



Biotech Daily

Friday June 14, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: DIMERIX UP 11%; OPTHEA DOWN 25%**
- * **DR BOREHAM'S CRUCIBLE: ISLAND THERAPEUTICS**
- * **TELIX WITHDRAWS \$350m US IPO**
- * **CORRECTION: FLINDERS UNIVERSITY**
- * **OPTHEA RAISES \$171.5m; RETAIL OFFER FOR \$56m MORE**
- * **LBT PLEADS SCHULTZ TO ASX 43% QUERY**
- * **IMAGION APPOINTS BRETT MITCHELL DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.33 percent on Friday June 14, 2024, with the ASX200 down 25.4 points to 7,724.3 points.

Fourteen of the Biotech Daily Top 40 were up, 18 were down, five traded unchanged and three were untraded.

Dimerix was the best, up 6.5 cents or 11.2 percent to 64.5 cents, with 9.7 million shares traded.

Actinogen, Impedimed and Micro-X climbed more than six percent; Universal Biosensors was up 5.7 percent; Nova Eye improved 4.65 percent; Medical Developments was up 3.85 percent; Paradigm, Percheron and Prescient rose more than two percent; Emvision and Neuren were up one percent or more; with Clinuvel, CSL, Resmed and Telix up by less than one percent.

Opthea led the falls, down 12 cents or 24.7 percent to 36.5 cents, with 7.8 million shares traded.

Cynata lost 7.5 percent; Avita and Next Science fell more than four percent; Genetic Signatures and Nanosonics were down three percent or more; Alcidion, Clarity, Medadvisor, Proteomics and Starpharma shed two percent or more; 4D Medical, Amplia, Cochlear, Orthocell and Pro Medicus were down one percent or more; with Cyclopharm, Mesoblast and Polynovo down less than one percent.

[DR BOREHAM'S CRUCIBLE: ISLAND PHARMACEUTICALS](#)

By TIM BOREHAM

ASX code: ILA

Share price: 6.3 cents; **Shares on issue:** 114,536,544; **Market cap:** \$7.2 million

Financials (March quarter 2024) receipts nil, cash outflows \$1.17 million, cash of \$1.58 million (pre-rights offer that raised \$1.95 million before costs)

Chief executive officer: Dr David Foster

Board: Dr Paul MacLeman (executive chair), Dr Foster, Dr Anna Lavelle, Al Hansen, Dr David Brookes

Identifiable major shareholders: Dr William James Garner 19.26%, Jason Alan Carroll 17.46%, Albert Hansen/Kesa Partners 9.69%

Apologies for bringing up the V – virus – word in a pandemic-weary world, but the mosquito-borne dengue fever is running rampant and spreading to geographies hitherto unaffected.

“Dengue is the most common viral disease transmitted by mosquitoes that affects people,” the European Centre for Disease Prevention and Control reports.

“Every year, tens of millions of cases are reported, and it causes about 20,000 to 25,000 deaths with a higher impact on children.”

Brazil accounts for the majority of cases, but Peru is also having its worst outbreak in history while India and South East Asia are not immune.

“It’s shaping up as a really, really bad year,” says Island Therapeutics CEO Dr David Foster.

Island is on the job with a repurposed molecule, ISLA-101, which promises to be a treatment for the symptoms, or a vaccine-like prophylactic.

The mechanism of action of ISLA-101 is to prevent the spread of infectious cells by breaking down the interaction between the viral and host protein.

Developed as a cancer drug but never approved, ISLA-101 shows “excellent activity” against all four dengue strains.

ISLA-101 is also recognized as safe, having undergone no fewer than 45 cancer trials in Europe and elsewhere.

Island is undertaking a phase II study, in anticipation of a phase III program pitched at US Food and Drug Administration approval.

Dengue fever – more than an itch

Spread by the Dengue mosquito or Asian Tiger mosquito, dengue fever is found in more than 100 tropical and sub-tropical countries of Asia, Africa and South America.

Most sufferers are asymptomatic. The trouble is, there are four different strains – DENV-1 to DENV-4 - and a second occurrence can be much worse.

Typically lasting a week, symptoms include vomiting, diarrhoea, headaches, seizures, itching, “pleural effusion” and even “altered minds”.

Dengue fever can also be fatal, although that is rare.

“Dengue fever is the very definition of an unmet medical need,” the company says.

Factors, including climate change, mean that half the population is at risk, as the pestilence is spreading from tropical countries - typically poor ones - to locations such as Florida, Texas, northern Queensland and the Mediterranean.

University of Oxford and National Aeronautics and Space Administration (NASA) data cheerily suggests large swathes of Australia will be environmentally vulnerable by 2050 – all the way down to northern and central NSW. When the multi-millionaire Byron Bay beautiful people are afflicted, we will never hear the end of it.

The company cites US dengue fever hospitalization costs of about \$US7,000 (\$10,600) per patient.

About Island

Island’s sole raison d’être is to further ISLA-101, identified by Johnson & Johnson as a potential cancer treatment. J&J donated the program – which had FDA investigational new drug (IND) status - to the US National Cancer Institute (NCI).

“We called the NCI and in effect they said you can have it,” Dr Foster says.

Meanwhile, Puerto Rico-based medical entrepreneur Dr William James Garner realized there was a growing problem with mosquito-borne viruses and stumbled on the work of Monash University biochemist Prof David Jans.

The company licenced what Dr Foster describes as Monash’s “elegant biology”, with further work at the Uni elevating the molecule to pre-clinical status.

Rather than starting with a compound and looking for a disease - the norm for drug development - Prof Jans started with the disease and then screened potential drugs for the target.

Not to be confused with current Percheron Therapeutics CEO and former Kazia chief Dr James Garner, Dr William (Bill) Garner founded Invion in 2012 and was a former director of fellow drug re-purposer Race Oncology.

Island listed on April 16, 2021, having raised \$7.5 million at 25 cents apiece. Dr Garner remains a 26 percent shareholder.

Dr Paul MacLeman is well known in biotech circles as chair of Adalta and former CEO of Genetic Technologies and IDT Australia.

SAD, not MAD

In April this year, Island reported “highly positive” new data from its safety and tolerability study for ISLA-101. Covering 24 patients in a single ascending dose, the pharmacokinetics study showed the required levels of ISLA-101 concentration in the blood after a single dose.

“The drug was safe and well tolerated,” Dr Foster says. “We are achieving the blood concentrations we want to see.”

The company had been girding for the second phase II dengue trial, called Peach (as in Prophylactic Examination of an Antiviral in a dengue Challenge Model).

In a June 3 update, the company said while it had intended to take a multiple ascending dose (MAD) approach, new modelling data suggested a single ascending dose (SAD) approach would “achieve effective blood concentrations above those shown to be effective at arresting the dengue virus in prior pre-clinical studies.”

In another tweak, the company is expanding the trial from a pure prophylactic focus to a therapeutic arm, “substantially increasing the data we obtain from the study”. The downside is that the study can’t be called Peach any more.

Based in Syracuse, New York, the trial will enrol about 15 healthy volunteers and ‘challenge’ (infect) them with an attenuated strain of the dengue virus.

The North East of the US isn’t known as a dengue hot spot - and that’s quite deliberate because the study needs to avoid anyone who has had the disease (Florida would have been more problematic).

Military backing

Island has the benefit doing the trial at the Walter Reed National Military Medical Centre, in which 20 ‘volunteers’ received the virus.

Dr Foster says the army has been trying to develop a dengue vaccine, but the efforts were a “little too hot” in that the subjects became too sick.

“Preferring not to throw the data or the vaccine candidate away, they elected to use the product, and study the mild form of dengue virus in healthy volunteers,” Dr Foster says.

The data is, in effect, a control group for the Island trial, given the army looked at the effects of the virus without a drug.

Dr Foster says Island initially was looking at a prophylactic study, but to do a vaccine in the field it would require enrolling thousands of people.

“Our current protocol calls for around 15 people; it is a very tiny number because it is so well controlled and we have the army data for comparisons,” he says.

The company hopes to complete enrolments in early July and dose in August, with results by the end of the calendar year.

“As far as clinical trials go, it’s a very fast study.”

The FDA has indicated a phase III study likely would need to be in a dengue-endemic country such as Singapore, Malaysia or the Philippines or Brazil.

Finances and performance

In March this year, Island completed a rights raising that brought in \$1.95 million to fund the phase I analysis and the phase II trial.

The terms were two for every five shares held, exercisable at six cents each, with a one-for-one option also exercisable at six cents. If investors had exercised these options by today - June 14 - they will receive a ‘piggy-back’ option exercisable at - you guessed it – six cents with a March 2025 expiry.

In total, these oppies have the potential to raise a further \$3.9 million.

In December last year, Island borrowed \$386,000 against its Federal Research and Development Tax Incentive for the 2023-'24 year. With accumulated interest, the fully-drawn sum is \$405,352, to be repaid when Island banks the Incentive in October.

On May 8, the company said that \$US625,000 of a \$US1.3 million US Congress grant could be reallocated from the Research Foundation of State University of New York to fund the trial costs directly.

The grant was to be used by the Foundation for follow-up lab testing and data analysis of the trial results.

Island is also eyeing an FDA Priority Review Voucher (PRV), under the agency’s tropical diseases program.

A PRV means that if the drug is approved, the company has fast-track approval for a second drug. These ‘Willy Wonka’ tickets are usually on-sold to other drug developers, with recent sales averaging \$US110 million.

Over the last 12 months Island shares have traded between 10 cents in early January and 5.5 cents in early May this year.

The shares peaked at 43 cents on April 30 2021, shortly after listing.

Sizin' the rivals

There is only a vaccine for secondary dengue infections - Sanofi Pasteur's Dengvaxia - but the limitations are almost comical: the vaccine is not for primary infection and should never be used by those without the disease - or for anyone aged under nine or over 45. It also can't be used as a prophylactic for short stay visits in dengue-endemic areas, "as the risks most likely outweigh potential benefits".

Takeda has a vaccine approved in some countries including Brazil and Europe, but for unclear reasons it withdrew its US submission.

In terms of small molecules, Johnson & Johnson has a treatment in phase II stage, with a different mechanism of action to ISLA-101.

Novartis also appears to be developing one, but Dr Foster is unfazed by the potential competition.

"Dengue fever is such a big problem," he says. "As with covid we need both vaccines and therapeutics to treat people at different stages."

Dr Boreham's diagnosis:

No company is an Island when it comes to drug repurposing, with others in the game including the ASX-listed Race Oncology (cancer), Paradigm Biopharmaceuticals (dodgy knees), Pharmaust (motor neuron disease) and LTR Pharma (erectile dysfunction).

The benefits are a proven safety profile and thus a faster route to market.

While dengue fever presents a vast unmet need, Island has chosen an indication conducive to small and short trials because the life cycle of the virus is only two weeks. While none of this guarantee's success, Island looks well-funded to the envisaged phase III stage.

"The next nine months will be incredible exciting and ... we should have a lot of inflexion points over the next 12 months," Dr Foster says.

Sadly, the excitement is yet to be reflected in Island's share price. When we last covered the stock in May 2021 Island was valued at \$31 million compared with today's \$7 million. Mind you, much of that is beyond management's control.

As the rights prospectus opines: "The stock market, particularly for biotechs, has experienced extreme price and volume fluctuations that have been unrelated or disproportionate to the operating performance of companies."

Now tell us something we didn't know ...

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never been to Byron Bay but secretly wants to cavort with the beautiful people.

TELEX PHARMACEUTICALS

Telex says it has withdrawn its proposed \$350 million US initial public offer to list on the Nasdaq, due to the offering's share issue price not being high enough.

Last week, Telex said it would offer 17,000,000 American depositary shares (ADSs) to raise about \$US200 million (\$A302 million) or \$A17.76 an ADS to list on the Nasdaq under the code 'TLX' (BD: Jun 6, 2024).

Today, the company said that its last closing price was \$16.46, with "recent all-time-highs at \$19.06".

Telex said it felt the proposed discounts to its share price were not "aligned to its duty to its existing shareholders".

The company said that "the proposed Nasdaq listing was not predicated on the need to raise capital".

According to one document filed to the Nasdaq, Telex had hoped to raise \$US232,058,500 (\$A349,590,018) through the issue of 19,550,000 shares or \$US11.87 per ADS or \$A17.88 per Australian share.

Sources told Biotech Daily that "US investors wanted much lower than \$US11.87 a share". Telex chief executive officer Dr Christian Behrenbruch told a teleconference that there was "strong interest from prospective healthcare and specialty biotech funds ... [but] the sticking point in the process was pricing".

"We had no lack of demand," Dr Behrenbruch said. "We had multiple coverage of the book [but] our share price has doubled during the period of engagement in preparation for this ... and that intrinsically makes valuation a very difficult task."

"I believe we had a book that was ... good a quality biotech company could hope for ... but not at a price discovery point that we were willing to accept," Dr Behrenbruch said.

"And again, I'll repeat that, that pricing essentially came down to the short period of rapid share price appreciation, and the trading volatility in the market over the last couple of weeks," Dr Behrenbruch said.

The US, the US public markets are still the most vibrant market in the world for Life Sciences and Biotechnology companies.

"I think I think it's generally known that we had, we have already quite a large number of US investors in our shareholder registry, so will absolutely continue to engage with US markets," Dr Behrenbruch said.

"Our commercial base of the company, our largest employee base is still here in the US, so we are, in many ways, very much a US company already and therefore, it makes sense for us to engage with the investor base," Dr Behrenbruch said.

In the announcement to the ASX Dr Behrenbruch said that "while this is not our desired outcome, Telex's strategic objectives must align with our duty to existing shareholders".

"I'd like to thank my team for the personal commitment and incredibly long hours put into this [initial public offer] process," Dr Behrenbruch said.

The company said that Jefferies, Morgan Stanley, Truist Securities and William Blair were joint book-running managers and underwriters for the offer.

Telex was up 15 cents or 0.9 percent to \$16.61 with 2.2 million shares traded.

FLINDERS UNIVERSITY

Last night's edition incorrectly reported that Brandon Capital was involved in the \$280 million Flinders University Health and Medical Research Building (HMRB).

A University media officer told Biotech Daily today that the University had been liaising with Brandon Capital on other matters, but it was not one of the partners for the building.

No sub-editors were hurt in making this correction.

OPTHEA

Opthea says its placement and institutional component of its rights offer have raised about \$171.5 million at 40.0 cents a share, with a retail offer for \$55.9 million more.

Earlier this week, Opthea said it hoped to raise-up to \$227.3 million at 40 cents a share in a \$10 million institutional placement and \$217.3 million, one-for-1.22, partially underwritten rights offer (BD: Jun 12, 2024).

Today, the company said the institutional rights offer raised about \$161.5 million alone, with eligible shareholders taking up about 61.4 percent of their entitlements, and the shortfall placed to both new and existing institutional shareholders as well as the underwriter.

Opthea said the fully-underwritten retail rights offer was for shareholders on the record date of June 14, 2024, would open June 19 and close July 10, 2024.

The company said participants in the placement and rights offer would receive one free attaching option for every three shares subscribed, exercisable at \$1.00 each and expiring June 30, 2026.

Opthea fell 12 cents or 24.7 percent to 36.5 cents with 7.8 million shares traded.

LBT INNOVATIONS

LBT has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 42.9 percent from a low of 1.4 cents to 2.0 cents on June 13, 2024 and noted a "significant increase" in the volume of shares traded.

LBT said it had lodged an announcement with the ASX in the morning of June 13, 2024 which, after consulting with the ASX, it withdrew after forming the view it was not market sensitive.

The company said it believed the resulting pause in trading and lift of the pause in trading announcements to the ASX on June 13 "may have resulted in speculation causing the recent increase in trading in its securities".

LBT was down 0.2 cents or 10 percent to 1.8 cents with 3.3 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it has appointed Brett Mitchell as a non-executive director, effective from June 14, 2024.

Imagion said Mr Mitchell was a director of Argent Biopharma, previously known as MGC (Medical Grade Cannabis) Pharmaceuticals, as well as lithium developer Delta Lithium, was the executive chair of Javelin Minerals and the non-executive chair of Uvre Limited.

On Tuesday, Auscann said that Mr Mitchell had resigned as a non-executive director for the company.

Last week, the company said its annual general meeting voted to pass a board spill resolution, and today said it intended to hold a meeting as required to re-elect its board of directors.

Imagion was up 0.2 cents or 2.7 percent to 7.5 cents.