Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Vaxxas

By TIM BOREHAM

Chief executive officer: David Hoey

Board: Dr Paul Kelly (chair), Dr Mark Ashton, Dr Manon M J Cox, Andrew Denver, Dr Dean Moss (Uniquest), Douglas Onsi, Dr Stephen Thompson (Brandon Capital)

Financials (for the financial year ending June 30, 2022): revenue $11.9 million

Major shareholders: One Ventures-led syndicate, Brandon Capital-led syndicate, Uniquest Pty Limited, Merck Inc (Merck Sharp and Dohme)

Vaxxas is a privately-owned company.

In future, when a nurse says "this won't hurt a bit" ahead of administering a vaccine, it will be wholly truthful statement.

It's also true that most injections are painless, or at least the psychological pain of anticipation is more discomforting than the actual penetration. In any event, vaccine programs would be easier with a delivery system other than a needle - and the Brisbane-based Vaxxas may have the solution.

For more than a decade, Vaxxas has been working on a device that delivers vaccines (and potentially other medications) into the body's largest organ – the skin. It's called a high-density microarray patch (HD-MAP).

Apart from being more comfortable, the procedure delivers the active ingredients more directly to where it counts.

Vaxxas enjoys the support of a number of specialist funds, as well as the US government's disaster preparedness agency and the drug company Merck.

Vaxxas chief executive David Hoey says the benefits of skin delivery are well understood.

"We have about 40 publications of animals models that show if you do it this way, you get a faster and stronger immune response," he says.

But as with green hydrogen, there's a big gap between a technology being accepted in a scientific sense and standing up commercially.

In this vein - pardon the pun - much of Vaxxas's work is about engineering the device so it can be manufactured in the millions, with a high degree of safety and accuracy.

"We are close to our first product and have five clinical programs underway and are about to start a sixth," Mr Hoey says.

The Vaxxas story

The Vaxxas tech was developed by the University of Queensland's biotechnology and nanoengineering department.

Vaxxas was founded in 2011 by the university's commercialization arm, Uniquest.

The technology gained the attention of Boston's Healthcare Ventures, in which the Queensland Investment Corporation was a partner.

Healthcare Ventures then joined a syndicate with One Ventures and Brandon Capital to invest in Vaxxas's first funding round.

Under an agreement inked in 2020, Merck of the US has exclusive rights to use the HD-MAP platform for an undisclosed Merck vaccine, with an option to use it for two others.

The company has also secured grants and funding worth more than $20 million, from the Bill and Melinda Gates Foundation and the World Health Organisation. These pertain to third-world vaccines for measles and rubella.

Vaxxas's development operations are based in Brisbane, a drop-punt from the famous 'Gabba ground, but its commercialization arm is based in Cambridge, Massachusetts.

A Brisbane native but a Boston resident for the past 30 years, Mr Hoey joined Vaxxas in 2010. His vast experience includes pre-clinical development of small molecule and biologic therapeutics, molecular diagnostic assays and platform and analytical instrumentation.

The Vaxxas board also includes One Ventures founder Dr Paul Kelly and Andrew Denver, the former chair of Universal Biosensors and a current Cochlear director.
(David Hoey is also a former Universal Biosensors director.)

About the device

The Vaxxas process involves concentrating the vaccine material in dry form and applying it to the patch in a way that ensures stability. A key advantage is the dry vaccine does not need to be refrigerated, which makes it especially helpful for use in developing countries.

Made from aluminium, the round devices consist of a spring, a retainer and thousands 0.33 millimetre spikes (projections) coated with the vaccine material.

The device is applied to the forearm or shoulder with two kilograms of force, for ten seconds. The spikes create thousands of ‘micro injuries’ on the skin, delivering the material into the dermis.

The injuries create an immune response, which Mr Hoey likens to someone’s arm going red after being scratched with a stick.

“That’s because the area is attracting immune cells,” he says. “Most of the body’s immune cells are under the skin. So, the vaccine is in a perfect position to be taken up by the immune cells and transplanted to the lymph nodes.

“When you put a needle into muscle, most of the vaccine ultimately doesn’t end up where it’s meant to be.”

BARDA be ready for the next outbreak

Vaxxas has a $US22 million ($A31 million) contract with the US Biomedical Advanced Research and Development Authority (BARDA), to develop the device for pandemic influenza.

Usability aside, a key advantage is that more vaccine can be made from less material.

Mr Hoey says the company showed the device to BARDA 12 weeks before the pandemic hit, with a delegation from the agency visiting Vaxxas’s prototype manufacturing line in January 2020.

The BARDA flu program is underway. Starting in the second half of 2023 and finishing in early 2024, the trial will enrol more than 400 people.

An outbreak of clinical trials

Vaxxas’s clinical work is centred not on proving the vaccines themselves, but assuring they work effectively and are stable in the skin-delivery format.

The company has carried out four safety-oriented phase I studies, three with a vaccine payload and one with blank cartridges.

Mr Hoey says the studies showed an enhanced immune response across 30 recipients.

In the case of a 200-person seasonal influenza study, only one sixth of a dose was required relative to a needle and syringe, with a “massively stronger and faster response”.

The company expects a further 500 people to be enrolled in three more studies, for Covid (of course) and BARDA’s “really big one”.

Next year the company enters it first phase II trial, for rubella and measles. This Gates-funded effort will be carried out in Gambia, Africa.

“The [work is] revolutionary because you don’t have to refrigerate it and it can be delivered with non-skilled staff,” Mr Hoey says. “You can get vaccines to places where you simply can’t get them, currently.”

Fronting the regulators

To date, all trials have been done in Australia according to Therapeutics Goods Administration standards, but the BARDA-funded study will be done locally under US Food and Drug Administration guidelines.

While each type of skin vaccine will have different approval paths, for US purposes the device will be deemed a combination product (a medical device with a drug component).

As one would expect, the vaccines can also be self-administered although this route is tricky from a regulatory perspective.

Mr Hoey notes that the approved injectable vaccines have already been used billions of times, so the safety profile is well-known*****.

He says the company also wants to work with novel vaccines. The Covid candidate, for instance, is being developed by the University of Texas National Institutes of Health as an improved version of an approved vaccine.

Finances and performance

Vaxxas is already chalking up meaningful service revenue - almost $12 million last financial year - sourced from BARDA and the Bill and Melinda Gates Foundation.

“We are getting to the point where we have product revenue coming up as well,” Mr Hoey says.

The company has raised $66 million in total: $51 million over two venture rounds in 2011 and 2015 and a $15 million investment from Merck in 2020.

Federal and state governments have also chipped in $38 million of non-dilutive funds, including an unquantified Queensland government grant to fund a 5,500 square metre manufacturing facility in Brisbane's Northshore Hamilton urban renewal precinct.

The Federal leg involves Vaxxas co-investing $10 million.

The company also has $20 million of funding from the Bill and Melinda Gates Divorced but Still Friends Foundation and the World Health Organisation, pertaining to the third-world vaccine program.

Mr Hoey says the company is in the expensive stage of clinical trials and ramping-up manufacturing, and will probably need another $US50 million over the next two years.

"We have been very fortunate in securing these large contracts with [BARDA], the Gates Foundation and Merck," he says.

"They are paying us to work with the material they provide, but we have to fund our own programs."

While the next funding is likely to be done privately, the company has a weather eye on an initial public offer (possibly on the Nasdaq).

Taking a jab at the rivals

With no clinical micro-needle studies being done outside of academia, Mr Hoey reckons Vaxxas is about five years ahead of its rivals.

So, who are the rivals?

Okay, there's Kindeva, which was divested from 3M and the Boston-based Vaxess Technologies (yes, they get misdirected mail from each other).

There's also Micron Biomedical of the US and the German-based LTS Lohmann (LTS Micro Array Patches).

Mr Hoey says their techniques differ somewhat and - in any event - needles are the real competition.

"The needle and syringe is a good competitor to have because no one wants it," he says. "We collectively have zero market share and needles and syringes have 100 percent.

"We're more of a community of micro-needle developers than competitors because we are creating awareness and the success of one will lead the success of others."

Of Vaxxas's 51 patents across 14 families, about half of them relate to the process technologies and have nothing to do with the patch per se.

Dr Boreham's diagnosis:

The science around skin delivery has been understood for 25 years, exemplified by common 'small molecule' delivery systems such as nicotine patches.

But no-one has cracked the industrialization aspect of making them at high speed in a sterile manner.

"You have to be able to make these things in the hundreds and millions and make them incredibly cheaply," Mr Hoey says. "We certainly want them to be less expensive than a needle."

Not surprisingly, Covid has delivered the vaccine market a massive shot in the arm - so to speak.

On market estimates the sector has grown from $US35 billion pre-pandemic to $US55 billion now and in 2020 will be worth around $US128 billion.

If Mr Hoey has his way, headline writers will need to come up with a convenient alternative to the 'jab' they've been using in vaccine-related stories.

"At some point, every vaccine will be given by skin delivery," he says. "It's better immunologically, patients prefer it and because you use less vaccine material it's economically better."

***** Anti vaxxers: don't write in.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He looks forward to 'jab' in headlines being relegated to yarns about boxing jousts … and not needling explanation.