Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Firebrick Pharma

By TIM BOREHAM

ASX code: FRE

Share price: 45.5 cents

Market cap: $76.8 million

Shares on issue: 168,844,205 (includes 62,732,537 shares escrowed for two years)

Co-founder and executive chair: Dr Peter Molloy

Board: Dr Molloy, Dr Stephen Goodall (co-founder and chief operating officer), Prof Phyllis Gardner (Firebrick intends to appoint another board member)

Financials (half year to December 31, 2021): revenue $3,372, loss of $1.54 million, total funds available $13.09 million*******

*** Post IPO figure that includes $4m of existing cash, IPO proceeds and an estimated $2.6 million Federal R&D tax incentive for the 2022-'23 year

Identifiable major shareholders: Aquarico Pty Ltd (Dr Molloy) 17.96%, Biotech Design (Dr Goodall) 17.96%, Carina Management Pty Ltd 2.84%.

Germ buster Dr Peter Molloy puts paid to the notion that the pandemic public hygiene measures have quashed the common cold (or the 'flu, for that matter).

"The common cold is quite resilient, cold numbers have not diminished as much as you might expect," he says. "The common cold is going to be around for a long time. While there may have been some suppression over the last two years, [numbers] will rebound."

The co-founder of recently-listed anti-viral play Firebrick Pharma, Dr Molloy says in pre-pandemic times Australian adults caught, on average, 60 million colds a year collectively. Kids sniffled their way through a further 50 million colds (and duly passed them on to everyone else in their orbit).

Firebrick is developing the base ingredient of a common product – Betadine – into a nasal spray that kills the culprit viruses.

Firebrick's variant, called Nasodine, will tackle the root cause rather than the symptoms, so in effect we're talking about an elusive common cold cure.

Firebrick also has a similar program to eliminate the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) within the nose, with South African studies proving promising to date.

Buoyed by what Dr Molloy dubs the 'Holy Grail' of a common cold curative, investors piled into Firebrick during their initial public offer and subsequent ASX listing on January 28.

The story to date

Firebrick was founded in 2012 by two familiar names - Dr Peter Molloy and Dr Stephen Goodall - to further the idea of a broad-spectrum cold treatment.

Dr Molloy is perhaps best known for heading Biota, which developed the Relenza influenza drug, before decamping to the US and the Nasdaq. He started out in the pharmaceutical industry at local drug institution FH Faulding where he was involved in developing and commercializing the Betadine products, notably Betadine Sore Throat Gargle.

"The fact it worked so well as a treatment for sore throats [which are usually caused by a virus] made me think if we could do something in the nose to interrupt that viral infection, we would have the world's first treatment for the common cold."

Dr Molloy later joined Biota and was involved in getting Relenza on track after more than a few issues with its distributor.

Dr Goodall was the chief operating officer of immune-oncology house Viralytics, famously taken over by Merck for a cool $502 million in 2018.

Betting on Betadine

Nasodine combines a polymer called povidone with molecular iodine. This base compound - and let's call it PVP-I - is also the active ingredient in Betadine and is used in hospitals for infection control.

The compound has been off-patent since 1976, but Firebrick has obtained method-of-use and formulation patents pertaining to the common cold and pandemic viral diseases.

Betadine initially was acquired in the 1950s by Purdue Pharma, which licenced it to Faulding. Purdue, of course, was more interested in its fabulous opioid Oxycontin - a case of backing the wrong horse given the ensuing billions of dollars of negligence writs that may destroy the company.

Faulding was taken over by Mayne Pharma and the Betadine rights ended up with Sanofi Aventis. Firebrick, by the way, derives its name from the color of PVP-I.

Missed it by that much

With the common cold, a 2017 phase I study enrolled 10 healthy volunteers, followed in 2018 by a phase II effort with 39 cold-afflicted patients.

Encouraged by the results, the company launched a phase III study in 2019, enrolling 260 'diseased' patients. On average, they were treated 40 hours after the onset of symptoms.

A raging success? Er, not quite - the trial failed its primary endpoint, with the results showing a statistically insignificant 8.4 percent positive clinical benefit. Dr Molloy describes the trial as "robust and well executed", but the company chose the wrong endpoint of impact on nasal symptoms, rather than overall cold severity.

"Compared with saline spray, Nasodine was effective in terms of overall cold severity for people who started treatment in the first 24 hours, for those with stronger symptoms at the start or for those with confirmed viral infections," Dr Molloy says. "Those things were important because they demonstrated the proof of principle that the product works."

The rhinovirus, by the way, accounts for 50 percent of adult colds and 70 to 80 percent of kids' sniffles. The second most common is a basket of coronaviruses which may have been more pathogenic in the past.

TGA tribulations

Undeterred by the trial setback, Firebrick lobbed a registration dossier with the Therapeutic Goods Administration which, unsurprisingly, declined to grant approval and handpassed the matter to its medicines advisory committee.

Firebrick awaits a formal rejection which will outline the agency's reasoning and thus inform the design of the next trial. The fresh phase III trial will recruit 350 patients based on five sites in Adelaide, Melbourne and South Africa.

Not surprisingly, the company will use overall severity as the primary endpoint and limit the analysis to patients treated within 36 hours and/or with stronger symptoms. This means the subjects in effect have to be pre-registered and ready to start treatment if and when the cold symptoms appear.

Because saline solution can also reduce the severity of colds, the placebo will be switched to colored water.

Gone in 60 seconds

Meanwhile, South African laboratory studies in 2020 showed that Nasodine killed the Sars-Cov-2 bug within 60 seconds.

A human trial then administered Nasodine to six patients shedding the virus through their nose. After one dose of four sprays per nostril, the results showed a 79 percent reduction in viral load after one hour. Reduced viral shedding was evident with five of the six patients within five minutes.

Expected to be launched before the end of March, a follow-on phase II study will administer repeat doses over several days.

But in a commercial vein, has SS Pandemic already left the port? Perhaps, but Dr Molloy says Covid-19 showed we were quite unprepared for a serious pandemic and we need to be ready for next one.

“A broad-spectrum antiviral nasal spray readily available for healthcare workers … could be an attractive way to reduce the spread of the virus in the next pandemic.”

Rival products soldier-on

As an over-the-counter (OTC) pharmacy product, Nasodine would ‘compete’ with a slew of other cold and ’flu products including Sudafed, Dimetapp and Codral.

But these offerings tackle the symptoms, rather than the viral source, of the cold. Post pandemic we’re unlikely to be ‘soldiering on’ and masking the symptoms, with one slight cough or sniffle likely to send culprits to the sick bay - or even Siberia.

According to Firebrick’s prospectus, pandemic measures such as isolation and hand sanitization resulted in local OTC cold and ’flu drug revenues falling to $385 million in calendar 2021, compared with $429 million in 2020 and $474 million in 2019.

Dr Molloy says Nasodine could be used in conjunction with cold and flu tablets, but hopes that as a first-in-class product Nasodine will be effective on its own.

He expects the remedy to retail for about $24 per 30-dose bottle – with a typical cold requiring 20 doses over five days.

Finances and performance

Firebrick has spent $10 million on trials to date and expects to spend another $5 million to complete the two phase III efforts.

The initial public offer raised $7 million with the issue of 35 million shares at 20 cents apiece. The company’s cash kitty currently stands at around $10 million, with an estimated $2.6 million research and development tax incentive for the 2022-’23 year.

Firebrick is funded for the next two or so years and Dr Molloy says the company does not expect to raise funds again, in the short term.

Firebrick shares moved smartly out of the blocks, trading as high as 65 cents on the first day's trading before closing 165 percent higher at 53 cents.

Despite the ratty market for speculative biotech plays, the shares have more or less held their ground and the company is valued at $84 million.

Dr Boreham's diagnosis:

While Firebrick has plans for extension products for outright cold prevention and eliminating golden staph (Staphylococcus aureaus), its short-term fortunes hinge on the phase III common cold trial and flow-on regulatory approval.

The outcome is somewhat binary, but a more finely-honed second effort should secure the TGA's seal of approval.

We would have expected the approval hurdle to be fairly low for an OTC cold product, given the number of unproven natural remedies already available. But given the safety aspects of nasal use, it's not the case.

We're also conscious that less severe colds might clear up in a couple of days anyway - not that that stops sufferers from spending big on often dubious products.

As for Sars-Cov-2, no-one expects the pesky virus to disappear altogether and if it doesn't remain a problem, another one will.

On the flag-flying front, Dr Molloy wants Nasodine to follow Relenza's lead as a home-grown global product.

"We want Firebrick to be seen as a successful Australian-born, Australian-based pharmaceutical company and projecting its value creation to the world."

Now that's a lofty aim that's nothing to sneeze at.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His Mum always told him to banish colds by gargling saline solution – Firebrand's 'placebo' – and we reckon she was on to something