, with 13.2 million shares traded. LBT climbed 19.35 percent; Alterity was up 14.3 percent; Avita rose 8.3 percent; Starpharma improved 5.6 percent; Antisense, Compumedics, Impedimed, Pharmaxis and Pro Medicus climbed more than four percent; Imugene, Mesoblast and Paradigm were up more than three percent; Ellex, Oncosil, Polynovo, Uscom and Volpara rose two percent or more; Immutep, Medical Developments, Nanosonics, Next Science and Orthocell were up more than one percent; with Cochlear, CSL and Resmed up by less than one percent.

Proteomics led the falls, down 3.5 cents or 8.2 percent to 39 cents, with 726,389 shares traded. Amplia lost eight percent; Cyclopharm fell 3.6 percent; Cynata, Opthea and Optiscan shed more than two percent; Kazia, Neuren and Telix were down one percent or more; with Clinuvel down 0.04 percent.

DR BOREHAM'S CRUCIBLE: EMVISION MEDICAL DEVICES

By TIM BOREHAM

ASX code: EMV

Share price: $1.315; **Market cap:** $83.8 million; **Shares on issue:** 63,759,832 (16,789,351 in ASX escrow)

Chief executive officer: Dr Ron Weinberger

Board: John Keep (chairman), Dr Weinberger, Scott Kirkland, Ryan Laws, Geoff Pocock, and Tony Keane.

Financials (March quarter 2020): receipts $46,000, cash outflows $798,000, cash balance $$6.06 million, quarters of available funding 7.6

Identifiable major shareholders: Uniquest Pty Ltd 9.41%, Scott Kirkland 5.87%, Ryan Laws 5.19%.

Emvision chief Ron Weinberger brings a rarefied perspective to the prospective device maker: he was a mover and shaker behind the $2 billion market cap probe sterilizing house Nanosonics.

As one could imagine, Dr Weinberger learnt a few do's and don't's during Nanosonics' elongated evolution, including the importance of focusing on one or two applications instead of trying to solve all the world's health challenges.

"You will have significant successes and also face significant issues," he says. "I'm five foot four and I'm bald. When I started at Nanosonics I was six feet two and had lots of hair."

Emvision's challenge is to perfect and commercialize a portable helmet-like device to detect strokes and other brain injuries in a timely and non-invasive manner, as well as to provide more interpretation as to what's going on in the grey matter.

But true to Dr Weinberger's ethos of not taking on the world, Emvision does not aspire to replace the current stroke imaging methods: computer tomography (CT) or magnetic resonance imaging (MRI) scans.

Based on electromagnetic microwave imaging, Emvision's devices are intended to be used in hospitals as an adjunct to these accepted methods. But much of the sizzle in the company's story lies with the devices being used in ambulances and other "first responder" situations (as the yanks would put it).

According to the World Health Organisation, strokes are the second biggest cause of death and the leading cause of permanent disability. Incorrect or delayed diagnoses can result in permanent disability and death.

One in six people will have a stroke and five million will die. One third of stroke patients will have another stroke and stroke patients who enter hospital for other indications account for roughly 10 percent of all strokes.

A stroke of fortune … and hard work

Emvision is the culmination of a decade of research at the University of Queensland. The underlying algorithm and antenna technology was co-invented by Professors Amin Abbosh and Stuart Crozier. The former is a leader in electromagnetic microwave imaging; the latter created technology central to MRI machines.

Emvision was formed in July 2017 by Scott Kirkland and Ryan Laws, for the purpose of acquiring this tech from the university's commercialization arm, Uniquest. Mr Kirkland held senior sales positions at San Francisco's Quantcast, while Mr Laws has a history of investing in - and arranging funding for - emerging companies.

Emvision listed in mid-December 2018, having raised $6 million at 25 cents apiece. Dr Weinberger has been the CEO since the listing, but in April this year was elevated to the board as managing-director (at the same time, executive chairman John Keep became 'normal' chair).

Emvision has other strong Nanosonics links: head of design and development Robert Tiller worked on the original Trophon, while regulatory affairs head Ruth Cremin held an identical role at Nanosonics.

Thirty-second stroke detection

Once fitted, the helmet devices can take an image in about 30 seconds and interpret it in less than three minutes. The entire process can be done on a laptop.

Dr Weinberger says CT/MRI scans are "Very well-established utilities and do a very good job".

But the truth is they very heavy and bulky - and very fixed. The machines are also heavily in demand in hospitals, which need to prioritize use, strictly.

"We are trying to provide different data that can be done by the bedside," Dr Weinberger says.

The 'algos' create an image which is compared to the "ground truth": the pictures from the MRI-CT scans.

"We are able to provide very high contrast images between damaged and normal tissue, whereas an MRI/CT without contrast agents is pretty grey," Dr Weinberger says.

"In one particular patient we not only picked up the effects of the new stroke, but could identify damaged tissue surrounding an old stroke."

The device has the potential to detect cellular changes by monitoring the electrical properties of the tissue as they change in response to the injury. While much of the company's intellectual property is based on the imaging algorithms, the company's "secret sauce" lies in how the software integrates with the hardware.

The view from the clinic

Having done trials on healthy humans, the company launched a pilot clinical trial at Brisbane's Princess Alexandra Hospital. The trial kicked off in January 2020, just in time for the coronavirus to put a shuddering halt to trials on April 2. It has been restarted.

The trial aims to enroll both haemorrhagic (bleed) and ischemic (blockage) stroke patients - 30 in all - and is about halfway through this process.

Dr Weinberger says the primary purpose of the trial is to generate data on the electromagnetic scattering effects in the brain, so that the algorithms can be improved and refined.

In April, the company reported clinical results from two patients, showing a "strong correlation" between Emvision's imaging and the "ground truth" scans. The images were reconstructed by creating a map of electromagnetic wave "scattering" that results from the contrast between the ischemic (blood flow deprived) and healthy brain tissue.

Emvision's clinical adviser and stroke expert Prof Michael O'Sullivan dubbed the results as "highly promising", adding: "In both cases the scans were clearly positive and provided a good guide to the extent of brain tissue damaged or under threat."

Keepin' it real

Dr Weinberger says it's one thing to get a nice image of the injured tissue, but it's little more than a pretty picture if the clinicians can't do anything about it.

In the first aid context, in-situ detection could enable a paramedic to identify the stroke as clot-based and dispense a clot-dissolving drug.

"There's a golden hour once you have had a stroke - and that's when there's the ability to make the biggest impact with intervention," he says.

"You can have tremendously improved outcomes. The longer these things go on, the more damage there can be."
Once in hospital, the patient may have to wait between 24 and 48 hours for a follow-up MRI/CT scan and there's no way of bedside monitoring in this critical period.

"One third of patients with a primary stroke will have a recurrence or a new stroke," Dr Weinberger says. "Sometimes the clot is pulled out, but this can damage the blood vessel."

What's next?

Emvision plans to seek marketing approval from the local Therapeutic Goods Administration, but also tackle the US Food and Drug Administration "in parallel". European device regulation is in disarray post-Brexit and can wait.

Dr Weinberger says the company will need to carry out a pivotal trial, enrolling "a few hundred" patients across multiple sites.

"We will have well-defined objectives that we are in the process of determining," he says. "I've been around long enough in our industry to see companies shoot for the stars with five objectives. Then one fails and the share price plummets."

Dr Weinberger says the company hopes to kick off its pivotal trial within the next 12 months, in view of a regulatory submission in late 2021 and commercial launch in 2022.

Also in alliance with the University of Queensland, Emvision has a secondary program to develop a torso scanner to monitor the severity of non-alcoholic fatty liver disease.

Finances and performance

Last November, Emvision tapped the market for $4.5 million in a placement at 74 cents, a 13 percent discount to the prevailing price.

With $6 million in the bank, Dr Weinberger says there's enough dosh to complete the trial and the company is "well capitalized at this point".

Emvision spent $1.08 million on research and development funding, but received $237,000 in Cooperative Research Centre (CRC) funding. Emvision was awarded a $2.6 million government CRC grant in late 2017.

By March 2020, CRC program partners - including GE Healthcare, the University of Queensland and Queensland's Metro South Hospital and Health Services - had chipped in a further $910,000.

As with Nanosonics - and sorry to stretch the comparison - Emvision envisages a "razor blade" model by which the company generates substantial revenue from consumables and servicing the units.

The consumable in this case is a flexible single-use cap worn by the patient under the helmet, for infection control and improved signalling.

On back-of-the-envelope sums, the dollars add up: Princess Alexandra admits an average of five stroke patients per day, or 1,825 a year (ok – 1,830 in a leap year). Charge, say, $20 per cap and that's $35,000 a year just for one ward in one hospital - assuming the patients are scanned only once.

Dr Weinberger notes that in the US, preventative maintenance accounts for 14 percent of the annual cost of running a typical device.

Shares have run strongly on April's initial trial results and are trading around record levels, having slumped from 90 cents to 43 cents during the February/March overall market selloff.

The next 'Packer Whacker'?

Dr Weinberger's ultimate ambition is to see the devices installed in every ambulance: the stroke version of the Packer Whackers (the late tycoon funded defibrillators for all NSW ambos after suffering a near fatal heart attack in 1990).

As with Nanosonics Trophons that can be operated by nurses, Emvision's devices will be designed to be used easily in the field. A paramedic could conduct the scan and send the images to the hospital via telemetry, ahead of the patient's arrival.

Ambulance organizations and the Royal Flying Doctor Service are keen. Speaking of the latter, the device has particular appeal in regional areas where a high-end CT or MRI scan is about as proximate as an Uber Eats delivery.

Dr Boreham's diagnosis:

Dr Weinberger says one of the keys to succeeding in device development is not to strive for perfection, but to keep in mind the practical considerations of everyday usage.

For example: where will the device be stored at night?

While devices need not be revolutionary, they do have to offer something that others can't - and on this note Emvision does have 'same but different' competitors.

For instance, an Austrian company has a mobile stroke imaging device with around 200 antennae compared to 16 for the Emvision device. "It's very large by comparison and you have to pull the bed away from the wall," Dr Weinberger says.

Other device makers have "portable" CT scanners weighing around 600 kilograms.

"There's always going to be someone having a crack at this, but we think we have a very good advantage in terms of price and our value proposition," he says.

As with Dr Weinberger, your columnist can remember when Nanosonics - apologies, again - had a similar market cap of a modest $80 million.

"Nothing happens overnight," he says. "But eventually the fairy godmother will turn up and you get turned from a pumpkin to a prince and everyone forgets you were a pumpkin for a while."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He's still trying to find the damn shoe that fits properly, but fortunately he is partial to pumpkin soup in the winter months.

REDHILL BIOPHARMA

Redhill says it has expanded the trial sites for its 270-patient phase II/III trial of opaganib for Covid-19 and has been approved for a parallel US study.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010)

Last week, the company said it had applied to Russia's Ministry of Health for a randomized, double-blind, parallel-arm, placebo-controlled trial to study the effect of cancer drug opaganib, formerly Yeliva or ABC294640, in patients with severe Covid-19 pneumonia, requiring hospitalization and supplemental oxygen (BD: Jun 11, 2020).

Today, Redhill said the trial would be expanded to Italy, the UK and other countries.

In April, the company said it has submitted an investigational new drug application to the US Food and Drug Administration to evaluate opaganib in a 40-patient clinical study of adults diagnosed with Covid-19 and pneumonia (BD: Apr 21, 2020).

Today, Redhill said the randomized, double-blind, placebo-controlled phase IIa trial of obpaganib in the US had been approved by the FDA and was open for recruitment.

The company said the US trial was "not powered for statistical significance".

Redhill said that a total of 141 subjects had been dosed with opaganib in ongoing and completed phase I and II clinical studies. under expanded access programs in the US and Israel, and the studies had established consistent safety and tolerability in humans.

Redhill medical director Dr Mark Levitt said that "in line with the global shift from a focus on compassionate use programs to adequately controlled clinical studies, our highest priority is on generating robust data in a controlled setting for regulatory purposes".

"Following our submission of the clinical trial application in Russia last week, we have submitted similar applications in the UK and Italy, and we are looking to expand the study to additional countries and start treating patients soon," Dr Levitt said.

"This study, along with the ongoing phase IIa study in the US, should allow us to enrol patients faster to evaluate the efficacy of opaganib against Covid-19 and bring this promising therapy one step closer to those who need it," Dr Levitt said.

On the Nasdaq, Redhill was down 12 US cents or 1.78 percent to $US6.64 ($A9.69) with 557,324 shares traded.

OPYL

Opyl says it expects to raise $738,800 following commitments from new and existing shareholders for up to 7,388,000 shares at 10 cents a share.

Opyl said the funds would go to working capital as it gained new contracts for its digital and social media platforms.

The company said the placement price was a 23.1 percent discount to the last closing price on June 17, 2020.

Opyl said Morgans Corporate was the lead manager to the placement.

Opyl fell three cents or 23.1 percent to 10 cents.

NUHEARA

Nuheara says its Iqbuds Max hearing and sound filtering earbuds are ready for international distribution to fulfil "almost 5,000" pre-ordered units.

Nuheara chief executive officer Justin Miller said it remained "a massive task to manage global logistics in a Covid-19 afflicted world, but we look forward to ensuring our back orders are fulfilled as quickly as possible".

Nuheara was up 0.1 cents or 7.1 percent to 1.5 cents with 11.1 million shares traded.

NOXOPHARM

Noxopharm says it is planning a 40-patient, phase I 'Noxcovid-1' trial of Veyonda for Covid-19 in Ukraine and Moldova, as it awaits approval for a US Veyonda trial.

In April, Noxopharm said that idronoxil, the active ingredient in Veyonda, or NOX66, inhibited "a key inflammatory pathway involved in a process known as a cytokine storm" or septic shock, and that it would seek US Food and Drug Administration guidance for a clinical trial for Covid-19 patients (BD: Apr 1, 21, 2020).

Today, the company said it had "received a prompt and extensive response from the FDA, with the company agreeing to certain recommended design changes in the clinical protocol".

Noxopharm said the European proof-of-concept, dose-escalation trial would study patients who had been admitted to hospital for respiratory insufficiency associated with Covid-19, without requiring artificial ventilation, with the endpoints of safety, tolerability, clinical responses and cytokine data.

Noxopharm chief executive officer Dr Graham Kelly said septic shock was "a lethal condition that occurs when the body experiences severe tissue damage associated with viral and bacterial infections and trauma".

"Instead of the body repairing the damage, the repair process goes into overdrive and creates even more damage," Dr Kelly said.

"Apart from Covid-19 patients, septic shock is thought to be responsible for about 10 million deaths worldwide every year, or one in five deaths," Dr Kelly said.

"Covid-19 simply has brought to the fore the lack of an effective treatment for this very common but severe problem," Dr Kelly said.

"Veyonda works in the laboratory in a way that indicates the potential to block the formation of the so-called cytokine storm leading to septic shock," Dr Kelly said.

"We need to confirm this in a clinical setting as quickly and as cost-effectively as we can," Dr Kelly said.

"The implications for the company in having a positively acting drug are very substantial and that is the main reason why we have chosen to run a phase I study in Europe," Dr Kelly said.

Noxopharm was up 1.5 cents or 7.9 percent to 20.5 cents with 3.7 million shares traded.

IMMURON
COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Immuron says it will work with the CSIRO to develop a therapeutic for entero toxigenic Escherichia coli and Campylobacter for the US Department of Defense.

Last year, Immuron said it had a $5.5 million collaboration with the US Department of Defense to work with the Naval Medical Research Center (NMRC) to develop a Campylobacter and entero-toxigenic Escherichia coli-specific anti-microbial preventive for travellers' diarrhoea with its bovine colostrum-based technology (BD: Oct 2, 2019).

Today, the company said it had an agreement with the CSIRO to produce a hyper-immune bovine colostrum product using vaccines developed by the NMRC.

Immuron said the work with the CSIRO would be conducted at the Department of Agriculture and Water Resources facilities in Armidale, New South Wales.

The company said the NMRC submitted a pre-investigational new drug information package for the therapeutic to the US Food and Drug Administration on June 10, 2020 and planned to file an application to the FDA, with two phase II clinical trials of the preventative therapeutic planned for 2021.

Immuron was up three cents or 10.2 percent to 32.5 cents with 7.7 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says it has appointed Aenorasis SA to distribute of its human telomerase reverse transcriptase (hTERT) adjunct test for bladder cancer in Greece and Cyprus.
Sienna said the Athens-based Aenorasis was also the exclusive distributor of a brand of liquid-based cytology products, used in conjunction with Sienna's hTERT test.
The company said Aenorasis would "soon begin sales and technical training with Aenorasis staff, in addition to setting up two reference laboratories in Greece".
Sienna said that bladder cancer was the sixth most commonly occurring cancer in men and the seventeenth in women, with Greece having the second highest rate of bladder cancer in the world after Lebanon, recording 2,100 new cases in 2018.
The company said that an estimated 10,000 urine cytology tests were performed each year in Greece and Cyprus.
Sienna was unchanged at 6.9 cents.

GI DYNAMICS

GI Dynamics says it has received $US750,000 ($A1,093,403) through the issue of an unsecured convertible promissory note, or bridge note, to the Crystal Amber Fund.
GI Dynamics said the bridge note had a compound interest rate of five percent, which would increase to eight percent if the note went into default.
The company said the bridge note principal and all unpaid accrued interest would become due and payable, at the St Peter Port, Guernsey Island-based Crystal Amber's discretion, or six months following the issue date.
GI Dynamics said that in terms of financing beyond the bridge note, it had "not been able to agree to the terms of a potential fundraising".
GI Dynamics fell 0.1 cents or 20 percent to 0.4 cents with 2.5 million shares traded.

IMAGION BIOSYSTEMS

Imagion says shareholders will vote to issue 10 million performance rights and six million options to chief executive officer Bob Proulx, and 2,500,000 director options.
Imagion said it proposed to issue Mr Proulx performance rights as a long-term incentive for the achievement of milestones.
The company said Mr Proulx would be issued options as part of his remuneration package, which would vest in three equal tranches on May 1, 2021 to 2023, exercisable at 2.8 cents within five years.
Imagion said shareholders would vote to issue 500,000 options each to non-executive directors Dianne Angus, Michael John Harsh, David Ludvigson, Jovanka Naumoska, Mark Van Asten, or their respective nominees, as part of their remuneration packages for the 24 months to April 30, 2022.
The company said the director options would vest in equal tranches on May 1, 2021 and May 1, 2022, exercisable at 2.8 cents within five years.
Imagion said shareholders would vote to adopt the remuneration report, re-elect directors Ms Angus, Mr Harsh and Ms Naumoska, ratify the issue of shares and options, approve the issue of new options, including to the lead management of past and future capital raisings, approve the equity incentive plan, and approve a 10 percent placement facility.
The meeting will be held as online on July 22, 2020 at 11 am (AEST).
Imagion was up 0.2 cents or 7.1 percent to three cents with five million shares traded.

IMMURON

Immuron executive vice-chairman Peter Anastasiou says he has reduced his holding from 18,273,644 shares (10.31%) to 12,742,956 shares (7.15%).

Mr Anastasiou said that between June 15 and 17, 2020 he disposed of shares through on market trades, with the single largest sale 2,907,236 shares for $889,770 or 30.6 cents a share.

Following an Immuron announcement on June 9 that its research collaboration on campylobacter and Escherichia coli with the US Naval Medical Research Center was back on-track and the Centre had requested a pre-investigational new drug application meeting with the US Food and Drug, Immuron climbed as much as 442.2 percent from 8.3 cents to a high of 45 cents, closing at 30 cents (BD: Jun 9, 10, 2020).

CRONOS AUSTRALIA

Cronos says that Peter Righetti has resigned as executive director and chief operational officer, effective from June 19, 2020.

Cronos said Mr Righetti's executive role would not be replaced and Mr Righetti would continue to work for the company for up to 12 months.

Cronos was up 0.8 cents or 10.4 percent to 8.5 cents with 1.2 million shares traded.