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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:** $1.42

**Market cap:** $360.2 million

**Shares on issue:** 253,644,634

**Chief executive officer:** Dr Chris Behrenbruch

**Board:** (Harry) Kevin McCann (chairman), Dr Behrenbruch, Dr Andreas Kluge (co-founder), Dr Mark Nelson, Oliver Buck, Jann Skinner

**Financials (March quarter):** revenue $1.14 million, cash outflows $14.11 million, cash on hand $34.5 million, current quarters of funding: 2.4; **(2019 year):** revenue of $3.48 million (previously $195,000), loss after tax $27.8 million (previously $13.8 million deficit).

**Major shareholders:** Elk River Holdings (Dr Behrenbruch) 9.74%, Dr Kluge 9.74%, Fidelity International 7.93%.

A mere four years after being formed and two and a half years after listing on the ASX, the developer of oncology imaging devices is on the cusp of commercializing its first product.

As chief business officer Dr David Cade says: "We have made an extraordinary amount of progress in those intervening short years."

(Then again, it helps to IPO with phase II and III trials underway rather than at the lab-bench stage.)

Specifically, the company has just filed a European marketing application for its prostate cancer imaging agent.

A US submission is “almost ready to go” as well.

Meanwhile, Telix’s proposed antibody-based imaging product for renal (kidney) cancer is subject to a phase III registration trial.

Beyond that, Telix aspires to develop actual treatments based on its radio immunotherapy or molecularly targeted radiation (MTR).

As an exponent of nuclear medicine, Telix shares some traits with the lung imaging outfit Cyclopharm, which we covered last week.

Telix also has more than passing similarities with Sirtex Medical – the targeted radiation house taken over by China’s CDH Investments for a chunky $1.9 billion in 2018.

**Inside the Telix machine**

Telix was founded in November 2015 by Dr Chris Behrenbruch and Dr Andreas Kluge and incorporated in November 2015.

Dr Kluge founded the Dresden-based radiopharmaceutical outfit Therapeia, which owned the background technology to TLX-101.

Telix acquired Therapeia in October for a nominal cash sum and the assumption of about $1 million of debt.

Dr Behrenbruch is also the executive director of wound-care play Factor Therapeutics, and left Amplia Therapeutics in February having achieved the reformation of the previous Innate Immunotherapeutics – and once was best known for his authorship of the defunct biotech critique, ASX Long Tail.

Dr Cade joined last October, having been chief medical officer at Cochlear. Before that, he held senior roles at Sirtex.

While at Sirtex, Dr Cade took a good look at Telix’s assets and tried to convince Sirtex to invest in the company, but the conservative directors demurred.

In one of the biggest life science initial public offers (IPO) since CSL’s in 1994, Telix listed in November 2017 after raising $50 million at 65 cents apiece.

(Reva raised $85 million in December 2010 and filed for bankruptcy in January this year. GI Dynamics raised $80 million in August 2011 and, unable to raise funds, is awaiting advice from the ASX about delisting.)

The offer was backed by a cabal of heavyweights including private equity house CVC and former Macquarie Bank chief Allan Moss (Telix chairman Kevin McCann formerly chaired Macquarie, so there's a deep pocket link).

In 2018, Telix exercised a $US10 million ($AUD15.6 million) option to buy French biotech Atlab, which held clinical data and manufacturing intellectual property relevant to the prostate cancer program.

**A more targeted approach**

A relatively new discipline, molecularly targeted radiation allows radioactive isotopes to be delivered via Telix's patented molecules in a selective way, so that they only reach the tumors in question.

In the most layperson of terms, these agents attach to biological targets expressed by the cancers and that's how the radiation can be delivered without blasting away at healthy cells as well.

Alternatively, molecularly targeted radiation can be used as an enhanced diagnostic tool based on existing hospital imaging equipment.

A current problem with imaging is that it uses the unstable gas iodine, which creates "noisy" images and is poor at detecting smaller tumors.

**Prostate imaging**

Telix's prostate cancer imaging agent is called TLX591-CDx (as in companion diagnostic).

The aforementioned European application is via the Danish Medicines Agency - and let's hope 'our' Crown Princess Mary puts in a good word.

"The use of our technology has also now been written into clinical practice guidelines in Europe and the US, so we expect rapid adoption post-approval," Dr Behrenbruch says.

The Danish submission pertains to imaging of patients with elevated prostate specific antigen (PSA) after radical prostatectomy (prostate removal) or radiation therapy.

Dubbed as "men's breast cancer" because it is so common, prostate cancer is diagnosed in 175,000 patients a year, in the US alone.

Many undergo a prostatectomy and are cured. But about 70,000 of them relapse and require prostate specific antigen (PSA) blood tests.

The trouble is that current diagnostic imaging scans only have enough resolution to detect a one centimetre tumor, by which time it is too late.

Telix's agent enables a positron emission tomography (PET) scan to show a more accurate picture of the biology of the recurrence; and whether repeat surgery or radiation therapy is needed.

In February, Telix received positive feedback from the US Food and Drug Administration, which deemed the current safety and efficacy data to be sufficient.

The key reason for this is, that while unapproved, 11,500 doses have been used for clinical trials or for special access and compassionate use.

"The FDA is very familiar with the drug because it is being used in US clinical trials already," Dr Cade says.

**Renal imaging**

Known as Zircon, the phase III trial for Telix's renal cancer imaging agent TLX250-CDx is recruiting 252 patients across 26 sites.

After Covid-19 related delays, the Zircon study is expected to be fully up and running again in September.

Depending on the results, the company plans to submit this one as an NDA (new drug application) to the FDA – hooray, hooray.

Zircon is designed to enroll patients scheduled for a partial nephrectomy (that is, the kidney lump is removed by a surgical urologist).

The trial involves the patient being injected with the imaging agent and then undergoing a positron emission tomography (PET) scan, which determines whether the lump is a nasty clear cell renal cell carcinoma or something more benign.

The PET scan is then compared with the surgically removed specimen that comes back in a bottle 10 days later.

"So, we're looking at the sensitivity and specificity of the imaging test compared with tissue histology, which is the 'source of truth'," Dr Cade says.

He says many patients having scans for upper abdominal pain are found to have an asymptomatic kidney mass.

But the only way of knowing for sure is with an invasive biopsy (which is painful and risks the needle leaving a trail of cancer cells along the entry route).

"So, there's a great need to for a non-invasive PET scan to work out what it is with high sensitivity. That's a diagnostic capability that doesn't presently exist."

## A prostate treatment?

While less advanced that the imaging product, a prostate cancer therapy would put Telix in a similar category to Sirtex and its SIR-Spheres liver cancer therapy.

Dr Behrenbruch says that apart from commercializing an imaging product, the “big event” for 2020 will be the launch of a phase III trial, called Prostact, for second-line metastatic prostate cancer.

“After a huge amount of work, the team is now ready to engage with the FDA on this program,” he told shareholders at the company’s ‘virtual’ annual general meeting, this week.

“We expect to get a meeting around mid-July, assuming that Covid-19 isn’t pushing out timelines too badly.”

Telix also has a less advanced glioblastoma (brain cancer) program, TLX101-CDx, which has started recruiting 22 patients for a phase I/II study.

## Financials and performance

Telix reported revenue of $3.5 million and orders of $4.4 million in calendar 2019, both pertaining to the aforementioned prostate cancer imaging kits.

“Although nascent and hardly indicative of the market opportunities we are pursuing, this revenue is also meaningful because it required the company to develop the framework and infrastructure to deliver a commercial product,” Dr Behrenbruch says.

Telix’s March quarter revenues of $1.14 million were affected by the Covid-19-related slowdown in clinical work.

At the end of March, the company reported cash of just under $35 million, having raised $45 million in a private placement and share purchase plan last August (at $1.30 a share).

Dr Cade says this cash should be enough to last until mid-2021 and support the two imaging product launches.

But a prostate therapy trial would require $70 million to $90 million, probably funded by a capital raising of $100 million or so.

Dr Cade expects the company to undertake the trial itself, rather than take on a partner.

“I don’t think it’s beyond a small Australian life sciences company to do it,” Dr Cade says.

“We will probably steer towards a capital raise and run the trial ourselves with a big [contract research organization] partner.”

He notes the company undertook the renal imaging trial off its own bat.

With prostate imaging, Telix models annual revenues around $US105 million ($166 million).

The kidney imaging market is thought to be one quarter the size of the prostate cancer market.

Meanwhile, Telix shares have traded as low as 48 cents (March 2018) and as high as $1.91 (late November 2019).

“We have accomplished an enormous amount since the last capital raise that is not reflected in the company’s current share price,” Dr Behrenbruch says.

**Dr Boreham’s diagnosis:**

While the company describes its business as “theranostics” - therapeutics and diagnostics (geddit?) - Dr Behrenbruch says “the largest value inflection points that Telix will achieve over the next two to three years will come from the therapeutics side of the business”.

Ultimately, Telix aspires to become the fourth mega-sized Aussie life sciences outfit, joining CSL, Resmed and Cochlear on the podium of global champions.

“But we don’t want to join companies like Sirtex and Peplin that were sold mid-stage to offshore buyers,” Dr Cade says. “We want jobs for our kids.”

Telix won’t be an overnight success, but we can only agree with Dr Cade’s assertion that 2020 will be a “pivotal year” for the company.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He still struggles with the spelling of ‘prostrate’ and ‘prostate’, but it’s not quite as embarrassing as confusing ‘public’ with ‘pubic’.***