



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: LTR Pharma

By TIM BOREHAM

ASX code: LTP

Share price: \$1.215

Shares on issue: 153,901,979

Market cap: \$187.0 million

Executive chair: Lee Rodne

Board: Mr Rodne, Dr Julian Chick, Maja McGuire

Financials (year to June 30, 2024): revenue nil, loss of \$9.95 million (\$1.45 million deficit previously), cash of \$3.1 million (up 79%) ahead of \$10.5 million capital raising

Identifiable major shareholders: Mr Rodne 34% interest, Strategic Drug Solutions 3.8%, Trexapharm 2.7%.

When we were kids eyeing an unobtainable treat or the not-so-imminent arrival of Santa, Mum used to tell us to be patient. Patience, indeed, is a virtue and an admirably quality to exhibit throughout one's adult life.

But there are circumstances when even a Job-like quotient of patience will not suffice - and one of them is waiting for the effect of erectile dysfunction tablets to kick in.

According to LTR Pharma, oral drugs such as Viagra and Cialis can take more than an hour to have their desired effects.

Yes, there's such a thing as foreplay but in such a time span the amorous vibe is likely to be surpassed by the imperative of vacuuming the hall or emptying the dishwasher.

LTR Pharma is developing a nasally-delivered variant of the same drug class which, on evidence to date, hits peak bloodstream levels within nine to 15 minutes.

LTR founder and executive chair Lee Rodne says 50 percent of men stop taking the current tablets within a year, because of the timing problem and side effects.

"A lot of guys don't realize that Viagra is very variable as a tablet because of the delivery mechanism," Mr Rodne says.

"It has to go through your gut and your liver; sometimes it is effective but sometimes it is not effective at all."

The rise and rise of LTR

Mr Rodne founded LTR based on technology acquired from California's Strategic Drug Solutions, with pharmacologist Prof Moses Chow credited as the inventor.

Then an executive with iron-ore producer Fortescue Metals, Mr Rodne was hand-picked by Fortescue founder Dr Andrew 'Twiggy' Forrest to lead the company's health spin-off Allied Medical.

Mr Rodne led Allied for 10 years, merging it with Biomed to become Allied Healthcare and then Admedus and now heart transcatheter play Anteris Technologies.

Mr Rodne's Allied experience led him to a group of medical researchers and manufacturers who asked him for help with a project to make erectile dysfunction treatments more effective and consistent.

Under the deal with Strategic Drug Solutions, LTR Pharma can use the technology in any way, but its current sole focus is on erectile dysfunction (ED).

LTR Pharma listed on December 11 last year, having raised \$7 million at 20 cents apiece.

Mr Rodne owns 59 percent of the company, with fellow director Dr Julian Chick accounting for 19.7 percent.

Dr Chick has been involved in no fewer than 16 start-ups and helmed the ASX-listed Avexa, which tried to develop an HIV drug but eventually went coal mining in Alabama instead.

He is the chair of pot play Cann Group and is behind the proposed ASX listing of a nerve regeneration company called Renerate.

About Spontan

Spontan - as in spontaneous - is a drug and device combination to deliver vardenafil, the basis of Levitra and Staxyn.

Vardenafil is a PDE5 inhibitor, which target receptors that relax muscles and increase blood flow to the penis.

Other PDE5 inhibitors are behind Pfizer's Viagra (sildenafil), the first to market in 1998, Cialis (tadalafil) and Stendra (avanafil).

All these PDE5s are pretty much same-same, but vardenafil was deemed the most suitable for nasal reformulations.

Mr Rodne says current side-effects include heartburn and joint pain, which are all the result of the oral tablets going through the gastro-intestinal tract.

Spontan, of course, goes straight to the blood stream.

Why not earlier?

Mr Rodne says Spontan currently faces no competition, but the lingering question is why big pharma - notably trailblazer Pfizer with its 'Pfizer riser' - didn't crack the nasal channel.

Cialis, Viagra and Levitra, the three biggest-selling erectile dysfunction drugs are now off-patent and subject to generic competition. Stendra's patent expires in April 2025.

"Pfizer looked into it [nasal delivery] but it's very hard to work because of the [PDE5] chemical structure," he says. "It tends crystallize when in liquid form, so you can't just crush up a chemical tablet, put it in a bottle and expect to be able to spray it."

The nub of LTR's smarts is the ability to keep the drug soluble and enhance drug interaction.

Where's the evidence?

LTR Pharma's proof of efficacy to date is a small local trial and 'real world' usage evidence.

On June 7 this year the company said an 18-man bio-availability trial showed Spontan hit peak bloodstream levels in nine to 15 minutes – an average of 12 minutes – compared with an average 56 minutes and as much as 150 minutes for oral vardenafil.

The healthy adults were given two single 5.0mg doses of Spontan, as well as a 10mg dose of the oral version after a respectable crossover period.

Given the drug is known to be effective once it reaches the bloodstream, that's all the trial had to prove. In other words, the subjects weren't being assessed on the quality of erections and lovemaking by a white-coated researcher at the end of the bed.

Early in the piece, LTR became eligible for the local Therapeutics Goods Administration's special access scheme and then the authorized prescriber scheme. These allow unapproved treatments to be administered.

Initially, Spontan was prescribed by two men's health doctors, but has spread to a broader cohort. A notable prescriber is urology expert Prof Eric Chung of the University of Queensland.

Taking it slowly

Mr Rodne says the company won't reveal current patient use - which is on the rise - because it doesn't want investors to focus on sales for what is still a research and development-stage company transitioning to commercial phase.

"Before we do that fully, we want specific feedback on patient use, such as whether they are using it in combination with other products," he says.

"We also want to produce education videos on how to use the product and we have some more packaging work to do and ensure patients can follow the instructions clearly."

That said, the company hopes the trial and the real-world data will support a marketing application to the TGA initially and the US Food and Drug Administration in early to mid-2025.

The FDA filing is expected to be under the 505(b)(2) route, pertaining to a "change in route of administration for already approved drug".

"We expect to use the data packages for both agencies, but our home market is important for us," Mr Rodne says.

While the requirement for further trials is unclear, the company expects more investigator-led studies here, with a standard requirement for an animal toxicology study.

Take your partners

In the meantime, LTR is in confidential licencing and partnering discussions with pharmaceutical companies.

"We will run these discussions until [mid] 2025 and see what sort of value we can create," Mr Rodne says. "They would not waste their time if they were not interested."

In mid-August, LTR entered a co-development agreement with the New York-listed Aptar Pharma, a developer of nasal spray medicines used by drug companies including Pfizer and Johnson & Johnson.

“They [Aptar] don’t partner with everyone: it needs to be a differentiated product with a big market and significant data.”

As LTR’s device partner, Aptar will carry out market and regulatory readiness work, such as meeting with the agencies and formulation studies.

“Aptar has more than 25 products approved with the FDA, so we don’t have to prove [the device works] in the same way we don’t have to prove the drug works, because it has already been approved in oral form.”

Indeed, the PDE5 tablets have been tested on hundreds of thousands - if not millions - of patients and cost more than \$US1 billion to develop.

Telehealth

Earlier this month, LTR entered a joint venture with a West Australian men's health group, the Restorative Sexual Health Clinic, for an online healthcare platform.

“The online platform will provide a discrete and convenient channel for men to access professional healthcare services and prescribed treatments,” Mr Rodne says.

The platform is expected to launch in the March quarter of next year.

Finances and performance

Shortly after the positive trial results, LTR bolstered its \$7 million of IPO funds with a \$10.5 million placement, struck at 73 cents apiece (a 19 percent discount).

Mr Rodne says LTR has sufficient cash – three years - beyond the likely timelines for regulatory approval and commercial partnering.

The company intends to devote some of the funds to building an online sales channel, to avail of the rapid rise in digital prescriptions (in fact, the lion’s share of erectile dysfunction scripts is written remotely).

LTR Pharma’s annual report shows a contingent liability of \$US3 million, by way of potential milestone payments to Strategic Drug Solutions.

LTR Pharma shares have always traded above their 20 cents listing price, bottoming at 27 cents two days after the IPO and peaking at \$2.06 on October 10 this year.

Dr Boreham's diagnosis:

Mr Rodne says that as a company focused on a single re-purposed drug, LTR Pharma is a simple story to understand.

Spontan also addresses a high unmet need, with an estimated 322 million of the world's blokes estimated to suffer erectile difficulties.

Of these, close to half are in China, which might explain the nation's sagging birth rate. Australian blokes can't exactly stand proud, either, with the condition affecting more than 60 percent of over 45s.

The value of the erectile dysfunction market is estimated at \$US4.52 billion, with the US accounting for 30 percent despite having less than 10 percent of the sufferers.

The market is expected to grow to \$US6 billion by 2028, despite what Mr Rodne describes as a complete lack of erectile dysfunction treatment innovation.

While LTR Pharma is an easy-to-understand proposition, there's no plan B if Spontan fails to gain market approval or flops at launch.

An unexpected rival could also emerge, but Mr Rodne believes the coast is clear.

The endgame for LTR is unclear - it might go all the way to market on its own— but it would be stiff for the company to fail at this point.

After all, Spontan would seem to be a great way for, say, Pfizer, to re-establish patent life on its famed blue pill.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He doesn't have a Job-like quotient of patience, so will ensure the dishwasher stays off at the crucial moment.