Biotech Daily

Friday November 8, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NEUREN UP 15%; PRESCIENT, SYNTARA DOWN 5%**

*** DR BOREHAM'S CRUCIBLE: IMRICOR MEDICAL SYSTEMS**

*** AVITA 9-MONTH REVENUE UP 27% TO $69m; LOSS UP 78% TO $75m**

*** QUEENSLAND UNI $1m FOR LUCIA BIO START-UP**

*** UNIVERSAL BIO: HENRY SCHEIN US XPRECIA PRIME DISTRIBUTOR**

*** IMUGENE 1st AUSTRALIA PHASE Ib AZER-CEL LYMPHOMA SITE**

*** ARTRYA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** MAYNE RESPONDS TO MEDIA SPECULATION**

MARKET REPORT

The Australian stock market was up 0.84 percent on Friday November 8, 2024, with the ASX200 up 68.8 points to 8,295.1 points.

Twenty-six of the Biotech Daily Top 40 companies were up, 10 fell and four traded unchanged. All four Big Caps were up.

Neuren was the best for the third day in a row, up $2.17 or 15.1 percent to $16.57, with 1.95 million shares traded.

Dimerix was up eight percent; Immutep improved 7.4 percent; Medadvisor was up six percent; Compumedics and Impedimed climbed more than five percent; Atomo, Paradigm and Universal Biosensors rose four percent or more; Mesoblast, Opthea and Orthocell were up more than three percent; Amplia, Clarity, Curvebeam, Imugene, Micro-X and Pro Medicus rose two percent or more; Alcidion, Aroa, Cochlear, Medical Developments, Percheron, Polynovo, Proteomics and Resmed were up more than one percent; with Clinuvel, CSL, Nanosonics and Telix up by less than one percent.

Prescient and Syntara led the falls, both down 0.2 cents or 4.65 percent to 4.1 cents, with 236,813 shares and 2.4 million shares traded, respectively.

Avita fell 4.1 percent; Nova Eye lost 3.3 percent; Cyclopharm and Emvision shed more than two percent; 4D Medical and Resonance were down one percent or more; with Genetic Signatures and SDI down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMRICOR MEDICAL SYSTEMS

By TIM BOREHAM

ASX code: IMR

Share price: 71 cents; **CDIs on issue:** 270,175,766; **Market cap:** $191.8 million

Founder and executive chair: Steve Wedan

Board: Mr Wedan, Mark Tibbles (deputy chair), Anita Messal, Peter McGregor, Dr Jeffrey Leighton

Financials: (Six months to June 30, 2024) revenue $US408,000 (up 105%), net loss after tax $US6.9 million ($US9.2 million loss previously).
(September quarter 2024) receipts $US305,000, net cash outflows $US4 million, cash balance $US19.6 million, 4.9 quarters of available funding

Identifiable major shareholders: Saville Capital 6.01%, Hart Capital 5,87%, Warren G Herreid II (including Kahr Foundation) 4.60%, HR Global LLC 4.15%, Siemens Medical 3.10%, Mark Tibbles 2.31%, Steve Wedan 1.9%.

Most biotechs savor the moment when they chalk up their first sales, but Imricor founder and CEO Steve Wedan almost regrets the company is generating small initial revenues in Europe from its novel ablation catheters.

"I almost wish we weren't, because there are companies in our space that aren't yet commercial and have a valuation three times ours," he says.

Ah! The old conundrum of being valued more extravagantly at the 'blue sky promises' stage than at commercialization.

"But (entering Europe) was the right thing to do," Mr Wedan says. "It establishes sites and grows our sales base."

The only ablation catheter designed for use with a magnetic resonance imaging (MRI) scanner, the company's mainstay Vision-MR has been approved in Europe for type I atrial flutter (AFL) since 2020.

As well as offering superior images to x-rays, MRIs don't involve the use of harmful radiation and contrast dyes.

The company is carrying out a trial pitched at obtaining US Food and Drug Administration (FDA) approval for AFL, as well as a trial for European approval for the trickier ventricular tachycardia (VT). Australian approval awaits.

"We take a time-consuming procedure with poor outcomes, to one that is efficient and quicker," Mr Wedan says.

About Imricor

An American electrical engineer, Mr Wedan founded Imricor to devise heart procedure catheters that could be guided by MRI, rather than traditional x-ray fluoroscopy.

Given his role at General Electric (GE) Medical Systems designing MRI scanners, he was familiar with unsuccessful attempts by the major heart companies to design such devices.

He was spurred by consultancy work with Maryland's Johns Hopkins Hospital, where doctors asked him to design MRI-friendly probes. Mr Wedan founded Imricor in 2006, with an initial focus on VT ablation.

The MRI-guided procedure is called interventional cardiac magnetic resonance (ICMR) imaging. The first human ICMR procedure was carried out at Germany's Leipzig Heart Centre in 2011.

In 2012, Imricor licenced its technology to Dutch technology giant Koninklijke Philips and in 2018 inked its first contract with the Dresden Heart Centre.

Imricor listed on the ASX on August 30, 2019, having raised $13 million at 83 cents apiece.

The company is based in Burnsville, Minnesota, where it makes the devices and carries out research and development.

Imricor doesn't have any activities in Australia. It listed on the ASX after Mr Wedan was inspired by an ASX roadshow, spruiking the benefits of the antipodean bourse to US tech companies.

As Imricor's founder, chair, CEO and president, Mr Wedan is the heart and soul of the company (yep - pun intended).

About ablation (not ablution)

Cardiac ablation addresses heart arrhythmias, or irregular heartbeats, manifested in right-side atrial flutter or left-side atrial fibrillation or ventricular tachycardia (rapid heartbeat).

Administered via a catheter through the vein, cardiac ablation uses electric impulses to scars abnormal heart tissue, blocking irregular electric signals and restoring a normal heartbeat. The process is carried out by electro-physiologists, who are specially trained cardiologists.

Any successful medical device company needs to be tackling a real and present problem and in Imricor's case it's the poor success rate of cardiac ablation.

Another problem is that x-rays need potentially toxic dyes to be able to 'see' the heart.

By the 1990s, doctors became concerned about patients' radiation exposure (especially as they lived longer and had more scans).

While the device is approved for atrial flutter in 31 countries, Imricor is actively selling in eight European nations and recently gained approval in Saudi Arabia and Qatar.

Seven European hospitals are active - or pending - users. These include Germany's Leipzig Heart Centre, Cardiovascular Institute of South Paris, Amsterdam University Medical Centre and Croatia's Dubrava University Hospital.

Imricor has also developed the Vision-MR dispersive electrode, which minimizes eddy currents induced on the device's conductive pads during MRI scanning.

Then there's the Advantage-MR EP (electro-physiology) recorder/stimulation system, which is the hardware that enables the catheters to be deployed.

A key point is that Imricor is not inventing a new therapy, but is merely making the procedures MRI-compatible.

On trial

Called Visibl AFL, the trial to support US FDA approval is at four sites: Johns Hopkins, Cardiovascular Institute of South Paris, Switzerland's Lausanne University and Amsterdam University Medical Centre.

The trial intends to enrol 91 patients, but this number can be reduced to 74 patients if safety endpoints hit the mark. Imricor hopes to complete the trial by the end of the year, with FDA approval targeted for mid-2025.

"It's a pretty low risk trial because it is a repeat of what we did in Europe," Mr Wedan says - a reference to an earlier trial of 35 patients that had a 100 percent success rate.

Mr Wedan says approvals for new indications could be relatively quick because the consent relates to the catheter and associated cables, sheaths and ablation generator, rather than the disease itself.

Meanwhile, the company is carrying out a European trial to support an indication expansion to ventricular tachycardia (VT). This is a big deal, because VT requires access to the left side of the heart, which for physiological reasons is hard to access. To achieve this, the device incorporates a steerable sheath and trans-septal needle.

Dubbed Visabl-VT, the trial expects to enrol 64 patients across initial sites in the Netherlands and Germany.

The company expects its first-in-human VT case in the next month or two.

"It's the first time MRI will be showcased for these procedures and I couldn't be more excited about it," Mr Wedan says.

The trial is expected to complete by September 2025, with European approval targeted for mid-2026.

Finances and performance

Imricor recorded revenue of $US405,000 in the six months to June 30, 2024, mainly consisting of equipment sales ($US176,000) and consumables ($US154,000). Service and consulting fees made up the rest.

In July, Imricor raised $35 million in a two-tranche placement, at 52 cents a share (a 12 percent discount). The raising required shareholder approval, which was duly granted.

In September, the company followed up with a $2.92 million placement to existing investors, at 38 cents apiece.

Imricor also has a convertible note on issue, a legacy of when the company was private. The accounts record a liability of $US7.77 million, with outstanding principal and interest payments of $US5.7 million. To date, the company has expended $US105 million to develop the devices.

Over the last 12 months Imricor shares have traded between 42 cents (June 19 last year) and 78 cents on October 18 this year. The shares hit an all-time high of $2.78 on October 30, 2020 and traded as low as 14 cents in June 2022.

The size of the prize

As with most matters medical, economics are all-important.

In the case of VT procedures, Mr Wedan expects the device to be cheaper because two of the gadgets currently required - a mapping and intra-cardiac echo catheter - won't be.

The company cites a cost of interventional cardiac magnetic resonance (ICMR)-VT ablations in the US at $US6,500, compared with $US9,618 for an x-ray guided procedure.

ICMR atrial flutter ablations cost around $US4,440, compared with $US4,000 for x-ray guided ones. In the US, ablation surgery is reimbursed at $US22,653 - including the cost of the device - with the surgeon pocketing $US700.

Mr Wedan says Imricor's device will reduce VT surgery time from around six hours to "a couple of hours".

"If the doctor can do two procedures a day rather than just one because they take less than three hours instead of more than five, they would make more money that day."

Can't argue with those sums.

Imricor expects to sell the devices for $US6,000 with a gross margin of 70 percent.

The company envisages the classic razor blade model, by which clinics buy the recorder/stimulator device and purchase the single-use catheters and electrodes for each new patient.

Hearts a flutter in Europe

In Europe, meanwhile, currently about 1,000 ICMR laboratories perform an average of 70 atrial flutter procedures each a year. The company estimates that snaring five percent of this would generate revenue of $US12 million, at an average $US3,500 per procedure.

The expected US market is about 1,100 sites, but revenues likely would be double that because of the availability of reimbursement. Given the US accounts for about half of the $US8 billion global ablation market, why tackle Europe first?

The roundabout reason is the company was involved in a seven-year project with the FDA on MRI compatibility and being a research partner with the agency was not conducive to being regulated by it.

“So, we took the commercial stuff and went to Europe first,” Mr Wedan says.

As you do.

Dr Boreham’s diagnosis:

Mr Wedan notes the AFL market is shrinking – and that’s not a reference to Australia’s indigenous football code – but the ventricular tachycardia (VT) market is growing.

“There are lots of reasons, but one of them is that more people are alive with better cardiac care and VT becomes more prevalent with age,” he says. “Also, more people at risk of VT will be sent for a procedure, rather than monitoring or being implanted with an implanted defibrillator or drug therapy.”

He adds the current curatives are only 50 percent to 60 percent effective. “Ablation is curative, a defibrillator is there to help you if you need it.”

Imricor looks to be heading in the right direction, but one nagging doubt is why the big heart device makers didn’t think of an MRI-compliant catheter themselves, given that MRIs have been around since the 1970s. The answer is they don’t have the requisite smarts in understanding MRI electromagnetic fields.

Barring any unforeseen rivals emerging, Imricor will have a 100 percent share of the MRI-guided market. Meanwhile, Mr Wedan dubs 2024 as the company’s best year to date.

“We have put the pandemic behind us and re-launched our products and are growing the sites and number of procedures.”

He adds that the company won’t really be a revenue story in 2024 or 2025, with the fruits of its labors becoming more apparent in 2026.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never had an ablation, but plenty of morning ablutions to keep himself nice.

AVITA MEDICAL

Avita says revenue for the nine months to September 30, 2024 was up 27.1 percent to $US45,681,000 ($A68,599,000), with net loss after tax up 77.5 percent to $US50,256,000 ($A75,469,000).

Avita said sales revenue for the three months to September 30, 2024, primarily from sales of its Recell Go spray-on skin for burn wounds, were up 42.1 percent to $US19,394,000, compared to the previous corresponding period.

Earlier this year, the company said it had US Food and Drug Administration approval to market and sell its Recell Go autologous cell harvesting device for thermal burn wounds and full-thickness skin defects; and later, said the first US patient had been treated following commercial roll-out (BD: May 31, Jun 6, 2024).

Today, the company said its increased net loss for the nine months was due to a $US17,011,000 rise in sales and marketing expenses, administrative expenses increasing $US5,487,000 due to higher salaries and benefits and a $US1.5 million increase in research and development costs.

Avita chief executive officer Jim Corbett said that with more than “75 percent of our revenue base now transitioned to Recell Go and the anticipated launch of Cohealyx in 2025, we are positioned to address a broad continuum of wound care needs”.

Avita said diluted loss per share for the nine months was up 74.1 percent to $US1.95.

The company said that it had cash and cash equivalents of $US18,639,000 at September 30, 2024 compared to $US50,854,000 at September 30, 2023.

Avita fell 15 cents or 4.1 percent to $3.50 with one million shares traded.

UNIVERSITY OF QUEENSLAND

The University of Queensland says its partnership with Molecule to Medicine (MTM) has invested an initial $1 million in Lucia Bio, a Brisbane biotechnology start-up.

The University said the partnership between its commercialization company Uniquest and the Oxford, England and Melbourne-based MTM would form “new biotechnology companies in Brisbane and translate academic research into new medicines”.

The University of Queensland said the fund invested $1 million in Lucia Bio, a spin-out from its School of Biomedical Sciences developing an anti-inflammatory treatment.

Uniquest chief executive officer Dr Dean Moss said the company would initially focus on the potential to treat neuro-inflammation in people suffering from degenerative diseases such as Alzheimer’s disease, Parkinson’s disease and motor neuron disease.

The University of Queensland said Lucia Bio was the first “entity to be established as part of MTM's expansion into Australia”.

The University said the partnership expanded Uniquest’s long-standing relationship with MTM co-founder and chief executive officer Kirsty McCarthy, who had been chief executive officer of the University’s spin-out company Spinifex Pharmaceuticals when it was acquired by Novartis for $US200 million ($A300 million) in 2015.

Dr Moss said the collaboration would benefit the University of Queensland and Brisbane biotechnology start-up companies.

“MTM is renowned for bringing together the right people, funding and innovative technologies to create successful biotechnology companies with the capability to advance new therapies for patients that need them,” Dr Moss said.

“This partnership brings potential treatments a step closer to the clinic, with investment from the Uniquest extension fund … [and] is an example of the fund delivering on its mandate to foster new technologies from [the University of Queensland] and enable the creation of a new biotechnology company here in Brisbane,” Dr Moss said.

UNIVERSAL BIOSENSORS

Universal Biosensors says New York's Henry Schein will distribute and sell its Xprecia Prime blood coagulation monitoring device and test strips in the US.

Earlier this year, Universal Biosensors said it had US Food and Drug Administration 510(k) approval for its Xprecia Prime blood coagulation analyzer (BD: Mar 19, 2024).

Today, the company said Henry Schein would be a "non-exclusive distributor for an initial term of one year, with annual extensions by agreement".

Universal Biosensors said Henry Schein was "one of the US's largest and most influential distributors of medical products" and would be its first US distributor.

The company did not disclose the commercial terms of the agreement.

Universal Biosensor's chief executive officer John Sharman said that "Henry Schein undertook a comprehensive product review before agreeing to partner Xprecia Prime".

"Henry Schein service thousands of coagulation clinics and hospitals throughout the US which can now access Xprecia Prime through the Henry Schein network," Mr Sharman said. "First sales are expected in the coming weeks."

"Over recent months we have recruited key staff to build our US Xprecia business," Mr Sharman said.

Universal Biosensors was up half a cent or four percent to 13 cents.

IMUGENE

Imugene says it has opened the first Australian trial site for its open-label, phase Ib trial of 'azer-cel' chimeric antigen receptor (Car) T-cells for B-cell lymphoma.

In 2023, Imugene said it would acquire 'azer-cel', or azercabtagene zapreleucel, CD19 chimeric antigen receptor T-cell therapy for blood cancers (BD: Aug 16, 2023).

Later, the company said that it had dosed the first of 10 patients in its phase Ib trial of its 'azer-cel' for non-Hodgkin's lymphoma and B-cell acute lymphocytic leukemia, with trial sites open for enrolment in the US (BD: Nov 10, 2023).

Earlier this year, Imugene said that it had "three complete responses" of the 10 patients treated so far in its phase Ib trial of azer-cel for large B-cell lymphoma, with azer-cel found to be safe and tolerable (BD: Sep 2, 2024).

According to the US National Library of Medicine's Clinical Trials website, the non-randomized, open-label, dose-escalation and dose-expansion phase I/Ib study of 'azer-cel' in adults with non-Hodgkin lymphoma would enrol up-to 129 patients.

Today, the company said Sydney's Royal Prince Alfred Hospital would begin patient recruitment this month, which was "another significant milestone in the development of this promising off-the-shelf, allogeneic Car T-cell therapy".

Imugene managing-director Leslie Chong said the company was "proud to be able to bring this trial to Imugene's home country and provide an opportunity for Australian patients to benefit from this unique technology."

"This is the first of up to five sites we plan to open in Australia, as we seek to speed up enrolment and deliver improved outcomes in this form of blood cancer," Ms Chong said.

Imugene was up 0.1 cents or 2.2 percent to 4.6 cents with 27.8 million shares traded.

ARTRYA

Artrya has requested a trading halt "pending the release of an announcement regarding a proposed capital raising".

Trading will resume on November 12, 2024, or on an earlier announcement.

Artrya last traded at 50 cents.

MAYNE PHARMA GROUP

Mayne Pharma says in response to “media speculation in [the] Australian Financial Review” that Jefferies Australia has been appointed as its financial adviser.

Mayne Pharma said it confirmed “that Jeffries is its financial adviser and continues to support the company in assessing its strategies for maximizing shareholder value”.

The company did not respond to comments in the Australian Financial Review, saying it would “keep the market informed in accordance with its continuous disclosure obligations”.

Mayne Pharma was up 67 cents or 15.1 percent to $5.10 with 435,814 shares traded.