Biotech Daily

Friday May 10, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: SYNTARA UP 12.5%; PRESCIENT DOWN 5%**

*** DR BOREHAM'S CRUCIBLE: IMMURON**

*** BURNET LAUNCHES $6.5m BURNEXT ACCELERATOR**

*** HERAMED TO RAISE $2.75m, TIM CHAPMAN CHAIR, CUTS COSTS**

*** FIRB APPROVES $251m PROBIOTEC SALE TO PYRIDAM**

*** MAYNE WINS 2 US NEXTSELLIS PATENTS**

*** TISSUE REPAIR TO RELEASE 4.7m ESCROW SHARES**

*** ACORN TAKES 5% OF AROA**

*** VIBURNUM TAKES 29% OF UNIVERSAL BIOSENSORS**

*** AUSTRALIAN ETHICAL INCREASES, DILUTED TO 16% OF SOMNOMED**

*** FIL (FIDELITY) DILUTED TO 8% OF SOMNOMED**

*** 'TWIGGY' FORREST, TATTARANG INCREASE, DILUTED TO 6% OF EMYRIA**

MARKET REPORT

The Australian stock market was up 0.35 percent on Friday May 10, 2024, with the ASX200 up 27.4 points to 7,749.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell, six traded unchanged and one was untraded.

Syntara was the best, up 0.2 cents or 12.5 percent to 1.8 cents, with 601,947 shares traded. 4D Medical climbed 8.1 percent; Imugene and Opthea improved more than seven percent; Nova Eye was up 6.1 percent; Paradigm was up 3.7 percent; Clinuvel rose two percent; Impedimed, Orthocell and SDI were up more than one percent; with CSL, Cyclopharm, Resmed and Telix up by less than one percent.

Prescient led the falls, down 0.2 cents or 4.65 percent to 4.1 cents, with 1.1 million shares traded. Cynata and Starpharma fell four percent or more; Alcidion, Atomo and Compumedics lost more than three percent; Mesoblast and Next Science shed more than two percent; Clarity, Dimerix, Emvision, Immutep, Micro-X, Neuren, Percheron and Pro Medicus were down more than one percent; with Avita, Cochlear, Genetic Signatures, Nanosonics, Polynovo and Proteomics down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMMURON

By TIM BOREHAM

ASX code: IMC; **Nasdaq code:** IMRN

Share price: 8.9 cents; **Shares on issue:** 227,998,346; **Market cap:** $20.3 million

CEO: Steven Lydeamore

Board: Paul Brennan (chair), Dr Roger Aston, Daniel Pollock, Prof Ravi Savarirayan

Financials (half year to December 2023): revenue $2.355 million (up 304%), loss of $2.068 million (previously a $1.98 million deficit), net tangible assets 7.62 cents (down 17%), cash of $15.2 million (down 18%).

Identifiable major shareholders: Bank of New York Mellon Group 35.2% (the only substantial shareholder; BNY Mellon holds the ADRs listed on Nasdaq). Immuron's management and board hold collectively 1.5%

Steve Lydeamore's advice to peers seeking to do business with the US military is to be armed with a high knowledge readiness level (KRL) when it comes to interpreting acronyms such as … KRL.

The head of traveller's diarrhoea fighter Immuron, Mr Lydeamore cautions the usual business partnership rules of civvy street may not be valid. When seeking grant funding, applicants need to follow the guidelines to the letter or else be confined to barracks.

Potential partners for the US Department of Defense's (DoD's) health programs also have to navigate an array of agencies. For instance, the Armed Forces Research Institute of Medical Sciences (AFRIMS) is devoted to optimizing "soldier lethality" by preventing infectious diseases.

The Uniformed Services University (USU) seeks to ensure the "overall well-being of war fighters, as well as [enabling] dual benefit outcomes that will improve civilian health".

And don't confuse the Naval Medical Research Command (NMRC) with the US Army Medical Research and Development Command (USAMRDC), or civil war will erupt.

"Even when the acronym is right, sometimes they change their name," Mr Lydeamore says, noting the NMRC used to be the Naval Medical Research Centre.

We've got the enemy on the run - not the runs

How is this relevant to Immuron, which specialises in immunotherapies for gut-mediated diseases that result in diarrhoea?

The answer is that diarrhoea is number one of 57 infectious diseases that affect front-line soldiers. Around four-fifths of troops on deployment will suffer the trots and the casualties are likely to mount as antibiotic resistance increases.

Legend has it that Napoleon lost at Water-loo because half his troops had dysentery.

Dubbed by Mr Lydeamore as “travel insurance for your holiday” Immuron’s lead product Travelan is a well-established prophylactic for travellers’ diarrhoea having been sold over-the-counter (OTC) in Australia since 2004. It is sold in the US and Canada.

Since July last year, Travelan has been sold on the online Amazon platform and will also be available through retail chain Walmart’s online portal.

While the Australian Therapeutic Goods Administration has approved Travelan as an OTC complementary medicine, the US Food and Drug Administration has not, and it can only be marketed as a dietary supplement.

Studies to date have shown that Travelan binds to 180 pathogenic strains of bacteria.

Now, Immuron is in the throes of multiple clinical trials - one on the cusp of phase III - to prove the efficacy of Travelan against specific diarrhoea-inducing pathogens (see below).

Three of the trials are supported by the US, which wants its troops to hit the ground running … not with the runs.

Let’s run through a bit of history

Based at Blackburn North in eastern Melbourne, Immuron has a long history having been founded as Anadis in 1994. The company listed on the ASX in 1999, when we were all waiting for the Y2K computer virus to end the world.

Spoiler alert: it didn’t. And neither did the ‘real’ Covid virus two decades later.

In 2004, Anadis listed Travelan as an over-the-counter product. The company adopted its current name in 2008 and listed on the Nasdaq in July 2017. The technology is based on its bovine immunotherapy platform. Along the way, programs for the liver disease non-alcoholic steato-hepatitis (NASH), the bowel disorder colitis and Covid were canned.

The former head of the ASX-listed Anatara Lifesciences, Mr Lydeamore joined in June 2022, replacing Dr Jerry Kanellos and in June 2023, chair Dr Roger Aston relinquished the position to become a non-executive director. The former head of Polynovo and fellow Immuron director, Paul Brennan, was anointed chair.

All the goodness of cow’s milk

Travelan (active ingredient IMM-124E) is based on the natural immunity-boosting goodness of colostrum, the ‘first milk’ delivered by mummy cows to their calves immediately after birth.

Mr Lydeamore says while Immuron's know-how is well known, it is rarely used commercially.

The pregnant cow is given a vaccine to 13 different types of entero-toxigenic Escherichia coli (ETEC). In response, the beast produces polyclonal antibodies in the colostrum that target specific pathogens. Half the colostrum is whisked away in a bucket, spray dried and turned into tablets.

Unlike other marketed colostrum, Immuron's has a high immunoglobulin count and hyper-immune factor produced by the vaccine. The colostrum is processed by Synlait in New Zealand, but the company is mulling moving production to Victoria.

On the cusp of phase III

Immuron has four clinical programs, three of them funded by the military.

On March 7, Immuron shares soared 80 percent after the company announced top-line results from a phase II study assessing the efficacy of Travelan in preventing entero-toxigenic Escherichia coli (ETEC).

The data will be used to support an FDA application for a phase III registration study.

In January last year, the US DoD awarded Immuron a $US3.43 million ($5.2 million) grant, to carry out the phase II trial. The study was pitched at a daily dosing regimen most suited to deployed US troops visiting developing countries. In other words, taking the pill three times a day is not practicable when you are holed up in a rice paddy surrounded by enemy fire.

Sixty healthy volunteers were recruited and randomly assigned to receive a single oral daily dose of Travelan, or placebo.

Dosing commenced prior to "challenge" with ETEC and continued for seven days thereafter.

But only 37 percent of the control group fell ill, despite the sick-inducing Escherichia coli dose. "You don't need much E coli to get traveller's diarrhoea and they were given a huge amount, so it was surprising so many weren't sick," Mr Lydeamore says.

This meant the study couldn't support the primary endpoint of a statistically significant difference between the incidence of moderate to severe ETEC-attributed diarrhoea.

But in the treated group, the results showed 66.7 percent "protective efficacy" against severe diarrhoea. Also, 83 percent fewer treated subjects required early antibiotic treatment, while none required intravenous rehydration.

Why anyone would agree to be "challenged" with a pathogen likely to make them ill?

Mr Lydeamore says the participants were well-remunerated, but some were motivated by curiosity rather than money. Or they were simply masochists.

Other studies

Immuron's second most advanced study - funded by the US Naval Medical Research Command (NMRC) – is a phase II trial for the campylobacter pathogen, being carried out at Johns Hopkins University in Baltimore, Maryland.

Top-line results from the 30-patient trial, known as Campetec, are due later this year.

In a giant 'real world' study to support the company's FDA entreaties, the Uniformed Services University (USU) is carrying out a Travelan field trial.

Around 554 US and UK soldiers assigned to high-risk regions have been drafted - er - recruited.

In conjunction with Monash University, a fourth trial is another colostrum-based therapeutic, IMM-529 for Clostridioides difficile (C-difficile).

An earlier trial in Israel failed to recruit and was discontinued, but the company is using the safety data to support a phase II study.

Finances and performance

Travelan sales were $1.3 million in the third (March) quarter, 51 percent higher than the second quarter and 75 percent higher year-on-year.

Australian sales were $900,000, up 66 percent and 99 percent respectively while the US accounted for most of the remainder.

Immuron's December half-year loss was $2.068 million compared with $1.98 million previously, leaving December-end cash of $15 million.

The phase III stage would likely require two trials of 600 patients each, costing $5 million each.

"We will meet with the Department of Defense to look at non-dilutive funding, but regardless, the board decided to move forward with this program," Mr Lydeamore says.

On March 8 this year, Immuron shares peaked at a 12-month high of 14 cents, having doubled from the year's low of seven cents on the ETEC phase III news.

The shares peaked at $15 in late 2004.

Mr Lydeamore says the company is happy to remain Nasdaq-listed despite the additional cost, given the higher liquidity and as a platform for equity raising (the company last raised funds in 2020).

Nasdaq-based holders account for 35 percent of the register, but with no dominant shareholder.

The real show-stopper

Travellers have the choice of three diarrhoea products: Travelan, and the loperamide-based Imodium and Gastrostop (the biggest seller).

The latter two block the diarrhoea after the fact, rather than preventing it (while provide valuable breathing space for stricken travellers to get to a decent dunny).

Antibiotics are rarely prescribed for prevention because of antimicrobial resistance, but oral rehydration salts are often used for post-infection recovery.

Travelan doesn't kill the pathogens per se, but stops them from attaching to the gut wall and neutralises the toxins at source.

As a preventive, Travelan ideally it is taken two days before travel and with every meal while travelling.

A 30-tablet Travelan pack sells here for about $35 and $US35 on Amazon.

Dr Boreham's diagnosis

While Travelan is proven to be effective - 900,000 doses have been sold to date - the product has been more of a way of keeping the lights on, rather than a business in its own right.

"The problem is it hasn't been marketed appropriately and we have spent our energies on research and development," Mr Lydeamore says.

The company assesses the US diarrhoea market at $US1 billion a year, with 60 million Americans visiting - or invading - high-risk regions annually.

Of these, around half will self-medicate and visit a chemist.

But the other half will consult a doctor, so without an approved product the company is missing out on what it estimates to be a $US100 million opportunity (based on snaring 15 percent of this market).

Immuron is also mulling entering the Asian and European markets.

Given these expansion options and the US military's enthusiastic backing of the trials, Immuron finally looks to be going places after three decades of promises.

One could say the company is hot to trot.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Hopefully he has some runs on the board anyway.

BURNET INSTITUTE

The Burnet Institute says it is investing an initial $6.5 million in the Burnext accelerator “to fast-track research into real-world outcomes to improve human health”.
The Burnet Institute said Burnext would take research projects through “a process of milestone-driven project planning and delivery, to ensure outcomes within 24 months”.
The Institute said that the accelerator model removed funding barriers, which limited the ability of researchers to develop ideas into outcomes.
The Burnet said an Office for Research Translation would be led by director Jennifer Barnes, for Burnet’s translational activities, including the Burnet Diagnostics Initiative, the Burnet Vaccine Initiative and Burnext.
The Burnet Institute said that projects would enter the accelerator for a fixed period, with progress expected to be transformative rather than incremental.
The Institute said that Burnet scientific director for research translation Prof Heidi Drummer would work in the Office for Research Translation, providing a whole-of-Institute focus for projects, including those being undertaken by Burnext.
Prof Drummer said Burnext would accelerate existing research projects that might otherwise take many years to produce outcomes.
“Currently, the process to progress academic research is slow, with researchers required to dedicate large amounts of time to writing grant applications that have low success rates,” Prof Drummer said. “Burnext will provide the necessary funds to progress these projects to the next stage of development, without the uncertainty of needing to rely on competitive grant processes.”
Burnet director and chief executive officer Prof Brendan Crabb said Burnext wasn’t focused solely on commercial outcomes, but was “open to projects across our research spectrum, including life science programs, public health interventions and international development projects”.
“Burnext is the missing component in our suite of research translation initiatives at Burnet and complements our other commercialization activities, ensuring we can fully support our innovations from concept to implementation,” Prof Crabb said. “We are looking for the next big breakthrough that is going to improve health.”
The Institute said two projects would enter the program, with additional projects to be included as capacity expands, Burnext was open to applications from Burnet researchers, with successful projects to be announced in June.
The Burnet Institute said that recruitment for an advisory board and staff was underway.

HERAMED

Heramed says it remains in a suspension, has “firm commitments” to raise $2.75 million, has appointed interim director Tim Chapman as chair and will cut costs.
Heramed said it would raise $2.35 million through convertible notes at $1 each, $350,000 in a placement at one cent a share and $50,000 from the issue of shares at one cent each to Mr Chapman, subject to shareholder approval.
The company said it intended “to add additional directors … during the next phase of commercialization … [and would] restructure, right-size and scale the company” to reduce costs by about $2 million a year, with the benefits expected by 2025.
Heramed said Westar Capital was lead manager to the raise and would receive a six percent fee and 67.5 million options exercisable at one cent each within three years, subject to shareholder approval.
Heramed remained in a suspension and last traded at 1.7 cents (BD: May 9, 2024).

PROBIOTEC

Probiotec says the Foreign Investment Review Board has approved its scheme of arrangement to be acquired by Jakarta's PT Pyridam Farma Tdk for $251,3 million.
Last year, Probiotec said it had a binding scheme implementation deed to be acquired by PT Pyridam Farma Tdk at $3.00 a share, a 26 percent premium to the one-month volume weighted average price, valuing it at $251.3 million (BD: Dec 22, 2023).
Today, the company said a scheme meeting would vote online and at Arnold Bloch Leibler, Level 21, 333 Collins Street Melbourne on May 29, 2024 at 10am (AEST).
Probiotec said subject to shareholder approval its last day of trading would be June 5 and that the scheme would be implemented on June 18, 2024.
Probiotec was up three cents or 1.05 percent to $2.90.

MAYNE PHARMA

Mayne Pharma says the US Patent and Trademark Office has granted two patents for its Nextsellis oral contraceptive pill.
Mayne Pharma said the patents, both titled 'Orodispersible dosage unit containing an estetrol component' relating to the composition of materials and manufacture, respectively, and protected its intellectual property for both patents until June 17, 2036.
Mayne Pharma chief executive officer Shawn O'Brien said Nextsellis was "the flagship product in our women's health portfolio, and we are thrilled about the issuance of these new patents".
Mayne Pharma fell 11 cents or 1.5 percent to $7.01.

TISSUE REPAIR

Tissue Repair says that it will release 4,656,830 shares from "voluntary escrow" along with 13,640,000 options, on May 18, 2024.
Tissue Repair said that following the release it would have 60,464,843 shares on issue.
Tissue Repair fell half a cent or 2.1 percent to 23 cents.

AROA BIOSURGERY

Melbourne's Acorn Capital says it has become a substantial shareholder in Aroa with 17,278,636 shares, or 5.02 percent.
Acorn said that through Citicorp, State Street Bank, JP Morgan, Northern Trusty and BNP Paribas it bought and sold shares between January 16 and May 8, 2024, with the single largest purchase 1,470,000 shares on March 22, 2024 for $779,841, or 53.05 cents a share.
Aroa was up half a cent or one percent to 51.5 cents.

UNIVERSAL BIOSENSORS

Viburnum Funds Pty Ltd says it has increased its substantial shareholding in Universal Biosensors from 57,552,221 shares (24.87%) to 87,058,827 shares (29.21%).
Perth's Viburnum said with Coleman Superannuation Fund it bought 29,506,606 Chess depository interests (CDIs) in an entitlement offer for $4,425,991, or 15.0 cents a share.
This week, Universal Biosensors said it raised $10 million at 15 cents per CDI in a one-for-3.47 rights offer, taking the total raised to $12.5 million (BD: Mar 22, May 8, 2024).
Universal Biosensors was unchanged at 13 cents.

SOMNOMED

Australian Ethical says it has increased its substantial shareholding in Somnomed and been diluted from 24,530,768 shares (18.03%) to 34,243,860 shares (15.85%).
The Sydney-based Australian Ethical said that on April 30 and May 3, 2024 it bought 9,713,092 shares for $2,039,749, or 21.0 cents a share.
On Monday, Somnomed said it had raised $16.8 million at 21 cents a share in its retail rights offer, taking the total raised to $22.6 million (BD: Apr 10, May 6, 2024).
Somnomed fell two cents or 9.1 percent to 20 cents.

SOMNOMED

The Hong Kong-based FIL Limited (Fidelity) says its 17,800,389 substantial share-holding has been diluted from 13.08 percent to 8.24 percent (see above).

EMYRIA

Perth's Tattarang Ventures Pty Ltd says it has increased and been diluted in Emyria from 20,000,000 shares (7.29%) to 23,817,777 shares (5.82%).
In 2021, Emyria said it had raised $5 million at 25 cents a share from the Dr Andrew 'Twiggy' Forrest-controlled Tattarang (BD: Nov 22, 2021).
Today, Tattarang said with Tenmile Ventures, the Peepingee Trust, Nicola Forrest and Dr Forrest it bought 3,817,777 shares between November 24, 2021 and May 9, 2024 for $656,000, or 17.2 cents a share and on May 7, 2024 was diluted in a placement.
Last month, Emyria said it had "firm bids" to raise $2.3 million in a placement at five cents a share, a 12.28 percent discount to the last traded price (BD: Apr 23, 2024).
Emyria was up 0.3 cents or 6.4 percent to five cents.