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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Dimerix

By TIM BOREHAM

ASX code: DXB

Share price: 17 cents

Shares on issue: 404,142,324

Market cap: $68.7 million

Chief executive officer: Dr Nina Webster

Board: Hugh Alsop, Dr Webster, Dr Sonia Poli, Clinton Snow (the company currently does not have a chair)

Financials (year to June 30, 2023): revenue nil, net loss $13.8 million (previous $10.4 million deficit), accumulated losses $52.1 million (previously $38.2 million), cash of $7.99 million (down 18%) - ahead of Advanz Pharma licencing deal

Identifiable major holders: Peter Meurs 16.1%, Andrew Coates 2.9%, Philip Scott 2.2%, Bavaria Bay Pty Ltd (Perth high net worth individuals) 1.8%

Ask any chief of a development-stage biotech about the prospect of a partnering or licencing deal and they will refer to a multitude of discussion with big pharma - all couched in suitably vague terms.

But when Dimerix chief Dr Nina Webster referred to "material offers" and signing non-binding term sheets on "commercially attractive opportunities" it sounded like she was doing more than going through the motions.

Lo and behold, the kidney drug developer has followed through with an exclusive licencing deal for its lead compound DMX200, to treat focal segmental glomerulo-sclerosis (FSGS).

Dimerix is in phase III trials for FSGS, a rare - but not too rare - disease that causes kidney scarring and ultimately leads to the spuds (see below) failing.

With a headline worth of “up to” $230 million, the compact is with the London-based Advanz Pharma Corp and pertains to Europe, the UK, Switzerland as well as here and in New Zealand (see Biotech Daily October 5, 2023).

There’s a notable exception - the US - and it’s a case of ‘watch this space’ as to what Dimerix will do in this crucial geography.

While some aspects of the deal remain murky - notably the timing and nature of the milestones - investors reacted by sending the shares as much as 16.9 cents, or 277 percent higher over the next two trading days.

Dr Webster says she is “absolutely thrilled” about the deal, which pertains only to FSGS and not to any other indication or drugs Dimerix might develop.

“The deal validates our asset and our ability to partner,” Dr Webster says.

“It really puts us in a far stronger position to work towards bringing out an exciting drug candidate to FSGS patients currently with limited treatment options.”

The story to date

Dimerix was founded in 2004 by Dr James Williams and former Macquarie Group adviser Liddy McCall, based on technology developed at the University of Western Australia.

The Williams-McCall tag team co-founded Tessitura Pty Ltd and then biotech investor Yuuwa Capital.

Dimerix Bioscience was acquired in July 2015 by the ASX-listed Sun Biomedical, , which was developing saliva-based drug tests and then changed its name to Dimerix Limited in November 2015.

Patent lawyer and scientist Kathy Harrison was appointed inaugural CEO in August 2017, having been the company’s sole employee when she joined in 2014.

A year later the company appointed Dr Webster as CEO.

Also a patent lawyer, Dr Webster had held senior positions at drug companies including Wyeth Pharmaceuticals (now Pfizer), Acrux (as commercial director) and Immuron.

Last December, chair and founder Dr Williams quit the Dimerix board, which coincided with the Yuuwa fund being wound up (as per schedule) and ceasing to be a Dimerix shareholder.

The deets of the deal

Headquartered in London and backed by the multi-billion-dollar Nordic Capital, Advanz Pharma specializes in rare diseases.

Advanz will use this expertise to promote the product across the geographies in which it has a sales presence.

The back-ended deal sees Dimerix receive EUR6.5 million ($A10.8 million) in upfront cash. A further EUR132 million ($A219 million) is receivable in milestone payments, while the company is also entitled to royalties should the drug be commercialized.

Dr Webster says the royalties are in the mid-teen to 20 percent range and a combination of development, commercialization and sales triggers.

While Dimerix remains responsible for the carriage of the phase III trial, Advanz becomes responsible for regulatory filings and sales and marketing.

The parties have agreed to share any data, which means Dimerix can apply it to approval efforts outside the geographies covered by the agreement.

What's next?

More deals covering other geographies, of course.

"Once you have the first deal over the line, then negotiations for the others become a little easier," Dr Webster says.

"They are more comfortable that other people have done the due diligence and seen everything in our bottom drawers that they can possibly see."

She's offering no guidance on timing: "deals get done when they get done". But if it's any guide, the Advanz deal took 16 months to formulate.

While there are no approved drugs for FSGS, third-party reports estimate the market size at $US6 billion a year by 2032, across eight key geographies. Europe has $US990 million of this market, with the US accounting for $US2.05 billion and China $US2.8 billion.

Unlike many studies, the current FSGS trial has been designed to suit the requirement of the Chinese regulator, as well as US and European drug gatekeepers.

"China has one of the biggest kidney disease incidences in the world and it is thus an attractive market," Dr Webster says.

Presumably, the company's key priority now is to seal a US deal but it may prefer to wait until after (positive) trial data is released. At that stage, partners may be more willing to sign up but they would also have to pay a higher upfront.

Protecting the potatoes

Focal segmental glomerulo-sclerosis attacks the kidney's filtering units - glomeruli - causing irreversible scarring and permanent kidney damage.

About half of the patients will have end-stage failure in less than five years and many won't respond to transplants.

Kidney failure typically occurs within five years of diagnosis, with 60 percent of patients receiving a transplant experiencing recurring FSGS.

The focal point of Dimerix - pardon the pun - has been its phase III trial, dubbed Action3, a randomized, double-blinded effort, enrolling 286 patients across 70 sites in 11 countries, with at least 72 recruited to date.

The patients have received a dose of the standard-of-care therapy, a blood pressure med called an angiotensin II receptor blocker (ARB).

The primary endpoint is the reduction in the amount of protein (from blood) in the urine - proteinuria - similar to what the company achieved in an earlier phase II trial.

Proteinuria in the blood is a poor omen of kidney function.

This 2020 study showed a circa 17 percent proteinuria reduction relative to placebo, on top of a 15 to 20 percent benefit from the standard-of-care ARB (as measured by published data).

Interim results from the two-year phase III study are slated for March 15, 2024, so pop that date in your diary.

The second readout is after first 144 patients reach 35 weeks treatment.

"If the data is compelling, the second analysis has the potential for an accelerated or conditional approval in some territories," Dr Webster says.

Beyond FSGS

While Dimerix's clear priority is FSGS the company has another drug candidate called DMX700, which targets major lung ailments including chronic obstructive pulmonary disease (COPD).

DMX700 works by blocking the interleukin-8 (IL-8) receptor, which is expressed at elevated levels in sick patients. This in turn causes lung tissue damage.

Research is at the mice-and-pigs stage, but results to date have shown an 80 percent decrease in lung injury in mice, relative to control.

The COPD treatment market was estimated at $US18 billion in 2021 and is tipped to rise to $27 billion by 2027 - a compound annual growth rate of 7.3 percent.

“COPD is the third largest cause of death in the world, and is the only one with an increasing mortality rate,” Dr Webster says.

The company is also mulling a program for diabetic kidney disease, which is a bigger market than FSGS but better served.

The company is collaborating with the Australian Centre for Accelerating Diabetes Innovations on a potential diabetic kidney disease trial.

Finances and performance

In June, Dimerix went to the well to raise $12 million of equity at 8.0 cents a share, in a complex mix of a rights offer, options and convertible notes.

With the Advanz $10.8 million upfront payment flowing to Dimerix within a month, Dr Webster says the company is now fully funded to complete the FSGS trial costed at $25 million to $30 million.

“We are well and truly funded for that and beyond,” she says, adding you “never say never” to a capital raising.

Courtesy of the soaring share price, the company’s $19 million cash position could be bolstered by millions of dollars via the exercise of around 92 million in-the-money options over the next 20 months.

This is because investors taking part in the June raising received two options for every two shares held, one short term and one long term.

The short-term ones are exercisable before March 2024 at 12.4 cents, while the long-term ones are exercisable at 15.6 cents by June 2025. These dates are not arbitrary: they coincide with the expected part one and part two Action3 read-outs.

Over the last 12 months Dimerix shares have traded between six cents (at various times in 2023) and their October 6 zenith of 23 cents. They hit an all-time high of 73 cents in September 2020.

What’s in a name?

We’ve referred to DMX200 as such, but in September the FDA approved the company’s request to name the molecule Qytovra (pronounced kai-toe-vra).

Qytovra sounds like Russian for ‘finding names for new drugs that have not already been taken is getting bloody hard’.

But naming a drug is not all about pony-tailed marketing types in ‘ideation’ sessions, with any new moniker heavily scrutinized by regulators.

Names must pass several tests, including not being mistaken for another drug because of a doctor’s scrawled handwriting.

They also cannot have an unfortunate meaning in a different language.

Dr Boreham’s diagnosis:

Coming amid a flurry of transactions and approvals in the sector, the Dimerix deal heralds a definitive turnaround in sentiment in the sector.

Last week, Pharmaxis disposed of its loss-making mannitol (Bronchitol) business to focus on cancer drugs, while Cyclopharm won FDA assent for its lung cancer imaging tool after a mere three-decade wait.

Also last week, Noxopharm shares whooshed up 61 percent after the FDA granted investigational new drug application approval for CRO-67, its dual-cell drug candidate, to begin trials for pancreatic cancer.

And do we need to mention Neuren Pharmaceuticals and its spectacular success with FDA approval of tis drug for Rett syndrome?

As recently as last June, your columnist opined that the stock appeared to be priced for failure of the FSGS trial. Indeed, ahead of last week’s deal it was trading on an enterprise value of a mere $12 million (a market cap of $20 million less $8 million cash).

“This is really a new era for Dimerix as we join the few companies in Australian biotech that have successfully traversed the gap between R&D and commercialization,” Dr Webster says.

In all the excitement, though, let’s not forget the drug still needs to be approved for Dimerix to enjoy the full fruits of its labours.

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has been assured his name does not mean anything rude in Spanish … or Russian