



Biotech Daily

Friday September 2, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: DIMERIX UP 11%;
- UNIVERSAL BIOSENSORS DOWN 8%**
- * **DR BOREHAM'S CRUCIBLE: VAXXAS PTY LTD**
- * **BOTANIX RAISES \$7.5m**
- * **EPSILON RAISES \$1.65m**
- * **AVITA WINS JAPAN RECELL INSURANCE COVER**
- * **CRESO: WALMART BUYS \$315k SIERRA SAGE SKINCARE HERBS**
- * **CSL \$12m CEO PAUL PERREAU PERFORMANCE SHARES AGM**
- * **NOXOPHARM PLEADS SCHULTZ TO ASX 18% PRICE QUERY**
- * **NEUROTECH CEO DR ALEXANDRA ANDREWS 'TRANSITIONS' TO COO**

MARKET REPORT

The Australian stock market fell 0.25 percent on Friday September 2, with the ASX200 down 16.9 points to 6,828.7 points.

Eight of the Biotech Daily Top 40 stocks were up, 22 fell, six traded unchanged and four were untraded.

Dimerix was the best, up 1.5 cents or 10.7 percent to 15.5 cents, with 550,282 shares traded. Next Science and Starpharma climbed five percent or more; Genetic Signatures was up 3.3 percent; Clinuvel and Orthocell rose more than two percent; Immuteq and Neuren were up more than one percent; with CSL and Resmed up less than one percent.

Universal Biosensors led the falls, down two cents or 7.55 percent to 24.5 cents, with 389,159 shares traded; followed by Patrys down 7.4 percent to 2.5 cents, with 1.1 million shares traded.

Antisense lost 6.7 percent; Polynovo fell 4.9 percent; Atomo, Emvision and Micro-X were down more than three percent; Cyclopharm, Imugene, Kazia and Prescient shed two percent or more; Actinogen, Mesoblast, Nanosonics, Oncosil, Paradigm, Pharmaxis, Proteomics and Telix were down more than one percent; with Avita, Cochlear, Medical Developments and Pro Medicus down by less than one percent.

[DR BOREHAM'S CRUCIBLE: VAXXAS PTY LTD](#)

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 (Uniquist), 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, Uniquist 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, and founded in 2011 by the university's commercialization arm, Uniquist.

It 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 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 its 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 needing explanation.

BOTANIX PHARMACEUTICALS

Botanix says it has “firm commitments” to raise up to \$7.5 million in an oversubscribed placement at 6.6 cents a share.

Botanix said investors would receive one attaching option for every two shares bought in the placement, exercisable at nine cents each within 18 months of issue.

The company said that the offer price was a 17.5 percent discount to the last traded price on August 30, and an 18.7 percent discount to the 15-day volume-weighted average price prior to the trading halt.

Botanix said the funds would be used for filing a US Food and Drug Administration application for sofpironium bromide for primary axillary hyperhidrosis (excessive underarm sweating), preparation for a US commercial launch, enhancing quality and manufacturing capabilities for sofpironium bromide and for general working capital purposes.

Botanix said it expected to file its FDA new drug application by October 2022, and that it expected a 12-month review process for approval.

The company said Euroz Hartleys was the sole lead manager and book runner for the placement.

Botanix fell 0.8 cents or 10 percent to 7.2 cents with 4.5 million shares traded.

EPSILON HEALTHCARE

Epsilon says it has “firm commitments” to raise up to \$1.65 million in a placement at 2.75 cents a share, a 23.5 percent discount to the 15-day volume-weighted average price.

Epsilon said that pending approvals, shareholders would receive three attaching options for every four shares bought in the placement, exercisable at five cents within three years of issue.

The company said the funds would be used for its Southport Queensland factory, working capital and inventory ramp-up as it expanded its operations.

Epsilon was down 0.7 cents or 21.2 percent to 2.6 cents with 4.6 million shares traded.

AVITA MEDICAL

Avita says its Tokyo-based partner Cosmotec has received Japan Ministry of Health, Labour and Welfare insurance coverage for its Recell burns system.

Avita chief executive officer Dr Mike Perry said the company was “very pleased that the Japanese Ministry of Health, Labour and Welfare has granted the Recell System marketing approval with favorable reimbursement that will be aligned with pricing in the United States.”

“We look forward to continuing to work with our partner, Cosmotec, as they launch and promote Recell in the Japanese market,” Dr Perry said.

Avita fell one cent or 0.55 percent to \$1.81.

CRESO PHARMA

Creso says its subsidiary Sierra Sage Herbs has received a \$US214,000 (\$A315,330) order from Walmart for its natural skincare collection.

Creso managing-director William Lay said he expected delivery of the maiden order in September “with products to be on shelves in the weeks following.”

The company said the products were under the Green Goo brand and targeted “anti-aging, acne and eczema”.

Creso was up 0.1 cents or 2.6 percent to 3.9 cents with 3.5 million shares traded.

CSL

CSL says its annual general meeting will vote to grant up-to 41,483 performance share units worth \$US8,399,943 (\$A12,170,300) to chief executive officer Paul Perreault. CSL said the proposed long-term incentive was equivalent to 450 percent of Mr Perreault's base salary of \$US1,866,654 (\$A2,750,361), to be paid in two tranches, and pending performance hurdles.

Last year, the company said it intended to grant Mr Perreault up to 31,640 performance share units worth \$US7,214,120 (\$A9,803,490), and that 25.7 percent of votes opposed the motion (BD: Sep 3, Oct 12, 2021).

Previously, opposition to Mr Perreault's rights has ranged from 8.35 to 27.25 percent (BD: Oct 15, 2014; Oct 15, 2015; Oct 12, 2016; Oct 18, 2017; Oct 18, 2018, Oct 17, 2019).

Today, CSL said investors would vote on the remuneration report and the election of directors Dr Megan Clark and Marie McDonald.

The meeting will be held in person at Melbourne Convention and Exhibition Centre on October 12, 2022 at 10am (AEDT).

CSL was up \$2.20 or 0.75 percent to \$295.99 with 502,869 shares traded.

NOXOPHARM

Noxopharm has told the ASX it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price increased 18.4 percent from a low of 24.5 cents on August 31 to a high of 29 cents yesterday, September 1, and noted a "significant increase" in trading volume.

Noxopharm fell four cents or 13.6 percent to 25.5 cents with 1.1 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says chief executive officer Dr Alexandra Andrews will "transition to a new position of chief operating officer, effective immediately".

Neurotech chair Mark Davies thanked Dr Andrews "for her commitment to the role of [chief executive officer] with Neurotech during an important period for the company, where she guided us through the phase I/II clinical trial of NTI164 in children with autism spectrum disorder and the subsequent reporting of clinically meaningful data".

In July, Neurotech said 13 of 14 patients in its phase I/II trial of NTI164 marijuana for autism spectrum disorder showed symptom improvement after a 28-day course with no serious adverse events at doses ranging from 5mg/kg to 20mg/kg (BD: Jul 8, 2022).

"This saw a period of significant growth and share price appreciation," said Mr Davies.

"We are pleased Alex will continue with the company in her new capacity of chief operating officer, where she will be providing key scientific, strategic and management input into Neurotech's manufacturing, intellectual property, pre-clinical research and clinical trial development moving forward," Mr Davies said.

Neurotech fell 0.6 cents or 5.7 percent to 9.9 cents with 1.1 million shares traded.