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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: $2.60; **Market cap:** $717.2 million; **Shares on issue:** 275,842,022

Chief executive officer: Dr Christian Behrenbruch

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

Financials (September quarter 2020): receipts $823,000, cash outflows $2.18 million, cash of $25.7 million (ahead of the China deal that injected $35 million of equity)

Major shareholders: Gnosis Verwaltungsgesellschaft (Dr Kluge) 8.95%, Elk River Holdings (Dr Behrenbruch) 8.95%, Grand Decade (China Grand Pharmaceuticals) 7.59%, Fidelity International 7.28%.

In media circles, the qualifier "up to" has been a handy one for headline writers over the years.

For instance, road workers vilified as bone lazy earn "up to" a six-figure wage for brandishing a lollipop, when in fact that number is the outlier for a toiler working overtime or night shifts seven days a week.

The same caution should be applied to life science deals with big pharma that promise "up to" many hundreds of millions of milestone and royalty payments - if the device actually gets to market and blitzes sales.

On this note, Telix Pharmaceuticals headline deal with the Hong Kong China Grand Pharmaceutical is worth “up to” $445 million, with ongoing royalties possibly exceeding this number.

That’s predicated on the company’s key imaging and therapeutic products achieving approval and sales in greater China. But our point is the amount includes a $US25 million ($AUD35 million) non-refundable upfront prepayment and a $US25 million equity investment in Telix - with no “up to” qualifier.

In other words: 70 million bucks are definitely coming through the door.

“We are delighted to be working with such a strong partner,” purrs Telix chief Dr Chris Behrenbruch. “We like the culture and the can-do attitude of the company.”

Dr Behrenbruch says Telix might have been seen as focused on the US and Europe at the time of its 2017 listing - and indeed it was.

But the company had already identified the potential of Asia - especially Japan which has a mature nuclear medicine industry.

‘Theranostics’

Telix dubs itself a “theranostics” company, in that it’s developing both imaging (diagnostic) and cancer therapies on its molecularly targeted radiation (MTR) platform. And putting them in the correct order of diagnostics and therapy would have led to the very catchy “diarapy” which sounds more like what little babies do.

A relatively new discipline, molecularly targeted radiation allows radioactive isotopes to be delivered to biological targets expressed by the cancers. As a result, healthy cells are not irradiated in the process.

Current imaging uses the unstable gas iodine, which creates “noisy” images and is poor at detecting smaller tumors.

On the imaging side, Telix is focused on renal cancer (TLX250-CDx) and prostate cancer (TLX591-CDx and TLX599-CDx). CDx is not a compact disc containing adult material: it means “companion diagnostics”. Telix is developing therapies for these indications as well as glioblastoma, or brain cancer (TLX 101).

As an MTR play, Telix shares traits with the formerly ASX-listed Sirtex Medical, which is run by none other than CGP (having acquired 49 percent of the company for $1.9 billion in 2018).

Who is Telix?

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

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

Dr Kluge founded the Dresden-based radio-pharmaceutical outfit Therapeia, acquired by Telix for a nominal cash sum and the assumption of about $1 million of debt.

Dr Behrenbruch was also the executive director and now non-executive director of Factor Therapeutics, which has pivoted from human wound care to veterinary imaging. He was also on the board of Amplia Therapeutics, which he co-founded, but quit in February this year to focus on Telix.

Chief business officer Dr David Cade joined October 2019, having been chief medical officer at Cochlear. Before that, he held senior roles at Sirtex.

The deal dissected

The China deal means that China Grand Pharmaceutical becomes the exclusive partner for Telix in greater China (mainland China, Hong Kong, Macau and Taiwan).

The partnership is for an initial 10-year term for any therapies, with the clock to start ticking after marketing authorization. The imaging deal is over 15 years.

As well as the aforementioned $35 million upfront payment, Telix is eligible for up to $US69 million ($AUD100 million) of milestone payments on approval from China's medical regulator, the National Medical Products Administration (NMPA).

There's a further $US156 million in sales milestones. CGP will also chuck in up-to $US65 million of clinical costs for prostate cancer (TLX591) and renal cancer (TLX250).

The imaging side is described as a sales, marketing and distribution partnership for the renal and prostate cancer diagnostics. CGP has minimum annual purchase obligations for exclusivity to be maintained.

While Telix remains responsible for manufacturing and clinical development, CGP's task is to steer approval applications through the NMPA.

Telix is heartened that the agency recently approved Sirtex's Sir-Spheres for liver cancer, with this assent based on data from foreign trials.

Having said that, Telix is willing to expand its current trials to include some Chinese patients.

Telix's PET project

While positron emission tomography (PET) screening is common in the US, Europe and Japan, in Asia the more common technique is more likely to be single photon emission computer tomography (Spect).

While China has seen huge growth in PET, it has a large incumbent Spect base.

In the case of prostate cancer, men are typically diagnosed at a late stage, while renal cancer is more likely to be picked up incidentally from abdominal imaging.

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

"Millions of men will get access to our prostate cancer imaging because of our commitment to get Spect as well as PET solutions for prostate cancer," Dr Behrenbruch says.

Going nuclear on pricing

While Telix's corporate mantra is "no patient left behind", cost is a key factor.

In the case of prostate cancer, Telix competes with another lutetium-based imaging product, Novartis's PSMA-617.

As well as offering claimed advantages such as a single dose rather than multiple doses. TLX519 uses only about 20 percent of the lutetium isotope, the costliest component.

"In a price sensitive market, the one thing that matters most is the isotope cost," Dr Behrenbruch says. "We can make money where our competitors struggle."

Meanwhile …

Telix currently is awaiting European marketing approval for its prostate cancer imaging agent, filed in April this year. The submission pertains to the imaging of patients with elevated prostate specific antigen (PSA) after radical prostatectomy (prostate removal) or radiation therapy.

In September Telix followed up with an application to the US Food and Drug Administration, citing clinical data from more than 600 patients as well as peer-reviewed literature.

The agent is available for special access use in the US and Europe, with 12,000 men treated last financial year.

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

Dubbed as "men's breast cancer" because it is so common, prostate cancer is diagnosed in 175,000 patients annually 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.

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

The company expects TLX250-CDx to be the first imaging agent specifically intended for the non-invasive assessment of patients with clear cell renal carcinoma, the most common form of kidney cancer.

In August, the company started a phase I/II study in Japan. Called Zirdac-JP the study aims to recruit 40 patients as a supplement to its phase III global trial, Zircon.

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

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

A prostate treatment?

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 patients with PSMA expressing castration-resistant prostate cancer (mCRPC).

Telix is due to meet the FDA on November 23 to yak about final study design for the Prostact trial, which is likely to recruit 550 to 600 patients.

The company hopes the regulator will allow it to "enrich" the patient selection with use of its prostate cancer imaging, to hone in on the most suitable subjects with mCRPC.

Financials and performance

Six months ago, Telix was talking about a partnering deal to fund the estimated $70 million to $80 million cost of the prostate cancer therapy trial.

Now, the China Grand equity investment and a research and a development tax refund mean the company will go into 2021with a cash kitty of $100 million.

"The company will not have to raise additional capital in the near future," Dr Behrenbruch says.

Telix chalked up sales of a tad over $800,000 in the September (third) quarter and revenue of $3.5 million in calendar 2019 from prostate cancer imaging kits.

The $35 million of China Grand placement shares were issued at $1.69 each !!!!million, which reflected the then market price rather than a steep discount typically seen with such deals. CGP cannot trade the shares for 12 months from the date of issue.

Management estimates the CGP relationship will cost the company $3 million to service annually.

The company last raised $45 million via a placement and share purchase plan in August 2019.

Telix models annual revenues from prostate imaging at the midpoint of $US105 million ($166 million).

The kidney market is about one quarter of the size.

Meanwhile, Telix shares have traded as low as 48 cents (March 2018) and peaked at $2.64 this week (November 11, lest we forget).

Dr Boreham's diagnosis:

Just over four years after its genesis, Telix has done well to be on the cusp of commercializing its first diagnostic product.

Ultimately, the biggest prize lies in therapeutics rather than diagnostics. If approvals are forthcoming, there's no reason Telix can't become another multi-billion dollar market cap Aussie biotech champion.

While Telix remains focused on Western world markets, in Asia it's eyeing an immature but developing nuclear medicine landscape.

"In general, the isotope supply chain is not as well established as in other regions, although we see this changing very rapidly over the next five to seven years," Dr Behrenbruch says.

"The main opportunity lies in the volume of patients in important oncology indications with large unmet medical needs."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has scored "up to" 27 not-out in backyard cricket, but his batting average is more like two.