Biotech Daily

Friday October 4, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: MESOBLAST UP 10%; CLARITY DOWN 12%**

*** DR BOREHAM'S CRUCIBLE: EMVISION MEDICAL DEVICES**

*** CONTROL BIONICS $400k NDIS APPROVALS; EQUIPMENT LEASING**

*** FDA DENIES NEUROTECH NTI164 PANDAS/PANS ORPHAN STATUS**

*** RESPIRI PROGRAMS 'REDUCE RE-HOSPITALIZATION 56%'**

*** TELIX DOSES 1st PHASE II TLX250-CDx RENAL CELL CANCER PATIENT**

*** MONASH UNI TRIALS SODIUM SELENATE FOR DEMENTIA**

*** CONTROL BIONICS RECEIVES $737k FEDERAL R&D TAX INCENTIVE**

*** ADALTA RECEIVES $1.8m FEDERAL R&D TAX INCENTIVE**

*** VANGUARD, ASSOCIATES TAKE 5% OF OPTHEA**

MARKET REPORT

The Australian stock market fell 0.67 percent on Friday October 4, 2024, with the ASX200 down 55.2 points to 8,150.0 points.

Sixteen of the Biotech Daily Top 40 companies were up, 15 fell, eight traded unchanged and one was untraded.

Mesoblast was the best, up 14 cents or 10.4 percent to $1.49, with 18.3 million shares traded. Cyclopharm climbed 6.7 percent; Actinogen and Atomo improved four percent or more; Amplia, Opthea and Resonance were up three percent or more; Aroa, Cochlear, Emvision, Immutep, Nova Eye, Orthocell and SDI were up one percent or more; with Clinuvel, CSL, Pro Medicus and Telix up by less than one percent.

Clarity led the falls, down $1.06 or 12.1 percent to $7.67, with 1.85 million shares traded. 4D Medical lost 8.6 percent; Micro-X and Paradigm were down seven percent or more; Genetic Signatures and Proteomics fell more than six percent; Curvebeam, Nanosonics, Neuren and Polynovo were down more than three percent; Prescient and Syntara shed more than two percent; Avita, Cynata and Impedimed were down more than one percent; with Resmed down by 0.3 percent.

DR BOREHAM'S CRUCIBLE: EMVISION MEDICAL DEVICES

By TIM BOREHAM

ASX code: EMV

Share price: $2.08

Shares on issue: 85,424,884

Market cap: $177.7 million

Chief executive officer: Scott Kirkland

Board: John Keep (chair), Mr Kirkland, Geoff Pocock, Tony Keane, Dr Phillip Dubois, Patryk Kania

Financials (year to June 30, 2024) revenue nil, loss of $2.7 million ($3.9 million deficit previously), cash balance $18.6 million (up 88%)

Identifiable major shareholders: Keysight Technologies Inc 8.7%, Scott Kirkland 5.0%, Ryan Laws 3.72%, Paul and Angelique Brown 1.7%

Despite the stunning advances in medical science - keyhole and robotic surgery and the like - the seemingly simpler challenges often remain unsurmounted.

One of them is the ability to determine whether a stroke is the most common ischemic form - a blockage - or haemorrhagic (a bleed).

The difference is not just academic, because treating haemorrhagic patients with anti-clotting drugs - the remedy for the more common ischemic strokes - can be fatal.

They will bleed out.

What's more, time is critical in treating strokes, with the 60 minutes post-event dubbed the Golden Hour. First responders such as paramedics have their hands tied before the status of the stroke (or whether it's a stroke at all) is clarified.

Emvision seeks to change all of that with its portable imaging tool - dubbed Emu - and an even lighter variant called First Responder. The devices can diagnose a stroke (and what type) at the bedside in an emergency ward, in an ambulance, or at the scene of the mishap.

Having undertaken a number of trials already, Emvision can't be accused of sticking its head in the sand on the extent of the problem.

About strokes

Strokes are the world's second biggest killer, with 15 million cases a year (55,000 in Australia, or 150 per day). Five million of these patients will die and one-third will have a permanent disability.

As mentioned, the strokes need to be identified urgently.

Currently, the American Heart Association recommends rapid brain imaging, typically starting with a non-contrast computed tomography (NCCT) scan.

While NCCT scans are very good at ruling out haemorrhage, they are not so good with detecting acute ischemia.

CT (computed tomography), CT, angiogram, CT perfusion or magnetic resonance imaging (MRI) scans are often needed, but the gear required is bulky, expensive and needs specialist operators.

About Emvision

Emvision was formed in July 2017 by Scott Kirkland and Ryan Laws, to acquire the technology from the University of Queensland'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.

"After a career in sales and marketing, I was quite simply looking for an opportunity to create a bigger positive impact and healthcare felt like a pretty good place to start," Mr Kirkland says.

The underlying algorithm and antenna technology were co-invented by the university's professors Prof Amin Abbosh and Prof Stuart Crozier.

Initially, the inventors came up with portable scanner prototypes with versions for the skin, for the torso and for the brain.

But market research showed the greatest unmet clinical need and commercial opportunity was in point-of-care brain imaging, in particular acute stroke care.

Emvision listed in mid-December 2018, having raised $6 million at 25 cents apiece.

About the devices

Emu and First Responder won't replace the current CT or MRI-based stroke imaging methods. As with most medical algorithms, they create high-contrast, supplementary images that are compared to the grey-ish pictures from MRI-CT scans.

The added clarity means that not only can new strokes be identified, but also damaged tissue around an old stroke site.

“We are also focused on providing better bedside monitoring for patients at risk of deterioration, including complications and perioperative stroke,” Mr Kirland says.

The patients may be too unwell to be transported to the radiology department.

The size of a current medical cart, Emu weighs around 100 kilograms, compared with around 600 kilos for the current imaging kit.

Weighing in at a mere 10kg, the backpack-sized First Responder is designed for use by paramedics at the scene.

“Ambulances are notoriously strict on space; they joke they count every bandage,” Mr Kirkland says.

Based on electro-magnetic microwave imaging, the helmet-like devices can take an image and diagnose the type of stroke within five minutes. The entire imaging process can be done on a laptop, and the devices have been simply designed to enable use by paramedics and bedside nurses.

Emvision has established a pilot production facility at its Macquarie Park HQ in western Sydney, capable of producing one Emu a week (with the ability to expand to four).

In the clinic

In late May, Emvision released results for the second stage of its multi-site, pre-validation trial of Emu, which in total covers the images of 240 suspected stroke victims.

These patients with stroke-like symptoms had presented to three high-volume emergency departments: Royal Melbourne Hospital, Brisbane’s Princess Alexandra Hospital and Sydney’s Liverpool Hospital.

“Highly promising” initial results from the 180 stage-two images showed the algorithm behind Emu was able to differentiate between haemorrhagic, ischemic and non-stroke events. A readout from stage three, covering 30 haemorrhagic stroke patients, is expected in “coming months”.

The next step is a validation (pivotal) trial, aimed at supporting US Food and Drug Administration (FDA) approval under the de-novo (new device) route.

In collaboration with the Australian Stroke Alliance (ASA), Emvision plans to test First Responder on healthy volunteers, road ambulances and the Royal Flying Doctor Service.

It is also being trialled in mobile stroke ambulances - of which there are only 40 worldwide, disturbingly; of which one is in Melbourne, with a second planned for Victoria.

The path to market

In late September, the company was due to meet with the FDA to discuss the structure of a validation study to support the planned approval application.

Often attached to teaching hospitals, around 1,600 comprehensive and primary stroke centres service the highest volume of patients.

They have a particular interest in neuro-monitoring, especially for intensive-care patients.

Then there are the about 1,300 critical access hospitals in small regional areas. At least 35 miles from any other hospital, these facilities have fewer than 25 inpatient beds but operate around-the-clock.

This definition is significant because the Centers for Medicare & Medicaid Services (CMS) confers them with financial benefits such as 101 percent reimbursement.

“To maintain accreditation, these small centres seek technology that is easy to use, does not require specialist operators and enables timely and efficient transfer of potential long-length-of-stay patients,” Mr Kirkland says.

Lo and behold, these include acute stroke patients.

The company plans a distribution deal in the US, but Mr Kirkland warns a tie up with a large player is “not a guaranteed recipe for success”.

Finances and performance

Emvision is doing well to tap non-dilutive funding from several sources.

The company claimed ‘revenue’ of $11.56 million for the year to June 2024, up 63 percent. But let’s call it ‘other income’ because the funds consisted of grants the Federal Research and Development Tax Incentives and some bank interest.

Of the $4.3 million of grant income, the company pocketed $1.8 million from the Australian Stroke Association’s Golden Hour project and just under $2.5 million from the Modern Manufacturing Medical Products Manufacturing Translation Stream Project.

Yep, it’s a mouthful - but money is money.

In February 2024, the company executed a $15.28 million placement at $2.05 a share to the New York-listed Keysight Technologies, a long-term strategic collaborator.

In January 2024, the company said it would receive $2.5 million of non-dilutive funding from the NSW Medical Devices Fund.

The amount only becomes repayable when the company achieves $500,000 of underlying profit: in other words, well into commercialization.

With clinical activity ramping up, Emvision's expenses increased 40 percent to $12.19 million.

But the Keysight raising means the company has a handy $18.6 million in the bank - enough to fund the validation trial.

Emvision shares have gained 30 percent over the last year, with the stock trading as low as $1.47 (December 12, 2023) and as high as $2.68 (March 25, 2024).

The shares peaked at $4 in November 2020, not long after troughing at 50 cents in March that year (at the onset of the pandemic).

Sizin' the rivals

No fewer than five ASX-listed companies are involved in stroke detection or treatment.

Emvision's nearest ASX device comparator is Micro-X, which is also developing a portable (x-ray based) stroke detector for frontline use.

Micro-X is not a pure-play stroke exposure because it is also applying its tech to bomb disposal and airport baggage screening.

Speaking generally, Mr Kirkland says rival devices do not emulate Emvision's wares in terms of usability, portability and cost effectiveness.

"We are the only late development-stage, well-funded organization building a compelling body of clinical evidence in the ultra-high frequency radio signal sensing and imaging space," he says.

In contrast, most 'rivals' aim to make existing CT or MRI machines smaller and are not focusing on stroke diagnosis, per-se.

Yes, there's an A.I. angle

"Without the advances in widely available and low-cost computing power that we see today, our work would have been incredibly challenging just 10 years ago," Mr Kirland says.

The company used high-performance computing to design the software and the algorithms.

"Within the product, we use artificial intelligence … to interpret complex signal interactions and derive a neuro-diagnostic output," Mr Kirkland says.

"That is: blood or not, clot or not."

Dr Boreham's diagnosis:

Let's run through the numbers on Emvision's addressable market.

Assuming one Emu device per stroke ward, intensive care unit and emergency department, that adds up to an addressable market of 10,200 units in the US.

"Outside of the US, we believe the global addressable is around 92,000 [units]," Mr Kirkland says.

The company expects Emu to sell for $US150,000 ($A225,000), with attached service contracts and consumables of a further $US25 per patient.

The First Responder pricing has not been decided, but the consumables are expected to be around $US50 per patient.

There are about 60,000 road ambulances and 1,000 air ambulances in the US, with around 120,000 across the Western world.

"Our view is this could go in every ambulance, as with a defibrillator or ECG [electrocardiogram device] but you start with a portion of a fleet, do reference studies and build out," Mr Kirkland says.

So, all of that adds up to … a lot of dollars.

But a potential larger opportunity is for quick diagnosis of traumatic brain injury (TBI), an even bigger market than stroke with 50 million to 60 million cases a year (26 million of them medically treated).

Mr Kirkland says Emvision is targeting market entry late next year, depending on the progress of the validation trial and the de novo submission.

This timing sounds ambitious, but there's no denying the size of the market and the unmet medical need.

And like the avian representative on Australia's coat of arms there's only one way to go and that's forward.

"Both Emu and First Responder are [targeting] potential multi-billion-dollar markets," Mr Kirland says.

"The key of course is where do you start?"

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He usually doesn't know where to start – beginning with getting out of bed in the morning.

CONTROL BIONICS

Control Bionics says it has $400,000 in Australian National Disability Insurance Scheme (NDIS) approvals and launched a 12-month leasing program for its Trilogy system.
Control Bionics said the NDIS approvals would be recognized as revenue as devices were shipped to customers, with the $400,000 in eight weeks worth more than it received "from the NDIS over the previous five months".
Control Bionics said it had "nearly $1.0 million currently awaiting approval from the NDIS or expected to be submitted shortly".
The company said it was "encouraged" by the engagement with the NDIS and was "confident we will see continued approvals from the agency in the coming months".
Control Bionics said the NDIS had approved its first application for a leasing program of its Trilogy system for neuro-degenerative conditions, which would allow its "customers to lease the device for 12 months at a lower cost than purchasing outright".
According to its website, the Neuronode Trilogy combined touch, eye control and electro-myography, or spatial, control for a faster and less fatiguing speech generating device.
The Control Bionic website said the Trilogy had "three access methods to provide a flexible communication solution for those with complex speech and physical needs".
The website said a three-month rental for the Trilogy Neuronode with buyout option started from $8,000, with the outright purchase price was more than $20,875.
The company said it was preparing to launch a similar leasing program for Neuronode.
Control Bionics was up one cent or 14.3 percent to eight cents.

MONASH UNIVERSITY

Monash University says it will conduct a 120-participant, 12-month, phase IIb trial of sodium selenate for behavioral variant fronto-temporal dementia (BVFTD).
Monash said that unlike other types of dementia, there were no approved treatments for BVFTD and it could affect individuals as young as 35 years old.
The University said fronto-temporal dementia was rare but caused "progressive damage and shrinkage to either or both the frontal or temporal lobes of the brain, along with behavioral changes such as impulsivity, inappropriate behavior and … loss of language".
Monash University said the trial would enrol patients diagnosed as "possible or probable" BVFTD, and it would involve cognitive tests, brain scans and regular phone check-ins.
The University said patients would receive either 52 weeks of treatment with sodium selenate, or placebo, and that the study would compare changes to brain volume and tau protein levels, rate of cognitive decline and behavioral changes.
Monash said a 12-participant, 2022 study had shown sodium selenate to be well tolerated and safe in people diagnosed with fronto-temporal dementia.
The University said the study, titled 'A phase 1b open-label study of sodium selenate as a disease-modifying treatment for possible behavioural variant frontotemporal dementia' was published in the journal Alzheimer's Association and was available at: https://alz-journals.onlinelibrary.wiley.com/doi/10.1002/trc2.12299.
The study said all participants completed the study, with 64.7 percent of adverse events reported being mild and only one serious adverse event, which was not treatment related.
The publication said that there was no evidence for change in tau protein levels, with "small declines in [magnetic resonance imaging] and cognitive and behavioral measures … observed over the treatment period".
Monash University's Prof Terence O'Brien said that sodium selenate was inexpensive, "which is important, as we've seen recently that new promising treatments for dementias can cost much more than what governments and ordinary people can afford".

NEUROTECH INTERNATIONAL

Neurotech says the US Food and Drug Administration has denied its orphan drug status application for the marijuana-based NTI164 for paediatric neuro-psychiatric disorders.

In July, Neurotech said it had applied to the FDA for orphan drug designation for its marijuana-based NTI164 for paediatric autoimmune neuro-psychiatric disorders associated with streptococcal infections (Pandas) and paediatric acute-onset neuro-psychiatric syndrome (Pans) (BD: Jul 9, 2024).

Last year, the company said a 15-patient, phase I/II trial of NTI164 for children with Pandas/Pans met its primary endpoint for anxiety and depression, with a 30 percent improvement in overall symptoms from week four onward (p = 0.016) (BD: Oct 6, 2024).

Today, the company said the FDA rejected the designation on the grounds that Pandas/Pans might "not constitute the definition of a rare disease" in the US, citing a study showing a prevalence rate of one in 200 children, with the designation requiring fewer than 200,000 occurrences in the US.

Neurotech said the FDA prevalence had "no supportive peer-reviewed data".

The company said the FDA "felt it was unclear a distinction can be made for Pans as a separate disease, after consultation with the Division of Psychiatry, Office of New Drugs, Centers for Drug Evaluation and Research".

Neurotech said the FDA had granted it 12-months to address the agency's objections and had requested it provide the FDA with supportive data and references regarding the Pandas/Pans distinction.

The company said that, in consultation with its regulatory advisors, it would "consider providing a response to the FDA in the months ahead".

Neurotech said the FDA had no objections to its non-clinical and clinical evidence supporting the application, or NTI164's mechanism of action, efficacy in pre-clinical and human trials, and the relevance of NTI164 to Pandas/Pans.

The company said the decision did "not impact [its] development plans for Pandas/Pans".

Neurotech said it expected the outcome of its FDA orphan drug designation application for NTI164 for Rett Syndrome "prior to December 2024".

Neurotech fell 0.9 cents or 15.5 percent to 4.9 cents with 4.5 million shares traded.

RESPIRI

Respiri says its patient programs reduced re-hospitalization by 56 percent, length of stay by 42 percent and emergency room visits by 47 percent.

Respiri said repeat hospitalization was a major focus of the US Centers of Medicare and Medicaid (CMS) and was a measure of the effectiveness of hospital patient healthcare provision, with the CMS fining more than 50 percent of US hospitals for breaching accepted levels of readmission.

The company said New York Cancer and Blood Specialists had provided 3,000 more patients for its programs, and the expanded program would lead to an additional $US1.2 million ($A1.75 million) in annualized revenue.

Respiri said it had increased its number of monthly reimbursed services with Boston's Ceras, increasing revenue for each patient per month from $US49.00 to $US74.00.

The company said that it had expanded its services at the University of Alabama Hospital to the university's second healthcare system, and that services included transitional care management, remote patient monitoring and chronic care services.

Respiri managing-director Marjan Mikel said "our programs deliver better outcomes for patients resulting in reduced costs for our clients … another significant step forward".

Respiri fell 0.2 cents or 4.8 percent to four cents with 10.0 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has dosed the first of 91-patients in its single-centre, phase II trial of TLX250-CDx imaging agent for recurrent clear cell renal cell carcinoma post-surgery.

In an email announcement not released to the ASX, Telix said the trial would compare its positron emission tomography (PET) agent TLX250-CDx, or Zirconium-89-girentuximab, with conventional imaging, or contrast-enhanced computed tomography (CT), alone.

The company said the investigator-led trial was being conducted by the University of California, Los Angeles' Prof Brian Shuch, was designed to identify recurrent clear cell renal cell carcinoma, including metastatic disease, and was one of multiple trials underway or planned which could inform label expansion for TLX250-CDx.

In 2022, Telix said its 300-patient, phase III trial of TLX250-CDx for imaging clear-cell renal cancer met its primary endpoints, with 86 percent sensitivity and 87 percent specificity (BD: Nov 7, 2022).

At that time, the company said TLX250-CDx had US Food and Drug Administration breakthrough designation and it intended to file a biologics licence application for approval as a PET/CT imaging agent to characterize indeterminate renal masses previously identified on CT or magnetic resonance imaging as clear-cell renal cancer or non-clear-cell renal cancer.

Earlier this year, Telix said it had filed a biologics licence application for TLX250-CDx with the FDA, which later was rejected due to a filing issue in the chemistry, manufacturing and controls package (BD: Jun 3, Jul 31, 2024).

At that time, the company said the FDA had required the issue to be resolved before the application could advance to a full review, and that it expected to be able to complete remedial actions within about 90 days and resubmit the application.

In today's email, Telix chief medical officer Dr David Cade said the company was "pleased that a first patient has been imaged in the … trial, which supports potential label expansion for TLX250-CDx into recurrent, metastatic disease".

Telix was up three cents or 0.15 percent to $20.48 with 611,461 shares traded.

CONTROL BIONICS

Control Bionics says it has received $736,794 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Control Bionics said the incentive related to research and development expenditure for the year to June 30, 2024.

The company said that it had used the funds to repay its loan with Radium Capital, leaving a residual amount of $288,587.

ADALTA

Adalta says it has received $1.77 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Adalta said the incentive related to research and development expenditure for the year to June 30, 2024.

The company said it would use part of the refund to repay in full a $1.4 million loan from the Victoria State Government.

In April, Adalta said it had extended final repayment of its research and development tax incentive loan with the Treasury Corporation of Victoria from April 30 to October 31, 2024, with loan interest rate unchanged (BD: Apr 29, 2024).

Adalta was unchanged at 1.85 cents.

OPTHEA

Vanguard Group says that with its associated entities it has become a substantial shareholder in Opthea with 62,130,152 shares, or 5.047 percent.

The Philadelphia, Pennsylvania-based Vanguard said that between May 31 and September 20, 2024 with Brown Brothers Harriman, Bank of New York Mellon, JP Morgan Chase and State Street it bought and sold shares at prices ranging from 34.0 cents to 80.0 cents a share.

Opthea was up 2.5 cents or three percent to 85 cents with 5.85 million shares traded.