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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: $18.61; **Shares on issue:** 334,640,424; **Market cap:** $6.23 billion

Chief executive officer: Dr Christian Behrenbruch

Board: Kevin McCann (chair), Dr Behrenbruch, Dr Andreas Kluge (co-founder), Dr Mark Nelson, Jann Skinner, Tiffany Olson

Financials (June half 2024): revenue $US364 million (up 65%), adjusted Ebitda $US57.5 million (up 66%), net profit $US41.5 million ($US10 million loss previously), cash balance $US118.8 million (down 3.5%) ahead of convertible bond issue that raised $650 million.

Major shareholders: Gnosis Verwaltungsgesellschaft (Dr Kluge) 7% Elk River Holdings (Dr Behrenbruch) 7%, Grand Pharma (China Grand Pharmaceuticals) 3.3%.

Telix CEO and co-founder Dr Chris Behrenbruch is blunt about why some fund managers believe the ASX market darling is entering 'overvalued' territory.

"The fundies probably hate [us] because they didn't get their act together and invest in the company when it wasn't worth very much," he says.

"They missed out on getting a 30-bagger [a 30-fold gain] from the Telix IPO in 2017."

He adds Telix now focuses much of its investor relations efforts in the US, because fund managers there "are better able to understand [the company] and have the interest in doing the work."

That said, Telix should have lost no friends after last week revealing a 65 percent half-year revenue surge and a net profit of just under $US30 million, a turnaround from a previous $US14.3 million loss.

Telix is a complex case of multiple diagnostic and therapeutic programs - and to the untrained observer the lead indication is acronym and jargon soup.

In a nutshell, Telix is gaining market share with its first approved US product Illuccix, an isotopic tool for prostate cancer imaging. US approvals are also pending for renal (kidney) cancer and brain cancer diagnostics and potential European, UK and Brazilian approval of Illuccix.

The story to date

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

While rivals' time-sensitive isotopes are produced in costly cyclotrons, Telix's can be generated at a network of nuclear pharmacies across the US.

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.

"No one was interested in commercializing PSMA-11 [prostate specific membrane antigen-11] (Illuccix) in the US, despite the unmet need."

In early 2017 Telix acquired the Dresden-based radio-pharmaceutical outfit Therapeia, founded by Dr Andreas Kluge.

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

Dr Behrenbruch was the executive director of the defunct Factor Therapeutics and was also on the board of Amplia Therapeutics.

In 2020, Telix inked a 10-year deal with China Grand Pharmaceutical, worth "up to" $US225 million from market authorization. The Hong Kong-based entity became the exclusive partner in greater China for any approved Telix therapy. Telix is Melbourne-based, but most of its commercial activity is in the US.

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.

Meanwhile, Telix has lodged an approval application with the US Food & Drug Administration for a variant agent, TLX007-CDx, which will expand geographical coverage of PSMA-PET imaging to all PET cameras.

The agency must respond by March 24 next year.

Dr Behrenbruch says, to date, Illuccix has snared a 35 percent share of the US prostate imaging market, trending to 40 percent. He says that's a "stellar" performance given Telix was second to market, behind arch-rival Lucentis.

He says with PSMA imaging oriented to metropolitan clinics and academic centres, there's still the opportunity to win market share in US regional areas.

"No-one wants to travel two to three hours to the big smoke to get a scan."

Prostate therapy next?

In November 2023, the company dosed its first patient for a phase III global prostate cancer therapy study, called Prostact Global for treating adult patients with PSMA-positive metastatic castrate-resistant prostate cancer (mCRPC). This program uses the lutetium-based TLX-591.

The patients are also treated with the standard-of-care chemotherapy drugs, or the standard-of-care alone. The therapy aims to satisfy "unmet medical need across the full prostate cancer treatment journey" from first recurrence to metastatic disease.

To date, 242 patients have been treated with TLX591 across eight phase I and II studies, including the 28-patient Prostact Select study that showed median progression-free survival of 8.8 months.

This compares favorably with radio-ligand agents "at a similar stage of development".

Multiple US Prostact Global sites are being activated and preparing to dose first patients, with recruitment continuing at Asian Pacific sites.

In a separate, completed proof-of-concept trial called Cupid, Telix tested an engineered antibody, TLX-592 for advanced prostate cancer. The company intends to progress to a phase I/II study later this year.

Kidney problem 'minor and fixable'

On July 31, the company said the FDA had rejected its filing for approval of Zircaix, for imaging clear cell renal carcinoma (the most common form of kidney cancer).

The problem was an "unacceptable defect" in a 0.22-micron filter used in the automated dispensing process. (One micron is one millionth of one metre.)

Dr Behrenbruch said the issue was “relatively minor and fixable”, with remediation underway. He stresses the dossier was rejected only because of the single manufacturing problem, rather than clinical issues.

Earlier, a supporting phase III trial, dubbed Zircon, met its primary and secondary endpoints in terms of both sensitivity and specificity (the ability to detect false positives and negatives).

Dr Behrenbruch says Zircaix would fit snugly with Illuccix, as it would be sold to the same urologists and urologic oncologists.

“We are confident we have four to five years of clear breathing room before we have to worry about a new entrant,” he says.

On the therapy side, two kidney combination trials are at phase II and pre-clinical stages, with clinical data expected later this year.

Brain cancer

Dr Behrenbruch has a soft spot for the company’s glioblastoma (brain cancer) program, given the under-served market for the aggressive disease.

The diagnostic, Pixclara, has completed phase III and a marketing application was filed to the FDA on Wednesday.

In the meantime, patients - including children - are being treated under an early access program.

On the therapeutic side, Telix is enrolling two trials for both recurring glioblastoma and new patients.

Pixclara has FDA ‘orphan’ designation, given there’s a relevant market of fewer than 40,000 patients (albeit worth $US90 million a year).

“It’s a small market initially … but we see tremendous opportunity to expand the utility of this product to [other] central nervous system malignancies,” Dr Behrenbruch says.

Deals, deals, deals

Telix has been liberating some of its swelling cash reserves with a string of bolt-on acquisitions.

In February this year, the company acquired QSAM Biosciences Inc, which is developing a potential radio-therapy for primary and metastatic bone cancer (the condition afflicts about 400,000 new patients in the US each year).

In April, the company completed the purchase of the Austin-based Isotherapeutics, which provides bio-conjunction and radio-chemistry services.

In the same month, Telix completed the acquisition of the Canadian radio-isotope producer ARTMS Inc for $US57.5 million upfront (cash and scrip) with $US24.5 million in potential future earnouts.

Earlier, the company bought two artificial intelligence (AI) and robotics innovators.

Finances and performance

Telix's half-year numbers show the dollars are rolling in, with revenue up 36 percent to $US364 million and a previous $US10 million loss morphing into a $US41.5 million profit.

With reduced costs as a proportion of sales, gross margin improved by three percent.

Management confirmed calendar 2024 revenue guidance of $US490 million to $US510 million ($A745 million to $A776 million), a 10 percent increase on previously enunciated guidance and circa 50 percent better than the 2023 result.

Approval of the brain cancer and kidney diagnostic tools would expand the company's estimated total addressable market to $US4.5 billion.

During the half year, the company spent $US83.9 million - 23 percent of revenue - on research and development.

Over the last 12 months, Telix shares have traded between $8.48 (September last year) and a record $20.30 (July 23 this year).

The shares plumbed a record low of 43 cents in early 2018 and no-one rang the bell, sadly.

No to Nasdaq – for now

In early January, Telix announced plans to list on the Nasdaq, with an accompanying IPO. But in mid-July the company pulled the plans, because the pricing was at an unacceptable discount.

Instead, Telix is raised a chunky $650 million via convertible bonds to be listed on the Singaporean exchange.

A feature of the "low-cost, non-dilutive" financing is that the bond holders will pay $24.78 per share on conversion on or around July 30, 2029, a 32.5 percent premium on the reference price of $18.70.

They also receive an annual coupon of 2.0 to 2.75 percent.

In effect, the bondholders believe that Telix shares will be even higher than $24.78 within five years. If the shares disappoint, they remain as bond holders

Dr Boreham's diagnosis:

Along with the monster fund raising, Telix's revenue trajectory shows the $6.4 billion market cap entity has its big boy's pants on - despite the lack of a Nasdaq presence.

Dr Behrenbruch is unperturbed by suggestions that Telix's fortunes have peaked.

"Zircaix is potentially bigger for Telix than Illuccix - and it's not as if we won't continue to perform well on the prostate cancer side," he says.

Dr Behrenbruch reckons that in a few years Telix will glean 30 to 40 percent of revenue from outside the US, in jurisdictions including Brazil where Illuccix approval is pending.

From 2027, the company expects another growth spurt as its therapeutic molecularly targeted radiation comes on market.

"When that happens our revenue and the valuation multiples change dramatically," Dr Behrenbruch says.

"There's still lots to look forward to."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He looks forward to obtaining one … one day.