Biotech Daily

Friday October 10, 2025

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: LTR Pharma

By Tim BOREHAM

ASX code: LTP

Share price: 66.5 cents

Shares on issue: 112,599,375

Market cap: $74.9 million

Executive chair: Lee Rodne

Board: Mr Rodne, Dr Julian Chick, Maja McGuire

Financials (year to June 30, 2025): revenue $145,779 (nil previously), other income (interest, RDTI) $1.96 million ($49,331 previously), loss of $5.59 million ($6.95 million deficit previously), cash of $31.8 million (up 925%)

Identifiable major shareholders: Mr Rodne 29%, Dr Chick 10%, Strategic Drug Solutions 3.28%, Trexapharm 2.3%. Go Medical Industries 1.5%.

In drug development, real world evidence can be just as valuable as clinical proof – and LTR Pharma has brought out a big gun in its quest to further the world's first nasal spray-delivered erectile dysfunction (ED) treatment.

The weapon is Melissa Hadley Barrett, a Perth based sexologist and nurse practitioner and founder of the Restorative Health Clinic.

At an LTR investor presentation last week, Ms Barrett outlined the under-appreciated extent of problems in the bedroom.

One in five men under 40 suffer erectile dysfunction and the number rises to one in three in the 50s cohort and then 50 percent for the 60s age group.

Thereafter, four in five men are afflicted.

Ms Barrett likens erectile dysfunction to a knee or hip replacement: a sign the body is ageing.

She says it's "fascinating" that men accept the rest of their bodies wear out, but assume their penises don't.

Erectile dysfunction is also linked to ailments such as back pain as well as prostate surgery.

Contrary to common belief, a lack of testosterone may cause loss of libido, but it does not prevent erections.

Increasingly, younger men are affected, which Ms Barrett attributes to performance anxiety resulting from the use of online porn.

So, erectile dysfunction is not just an old blokes' disease.

Meanwhile, couples are sweeping the problem under the doona.

"[Men] would do anything to fix a limp arm, so why are they embarrassed about their other bits?" she asks.

A hard man is always good to find

In a joint venture, Restorative Health Clinic and LTR Pharma have created a telehealth platform, dubbed – naturally – Hard Made Easy.

(Ms Barrett also has a podcast monikered The Penis Project, which "focuses on men's issues from real men's viewpoints").

Crucially for LTR, Ms Barrett is a keen advocate of Spontan, a nasal spray reformulation of the oral vardenafil (Levitra).

LTR claims that Spontan works in five to 10 minutes, rather than an hour or more for oral drugs such as Levitra, Cialis and the famed Viagra. This is because the active agent goes directly to the bloodstream, rather than the gut and liver first.

Spontan also has a long, 18-month, shelf life.

LTR founder and executive chair Lee Rodne notes about half of the users of the oral drugs give up taking them, either because of side effects (such as heartburn and joint pain) or the prolonged waiting time.

Early patient results arouse interest

Regulators are yet to approve Spontan but that doesn't mean patients aren't being treated.

As of last week, nurse practitioner Ms Barrett had prescribed Spontan to 638 men, under the local Therapeutic Goods Administration's (TGA's) special access scheme.

The clinic's follow-up survey of 100 patients showed that all were able to get an erection, while just over half managed to have sex.

While 50 percent success might sound like a flop, in drug terms that's a good run rate.

For example, cholesterol-lowering statins only work about one third of the time.

The survey also showed 17 of the users complained of nasal discomfort such as fuzzy sinuses.

"But it gets less every time you use it," Ms Barrett says.

She stresses that as with oral erectile dysfunction versions, the spray must be consider with other factors such as abating alcohol use, smoking and obesity.

With treatment, 80 percent of erectile dysfunction sufferers will see their erectile function restored.

About LTR Pharma

A former executive with iron-ore producer Fortescue Metals, Mr Rodne led Dr Andrew 'Twiggy' Forrest's health spin-off, Allied Medical, for a decade.

A group of medical researchers and manufacturers asked him for help with a project to make erectile dysfunction treatments more effective and consistent.

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

LTR Pharma listed on December 11 2023, having raised $7 million at 20 cents apiece.

Mr Rodne owns around 30 percent of the company.

Fellow director Dr Julian Chick has been involved in no fewer than 16 start-ups and helmed the ASX-listed Avexa, which developed the HIV drug apricitabine (ATC), but failed to raise funds for a phase III trial, closing the program in 2016.

Dr Chick heads the nerve repair play Renerve, which listed on the ASX in late 2024.

In August 2024, LTR entered a co-development agreement with the New York-listed Aptar Pharma. Aptar develops nasal spray medicines, used by companies including Pfizer and Johnson & Johnson.

In January 2025, LTR inked a local national pharmacy distribution with drug wholesaler Symbion, owned by the ASX-listed EBOS Group.

Locally, Spontan has been prescribed by other men's health doctors, notably urology expert Prof Eric Chung of the University of Queensland.

In December last year, LTR struck an access agreement with Men's Health Downunder, Australia's largest men's health pharmacy.

About Spontan

Spontan delivers vardenafil, which underpins the oral drugs Levitra and Staxyn, as a nasal spray.

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

Pfizer's Viagra is based on the PDE5 inhibitor sildenafil. Viagra was launched in 1998 but long has been off-patent.

Mr Rodne contends that Viagra is still the most recognized oral erectile dysfunction pill because it was the first - but that doesn't make it the best.

Cialis and Stendra use the PFE5 variants tadalafil and avanafil, respectively.

Ms Barrett notes that other treatments include penile implants and injections, oral strips and cannabis.

But they're not for everyone and can be a tad impractical.

In case you're wondering, the big oral erectile dysfunction drug makers have dabbled with spray versions. But they weren't able to crack the code because of a problem with the agent crystallizing.

On trial

LTR's route to market has been made easier because PDE5 tablets are a 'known known', having been used by millions of patients already.

LTR Pharma has carried out a small, 18-man trial to confirm Spontan's speedy efficacy and bio-availability.

Released in October last year, the results showed Spontan achieved 470 percent faster absorption than oral vardenafil tablets - 12 minutes versus 56 minutes – at half the dose.

Peak concentration was 115 percent higher.

LTR now plans a follow-on, 25-patient phase II trial, in Sydney. In line with the FDA’s wishes, the trial will focus on over 65-year-olds.

Following that, the company will mount a bigger phase III trial in the US, in late 2026 or early 2027.

But LTR targets first US launch in mid-2026 - well ahead of approval.

This is because the company has launched a US variant product, called Roxus.

Also based on vardenafil, Roxus avails of the FDA’s 503A personalized healthcare pathway. “It's basically two approval pathways with different data requirements for the FDA, so it’s best to separate [Roxus and Spontan],” Mr Rodne says.

“Because of this, they won't be identical products but fairly close”.

The company is pursuing the FDA's 503A personalized healthcare pathway for Roxus.

“Spontan is heading down the FDA's 505(b)(2) pathway, which governs a change of route of administration [for an already approved drug]”.

Unlike here, US drug makers can advertise their wares. Given the subject matter, advertising creatives will have a field day.

The company is planning a local TGA application and is talking to European regulators.

“But our prime focus is the FDA,” Mr Rodne says.

Finances and performance

LTR Pharma has gone to the equity well twice, post listing.

In mid-2024, LTR raised a $10.5 million placement, struck at 73 cents apiece (a 19 percent discount). Later that year the company raised a further $25 million in a placement, at 92 cents per share (a 12 percent discount).

LTR reported revenue of $145,779 in the year to June 30 2025, compared with nil previously. The company lost $5.59 million, compared with the previous $6.95 million deficit.

With around $30 million in the bank, Mr Rodne says LTR is well placed to fund the trials. The company costs the phase II effort at $2 million to $3 million.

Restorative Health Clinic sells Spontan at $200 to $250 - enough for 30 'occasions'. The company cites a gross margin of 90 percent plus.

Generic forms of Viagra sell for $20 for a pack of 12 tablets and 5mg tadalafil costs $30 for 28 tablets.

Over the last 12 months LTR shares have traded between $1.93 (mid-November last year) and 25 cents (early May last year).

The stock peaked at $2.06 in October 2023 - but nothing stays up forever.

"We were the IPO of the year in 2023 and … it was natural to have over-excitement," Mr Rodne says.

Expanding horizons

In a case of 'now for something completely different', LTR is party to a venture to develop 'nature identical', pharmaceutical-grade omega-3 oils.

The venture, Lev Omega Pty Ltd was founded by LTR, food additives supplier Green Blue Health Pty Ltd and product innovator Levur Pty Ltd.

Derived from fish, omega-3 oils are widely accepted as having cardiovascular and anti-inflammatory health benefits.

It's good for kids' brain development and most infant formulas contain docosahexaenoic acid (an omega-3 oil component).

The trouble is, overfishing and ocean pollution is constraining supply. This underscores the need for "scalable, sustainable alternatives".

Lev Omega plans to supply its ingredients to the pharmaceutical and food additive sectors.

Mr Rodne says the "opportunistic" move didn't cost LTR anything upfront.

But this week LTR Pharma tipped $1 million into the venture, as a research and development contribution.

Off its own bat, LTR is developing Oroflow. This is a novel treatment for "oesophageal motility disorders" or swallowing difficulties.

Oroflow's mechanism of action is to relax the oesophagus.

The company intends Oroflow to deliver faster relief than current remedies that include dilation, surgery, or Botox injections.

Dr Boreham's diagnosis:

Spontan may not be the best treatment for all erectile dysfunction sufferers. But as Ms Barrett says: "It's another tool in the toolbox".

It's impossible to overdose on it and the company and Ms Barrett suggest that Spontan could improve the sex lives of men with healthy erectile function.

Spontan addresses a high unmet need, with more than 300 million of the world's blokes estimated to suffer erectile difficulties.

The global erectile dysfunction market is projected to be worth $US6 billion by 2028.

While erectile dysfunction afflicts all nationalities, the US presents the best commercial prospects.

Mr Rodne cites one clinic in Dallas that alone writes 700,000 erectile dysfunction scripts each year - which shows that things in Texas are not always bigger.

On back of the envelope sums, capturing 10 percent of the prescriptions of this outlet alone implies revenue of around $14 million.

The current price difference between Spontan and Viagra et al may deter price-conscious lovers who don't mind an hour or more of foreplay.

Or a chance to load the dishwasher before they get down to it.

For many, price won't be an issue and they will go for it.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he will still rise to the occasion.