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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: $21.05

Shares on issue: 338,399,059

Market cap: $7.1 billion

Co-founder and chief executive officer: Dr Christian Behrenbruch

Board: Tiffany Olson (chair), Dr Behrenbruch, Dr Mark Nelson, Jann Skinner, Marie McDonald (chairman Kevin McCann retired in May 2025)

Financials (June quarter 2025): revenue $US204 million (up 63%)

Calendar 2024 year: revenue $783.2 million (up 55.85%), net profit after tax $49.9 million (up 9.6-fold)

Major shareholders: Gnosis Verwaltungsgesellschaft (Dr Kluge) 6.1% Elk River Holdings (Dr Behrenbruch) 6.3%, Grand Pharma (China Grand Pharmaceuticals) 1.8%.

With multiple clinical trials and approval applications in train, nuclear medicine superstar Telix is like one of those irritatingly brilliant, all-round students.

We're thinking of the straight A school captain who stars in the school play, while padding up for the First XI in between clarinet lessons.

But when Goody Two Shoes' Latin grade slips to B+, panic ensues - mainly on the part of overbearing 'parents' (investors).

Last week, Telix experienced the corporate version of such angst when it revealed the US Securities and Exchange Commission (SEC) had subpoenaed "various documents and information".

While disclosing the information in a report titled 'Telix Reports $204m Revenue, Up 63% YOY' the company said the SEC subpoena "does not extend to Telix commercial and late-stage precision medicine products including Illuccix, Gozellix, Zircaix, Pixclara and Scintimun".

The company dubbed the entreaty a "fact finding request", but investors birched the stock by 15 percent.

Telix has a nearer-term focus on winning US Food and Drug Administration approval for two imaging products and says the longer-term therapy programs will continue unchanged.

But the mysterious episode is not the first time that Telix has slipped up.

In April, the FDA knocked back Telix's marketing application for its brain cancer (glioma) diagnostic, telling the company to do more homework.

Management said the setback (by way of a Complete Response Letter) was merely temporary and the company would do what Headmaster requested.

A year ago, the FDA also rejected the company's filing for its kidney cancer diagnostic Zircaix, on account of an "unacceptable manufacturing defect".

Telix founder, CEO and head prefect Dr Chris Behrenbruch dubbed the glitches were "relatively minor and fixable".

Indeed, the company re-filed the application and the market awaits an FDA decision by the end of August.

Telix machine is clicking along

To date, Telix has derived most of its revenue in the US, from its approved prostate cancer imaging agent Illuccix.

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.

Elevated levels in the blood of PSA, a protein, can be a marker of prostate cancer. PSMA (prostate-specific membrane antigen) is a protein on the surface of prostate cancer cells.

Illucix is approved in 17 countries, including the US, the UK, Brazil, Germany, France, Canada and Australia.

In March, the FDA approved a second diagnostic, Gozellix (for metastatic castrate resistant prostate cancer).

Telix hopes to launch Gozellix in the US in the current quarter by October.

A bit of history

Dr Behrenbruch founded Telix in 2015 out of a “deep frustration” that there was a burgeoning interest in nuclear medicine technologies, but few commercial players.

In early 2017, Telix acquired the Dresden-based radio-pharmaceutical outfit Therapeia, founded by Dr Andreas Kluge. Dr Kluge retired from the board in September last year.

Telix listed in November 2017, after raising $50 million at 65 cents apiece.

In November 2024, the company listed on the Nasdaq, having abandoned a $300 million initial public offer in favour of a $650 million non-US corporate bond issue.

Dr Behrenbruch was the executive director of the now defunct Factor Therapeutics and was also on the board of the very un-defunct pancreatic cancer tearaway, Amplia Therapeutics.

In 2020, Telix inked a 10-year deal with China Grand Pharmaceutical, worth “up to” $US225 million, The Hong Kong-based entity became the exclusive partner in greater China for any approved Telix therapy.

Telix remains Melbourne based, but most of its commercial activity is in the US.

Good golly, it’s Gozellix

In March this year, the FDA approved the company’s gallium isotope-based Gozellix, for PET scanning of lesions showing PSMA.

While not an expansion to a completely new indication, Gozellix extends the company’s US prostate cancer imaging market reach by an estimated five to 10 percent.

Gozellix is for prostate cancer patients with suspected metastasis, who are candidates for initial definitive therapy (prostate removal or broader radiation treatment).

It’s also for those with suspected recurrence, based on elevated PSA levels.

“The ability to reliably deliver the product much further from its point of production means Gozellix can reach PET cameras that are currently not served by any PSMA imaging providers,” the company says.

Gozellix has a longer shelf life of up to six hours, about three times more than Illucix. It can also be used on older scanning machines.

On the acquisition trail

To expand its repertoire and bolster its manufacturing oomph, Telix has continued an acquisitive splurge.

In January, Telix acquired a “proprietary novel biologics technology” from antibody engineering company Imaginab Inc.

The platform has small, engineered antibody formats that enable specific radiation targeting of cancer.

The deal delivers a “state-of-the-art” research facility in Los Angeles, adding to existing capacity at Sacramento, Angleton (Texas) and across the border in Vancouver.

In September 2024, Telix spent $388 million to acquire RLS Radiopharmacies, to expand its North American manufacturing and distribution footprint.

RLS derives revenue from providing radio-pharmacy products to third party clients.

In April, the company bought the Austin-based Isotherapeutics (radio-chemistry services) and the Canadian radio-isotope producer Artms Inc.

Let’s get clinical

It’s hard to do justice to Telix’s extensive clinical program in a few paragraphs, but here goes …

By the end of the year, the company should unveil an initial safety and dosing readout for its phase III prostate cancer therapy candidate, the lutetium-based TLX-591.

The study, Prostact Global, has enrolled 30 men for the part one phase. These patients have PSMA-positive metastatic castrate-resistant prostate cancer, with the standard-of-care chemotherapy drugs, or the standard-of-care alone.

To date, TLX-591 has been evaluated in 242 patients across eight phase I/II studies, with “evidence of anti-tumor effect and a clear dose response profile for key measures of efficacy”.

Telix also has mid-stage brain and kidney cancer therapy programs and another one for bone marrow conditioning; as well as earlier stage programs for musculo-skeletal conditions including soft tissue sarcoma, bone metastases and “pain palliation”.

Readers should peruse the company 127-page investor presentation from June 11, but only if they are feeling strong.

https://announcements.asx.com.au/asxpdf/20250611/pdf/06kn42znh0567z.pdf.

Finances and performance

Telix reported revenue of $US204 million for the June 2025 quarter, up 63 percent year-on-year and a 10 percent increment on the March 2025 quarter.

(As of January this year, the company reports in US dollars.)

Sales of Illuccix accounted for $US154 million, up 25 percent year-on-year. RLS contributed $US46 million of sales, 39 percent higher than the March quarter.

Dr Behrenbruch notes Illuccix dose volumes rose seven percent, quarter-on-quarter.

He says despite “emerging competitive pricing pressure” Telix has “effective strategies” to maintain average selling prices.

Not irrelevantly, in July, Gozellix was granted a permanent Healthcare Common Procedure Coding System code.

Telix expects to obtain transitional pass-through (TPT) payment status, which provides additional Medicare reimbursement to hospitals using innovative medical devices or drugs.

TPT should apply from October 1 with reimbursement of around $US1,000 per dose, almost twice that applying to Illuccix.

In calendar 2024, Telix expended $US195 million on research and development, up 50 percent. This year the number should be 20 to 25 percent higher again.

Telix has maintained calendar 2025 guidance of $US770 million to $US800 million, having chalked up first half-year revenue of $US390 million.

We’ll know about the innards of Telix’s financials at its full-year results on August 21.

Over the last 12 months Telix shares have irradiated between $17.44 (early September last year) and a record $31.14 in late January this year.

In November 2017 the shares were worth 13 cents.

Telix trumps tariffs with US manufacturing

Telix says it won't be affected by Trump's drug pricing and tariff proposals.

Given Telix's just-in-time products are made in the US out of necessity, they are as American as apple pie and a Colt AR-15 rifle under the bed.

"This will continue to be the case for new products the company expects to launch in 2025" the company says.

As for drug pricing, the Trump administration plans to benchmark certain local therapeutics against those charged in the cheapest of the industrialized nations.

Telix reckons it's in the clear because "localized production makes international pricing comparisons challenging to benchmark".

In any event, the company promises "pharmaco-economically defensible" pricing.

What the brokers say

Broking analysts maintain their faith in Telix, despite the distraction of the SEC probe (if we can call it that) and stiffening prostate imaging competition.

Broker Jefferies says such SEC entreaties are common, but the issues might take two years or so to resolve.

UBS suggests any disclosure shortcomings may relate to Telix's dual ASX/Nasdaq listing, with the company needing to satisfy different requirements across the Pacific.

On competition, UBS notes that the seven percent uptick in Illucix sales shows Telix is winning market share in a hotter market.

The firm believes the launch of Gozellix (and its TPT status) has relieved some of the pricing pressure.

UBS values Telix at $36 a share, while Jefferies and Bell Potter plump for a $34 price target. The latter does so on the expectation of FDA approval of Zircaix.

UBS says the current valuation assumes "total scientific and clinical failure" of the therapeutic programs.

Valuing the stock at $35, Wilsons says Gozellix provides "exciting upside" and Telix has "so many options available to it both competitively and operationally".

The only Grumpy Bob is Morningstar, which in April described Telix as overvalued by about 40 percent. The research house opined Telix's product pipeline remained "commercially unproven in an increasingly competitive market."

Dr Boreham's diagnosis:

Telix faces a pile of homework, but we concur the company can remain dux of the radio-imaging class despite the regulatory issues.

We should stress that Telix is solidly profitable: UBS plugs in a net profit of $138 million for the current year, rising to $292 million in 2026 and $480 million in 2027.

Telix cites a current US prostate cancer imaging market at US$2.5 billion to $US3.5 billion.

But with expanded indications, this figure swells to $US6.7 billion across 1.7 million scans annually.

One might think the medical world had nuclear diagnostics down pat by now, but evidently there are isotopes and there are isotopes.

In the past, Dr Behrenbruch has described Zircaix as potentially bigger for Telix than Illuccix.

Not that he expects the prostate business to slow down.

Beyond imaging, if Telix can crack a better therapy for the key cancers in its remit, then its $7 billion market valuation looks only the start.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. So, it goes. But give him an isotope and he will take a stab at where to stick it, so it glows