Biotech Daily

Friday December 18, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: RESONANCE UP 10%; MESOBLAST DOWN 36%**

*** DR BOREHAM'S CRUCIBLE: MICRO-X**

*** MESOBLAST: DSMB HALTS REMESTEMCEL-L COVID-19 ARDS TRIAL**

*** 4D: XV LVAS SCANS 1st COMMERCIAL PATIENT**

*** AUSTCO RECEIVES $489k LEGAL SETTLEMENT**

*** IMPEDIMED WINS HITRUST CERTIFICATION FOR CYBER SECURITY**

*** PARADIGM PREPARES FDA IND FOR PPS FOR OSTEOARTHRITIS**

*** MAYNE EXTENDS DEBT FACILITY, REDUCES DEBT TO $208m**

MARKET REPORT

The Australian stock market fell 1.2 percent on Friday December 18, 2020, with the ASX200 down 81.2 points to 6,675.5 points.

Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and one was untraded.

Resonance was the best, up two cents or 9.8 percent to 22.5 cents, with 831,009 shares traded. Telix climbed 8.6 percent; Cyclopharm improved 7.8 percent; Proteomics was up 6.5 percent; Impedimed and Starpharma were up four percent or more; Nanosonics and Pro Medicus rose two percent or more; Clinuvel, Resmed and Universal Biosensors were up more than one percent; with CSL and Medical Developments up by less than one percent.

Mesoblast led the falls, falling as much as $1.69 or 44.8 percent to $2.08 before closing down $1.36 or 36.1 percent at $2.41, with 74.9 million shares traded. After two days of climbing, Antisense retreated 16.7 percent to 12.5 cents, with 14.5 million shares traded.

Cynata and Immutep lost more than five percent; Amplia, Dimerix and Nova Eye fell more than four percent; Alterity and Paradigm were down more than three percent; Avita, Genetic Signatures, Neuren, Opthea and Polynovo shed two percent or more; Compumedics, Pharmaxis and Prescient were down more than one percent; with Cochlear and Next Science down by less than one percent.

DR BOREHAM'S CRUCIBLE: MICRO-X

By TIM BOREHAM

ASX code: MX1

Market cap: $125.6 million; **Share price:** 38.5 cents; **Shares on issue:** 359,341,753

Chief executive officer: Peter Rowland

Board: Patrick O'Brien (chair*****), Mr Rowland, Yasmin King, Dr Alexander Gosling, David Knox, Jim McDowell******

***** Mr O'Brien will step down in favor of Mr Knox in early 2021

****** Mr McDowell rejoins the board on January 1 2021. He was a director between September 2017 and August 2018, but resigned to take up the role of chief executive of South Australia's Department of Premier and Cabinet

Financials (September quarter 2020): receipts $1.9 million, operating cash outflows $2.5 million, cash balance $15.54 million, quarters of available funding: six*******

******* The company has a $3 million loan facility with the South Australian Government Financing Agency, fully drawn and a half-drawn $10 million convertible note facility with Thales AVS France.

Identifiable major holders: Perennial Value Management 12.2%, Tiga Trading/Thorney Investments 7.3%, Regal Funds Management 6%.

For smug non-Croweaters who claim the closest Adelaide has got to technical innovation is a pie floater: shame on you.

In the medical device sphere, Adelaide-based LBT Innovations is taking on the world with its automated Petri dish sampling, while Ellex Medical Lasers refined ophthalmology devices.

Now, Micro-X is striving to do the same with its bonsaied x-ray imaging devices that are lighter and more portable than the current standard-of-care.

Based on its patented cold cathode know-how, Micro-X is also pursuing airport security, stroke detection and explosives detection applications - all from its Tonsley HQ and a toiling staff of 23 engineers and scientists.

Micro-X's mobile medical X-ray device, the Carestream DRX Revolution Nano, is already approved and sold in 14 countries, with sales surging this year because of the pandemic.

At the behest of the Australian Defence Force (ADF) the company also developed a "ruggedized" variant, the Rover, aimed at military applications such as mobile army hospitals.

The next step is a lightweight computerized tomography (CT) brain scanner for in-ambulance diagnosis of strokes in the crucial first hour when damage can be minimized.

“We are the only cold cathode x-ray technology company in medical devices in the world,” says chief executive Peter Rowland.

“We have products in the market, we have revenue and multiple new product lines in design and massive addressable markets.”

We can do it better

Micro-X was founded nine years ago based on technology acquired from Xinray, a University of North Carolina spin-off company.

Originally, the product was to be developed by Xinray but progress was slow - partly because of the different mindset of the academic-oriented Xinray camp versus Micro-X’s manufacturing-oriented engineers.

So Micro-X decided to make its own carbon nanotubes (CNTs), focusing on mass producing them with consistent quality.

“Three years ago, we started a research study in Adelaide with some very clever people and got to the bottom of how the carbon nanotubes really work - and it was nothing like in the published material,” Mr Rowland says.

Micro-X listed on the ASX almost five years ago, to the day, on December 21, 2015.

Apart from being a proud Scotsman, Mr Rowland is the former chief executive of the aforementioned Ellex and among other positions was business development head of BAE Systems.

Micro-X tech explained … sort of

X-rays still sound science fiction-y but the underlying technology is little changed since Germany physicist Wilhelm Rongen’s accidental brainwave in 1895: a heated filament cathode that generates electrons in a vacuum tube.

These electrons are then accelerated by high voltage on to a tungsten anode target to produce x-rays on impact. In short, the process is inefficient because a lot of waste heat is produced and the electrons don’t all move in the right direction.

Micro-X’s cold cathode technique is based on an array of four-nanometer wide carbon tubes, under an electrified fine mesh structure.

While standard CT scanners use only one x-ray source to rotate around an object, these electronically-controlled x-ray tubes enable x-ray beams to be fired from different angles and with no moving parts.

The upshot is the tubes can be made substantially smaller and 95 percent lighter - one kilogram compared with 20 kilograms.

As well as perfecting the tubes themselves, the company is well progressed with engineering work for a high voltage generator, the other key component of an x-ray kit.

“In the old days you would have an x-ray source and a high voltage power supply and you would connect the two with a cable,” Mr Rowland says.

With Micro-X’s future ultra-light design the generator will be integrated with the device.

Good boy, Rover

Rover is a variant of the Nano, a cart-and-detector package for remote and military use.

As with the Nano, the Rovers weigh 95kg compared with 350-600kg for a standard mobile x-ray unit and are more durable and maneuverable.

The Australian Defence Force helped fund Rover’s initial development, while Mr Rowland reports “really good progress” with the US military.

“They are waking up to the fact the dream they thought they could never have - full acute x-ray performance in a light unit - is now achievable.”

The company won US (510k) device approval for the Rovers in July.

The Australian Defence Force recently tendered out its entire mobile hospital function. The $300 million turnkey contract was won by Saab Australia, which subbed out the radiology component to Micro-X.

The quantum of the deal is modest – low seven figures – but ‘official supplier to the ADF’ status will help the company’s North America sales efforts.

In September this year, the World Health Organisation bought $1.4 million of Rovers for relief work in remote Pacific island locations.

Airport screening

Of all the company’s planned products, Mr Rowland says self-service airport screening has the most public resonance because almost every flyer has been inconvenienced by a lengthy scanning queue.

“The idea is that travelling life will be more pleasant and that really grabs people.”

The airport security push is spurred by the US Transportation Security Administration and its parent agency the US Department of Homeland Security.

In November, the latter agreed to fund Micro-X up to $US1.5 million ($A2 million) to design a self-service baggage scanner. Separately, Micro-X is being funded up to $US2.5 million to design a self-service security portal, in an alliance with Melbourne company Elenium Automation and the Monash University (Monash Art Design & Architecture).

There are more benefits at stake than avoiding the spectacle of beltless and shoeless passengers getting the once-over by over-eager security guards: the TSA spends $US3.8 billion a year on security staff, so if it can even halve this number that's a couple of billion more to prop up the nation's creaking budget.

The company also won two contracts with the British Government's transport department, under its Future Aviation Security Solutions program. These deals pertain to funding the development of lightweight x-ray imaging for detecting explosives hidden in consumer devices.

Stroke me, stroke me

Called Tomo, the ring-shaped stroke imaging device would be small and light enough to be standard kit in ambulances.

"The brain [device] is the singularly most exciting thing we are doing," Mr Rowland says.

"It's going to be such a simple product to have a CT scanner rugged and small enough and cheap enough to be fitted in every ambulance."

He notes that if stroke victims don't get treated within the first hour - dubbed the Golden Hour by medicos - they will end up with some permanent disability.

Micro-X's challenge was to replicate the imaging performance of the current standard of care, an eight-slice helical, or spiral, CT scan.

"We have managed to do that and we think we can do one better, with ability to diagnose a one millimetre bleed in the hardest place in the brain to find it," he says.

The federal government's Medical Research Future Fund (MRFF) funded the initial concept development phase.

The company is now "breathlessly waiting" to see if it will receive full development funding from the Australian Stroke Alliance, ultimately funded by the MRFF's second phase of its Frontier Medicine Program.

Mr Rowland envisages each machine would cost $100,000, which compares with the potential $150,000 cost to the health system of treating a stroke patient with high permanent disability resulting from delayed diagnosis.

"If you save one person from a high-level disability you are ahead for the year," he says.

And in some (non) exclusive news …

Micro-X attributes its early sales momentum to its tie up with its worldwide distributor, Carestream Health Inc (formerly Kodak Medical Imaging).

Carestream and Micro-X struck a five-year exclusive agreement in 2016, but in November this year the deal was modified to allow Micro-X to sell directly or via other agents.

The philosophy behind this is that the radiology profession is conservative and resists change, so if more parties are trying to sell novel devices it will help to raise awareness to the benefit of everyone.

“A lesser company would have hung on to exclusivity for as long as they could,” Mr Rowland says.

A five-year head start

Mr Rowland says that while the company is the clear leader in cold cathode x-ray tech, potential rivals are nipping at its heels.

Probably the closest is the Nasdaq listed Israeli company Nano-X Imaging, which soared to a $US3 billion market valuation after its August debut initially valued the stock at $US200 million.

Nano-X is also developing a stationary CT imager, but Micro-X has disputed Nano-X’s claim that it was the first company to perfect a cold cathode x-ray technology.

Mr Rowland reckons Micro-X has a five-year head start.

Finances and performance

Micro-X chalked up $3.8 million of Nano sales in the year to June 30, 2020, with $3.3 million of other income from grants and research and development tax refunds.

The Nanos proved popular during the pandemic because they allow for bedside imaging, which reduces the risk of infection resulting from patients being moved from ward to ward.

The company has raised $31.5 million of equity over the last 12 months: $16.5 million from a placement in December last year and $15 million from a placement and rights issue in April and May this year.

The company has a circa $15 million cash balance, enough to last into 2022.

Since listing Micro-X shares have traded between 56 cents (December 24, 2015) and 10 cents (March 24, 2020).

Any other bright ideas?

Micro-X envisages a product for door-to-door imaging - ideal for aged-care facilities and avoiding the need for patients to go to hospital outpatient clinics.

The company also sees strong prospects in the small animal veterinary market, because vet clinics tend to use the antiquated film-based equipment discarded by hospitals.

The US Army recently invited the company to tender for a vet opportunity - veterinarian, not veteran - pertaining to the x-ray healthcare of bomb-sniffing canines. The army employs a vast, er, army of dogs for the task. But they have a low attention span and can only work effectively for an hour or so, which means thousands are needed and they're expensive to train.

The company is also developing an imaging camera for one sided-viewing of suspected improvised explosive devices. In 10 seconds, the device can determine whether a backpack contains a bomb or a mouldy sandwich.

The company has just got back its initial test results.

"The images were absolutely spectacular, better than we ever thought," Mr Rowland says.

Dr Boreham's diagnosis:

The company's outgoing chairman Patrick O'Brien describes 2020 as a "truly remarkable year" for the company, which in effect has graduated from a tech developer to a commercial business. But while Micro-X shares have gained traction in recent weeks, the stock is still off its 50 cents listing price. One explanation is that in taking its tech in-house, the company has incurred costs not envisaged in its original plans.

"On the other hand, our security is a lot higher because we now own and control the manufacturing process and our patents," Mr Rowland says.

"We are a much better investment proposition as a result of all of those challenges."

In the mid-term, Micro-X will focus on building Rover sales, securing more regulatory approvals and executing the Saab military contract.

Mr Rowland says the company has reached an "inflexion point" in its development, which is terrific.

It also means Micro-X has no excuses for not racking up meaningful revenue, hopefully before its rivals catch up.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. As a Melburnian he has always been nice to Adelaidians but my they do talk funny, especially when they are going on about Stobie poles and pie floaters.

MESOBLAST

Mesoblast says the data safety monitoring board has recommended halting the trial of remestemcel-L for Covid-19-related acute respiratory distress syndrome (Ards)

Mesoblast said the board's third interim analysis of 180 patients found that the trial was "not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment".

"The DSMB recommended that the trial 'complete' with the currently enrolled 223 patients, and that all be followed-up as planned," the company said.

Mesoblast said the Board reported that there were no safety concerns.

The company said the randomized, controlled trial of remestemcel-L in ventilator-dependent patients with moderate to severe Ards due to Covid-19 infection "was powered to achieve a primary endpoint of 43 percent reduction in mortality at 30 days for treatment with remestemcel-L on top of maximal care in a trial of 300 patients".

"This projected mortality reduction was based on pilot data observed during the initial stages of the pandemic when control mortality rates were exceedingly high and prior to new evolving treatment regimens that have reduced disease mortality in ventilated patients," Mesoblast said.

The company said that at the time of the announcement, the trial had not accrued data on the secondary endpoints, which included days alive off mechanical ventilation at 60 days post randomization, overall survival, days in intensive care, duration of hospitalization, and cardiac, neurological, and pulmonary organ damage, with measures of circulating cytokines and inflammatory markers to be evaluated.

Mesoblast said that "none of these were included in the interim analysis" and the trial would evaluate all 223 enrolled patients through 60 days of follow-up to study potential treatment effects on these outcomes.

The company said that it and Novartis would analyze the results "to identify meaningful clinical outcomes that may guide decisions on the development program for remestemcel-L in non-Covid Ards.

Mesoblast said that as the pandemic evolved "numerous changes in the treatment regimens for Covid-19 patients occurred, including both prior to and while on mechanical ventilation that may have an effect on the mortality endpoint in the trial".

"These include extended management of patients prior to ventilator support, and use of experimental therapies such as dexamethasone, antivirals, and re-purposed immunomodulatory agents," the company said.

"All of these may have changed the natural course of ventilated patients and reduced overall mortality rates during the trial compared to the early stages of the pandemic," Mesoblast said.

The company said it entered into an up to $1.9 billion licence and collaboration agreement with Novartis on November 20 for the development, manufacture and commercialization of remestemcel-L, with an initial focus on the treatment of Ards, including that associated with Covid-19, and other indications (BD: Nov 20, 2020).

Mesoblast said that the closing of the Novartis agreement was subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions.

The Hart-Scott-Rodino Antitrust Improvements Act provides for a 30-day waiting period from filing documents to US authorities for those authorities to ask questions prior to a merger or deal being finalized.

Mesoblast fell as much as $1.69 or 44.8 percent to $2.08 before closing down $1.36 or 36.1 percent at $2.41 with 74.9 million shares traded.

4D MEDICAL

4D says it has scanned its first commercial Australian patient with its x-ray velocimetry lung ventilation analysis software (XV LVAS) respiratory diagnostic.
4D said the XV technology was four-dimensional, or 3-D over time, lung imaging that used mathematic models and algorithms to convert X-ray scans into data to help physicians manage patients with respiratory diseases, while using existing hospital equipment.
In September, the company said the Australian Therapeutic Goods Administration had approved the sale of its XV LVAS, six months ahead of schedule (BD: Sep 30, 2020).
Today, 4D said the patient was scanned in Victoria, where the national rollout of the XV LVAS software was expected to being in 2021.
4D chief executive officer Dr Andreas Fouras said the company was “pleased to hit yet another milestone ahead of schedule and see our end-to-end [software-as-a-service] clinical solution perform flawlessly in a real-world setting”.
“Covid-19 has seen traditional spirometry assessments shut down and our technology also provides an excellent alternative for patients who need regular and more detailed lung health assessments”, Mr Fouras said.
“While this might be our first ever Australian patient report, we expect to scale up quickly and begin to make a real difference to lung health in Australia,” Dr Fouras said.
4D was up 18 cents or 8.5 percent to $2.29 with one million shares traded.

IMPEDIMED

Impedimed says it has received Health Information Trust Alliance certification, a standardized US review which confirms the strength of a company’s cyber security.
Impedimed said the Frisco, Texas-based Health Information Trust Alliance (Hitrust) was established to assist organization in effectively managing data and information risk to comply with the requirements and standard of US regulatory bodies for businesses.
The company said that Hitrust certification was often requested in addition to US Health Insurance Portability and Accountability Act of 1996 and Business Associate compliances.
Impedimed said the assessment reviewed the privacy and security of its policies, procedures and controls, and certified that Impedimed was at the required standard.
Impedimed managing-director Richard Carreon said Impedimed believed in “a strong commitment to confidentiality, integrity and availability of its customers’ data and sought a risk management framework which encompassed these beliefs”.
“Hitrust is the benchmark for certification, providing our customers and their patients assurance their data is secure”, Mr Carreon said.
“We are very pleased with this outcome, which aligns with our goal of continuous improvements in the safeguarding of customer and patient data through our [internet] cloud-based technology”, Mr Carreon said.
Impedimed was up half a cent or four percent to 13 cents with 1.4 million shares traded.

AUSTCO (FORMERLY AZURE HEALTHCARE)

Austco says it had been paid $489,000 from an unnamed party following “legal proceedings in respect to a breach by a party of a non-compete clause”.
Austco said a subsidiary company filed the claim, which “moved quickly to a mediation” and was settled in the full requested amount.
The company said the payment would be recognized in its half yearly report for the six months to December 31, 2020.
Austco was unchanged at 10.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it will file a US Food and Drug Administration investigational new drug submission for its phase III trial of pentosan polysulfate sodium (PPS) by April 2021.
Paradigm said that following written FDA feedback regarding the approval process of its injectable pentosan polysulfate sodium (PPS), or Zilosul, for osteoarthritis, it would strengthen the investigational new drug submission by increasing the number of patients in its clinical studies and unifying the clinical trial protocol across the US, Europe and Australia to enable “registrations in multiple jurisdictions, saving time and money”.
The company did not disclose the number of patients planned for the trial but said it planned to begin enrolling patients in “mid-2021” at up-to 55 US sites and 10 Australian sites, with results expected by October 2023.
Paradigm said that once the IND was approved, it would begin enrolment in the randomized, double-blind, placebo controlled, PARA002 trial to determine the lowest effective dose, and then the safety and efficacy of PPS.
Paradigm fell nine cents or 3.5 percent to $2.45 with 1.7 million shares traded.

MAYNE PHARMA

Mayne says it has extended its three-year debt facility from November 2021 to November 2024 and has reduced its net financial debt to $208 million.
Mayne said it now had a $US100 million ($A131.5 million) four-year loan facility to November 2024, a $US200 million five-year loan facility to November 2023, a $US50 million financing facility, and $US20 million and $A10 million in working capital loan facilities.
The company said it had benefitted from foreign exchange and free cash flow and had “significant head room under its bank covenants”.
Mayne was up half a cent or 1.4 percent to 36 cents with 2.9 million shares traded.