



Biotech Daily

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Daily news on ASX-listed biotechnology companies

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 (the company also 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 Illucix, 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 been cash flow positive for the third successive stanza.

"Overall, it's been a pretty compelling quarter," purrs Telix co-founder and chief executive Dr Chris Behrenbruch.

Quixotic as ever, investors knocked up to 17 percent off the share price in their immediate response.

The company 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 a little bit more given the shares had run up 77 percent over the preceding 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 of its commercial activity is in the US. The company has also 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.

Illuccix 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 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 Prostact, 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.

In the US, 155,000 kidney cancers are found from abdominal scans targeting other conditions, with 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 Illucix 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 Illucix 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 late September 2022) to the all-time high of \$12.50 (in mid-June 2023). The shares plumbed a record low of 43 cents 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”.

He adds that as the company increases sales, “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 Pharmaceuticals.

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.