



Biotech Daily

Friday July 28, 2023

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.7 percent on Friday July 28, 2023, with the ASX200 down 52.3 points to 7,403.6 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, four traded unchanged and three were untraded. All three Big Caps fell.

Actinogen was the best, up 0.3 cents or 8.8 percent to 3.7 cents, with 524,110 shares traded. Cyclopharm and Universal Biosensors climbed six percent or more; Alcidion and Dimerix improved more than four percent; Opthea was up 3.6 percent; Emvision, Nova Eye and Pro Medicus rose two percent or more; Antisense, Orthocell and Paradigm were up more than one percent; with 4D Medical and Next Science up less than one percent.

Proteomics led the falls, down 6.5 cents or 7.5 percent to 80 cents, with 109,178 shares traded. Medical Developments fell 7.3 percent; Atomo, Cynata and Impedimed shed more than six percent; Compumedics was down 5.6 percent; Volpara fell 4.3 percent; Immutep, Neuren and Pharmaxis were down more than three percent; Amplia and Polynovo shed more than two percent; Clinuvel, Mesoblast, Nanosonics, Prescient and Telix were down more than one percent; with Avita, Cochlear, CSL, Genetic Signatures and Resmed down by less than one percent.

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

By TIM BOREHAM

ASX Code: TLX

Share price: \$11.25; **Shares on issue:** 318,808,268; **Market cap:** \$3.59 billion

Chief executive officer: Dr Christian Behrenbruch

Board: Kevin McCann (chair), Dr Behrenbruch, Dr Andreas Kluge (co-founder, currently on a leave of absence), Dr Mark Nelson, Jann Skinner, Tiffany Olson

Financials (June half 2023): receipts \$195.3 million (up 2,560.1), net operating cash flow \$13.3 million, cash balance \$131.7 million (up 8.5%), drawn debt \$6 million (Telix has an undrawn \$15 million debt facility)

Major shareholders: Gnosis Verwaltungsgesellschaft (Dr Kluge) 7.12%, Elk River Holdings (Dr Behrenbruch) 7.24%, Grand Decade (China Grand Pharmaceuticals) 3.44%

The home-grown oncology radiology leader last week confirmed the strength of its assault on the US market, posting a 21 percent leap in June quarter revenue that implies a lofty annualised run rate of \$480 million.

Derived from Telix's approved prostate imaging tool Illuccix, the quarterly revenue of \$121 million marked the fifth consecutive quarterly increase since Telix imaged its first commercial dose to retired Indianapolis rail worker Larry Doone, in April 2022.

Telix has also been cash flow positive for the third successive stanza.

"It's been a pretty compelling quarter," purrs Telix chief executive Dr Chris Behrenbruch.

Quixotic as ever, investors knocked up to 17 percent off the share price in their immediate response. Telix says the "price response does not reflect the state of the business" and there appears to be no smoking gun. The results more than met expectations, but perhaps investors wanted more given the shares had run 77 percent over the prior four months.

Management's task is to maintain the momentum of its Illuccix sales while pursuing its busy development agenda - notably pending approval applications for renal (kidney) cancer and brain cancer diagnostics.

A potted history

Telix was founded in November 2015 by Dr Behrenbruch and Dr Andreas Kluge. Telix listed in November 2017 after raising \$50 million at 65 cents apiece.

Currently on personal leave Dr Kluge founded the Dresden-based radio-pharmaceutical outfit Therapeia, which was acquired by Telix.

Dr Behrenbruch was also the executive director of the defunct Factor Therapeutics and was also on the board of Amplia Therapeutics. He also authored a punchy biotech newsletter called The ASX Long Tail, which proved to be a tad too spicy for the lawyers.

Telix is Melbourne-based, but most commercial activity is in the US. The company has just completed a manufacturing mega facility in the Belgian (and beer) capital of Brussels.

In 2020, Telix inked a 10-year deal with China Grand Pharmaceutical, worth “up to” \$45 million. The Hong Kong-based entity became the exclusive partner in those parts for any approved Telix therapy.

The story to date

Telix is developing both imaging (diagnostic) and cancer therapies on its molecularly targeted radiation (MTR) platform. While MTR is a new discipline there is nothing new about cancer radio-diagnosis, which dates back more than a century.

The Telix experience shows that in terms of their efficacy and ease of use, all isotopes - radioactive versions of an element - are not created equally.

While rival isotopes are produced in costly cyclotrons, Telix’s can be generated at any of the 200-plus ‘nuclear pharmacies’ in the US. Given the time-sensitive nature of transporting the isotopes, Dr Behrenbruch reckons Telix is more of a logistics company than a health company.

We guess that makes Dr Behrenbruch the Lindsay Fox of the sector, although we are yet to see him clad in the trucker’s uniform of a blue singlet and Stubbies.

“We are hanging our hat not just on distribution and supply chain reliability, which we believe is best in the industry, but clinical reliability and dependency as well,” he says.

Better prostate imaging

Approved in the US, Canada and Australia, Illuccix is a kit for preparing gallium-68 gozetotide - more commonly known as a PSMA-11 injection - for positron emission tomography (PET) scans and is used for prostate cancer patients suspected of having either metastasized growths or a recurrence based on elevated PSA (prostate specific antigen) levels.

“This has been a seriously fun product to launch, we are impacting a lot of patients’ lives,” Dr Behrenbruch says.

The company spooked the market when it withdrew its European application in September last year, despite 56,000 Europeans having been injected up to that date. But the paperwork has since been resubmitted.

Dr Behrenbruch admits the company was “incredibly lucky” to achieve FDA consent (in November 2021) only because the agency at the time prioritized manufacturing site inspection for vaccine makers.

Telix is now confident of European and UK approval for Illuccix, while the tool is under regulatory review in several other jurisdictions.

In January 2023, the company dosed its first patient for a global prostate cancer imaging study, called Prostack, aimed at exploring “unmet medical need across the full prostate cancer treatment journey” from first recurrence to metastatic disease.

Kidneys next?

The next cab off the Telix rank is its second product TLX250-CDx, which would be the first imaging agent for the non-invasive assessment of patients with clear cell renal carcinoma, the most common form of kidney cancer.

In November last year, Telix outlined positive results from its phase III global trial called Zircon, which showed “unprecedented specificity and sensitivity”.

The trial enrolled around 300 patients scheduled for a partial nephrectomy (that is, the kidney lump is removed by a surgical urologist).

Dr Behrenbruch says Telix expects an FDA filing as a biologics licence application this calendar year. A recent pre-review meeting with the agency was “very satisfactory” - and he is not just talking about the tea and cookies.

The company puts the US kidney cancer imaging market at about \$US1 billion, a similar size to the prostate imaging market, with 155,000 kidney cancers found from abdominal scans targeting other conditions, and a further 55,000 kidney scans at surgical stage.

Shoot for the stars

Meanwhile, Telix has a trio of extension program underway for TLX250-CDx with the stellar titles of Starburst, Starlight and Starstruck.

The Starburst trial targets CA19, the protein overexpressed on the surface of clear cell renal cell carcinomas.

The point of interest is that the biomarker is also evident in other advanced-stage solid tumors with a poor prognosis, including breast, cervical, colorectal, head and neck, lung, ovarian, pancreatic and vulval.

“Starburst is exploring these tumor types in a refractory setting, to assess whether tumor sites can be targeted both for imaging and potentially therapeutic purpose,” says Telix chief medical officer Dr Colin Hayward.

There are two Starlight trials pitched at combining Telix's agent with the standard-of-care immune-oncology.

Finally, Starstruck combines TLX250 with Merck KGaA's peposertib, a DNA damage response inhibitor, for solid tumors.

"It's gratifying to see that all these studies are up and running and they all have patients and a ton of investigator interest," Dr Behrenbruch says.

It's all in the head

Described as "under-discussed and under-appreciated" by Dr Behrenbruch, the glioblastoma (glioma) program is steaming to marketing application stage with an FDA entreaty expected within months. The product is called TLX-101-CDx.

Management estimates a US market of 38,800 patients worth \$US90 million a year.

"It's a small market initially, because our indication will be narrowly focused," Dr Behrenbruch says. "But we see tremendous opportunity to expand the utility of this product to [other] central nervous system malignancies."

The program has an orphan designation.

A.I.: coming to a surgery near you

Rather than simply being about "eyeballing images" Telix has made two bolt-on acquisitions to expand Illucix from up-front diagnosis into guiding real-time decisions in the operating theatre.

"This is about ... looking at the map of the disease and making the best decision about the best treatment," Dr Behrenbruch says.

In April this year, Telix bought the Vienna based Dedicaid, which brings artificial intelligence (AI)-based clinical decision support software to the table. The tool enhances the ability to predict disease progression and to finesse the treatment response.

Telix also bought UK-based Lightpoint Medical, which is all about detecting tumors during surgery in a targeted way.

Lightpoint has developed Sensei, a robotic gamma probe. Smaller than a AAA battery, Sensei is pressed robotically against a lymph node or section of tissue which is assessed for cancer.

"This is taking Illuccix right to the front line of surgical interventions," Dr Behrenbruch says.

In the US, 288,300 men will be diagnosed with prostate cancer this year, with about 100,000 receiving a radical prostatectomy. At least 85 percent of these are performed via keyhole surgery with the assistance of robots.

Finances and performance

Perhaps the most telling sign of Telix's new-found maturity is the \$5.8 million of income tax handed to the Internal Revenue Service for calendar 2022. While many companies complain about the so-called fiscal fiend, paying tax is a problem that many a loss-making biotech would love to have.

Telix generated \$120.7 million of revenue in the June quarter, up 21 percent on the March quarter and mainly from US Illuccix sales. The positive net cash flow of \$10.8 million took cash to \$131.7 million.

"This clearly shows Telix can self-fund its product development activities through its commercial operations," says chief financial officer Darren Smith.

Dr Behrenbruch says Telix is "robustly trending" to 30 percent market share with Illucix in the US, with an even mix of new and existing customers.

Over the last 12 months, Telix shares have traded between \$4.56 (in September 2022) to the all-time high of \$12.50 (in June 2023). The record low of 43 cents was in early 2018.

Dr Boreham's diagnosis:

In the ever-changing nuclear medicine game, one danger for Telix watchers is the risk of more intense US competition eroding the returns from Illuccix. Choosing his words carefully, Dr Behrenbruch says the market indeed is competitive but this "does not translate into a pricing discount per se ... [and] there is always a trade-off between acquiring market share and pricing".

While volume incentives are likely to become more common "so far pricing has been extremely stable".

With a \$100 million annual research and development budget, Telix plans to be what Dr Behrenbruch dubs as the "household name" in urological oncology.

We suspect householders will not be talking about Illuccix in the same breath as Omo or Coca-Cola, but we get the drift. Brand name or not, Telix shows just what an Australian life sciences play is capable of on the world stage - as with sector hero Neuren.

The Holy Grail is the ability for Telix to expand the use of its magical isotopes to actual cancer treatment. Artificial intelligence also opens up eye-boggling opportunities in the longer term, although Robosurgeon probably will power up sooner than you think.

In the shorter term, Dr Behrenbruch says investors can expect a "ton of important data" from the company's various trials over the next 12 months. The subtext is that while Telix may be worth a chunky \$3.5 billion, the best days are ahead for the company.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is a well-recognised household name when the kids need money and there are chores to be done.

PACIFIC EDGE

Pacific Edge says Novitas does not consider its Cxbladder urine tests “medically reasonable and necessary” the threshold for US medical coverage.

Earlier this month, Pacific Edge said Novitas had delayed implementing a ‘local coverage determination’ that would have removed US Medicare cover for its Cxbladder tests, after warning that some patients might have to pay for the test (BD: Jul 6, 2023).

Today, the company said stakeholders could submit comments to Novitas between July 27 and September 9, 2023 and that there would be an open public meeting about the coverage determination on August 11, 2023.

Pacific Edge chief executive officer Dr Peter Meintjes said the company continued to believe the reviews of the coverage “appear to misunderstand the intended use of the Cxbladder tests, which is to ‘rule out’ patients who would otherwise receive an unnecessary cystoscopy and that this has significant clinical value to physicians, patients and payers like Medicare”.

“Pacific Edge and its [key opinion leaders] will take the opportunity at the open meeting to present Novitas with important bladder cancer-specific medical knowledge regarding how clinical diagnostic tests such as Cxbladder with high negative predictive value, when used on patients that have a substantiated suspicion of cancer after presenting with haematuria, are a benefit to those patients and the Medicare program,” Dr Meintjes said. Pacific Edge fell 2.5 cents or 15.6 percent to 13.5 cents.

IMEX HEALTH SERVICES

Imex says receipts from customers for the six months to June 30, 2023, were up 14.2 percent to \$8,835,000 compared to the previous corresponding period.

Imex said receipts for the three months to June 30 from its radiology information systems and picture archiving and communications system, were up 5.6 percent to \$4,447,000.

The company said it was \$296,000 cash flow positive for the three months to June 30, with cash and equivalents of \$1,967,000, compared to \$856,000 at June 30, 2022.

Imex was untraded at 60 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says customer receipts for the year to June 30, 2023 were up 29.2 percent to \$8,771,000 compared to the previous corresponding period.

Genetic Technologies said sales of its Genetype genomic risk tests were up 3.5 percent to \$2,084,000 for the three months to June 30.

The company said it had a cash burn of \$2,685,000 for the three months to June 30, with cash and cash equivalents of \$7,853,000 compared to \$11,733,000 at June 30, 2022.

Genetic Technologies was up 0.05 cents or 25 percent to 0.25 cents.

CANN GROUP

Cann Group says its rights offer at 12 cents a share has raised \$4.46 million of a -hoped-for \$11.7 million.

In June, Cann Group said the one-for-four, non-renounceable rights offer was at a 20 percent discount to the 5-day volume weighted average price (BD: Jun 15, 2023).

Today, the company said the \$7.2 million shortfall shares would be offered to sophisticated and professional investors by lead manager PAC Partners Securities.

Cann Group fell 1.5 cents or 10 percent to 13.5 cents with one million shares traded.

IMMUTEP

Immutep says it has dosed the first of up-to 40 patients in its phase II trial of eftilagimod alpha with radiotherapy and pembrolizumab for soft tissue sarcoma.

Immutep said it was conducting the 'chemotherapy-free', open-label study of eftilagimod alpha, or efiti (formerly IMP-321), with pembrolizumab (Keytruda) and radiotherapy at the Warsaw, Poland-based Maria Skłodowska-Curie National Research Institute of Oncology. In April, the company said that soft tissue sarcoma was an orphan disease, with a high unmet medical need and poor prognosis and the investigator-led trial would be the first time that efiti would be studied as a neo-adjuvant for non-metastatic cancer prior to surgery (BD: Apr 17, 2023).

Immutep fell one cent or 3.1 percent to 31 cents with 1.4 million shares traded.

PHARMAUST

Pharmaust says it has completed dosing the third cohort in its monepantel for motor neuron disease trial, and subject to safety approval will move to cohort four.

In June, Pharmaust said it has begun dosing the third cohort for its monepantel for motor neuron disease trial at 6.0mg/kg (BD: Jun 9, 2023).

Today, the company said all participants from cohorts one, two and three had elected to continue with their monepantel treatment.

Pharmaust was up 0.3 cents or 3.85 percent to 8.1 cents.

RECCE PHARMACEUTICALS

Recce says it has completed dosing its up-to 16 patient, phase I/II trial of R327 for urinary tract infection ahead of schedule, and that it was "safe and well tolerated".

Recce chief executive officer James Graham said that at the two faster infusion rates of 2,500mg across male and female subjects R327 was "safe and well tolerated".

"Completing dosing well ahead of schedule is a welcomed confirmation that we are on track in achieving study objectives," Mr Graham said.

Recce was up four cents or 5.9 percent to 71.5 cents.

RECCE PHARMACEUTICALS

Recce says it has received \$98,428 from the Government of Canada under its Scientific Research and Experimental Development Tax Incentive.

Recce said the rebate was in addition to its Australia Tax Incentive.

TRUSCREEN

Truscreen says its annual general meeting will vote to issue 13,000,000 options to the chief executive officer and directors.

Truscreen said that shareholders would vote to issue 7,000,000 options to chief executive officer Dr Beata Ebling and 3,000,000 options each to chair Tony Ho and director Chris Horn, all exercisable at four cents each by July 15, 2026.

The company said the meeting would vote to adopt the remuneration report, re-elect Juliet Hull as a director and ratify the prior issue of 20,000,000 shares.

The meeting will be held virtually and at Link Market Services, Level 30, PWC Tower, 15 Customs Street, West Auckland at 11am (NZST).

Truscreen was untraded at 2.6 cents.

LIVING CELL TECHNOLOGIES

Living Cell says its extraordinary general meeting will vote to change its name to Algorae Pharmaceuticals and issue two directors 40,000,000 'performance' shares each.

Living Cell said that shareholders would vote to issue the performance shares to directors David Hainsworth and Bradley Dilkes pending: two collaborations; two patent applications filed; reaching a market capitalization of \$50 million; and ethics approval to begin two clinical trials.

Earlier this week, the company filed a provisional patent application for the marijuana combination drug AI-116 for dementia, but omitted the jurisdiction of filing, patent title and duration (BD: Jul 26, 2023).

Living Cell said that the other ingredient was "another off-patent pharmaceutical ingredient".

Last year, Living Cell said that Mr Hainsworth and Mr Dilkes replaced directors Prof Bernie Tuch, Robert Willcocks and Dr Andrew Kelly prior to the annual general meeting, following a section 249D requisition (BD: Sep 14, Oct 31, 2022).

Mr Dilkes and Mr Hainsworth are directors of Alignment Capital.

Today, the notice of meeting said that shareholders would vote to ratify the issue of pre-entitlement offer 100,000,000 shares and 50,000,000 options, 75,000,000 shares and 37,500,000 options under the Greenshoe placement and 100,000,000 lead manager options to Alignment Capital, and approve the issue of 32,107,493 lead manager options to Alignment Capital.

The meeting will be held at Thomson Geer, Level 23, Rialto South Tower, 525 Collins Street, Melbourne on September 1, 2023 at 12pm (AEST).

Living Cell fell 01 cents or 5.9 percent to 1.6 cents.

STARPHARMA HOLDINGS

Starpharma has requested a trading halt pending "an announcement to the market regarding a partnered program".

Trading will resume on August 1, 2023 or on an earlier announcement.

Starpharma was untraded at 32.5 cents.